

Title: Consultation on amending allergen provisions contained within domestic food information legislation for food prepacked for direct sale IA No: 2019/1218 RPC Reference No: RPC-4323(2)-DEFRA Lead department or agency: Defra Other departments or agencies: Food Standards Agency, Food Standards Scotland				Impact Assessment (IA)	
				Date: 12 June 2019	
				Stage: Legislation	
				Source of intervention: Domestic	
				Type of measure: Secondary legislation	
				Contact for enquiries: Sarah Cunningham	
Summary: Intervention and Options				RPC Opinion: Green rated; fit for purpose	
Cost of Preferred (or more likely) Option: Option 4 (full ingredient labelling)					
Total Net Present Value (£m)	Business Net Present Value (£m)	Net cost to business per year (£m)	One-In, Three-Out	Business Impact Target Status	
-321.8	-272.2	31.6	Not in scope	Non qualifying provision	
What is the problem under consideration? Why is government intervention necessary?					
<p>The primary issue under consideration is an imperfect information problem, where consumers do not know what is in the prepacked for direct sale (PPDS) foods that they are buying. A distinction is made in the regulations on food allergen information provision between foods that are prepacked and those that are 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 necessarily the case for PPDS foods.</p> <p>Government intervention is necessary to help mitigate the public health risk associated with allergens, and ensure that consumers are given clear and consistent information. As there is no cure for food allergies and intolerances, the only way to manage the condition is to avoid food that makes the person ill. Although a very small number of market leaders are starting to add allergen information on PPDS products voluntarily, this is not the case for most Food Business Operators. Having consistency is key for protecting consumers from making unsafe choices.</p>					
What are the policy objectives and the intended effects?					
<p>The overarching objective of the policy is to improve the provision of information to consumers about food allergens present in PPDS foods. As consumers often do not know the difference between pre-packaged and PPDS food which have different allergen labelling requirements, Government wants to protect consumers by providing consistency on allergen labelling for these products</p> <p>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 and to improve consumer confidence.</p>					
What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)					
<p>Non-regulatory options</p> <p>0. Do nothing. 1. Promote best practice.</p> <p>Regulatory options</p> <p>2. Mandate "ask the staff" labels on packages of PPDS foods. 3. Mandate name of the food and allergen labelling (<i>i.e.</i> 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. This is the preferred option</p> <p>All options are assessed relative to the 'Do nothing' (Option 0).</p> <p>The FSA, the independent government department that led the analysis of the consultation responses, advised Defra to introduce full ingredient labelling with a 2 year implementation period. After careful consideration of consultation responses, advice of the Food Standards Agency, and</p>					

the potential effects each option might have on UK consumers, businesses and local authorities, the Government intends to take forward option 4 in England and Northern Ireland, mandating full ingredient labelling for all PPDS foods.

From consultation responses we were told that option 1 was seen as lacking in legal standing, and that for individual's option 4 was the preferred policy option, with 73% of individuals supporting this. Option 3 was seen as unsatisfactory, as many people have allergies out of the 14 allergies listed in Annex II of FIC, and we are no table to amend this list whilst we are a member of the EU. Many respondents indicated that option 2 would not provide consumers with the clarity that they needed to make safe food choices.

Will the policy be reviewed? Yes If applicable, set review date: December 2024

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: n/a	Non-traded: n/a	

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 Minister Goldsmith:



Date: 3rd September 2019

Summary: Analysis & Evidence

Policy Option 1

Description: Promote best practice

FULL ECONOMIC ASSESSMENT

Price Base Year 2016	PV Base Year 2017	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: -3.3	High: -6.4	Best Estimate: -5.2
COSTS (£m)	Total Transition (Constant Price) Years		Average Annual (excl. Transition) (Constant Price)		Total Cost (Present Value)
Low	3.4		0.0		3.3
High	6.7		0.0		6.4
Best Estimate	5.4		0.0		5.2
Description and scale of key monetised costs by 'main affected groups' Costs to Government: The main costs to Government centre on the development of best practice materials (including new guidance and training materials). There will likely be costs for local authorities in familiarising staff with any new technical guidance. Costs to Business: Businesses will also have to familiarise themselves with any new technical guidance, this familiarisation cost will be significantly larger than that those on Government.					
Other key non-monetised costs by 'main affected groups'					
BENEFITS (£m)	Total Transition (Constant Price) Years		Average Annual (excl. Transition) (Constant Price)		Total Benefit (Present Value)
Low	Unquantified		Unquantified		Unquantified
High	Unquantified		Unquantified		Unquantified
Best Estimate	Unquantified		Unquantified		Unquantified
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 potentially fatalities.					
Key assumptions/sensitivities/risks					Discount rate (%) 3.5
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: 0.6	Benefits: n/a	Net: -0.6	
			2.5

Summary: Analysis & 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 2016	PV Base Year 2017	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: -32.4	High: -94.1	Best Estimate: -64.2
COSTS (£m)		Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)	
Low		6.7	3.1	32.4	
High		12.1	9.9	94.1	
Best Estimate		9.9	6.5	64.2	

Description and scale of key monetised costs by 'main affected groups'

Cost to Government: Government (local authorities) will face familiarisation costs associated with new legislation. Local authorities will face an increase in enforcement costs.

Costs to Businesses: Businesses will also face familiarisation costs. Some businesses (such as Quick service restaurants and sandwich shops) will experience transitional costs of new labelling and then the on-going costs of labelling (if they previously did not label). The costs to business are significantly larger than those affecting local authorities.

Other key non-monetised costs by 'main affected groups'

Cost to Business: It is difficult to assess the cost of providing written information when requested, as it is difficult to assess the cost of providing written information when requested. Some businesses may provide printed information (like a leaflet), whereas others may provide handwritten information (which would effectively be a near zero cost to business).

BENEFITS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Unquantified	Unquantified	Unquantified
High	Unquantified	Unquantified	Unquantified
Best Estimate	Unquantified	Unquantified	Unquantified

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 could 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.
- 4) Some businesses may have already moved to (or are in the process of) implementing improved labelling, so the extent of businesses affected may be smaller than anticipated.

BUSINESS ASSESSMENT

Direct impact on business (Equivalent Annual) £m:			Score for Business Impact Target (qualifying provisions only) £m:
Costs: 7.1	Benefits: N/A	Net: -7.1	31.1

Summary: Analysis & Evidence

Policy Option 3

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

FULL ECONOMIC ASSESSMENT

Price Base Year 2016	PV Base Year 2017	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: -101.8	High: -324.9	Best Estimate: -214.9
COSTS (£m)		Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)	
Low		84.2		2.9	104.2
High		271.6		8.5	328.9
Best Estimate		178.7		5.8	218.1
<p>Description and scale of key monetised costs by 'main affected groups'</p> <p>Costs to Government: Government (local authorities) will face familiarisation costs associated with new legislation (larger than that under option 2). Local authorities will face an increase in enforcement costs (again larger than those in option 2).</p> <p>Costs to Business: The main costs to business will occur due to the initial transitional costs of introducing labelling (this is more substantial than that of Option 2) to PPDS products and the on-going cost of labelling. In addition business will also experience costs due to familiarisation of the new legislation that is introduced. Costs to businesses are larger than those on Government.</p>					
<p>Other key non-monetised costs by 'main affected groups'</p> <p>Costs to Business: Businesses may experience indirect costs associated with labelling of PPDS products. These would include the difficulty to substitute ingredients without having to update the label.</p>					
BENEFITS (£m)		Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)	
Low		Unquantified		Unquantified	Unquantified
High		Unquantified		Unquantified	Unquantified
Best Estimate		Unquantified		Unquantified	Unquantified
<p>Description and scale of key monetised benefits by 'main affected groups'</p> <p>n/a</p>					
<p>Other key non-monetised benefits by 'main affected groups'</p> <p>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 could 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 EU's list of 14) who previously avoided the PPDS market due to low confidence in provision of information.</p>					
Key assumptions/sensitivities/risks				Discount rate (%)	3.5
<p>1) It may be challenging for some businesses to implement accurately, 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. This will be particularly problematic for individuals that are allergic to foods that are not in Annex II of FIC</p> <p>4) Businesses will have to improve their allergen management systems so that staff know how to label products accurately.</p> <p>5) Some businesses may have already moved to (or are in the process of) implementing improved labelling, so the extent of businesses affected may be smaller than anticipated.</p>					

BUSINESS ASSESSMENT

Direct impact on business (Equivalent Annual) £m:			Score for Business Impact Target (qualifying provisions only) £m:
Costs: 24.6	Benefits: N/A	Net: -24.6	108.0

Summary: Analysis & 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 2016	PV Base Year 2017	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: -155.6	High: -482.5	Best Estimate: -321.8
COSTS (£m)		Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)		Total Cost (Present Value)
Low		115.2	5.8		155.6
High		367.9	16.8		482.5
Best Estimate		242.9	11.5		321.8

Description and scale of key monetised costs by 'main affected groups'

Costs to Government: Government (local authorities) will face familiarisation costs associated with new legislation (larger than that under option 3). Local authorities will face an increase in enforcement costs (again larger than those in option 3).

Costs to Business: The main costs to business will occur due to the initial transitional costs of introducing labelling (this is more substantial than that of Option 3 as more businesses will likely be affected) to PPDS products and the on-going cost of labelling (again larger than that in Option 3). In addition business will also experience costs due to familiarisation of the new legislation that is introduced. Costs to businesses are significantly larger than those on Government.

Other key non-monetised costs by 'main affected groups'

Costs to Business: Businesses may experience indirect costs associated with labelling of PPDS products. These would include the difficulty to substitute ingredients without having to update the label. Additionally businesses that currently do not know the full ingredients of all the goods they sell, will need to determine the cost of these.

BENEFITS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
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 could lead to a reduction in the number of food allergen related incidents and fatalities associated with PPDS foods. Businesses may receive increased footfall from consumers who previously avoided the PPDS market due to low confidence in 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 (%)
<p>Key assumptions/sensitivities/risks</p> <ol style="list-style-type: none"> 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. 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 and divert resources away from providing staff with allergen training. 4) Businesses will have to improve their allergen management systems so that staff know how to label products accurately. 5) Some businesses may have already moved to (or are in the process of) implementing improved labelling, so the extent of businesses affected may be smaller than anticipated. 	3.5

BUSINESS ASSESSMENT

Direct impact on business (Equivalent Annual) £m:			Score for Business Impact Target (qualifying provisions only) £m:
Costs: 36.0	Benefits: N/A	Net: -36.0	

Evidence Base

Background and Scope

General background on food hypersensitivity

Food hypersensitivity is where people adversely react when eating certain foods and is divided into food allergy and non-allergic food hypersensitivity (food intolerance). 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, but this figure does not include those with food intolerances. In addition, it is estimated that 1 in 100 people have coeliac disease, an auto-immune condition which causes damage to the gut lining when gluten is present in food.

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 allergies and intolerances. 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 ingredients in products to allow them to make safe food choices. Continuing fatalities and effects on public health have raised the issue of whether the current regulatory framework for the provision of allergen information for PPDS foods is sufficient to give consumers the information they need to make safe food choices.

Legislative background

The EU Food Information to Consumers Regulation (FIC) provides the legislative framework around the provision of food allergen information, and 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 the FIC in the UK. In 2011 the Food Information to Consumers Regulation (FIC) introduced new rules for Food Business Operators relating to the labelling and provision of allergen information. Food Business Operators 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. FIC and FIR will be transposed into UK law under the EU (Withdrawal) Act 2018 when the UK exits the EU.

In the UK, in recognition of the wide variety of out-of-home eating establishments and following consultation with stakeholders including business and patient groups, FIR introduced a flexible approach for allergen information for non-prepacked foods, including prepacked for direct sale (PPDS) food, to be made available by any means the food business chooses, including orally by a member of staff. Where the Food Business Operator chooses not to provide food allergen ingredients information on a menu, for example, there must be an 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 where the customer chooses the food.

Enforcement of regulations

Separate but parallel FIR enforcement regulations exist in each of the four 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 1990 (England, Wales and Scotland) or the Food Safety (Northern Ireland) Order 1991 which can result in fines or imprisonment. Within Local Authorities enforcement is shared between Trading Standards and Environmental Health.

Current allergen information provision

Prepacked foods

Food which is prepacked, for example a ready meal sold in a supermarket, must be clearly labelled with all ingredients and allergenic ingredients from the list of 14 substances or products causing allergies or intolerances, listed in Annex II of FIC and set out in Annex I of this document. Allergenic ingredients must stand out from other ingredients, for example by being in **bold** text.

The Food Standards Agency's (FSA) interpretation of prepacked foods, derived from Article 2(2)(e) of FIC, is provided here for clarity:

***“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.”*

Non-prepacked foods

Under FIC, non-prepacked food includes:

- food not packed, such as loose items sold to the consumer without packaging;
- food packed on the sales premises at the consumer's request; and
- food prepacked for direct sale (PPDS).

Which category of non-prepacked a food falls into depends on where and when it is packed in relation to the point at which it is offered for sale. This can differ for the same products according to the way a business operates e.g. where a business prepacks some foods on the premises in anticipation of a peak period of sales (PPDS), but otherwise packs the food at the consumer's request.

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.

What are PPDS foods?

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

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

- *It is expected that the customer is able to speak with the person who made or packed the product to ask about ingredients.*
- *Foods that could fall under this category could include meat pies made on site and sandwiches made and sold from the premises in which they are made¹.”*

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

Examples of PPDS foods

PPDS foods may be available to consumers in out-of-home and retail environments.

In an out-of-home environment such as a sandwich shop, café or burger bar, any food that is prepacked on the premises in anticipation of an order, before being offered for sale, would be considered to be PPDS. Examples may include foods which the consumer self-selects from a chiller cabinet or has to ask a member of staff for, for example, a sandwich or boxed salad on display behind a counter. Food ordered and collected in person by a consumer in a takeaway, may be PPDS if it was packed before it was offered for sale, for example, a wrapped burger, boxed fried chicken or wedges under a hot lamp.²

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

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

Not PPDS foods

The following are not PPDS but would be considered to be packed on the sales premises at the consumer's request:

- Foods that are freshly prepared and wrapped after the consumer has placed their order, for example a sandwich or burger that is made and wrapped to order.
- Foods that are pre-prepared but not prepacked, for example a sandwich or slice of pizza made in the morning and displayed behind a counter in anticipation of the lunchtime rush and subsequently wrapped for the consumer on ordering.

Food not packed, such as loose items sold to the consumer without packaging and meals served in a restaurant or café are neither PPDS nor packed at the consumer's request.

Scope of the consultation

The consultation focused on improving the provision of information to consumers about food allergens present in PPDS foods so they have greater confidence in the safety of these foods.

Out of scope

The following issues fall outside the scope of the consultation:

² Allergen information provision for foods sold via Distance Communication is governed by Article 14 of FIC. Article 14 does not allow for National Measures as to how allergen information is provided. Online ordering such as direct online or telephone takeaway or restaurant ordering as well as direct online supermarkets and ordering hubs are required to provide allergen information 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.

- The regulation of Precautionary Allergen Labelling (PAL) statements to indicate the unintentional presence of food allergens due to cross-contamination.

This consultation was concerned specifically with the provision of allergen information for intentional ingredients in PPDS foods. FSA guidance on PAL advises that it should only be used when there is a genuine, assessed, unavoidable risk that good manufacturing practice cannot avoid.

- 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 FIC, 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.

- Food which is prepacked (such as a ready meal sold in a supermarket).

Under current regulations, prepacked food must be clearly labelled with all ingredients and allergenic ingredients from the list of 14 substances or products causing allergies or intolerances, listed in Annex II of FIC.

- Food not packed (such as meals served in a restaurant or café), and food packed on the sales premises at the consumer's request (such as a sandwich prepared in front of the customer, cheese or meat sold loose from a delicatessen counter or bread or pies sold at bakeries).

There is an expectation that in these circumstances, because foods are not already prepacked at the point that the consumer is making their choice, consumers will talk to staff about their allergy requirements so that they can make safe food choices. For example, consumers may request adaptations to the food, such as leaving out an ingredient, before the food is packed and sold. The consumer has a responsibility to tell the food business about their allergy or intolerance, and the business is legally required to provide accurate and clear information on food allergens making it a dual responsibility to help safe selection of foods. To encourage this practice, FSA launched the #EasytoAsk campaign supported by allergy patient groups to remind food businesses to ask customers about dietary needs and empower young people in particular, to ask about allergens when eating out.

Problem under consideration and rationale for intervention

The Government review of allergen information provision for PPDS food followed the conclusion of the Coroner's inquest into the death of a 15 year old who died after eating a PPDS sandwich. The coroner's report noted that allergens on PPDS products were not labelled adequately or clearly on the packaging, and subsequent campaigning by consumers raised the issue of whether the current regulatory framework for the provision of allergen information for PPDS is sufficient to give consumers the information they need to make safe food choices.

The overarching objective of the policy is therefore 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.

The consultation responses support the need for Government intervention. 1876 responses were received in total during the 9 week consultation, with the majority of responses (86%) from individuals. A high majority of individuals indicated a preference for more allergen information on packaging, either allergen only labelling (8%) or full ingredients (73%). Only 4% of individuals expressed a preference for non-labelling options (options 1 and 2). Analysis of the responses also established a strong desire amongst consumers for a consistent approach to allergen information provision for PPDS food. Approximately 90% of individuals who responded to the consultation believe that all businesses, regardless of size, should be required to implement any of the proposed options. Support for this was lower amongst businesses and showed a split with 80% of medium and large businesses supporting a consistent approach as compared to 40% of small and micro businesses. Although some large businesses are going beyond the minimum requirement for provision of allergen information, Government intervention is required to achieve consistency in provision of allergen information for PPDS food. Currently there is flexibility in the approach for allergen information for non-prepacked foods, including prepacked for direct sale (PPDS) food, which can be made available by any means the food business chooses, This has created a lack of

consistency for allergen labelling between pre-packaged foods and PPDS foods, which consumers can find confusing

Intervention is required as non-legislative options were seen as lacking in legal standing and did not go far enough according to responses to the consultation. Consumers have difficulty in getting accurate information and this would continue to be an issue without government intervention. There is a lack of trust in current system and consumers told us this in the consultation. Legislative change is needed to increase confidence from consumers and to progress change.

In addition to responses from individuals, 126 responses were received from businesses, 83 from public sector bodies and 29 from non-governmental organisations (NGOs). Overall, respondents expressed a wide range of views about the four different options and no single option carried the support of more than one group. 41% of businesses expressed a preference for option 2, citing ease of implementation, and opportunity for ingredient substitution without having to re-label products with a resulting reduced risk of mislabelling and cost impact. A small majority of public-sector bodies (39%) identified option three as their preferred legislative option, with a majority of NGOs (42%) identifying multiple options as their preference.

As well as the digital submissions, a series of stakeholder engagement workshops were held across England, Wales and Northern Ireland to get the views of stakeholders. Over 150 people from different groups participated including allergic consumers, young allergic consumers, businesses, patient groups and enforcement officers. Information gathered both through the workshops and the digital submissions has been used to develop the analysis of each policy option.

In the consultation responses and the discussions held during our stakeholder workshops, there was a general desire (from not only consumers, but businesses and local authorities) for there to be no exemption for SMBs. We considered mitigating actions that we could take for SMEs, which included having a phased implementation dependent on business size, and also having a two tier system in order to alleviate concerns from SMBs.

The reason why we have not created exemptions or mitigations for SMBs is the difficulty for consumers to distinguish whether a business they have entered is a small or micro business. By having exemptions consumers would not necessarily be aware of, would create confusion which is what we are aiming to avoid. Also, there was a fear from some SMB's that by not being held to the same standard, consumers may feel that their products could be regarded negatively or unsafe in comparison to larger businesses. Additionally, local authorities were concerned that any exemption based on business size would create difficulties for enforcement officers who would not have access to the necessary business information to determine whether a business is a SME or not at the time of inspection. The message that was put forward by stakeholders, was that there should be consistency in the requirements on businesses with regards to the labelling of PPDS food, holding all FBO's to the same standard. To help SMB's the FSA will be providing specific advice to help them implement this change.

Comparisons with other EU Member States

Article 44 of FIC authorises Member States to adopt national measures concerning the means through which allergen information is made available for non-prepacked food. There are a number of approaches taken by EU Member States and other countries to the provision of allergen information. Most Member States do not require the provision of written allergy information for non-prepacked food. There is some variation as to how information should be provided but typically information can be provided orally and followed up with written information. This is the case in Germany, Italy, Spain³, Denmark⁴ and Austria⁵. The Netherlands stipulate that where non-prepacked food is sold, there must be a clearly visible sign that informs the consumer that allergen information is available and how it can be obtained⁶, this is the same as required by regulations in the UK.

As far as can be determined, three Member States; France, Latvia, and the Republic of Ireland, currently require written allergen information to be provided, but they do not specify that it must be on the packaging. In the Republic of Ireland, written allergen information for all non-pre packed food (there is no distinction made for PPDS) must be available in writing before the consumer orders the food. The written information must clearly identify allergens contained in the food or beverage. How the Food Business Operator (FBO) provides allergen information is not determined but it must be in a legible handwritten or printed format. Food allergen information can be communicated verbally at any time.

Outside of the EU, Norway applies the same rules as the Republic of Ireland. In other countries, non-prepacked foods in Australia and New Zealand must declare the major allergens named in Food Standards Australia New Zealand, Food Standards Code—Standard 1.2.3.⁷ The allergen information must either accompany or be displayed with the food, on a shelf label for example, or must be provided to the purchaser upon request.⁸ In the USA, the Food Allergen Labelling and Consumer Protection Act (FALCPA) is the primary federal law governing how allergens are represented on packaged foods but does not currently apply to non-prepacked food.⁹

Analysis has not been undertaken by other Member States on the effectiveness of different levels of regulation for PPDS, and we have not been able to find any reviews of allergen information regulations outside of the EU. This is because legislation for EUFIC allergen labelling provisions were introduced in 2013/2014 across Europe and so it is too early for the impacts to have been assessed.

Policy objective and options

Through the consultation we sought views on non-regulatory and regulatory policy options to improve the provision of allergen information to consumers for PPDS foods.

The overarching objective of the policies is to improve the provision of information to consumers about food allergens present in PPDS foods. All options are intended to address the policy objective, through a range of regulatory and non-regulatory means. Each option considers various measures that could be put in place to alleviate consumer concerns related to allergen information provision on PPDS foods. Options 1 to 4 represent a sliding scale moving from non-regulatory measures to increasingly prescriptive regulatory measures. Option 1 is aimed at raising consumer confidence without regulatory intervention, through encouraging changes to business practices around allergens through guidance and training, and campaigns to raise awareness for allergic consumers. Options 2 to 4 consider leveraging regulatory measures in order to achieve the same objective of improving the provision of information to consumers.

Evaluation

The impact of the policy will be assessed throughout implementation of the policy, and will be formally reviewed in autumn 2024, with businesses having been implementing this for three years at this point, due to the two year implementation period, which may result in a lighter touch review being required, dependant on analysis available. Policy outcomes will be measured through understanding the impact of the PPDS measures on business and

³ www.foodallergy.org

⁴ Buch-Weeke, T. (2015). Denmark: National Measure for Non-Prepacked Food in Denmark. *European Food and Feed Law Review: EFFL*, 10(2), 145.

⁵ Kostenzer, E. M. (2014). Austria: Allergen information for non-prepacked foods. *European Food and Feed Law Review : EFFL*, 9(6), 403-405.

⁶ Hoogenraad, E., & Duivenvoorde, B. (2015). The netherlands: Country report on national measures for non-prepackaged food: The netherlands. *European Food and Feed Law Review : EFFL*, 10(2), 154.

⁷ <https://www.legislation.gov.au/Details/F2017C00418>

⁸ <https://www.legislation.gov.au/Details/F2018C00464>

⁹ <https://www.foodallergy.org/education-awareness/advocacy-resources/food-labels>

consumers. To monitor and assess this impact, data will be collected with local authorities, businesses, allergy patient groups and other consumer stakeholders, to measure how consumer confidence of labelling in PPDS foods has changed and that the number of allergen-related incidents has reduced. Through these stakeholders we will collect data on how businesses have approached implementation of the new rules and whether the allergen labelling standards are at a high level. The FSA will be measuring the provision of allergen information for consumers by food businesses in the next few months, which will include a questions on PPDS to provide a baseline of how information is provided for PPDS food.

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. Note that each option need not be considered as exclusive; options may be combined, for example, the non-regulatory option may build upon regulatory options in an escalating hierarchy, or different options may be applied to different sizes of businesses in a two-tiered approach.

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. The Government has concluded that current policy is not satisfactory, and this option does not adequately address the main objective (see above).

Policy Option 1. 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 and consumers to review their knowledge, skills and actions to ensure a safer environment for consumers. It would encompass best practice for all non-prepacked foods, including PPDS. Options for promoting best practice may include:

- Best practice guidance for the catering sector to be developed by industry in partnership with FSA and allergy support organisations and made available to all local authorities.
- Technical training to be delivered to local authorities by the FSA.
- E-learning training for FBOs and local authorities to be refreshed by the FSA.
- Quick start and technical guidance on allergen information rules to be developed for FBOs and local authorities by the FSA.
- Public information campaign utilising social and traditional media channels to highlight allergen knowledge and awareness for FBOs and the general public. To be led by the FSA in partnership with key stakeholders such as OGDs, allergy patient groups, trade bodies, local authorities and caterers.

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 objectives. Some businesses are already taking action to strengthen their allergen information provision. The FSA and FSS see a public awareness/ best practice campaign as essential, whatever the outcome of this review. In relation to this, FSA have launched the #EasytoAsk campaign and relevant businesses have indicated a willingness to directly support a larger repeat of this campaign in their approach to allergen labelling, which could significantly increase awareness. FSS will consider what additional work may be needed in the light of consultation responses.

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 packaging of food prepacked for direct sale, with supporting information for consumers in writing

In the absence of a full list of ingredients, or a list of the allergens contained within the product on the packaging, food prepacked for direct sale would include a label/sticker on the packaging advising consumers to “ask the staff” about allergens. When asked about allergens, staff would have to provide supporting information in writing upon request, before the food was purchased. This information would comprise of either:

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

This sticker would not eradicate the need for businesses to clearly indicate to consumers how allergen information is to be made available for other non-prepacked foods. An example of what the sticker may look like is:



Of the regulatory options proposed, this option is the least costly to implement and is already being rolled out by a number of 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. This risk applies to all options that put allergen information in writing, including options 3 and 4.

This does not seek to create new law on matters of liability between commercial parties or between commercial parties and consumers. The incentive to deliver this policy is not based on economic liability but on regulatory sanctions. Appropriate enforcement and inspection will be sufficient to drive the policy objectives. This is looking to insert additional requirements as to what FBOs must provide information on, not to prohibit them from saying other things, **with this point applying to options 3 and 4.**

Policy option 3. Mandate name of the food and allergen labelling on packaging 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 the FIC the product intentionally 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 non-allergenic 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 small and micro businesses, 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 and may potentially discourage dialogue with staff. In addition, people who are allergic to ingredients that are not on the list of 14 allergenic ingredients laid out in Annex II of the FIC will not

benefit from option 3. Overall, the risk of mislabelling is less for this option than the mislabelling risk associated with option 4.

This option may also lead to businesses removing certain foods from their menu or limit changes to menus (e.g. one-off specials), thus reducing consumer choice in general. It may require new labelling processes to be instituted on business premises and would require substantial training of staff, to equip them with the knowledge and skills to implement allergen labelling procedures accurately. This option may prompt changes in business practices, e.g. moving from PPDS foods to packing foods on the premises at the consumer's request or displaying unwrapped food which could increase the risk of cross-contact with allergens.

Policy option 4. Mandate name of the food and full ingredient list labelling, with allergens emphasised, on packaging of food prepacked for direct sale

This option introduces a regulatory measure requiring PPDS foods to have a label naming the food and listing the full ingredients with allergens emphasised on the packaging.

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

- a. the name of the food
- b. the list of ingredients
- c. any ingredient or processing aid listed in FIC 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, would be emphasised to stand out from the other ingredients in the list.

This option introduces a consistent approach to labelling of ingredients for food that is prepacked and prepacked for direct sale. Businesses are required, in FIC, to provide a basis for consumers to make informed choices and to prevent any practices that may mislead the consumer. It may give food allergic consumers more trust in the food they are eating and help consumers with food allergies and intolerances beyond those mandatorily defined by FIC. It doesn't rely on staff having to provide accurate information on allergens directly to consumers, which, as stated in option 2, the age group 16-24 are seen as particularly vulnerable and not confident in asking for this information, but instead labelling process will be required on the premises, and staff will need to be sufficiently trained to implement 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. Many people have allergies to substances and products outside of the 14 listed in Annex II of FIC, and this option will support these consumers. Another reason for choosing option 4 is to bring PPDS allergen labelling in line with pre-packaged food. Options 2 and 3 would create another set of labelling requirements between pre-packaged and PPDS food which would only add to consumer confusion that already exists. 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 or limit changes to menus (e.g. one-off specials), 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.

This option requires businesses to list ingredients intentionally contained within a product under a heading which consists of or includes the word 'ingredients'. We do not expect precautionary allergen labelling (e.g. may contain) to increase as a result of introducing this option, as any precautionary allergen label would need to be in addition to the ingredient list and shown separately from the ingredient list to avoid misleading the consumer. Full ingredient labelling is unlikely to increase unnecessary precautionary allergen labelling.

Composition of the PPDS market

The exact size and extent 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 (and specific outlets) sell 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 some assumptions in order to set out what is in scope of this assessment.

Different types of Food Business Operators

In terms of this Impact Assessment, it is important to consider the different types of Food Business Operators (FBOs) that likely have the capability to sell PPDS food products. By considering the type of FBO, we will likely be able to determine the level of allergen information they currently provide and be able to assess their capability to adjust to the policy options that are being proposed.

The key categories of business that we have considered are:

- Supermarkets;
- Specialised food retailers – such as butchers, bakers and independent grocers;
- Quick Service Restaurants(QSR)/Cafés/Sandwich shops, etc.;
- A sub component of this being Independent producers – such as those who sell at fairs and markets, etc.;
- Institutional caterers (i.e. operation of Schools and colleges/Hospitals canteens).

When assessing the impacts on business in this paper, we will address each of these sub-categories of food businesses in turn, to account for the differences in how they operate or how they may be impacted.

We also acknowledge that some businesses who currently sell PPDS goods may choose to sell these goods as PPCR or loose, in the event that any policies proposed as part of this review came into force.

This impact assessment does not look at the impacts on Scotland, therefore will focus only on the costs and benefits accrued on the rest of the United Kingdom. To comply with Scottish Government requirements, Food Standards Scotland are developing a separate Business and Regulatory Impact Assessment.

Size of PPDS market

Supermarkets

The supermarkets sector is one which is very much dominated by the large retailers, however there is still significant presence from smaller independent retailers. Based on figures from the ONS Business: size, activity and location¹⁰, there were 27,970 businesses in the 'Retail sale in non-specialised stores with food, beverages or tobacco predominating' sector (SIC code 47.11) in 2018.

Further government statistics⁶ indicate that 99% of businesses in this sector are either micro (less than 9 employees) or small (between 10 and 49 employees).

Specialised food retailers

The make-up of the specialised food retailers sector is varied: containing businesses such as butchers, bakers and grocers. In the ONS data⁶ there were 15,925 businesses in the specialised food retail sector¹¹. The percentage of businesses which are micro or small is 99%⁷.

QSR/Cafés/Sandwich shops, etc.

These businesses selling PPDS foods will be part of the wider 'Restaurants and mobile food service activities' sector (SIC code 56.1). Based on ONS⁶ statistics we know that this sector has approximately 79,350 businesses. 98%⁷ of these businesses being micro or small.

It should be acknowledged that not all of SIC code 56.1 falls under the scope of this Impact Assessment. Traditional sit down restaurants and take-aways make up a significant proportion of this sector but are not in the scope of this analysis, as they sell food which is either packed at the consumers request or loose. To address this we have assumed that these businesses account for a third of the sector (based on unpublished ONS data). Therefore we have adjusted figures for both the number of businesses and outlets in this SIC code.

¹⁰ ONS – Business: Activity, size and location (2018) -

<https://www.ons.gov.uk/businessindustryandtrade/business/activitysizeandlocation/datasets/ukbusinessactivitysizeandlocation>

¹¹ For the purposes of this impact assessment, the number of business was estimated as those in SIC code 47.2 (Retail sale of food, beverages and tobacco in specialised stores) minus SIC codes 47.25 (Retail sale of beverages in specialised stores) and 47.26 (Retail sale of tobacco products in specialised stores).

Institutional Caterers

For the purposes of this impact assessment, we are concerned not with the schools, colleges or hospitals themselves, but the businesses who are contracted to run and operate their canteens. According to the ONS⁶ there are 2,185 businesses in the 'Other food serving activities' sector (SIC code 56.29). The proportion of businesses in this sector that are micro or small is 96%.

Summary of business statistics

Table 1 below provides a summary of the number of businesses that have been included in this analysis.

	Relevant Industry (SIC) code(s)	Number of businesses in sector	Percentage of Small or Micro businesses
Supermarkets	47.11	27,970	99%
Specialised Food Retailers	47.2 minus 47.25 and 47.26	15,925	99%
QSR/Cafes/Sandwich...	56.1	79,350	98%
Institutional Caterers	56.29	2,185	96%

Table 1: Summary of business statistics (not including Scotland)

The number of businesses in the QSR/Cafes/Sandwich shops sector, as listed in table 1, is for the entire sector. For the rest of this impact assessment, we will use an adjusted (reduced by one third) figure of 52,900.

In addition to the number of businesses, the number of outlets⁷ in each sector has been used in this analysis. The breakdown by sector and country for the number of outlets is shown in table 2.

	England	Scotland	Wales	Northern Ireland	United Kingdom	United Kingdom (minus Scotland)
Supermarkets	39,700	4,635	2,310	1,295	47,940	43,305
Specialised Food Retailers	19,315	2,320	1,150	855	24,640	21,320
QSR/Cafes/Sandwich...	86,085	8,710	4,860	2,960	102,615	93,905
Institutional Caterers	11,365	725	405	145	12,640	11,915

Table 2: Number of outlets by sector and region

Similar to the number of businesses, we have adjusted the number of QSR/Cafes/Sandwich shops outlets down by one third to 62,603. This figure will be what is used for this sector in this impact assessment.

For the purposes of this impact assessment, we have assumed that the number of businesses selling PPDS over the appraisal period, will remain constant.

We have noted that the number of businesses in our interested sectors change over time, with this varying based on business type (and in some cases this year to year change is erratic). For example the number of businesses in the Supermarkets sector has increased slightly over the last 10 years (approximately 4%), while the number of Specialised Food Retailer businesses has decreased more significantly (approximately 13%), but smaller in terms of overall number.

The decision was taken to assume that the number of businesses to remain constant over time as the number of businesses who employ the usage of the PPDS format is already uncertain, due to multiple factors (one of which being that new legislation may deter new businesses from using PPDS). So we have elected to simplify this by assuming that the number of businesses selling PPDS will remain constant over the period of appraisal.

Dominance of large firms in interested sectors

To help guide our approach in making assumptions and costing the policy options being considered, it is important to consider the potential disparities across the sectors that we have identified as being of interest. We used Business Population Estimate data (BEIS 2018¹²) to determine the share of turnover and employment held by businesses of different size.

Unfortunately the published data does not go beyond 3 digit SIC code level. So for the Supermarkets (SIC code 47.11) and Institutional Caterers (SIC code 56.29) we have assumed that the shares for the 3 digit SIC code that they sit under (47.1 and 56.2 respectively) are representative of them.

	Micro	Small	Medium	Large
Supermarkets	4.9%	2.3%	1.1%	91.6%
Specialised Food Retailers	42.4%	23.7%	9.2%	24.7%
QSR/Cafes/Sandwich...	22.6%	21.4%	11.0%	45.1%
Institutional Caterers	15.8%	12.3%	6.8%	65.1%

Table 3: Share of sector turnover by business size

	Micro	Small	Medium	Large
Supermarkets	7.1%	3.7%	1.5%	87.8%
Specialised Food Retailers	39.1%	25.4%	8.3%	27.2%
QSR/Cafes/Sandwich...	26.7%	26.3%	10.5%	36.5%
Institutional Caterers	8.4%	9.4%	6.3%	75.9%

Table 4: Share of sector employment by business size

What these statistics show is that there is a significant dominance by large businesses (both in terms of turnover and employees) in the Supermarkets and Institutional caterers sectors. Meanwhile in the Specialised Food Retailers and Quick Service Restaurants etc. there is much more of an even distribution, with small and micro businesses accounting for almost two thirds of both employment and turnover in the Specialised Food Retailers sector (and over half in the QSR, etc. sector).

These variations illustrate further why, for purposes of assessing the impact on businesses, it is important to address each sector individually.

Prevalence of PPDS goods

One of the key aims of our consultation was to better understand the extent of the usage of PPDS goods by businesses. Two of the questions that were asked as part of the consultation related to: how many PPDS goods you sell and what proportion of the goods that you sell do PPDS goods represent (with suggested ranges given for both questions). These questions allowed us to not only establish the number of PPDS goods that a business sells, but also how important the preparation method is to a business. Furthermore we were able to establish whether the size of a business (based on the number of employees) was a factor in whether or not PPDS was more likely to be used.

¹² BEIS: Business Population Estimates (includes breakdown by size of business) - <https://www.gov.uk/government/statistics/business-population-estimates-2018>

Of the 126 businesses who responded to our consultation, only 80 stated that they sell PPDS (which represented 63.5% of the total number of businesses who responded). This rate varied when broken down by business size (with the larger businesses who responded more likely to state that they sell PPDS):

- Micro 40.5%,
- Small 63.6%,
- Medium 64.3%,
- Large 86.8%.

From the information gathered during our consultation, we found that for small and micro businesses PPDS products were likely to represent a higher proportion of the goods they sold, than was the case for medium and large businesses.

Size of Business	Percentage of products sold that are PPDS					
	9% or less	10 – 29%	30 – 49%	50 – 69%	70 – 89%	90 – 100%
Micro	36%	29%	7%	0%	0%	29%
Small	25%	15%	35%	10%	15%	0%
Medium	56%	11%	33%	0%	0%	0%
Large	31%	31%	16%	9%	3%	9%

Table 5: Rate of respondents reporting that PPDS represents a certain percentage of their goods

	Low estimate of PPDS Percentage ¹³	Central Estimate of PPDS Percentage	High Estimate of PPDS Percentage
Micro	31%	37%	44%
Small	28%	36%	44%
Medium	11%	18%	25%
Large	23%	31%	30%

Table 6: PPDS goods as a percentage of all goods (by business size)

However when we look at the number of different PPDS products that businesses stated that they each sold, we found that despite medium and large businesses reporting less of a reliance on PPDS goods (in terms of the percentage of total goods) they typically sold a substantially greater number of different products than small and micro businesses.

¹³ Low, central and upper estimates were calculated using the limits of the bands that were used in the question and the average of those. For example for the 10-29% band, the lower bound was 10% while the upper bound was 29%. These were then multiplied by the percentage of responses that those bands received and summed to get estimates of the average across that size of business.

	Number of different PPDS goods sold				
Size of Business	1 to 10	11 to 19	20 to 29	30 to 49	50+
Micro	57%	21%	14%	0%	7%
Small	14%	14%	24%	19%	29%
Medium	11%	11%	11%	22%	44%
Large	6%	3%	9%	9%	72%

Table 7: Rate of respondents reporting that they sell a certain number of different PPDS products

	Low estimate of Number of PPDS Goods	Central Estimate of Number of PPDS Goods	High Estimate of Number of PPDS Goods
Micro	9	19	28
Small	26	52	78
Medium	32	69	106
Large	41	97	152

Table 8: Number of different PPDS goods sold (by business size)

From the figures gathered during our consultation we can see that despite small and micro businesses selling substantially less PPDS products when compared to medium and large businesses, those goods represent a greater proportion of the goods that they sell. Therefore we can infer that PPDS goods are not only more prominent in small and micro businesses but that these smaller businesses are likely to be more reliant on these type of goods also. This difference in the prevalence of PPDS goods could be a determinant in a business's ability to adjust to the policies being proposed. In addition it may be a factor in a business's decision to shift away from PPDS to other forms of preparation (such as PPCR or loose).

It is important to note that the findings here are based solely on the responses received during our consultation and may not provide an exact picture of the usage of PPDS goods across all businesses. The number of business responses (126) is rather small, when compared to number of businesses we are expecting to be affected by these policies.

Furthermore we need to keep in mind that public consultations are not necessarily representative of the wider population and while anyone can submit their views, individuals and organisations who are more able and willing to respond are more likely to participate.

Due to this likelihood for self-selection, the emphasis of this analysis has not been to count how many respondents held a particular view. Instead it has been largely qualitative, with the aim being to understand the range of key issues raised by respondents, and the reasons for holding their particular views. This includes potential areas of agreement and disagreement between different groups of respondents.

Within each of the accompanying workshops, participants had the opportunity to discuss the benefits and risks of the policy options, and which was their preferred. These discussions were conducted in small groups, and therefore there is a risk that participants were biased in their opinion, or did not feel comfortable expressing views that differed from the majority of the group. With that in mind, any preferences expressed within these discussions did not supersede the individual's or business's response to the online consultation. The aim of these discussions was to understand the reasons behind the views expressed.

Why businesses currently sell PPDS goods

Businesses may choose to sell goods as PPDS instead of PPCR for several different reasons. Utilising PPDS can be a method employed to combat cross contamination. Particularly if the alternative method of preparation is leaving the good lying unwrapped.

Some businesses elect to sell goods as PPDS to allow for increased speed of sale. This allows them to achieve a higher throughput and ultimately turnover that they may not necessarily achieve by selling loose foods or packing food at the consumers request. Some businesses may choose to do so to meet demand during peak periods, where they anticipate what will be required or prepare items which they know to be popular.

Other businesses choose to use the PPDS format as a way of preparing foods towards the end of the day. This practice is common place in supermarkets, particularly with regards to their hot food counter.

Switching away from PPDS

For this impact assessment, we have assumed that businesses who currently sell products as PPDS will continue to do so after these policy options have been implemented. Businesses communicated to us during the consultation period that they would have to consider whether they will continue to do so. Part of this consideration would be based on whether the Government intends to carry out further work changing the legislation relating to non-prepacked foods.

For some businesses, PPDS is the only means by which they can operate (or operate to an efficiency which is profitable). This is likely to be more of an issue in businesses where there are peak periods and PPDS is used as a means to meet peak demand. Therefore if they were to switch to PPCR (or loose) then the rate at which they can serve customers is likely reduced. Businesses may then experience a drop in turnover (which may be viewed as an indirect cost to business of these options). However we do not have enough information on the point at which businesses would switch to inform this. Similarly we do not know the impact that switching away from PPDS would have on the profitability of specific food businesses.

The ease with which a business can switch away from PPDS may also be linked to the size of business. It is likely the case that the smaller the business the easier it may be for them to switch from PPDS to PPCR or loose, likely due to the overall number of PPDS products that they sell being less than that sold in larger businesses. Furthermore the likelihood of a business's switching this will also largely depend on the reason why a given business sells PPDS currently.

There may also be impacts on consumers, if businesses were to shift from PPDS to loose or PPCR, then there could be an increased risk of cross contamination. Therefore the result could be that we would trade one potential food health risk for another.

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 Book¹⁴.

If the policy is successful, benefits may be accrued through:

- improved provision of allergen information to consumers relating to food prepacked for direct sale;
- 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 prepacked for direct sale food;
 - which greatly benefits not only the consumer in avoidance of said negative experiences, but also the government in avoided treatment costs;
- and a reduction in fatalities due to allergic reaction.

The benefits have been assessed, however due to the uncertainty regarding how many allergen related incidents occur due to PPDS items we cannot say that these are fully representative. As a result of this we have undertaken illustrative analysis to show potential benefits that could be achieved.

The main categories of costs to be considered are:

- familiarisation costs (for businesses and government) associated with any new legislation and/or guidance that is issued;
- additional time spent by government (local authorities) enforcing any new legislation;
- training costs for government as a result of new guidance being issued;
- labelling costs for businesses (either amending current labels or adorning new ones);
- increased difficulty of businesses to substitute goods/ingredients of PPDS products;
- increased difficulty for businesses in developing new product lines which may be sold as PPDS;
- cost to business of determining the constituent ingredients of PPDS goods.

These costs are not exclusive to any one group, some will apply to both businesses and government.

The costs listed in this impact assessment likely do not reflect the complete picture of those associated with policy options considered. Due to incomplete information and uncertainty over the extent/coverage of certain costs, we are unable to provide a best estimate of all the costs that may occur.

The benefits of each policy option are introduced alongside the costs of each option, however a greater discussion of the potential health benefits in general has been included in Annex K The primary purpose of the annex is to provide an illustration of the comparative value of some of the benefits with respect to the monetised costs.

The Department ran a nine week consultation and held eight stakeholder workshops to help fill the evidence and knowledge gaps which were identified in the previous impact assessment. The full extent to which previous information issues were or were not addressed during the consultation period shall be discussed thoroughly.

It is difficult to establish a precise 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 have already begun to do more than is the minimum requirement, so some may already be carrying out what our policy options set out.

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

Potential for over/under-estimation of costs

Due to the uncertainty surrounding our understanding of the exact number of businesses that sell PPDS foods, we may overestimate the number of businesses who will be affected by these policy options. We have made an attempt to adjust for this, however there is still a likelihood that we have overestimated the number of businesses. This may lead to us overestimating the costs.

We have made an assumption that Supermarkets and Specialised Food Retailers already employ practices similar to Option 3, however this may not be true of every business in these sectors. Therefore this may indicate that our costings for these types of business for Options 2 and 3 to be underestimated.

Similarly we know that some businesses have begun to implement (or are in the process implementing) full ingredient labelling, particularly in the QSR/Cafes/Sandwich shops sector, however the exact extent to which this is happening is unknown. The Department made attempts to establish the current labelling practices of businesses at consultation stage. What became apparent was it would be impossible to accurately determine the extent to which businesses have already adopted full ingredient labelling. One example of the difficulties faced is, in addition to the

¹⁴ The Green Book: appraisal and evaluation in central government - <https://www.gov.uk/government/publications/the-green-book-appraisal-and-evaluation-in-central-government>

uncertainty on a business to business base there is also an inconsistent picture within businesses (on an outlet to outlet basis). In different cases businesses who have indicated the intention to implement full ingredient labelling are still to do so across all of their own outlets. Furthermore the department is unable to assess whether the full ingredient labelling that is being adopted by businesses, fulfils the necessary criteria for such labelling that will be set out in legislation. As a result the department is not in possession of sufficient evidence to make an estimation of the number of businesses already implementing full ingredient labelling. For the purposes of this impact assessment, we have assumed that no business currently has full ingredient labelling. As we know this not to be the case, we have likely overestimated the extent of the costs/impact of Option 4 as result. As we know this not to be the case, we have likely overestimated the extent of the costs/impact of Option 4 as result. Illustrative costings have been included in Annex J, showing the reduction in costs (for Option 4) that occur when businesses begin to voluntarily move towards full ingredient labelling.

Comparison with pre-consultation stage Impact Assessment

The costs that have been presented in this impact assessment are larger than those presented in the Department's pre-consultation stage IA. Looking at the comparative costing of the preferred policy option (Option 4), the pre-consultation stage impact assessment estimated the net present value (NPV) to be £-10.4 million, while we now estimate this to be £-321.8 million.

This increase in the magnitude of the anticipated costs (to both businesses and local authorities) is a result of our improved understanding of the PPDS market from the previous impact assessment to now. In the initial impact assessment we set out some assumptions relating to the size of the PPDS market and how businesses use the preparation method. These assumptions were then tested during the consultation process (in both the consultation itself and the stakeholder workshops that were held) and based on the feedback we received, we now have a different understanding of certain aspects of the PPDS market.

As a result we now anticipate that the range of affected businesses is much larger than previously thought, with this increase in affected businesses being one of the most significant drivers in explaining the increase in the cost to businesses. The increased number of businesses in scope will also affect the local authorities, due to the requirement for these businesses to receive enforcement visits.

Similarly we now have an improved understanding of the current labelling practices of businesses in the affected sectors, which has lead us to anticipate more on-going costs in this impact assessment that were not considered at the previous stage.

The impacts on local authorities have also increased from the previous impact assessment, again as a result of improved understanding of the impacts on them and how they operate. For local authorities (and businesses too), during the consultation process they articulated clearly that the assumed time taken for familiarisation was too conservative in the previous impact assessment and needed revision.

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.

It should be noted that we have assumed a different baseline position (in terms of current labelling practices) for different types of businesses. For supermarkets and Specialised Food Retailers, we assume that in the baseline scenario they already implement labelling similar to what is being proposed in Option 3. Meanwhile in QSR/Cafes/Sandwich shops and Institutional catering we assume that they do not go beyond the current information provision requirements.

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 scenario.

However if the government were to provide new technical guidance specific to PPDS, we would expect businesses to familiarise themselves with this new guidance. This is what currently provides businesses with information regarding what is defined as PPDS (and other similar definitions and guidelines).

Familiarisation costs

This cost has been monetised. There may be a one-off cost for businesses, associated with reading and familiarising themselves with any new guidance (such as new technical guidance) that is produced. Time will be spent acquiring, reading and understanding the implications of the new guidance 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 guidance, by their hourly wage rate. The relevant average hourly rate (from ONS Annual Survey of Hours and Earnings data¹⁵) has been up-lifted (by 30%) to take into account the non-wage labour costs and overheads (which is the standard methodology).

We assume¹⁶ that all businesses selling PPDS foods will need to familiarise themselves with this new guidance. However the time taken by each business will vary depending on size (i.e. number of employees) as well as the number of outlets that they have.

We assume that for small and micro businesses it would take one member of staff one hour to read and familiarise themselves with any new guidance. For medium and large businesses we assume that it will take one member of staff 1.5 hours to read and familiarise themselves with any new guidance. In addition, we have assumed that there will be an additional hour of familiarisation cost (per outlet) to reflect the need to disseminate any new understanding/knowledge to other members of staff.

For Supermarkets and Institutional Caterers we have assumed that a regulatory professional will carry out this familiarisation process. For Specialised Food Retailers we have assumed that a food preparation tradesperson (i.e. head butcher or baker) will do so. While for Quick Service Restaurants and sandwich shops we assume that a manager or proprietor will be responsible for familiarisation.

The average hourly wage for 'Quality assurance and regulatory professionals' is £24.13 according to 2018 ONS: Annual Survey of Hours and Earnings (ASHE) data (see Annex A). This wage rate is then uprated by 30% to £31.37. For small and micro businesses the familiarisation cost is £31.37, while the cost for medium and large businesses is £47.06. The individual outlet familiarisation cost is also £31.37.

The average hourly wage for 'Food preparation and hospitality trades' is £10.16 according to 2018 ASHE data (see Annex B). This wage rate is then uprated by 30% to £13.21. For small and micro businesses the familiarisation cost is £13.21, while the cost for medium and large businesses is £19.82. The individual outlet familiarisation cost is also £13.21.

The average hourly wage for 'Restaurant and catering establishment managers and proprietors' is £11.93 according to the 2018 ASHE data (see Annex C). This wage rate is then uprated by 30% to £15.51. For small and micro businesses the familiarisation cost is £15.51, while the cost for medium and large businesses is £23.27. The individual outlet familiarisation cost is also £15.51.

¹⁵ ONS Annual Survey of Hours and Earnings (ASHE) 2018 - <https://www.ons.gov.uk/employmentandlabourmarket/peopleinwork/earningsandworkinghours/datasets/regionbyoccupation4digitsoc2010asheta> ble15

¹⁶ Our assumptions for time spent for familiarisation are based on discussions with businesses during our stakeholder workshops, as well as consultation responses received.

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

Then the total cost to each type of business was calculated by multiplying the cost per business by the relevant number of businesses, then adding the cost per outlet multiplied by the relevant number of outlets. The total familiarisation costs for all businesses in the scope of this review are shown in table 3.

	Low Estimate Familiarisation Costs (£m)	Central Estimate Familiarisation Costs (£m)	High Estimate Familiarisation Costs (£m)
Total Familiarisation costs	£3.09	£4.97	£6.14

Table 9: Estimated familiarisation costs to business under Option 1

Costs to consumers

Business may seek to pass any increase in costs on to consumers. The extent to which these costs will be passed on will depend on a number of factors relating to supply and demand of the products. Given the uncertainties, we have not assumed a specific level of pass on and it should be noted that these costs are not additional to those set out above but about the incidence of the costs.

Costs to Government

What has been defined in this Impact Assessment as 'Best Practice' may not be the exact approach taken by Government should this policy Option be taken forward. However the following discussion of costs are there to indicate the potential costs which may arise for Government based on what has been suggested as possible methods to achieve 'Best Practice'.

Work by Government developing 'Best Practice' materials

In order to deliver the aspects highlighted as potential best practice options, there will need to be work carried out by government officials to prepare the requisite materials. We have assumed that to develop a media campaign, one working time equivalent (WTE) for a period of four months will be required. Similarly to develop technical guidance one WTE for a period of nine months will be required. Lastly to apply the new guidance that is developed and update the existing FSA training, half of a WTE for a period of 12 months will be required. This results in 1.6 WTE being required to implement this work.

Our assumption is that this work will be undertaken by a team which is comprised of both HEO and SEO grades evenly. Therefore the associated wage costs for this work will be the average of the two grades (including overheads¹⁷). A sensitivity analysis (of +/- 20%) has been applied to provide lower and upper estimates.

Finally to estimate the total labour costs, we multiply the average wage cost by the WTE that is required.

	Low Estimate of Labour Costs (£m)	Central Estimate of Labour Costs (£m)	High Estimate of Labour Costs (£m)
Total labour cost	£0.06	£0.08	£0.09

Table 10: Estimated labour costs associated with developing best practice materials

External contractors working with Government

In partnership with Government (FSA) external contractors will likely be required to help produce e-learning, marketing campaigns, provide PR services and assist with the development/implementation of some of the best practice materials. It has been estimated that in total, the labour requirement will be two WTEs for a period of 12 months. Despite this work being carried out by non-Government employees, the cost will be met by Government so is counted as such.

Similar to the costs to business for familiarisation, we have used ONS ASHE data to ascertain the average annual wage for these professionals. The average annual salary for 'Public relations professionals' (SOC code – 2472) was £36,191. ONS ASHE data lowest and highest decile salaries for each occupation (see Annex D) have been used to produce low and high end estimates.

¹⁷ Based on FSA data, we estimate this to be approximately £44,000 and £52,000 for HEO and SEO grades respectively.

The average annual salary for 'Web design and development professionals' was £33,502 (see Annex E). Due to uncertainty in the how much one role will be required more than the other, the mean of the two annual salaries was calculated. As with previous calculations for familiarisation costs to businesses, the salaries have been uplifted by 30%.

The cost of the external labour required is then estimated by multiplying the mean annual salary of the two occupations by the labour required (two WTE).

	Low Estimate of External Labour Costs (£m)	Central Estimate of External Labour Costs (£m)	High Estimate of External Labour Costs (£m)
External labour costs	£0.04	£0.09	£0.11

Table 11: Estimated cost of external contractor labour

Administering training workshops

In addition to developing (or more precisely updating current) training, there would be a need for there to be new face to face training sessions with enforcement officials. This has been carried out previously by the FSA and is the basis of the costs included here.

Previously training was implemented over an 18 month period (during a total of 30 workshops) to approximately 1,500 environmental health officers (EHOs) and trading standards officers (TSOs). The budget for this was estimated at £120,000. This represents the approximate cost per EHO/TSO to be £80.

Currently, according to FSA figures, there are 1,793¹⁸ food hygiene and food standards inspectors. Therefore assuming that the cost per EHO/TSO to still be representative, the cost of administering training has been estimated by multiplying the cost per EHO/TSO by the number of food hygiene/standards staff.

To provide a range of estimates, a sensitivity analysis of +/- 20% has been applied to the calculated costs.

It is important to note that the administering of training can only happen once the training itself has been updated. Therefore the cost of administering training will not begin until Year 1, with only two thirds of this cost being felt at this time (as workshops took 18 months to implement previously. The final third of the training costs will fall in Year 2.

	Low Estimate of Training Costs (£m)	Central Estimate of Training Costs (£m)	High Estimate of Training Costs (£m)
Training costs	£0.11	£0.14	£0.17

Table 12: Estimated cost of administering training workshops

It has been noted that the training workshops could be replaced by the production of an educational video due to the limited focus (primarily on PPDS products) of the update to the training. This would likely only happen if it was assessed to be a more cost effective and efficient method than the face to face workshops that are proposed here.

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 any new guidance on their inspection body (local authority). Again the current guidance is what defines what PPDS is, so any alteration to it will have implications not just for the businesses who sell PPDS but also those who enforce the current allergen information provisions.

We assume that for Option 1, each Trading Standards Officer (TSO) and Environmental Health Officer (EHO) will take three hours¹⁹ to read and familiarise themselves with the any new guidance. In addition to this, there will be an additional working day (7.4 hours) per local authority for EHO/TSOs to reach a consensus on how to proceed with the new guidance.

According to 2018 ASHE data, the average wage rate for a 'Trading standards officer' (SOC code - 3565) is £17.48 (see Annex F). This is then uprated by 30% to £22.72.

According to 2018 ASHE data, the average wage rate for an 'Environmental health professional' (SOC code - 2463) is £19.00 (see Annex G). This is then uprated by 30% to £24.70. In some local authorities a TSO will carry

¹⁸ This figure is based on FSA statistics for UK full time equivalent (FTE) staff for 2017/18.

¹⁹ Familiarisation time is based on discussions during our workshops with Local Authorities. They felt that the time stated in the previous impact assessment did not reflect the true nature of their work. All times used in this impact assessment aim to reflect the collective thoughts and views of not only those who attended the workshops but those who responded to our consultation as well.

out inspections and in others an EHO will do so. Accordingly, the average of the two uprated hourly wages has been calculated. The average uprated wage is calculated to be £23.71. Therefore the cost for familiarisation per EHO/TSO is £71.14 and the familiarisation cost per local authority (inspection body) is £175.47.

As with the familiarisation cost to businesses, low and high end hourly wages were used (based on the decile data in ASHE) to produce low and high estimates for familiarisation costs.

The total familiarisation cost to government is found by multiplying the cost per EHO/TSO by the number of EHO/TSO (1,793). This is then added to the familiarisation cost per local authority multiplied by the relevant number of local authorities²⁰ who would be carrying out visits on businesses.

As with the training costs, the costs associated with familiarisation can only come into effect once new guidance is produced. Therefore any cost associated with familiarisation will not be felt until Year 1.

The range of estimates calculated for familiarisation cost to business are listed below in table 13.

	Low Estimate Familiarisation Cost (£m)	Central Estimate Familiarisation Cost (£m)	High Estimate Familiarisation Cost (£m)
Total familiarisation cost for Government	£0.09	£0.13	£0.14

Table 13: Estimated familiarisation costs to Government under Option 1

Summary of the Total Costs to Government

	Low Estimates (£m)	Central Estimates (£m)	High Estimates (£m)
Total Labour Costs	£0.10	£0.17	£0.20
Delivery of training	£0.11	£0.14	£0.17
Familiarisation costs	£0.10	£0.14	£0.16
Total costs	£0.32	£0.45	£0.61
Total – Year 0	£0.10	£0.17	£0.20
Total – Year 1	£0.18	£0.2	£0.3
Total – Year 2	£0.04	£0.05	£0.06

Table 14: Estimated total cost to Government

Benefits

The benefits of this option 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 and therefore the effect that this would have on reducing allergen related incidents in PPDS.

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

²⁰ Local authority split: England – 353, Wales – 22, Northern Ireland - 11

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

Costs to businesses

Familiarisation Costs.

The methodology used here is similar to that used for the familiarisation costs for businesses under Option 1. We have assumed that the same occupations will undertake the familiarisation as outlined in Option 1.

As before 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.

For option 2 we assume²¹ that for small and micro businesses it would take one member of staff two hours to read and familiarise themselves with new legislation. For medium and large businesses we assume that it will take one member of staff three hours to read and familiarise themselves with new legislation. In addition, we have assumed that there will be an additional hour of familiarisation cost (per outlet) to reflect the need to disseminate any new understanding/knowledge to other members of staff.

For Supermarkets and Institutional Caterers, the small and micro business familiarisation cost is £62.74, while the cost for medium and large businesses is £94.11. The individual outlet familiarisation cost is £31.37.

For QSR/Cafes/Sandwich Shops the small and micro business familiarisation cost is £26.42, while the cost for medium and large businesses is £39.63. The individual outlet familiarisation cost is £13.21.

For QSR/Cafes/Sandwich Shops the small and micro business familiarisation cost is £31.02, while the cost for medium and large businesses is £46.53. The individual outlet familiarisation cost is £15.51.

Then using the same methodology as that used in option 1, the estimates in table 15 were produced.

	Low Estimate Familiarisation Costs (£m)	Central Estimate Familiarisation Costs (£m)	High Estimate Familiarisation Costs (£m)
Total Familiarisation costs	£4.34	£6.96	£8.58

Table 15: Estimated familiarisation costs to business under Option 2

Labelling Costs.

This cost has been monetised. Under this option businesses will be required to include “Ask the staff” as part of the labelling on PPDS foods. In order to assess this costs, we will address each of our interested sectors in turn.

Supermarkets

During our consultation and stakeholder workshops, we came to understand that Supermarkets already carry out labelling on their PPDS products to a standard that is very much equitable to what is being proposed as Option 3 in this review. This is particularly true for the large supermarkets, who (as illustrated previously) account for approximately 90% of the sector (both in terms of turnover and employees).

Given that the proposed legislation will allow for any business that already labels their PPDS goods (either with just the allergens or the full ingredients) will not be required to include ask the staff labelling on their PPDS products.

We assume that these businesses would not experience any additional costs as a result of Option 2 being implemented.

Specialised food retailers

Similar to supermarkets, based on our consultation and workshops, it is our understanding that for PPDS goods that would require labelling many businesses are already providing information similar to Option 3.

Another factor that likely will reduce the likelihood of a need to add this type of label, is the increased prevalence of single ingredient PPDS items ((such as a steak or fillet of fish) compared to other sectors considered here. As the name of these products are the ingredients, these products already provide full ingredient labelling so would be going beyond the requirements of Option 2.

Therefore we assume that there will be not be any additional costs to these businesses as a result of Option 2.

²¹ Our assumptions for time spent for familiarisation are based on discussions with businesses during our stakeholder workshops, as well as consultation responses received.

QSR, Sandwich Shops, etc.

Unlike as discussed for Supermarkets and Specialised food retailers, we do not have a firm understanding of the extent to which these businesses already provide allergen (or full ingredient) labelling on their PPDS products.

We know that some businesses (in particular the largest) have begun to move towards more intensive labelling options (more akin to Options 3 and 4) but do not know for sure the extent of this across the sector.

For those businesses that do not currently label their PPDS products, there will be an initial transitional cost of labelling and then an additional on-going cost for each year of this appraisal, from the time it is required to be implemented onwards.

Institutional caterers

Similar to QSR, Sandwich shops, etc. we do not have a firm understanding of the extent to which businesses already provide allergen or full ingredient labelling on their PPDS products.

For those businesses that do not currently label their PPDS products, there will be an initial transitional cost of labelling and then an additional on-going cost for each year of this appraisal, from the time it is required to be implemented onwards.

Calculation of costs – Transitional Costs: QSR and Sandwich shops

For these calculations we have combined the two sectors (QSR... and Institutional Caterers).

Based on previous research²², we know that for minor labelling changes the range in cost per stock keeping unit (SKU) is £10 - £1,800²³. Uprating these to 2019 prices²⁴, we then assume that the cost of re-labelling to be the lower estimate per SKU for small and micro businesses, and upper estimate per SKU for medium and large businesses.

Our assumption is that an SKU can be equated to a distinct PPDS food product in these businesses and that the cost to make a label change can be equated to the cost of introducing a brand new label to the packaging of a PPDS product.

We assume, 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, including single ingredient items). 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 (using those that we stated in the composition of the PPDS market section).

A sensitivity analysis (of +/- 20%) was used to estimate a lower and upper bound for labelling costs to these businesses.

	Low estimate of labelling costs (£m)	Central Estimate of labelling costs (£m)	High Estimate of labelling costs (£m)
Micro	£0.40	£0.50	£0.59
Small	£0.09	£0.12	£.14
Medium	£1.27	£1.59	£1.91
Large	£0.35	£0.43	£0.52
Total	£2.11	£2.63	£3.16

Table 16: Transitional labelling costs for QSR, Sandwich shops, etc. and Institutional Caterers due to Option 2

²² 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>

²³ The assumed range in the cost per SKU is due to the complexity of the labelling that businesses will likely choose to implement (smaller businesses more likely to have simple labelling).

²⁴ 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>

For this impact assessment, we are assuming that for Option 2 there will be a 12 month implementation period (from the introduction of the new legislation) before businesses will be required to have this standard of labelling on their products. Therefore these labelling costs will not come into effect until the second year of our appraisal.

Calculation of Costs – On going costs: QSR and Sandwich shops

In addition to the initial costs of adopting a label on PPDS products, we will also need to account for the on-going cost of labelling these products. This on-going cost will simply be the marginal cost of each additional label. In order to calculate this, we have assumed that the average outlet/unit in QSR, Sandwich shops and Institutional catering sell approximately the same number of products. We estimate this to be around 25,000 PPDS products annually per outlet²⁵.

We have estimated that the typical FBO outlet will spend approximately £100.00 annually on labels. Based on the cost of a single label being £0.004²⁶.

We previously set out the number of outlets by sector. For QSR this was 62,603 and for Institutional catering it was 11,915. Therefore we have calculated the annual on-going cost for each sector by multiplying the cost of labels per outlet by the number of outlets themselves.

Low and High estimates have been calculated based on the range of the number of PPDS products sold across all businesses.

In order to provide estimates by business size, the employment shares from table 4 have been used as a means to attribute these costs by business size.

	Low estimate of labelling costs (£m)	Central Estimate of labelling costs (£m)	High Estimate of labelling costs (£m)
Micro	£0.76	£1.67	£2.59
Small	£0.74	£1.65	£2.55
Medium	£0.30	£0.66	£1.02
Large	£1.03	£2.29	£3.54
Total	£2.83	£6.26	£9.69

Table 17: On-going labelling costs for QSR, Sandwich shops, etc. and Institutional Caterers due to Option 2

These on-going costs would come into effect from the same year as the transitional labelling costs are assessed.

Provision of written information

This is currently non-monetised, 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.

In addition it has not been defined the medium in which businesses must provide this written information. It could simply be in writing at the time of purchase which would have a near zero additional cost.

Furthermore as the information that must be provided in writing can be either full ingredients or simply allergens, there would be no additional cost for collating the information necessary (as businesses should already be able to provide this under current legislation).

Training Costs.

This has not been monetised. During our consultation we spoke with a variety of businesses (from different industries/sectors). It is now our understanding that businesses already provide training which includes allergen training. Others even offer specific allergen training modules. Moreover many make use of the FSA produced training, if they are unable to develop their own (which is often the case for smaller businesses). Businesses indicated that they would not need to alter any allergen training they provide. Moreover it became clear during the consultation that allergen issues in food businesses are more likely to be a result of the high staff turnover (typical in retail and foodservice) or lack of experience in encountering these situations, rather than an issue with the training that they have received.

²⁵ This figure is estimate is based on information from Horizons Data Services (2015) relating to the number of meals sold per outlet. We have used the information gathered from our consultation on the prevalence of PPDS goods (as a proportion of total goods sold) to estimate the number of PPDS goods sold per outlet.

²⁶ <https://www.ers-online.co.uk/p5128/ers-media-thermal-transfer-labels-blank-desktop-label-printers>

Although not explicitly required, businesses may choose to improve staff training practices. It is not clear what specific form of additional training would be necessary to enable businesses to implement this option effectively.

Enforcement Costs

Food businesses already undergo inspections by Trading Standards Officers and Environmental Health Officers. These are the primary method of enforcement used by local authorities and are carried out on the basis of a combination of risk and intelligence. Any preparation a business will need to do will not change.

We estimate that for Option 2 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 years²⁷. This estimate of the additional time required is based on both the responses to our consultation and engagement with local authorities during our stakeholder workshops.

During these inspections it would be inspected that a member of staff, most likely the owner/proprietor (in smaller establishments) or the outlet manager, would accompany the EHO/TSO carrying out the inspection. We will use the uprated average wage rate of 'Food preparation and hospitality trades' and 'Restaurant and catering establishment managers and proprietors' (£14.36) that was used to estimate familiarisation costs, as the time cost associated with inspections. Therefore the additional cost per inspection is £3.59.

The total cost of enforcement is the cost per inspection multiplied by the frequency of inspections per year for each business, finally multiplied by the number of affected outlets that are in scope of this review (approximately 134,466). The number of outlets excludes small and micro retailers, as due to our assumption that they do not sell PPDS goods then they would not incur any additional enforcement time during an inspection.

These costs will be on-going from the point at which businesses are required to implement "Ask the Staff" labelling (i.e. after the 12 month implementation period).

	Low Estimate Enforcement Cost (£m)	Central Estimate Enforcement Cost (£m)	High Estimate Enforcement Cost (£m)
Micro	£0.03	£0.05	£0.06
Small	£0.03	£0.04	£0.05
Medium	£0.01	£0.02	£0.02
Large	£0.10	£0.14	£0.21
Total	£0.17	£0.24	£0.29

Table 18: Estimated enforcement costs to business under Option 2

Costs to consumers

Business may seek to pass any increase in costs on to consumers. The extent to which these costs will be passed on will depend on a number of factors relating to supply and demand of the products. Given the uncertainties, we have not assumed a specific level of pass on and it should be noted that these costs are not additional to those set out above but about the incidence of the costs.

Costs to Government

Familiarisation Costs.

The methodology used here is similar to that used for the familiarisation costs for government under Option 1.

As before, 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 inspection body (local authority).

We assume that for Option 2, each Trading Standards Officer (TSO) and Environmental Health Officer (EHO) will take one working day²⁸ (7.4 hours) to read and familiarise themselves with the new regulations. In addition to this, there will be an additional working day (7.4 hours) per local authority for EHO/TSOs to reach a consensus on how to proceed with the new legislation.

²⁷ Trading Standards Wales (accessed 22/11/2018) - <https://www.tradingstandardswales.org.uk/help/foodinspect.cfm>

²⁸ Familiarisation time is based on discussions during our workshops with Local Authorities. They felt that the time stated in the previous impact assessment did not reflect the true nature of their work. All times used in this impact assessment aim to reflect the collective thoughts and views of not only those who attended the workshops but those who responded to our consultation.

Using the same wage rates as outlined under Option 1, the cost for familiarisation per EHO/TSO is £175.47 and the familiarisation cost per local authority (inspection body) is £175.47.

As with the familiarisation cost to businesses, low and high end hourly wages were used (based on the decile data in ASHE) to produce low and high estimates for familiarisation costs.

The total familiarisation cost to government was calculated using the same methodology as Option 1.

Unlike Option 1, the cost of familiarisation will occur immediately (i.e. Year 0).

The range of estimates calculated for familiarisation cost to business are listed below in table 18.

	Low Estimate Familiarisation Cost (£m)	Central Estimate Familiarisation Cost (£m)	High Estimate Familiarisation Cost (£m)
Total familiarisation cost for Government	£0.22	£0.32	£0.35

Table 19: 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 for Option 2 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 years²⁹.

We will use the uprated average wage rate of EHOs and TSOs (£23.71) that we calculated for familiarisations cost, as the time cost associated with inspections. Therefore the additional cost per inspection is £5.93.

The total cost of enforcement is the cost per inspection multiplied by the frequency of inspections per year for each business, finally multiplied by the number of affected outlets that are in scope of this review (approximately 134,466 outlets across our sectors of interest).

These costs will be on-going for the entire appraisal period.

	Low Estimate Enforcement Cost (£m)	Central Estimate Enforcement Cost (£m)	High Estimate Enforcement Cost (£m)
Total enforcement costs	£0.27	£0.40	£0.44

Table 20: Estimated enforcement costs to Government under Option 2

Benefits

The benefits of this option 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 (with respect to Option 1) in reducing the likelihood of incidents due to allergic reactions from PPDS foods.

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 encouraged 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 may allow for allergy suffering consumers to have an improved choice of where to buy food from.

This too implies a potential 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.

²⁹ Trading Standards Wales (accessed 22/11/2018) - <https://www.tradingstandardswales.org.uk/help/foodinspect.cfm>

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

Costs to businesses

Familiarisation Costs.

The methodology used here is similar to that used for the familiarisation costs for businesses under Options 1 and 2. We have assumed that the same occupations will undertake the familiarisation as outlined in Option 1.

For option 3 we assume³⁰ that for small and micro businesses it would take one member of staff half a working day (3.7 hours) to read and familiarise themselves with new legislation. For medium and large businesses we assume that it will take one member of staff 0.75 working days (5.6 hours) to read and familiarise themselves with new legislation. In addition, we have assumed that there will be an additional hour of familiarisation cost (per outlet) to reflect the need to disseminate any new understanding/knowledge to other members of staff.

For Supermarkets and Institutional Caterers the small and micro business familiarisation cost is £116.07, while the cost for medium and large businesses is £175.67. The individual outlet familiarisation cost is £31.37.

For Specialised Food Retailers the small and micro business familiarisation cost is £48.88, while the cost for medium and large businesses is £73.98. The individual outlet familiarisation cost is £13.21.

For QSR/Cafes/Sandwich shops the small and micro business familiarisation cost is £57.39, while the cost for medium and large businesses is £86.86. The individual outlet familiarisation cost is £15.51.

Then using the same methodology as that used in option 1, the estimates in table 21 were produced.

	Low Estimate Familiarisation Costs (£m)	Central Estimate Familiarisation Costs (£m)	High Estimate Familiarisation Costs (£m)
Total Familiarisation costs	£6.47	£10.34	£12.73

Table 21: Estimated familiarisation costs to business under Option 3

Labelling Costs

This cost has been monetised. Under this option businesses will be required to label the allergens (from the list of 14) on PPDS foods. In order to assess this cost, we will address each of our interested sectors in turn.

Supermarkets

As stated during the costs associated with Option 2. During our consultation and stakeholder workshops, we came to understand that Supermarkets already carry out labelling on their PPDS products to a standard that is very much equitable to what is being proposed as Option 3 in this review. This is particularly true for the large supermarkets, who (as illustrated previously) account for approximately 90% of the sector (both in terms of turnover and employees).

Therefore we assume that Supermarkets are already implementing Option 3 labelling and would not be subject to any costs as a result.

Specialised food retailers

Similar to as stated in Option 2, based on our consultation and workshops, it is our understanding that for PPDS goods that would require labelling many businesses are already providing information similar to Option 3.

Another factor that likely will reduce the likelihood of a need to add this type of label, is the increased prevalence of single ingredient PPDS items ((such as a steak or fillet of fish) compared to other sectors considered here. As the name of these products are the ingredients, these products already provide full ingredient labelling so would be going beyond the requirements of Option 3.

Therefore we assume that there will be not be any additional costs to these businesses as a result of Option 3.

QSR, Sandwich Shops, etc.

As stated in option 2, we do not have a firm understanding of the extent to which these businesses already provide allergen (or full ingredient) labelling on their PPDS products. We know that some businesses (in particular the

³⁰ Our assumptions for time spent for familiarisation are based on discussions with businesses during our stakeholder workshops, as well as consultation responses received.

largest) have begun to move towards more intensive labelling options (more akin to Options 3 and 4) but do not know for sure the extent of this across the sector.

For those businesses that do not currently label their PPDS products, there will be an initial transitional cost of labelling and then an additional on-going cost for each year of this appraisal, from the time it is required to be implemented onwards.

Institutional caterers

Similar to QSR, Sandwich shops, etc. we do not have a firm understanding of the extent to which businesses already provide allergen or full ingredient labelling on their PPDS products.

For those businesses that do not currently label their PPDS products, there will be in initial transitional cost of labelling and then an additional on-going cost for each year of this appraisal, from the time it is required to be implemented onwards.

Calculation of costs – Transitional Costs: QSR and Sandwich shops

For these calculations we have combined the two sectors (QSR... and Institutional Caterers). We have used the same costs per SKU as outlined in Option 2.

As part of our consultation we sought to understand the usage of PPDS products by businesses. The results of our attempt to establish the number of PPDS products sold by businesses was outlined in the 'Composition of the PPDS market' section of this impact assessment.

We have continued with our assumption, that an SKU can be equated to a distinct PPDS food product in these businesses and that the cost to make a label change can be equated to the cost of introducing a brand new label to the packaging of a PPDS product.

Using the results of our consultation, multiplying the number of PPDS products sold by businesses (broken down by business size) by the number of businesses in those size categories, we were able to attain the total number of PPDS products sold in each sector (by business size).

		Lower Estimate	Central Estimate	High Estimate
QSR, etc.	Micro	393,493	789,990	1,186,487
	Small	262,933	516,408	769,883
	Medium	23,904	51,081	78,259
	Large	7,370	17,362	27,353
Institutional Caterers	Micro	17,119	34,369	51,619
	Small	7,278	14,295	21,311
	Medium	1,538	3,286	5,035
	Large	1,361	3,207	5,052
Table 22: Total number of different PPDS products sold by businesses				

In order to determine the total labelling costs to business, we have multiplied the cost per SKU by the number of by the number of PPDS products sold (as defined by business size).

	Low estimate of labelling costs (£m)	Central Estimate of labelling costs (£m)	High Estimate of labelling costs (£m)
Micro	£4.63	£9.30	£13.97
Small	£3.05	£5.99	£8.92
Medium	£51.66	£110.39	£169.12
Large	£17.73	£41.76	£65.80
Total	£77.07	£167.44	£257.81
Table 23: Labelling costs for QSR, Sandwich shops, etc. and Institutional Caterers due to Option 3			

It should be noted that due to the fact that we know businesses have already begun to move towards improved allergen or ingredient labelling, that the costs listed here likely overestimate the actual costs to business as a result of Option 3.

For this impact assessment, we are assuming that for Option 3 there will be an 18 month implementation period (from the introduction of the new legislation) before businesses will be required to have this standard of labelling on their products. Therefore these labelling costs will not come into effect until the second year of our appraisal, at which point we will assess half of the annual cost for this year.

Calculation of Costs – On going costs: QSR and Sandwich shops

We assume that this will be the same cost as calculated for option 2, due to the number of total labels required being the same across both of the options.

Indirect costs associated with new labelling.

This is a non-monetised cost. . Introducing labelling (or increasing labelling requirements) 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. This practice is more likely in smaller businesses, as larger businesses will have contracts with suppliers and other means to absorb fluctuations in costs. Without this option to substitute for cheaper alternatives, some businesses may be forced to raise the price of their products.

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. A similar issue would arise if businesses were to buy in pre-printed labels for adhering to products after being made. For example if they were to run out of labels on a given day, they could no longer sell that good as PPDS.

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 requiring a label change).

With this there is also the potential for an increase in food waste. As highlighted, PPDS can help businesses to sell at a faster rate and to pack goods towards the end of the day. If this practice was limited then the amount of food being wasted in some businesses could increase.

An additional aspect that may affect businesses is the rate at which they produce new products, or whether they feature seasonal PPDS products. This will be largely driven by the potential cost for having to develop additional new labels that they previously did not have to.

An attempt was made during the consultation stage to establish the rate at which businesses change products and whether they would anticipate allergen labelling to reduce this rate (or reduce the likelihood of seasonal products). We were not able to ascertain this from businesses, however they did agree that increasing the labelling requirements would be likely to increase their considerations before introducing a new PPDS product.

Training Costs.

This has not been monetised. During our consultation we spoke with a variety of businesses (from different industries/sectors). It is now our understanding that businesses already provide training which includes allergen training. Others even offer specific allergen training modules. Moreover many make use of the FSA produced training, if they are unable to develop their own (which is often the case for smaller businesses). Businesses indicated that they would not need to alter any allergen training they provide. Moreover it became clear during the consultation that allergen issues in food businesses are more likely to be a result of the high staff turnover (typical in retail and foodservice) or lack of experience in encountering these situations, rather than an issue with the training that they have received.

Although not explicitly required, businesses may choose to improve staff training practices. It is not clear what specific form of additional training would be necessary to enable businesses to implement this option effectively.

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 which of the 14 allergens 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).

Enforcement Costs

The methodology used is the exact same as that used under Option 2, however there has been an adjustment to the assumed increase in enforcement time per visit.

We estimate that for Option 3 the additional time required during an inspection of each outlet would be 30 minutes. It is our assumption that outlets selling PPDS foods are inspected once every 2 years. This estimate of the additional time required is based on both the responses to our consultation and engagement with local authorities during our stakeholder workshops.

During these inspections it would be inspected that a member of staff, most likely the owner/proprietor (in smaller establishments) or the outlet manager, would accompany the EHO/TSO carrying out the inspection. We will use the uprated average wage rate of 'Food preparation and hospitality trades' and 'Restaurant and catering establishment managers and proprietors' (£14.36) that was used to estimate familiarisation costs, as the time cost associated with inspections. Therefore the additional cost per inspection is £7.18.

The total cost of enforcement is the cost per inspection multiplied by the frequency of inspections per year for each business, finally multiplied by the number of affected outlets that are in scope of this review (approximately 134,466 outlets across our sectors of interest).

These costs will be on-going after the completion of the 18 month transition period.

	Low Estimate Enforcement Cost (£m)	Central Estimate Enforcement Cost (£m)	High Estimate Enforcement Cost (£m)
Micro	£0.07	£0.09	£0.11
Small	£0.06	£0.08	£0.10
Medium	£0.03	£0.03	£0.04
Large	£0.20	£0.27	£0.33
Total	£0.35	£0.48	£0.59

Table 24: Estimated enforcement costs to business under Option 3

Costs to consumers

Business may seek to pass any increase in costs on to consumers. The extent to which these costs will be passed on will depend on a number of factors relating to supply and demand of the products. Given the uncertainties, we have not assumed a specific level of pass on and it should be noted that these costs are not additional to those set out above but about the incidence of the costs. If businesses (in particular Small and Micro) businesses were no longer able to operate (or operate at a full capacity) as a result of increased costs due to increased labelling requirements, this may lead to a reduction in choice for consumers. However the extent to which this would happen is unknown and is linked very closely to the rate that businesses would switch away from PPDS.

Costs to Government

Familiarisation costs.

The methodology used here is similar to that used for the familiarisation costs for government under Option 1.

As before, 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 inspection body (local authority).

We assume that for Option 3, each Trading Standards Officer (TSO) and Environmental Health Officer (EHO) will take three working days³¹ (22.2 hours) to read and familiarise themselves with the new regulations. In addition to this, there will be an additional working day (7.4 hours) per local authority for EHO/TSOs to reach a consensus on how to proceed with the new legislation.

Using the same wage rates as outlined in option 1, the cost for familiarisation per EHO/TSO is £526.41 and the familiarisation cost per local authority (inspection body) is £175.47.

The total familiarisation cost to government was calculated using the same methodology as Options 1 and 2.

As with Option 2, the cost of familiarisation will occur immediately.

The range of estimates calculated for familiarisation cost to business are listed below in table 24.

³¹ Familiarisation time is based on discussions during our workshops with Local Authorities. They felt that the time stated in the previous impact assessment did not reflect the true nature of their work. All times used in this impact assessment aim to reflect the collective thoughts and views of not only those who attended the workshops but those who responded to our consultation also.

	Low Estimate Familiarisation Cost (£m)	Central Estimate Familiarisation Cost (£m)	High Estimate Familiarisation Cost (£m)
Total familiarisation cost for Government	£0.65	£0.95	£1.04
Table 25: Estimated familiarisation costs to Government under Option 3			

Enforcement costs.

The methodology used is the exact same as that used under Option 2, however there has been an adjustment to the assumed increase in enforcement time per visit.

This new legislation will be enforced during inspections by Trading Standards Officers or Environmental Health Officers. We estimate that for Option 3 the additional time required during an inspection of each outlet would be 30 minutes. It is our assumption that outlets selling PPDS foods are inspected once every 2 years³².

We will use the uprated average wage rate of EHOs and TSOs (£23.71) that we calculated for familiarisations cost, as the time cost associated with inspections. Therefore the additional cost per inspection is £11.86.

The total cost of enforcement is the cost per inspection multiplied by the frequency of inspections per year for each business, finally multiplied by the number of affected outlets that are in scope of this review (approximately 134,466 outlets across our sectors of interest).

These costs will be on-going for the entire appraisal period.

	Low Estimate Enforcement Cost (£m)	Central Estimate Enforcement Cost (£m)	High Estimate Enforcement Cost (£m)
Total enforcement costs	£0.55	£0.80	£0.88
Table 26: Estimated enforcement costs to Government under Option 3			

Benefits

The benefits of this option 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.

³² Trading Standards Wales (accessed 22/11/2018) - <https://www.tradingstandardswales.org.uk/help/foodinspect.cfm>

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

Costs to businesses

Despite monetised costings in the pre-consultation stage impact assessment indicating there to be no difference between Options 3 and 4, we now 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 used the consultation to improve our understanding of the extent of the costs of this option.

Familiarisation Costs.

The methodology used here is very similar to that used for the familiarisation costs for businesses under Options 1, 2 and 3. We have assumed that the same occupations will undertake the familiarisation as outlined in Option 1.

For option 4 we assume³³ that for small and micro businesses it would take one member of staff one working day (7.4 hours) to read and familiarise themselves with new legislation. For medium and large businesses we assume that it will take one member of staff 1.5 working days (11.1 hours) to read and familiarise themselves with new legislation. In addition, we have assumed that there will be an additional hour of familiarisation cost (per outlet) to reflect the need to disseminate any new understanding/knowledge to other members of staff.

For Supermarkets and Institutional Caterers the small and micro business familiarisation cost is £232.14, while the cost for medium and large businesses is £348.21. The individual outlet familiarisation cost is £31.37.

For Specialised Food Retailers the small and micro business familiarisation cost is £97.76, while the cost for medium and large businesses is £146.63. The individual outlet familiarisation cost is £13.21.

For QSR/Cafes/Sandwich Shops the small and micro business familiarisation cost is £114.78, while the cost for medium and large businesses is £172.16. The individual outlet familiarisation cost is £15.51.

Then using the same methodology as that used in option 1, the estimates in table 26 were produced.

	Low Estimate Familiarisation Costs (£m)	Central Estimate Familiarisation Costs (£m)	High Estimate Familiarisation Costs (£m)
Total Familiarisation costs	£11.10	£17.70	£21.75

Table 27: Estimated familiarisation costs to business under Option 4

Labelling Costs.

This cost has been monetised. Under this option businesses will be required to label PPDS foods with a list of the full ingredients (including the allergens being emphasised). In order to assess this costs, we will address each of our interested sectors in turn.

Supermarkets

As stated during the costs associated with Option 2 and 3. During our consultation and stakeholder workshops, we came to understand that Supermarkets already carry out labelling on their PPDS products to a standard that is very much equitable to what is being proposed as Option 3 in this review. This is particularly true for the large supermarkets, who (as illustrated previously) account for approximately 90% of the sector (both in terms of turnover and employees).

However we assume that small and micro Supermarkets (which are likely corner shops or similar establishments) will not sell PPDS foods due to the manner in which they operate. So for the purposes of assessing the costs for Supermarkets we will only look at medium and large businesses.

Specialised food retailers

Based on our consultation and workshops, it is our understanding that for PPDS goods that would require labelling many businesses are already providing information similar to Option 3.

Another factor that likely will reduce the likelihood of a need to add this type of label, is the increased prevalence of single ingredient PPDS items ((such as a steak or fillet of fish) compared to other sectors considered here. As the name of these products are the ingredients, these products already provide full ingredient labelling so would be going beyond the requirements of Option 3.

³³ Our assumptions for time spent for familiarisation are based on discussions with businesses during our stakeholder workshops, as well as consultation responses received. The additional time required compared to Option 3, is due to the addition of different requirements in terms of information that businesses will need to provide and that they will need to assess.

Therefore we have assumed that this will be treated as the addition of a second label on each PPDS product in this sector, as a result of Option 4. For these businesses, there will be an initial transitional cost of labelling and then an additional on-going cost for each year of this appraisal, from the time it is required to be implemented onwards.

QSR, Sandwich Shops, etc.

As stated in option 2, we do not have a firm understanding of the extent to which these businesses already provide allergen (or full ingredient) labelling on their PPDS products. We know that some businesses (in particular the largest) have begun to move towards more intensive labelling options (more akin to Options 3 and 4) but do not know for sure the extent of this across the sector.

For those businesses that do not currently label their PPDS products, there will be in initial transitional cost of labelling and then an additional on-going cost for each year of this appraisal, from the time it is required to be implemented onwards.

Institutional caterers

Similar to QSR, Sandwich shops, etc. we do not have a firm understanding of the extent to which businesses already provide allergen or full ingredient labelling on their PPDS products.

For those businesses that do not currently label their PPDS products, there will be in initial transitional cost of labelling and then an additional on-going cost for each year of this appraisal, from the time it is required to be implemented onwards.

Calculation of costs – Transitional costs: Supermarkets and Specialised food retailers

For these calculations we have combined the two sectors (Supermarkets and Specialised food retailers).

We have used the same costs per SKU as outlined in Option 2 for QSR/Cafes/Sandwich shops and Institutional Caterers. As stated in Option 3, we have used the number of PPDS products sold by businesses as outlined in the 'Composition of the PPDS market' section of this impact assessment.

Using the same methodology as outlined in Option 3 (but for Supermarkets and Specialised Food Retailers) we attained the Total number of PPDS products shown in table 27.

		Lower Estimate	Central Estimate	High Estimate
Supermarkets	Micro	Not included	Not included	Not included
	Small	Not included	Not included	Not included
	Medium	4,849	10,362	15,875
	Large	1,672	3,940	6,207
Specialised food retailers	Micro	128,249	257,477	386,704
	Small	54,649	107,333	160,017
	Medium	9,136	19,524	29,911
	Large	935	2,202	3,469

Table 28: Total number of different PPDS products sold by businesses

Using the same methodology as in Option 3, the transitional labelling cost for Supermarkets and Specialised Food Retailers was calculated.

	Low estimate of labelling costs (£m)	Central Estimate of labelling costs (£m)	High Estimate of labelling costs (£m)
Micro	£1.45	£2.90	£4.36
Small	£0.62	£1.21	£1.81
Medium	£18.55	£39.64	£60.73
Large	£5.30	£12.47	£19.65
Total	£25.91	£56.23	£86.55

Table 29: Transitional labelling costs for Supermarkets and Specialised food retailers due to Option 4

Calculation of costs – Transitional costs: QSR... and Institutional Caterers

We have assumed that the costs to these businesses due to the implementation of Option 4, will be the same as Option 3 however there will be additional indirect costs (such as substitution flexibility) which are discussed later. Due to the same number of products which will be required to be labelled remaining the same across both scenarios. In addition as we are assuming that these businesses do not currently label PPDS products then this again simply involves adding a label that was not there previously.

	Low estimate of labelling costs (£m)	Central Estimate of labelling costs (£m)	High Estimate of labelling costs (£m)
Micro	£4.63	£9.30	£13.97
Small	£3.05	£5.99	£8.92
Medium	£51.66	£110.39	£169.12
Large	£17.73	£41.76	£65.80
Total	£77.07	£167.44	£257.81

Table 30: Transitional labelling costs for QSR, Sandwich shops, etc. and Institutional Caterers due to Option 3

Total transitional labelling costs for businesses due to Option 4

Therefore the total transitional labelling cost to business as a result of Option 4 is the sum of the costs to all of our interested sectors.

	Low estimate of labelling costs (£m)	Central Estimate of labelling costs (£m)	High Estimate of labelling costs (£m)
Micro	£6.08	£12.20	£18.33
Small	£3.66	£7.20	£10.73
Medium	£70.21	£150.03	£229.86
Large	£23.02	£54.23	£85.44
Total	£102.97	£223.67	£344.36

Table 31: Total transitional labelling costs for businesses due to Option 4

It should be noted that due to the fact that we know that some businesses have already begun to move towards improved allergen or ingredient labelling, that the costs listed here likely overestimate the actual costs to business as a result of Option 4.

For this impact assessment, we are assuming that for Option 4 there will be a two year implementation period (from the introduction of the new legislation) before businesses will be required to have this standard of labelling on their products. Therefore these labelling costs will not come into effect until the third year of our appraisal.

Calculation of Costs – On going costs: Supermarkets and Specialised Food Retail

In addition to the initial costs of adopting a label on PPDS products, we will also need to account for the on-going cost of labelling these products. This on-going cost will simply be the marginal cost of each additional label. In order to calculate this, we have assumed that the average outlet/unit in Supermarkets and Specialised food retail sell approximately the same total number of PPDS products as QSR, Sandwich shops and Institutional catering. We estimate this to be around 25,000 PPDS products annually per outlet.

We have estimated that the typical FBO outlet will spend approximately £100.00 annually on labels. Based on the cost of a single label being £0.004.

We previously set out the number of outlets by sector. For Supermarkets this was 43,305 and for Specialised Food Retail it was 21,320. Therefore we have calculated the annual on-going cost for each sector by multiplying the cost of labels per outlet by the number of outlets themselves

Low and High estimates have been calculated based on the range of the number of PPDS products sold across all businesses.

In order to provide estimates by business size, the employment shares from table 4 have been used as a means to attribute these costs by business size. As with the transitional labour costs, we will remove the contribution of micro and small businesses from our total estimates.

	Low estimate of labelling costs (£m)	Central Estimate of labelling costs (£m)	High Estimate of labelling costs (£m)
Micro	£0.42	£0.83	£1.24
Small	£0.27	£0.54	£0.81
Medium	£0.12	£0.24	£.36
Large	£2.01	£4.38	£6.74
Total	£2.83	£5.99	£9.16

Table 32: On-going labelling costs for Supermarkets and Specialised Food Retail due to Option 4

Calculation of Costs – On going costs: QSR and Sandwich shops

We assume that this will be the same cost as calculated for option 2, due to the number of total labels required being the same across both of the options.

Total on-going labelling costs for businesses due to Option 4

Therefore the total on-going labelling cost to business as a result of Option 4 is the sum of the costs to all of our interested sectors.

	Low estimate of labelling costs	Central Estimate of labelling costs	High Estimate of labelling costs
Micro	£1.22	£2.61	£3.99
Small	£1.07	£2.30	£3.53
Medium	£0.45	£0.97	£1.50
Large	£3.45	£7.57	£11.68
Total	£6.20	£13.45	£20.69

Table 33: Total on-going labelling costs for businesses due to Option 4

These costs would come into effect from the year after the transitional labelling costs.

Indirect costs associated with new labelling.

As highlighted in Option 3. Introducing labelling (or increasing labelling requirements) 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. This practice is more likely in smaller businesses, as larger businesses will have contracts with suppliers and other means to absorb fluctuations in costs. Without this option to substitute for cheaper alternatives, some businesses 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. Additionally this may impact on the rate in which businesses change suppliers, as the desire for some businesses to maintain a consistent supply of ingredients may begin to outweigh the need to source the cheapest ingredients. This may be more likely for large businesses who are more fixed in their menus and goods sold. This ultimately could reduce the opportunities for new businesses to become suppliers if those selling PPDS take this approach.

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. A similar issue would arise if businesses were to buy in pre-printed labels for adhering to products after being made. For example if they were to run out of labels on a given day, they could no longer sell that good as PPDS.

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 requiring a label change).

With this there is also the potential for an increase in food waste. As highlighted, PPDS can help businesses to sell at a faster rate and to pack goods towards the end of the day. If this practice was limited then the amount of food being wasted in some businesses could increase.

An additional aspect that may affect businesses is the rate at which they produce new products, or whether they feature seasonal PPDS products. This will be largely driven by the potential cost for having to develop additional new labels that they previously did not have to.

An attempt was made during the consultation stage to establish the rate at which businesses change products and whether they would anticipate allergen labelling to reduce this rate (or reduce the likelihood of seasonal products). We were not able to ascertain this from businesses, however they did agree that increasing the labelling requirements would be likely to increase their considerations before introducing a new PPDS product.

Training Costs.

This has not been monetised. During our consultation we spoke with a variety of businesses (from different industries/sectors). It is now our understanding that businesses already provide training which includes allergen training. Others even offer specific allergen training modules. Moreover many make use of the FSA produced training, if they are unable to develop their own (which is often the case for smaller businesses). Businesses indicated that they would not need to alter any allergen training they provide. Moreover it became clear during the consultation that allergen issues in food businesses are more likely to be a result of the high staff turnover (typical in retail and foodservice) or lack of experience in encountering these situations, rather than an issue with the training that they have received.

Although not explicitly required, businesses may choose to improve staff training practices. It is not clear what specific form of additional training would be necessary to enable businesses to implement this option effectively.

Costs of determining full ingredients.

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.

However there may be some cost in determining the full list of ingredients that is present in a PPDS product (particularly those containing composite ingredients like sauces). Businesses who do not currently have a system in place to record the full ingredients of each item they sell would need to establish one. The method in which this would be done can vary widely across the PPDS market. Some businesses may have a sophisticated database that they populate with this information while others may simply have something similar to a 'recipe book' which has a breakdown of the ingredients of all the items they sell. Furthermore they would then need to update (or verify) such information any time a new product is introduced or there is a change in supplier.

During our consultation and stakeholder workshops efforts were made to establish a cost for attaining this information. However it is unclear how many firms already have this information or have the systems in place to easily record it once attained. This uncertainty relating the determination of ingredients has resulted in us being unable to define what is already done and therefore ultimately what the impact would then be once this legislation comes into force. Furthermore businesses may choose to switch away from PPDS if collating this information was too difficult for them. As highlighted before it is likely easier for the smallest of businesses to switch from PPDS to other preparation methods and these businesses may be more likely to not currently have a system in place that records the full ingredients of the products they sell.

Enforcement Costs

The methodology used is the exact same as that used under Options 2 and 3, however there has been an adjustment to the assumed increase in enforcement time per visit.

We estimate that for Option 4 the additional time required during an inspection of each outlet would be 60 minutes. It is our assumption that outlets selling PPDS foods are inspected once every 2 years. This estimate of the additional time required is based on both the responses to our consultation and engagement with local authorities during our stakeholder workshops.

During these inspections it would be inspected that a member of staff, most likely the owner/proprietor (in smaller establishments) or the outlet manager would accompany the EHO/TSO. We will use the updated average wage rate of 'Food preparation and hospitality trades' and 'Restaurant and catering establishment managers and proprietors' (£14.36) that was used to estimate familiarisation costs, as the time cost associated with inspections. Therefore the additional cost per inspection is £14.36.

The total cost of enforcement is the cost per inspection multiplied by the frequency of inspections per year for each business, finally multiplied by the number of affected outlets that are in scope of this review (approximately 134,466 outlets across our sectors of interest).

These costs will be on-going after the completion of the 2 year transition period.

	Low Estimate Enforcement Cost (£m)	Central Estimate Enforcement Cost (£m)	High Estimate Enforcement Cost (£m)
Micro	£0.14	£0.19	£0.23
Small	£0.12	£0.17	£0.20
Medium	£0.05	£0.07	£0.09
Large	£0.39	£0.54	£0.66
Total	£0.70	£0.97	£1.17

Table 34: Estimated enforcement costs to business under Option 4

Costs to consumers

Business may seek to pass any increase in costs on to consumers. The extent to which these costs will be passed on will depend on a number of factors relating to supply and demand of the products. Given the uncertainties, we have not assumed a specific level of pass on and it should be noted that these costs are not additional to those set out above but about the incidence of the costs. If businesses (in particular Small and Micro) businesses were no longer able to operate (or operate at a full capacity) as a result of increased costs due to increased labelling requirements, this may lead to a reduction in choice for consumers. However the extent to which this would happen is unknown and is linked very closely to the rate that businesses would switch away from PPDS.

Costs to Government

Familiarisation costs.

The methodology used here is very similar to that used for the familiarisation costs for government under Options 1, 2 and 3.

We assume that for Option 4, each Trading Standards Officer (TSO) and Environmental Health Officer (EHO) will take five working days³⁴ (37 hours) to read and familiarise themselves with the new regulations. In addition to this, there will be an additional working day (7.4 hours) per local authority for EHO/TSOs to reach a consensus on how to proceed with the new legislation.

Using the same wage rates as outlined in option 1, the cost for familiarisation per EHO/TSO is £1,228.18 and the familiarisation cost per local authority (inspection body) is £175.47. The total familiarisation cost to government was calculated using the same methodology as Options 1, 2 and 3.

As with Options 2 and 3, the cost of familiarisation will occur immediately (i.e. Year 0).

The range of estimates calculated for familiarisation cost to business are listed below in table 33.

	Low Estimate Familiarisation Cost (£m)	Central Estimate Familiarisation Cost (£m)	High Estimate Familiarisation Cost (£m)
Total familiarisation cost for Government	£1.08	£1.58	£1.74

Table 35: Estimated familiarisation costs to Government under Option 4

Enforcement costs.

The methodology used is the exact same as that used under Options 2 and 3, however there has been an adjustment to the assumed increase in enforcement time per visit.

This new legislation will be enforced during inspections by Trading Standards Officers or Environmental Health Officers. We estimate that for Option 4 the additional time required during an inspection of each outlet would be one hour. It is our assumption that outlets selling PPDS foods are inspected once every 2 years³⁵.

³⁴ Familiarisation time is based on discussions during our workshops with Local Authorities. They felt that the time stated in the previous impact assessment did not reflect the true nature of their work. All times used in this impact assessment aim to reflect the collective thoughts and views of not only those who attended the workshops but those who responded to our consultation also.

³⁵ Trading Standards Wales (accessed 22/11/2018) - <https://www.tradingstandardswales.org.uk/help/foodinspect.cfm>

We will use the uprated average wage rate of EHOs and TSOs (£23.71) that we calculated for familiarisations cost, as the time cost associated with inspections. Therefore the additional cost per inspection is £11.86.

The total cost of enforcement is the cost per inspection multiplied by the frequency of inspections per year for each business, finally multiplied by the number of affected outlets that are in scope of this review (approximately 139,143 outlets across our sectors of interest).

These costs will be on-going from Year 3 of the appraisal period onwards (due to the two year implementation period).

	Low Estimate Enforcement Cost	Central Estimate Enforcement Cost	High Estimate Enforcement Cost
Total enforcement costs	£1.10	£1.60	£1.76
Table 36: Estimated enforcement costs to Government under Option 4			

Benefits

The benefits of this option 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 part of 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 from. 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.

Potential for businesses to move away from PPDS

All of the monetised costings in this impact assessment, have been under the assumption that all those businesses who currently sell goods as PPDS will continue to do so. However it is entirely plausible that a significant number of businesses could decide to switch from selling goods as PPDS, using the alternatives such as PPCR or loose. Some may even choose to get rid of all food prepared on premises altogether and focus on pre-packed products. Some stakeholders indicated that this may be a possible line of approach for them, depending on the option chosen and the resultant cost that it may have on their business as a result.

However it has been brought to our attention that some businesses rely on the PPDS format, due to its ability to help them meet higher demand at peak times, which other methods would not allow them to achieve. If these businesses were to switch to PPCR or loose in a bid to avoid any labelling costs, it would be possible that the output of their business may suffer instead (which in itself is a cost).

Therefore we cannot simply say that if businesses were to move away from PPDS, this will reduce the potential impact on businesses.

Specific Impact Tests

Small and Micro Business Assessment

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

We established the extent to which small and micro businesses (SMBs) feature in our understanding of the PPDS market earlier in this impact assessment. However we will briefly recap their significance in each sector.

	Supermarkets	Specialised Food Retailers	QSR, Sandwich Shops, etc.	Institutional Caterers
Micro	25,253 (90%)	13,706 (86%)	63,079 (79%)	1,830 (84%)
Small	2,527 (9%)	2,064 (13%)	14,896 (19%)	275 (13%)

Table 37: Number of businesses (including percentage of businesses in sector)

	Supermarkets	Specialised Food Retailers	QSR, Sandwich Shops, etc.	Institutional Caterers
Micro	4.9%	42.4%	22.6%	15.8%
Small	2.3%	23.7%	21.4%	12.3%

Table 38: Share of own sector turnover

Summary of costs to SMBs

Below is a summary of all the monetised costs on SMBs as a result of the proposed policy options.

			Low Estimate (£m)	Central Estimate (£m)	High Estimate (£m)
Option 1	Familiarisation	Micro	£1.39	£2.18	£2.67
		Small	£0.33	£0.51	£0.62
Option 2	Familiarisation	Micro	£2.44	£3.86	£4.75
		Small	£0.51	£0.78	£0.95
	Transitional Labelling	Micro	£0.40	£0.50	£0.60
		Small	£0.09	£0.12	£0.14
	On-going Labelling	Micro	£0.80	£1.77	£2.74
		Small	£0.80	£1.76	£2.72
Enforcement	Micro	£0.03	£0.05	£0.06	
	Small	£0.03	£0.04	£0.05	
Option 3	Familiarisation	Micro	£4.23	£6.72	£8.27
		Small	£0.80	£1.23	£1.50
	Transitional Labelling	Micro	£4.63	£9.30	£13.97
		Small	£3.05	£5.99	£8.92
	On-going Labelling	Micro	£0.80	£1.77	£2.74
		Small	£0.80	£1.76	£2.72
Enforcement	Micro	£0.07	£0.09	£0.11	
	Small	£0.06	£0.08	£0.10	
Option 4	Familiarisation	Micro	£8.13	£12.95	£15.93
		Small	£1.45	£2.30	£2.70
		Micro	£6.08	£12.20	£18.33

	Transitional Labelling	Small	£3.66	£7.20	£10.73
	On-going Labelling	Micro	£1.22	£2.61	£3.99
		Small	£1.07	£2.30	£3.53
	Enforcement	Micro	£0.14	£0.19	£0.23
		Small	£0.12	£0.17	£0.20
Table 39: Summary of costs to all SMBs in interested sectors					

Supermarkets

As discussed during the costs section of Option 4, we do not anticipate SMBs in the supermarket sector to sell PPDS goods. Therefore we do not expect there to be any cost of relabelling for these businesses as a result of the proposed policies. However they would still incur the familiarisation costs.

From BEIS business population estimate³⁶ statistics we can calculate that the average turnover of a micro business in SIC code 47.1 (the wider 3 digit SIC code that this sector is part of) is £375,641. The corresponding figure for small businesses is £1,528,596.

		Low Estimate (£m)	Central Estimate (£m)	High Estimate (£m)
Option 1	Micro	£0.49	£0.89	£1.14
	Small	£0.07	£0.13	£0.17
Option 2	Micro	£0.93	£1.68	£2.15
	Small	£0.12	£0.21	£0.27
Option 3	Micro	£1.67	£3.03	£3.87
	Small	£0.19	£0.34	£0.44
Option 4	Micro	£3.29	£5.96	£7.62
	Small	£0.35	£0.64	£0.81
Table 40: Summary of familiarisation costs for all SMBs in Supermarkets sector				

Specialised Food Retailers

Specialised food retail is a sector which is dominated more by SMBs than other sectors. Unlike the other sectors considered here, the majority (approximately 66%) of the sectors turnover is produced by SMBs.

According to BEIS business population estimate statistics, we can calculate that the average turnover of a micro business in SIC code 47.2 is £341,688. The corresponding figure for small businesses is £1,237,267.

			Low Estimate (£m)	Central Estimate (£m)	High Estimate (£m)
Option 1	Familiarisation	Micro	£0.22	£0.29	£0.38
		Small	£0.08	£0.10	£0.13
Option 2	Familiarisation	Micro	£0.36	£0.47	£0.61
		Small	£0.10	£0.13	£0.16
	Enforcement	Micro	£0.01	£0.01	£0.02
		Small	£0.01	£0.01	£0.01
Option 3	Familiarisation	Micro	£0.60	£0.78	£1.01
		Small	£0.13	£0.17	£0.22

³⁶ <https://www.gov.uk/government/statistics/business-population-estimates-2018>

	Enforcement	Micro	£0.02	£0.03	£0.04
		Small	£0.03	£0.04	£0.05
Option 4	Familiarisation	Micro	£1.12	£1.45	£1.87
		Small	£0.21	£0.27	£0.35
	Transitional Labelling	Micro	£1.45	£2.90	£4.36
		Small	£0.62	£1.21	£1.81
	On-going Labelling	Micro	£0.42	£0.83	£1.24
		Small	£0.27	£0.58	£0.87
	Enforcement	Micro	£0.04	£0.06	£0.07
		Small	£0.03	£0.04	£0.05
Table 41: Summary of costs to all SMBs in Specialised food retail					

QSR, Sandwich shops, etc.

The structure of this sector is similar to that of specialised food retail, in that SMBs account for a significant proportion (over half) of the sectors turnover.

According to BEIS business population estimate statistics, we can calculate that the average turnover of a micro business in SIC code 56.1 is £138,537. The corresponding figure for small businesses is £556,550.

			Low Estimate (£m)	Central Estimate (£m)	High Estimate (£m)
Option 1	Familiarisation	Micro	£0.62	£0.91	£1.05
		Small	£0.16	£0.24	£0.27
Option 2	Familiarisation	Micro	£1.07	£1.56	£1.80
		Small	£0.27	£0.39	£0.45
	Transitional Labelling	Micro	£0.38	£0.47	£0.57
		Small	£0.09	£0.11	£0.13
	On-going Labelling	Micro	£0.76	£1.67	£2.59
		Small	£0.74	£1.65	£2.55
	Enforcement	Micro	£0.02	£0.03	£0.04
		Small	£0.02	£0.03	£0.04
Option 3	Familiarisation	Micro	£1.82	£2.67	£3.08
		Small	£0.44	£0.65	£0.75
	Transitional Labelling	Micro	£4.44	£8.91	£13.38
		Small	£2.97	£5.83	£8.68
	On-going Labelling	Micro	£0.76	£1.67	£2.59
		Small	£0.74	£1.65	£2.55
	Enforcement	Micro	£0.04	£0.06	£0.07
		Small	£0.04	£0.06	£0.07
Option 4	Familiarisation	Micro	£3.47	£5.09	£5.86
		Small	£0.81	£1.22	£1.41
	Transitional Labelling	Micro	£4.44	£8.91	£13.38
		Small	£2.97	£5.83	£8.65

	On-going Labelling	Micro	£.76	£1.67	£2.59
		Small	£0.74	£1.65	£2.55
	Enforcement	Micro	£0.09	£0.12	£0.15
		Small	£0.09	£0.12	£0.14
Table 42: Summary of costs to all SMBs in QSR, Sandwich shops etc.					

Institutional Caterers

Small and Micro businesses account for a significantly smaller share of turnover in this sector compared to Specialised food retail and QSR, Sandwich shops etc. The impacts here are significantly smaller in aggregate, partly due to the relatively small size of the sector (in terms of number of businesses).

According to BEIS business population estimate statistics, we can calculate that the average turnover of a micro business in SIC code 56.2 (the wider 3 digit SIC code that this sector is part of) is £285,340. The corresponding figure for small businesses is £955,477.

			Low Estimate (£m)	Central Estimate (£m)	High Estimate (£m)
Option 1	Familiarisation	Micro	£0.05	£0.09	£0.11
		Small	£0.02	£0.04	£0.06
Option 2	Familiarisation	Micro	£0.08	£0.15	£0.19
		Small	£0.03	£0.05	£0.07
	Transitional Labelling	Micro	£0.02	£0.02	£0.02
		Small	£0.002	£0.003	£0.004
	On-going Labelling	Micro	£0.05	£0.10	£0.15
		Small	£0.05	£0.11	£0.17
	Enforcement	Micro	£0.001	£0.002	£0.002
		Small	£0.001	£0.002	£0.002
Option 3	Familiarisation	Micro	£0.13	£0.24	£0.31
		Small	£0.04	£0.07	£0.09
	Transitional Labelling	Micro	£0.19	£0.39	£0.58
		Small	£0.08	£0.16	£0.24
	On-going Labelling	Micro	£0.05	£0.10	£0.15
		Small	£0.05	£0.11	£0.17
	Enforcement	Micro	£0.003	£0.004	£0.004
		Small	£0.003	£0.004	£0.005
Option 4	Familiarisation	Micro	£0.25	£0.46	£0.58
		Small	£0.05	£0.10	£0.13
	Transitional Labelling	Micro	£0.19	£0.39	£0.58
		Small	£0.08	£0.16	£0.24
	On-going Labelling	Micro	£0.05	£0.10	£0.15
		Small	£0.05	£0.11	£0.17
	Enforcement	Micro	£0.01	£0.01	£0.01
		Small	£0.01	£0.01	£0.01
Table 43: Summary of costs to all SMBs in Institutional Catering					

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).

Small and Micro businesses selling PPDS may be less likely (than medium and large businesses) to have a system in place to record the full ingredients of the PPDS products that they sell. Therefore any costs associated with this may disproportionately affect SMBs. However we are unable to quantify this as the form that a business chooses to record this information (simple folder of ingredient lists vs computerised database) will further dictate the cost burden to businesses, with it not being clear which one a business would choose to introduce.

There may also be impacts on SMBs who supply businesses selling PPDS. As they will be required to provide those selling PPDS with the information they require to label their food correctly. If these firms are provided ingredients that are prepacked then they are already required to provide a full ingredient list of what is in their products. Similarly legislation already exists that requires suppliers to provide businesses selling food with the information they require to meet the labelling requirements set for them (i.e. to allow businesses selling PPDS to label to full ingredient labelling under Option 4). This legislation is not changing and will remain in place. However the information that they will be required to provide (for Option 4) will increase from a list of the allergens present to full ingredients. The degree to which what is provided already is unclear. Again, it should be noted that these businesses will likely be providing food/ingredients that is prepacked and therefore already is required to include the full ingredient list.

SMB suppliers to PPDS sellers may also be disproportionality impacted by the introduction of full ingredient labelling, if this leads to the rate at which PPDS sellers switch suppliers. This would mean that SMB suppliers may have reduced access to PPDS sellers and reduce their ability to sell to them.

Ability to absorb increased costs

It has been briefly discussed that businesses may choose to pass on increased costs incurred as a result of the proposed changes in legislation, but the department does not know the extent to which this would happen. This may be more likely to be necessary for SMBs to do. As we noted in the section outlining the PPDS market, PPDS products typically take up a higher share of the goods sold in SMBs. This fact combined with the lower turnover per business seen in SMBS, suggests that they will have less ability to absorb any cost increases and ultimately may be more likely to then pass these on to consumers.

Exemptions for SMBs

The Department consulted on whether there should be an exemption for SMBs for any of the Options being proposed. In addition to this the consultation sought to understand whether there may be demand for an exemption, where the threshold was not defined by the typical measure of business size by number of employees. Some of the potential alternatives were: business size as defined by turnover and business size defined by the number of outlets.

The exemptions that were consulted on fell into three categories. The first looked to use a combination of Options that allowed SMBs to label their food to a lower level of detail than medium and large businesses would be required to. For example in the case of the preferred option (Option 4), Medium and Large businesses would be required to provide full ingredient labelling while small and micro businesses may be required to either label only the allergens or have "Ask the Staff" labelling.

The second consideration was for there to be different implementation periods dependent on the size of business. This would allow SMBs longer to prepare for each option, than would be given to Medium and Large businesses. Again looking at the preferred option as an example, the Department has proposed a two year implementation period however it was considered to provide SMBs with longer time to prepare for this change in legislation (such as three years).

Lastly a combined approach of these two was considered, although only ever for Option 4. This may have taken the form of SMBs being given an extended implementation period, however during this time extension they would be required to implement one of Option 2 or 3, while working towards implementing full ingredient labelling.

The reasons for why none of these potential exemptions were ultimately chosen are very similar. In the responses we received to the consultation and the discussions held during our stakeholder workshops there was a general desire (from not only consumers, but businesses and local authorities) for there to be no exemption for SMBs.

The primary reason cited in our consultation responses and in our stakeholder workshops for there not being any form of exemption for SMBs, was to ensure that there was consistency within the PPDS market. As highlighted on numerous occasions' stakeholders did not want there to be differing standards for PPDS products, as this could create confusion for consumers and ultimately put them at risk. If one store selling PPDS products provided full ingredient labelling, consumers may come to expect this in others that may not be required to label to the same standard. This was reinforced by their view that consumers find it difficult to identify what is a small or micro business. Therefore they would not be able to tell upon entering an establishment, what the labelling requirements for PPDS would be. In addition there was concern that as consumers may come to expect there to be full ingredient labelling, upon visiting SMBs they potentially could infer that the presence of no label (or reduced labelling) indicated that it was safe to eat, rather than that business simply not being required to labelling to the same standard as medium and large businesses. Also, there was a fear from some SMB's that by not being held to the same standard, consumers may feel that their products could be regarded negatively or unsafe in comparison to larger businesses.

Having different labelling requirements based on business size was also sighted as a likely issue for enforcement officers, who would then also be required to identify what size a business was while conducting a visit (which may not be immediately apparent). As this would determine the standard to which they would need to assess a business against.

Therefore the message that was put forward by stakeholders, was that there should be consistency in the requirements on businesses with regards to the labelling of PPDS food and no exemption should be given. As the rationale of this intervention includes the desire for there to be a consistent labelling standard in the PPDS market, the decision was taken to include no exemption for SMBs. This also reflects the views and feedback received from stakeholders and businesses during the consultation.

Actions of SMBs

SMBs may choose to switch away from PPDS and use another method of preparation, as a means to avoid additional costs associated with full ingredient labelling (or any policy option that is implemented. As mentioned on several occasions it is likely that the smaller the business the easier it is to switch. This would not impact on the range of products sold, simply the format that they are presented in, so would not impact on the choice of products available to consumers.

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. Businesses however may choose to move away from PPDS to other forms of food preparation as a result of having to label PPDS foods.
 - The cost to businesses of the policy options considered are unlikely to prohibit the entry of new businesses in the PPDS food market. However the potential requirement to label PPDS food may incentivise new entrants to sell food as PPCR or loose (which does not require labelling) instead of PPDS.
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.
 - The requirement to label PPDS products may deter businesses (in particular small and micro businesses) from introducing seasonal PPDS products. Seasonal products can be a method to attract consumers and a reduced ability to produce or reduced rate of introduction of these may limit a business's ability to keep up with some of their competitors who are able to.
 - 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' (ASHE, 2018)

		Low end hourly wage	Average hourly wage	High end hourly wage
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 'Food preparation and hospitality trades' (ASHE, 2018)

		Low end hourly wage	Average hourly wage	High end hourly wage
Food preparation and hospitality trades	Original Wage	£7.83	£10.16	£13.12
	Up-lifted Wage	£10.18	£13.21	£17.06

Annex C: Average wage rate for 'Restaurant and Catering establishment managers and proprietors' (ASHE, 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

Annex D: Average gross annual salary for 'Public relations professionals' (ASHE, 2018)

		Low end hourly wage	Average hourly wage	High end hourly wage
Public relations professionals	Original Wage	£13,417	£34,826	£38,817
	Up-lifted Wage	£13,943	£36,191	£40,339

Annex E: Average gross annual salary for 'Web design and development professionals' (ASHE, 2018)

		Low end hourly wage	Average hourly wage	High end hourly wage
Web design and development professionals	Original Wage	£18,074	£32,850	£41,998
	Up-lifted Wage	£18,433	£33,502	£42,831

Annex F: Average wage rate for 'Trading standards officer' (ASHE, 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 G: Average wage rate for 'Environmental Health Professional' (ASHE, 2018)

		Low end hourly wage	Average hourly wage	High end hourly wage
Environmental Health Professional	Original Wage	£13.99	£19.00	£21.50
	Up-lifted Wage	£18.19	£24.70	£27.95

Annex H: 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.

Annex I: Allergenic Foods

There are 14 substances or products causing allergies or intolerances which (unless exempted³⁷) are legally considered to be mandatory information for consumers under FIC. This requirement is extended to all foods provided to consumers and includes food that is:

- Prepacked (e.g. a bar of chocolate, a sealed packet of crisps, a jar of sauce or a can of soup);
- Not prepacked (e.g. restaurant meals);
- Packed at the consumer's request (e.g. a deli sandwich prepared, wrapped and handed to the customer);
or
- 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 to the consumer on the packaging for prepacked foods, or, for non-prepacked foods, by any means the Food Business Operator chooses, including orally by a member of staff.

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;
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.

³⁷ Some ingredients made from the allergens listed above 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 possessing an allergenic risk to the consumer. A full list of exemptions is available at [Annex II of FIC](#)

Annex J: Effect of Voluntary Action on Costs

As noted some businesses have already begun to implement full ingredient labelling for PPDS foods, however we do not know the number of businesses in the PPDS market that have done so. We would expect that due to a combination of market pressures (such as competitors doing so) and public pressure, large businesses selling PPDS would likely move towards full ingredient labelling earlier than the legislation requires. Therefore we can provide indicative costings (for option 4) based on this voluntary action by large businesses.

The methodology used is the same as outlined in the main text of this impact assessment, however it has been assumed that large businesses have already begun to implement Option 4 so have not been included in the calculation of labelling costs. The familiarisation costs remain unchanged, as regardless of voluntary action taking place, there will still be the requirement for understanding the implications of the new legislation. Likewise the costs to government will remain unchanged too as the number of outlets that they will need to inspect will be unchanged too.

Total transitional labelling costs for businesses due to Option 4 - Voluntary Action

The total transitional labelling cost to business as a result of Option 4 is the sum of the costs to Micro, Small and Medium businesses in all of our interested sectors.

	Low estimate of labelling costs (£m)	Central Estimate of labelling costs (£m)	High Estimate of labelling costs (£m)
Micro	£6.08	£12.20	£18.33
Small	£3.66	£7.20	£10.73
Medium	£70.21	£150.03	£229.86
Total	£79.96	£169.43	£258.92

Table 44: Total transitional labelling costs for businesses due to Option 4 - Voluntary Action

This represents a reduction of £54.23m for the central estimate of initial labelling costs, with respect to our baseline of no businesses having made the move towards full ingredient labelling.

Total on-going labelling costs for businesses due to Option 4

The total on-going labelling cost to business as a result of Option 4 is the sum of the costs to Micro, Small and Medium businesses in all of our interested sectors.

	Low estimate of labelling costs	Central Estimate of labelling costs	High Estimate of labelling costs
Micro	£1.22	£2.61	£3.99
Small	£1.07	£2.30	£3.53
Medium	£0.45	£0.97	£1.50
Total	£2.74	£5.88	£9.01

Table 45: Total on-going labelling costs for businesses due to Option 4 - Voluntary Action

As stated before these costs would come into effect from the year after the transitional labelling costs.

This represents a reduction of £7.57m for the central estimate of annual on-going labelling costs, with respect to our baseline of no businesses having made the move towards full ingredient labelling. Over the course of the appraisal period this equates to an (undiscounted) total of £52.97m for the central estimate.

Effect of voluntary action on Net costs

Voluntary action by large businesses moving towards Option 4, holding all other aspects the same (business familiarisation costs and cost to government) would result in a noticeable change to the NPV and EANDCB calculations. The Best estimate of the Net Present Value (NPV) of option 4 changes from £-321.8m to £-228.0m. While the estimated annual net direct cost to business (EANDCB) improves from 31.6 to 22.0.

Annex K: Health Benefits

The key benefits of any of the policy interventions being proposed will be the health benefits due to reduced risk of consumers experiencing allergic reactions due to consuming PPDS foods of which they may not know the ingredients.

Impact of Food Allergies

Currently the FSA estimate that the annual number of deaths³⁸ due to food allergies to be 10 for England and Wales. Assuming that the rate of fatalities is consistent across the whole of the UK, then the UK total is estimated to be 12. These figures are for all food allergy related deaths each year and therefore may be a result of food preparation methods other than PPDS (such as pre-packed, PPCR or loose). We are unable to make any estimation as to the number of deaths directly attributable to PPDS foods each year.

The Department for Transport (DfT) publish statistics relating to the value of a prevented fatality (VPF). In 2018 they reported that a VPF was £1,897,129. Uplifting this to 2019 prices, we estimate the VPF to currently be £1,971,501. Therefore we can make the assumption that for each life saved due to improved allergen information provision, there would be a benefit of £1,971,501.

The FSA also estimate that food allergies result in approximately 27,000³⁹ hospital days each year. This is significantly less than the number of hospital days due to foodborne diseases (47,000). However the number of hospitalisations due to food allergies is almost twice that due to foodborne diseases (65% to 35% respectively).

Proportion of population with a Food Allergy

The Food Standards Agency (FSA) estimate that the percentage of the adult population who suffer from a food allergy to be between 1-2%⁴⁰. This rate then rises to between 5-8% for children.

Looking at ONS population estimates for 2017⁴¹, we can identify the number of adults⁴² and children across the UK.

	Adults	Children	Total Population
England	43,107,340	12,512,090	55,619,430
Scotland	4,334,980	1,089,820	5,424,800
Wales	2,460,309	664,856	3,125,165
Northern Ireland	1,410,051	460,783	1,870,834
United Kingdom	51,312,680	14,727,549	66,040,229
United Kingdom (without Scotland)	46,977,700	13,637,729	60,615,429

Table 46: ONS population estimates for 2017

Applying the FSA ranges (1-2% for adults and 5-8% for children) for those suffering from food allergies, we can estimate the number of afflicted members of the population.

³⁸ <https://www.food.gov.uk/sites/default/files/media/document/fifth-csa-report-allergy%20%281%29.pdf>

³⁹ <https://www.food.gov.uk/sites/default/files/media/document/fsa170306.pdf>

⁴⁰ <https://www.food.gov.uk/sites/default/files/media/document/fifth-csa-report-allergy%20%281%29.pdf>

⁴¹ <https://www.ons.gov.uk/peoplepopulationandcommunity/populationandmigration/populationestimates/bulletins/annualmidyearpopulationestimates/mid2017>

⁴² Adults being defined as those aged 18 and above.

	Lower bound estimate	Upper bound estimate
England	1,056,678	1,863,114
Scotland	97,841	173,885
Wales	57,846	102,395
Northern Ireland	37,140	65,064
United Kingdom	1,249,504	2,204,458
United Kingdom (without Scotland)	1,151,663	2,030,572

Table 47: Estimated number of people with Food Allergies

Quality adjusted life years (QALYs)

Work previously carried out by the FSA in conjunction with external academics⁴³, sought to understand the impact of food allergies and intolerances on affected consumers. The driver behind undertaking this work, was due to previously used figures for QALYs (and other similar measures) produced by other government departments, were not well suited to being attributed to food related illnesses. One of the results from this work was to produce estimates of the QALYs for both food allergies and intolerances.

	QALYs lost
IgE-mediated Food Allergy	4.202
Coeliac	4.030
Non-IgE-mediated Food Allergy	2.805
Food Intolerance	1.969

Table 48: QALY figures for Allergies and Food Intolerances

These QALYs are the total combined for all who suffer from each specific ailment (i.e. the QALY for every person suffering from a food intolerance is 1.969).

Hospitalisation due to Adverse Food Reactions

The NHS collect statistics⁴⁴ on the number of hospital admissions with 'Anaphylactic shock due to adverse food reaction' or 'Other adverse food reactions' as the diagnosis. For the financial year 2017-18, they reported that there were 2,192 and 4,975 respectively (resulting in a total of 7,167). These figures are for England only, so assuming that the rate of incidence is the same across the entirety of the UK, we have uplifted this (using our population estimates) to 7,811 for the United Kingdom (minus Scotland).

In addition to admission data, the NHS also publish reference costs⁴⁵ for the treatment of specific illnesses. The table below illustrates the reference costs for "Allergy or adverse allergic reaction". We have chosen not to include 'elective' hospital stays as these are likely not a result of an unexpected reaction.

⁴³ <https://old.food.gov.uk/sites/default/files/fs102087p1finrep.pdf>

⁴⁴ <https://digital.nhs.uk/data-and-information/publications/statistical/hospital-admitted-patient-care-activity/2017-18>

⁴⁵ <https://improvement.nhs.uk/resources/reference-costs/>

	Total cost	National average unit cost	Number of FCEs	Number of inlier bed days	Excess bed days
Non-elective long stay	£783,908	£1,368	573	1,437	n/a
Non-elective excess bed days	£279,129	£324	n/a	n/a	862
Non-elective short stay	£2,392,372	£347	6,903	n/a	n/a
Regular day or night admission	£28,646	£158	181	n/a	n/a
Day case	£830,274	£312	2,661	n/a	n/a
Table 49: Summary of NHS reference costs for Allergic reactions 2017-18					

It should be noted that these costs are for all allergic reactions, so the totals are not indicative of the total cost of the treatment of food allergies. However we can infer that the average costs are representative of those for food reactions: with the cost for a non-elective long stay (£1,368) being the average cost for a severe reaction and the non-elective short stay cost (£347) being the average cost of a mild reaction.

Relating potential health benefits to costs

Due to our inability to define the precise monetary value of the benefits that each policy option may provide, an alternative approach has been taken. For the low, central and high net present values (NPVs) for each of our four policy options, we have calculated the number of deaths prevented and non-elective long stays (NELS) avoided in order to offset these NPVs.

	Low Estimate of deaths prevented	Central Estimate of deaths prevented	High Estimate of deaths prevented
Option 1	1.64	2.61	3.25
Option 2	14.55	29.05	42.71
Option 3	51.79	88.90	115.79
Option 4	72.53	151.46	227.91
Table 50: Number of deaths prevented necessary to offset costs of Policy Options (over 10 year appraisal period)			

	Low Estimate of NELS avoided	Central Estimate of NELS avoided	High Estimate of NELS avoided
Option 1	2,357	3,759	4,677
Option 2	20,974	41,867	61,545
Option 3	74,641	128,113	166,869
Option 4	104,530	218,283	328,448
Table 51: Number of non-elective long stays avoided, necessary to offset costs of Policy Options (over 10 year appraisal period)			

Potential Health Dis-benefits

One aspect that must be considered is whether the additional labelling on PPDS products (full ingredient labelling in particular) may lead to an increase in the number of allergic reactions due to PPDS foods. Full ingredient labelling is already mandatory for pre-packed foods, however in food manufacturing labelling errors still occur. We cannot therefore assume that labelling will always be 100% accurate.

With the implementation of improved labelling we are assuming that consumers with food allergies may feel more confident purchasing PPDS foods, which is something they previously may not have purchased. Therefore there is the possibility that consumers may be overconfident in PPDS labelling and adverse reactions to PPDS foods may occur when they previously would not have.