

FINAL BUSINESS AND REGULATORY IMPACT ASSESSMENT

**Implementation of Improved Allergen Labelling on Prepacked for Direct Sale (PPDS)
Foods - The Food Information (Scotland) Amendment Regulations 2021**

Date: February 2021
Stage: Final
Source of intervention: UK
Type of measure: Regulation
Contact for enquiries: Calum Yule
01224 288367
Calum.yule@fss.scot



1. Title of Proposals

1.1. Implementation of improved allergen labelling for Prepacked for Direct Sale (PPDS) Foods.

2. Purpose and intended effect

• Objectives

2.1. To assess the issues, risks and benefits of moving towards mandatory labelling of PPDS foods following the outcome of the joint consultation with the Department of the Environment, Food and Rural Affairs and the other devolved administrations in 2019 on options to improve allergen information in this area.

2.2. The policy objective is to improve the provision of up front information to consumers about food allergens and other ingredients present in PPDS foods and reduce the risk of food allergic consumers suffering reactions. This proposed instrument is intended to require PPDS food to be labelled with the name of the food and ingredients information.

• Background

Legislative background

2.3. In 2014, Regulation (EU) 1169/2011 on the provision of food information to consumers (FIC) introduced new rules for Food Business Operators (FBOs) relating to the labelling and provision of allergen information, notably extending the need for allergen information to include non-prepacked foods. FBOs are under a duty to ensure that all mandatory food allergen information must be accurate, available and easily accessible to the consumer. FIC allows for Member States to introduce national measures as to how information is to be made available for non-prepacked foods. The Food Information (Scotland) Regulations 2014 (as amended) and equivalent regulations in Wales, England and Northern Ireland, are the domestic regulations that establish the enforcement measures for FIC in the UK and take up national flexibilities permitted under the EU rules. Since 1 January 2021, these EU rules have been converted into what is known as 'retained EU legislation' to make them workable following the UK's departure from the EU.

2.4. The national measures set out in the domestic regulations include giving food businesses the flexibility in how they provide the allergen information for non-prepacked foods, including PPDS food. Currently, the allergen information can be made available by any means the food business chooses, including orally by a member of staff. Where the FBO chooses not to provide written information on food there must be some form of signposting to where consumers may obtain allergen information such as an indication to speak to a member of staff either on a label attached to the food itself or on a notice, ticket or label that is readily discernible to the customer at the point of ordering. It is proposed that how allergen information is presented to the consumer, for PPDS food, is changed so that FBOs are required to provide this along with ingredient information on a label which is included on the food packaging, or on the packaging itself.

Allergenic Foods

2.5. There are 14 substances or products known to cause allergies or intolerances which (unless exempted) are legally considered to be mandatory information to consumers under retained Regulation (EU) No 1169/2011. This requirement applies to all foods provided to consumers and includes food that is not prepacked (*e.g.* restaurant meals); packed at the consumers' request (*e.g.* a deli sandwich prepared, wrapped and handed to the customer); or is PPDS (*e.g.* a sandwich prepacked on the premises 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 FBO to the consumer.

Namely:

- Cereals containing gluten, namely: wheat (such as spelt and Khorasan wheat), rye, barley, oats and their hybridised strains and products thereof;
- Crustaceans and products thereof;
- Eggs and products thereof;
- Fish and products thereof;
- Peanuts and products thereof;
- Soybeans and products thereof;
- Milk and products thereof (including lactose);
- Nuts, namely: almonds, hazelnuts, walnuts, cashews, pecan nuts, Brazil nuts, pistachio nuts, macadamia or Queensland nuts, and products thereof;
- Celery and products thereof;
- Mustard and products thereof;
- Sesame seeds and products thereof;
- Sulphur dioxide and sulphites >10mg/kg or 10mg/L;
- Lupin and products thereof;
- Molluscs and products thereof.

Prepacked for direct sale

2.6. While retained Regulation (EU) No 1169/2011 does not provide a specific definition of PPDS, it is not intended that this category of food should be covered by all the rules for prepacked foods and fits with other non-prepacked situations mentioned in the Regulation. However the proposed interpretation set out in FSS's draft technical guidance on allergen labelling is:

PPDS food is not prepacked food or food packed on the sales premises at the consumer's request. It is food that is packed **before** being offered for sale by the same food business to the final consumer:

- i) on the same premises; or

- ii) on the same site¹; or
- iii) on other premises if the food is offered for sale from a moveable and/or temporary premises (such as marquees, market stalls, mobile sales vehicles) and the food is offered for sale by the same food business who packed it.

2.7. PPDS foods may include:

- Sandwiches placed into packaging by the food business and sold from the same premises;
- Foods that are pre-weighed and packed such as cheese or meats from a delicatessen counter or baked goods from an in-store baker;
- Fresh pizzas from a delicatessen counter e.g. on a cardboard tray and wrapped in plastic;
- Boxed salads

Rationale for Government intervention

2.8. The rationale for government intervention is to correct for the information asymmetry between food businesses and consumers, in particular individuals at risk from food allergens. That is to say, currently not all prewrapped food must be labelled with allergen information. A key driver in this respect was the publication in October 2018 of the Coroner's report into the death of Natasha Ednan-Laperouse. The inquest concluded that the teenager died due to an anaphylactic reaction to sesame contained in a baguette which did not carry specific allergen information on the packaging or near the product on the shelf. One of the concerns raised by the Coroner in London was that the business, using local kitchens, was not required to undertake full labelling through an exemption in food labelling regulations for food sold PPDS. Following receipt of the Coroner's report, the Defra Secretary of State sought cross-government agreement to review the information needed on food sold on a PPDS basis, and Scottish Ministers agreed that this review should be undertaken across the UK.

2.9. In 2019, Food Standards Scotland along with the Department for the Environment, Food and Rural Affairs and the other devolved administrations held a joint public consultation on options to improve allergen information for PPDS food. The four policy options in that consultation were as follows:

- Option 1 – Promote best practice
- Option 2 – Mandate the use of 'ask the staff' labels on all PPDS foods.
- Option 3 – Mandate the name of the food and 14 allergens listed in the FIC Regulation on labels of all PPDS.

¹ In this instance 'site' refers to a building complex such as a shopping centre or airport terminal in which the same food business operates from more than one unit within the building complex.

- Option 4 – Mandate the name of the food and full ingredient listing on labels of all PPDS foods

2.10. The 2019 consultation also focused on the provision of allergen information in relation to intentional ingredients in PPDS foods and circumstances where there are opportunities for consumers to ask the food business about allergen information before making a purchasing decision.

2.11. Feedback from consumers strongly supported Option 4 and it was the most favoured consultation option overall, particularly for those consumers who are allergic or intolerant to foods which are not included in the list of 14 in the FIC. Business stakeholders offered mixed views on this option with notable support from some larger businesses with greater technical capacity to introduce full ingredient listing. However, smaller businesses were particularly concerned about the practical challenges and risks of moving towards mandatory full ingredients labelling for PPDS food. Equal numbers of non-Governmental Organisations and Public Sector Bodies supported this option.

2.12. Having reviewed and assessed responses to the consultation, Food Standards Scotland, recommended to Scottish Ministers that Option 4 offered the best level of protection for consumers and that further work should be undertaken to assess the benefits and risks for all sectors. Scottish Ministers supported Option 4 and asked Food Standards Scotland to assess with stakeholders how full ingredients listing can be achieved accurately and in ways that will provide greater certainty sought by consumers, as part of a staged implementation approach.

3. Consultation

Within Government

3.1. FSS has policy responsibility in Scotland for general food labelling. This includes the provision of information on the presence in food of any of the 14 substances or products known to cause allergies or intolerances as listed in Annex II to Regulation (EU) No 1169/2011. This consultation package was discussed with Scottish Government officials from the Food and Drink Policy team and Population Health Directorate.

Informal Stakeholder Engagement

3.2. In late 2019 and in early 2020, Food Standards Scotland carried out further informal engagement with stakeholders on implementation options and impacts with stakeholders representing food manufacturers, retailers, caterers and enforcement authorities. Stakeholders broadly welcomed the move towards providing consumers with fuller ingredients information on PPDS food, although concerns have been raised consistently regarding the cost of introducing new labelling systems for smaller businesses and the practical challenges of providing full ingredient information on existing labels. The scope and definition of PPDS foods that will be subject to the new requirements was a key feature of discussions with stakeholders. For example, caterers wrapping food in advance

of serving consumers such as sandwiches on a tray and food being held hot in fast food premises. Enforcement stakeholders raised concerns that a switch from preparing and wrapping food in advance for sale PPDS to packing food at the consumer's request could increase the risk of cross contamination. With time separation and effective cleaning between different products, cross contamination risks in a shared food preparation area can be controlled. Guidance covering general food labelling as well as specific allergen information requirements would also be needed.

Public Consultation

3.3. A nine week consultation was carried out in Scotland on the draft national legislation from 2nd October to 4th December 2020. This intended to build on the informal stakeholder engagement described above and further develop information on the benefits, costs and risks of the proposals for prepacked for direct sale food for each sector. A total of thirty-one responses were received from two hundred and seventy eight stakeholders who received the consultation. Alongside this consultation, FSS held additional informal discussions with various industry stakeholders. In these informal discussions FSS looked to speak directly with businesses to gain greater understanding of their thoughts on the proposals, including any risks they envisaged, the impact it may have on them financial or otherwise and also how prepared they felt to implement the changes.

3.4. The formal consultation was circulated to a wide group of industry bodies, retailers and enforcement officers whose knowledge would enable them to assess the policy options proposed and to identify further any impacts they may have. FSS has also reflected comments generated from informal engagement with stakeholders during late 2019 and early 2020.

3.5. While stakeholders generally welcomed the phased implementation approach for improving the information about PPDS food, a number of specific points were made as follows:

3.6. Food manufacturing sector – Most members will not be directly affected by a change to the labelling requirements for PPDS food, but are keen to understand what it means. This sector supplies ingredients to businesses that do provide PPDS food to consumers and appreciate the consumer interest in allergens and ingredient information. Members produce multiple streams and formulations of ingredients products e.g. food additives some of which will have allergen implications. Good communication of information through the supply chain to consumers will be needed as well as consumers making their requirements known. Businesses being able to print labels and having systems to support labelling information will be key, but they come at a cost.

3.7. Food retailers (High street baker, butcher and convenience stores) – Recognise that accurate information along the supply chain will be critical for successful implementation of full ingredients and allergen labelling of PPDS food. Having experienced staff supervise labelling is also a key point. The cost of labelling systems and the supporting software is a major investment for small businesses and normally done as part of a 10 year plan. The practical challenges of adding more information onto existing labels may make them

difficult to read and there is concern about actually increasing the number of product recalls if the information is wrong and the impact on businesses. There is also a lack of financial support for businesses to introduce new labelling systems. Knowing how to construct labels to deal with compound ingredients will be important and guidance could help with this.

3.8. Hospitality (caterers, licensed trade) – This sector is concerned at the impact of introducing mandatory ingredients information for all wrapped products, such as wrappers at burger restaurants. Clarity over which products are classed as PPDS is important in understanding changes. If businesses were to favour opening wrapped food prior to supply to consumers it could increase the risk of cross contamination with implications for consumer safety e.g. sesame seeds are electrostatic and can fly away. Catering situations are more difficult to control compared with manufacturing sites. In the licensed trade, while it may be businesses with café type operations that would be most affected, there is a lot of legislative changes to deal with and small businesses aren't always represented either individually or by trade bodies. With regard to smaller caterers and fish and chip shops, some businesses may pack foods in advance e.g. coleslaw, and labelling would place a large burden on them to ensure information is accurate. They also had concerns about some businesses being able to meet the current allergen requirements and the enforcement resources available.

3.9. Enforcement authorities – comments included that there is a risk of incorrect ingredients lists causing issues similar to recalls for prepacked food. There may be difficulties in ensuring consistency of ingredients bought in from other suppliers and the interpretation of PPDS needs to work across all food information. There was a suggestion that a specific sector approach might be needed to bring in changes to the information for consumers. In addition, some small businesses concerned about the practicalities of ingredients listing may stop PPDS food - potentially increasing the risk of cross contamination through products being made throughout the day rather than in controlled batches.

4. Options

4.1. **Option 1** – Do nothing. This option would retain the existing regulatory framework for PPDS food and continue with current guidance and public information campaigns to highlight the importance of having allergen information available for businesses and consumers. With this option, businesses continue to have a choice as to how they provide allergen information on PPDS foods and consumers would be encouraged to take responsibility for safeguarding their own health. However, this is discounted as a practical option because it would not require allergen and ingredient information up front and provide the greater level of information sought by consumers.

4.2. **Option 2** – Mandate the name of the food and full ingredient list labelling for PPDS food. This option would require that all food businesses who provide food prepacked for direct sale have a label with the name of the food and a full list of ingredients with allergens emphasised either attached to or printed directly on their packaging. If implemented, it would provide the information sought by consumers on pack.

Sectors and groups affected

4.3. The following groups will be affected by the proposed changes.

4.4. Consumers – Having accurate information about what is in food is important to consumers for a variety of reasons, not least those who suffer from a food allergy or intolerance. While there are 14 substances and products listed in the FIC Regulation known to cause food allergy and intolerance, this list is not exhaustive and there is strong interest in having information about other ingredients in food.

4.5. Enforcement Authorities – Enforcement of the rules on food labelling, including allergen information is the responsibility of Local Authority Environmental Health Departments. Introducing changes to legislation and guidance will involve familiarisation time costs to understand new requirements and consider them when planning inspection visits.

4.6. Businesses – Business will be the main group affected by the proposed amendment regulations. Businesses would incur costs in becoming familiar with new requirements and amending / updating labels and labelling systems. There may also be training costs for staff preparing and serving food to consumers which requires on pack labelling for the first time. These costs may also be passed on to the consumer.

Option Appraisal: Costs, Benefits and Risks

Option 1

4.7. Option 1 is the 'do nothing' scenario against which all other options are measured.

Costs

4.8. No monetary cost but the risk identified is a potential cost to consumers and similarly to business if reputational damage is incurred.

Benefits

4.9. There would be no additional benefit to consumers over the current approach, although some businesses may choose to provide allergen and ingredients information on pack.

Risks

4.10. Given that PPDS food is presented for sale wrapped and does not need to be labelled, the absence of information on pack may lead some consumers to incorrectly assume that no allergens are present. While FSS encourages consumers to have a conversation with food businesses to highlight any food allergies and intolerances, this does not always happen. As mentioned above, some businesses may choose to provide allergen and ingredients information on pack. If some businesses choose to do this then

this may create confusion and consumers may expect to have the information available in all cases if there are allergens present and if there aren't any listed then they assume a food is 'safe' for them. This was a concern raised following the inquest into the death of Natasha Ednan-Laperouse.

Option 2

4.11. Option 2 would require that all businesses who provide food prepacked for direct sale have the name of the food and a full list of ingredients with allergens emphasised either on a label attached to their packaging or printed directly on their packaging.

4.12. In addition to the existing national measure which requires the name of a food sold loose or PPDS to be displayed on a notice, ticket or label near the point where consumers choose food, there are other national measures relating to minced meat and products containing meat which need to be considered.

4.13. The FIC sets composition standards for the fat content and the meat protein: connective tissue ratio when certain terms are used to describe minced meat. Minced meat which does not comply with these standards may be sold in the UK provided the national mark (square mark) is shown on a notice, ticket or label. Under this proposal, minced meat which does not comply with the compositional standards e.g. minced meat with a low-fat content but higher in connective tissue, sold as PPDS would require the national mark on the label.

4.14. Indication of meat content for products containing meat – Similar to the name of the food requirement, an indication of the meat content would be required on the label of products containing meat sold as PPDS food.

4.15. To help consultees consider the effects of the proposals the consultation asked the following questions:

- Q1. How prepared are businesses to implement labelling of the name and full ingredient lists on PPDS foods?
- Q2. Are the estimated costs for businesses regarding familiarisation time with the changes and introducing updated labelling reasonable and are there other elements that should be taken into account?
- Q3. Do you agree with the benefits stated in the Business and Regulatory Impact Assessment and are there others that could be realised through this approach?
- Q4. How likely to occur are the types of risks mentioned in the Business and Regulatory Impact Assessment and what steps to mitigate them could be taken? Are there other risks that should be considered?
- Q5. Are the estimated costs for Local Authorities regarding the familiarisation and dissemination of the changes in the Business and Regulatory Impact Assessment reasonable?
- Q6. Are there additional risks and unintended consequences from the food law enforcement interest that should be considered and how could these be mitigated?

- Q7. Do you agree that as a consumer with a food allergy or intolerance, or if buying food on behalf of others with a food allergy or intolerance, you have a responsibility to inform businesses of these dietary requirements?

4.16. The questions and responses FSS received have been included in this document as feedback in the sections relating to consumers, businesses and Local Authorities as appropriate.

Consumers

Costs

4.17. The process of labelling food will attract additional costs and applying this to PPDS food represents a major change for businesses, particularly smaller businesses. Therefore, some or all of these costs may be passed on to consumers.

Benefits

4.18. PPDS food which is accurately labelled with allergen and ingredients information will give consumers increased confidence in those products. The presence of obvious information about what is in the food may also encourage those who have been reluctant to buy PPDS foods in the past to try a wider range of products.

4.19. The benefits have not been monetised. The benefits generated by this policy option includes an assumed improved success rate in reducing the likelihood of incidents due to allergic reactions. This is because this option requires that the 14 common allergens are always listed on the PPDS food product along with information on other ingredients that may cause allergy and intolerance.

4.20. Through consultation and informal talks with stakeholders we have also heard that some consumers can be reluctant to highlight any allergies or intolerances they have, with businesses, due to a variety of reasons, including feeling uneasy about talking about it or feeling awkward doing so in front of others. The addition of allergen labelling on PPDS products could help alleviate some of this feeling whilst still providing the consumer with the necessary information.

Risks

4.21. Responses to the consultation generally agreed that consumers should inform a business if they have a food allergy or intolerance. However there was concern that having more information on pack may discourage some consumers from making food businesses aware of their particular needs especially when a customer has an intolerance or allergy to a food item that is not included in the list of 14 allergens. FSS will continue to advise consumers to have conversations with food businesses such as the recent campaign with 'Young Scot' to encourage teenagers to speak up about food allergies when buying food. However, if businesses move away from supplying PPDS food, consumers would not be certain to receive the same benefits of having allergen and ingredients information on the label of food prepared and wrapped in store.

4.22. There was also some concern expressed by consumers who responded to the consultation, relating to staff understanding of allergies and intolerances. They felt that

training in these areas would be of benefit and may help mitigate some of the risks involved in labelling of PPDS food.

4.23. Consumers have expressed that they would like to see strict regulations around how businesses deal with mislabelled food. There is also concern that a more risk averse approach could lead to increased use of precautionary labelling by businesses, which could be confusing for consumers.

Enforcement Authorities

Costs

4.24. There will be additional costs to local authority health departments, mainly a one-off familiarisation cost. There are 210 enforcement officers throughout the 32 local authorities in Scotland and we estimate that it would take one Environmental Health Officer (EHO) from each local authority eight hours to read, familiarise themselves with the new regulations and discuss and disseminate information to other officers in their area. According to 2019 ASHE data, the hourly pay rate for Qualified Environmental Health Officers is £19.56² in Scotland – averaging approximately £25.43 per hour once uprated by 30% to account for non-wage labour costs and overheads. When disseminating the information it is estimated the time cost of the additional officers listening to the information to be one hour, at a cost of £4,526. The total one-off familiarisation cost is therefore estimated at approximately £11,036. While enforcement activity regarding PPDS food will be included as part of the risk based approach to food information inspections, there may be additional enquiries from businesses as they seek advice on adapting and improving their existing approaches to support the need to label additional foods. FSS understands that Officers may need additional time to assess business systems and the accuracy of new labels, however this additional time has not been monetised. This is due to consultation responses received, which say that the time spent, and therefore additional cost, will vary from business to business and depend on many elements such as size of business and whether they already provide labels on products or not.

Benefits

4.25. This option represents a change in how information about PPDS food is presented to consumers rather than a direct benefit to an enforcement approach.

Risks

4.26. Food businesses may struggle to adapt their systems to cope with both allergen and ingredients labelling of PPDS food and mistakes which lead to an incident affecting consumers will require enforcement resource to rectify. Allergy alerts and inaccurate information from suppliers may also require labels to be reprinted or altered at short notice.

4.27. It is possible that enforcement for non-compliance could increase, in line with this there is some concern that short of reporting cases for prosecution, there are no formal

² Using ASHE 2019 provision table 15.6a for hourly pay excluding overtime
<https://www.ons.gov.uk/employmentandlabourmarket/peopleinwork/earningsandworkinghours/datasets/regionbyoccupation4digitsoc2010ashtable15>

enforcement options available to local authorities currently, such as compliance notices. If Local authorities don't have means to properly enforce compliance they may find it hard to enforce the new regulations.

4.28. These changes may also lead to increased inspection times, which may impact on the number of businesses local authorities are able to inspect throughout the year. Local authorities have asked that this should be considered as part of the resource calculation under the Local Authority Recovery Plan.

Businesses

Costs

4.29. There will be additional costs associated with Option 2. These include familiarisation time as well as labelling costs (this cost will vary depending on the size of the business and whether or not the business can bulk buy labelling and packaging). Non-monetised costs to businesses include the risk of mislabelling and dealing with incidents.

Familiarisation costs

4.30. There will be a one-off familiarisation cost to business, estimated at £371,021 for the sector, to allow time to become familiar with revised legislation.

4.31. From a Scottish perspective, this figure is calculated by taking the Provisional 2019 Annual Survey of Hours and Earnings (ASHE)³ for 'Scotland, Restaurant and catering establishment managers and proprietors' £9.76 (median value) and uprating it by 30% to account for overheads, giving an hourly wage rate of £12.69. It is estimated that for small and micro businesses, the reading and understanding of the Regulation would take two hours within each firm in Scotland at £25.38. This does not however take into account time spent away from carrying out other tasks during the familiarisation process.

4.32. We assume for medium and large businesses that it would take one regulatory professional twelve hours to read, familiarise and then disseminate the relevant information to others (as they will have multiple outlets). The estimated familiarisation cost per medium and large businesses has been calculated by taking the Provisional 2019 ASHE⁴ for 'Scotland quality assurance and regulatory professionals' £22.43 (median value) and uprating it by 30% to account for overheads, giving an hourly wage rate of £29.16. Therefore it is estimated that for medium and large businesses, the cost to read and understand the Regulation within in each firm would be £349.92.

4.33. The total familiarisation cost to business is familiarisation cost per business multiplied by the relevant number of businesses. Therefore, in Scotland, for small and micro

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<https://www.ons.gov.uk/employmentandlabourmarket/peopleinwork/earningsandworkinghours/datasets/regionbyoccupation4digitsoc2010ashtable15>

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<https://www.ons.gov.uk/employmentandlabourmarket/peopleinwork/earningsandworkinghours/datasets/regionbyoccupation4digitsoc2010ashtable15>

businesses⁵ (10,965) we estimate a one off familiarisation cost of £278,292 to industry. For medium and large businesses⁶ (265) we estimate a one off familiarisation cost of £92,729. A small or micro business has been defined as a business with 49 or fewer employees, medium and large businesses have been defined as any business with 50 or more employees.

Labelling costs

4.34. There will also be additional costs based on the time needed to update systems to track ingredient information and produce labels. Time will also be needed to assess the effect and take corrective action in the event of recipe and ingredient changes. As a guide, costs for labelling changes for *prepacked food* range from around £11 to £2000 per product although the exact impact will depend on the size of the business, volume of product sold and complexity and frequency of any required labelling changes e.g. some businesses may use self-adhesive labels others may use pre-printed packaging.

4.35. Based on previous research⁷ and using 2018 prices, we know that for minor labelling changes they range in cost per stock keeping unit (SKU) is £10 - £1,800⁸. Uprating these to 2019/20 prices⁹, we then assume that the cost of re-labelling to be £10.41 per SKU for small and micro businesses, and £1,874 per SKU for medium and large businesses. It is our assumption that a SKU can be equated to a distinct PPDS food product, although less information would be needed in comparison with prepacked food.

Costs associated with new labelling

4.36. Businesses currently may look to change ingredients with close alternatives when prices rise as a means to keep costs low. Without this option to substitute for cheaper

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Businesses in Scotland, 2019 (SG publication: <https://www.gov.scot/publications/businesses-in-scotland-2019/>) Food and Beverage Service Activities category used for business figures

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Businesses in Scotland, 2019 (SG publication: <https://www.gov.scot/publications/businesses-in-scotland-2019/>) Food and Beverage Service Activities category used for business figures

⁷ 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>

⁸ The assumed range in the cost per SKU is due to a combination of both complexity (smaller businesses more likely to have simple labelling) and number of units of each product line (medium and large businesses will sell significantly more of a single PPDS product in a year).

⁹ Using 'GDP deflators at market prices, and money GDP June 2020' - <https://www.gov.uk/government/statistics/gdp-deflators-at-market-prices-and-money-gdp-june-2020-quarterly-national-accounts>

alternatives they may be forced to raise the price of their products. This restriction would restrict the addition/subtraction of an ingredient.

4.37. We have also received information during informal consultation with the Scottish Craft Butchers that business may need to purchase new equipment in order to meet the proposed changes to labelling requirements. It was estimated that a scale system could range from £5000 - £10,000 per machine per shop with additional software costs of £20,000 -£30,000. This represents a major investment for businesses and would be planned on an anticipated 10 year service period. Spread over 10 years this would be a yearly cost of between £2,500 and £4,000. As part of the business engagement carried out during the consultation, we spoke with a bakery owner and also a convenience store owner. We were advised by the bakery that equipment costs of around £5000 per machine plus software costs is a reasonable estimate at unit level. The convenience store owner told us that they pay around £15 a month for labelling software and 10p per label, additionally they had a one off cost of a standard laptop and printer which they thought to be around £1000. In addition, setting aside time to establish a labelling system and then keep it updated with ingredient changes and new product lines is essential. Assuming a lifespan of a laptop and printer of 5 years this would be a yearly cost of £480.

Training costs

4.38. This is currently a non-monetised cost. Although not explicitly required, many businesses carry out staff training and could include additional training on new food labelling requirements. Making use of guidance and on line training offered by FSS would help support businesses training plans. FSS is looking into updating the online training tool to reflect the changes to the requirements for PPDS food, as well as developing guidance to cover general labelling requirements as well as allergen information.

4.39. Potential for costs to come from:

- Training to staff members
- Distributing guidance/documentation to each outlet

Costs of determining allergens

4.40. Since December 2014, there has been a need for businesses to have allergen information available for PPDS food and a requirement on ingredient suppliers to provide allergen information to businesses serving consumers and mass caterers. However, business systems which currently focus on allergen information may need to be adapted to track full ingredient information and be capable of dealing with changes in products to support accurate labelling.

Benefits

4.41. Having accurate information on allergens and ingredients information on PPDS food would address concerns raised by consumers and increase their confidence in buying such products. This could lead to increased sales of PPDS food and provide valuable support to food allergic consumers in deciding which products are suitable for their needs. Continuing to sell PPDS foods also helps businesses prepare food in advance enabling

them to serve customers quickly at busy periods and on pack labelling would allow enable consumers to have a final check before eating a product.

Risks

4.42. Businesses would need to ensure that their systems to support accurate labelling of allergen and ingredients are supervised and sufficiently robust to deal with ingredient substitutions. The free FSS MenuCal system was intended for caterers although it guides users to identify allergens through a recipe approach which would help businesses to standardise their range of PPDS food and achieve consistent allergen and ingredients information for labelling purposes. The consultation responses also raised concerns around potential errors in labelling. This may be due to ingredient changes or lack of understanding of the information required within ingredients declarations or simply not complying with the requirement to provide information. It was also raised that many small businesses will change ingredients or the brand of ingredient, depending on what is available or is the best value at the time, this will make having a consistent allergen list difficult

4.43. Following on from this, business have expressed concerns that if arrangements for ensuring notification of recipe changes and/or potential contamination in pre-mixes were not sufficiently robust, it could lead to businesses unwittingly selling products with potential contamination and that they would have no way of preventing if the notification and alert procedures are not adequately connected.

4.44. Another risk is businesses may opt to stop selling PPDS food in favour of making food to order. This would make it more difficult to control cross contamination compared with preparing food in advance where work surfaces and utensils can be cleaned between making different products.

4.45. Although most respondents felt the interpretation of PPDS, as covered in the consultation, was clear, there was still a feeling from industry that there are some products that may cause confusion due to the nature of how they are displayed/packed. It was felt that additional examples of borderline products that will and won't fall under its scope would be useful in order to provide additional clarity and that this could be done through industry guidance.

4.46. It was also raised during the consultation that some business may struggle when providing accurate written information on their labelling as they are more comfortable providing it orally due to language issues. In line with this LAs also felt that having resources and tools (in multiple languages) to assist businesses comply, including practical examples would be important.

5. Scottish Firms Impact Test

5.1. While some businesses already label PPDS food, we estimate the number businesses potentially affected by these changes to be 11,230¹⁰, the consultation was

¹⁰ Businesses in Scotland, 2019 (SG publication: <https://www.gov.scot/publications/businesses-in-scotland-2019/>)

circulated to local authority enforcement officers and trade bodies whose local knowledge could help identify any additional business likely to be affected within Scotland. We also encouraged manufacturers and retailers to respond to this consultation in order to update the data we currently have. The consultation responses did not generate any information that contradicted our figures for number of businesses potentially affected in Scotland.

5.2. Competition Assessment

5.3. The proposed legislation will apply to all businesses who provide food prepacked for direct sale allowing businesses in Scotland to trade equally. It should not limit the number or range of businesses in Scotland either directly or indirectly or reduce the ability of, or incentives to, businesses to compete. Therefore, it is not expected to have a significant impact on competition.

5.4. Test run of business forms

5.5. No new or additional forms will be introduced by this proposal therefore no test run need be completed.

6. Legal Aid Impact Test

6.1. The Justice Directorate have confirmed that they expect the new regulations to have very little impact on the legal aid fund.

7. Enforcement, sanctions and monitoring

7.1. Enforcement

7.2. Enforcement of the regulations will be the responsibility of Local Authority Environmental Health Departments. Enforcement should be risk based and proportionate, in line with the approach taken with the current Scottish legislation on labelling. Enforcement officers would not be expected to initiate separate inspections in relation to the enforcement of these new provisions, but instead to include these as part of their existing regimes.

7.3. Sanctions

7.4. The Food (Scotland) Act 2015 contains a power to bring in compliance notices to support the enforcement of food and feed law. FSS is currently considering the introduction of compliance notices in respect of food and feed law, including food information requirements and proposals will be detailed in a separate consultation.

7.5. Monitoring

7.6. The effectiveness and impact of the regulations will be monitored via feedback from stakeholders, including Enforcement Agencies, as part of the ongoing policy process. Agency mechanisms for monitoring and review include; open fora, stakeholder meetings, surveys and general enquiries.

8. Summary and Recommendation

8.1. Option 2 – This is the preferred option.

8.2. Summary costs and benefits table

Option	Total benefit per annum: economic, environmental, social	Total cost per annum: economic, environmental social policy and administrative
1	None	
2	<p>Business will face one off familiarisation cost as well as costs associated with changes to labelling.</p> <p>Enforcement Authorities will be working to a consistent legal standard throughout the UK.</p>	<p>Businesses: an approximate one-off familiarisation cost of £371,021 to business. The cost of updating labelling systems range from £480 a year for a laptop and printer used by a convenience store (based on an expected system lifespan of 5 years) to £4,000 a year for a butchers scale system (based on an expected system lifespan of 10 years).</p> <p>Enforcement: One-off familiarisation cost estimated at approximately £11,036 across Scotland.</p>

9. Declaration and publication

I have read the impact assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) that the benefits justify the costs. I am satisfied that business impact has been assessed with the support of businesses in Scotland.

Minister's signatureCLARE HAUGHEY

Minister's titleMINISTER FOR MENTAL
HEALTH

Date10/02/2021

Contact point

Calum Yule
Labelling, Standards and Regulated Products Branch
Food Standards Scotland
Pilgrim House
Old Ford Road
Aberdeen
AB11 5RL
Tel: 01224 288 367
e-mail: Calum.Yule@fss.scot