

PARTIAL REGULATORY IMPACT ASSESSMENT

1. Title of Proposal

1.1. Review of National Provisions in the Food Labelling Regulations 1996 (as amended) ('FLR').

2. Purpose and intended effect

(i). Objective

- 2.1. The primary objective of this impact assessment is to inform policy on a number of national provisions in the FLR which have evolved over time and which have been largely unaffected by EU law, in preparation for the review of European food labelling legislation that is now underway.
- 2.2. This impact assessment is being considered on a UK-wide basis.

(ii). Background

Review of EU General Food Labelling and the UK National Provisions

- 2.3. The European Commission is currently reviewing EU general food labelling legislation. A draft proposal is expected later this year. This will form the basis for negotiation between Member States on what is likely to be a new directly-applicable EU Regulation on food information.
- 2.4. A consequence of an EU Regulation being adopted is that the national provisions in question would no longer be available to businesses in the UK. The UK must therefore consider which of the provisions if any it would like to see adopted into the new EU legislation and seek to negotiate for these in Brussels.
- 2.5. The following is a list of the national labelling provisions. A full description is provided below at paragraphs 20–11:
 - 'Provident Societies' provision Regulation 4(3)(b)
 - 'Charities' provision Regulation 4(3)(c)
 - 'Fortified Flour' provision Regulation 18(1)(e)
 - 'Added Ingredients' provision Regulation 18(2)
 - 'Manner of Presentation' flexibility Regulation 20(3)(b) and 21(3)(b)
 - 'Flour Confectionery' provision Regulation 23(1)(b)
 - 'Minor Accompaniment' provision Regulation 26(3) and 26(3)(A)

(iii). Rationale for government intervention

- 2.6. If these labelling provisions do not feature in the new directly-applicable EU Regulations, UK food businesses might have to comply with additional labelling requirements which may result in additional costs, some of which may be significant, particularly for some small businesses.
- 2.7. This consultation on the RIA will provide the opportunity for interested parties to make their own representations to the UK Government, and in particular, with respect to the potential impact on businesses, consumers and enforcement. These representations will inform the Government's thinking and the development of policy, which will in turn form the basis of negotiations in Brussels.

3. Consultation

(i). Within Government

3.1. The Agency has consulted closely with the Devolved Administrations and the Small Business Service (SBS) in developing the options described in this impact assessment. Other Government Departments, including the Department of Environment, Food and Rural Affairs (Defra), the Department of Trade and Industry (DTI) and the Cabinet Office (CO) have been kept informed of the progress of this exercise and the EU review of general food labelling.

(ii). Public consultation

Key stakeholders consulted

3.2. The Agency met with a wide range of key stakeholders between 2005 and 2006, including consumer organisations, trade associations and local authority enforcement bodies, to discuss the labelling provisions in question. The following groups were represented: Which?; Dairy UK; the National Association of British and Irish Millers; the National Association of Master Bakers; the Federation of Bakers; the British Retail Consortium; the Food and Drink Federation; Country Markets; the British Hospitality Association; the Biscuit, Cake, Chocolate and Confectionery Association; the National Farmers' Union; Provision Trade Federation; Scottish Baxters; Vinegar Brewers' Association/Honey Association; British Soft Drinks Association; the Co-operative Retail Trading Group; Specialist Cheesemakers' Association; British Meat Processors' Association and the Small Business Service. Their views have helped inform the options presented later in the document.

4. Options

- 4.1. The options for each national provision are outlined below at paragraphs 4.3 4.9 below.
- 4.2. The following are the Agency's recommended options in respect of the various provisions. The Agency seeks stakeholders' views on these recommendations, and to this end, detailed questions for affected stakeholders are included in **Annex B**.

4.3. Regulation 4(3)b - 'Provident Societies' Provision

Purpose	Under EU law, most pre-packed ¹ food has to comply with general food labelling requirements, except where the product is pre-packed for direct sale ² . Regulation 4(3)b provides a derogation from most of the general labelling requirements for pre-packed food prepared on domestic premises for sale for the benefit of the person preparing it by a society registered under the Industrial and Provident Societies Act 1965. However, these products still have to provide GM information where appropriate.
Sectors and Groups Affected	The sectors that would be affected if this provision were removed would include charities/societies registered under the Industrial and Provident Societies Act 1965. Country Markets Ltd (formerly a part of the Women's Institute) is believed to be the largest beneficiary.
Stakeholder views so far received	The consumer organisation Which? has reported that removal of this derogation would benefit consumers as it would provide ingredient information to facilitate informed choice. Country Markets Ltd, the main legal benefactor of this labelling provision as far as we understand, has informed the Agency that it would be able to take advantage of the current labelling exemption in the UK FLR for foods sold pre-packed for direct sale, if this labelling provision were no longer available. Consequently, they do not consider that their business would be affected.
Options	Outcome:
Option: Do nothing, but ensure provision for pre-packed for direct sale is retained	As this labelling provision would not feature in a new directly applicable EU Regulation, businesses in the UK would no longer be able to take advantage of it, and the products concerned would have to comply with general labelling requirements.
Costs	There will be no costs if this labelling provision were no longer available to businesses who currently take advantage of it in the UK, as they are able to take advantage of the 'pre-packed for direct sale' exemption in the UK FLR.
Benefits	The UK will be brought in-line with European labelling regulations, and any future reference as to labelling procedures for these societies will be easier to interpret.
Small Firms Impact Test	The Agency cannot identify any impact with respect to small firms for the potential removal of this exemption.
Competition Assessment	The Agency cannot identify any impact with respect to competition issues for the potential removal of this exemption

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¹ 'Pre-packed' is defined in EU law as where food is put into packaging before being offered for sale in such a way that, whether wholly or only partly enclosed, the food cannot be altered without opening or changing the packaging and is ready for sale to the ultimate consumer.

² 'Pre-packed for direct sale' is defined in the FLR as where food is pre-packed by the producer/retailer for sale by him on the premises where the food is produced/ packed or from other premises from which he conducts his business under the same name as the business conducted on the premises where the food is produced/packed.

Sustainability Assessment	Economic Economic impact of this provision no longer being available for UK businesses who currently take advantage of it (ie Option 1) should be small, as the key beneficiaries of this provision have noted that they will be able to carry on business as usual by applying other provisions in the FLRs. Because of lack of discernible benefit from negotiating for of this provision in the new EU legislation, the most economically sustainable option would be Option 1.
	Social The organisations who currently take advantage of this would be able to carry on their businesses.
	Increased consumer confidence in products and in the food labelling regime.
	Environmental
	There are no identified environmental impacts.
	Overall sustainability assessment
	The most sustainable option is Option 1; to do nothing.
Recommended Option	Do nothing, but ensure the provision for pre-packed for direct sale is retained at EU level.

4.4. Regulation 4(3)c – 'Charities' Provision

Purpose	Under EU law, most pre-packed food has to comply with general food labelling requirements, except where the product is pre-packed for direct sale. This regulation provides exemption from most of the general labelling requirements for foods prepared otherwise than in the course of a business carried on by the person preparing it. However, these products still have to provide GM information where appropriate.
Sectors and Groups Affected	Charities and public fund raising events such as school and Church fetes. Individuals preparing food for such events.
Stakeholder comments so far received	It was generally agreed that this provision was useful for one-off charity events such as school fetes and that it would be disproportionate to require labelling for such foods.
Option 1: Do nothing	Outcome: As this labelling provision would not feature in the new directly applicable EU Regulation, charity events/fetes or individuals in the UK would no longer be able to take advantage of it, and the products concerned would have to comply with general labelling requirements.
Option 2: Negotiate for adoption of provision at EU- level	Outcome If successful, organisations or individuals in the UK would not need to provide general labelling information on foods prepared for fund raising.
Costs	Option 1 – Do nothing There may be an unwillingness to contribute from those who usually make donations to such charitable events, once they realise that they will also have to spend time listing and labelling the ingredients for each item they produce. Depending on size, individual schools for example, can raise around £150 to £1000 per year through sales of foodstuffs at fetes and charity events (though only a small percentage of these foodstuffs will be affected). The elimination of this exemption may conceivably decrease donations and result in some loss of income from these events. Option 2: Negotiate for adoption of provision at EU-level There will be no incremental cost.
Benefits	Option 1 – Do nothing There will be some gain in relation to increased consumer information and choice, especially from those wishing to avoid certain foodstuffs and allergens, as they become better able to make informed choices. Option 2: Negotiate for adoption of provision at EU-level There will be no new benefits over and above those that charities experience at present.
Small Firms Impact Test	The Agency cannot identify any impact with respect to small firms arising from the potential removal of this exemption
Competition Assessment	The Agency cannot identify any impact with respect to competition issues arising from the potential removal of this exemption

Sustainability Assessment	Economic If this labelling provision were no longer available, there may be an economic impact on charity events for example, that may lose a percentage of their revenue, or be forced to provide labelling information at a cost disproportionate to their activity.
	Social If this labelling provision were no longer evallable, there may be adverse effect an abority.
	If this labelling provision were no longer available, there may be adverse effect on charity events/school fetes, potentially with negative publicity and public backlash.
	Facilitation of informed choice.
	Environmental
	There are no identified environmental impacts.
	Overall sustainability assessment
	The most sustainable option is Option 2; to negotiate for adoption of this provision at EU-level.
Recommended Option	Option 2 – Negotiate for adoption of provision at EU-level.

4.5. Regulation 18(1)e — 'Fortified Flour' provision

Purpose	In the UK the Bread and Flour Regulations 1998 require the mandatory addition of calcium, iron, niacin and thiamin to white and brown wheat flour. Regulation 18(1)e of the FLR exempts white and brown wheat flour to which only these nutrients have been added from the requirement to bear an ingredients list. Consequently, flour to which these nutrients have been added and flour products need only indicate 'flour' in the ingredients list.
Sectors and Groups Affected	Millers and bakers and all manufacturers of compound foods containing fortified flour, particularly –
	 National Association of Bakers Incorporated National Association of British and Irish Millers Ltd (NABIM) Federation of Master Bakers Vitamin / Mineral manufacturers All manufacturers of pre-packed food using flour as an ingredient
Stakeholder comments so far received	Removal of this labelling provision would facilitate consumer informed choice, but would affect a wide range of food categories and lead to longer ingredient lists.
	Trade associations were concerned that it would be costly, might create trade barriers with those Member States that were not keen on fortification and might prejudice consumers against products made with UK wheat flour.
	The issue of having labelling of these ingredients even at nutritionally insignificant levels, thereby potentially misleading consumers was also raised.
Options	Outcome
Option: Do nothing, but explore the possibility of agreeing a threshold below which labelling would not be required	This provision would not feature in new EU food labelling legislation and flour and flour products would have to indicate the added nutrients on the labelling. Agreement of a threshold of nutritional significance for the added nutrients, below which labelling would not be required would ensure the provision of consumer information where appropriate and avoid unnecessary labelling and additional costs to industry.
Costs	Whilst larger bakers will be able to incorporate label changes into their labelling cycles, smaller manufacturers may have to make un-planned amendments to their labelling to include such information. This may involve high short-term costs and there may be a small increase in price of the produce of some smaller manufacturers.
	There may be a section of the public who were previously unaware of the presence of the added nutrients, and who are not keen on fortification. These consumers may therefore choose to avoid product made with fortified flour. However, recent consumer feedback from the Agency's folic acid consultation indicates that even these consumers are unlikely to stop purchasing the product altogether.
	There may be a small loss in trade to those countries that were previously unaware of the fortificants and are highly adverse to consuming fortified products, reducing or eliminating their imports from the UK in the light of this knowledge.
Benefits	Consumers will be better able to make informed choices. Were the Agency to employ 'willingness to pay' or 'choice experiment' methodology, we predict, on the basis that the UK flour industry is worth approximately £1billion per year, welfare benefits to consumers (with respect to the ability to make better-informed choices) may amount to significant amounts of money on an on-going annual basis.
	There may also be increased possibilities brought about from labelling harmonisation, for new or additional trade across Europe.
	The agreement of a threshold level for labelling would significantly reduce additional costs to industry, particularly to small businesses.

Small firms Impact Test	Small firms may be disproportionately affected throughout the market for bread and other products containing wheat flour. This is mainly due to the lower frequency with which these firms re-design their labelling and a reduced ability to absorb these costs. This is likely to be a one-off cost. A longer transition period may help were this exemption to be lost.
Competition Assessment	In accordance with the small firms' impact assessment, a reduced ability to absorb any increase in costs may have a negative effect on the ability of smaller producers of these products being able to compete with larger producers in the short run.
	Depending on the awareness of non-UK consumers to the current fortificants in bread (and their attitudes towards these fortificants), the removal of this exemption has the potential either to improve or reduce the competitive nature of UK breads and UK wheat-flour products sold abroad in accordance with how the benefits of fortification are perceived.
	There is a small chance that there may be some shift from white to wholemeal bread. Therefore sole producers of white bread may find themselves less competitive to those that also produce wholemeal varieties.
	However, were this exemption to be lost, in the long-run, with labelling harmonisation, smaller producers may find they are more readily able to compete with larger firms, and break into new markets should the opportunity arise.
Sustainability	Economic
Assessment	Loss of this provision may have a significant economic impact on a wide range of businesses that currently take advantage of this regulation.
	Social
	Loss of this labelling provision may have significant adverse effect on businesses, particularly small and medium-sized enterprises (SMEs). There may be negative publicity and possible public backlash. However, this will facilitate increased ability for consumers to make better-informed choices.
	Environmental
	There are no significant identified environmental impacts. But deletion may result in stocks of packaging/labels being thrown away and this may have an environmental impact, although this could be overcome by building in sufficient transition periods.
	Overall sustainability assessment The most sustainable option is Option 2; to push for agreement of a threshold below which labelling would not be required.
Recommended Option	Do nothing, but explore the possibility of agreeing a threshold below which labelling would not be required. It is very unlikely that the UK would be successful in negotiating for this national provision at EU level.

4.6. Regulation 18(2) — 'Added Ingredients' provision

Purpose	Under EU law, cheese, butter, fermented milk and fermented cream and vinegar derived from fermentation from a single product need not bear an ingredient list. Regulation 18(2) of the FLR provides an exemption from the requirement to provide full ingredient listing where additional ingredients are added. In this case the requirement is to indicate only the 'added ingredients'. For example "Stilton cheese with added apricots". However, information on the use of irradiated and GM ingredients will have to be provided where appropriate.
Sectors and Groups Affected	All manufacturers of cheese, butter, fermented milk, fermented cream (yogurts) and vinegar and compound foods containing these foods.
Stakeholder comments so far received	The general view was that it would be unreasonable to require the provision of full ingredient listing for products that would not otherwise require it and where the added ingredients are declared. In such cases, it was felt that declaration of only the added ingredients should be sufficient and provide consumers with the same level of information.
Option 1: Do nothing.	Outcome This provision would not feature in the new directly-applicable EU legislation and these products would therefore have to comply with the full labelling requirements.
Option 2: Negotiate for inclusion in new EU legislation	Outcome If successful, this would result in this provision being retained in the UK, thereby avoiding unnecessary labelling and costs to industry. Foods to which this provision applies do not have to provide an ingredient list under EU law. It does not seem reasonable that the addition of one or more ingredients to such a product should entail full ingredient listing if the added ingredient is subsequently indicated on the labelling. There is no particular consumer protection issue arising from retaining this provision.
Costs	Option 1 – Do nothing Removing this exemption would be a highly costly labelling exercise for both small and large manufacturers. Consumers may be confused by the listing of ingredients that have until now been standard inputs to the production process. It is conceivable that some companies may be put off making enhanced products in the knowledge that every input will then have to be labelled. This may decrease innovation and consumer choice. Option 2 – Negotiate for inclusion in draft Commission proposal There are no identifiable incremental costs for negotiating the inclusion of this exemption into the proposal.
Benefits	Option 1 – Do nothing There are no discernible benefits for losing this exemption over and above those that can also be postulated for listing all ingredients in 'plain' foodstuffs such as cheese, vinegar etc. Option 2 – Negotiate for inclusion in new EU legislation Unnecessary and costly re-labelling would be saved for both small and large business alike.

Small Firms Impact Test	Small firms may be disproportionately affected. This is mainly due to the lower frequency with which these firms re-design their labelling and a reduced ability to absorb these costs into their accounts. This is likely to be a one-off cost. A longer transition period may help were this exemption to be lost. There may also be a relatively higher proportion of smaller firms that produce and rely upon niche products that may be affected, both with respect to the cost of labelling and by the small possibility of confused customers switching products.
Competition Assessment	In accordance with the small firms' impact assessment, a reduced ability to absorb any increase in costs may have a negative effect on the ability of smaller producers of these products being able to compete with larger producers in the short run. If customers are overly confused or put off by this new labelling, smaller firms may also be less able to compete with larger firms (with more diverse product ranges) in the event of customers switching products. However, were this exemption to be lost, in the long-run, with labelling harmonisation, smaller producers may find they are more readily able to compete with larger firms, and break into new markets, should the opportunity arise.
Sustainability Assessment	Economic Loss of this provision would have a significant impact on businesses that would the have to provide full ingredients information where previously only additional ingredients were listed. Social None identified. Environmental
	Loss of this provision may result in increased packaging.
	Overall sustainability assessment
	The most sustainable option would be Option 2; to negotiate for inclusion of this provision in the Commission's draft proposal.
Recommended Option	Option 2 – Negotiate for inclusion in new EU legislation

4.7. Regulations 20(3)b and 21(3)b — Manner of Presentation

Purpose	Articles 9 and 10 of Directive 2000/13/EC require the indication of durability to be followed by the date/a reference to where the date may be found, and/or storage conditions/reference to where storage conditions may be found on the labelling. In the FLR, Regulations 20(30)b and 21(3)b regarding the use of 'best before' and use of 'use by' respectively, allow manufacturers to place storage conditions separately from the words 'best before'/best before end' or 'use by'. There has been some suggestion that this is wider interpretation of EU law than is intended in the Directive.
Sectors and Groups Affected	All manufacturers of pre-packed food
Stakeholder comments received so far	Trade Associations: The latest Agency Legal advice is that, as currently drafted, Articles 9 and 10 of Directive 2000/13/EC <i>can</i> be interpreted to allow for the current trade practice, which is provided for by Regulations 20(3)b and 21(3)b. Therefore the issue here would seem to be that of resolving the apparent ambiguity in that provision as it is currently drafted in the Directive.
	Loss of this provision would have significant cost implications, as much of labelling technology has been built around the interpretation of EU legislation as drafted in this regulation.
	Loss of this provision may put consumers at a disadvantage, as it may discourage industry from providing some information it currently provides on a voluntary basis, such as storage information.
Option: Do nothing, but seek clarification/redrafting of Articles 9 and 10 of Directive 2000/13/EC	This would allow UK manufacturers to continue to take advantage of this provision and be in compliance with EU law.
Costs	Do nothing, but seek clarification/redrafting of Articles 9 and 10 of Directive 2000/13/EC
	There are no identifiable costs from negotiating to include this in the draft proposal.
Benefits	Option 1: Do nothing, but seek clarification/redrafting of Articles 9 and 10 of Directive 2000/13/EC
	There are no identifiable incremental benefits.
Small Firms Impact Test	Small firms may be disproportionately affected if these provisions were no longer available for use in the UK. This is mainly due to the lower frequency with which these firms re-design their labelling and a reduced ability to absorb these costs into their accounts. This is likely to be a one-off cost. A longer transition period may help were this exemption to be lost.
Competition Assessment	If this provision is removed it may reduce the ability of smaller producers to compete with larger producers in the short run.
	However, in time and with closer harmonisation of labelling provisions, smaller producers may find they are more readily able to compete with larger firms, and break into new markets should the opportunity arise.
Sustainability Assessment	As we are recommending a redraft of these provisions to better reflect EU law and so allow manufacturers to carry on their current practice, there would be no impact.
Recommended Option	Do nothing, but seek clarification/redrafting of Articles 9 and 10 of Directive 2000/13/EC

4.8. Regulation 23(1)b — 'Flour Confectionery' provision

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Purpose	Under EU law, most pre-packed food has to comply with general food labelling requirements, except where the product has been pre-packed for direct sale. Regulation 23(1)b in the FLR exempts flour confectionary products packaged in crimp cases or wholly transparent packaging from full labelling requirements, provided they are marked with only a name, lot mark and price. However, information on the use of irradiated and GM ingredients will have to be provided where appropriate.
Sectors and Groups affected	 National Association of Master Bakers (NAMB) Federation of Master Bakers Association of Bakery Ingredients Manufacturers Biscuit Cake, Chocolate and Confectionary Alliance
Stakeholder views so far received	NAMB reported that some of the products to which this regulation refers would be able to take advantage of current labelling exemptions for products sold pre-packed for direct sale, but flour confectionery in wholly transparent packaging (ie, effectively pre-packed) would have to comply with general labelling requirements. As a result, NAMB believe that their members would be significantly affected if this provision were no longer available.
	Consumer groups have commented that these products should at least be required to provide allergen information and possibly date marking where appropriate.
Option: Do nothing	Outcome
	This would result in this provision no longer being available for manufacturers to use in the UK when the new EU legislation is adopted. As a result manufacturers would have to comply with the full labelling requirements for these products.
Costs	The Agency estimates that removal of this exemption will affect approximately 100 small predominantly retail-based bakeries that also sell to third parties as part of their business, 100 wholesale bakeries, and 50 or more small establishments providing food and snacks predominantly to ethnic communities.
	For the 150 small retail bakeries and ethnic businesses affected, the Agency estimates that the removal of this exemption and the requirement to provide full labelling including ingredients, address etc will result in set-up costs of up to £410³ per business, followed by costs between £720 and £8,600 (depending upon the number of items sold per day) per business, per year thereafter⁴.
	Across all affected small bakeries and ethnic businesses in the UK (estimated 150 in total) these costs will amount to between £170,000 and £1,352,000 in the first year, and between £108,000 and £1,290,000 per year thereafter.
	However, the realities of being able to employ a person for less than an hour, or just a few hours, are not realistic. Therefore, it is likely this work would have to be absorbed either by current employees (through over time and/or improved productivity) or one new full or part-time member of staff.
	Cost estimates to predominantly wholesale businesses have not been estimated as yet.
	There will be an administration cost for all bakeries and retail outlets that sell such products from the time taken to read the legislation, decide whether it applies to their business or not, and if it does, deciding how to interpret and apply
	Costs can be reduced if companies allow long lead-in time for labelling changes.

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 $^{^3}$ Based upon purchase of a SATO CX400 thermal label printer at £345 plus £66.90 (one-day labour at the rate of £8.92 for managers in retailing and wholesaling) to set the machine, software and templates up.

⁴ Based upon it taking 10 seconds to label each item, labour costs at £6.35 per hour for bakers and flour confectioners, label costs of 0.53 pence (based upon 25,000 51mmx76mm thermal transfer labels bought for £132.00), calculated for businesses processing 125,

Benefits The gain from improved information to facilitate better-informed consumer choice regarding goods they purchase from retail outlets is likely to be significant. Were the Agency to employ 'willingness to pay' or 'choice experiment' methodology, we predict that on the basis of there being between 4.7 and 37.5 million (based upon 150 outlets selling between 125 and 1000 items per day, 250 days per year) of these products being sold each year in the UK, these benefits may amount to significant amounts of money on an on-going annual basis. Unless labels are sourced from abroad, UK labelling companies will benefit from an increase in the sale of labels and potentially also labelling machines. Based upon the calculations in the costs section for this option, these would amount to between £24,750 and £198,000 in extra label orders per year on an on-going basis. There may also be increased possibilities brought about from labelling harmonisation, for sales to new outlets in the UK and for trade across Europe. Possible increase in sales through improvements in customer confidence and knowledge of what is, or isn't, contained in the product. **Small Firm Impact** There will be a quantifiable effect on small firms as stated in the body of the text above. **Test** Perhaps the biggest issue is the ability of small firms to absorb between approximately one and two hours extra labour per day into their working practices. This will most likely have to come through over time and/or increase in productivity. The only alternative would be to employ one new full or part-time member of staff. With simple un-branded labelling, including the producers' name and address, the Agency does not consider that removal of this provision would result in these products being perceived as having been mass-produced; therefore companies would keep a degree of niche product status. Competition In accordance with the small firms' impact assessment, a reduced ability to absorb any increase in **Assessment** costs may have a negative effect on the ability of smaller producers of these products being able to compete with medium or larger-sized producers in the short run. However, if this provision were no longer available for manufacturers to use in the UK and with greater harmonisation of EU labelling provisions, smaller producers may find they are more readily able to compete with larger firms (many of whom already fully label ingredients), and break into new markets should the opportunity arise. Sustainability **Economic Assessment** The potential economic impact of this provision no longer being available in the UK may be significant and would have a disproportionate impact on small businesses. Social There will be benefits from increased information to facilitate consumer choice. **Environmental** Increased packaging. Overall sustainability assessment The most sustainable option is Option 1, Do Nothing. Recommended Option: Do nothing Option Whilst this provision benefits SMEs, the products being considered are essentially prepacked and it is unlikely that we would be able to negotiate successfully in Brussels for it to

250, 500, 1000 or 1500 items per day, for 250 business days per year). Actual calculated estimates were £716.88, £1433.75, £2867.50, £5735 and £8602.50 respectively.

be adopted at EU-level.

4.9. Regulation 26(3) and 26(3)A — 'Minor accompaniment' provision

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Purpose	Under EU law, most pre-packed food has to comply with general food labelling requirements, except where the product has been pre-packed for direct sale. Regulations 26(3) and 26(3)A exempt food sold in individual portions or supplied as a minor accompaniment to another food or service (e.g. sachets of tomato sauce in a restaurant) from much of the general labelling requirements. However, the presence of irradiated and GM ingredients, as well caffeine and allergenic ingredients will have to be indicated where appropriate.
Sectors and groups affected	 British Retail Consortium Food & Drink Federation Institute of Grocery Distribution Dairy Industry Association Ltd British Hospitality Association
Stakeholder views so far received	Trade Associations reported that some products to which these provisions apply may be able to take advantage of the current exemption in EU law and the FLR for small packages. However, as this is currently only applicable to very small packages (10 square centimetres or less), it was suggested that we could lobby for size threshold to be increased.
Option 1: Do	Outcome
nothing	This provision would not feature in the new directly applicable EU legislation and the products referred to would therefore have to comply with full labelling requirements where the surface area is greater than 10 squared centimetres.
	Comments:
	Removal of this provision would require such products to have full labelling. Due to the limited size of packaging, this information would be hard to read and of little use to consumers.
Option 2: Negotiate	Outcome
for change in small packages provision (Article 13(4) of Directive 2000/13/EC).	If successful, this provision as drafted in UK legislation would not feature in the new directly applicable EU legislation. However, a new harmonised provision would be in place that would essentially allow the current trade practice to continue, but with the additional requirement to provide allergen information (because small packages do have to indicate allergens).
	Comments:
	Extension of the small packages cut-off size would allow the majority of condiments to which regulation 26(3) and 26(3)A refer, e.g. tomato sauce, vinegar, brown sauce, tartar sauce, mustard and fat spreads produced in sachets and mini tubs to take advantage of this provision.
Costs	Option 1 – Do nothing
	There will be significant costs to smaller manufacturers of these products, who are unable to incorporate changes into a regular re-labelling cycle.
	Option 2– Negotiate for increase in small packages size allowance (Article 13(4)), and require allergen labelling.
	There will be incremental costs similar to those for Option 2.
Benefits	Option 1 – Do nothing
	There will be a small welfare gain to consumers wishing to know what is in these products

	Option 2 - Negotiate for increase in small packages size allowance (Article 13(4)), and require allergen labelling. There will be a welfare gain to consumers with allergies better able to make informed decisions
	This option will save many more manufacturers the expense of re-labelling than if Option 1 was recommended un-amended.
Small Firms Impact Test	Small firms may be disproportionately affected. This is mainly due to the lower frequency with which these firms re-design their labelling and a reduced ability to absorb these costs into their accounts. This is likely to be a one-off cost. A longer transition period may help were this exemption to be lost.
	However, the Agency is not aware of the proportion of these products currently on the market that are manufactured by smaller producers: we believe it to be the case that most of these products are miniature versions of those products manufactured by large branded companies.
Competition Assessment	In accordance with the small firms' impact assessment, a reduced ability to absorb any increase in costs may have a negative effect on the ability of smaller producers of these products being able to compete with medium or larger-sized producers in the short run.
	However, were this exemption to be lost, in the long-run, with labelling harmonisation, smaller producers may find they are more readily able to compete with larger firms, and break into new markets should the opportunity arise.
Sustainability	Economic
Assessment	Economic impact of deletion could be significant, as it would affect a wide range of companies, particularly in the hospitality sectors.
	Social
	None identified.
	Environmental
	Potential increase in packaging.
	Overall sustainability assessment
	The most sustainable option is Option 3; to negotiate for an increase in the cut-off size for the small packages provision (Article 13(4) of Directive 2000/13/EC, with the provision of allergen information.
Recommended Option	Option 2: Negotiate for change in small packages provision (Article 13(4)).

5. Enforcement, Sanctions and Monitoring

5.1 If the FSA recommended options are applied for all the affected existing UK national provisions the implications for enforcement authorities are not expected to be significant. There will be marginal increases in the length of existing inspection visits to food businesses to assess compliance with new or amended requirements. There may also be a small increase in the numbers of samples taken for analysis to check compliance. Taken together these are likely to add only minimally to existing enforcement costs and unlikely to exceed £50,000 for the UK as a whole.

6. Racial Equality

6.1. Deletion of the proposals would not have any racial equality impacts.

7. Implementation and delivery plan

- 7.1. This section will be completed after consultation and included in the full RIA.
- 8. Post-implementation review
- 8.1. This section will be completed after consultation and included in the full RIA.
- 9. Overall Summary and recommendation
- 9.1. This section will be completed after consultation and included in the full RIA.

Summary costs and benefits table

Option	Total benefit per annum: economic, environmental, social	Total cost per annum: - economic, environmental, social - policy and administrative
1		
2		
3		
4		

Declaration and publication

I have read the regulatory impact assessment the costs.	nt and I am satisfied that the benefits justify
Signed	Date

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Parliamentary Minister for Public Health

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QUESTIONNAIRE ON NATIONAL PROVISIONS IN THE UK FOOD LABELLING REGULATIONS 1996 AS AMENDED

Section 1: Categories of interested parties

- Q1. Which of the following best describes you or your organisation?
 - Charity
 - Consumer
 - Consumer group
 - Manufacturer/retailer/importer/wholesaler/trade association
 - Size of business, eg: Small, Medium or Micro Business:
 - Enforcement
 - Professional body (e.g. health or research organisation)
 - Individual
 - Other (please specify)

Section 2: General

- Q2. What are your views on the recommended options in the RIA? For example:
 - Do you support or oppose the UK Government negotiating for the retention of the provisions in EU law? Why?
- Q3. Would consumers be particularly affected by the loss of these provisions? If so, how?
- Q4. Are there any businesses (e.g. rural, ethnic minority, particular types of small business) that you think would be particularly affected by the lapsing of these provisions?
- Q5. Would there be any implications for enforcement officers if these provisions were no longer available in the UK?

Q6. Are there any other general comments you would like to make?

Section 3: Questions on the potential impact of the loss of the provisions

- Q7. What products would be affected by the lapsing of the provisions?
- Q8. If these provisions were to be lost, do you believe there are any other provisions you could employ to the same effect?
- Q9. Approximately what percentage of total product costs does labelling and packaging constitute? Please split these if possible.
- Q10. If the provision(s) were to be removed, what additional labelling would you have to provide?
- Q11. If you had to re-label, how much would this cost per product on average?
- Q12. Would products have to be repackaged? Y/N.
- Q13. What volume of products would be affected?
- Q14. What is the total value of these products?
- Q15. How many outlets would be affected?
- Q16. Who would absorb the costs (consumer or producer, and if split between the two, in what ratio)?
- Q17. Would the lapsing of the provisions have any other effects not mentioned above?
- Q.18. Could these changes be feasibly absorbed in your normal labelling cycle? If yes, how frequently do you redesign labels and how much transition time would you need to make these changes to fit into your normal labelling cycle?
- Q19. Are there any other costs that you would incur, over and above what you would do commercially, as a result of the removal of these provisions?

Section 4: Questions on the potential impact of the loss of particular provisions

'Provident Societies' provision (Regulation 4(3)b of the FLR

This regulation provides general labelling exemption for foods prepares on domestic premises and sold by a society registered under the Industrial Provident Societies Act 1965.

- Q20. How often/to what extent do such societies take advantage of this regulation?
- Q.21. What food products are sold by these societies?
- Q22. How much funds are raised through the sale of such foods?
- Q23. If this provision was to be no longer available, and products had to comply with full labeling requirements, would it become more difficult for members of the society/organisation, to carry out their business?
- Q.24. Please provide some indication and detail of additional costs of having to comply with labeling requirements?

'Charities' provision (Regulation 4(3)c of the FLR)

This regulation provides general labelling exemption for food prepared otherwise than in the course of business carried out by the person preparing it, for example fundraising/charity events/Church/school fetes.

- Q25. How often do these charity events take place?
- Q26. If this provision was lost, and products had to comply with full labeling requirements, would it become more difficult for such charity events to take place? Would those who donate food for such events for example be 'put-off'?
- Q27. Please provide some indication and detail of additional costs of having to comply with labeling requirements if possible.

Fortified Flour (Regulation 18(1)e of the FLR)

This regulation provides labelling exemption for nutrients added to wheat flour under the Bread and Flour 1998 Regulations, namely calcium, thiamine, niacin and iron.

- Q28. What are the trade issues involved, for example with respect to intra-Community trade?
- Q29. Would the increased labelling information result in a change in consumer purchasing pattern, for example, fortified and labelled UK flour/flour products versus unfortified imported flour/ flour products?
- Q30. Would the sector be affected by consumer perception that flour now has added ingredients?
- Q31. Would the market for wholemeal be affected (given that labelling requirements there would remain unchanged)?
- Q32. Where flour is present in only small amounts in a food, the introduction of a threshold level below which labelling would not be required, might help. What might a practical threshold level be?

Flour confectionery (Regulation 23(1)b of the FLR

This regulation provides exemption from most of the general labelling requirements for flour confectionery products packed in crimp case or wholly transparent packaging that have only the name, lot marking and price. Whilst some of these products can take advantage of exemption in the FLR for foods sold loose and pre-packed for direct sale, others are effectively pre-packed and are there unable to take advantage of such exemptions.

Q33. These food products are essentially pre-packed and would under the recent EU allergen legislation, require allergen information. We would like to have your views on whether you consider there is still need to try and continue to maintain this exemption.