

**EXPLANATORY MEMORANDUM TO
THE FOOD LABELLING (DECLARATION OF ALLERGENS) (ENGLAND)
REGULATIONS 2008**

2008 No.1188

1. This explanatory memorandum has been prepared by the Food Standards Agency and is laid before Parliament by Command of Her Majesty.

2. Description

2.1 These Regulations amend the Food Labelling Regulations to permanently exempt certain food ingredients from labelling as, due to processing, they no longer contain the allergenic component.

3. Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None.

4. Legislative Background

4.1 This instrument implements Commission Directive 2007/68/EC, of 27 November 2007, amending Annex IIIa to Directive 2000/13/EC of the European Parliament and of the Council as regards certain food ingredients by replacing the list of allergens in Schedule AA1 of the Food Labelling Regulations 1996 (as amended) with a revised list which includes those ingredients which are permanently exempt from allergen labelling. This Schedule also lists those allergens and products thereof that must be indicated in the labelling of food.

5. Territorial Extent and Application

5.1 This instrument applies to England.

5.2 Separate, but parallel, instruments apply to Wales, Scotland and Northern Ireland.

6. European Convention on Human Rights

6.1 As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required

7. Policy background

7.1 The Food Labelling Regulations 1996 (as amended) aim to ensure that consumers are properly informed about the nature and substance of the foods they buy and are protected from false or misleading descriptions. In 2004 these Regulations were amended to include a list of 12 allergens that have to be indicated on the label whenever they or their derivatives are used as deliberate ingredients in pre-packed food, including alcoholic drinks. Last year this list was amended to add two more allergens, molluscs and lupins.

7.2 In 2005 the Regulations were amended to implement EC legislation granting a provisional exemption from allergen labelling to certain specified ingredients which, due to processing, no longer contain the allergenic component. The Commission has now taken advice from the European Food Safety Authority and have issued Commission Directive 2007/68/EC. This Directive consolidates into one list the allergenic food ingredients that must be labelled, and certain products of these food ingredients that are now permanently excluded from the requirement for labelling as, due to processing, they no longer contain the allergenic component.

8. Impact

8.1 An Impact Assessment (IA) has been prepared for this Statutory Instrument and is attached to this memorandum at Annex 1.

8.2 The Local Authorities Coordinators of Regulatory Services (LACORS) were consulted during the preparation of the IA and they agreed that the reading and understanding the new legislation by local authorities would be in the region of £9,000.

9. Contact

9.1 Dionne Davey at the Food Standards Agency (Tel: 020 7276 8531 or E-mail: dionne.davey@foodstandards.gsi.gov.uk) can answer any queries regarding the instrument.

Summary: Intervention & Options

Department /Agency: Food Standards Agency	Title: Impact Assessment of The Food Labelling (Declaration of Allergens) (England) Regulations 2008	
Stage: Final	Version: 2.3	Date: 16 April 2008
Related Publications:		

Available to view or download at:

<http://www.food.gov.uk/foodindustry/regulation/ria/>

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

The European Union establishes legislation to ensure that foods that contain allergenic ingredients are correctly labelled. However, it recognises that some ingredients lose their allergenic properties when they are processed. In order to address this and prevent unnecessary labelling requirements Directive 2007/68/EC sets out a list of permanent exemptions for certain ingredients derived from a specified list of allergenic ingredients that have been processed and are therefore no longer allergenic. The Food Labelling (Declaration of Allergens) (England) Regulations 2008 will bring the permanent exemptions in Directive 2007/68/EC into force in UK law.

What are the policy objectives and the intended effects?

The objective of the policy is to ensure that consumers have clear information about allergens in food so that they can make fully informed choices.

In addition, implementation of this legislation on processed ingredients derived from allergenic sources will lead to greater choice by ensuring that the consumer will not be restricted in their choice by the unnecessary labelling of products derived from allergenic substances that have been processed and are no longer allergenic.

What policy options have been considered? Please justify any preferred option.

1. Do nothing.
2. Amend the Food Labelling Regulations 1996 (as amended) in line with the new EC changes.
3. To revoke the Food Labelling Regulations 1996 (as amended) and introduce new legislation consolidating the existing food labelling rules and this new EC change, within a single SI.

Option 2 is our preferred option, for the reasons set out in Section 3.

When will the policy be reviewed to establish the actual costs and benefits and the achievement of the desired effects? May 2011.

Ministerial/CEO Sign-off For final proposal/implementation stage Impact Assessments:

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) the benefits justify the costs.

Signed by the responsible Minister/Chief Executive*:

Dawn Primarolo**Date: 24th April 2008**

* for Impact Assessments undertaken by non-ministerial departments/agencies and NOT being considered by Parliament

Summary: Analysis & Evidence

Policy Option: 2	Description: Implementing in to UK the European Commission Directive (2007/68) to establish a list of ingredients exempt from allergen labelling.
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COSTS	ANNUAL COSTS		Description and scale of key monetised costs by 'main affected groups' Reading and understanding the new legislation as required by industry (£403,000) and local authorities (£9,000).
	One-off (Transition)	Yrs	
	£ 82,500	5	
	Average Annual Cost (excluding one-off)		
£ 0		Total Cost (PV)	£ 385,500
Other key non-monetised costs by 'main affected groups'			

BENEFITS	ANNUAL BENEFITS		Description and scale of key monetised benefits by 'main affected groups'
	One-off	Yrs	
	£ 0	5	
	Average Annual Benefit (excluding one-off)		
£ 0		Total Benefit (PV)	£ 0
Other key non-monetised benefits by 'main affected groups' Consumers will benefit from new rules, as more comprehensive labelling will increase information and choice as well as further protecting consumer health.			

Key Assumptions/Sensitivities/Risks

Price Base Year 2007	Time Period Years 5	Net Benefit Range (NPV) £ -385,500	NET BENEFIT (NPV Best estimate) £ -385,500
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What is the geographic coverage of the policy/option?	England			
On what date will the policy be implemented?	31/05/2008			
Which organisation(s) will enforce the policy?	local authorities			
What is the total annual cost of enforcement for these organisations?	£ Zero			
Does enforcement comply with Hampton principles?	Yes			
Will implementation go beyond minimum EU requirements?	No			
What is the value of the proposed offsetting measure per year?	£ n/a			
What is the value of changes in greenhouse gas emissions?	£ Zero			
Will the proposal have a significant impact on competition?	No			
Annual cost (£-£) per organisation (excluding one-off)	Micro zero	Small zero	Medium zero	Large zero
Are any of these organisations exempt?	No	No	N/A	N/A

Impact on Admin Burdens Baseline (2005 Prices)		(Increase - Decrease)	
Increase of £ zero	Decrease of £ zero	Net Impact	£ zero

Key: Annual costs and benefits: Constant Prices (Net) Present Value

Evidence Base (for summary sheets)

1. PURPOSE AND INTENDED EFFECT OF MEASURE

The proposed legislation will further amend the Food Labelling Regulations 1996 (FLR), by implementing into UK law Commission Directive 2007/68/EC which amends Directive 2000/13/EC of the European Parliament and Council of 20 March 2000, on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs.

The key objective of the proposed Regulations would be to ensure that consumers are properly informed about the presence of allergens in the pre-packed foods they buy, by amending the FLR to introduce a new Schedule AA1.

Separate but parallel legislation will be made in respect of Scotland, Wales and Northern Ireland.

2. BACKGROUND

Food labelling in Great Britain is principally governed by the Food Labelling Regulations 1996 (as amended) and certain provisions of the Food Safety Act 1990. The rules aim to:

- ensure that consumers are properly informed about the nature and substance of the foods they buy;
- protect consumers from false or misleading descriptions; and
- give the food industry a clear regulatory framework to work from, which does not restrict product innovation or inhibit the free movement of goods within the EU.

The requirement to label certain specified allergenic ingredients when they are used in pre-packed food was introduced in 2004 through the Food Labelling (Amendment) (England) (No.2) Regulations 2004. In addition, the Food Labelling (Amendment) (England) (No 2) Regulations 2005 provided temporary exemptions for a number of products derived from the specified allergenic ingredients identified in the Food Labelling (Amendment) (England) (No.2) Regulations 2004 for the period from November 2005 until November 2007. On 28 November 2007, in light of the opinions from the European Food Safety Authority (EFSA) on dossiers submitted by industry, the European Commission published Directive 2007/68/ EC identifying those derived ingredients that should be permanently exempt from the allergen labelling provisions.

This EU legislation is in line with the Agency's commitment to ensure that consumers are properly informed and can make informed choices through accurate labelling of pre-packed foods. By implementing the exemption list into UK law, consumer choice will not be restricted by the unnecessary labelling of products derived from allergenic substances that have been processed and are no longer allergenic. Some allergenic ingredients that have been covered by the temporary exemption have not been granted permanent exemptions and will now require allergen labelling. The new Regulations will clarify which foods are, and which foods are not, allergenic and increase the pre-packed foods available to allergic consumers and prevent unnecessary allergen labelling requirements for those foods.

3. OPTIONS

There are three options for the implementation of the provisions of Commission Directive 2007/68/EC. These are:

Option 1: Do nothing

Option 2: Implement EC requirements by further amending the Food Labelling Regulations 1996

Option 3: To revoke the Food Labelling Regulations 1996 (as amended) and introduce new legislation consolidating the existing food labelling rules and the new European requirements, within a single set of Regulations .

Option 1: Do nothing

This would not fulfil the Agency's commitment to provide the consumer with comprehensive labelling information in order to allow them to make fully informed choices and would lead to unnecessary

labelling of ingredients that are no longer allergenic. This option would also risk infraction proceedings from the European Commission. Option 1 is therefore not a practical option.

Option 2: Implement EC requirements

Implementing the Commission Directive would fulfil the UK's obligation under the EC Treaty, ensure consistency of labelling rules across the EU, facilitate informed consumer choice and allow UK manufacturers to operate freely and competitively within the single market. It would also maintain the exemption from allergen labelling requirements for products that contain many of the ingredients that were on the temporary exemption list (i.e. ingredients that, due to processing, are no longer allergenic), although a number of temporarily exempt derived products did not gain permanent exemption.

Option 3: To revoke the Food Labelling Regulations 1996 (as amended) and introduce new legislation consolidating the existing food labelling rules and the new European Requirements, within a single set of Regulations.

The area of food information and labelling is currently the subject of a fundamental review by the European Commission. It is expected that the outcome of the review will produce a single consolidated piece of legislation in the form of a directly applicable EC Regulation on food labelling. Therefore, it would be pragmatic to wait for the outcome of the European review before undertaking any exercise to consolidate all UK food labelling legislation.

In the light of the analysis above, the preferred option of the Agency is therefore Option 2.

4. CONSULTATION

Before the Directive was published the Food Standards Agency alerted businesses to the proposal and contacted both consumer and business stakeholders to obtain their opinions on the proposal. This ensured that the Agency negotiated with the Commission in the areas that would have the biggest impact on UK consumer groups and businesses.

The responses received from stakeholders fell broadly into two categories:

- The wine producing industry was concerned that no fining agent would receive permanent exemption. This would mean that a bottle of wine would have to declare the allergenic food source of the fining agent used in this process i.e. egg, milk or fish. However, the Food Standards Agency worked with the Commission and the wine industry and obtained a permanent exemption for using isinglass as a fining agent in wine making, as well as beer production. This approach was supported by evidence that none or very little of the fining agent is present in the final product and therefore highly unlikely to produce an allergic reaction in a sensitive individual. In addition, there is no documented evidence that isinglass has ever caused an allergic reaction.
- Industry was concerned that they would only receive six months to implement any label changes. An additional six months was negotiated, so that label changes would now have to be in place by 31 May 2009.

In addition, the Agency conducted a public consultation to allow all those interested in food and allergen labelling to comment on the draft domestic implementing legislation.

The new measures do not impact directly on the work of other government departments; however, they have been informed of the new Regulations and given the chance to be involved in their development. The Local Authorities Coordinators of Regulatory Services (LACORS) have been consulted on the enforcement of the Regulation and they indicated that they were content and supported option 2.

5. COSTS AND BENEFITS:

Business sectors affected

The businesses affected would be all food manufacturers engaged in the production of pre-packed foods.

Option 1

Costs

Under this option all manufacturers of pre-packed foods currently taking advantage of the temporary labelling exemptions would have to immediately start labelling ingredients derived from allergenic food, even if these ingredients have been designated as exempt, as the previously available temporary exemptions expired in November 2007, resulting in costs of designing and printing new labels.

There are unlikely to be any costs passed on to the NHS as a result of doing nothing. In this instance there would be inaccurate information available to consumers due to unnecessary labelling but there should not be an increase in hospital admissions or fatalities. However, the cost to the allergic consumer under this option would be in terms of a reduction in the foods available to them for consumption, as ingredients that are in practice no longer allergenic, would still be labelled with reference to the source allergenic food.

In the absence of implementation, many products, which currently contain ingredients that are given exemption by the new Directive, would have to be labelled in future - even though that ingredient no longer has the potential to cause an allergic reaction. It is therefore entirely possible that allergic consumers will assume that, if they eat these foods that are labelled as containing an allergenic ingredient and do not react, they have overcome their allergy. They may then start to eat other foods which contain the allergen and could suffer severe adverse reactions.

There would also be costs to UK Government if infraction proceedings were taken by the European Commission because of non-implementation.

Benefits

There are no benefits of not implementing this legislation.

Option 2

Under this option, most of the ingredients previously given temporary exemptions from labelling would be confirmed as permanently exempt.

There are a few cases where permanent exemptions from labelling were not given but transitional periods will be in place. These were:

- almonds/walnuts to flavour spirits
- celery leaf and seed oil
- celery seed oleoresin
- egg albumin fining agent for wine and cider
- fish gelatine as a carrier for flavours
- isinglass fining agent for cider
- lysozym (produced from egg) used in wine
- milk (casein) fining agent for wine and cider
- mustard oil
- mustard seed oil
- mustard seed oleoresin

Costs

For ingredients that were temporarily exempt and which have gained permanent exemption, no label changes are needed. For temporarily exempt ingredients that did not gain permanent exemption, labels and/or ingredient lists will have to be amended to indicate the specified allergens, or product formulations changed to remove or replace them with non-allergenic materials. This is not considered to have a significant impact on UK businesses as a result of the extended transition period that was negotiated.

As there is a transition period until 31 May 2009, it is anticipated that changes to the labels of pre-packed foods can be made within manufacturers' existing labelling cycles. Any costs arising should therefore be minimal. The British Retail Consortium has estimated the costs of re-labelling at approximately £1000 per product. However, the twelve months transitional period will cushion this effect by negating any extra costs that might be incurred as a result of having to print new labels out of the commercial cycle or remove products from sale whilst the labels are changed, and so the overall costs of any new labelling required is likely to be insignificant.

Businesses will need to allow time to read and understand the Regulations. However, due to the simplicity of the Regulations this should not be onerous. For most businesses we estimate that this would take approximately 30 minutes to read this at a rate of £11.19 (2006 Annual Survey of Hours and Earnings (ASHE) analysis by industry) based on 2 people to read the new legislation. There are approximately 18,000 UK manufacturers who may need to understand these Regulations, thus yielding a gross one-off administrative cost of £403,000.

There are 469 local authorities in the UK and, based on allowing 2 people ½ hour to read the new legislation at a rate of £9.95, it would cost £9333. Source – 2006 Annual Survey of Hours and Earnings analysis by Government Office by occupation.

The Agency considers that many firms will have an existing understanding of the composition of their ingredient inputs and therefore normal commercial sourcing practices are likely to inform producers of the likely allergenic make up of their product inputs. Even if clarification of the potential allergenic nature of upstream supplies is required this is not expected to involve significant cost.

Benefits

Implementing the Directive would fulfil the UK's obligation under the EC Treaty ensuring consistent labelling of pre-packed foods across the EU. Consumers will benefit from the new rules, as more comprehensive labelling will increase information and choice, and potentially further protect health. There is a significant advantage for the allergic consumer if the ingredients that do not pose an allergic risk continue to be exempt from the allergen labelling legislation. In addition, implementing the Directive will improve consumer choice as the ingredients that should be exempt would not have to be labelled.

It is further the case that by not implementing this Directive many more pre-packed foods will be subject to the allergen labelling legislation than would be by implementing it. It is therefore to the food industry's advantage that this Directive be implemented.

Option 3

Costs

Under this option, the costs given in option 2 would apply. However, option three would require a significant review and consolidation of the FLR which would delay the implementation of this Directive and would result in additional costs for Government. In addition, it would not be sensible to undertake such a review at a time when a Commission proposal for updating and consolidating EC general labelling rules is expected in the near future.

Benefits

Under this option, the benefits in option 2 would apply.

ENFORCEMENT, SANCTIONS AND REVIEW

Port Health Authorities (in relation to imported food) and Local Authority Trading Standards and Environmental Health Departments will be responsible for the enforcement of the new provisions. This remains unchanged from the existing enforcement arrangements.

REVIEW

The effectiveness of the Regulations will be monitored continuously through feedback from stakeholders. Agency mechanisms for monitoring and review include: open fora, stakeholder meetings, surveys and general enquiries from the public. The FSA will conduct a full review of the effectiveness of the Regulations by 2011.

GUIDANCE

Guidance on the application of the new requirements have been drawn up in full consultation with stakeholders and their impact will be kept under regular review.

ADMINISTRATIVE BURDENS

There are no requirements in the proposed legislation which require additional records to be kept and the transitional arrangement for label changes should prevent any additional cost being incurred by business. Therefore, no additional administrative burdens are envisaged.

Specific Impact Tests: Checklist

Ensure that the results of any tests that impact on the cost-benefit analysis are contained within the main evidence base; other results may be annexed.

Type of testing undertaken	<i>Results in Evidence Base?</i>	<i>Results annexed?</i>
Competition Assessment	No	Yes
Small Firms Impact Test	No	Yes
Legal Aid	No	No
Sustainable Development	No	Yes
Carbon Assessment	No	No
Other Environment	No	Yes
Health Impact Assessment	No	No
Race Equality	No	Yes
Disability Equality	No	Yes
Gender Equality	No	Yes
Human Rights	No	No
Rural Proofing	No	Yes

Directive 2000/13/EC (as amended) of the European Parliament and the Council of 20 March 2000, on the approximation of the laws of Member States relating to the labelling, presentation and advertising of foodstuffs, requires labelling of a specified list of allergenic ingredients as set out in Annex IIIa of that Directive.

Commission Directive 2005/26/EC, as corrected by Commission Directive 2005/63/EC, established a list of food ingredients or substances provisionally excluded from Annex IIIa mentioned above.

A number of applications for permanent exemption from the labelling requirement were submitted to the European Food Safety Authority (EFSA). On the basis of EFSA opinions and other available information, it was concluded that certain ingredients are not likely to cause adverse reactions in susceptible individuals and as such those ingredients should therefore be permanently exempted from Annex IIIa.

This resulted in Commission Directive 2007/68/EC of 27 November 2007, which amends Annex IIIa and sets out certain food ingredients or substances derived from these specified allergenic ingredients that can no longer cause adverse reactions in susceptible individuals.

Competition Assessment

The results from the Competition Assessment Guidelines indicate that the proposed Regulations will have little impact on the competitive structure or process within the pre-packed food markets. The potential costs are those relating to the updating of labels to reflect the new requirements of those ingredients that were not permanently exempt from labelling requirements in pre-packed foods. In almost all cases it is likely that these changes will be absorbed into the normal labelling changing cycle. All manufacturers would be affected and therefore there appears to be little significant threat to competition.

Small Firms Impact Test

An initial assessment of the impact to small businesses shows a potential impact via the need to determine whether or not allergenic ingredients are used in part-prepared foods or ingredients that are bought in and any re-labelling cost. Businesses of all sizes which handle these ingredients may incur some additional costs from setting in place these information checks and for re-labelling products to reflect the new requirements. Any such costs will be in relation to their size, turnover and number of product ranges, but as noted are not expected to be significant in nature.

Evidence from the Taskforce Report on the burdens of food regulations on Small Businesses suggests that some small food businesses have difficulties in keeping up to date with changes in legislation and getting advice on legal requirements. Failure to do so can prove expensive and the cumulative effect is often significantly burdensome. To help businesses understand the changes to the legislation the Agency has produced comprehensive guidance on allergen labelling requirements.

In addition, the Agency negotiated for a twelve month period to implement any label changes, which should help small businesses to reduce the cost by working these changes into their normal label review process.

Sustainable development

There may be a small impact on sustainability as small numbers of labels which remain unused by 31 May 2009 will have to be discarded at the end of this period. There will be a positive benefit for allergic consumers in clearly defined roles for processed allergenic ingredients.

Rural Impact

There are no impacts on rural issues

Race equality issues

The Food Standards Agency does not consider the proposed legislation will have any impact on race equality as there is no evidence to suggest that any one racial group will be affected any differently from any other.

Gender equality issues

The proposed legislation is not considered to have any impact that may vary according to a person's gender.

Disability equality issues

The proposed legislation is not considered to have any negative impact on persons with a disability.