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## PARTIAL REGULATORY IMPACT ASSESSMENT

### 1. Title of the proposal

The Food Labelling (Amendment) (England) (No. 2) Regulations 2005

### 2. Purpose and intended effect

#### (i) Objectives

- 2.1. The Regulations implement, in England, Commission Directive 2005/26/EC establishing a list of food ingredients or substances provisionally excluded from Annex IIIa of Directive 2000/13/EC of the European Parliament and of the Council.
- 2.2. The Regulations establish a list of ingredients derived from known allergens that are provisionally exempt from allergen labelling rules, because they are no longer allergenic.
- 2.3. The Regulations aim to ensure that consumers are properly informed about the allergens in the foods they buy and are protected from false or misleading descriptions in relation to allergens. The rules will also avoid over-labelling, preventing unnecessarily restricting consumer choice, and unnecessary labelling costs for industry.
- 2.4. Separate, but parallel legislation, will be made in respect of Scotland, Wales and Northern Ireland.

#### (ii) Background

##### *Introduction*

- 2.5. The Food Labelling Regulations 1996 (as amended) and certain provisions of the Food Safety Act 1990 and Trade Descriptions Act 1968, govern food labelling in Great Britain. These implement Directive 2000/13/EC on the labelling, presentation and advertising of foodstuffs. Separate, but parallel legislation exists in Northern Ireland where appropriate.
- 2.6. Consumers have indicated that they wish to be better informed about the foodstuffs they purchase, and specifically about their composition, even if full ingredient labelling will inevitably mean that more information is required on the

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label<sup>1</sup>. This information is particularly important for those with a food allergy or intolerance, so that they can identify the foods that they need to avoid.

- 2.7. Allergen labelling rules that came into force on 26 November 2004 (The Food Labelling (Amendment) (England) (No.2) Regulations 2004, implementing Directive 2003/89/EC of the European Parliament and of the Council), aimed to address this issue. They removed the “25% rule”<sup>2</sup> and thereby provided for more comprehensive labelling information. They also introduced a specified list of allergens, which have to be indicated on the labelling, whenever they are used in foods, including alcoholic drinks. Manufacturers have a transition period of 12 months, after which products that do not comply with the new rules will be prohibited.
- 2.8. The specified allergens are listed at **Table A**. This list was drawn up by the European Commission, based on scientific advice on the most common food allergies in the EU, although allergies to some of these foods, such as celery and mustard, are geographically restricted.
- 2.9. When negotiations on Directive 2003/89/EC were being finalised, it was recognised that some processed ingredients derived from the specified allergens would be unlikely to trigger allergic reactions (non-allergenic derived ingredients). Provision was therefore made in that Directive for such ingredients to be exempt in future from allergen labelling requirements based on supporting scientific evidence (dossiers submitted to the European Food Safety Authority (EFSA)).
- 2.10. Following evaluation of the scientific evidence by EFSA, the Commission originally planned to draw up a provisional list of these ingredients by November 2004. However, subsequent delays meant this list (Annex to Directive 2005/26/EC) was not published in the Official Journal of the European Union until 22 March 2005. The list can be found in **Table B** of this document. The exemptions apply to the ingredients listed, manufactured according to the methods and uses described in the dossiers. Member States are required to implement Directive 2005/26/EC by 21 September 2005.
- 2.11. The Commission is due to finalise the list by 25 November 2007 following advice from EFSA.

**(iii) Rationale for government intervention**

- 2.12. Directive 2005/26/EC, and therefore the Food Labelling (Amendment) (England) (No.2) Regulations 2005, address the following risks:
  - (i) Unnecessary restriction of consumer choice.
  - (ii) Potential to create a false sense of security for allergic consumers.
  - (iii) Unnecessary labelling for industry.

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<sup>1</sup> Consumer attitudes to food labelling (Ipsos-RSL) (2000); Better Food Labelling Initiative – written responses (2000)

<sup>2</sup> Under the “25% rule” individual ingredients making up a compound ingredient do not have to be listed if the compound ingredient makes up less than 25% of the finished product.

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A description of each risk follows:

**Unnecessary restriction of consumer choice**

- 2.13. Under The Food Labelling (Amendment) (England) (No.2) Regulations 2004, manufacturers will have to indicate the presence of the specified allergens or their derivatives in pre-packed foods, including alcoholic drinks. This indication will have to make a clear reference to the source allergen, unless this is already clear from the sale name of the food, for example, milkshake. In the case where a derived ingredient is no longer allergenic, flagging it up as an allergen would not improve consumer safety, but it would restrict consumer choice. It is therefore important to avoid this from a consumer point of view. The aim of Directive 2005/26/EC is to ensure that consumers are provided with accurate food safety information, whilst avoiding unnecessary restriction of choice.

**Potential to create a false sense of security for allergic consumers**

- 2.14. Labelling products as allergenic when they are no longer allergenic may devalue the strength of allergen labelling in protecting consumers. Allergic consumers may know from past experiences or their own research that products containing certain ingredients derived from allergenic ingredients are safe to eat. Labelling these products as containing allergens will confuse these consumers and reduce their trust in the protection given through allergen labelling. They may also be tempted to consume other products that contain allergens under the misperception that these are also safe for them to consume.

**Unnecessary labelling for industry**

- 2.15. Where there is no longer any health risk (i.e. where ingredients are no longer allergenic) it would be sensible for industry not to have to label the non-allergenic derived ingredients listed as exemptions.

**3. Consultation**

- 3.1. The Agency consulted a wide range of stakeholders including other Government Departments, during the development of Directive 2003/89/EC. Consultation exercises in 2001 and 2002 recognised that not all derived ingredients need to be specified as allergens.
- 3.2. There were concerns that the rules would require labelling of ingredients that were no longer allergenic. Stakeholders, including allergy support groups, manufacturers and retailers all supported the principle of exempting from labelling ingredients that are no longer allergenic. Allergy support groups in particular supported the amendment as this would avoid potential confusion caused by over-labelling, a reduction in consumer confidence and further restrictions in choice of food for allergic consumers. Manufacturers and

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retailers also supported the amendment, as it would avoid over-labelling and unnecessary relabelling costs.

- 3.3. In addition, over 1000 interested parties were consulted during the implementation of the Food Labelling (Amendment) (England) (No.2) Regulations 2004 from 21 June to September 2004 (a summary of responses is available at: <http://www.food.gov.uk/multimedia/pdfs/allergenresponsesengland.pdf>)

**4. Options**

- 4.1 There are two options for transposing the provisions of Directive 2005/26/EC.

- 4.2 These are:

**Option 1:** do nothing

**Option 2:** implement requirements of Directive 2005/26/EC

**Option 1:**

- 4.3 This would not fulfil the Agency's commitment to ensure that consumers are properly informed through accurate labelling to enable them to make a fully informed choice. Flagging up ingredients as allergenic when they are no longer allergenic would further restrict consumer choice.
- 4.4 Labelling products as allergenic when they are no longer allergenic may devalue the strength of allergen labelling in protecting consumers. Allergic consumers may know from past experiences or their own research that products containing certain ingredients derived from allergenic ingredients are safe to eat. Labelling these products as containing allergens will confuse these consumers and reduce their trust in the protection given through allergen labelling. They may also be tempted to consume other products that contain allergens under the misconception that these are also safe for them to consume.
- 4.5 Labelling as allergenic ingredients that are no longer allergenic will burden manufacturers with unnecessary labelling costs.
- 4.6 This option would risk infraction proceedings from the Commission against the UK under Article 226 of the EC Treaty; other Member States could also initiate proceedings under Article 227. Option 1 is therefore not a practical option.

**Option 2:**

- 4.7 Implementing Directive 2005/26/EC would fulfil the Agency's commitment to ensure that consumers are properly informed through accurate labelling to enable them to make a fully informed choice. There may also be some associated benefits for businesses as a result of increased consumer confidence in products carrying more informative labels.

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- 4.8 This option would avoid unnecessary relabelling costs for industry. From 25 November 2005, manufacturers will not need to indicate the presence of derived non-allergenic ingredients set out in Directive 2005/26/EC.
- 4.9 This option would fulfil the UK's obligation under the EC Treaty, ensure consistent labelling rules across the EU, facilitate informed consumer choice, and allow UK manufacturers to operate freely and competitively within the single market.

**5. Costs and Benefits****(i) Sectors and groups affected**

- 5.1 The food industry is diverse. This provision will benefit a wide range of food retail and manufacturing businesses who will not have to label unnecessarily.

**(ii) Benefits****Option 1 – Do nothing**

- 5.2 Under this option, the current rules would continue unchanged: from 25 November 2005, manufacturers will have to indicate the presence of the specified allergens even if a derived ingredient is no longer allergenic. There are no benefits, financial or otherwise, in following this option.

**Option 2 - Implement requirements of Directive 2005/26/EC**

- 5.3 This option would fulfil the Agency's commitment to ensure that consumers are properly informed through accurate labelling to make a fully informed choice. Where a derived ingredient (as specified in Table 2 of this document) is no longer allergenic, allergen labelling would not be required, and therefore would not restrict consumer choice.
- 5.4 There may also be some associated benefits for businesses as a result of increased consumer confidence in products carrying more informative labels and would avoid unnecessary relabelling costs.
- 5.5 Under this option the UK would not invoke infraction proceedings from the Commission or other Member States.

**(iii) Costs****Option 1 – Do nothing**

- 5.6 Under this option, from 25 November 2005 manufacturers will have to indicate the presence of the specified allergens even if a derived ingredient is no longer allergenic. This will mean many products will have to be relabelled, when there is no need. The cost of relabelling is estimated to be in the region of £1,000 per product.

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- 5.7 It is not known exactly how many products, which contain derived non-allergenic ingredients will be affected by the new allergen rules. This will potentially lead to significant relabelling costs.

**Option 2 - implement requirements of Directive 2005/26/EC**

- 5.8 The proposed new regulations establish a list of ingredients provisionally exempt from the allergen labelling rules. As a result industry will not have to extend allergen labelling to products containing derived non-allergenic ingredients. This will therefore not impose any additional costs on industry.

**6. Small Firms Impact Test**

- 6.1 The Food Standards Agency have been unable to identify any negative impacts on small firms as a result of the proposal, we believe that the proposals could be beneficial to small firms. The views of small firms and their representatives have been actively sought during the consultation process. The Agency has consulted the Small Business Service who are happy with this approach.

**7. Competition Assessment**

- 7.1 The results from the competition filter indicate that the proposed Directive will have no significant impact on the competitive structure within the pre-packed food sector. Additional labelling costs are avoided by granting exemptions from allergen labelling requirements, to products containing specific non-allergenic ingredients derived from allergenic foods. Furthermore, there are no effects on entry barriers to this sector.

**8. Racial Equality**

- 8.1 The Food Standards Agency does not consider that implementing these Regulations will have any impact on racial equality issues.

**9. Enforcement, sanctions and monitoring**

- 9.1 Port Health Authorities (in relation to imported foods) and Local Authority Trading Standards and Environment Health Departments will be responsible for enforcement of the new provisions. Enforcement authorities' representatives have been consulted and have indicated there to be no additional costs.

**[Sections 11-14 will be completed after the consultation, as per Cabinet Office guidelines]**

**10. Implementation and delivery plan****11. Post-implementation review****12. Summary and recommendations**

- 12.1 The proposals here provide for a new regulation establishing a list of ingredients provisionally exempt from allergen labelling rules. As a result this

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ensures that consumers are provided with accurate food safety information, whilst avoiding unnecessary restriction of choice and industry will not have to extend allergen labelling to products containing derived non-allergenic ingredients.

12.2 The Food Standards Agency therefore recommends the adoption of **Option 2**.

**Summary costs and benefits table**

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

**13. Declaration and publication**

**I have read the regulatory impact assessment and I am satisfied that the benefits justify the costs**

**Signed .....**

**Date**

**Minister's name, title, department**

**Contact point**

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**LIST OF ALLERGENIC INGREDIENTS AS SPECIFIED UNDER  
DIRECTIVE 2003/89/EC**

- cereals containing gluten (ie wheat, rye, barley, oats, spelt, kamut or their hybridised strains)
- crustaceans
- eggs
- fish
- peanuts
- soybeans
- milk
- the following nuts: Almond, Hazelnut, Walnut, Cashew, Pecan nut, Brazil nut, Pistachio nut, Macadamia nut and Queensland nut
- celery
- mustard
- sesame seeds
- sulphur dioxide and sulphites at concentrations of more than 10 mg/kg or 10 mg/litre expressed as SO<sub>2</sub>.

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Table B

LIST OF NON-ALLERGENIC DERIVED INGREDIENTS AS SPECIFIED  
UNDER DIRECTIVE 2005/26/EC

<i>Column 1</i> <i>Allergenic ingredient</i>	<i>Column 2</i> <i>Exempt ingredients originating from allergenic ingredient</i>
Cereals containing gluten	Wheat based glucose syrups including dextrose <sup>1</sup> . Wheat based maltodextrins <sup>1</sup> . Glucose syrups based on barley. Cereals used in distillates for spirits.
Eggs	Lysozym (produced from egg) used in wine. Albumin (produced from egg) used as fining agent in wine and cider.
Fish	Fish gelatine used as carrier for vitamins and flavours. Fish gelatine or Isinglass used as fining agent in beer, cider and wine.
Soybean	Fully refined soybean oil and fat <sup>1</sup> . Natural mixed tocopherols (E306), natural D-alpha tocopherol, natural D-alpha tocopherol acetate, natural D-alpha tocopherol succinate from soybean sources. Vegetable oils derived phytosterols and phytosterol esters from soybean sources. Plant stanol ester produced from vegetable oil sterols from soybean sources.
Milk	Whey used in distillates for spirits. Lactitol. Milk (casein) products used as fining agents in cider and wines.
Nuts	Nuts used in distillates for spirits. Almonds and walnuts used as flavour in spirits.
Celery	Celery leaf and seed oil. Celery seed oleoresin.
Mustard	Mustard oil. Mustard seed oil. Mustard seed oleoresin.

Note

<sup>1</sup> And their products, in so far as the process that they have undergone is not likely to increase the level of allergenicity assessed by the European Food Safety Authority for the relevant product from which they originated.