

Explanatory Memorandum

THE FOOD LABELLING (DECLARATION OF ALLERGENS) (WALES) REGULATIONS 2007

This Explanatory Memorandum has been prepared by The Food Standards Agency Wales and is laid before the National Assembly for Wales.

Description

This instrument implements Commission Directive 2006/142/EC, of 22 December 2006, amending Annex IIIa of Directive 2000/13/EC, by adding lupin and molluscs to the list of allergens in Schedule AA1 of the Food Labelling Regulations 1996 (as amended). This Schedule lists those allergens and products thereof that must be indicated in the labelling of food. The new Regulations are required to help protect the food-allergic individual, in particular those people who are allergic to either lupin or molluscs.

Matters of special interest to the National Assembly's Legislation Committee

None.

Legislative Background

The powers enabling the Regulations to be made are contained in the Food Safety Act 1990 sections 17(1), 26(1) (a) and (3) and 48(1) of the Food Safety Act 1990 are exercisable by Welsh Ministers. The Regulations are subject to the negative resolution procedure.

Purpose and intended effect of the legislation

These Regulations:

- add lupin and molluscs to the list of allergens in Schedule AA1 of the Food Labelling Regulations 2006 (as amended)

Implementation

It is intended that these Regulations will come in force on 23 December 2007. Similar legislation will also come into force in England, Scotland and Northern Ireland on 23 December 2007.

The implementation of these Regulations would fulfil the UK's obligations under the EC Treaty and will provide Local Authorities with the power to enforce against food business operators who are not in compliance with the new Regulations. Failure to implement these Regulations in Wales by the coming into force date of 23 December 2007 would lead to inconsistency in UK law.

Consultation

Full details of the consultation undertaken are included in the RIA below.

Regulatory Impact Assessment

Options

Option 1: Do nothing

Option 2: Implement EC requirements

Option 3: Implement EC requirements and extend labelling to cover non-prepacked foods (loose and pre-packed for direct sale)

Option 1 – Do nothing

1. Do not implement Directive 2006/142/EC into UK law. 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 not provide adequate protection to the health of consumers who are allergic or intolerant to lupin or molluscs. It would also create differences between Member States and lead to barriers to trade within the single European market. This option would also 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 or desirable option.

Option 2: Implement EC requirements

2. Implementing fully the provisions of Directive 2006/142/EC into UK law would fulfil the Agency's commitment to ensure that consumers are properly informed through accurate labelling, which would enable food allergic consumers to make informed choices. The Agency believes that there may also be some associated benefits for businesses as a result of increased consumer confidence in products carrying more informative labels.
3. 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 European market. Allergen information is not required in the case of food which is sold loose, food which is pre-packed for direct sale or fancy confectionery products and, therefore, it would not be required for lupin or molluscs either.

Option 3 – Extend implementation to cover foods sold non-prepacked

4. Under Directive 2000/13/EC Member States have the option to use national provisions to extend labelling requirements for pre-packed foods to food sold non-prepacked. This option would go beyond the

provisions of Directive 2006/142/EC by extending consumer protection into an area previously not covered by legislation. In addition, any legislation to extend these provisions for lupin and molluscs to cover foods sold other than pre-packed or pre-packed for direct sale would not be consistent with the provisions for the other allergenic ingredients on Schedule AA1 of the Food Labelling Regulations 1996.

5. Food labelling legislation is harmonised at EU level and currently does not address the issue of allergen advisory labelling for foods sold either pre-packed for direct sale or foods sold other than pre-packed.
6. However, the Commission is currently reviewing all food labelling legislation and might consider this area, but this will take a number of years. It is difficult for the UK to introduce national measures in an area of EU competence. If the UK were to implement national legislation now, there could potentially be two changes for businesses – i.e. one now and another following the review by the European Commission. Implementing this option would result in different requirements for lupin and molluscs compared to other food allergens, which would be confusing for consumers, industry, and enforcers.

Flexibility

7. The Commission Regulation does not offer any flexibility on the implementation of its provisions.

Costs and Benefits

Sectors and Groups affected

8. It is estimated that 1 in every 55 children have a peanut allergy¹ and it is thought that approximately a third of these children will react to lupin. In 1999 a French research team investigated the risk of cross-allergy to lupin in 24 people who were allergic to peanuts². They found that 44 per cent reacted positively to a skin prick test with lupin flour and seven out of eight who took challenge tests reacted positively. The principal allergen in lupin flour was also found in peanuts.
9. The proposed legislation will help those with food allergies to lupin and molluscs to avoid foods which contain these ingredients. However, the new legislation will potentially affect manufacturers and retailers of pre-packed foods as these businesses will need to review the origins and

¹ Tariq, SM et al. Cohort study of peanut and tree nut sensitisation by age 4 years. (1996) *British Medical Journal* **313** 514-517 and Hourihane JO, Aiken R, Briggs R, Gudgeon LA, Grimshaw KE, Dunngalvin A, Roberts SR. The impact of government advice to pregnant mothers regarding peanut avoidance on the prevalence of peanut allergy in United Kingdom children at school entry. *J Allergy Clin Immunol*. 2007 May;119(5):1197-202

² Moneret-Vautrin DA, Guérin L, Kanny G, Flabbee J, Frémont S, Morisset M (1999). Cross-allergenicity of peanut and lupine: The risk of lupine allergy in patients allergic to peanuts *J Allergy Clin Immunol* 104:883-8

composition of all ingredients, flavourings and finished products to establish whether any of these newly-specified allergens are present. Labels and/or ingredient lists will also have to be amended to indicate the specified allergens, or product formulations changed to remove or replace them with non-allergenic materials.

Benefits

Option 1 – Do nothing

10. Under this option, the current rules would remain unchanged. Food manufacturers will continue to indicate the presence of the specified allergens as stipulated in Annex IIIa of Directive 2000/13/EC before it was amended by Directive 2006/142/EC.

Option 2 - Implement EC requirements

11. Implementing the Directive would fulfil the UK's obligation under the EC Treaty ensuring consistent labelling of pre-packed foods across the EU.
12. Consumers will benefit from the new rules, as more comprehensive labelling will increase information and further promote informed choice. In particular, those with food allergies and food intolerance to lupin and molluscs will find it easier to select products that do not contain the ingredients that they are trying to avoid.
13. There is evidence that those with food allergy spend a longer time doing their shopping³. The new rules may therefore reduce associated search costs for consumers as the labelling of products containing lupin and molluscs and their derivatives should be clearer and more consistent. However, the amount and value of time saved is difficult to quantify. In addition, potential reductions in fatalities or near fatal reactions requiring hospitalisation as a consequence of this legislation are likely to further increase the benefits.
14. Industry may also gain benefits from the proposed Regulations through increased consumer confidence as a result of products carrying more informative labels and the facilitation of trade as UK manufacturers can operate freely and competitively within the single European market. However, there will be a cost to industry from reading the new legislation and changing the labels on a small number of pre-packed foods; this is set out in more detail in the cost section below.

Option 3 - Extend implementation to cover foods sold non-prepacked

15. Under this option consumers may benefit, as more comprehensive information on all of the ingredients in Schedule AA1 of the Food

³ Gowland 2002, 'May Contain' Labelling – The Consumer's Perspective.

Labelling Regulations 1996 will be available to them from all outlets where foods are sold other than pre-packed, for example bakeries and restaurants.

16. There is evidence which suggests that foods purchased from catering and fast food outlets present a greater risk to food allergic consumers than pre-packed foods, in terms of the number of fatal and near-fatal allergic reactions occurring. Although not broken down between pre-packed and non-prepacked foods, current estimates indicate that in total around 10 people die each year in the UK as a result of allergic reactions to food⁴. In 2004/5 there were 829 hospital admissions in England caused by anaphylactic reactions to food⁵. There is a cost to the person concerned and to the National Health Service for every anaphylactic shock reaction, which can result in a stay in hospital. In 2005 the average cost for (non-elective) treatments of shock and anaphylaxis was £471 per treatment⁶. Without intervention, allergic reactions as a consequence of allergic consumers not realising that a food contains an ingredient to which they are allergic, will continue to occur.

Costs

Option 1 – Do nothing

17. Doing nothing has implications for both the direct costs to the NHS and indirect costs to the wider economy from allergy related illnesses. The direct cost to the NHS of managing allergic diseases has recently been estimated at over £1 billion per annum in the UK⁸ and primary care prescribing costs are around £0.9 billion per annum, or 11% of the total drugs budget. However, the proportion of this relating to lupin and mollusc allergy is likely to be low when compared to hay fever and asthma due to environmental factors. The recent Department of Health review on allergy services⁷ highlighted that the indirect costs of allergic diseases, such as school or workdays lost, lower productivity or diminished quality of life, are potentially huge. However, these were not quantified.
18. This option would also 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 - implement fully the provisions of Directive 2006/142/EC

⁴ Pumphrey and Gowland "The Journal of Allergy and Clinical Immunology" 2007

⁵ <http://www.hesonline.org.uk/Ease/servlet/ContentServer?siteID=1937&categoryID=214>

⁶ <http://www.dh.gov.uk/assetRoot/04/13/32/28/041332328.xls>

⁷ National Allergy Strategy Group (NASG) October 2006

19. Under this option, the new rules will affect producers of pre-packed foods that contain the specified allergens, which are not currently identified on the label. We would expect some of the food industry to undertake a re-design of labels, with the effect varying according to the number and types of products they produce. The British Retail Consortium has estimated the costs of re-labelling a product line at approximately £1000 each. However, it is anticipated that changes can be made within manufacturers' existing commercial labelling cycles. Any costs arising should therefore be minimal. The proposed one year transitional period will also greatly cushion this effect of any extra costs that may be incurred as a result of having to remove any products from sale.
20. Although, we do not have evidence on the total number of food product lines that will be affected, but we would expect this to be limited. In addition, it is likely that, because of the already existing requirement to declare crustaceans, many manufacturers are already declaring molluscs or the more generic "shellfish", on the label.
21. There may be limited costs associated with additional checking of the composition of compound ingredients that are bought in for these two additional allergens.
22. Businesses will need to allow time to read and understand these Regulations. However, due to the simplicity of these Regulations this should not be onerous. For most businesses we estimate that it would take approximately 20 minutes to read the Regulations.
23. This option will also affect the public bodies (Local Authorities and Public Analysts) charged with responsibility for implementing and enforcing legislation in this area. LACORS have estimated the cost of enforcement to be in the region of £20,000 per annum based on a notional figure of 400 samples at £50 per sample. An estimate of the cost of the time taken by local authority enforcement officers to read the legislation and guidance is £22.18.⁸

Option 3 - Extend implementation to cover non-prepacked foods

24. Industry has indicated that in terms of labelling or point of sale notices, staff training and traceability procedures, the costs of introducing this option may be quite high for those businesses providing foods, which are not pre-packed or pre-packed for direct sale, and these businesses may find this cost difficult to absorb. However, the numbers of businesses affected and to what extent is not known.

⁸ Figure taken from the 2006 ONS Annual Survey of Hours and Earnings of Public Service Professionals of £17.06 per hour (median value) with an additional 30% to cover overheads in line with standard cost model.

Small Firms Impact Test

25. The addition of lupin and molluscs to Schedule AA1 of the Food Labelling 1996 will affect a limited number of businesses. It is understood that many small bakers are in the process of re-formulating to remove the lupin content from their products in an effort to avoid additional labelling requirements.
26. However, an initial assessment of the impact to small businesses shows that the main impact will be the work needed 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, are likely to incur some additional costs from setting in place these additional information checks and for re-labelling products to reflect the new requirements. These costs will be in relation to their size, turnover and number of product ranges.
27. 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 updated comprehensive guidance on allergen labelling requirements.

Race, Gender Equality and Sustainability Impacts

28. The FSA does not consider that the new legislation has any impact on race or gender equality as there is no evidence to suggest that any group is likely to react to either molluscs or lupin more than any other group.
29. There may be a small impact on economic sustainability as some labels which remain unused by 22 December 2008 will have to be discarded at the end of this period.
30. There are no impacts on rural issues.

Environmental Impact

31. There are no environmental effects of the proposals/new legislation.

Enforcement, sanctions and monitoring

32. Local food authorities are responsible for enforcing the Regulations. The amending Regulations bring no new enforcement responsibilities.

Competition assessment

33. The results from the competition filter and new 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 disclosing lupin and molluscs ingredients in pre-packed foods. In most 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.

Consultation

34. The Food Standards Agency Wales carried out a 12-week consultation from the 14th June to 6th September 2007 on proposed Regulations to implement Commission Directive 2006/142/EC.
35. Stakeholders, including industry, enforcement and consumer representatives were invited to comment on the draft Regulations the draft Regulatory Appraisal and new draft guidance. The consultation package was posted on the Agency's website. Overall, 20 responses were received to the consultation across the UK. Thirteen responses were received to the England consultation of which, seven had no comment to make, five favoured Option 2 and only one respondent favoured Option 3. Four responses were received Scotland's consultation of which, three favoured option 2 while one had no comment to make.
36. Fifty two interested parties were consulted in Wales, three responses were received. Two respondents HCC (Hybu Cig Cymru- Meat Promotion Wales) and The Welsh Consumer Council had no comment to make while one respondent WHOTS (Wales Heads of Trading Standards) favoured Option 2.
37. No policy changes to the draft Regulations were identified as a consequence of the public consultation.

Post-implementation review

38. The Agency will consider this legislation as part of the on going labelling review and will also monitor stakeholder meetings and general enquires from the general public to inform a discussion 12 months post implementation.

Summary

39. Making these Regulations will enable us to fulfil our community obligations and will benefit consumers and industry. Failure to make these Regulations would result in a serious breach of the UK's

obligations under the EC Treaty and would attract infraction proceedings by the Commission against the UK along with the possibility of heavy fines. For these reasons the Agency favours implementation of the provisions of Commission Regulation 226/142/EC via the Food Labelling (Declaration of Allergens) (Wales) Regulations 2007.