

REGULATORY APPRAISAL

FOOD, WALES

THE FOOD LABELLING (AMENDMENT) (WALES) REGULATIONS 2005

Purpose and intended effect of measure

1. These Regulations further amend the Food Labelling Regulations 1996 in so far as they apply in relation to Wales. These Regulations implement in Wales Commission Directive 2004/77/EC amending Directive 94/54/EC as regards the labelling of certain foods containing glycyrrhizinic acid (which occurs naturally in the liquorice plant *Glycyrrhiza glabra*) and its ammonium salt (which is manufactured from aqueous extracts of the liquorice plant).
2. Parallel legislation will be made in respect of England, Scotland and Northern Ireland.
3. The new rules require confectionery and drinks containing certain levels of glycyrrhizinic acid and its ammonium salt to be labelled with the indication “contains liquorice” and for this to be coupled with a health warning in certain cases.

Background

Food Labelling Regulations 1996

4. Food labelling in Great Britain is governed by the Food Labelling Regulations 1996 and certain provisions of the Food Safety Act 1990 and Trade Descriptions Act 1968. The Regulations implement Directive 2000/13/EC on the labelling, presentation and advertising of foodstuffs. Separate, but parallel legislation exists in Northern Ireland where appropriate.
5. The rules 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, and that industry has a clear regulatory framework, which does not restrict product innovation or inhibit the free movement of goods within the EU.
6. Foods sold pre-packed for direct sale and non pre-packed (such as those sold at delicatessen counters, or as meals in catering establishments) are exempt from most of the labelling requirements in the Food Labelling Regulations 1996.

Glycyrrhizinic acid and ammonium salt

7. Glycyrrhizinic acid occurs naturally in the liquorice plant *Glycyrrhiza glabra* while its ammonium salt is manufactured from aqueous extracts of the liquorice plant. Glycyrrhizinic acid and its ammonium salt are included in the Community register of flavouring substances laid down by Commission Decision 1999/217/EC of 23 February 1999, adopting a register of flavouring substances used in or on foodstuffs. This was drawn up in

application of Regulation (EC) No 2232/96 of the European Parliament and of the Council of 28 October 1996.

8. Consumption above a certain level of glycyrrhizinic acid and its ammonium salt may give rise to, or exacerbate, hypertension (i.e. abnormally elevated blood pressure). Exposure to glycyrrhizinic acid and its ammonium salt occur mostly via consumption of liquorice confectionery, including chewing gum, herbal teas and other beverages.
9. The EU Scientific Committee on Food (SCF) (opinion of 4 April 2003), concluded that an upper limit for regular ingestion of 100mg/day of glycyrrhizinic acid and its ammonium salt provides a sufficient level of protection for the majority of the population. However, the Committee noted that within the human population there are subgroups for which this upper limit might not offer sufficient protection. These subgroups comprise people with medical conditions related to disturbed water and electrolyte homeostasis.
10. Labelling the presence of glycyrrhizinic acid or its ammonium salt in confectionery and beverages will provide clear information and enable consumers, particularly those who may suffer with such medical conditions, to make informed choices. In addition, where products contain high levels of glycyrrhizinic acid or its ammonium salt, consumers will be informed that excessive intake should be avoided.

The New Rules in Directive 2004/77/EC

11. The new rules will require an indication of the presence of glycyrrhizinic acid or its ammonium salt (whether due to addition of these substances or the liquorice plant) in confectionery or drinks, unless this is already included in the name under which the product is sold or in the ingredients list, and for this to be coupled with a warning in certain cases, as set out below. These indications must be given after the ingredients list or, where an ingredients list is not required, near the name of the food.

Labelling Requirements

<p>any confectionery which contains a relevant concentration of at least 100mg/kg but less than 4g/kg;</p> <p>any drink which contains more than 1.2 per cent by volume of alcohol and a relevant concentration of at least 10mg/l but less than 300mg/l;</p> <p>and</p>	<p>that food shall be marked or labelled with the indication “contains liquorice”, unless the term “liquorice” appears in the list of ingredients or in the name of the food.</p> <p>“</p>
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any drink which does not contain more than 1.2 per cent by volume of alcohol and which contains a relevant concentration of at least 10mg/l but less than 50mg/l	“
any confectionery which contains a relevant concentration of at least 4g/kg;	that food shall be marked or labelled with the indication “contains liquorice – people suffering from hypertension should avoid excessive consumption”
any drink which contains more than 1.2 per cent by volume of alcohol and a relevant concentration of at least 300mg/l,	“
and	
any drink which does not contain more than 1.2 per cent by volume of alcohol and which contains a relevant concentration of at least 50mg/l	“

12. There are exemptions from these labelling requirements in the case of food which is not prepacked, food which is prepacked for direct sale, fancy confectionery products, small packages and certain indelibly marked glass bottles.

Risk Assessment

13. Commission Directive 2004/77/EC and, therefore, the Regulations address the risk that consumers suffering from hypertension may consume harmful amounts of glycyrrhizinic acid and/or its ammonium salts due to its presence not being declared on prepacked food.

14. Hypertension is a major risk factor for strokes and coronary heart disease. These circulatory diseases are the commonest causes of death in Wales – in 2000 they accounted for four deaths in every ten.

15. Consumption of glycyrrhizinic acid and its ammonium salt can give rise to, or exacerbate, hypertension. The European Scientific Committee has concluded that an upper limit for regular ingestion of 100 mg/day of glycyrrhizinic acid and its ammonium salt, provides sufficient level of protection for the majority of the population, however, consumption above this level may give rise to hypertension.

16. These findings make it desirable to provide labelling which gives the consumer clear information on the presence of glycyrrhizinic acid or its ammonium salt, so that those with hypertension may avoid the food in question. It could help to contribute in decreasing the burden of high blood pressure and improve public health.

Options

17. In respect of this legislation the “Do nothing option” is not an option, as it would lead ultimately to infraction proceedings against the National Assembly for Wales by the European Commission. Therefore, the “Make the Legislation” option, to implement the changes required to comply with European legislation, is being recommended.
18. In addition, implementing the Commission Directive would fulfil the UK’s obligation under the EC Treaty, facilitate informed consumer choice, improve health protection for certain consumers and allow UK manufacturers to operate freely and competitively within the single market. There may also be some associated benefits for businesses as a result of increased consumer confidence in products carrying more informative labels. However, this information would not be required in the case of food which is not prepacked, food which is prepacked for direct sale, fancy confectionery products, small packages (the largest surface of whose packaging has an area of less than 10 square centimetres) and certain indelibly marked glass bottles.

Cost and benefits

Business sectors affected

19. Following consultation with trade/retail organisations, it appears the new rules will have an impact on two UK businesses (neither of which are based in Wales). All other manufacturers appear to produce products where the content of glycyrrhizinic acid and its ammonium salt is well under the level that triggers the health warning requirement. In addition, so far as we have been able to establish, where products are required to indicate that the product contains liquorice, all such products already comply with the new rules, either by including the word liquorice in the name of the food or in the ingredients list, and the new rules should not therefore change the current status quo.
20. Only manufacturers who produce confectionery products that contain 4g/kg or above of glycyrrhizinic acid and its ammonium salt will need to label their products: “contains liquorice – people suffering from hypertension should avoid excessive consumption”. We are aware of only two such UK manufacturers (neither of which are based in Wales) who fall into this category. We do not, therefore, anticipate any additional costs to industry in Wales as a result of the implementation of this measure.

Costs

21. The businesses described above in paragraph 20 will be required to make labelling changes for one to two products. The one off costs of changing the labels are estimated by the industry to be in the range of £500 – £1K per product. The costs associated with the changes required by the new rules are expected to offset by businesses incorporating them into routine redesign cycles. The rules allow a transitional period of 12 months from the date when the rules come into force, for the necessary changes to be made. In addition, the sale of products labelled prior to the coming into

force date would continue to be allowed until stocks are exhausted. This will ensure no extra costs are incurred as a result of having to remove products from sale.

22. These regulations implement an EC Directive. There is no reasonable alternative to introducing the proposed amending regulations since failure to do so could lead to criticism. Non-implementation would also lead to undoubtedly successful legal proceedings against the UK in the European Court of Justice, as the terms of the measures require the implementation of all their provisions. The cost of non-implementation would include the costs of infraction proceedings to the UK Government as well as any financial penalties imposed.

Benefits/Health Impact Assessment

23. The benefits of these Regulations relate to the provision of clear information on the presence of glycyrrhizic acid and its ammonium salt, allowing the consumer to make informed choices. Given the health risk relating to excessive consumption of products containing glycyrrhizic acid to hypertension, the proposal has the potential to contribute in decreasing the burden of high blood pressure and its associated diseases. If the Regulation contributes only to a very small reduction in these risks, the resulting benefit is still likely to be substantial enough to justify this proposal.

Public Services Threshold Test

24. In accordance with Cabinet Office guidelines, a public services threshold test was carried out in consultation with the Local Authorities Co-ordinators of Regulatory Services (LACORS). LACORS identified cost implications of less than £10,000 in total per annum for public services across England and Wales, £500 of which has been notionally attributed to Wales.

Issues of equity and fairness

25. The Food Labelling (Amendment) (Wales) Regulations 2005 will continue to fulfil European commitments and, as such, should not have any disadvantageous effects on the competitiveness of UK businesses with businesses in other Member States.

Small Firms Impact Test

26. Following the advice of the Small Business Service the initial sounding of the small firms impact test was conducted through consultation with trade/retail organisations. We are aware of only one manufacturer (not based in Wales), (which falls within the medium sized business category), which would be affected. However, they are a subsidiary of a large manufacturer. They have two products which would require labelling changes and costs for both are estimated by the manufacturer to be less than £1000.
27. The Small Business Service concurs that these proposals will not have a significant impact on small businesses.

Competition Assessment

28. The Regulations are not anticipated to have any significant impact on competition. Initial consultation suggests that where products are required to indicate that the product contains liquorice, all such products already comply with the new rules, either by including the word liquorice in the name of the food or in the ingredients list, and so the legislation in this regard maintains the status quo for the existing firms in this sector, whilst not imposing any higher barriers to entry for new entrants.
29. For products which contain above the threshold level of glycyrrhizinic acid, the Instrument requires that a further message must be added after the list of the ingredients, warning consumers suffering from hypertension to avoid excessive consumption. For a very small number of products, this will have labelling implications although it is not anticipated that this relatively small, one-off cost will significantly impact upon these companies so as to have a material effect on competition. However, one manufacturer based in England had indicated potential high additional costs to purchase equipment. We now understand that the manufacturer has found a way to incorporate the extra text, without the need to purchase new equipment.
30. Potential impacts can further be reduced given the opportunities to incorporate changes into re-labelling cycles and so the structure and dynamics of this sector are likely to remain unchanged.

Sustainable Development

31. The Food Standards Agency Wales does not consider that implementing these Regulations will have any impact on sustainability issues.

Enforcement and sanctions

32. Enforcement of food labelling legislation is the responsibility of Local Authority Public Protection Departments or Port Health Authorities (in relation to imported foods).
33. A Public Services Threshold Test was carried out by the Food Standards Agency Headquarters to assess the additional costs to public services in England and Wales. This is reported in paragraph 23 above.
34. Persons convicted of an offence under these Regulations would be liable on a summary conviction to a fine, not exceeding level 5 on the standard scale (currently £5,000).

Monitoring and review

35. The effectiveness of the Regulations will be monitored via feedback from stakeholders as part of the on-going policy process. Agency mechanisms for monitoring and review include: open fora; stakeholder meetings; surveys; Consumer Committee and general enquiries from the public.
36. Guidance notes on the application of the new requirements are being drawn up in full consultation with stakeholders and their impact kept under regular review.

Consultation

With Stakeholders

37. The Food Standards Agency Wales carried out a 12-week consultation from 20 December 2004 to 14 March 2005. Stakeholders, including industry, enforcement authorities and consumer representatives, were invited to comment on the draft Regulations and the draft Regulatory Appraisal. A copy of the consultation package was also posted on the Agency's website. A list of those consulted in Wales is attached at Annex 1. Parallel consultations were carried out on England, Scotland and Northern Ireland.
38. 10 replies were received UK wide in response to the consultation; one in response to the Wales consultation (Wales Consumer Council); eight in response to England's and one in response to Scotland's. No replies were received in response to the consultation conducted in Northern Ireland.
39. The reply received in response to the Wales consultation merely acknowledged receipt of the documents and made no substantive comment. The Scottish response welcomed the measure.
40. Of the 8 replies received in response to the England consultation two were from consumers, one was from a consumer organisation, two were from other interested organisations, two were from industry bodies and one was from an enforcement organisation. None of the respondents made any comments on the Regulations themselves. Two respondents (a consumer and an interest group) were in favour of the proposed changes, noting that it would help consumers identify the presence of glycyrrhizinic acid in prepacked food. One respondent (a consumer) noted that the RA seemed unnecessarily complex, considering the labelling issue is to be a small one, whilst another respondent (an interest group) suggested an alternative form of warning that they felt should be used in the labelling of this ingredient. The enforcement organisation noted that monitoring compliance with the new rules would require analysis of samples for the presence of glycyrrhizinic acid, and consequently wondered if the Food Standards Agency had any information on methods of analysis that would be suitable. It is for Public Analysts to advise on methods of analysis.
41. No policy changes to the draft Regulations were identified as a consequence of the public consultation.

With Subject Committee

42. There has been no prior scrutiny of the proposed Regulations by the Health and Social Services Committee. However, the Regulations were notified to the Committee via the list of forthcoming legislation on 24 November 2004, (HSS(2)-14-14, paper 2b, reference number FS 16(04)), but were not identified for detailed scrutiny.

Summary and recommendations

43. The Food Labelling (Amendment) (Wales) Regulations 2005 serve an important consumer protection measure. They should be made to ensure compliance with our Community obligations and deliver intended consumer health protection and trade benefits.
44. The proposed legislation has the potential benefit of allowing consumers to make informed choices and the potential to contribute towards decreasing the burden of hypertension and its associated diseases. For products with levels less than the threshold level of glycyrrhizinic acid or its ammonium salt the RA indicates that products are already appropriately labelled. A few confectionery products have been identified that will require the additional warning due to levels exceeding 4g/kg (none of which are manufactured in Wales). In the context of the relatively small, one-off costs which may be experienced by some firms, these measures can therefore be seen to be proportional.

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ANNEX A

LIST OF STAKEHOLDERS CONSULTED IN WALES

Company Name	Contact
Abergavenny Fine Foods	A J Craske
ADAS Wales	Cate Barrow - Food Business Development Manager
All Wales Dietetic Advisory Committee	Judyth Jenkins
The Association of Public Analysts	Paul Lenartowicz - Vice President
B. Sidoli & Sons Ltd Bar and Restaurant Foods Ltd	Mr Mark Dukes
Biotrace Limited	Colin Hunt
Business Connect Heart of Wales Clark's Original Pies	Claire Carter Ceri J Baillie
Co-operative Group (CWS) Ltd	Wendy Cave
Dairy Strategy Group	Mr Gareth Evans
Dee Dairy Services Eversheds (Wales) Farmers' Union of Wales	Mrs J Higginbothom Mrs A Henning Mr Arwyn Owen, Director of Policy
Federation of Small Businesses (North Wales) Food Quality Panel	(North Gwyn Evans, Chairman Lynn Hoskins
Food Safe	Mr R Dailley
G C Hahn & Co Ltd Good Food Distributors	The Secretary Mr K F Powell
Halo Foods Ltd	Elizabeth Williams
Iceland Frozen Foods	Peter Lee
British Institute for Allergy and Environmental Therapy LACORS (Welsh Officer)	The Secretary Ms Susan Perkins
International Federation for Home Economics Meridian Foods Monmouthshire Food Initiatives Officer	Ms Jane Lloyd Hughes Mrs Brenda Davies Ms T Turner

National Farmers Union (Wales)	Mrs Mary James
National Federation of Womens Institutes - Wales	Rhian Connick
Peters Food Service Ltd	David Jackson
Powys Food Futures Group	Richard Pitts
Rachel's Dairy	Joanna Tett
RCT Trading Standards Dept	Mr J Frow
Red Star BioProducts	Mr Derek Mitchell, Quality Manager
Ruddock & Sherratt	R A Ennion
School of Environmental Sciences	Professor G Coleman
Society of Directors of Public Protection	Mr Lester Lewis
Society of Directors of Public Protection - North Wales	Kevin P Jones, Panel Chairman
Society of Directors of Public Protection Wales - Trading Standards Group	Steve Delahaye, Secretary
T/A Source Foods	Mr P Chaplin
The Speciality Sauce Co. Ltd	Chris Price-Jones
Tillery Valley Foods Ltd	Mr T B Dickens
Tovali Ltd	Eurwyn Harries
Wales Council for Voluntary Action	Delyth Higgins
Wales Young Farmers' Club	Lowri Jones
Welsh Beekeepers Association	Ms M M Phillips
Wales Centre For Health	David Seal
Welsh Consumer Council	Viv Sugar, Chair
Chartered Institute of Environmental Health in Wales	Mr Paul Handby, Development Co-ordinator
Welsh Food Laboratories	Mr Norman Biggs
Welsh Food Microbiological Forum	Mrs Ceri Edwards, Secretary
WDA Food Directorate	Mr Wynfford James, Director
Woodward Food Service	Tim Goff
Zorba Foods	Gerry Devine
UWIC	Katherine Gallimore
PRP Training Ltd	Charles Stevens
University of Wales Aberystwyth	Miss Norma Wells

WDA Agri-Food Development	Mr Arwyn Davies
Welsh Local Government Association	Mr Sandy Blair
Department of Food Science & Technology - ISSUE BY EMAIL ONLY	Dr David Lindsay
Institutes of Rural Health	Jane Randall-Smith Chief Executive
Age Concern Cymru	Ms Deborah Meehan
Welsh Food Alliance	Jean Sullivan
Commission for Racial Equality	Dr Mashuq Ally
Friends of the Earth Cymru	Gordon James
Institute of Consumer Sciences	Mrs Jean Jones
Royal National Institute for the Blind	W Price, PA/Director
Wales Council for the Blind	Ms Vanessa Webb
Wales Council for the Deaf	Mrs Merryl Roberts
Vydex Nutrition	Ms Maureen Iliffe
Institute of Consumer Sciences	Sharon Morris, Executive Officer Lonsdale House
Chartered Institute of Environmental Health in Wales	Julie Barratt, Director
	Diane McCrea