

REGULATORY APPRAISAL

FOOD, WALES

THE MISCELLANEOUS FOOD ADDITIVES (AMENDMENT) (WALES) REGULATIONS 2005

Background

Commission Directive 2003/95/EC

1. Directive 2003/95/EC of 27 October 2003, which was published in the Official Journal of the European Communities on 31 October 2003, amends Directive 96/77/EC for the fifth time. The changes are as follows:

- The existing purity criteria for E 251 (sodium nitrite) and E 459 (beta-cyclodextrin) have been amended to take account of technical progress by permitting liquid sodium nitrite to be produced by an additional manufacturing process and beta-cyclodextrin to be manufactured from an additional source; and
- In response to the Scientific Committee on Food's (SCF) opinion of 6 May 2002 on ethylene oxide residues in food additives, a new limit of 0.2 mg/kg for ethylene oxide has been included in the specific purity criteria for E431 – 436 (polysorbates) and polyethylene glycol 6000.

Directive 2004/45/EC

2. Directive 2004/45/EC of 16 April 2004, which was published in the Official Journal of the European Communities on 20 April 2004, amends Directive 96/77/EC for the sixth time. The changes are as follows:

- The specifications have been amended to take account of the SCF opinion on carrageenan (a seaweed thickener), expressed on 5 March 2003. The specifications for E407 (carrageenan) and E407a (processed eucheuma seaweed) now limit the level of low molecular weight carrageenan to not more than 5%;
- The minimum Ash content for E407a (processed eucheuma seaweed) has been increased to 15%; and
- New specifications have been included for three additives, E907 (hydrogenated poly-1-decene – a glazing agent), E1517 (glyceryl diacetate – a carrier solvent used to assist flavourings to dissolve) and E1519 (Benzyl alcohol – also a carrier solvent) which have recently been evaluated for safety by the SCF. Provisions authorising the use of these additives have been included in European Parliament and Council Directive 2003/114/EC amending Directive 95/2/EC on food additives other than colours and sweeteners.

Purpose and Intended Effect

3. These Regulations will transpose and implement Commission Directives 2003/95/EC and 2004/45/EC. The new regulations will amend the Miscellaneous Food Additives Regulations 1995 (as amended) in Wales to implement the fifth and sixth amendments to Commission Directive 96/77/EC, which lays down specific purity criteria for food other than colours and sweeteners throughout the EU. The legislation forms part of a continuing programme to update EU specifications for food additives, which are used to ensure the purity of food additives.

Risk Assessment

4. The changes set out in Directives 2003/95/EC and 2004/45/EC take account of technical progress, the need for new purity criteria for newly permitted additives, and the need to amend the specifications for certain additives to improve their safety in line with advice from the European Commission's Scientific Committee on Food - now the European Food Safety Authority's Scientific Panel on Food Additives.

Options

5. These Regulations implement EC Decisions. 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 both measures require the implementation of all their provisions. The costs of non-implementation would include the costs of infraction proceedings to the UK Government as well as any financial penalties imposed. Therefore the non-implementation of these measures is not really an option.

Benefits

Social

6. Full implementation to amend the specifications for certain additives to improve their safety in line with advice from the European Food Safety Authority's Scientific Panel on Food Additives, which will have actual health implications and protect the health of the consumer.

Economic

7. There would appear to be no identifiable economic benefits or disadvantages arising from either the non-implementation or the full implementation of Commission Decisions 2003/95/EC and 2004/45/EC.

Environmental

8. There would appear to be no identifiable environmental benefits or disadvantages arising from either the non-implementation or the full implementation of Commission Decisions 2003/95/EC and 2004/45/EC.

Financial Implications for Wales

9. Enforcement of this legislation is the responsibility of Local Authority Public Protection Departments in Wales. The public consultation exercise invited comments on any additional costs envisaged in implementing the Regulations. The Food Standards Agency suggested that there would be no financial impact

on business arising from the proposed legislation. Industry has confirmed that this is the case. No comments were forthcoming from the Local Authorities Co-ordinators of Regulatory Services (LACORS) (the co-ordinating body for local authority trading standards departments in England and Wales) or the Welsh Local Government Association. No additional costs to local authorities or the Assembly have been identified either.

Equality and Fairness

10. Full implementation of these two measures is very unlikely to disadvantage the UK industry. The Regulations will apply to all food manufacturers, as appropriate.

Consultation with Small Businesses (The Small Firms Impact Test)

11. The Federation of Small Businesses stakeholders were included in the consultation on the draft Regulations but did not respond.

Enforcement and Sanctions

12. Enforcement of the food additives legislation is the responsibility of Local Authority Public Protection Departments in Great Britain and the Department of Agriculture and Rural Development in Northern Ireland. Enforcement includes the taking of samples of foods and the testing of them for the presence of various ingredients. In general, accredited agricultural analysts on behalf of Local Authorities usually undertake this type of work. Neither measure specifies any additional levels of sampling or analysis.

Monitoring and Review

13. The Food Standards Agency will consider proposals from stakeholders for any further changes to the rules that they consider necessary in the light of experience, and the effectiveness, of the new legislation.

Consultation

With Stakeholders

14. The Food Standards Agency Wales carried out a consultation from 16 July 2004 to 30 September 2004. Stakeholders included all Assembly Members, and consumer and industry representative bodies (a full list of consultees is at Annex A). They were invited to comment on the draft Regulations and any costs associated with the implementation of the Regulations. No comments were received. Parallel consultations were carried out in England, Scotland and Northern Ireland and did not attract comments from stakeholders. No policy changes to the draft Regulations were identified as a consequence of the public consultation.

With Subject Committee

15. There has been no prior scrutiny of the proposed Regulations by the Health and Social Services Committee. However, these Regulations have been, notified to the Committee via the list of forthcoming legislation, put to the Committee on 3 March 2004 (Item No. FS 05(04) on the Food Standards Agency schedule) and in successive meetings but has not been identified for scrutiny.

Summary

16. In the light of these considerations, it is recommended that Commission Directive 2003/95/EC and Commission Decision 2004/45/EC is implemented in Wales by the Miscellaneous Food Additives Amendment Regulations 2005.

Contact Point

Helen George

Food Standards Agency Wales

11th Floor, Southgate House

Wood Street, Cardiff CF10 1EW

Telephone: 029 2067 8906

Fax: 029 2067 8918

E-mail: Helen.george@foodstandards.gsi.gov.uk