EXECUTIVE NOTE

THE FOOD FOR PARTICULAR NUTRITIONAL USES (ADDITION OF SUBSTANCES FOR SPECIFIC NUTRITIONAL PURPOSES) (SCOTLAND) REGULATIONS 2009
SSI 2009/427

1. The above instrument was made by the Scottish Ministers in exercise of the powers conferred by sections 16(1)(a) and (f), 17(2), 26(1)(a) and (3) and 48(1) of the Food Safety Act 1990 and all other powers enabling them to do so. This instrument is subject to the negative resolution procedure.

Policy Objectives

2. The purpose of this instrument is to provide execution and enforcement provisions in Scotland for Commission Regulation (EC) No. 953/2009 ("the Commission Regulation") on the substances that may be added for specific nutritional purposes in foods for particular nutritional uses. The main purpose of the Regulations is to align domestic law with EC law to consolidate and amend the list of permitted substances for use in foods for particular nutritional uses ('Parnuts foods').

3. The Commission Regulation consolidates and amends current EC legislation providing for the addition of certain substances to Parnuts foods. It repeals Directive 2001/15/EC and Directive 2004/6/EC with effect from 31 December 2009.

4. The Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes (Scotland) Regulations 2009 ("the Regulations") revoke:-

- the Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (Scotland) Regulations 2002 (SSI 2002/397); and
- the Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes (Scotland) Amendment Regulations 2004 (S.S.I 2004/90) and 2006 (S.S.I. 2006/556).

Policy Background

5. EC legislation requires that foods for particular nutritional uses are safe and that they meet the nutritional requirements of the persons for whom they are intended. A Parnuts food is a food which, owing to its special composition or process of manufacture, is clearly distinguishable from food intended for normal consumption, and is sold in such a way as to indicate its suitability for its claimed nutritional use. Examples of Parnuts foods include - infant formulae, follow-on formulae and medical foods.

6. To facilitate consumer choice, the widest possible choice of substances such as vitamins, minerals and amino acids should be available for use in foods for particular nutritional uses. To ensure consumer protection, it is also important that the safety of these substances is scientifically proven before they are used in the manufacture of foods for particular nutritional use.

7. In order to fulfil these requirements, a European Commission Directive was agreed in 2001 (Directive 2001/15/EC) which listed the types of chemical substances that may be used in the manufacture of foods for particular nutritional uses. Any chemical substance that is listed in the Directive must have received a favourable scientific evaluation either by the European Food Safety Authority (EFSA), or its forerunner, the Scientific Committee on Food (SCF).

8. If a manufacturer wishes a new substance to be added to the list of authorised substances in Directive 2001/15/EC the new substance must first receive a positive assessment from EFSA. The European Commission Standing Committee on the Food Chain and Animal Health (SCoFCAH) must then agree that the new substance should be added to the relevant list in Directive 2001/15/EC.

9. Commission Directive 2004/6/EC implemented a derogation which permitted the use of new substances in parnuts foods until 31st December 2006. Each substance listed in 2004/6/EC would have had to be approved by EFSA and then included in the Annex to 2001/15/EC before 31st December 2006 in order to permit its continued use in parnuts foods within the EC after that date.

10. The length of the derogation was extended by Directive 2007/26/EC as EFSA had not completed this list by that time. EFSA has now given favourable opinions on some of these substances and they are included in the Annex to the Commission Regulation.

11. Earlier this year the European Commission published the Commission Regulation to consolidate and amend Directive 2001/15/EC. This increases the range of sources of vitamins and minerals and other substances that may be added to foods for particular nutritional uses and represents simplification of current legislation as the provisions will be consolidated into a single regulation making it easier to read.

Consultation

12. Article 9 of EC Regulation 178/2002, laying down the general principles and requirements of food law, requires open and transparent public consultation on the revision of food law, save in measures made in circumstances of urgency. The Agency previously consulted all interested parties throughout the duration of EU negotiations on the Commission Regulation, the only responses received were ‘no comment’. On this basis, we considered that a shortened consultation was appropriate and this allows us to update domestic legislation

according to the timetable set by the Commission which is of benefit to all stakeholders.

13. The Food Standards Agency consulted 188 interested parties (industry, consumer groups and enforcement authorities) in Scotland on the proposed Regulations. The consultation documents were also made available on the Food Standards Agency website. Within Government, the Food Standards Agency consulted the Scottish Government Health Directorate. Only one response ('no comment') was received.

14. A list of the interested parties consulted is attached.

Financial Implications

15. The primary business sector that will be affected by the regulatory proposals are manufacturers of foods for particular nutritional uses. The consultation generated only one response, a 'no comment'.

16. We do not expect the coming-into-force date to pose a problem to manufacturers of parnuts foods as the date coincides with the expiration of the derogation, outlined in paragraphs 9 and 10. Therefore it is assumed that the measures proposed impose no new financial burdens.

17. The Regulations would not impose any significant new burden on Government or enforcement officers. Rural areas and members of the ethnic communities, or of any particular racial group are unaffected by these proposals. Charities and voluntary organisations are unaffected by these proposals.

18. A Regulatory Impact Assessment has not been prepared to accompany these Regulations as no costs have been identified.

Contact

19. Tracey Thomas at the Food Standards Agency Scotland (Tel: 01224 285111 or e-mail: Tracey.Thomas@foodstandards.gsi.gov.uk) can answer any queries regarding the instrument.

LIST OF INTERESTED PARTIES

Aberdeen City Council
Aberdeen University
Aberdeenshire Council
Adam Smith College
AG BARR (Finlays NMW)
Angus Council
Aquascot Ltd
Argyll & Bute Council
Bell Bakers Limited
BMA Scotland
British Hospitality Association
British Soft Drinks Association
Cardowan Creameries Ltd
Care Commission
Centre for Public Health Nutrition Research
City of Edinburgh Council
Clackmannanshire Council
Co-operative Group (CWS) Ltd
Comhairie Nan Eilean Siar
Comhairle Nan Eilean Siar
Consumer Focus Scotland
COSLA
Dairy UK - Scotland
Direct & Care Services
Dumfries & Galloway Council
Dundee City Council
East Ayrshire Council
East Dunbartonshire Council
East Lothian Council
East Renfrewshire Council
Edinburgh Community Food Initiative
Falkirk Council
Federation of Small Businesses
Fife Council
Food Additives & Ingredients Association
Food Industry (North) Development Services
Food Innovation Institute (F2i)
Food Microbiology, Fish Handling and Processing
Food Partners Ltd.
Food Safety Authority of Ireland
Food Training & Consultants Company
G McWilliam (Aberdeen) Ltd
Glasgow Caledonian University
Glasgow City Council
Glasgow Metropolitan College

Glasgow Scientific Services
Glasgow University Veterinary School
H.R. Bradford (Bakers) Ltd
Hallmark Meat Hygiene Ltd/ AA Duncan & Son
Health Promotion Service
Health Protection Scotland
Helen Glass
Highland Council
HUSH
Ingram Brothers Ltd.
lnverclyde Council
J G Ross (Bakers) Ltd
JWC Services Ltd.
Kettle Produce Ltd.
Klinge Foods Ltd.
Lactalis McLelland Limited
Mackies Of Scotland
MacPhie of Glenbervie Ltd
Meat and Livestock Commission
Midlothian Council
Moray Seafood Ltd
Napier University
Neville Craddock Association
NHS Ayrshire & Arran
NHS Borders
NHS Fife
NHS Fife - Nutrition & Dietic Dept.
NHS Grampian
NHS Greater Glasgow & Clyde
NHS Tayside
North Ayrshire Council
North Lanarkshire Council
Oatmeal of Alford
Orkney Herring Co Ltd
Orkney Islands Council
Paterson Arran Limited
Perth & Kinross Council
Quality Meat Scotland
Queen Margeret University College
Regulatory Solutions
Renfrewshire Council
Robert Gordon University
Rowett Research Institute
Royal Environmental Health Institute for Scotland
Rum a
Scotch Whisky Association
Scotch Whisky Research Institute
Scotland Excel
Scottish Association of Master Bakers
Scottish Borders council

Scottish Chambers of Commerce
Scottish Environmental Research Centre
Scottish Federation of Meat Traders
Scottish Food & Drink Federation
Scottish Food Enforcement Liaison Committee
Scottish Food Enforcement liaison Committee FSSC
Scottish Government
Scottish Grocers Federation
Scottish Health Food Retailers Association
Scottish Newcastle UK
Scottish Qualifications Authority
Shetland Islands Council
SN DRT
Soil Association Scotland
South Ayrshire Council
South Lanarkshire Council
Stirling Council (Catering & Cleaning)
SUSTAIN
T & L Food Services Ltd
Tayside Scientific Services
The Association of Meat Inspectors
The British Dietetic Association
The Glenside Group Ltd.
The Halal Food Authority
The Highland Council
The Infant & Dietetic Foods Association Ltd
The Moray Council
Tilquhillie Fine Foods
University of Aberdeen
University of Dundee
Vegetarian Economy & Green Agriculture (VEGA)
Verner Wheelock Associates
Vion
Walkers Shortbread Ltd
West Dunbartonshire Council
West Lothian Council
Wicken Fen Wholesome Foods
Womens Food & Farming Union