1. **Subordinate legislation:** The Committee will consider the following negative instruments-

   The Materials and Articles in Contact with Food (Scotland) Amendment Regulations 2009 (SSI 2009/426); and

   The Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes (Scotland) Regulations 2009 (SSI 2009/427).
The papers for this meeting are as follows—

**Agenda Item 1**

Note by the clerk  
SSI.2009.426  
SSI.2009.427
### Abridged Subordinate Legislation Briefing

#### Negative Instruments

<table>
<thead>
<tr>
<th>Name</th>
<th>Deadline</th>
<th>Motion to Annul</th>
<th>Purpose</th>
<th>Drawn to attention by SLC?</th>
</tr>
</thead>
<tbody>
<tr>
<td>The Materials and Articles in Contact with Food (Scotland) Amendment Regulations 2009 (SSI 2009/426)</td>
<td>18 Jan</td>
<td>No</td>
<td>These Regulations further amend the Materials and Articles in Contact with Food (Scotland) Regulations 2007 in order to provide for the execution and enforcement of Commission Regulation (EC) No. 450/2009 on active and intelligent materials and articles intended to come into contact with food. The Regulations also amend the definition of “import” in the principal Regulations.</td>
<td>The SLC had no comments to make on this instrument.</td>
</tr>
<tr>
<td>The Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes (Scotland) Regulations 2009 (SSI 2009/427)</td>
<td>18 Jan</td>
<td>No</td>
<td>These Regulations, which extend to Scotland only, make provision for the execution and enforcement of Commission Regulation (EC) No. 953/2009 on substances that may be added for specific nutritional purposes in foods for particular nutritional uses. The Commission Regulation repeals and replaces Commission Directive 2001/15/EC on substances that may be added for specific nutritional purposes in food for particular nutritional uses and Commission Directive 2004/6/EC derogating from Directive 2001/15/EC to postpone the application of the prohibition of trade to certain products.</td>
<td>The SLC had no comments to make on this instrument.</td>
</tr>
</tbody>
</table>

Where instruments have been drawn to the Committee’s attention, the relevant extract from the SLC report is given as an annex to this paper.

If members have any queries or points of clarification on the instrument which they wish to have raised with the Scottish Government in advance of the meeting, please could these be passed to the Clerk to the Committee as soon as possible.
1. Description

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

2. Policy Objective

2.1 This instrument, by amending the Materials and Articles in Contact with Food (Scotland) Regulations 2007, provides for the enforcement in Scotland of certain provisions contained in Commission Regulation (EC) No 450/2009 (“the AIM Regulation”) on active and intelligent materials and articles intended to come into contact with food.

2.2 Active materials are those that are designed to react with the food or its immediate environment with which they are in contact so as to alter it in some way (e.g. improve keeping qualities), and intelligent materials react in such a way as to provide information about the food.

3. Policy & legislative background

- What is being done and why

3.1 The purpose of making this instrument is to ensure that the provisions outlined above are in place by the deadline set out in the AIM Regulation and provide the necessary powers to enforcement authorities for the effective enforcement of the AIM Regulation.

3.2 The intention is to protect the consumer through adequate labelling and to protect them against accidentally eating non-consumable parts of packaging and, through requirements to declare the compliance of the material or article business to business along the supply chain, against food contamination by chemicals whose ingestion would carry serious long term and unacceptable risk to consumer health, in particular among vulnerable people.

3.3 The general principles on all food contact materials and articles intended to come into contact with foodstuffs are established in Regulation (EC) No. 1935/2004. This lays down the framework of regulation for all materials and articles intended to come into contact with food, including those classed as ‘active; and ‘intelligent’. The enforcement of provisions for that Regulation is implemented in Scotland by The Materials and Articles in Contact with Food (Scotland) Regulations 2007. This instrument will amend the 2007 Regulations to take into account certain provisions of the AIM Regulation.

3.4 These provisions relate to particular labelling and declarations requirements for goods placed on the market. They specifically concern the labelling of parts of the packaging that could be wrongly taken by some consumers to be edible, the written declaration of legal compliance to accompany active and intelligent materials and articles prior to retail sale, and the production, to enforcement authorities on request, of supporting documentation to substantiate the declaration of compliance.

3.5 These provisions need to be in place by 19th December 2009 to ensure that enforcement authorities have the necessary powers to act under the AIM Regulation at the time they become applicable throughout the European Community. The requirements of the remainder of the
AIM Regulation become applicable following adoption of the Community list of substances approved for use in active and intelligent materials, anticipated to be in July 2010.

4. **Territorial Extent and Application**

4.1 This instrument applies in relation to Scotland only. Separate but parallel legislation is being enacted for England, Northern Ireland and Wales.

5. **Consultation**

5.1 The Food Standards Agency (“the Agency”) held two informal consultations with stakeholders in 2006 and later in 2008. Neither consultation raised any pertinent issues about the cost implications in relation to the AIM Regulation from businesses or enforcement authorities.

5.2 The Agency held a four week consultation with stakeholders and enforcement authorities in 2009. Two hundred and ten stakeholders were consulted on these proposals. These included food industry organisations, those manufacturing food contact materials, consumer organisations, as well as those with other interests in food contact materials and local enforcement authorities.

5.3 One response was received from Aberdeen City Council to acknowledge receipt of the consultation.

6. **Guidance**

6.1 Guidance for business has not been developed as this is a temporary measure as the requirements on them arise from the European regulation and not this SSI. However, full guidance for all parties on the entirety of the EU and National regulations will be issued when the other provisions of the European Regulation are addressed by a full SSI that will replace the current 2007 regulations and this amending SSI by the middle of next year.

7. **Financial Effects**

7.1 The AIM regulation applies to all businesses as the provisions relate specifically to labelling of parts of the package, as well as the written declaration of legal compliance which should be shown to enforcement authorities upon request. The Regulation would also give local authorities responsibility for enforcing these provisions.

7.2 The primary business sector that will be affected by the regulatory proposals will be manufacturers, importers, converters and fillers of food contact materials and in particular, those manufacturers that use active and intelligent systems in their products. No comments were received from businesses in this instance. European representative bodies of industry sectors and consumers were routinely involved throughout the European negotiations.

7.3 All respondents were thanked for their comments and where required, responses were sent.

7.4 These proposals have no particular impact on charities or voluntary organisations; rural areas; nor on members of the ethnic communities or any particular racial group.

7.5 There may be an impact on the Agency in its role as the competent authority as defined by the proposed Regulations and as and when it carries out compliance surveys on goods on the market. This impact may involve having to carry out more research into the migration of substances from food contact materials, including work to establish methodologies for determining such migration and to ensure compliance with the legislation.

7.6 A Regulatory Impact Assessment has not been prepared for this instrument.

8. **Regulating small business**

8.1 The impact on small and medium sized businesses is unlikely to be significant. This view has been supported by industry following earlier consultations, when they indicated that the proposals would not disproportionately affect them, nor would they hinder competitiveness.
Such businesses are also encouraged to respond to issues which they feel may have an impact on their ability to compete in the wider market. To date no comments have been received from small businesses.

9. Monitoring & review

9.1 Central and local authorities in Scotland routinely monitor foodstuffs on sale to the public to ensure compliance with the Regulations. The results of this work carried out by the Agency are published and are available on the agency’s website at:

http://www.food.gov.uk/science/research/researchinfo/contaminantsresearch/

9.2 We shall therefore, routinely survey materials and articles on the market to ensure compliance with the Regulations. The Agency will work with enforcement authorities where problems or suspected infringements of the Regulations arise. The effectiveness of the Regulations will be also be monitored via feedback from stakeholders as part of the ongoing policy process and will be reviewed in March 2011.

10. Contact:

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Food Standards Agency Scotland,
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Aberdeen, AB11 6NJ
01224 285170
fiona.bruce@foodstandards.gsi.gov.uk
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’).


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

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.
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.

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).

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.

Commission Directive 2004/6/EC implemented a derogation which permitted the use of new substances in peanuts 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 peanuts foods within the EC after that date.

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.

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

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 peanuts 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
Comhairle 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.
Inverclyde 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 Margaret 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