EXECUTIVE NOTE

THE FOOD SUPPLEMENTS (SCOTLAND) AMENDMENT REGULATIONS 2007 SSI/2007/78

The above instrument is made by Scottish Ministers in exercise of the powers conferred by Sections 16(1)(a) and (e) and 17(1) of the Food Safety Act 1990 and of all other powers enabling them on that behalf, having had regard in accordance with Section 48(4A) of that Act to relevant advice given by the Food Standards Agency and after consultation as required by Article 9 of Regulation (EC) No 178/2002 of the European Parliament and of the Council. The instrument is subject to negative resolution procedure.

Policy Objectives

1. This instrument, which extends to Scotland, amends the Food Supplements (Scotland) Regulations 2003, SSI 2003/278.

    - in order to implement Directive 2006/37/EC amending Annex II to Directive 2002/46/EC of the European Parliament and of the Council as regards the inclusion of certain substances.

2. These Regulations :

    - add another form of the vitamin folate and another form of the mineral iron to the positive list in Schedule 2 to the 2003 Regulations (regulation 5) and make a consequential amendment (regulation 4);

    - update the definition of Directive 2002/46/EC in the 2003 Regulations (regulation 3).

Legislative Background

3. The 2003 Regulations prohibit the sale of a food supplement in the manufacture of which a vitamin or mineral has been used unless that vitamin or mineral is listed in Schedule 1 to those Regulations and is in a form listed in Schedule 2 (the positive lists), subject to a transitional provision (regulation 5 and Schedules to those Regulations).

4. Derogation from the requirement for vitamin and mineral substances to be listed in the Annexes to the Directive has been allowed in the UK where safety dossiers were submitted for assessment by the European Food Safety Authority (EFSA) not later than 12 July 2005. The derogation may apply until the end of 2009.

5. The derogation to Article 4(1) of Directive 2002/46/EC applies to the two substances in the UK, therefore they may currently be used in food supplements in the UK market.

6. Implementation of Directive 2006/37/EC will allow products containing the two substances to be sold throughout the EU indefinitely.

Consultation

7. A consultation package was issued to a wide range of stakeholders on 13 November 2006 on the draft Scottish Statutory Instrument and draft Regulatory Impact Assessment. A full list of consultees is attached. This meets the consultation requirements of Article 9 of Regulation (EC) No 178/2002 of the European Parliament and the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.

8. The consultation period was less than the recommended 12 weeks, to meet both the EU timetable and parliamentary timing and so ensure parallel implementation. Extra efforts to make this shortened consultation as effective as possible included additional informal consultation with key stakeholders.

Other Administrations

9. Similar Regulations will apply in England, Wales and Northern Ireland.

Financial Effects

10. The inclusion of the substances in the proposed Regulations makes no substantial change to the products available on the market, therefore the instrument itself is not considered to incur significant additional costs to either industry or enforcement authorities.

Food Standards Agency Scotland
09 February 2007

THE FOOD SUPPLEMENTS (SCOTLAND) AMENDMENT REGULATIONS 2007

Consultee List

Aberdeen City Council
Aberdeen University
Aberdeenshire Council
Angus Council
Animal Health Distributors Association (UK)
Argyll & Bute Council
Association of Public Analysts
Ayr, Prestwick & Troon LHCC
Balfron High School
Bearsden Academy
Beatson Institute for Cancer Research
Biomedical Research Centre
Blairgowrie High School
British Dietetic Association
British Egg Products Association
British Nutrition Foundation
Brooks-Carter Clinic
Cairnton House
Cameron Hospital
Castle MacLellan Foods
Centre for Public Health Nutrition Research
Charis Innovative Food Services Ltd
City of Edinburgh Council
Clackmannanshire Council
Comhairle Nan Eilean Siar
Convention of Scottish Local Authorities (CoSLA)
Diary UK - Scotland
Dumfries & Galloway Council
Dundee City Council
Dundee Primary Care Division
East Ayrshire Council
East Dunbartonshire Council
East Lothian Council
East Renfrewshire Council
Edinburgh Community Food Initiative
ES – Falkirk Council
Fife Council
Fife Council Environmental Services
Food Certification (Scotland) Ltd
Food Industry Foundation (F2i)
Food Training & Consultants Co.
Forth Valley Primary Care NHS Trust
Forum of Private Business (Scotland) Ltd
FRS Marine Laboratory
Galashiels Academy
Glasgow City Council
Glasgow Scientific Services

Glenrothes College
Grants Foods Scotland Ltd
Greater Glasgow NHS Board
Greenwood Academy
Health Services Research Unit
Highland Council
Highland NHS Board
Hutchison Associates Ltd
Inverclyde Council
Kingdom Bakers Ltd
LACORS
Lanarkshire Health Board
Lees of Scotland
Lightbody Celebration Cakes
Lothian Primary Care Trust
Mackays Ltd
Macsween of Edinburgh
McAusland Crawford
Midlothian Council
Napier University
Neogen Europe Ltd
Neville Craddock Association
NHS Grampian Health Promotions
NHS Greater Glasgow & Clyde
NHS Health Scotland
NHS Tayside
North Ayrshire Council
North Lanarkshire Council
Orkney Herring Co Ltd
Orkney Islands Council
P&C Productions
Perth & Kinross Council
Purely Scottish Mineral Water Distribution Ltd
Queen Margaret University College
Regulatory Solutions
Robert Gordon University
Robert Wisemans Dairies
Roche Vitamins (UK) Ltd
Rowett Research Institute
Royal College of Physicians & Surgeons of Glasgow
Royal Environmental Health Institute of Scotland
SAC
Sanquhar Academy
Scotch Whisky Research Institute
Scottish Association of Master Bakers
Scottish Borders Council
Scottish Chambers of Commerce
Scottish Civic Forum

THE FOOD SUPPLEMENTS (SCOTLAND) AMENDMENT REGULATIONS 2007

Consultee List

Scottish Commission for the Regulation of Care
Scottish Committee Public Health Medicine
Scottish Consumer Council
Scottish Crop Research Institute
Scottish Enterprise Food & Drink
Scottish Executive
Scottish Food Safety Officers Association
Scottish Food Service Project
Scottish Health Food Retailers Association
Scottish Parliament
Scottish Retail Consortium
Scottish Salmon Producers Organisation
Scottish Salmon Smokers Association
Scottish Shellfish Marketing Group Ltd
Scottish Universities Environmental Research
Sea Fish Industry Authority
SEERAD
SEHD
Shetland Islands Council
Simply Healthy – The Health Store
Society of COs Environmental Health in Scotland
South Ayrshire Council
South Lanarkshire Council
Spicemanns Ltd
Stirling Council
Stirling Council (Catering & Cleaning)
Tayside NHS Board
TESCO Stores Ltd
The British Dietetic Association
The Cheese Company
The Deeside Water Company Ltd
The Halal Food Authority
The Moray Council
The National Trust for Scotland
The Sandwich Company
United Central Bakeries Ltd
University of Abertay
University of Dundee
University of Edinburgh
University of Glasgow
University of Paisley
Vegetarian Economy & Green Agriculture (VEGA)
Verner Wheelock Associates

Well Being 4 All
West Dunbartonshire Council
West Lothian Council
Wight Chiropractic Clinic
Yorkhill NHS Trust
Zonker Organics
8 members of public

FULL REGULATORY IMPACT ASSESSMENT

1 TITLE OF PROPOSAL

1.1 The proposal is for a Scottish Statutory Instrument (SSI) with the title : The Food Supplements (Scotland) Amendment Regulations 2007

2 PURPOSE AND INTENDED EFFECT

Objective

2.1 The proposed Regulations implement, in Scotland, Directive 2006/37/EC of 30 March 2006 amending Directive 2002/46/EC relating to food supplements ('the Directive'). They amend the Food Supplements (Scotland) Regulations 2003, SSI 2003/278.

Important Note

2.2 Further amendments to the Directive are expected between 2007-2009. These will add further substances to the lists in the Annexes to the Directive and these changes will subsequently be implemented into national legislation.

3 Devolution

3.1 Directive 2006/37/EC must be implemented into national legislation in Scotland in order to comply with general Community legislation by 30 April 2007.

3.2 The proposed Regulations would apply to Scotland only. Similar parallel legislation will be made in England, Wales and Northern Ireland.

4 Background

4.1 The Directive, which is implemented in Scotland by The Food Supplements (Scotland) Regulations 2003 SSI/278, lays down certain requirements relating to food supplements.

4.2 Food supplements are defined as food sold in dose form whose purpose is to supplement the normal diet, and which is a concentrated source of a vitamin or mineral or other substance with a nutritional or physiological effect, alone or in combination.

4.3 The Directive lays down a framework for Community rules on food supplements marketed as foodstuffs in order to promote the free movement of goods; ensure a high level of consumer protection; facilitate consumer choice through improved labelling requirements; and facilitate efficient monitoring of food supplements on the market.

4.4 The Directive specifies the vitamin and mineral substances, forms and units of measurement which may be used in food supplements and the labelling, presentation and advertising allowable. Positive lists of permitted vitamins and minerals and their sources are included in the Annexes to the Directive. Modifications to the positive lists in the Directive shall be adopted following a positive assessment of safety data by the European Food Safety Authority (EFSA) and agreement by Member States at the Standing Committee of the Food Chain and Animal Health.

4.5 Derogation from the requirement for vitamin and mineral substances to be listed in the Annexes to the Directive has been allowed in the UK, where safety dossiers were submitted for assessment by EFSA not later than 12 July 2005. Derogation may apply until the end of 2009, if EFSA has not given an unfavourable opinion in respect of the use of that substance.

4.6 The Directive provides that specific rules concerning nutrients other than vitamins and minerals should be laid down at a later stage, provided that adequate and appropriate data about them become available. It also provides scope for future amendments to establish maximum and minimum levels of nutrients used in food supplements.

4.7 Directive 2006/37/EC amends the Directive by adding two new substances to the positive lists in Annex II. The derogation to Article 4(1) of the Directive applies to those substances in the UK, therefore they may currently be used in food supplements on the UK market. Implementation of Directive 2006/37/EC by Member States will allow products containing the two substances to be sold throughout the EU indefinitely.

5 Provisions in the proposed Regulations

The key proposals for the amendment Regulations are:

5.1 **In Schedule 1** (which lists vitamins and minerals which may be used in the manufacture of food supplements)

- to amend the heading ‘FOLIC ACID’ to ‘FOLATE’.

5.2 **In Schedule 2** (which sets out the form of vitamin and mineral substances which may be used in the manufacture of food supplements) to make the following changes :

- **Section A (Vitamins)** - to amend the heading ‘FOLIC ACID’ to ‘FOLATE’ and under that revised heading insert Calcium-L-methylfolate as a substance that can be used in food supplements
- **Section B (Minerals**) - insert Ferrous bisglycinate as a substance that can be used in food supplements.

6 Rationale for Government Intervention

6.1 Both Calcium-L-methylfolate and Ferrous bisglycinate have received a favourable opinion from EFSA and agreement at the Standing Committee of the Food Chain and Animal Health.

6.2 The amended Directive and the implementing Regulations address the risk that certain food supplements not currently included in the Annexes would otherwise have to come off the market. The new legislation will permit the continued marketing of products and increase the number of substances listed in the legislation that can be added to food supplements, thereby enabling continuing consumer choice and reducing the impact of Directive 2002/46/EC on industry.

6.3 The heading 'Folic acid' in Annex II of the Directive 2002/46/EC has been amended to 'Folate' to allow a broader range of substances to be added to the list, including calcium-L-methylfolate. In amending the national Regulations, this change has been applied to the headings in both Schedule 1 and Schedule 2. This is needed to give legal effect to the intention and purpose of the change to Annex II of the Directive. There is no change to the labelling requirements for food supplements.

7 CONSULTATION

7.1 Consumer and health professional groups, manufacturers and industry bodies, enforcement bodies, individuals and other government departments have been formally consulted on these draft amending Regulations.

Result of Consultation in Scotland

7.2 Food Standards Agency Scotland received one response which was supportive of the proposals which was fed into the UK summary of responses.

Result of UK-wide Consultation

7.3 In response to the formal consultation, 7 responses were received UK-wide.

7.4 The majority of the responses supported the introduction of the Regulations. Two trade associations made comments which have been noted and will be followed up as necessary. However, they did not raise impact or cost implications, or objections to the proposed Regulations, therefore no changes were made to the text of the SSI as a result of the consultation.

7.5 A summary of responses received will be made publicly available, including on the Food Standards Agency's website.

8 OPTIONS

Flexibility

8.1 Directive 2006/37/EC ('the amending Directive') does not offer flexibility in its implementation. Options for transposing the provisions are limited to:

8.1.1 **Option 1**: Do nothing. This would mean that the amending Directive would not be implemented.

8.1.1.1 Failure to implement would bring risks and disbenefits to consumers, industry, enforcement authorities and Government. Consumers would no longer have access to a number of beneficial products currently on the market and industry, which would have to remove products from the market. It would also intensify the burden on enforcement authorities whose officers would have increased enforcement responsibilities. Failure to implement would also be a risk to Government as it would create a serious breach of the UK's obligations under the EC Treaty. This would attract infraction proceedings by the Commission against the UK under Article 226 of the EC Treaty and carry with it the likelihood of heavy fines. Other Member States could also initiate action under Article 227. Ultimately, the UK would be forced to implement.

8.1.2 **Option 2**: Implement the provisions of the amending Directive by 30 April 2007 as required in accordance with Article 2 of that Directive.

8.1.2.1 There are no risks or disbenefits attached to Option 2.

9 COST AND BENEFITS

Sectors and Groups affected

9.1 The sectors and groups affected will be the same as those identified in the RIA which accompanied the original Regulations as below.

Business Sectors affected

9.2 Businesses affected by the amendment are companies producing or distributing those food supplements added to the positive lists. In the UK, the majority of food supplement sales are from pharmacies and grocery multiples. Health food shops and other retail outlets, such as drug stores, account for the rest of the market. The estimated market value for all food supplements in the UK in 2005 was £362m. As the inclusion of the substances under discussion in this document makes no substantial change to the products available on the market, it is unlikely that significant costs relating to alteration of labelling, reformulation or loss of products will be incurred by these businesses.

Consumers affected

9.3 We do not envisage any impact as a result of this legislation on consumers generally, nor specifically in terms of gender, age, health or income. We consider that the legislation will have no impact on disabled people or those living in different regions or in rural communities. We believe that the proposal will have no impact on racial equality issues.

Voluntary Organisations and Charities

9.4 We are not aware of any charities or voluntary organisations that would be affected by the legislation.

Public Sector

9.5 Government and enforcement officers would not be significantly affected by the legislation – implementation would benefit enforcement officers, by maintaining the status quo and government, by removing the risk of incurring infraction proceedings.

Benefits

9.6 **Option 1**: failure to implement would not bring any benefits to consumers, industry, enforcement authorities or Government as it would not allow products containing the two substances to be sold throughout the EU indefinitely.

9.7 **Option 2:** implementation maintains benefits to consumers, industry, enforcement authorities and Government. It benefits consumers by maintaining consumer choice; industry by permitting the continued marketing of products; enforcement officers by maintaining the status quo and Government by removing the risk of invoking infraction proceedings. Implementation will allow products containing the two substances being added to the positive lists in Annex II to be sold throughout the EU indefinitely.

Costs

9.8 **Option 1**: Potential costs to government due to under-implementation of EC Directive.

9.9 **Option 2**: We consider that there are no costs to consumers, businesses, enforcement authorities or Government associated with implementation of these amendments to the Directive, other than administrative costs to the Government.

9.10 The environmental impact of the new Regulations is likely to be negligible.

10 Small Firms Impact Test

10.1 The Agency considers that the proposal will have no impact specifically on small firms. This was confirmed by the Small Business Service.

11 Impact on Regions

11.1 Any regional differences in benefit due to the new legislation would depend upon the location of the relevant business. We are not aware of any differential impact.

12 Test Run of Business Forms

12.1 There are no new forms associated with this piece of legislation.

13 Competition Assessment

13.1 Results of the competition filter questionnaire at www.cabinetoffice.gov.uk/regulation/ria/ria guidance/competition assessment.asp indicated that undertaking a detailed analysis of competition effects would be unnecessary. The market affected is the food supplements industry. This is fairly fragmented with a large supply base including large pharmaceutical companies, high street names and both large and small specialist companies. The changes will enable the two substances to be marketed across Europe in addition to the UK as at present.

No	Question	Y/N
1	In the market(s) affected by the new regulation, does any firm have more than 10% market share?	Y
2	In the market(s) affected by the new regulation, does any firm have more than 20% market share?	Y
3	In the market(s) affected by the new regulation, does any firm have more than 50% market share?	N
4	Would the cost of regulation affect some firms substantially more than others?	Unlikely
5	Is the regulation likely to affect the market structure, changing the number or size of firms?	Unlikely as the changes are incremental and no single firm utilises only one or two substances
6	Would the regulation lead to higher set-up costs for new or potential firms that existing firms do not have to meet?	N
7	Would the regulation lead to higher ongoing costs for new or potential firms that existing firms do not have to meet?	N
8	Is the market characterised by rapid technological change?	N
9	Would the regulation restrict the ability of firms to choose the price, quality, range or location of their products?	N

14 Enforcement, Sanctions and Monitoring

14.1 Local Authorities are responsible for enforcing The Food Supplements (Scotland) Regulations 2003. Responsibilities for enforcement, sanctions and monitoring are the same as those set out in the original legislation namely :

14.1.1 The penalty on conviction for an offence under the domestic Regulations is a fine not exceeding level 5 on the standard scale (currently £5,000).

14.1.2 The Regulations will be monitored via feedback from stakeholders as part of the ongoing policy process.

14.1.3 Article 4(8) of the Directive states that, not later than 12 July 2007, the Commission shall submit to the European Parliament and the Council a report on whether the Directive should be amended to increase its scope to include other nutrients as well as vitamins and minerals including a proposal for any amendments to the Directive that the Commission deems necessary.

15 Post-implementation review

15.1 The Directive does not provide a specific review date and there is no provision in the main Directive for a review. It is likely, however, that further amendments to the Annex of 2002/46/EC will be made by further amending Directives following future scientific evaluation of more vitamin and mineral substances by EFSA.

15.2 Food Standards Agency Scotland is committed to ensuring that all Regulations introduced are, and remain, proportionate and fit for purpose. In line with Scottish Executive guidance provided by Improving Regulations in Scotland (IRIS) Unit, we will review the continued effectiveness of this Regulation through the use of a Review Regulatory Impact Assessment. This will be completed within 10 years of the date of the Regulation coming into force.

16 SUMMARY AND RECOMMENDATION

16.1 Food Standards Agency Scotland is obliged to implement the provisions of Directive 2006/37/EC into Scottish law. The Agency recommends that **Option 2** is the best course of action. It will fulfil the UK's community obligations by providing for the Directive's enforcement, allowing the Agency to fulfil objectives in producing these Regulations. These objectives were :

16.1.1 to fulfil our Community obligation to implement the provisions of the Directive;

16.1.2 to maintain the widest possible consumer choice of safe and properly labelled food supplements;

16.1.3 to ensure adequate protection of public health yet reduce the negative impact on industry.

Declaration :

I have read the Regulatory Impact Assessment and I am satisfied that the benefits justify the costs.

Signed by the responsible Minister : **LEWIS MACDONALD**……..

Date : **14th February 2007**…….

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REGULATORY IMPACT ASSESSMENT

1. **Title of proposed regulations**: The Food Supplements (Scotland) Regulations 2003

2. Purpose and Intended Effect of the Measure

2(i) Purpose

The Regulations implement, in Scotland, Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member State (MS) relating to food supplements. The Regulations concern the composition and labelling of food supplements.

2(ii) Intended Effects

The Directive lays down a framework for Community rules on food supplements marketed as foodstuffs in order to promote the free movement of goods; ensure a high level of consumer protection; facilitate consumer choice through improved labelling requirements; and facilitate efficient monitoring of food supplements on the market. The Regulations implement Directive 2002/46/EC and introduce measures, in Scotland, to meet the following objectives:

- introduce into legislation, for the first time, a definition of the term ‘food supplement’;
- introduce into legislation, for the first time, a list of the vitamins and minerals that may be used in food supplements together with a list of the permitted chemical forms (sources) of these vitamins and minerals - the so-called ‘positive lists’;
- prohibit the sale of vitamin or mineral supplements unless these compositional requirements are met, subject to a transitional provision;
- prohibit the sale of a food supplement to the ultimate consumer unless it is in a pre-packaged form;
- introduce mandatory labelling requirements for food supplements in addition to those applied to most foodstuffs by the existing Food Labelling Regulations 1996 (as amended); and prohibit the sale of food supplements that do not comply with these requirements;
- make provision as to responsibilities for enforcement; create offences and penalties and apply certain provisions of the Food Safety Act 1990. The Regulations also provide a defence in relation to exports, in accordance with Articles 2 and 3 of Council Directive 89/397/EEC (OJ No. L186, 30.6.89, p.23) on the official control of foodstuffs.

2(iii) Devolution

EC Directive 2002/46/EC must be implemented into national legislation in Scotland in order to comply with general Community legislation by 31 July 2003. Similar, parallel legislation will be adopted in England, Wales and Northern Ireland to bring the whole of the UK into line with the general community.

3. Background

Prior to the adoption of Directive 2002/46/EC there was neither a definition of the term 'food supplements' nor any specific legislation on food supplements in EU or in UK law. There are an increasing number of products marketed in the Community as foods containing concentrated sources of nutrients and presented as supplementing the intake of those nutrients from the normal diet. These products have, up to now, been regulated by different national rules that have resulted in different levels of consumer choice, have impeded free movement of food supplements, created unequal conditions of competition and have had a direct impact on the functioning of the internal market.

At present, in Scotland most products described as dietary or food supplements are regulated as foods and subject to the general provisions of the Food Safety Act 1990, the Food Labelling Regulations 1996 (as amended) and the Trade Descriptions Act 1968. The Food Safety Act makes it an offence to sell food that is not safe for consumption, not of the nature, substance or quality demanded by the consumer or that is falsely or misleadingly described or labelled. The Trade Descriptions Act lays down general prohibitions on misdescriptions of goods provided in the course of trade. The Food Labelling Regulations lay down general labelling requirements and prohibit the use of medicinal claims.

Food supplements, like other foods, are not required to demonstrate their efficacy before marketing, nor are they subject to prior approval unless they are genetically modified or are "novel". It is the responsibility of the manufacturer, importer or distributor to ensure that their product complies with the necessary legislation.

The Directive offers MS a number of areas of flexibility when transposing the provisions of Directive 2002/46/EC; these are as follows:

- **Article 4** contains a derogation allowing MS to permit, in their territory, the continued use of vitamins and minerals not on the 'positive lists' until 31 December 2009. This derogation may be applied to each substance in question subject to three conditions:

1) that the substance was used in one or more food supplements marketed in the Community on the date of entry into force of the Directive (12 July 2002),

2) that a safety dossier is submitted to the Commission no later than 12 July 2005 *and*
3) that the European Food Safety Authority (EFSA) has not given an unfavourable opinion in respect of the use of that substance in the manufacture of food supplements;

- **Article 10** allows MS to require the manufacturer or the person placing a food supplement product on the market to notify the competent authority of that by forwarding to it a model of the label used for the product;

- **Article 15** requires MS to bring into force laws, regulations and administrative provisions necessary to prohibit trade in products which do not comply with the Directive from 1 August 2005 at the latest.

4. Risk Assessment

4(i) Risks

In implementing the Directive the Regulations have been drafted to address the following risks:

1. a risk to consumers from the marketing of food supplement products that are unsafe due to their composition (quantity or source of vitamin or mineral contained) or are inadequately labelled;
2. a risk of distortion of the internal market for food supplements;
3. a risk to industry (businesses and their employees) that a large number of safe products currently on the market in this country could be removed from sale unnecessarily; *and*
4. a risk to consumers that consumer choice could be unnecessarily reduced by removing safe products from the market.

4(ii) Risk To Consumers

A large number of people consume food supplements. A target group index (TGI) survey of 25,000 UK adults in 1998 showed that 40.9% of consumers were users of vitamins and minerals with the greatest use being in the 55+ years age group[1]. In general, women are greater users than men (47% compared to 35% according to TGI survey 2000). Typical regular consumers of food supplements are women aged 45 years and over and men over 65 years[2]. Trends in the UK population indicate that the percentage of the population in these age groups is likely to increase over the next few years. Consequently, if current trends continue, the number of older consumers of food supplements is likely to rise. It is known that older people are

[1] Ransley, J.K., Donnelly, J.K., Reed, N.W. (eds) (2001) Food and Nutritional Supplements. Berlin: Springer Verlag.
[2] Greenhalgh, A et al. Cited in Ransley, J.K., Donnelly, J.K., Reed, N.W. (eds) (2001) Food and Nutritional Supplements. Berlin: Springer Verlag.

more susceptible to adverse side effects of some medicines. There is a general absence of evidence on whether or not older people are at risk from high levels of supplements, except in the case of manganese for which there is evidence of increased risk.

Data from the UK Women's Cohort Study[2] showed that the mean annual expenditure per person was £88 within a range from £5 - £360. Those from higher socio-economic groups spent more on supplements than those from lower socio-economic groups.

There is no UK system for recording adverse reactions to food supplements. A very small number of adverse reactions are reported through the General Practitioner (GP) yellow card system used for medicines. However, consumers and GPs are unlikely to suspect food supplements as being a possible cause of ill health, except if a rapid response, such as nausea or vomiting is experienced soon after taking the supplement. Thus, although the number of reported adverse reactions associated with food supplements is low compared with the numbers of products on the market, no conclusions can be drawn about the actual incidence of adverse reactions.

In 1998 the UK set up an Expert Group on Vitamins and Minerals in response to concerns about consumption of high dose food supplements and to inform discussions at EU level about maximum limits of vitamins and minerals in food supplements. The group published its report on the 8 May 2003. The Directive sets out a framework within which maximum levels of vitamins and minerals in food supplements will be set in future. This, together with the fact that the 'positive lists' consist of substances whose safety has been assessed, means that the Directive and hence the Regulations, will provide a basis for increased consumer protection.

4(iii) Risk of Distortion of the Internal Market

Within the EU the size of the market for vitamin and mineral food supplements varies widely from one MS to another with the UK and the Netherlands having particularly large markets. Across the UK the increased growth in sales of vitamin, mineral and other food supplements over the period from 1994 to 1998 was 55%[3].

[3] Ransley, J.K., Donnelly, J.K., Reed, N.W. (eds) (2001) Food and Nutritional Supplements. Berlin: Springer Verlag.

4(iv) Risk To Industry

The new compositional standards potentially present more of a risk to industry than to consumers since the 'positive list' of permitted vitamin and mineral sources currently exclude some 270 individual sources of vitamins and minerals presently contained in food supplements produced and/or marketed in this country. However, in the main this group comprises different sources of 19 permitted vitamins and minerals. For only six minerals used in UK products are there no sources listed. These new compositional standards could result in the loss of some food supplement products from the market in the long-term. However, the 'positive lists' remain open and sources may be added to them after assessment of safety dossiers submitted to the Commission for assessment by an EU Scientific Committee.

Implementation of the Directive in all MS is intended to remove the current distortion of the internal market and may open up markets for UK products in other MS although it could also have the effect of restricting the range of products currently on sale in this country.

4(v) Consumer Choice

Any reduction in the range of products on the market would also reduce consumer choice. For products containing substances excluded from the 'positive lists' but which are currently marketed in the UK, this reduction in choice appears unnecessary.

5. Issues of Equity and Fairness

It is intended that the provisions of Directive 2002/46/EC apply to all businesses throughout the Community. There is no disadvantage for Scottish businesses. The new Regulations will be equally applicable to large and small businesses concerned with the production or sale of food supplements. For manufacturers the Regulations may, in the long-term, have a greater negative impact on those that produce or use vitamin and mineral sources currently excluded from the 'positive lists' than on those that produce or use substances already on the 'positive lists'. For retailers the long-term impact of the Regulations is likely to depend upon the Regulations' effect on the number of products on the market. However, the full extent of the impact will not be known until the end of the derogation period i.e. 31 December 2009.

6. Options and Benefits

6(i) Options

There are a number of options for transposing the provisions of Directive 2002/46/EC:

Option 1: do nothing i.e. fail to implement the Directive;
Option 2: implement all the provisions of the Directive that must be transposed into national legislation and also the provisions of Article 10;
Option 3: implement all the provisions of the Directive that must be transposed into national legislation and do not transpose the provisions of Article 10;
Option 4: implement all the provisions of the Directive that must be transposed into national legislation; do not transpose the provisions of Article 10; make use of the derogation in Article 4(6).

6(ii) Benefits and Disbenefits of Options

Option 1: failure to implement the Directive could, for a limited period of time, be perceived to avoid disbenefits to consumers as a result of reduced consumer choice. However, it would fail to deliver improved long-term consumer protection, particularly to older consumers. If we failed to implement the Directive, consumers in Scotland would benefit from the continued availability of all those products currently on the market until transposition was forced upon us. The food supplement industry would not suffer the restrictions on the number of substances that could be used to manufacture food supplements. However, failure to implement would represent a serious breach of the UK's obligations under the EC treaty and would be likely to attract infraction proceedings. Ultimately this is not a viable option.

Option 2: implementation of all the provisions of the Directive would lead to the greatest change from the current regulatory regime in Scotland. It would bring consumer benefits in terms of improved consumer protection but some disbenefits to consumers in terms of reduced choice. They may however, have greater confidence in those products remaining on the market. There would be disbenefits to manufacturers and sellers of food supplements in terms of products lost from the market without the ameliorating effect of the transitional arrangements offered by the derogation in Article 4 (see option 4). Furthermore, the provisions of Article 10 of the Directive would result in industry having to meet the notification requirements each time a product was brought to market. Although implementing the Directive in full (including Article 10) would bring small consumer benefits through closer monitoring of the market, the additional benefit would not be sufficient to outweigh the disbenefits discussed above.

Option 3: implementing all of the provisions of the Directive that must be transposed into national legislation without implementing Article 10. This provides the same benefits and disbenefits for consumers and industry as option 2, except that the costs and administrative burdens associated with notification would not apply.

Option 4: Making use of the derogation in Article 4(6) of the Directive, which allows us to permit the continued use of vitamins and minerals not on the 'positive lists' until 31 December 2009, would benefit consumers and industry by maintaining a wide consumer choice of food supplement products and continued sale of products already on the market for the longest possible time. This represents a situation as close as possible, within the constraints imposed by the Directive, to the current regulatory regime in Scotland. Compared with Options 2 and 3 this option reduces the risk to consumers and industry of losing products from the market before 2005.

Some responses to the consultation suggested a fifth option: implementing the Directive in full, but seeking an amendment prior to the regulations coming into force to allow national marketing of products considered safe but otherwise not on the 'positive list'. This would have the same benefits and disbenefits for consumers as option 4. For the industry, an obligation would still remain to demonstrate that the products to be marketed nationally were indeed safe for consumers. This would be a similar burden to the production of dossiers for products to be added to the 'positive list' on a community basis under option 4. However, there would be the disbenefit to industry that purely national permitted marketing rather than community wide marketing would fail to open up the European market to such products, which would be achieved under option 4. This option would not lead to harmonisation of the market. It is unlikely that the Commission would consider the reopening discussions on a Directive on which it has so recently secured a qualified majority. Ultimately this fifth option is not viable.

7. Background to the industry

The UK retail market for vitamins, minerals and other food supplements was valued at £335 million in 2000, an increase over 1999 of 2% in real terms[4]. The range of products on sale in the UK is greater than in many other MS. The levels of vitamins and minerals found in food supplements on the market here are, in many cases, higher than in other MS where levels are limited to 1-3 times the recommended daily allowance (RDA). Currently, some products sold under food law in the UK are restricted to sale under medicines legislation in other MS.

[4] Vitamin and Mineral Supplements. (May 2001) Mintel.

For food supplements supplied in the UK, manufacturers (figures for the year 1999) include multinational companies (approximately 41% of the market), private label companies (38.6%) and a number of small, specialist manufacturers which focus on supplying specialist products to different retail sectors e.g. pharmacy, health food and grocery stores.

In the UK (figures for 1999), approximately 40% of retail sales are accounted for by pharmacy chains, 26% by grocery multiples, 16% by health food shops, 13% by other drug stores and 5% by other retail outlets.

Figures provided by the Health Food Manufacturers' Association and The National Association of Health Stores indicate that there are approximately 7000 employees in the manufacturing sector and approximately 10,000 in retail (full and part-time) across the UK.

The Regulations will affect businesses involved in the production and sale of products marketed as food supplements. Any long-term impact of the Regulations on the range of products on the Scottish market would affect businesses involved in the manufacture and sale, including retail sale (e.g. health food shops, nutritional therapists), of food supplements and businesses involved in the manufacture and sale of vitamin and mineral sources used as ingredients in food supplements. Such businesses include both large companies and small and medium-sized enterprises (SMEs), which include specialist retail businesses.

8. Compliance Costs for Businesses

8(i) Compliance Costs

The most significant costs to business will arise from the decision of whether to submit safety dossiers for vitamin and mineral sources not currently on the 'positive lists', whether to reformulate products to include only ingredients contained on the 'positive lists', or whether to remove products from the market. Compliance costs also arise from new mandatory labelling requirements and possible loss of products from the market.

8(i.a) Labelling

Options 2, 3 and 4 above each involve costs to businesses arising from new labelling requirements. Initial cost estimates provided by food supplement manufacturers suggest that they could incur an increase in labelling costs of the order of £300 - £500 per product (a total of around £10m for the industry).

These costs will be difficult to offset through planned relabelling costs during the three-year transitional period as further labelling amendments (for example in relation to GM labelling and allergen labelling) will also impact on the planned relabelling activity. The overall impact on costs could be reduced, however, if the timelines for these amendments are co-ordinated. This is an issue that Food Standards Agency officials can pursue in Brussels.

8(i.b) Dossier preparation

Businesses that wish to continue to produce vitamin and mineral ingredients or wish to continue to produce and market food supplements with ingredients currently excluded from the 'positive lists' may choose to bear the costs of dossier preparation, or share the costs if collaboration between companies takes place. This would be a new, one-off cost.

The costs of submitting safety dossiers in support of ingredients not on the 'positive lists' are difficult to estimate but industry estimates that they might be as high as £80,000 – £250,000 per dossier. Under the Food Safety Act 1990 manufacturers and retailers are already prohibited from selling food which would be injurious to health and therefore should already have some safety information available in relation to products on the market which will reduce the cost of the safety dossiers. However, it is acknowledged that many may not have some data (e.g. toxological data) listed in the guidance on dossier content.

Industry representatives have attempted to have discussions with the Commission in order to work out an efficient and cost-effective procedure for preparing and submitting dossiers. The Food Standards Agency has also made contact with the Commission in order to facilitate such discussions where possible.

Once a dossier has been assessed and given a positive opinion by the EFSA and subsequently added to the 'positive lists', any food supplement business in the EU, not just the one(s) responsible for submitting the dossier, will be permitted to use that substance in their products.

8(i.c) Reformulation

Alternatively, businesses may choose to switch their resources to working with substances already on the 'positive lists' by reformulating products. Presumably such a decision would be based on a financial judgement that this course of action was likely to be more profitable in the long-term. Estimates of the cost of reformulating products if ingredients currently used are not on the 'positive lists' are up to £3,000 per product (a total of up to £4m for the industry as a whole based on the industry's estimate that 5% of the market might be affected).

8(i.d) Loss of products

Companies currently using substances missing from the ‘positive lists’ for which safety dossiers are not submitted and in due course given ‘positive opinions’ will eventually be prohibited from manufacturing and selling products. In the main these are specialist brand companies.

8(i.e) Costs for a Typical Business

Indications are that there is no such thing as a typical business in this sector. Cost estimates gathered during the consultation process ranged from an indication that the impact of the Regulations is likely to be negligible, despite one-off costs for product and labelling changes, while others have indicated that there could be a loss of up to 100% of their turnover. A trade association considered that independent health food stores are likely to lose up to £28.4million trade value (15% of turnover) if the Directive is fully implemented.

8(ii) Small Business 'Litmus Test'

During the UK consultation process the Food Standards Agency has endeavoured to establish the proportion of small businesses in the food supplements industry and the impact of the regulations on them. The Small Business Service was included in the UK consultation. In addition the Agency has been in contact with small businesses to determine if there are any issues that are particularly significant to them.

Generally, small manufacturing businesses would be likely to bear the same costs as larger companies, but these would be proportionately more onerous. In particular, the costs of dossier preparation for small businesses would be more burdensome. Where specialist retailers are involved a reduction in range of products may have a significant impact on their turnover and competitiveness.

9. Competition Assessment

Currently there are five large producers of supplements, with a significant number of medium-sized and smaller, highly specialised brands (including many own labels). There are three companies that each account for more than 10% of the market, with the top two accounting for over 20%; together all three account for 55% of the total market (by value) (Mintel, 2001). The structure of this (still growing) market is characterised by a wide diversity of suppliers, including recent new entrants (mainly small specialist suppliers).

Retaining the existing legislation under option 1 would not have a significant impact on competition since this would maintain the status quo.

Food Standards Agency Scotland expect producers of food supplements would have to bear most of the cost associated with these Regulations under options 2-4.

Options 2 and 3 are broadly similar as both seek to implement into national legislation all the obligatory provisions of the Directive. Both options might raise some competition concerns. Either option would create some small costs for business in the form of labelling requirements, but a more significant cost would arise for businesses wishing to continue to market vitamin and mineral supplements currently excluded from the 'positive lists'[5]. Such businesses would have to prepare safety dossiers to which a positive opinion would need to be given by the EFSA. Smaller businesses, particularly those which specialise in the supply of particular supplements, may be less able to pay this one-off sum. Businesses producing specialist, niche products are likely to be most affected by this but the Food Standards Agency does not have any information on what proportion of overall revenue may be derived from such products.

To seek to reduce the impact on businesses, option 4 proposes making use of the derogation that would permit, subject to specific criteria being met, the continued use of vitamins and minerals not on the 'positive list' until 31 December 2009. The Regulations allow industry the maximum time for submission of safety dossiers and thus allows the costs to be spread over financial years and allows revenues to be generated by these products for the maximum length of time

The Regulations may increase barriers to entry in some of the more specialised areas of the market, particularly in the short term. However, they will not lead to either higher set up, or ongoing, costs, for new entrants (over and above existing firms). This market is characterised by small compositional changes (to add value and induce brand loyalty) rather than rapid technological change. The Regulations may restrict the ability of firms to choose the range of the products they market in the short-term but overall is not likely to have a significant impact on competition levels if option 4 is adopted. The effect of dossier costs on small specialised businesses, and impact on product innovation, remain a concern.

[5] At this stage, it is unclear what proportion of supplements currently manufactured or used in products in Scotland would be on the 'positive list'.

10. Enforcement and Sanctions

Enforcement of the Scottish Regulations will be the responsibility of local authorities. It is expected that the monitoring of new label requirements and products permitted for sale under the Regulations will continue as part of existing enforcement procedures. Consequently, additional costs to local authorities are not anticipated.

The penalty on conviction for an offence under the domestic Regulations is a fine not exceeding level 5 on the standard scale (currently £5,000).

11. Monitoring and Review

The Regulations will be monitored via feedback from stakeholders as part of the ongoing policy process.

Article 4(8) of the Directive states that, not later than 12 July 2007, the Commission shall submit to the European Parliament and the Council a report on whether the Directive should be amended to increase its scope to include other nutrients as well as vitamins and minerals including a proposal for any amendments to the Directive that the Commission deems necessary.

In addition, the Scottish Executive is committed to ensuring that all Regulations are, and remain, proportionate and fit for purpose. In line with Scottish Executive guidance the continued effectiveness of this Regulation will be assessed through the use of a Review Regulatory Impact Assessment that will be completed before 31 July 2013.

12. Consultation

A written public consultation exercise on the draft regulations and partial regulatory impact assessment was carried out in Scotland over a 13 week period from November 2002 to February 2003. 167 Scottish stakeholders were contacted including consumers, health professionals, manufacturers, retailers, health food industry trade associations, enforcement authorities, Scottish Executive departments and other individuals with an interest in food supplements. The consultation was also freely available on the Agency's website.

10 responses to the consultation were received and one further stakeholder responded to the Regulatory Impact Assessment Questionnaire only. Of these, seven made substantive comments. One was broadly supportive of the Regulations while six focussed on the issues surrounding the inclusion of nutrient sources on the 'positive lists', the costs of preparation of dossiers and the potentially negative impacts of the Regulations, which are covered at paragraphs 8 and 9 above. No issues specifically relevant to Scotland were identified.

Comments were received from consumer representatives on a UK basis. Generally, consumer groups supported the Regulations, the introduction of the 'positive lists' and labelling requirements but expressed a concern about the potential impact on consumer choice.

A summary of the comments made can be viewed at the Food Standards Agency's website. All substantive comments were taken into consideration when drafting the Regulations.

13. Cost Benefits Analysis

The benefits and costs of the options associated with these Regulations are considered here. Only those costs which could both be quantified (usually within ranges) and given monetary values were explicitly considered. A summary of the costs and benefits is given in the table in Annex 1. This summary indicates that no option yields a net positive economic benefit.

Option 1 is not recommended due to problems associated with estimating the true level of benefits (the avoidance of adverse reactions, and the extent of current under reporting); furthermore, this option is not viable since it would result in the UK failing to fulfil its Community obligations.

Of the viable options, option 4 is recommended because, compared with options 2 and 3, the full use of MS derogation drastically reduces the costs on industry (by giving companies a longer period in which to adjust, thereby considerably reducing their costs) whilst still allowing health benefits to be derived. In order for this option to break even (and therefore surpass the option of doing nothing) adverse reactions would need to be ten fold greater than those levels currently reported (i.e. ten cases per year). It is important to note that this option means that some of the adverse reactions are less likely to be avoided until later – it has been assumed these will not appear until year five.

14. Summary and Recommendations

The UK is obliged to implement the provisions of Directive 2002/46/EC into Scottish law. Food Standards Agency Scotland recommends that option 4, is the best course of action, which allows the Agency to fulfil objectives in producing these Regulations. These objectives were;

1) to fulfil the Community obligation to implement the provisions of the Directive
2) to maintain the widest possible consumer choice of safe and properly labelled food supplements
3) to ensure adequate protection of public health yet reduce the negative impact on industry.

Declaration:

I have read the Regulatory Impact Assessment and I am satisfied that the benefits justify the costs.

Signed by the responsible Minister:.....

Date:.....……

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Annex 1

16.1.3.1 Summary of Cost Benefit Analysis – All Figures in £Mn

16.2 *Option*	16.2.1 Discounted Costs	Discounted Benefits	Discounted Net Benefits (NPV)
1 – Do Nothing (no costs to industry, society continues to bear health costs)	£0.20	0	- £0.20
2 – Implement, no derogation plus extra labelling costs (full costs to industry, extra costs to Agency officials, full health costs avoided)	£18.92	£0.20	- £18.73
3 – Implement, no derogation (costs to industry, full health costs avoided)	£18.32	£0.20	- £18.12
4 – Implement with full derogation (reduced costs to industry, full health costs avoided)	£0.96	£0.11	- £0.85

October 2002 Prices. Discount rate 3.5%. Costs and benefits over a 10-year period

Benefits relate solely to the avoidance of the economic costs associated with adverse reactions to food supplements. Although data are available there is believed to be massive under reporting; *available* data have reported 11 cases in an 11-year period – an average of 1 per annum. Most of these reactions have been minor and relate most closely to health state F[6] and

[6] Slight to moderate pain 2-7 days; some restrictions on work and leisure; full return to normal health state within 3 months based on average cost to UK society of this - DoT figure taken from Jones-Lee et al (1993)

benefits have been calculated on the avoidance of this state[7]. The calculations are based on the avoidance of all these cases (1 per annum over a 10-year period): this figure is widely thought to be a very large underestimate[8].

Costs relate to four different areas:

- **relabelling** at a one-off (industry estimated) cost of £10Mn, (at £3-500 per product) where member state derogation is not used (options 2 and 3);

- **dossier preparation** which industry estimates will be in the region of £80-250,000 (a total one-off cost of £0.99Mn based on range mid point and 6 dossiers) *or* **reformulation** if manufacturers choose not to submit dossiers (and inputs are not currently on 'positive list') with industry estimating a one-off cost of £4mn (£3,000 per product with 5% of product lines affected). The costs of dossier preparation only have been included in the calculations on the assumption that industry would wish to minimise costs (options 2,3 and 4);

- **revenue losses** to industry (manufacturers and retailers) if products not on 'positive lists' are withdrawn and because of their highly specialised nature are not replaced in the short-term (estimated to be 5% of the current market). It does not include any estimates associated with utility losses for consumers. This cost can be avoided if member state derogation used i.e. products can continue to be sold before dossiers approved – therefore only affects options 2 and 3;

- **Additional label supply and enforcement costs** (option 2 only). The former falls on industry to supply copies of all new product labels to the Food Standards Agency and assumed the bulk of these will be required in early part of this regulation coming into force[9]. The latter is administrative costs that will fall on the Food Standards Agency for logging each of these new labels[10].

[7] Average cost of each case was estimated at £22, 901 in June 2000 prices (DoT). Prices in calculations adjusted to October 2002 using RPI-all items index.
[8] However on the converse side it is likely that not all adverse reactions would be avoided
[9] There are approximately 20,000 product lines, it is assumed all these will be registered in the first year, with 2% of this total each year thereafter to represent new products at an assumed label supply cost of £5.
[10] For 20,000 product line, all logged in the first year and then 2% of this total for each year thereafter to represent new products – assumed each log will cost the Food Standards Agency £25 in staff and associated costs.