EXECUTIVE NOTE

1. THE FOOD SUPPLEMENTS, VITAMINS, MINERALS AND OTHER SUBSTANCES (SCOTLAND) REGULATIONS 2009 (SSI 2009/438)

The above instrument was made by the Scottish Ministers in exercise of the powers conferred by sections 16(1)(a) and (e),17(1) and (2) and 48(1) of the Food Safety Act 1990, as read with paragraph 1A of Schedule 2 to the European Communities Act 1972, and all other powers enabling them to do so. This instrument is subject to negative resolution procedure.

2. Policy Objectives

a. The purpose of the instrument is to implement into Scottish Law additions to lists of vitamins, minerals and their sources permitted for use in food supplements, made by Commission Regulation (EC) No 1170/2009 of 30 November 2009, amending Directive 2002/46/EC of the European Parliament and of the Council and Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards the lists of vitamins and minerals and their forms that can be added to foods, including food supplements (O.J. L 314, 1.12.2009, p. 36) ("the 2009 EC Regulation").

b. The instrument amends the Food Supplements (Scotland) Regulations 2003 to provide direct, ambulatory, references to the lists of permitted vitamins, minerals and their sources set out in European Community legislation and, to update references in the national regulations to legislation which has been amended since they were enacted.

c. The instrument also amends the Addition of Vitamins, Minerals and other Substances (Scotland) Regulations 2007 to provide for the execution and enforcement of additions to the lists of vitamins, minerals and their sources permitted for addition to food, as set out in European Community legislation.

3. Legislation

Necessity for failure to comply with the 21 day rule

The instrument is to come into force on 1 January 2010 and a letter will be lodged with the Presiding Officer explaining why the instrument will not comply with the 21 day rule. There are 2 principal reasons for this failure to comply.

Firstly, the 2009 EC Regulation was not published in the Official Journal of the European Communities until 1 December 2009, and comes into force on 21 December 2009. No steps to implement could be taken until that Regulation had been published. However, the instrument needs to be in force on 1 January 2010 in order to permit the continued use of 67 vitamin and mineral sources in food supplements which are currently permitted for use

under a derogation which will expire on 31 December 2009 (see further details in paragraph X below).

Secondly, similar provisions are being made in the other UK administrations to come into force on 1 January 2010, and it is important for food supplement producers that there is uniform implementation of the 2009 EC Regulation throughout the UK.

General Legislative Background

a. The instrument implements the 2009 EC Regulation in Scotland.

b. The instrument amends the Food Supplements (Scotland) Regulations 2003, as amended, (the Food Supplements Regulations) to update references to other legislation which has been amended since the Food Supplements Regulations were enacted. In particular, the instrument updates the reference, in regulation 3(2), to Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (as amended by Directives 2002/98/EC, 2003/63/EC and 2004/24/EC) as regards the definition of 'medicinal products' and the reference, in regulation 6(3)(e), to the Annex to Council Directive 90/496/EEC of 1 December 1990 on nutrition labelling for foodstuffs as regards recommended daily allowances, energy conversion factors and definitions

c. It also updates the definition of "EC Regulation" in the Addition of Vitamins, Minerals and Other Substances (Scotland) Regulations 2007 to include the amendments made by the 2009 EC Regulation.

4. Policy Background

Food Supplements

a. The Food Supplements Regulations implement, in Scotland, Directive 2002/46/EC of the European Parliament and of the Council on the approximation of the laws of Member States relating to food supplements (the Food Supplements Directive).

b. The Food Supplements Regulations prohibit the sale of food supplements containing vitamins and minerals not listed in Schedule 1 to these Regulations and those which are not in a form listed in Schedule 2 to these Regulations, these schedules reflecting the vitamins and minerals and their sources respectively set out in Annexes I and II to the Food Supplements Directive.

c. The Food Supplements Directive affords a derogation for the use of vitamin and mineral substances not listed in its Annexes which expires on 31 December 2009. This is provided for by Regulation 5(3) of the Food Supplements Regulations and is conditional upon dossiers supporting the use of substances having been submitted for assessment by the European Food Safety Authority (EFSA) by 12 July 2005 and the absence of an unfavourable opinion from EFSA as to their safety for use in food supplements.

d. In the UK, all vitamin and mineral substances for which dossiers were submitted were permitted for use in food supplements under the terms of the derogation. 67 vitamin and mineral sources which are currently used under the derogation were given favourable opinions by EFSA. Regulation 1170/2009 will amend the Annexes to Food Supplements Directive to incorporate these vitamin and mineral sources.

e. The instrument amends the Food Supplements Regulations to implement the amendments to the Annexes to the Food Supplements Directive, in so doing permitting the continued use of these 67 vitamin and mineral sources in food supplements after the expiry of the derogation on 31 December 2009. The instrument will achieve this by amending the Food Supplements Regulations to make direct, ambulatory, references to the lists of vitamins, minerals and their sources set out in Annexes I and II to the Food Supplements Directive, in exercise of the power to make ambulatory references provided by paragraph 1A of Schedule 2 to the European Communities Act 1972. This will obviate the necessity for national regulations to be made each time an amendment is made to the annexes to the Directive.

f. The Food Supplements Regulations make references to other legislation in Regulation 3(2) and Regulation 6(3) (e). The instrument makes amendments to the Regulations in order to update references to this legislation which has been amended since the Regulations were enacted and inserts a new regulation 12 to provide a transitional provision with regard to the requirements of Regulation 6(3) (e), as amended.

Foods to Which Vitamins and Minerals are Added ('Fortified Foods')

g. The Addition of Vitamins, Minerals and Other Substances (Scotland) Regulations 2007 provide for the enforcement, in Scotland, of Regulation 1925/2006 of the Parliament and the Council on the addition of vitamins and minerals and of certain other substances to foods.

h. The instrument will provide for the enforcement, in Scotland, of the amendments to Regulation (EC) No. 1925/2006 to be effected by Regulation 1170/2009 by updating the definition of "the EC Regulation" in regulation 2 of the Addition of Vitamins, Minerals and Other Substances (Scotland) Regulations 2007.

5. Consultation

a. A public consultation on a draft of the instrument based on the draft of Regulation 1170/2009 which underwent the European 'regulatory procedure with scrutiny' and an associated partial Regulatory Impact Assessment was carried out by the Food Standards Agency Scotland from 29 September to 10 November 2009. Food Standards Agency Scotland consulted with 134 Stakeholders (industry, consumer groups and enforcement authorities) on the new instrument. Within Government the Agency consulted with the Scottish Government and Scottish Government Health Authorities. A list of consultees is attached at the end of Annex A.

b. No responses were received from Scottish stakeholders. A total of 11 responses to the consultation were received across the UK.

c. A summary of consultation responses including details of the additional amendments to the Food Supplements Regulations identified by the Food Standards Agency during the consultation has been published on the Food Standards Agency's website.

6. Regulatory Impact

A Regulatory Impact Assessment has been prepared for the instrument.

7. Regulating small business

The legislation applies to small business.

8. Monitoring & review

A review of the costs and benefits will be carried out during January 2015.

9. Contact

Caroline Thomson at the Food Standards Agency Scotland Tel: 01224 285146 or email: caroline.thomson@foodstandards.gsi.gov.uk can answer any queries regarding the instrument.

FINAL REGULATORY IMPACT ASSESSMENT

1. Title of the Proposal

The Food Supplements, Vitamins, Minerals and Other Substances (Scotland) Regulations 2009 ("the 2009 Regulations")

2. Purpose and Intended Effect of the Measure

Commission Regulation (EC) No. 1170/2009 of the European Parliament and of Council of 30 November 2009 amending Directive 2002/46/EC of the European Parliament and of the Council and Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards the lists of vitamin and minerals and their forms that can be added to foods, including food supplements (OJ No. L314, 1.12.2009, p.36) ('Regulation 1170/2009') will further amend Directive 2002/46/EC of the European Parliament and of the Council on the approximation of laws of the Member States ('the Food Supplements Directive') to permit the use of an additional 67 vitamin and mineral sources in food supplements following favourable safety assessments from the European Food Safety Authority (EFSA). These vitamin and mineral sources are currently permitted for use in the UK under a derogation which expires on 31 December 2009.National legislation is necessary to legally permit their continued use. National regulations are necessary to give swift domestic legal effect to current and future amendments to the lists in the Directive.

Regulation 1170/2009 will also amend Regulation (EC) No. 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods ('Regulation 1925/2006') to permit the use of a further 10 vitamin and mineral sources for addition to foods. Government intervention is necessary to give domestic legal effect to the enforcement provisions necessary to implement the amendments made by Regulation 1170/2009 to Regulation 1925/2006.

Intended effect

The intended effect of 2009 Regulations is to:

- Amend the Food Supplements (Scotland) Regulations 2003 ("the 2003 Regulations") to permit the continued use of 67 vitamin and mineral sources in food supplements and, to give automatic effect, in national law, to any future changes to the Food Supplements Directive which relate to the lists of vitamins, minerals and their sources permitted for use in food supplements.

- Give domestic legal effect to the enforcement provisions necessitated by changes made by Regulation 1170/2009 to Regulation 1925/2006.

- Update references in the national food supplements Regulations to legislation which has been amended since the Regulations were enacted.

(i) Background

1. Food Supplements

The Food Supplements Directive is implemented, in Scotland by the 2003 Regulations').

Use of Vitamins and Minerals in Food Supplements

Lists of vitamins and minerals (e.g. Vitamin C, Magnesium etc.) and the specific sources of these (e.g. Calcium L-ascorbate, Magnesium lactate etc) permitted for use in food supplements are set out at Annexes I and II respectively to the Food Supplements Directive . These lists are replicated in the 2003 Regulations in Schedules 1 and 2 respectively.

Derogation

Article 4(6) of the Food Supplements Directive allows a derogation for the use of sources of vitamin and minerals which are not listed in Annex II to the Directive. The derogation, which is implemented by regulation 5(3) of the 2003 Regulations, and expires on 31 December 2009, is conditional upon:

- The vitamin or mineral source having been used in the manufacture of food supplements on sale in the European Community on 12 July 2002;

- A dossier supporting the use of the vitamin or mineral source having been submitted for assessment by the European Food Safety Authority (EFSA) by 12 July 2005;

- The absence of an unfavourable opinion from EFSA as to the safety of the vitamin or mineral source for use in food supplements.

In the UK, all vitamin and mineral sources for which dossiers were submitted in accordance with the terms of the derogation were permitted for use in food supplements.

Commission Regulation (EC) No. 1170/2009

Regulation 1170/2009 will add 67 vitamin and mineral sources which have received favourable opinions from EFSA to the list in Annex II to the Food Supplements Directive and add 2 minerals to Annex I.

Annexes I and II to Regulation 1170/2009 will replace Annexes I and II respectively to the Directive:

- **Annex I** to Regulation 1170/2009 consolidates the vitamins and minerals currently permitted for use in food supplements, with 2 additional minerals – Boron and Silicon - arising from favourable opinions from EFSA on sources of these minerals. Boron and Silicon will appear in Annex I to the Directive for the first time.

- **Annex II** to Regulation 1170/2009 consolidates the vitamin and mineral sources currently permitted for use in food supplements with an additional 67 which have received favourable opinions from EFSA as to their bioavailability and safety for use in food supplements. Sources of Boron and Silicon will appear in Annex II to the Directive for the first time.

The 2009 Regulations will come into force on 1 January 2010 immediately after the derogation expires. They will implement the amendments effected to the Food Supplements Directive by Regulation 1170/2009, principally by:

- Amending regulation 5(1)(a) and (b) of the 2003 Regulations to refer directly to Annexes I and II to the Food Supplements Directive, rather than to Schedules 1 and 2 to the 2003 Regulations.

- Removing Schedules 1 and 2 to the 2003 Regulations.

- Removing regulation 5(3) of the 2003 Regulations which makes references to the derogation afforded by Article 4(6) of the Food Supplements Directive which expires on 31 December 2009.

Any future amendments to the lists of vitamins, minerals and their sources permitted for use in food supplements in Annexes I and II to the Food Supplements Directive will have automatic effect in national law. This will mean that industry will be able to place food supplements containing newly approved sources of vitamins and minerals on the market as soon as the relevant amendments to the Food Supplements Directive come into force, which may offer commercial advantages. Stakeholders will be kept informed during the development of any relevant European Union (EU) amending legislation and will have the opportunity to make comments.

Any amendments to the Food Supplements Directive other than to the Annexes as applied by regulation 5 (i.e. relating solely to the vitamins and minerals and their sources permitted for use in food supplements) will not have automatic effect in national law. This will include any future amendments to set maximum and minimum levels for vitamins and minerals in daily doses of food supplements under Article 5 of the Directive. National legislation will still be required to implement amendments to the Directive of this kind, along with full, formal, public consultation.

2. Foods to which Vitamins and Minerals are Added ('Fortified Foods')

The Addition of Vitamins, Minerals and Other Substances (Scotland) Regulations 2007 as amended ("the 2007 Regulations") give domestic legal effect to Regulation 1925/2006.

The 2009 Regulations will provide for the enforcement of the amendments made by Regulation 1170/2009 to Regulation 1925/2006, by updating the definition of "the EC Regulation" in regulation 2 of 2007 Regulations.

3. Consultation

(i) Within Government

The 2009 Regulations do not impact directly on the work of other Government departments but the Scottish Government, Scottish Government Health Officials and the Improving Regulation In Scotland Unit within the Scottish Government were consulted since this Regulation will impact on their responsibilities.

The Local Authorities Coordinators of Regulatory Services (LACORS) were consulted and they confirmed that the time and costs detailed within the RIA are realistic.

(ii) Informal Consultation

The Food Standards Agency undertook a series of informal consultations with stakeholders during 2009. On 2 April 2009, a letter was sent to stakeholders and enforcement authorities reminding them of the ending of the derogation period, providing a comprehensive overview of the situation and inviting comments on the vitamin and mineral sources which were included in a very early draft what became Regulation 1170/2009.

On 17 February, 16 June and 7 July 2009 short, informal, consultations were undertaken with stakeholders by e-mail on drafts of what became Regulation 1170/2009 prior to their consideration at meetings of the EU Standing Committee on the Food Chain and Animal Health (SCoFCAH). The draft of the Regulation which achieved a qualified majority vote in SCoFCAH on 15 July 2009 was circulated to stakeholders and enforcement authorities on 28 July 2009.

(iii) Formal Public Consultation

In Scotland, a public consultation on the draft statutory instrument was carried out between 29 September and 10 November 2009. Parallel consultations were issued in England, Wales & Northern Ireland. The Scottish consultation package was sent to known stakeholders, including enforcement authorities, by e-mail and in hard copy to stakeholders without e-mail addresses. It was also published on the Food Standards Agency's website at:

http://www.food.gov.uk/consultations/consultscot/2009/supvitminscot09

There were no responses to the Scottish consultation

A total of 11 responses to the consultation were received from across the UK, all from food supplements stakeholders. The majority of those who submitted substantive comments supported permitting the use of the 67 additional vitamin and mineral sources in food supplements. Two stakeholders supported permitting the use of the additional vitamin and mineral sources, but were concerned about the effect of the proposal to give automatic effect, in national law, to amendments to Food Supplements Directive in this regard may have on Parliamentary scrutiny. One respondent gave qualified support to permitting the use of the additional vitamin and mineral sources in food supplements but queried the procedures for their assessment by the European competent authorities, the omission of certain substances and the addition of a particular mineral source. One respondent made a suggestion about the provision of guidance in respect of a particular vitamin source. Two respondents had no comments.

A summary of responses to the consultation which reflects the further necessary amendments to the 2003 Regulations identified by the Food Standards Agency during the consultation (see below) will be published on the Food Standards Agency's website at:

http://www.food.gov.uk/consultations/consulteng/2009/?completed=Yes

Further Necessary Amendments Identified During the Consultation

During the public consultation, the Food Standards Agency identified further amendments to the 2003 Regulations as being necessary in order to update references to other legislation which has been amended since the Regulations were enacted, specifically:

(i) The reference, in regulation 3(2), to Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use as regards the definition of 'medicinal products', to which there have been further amendments;

(ii) The reference, in regulation 6(3)(e), to the Annex to Council Directive 90/496/EEC on nutrition labelling for foodstuffs as regards recommended daily allowances, energy conversion factors and definitions which was revised by Commission Directive 2008/100/EC amending Council Directive 90/496/EEC on nutrition labelling for foodstuffs as regards recommended daily allowances, energy conversion factors and definitions.

Regulation 6(3)(e) of the 2003 Regulations implements Article 8(3) of the Food Supplements Directive which requires that the amounts of vitamins and minerals in recommended daily doses of food supplements are expressed on product labelling as a percentage of any recommended daily allowance (RDA) set out in the Annex to Council Directive 90/496/EEC. Directive 2008/100/EC, which came into force in November 2008, amended Council Directive 90/496/EEC and, amongst other things, made amendments to the RDAs for certain vitamins and minerals.

All relevant food, including food supplements, must comply with Council Directive 90/496/EEC, as amended, by 31 October 2012. The implementation, in Scotland, of Directive 2008/100/EC and its impact on stakeholders, was the subject of a public consultation conducted by the Food Standards Agency between 6 March and 29 May 2009. All stakeholders, including food supplements stakeholders, were consulted. The Scottish consultation documents, a summary of UK consultation responses can be found on the Food Standards Agency website at:

http://www.food.gov.uk/consultations/consultscot/2009/draftfoodlabelnutdecscotregs

http://www.food.gov.uk/multimedia/pdfs/consultationresponse/respondraftfoodlabelnutdecen.pdf

4. Options

Option 1: Do nothing.

Option 2: National regulations to implement amendments to the Food Supplements Directive, in so doing giving automatic effect, in national law, to future amendments to the Food Supplements Directive with regard to vitamins, minerals and their sources permitted for use in food supplements.

The preferred option is **Option 2**. If national regulations are not enacted, this would have the effect of prohibiting, from 1 January 2010, the use of 67 vitamin and mineral sources in food supplements which would otherwise be permitted for such use and expose the UK to possible infraction proceedings by the European Commission. Not giving automatic effect to amendments to the Directive as regards the vitamins, mineral and their sources permitted for use in food supplements would mean that newly approved sources would not be available for use by industry

until national implementing legislation comes into force causing delays and disadvantaging industry. If national regulations are not enacted, national enforcement powers in relation to Regulation 1925/2006 would not extend to that Regulation, as amended.

5. Costs and benefits

Sectors and groups affected

Food Businesses affected by these amendments are those that market food supplements and consumers.
Option 1

Costs
If national regulations are not enacted, this would have the effect of prohibiting, from 1 January 2010, the use of 67 vitamin and mineral sources in food supplements which would otherwise be permitted for such use. Costs to the food supplements industry would arise from the loss to the market, from 1 January 2010, of products containing these sources. Businesses would also have to remove relevant exisiting products from sale from 1 January 2010. It would also expose the UK to possible infraction proceedings by the European Commission. If exisiting products had to be removed from sale from 1 January 2010 there would also be a reduction in consumer choice**.**

Benefits

Option 1.Failure to implement would not bring any benefits to consumers, industry, enforcement authorities or government

Option 2: Benefits are outlined

Option 2

Benefits to Food Businesses:

- Continued, uninterrupted, use in food supplements of 67 vitamin and mineral sources currently permitted for use under the derogation after its expiry on 31 December 2009.

- Certainty as to the vitamin and minerals and their sources permitted for use in food supplements.

- Certainty should improve compliance and reduce the need for enforcement interventions.

- Vitamin and minerals and their sources permitted for use in food supplements will, for the first time, be harmonised across the EU, facilitating free trade in vitamin and mineral food supplements.

- Giving automatic effect, in national law, to any future changes to the Food Supplements Directive which specifically relate to vitamins, minerals and their sources permitted for use in food supplements will enable industry to place food supplements containing newly approved

sources of vitamins and minerals on the market as soon as the relevant amendments to the Food Supplements Directive come into force, which may offer commercial advantages.

The majority of those who submitted substantive comments to the public consultation (see the section entitled 'Consultation' below for full details) supported permitting the use of the 67 additional vitamin and mineral sources in food supplements.

Costs to Food Businesses

It is expected that there may be one-off costs involved in being aware of, and becoming familiar with, the amendments to the national regulations. We expect that most of the businesses affected will be in the food manufacturing sector, with minimal impacts to food supplement retailers. Accordingly, we have used SIC code 10.89[1] to estimate the number of businesses affected and believe this will be an overestimate as it includes manufacturers of other food products, including food supplements[2].

It is estimated by the Agency that it would take one manager 15 minutes to read the Schedule. To estimate the cost to business, the average hourly pay rate for managers in storage, retailing and distribution of £11.90[3], is up-rated by 30% to account for overheads to £15.47 or £3.09 per 15 minutes. Multiplying out by the estimated number of businesses affected, (likely to overestimate) amounts to £2,700 for the UK (rounded).

Manufacture of other food products n.e.c.	**SIC Code 10.89**	**Total Costs**	
Scotland	65	£	201
England	740	£	2,287
Wales	50	£	155
Northern Ireland	20	£	62
UK	875	£	2,704

There may be some retailers who also need to be aware and become familiar with the amendments to national regulations. Accordingly, we have used SIC Code 47.29[4] to estimate the number of retailers affected[5] but acknowledge that this is an overestimate. Therefore the true cost will be nearer to £2,700 than £21,700 (£19,034 + £2,704). Figures rounded.

Other retail sale of food in	**SIC Code**	**Total Costs**

1 http://www.statistics.gov.uk/methods_quality/sic/downloads/SIC2007explanatorynotes.pdf

2 10.89 Manufacture of other food products n.e.c. This class includes:
- manufacture of soups and broths
- manufacture of artificial honey and caramel
- manufacture of perishable prepared foods, such as: sandwiches; fresh (uncooked) pizza
- manufacture of food supplements and other food products n.e.c.

3 Used as no other appropriate category could be found: Annual Survey of Hours & Earnings 2009 http://www.statistics.gov.uk/StatBase/Product.asp?vlnk=15313

4 SIC Code 47.29 Other retail sale of food in specialised stores
This class includes:
- retail sale of dairy products and eggs
- retail sale of other food products n.e.c.

5 Using wage rate of £3.09 as per previous calculation

specialised stores	47.29		
Scotland	440	£	1,360
England	5,235	£	16,176
Wales	325	£	1,004
Northern Ireland	160	£	494
UK	6,160	£	19,034

Benefits to Enforcement Authorities

- Certainty as to the vitamin and minerals and their sources permitted for use in food supplements, facilitating official controls.

- Certainty should improve compliance and reduce the need for interventions by enforcement authorities in connection with the use of vitamin and mineral sources in food supplements.

- Harmonisation of vitamin and minerals and their sources permitted for use in food supplements will facilitate official controls.

Costs to Enforcement authorities

We expect that there will be one-off costs involved in being aware of, and becoming familiar with, the amendments to the national regulations. It is estimated by the Agency that it would take one local authority officer in each of the 469 local authorities in the UK 15 minutes to be aware of, and become familiar with, the amendments to the national regulations including fortified foods. With an average hourly pay rate for trading standards officers[6] of approximately £15.58 which, in-line with the standard cost model is then up-rated by 30% to account for overheads to £20.25 and £4.05 per 15 minutes. This would be equivalent to a one-off familiarisation cost of approximately £1,000 for the UK (rounded) assuming that one officer can then disseminate this information to colleagues.

LA familiarisation costs	Local Authorities with Food Standards Responsibility	Total Cost
Scotland	**32**	**£ 130**
England	**151**	**£ 612**
Wales	**22**	**£ 89**
Northern Ireland	**26**	**£ 105**
UK total	**231**	**£ 936**

6 ASHE 2009 ibid. Inspectors of factories, utilities and trading standards

Total monetised costs to local authorities and business would amount to £4,000 to £23,000 for the UK as a whole (rounded to nearest thousand). However, as outlined above, we believe the true familiarisation costs will be closer to £4,000.

Benefits to consumers:

- Continued availability in food supplements of 67 vitamin and mineral sources currently permitted for use under the derogation after its expiry on 31 December 2009.

- Harmonisation of vitamin and minerals and their sources permitted for use in food supplements may generate commercial competition which may yield benefits to consumers in terms of reduced costs and product innovation.

Costs to Consumers

There will be no additional costs to consumers.

Administrative Burden Costs

Option 1 may lead to business reformulating, re-labelling and re-packaging products to achieve compliance to enable them to be marketed and there would be a significant additional administrative burden.

There would be no additional administrative burdens to business from **Option 2**.

6. Small Firms Impact Test

We do not expect any specific issues arising for small firms as a result of this policy. It is expected that there may one-off costs involved in being aware of, and becoming familiar with, the amendments. It is anticipated that this will affect the food manufacturing sector, with minimum impact to food supplement retailers.

7. Legal Aid impact test

This Directive does not introduce new criminal sanctions or civil penalties: therefore there are no implications for legal aid.

8. Test Run of Business Forms

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

9. Competition Assessment

The proposed legislation does not impose any significant costs to industry and applies to all manufacturers equally.

10. Enforcement, sanctions and monitoring

Responsibilities for enforcement, sanctions and monitoring are the same as those set out in the original regulations and will continue to be carried out by the relevant enforcement authorities using existing enforcement powers.

11. Simplification

The harmonisation, across the EU, of vitamins, minerals and their sources permitted for use in food supplements simplifies the legislative position in this area and should benefit business.

The preferred option should simplify and shorten the process for implementing future changes to the lists of vitamins, minerals and their sources permitted for use in food supplements.

12. Implementation and delivery plan

Regulation 1170/2009 will come into force on 21 December 2009 and The Food Supplements, Vitamins, Minerals and Other Substances (Scotland) Regulations 2009 will come into force on 1 January 2010.

13. Post implementation review

A review of the costs and benefits will be carried out during January 2015.

14. Sustainable development

Option 1 would have a significant negative economic and environmental impact resulting from the requirement to remove and destroy existing products from the market from 1 January 2010. Businesses would have to develop new products and packaging to replace those lost to the market

Option 2 would allow the continued use of existing product and packaging and there would be no significant economic and environmental impact.

Option 2 is therefore more sustainable.

15. Summary and recommendation

Option 2: National regulations to implement amendments to the Food Supplements Directive, in so doing giving automatic effect, in national law, to future amendments to the Food Supplements Directive with regard to vitamins, minerals and their sources permitted for use in food supplements.

The recommended option is **Option 2**. If national regulations are not enacted, this would have the effect of prohibiting, from 1 January 2010, the use of 67 vitamin and mineral sources in food supplements which would otherwise be permitted for such use and expose the UK to possible infraction proceedings by the European Commission. Not giving automatic effect to amendments to the Directive as regards the vitamins, mineral and their sources permitted for use in food supplements would mean that newly approved sources would not be available for use by industry until national implementing legislation comes into force causing delays and disadvantaging

industry. If national regulations are not enacted, national enforcement powers in relation to Regulation 1925/2006 would not extend to that Regulation, as amended.

16. Devolution

The proposed regulations will apply in Scotland only. Parallel legislation to implement will be introduced in England, Wales & Northern Ireland.

17. Declaration and Publication

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

Signed:

Date:

Minister's Name , Title & Department:

Shona Robison, Minister for Public Health & Sport, Scottish Executive Health Directorate.

Contact point for enquiries and comments

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