

## FOOD STANDARDS AGENCY CONSULTATION

### The Food Supplements (England) and Addition of Vitamins, Minerals and Other Substances (England) (Amendment) Regulations 2009

#### CONSULTATION SUMMARY PAGE

<b>Date consultation launched:</b>	<b>Closing date for responses:</b>
28 September 2009	9 November 2009

#### Who will this consultation be of most interest to?

Manufacturers and retailers of food supplements; manufacturers and retailers of foods, other than food supplements, with added vitamins or minerals ('fortified foods'); enforcement authorities; nutrition professionals and the wider general public who consume food supplements or fortified foods.

#### What is the subject of this consultation?

National regulations relating to England (a) to permit to the continued use in food supplements of 67 vitamin and mineral sources currently permitted for use under a legislative provision which expires on 31 December 2009; (b) to give automatic effect to any future changes to the Annexes to Directive 2002/46/EC relating to vitamins, minerals and the sources of these permitted for use in food supplements; and (c) to provide for the execution and enforcement of Article 2 of the new Commission Regulation which adds one mineral to Annex I of Regulation (EC) No. 1925/2006 on addition of vitamins and minerals and of certain other substances to foods and 2 vitamin formulations and 8 mineral substances to Annex II.

#### What is the purpose of this consultation?

To seek comments on the draft Food Supplements (England) and Addition of Vitamins, Minerals and Other Substances (England) (Amendment) Regulations 2009 and accompanying Impact Assessment. Separate legislation will need to be enacted in Scotland, Wales and Northern Ireland which will be subject to separate consultations in those parts of the United Kingdom.

#### Responses to this consultation should be sent to:

**Ms T. Callis,**  
**GM Labelling and Food Supplements Branch,**  
**Novel Foods, Additives and Supplements Division,**  
**FOOD STANDARDS AGENCY**  
**Tel: 0207 276 8597**  
**Fax: 0207 276 8564**

**Postal address:**  
**Room 5B,**  
**Aviation House,**  
**125 Kingsway,**  
**London,**  
**WC2B 6NH.**  
**E-mail: [tracey.callis@foodstandards.gsi.gov.uk](mailto:tracey.callis@foodstandards.gsi.gov.uk)**

**Is an Impact Assessment included with this consultation?**

Yes

See Annex A for reason.



# **The Food Supplements (England) and Addition of Vitamins, Minerals and Other Substances (England) (Amendment) Regulations 2009**

## **DETAIL OF CONSULTATION**

### **Introduction**

#### **Food Supplements**

The EC Food Supplements Directive 2002/46/EC (as amended) is implemented, in England, by The Food Supplements (England) Regulations 2003 (SI 2003 No. 1387) (as amended) ('the Food Supplements Regulations'). 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 respectively set out at Annexes I and II to the Directive. These lists are replicated in Schedules 1 and 2 to the Food Supplements Regulations respectively.

#### ***Derogation***

Article 4(6) of the Directive affords 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 in England by Regulation 5(3) of the Food Supplements 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 United Kingdom (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.

#### **Addition of vitamins and minerals to foods (other than food supplements)**

The directly applicable Regulation (EC) No 1925/2006 on the addition of vitamins, minerals and other substances to foods lists the vitamins and minerals (Annex I) and the vitamin formulations and mineral substances (Annex II) that can voluntarily be added to food.

Provisions for the execution and enforcement of the Regulation, in England, are made in The Addition of Vitamins, Minerals and Other Substances (England) Regulations 2007 (SI 2007 No. 1631).

## **Draft Commission Regulation amending Directive 2002/46/EC and Regulation (EC) No 1925/2006 as regards the lists of vitamins and minerals and their forms that can be added to foods, including food supplements**

### **Food Supplements**

Article 1 of the Commission Regulation would add 2 minerals – Boron and Silicon - arising from favourable EFSA opinions on sources of these minerals, to Annex I to Directive 2002/46/EC. It would also add 67 vitamin and mineral sources which have received favourable opinions from EFSA to Annex II to Directive 2002/46/EC. This would be achieved by replacing the Annexes I and II to the Directive with those set out in Annexes I and II to the Commission Regulation.

- **Annex I to the Commission Regulation** would consolidate 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 would appear in Annex I to Directive 2002/46/EC for the first time.
- **Annex II to the Commission Regulation** would consolidate 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 would appear in Annex II to Directive 2002/46/EC for the first time.

### **Addition of vitamins and minerals to foods (other than food supplements)**

Article 2(1) of the Commission Regulation would add 1 mineral – boron - arising from favourable EFSA opinions on sources of this mineral, to Annex I to Regulation (EC) No 1925/2006. Article 2(2) would add 2 vitamin formulations and 8 mineral substances which have received favourable opinions from EFSA to Annex II to Regulation (EC) No 1925/2006. This would be achieved by replacing Annex II to Regulation (EC) No 1925/2006 with that set out in Annex III to the Commission Regulation.

- **Article 2(1) of the Commission Regulation** would add one mineral - Boron - arising from favourable opinions from EFSA on sources of this mineral, to Annex I to Regulation (EC) No 1925/2006. Boron would appear in Annex I to the Regulation for the first time.
- **Annex III to the Commission Regulation** would consolidate the vitamin and mineral sources currently permitted for use in the fortification of food with an additional 10 which have received favourable opinions from EFSA for such use. Sources of Boron would appear in Annex II to Regulation (EC) No 1925/2006 for the first time.

## **The Food Supplements (England) and Addition of Vitamins, Minerals and Other Substances (England) (Amendment) Regulations 2009**

### **Food Supplements**

The proposed national regulations would come into force on 1 January 2010 following the expiry of the derogation period. They would implement the amendments effected to the Directive 2002/46/EC by the Commission Regulation principally by:

- Amending Regulation 5(1)(a) and (b) of the Food Supplements Regulations to refer directly to Annexes I and II to the Directive as amended by the Commission Regulation, rather than to Schedules 1 and 2 to the Food Supplements Regulations.
- Removing Schedules 1 and 2 to the Food Supplements Regulations.
- Removing Regulation 5(3) of the Food Supplements Regulations which makes references to the derogation afforded by Article 4(6) of Directive 2002/46/EC.

**Any future amendments to the lists of vitamins, minerals and their sources permitted for use in food supplements in Annexes I and II to Directive 2002/46/EC would have automatic effect in England. This would mean that new sources of vitamins and minerals would be available for use by the food supplements industry in England as soon as legislative changes come into force at European level which may offer commercial advantages. As has been the case with the draft Commission Regulation, stakeholders would be kept informed during the development of any relevant European amending legislation and would have the opportunity to make comments.**

**Any amendments to the 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) would not have automatic effect. This would 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 would still be required to implement amendments to the Directive of this kind, along with full, formal, public consultation.**

### **Addition of vitamins and minerals to foods (other than food supplements)**

In order to provide for the execution and enforcement, in England, of the amendments to Regulation (EC) No 1925/2006 which would be effected by Article 2 of the Commission Regulation, it would be necessary to amend The Addition of Vitamins, Minerals and Other Substances (England) Regulations 2007. This would be achieved by way of regulation 3 of The Food Supplements (England) and Addition of Vitamins, Minerals and Other Substances (England) (Amendment) Regulations 2009.

We are not aware of the use, or proposed use, of any of these new vitamin formulations or mineral substances in fortified foods.

## Proposals

### Key Proposals:

National Regulations to amend the Food Supplements Regulations and The Addition of Vitamins, Minerals and Other Substances (England) Regulations 2007 to:

- (1) Implement amendments to the lists of vitamins and minerals and their sources permitted for use in food supplements respectively set out in Annexes I and II to Directive 2002/46/EC as amended by the new Commission Regulation.
- (2) Give automatic legal effect, in England, to future amendments to Annexes I and II to Directive 2002/46/EC as applied by regulation 5 of the Food Supplements Regulations (i.e. **solely** in relation to the vitamins and minerals and their sources permitted for use in food supplements).
- (3) Provide for the execution and enforcement of Regulation 1925/2006 as amended by the new Commission Regulation.

## Consultation Process

### Food supplements

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 of the Commission Regulation.

On 17 February, 16 June and 6 July 2009 short, informal, consultations were undertaken with stakeholders by e-mail on drafts of the Commission Regulation prior to their consideration at meetings of the EU Standing Committee on the Food Chain and Animal Health (SCoFCAH). The draft of the Commission Regulation which achieved a qualified majority vote in SCoFCAH on 15 July 2009 was circulated to stakeholders and enforcement authorities on 28 July 2009.

It is clearly desirable for the national regulations to come into force on 1 January 2010, immediately after the derogation period ends, to allow the continued use of the 67 vitamin and mineral sources which are to be added to the lists in the Annexes to the Food Supplements Directive. However, the draft Commission Regulation is subject to, and is currently undergoing, the European 'regulatory procedure with scrutiny' which involves its consideration by the European Parliament and the Council.

The later in 2009 the finalised Commission Regulation is published in the Official Journal of the European Communities (OJ), the more unlikely it is that a coming into force date for the national regulations of 1 January 2010 can be achieved. In order to maximise the possibility of bringing national legislation into force on this date, this public consultation is being carried out on the draft Statutory Instrument relating to

England, prepared on the basis of the draft Commission Regulation, for a shortened period of 6 weeks.

Due to the nature of the draft Commission Regulation, the Food Standards Agency is of the view that it is likely to emerge from the scrutiny process unchanged and, at this stage, the Agency cannot foresee any reason which might delay its progress through the process. A strategy has, however, been devised to deal with circumstances where the finalised Commission Regulation is not published early enough to allow national legislation to be made and come into force on 1 January 2010 or where the Commission Regulation is substantially changed via the scrutiny process, necessitating a further public consultation. All stakeholders, including enforcement interests, will be advised of these arrangements should the need arise.

### **Addition of vitamins and minerals to foods (other than food supplements)**

On 17 February and 16 June 2009 short, informal, consultations on drafts of the Commission Regulation were also undertaken with those stakeholders interested in 'fortified foods'.

All responses received as part of this consultation will be given careful consideration and will be summarised and published on the Agency's website in due course.

#### **Questions asked in this consultation:**

**The Food Standards Agency is seeking comments from all stakeholders on the proposed amendments to the national legislation as outlined in this consultation package and the costs and benefits in the accompanying Impact Assessment.**

### **Impact Assessment**

The accompanying impact assessment applies only to amendments to the Food Supplements Regulations.

With regard to amendments to the Addition of Vitamins, Minerals and Other Substances (England) Regulations 2007 we are not aware of the use, or proposed use, of either of the 2 new vitamin formulations or any of the 8 new mineral substances in fortified foods. Therefore, we do not expect these changes to impose any additional burdens or costs on manufacturers, retailers or enforcement authorities. For this reason we have not prepared an impact assessment in relation to these particular amendments. **However, if you consider that they will impose additional costs on businesses or the public sector, please provide evidence and estimated costs in your response to this consultation and we will consider preparing an impact assessment.**

We welcome comments from all stakeholders. Please send your response by e-mail or post using the contact details towards the top of this page.

## **Other relevant documents**

Council Document ST12695/09: Draft Commission Regulation 12695/09 amending Directive 2002/46/EC and Regulation (EC) No. 1925/2006 as regards the lists of vitamins and minerals and their forms that can be added to foods, including food supplements (attached at **Annex D**).

## **Responses**

**Responses are required by close on 9 November 2009.** Please state, in your response, whether you are responding as a private individual or on behalf of an organisation/company (including details of any stakeholders your organisation represents).

Thank you on behalf of the Food Standards Agency for participating in this public consultation.

Yours,

**Colin Clifford**  
**GM Labelling and Food Supplements Branch**  
**Novel Foods, Additives and Supplements Division**

## **Enclosed**

**Annex A:** Standard Consultation Information

**Annex B:** Impact Assessment

**Annex C:** The Food Supplements (England) and Addition of Vitamins and Minerals and Other Substances (England) (Amendment) Regulations 2009

**Annex D:** Draft Commission Regulation (Council Document ST12695/09)

**Annex E:** Vitamins, Minerals and their Sources to be added to the Annexes in Directive 2002/46/EC and Regulation (EC) No 1925/2006

**Annex F:** List of interested parties

**STANDARD CONSULTATION INFORMATION**

**Queries**

1. If you have any queries relating to this consultation please contact the person named on page 1, who will be able to respond to your questions.

**Publication of personal data and confidentiality of responses**

2. In accordance with the FSA principle of openness our Information Centre at Aviation House will hold a copy of the completed consultation. Responses will be open to public access upon request. The FSA will also publish a summary of responses, which may include personal data, such as your full name and contact address details. If you do not want this information to be released, please complete and return the Publication of Personal Data form, which is on the website at

<http://www.food.gov.uk/multimedia/worddocs/dataprotection.doc>

Return of this form does not mean that we will treat your response to the consultation as confidential, just your personal data.

3. In accordance with the provisions of Freedom of Information Act 2000 / Environmental Information Regulations 2004, all information contained in your response may be subject to publication or disclosure. If you consider that some of the information provided in your response should not be disclosed, you should indicate the information concerned, request that it is not disclosed and explain what harm you consider would result from disclosure. The final decision on whether the information should be withheld rests with the FSA. However, we will take into account your views when making this decision.
4. Any automatic confidentiality disclaimer generated by your IT system will not be considered as such a request unless you specifically include a request, with an explanation, in the main text of your response.

**Further information**

5. A list of interested parties to whom this letter is being sent appears at Annex F. Please feel free to pass this document to any other interested parties, or send us their full contact details and we will arrange for a copy to be sent to them direct.
8. Please let us know if you need paper copies of the consultation documents or of anything specified under 'Other relevant documents'.
9. This consultation has been prepared in accordance with HM Government Code of Practice on Consultation, available at:

<http://www.berr.gov.uk/files/file47158.pdf>.

The Consultation Criteria are available at:

<http://www.berr.gov.uk/whatwedo/bre/consultation-guidance/page44458.html>

10. Criterion 2 of HM Government Code of Practice on Consultation states Consultations should normally last for at least 12 weeks with consideration given to longer timescales where feasible and sensible. This consultation is being held for a period of 6 weeks in order to maximise the possibility of bringing national legislation into force on 1 January 2010 for the reasons given in the consultation document.
11. The Code of Practice states that an Impact Assessment should normally be published alongside a formal consultation. Please see the Impact Assessment at Annex B.
12. For details about the consultation process (not about the content of this consultation) please contact: Food Standards Agency Consultation Co-ordinator, Room 2C, Aviation House, 125 Kingsway, London, WC2B 6NH. Tel: 020 7276 8630.

#### **Comments on the consultation process itself**

13. We are interested in what you thought of this consultation and would therefore welcome your general feedback on both the consultation package and overall consultation process. If you would like to help us improve the quality of future consultations, please feel free to share your thoughts with us by using the Consultation Feedback Questionnaire at:

<http://www.food.gov.uk/multimedia/worddocs/consultfeedback.doc>

14. If you would like to be included on future Food Standards Agency consultations on other topics, please advise us of those subject areas that you might be specifically interested in by using the Consultation Feedback Questionnaire at:

<http://www.food.gov.uk/multimedia/worddocs/consultfeedback.doc>

The questionnaire can also be used to update us about your existing contact details.

## Summary: Intervention & Options

<b>Department/Agency:</b> Food Standards Agency	<b>Title:</b> Impact Assessment for The Food Supplements (England) and Addition of Vitamins, Minerals and Other Substances (England) (Amendment) Regulations 2009	
<b>Stage:</b> Draft	<b>Version:</b> 1	<b>Date:</b> 18 September 2009
<b>Related Publications:</b> Council Document ST12695/09: Draft Commission Regulation amending Directive 2002/46/EC and Regulation (EC) No. 1925/2006 as regards the lists of vitamins and minerals and their forms that can be added to foods, including food supplements.		

Available to view or download at:

Contact for enquiries: **Colin Clifford**

Telephone: **020 7276 8568**

### What is the problem under consideration? Why is government intervention necessary?

#### Food supplements

In order to facilitate free trade and protect public health, vitamins, minerals and sources of these permitted for use in food supplements are set out in the European Food Supplements Directive 2002/46/EC. A European Commission Regulation has been drafted so as to amend the Directive to permit the use of a further 67 vitamin and mineral sources following favourable safety assessments from the European Food Safety Authority (EFSA). These sources are currently permitted for use in England under a legislative provision which expires on 31 December 2009. Government intervention is necessary to legally allow the 67 vitamin and mineral sources in the UK. Currently, national regulations relating to England are necessary to implement amendments of this kind to the Directive. Government intervention is necessary to process changes into UK law swiftly.

### What are the policy objectives and the intended effects?

The policy objectives are to amend national legislation relating to England to:

- Permit the continued use of 67 vitamin and mineral sources in food supplements.
- Give automatic effect, in England, to any future changes to Directive 2002/46/EC which specifically relate to vitamins, minerals and their sources permitted for use in food supplements.

### What policy options have been considered? Please justify any preferred option. [max 430 characters]

**Option 1:** Do nothing.

**Option 2:** Implement national regulations relating to England to permit the continued use of 67 vitamin and mineral sources in food supplements and to give automatic effect to any future changes to Directive 2002/46/EC which relate to the vitamins, minerals and their sources permitted for use in food supplements.

The preferred option is Option 2. Not to implement the amendments to be effected to the Directive would have the effect of prohibiting the use of 67 vitamin and mineral sources in food supplements which would otherwise be available for use and would disadvantage UK industry, limit consumer choice and expose the UK to the possibility of infraction proceedings by the European Commission. Giving automatic effect, in England, to amendments of this kind would mean that new sources of vitamins and minerals would be available for use by the food supplements industry in England as soon as legislative changes come into force at European level which may offer commercial advantages.

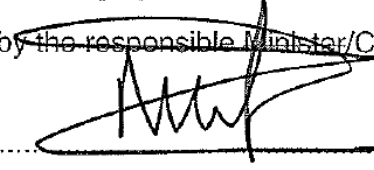
### When will the policy be reviewed to establish the actual costs and benefits and the achievement of the desired effects?

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

**Ministerial/CEO Sign-off** For consultation stage Impact Assessments:

*I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.*

Signed by the responsible Minister/Chief Executive\*:

A handwritten signature in black ink, consisting of several loops and a long horizontal stroke at the end.

.....Date: 23 September 2009

\* for Impact Assessments undertaken by non-ministerial departments/agencies and NOT being considered by Parliament

## Summary: Analysis & Evidence

<b>Policy Option: 1</b>	<b>Description: National Legislation to Implement amendments to the EC Food Supplements Directive 2002/46/EC to be effected by the Commission Regulation</b>
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<b>COSTS</b>	<b>ANNUAL COSTS</b>	Description and scale of <b>key monetised costs</b> by 'main affected groups'  Not quantified at this stage – information is sought from stakeholders through this consultation IA  Food Business Operators, Enforcement Authorities				
	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 70%; padding: 5px;"><b>One-off</b> (Transition)</td> <td style="width: 30%; text-align: center; padding: 5px;"><b>Yrs</b></td> </tr> <tr> <td style="padding: 5px;">£</td> <td></td> </tr> </table>		<b>One-off</b> (Transition)	<b>Yrs</b>	£	
	<b>One-off</b> (Transition)		<b>Yrs</b>			
	£					
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<b>Average Annual Cost</b> (excluding one-off)						
£ Not known						
<b>Total Cost (PV)</b>		£				
Other <b>key non-monetised costs</b> by 'main affected groups'						

<b>BENEFITS</b>	<b>ANNUAL BENEFITS</b>	Description and scale of <b>key monetised benefits</b> by 'main affected groups'  Not quantified at this stage – information is sought from stakeholders through this consultation IA  Food Business Operators, Enforcement Authorities, Consumers				
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	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 70%; padding: 5px;"><b>Average Annual Benefit</b> (excluding one-off)</td> <td></td> </tr> <tr> <td style="padding: 5px;">£ Not known</td> <td></td> </tr> </table>		<b>Average Annual Benefit</b> (excluding one-off)		£ Not known	
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£ Not known						
<b>Total Benefit (PV)</b>		£				
Other <b>key non-monetised benefits</b> by 'main affected groups' It is expected that industry will benefit from swifter implementation of EU legislation and greater certainty once EU decisions have been taken. Further clarity on these benefits is being sought from stakeholders through this consultation IA.						

Key Assumptions/Sensitivities/Risks
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Price Base Year	Time Period Years	<b>Net Benefit Range (NPV)</b> £	<b>NET BENEFIT (NPV Best estimate)</b> £
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What is the geographic coverage of the policy/option?	England								
On what date will the policy be implemented?	1 January 2010								
Which organisation(s) will enforce the policy?	LAs & PHAs								
What is the total annual cost of enforcement for these organisations?	£								
Does enforcement comply with Hampton principles?	Yes								
Will implementation go beyond minimum EU requirements?	No								
What is the value of the proposed offsetting measure per year?	£								
What is the value of changes in greenhouse gas emissions?	£								
Will the proposal have a significant impact on competition?	Not Known								
Annual cost (£-£) per organisation (excluding one-off)	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 25%; text-align: center;">Micro</td> <td style="width: 25%; text-align: center;">Small</td> <td style="width: 25%; text-align: center;">Medium</td> <td style="width: 25%; text-align: center;">Large</td> </tr> <tr> <td style="padding: 5px;">Are any of these organisations exempt?</td> <td style="text-align: center;">No</td> <td style="text-align: center;">No</td> <td style="text-align: center;">No</td> </tr> </table>	Micro	Small	Medium	Large	Are any of these organisations exempt?	No	No	No
Micro	Small	Medium	Large						
Are any of these organisations exempt?	No	No	No						

<b>Impact on Admin Burdens Baseline</b> (2005 Prices)		(Increase - Decrease)
Increase of £	Decrease of £	<b>Net Impact</b> £

Key: Annual costs and benefits: (Net) Present

## Evidence Base (for summary sheets)

### **Reason for Intervention**

In order to facilitate free trade and protect public health, vitamins, minerals and sources of these permitted for use in food supplements are set out in the European Food Supplements Directive 2002/46/EC. A European Commission Regulation has been drafted so as to amend the Directive to permit the use of a further 67 vitamin and mineral sources following favourable safety assessments from the European Food Safety Authority (EFSA). These sources are currently permitted for use in England under a legislative provision which expires on 31 December 2009. Government intervention is necessary to legally allow the 67 vitamin and mineral sources in the UK.

Currently, national regulations relating to England are necessary to implement amendments to the Directive of this kind. Government intervention is necessary to process changes into UK law swiftly.

### **Intended effect**

The intended effect is to permit the continued use of 67 vitamin and mineral sources in food supplements and to give automatic effect, in England, to any future changes to Directive 2002/46/EC which relate to the vitamins, minerals and their sources permitted for use in food supplements.

### **Background**

#### ***Introduction***

The EC Food Supplements Directive 2002/46/EC (as amended) is implemented, in England, by the Food Supplements (England) Regulations 2003 (SI 2003/1387) (as amended) ('the Food Supplements 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 respectively set out at Annexes I and II to the Directive. These lists are replicated in Schedules 1 and 2 to the Food Supplements Regulations respectively.

#### ***Derogation***

Article 4(6) of the Directive affords 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 in England by regulation 5(3) of the Food Supplements 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 United Kingdom (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.

### ***Draft Commission Regulation (Council Document ST12695/09)***

The draft Commission Regulation has been prepared so as to add 67 vitamin and mineral sources which have received favourable opinions from EFSA to the lists in Annexes I and II to Directive 2002/46/EC. Annexes I and II to the Commission Regulation would respectively replace Annexes I and II to the Directive.

- **Annex I** 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 would appear in Annex I to the Directive for the first time.
- **Annex II** 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 would appear in Annex II to the Directive for the first time.

### **The Food Supplements (England) and Addition of Vitamins, Minerals and Other Substances (England) (Amendment) Regulations 2009**

The proposed national regulations would come into force on 1 January 2010 following the expiry of the derogation period. They would implement the amendments effected to the Directive 2002/46/EC by the Commission Regulation principally by:

- Amending Regulation 5(1)(a) and (b) of the Food Supplements (England) Regulations 2003 (as amended) to refer directly to Annexes I and II to the Directive as amended by the Commission Regulation, rather than to Schedules 1 and 2 to the national Regulations.
- Removing Schedules 1 and 2 to the Food Supplements (England) Regulations 2003 (as amended).
- Removing Regulation 5(3) which makes references to the derogation afforded by Article 4(6) of Directive 2002/46/EC.

**Any future amendments to the lists of vitamins, minerals and their sources permitted for use in food supplements in Annexes I and II to Directive 2002/46/EC would have automatic effect in England. This would mean that new sources of vitamins and minerals would be available for use by the food supplements industry in England as soon as legislative changes come into force at European level which may offer commercial advantages. As has been the case with the draft Commission Regulation, stakeholders would be kept informed during the development of any relevant European amending legislation and would have the opportunity to make comments.**

**Any amendments to the 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) would not have automatic effect. This would 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 would still be required to implement amendments to the Directive of this kind, along with full, formal, public consultation.**

## **Options**

**Option 1:** Do nothing.

**Option 2:** Implement national regulations relating to England to permit the continued use of 67 vitamin and mineral sources in food supplements and to give automatic effect to any future changes to Directive 2002/46/EC which relate to the vitamins, minerals and their sources permitted for use in food supplements.

The preferred option is **Option 2**. Not to implement the amendments to be effected to the Directive by the Commission Regulation would have the effect of prohibiting the use of 67 vitamin and mineral sources in food supplements which would otherwise be available for use, limit consumer choice and would expose the United Kingdom to the possibility of infraction proceedings by the European Commission. Giving automatic effect to amendments of this kind in England would mean that new sources of vitamins and minerals would be available for use by the food supplements industry in England as soon as legislative changes come into force at European level which may offer commercial advantages.

## **Costs and benefits of options**

### ***Option 1***

Not to implement the amendments to be effected to Directive 2002/46/EC by the Commission Regulation would have the effect of prohibiting the use of 67 vitamin and mineral sources in food supplements which would otherwise be available for 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 existing products from sale from 1 January 2010. It would also expose the United Kingdom to the possibility of infraction proceedings by the European Commission.

Are food businesses able to illustrate what the costs of option 1 would be? Are there any other costs to food businesses?
--

If existing products had to be removed from sale from 1 January 2010 there would also be a reduction in consumer choice.

### ***Option 2***

#### ***Benefits to Food Businesses:***

- Continued, uninterrupted, use in food supplements of 67 vitamin and mineral sources currently used under the derogation afforded by Article 4(6) of the Food Supplements Directive 2002/46/EC after the expiry of the derogation on 31 December 2009.
- Certainty as to the vitamin and minerals and their sources permitted for use in food supplements.
- Certainty should improve 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 European Community, facilitating free trade in vitamin and mineral food supplements.

Are food businesses able to illustrate what the benefits from option 2 would be? Are there any other benefits to food businesses?
--

### **Costs to Food Businesses:**

One-off costs involved in being aware of, and becoming familiar with, the amendments to the national regulations.

How long would it take Food Businesses to become aware and familiar with amendments to national regulations on vitamins and mineral sources e.g. 15 minutes, 30 minutes?  
Who in the organisation would typically become familiar with such amendments?

### **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 facilitates official controls.

Are enforcement officers able to illustrate what the benefits from Option 2 would be?  
Are there any other benefits to enforcement officers?

### **Costs to food / feed authorities:**

One-off costs involved in being aware of, and becoming familiar with, the amendments to the national regulations.

How long would it take enforcement officers to become aware and familiar with amendments to national regulations on vitamin and mineral sources e.g. 15 minutes, 30 minutes?

### **Benefits to consumers:**

- Continued availability in food supplements of 67 vitamin and mineral sources currently used under the derogation afforded by Article 4(6) of the Food Supplements Directive 2002/46/EC after the expiry of the derogation 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.

Are there any other benefits that would accrue 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.

## **Consultation**

### ***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 of the Commission Regulation.

On 17 February, 16 June and 6 July 2009 short, informal, consultations were undertaken with stakeholders by e-mail on drafts of the Commission Regulation prior to their consideration at meetings of the EU Standing Committee on the Food Chain and Animal Health (SCoFCAH). The draft of the Commission Regulation which achieved a qualified majority vote in SCoFCAH on 15 July 2009 was circulated to stakeholders and enforcement authorities on 28 July 2009.

### ***Formal Consultation***

A public consultation on the draft statutory instrument relating to England is being carried out between 28 September and 9 November 2009. The consultation package is being sent to known stakeholders, including enforcement authorities, by e-mail and in hard copy to stakeholders without e-mail addresses. It is also being published on the Food Standards Agency's website.

We invite stakeholders to inform us if there any costs and benefits specific to small firms that we have not considered.

## **Enforcement**

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.

## **Simplification**

The harmonisation, across the European Community, 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.

## **Implementation and Review**

The Commission Regulation effecting amendments to the Food Supplements Directive 2002/46/EC will come into force on [1 January 2010] and the national legislation would come into force on [the same date].

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

## Specific Impact Tests: Checklist

Use the table below to demonstrate how broadly you have considered the potential impacts of your policy options.

**Ensure that the results of any tests that impact on the cost-benefit analysis are contained within the main evidence base; other results may be annexed.**

Type of testing undertaken	<i>Results in Evidence Base?</i>	<i>Results annexed?</i>
Competition Assessment	Yes	No
Small Firms Impact Test	Yes	No
Legal Aid	No	No
Sustainable Development	Yes	No
Carbon Assessment	No	No
Other Environment	No	No
Health Impact Assessment	No	No
Race Equality	Yes	No
Disability Equality	Yes	No
Gender Equality	Yes	No
Human Rights	No	No
Rural Proofing	No	No

## **Competition Assessment**

We do not expect any competition issues arising from this policy. However, we invite stakeholders to comment.

## **Small Firms Impact Test**

We do not expect any specific issues arising for small firms as a result of this policy. However we invite stakeholders to comment.

## **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.

## **Race equality issues**

We do not expect any specific race equality issues arising as a result of this policy. However we invite stakeholders to comment.

## **Gender equality issues**

We do not expect any specific gender equality issues arising as a result of this policy. However we invite stakeholders to comment.

## **Disability equality issues**

We do not expect any specific disability equality issues arising as a result of this policy. However we invite stakeholders to comment.

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 STATUTORY INSTRUMENTS
 

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2009 No.

## FOOD, ENGLAND

 The Food Supplements (England) and Addition of Vitamins,  
 Minerals and Other Substances (England) (Amendment)  
 Regulations 2009

<i>Made</i>	- - - -	2009
<i>Laid before Parliament</i>		2009
<i>Coming into force</i>	- -	1st January 2010

The Secretary of State makes the following Regulations in exercise of the powers conferred by sections 16(1)(a) and (e), 17(1) and (2), 26(1)(a) and (3) and 48(1) of the Food Safety Act 1990(a) and now vested in him(b), as read with paragraph 1A of Schedule 2 to the European Communities Act 1972(c).

In accordance with section 48(4A) of the Food Safety Act 1990, the Secretary of State has had regard to relevant advice given by the Food Standards Agency.

These Regulations make provision for a purpose mentioned in section 2(2) of the European Communities Act 1972 and it appears to the Secretary of State that it is expedient for any reference to an Annex to Directive 2002/46/EC of the European Parliament and of the Council on the approximation of the laws of the Member States relating to food supplements(d) to be construed as a reference to that Annex as amended from time to time.

As required by Article 9 of Regulation (EC) No. 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the

- 
- (a) 1990 c. 16; section 1(1) and (2) (definition of “food”) was substituted by S.I. 2004/2990. Sections 17 and 48 were amended by paragraphs 12 and 21 respectively of Schedule 5 to the Food Standards Act 1999 (1999 c.28), “the 1999Act”. Section 48 was also amended by S.I. 2004/2990. Section 26(3) was amended by Schedule 6 to the 1999 Act. Section 53(2) was amended by paragraph 19 of Schedule 16 to the Deregulation and Contracting Out Act 1994 (1994 c.40), Schedule 6 to the 1999 Act and S.I. 2004/2990.
- (b) Functions formerly exercisable by “the Ministers” (being, in relation to England and Wales and acting jointly, the Minister of Agriculture, Fisheries and Food and the Secretaries of State respectively concerned with health in England and food and health in Wales and, in relation to Scotland, the Secretary of State) are now exercisable in relation to England by the Secretary of State pursuant to paragraph 8 of Schedule 5 to the 1999 Act. Functions of “the Ministers”, so far as exercisable in relation to Wales, were transferred to the National Assembly for Wales by the National Assembly for Wales (Transfer of Functions) Order 1999 (S.I. 1999/672) as read with section 40(3) of the 1999 Act and thereafter transferred to the Welsh Ministers by paragraph 30 of Schedule 11 to the Government of Wales Act 2006 (2006 c.32). Those functions, so far as exercisable in relation to Scotland, were transferred to the Scottish Ministers by section 53 of the Scotland Act 1998 (1998 c. 46) as read with section 40(2) of the 1999 Act.
- (c) 1972 c.68. Paragraph 1A of Schedule 2 was inserted by section 28 of the Legislative and Regulatory Reform Act 2006 (2006 c.51).
- (d) OJ No. L183, 12.7.2002, p.51, as last amended by Commission Regulation (EC) No. [ ]/2009 amending Directive 2002/46/EC and Regulation (EC) No. 1925/2006 as regards the lists of vitamins and minerals and their forms that can be added to foods, including food supplements (OJ No. L[ ]).

European Food Safety Authority and laying down procedures in matters of food safety<sup>(a)</sup> there been open and transparent public consultation during the preparation of the following Regulations.

### **Title and commencement**

1. These Regulations may be cited as the Food Supplements (England) and Addition of Vitamins, Minerals and Other Substances (England) (Amendment) Regulations 2009 and come into force on 1st January 2010.

### **Amendment of the Food Supplements (England) Regulations 2003**

2.—(1) The Food Supplements (England) Regulations 2003<sup>(b)</sup> are amended in accordance with the following paragraphs.

(2) In paragraph (1) of regulation (2) (interpretation), for the definition “Directive 2002/46” there is substituted the following definition—

““Directive 2002/46” means Directive 2002/46/EC of the European Parliament and of the Council on the approximation of the laws of the Member States relating to food supplements as last amended by Commission Regulation (EC) No. [ ]/2009 amending Directive 2002/46/EC and Regulation (EC) No. 1925/2006 as regards the lists of vitamins and minerals and their forms that can be added to foods, including food supplements<sup>(c)</sup>”.

(3) Immediately after paragraph (3) of regulation 2 (interpretation) there is inserted the following paragraph—

“(4) In these Regulations any reference to an Annex to Directive 2002/46 is a reference to that Annex as amended from time to time.”.

(4) In regulation 5 (prohibitions on sale relating to composition of food supplements)—

- (a) at paragraph (1), omit the words ‘subject to paragraph (3)’;
- (b) at sub-paragraph (a) of paragraph (1), for the words ‘column 1 of Schedule 1’ there is substituted the words “Annex I to Directive 2002/46”;
- (c) at sub-paragraph (b)(i) of paragraph (1), for the words “Schedule 2” there is substituted the words “Annex II to Directive 2002/46”; and
- (d) paragraph (3) is omitted.

(5) In regulation 6 (restrictions on sale relating to labelling etc of food supplements), for sub-paragraph (b) of paragraph (3) there is substituted the following sub-paragraph.

“(b) in the case of a vitamin or mineral listed in Annex I to Directive 2002/46 be given using the relevant unit specified in brackets after the name of that vitamin or mineral”.

(6) Schedule 1 (vitamins and minerals which may be used in the manufacture of food supplements) and Schedule 2 (form of vitamin and mineral substances which may be used in the manufacturer of food supplements) are omitted.

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(a) OJ No. L31, 1.2.2002, p.1, as last amended by Regulation (EC) No. 596/2009 of the European Parliament and of the Council adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468 with regard to the regulatory procedure with scrutiny: Adaptation to the regulatory procedure with scrutiny – Part Four (OJ No. L188, 18.7.2009, p.14).

(b) S.I. 2003/1387, amended by S.I. 2007/330; there are other amending instruments but none is relevant.

(c) OJ No. [ ].

**Amendment of the Addition of Vitamins, Minerals and Other Substances (England) Regulations 2007**

3.—(1) The Addition of Vitamins, Minerals and Other Substances (England) Regulations 2007<sup>(a)</sup> are amended in accordance with the following paragraph.

(2) In paragraph (1) of regulation 2 (interpretation), for the definition “the EC Regulation”, there is substituted the following definition—

““the EC Regulation” means Regulation (EC) No. 1925/2006 of the European Parliament and of the Council on the addition of vitamins and minerals and of certain other substances to foods<sup>(b)</sup> as last amended by Commission Regulation (EC) No. [ ]/2009 amending Directive 2002/46/EC and Regulation (EC) No. 1925/2006 as regards the lists of vitamins and minerals and their forms that can be added to foods, including food supplements.” .

Signed by authority of the Secretary of State for Health

Date

*Name*  
Minister of State,  
Department of Health

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(a) S.I. 2007/1631.

(b) OJ No. L404, 30.12.2006, p.26.



**Annex D**

**COUNCIL OF  
THE EUROPEAN UNION**

**Brussels, 20 August 2009**

**12695/09**

**LIMITE**

**DENLEG 73**

**COVER NOTE**

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from: European Commission  
date of receipt: 19 August 2009  
to: General Secretariat of the Council

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Subject: Draft Commission Regulation amending Directive 2002/46/EC and Regulation (EC) No 1925/2006 as regards the lists of vitamins and minerals and their forms that can be added to foods, including food supplements

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Delegations will find attached Commission document D005352/03.

Encl.: D005352/03



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels,  
C(2009)  
D005352/03

final

Draft

**COMMISSION REGULATION**

**of**

**amending Directive 2002/46/EC and Regulation (EC) No 1925/2006 as regards the lists  
of vitamins and minerals and their forms that can be added to foods, including food  
supplements**

**(Text with EEA relevance)**

**EN**

**EN**

Draft

## COMMISSION REGULATION

of

**amending Directive 2002/46/EC and Regulation (EC) No 1925/2006 as regards the lists of vitamin and minerals and their forms that can be added to foods, including food supplements**

**(Text with EEA relevance)**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to 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 States relating to food supplements<sup>1</sup>, and in particular Article 4(5) thereof,

Having regard to 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<sup>2</sup>, and in particular Article 3(3) thereof,

After consulting the European Food Safety Authority,

Whereas:

- (1) Annexes I and II to Directive 2002/46/EC establish the lists of vitamins and minerals, and for each of them the forms, that may be used for the manufacture of food supplements. Modifications to these lists are to be adopted in compliance with the requirements laid down in Article 4 of that Directive and in accordance with the procedure referred to in its Article 13(3).
- (2) Annexes I and II to Regulation (EC) No 1925/2006 establish the lists of vitamins and minerals, and for each of them the forms, that may be added to food. Modifications to these lists are to be adopted in compliance with the requirements laid down in Article 3 of that Regulation and in accordance with the procedure referred to in its Article 14(3).
- (3) New vitamin and mineral forms have been evaluated by the European Food Safety Authority. The substances which have received a favourable scientific opinion and for which the requirements laid down in Directive 2002/46/EC and in Regulation (EC) No 1925/2006 are complied with should be added to the respective lists in those acts.
- (4) Interested parties were consulted and the provided comments were taken into consideration.

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<sup>1</sup> OJ L 183, 12.7.2002, p. 51.

<sup>2</sup> OJ L 404, 30.12.2006, p. 26.

- (5) Following the scientific evaluation by the European Food Safety Authority, it is appropriate to introduce specifications for some vitamin and mineral substances for their identification.
- (6) Directive 2002/46/EC and Regulation (EC) No 1925/2006 should therefore be amended accordingly.
- (7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

*Article 1*

Annexes I and II to Directive 2002/46/EC are replaced respectively by the texts in Annex I and II to this Regulation.

*Article 2*

Regulation (EC) No 1925/2006 is amended as follows:

- (1) In Annex I, the word "Boron" is added in the list in point 2.
- (2) Annex II is replaced by the text in Annex III to this Regulation.

*Article 3*

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

*For the Commission*  
*Androulla VASSILIOU*  
*Member of the Commission*

## ANNEX I

### "ANNEX I

#### **Vitamins and minerals which may be used in the manufacture of food supplements**

1. Vitamins

Vitamin A ( $\mu\text{g RE}$ )

Vitamin D ( $\mu\text{g}$ )

Vitamin E (mg  $\alpha$ -TE)

Vitamin K ( $\mu\text{g}$ )

Vitamin B1 (mg)

Vitamin B2 (mg)

Niacin (mg NE)

Pantothenic acid (mg)

Vitamin B6 (mg)

Folic acid ( $\mu\text{g}$ )\*

Vitamin B12 ( $\mu\text{g}$ )

Biotin ( $\mu\text{g}$ )

Vitamin C (mg)

2. Minerals

Calcium (mg)

Magnesium (mg)

Iron (mg)

Copper ( $\mu\text{g}$ )

Iodine ( $\mu\text{g}$ )

Zinc (mg)

Manganese (mg)

Sodium (mg)

Potassium (mg)

Selenium (µg)

Chromium (µg)

Molybdenum (µg)

Fluoride (mg)

Chloride (mg)

Phosphorus (mg)

Boron (mg)

Silicon (mg)

- 
- \* Folic acid is the term included in Annex I of Commission Directive 2008/100/EC of 28 October 2008 amending Council Directive 90/496/EEC on nutrition labelling for foodstuffs as regards recommended daily allowances, energy conversion factors and definitions for nutrition labelling purposes and covers all forms of folates."

## ANNEX II

### "ANNEX II

#### **Vitamin and mineral substances which may be used in the manufacture of food supplements**

- A. Vitamins
1. VITAMIN A
    - (a) retinol
    - (b) retinyl acetate
    - (c) retinyl palmitate
    - (d) beta-carotene
  2. VITAMIN D
    - (a) cholecalciferol
    - (b) ergocalciferol
  3. VITAMIN E
    - (a) D-alpha-tocopherol
    - (b) DL-alpha-tocopherol
    - (c) D-alpha-tocopheryl acetate
    - (d) DL-alpha-tocopheryl acetate
    - (e) D-alpha-tocopheryl acid succinate
    - (f) mixed tocopherols\*
    - (g) tocotrienol tocopherol\*\*
  4. VITAMIN K
    - (a) phylloquinone (phytomenadione)
    - (b) menaquinone\*\*\*
  5. VITAMIN B1
    - (a) thiamin hydrochloride
    - (b) thiamin mononitrate
    - (c) thiamine monophosphate chloride

- (d) thiamine pyrophosphate chloride
- 6. VITAMIN B2
  - (a) riboflavin
  - (b) riboflavin 5'-phosphate, sodium
- 7. NIACIN
  - (a) nicotinic acid
  - (b) nicotinamide
  - (c) inositol hexanicotinate (inositol hexaniacinate)
- 8. PANTOTHENIC ACID
  - (a) D-pantothenate, calcium
  - (b) D-pantothenate, sodium
  - (c) dexpanthenol
  - (d) pantethine
- 9. VITAMIN B6
  - (a) pyridoxine hydrochloride
  - (b) pyridoxine 5'-phosphate
  - (c) pyridoxal 5'-phosphate
- 10. FOLATE
  - (a) pteroylmonoglutamic acid
  - (b) calcium-L-methylfolate
- 11. VITAMIN B12
  - (a) cyanocobalamin
  - (b) hydroxocobalamin
  - (c) 5'-deoxyadenosylcobalamin
  - (d) methylcobalamin

12. BIOTIN

- (a) D-biotin

13. VITAMIN C

- (a) L-ascorbic acid
- (b) sodium-L-ascorbate
- (c) calcium-L-ascorbate\*\*\*\*
- (d) potassium-L-ascorbate
- (e) L-ascorbyl 6-palmitate
- (f) magnesium L-ascorbate
- (g) zinc L-ascorbate

B. Minerals

calcium acetate

calcium L-ascorbate

calcium bisglycinate

calcium carbonate

calcium chloride

calcium citrate malate

calcium salts of citric acid

calcium gluconate

calcium glycerophosphate

calcium lactate

calcium pyruvate

calcium salts of orthophosphoric acid

calcium succinate

calcium hydroxide

calcium L-lysinate

calcium malate  
calcium oxide  
calcium L-pidolate  
calcium L-threonate  
calcium sulphate  
magnesium acetate  
magnesium L-ascorbate  
magnesium bisglycinate  
magnesium carbonate  
magnesium chloride  
magnesium salts of citric acid  
magnesium gluconate  
magnesium glycerophosphate  
magnesium salts of orthophosphoric acid  
magnesium lactate  
magnesium L-lysinate  
magnesium hydroxide  
magnesium malate  
magnesium oxide  
magnesium L-pidolate  
magnesium potassium citrate  
magnesium pyruvate  
magnesium succinate  
magnesium sulphate  
magnesium taurate  
magnesium acetyl taurate

ferrous carbonate  
ferrous citrate  
ferric ammonium citrate  
ferrous gluconate  
ferrous fumarate  
ferric sodium diphosphate  
ferrous lactate  
ferrous sulphate  
ferric diphosphate (ferric pyrophosphate)  
ferric saccharate  
elemental iron (carbonyl+electrolytic+hydrogen reduced)  
ferrous bisglycinate  
ferrous L-pidolate  
ferrous phosphate  
iron (II) taurate  
cupric carbonate  
cupric citrate  
cupric gluconate  
cupric sulphate  
copper L-aspartate  
copper bisglycinate  
copper lysine complex  
copper (II) oxide  
sodium iodide  
sodium iodate  
potassium iodide

potassium iodate  
zinc acetate  
zinc L-ascorbate  
zinc L-aspartate  
zinc bisglycinate  
zinc chloride  
zinc citrate  
zinc gluconate  
zinc lactate  
zinc L-lysinate  
zinc malate  
zinc mono-L-methionine sulphate  
zinc oxide  
zinc carbonate  
zinc L-pidolate  
zinc picolinate  
zinc sulphate  
manganese ascorbate  
manganese L-aspartate  
manganese bisglycinate  
manganese carbonate  
manganese chloride  
manganese citrate  
manganese gluconate  
manganese glycerophosphate  
manganese pidolate

manganese sulphate  
sodium bicarbonate  
sodium carbonate  
sodium chloride  
sodium citrate  
sodium gluconate  
sodium lactate  
sodium hydroxide  
sodium salts of orthophosphoric acid  
potassium bicarbonate  
potassium carbonate  
potassium chloride  
potassium citrate  
potassium gluconate  
potassium glycerophosphate  
potassium lactate  
potassium hydroxide  
potassium L-pidolate  
potassium malate  
potassium salts of orthophosphoric acid  
L-selenomethionine  
selenium enriched yeast\*\*\*\*\*  
selenious acid  
sodium selenate  
sodium hydrogen selenite  
sodium selenite

chromium (III) chloride  
chromium (III) lactate trihydrate  
chromium nitrate  
chromium picolinate  
chromium (III) sulphate  
ammonium molybdate (molybdenum (VI))  
potassium molybdate (molybdenum (VI))  
sodium molybdate (molybdenum (VI))  
calcium fluoride  
potassium fluoride  
sodium fluoride  
sodium monofluorophosphate  
boric acid  
sodium borate  
choline-stabilised orthosilicic acid  
silicon dioxide  
silicic acid\*\*\*\*\*

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\* alpha-tocopherol <20%, beta-tocopherol <10%, gamma-tocopherol 50 – 70% and delta-tocopherol 10 - 30%

\*\* Typical levels of individual tocopherols and tocotrienols:

- 115 mg/g alpha-tocopherol (101 mg/g minimum)
- 5 mg/g beta-tocopherol (<1 mg/g minimum)
- 45 mg/g gamma-tocopherol (25 mg/g minimum)
- 12 mg/g delta-tocopherol (3 mg/g minimum)
- 67 mg/g alpha-tocotrienol (30 mg/g minimum)
- <1 mg/g beta-tocotrienol (<1 mg/g minimum)
- 82 mg/g gamma-tocotrienol (45 mg/g minimum)
- 5 mg/g delta-tocotrienol (<1 mg/g minimum).

\*\*\* Menaquinone occurring principally as menaquinone-7 and, to a minor extent, menaquinone-6.

\*\*\*\* May contain up to 2% of threonate.

\*\*\*\*\*Selenium-enriched yeasts produced by culture in the presence of sodium selenite as selenium source and containing, in the dried form as marketed, not more than 2.5 mg Se/g. The predominant organic selenium species present in the yeast is selenomethionine (between 60 and 85% of the total extracted selenium in the product). The content of other organic selenium compounds including selenocysteine shall not exceed 10% of total extracted selenium. Levels of inorganic selenium normally shall not exceed 1% of total extracted selenium.

\*\*\*\*\*In the form of gel."

## ANNEX III

### "ANNEX II

#### VITAMIN FORMULATIONS AND MINERAL SUBSTANCES WHICH MAY BE ADDED TO FOODS

##### 1. Vitamin formulations

###### VITAMIN A

retinol

retinyl acetate

retinyl palmitate

beta-carotene

###### VITAMIN D

cholecalciferol

ergocalciferol

###### VITAMIN E

D-alpha-tocopherol

DL-alpha-tocopherol

D-alpha-tocopheryl acetate

DL-alpha-tocopheryl acetate

D-alpha-tocopheryl acid succinate

###### VITAMIN K

phylloquinone (phytomenadione)

menaquinone\*

###### VITAMIN B1

thiamin hydrochloride

thiamin mononitrate

###### VITAMIN B2

riboflavin

riboflavin 5'-phosphate, sodium

###### NIACIN

nicotinic acid

nicotinamide

PANTOTHENIC ACID

D-pantothenate, calcium

D-pantothenate, sodium

dexpanthenol

VITAMIN B6

pyridoxine hydrochloride

pyridoxine 5'-phosphate

pyridoxine dipalmitate

FOLIC ACID

pteroylmonoglutamic acid

calcium-L-methylfolate

VITAMIN B12

cyanocobalamin

hydroxocobalamin

BIOTIN

D-biotin

VITAMIN C

L-ascorbic acid

sodium-L-ascorbate

calcium-L-ascorbate

potassium-L-ascorbate

L-ascorbyl 6-palmitate

## 2. **Mineral substances**

calcium carbonate

calcium chloride

calcium citrate malate  
calcium salts of citric acid  
calcium gluconate  
calcium glycerophosphate  
calcium lactate  
calcium salts of orthophosphoric acid  
calcium hydroxide  
calcium malate  
calcium oxide  
calcium sulphate  
magnesium acetate  
magnesium carbonate  
magnesium chloride  
magnesium salts of citric acid  
magnesium gluconate  
magnesium glycerophosphate  
magnesium salts of orthophosphoric acid  
magnesium lactate  
magnesium hydroxide  
magnesium oxide  
magnesium potassium citrate  
magnesium sulphate  
ferrous bisglycinate  
ferrous carbonate  
ferrous citrate  
ferric ammonium citrate  
ferrous gluconate

ferrous fumarate  
ferric sodium diphosphate  
ferrous lactate  
ferrous sulphate  
ferric diphosphate (ferric pyrophosphate)  
ferric saccharate  
elemental iron (carbonyl + electrolytic + hydrogen  
reduced)  
cupric carbonate  
cupric citrate  
cupric gluconate  
cupric sulphate  
copper lysine complex  
sodium iodide  
sodium iodate  
potassium iodide  
potassium iodate  
zinc acetate  
zinc bisglycinate  
zinc chloride  
zinc citrate  
zinc gluconate  
zinc lactate  
zinc oxide  
zinc carbonate  
zinc sulphate  
manganese carbonate

manganese chloride  
manganese citrate  
manganese gluconate  
manganese glycerophosphate  
manganese sulphate  
sodium bicarbonate  
sodium carbonate  
sodium citrate  
sodium gluconate  
sodium lactate  
sodium hydroxide  
sodium salts of orthophosphoric acid  
selenium enriched yeast\*\*  
sodium selenate  
sodium hydrogen selenite  
sodium selenite  
sodium fluoride  
potassium fluoride  
potassium bicarbonate  
potassium carbonate  
potassium chloride  
potassium citrate  
potassium gluconate  
potassium glycerophosphate  
potassium lactate  
potassium hydroxide  
potassium salts of orthophosphoric acid

chromium (III) chloride and its hexahydrate

chromium (III) sulphate and its hexahydrate

ammonium molybdate (molybdenum (VI))

sodium molybdate (molybdenum (VI))

boric acid

sodium borate

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\* Menaquinone occurring principally as menaquinone-7 and, to a minor extent, menaquinone-6.

\*\* Selenium-enriched yeasts produced by culture in the presence of sodium selenite as selenium source and containing, in the dried form as marketed, not more than 2.5 mg Se/g. The predominant organic selenium species present in the yeast is selenomethionine (between 60 and 85% of the total extracted selenium in the product). The content of other organic selenium compounds including selenocysteine shall not exceed 10% of total extracted selenium. Levels of inorganic selenium normally shall not exceed 1% of total extracted selenium."

**Vitamins, Minerals and their Sources to be added to the Annexes in Directive 2002/46/EC and Regulation (EC) No 1925/2006**

**Directive 2002/46/EC (Food Supplements)**

***Annex I – Permitted Vitamins and Minerals***

**Minerals:**

Boron  
Silicon

***Annex II – Permitted Vitamin and Mineral Sources***

***Vitamin Sources:***

**Vitamin B1**

thiamine monophosphate chloride  
thiamine pyrophosphate chloride

**Niacin**

inositol hexanicotinate  
(inositol hexaniacinate)

**Pantothenic Acid**

pantethine

**Vitamin B6**

pyridoxal 5'-phosphate

**Vitamin B12**

5'-deoxyadenosylcobalamin  
methylcobalamin

**Vitamin C**

magnesium L-ascorbate  
zinc L-ascorbate

**Vitamin E**

mixed tocopherols\*  
tocotrienol tocopherol\*

**Vitamin K**

menaquinone\*

**Mineral Sources:**

boric acid	copper bisglycinate	potassium L-pidolate
calcium acetate	ferrous L-pidolate	potassium malate
calcium L-ascorbate	ferrous phosphate	potassium molybdate (Molybdenum (VI))
calcium bisglycinate	iron (II) taurate	selenious acid
calcium citrate malate	L-selenomethionine	selenium enriched yeast*
calcium fluoride	magnesium acetyl taurate	silicic acid gel*
calcium L-lysinate	magnesium L-ascorbate	silicon dioxide
calcium L-pidolate	magnesium bisglycinate	sodium borate
calcium L-threonate	magnesium L-lysinate	sodium monofluorophosphate
calcium malate	magnesium L-pidolate	zinc L-ascorbate
calcium pyruvate	magnesium malate	zinc L-aspartate
calcium succinate	magnesium potassium citrate	zinc bisglycinate
calcium sulphate	magnesium pyruvate	zinc L-lysinate
choline-stabilised orthosilicic acid	magnesium succinate	zinc L-pidolate
chromium (III) lactate trihydrate	magnesium taurate	zinc malate
chromium nitrate	manganese ascorbate	zinc mono-L-methionine sulphate
chromium picolinate	manganese bisglycinate	zinc picolinate
copper (II) oxide	manganese L-aspartate	
copper L-aspartate	manganese pidolate	

\* With conditions of use (see draft Commission Regulation at Annex D)

**Regulation (EC) No 1925/2006 (Fortified Foods)**

***Annex II – Permitted Vitamin and Mineral Sources***

**Vitamin Sources:**

**Vitamin K**

Menaquinone\*

**Folic Acid**

calcium-L-methylfolate

**Mineral Sources:**

boric acid

calcium citrate malate

calcium malate

ferrous bisglycinate

magnesium potassium citrate

selenium enriched yeast\*

sodium borate

zinc bisglycinate

\* *With conditions of use (see draft Commission Regulation at Annex D)*

## List of Interested Parties

4Children  
 ABF Grain Products Ltd  
 Adams Wilson & Associates  
 Advanced Health & Diet Solutions Ltd  
 Advertising Association  
 Advisory Body for Social Services Catering  
 Agricultural Industries Confederation  
 Albion Advanced Nutrition  
 Alcon Laboratories (UK) Ltd  
 Alliance for Natural Health  
 Allied Bakeries Ltd  
 Allied Technical Centre  
 Allsports International Ltd  
 Amway (Europe)  
 ANH Consultancy Ltd  
 Animal Medicines Inspectorate  
 Anna Revell  
 AOR (Europe) Ltd  
 APCO EUROPE/ APCO Worldwide  
 Arkopharma (UK) Ltd  
 Asda  
 Ashwell Associates  
 Associate Parliamentary Food & Health Forum  
 Associated British Foods Plc  
 Association of British Pharmaceutical Industries  
 Association of Cereal Food Manufacturers  
 Association of Port Health Authorities  
 Association of Public Analysts  
 Association of the European Self-Medication Industry  
 Au Naturel (UK) Inc  
 Authentix  
 Ay Jay Direct  
 Barry Atwood  
 Bath & North-East Somerset Trading Standards  
 Bausch & Lomb (UK) Ltd  
 Bayer Healthcare  
 Beadle House Clinic  
 Berry Ottaway & Associates Ltd  
 BHF Health Promotion Research Group  
 BHM Health Group  
 Bio Life  
 Biocalth International  
 BioCare  
 Biohealth Ltd  
 Blue Rubicon  
 Bodycote Law Labs  
 Boehringer Ingelheim Ltd  
 Booker Ltd  
 Boots  
 BPEX and EBLEX  
 BR Pharmaceuticals Ltd  
 Brakes Group  
 Bristol City Council  
 Bristows  
 Britannia Health Products Ltd  
 British Association for Applied Nutrition & Nutritional Therapy  
 British Beer and Pub Association  
 British Complementary Medicine Association  
 British Dental Association  
 British Dietetic Association  
 British Egg Industry Council  
 British Heart Foundation  
 British Herbal Medicine Association  
 British Hospitality Association  
 British Medical Association  
 British Nutrition Foundation  
 British Retail Consortium  
 British Society for Ecological Medicine  
 British Soft Drinks Association Ltd  
 British Sugar Plc  
 Britvic Soft Drinks Ltd  
 Brunel Healthcare  
 Buckton Scott Ltd  
 Business in Sport and Leisure  
 Cabinet Office  
 Cadbury Schweppes  
 Cambridge Commodities Ltd  
 Cambridge Manufacturing Company Ltd  
 CAMedica  
 Campden BRI  
 Cantox Health Services International  
 Capital Cliff Ltd  
 Caring Clinic (The)  
 Centrum  
 Cereal Partners (Nestle)  
 Cereal Partners UK  
 Chartered Institute of Environmental Health  
 Chefaro  
 Coca-Cola Great Britain and Ireland  
 Cognis UK Ltd  
 Community Foods Ltd  
 Compassion in World Farming  
 Consensus Action on Salt and Health  
 Consumer Focus  
 Consumers for Health Choice  
 Co-op / Brunel/ Somerfield  
 Co-operative Group  
 Co-operative Group (The)  
 Cornelius Produce Co Ltd  
 COSUCRA  
 Council for Responsible Nutrition  
 Covington & Burling  
 Crop Protection Association  
 Cumbria County Council  
 Cytoplan  
 Dailycer Ltd  
 Dairy Council  
 Dairy Crest Group Plc  
 Dairy UK Ltd  
 Damon Wallis  
 Danone Waters & Dairies UK Ltd  
 Department for Business, Innovation and Skills  
 Department for International Development  
 Department for Culture, Media and Sport

Diabetes UK  
 DPR Nutrition Limited  
 Dr D Downing  
 Dr John Meldrum  
 Dr Marilyn Glenville Clinic  
 Dr Nuria Booth  
 Dr Patrick Kingsley  
 Dr Peter Hinde  
 Dr Reckeweg  
 Dr Richard Moody  
 DSM  
 EAS UK Ltd  
 Eclipse Scientific Group  
 Efamol Ltd  
 Elizabeth Burnett  
 European Research into Consumer Affairs  
 Eversheds  
 F I Data Services  
 Federation of Small Businesses  
 Ferrosan Ltd  
 Firmenich UK Ltd  
 Food Additives and Ingredients Association  
 Food and Drink Federation  
 Food Commission UK Ltd  
 Food Policy Update  
 Food Standards Australia New Zealand  
 Foodaware (Consumers Food Group)  
 Foreign and Commonwealth Office  
 Foresight  
 Fortuna Healthcare  
 Forum of Private Business  
 Forum Products Ltd  
 Frensenius Kabi Ltd  
 Friends of the Earth  
 Fulcrum Health Ltd  
 G & G Food Suppliers Ltd  
 G R Lane Health Products  
 Galactosaemia Support Group  
 Gee Lawson Nutritional  
 Genuine Empowerment of Mothers in Society  
 Glaxosmithkline  
 Glutafin  
 Goldshield Healthcare Direct  
 Good Health Naturally  
 Grayshott Health Foods  
 Hadley Wood Healthcare Centre  
 Halal Food Authority (The)  
 Harrods Ltd  
 Health + Plus Ltd  
 Health Food Manufacturers' Association  
 Health Interlink Ltd  
 Health Perceptions UK  
 Health Protection Agency (HPA)  
 Health Quest  
 Herbalife Europe Ltd  
 HFMA Labelling, Advertising and Promotional  
 Advice  
 Higher Nature  
 Hildreth and Cocker Ltd  
 Hipp - Werk Georg HippOHG  
 Holford and Associates  
 Holland and Barrett  
 Honeyrose Products Ltd  
 Horesham Nutraceuticals Ltd  
 Hospital Caterers Association  
 Howard Foundation Research Group  
 IGD  
 ILS Ltd  
 Infant and Dietetic Foods Association  
 Innocent Drinks Ltd  
 Institute for Complementary and Natural  
 Medicine  
 Institute for Optimum Nutrition (The)  
 Institute of Chemical Engineers  
 Institute of Food Research  
 Institute of Food Science and Technology  
 Interested Party  
 InterHealth Nutraceuticals Inc  
 International Ayurveda Foundation  
 ISKCON  
 ISO Dynamic  
 J Woodcock  
 Jarrow Formulas Inc.  
 Juliette Kellow  
 Kanegrade  
 Kellogs  
 Kerry Foods Ltd  
 Kinetic Natural Products  
 Kraeber (UK) Ltd  
 Kudos  
 Laboratory of the Government Chemist  
 LACORS  
 Lamberts Healthcare Ltd.  
 Laura Dance  
 Leatherhead Food International  
 Leatherhead Food Research Association  
 Lew Zachs  
 Life Source Supplements Ltd  
 Lifeplan  
 Lifes2Good  
 Linda Beveridge  
 Liz Downing  
 London Metropolitan University  
 Lovells  
 Lyn Anderson  
 Margaret Anderson & Associates  
 Marks and Spencer Plc  
 Mars Drinks  
 Mars UK Ltd  
 McDonald's Restaurants Ltd  
 McIntyre Consultants Ltd  
 Meat and Livestock Commission  
 Medicago Ltd  
 Medicines and Healthcare products Regulatory  
 Agency  
 Melanie Ruffell  
 Metabolics Ltd  
 Midwives Information and Resource Service  
 Mineral Check Ltd  
 Miss Alison Day  
 Moss Pharmacy  
 MotherHem Ltd  
 MPL Marketing Services Ltd  
 Mr & Mrs White  
 Mr Chris Dunk  
 Mr Derek Whatmore

Mr Duke  
 Mr Edward Langridge  
 Mr Edward Sanderson  
 Mr John Kirkham  
 MRC - Human Nutrition Research  
 MRI Ltd (Mineral Resources Inter. UK)  
 Mrs G Ward  
 Mrs Jan Robertson  
 Mrs Nicholas Parsons  
 Ms Carol Fisher  
 Ms Davina Birchenall  
 Ms Elizabeth Oliver  
 Ms Mary Strugar  
 Ms Mina Mistry  
 Ms Yvonne Sharrat  
 Musashi  
 National Association of British and Irish Millers  
 (NABIM)  
 National Association of Care Catering  
 National Association of Cider and Perry Makers  
 National Association of Health Stores  
 National Association of Master Bakers  
 National Childbirth Trust  
 National Consumer Council  
 National Consumer Federation  
 National Council of Women of Great Britain  
 National Farmers' Union  
 National Federation of Consumer Groups  
 National Federation of Women's Institutes  
 National Institute for Health and Clinical  
 Excellence  
 National Institute of Medical Herbalists  
 National Office of Animal Health  
 National Pharmacy Association  
 National Starch and Food Innovation  
 Natural Health Practice  
 Natural Options  
 Natural Practice (The)  
 Natural Products Magazine  
 Natural-Immunogenics (UK) Ltd  
 Nature's Aid  
 Nature's Life  
 Nature's Own  
 Natures Remedies  
 Nature's Sunshine Products  
 Nestle Confectionery (UK)  
 NMB Consulting  
 Northern Foods Plc  
 NSA International, Inc  
 Nu-Mega Ingredients Ltd  
 Nutragen Ltd  
 NutraHealth Ltd  
 Nutralife (UK) Ltd  
 Nutri (Imports & Exports) Ltd  
 Nutri Centre (The)  
 Nutri Labs  
 Nutri Ltd  
 Nutricia Ltd  
 Nutrigenomx Consultancy  
 NutriGold Ltd  
 Nutrilaw  
 Nutrilicious  
 Nutri-Link UK  
 Nutritech Consultancy Ltd  
 Nutrition 21  
 Nutrition and Allergy Clinic  
 Nutrition Points Ltd  
 Nutrition Society (The)  
 Nutritional Therapy Council  
 Nutri-West  
 Optima Health and Nutrition  
 Oral Technologies  
 Orangina Group  
 Orchard House Foods  
 Organix Brands Plc  
 Passion4Health International Ltd  
 Paul Anthony Taylor  
 PepsiCo UK  
 Perfect UK  
 Perrigo UK  
 Pesticide Action Network UK  
 Peter Black Healthcare Ltd.  
 Pharmadass / Health Aid  
 Pharma-Nord UK Ltd  
 Pizza Hut (UK) Ltd  
 Positive Nutrition Ltd  
 Potters Herbal Supplies Ltd  
 Power Health Products Ltd  
 Premier Foods Plc  
 Princes Foundation for Integrated Health  
 Principle Healthcare  
 Procter & Gamble UK and Ireland  
 Proprietary Association of Great Britain  
 Provision Trade Federation  
 Quest Vitamins  
 QVC  
 Raworth Nutrition College  
 Re-Action Sales & Marketing  
 Reading Scientific Services Ltd  
 Reigate and Banstead Borough Council  
 Roche  
 Romada Healthcare  
 Royal College of Paediatrics and Child Health  
 Royal College of Physicians  
 Royal Free & University College Medical School  
 Royal Pharmaceutical Society of Great Britain  
 Royal Society for Public Health  
 Rubicon Technical Ltd  
 S & D Chemicals Ltd  
 Sage Organic Ltd  
 Sainsbury Supermarkets Ltd  
 Salus UK Ltd  
 Sami Labs Ltd  
 SDR  
 Seven Seas Ltd  
 Shoosmith & Harrison Solicitors  
 SHS International Ltd  
 SiS (Science in Sport) Ltd  
 Society of Homeopaths  
 Society of Independent Brewers  
 Solaray Nutritional Supplements  
 Solgar  
 Solo Nutrition Ltd  
 Somerfield / Coop / Brunel  
 Somerfield Stores Ltd  
 Spatone

St George's, University of London  
Sugar Bureau (The)  
Surrey County Council  
Sustain - The Alliance for Better Food and Farming  
Swiss Natural Sources  
Tesco Stores Plc  
Tianshi UK Plc  
Trading Standards Institutes  
Transport and General Workers Union  
Trimeasy  
Typhoo Tea Ltd  
U.S. Commercial Service  
UCIB - Solabia Group  
UK Sport  
UK VLCD Industry Group  
Unichem/Alliance  
Unilever Plc  
Unipath  
University of Reading  
University of Southampton  
Valupak  
Vega Nutritionals Ltd  
VEGA Research  
Vegan Society (The)

Vegetarian Society (The)  
Vibrant Life Ltd  
Viridian Nutrition Ltd  
Vitabiotics Ltd  
Vitamer Labs  
Vitrition UK Ltd  
Waitrose Ltd  
Wallace Manufacturing  
Walsall Metropolitan Borough Council  
Warburton  
Warwickshire County Council  
Wassen International Ltd  
Weetabix Ltd  
What Doctors Don't Tell You  
Which?  
Whitehouse Consultancy Ltd (The)  
Whitworths Foods Group Ltd  
Wholistic Nutritional Therapy  
Wild Oats Natural Foods  
Wine and Spirit Trade Association  
Wm Morrison Supermarkets Plc  
Woods Supplements  
Worcestershire Scientific Services  
Wyeth Consumer Healthcare