EXPLANATORY MEMORANDUM TO

THE FOOD SUPPLEMENTS (ENGLAND) (AMENDMENT) REGULATIONS 2007

2007 No. 330

1. This explanatory memorandum has been prepared by the Food Standards Agency and is laid before Parliament by Command of Her Majesty.

2. Description

2.1 This instrument implements European Commission Directive 2006/37/EC which amends Commission Directive 2002/46/EC. The amendment to the Directive makes changes to the Annex which lists the vitamins and minerals and their sources which may be used in the manufacture of food supplements. It amends one of the headings ('folic acid' to 'folate') and also adds two new sources of vitamins and minerals which may be used in the manufacture of food supplements (another form of the vitamin folate and another form of the mineral iron).

3. Matters of special interest to the Joint Committee on Statutory Instruments or the Select Committee on Statutory Instruments

3.1 None

4. Legislative Background

4.1 The Food Supplements (England) Regulations 2003 (SI 2003 1387) implement harmonised EU measures contained in European Commission Directive 2002/46/EC (as amended) relating to food supplements ("the Directive"). The Directive specifies the vitamin and mineral substances, forms and units of measurement which may be used in food supplements and the labelling, presentation and advertising allowable. Positive lists of permitted vitamins and minerals and their sources are included in the Annexes to the Directive. Modifications to the positive lists in the Directive can be adopted following a positive assessment of safety data by the European Food Safety Authority (EFSA) and agreement by Member States at the Standing Committee of the Food Chain and Animal Health.

4.2 A transposition note is attached.

5. Extent

5.1 This instrument applies to England. Separate but parallel legislation is being made for Scotland, Wales and Northern Ireland.

6. European Convention on Human Rights

6.1 As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

7. Policy background

7.1 Food supplements are defined as food sold in dose form whose purpose is to supplement the normal diet, and which is a concentrated source of a vitamin or mineral or other substance with a nutritional or physiological effect, alone or in combination. The Directive lays down a framework for Community rules on food supplements marketed as foodstuffs in order to promote the free movement of goods; ensure a high level of consumer protection; facilitate consumer choice through improved labelling requirements; and facilitate efficient monitoring of food supplements on the market.

7.2 The Directive specifies the vitamin and mineral substances, forms and units of measurement which may be used in food supplements and the labelling, presentation and advertising allowable. Positive lists of permitted vitamins and minerals and their sources are included in the Annexes to the Directive.

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

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

7.5 The amendment will add to the positive list those substances which have now been evaluated by EFSA and have received a positive opinion. The changes will enable products containing the two substances, which are currently marketed in the UK under a temporary derogation, to continue to be available indefinitely and thereby enable continued consumer choice. The amendment also changes the heading ‘Folic acid’ to ‘Folate’ to allow a broader range of substances to be added to the list in future. Further amendments to the Directive are expected between 2007 and 2009. These will add further substances to the lists in the Annexes to the Directive and these changes will subsequently be implemented into national legislation.

8. Impact

8.1 A Regulatory Impact Assessment is attached to this memorandum.

8.2 The Food Standards Agency consulted all stakeholders on the proposed regulations. The primary business sector that will be affected by the regulatory proposals will be manufacturers of food supplements. However, consultation has confirmed that the measures proposed impose no new financial burdens. Rural areas and members of the ethnic communities of any particular racial group are unaffected by these proposals. Charities and voluntary organisations are unaffected by these proposals.

9. Contact

Karen Pratt at the Food Standards Agency Tel: 020 7276 8568 or e-mail: karen.pratt@foodstandards.gsi.gov.uk can answer any queries regarding the instrument.

FULL REGULATORY IMPACT ASSESSMENT

The Food Supplements (England) (Amendment) Regulations 2007

PURPOSE AND INTENDED EFFECT OF THE REGULATIONS

Objective

1. These Regulations implement, in England, Directive 2006/37/EC of 30 March 2006 amending Directive 2002/46/EC relating to food supplements ('the Directive'). They amend the Food Supplements (England) Regulations 2003, SI 2003/1387. Parallel implementing legislation will be made in Scotland, Wales and Northern Ireland.

Important Note

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

Background

3. The Directive, which is implemented in England by The Food Supplements (England) Regulations 2003 SI 1387, lays down certain requirements relating to food supplements.

4. Food supplements are defined as food sold in dose form whose purpose is to supplement the normal diet, and which is a concentrated source of a vitamin or mineral or other substance with a nutritional or physiological effect, alone or in combination. The Directive lays down a framework for Community rules on food supplements marketed as foodstuffs in order to promote the free movement of goods; ensure a high level of consumer protection; facilitate consumer choice through improved labelling requirements; and facilitate efficient monitoring of food supplements on the market.

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

6. Derogation from the requirement for vitamin and mineral substances to be listed in the Annexes to the Directive has been allowed in the UK, where safety dossiers were submitted for assessment by EFSA not later than 12

July 2005. Derogation may apply until the end of 2009, if EFSA has not given an unfavourable opinion in respect of the use of that substance.

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

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

Provisions in the Regulations

9. The key proposals for the amendment Regulations are:

- In Schedule 1 (which list vitamins and minerals which may be used in the manufacture of food supplements), to amend the heading 'FOLIC ACID' to 'FOLATE'.
- In Schedule 2 (which sets out the form of vitamin and mineral substances which may be used in the manufacture of food supplements) to make the following changes-
    - Section A (Vitamins) to amend the heading 'FOLIC ACID' to 'FOLATE' and under that revised heading insert Calcium-L-methylfolate as a substance that can be used in food supplements
    - Section B (Minerals) insert Ferrous bisglycinate as a substance that can be used in food supplements.

Rationale for Government Intervention

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

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

12. The heading 'Folic acid' in Annex II of the Directive 2002/46/EC has been amended to 'Folate' to allow a broader range of substances to be added to

the list, including calcium-L-methylfolate. In amending the national Regulations, this change has been applied to the headings in both Schedule 1 and Schedule 2. This is needed to give legal effect to the intention and purpose of the change to Annex II of the Directive. There is no change to the labelling requirements for food supplements.

CONSULTATION

13. Consumer and health professional groups, manufacturers and industry bodies, enforcement bodies, individuals and other government departments have been formally consulted on these draft amending Regulations. In response to the formal consultation seven responses were received and these will be made publicly available including on the website. The majority of these supported the introduction of the regulations. Two trade associations made comments and these have been noted and will be followed up as necessary, but they did not raise impact or cost implications, or objections to the regulations.

OPTIONS

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

    Option 1: Do nothing, i.e. fail to implement the amending Directive.

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

15. Option 1 - Failure to implement would bring risks and disbenefits to consumers, industry, enforcement authorities and Government. Consumers would no longer have access to a number of beneficial products currently on the market and industry, which would have to remove products from the market. It would also intensify the burden on enforcement authorities whose officers would have increased enforcement responsibilities. Failure to implement would also be a risk to Government as it would create a serious breach of the UK's obligations under the EC Treaty. This would attract infraction proceedings by the Commission against the UK under Article 226 of the EC Treaty and carry with it the likelihood of heavy fines. Other Member States could also initiate action under Article 227. Ultimately the UK would be forced to implement.

16. Option 2 - there are no risks or disbenefits attached to Option 2.

Flexibility

17. Directive 2006/37/EC does not offer any implementation flexibility.

COST AND BENEFITS

18. The sectors and groups affected will be the same as those identified in the RIA which accompanied the original Regulations (see Appendix).

Business Sectors affected

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

Consumers affected

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

Voluntary Organisations and Charities

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

Public sector

22. Government and enforcement officers would not be significantly affected by the legislation.

Benefits

23. Option 1: failure to implement would not bring any benefits to consumers, industry, enforcement authorities or Government.

24. Option 2: implementation maintains benefits to consumers, industry, enforcement authorities and Government. It benefits consumers by maintaining consumer choice; industry by permitting the continued marketing of products; enforcement officers by maintaining the status quo and Government by removing the risk of incurring infraction proceedings.

Costs

25. There are no costs to consumers, businesses, enforcement authorities or Government associated with implementation of these amendments to the Directive, other than administrative costs to the Government.

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

SMALL FIRMS IMPACT TEST

27. We consider that the proposal will have no impact specifically on small firms. This was confirmed by the Small Business Service.

Impact on Regions

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

COMPETITION ASSESSMENT

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

ENFORCEMENT, SANCTIONS AND MONITORING

30. Local Authorities are responsible for enforcing The Food Supplements (England) Regulations 2003. Responsibilities for enforcement, sanctions and monitoring are the same as those set out in the original legislation (see Appendix).

Post implementation review

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

SUMMARY AND RECOMMENDATION

32. We are obliged to implement the provisions of Directive 2006/37/EC into national legislation. We recommend that option 2, which we have chosen as the best course of action, allows us to fulfil our objectives in producing these Regulations. These objectives were 1) to fulfil our Community obligation to implement the provisions of the Directive 2) to maintain the widest possible consumer choice of safe and properly labelled food supplements 3) to ensure adequate protection of public health yet reduce the negative impact on industry.

Declaration

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

Signed by the responsible Minister: Caroline Flint
Date: 6 February 2007

Contact point:

Karen Pratt
Novel Foods, Additives and Supplements Division
Food Standards Agency
Room
Aviation House
125 Kingsway
London WC2B 6NH

Tel. 020 7276 8568

E-Mail: karen.pratt@foodstandards.gsi.gov.uk

Appendix to Regulatory Impact Assessment

FULL REGULATORY IMPACT ASSESSMENT

THE FOOD SUPPLEMENTS (ENGLAND) REGULATIONS 2003.

I. PURPOSE AND INTENDED EFFECT OF MEASURE

The objective

1. The Regulations implement, in England, 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. Parallel legislation will be made in Scotland, Wales and Northern Ireland.

The background

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

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

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

5. Food supplements, like other foods, are not required to demonstrate their efficacy before marketing, nor are they subject to prior approval unless they are genetically modified or are "novel". It is the responsibility of the

manufacturer, importer or distributor to ensure that their product complies with the necessary legislation.

6. The Regulations implement Directive 2002/46/EC and introduce measures, in England, to meet the following objectives:

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

Risk assessment

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

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

These risks are discussed below.

Risk to consumers from marketing of food supplement products that are unsafe due to their composition (quantity or source of vitamin or mineral contained) or are inadequately labelled

7. A large number of people consume food supplements. A target group index (TGI) survey of 25,000 UK adults in 1998 showed that 40.9% of consumers were users of vitamins and minerals with the greatest use being in the 55+ years age group[1][1]. In general, women are greater users than men – a TGI survey in 2000 showed that 47% of women use vitamins

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

and other supplements compared with only 35% of men. Typical regular consumers of food supplements are women aged 45 years and over while amongst men, the highest rate of use is among those aged over 65 years. The reason that is generally given for higher usage among women is that, compared with men, they tend to be more health-conscious, more aware of diet and more interested in preventative health care[2]. Trends in the UK population indicate that the percentage of the population made up of women in the key age group 45 – 64 years and men in the age group 64 years and older is likely to increase over the next few years. Consequently, if current trends continue, the number of older consumers of food supplements, is likely to rise.

9. The 1998 TGI survey also revealed an association between vitamin and other food supplement use, with higher socio-economic groups (AB and C1) being the main users. Data from the UK Women's Cohort Study[2] showed that the mean annual expenditure per person was £88 within a range from £5 - £360. Those from higher socio-economic groups spent more on supplements than those from lower socio-economic groups.

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

11. It is known that older people are more susceptible to adverse side effects of some medicines. There is a general absence of evidence on whether or not older people are at risk from high levels of supplements, except in the case of manganese for which there is evidence of increased risk. In 1998 the UK set up an Expert Group on Vitamins and Minerals in response to concerns about consumption of high dose food supplements and to inform discussions at EU level about maximum limits of vitamins and minerals in food supplements; the group is expected to publish its report in May 2003. The Directive sets out a framework within which maximum levels of vitamins and minerals in food supplements will be set in future. This, together with the fact that the 'positive lists' consist of substances whose safety has been assessed, means that the Directive and hence the Regulations, will provide a basis for increased consumer protection.

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

Risk of distortion of the internal market for food supplements

12. In the UK, the retail market for vitamins, minerals and other supplements was valued at £335 million in 2000, an increase over 1999 of 2% in real terms[3]. Currently in the UK multivitamin products make up 25% of the dietary supplement market, while vitamin C products make up 13.6% and mineral supplements 7.7%.

13. Within the EU the size of the market for vitamin and mineral food supplements varies widely from one MS to another with the UK and the Netherlands having particularly large markets. Consumption habits also vary from country to country – vitamin supplements are more popular in Italy and the UK while in France, Germany and Spain other food supplements, including mineral supplements, are more popular. In Italy, the market for food supplements is underdeveloped with consumers showing evidence of experimentation with a range of products, in particular multivitamins and vitamin E.

14. Across the UK, Italy, Germany, Spain and France there was increased growth in sales of vitamin, mineral and other food supplements over the period from 1994 to 1998. The size of the increase ranged from 1.4% in Germany to 61% in Italy and was 55% in the UK[4].

15. In England, the range of products on sale is greater than in many other Member States and the levels of vitamins and minerals found in food supplements on the market here are, in many cases, higher than in other Member States where levels are limited to 1-3 times the RDA (recommended daily allowance). Currently, some products sold under food law in the UK are restricted to sale under medicines legislation in other MS. Implementation of the Directive in all Member States is intended to remove the current distortion of the internal market for food supplements due to the diverse regulatory regimes in place at present. It may open up markets for English products in other Member States although it could also have the effect of restricting the range of products currently on sale in this country.

Risk to industry that a large number of safe products currently on the market in this country could be removed from sale unnecessarily

16. The Directive states that Member States must bring into force laws, regulations or administrative procedures necessary to prohibit trade in non-compliant products from three years after its entry into force (i.e. from 1 August 2005) at the latest. A food supplement product would fail to comply with the Directive if, for example, its labelling did not meet the relevant new requirements or it contained vitamin or mineral sources that were excluded from the 'positive lists'.

17. The new compositional standards potentially present more of a risk to industry than to consumers since the 'positive list' of permitted vitamin and

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

mineral sources currently exclude some 270 individual sources of vitamins and minerals presently contained in food supplements produced and/or marketed in this country. However, in the main this group comprises different *sources* of 19 permitted vitamins and minerals; in practical terms, the Regulations only exclude from use a total of six minerals (not all essential for human beings) and no vitamins currently used in marketed products. These new compositional standards could result in the loss of some food supplement products from the market in the long-term. However, the 'positive lists' remains open and sources may be added to them after assessment of safety dossiers submitted to the Commission for assessment by an EU Scientific Committee.

Risk to consumers that consumer choice could be unnecessarily reduced by removing safe products from the market

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

OPTIONS

19. The Directive offers Member States a number of areas of flexibility when transposing the provisions of the Directive; these are as follows:

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

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

II. that a safety dossier is submitted to the Commission no later than 12 July 2005 *and*

III. that the European Food Safety Authority (EFSA) has not given an unfavourable opinion in respect of the use of that substance in the manufacture of food supplements;

- Article 10 of Directive 2002/46/EC allows Member States to require the manufacturer or the person placing a food supplement product on the market to notify the competent authority of that by forwarding to it a model of the label used for the product;
- Article 15 of the Directive requires Member States to bring into force laws, regulations and administrative provisions necessary to prohibit trade in products which do not comply with the Directive from 1 August 2005 *at the latest*.

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

Option 1: do nothing i.e. fail to implement the Directive;

Option 2: implement all the provisions of the Directive that must be transposed into national legislation and also the provisions of Article 10;

Option 3: implement all the provisions of the Directive that must be transposed into national legislation and do not transpose the provisions of Article 10;

Option 4: implement all the provisions of the Directive that must be transposed into national legislation; in addition, do not transpose the provisions of Article 10; also make use of the derogation in Article 4(6).

Each of these options carries a number of risks to consumers, industry, Government and officials; these are discussed below.

21. A number of consultees recommended that there is a fifth option, that is that we should seek an amendment to the Directive prior to the Regulations coming into force to allow MS to permit on their national markets those products considered safe but which would otherwise lie outside the technical scope of the Directive. It is our considered view that since negotiations on the Directive were concluded some time ago, it is not likely that the Commission would consider reopening negotiations, furthermore, during negotiations on the Directive the UK secured provisions which enable MS to allow continued sale of products which do not comply with the compositional requirements up to 31 December 2009 provided certain criteria are met.

22. Option 1: failure to implement the Directive could, for a limited period of time, avoid disbenefits to consumers as a result of reduced consumer choice and disbenefits to industry from restrictions on the number of substances that could be used in manufacture of food supplements. However, there is a risk that this option would fail to deliver improved consumer protection, particularly to older consumers. For the Government, failure to implement the Directive would be a serious breach of the UK's obligations under the EC treaty. Although elements of the Directive are already covered by our national legislation not all aspects are covered. To omit proper transposition would be likely to attract infraction proceedings. Ultimately this is not a viable option.

23. Option 2: represents the strictest approach we could take to implementing the Directive and, compared to other options, would lead to the greatest change from the current regulatory regime in England. Implementation of all the provisions of the Directive would represent a disbenefit to consumers in terms of reduced choice, and a disbenefit to industry in terms of products lost from the market without the ameliorating effect of the derogation in Article 4 (see Option 4). Furthermore, if we were to implement the provisions of Article 10 of the Directive, this would result in industry bearing a small new cost to meet the notification requirements each time a product were brought to market. Handling receipt of such notifications would also risk placing a new administrative burden on officials at the Food Standards Agency.

24. Option 3: represents a situation the same as Option 2 except that the costs and administrative burdens associated with notification would not apply.

25. Option 4: represents a situation as close as possible, within the constraints imposed by the Directive, to the current regulatory regime in England. Compared with Options 2 and 3 this option reduces the risk to consumers and industry of losing products from the market before 2005.

Business sectors affected

24. The Regulations will affect businesses involved in the production and sale of products marketed as food supplements. Any charities and voluntary organisations that sell or supply food supplements in the course of their business could be affected by the Regulations; we are not aware of any charities and voluntary organisations that would be so affected.

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

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

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

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

Issues of equity and fairness

29. The Regulations will be equally applicable to large and small businesses concerned with the production or sales of food supplements. For manufacturers the Regulations may, in the long-term, have a greater negative impact on those that produce or use vitamin and mineral sources currently excluded from the 'positive lists' than on those that produce or use substances already on the 'positive lists'. For retailers the long-term impact of the Regulations is likely to depend upon the Regulations' effect on the number of products on the market. The full extent of the impact will probably not be known until after 31 December 2009.

BENEFITS

30. Each of the four options outlined above carries a number of benefits to consumers, industry and Government officials.

31. Option 1: could bring some short-lived benefits to consumers and to industry. The current regulatory regime in England allows the marketing of a wide range of food supplements containing a huge variety of nutrients in a wide range of dosages. If we failed to implement the Directive, consumers in England would benefit from the continued availability of all those products currently on the market until transposition was forced upon us. The UK's large food supplement industry would benefit because it would not suffer the loss of products that the Directive and implementing legislation may cause. However, this option i.e. failure to implement the Directive is not a viable option.

32. Option 2: implementation of all the provisions of the Directive would bring consumer benefits in terms of improved consumer protection and benefit to Government by contributing towards the UK fulfilling its Community obligations thereby avoiding the risk of infraction proceedings from the Commission.

33. If we were to implement the provisions of Article 10 of the Directive this could, possibly bring minimal benefits to consumers through improved monitoring of the food supplements market but we do not believe that, in the context of the improved consumer protection the Regulations bring, this additional benefit would be large enough to outweigh the disbenefits discussed above.

34. Option 3: transposing all the obligatory provisions of the Directive and not transposing the provisions of Article 10 would bring benefits to consumers in terms of improved consumer protection.

35. Option 4: making use of the derogation in Article 4(6) of the Directive, which allows us to permit the continued use of vitamins and minerals not on the 'positive lists' until 31 December 2009, would benefit consumers and industry by maintaining a wide consumer choice of food supplement products and continued sale of products already on the market for the longest possible time.

COSTS

36. Compliance costs due to the Regulations arise from new mandatory labelling requirements, voluntary dossier preparation, voluntary reformulation and possible loss of products from the market.

Compliance costs - labelling

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

figures because in this fast-moving industry they would be significantly offset by planned relabelling costs during the three-year transitional period allowed following the entry into force of the Directive.

40. However, a number of respondents to consultation pointed out that there are several different regulations currently under discussion that will require labelling amendments during the next few years (for example the requirements for GM labelling and allergen labelling). They estimated that the usual 'planned relabelling' activity will be exceeded at least once if not twice (associated costs for industry £10m-£20m) if the timelines for these changes are not co-ordinated. This is an issue that Food Standards Agency officials can pursue in Brussels.

Compliance costs - dossier preparation

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

42. Respondents to consultation continue to voice concerns that dossier preparation is time-consuming and expensive and that many suppliers lack the resources or the will to carry out the required work. While accepting that a dossier is necessary for each substance to be added to the 'positive lists' they suggest pragmatic solutions drawing on procedures in other pieces of legislation e.g. establishing a history of safe use.

43. The costs of submitting safety dossiers in support of ingredients not on the positive lists are difficult to estimate but industry estimates that they might be as high as £80,000 – £250,000 per dossier where significant safety data are not already available. Industry representatives have attempted to have discussions with the Commission in order to work out an efficient and cost-effective procedure for preparing and submitting dossiers. The Food Standards Agency has also made contact with the Commission in order to facilitate such discussions where possible.

44. In our view it is likely that it will be unnecessary to submit an individual dossier for each of the substances currently excluded from the 'positive lists' since it may make sense, in scientific terms, to cover related substances in one submission. The good thing about the system is that once a dossier has been assessed and given a positive opinion by the EFSA and subsequently added to the positive lists, any food supplement business in the EU, not just the one(s) responsible for submitting the dossier, will be permitted to use that substance in their products. However, we understand that this may be seen as a disincentive for some manufacturers.

Compliance costs - reformulation

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

Compliance costs - loss of products

46. Companies currently using substances missing from the 'positive lists' for which safety dossiers are not submitted and in due course given 'positive opinions' will eventually be prohibited from manufacturing and selling products. In the main these are specialist brand companies. In responding to consultation, one of the major trade associations summarised the results of a survey of its members in 2002 which indicated that the effect of the 'positive lists' in reducing the number of ingredients available for use could account for losses ranging from 4% - 100% of turnover for different companies, the average being 39%.

Costs for a typical business

47. Responses to consultation indicate that there is no such thing as a typical business in this sector. One very large company provided a detailed response to the consultation which indicated that for this company, the impact of the Regulations is likely to be negligible, despite one-off costs for product and labelling changes.

Any other costs

48. Industry respondents to consultation suggested that in the event the Regulations finally result in loss of products from the marketplace this could lead to consumer confidence in the food supplements industry and its products being undermined.

SMALL FIRMS' IMPACT TEST

49. The Small Business Service (SBS) and relevant SMEs, including some identified by colleagues at the SBS, were consulted on the draft Regulations. We received a detailed response from one specialist, small retail business and while this business is in Scotland, it is likely to be representative of similar businesses in England too; some of its comments are included here.

50. This business reported that the Regulations would lead to new costs in staff training (estimated at under 0.4% annual turnover) if products were removed from the market; it also estimated that in the worst case scenario, if its range of specialist products was significantly reduced over time this

would have a severe impact on its competitiveness and ultimately could lead to it going out of business.

51. A response from one of the major trade associations in this sector indicated that small manufacturing businesses would be likely to bear the same costs as larger companies but that these would be proportionately more onerous than for larger ones. At best, companies could be forced to discontinue a wide range of products resulting in costs that would be a "very considerable loss to any company and particularly an SME" and, at worst, some businesses might no longer be viable.

COMPETITION ASSESSMENT

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

53. We would expect producers of vitamins and other dietary supplements to bear most of the cost associated with these Regulations under options 2-4. Currently there are five large producers of supplements, with a significant number of medium-sized and smaller, highly specialised brands (including many own labels). There are three companies that each account for more than 10% of the market, with the top two accounting for over 20%; together all three account for 55% of the total market (by value) (Mintel, 2001). The structure of this (still growing) market is characterised by a wide diversity of suppliers, including recent new entrants (mainly small specialist suppliers).

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

55. To seek to reduce the impact on businesses option 4 proposes making use of the derogation that would permit, subject to specific criteria being met, the continued use of vitamins and minerals not on the 'positive list' until 31 December 2009.

56. These Regulations may increase barriers to entry in some of the more specialised areas of the market, particularly in the short term. However, it will

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

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

ENFORCEMENT AND SANCTIONS

57. The Regulations will be enforced by food authorities. Any person committing an offence under the Regulations will be liable on summary conviction to a fine not exceeding level 5 on the standard scale. The Home Office has confirmed that it is content with the offences and level of penalty set. Local Authorities Co-ordinators of Regulatory Standards (LACORS) were consulted on the draft Regulations and did not comment on the enforcement provisions.

MONITORING AND REVIEW

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

CONSULTATION

59. Over two hundred copies of the consultation documents were sent out to interested parties including consumers and health professional groups, manufacturers and retailers of food supplements, representatives of the health food industry, trade associations, enforcement authorities and other individuals. other Government departments (Health, Trade and Industry, Medicines Control Agency, Environment, Food and Rural Affairs, Foreign and Commonwealth Office, International Development, Small Business Service) were also consulted.

60. Of consumers consulted, three individual consumers and one consumer group responded formally to the consultation. Individual consumers voiced concerns over the potential impact that the ‘positive lists’ and dossier preparation could have on consumer choice and on the food supplement industry. The consumer group generally supported introduction of the Regulations including introduction of the ‘positive lists’. Two of the individual consumers also commented on elements of the new labelling requirements, specifically the requirement to include a statement to the effect that food supplements should not be used as a substitute for a varied diet.

61. The Directive does not allow MS any flexibility around the positive lists, dossier preparation or the inclusion of certain labelling statements

therefore no changes were made to the draft SI as a result of these comments.

62. Enforcement authorities were consulted but did not comment on the draft Regulations.

63. Substantive responses to the consultation were received from two major trade associations, two major health food chains and one industry-focussed lobby group. These respondents welcomed the fact that, in drafting the SI we had made use of flexibility within the Directive which enabled us to prohibit trade in non-compliant products from the latest possible date allowed; make use of the derogation in Article 4 to allow continued sale of products, subject to criteria in Article 4 being met; and not to require notification of marketing.

64. However, these respondents focussed very much upon the potentially negative impacts of the Regulations upon the industry and cited in particular the costs associated with dossier preparation, reformulation, label changes and loss of products. They also expressed concern over the imposition of unnecessary restrictions upon the market in the UK compared with the opening up of markets in other EU Member States and the potential loss of consumer confidence in the UK food supplement industry and its products due to poor understanding among consumers of the reasons for potential reductions in the range of products available in the home marketplace.

65. While acknowledging these important concerns, we were not in a position to amend the SI in any way that would reduce the impact of the Regulations in these areas since in drafting the SI we had already made use of all the flexibility available within the Directive.

66. In response to consultation, industry representatives did provide some new figures for costs which have been incorporated into this RIA but did not change the overall picture as we had been in close contact with our stakeholders throughout the lengthy negotiations on the Directive and recent drafting of the Statutory Instrument.

67. Consumers and industry representatives who responded to consultation made comments upon the detail of the drafting in some parts of the Regulation. These comments have been considered and, where appropriate, incorporated in the final version of the Regulations.

68. The responses to consultation have not changed our recommendation for how to proceed in order to implement Directive 2002/46/EC.

COST BENEFIT ANALYSIS

69. The benefits and costs of the options associated with these Regulations are considered here. Only those costs which could both be quantified (usually within ranges) and given monetary values were explicitly considered. A summary of the costs and benefits is given in the table in

Annex 1. This summary indicates that no option yields a net positive economic benefit.

70. Option 1 would appear to be the least worst approach on the basis of the cost benefit analysis but is not recommended due to problems associated with estimating the true level of benefits (the avoidance of adverse reactions, and the extent of current under reporting); furthermore, this option is not viable since it would result in the UK failing to fulfil its Community obligations.

71. Of the viable options, option 4 is recommended because, compared with options 1 and 2, the full use of member state derogation drastically reduces the costs on industry (by giving companies a longer period in which to adjust, thereby considerably reducing their costs) whilst still allowing health benefits to be derived. In order for this option to break even (and therefore surpass the option of doing nothing) adverse reactions would need to be ten fold greater than those levels currently reported (i.e. ten cases per year). It is important to note that this option means that some of the adverse reactions are less likely to be avoided until later – it has been assumed these will not appear until year five.

SUMMARY AND RECOMMENDATION

72. We are obliged to implement the provisions of Directive 2002/46/EC into national legislation. We recommend that option 4, which we have chosen as the best course of action, allows us to fulfil our objectives in producing these Regulations. These objectives were 1) to fulfil our Community obligation to implement the provisions of the Directive 2) to maintain the widest possible consumer choice of safe and properly labelled food supplements 3) to ensure adequate protection of public health yet reduce the negative impact on industry.

Declaration:

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

Signed by the responsible Minister:.....

Date:.....……

CONTACT POINT
Vivien Lund
Food Labelling and Standards Division
Food Standards Agency
Room 115B
Aviation House
125 Kingsway
London WC2B 6NH

Telephone: 0207-276-8169
Fax: 0207-276-8193
E-mail: vivien.lund@foodstandards.gsi.gov.uk

Annex 1

Summary of Cost Benefit Analysis – All Figures in £Mn

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

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

Benefits relate solely to the avoidance of the economic costs associated with adverse reactions to food supplements. Although data are available there is believed to be massive under reporting; data provided to the Food Standards Agency include 11 cases in an 11-year period – an average of 1 per annum. Most of these reactions have been minor and relate most closely to health state F[6] and benefits have been calculated [7]on the avoidance of this state[7]. The calculations are based on the avoidance of all these cases (1 per annum over a 10-year period): this figure is widely thought to be a very large underestimate[8].

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

[7] Average cost of each case was estimated at £22, 901 in June 2000 prices (DoT). Prices in calculations adjusted to October 2002 using RPI-all items index.

[8] However on the converse side it is likely that not all adverse reactions would be avoided

Costs relate to four different areas:

- **relabelling** at a one-off (industry estimated) cost of £10Mn, (at £3-500 per product) where member state derogation is not used (options 2 and 3);
- **dossier preparation** which industry estimates will be in the region of £80-250,000 (a total one-off cost of £0.99Mn based on range mid point and 6 dossiers – (the number in preparation we are aware of)) *or* **reformulation** if manufacturers choose not to submit dossiers (and inputs are not currently on positive list) with industry estimating a one-off cost of £4mn (£3,000 per product with 5% of product lines affected). The costs of dossier preparation only have been included in the calculations on the assumption that industry would wish to minimise costs (options 2,3 and 4);
- **revenue losses** to industry (manufacturers and retailers) if products not on positive lists are withdrawn and because of their highly specialised nature are not replaced in the short-term (estimated to be 5% of the current market). It does not include any estimates associated with utility losses for consumers. This cost can be postponed if the member state derogation is used i.e. products can continue to be sold before dossiers approved – therefore only affects options 2 and 3;
- **Additional label supply and enforcement costs** (option 2 only). The former falls on industry to supply copies of all new product labels to the FSA and assumed the bulk of these will be required in early part of this regulation coming into force[9]. The latter is administrative costs that will fall on the FSA for logging each of these new labels[10].

[9] There are approximately 20,000 product lines, it is assumed all these will be registered in the first year, with 2% of this total each year thereafter to represent new products at an assumed label supply cost of £5.

[10] For 20,000 product line, all logged in the first year and then 2% of this total for each year thereafter to represent new products – assumed each log will cost the FSA £25 in staff and associated costs.

TRANSPOSITION NOTE: THE FOOD SUPPLEMENTS (ENGLAND) REGULATIONS 2003 AS AMENDED BY THE FOOD SUPPLEMENTS (ENGLAND) (AMENDMENT) REGULATIONS 2007

Commission Directive 2006/37/EC amends 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. It sets out rules governing the labelling and composition of food supplements. The rules on composition only apply in relation to vitamins and minerals at this stage.

This Transposition Note outlines how the main elements of Directive 2002/46/EC were transposed into legislation in England and how the amendment Directive 2006/37/EC will be transposed. Articles 5, 6(2), 10 -14 and 15(a) of Directive 2002/46/EC were not transposed through the Food Supplements (England) Regulations 2003. Article 5 Directive 2002/46/EC requires further EC action; the provision of Article 6(2) was implemented by the Food Labelling Regulations 1996, regulation 40 and Schedule 6, Part I and paragraph 2; we did not exercise the discretionary provision in Article 10; Articles 11-14 did not need specific provisions in the Statutory Instrument; and Article 15(a) did not need an implementing provision in the SI because there was no existing prohibition on sale of compliant products.

Article	**Objective**	**Implementation**	**Responsibility**
Article 1 (read with Article 3)	Restricts the scope to food supplements marketed as foodstuffs and presented as such and excludes medicinal products as defined by Directive 2001/83/EC. Prohibits the sale of a food supplement to the ultimate consumer unless it is prepacked.	Regulations 3(1) and 3(2) Regulations 2(2) and 4	Secretary of State for Health
Article 2	Defines the term 'food supplement'.	Regulation 2	Secretary of State for Health
Article 3	Provides that food supplements may be marketed only if they comply with the rules laid down.	Regulations 4 to 6	Secretary of State for Health
Article 4 (read with Article 3)	Prohibits the sale of a food supplement in the manufacture of which a vitamin or mineral has been used, unless certain compositional requirements are met, subject to a transitional provision.	Regulation 5 and Schedules 1 and 2	Secretary of State for Health
Article 6(1), 6(3),	Prohibits the sale of a food supplement that is ready for	Regulation 6 and Schedule 1	Secretary of State for Health

7,8,9 (read with Article 3 and Recital (17)	delivery to the ultimate consumer or a catering establishment unless certain requirements as to labelling, presentation and advertising of the product are met.		
Article 15(b)	Sets the date from which trade in non-compliant products is prohibited.	Regulation 1	Secretary of State for Health
Annex I	Lists the vitamins and minerals that may be used in the manufacture of food supplements.	Schedule 1	Secretary of State for Health
Annex II	Lists the forms of vitamin and mineral substances that may be used in the manufacture of food supplements.	Schedule 2	Secretary of State for Health

Commission Directive 2006/37/EC amending annex II to Directive 2002/46/EC

Article 1	Outlines the amendment to Annex II	Regulations 3 to 5	Secretary of State for Health