

**Explanatory Memorandum to the Food Supplements (Wales) and Addition of Vitamins, Minerals and Other Substances (Wales) (Amendment) Regulations 2009**

**This Explanatory Memorandum has been prepared by the Food Standards Agency Wales and is laid before the National Assembly for Wales in conjunction with the above subordinate legislation and in accordance with Standing Order 24.1.**

**Minister's Declaration**

In my view, this Explanatory Memorandum gives a fair and reasonable view of the expected impact of the Food Supplements (Wales) and Addition of Vitamins, Minerals and Other Substances (Wales) (Amendment) Regulations 2009. I am satisfied that the benefits outweigh any costs.

*Gwenda Thomas*

**Deputy Minister for Health and Social Services**

8 December 2009

## **Description**

1. EC Regulation (EC) No. 1170/2009 amends the Food Supplements (Wales) Regulations 2003 to provide for additions, made by European legislation (EU) to the lists of vitamins, minerals and their sources permitted for use in food supplements set out in existing EU legislation. The Statutory Instrument also amends the Food Supplements Regulations to provide for direct, ambulatory, references to the lists of permitted vitamins, minerals and their sources set out in EU legislation and to update references in the Regulations to EU legislation.

2. The Instrument also amends the Addition of Vitamins, Minerals and Other Substances (Wales) Regulations 2007 to provide for additions to the lists of vitamins, minerals and their sources permitted for addition to food set in EU legislation.

## **Matters of special interest to the Subordinate Legislation Committee.**

3. None

## **Legislative background**

4. Welsh Ministers have the powers to make these Regulations under Sections 16(1)(a) and (e) , 17(1) and (2) of the Food Safety Act 1990. Functions transferred to the National Assembly for Wales are now exercisable by Welsh Ministers by virtue of paragraph 30 of Schedule 11 to the Government of Wales Act 2006.

5. These Regulations are being made to enforce, within Wales, Regulation (EC) No. 1170/2009 of the European Parliament and of the Council of 1 December 2009 which will amend the (EC) Food Supplements Directive 2002/46/EC, and also amend Regulation (EC) No.1925/2006.

6. (EC) Regulation No.1170/2009 is directly applicable in the UK; however a Wales Statutory Instrument (SI) is required to provide for the execution and enforcement of Commission Regulation (EC) No. 1170/2009.

## **Purpose and intended effect of the legislation.**

### **Policy Background**

#### **Food Supplements**

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

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

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

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

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

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

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

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

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

#### **Consultation outcome**

15. Details of the consultation undertaken are included in the Regulatory Impact Assessment below.

#### **Guidance**

16. The Food Standards Agency’s UK guidance on the Food Supplements Regulations will be revised to reflect the amendments effected by the instrument as part of a review of this guidance. The revised guidance will be subject to public consultation before being made available on the Food Standards Agency website.

17. The Food Standards Agency will also be writing to stakeholders to inform them of the legislative changes.

## **Regulatory Impact Assessment (RIA)**

**Option 1** : Do nothing

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

The preferred option is **Option 2**. If national regulations are not enacted, this would have the effect of prohibiting, from 1 January 2010, the use of 67 vitamin and mineral sources in food supplements which would otherwise be permitted for such use and expose the UK to possible infraction proceedings by the European Commission. Not giving automatic effect to amendments to the Directive as regards the vitamins, mineral and their sources permitted for use in food supplements would mean that newly approved sources would not be available for use by industry until national implementing legislation comes into force causing delays and disadvantaging industry. If national regulations are not enacted, national enforcement powers in relation to Regulation 1925/2006 would not extend to that Regulation, as amended.

### **Costs and benefits**

**Option 1** - If national regulations are not enacted, this would have the effect of prohibiting, from 1 January 2010, the use of 67 vitamin and mineral sources in food supplements which would otherwise be permitted for such use. Costs to the food supplements industry would arise from the loss to the market, from 1 January 2010, of products containing these sources. Businesses would also have to remove relevant existing products from sale from 1 January 2010. It would also expose the UK to possible infraction proceedings by the European Commission. 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 permitted for use under the derogation after its expiry on 31 December 2009.

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

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

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

Giving automatic effect, in national law, to any future changes to the Food Supplements Directive which specifically relate to vitamins, minerals and their sources permitted for use in food supplements will enable industry to place food supplements containing newly approved sources of vitamins and minerals on the market as soon as the relevant amendments to the Food Supplements Directive come into force, which may offer commercial advantages.

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

### Costs to Food Businesses

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

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

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

There may be some retailers who also need to be aware and become familiar with the amendments to national regulations. Accordingly, we have used SIC Code

1 [http://www.statistics.gov.uk/methods\\_quality/sic/downloads/SIC2007explanatorynotes.pdf](http://www.statistics.gov.uk/methods_quality/sic/downloads/SIC2007explanatorynotes.pdf)

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

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

47.29<sup>4</sup> to estimate the number of retailers affected<sup>5</sup> but acknowledge that this is an overestimate. Therefore the true cost will be nearer to £2,700 than £21,700 (£19,034 + £2,704). Figures rounded.

Other retail sale of food in specialised stores	SIC Code 47.29	Total Costs	
England	5,235	£	16,176
Scotland	440	£	1,360
Wales	325	£	1,004
Northern Ireland	160	£	494
UK	6,160	£	19,034

### Benefits to Enforcement Authorities

- Certainty as to the vitamin and minerals and their sources permitted for use in food supplements, facilitating official controls.
- Certainty should improve compliance and reduce the need for interventions by enforcement authorities in connection with the use of vitamin and mineral sources in food supplements.
- Harmonisation of vitamin and minerals and their sources permitted for use in food supplements will facilitate official controls.

### Costs to food / feed authorities

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

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

4 SIC Code 47.29 Other retail sale of food in specialised stores

This class includes:

- retail sale of dairy products and eggs
- retail sale of other food products n.e.c.

5 Using wage rate of £3.09 as per previous calculation

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

<b>UK total</b>	<b>231</b>	<b>£</b>	<b>936</b>
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Total monetised costs to local authorities and business would amount to £4,000 to £23,000 for the UK as a whole (rounded to nearest thousand). However, as outlined above, we believe the true familiarisation costs will be closer to £4,000.

### **Benefits to consumers:**

- Continued availability in food supplements of 67 vitamin and mineral sources currently permitted for use under the derogation after its expiry on 31 December 2009.
- Harmonisation of vitamin and minerals and their sources permitted for use in food supplements may generate commercial competition which may yield benefits to consumers in terms of reduced costs and product innovation.

### **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 UK 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 what became Regulation 1170/2009 prior to their consideration at meetings of the EU Standing Committee on the Food Chain and Animal Health (SCoFCAH). The draft of the Regulation which achieved a qualified majority vote in SCoFCAH on 15 July 2009 was circulated to stakeholders and enforcement authorities on 28 July 2009.

#### **Formal Consultation**

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

<http://www.food.gov.uk/consultations/consulteng/2009/supvitmin>

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

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

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

### **Further Necessary Amendments Identified During the Consultation**

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

- (i) The reference, in Regulation 3(2), to Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use as regards the definition of 'medicinal products', to which there have been further amendments;
- (ii) The reference, in Regulation 6(3)(e), to the Annex to Council Directive 90/496/EEC on nutrition labelling for foodstuffs as regards recommended daily allowances, energy conversion factors and definitions which was revised by Commission Directive 2008/100/EC amending Council Directive 90/496/EEC. This amendment will complete the implementation of Directive 2008/100/EC in Wales (see below).

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

amongst other things, made amendments to the RDAs for certain vitamins and minerals.

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

<http://www.food.gov.uk/consultations/consulteng/2009/draftfoodlabelnutdecengregs>

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

<http://www.food.gov.uk/multimedia/pdfs/iafoodlabellingregs09.pdf>

## **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.

## **Competition Assessment**

The Food Standards Agency does not anticipate any competition issues arising from this policy.

## **Post Implementation Review**

Regulation 1170/2009 will come into force on 21 December 2009 and the Food Supplements (Wales) and Addition of Vitamins, Minerals and Other Substances (Wales) (Amendment) Regulations 2009 will come into force on 1 January 2010.

A review of the costs and benefits will be carried out in 2015. Separate but parallel legislation will be required for England, Scotland and Northern Ireland.