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Welsh Government

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Food Supplements

Guidance notes on legislation implementing
Directive 2002/46/EC on food supplements

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Intended audience

This guidance is aimed at all companies that manufacturer, process, distribute, use, sell or import food supplements, and those local authorities who are responsible for enforcing the legislation in this area.

Legislation on food supplements is implemented on a devolved basis, however this guidance applies across the UK.

Executive summary

The EU Food Supplements Directive 2002/46/EC came into force on 1 August 2005 and is implemented in the UK by the Food Supplements (Wales) Regulations 2003 (as amended), and equivalent regulations in England, Scotland and Northern Ireland. The Regulations specify compositional and labelling requirements of food supplements, including the vitamin and mineral substances permitted for use in food supplements.

The information set out in this document aims to provide non-statutory guidance on the rules, which apply to food supplements under these Regulations.

Last updated

September 2011 to update references to legislation in this area and reflect the transfer of responsibility for nutrition policy in England and Wales from the Food Standards Agency to the respective health departments (Department of Health in England and Health Improvement Division, Welsh Government in Wales) on 1 October 2010. No other significant changes have been made.

The Department of Health has responsibility for national and EU legislation on food supplements within England. The responsibility for the policy area of food supplements legislation in Wales has moved to the Welsh Government. The Food Standards Agency Devolved Administrations of Scotland, and Northern Ireland are responsible for national legislation in their own administrations where separate but similar regulations apply.

January 2012 to insert references to Commission Regulation (EU) No 1161/2011, amending the list of mineral substances in Annex II of Directive 2002/46/EC.

IMPORTANT NOTE

These notes have been produced with the aim of providing, non-statutory guidance on the following Regulations:

- The Food Supplements (Wales) Regulations 2003 WSI 2003 No. 1719 (W186)
- The Food Supplements (England) Regulations 2003 SI 2003 No. 1387
- The Food Supplements (Scotland) Regulations 2003 SSI 2003 No. 278
- The Food Supplements (Northern Ireland) Regulations 2003 Statutory Rule 2003 No. 273

As amended by:

- The Food Supplements (Wales) (Amendment) Regulations 2007 WSI 2007 No.1076 (W114)
- The Food Supplements (Wales) and Addition of Vitamins, Minerals and Other Substances
The Food Supplements (England) (Amendment) Regulations 2007 SI 2007 No. 330
- The Food Supplements (England) and Addition of Vitamins and Minerals and Other Substances (England) (Amendment) Regulations 2009 SI 2009 No. 3251
- The Food Supplements (Scotland) Amendment Regulations 2007 SSI 2007 No. 78
- The Food Supplements, Vitamins, Minerals and Other Substances (Scotland) Regulations 2009 SSI 2009 No. 438
- The Food Supplements (Amendment) Regulations (Northern Ireland) 2007 Statutory Rule 2007 No. 116
- The Food Supplements and the Addition of Vitamins, Minerals and Other Substances (Amendment) Regulations (Northern Ireland) 2009 Statutory Rule 2009 No. 407

The notes are intended to be read in conjunction with:

- the Regulations listed above;
- Council Directive 2002/46/EC on the approximation of the laws of the Member States relating to food supplements
- Commission Regulation (EC) No. 1170/2009 amending Directive 2002/46/EC and Regulation (EC) 1925/2006 regarding the lists of vitamins and minerals and their forms that can be added to foods, including food supplements.
- Commission Regulation (EU) No. 1161/2011 amending Directive 2002/46/EC, Regulation (EC) 1925/2006, and Regulation (EC) No. 953/2009 as regards the lists of mineral substances that can be added to food.
- The Food Labelling Regulations 1996 (as amended) and relevant guidance notes that are available on the National Archive website
(<http://webarchive.nationalarchives.gov.uk/20100817075455/http://www.food.gov.uk/foodindustry/guidancenotes/>)

- The Food Labelling Regulations (Northern Ireland) 1996 Statutory Rule 1996 No. 383 (for Northern Ireland)
- The Novel Foods Regulation (EC) No 258/97
- Regulation 178/2002/EC of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. (Implemented in the UK by the General Food Regulations 2004 SI 2004 No. 3279 and The General Food Regulations (Northern Ireland) 2004 Statutory Rule 2004 No. 505.
- The Consumer Protection from Unfair Trading Regulations 2008

The examples in these notes are provided for illustration only. The guidance notes cannot cover every situation and you will need to familiarise yourself with the relevant legislation itself to see how it applies in your circumstances. The UK regulations have been amended several times, therefore you may find it useful to also consult EC Directive 2002/46/EC, which is available in consolidated form for ease of use. A copy of the consolidated Directive is available on the European Commission's website ([click here](#)).

Copies of the UK legislation are available from the Stationery Office (Tel: 0870 600 5522; or free to view at: www.legislation.gov.uk)

Copies of the EU legislation are available on the European Commissions website at: <http://eur-lex.europa.eu/en/index.htm>

Introduction

The Food Supplements (Wales) Regulations 2003 WSI 2003 No. 1719 (W186) and equivalent regulations in England, Scotland and Northern Ireland¹, implement the provisions of 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 (as amended). Directive 2002/46/EC is referred to throughout these guidance notes as “the Directive” and the implementing UK regulations will be referred to collectively throughout these notes as “the Regulations”.

Purpose

These guidance notes have been produced with the aim of providing informal, non-statutory guidance on the Regulations and should be read in conjunction with them. These guidance notes are not exhaustive.

Status

These notes are advisory only. Any legal queries should be resolved by reference to the Regulations and the Directive. Enforcement officers should be approached for advice on any point, although ultimately only the courts can interpret the law.

Interpretation of the Regulations

In these notes we have indicated the practices that we believe are acceptable. However our advice is not definitive, and we strongly urge those planning to follow those practices in respect of which more than one interpretation of the Regulations is possible to seek the agreement of their Home Authority (i.e. the local authority designated as the relevant decision-making base for their enterprise) before taking any definite action.

The details of your nearest enforcement office can be obtained on the Food Standards Agency’s website by using the on-line search engine at:

<http://www.food.gov.uk/enforcement/enforceessential/yourarea/>

In the case of small businesses or individuals who do not have a Home Authority, queries should be forwarded to the enforcement authority, that is, the Trading Standards or Environmental Health Department within their own local authority. For companies wishing to import into the UK, the Port Health Authority should be contacted, or their importing agents in the UK should contact the enforcement authority within their own local authority.

¹ The Food Supplements (England) Regulations 2003 SI 2003 No. 1387 (as amended); the Food Supplements (Scotland) Regulations 2003 SSI 2003 No. 278; and the Food Supplements (Northern Ireland) Regulations 2003 Statutory Rule 2003 No. 273

Organisation of the Regulations

The Regulations are split into the following sections:

Title, commencement and extent (the England Regulations) / Citation, commencement and extent (the Scotland Regulations) / Citation, application and commencement (the Wales Regulations) / Citation and commencement (the Northern Ireland Regulations) (regulation 1)

This section contains the title by which the Regulations may be cited - The Food Supplements (England) Regulations 2003 / The Food Supplements (Scotland) Regulations 2003 / The Food Supplements (Wales) Regulations 2003 / The Food Supplements (Northern Ireland) Regulations 2003 as the case may be; the coming into force date - 1 August 2005; and the country in which the SI applies.

Interpretation (regulation 2)

This section includes definitions for specific terms used and refers to the Directive for other terms used in both the Regulations and the Directive. Other terms used in the Regulations but not in the Directive have the same meaning as in the enabling legislation (the Food Safety Act 1990 for England, Wales and Scotland; the Food Safety (Northern Ireland) Order 1991 for Northern Ireland).

The regulation was amended by The Food Supplements (England) and Addition of Vitamins and Minerals and Other Substances (England) (Amendment) Regulations 2009 (and equivalent Regulations in the devolved administrations), which introduced an ‘ambulatory’ reference to automatically align the UK Regulations with the Annexes of Directive 2002/46/EC, as amended from time to time.

Scope of Regulations (regulation 3)

This section sets out which products are covered by the Regulations and those that are not covered.

Restriction on form in which food supplements are sold to the ultimate consumer (regulation 4)

This section prohibits the sale of a food supplement to the ultimate consumer unless it is pre-packed.

Prohibitions on sale relating to the composition of food supplements (regulation 5)

This section prohibits the sale of a food supplement in the manufacture of which a vitamin or mineral has been used, unless the compositional and purity requirements set out in regulation 5 are met.

This regulation was amended by The Food Supplements (England) and Addition of Vitamins and Minerals and Other Substances (England) (Amendment) Regulations 2009

(and equivalent Regulations in the devolved administrations). This amendment reflects the adoption of Commission Regulation (EC) No. 1170/2009, introducing the list of vitamins and minerals permitted for use in food supplements – as set out in the annexes of the Commission Regulation.

Restrictions on sale relating to the labelling etc of food supplements and (regulation 6) and manner of marking or labelling (regulation 7)

This prohibits the sale of a food supplement which is ready for delivery to the ultimate consumer or a catering establishment unless certain requirements as to the labelling, presentation and advertising of the product, set out in regulations 6 and 7, are met.

Enforcement (regulation 8)

This provides for the authorities responsible for the enforcement of these Regulations.

Offences and penalties (regulation 9)

This creates offences and penalties in relation to the Regulations.

Defence in relation to exports (regulation 10)

This provides a defence in relation to exports, in accordance with Articles 2 and 3 of Council Directive 89/397/EEC on the official control of foodstuffs.

This defence was revoked in the Regulations by the Official Feed and Food Control Regulations 2005, but still applies and has been moved to the General Food Regulations 2004 (as amended).

Application of various provisions of the Act (the England, Wales and Scotland Regulations) / Application of various provisions of the Order (the Northern Ireland Regulations) (regulation 11)

This lists the sections of the Food Safety Act 1990 that apply (in England, Scotland and Wales) or the sections of the Food Safety (Northern Ireland) Order 1991 that apply (in Northern Ireland).

Transitional provisions (Regulation 12)

This creates a defence relating to food supplements labelled with the old recommended daily allowance (RDA) in Directive 90/496/EC. These may be sold until 31 October 2012, when the new RDAs stipulated in Directive 2008/100/EC come into force.

This new Regulation was inserted by the Food Supplements (Wales) and Addition of Vitamins and Minerals and Other Substances (Wales) (Amendment) Regulations 2009 (and equivalent Regulations in the devolved administrations).

Q&A

Regulation 1

1. When do the Regulations come into force?

The Regulations came into force on 1 August 2005.

2. The Regulations prohibit sale in non-compliant products from 1 August 2005. Does this mean that all non-compliant products cannot be sold after that date or will there be a sell-through period in which manufacturers / retailers can sell old stock?

From 1 August 2005 it became illegal to sell food supplement products that do not comply with the requirements of these Regulations. There is not a sell-through period.

Regulation 2

3. What is the definition of a food supplement?

The definition of “food supplement” in regulation 2 says that “food supplement means any food the purpose of which is to supplement the normal diet and which –

- a) is a concentrated source of a vitamin or mineral or other substance with a nutritional or physiological effect, alone or in combination; and
- b) is sold in dose form”.

The definition of “dose form” in regulation 2 says that “dose form means a form such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids or powders designed to be taken in measured small unit quantities”.

The definition of ‘to supplement’ can be interpreted as ‘taken in addition to’ the diet.

Assuming the product in question was not a medicinal product as defined by Directive 2001/83/EC, the provisions of the Food Supplements Regulations 2003 would be relevant. The definition of “food supplement” in the Regulations is concerned with food “the purpose of which is to supplement the normal diet”. This definition is taken from Directive 2002/46/EC. By virtue of regulation 2(3) of the Regulations, the expression “to supplement the normal diet” has the same meaning in the Regulations as it has in the Directive. The recitals to the Directive set the scene for interpreting that expression. Only the courts can interpret the legislation authoritatively.

4. Now that these Regulations are in place does this mean that food supplements are no longer subject to other legislation?

Food supplements, as defined, still have to comply with all the relevant food and other legislation.

In Wales, England and Scotland products that meet the definition of *food supplement* in these Regulations are subject to these Regulations as well as to the general provisions of the General Food Regulations 2004, the Food Labelling Regulations 1996 (as amended) and the Consumer Protection from Unfair Trading Regulations 2008. In Northern Ireland products that meet the definition of *food supplement* in these Regulations are subject to these Regulations as well as to the general provisions of the General Food Regulations (Northern Ireland) 2004 and the Food Labelling Regulations (Northern Ireland) 1996.

5. The definition of the term food supplement in Regulation 2 states that a food supplement "means any food the purpose of which is to supplement the normal diet....." What is meant by a 'normal diet'?

By virtue of regulation 2(3) of the Regulations, the expression "to supplement the normal diet" has the same meaning in the Regulations as it has in the Directive. The recitals to the Directive set the scene for interpreting that expression. Only the courts can interpret the legislation authoritatively.

Regulation 3

6. Which products do these Regulations apply to?

These Regulations apply to food supplement products that meet the definition of "food supplement" in regulation 2 of these Regulations and that are presented as such. These Regulations do not apply to medicinal products as defined by Directive 2001/83/EC.

7. What if I think a particular product may not be a food supplement but might be a medicinal product?

Some products that are presented as food supplements may be regarded in law as medicinal products. This is a complex legal area where some products fall on the borderline between the two categories.

A product presented for treating or preventing disease, or which may be administered with a view to restoring, correcting or modifying physiological function in humans, falls within the definition of a medicinal product and is subject to the requirements of the Medicines Directive 2001/83/EEC, the Medicines Act 1968, and the Medicines For Human Use (Marketing Authorisations etc) Regulations 1994.

On 30 April 2004 the Traditional Herbal Medicinal Products Directive (2004\24\EC) came into force. This establishes a harmonised legislative framework for authorising the marketing of traditional herbal medicinal products by means of a simplified registration procedure.

In the first instance, manufacturers are advised to approach their Home Authority or local enforcement authority for advice on which category would apply to a particular product. Ultimately, the control of medicinal products is the responsibility of the Medicines and Healthcare products Regulatory Agency (MHRA), which is an executive agency of the Department of Health.

The MHRA can advise on whether a product is medicinal and you should contact the Borderline Section for advice: Borderline Section, Inspection & Enforcement Division, Medicines and Healthcare products Regulatory Agency, 151 Buckingham Palace Road, London SW1W 9SZ; Tel: 020 3080 6759;email: Medicines.Borderline.advice@mhra.gsi.gov.uk

Regulation 4

8. Regulation 4 says that any food supplement sold to the ultimate consumer must be prepacked. Who is the 'ultimate consumer' and what does 'prepacked' mean?

In Regulation 2, "ultimate consumer" is defined as meaning "any person who purchases otherwise than -

- a) for the purpose of resale;
- b) for the purposes of a catering establishment; or
- c) for the purposes of a manufacturing business".

Regulation 2(2) states that "a food supplement shall be regarded as "pre-packed" for the purposes of these Regulations if -

- a) it is ready for sale to the ultimate consumer or to a catering establishment, and
- b) it is put into packaging before being offered for sale in such a way that the food supplement cannot be altered without opening or changing the packaging".

Regulation 5

NOTE - This section previously related to the initial establishment of a list of vitamins and minerals permitted for use in food supplements, while allowing products to remain on the market until 31/12/2009. This initial process was completed resulting in the publication of Commission Regulation (EC) No. 1170/2009. This Guidance document has been updated to reflect these changes, removing historical information to provide clarity on the current rules.

9. What vitamin and mineral sources can be used in food supplements?

Only the vitamins and minerals listed in the Annexes to the Food Supplements Directive may be used.

A consolidated list is available on the European Commission's website at:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2002L0046:20111205:EN:PDF>

10. How are the lists of permitted vitamins and minerals in the Annexes to the Directive amended?

The European Commission, will from time to time, amend the list of permitted vitamins and minerals in the Annexes to the Directive following consultation with Member States. To ensure UK legislation reflects these changes, an 'ambulatory reference' has been added to the UK Regulations² to automatically align them with EU law. This ensures UK businesses are permitted to use new substances added to the list without delay.

The Regulations were amended by The Food Supplements (Wales) and Addition of Vitamins, Minerals and Other Substances (Wales) (Amendment) Regulations 2009 WSI 2009 No. 3252 (W.282) (and equivalent Regulations in the devolved administrations). This amendment removed schedules 1 and 2 of the original Regulations, and replaced them with a reference to the Annexes of the Directive, as amended from time to time.

11. What is the process for adding new nutritional substances to the list in the annex to the Directive?

Vitamin and mineral substances may be considered for inclusion in the lists following the evaluation of an appropriate scientific dossier concerning the safety and bioavailability of the individual substance by the European Food Safety Authority (EFSA).

² Article 2, paragraph 3 of The Food Supplements (England) and Additions of Vitamins and Minerals and Other Substances (England) (Amendment) Regulation 2009, SI No. 3251 and equivalent Regulations in Scotland, Wales and Northern Ireland.

Requests for the inclusion of a new nutritional substance in the Directive should be submitted to the European Commission. Guidance on the procedure that should be followed for the submission of requests for substances to be considered for inclusion in the permitted list is available on the Commission website:

http://ec.europa.eu/food/food/labellingnutrition/supplements/index_en.htm

12. Regulation 5(1) says that food supplements containing vitamins and minerals may only contain those vitamins / minerals listed in Annex I in the forms listed in Annex II of Directive 2002/46/EC. Do the Regulations prohibit the use of 'natural sources' of vitamins / minerals e.g. cod liver oil as a source of vitamin A?

This issue was discussed at a meeting of the Standing Committee on the Food Chain and Animal Health 2 October 2002. The Committee agreed that ingredients that naturally contain a nutrient can be included in food supplements. They would have to be declared in the list of ingredients as such. In addition, their natural content of a nutrient would contribute to the total quantity of that nutrient with respect to any restriction on nutrient levels and to declared amounts in nutrition labelling. Therefore any maximum levels set for food supplements would apply to the total amount of the nutrient present in the product resulting from all its ingredients. Similarly, the declared amount of a nutrient in nutrition labelling should be the total amount of the nutrient in the product.

For example - Which would be correct: 'Cod Liver Oil' or 'Vitamin A as Cod Liver Oil'? The declaration in the ingredients list should be "cod liver oil". A food business operator should also be aware of the subtle difference between existing natural sources and 'novel' sources of vitamins and minerals. Any vitamin or mineral obtained from a 'novel' source would be subject to the terms and conditions of the Novel Foods Regulation (EC) No 258/97.

13. What procedure will have to be followed in order to add to Annex II a 'novel' source of a vitamin or mineral?

Any novel ingredient requires authorisation under the EU procedures for novel foods (regulation (EC) No 258/97), unless it has a significant history of consumption in one or more EU member states prior to May 1997. This involves making an application to one of the member states, which will either prepare an initial assessment report for distribution to the other member states or issue an opinion that the ingredient is closely equivalent to one that is already on the market.

14. Regulation 5 refers to "relevant purity criteria". Where are these set out?

No specific purity criteria have been set under the Directive. Article 4 of the Directive makes provision for Community purity criteria for substances listed in Annex II to the Directive to be adopted in future through standing committee procedures. This is for those substances for which purity criteria are not already laid down by EC legislation (e.g. in legislation on food additives).

For those substances for which purity criteria are not set out in existing EC legislation, until the Community adopts purity criteria, generally acceptable purity criteria recommended by international bodies may be used e.g. Joint FAO/WHO Committee on Food Additives (JECFA) and the European Pharmacopoeia.

Regulation 6

15. Has the term “food supplement” become a prescribed name?

Regulation 6(1) of these Regulations makes the term “food supplement” a prescribed name for the purposes of regulation 6(1) of the Food Labelling Regulations 1996 as amended.

16. Does the term "food supplement" have to appear stand-alone on the label?

The term “food supplement” must appear on the label and can appear stand-alone as stated in the Food Labelling Regulations 1996 6(1), which requires the name prescribed by law to be used. However, Regulation 6(3) of this regulation allows a qualification of this with other words to make it more precise e.g. “Food Supplement – containing vitamins and minerals”. Manufacturers would be encouraged to use the more descriptive option.

17. Regulation 6(2)(a) states that a food supplement label must include the name of the category of any vitamin or mineral or other substance with a nutritional or physiological effect which characterises the product or an indication of the nature of that vitamin or mineral or other substance. What do these phrases mean?

In our view the *name of the category of any vitamin or mineral or other substance with a nutritional or physiological effect* refers to terms such as, but is not limited to, "vitamin", "mineral", "amino acid", "fatty acid". Vitamin or mineral or with herbs would suffice. While regulation 6(2)(a) of these Regulations gives these as alternate requirements, we would prefer to see both given where this is possible and likely to be meaningful to the consumer.

18. Regulation 6(2)(a) requires that the name of the category or any vitamin or mineral or other substance with a nutritional or physiological effect which characterises the product or an indication or the nature of that vitamin or mineral or other substance be included in the labelling. Does this have to be in the same field of vision as the name "food supplement"?

The Regulations do not require that these two pieces of information be in the same field of vision. However, it would be useful to the consumer if they were together.

19. What is the "portion of the product recommended for daily consumption" referred to in regulation 6(2)(b)?

This means the amount of the food supplement to be taken per day (e.g. the number of tablets or capsules) as recommended on the label. Questions 28 and 29 refer.

20. Regulation 6(2)(c) states that labels should carry a warning not to exceed the stated recommended daily dose. Does this exact wording have to be used?

In our view it is not necessary to use the exact wording used in regulation 6(2)(c). It would be acceptable, for example, for a statement to warn against exceeding the recommended daily "intake". The important thing is that the message is clear to consumers.

21. Regulation 6(2)(d) states that labels should carry a statement to the effect that food supplements should not be used as a substitute for a varied diet. Does this exact wording have to be used?

No, but the message must be clear to consumers.

22. Regulation 6(2)(e) states that labels should carry a statement to the effect that the product should be stored out of the reach of young children. Does this exact wording have to be used?

In our view it is not necessary to use the exact wording used in regulation 6(2)(e). It would be acceptable, for example, for a label to carry a caution to keep out of the reach of children. The important thing is that the message is clear to consumers.

Regulation 6(2)(f) and Regulation 6(3)(a-e)

23. Regulation 6(2)(f) requires that the amount of any vitamin or mineral or other substance with a nutritional or physiological effect which is present in the product must be stated on the label. If a food supplement product contains more than one source of a mineral should all sources be considered when declaring the quantity of that mineral on the label?

Yes, our view is that all sources of nutrients in a product should be taken into account when declaring the quantities of nutrients on the label.

24. Annex I and II of the Directive uses the style "Vitamin B12" rather than "Vitamin B₁₂". Can either style be used on the labelling?

No. Enforcement authorities are advising manufacturers and packagers to change their labelling to reflect the format as set out in the Annexes of the Directive.

25. Annex I to the Directive sets out the units that must be used in relation to the listed vitamins and minerals. May other units be used instead?

No. Article 8(1) of Directive 2002/46/EC is clear in its requirements to use the units specified in Annex 1 to the Directive. This is reflected in regulation 6(3)(b).

26. The units of measurement for vitamin A, E and niacin given in Annex I of the Directive include "RE", "TE" and "NE" respectively. Is it necessary to include these on the label?

Yes as in the case of a vitamin or mineral listed in Annex I, the relevant unit specified must be used. These Regulations do not require any change to the way quantities of vitamins are calculated – see table below.

VITAMIN TO BE CALCULATED AS

VITAMIN	TO BE CALCULATED AS
Vitamin A	retinol <i>or</i> retinol equivalent on the basis that 6µg β-carotene or 12µg of other biologically active carotenoids are equivalent to 1µg of retinol
Vitamin D	ergocalciferol (vitamin D2) <i>or</i> cholecalciferol (vitamin D3)
Vitamin E	D-α tocopherol equivalent on the basis that 3.3 mg α tocotrienol or 10mg γtocopherol are equivalent to 1 mg D-α tocopherol
Vitamin C	Ascorbic acid or dehydroascorbic acid
Thiamin	thiamin
Riboflavin	riboflavin
Niacin	nicotinic acid <i>or</i> nicotinamide <i>or</i> niacin equivalent on the basis that 60mg of tryptophan equal 1mg of niacin equivalent
Vitamin B6	pyridoxine
Folic Acid	total folates
Vitamin B12	cobalamines
Biotin	biotin
Pantothenic acid	D-pantothenic acid

27. What unit should be used for vitamins or minerals not listed in Annex I of the Directive or for non-vitamin or mineral ingredients of food supplements?

Any appropriate unit may be used. Annex I of the Directive includes all 13 internationally recognised vitamins so there should be no unlisted vitamins.

28. If the information required by regulation 6(2)(b) is expressed as a range of possible daily intakes, how should the information required by regulation 6(3)(c) be expressed?

If the recommended daily intake of a product were given as a range – for example "take 2-4 tablets per day" - then it would be satisfactory to give the amount of vitamin or mineral per portion of the product per 2 tablets as long as this was clear.

The important thing is that the information in these statements must be presented in such a way that it is clear to the consumer.

29. Is there any flexibility in the way the information required by regulation 6(3)(c) may be expressed?

Yes. For example, if the recommended daily intake of a product were 6 tablets - expressed as "take 2 tablets 3 times per day" on the label - then the quantification per total daily intake should be expressed.

The important thing is that the information in these statements must be presented in such a way that it is clear to the consumer.

30. Regulation 6(3)(d) requires that the amount of any vitamin or mineral or any other substance with a nutritional or physiological effect stated on the label be the average amount based on the manufacturer's analysis of the product. Are there any statutory tolerances laid down?

No. Regulation 6(3)(d), which implements the first paragraph of Article 9(1) of the Directive, states that this amount must be "an average amount based on the manufacturer's analysis of the product". The second paragraph of Article 9(1) of the Directive allows for the future setting of European rules on tolerances to be set by Standing Committee procedures. In the meantime, generally-accepted tolerances may continue to be used.

31. The Directive allows for the future adoption of maximum and minimum levels for vitamins and minerals added to food supplements. Have these been set or are there any national recommendations?

No levels have been set at European level. In the meantime, the Expert Group on Vitamins and Minerals (EVM) is an independent expert advisory committee in the UK which was asked to advise on safe levels of intakes of vitamins and minerals in food supplements and fortified foods. The EVM was asked to consider only vitamins and minerals sold under food law.

Link to final report below:

<http://www.food.gov.uk/multimedia/webpage/vitandmin/120281>

Following the publication of this report, the Food Standards Agency in consultation with industry, issued advice covering advisory statements to be included on labels and, in a limited number of cases, suggested reformulation.

The recommendations in the table on the Food Standards Agency website have been agreed on the basis of the scientific evidence considered by the EVM and may be amended in future in the light of new information. This approach is seen as an important element of the safety-based regulation of food supplements, as it demonstrates a risk management approach which both protects consumer health and enables informed consumer choice. This information can be accessed on the National Archive at:

<http://tna.europarchive.org/20110116113217/tna.europarchive.org/20110116113217/http://www.food.gov.uk/foodindustry/guidancenotes/labelregsguidance/supplementreformguidance>

32. Regulation 6(3)(e) says that as well as having to express the amount of certain vitamins or minerals in a food supplement as a percentage of the relevant recommended daily allowance (RDA) they may also be given in graphical form. How may this be done?

Article 6(3) of Directive 90/496/EEC on nutrition labelling for foodstuffs states that information on quantities of nutrients may be given in graphical form according to formats to be determined by regulatory procedures. These formats have not yet been agreed by Standing Committee and until such time as they are agreed graphical representation is considered inappropriate.

33. Do the labelling requirements in the Regulations apply to all food supplement products or only to those containing vitamins or minerals?

The labelling requirements set out in regulations 6 and 7 apply to all products that meet the definition of "food supplement" in regulation 1 and which are presented as food (see regulation 3) whether or not they contain vitamins or minerals. Non-vitamin and mineral substances have to comply with the labelling requirements of both Directive 2002/46/EC and 2000/13/EC on the labelling, presentation and advertising of foodstuffs.

34. The Food Supplement Regulations require additional information to be included on food supplement labels. Is this the case even though these labels may be quite small?

Yes. There are no exemptions for small packages.

35. Do the labelling requirements in these Regulations say anything about the names of vitamins or minerals that should be used in ingredients lists on food supplement product labels?

No. By way of example, for vitamin E it remains the case that the name "vitamin E" must be used as required by the Food Labelling Regulations 1996 (as amended), and it is not necessary in addition to give the particular form of vitamin E such as D-alpha-tocopherol.

36. Regulation 6(4) says that the labelling, presentation or advertising of a food supplement must not include any mention, express or implied, that "a balanced and varied diet cannot provide appropriate quantities of nutrients in general". Does this exact wording have to be used?

No, but the message must be clear to consumers that they can obtain appropriate quantities of nutrients from a balanced and varied diet.

Regulation 7

37. What do these Regulations require in terms of the manner of marking or labelling of any food supplement sold ready for delivery to the ultimate consumer or sold ready for delivery to a catering establishment in prepacked form?

Regulation 7(1) requires that the labelling particulars in regulation 6(2) must be:

- on the packaging;
- or on a label attached to the packaging; or
- on a label which is clearly visible through the packaging.

Where the sale is otherwise than to the ultimate consumer these particulars may, alternatively, be on commercial documents relating to the food supplement provided that these documents meet the criteria set out in the final paragraph of regulation 7(1).

In addition, regulation 7(3) requires that these particulars are easy to understand, clearly legible and indelible and when a food supplement is sold to the ultimate consumer these particulars are marked in a conspicuous place in such a way as to be clearly visible.

Further, regulation 7(4) requires that these particulars are not in any way hidden, obscured or interrupted by any other written or pictorial matter.

38. What do these Regulations require in terms of the manner of marking or labelling of any food supplement sold ready for delivery to a catering establishment and is not prepacked?

Food supplements may only be sold to the consumer in pre-packed form, however, these Regulations recognise that food supplements may be delivered in bulk supply to retailers or catering establishments ready for packing on the premises for sale to the ultimate consumer (i.e. business to business sales). Hence the inclusion of provisions in regulation 7(2) for the labelling of food supplements which are sold ready for delivery to a catering establishment but are not prepacked as well as the inclusion of provisions in regulation 7(1) which cover the sale of pre-packed food supplements to catering establishments.

Regulation 7(2) requires that the labelling particulars in regulation 6(2) must be:

- on a label attached to the food supplement; or
- on a ticket or notice which is readily discernible by the intending purchaser at the place where he chooses the food supplement; or
- in commercial documents relating to the food supplement where it can be guaranteed that such documents either accompany the food supplement to which they relate or were sent before, or at the same time as, delivery of the food supplement.

In addition, regulation 7(3) requires that these particulars are easy to understand, clearly legible and indelible.

Further, regulation 7(4) requires that these particulars are not in any way hidden, obscured or interrupted by any other written or pictorial matter.

39. Does a company have to notify the competent authority of the placing on the market of a food supplement by forwarding a model of the label used for the product under article 10 of the Food Supplements Directive?

The Directive allows Member States to require notification if they so wish. The UK has taken the decision not to request prior notification, reducing the burden on UK businesses.

Contacts

The Welsh Government, Department of Health and the Food Standards Agency in Scotland and Northern Ireland do not authorise or check the composition or labelling of individual products. **For advice on specific products, including the checking of labels**, please contact your local Trading Standards or Environmental Health office, the details of which can be obtained on the Food Standards Agency's website by using the on-line search engine at:

<http://www.food.gov.uk/enforcement/enforceessential/yourarea/>

If you require further advice relating to these Guidance Notes, please contact:

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Cangen Bwyd a Gweithgarwch Corfforol / Food & Physical Activity Branch

Is-adran Gwella Iechyd / Health Improvement Division

Adran Iechyd y Cyhoedd a'r Proffesiynau Iechyd / Department for Public Health and Health Professions

Llywodraeth Cymru / Welsh Government

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Copies of the legislation mentioned in these Guidance Notes are available from The Stationery Office (Tel: 0870 600 5522; www.legislation.gov.uk).