GUIDANCE NOTES ON LEGISLATION IMPLEMENTING DIRECTIVE 2002/46/EC ON FOOD SUPPLEMENTS

IMPORTANT NOTE

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

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

2. **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**
- **The Food Labelling Regulations 1996 (as amended) and relevant guidance notes that are available on the Food Standards Agency's website (www.food.gov.uk) (for England, Scotland and Wales)**
- **The Food Labelling Regulations (Northern Ireland) 1996 Statutory Rule 1996 No. 383 (for Northern Ireland)**
- **The Food Safety Act 1990 (for England, Scotland and Wales)**
- **The Food Safety (Northern Ireland) Order 1991 (for Northern Ireland)**
- **The Novel Foods Regulation (EC) No 258/97**

3. **The examples in these notes are provided for illustration only.**

4. **The notes and examples should not be taken as an authoritative statement or interpretation of the law, as only the courts have this power.**

Contents **Page**

Introduction

The Food Supplements (England) Regulations 2003 SI 2003 No. 1387, the Food Supplements (Scotland) Regulations 2003 SSI 2003 No. 278, the Food Supplements (Wales) Regulations 2003 WSI 2003 No. 1719 (W186) and the Food Supplements (Northern Ireland) Regulations 2003 Statutory Rule 2003 No. 273 implement in England, Scotland, Wales and Northern Ireland respectively 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. Directive 2002/46/EC is referred to throughout these guidance notes as “the Directive”. These Statutory Instruments and Statutory Rule 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 authoritative, 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.

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.

Organisation of the Regulations

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)

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)

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.

Scope of Regulations (regulation 3)

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)

Prohibits the sale of a food supplement to the ultimate consumer unless it is prepacked.

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

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, subject to a transitional provision.

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

Prohibit 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)
Provides for the authorities responsible for the enforcement of these Regulations.

Offences and penalties (regulation 9)
Creates offences and penalties in relation to the Regulations.

Defence in relation to exports (regulation 10)
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.

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)
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).

QUESTIONS AND ANSWERS

REGULATION 1

1. When do the Regulations come into force?

The Regulations come 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 will be illegal to sell food supplement products that do not comply with the requirements of these Regulations. There will not be a sell-through period. However, products fulfilling the criteria for the derogation in regulation 5(3) may be sold (see question 12 below).

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 England, Scotland and Wales 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 Food Safety Act 1990, the Food Labelling Regulations 1996 (as amended) and the Trade Descriptions Act 1968.

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 Food Safety (Northern Ireland) Order 1991, The Food Labelling Regulations (Northern Ireland) 1996 Statutory Rule 1996 No. 383 and the Trade Descriptions Act 1968.

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'

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 appear 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.

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.

For further information on registration, which is based on evidence of traditional use, safety and quality. Manufacturers are advised to approach their home authority or local enforcement authority for advice.

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, Market Towers, 1 Nine Elms Lane, London SW8 5NQ; tel: 020 7084 2602 / 2759; fax: 020 7084 2439.

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 prepacked 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

9. Regulation 5(1) says that food supplements containing vitamins and minerals may only contain those vitamins / minerals listed in Schedule 1 in the forms listed in Schedule 2. 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. It was agreed that 'natural sources' of vitamins and minerals will continue to be permissible after the Directive comes into force. The relevant section of the minutes of the 2/10/02 meeting states: *"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".

Operator should also be aware of the subtle difference between existing natural sources and 'novel' sources of vitamins and minerals. Any vitamin or mineral obtain from a 'novel' source would be subject to the terms and conditions of the Novel Foods Regulation (EC) No 258/97.

Member States are responsible for implementing the legislation so they should be the first point of contact on these matters.

10. Will the Schedules to the Regulations be amended in future?
Yes, they will be amended as the lists in the Annexes to the Directive are amended.

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

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 procedure. 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. JECFA and the European Pharmacopoeia.

12. What if I want to market in the UK, after 1 August 2005, a food supplement containing a vitamin or mineral or a vitamin or mineral source not listed in Schedule 1 or Schedule 2?

Regulation 5(3) provides derogation from the prohibition imposed by regulation 5(1) until 1 January 2010. Regulation 5(3) means that if the vitamin or mineral or vitamin or mineral source in question was used in the manufacture of a food supplement which was on sale in the European Community (EC) on 12 July 2002 (regulation 5(3)(a)) then it may continue to be used in the manufacture of food supplements sold in the UK provided a dossier supporting use of the substance in question was submitted to the Commission by the Food Standards Agency or a member State other than the UK by 12 July 2005 (regulation 5(3)(b)) and provided that the EFSA has not given an unfavourable opinion in respect of use of that substance in the manufacture of food supplements (regulation 5(3)(c)).

13. 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?

Although stated in the Directive, the UK has taken the decision not to request this information for notifications to reduce the burden on companies.

14. For a substance to qualify for the derogation provided for in regulation 5 does it have to satisfy all of the criteria in regulation 5(3)?

Yes, to qualify for the derogation a substance must satisfy all of the criteria set out in regulation 5(3)(a) and 5(3)(b) and 5(3)(c).

15. If a company marketed a product as Brand name X on 12 July 2002 can it now market a product with identical formulation under Brand name Y by making use of the derogation in regulation 5(3)(a - c)?

The derogation in Article 4(6) of Directive 2002/46/EC, as implemented by regulation 5(3) of these Regulations, is given in respect of vitamin and mineral "substances" not products. The names of products are not relevant to making use of the derogation.

16. Is there any guidance on the content and submission of these dossiers?

The European Commission has issued a document entitled "Administrative guidance on submissions for safety evaluation of substances added for specific nutritional purposes in the manufacture of foods (SCF/CS/ADD/NUT/28)". This document should be read in conjunction with "Guidance on submissions for safety evaluations of sources of nutrients or of other ingredients proposed for use in the manufacture of foods SCF/CS/ADD/NUT/21 Final 12 July 2001" issued by the former Scientific

Committee on Food (SCF). This is available at http://europa.eu.int/comm/food/fs/sc/scf/out100_en.pdf

The SCF's guidance suggests that dossiers should include a section on Biological and Toxocological Data however, in the Food Standards Agency's view, the guidance does not provide a checklist that has to be slavishly complied with. SCF/CS/ADD/NUT/21 refers to the SCF guidance on submissions for food additive evaluations (SCF/CS/ADD/GEN/26). (SCF/CS/ADD/GEN/26) states that there is "no fixed program of testing laid down". The minimum toxicity data required will depend on the substance being assessed. For some compounds, no specific toxicological hazards may be identified. However, for others more information would be needed to provide reassurance that their use in food supplements would not cause harm.

The Food and Agriculture Organisation and World Health Organisation expert consultation guidance on application of risk analysis to food standards issues (http://www.who.int/entity/foodsafety/publications/micro/en/march1995.pdf), which has been used by the SCF upper levels task force, and which is relevant to the consideration of dossiers for nutrients in food supplements, explains that you should assess the data you have as a starting point. It may also, in some instances, be appropriate for documents such as The Joint FAO/WHO Expert Committee on Food Additives (JECFA) evaluations to be included in these dossiers.

In our view, any company considering compiling a dossier and looking for help in deciding what data should be included and what, if any, new studies should be conducted, could consider seeking advice from a toxicologist experienced at working with advisory committees; for example, experience of submitting dossiers for the approval of food additives would be relevant.

It is not ethical to conduct animal studies that cannot be justified and the EFSA is well aware of the sensitivity of the issue of animal testing. The EFSA panels and working groups will no doubt bear this in mind when assessing dossiers submitted in support of nutrients and nutrient sources for food supplements.

In a meeting with interested parties in October 2003, the chair of the EFSA scientific panel on food additives, flavourings, processing aids and materials in contact with food has indicated that-

- the panel is keen to avoid unnecessary tests, particularly those involving animals. The administrative and technical data set out in sections 1 and 2 of the SCF "Guidance on submissions for safety evaluations of sources of nutrients or of other ingredients proposed for use in the manufacture of foods" are important as they establish the identity and purity of the material, and full information on these is needed. As for the biological and toxicological data in Section 3, applicants should submit available safety data and EFSA would then advise whether further data were required.

The situation is set out in the minutes of a meeting of the panel (available at www.efsa.eu.int/pdf/minutes_afc_02_adopted_en.pdf);

- in deciding what further data may be required, the panel will take into account similarities with substances which have already been approved either as nutrient sources or as additives. In these cases, references the relevant assessment (e.g. additive, parnuts or JECFA assessment) should be supplied;
- bioavailability is an important characteristic and will affect the toxicology requirements. Information will be required when bioavailability is different from that of sources already listed;
- combined dossiers for similar substances (e.g. different salts of a 'new' anion) will be welcome;
- the requirement at section 2.6.1. of the SCF guidance for 'justification of a new source could be fulfilled by simply indicating that a 'different' source was needed;
- sources of nutrients not on Annex I are likely to require significant toxicological data.

The contact at the EFSA who would be able to provide further information about the content of dossiers is Torben Hallas-Moller (email: Torben.HALLAS-MOLLER@efsa.eu.int).

The Food Standards Agency does not plan to produce formal guidance on preparation of dossiers in relation to the food supplements Directive, however, the Agency has offered to provide advice on the technical aspects of the dossiers before submission to the EFSA providing that industry make such requests in a co-ordinated fashion and providing they are submitted by 20 May 2005.

17. If a dossier supporting the use of a substance not listed in Schedule 1 or Schedule 2 to these Regulations is being submitted via the UK Food Standards Agency by what date must it reach the Agency?

In order to give the Food Standards Agency time to send dossiers on to the European Commission by 12 July 2005, the Food Standards Agency requests that dossiers suitable for submission to the Commission are sent to reach the Food Standards Agency (see address at the end of these guidance notes) no later than 17 June 2005. The Agency cannot guarantee that any dossiers received after 17 June 2005 will be submitted to the Commission by 12 July 2005.

18. Should all such dossiers for submission through the UK be sent to the Food Standards Agency in London?

Dossiers for submission to the European Commission through the UK may be sent to Food Standards Agency offices in London, Aberdeen, Cardiff or Belfast. Contact details are given at the end of these guidance notes.

19. What will the Food Standards Agency do with dossiers?

The Food Standards Agency will send dossiers to the European Commission. The Agency will not undertake any assessment of dossiers. However, Agency officials have offered to provide advice on the technical aspects of the dossiers before submission to the Commission providing that such requests are made in a co-ordinated fashion and that they are submitted by 20 May 2005.

20. Will the Food Standards Agency only accept dossiers for substances on the market in the UK on 12 July 2002 or will the Agency also be prepared to accept dossiers for substances that are lawfully on the market in other EU member States?

The Regulations do not require that a dossier be submitted by a MS in which the substance in question is lawfully on the market. Therefore, the Food Standards Agency will transmit any such dossiers on to the Commission.

21. For a company marketing products in the UK to be able to take advantage of the derogation provided for in regulation 5, does the dossier for the substance in question have to be submitted via the UK Food Standards Agency?

No, the dossier may be submitted by any EU member State as the Food Standards Agency will give derogation for nutrients and nutrient sources where a dossier has either been submitted to the UK or to another EU Member State. Companies who wish to use nutrients or nutrient sources in other Member States should check with the relevant competent authority on their requirements with respect to granting derogation.

22. How will we know what dossiers have been submitted to EFSA?

Commission Regulation (EC) No. 1304/2003 of 11 July 2003 on the procedure applied by the EFSA to requests for scientific opinions referred to it states, in Article 2, that the Authority shall establish a register of requested opinions which is accessible to the public. It also states that this register shall allow the progress of requests for opinions to be followed with effect from the date on which they are received. This register is accessible on EFSA's website under "Science / Register of requested opinions" at http://www.efsa.eu.int/register/qr_panels_en.html. A list of those dossier submitted though the UK and other member states is available at http://www.food.gov.uk/foodindustry/vitmin

23. How will EFSA make known its positive or negative opinions on dossiers submitted in support of addition of substances to Annexes 1 or 2 to the Directive?

The register on the EFSA website is updated to show the "status" of requested opinions.

24. If a company has already submitted a dossier to support addition of a vitamin or mineral substance to the parnuts positive list in Directive 2001/15/EC and now wants that substance added to one of the Annexes to the Food Supplements Directive what should it do?

The company should inform the European Commission. It would also be helpful if the company lets the Food Standards Agency know and the Agency will also write to the European Commission informing them and requesting confirmation that a separate dossier will not be needed.

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

Any source that is not listed in Annex II and does not qualify for the derogation described above (see question 12 above) will need to be notified to the Commission, who will seek advice from EFSA before asking member states to agree to an amendment to the lists, if considered appropriate. In addition any new 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. In practice, the report from the Member State could be used by EFSA as the basis for the evaluation that is required under directive 2002/46.

26. What if a vitamin or mineral or vitamin or mineral source is not listed in Schedule 1 or Schedule 2, had been on sale in the EC before 12 July 2002, but was not actually on sale in the EC on 12 July 2002. Can I still make use of the derogation in regulation 5(3)(a-c)?

No, in this case the derogation may not be used since the criterion in regulation 5(3)(a) is not met. Food supplements containing the substance in question would have to be taken off the market by 31 July 2005. A dossier in support of use of that substance in food supplements could still be submitted to the EFSA for assessment (see recitals 10 and 12 of the Directive) and if EFSA gave a favourable opinion that substance could then be added to the relevant list in Annex I or Annex II to the Directive through standing committee procedure (Article 4(5) of the Directive).

27. What if I want to use a vitamin or mineral or a vitamin or mineral source that was not on sale in the EC before or on 12 July 2002?

A dossier supporting use of the substance in question may be submitted to the EFSA for assessment (see recitals 10 and 12 of the Directive). If EFSA gives a favourable opinion that substance may then be added to the relevant list in Annex I or Annex II to the Directive through standing committee procedure (Article 4(5) of the Directive).

28. If the substance in question was used in food supplements on the market in the EC after (but not on) 12 July 2002, a dossier has been submitted but a positive opinion not given by 31 July 2005, will such food supplements have to be taken off the market on 31 July 2005?

Yes. However, they could be put back on the market if EFSA gave a positive opinion on the use of the substance in question in food supplements after that and the relevant Annex to the Directive is amended.

29. Regulation 5(3) states that the prohibitions in 5(1) shall not apply until 1 January 2010 providing the criteria in 5(a-c) are met. Does this mean that substances continuing to be sold under the terms of the derogation in 5(3)(a-c) will have to come off the market on 1 January 2010 in any case?

The Food Standards Agency's understanding is that by this date, the Commission intends that the lists in the Annexes to the Directive will have been amended by adding the names of any substances that have received positive opinions from EFSA. In this case, food supplements containing those substances will be able to be sold after 1 January 2010.

The Agency's understanding is that if there are any substances being sold under the terms of the derogation and for which EFSA has not completed dossier assessment by 1 January 2010, the European Community will set a date for extension of the derogation.

30. If I continue to market after 1 August 2005 a food supplement product containing a vitamin or mineral substance not listed in Schedule 1 or Schedule 2 under the derogation provided for in regulation 5 of these Regulations and the EFSA gives an unfavourable opinion in respect of that substance at some date after 1 August 2005, how long does the derogation last?

The derogation would last until such time as the EFSA opinion is published. Article 29(7) of Regulation 178/2002/EC says, “The Authority's internal rules shall specify requirements in regard to format, explanatory background and publication of a scientific opinion.”

REGULATION 6

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

It is a necessary consequence of regulation 6(1) of these Regulations that food supplement is a prescribed name for the purposes of regulation 6(1) of the Food Labelling Regulations 1996 as amended.

32. 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 as 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.

33. 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?

The Food Standards Agency's view is that 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". The Agency's view is that vitamin or mineral or with herb would suffice. While regulation 6(2)(a) of these Regulations gives these as alternate requirements, the Food Standards Agency would prefer to see both given where this is possible and likely to be meaningful to the consumer.

34. 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, the Food Standards Agency’s view is that it would be useful to the consumer if they were together.

35. 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 45 and 46 refer.

36. 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?

The Food Standards Agency's view is that 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.

37. 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.

38. 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?

The Food Standards Agency's view is that 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)

39. 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, the Food Standards Agency's view is that all sources of nutrients in a product should be taken into account when declaring the quantities of nutrients on the label.

40. Column 1 of Schedule 1 to these Regulations uses the style "Vitamin B1" rather than "Vitamin B_1". Can either style be used on the labelling?

No. LACORS have indicated that enforcement authorities are advising manufacturers and packagers to change their labelling to reflect the requirements of the new legislation.

41. Column 2 of Schedule I to these Regulations sets out the units that must be used in relation to the vitamins and minerals set out in Column 1. 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 and therefore in Column 2 of Schedule 1 to these Regulations. This is reflected in regulation 6(3)(b). This is the case even if these units are different from the ones customarily used at present in the UK.

42. These Regulations require that the quantity of biotin in a food supplement be given on the label in micrograms. The Food Labelling Regulations 1996 specify milligrams as the units for biotin. Which units should be used on the labelling of food supplements?

Article 8(1) of Directive 2002/46/EC is clear in its requirements to use the units specified in Annex 1 to the Directive and therefore in Column 2 of Schedule 1 to these Regulations. Therefore, on a food supplement label the quantity of biotin in a product must be given in micrograms. We understand that this anomaly is likely to be removed during the review of Directive 90/496/EEC.

43. The units of measurement for vitamin A, E and niacin given in column 2 of Schedule I include "RE", "TE" and "NE" respectively. These abbreviations are not customarily included on labels at present. Is it necessary to include these from 1 August 2005?

Yes as in the case of a vitamin or mineral listed in column 1 of schedule 1 the relevant unit specified in column 2 must be used – this is in line with Directive 2002/46/EC. These new Regulations do not require any change to the way quantities of vitamins are calculated – see below.

VITAMIN	TO BE CALCULATED AS
Vitamin A	retinol *or* retinol equivalent on the basis that 6μg β-carotene or 12μg of other biologically active carotenoids 1μg of retinol equivalent
Vitamin D	ergocalciferol (vitamin D_2) *or* cholecalciferol (vitamin D_3)
Vitamin E	D-α tocopherol equivalent on the basis that 3.3 mg α tocotrienol or 10 mg γtocopherol are equivalent to 1 mg D-α tocopherol
Vitamin C	Ascorbic acid or dehydroascorbic acid
Thiamin	thiamin
Riboflavin	riboflavin
Niacin	nicotinic acid *or* nicotinamide *or* niacin equivalent on the basis that 60mg of trytophan equal 1mg of niacin equivalent
Vitamin B_6	pyridoxine
Folic Acid	total folates
Vitamin B_{12}	cobalamines
Biotin	biotin
Pantothenic acid	D-pantothenic acid

44. What unit should be used for vitamins or minerals not listed in Schedule 1 or for non-vitamin or mineral ingredients of food supplements?

Any appropriate unit may be used. Schedule 1 of the regulation includes all 13 internationally recognised vitamins so there should be no unlisted ones.

45. 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.

46. 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.

47. 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 procedure. In the meantime, generally-accepted tolerances may continue to be used.

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/science/ouradvisors/vitandmin/120281

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

The recommendations in the table on the FSA 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 at:
http://www.food.gov.uk/foodindustry/guidancenotes/labelregsguidance/supplementreformguidance

48. 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 procedure. These formats have not yet been agreed by Standing Committee and until such time as they are agreed graphical representation is considered inappropriate.

49. Do the labelling requirements in the new 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 and 2000/13 EC.

50. These new Regulations require new, additional information to be included on food supplement labels. Is this the case even though these labels may be quite small?

Yes.

51. 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, and it is not necessary in addition to give the particular *form* of vitamin E such as D-alpha-tocopherol.

LACORS have indicated that enforcement authorities are advising manufacturers and packagers to change their labelling to reflect the requirements of the new legislation.

52. 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 balances and varied diet.

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

Any food supplement sold ready for delivery to the ultimate consumer or to a catering establishment must be marked or labelled in accordance with regulations 6(1) - 6(4). It must also be labelled as required by the relevant provisions of Part II of the Food Labelling Regulations 1996 (as amended). Refer to questions 40 and 51.

REGULATION 7

54. 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 and prepacked?

These Regulations recognise that food supplements may be sold in places such as gyms and sports clubs as well as in normal retail outlets such as supermarkets and pharmacies. Hence the inclusion of a provision recognising sale of food supplements in "catering establishments" (defined in regulation 2).

Regulation 7(1) requires that the particulars of the labelling with which the product is required to be labelled by virtue of 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.

55. 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 not prepacked?

These Regulations recognise that food supplements delivered to gyms, sports clubs or other retail outlets may either be delivered pre-packed and ready for sale to the ultimate consumer or may be delivered in bulk supply ready for packing on the premises for sale to the ultimate consumer. 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 pre-packed 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 particulars of the labelling with which the product is required to be labelled by virtue of 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.

Enquiries

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

Iulia Young
Novel Foods, Additives and Supplements Division
Food Standards Agency
Room 115C
Aviation House
125 Kingsway
London WC2B 6NH
Tel: 020 7276 8568
Fax: 020 7276 8564

Hilary Neathey
Food Standards Agency (Wales)
11th Floor Southgate House
Wood Street
Cardiff
CF10 1EW
Tel: 029 2067 8909
Fax: 029 2067 8918

Tracy Mcken
Food Standards Agency (Scotland)
St Magnus House 6th Floor
25 Guild Street
Aberdeen
AB11 6NJ
Tel: 01224 285 175
Fax: 01224 285 110

Anne-Marie Chambers
Food Standards Agency (Northern Ireland)
10A-10C Clarendon Road
Belfast
BT1 3BG
Tel: 028 9041 7714
Fax: 028 9041 7726

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