

GUIDANCE NOTES ON THE EUROPEAN COMMUNITIES (FOOD SUPPLEMENTS REGULATIONS) 2003, S.I. NO.539 OF 2003 AND THE NOTIFICATION OF FOOD SUPPLEMENTS.

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Scope

The scope of this document is to provide information on the implementation, enforcement and compliance with the Food Supplements Regulations Statutory Instrument No. 539 of 2003 (and Directive 2002/46/EC) on food supplements currently on sale in Ireland, those being manufactured or being imported directly, or through third parties *i.e.* agents.

This document is designed with manufacturers, importers, distributors and retailers of food supplements as well as the enforcement officers in mind.

Definitions in law

¹Competent Authority The Food Safety Authority of Ireland

¹Food supplements *Foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological² effect, alone or in combination, marketed in dose form, namely forms 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 and powders designed to be taken in measured small unit quantities;*

¹Nutrients *(i) vitamins, (ii) minerals.*

³Labelling *Shall mean any words, particulars, trade marks, brand name, pictorial matter or symbol relating to a foodstuff and placed on any packaging, document, notice, label, ring or collar accompanying or referring to such foodstuffs.*

¹ Directive 2002/46/EC on the approximation of the laws of Member States relating to food supplements

² See section 3 for classification of products. Physiological = non medicinal.

³ Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs

⁴Medicinal product *Any substance or combination of substances presented for treating or preventing disease in human beings.*
until end October 2005.

Any substance or combination of substances which may be administered to human beings with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings is likewise considered a medicinal product.

⁵Medicinal Product *(a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or*
from end of October 2005

(b) Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.

⁶Placed on the market *(a) import, (b) sell, (c) offer or expose for sale, (d) invite the making by a person of an offer to*

⁴ Directive 2001/83/EC on the Community code relating to medicinal products for human use.

⁵ Directive 2004/27/EC amending Directive 2001/83/EC on the Community code relating to medicinal products for human use. **This definition does not come into Irish Law until October 2005.**

⁶ Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 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

purchase and (e) distribute free of charge in Ireland. This would also include the internet, network marketing and direct sales.

Introduction

The Food Supplement Regulations, SI 539 of 2003 (The Regulations) implement for Ireland 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 (The Directive).

This Directive applies equally to all sectors of the food supplement industry; manufacturers, importers, distributors, retailers including website sales, company mail order sales and network marketing as well as the traditional retail routes of sale.

In the case of internet, mail order and network marketing sales, although the website/company/product may not be of Irish origin, once it is brought onto the Irish market via any route for sale to the public (see definition for placed on the market), the importer is responsible for the notification to the Food Safety Authority of Ireland (FSAI) of products.

If a food supplement is imported into Ireland with the sole purpose of exporting it, it is not considered to have been placed on the Irish market as it has not been made available to the public. However, once it is made available to the public via any route, then the food supplement comes under the scope of the Regulations.

Article 12 on Food and feed exported from the Community of Regulation 178 of 2002⁷, states:

⁷ Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 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

1. Food and feed exported or re-exported from the Community for placing on the market of a third country shall comply with the relevant requirements of food law, unless otherwise requested by the authorities of the importing country or established by the laws, regulations, standards, codes of practice and other legal and administrative procedures as may be in force in the importing country. In other circumstances, except in the case where foods are injurious to health or feeds are unsafe, food and feed can only be exported or re-exported if the competent authorities of the country of destination have expressly agreed, after having been fully informed of the reasons for which and the circumstances in which the food or feed concerned could not be placed on the market in the Community.

2. Where the provisions of a bilateral agreement concluded between the Community or one of its Member States and a third country are applicable, food and feed exported from the Community or that Member State to that third country shall comply with the said provisions

Organisation of the Regulations

Title, commencement and extent

- Contains the title by which the Regulations may be cited, the coming into force.

Interpretation

- Includes definitions for specific terms used and refers to the Directive for other terms not specified.

Restriction on sale

- Effectively requires the notification food supplements intended for sale in Ireland.
- Identifies the 'competent authority'.

Enforcement

- Provides for the authorities responsible for the enforcement of these Regulations.

Offences and penalties

- Gives details of the offences which may be committed under the provisions of these Regulations.

Application of various provisions of the Food Safety Authority of Ireland Act, 1998.

- Lists the sections of the Food Safety Authority of Ireland Act 1998 which apply.

Table 1. Key Dates with regards to the Food Supplements Directive

Date	Action required
[From June 2002]	Notification to the FSAI required for any new food supplements containing vitamins and minerals coming onto the Irish market
31 July 2004	European Food Safety Authority to set the maximum levels at which vitamins and minerals can be added to the food supplement. Currently pending.
12 July 2005	Submissions of safety dossiers to the European Food Safety Authority for assessment
31 July 2005	All food supplement labels (including those on the market prior to the advent to the Directive) to comply with the food supplements Directive. See section 18 with regards to a sell through period.
1 August 2009	Prohibit trade in products which do not comply with the Directive (Full derogation taken by Ireland)
31 August 2009	Deadline for member states to allow in their territory the use of vitamins and minerals not listed in Annex 1 or in forms not listed in Annex 2 provided (a) the substance in question is used in one or more food supplements marketed within the Community on the date of entry into force of this Directive and (b) the EFSA has not given an unfavourable opinion in respect of the use of that substance or its use in that form, in the manufacture of food supplements, on the basis of a dossier supporting use of the substance in question to be submitted to the Commission

Difference between food supplements and medicines.

The definition of a food supplement can be found in the definition section of this document.

There are a wide range of nutrients and other substances used as ingredients that might be present in food supplements including, but not limited to, vitamins, minerals amino acids, essential fatty acids, fibre and various plants and herbal extracts (recital 6 of Directive).

However as a first stage the Directive lays down specific rules for vitamins and minerals used as ingredients in food supplements. Food supplements containing vitamins and/or minerals as well as other substances used as ingredients should also be in conformity with the specific rules on vitamins and minerals as laid down in the Directive.

Specific rules concerning nutrients, other than vitamins and minerals or other substances used as ingredients of food supplements will be laid down at a later stage.

Sometimes a product containing vitamins and/or minerals can come within the terms of medicinal product legislation by virtue of its composition, labelling, presentation or medicinal claims. If this occurs, the product is legally regarded as a medicinal product. The current European Union definition of a medicinal product is given in article 1 of Directive 2001/83/EC and can be found in the definition section of this document.

However it should be noted that the E.U. legislation on medicinal products is set to change in October 2005, with the amending of Directive 2001/83/EC by Directive 2004/27/EC. In this new Directive, a revised

definition for a medicinal product is given (which can also be found in the definition section of this document).

Some products can come within the terms of medicinal product legislation in a number of ways, for example, when medicinal claims⁶ are made in association with the product.

The Irish Medicines Board (IMB) is the competent authority for medicinal products in Ireland, apart from veterinary immunological medicinal products which are currently regulated by the Department of Agriculture and Food. Queries with regards to the definition of a medicinal product should be directed to the IMB

The regulations do not apply where a product clearly comes under the definition of other product categories, including medicines biocides,, foods for particular nutritional purposes and foods for special medical purposes.

Where the classification of a product is unclear, the FSAI will liaise with the IMB, DOHC and the individual manufacturing/importing business, as appropriate.

Notification of food supplements.

Article 10 of the Food Supplements Directive 2002/46/EC states that to facilitate efficient monitoring of food supplements, Member States may require the manufacturer or the person placing the product on the

⁶ A medicinal claim states or implies that a product presented has the property of treating or preventing disease in human beings. In order to be permitted to make a medicinal claim, a product must be registered as a medicinal product in accordance with Directive 2001/83/EC and related Irish law, unless an exemption exists which removes the need for registration.

market in their territory to notify the competent authority of that placing on the market by forwarding it a model of the label used for the product. Ireland makes use of the provision through the Regulations which require notification to the FSAI of placing on the market of food supplements (followed, where necessary, by provision of supplementary material). This requirement applies when the product is manufactured in or imported into Ireland and is being placed on the Irish market for the first time.

The Regulations effectively require food supplements to be notified to the FSAI when placed on the market in Ireland for the first time.

As a first stage, this notification procedure applies only to food supplements containing vitamins and minerals covered by the E.U. Directive.

Products which are manufactured in Ireland for export and which are not to be placed on the Irish market do not need to be notified to the FSAI.

Where the products are destined for another EU Member State, it will be necessary for the notification requirements of that country to be complied with.

Where the export of a food supplement is to a country outside of Europe, the requirements of the supplements Directive must still be complied with even if the product is not marketed within Europe unless otherwise requested by the authorities of the importing country or established by the laws, regulations, standards, codes of practice or other legal or administrative procedures as may be in force in the importing country. These provisions are set out in Article 12 of Regulation 178/2002 on general

food law. However as previously stated once it is made available to the public by it being placed on the Irish market via any route, then the food supplement comes under the jurisdiction of the FSAI.

Food Supplement Labels

The specific labelling requirements of a food supplement are set out in the food supplements Directive and require the following particulars:

- a) The names of the categories of nutrients or substances that characterise the product or an indication of the nature of those nutrients or substances
- b) The portion of the product recommended for daily consumption
- c) A warning not to exceed the stated recommended daily dose
- d) A statement to the effect that food supplements should not be used as a substitute for a varied diet
- e) A statement to the effect that the products should be stored out of the reach of young children.

However the label will also need to comply with the general food labelling Regulations, the allergens Directive and the Foods for Particular Nutritional Uses Directives. A good reference point for labelling is the FSAI report 'The Labelling of Food in Ireland 2002'⁸ which can be found on the FSAI website.

Food supplements to be notified.

Not all supplements need to be notified, it is only required for food supplements containing vitamins and minerals as covered by the Directive. As previously mentioned, the notification requirements apply to

⁸ This document is currently under review for updating. It is expected that the new labelling report will be available in 2005.

food supplements that are placed on the market in Ireland for the first time since the advent of the food supplements Directive. The effective date given in S.I. 539 of 2003 for this is the 12th of June 2002.

In addition to the above, food products that do not comply with the definition for food supplements are not subject to these Regulations and therefore do not need to be notified under this Directive. Examples include:

- Conventional food products bearing a nutrition claim or health claim, such as low salt baked beans, reduced salt tomato ketchup, low fat yoghurt.
- Conventional food products containing added vitamins or minerals, such as vitamin-enriched breakfast cereals.
- Foods for Special Medical Purposes and Particular Nutritional Uses.
- Foods intended to meet the expenditure of intense muscular effort, especially for sportsmen.

These examples have or will have their own specific Directives and Regulations.

Notification of variation in food supplement products.

A food supplement that has already been notified to the FSAI under these Regulations but which has since been reformulated should be notified as if it were a new product and also a copy of the new label is required. A separate notification as if it were a new product is required for each food supplement including a variation in:

- Flavour
- Packaging size
- Ingredients

- Ingredient levels
- Claims etc.

When to notify Food Safety Authority of Ireland.

In Ireland food supplements are required to be notified (followed, where necessary, by provision of supplementary material) to the FSAI before such products are placed on the Irish market. This requirement applies when the product is manufactured in or imported into Ireland and placed on the market for the first time.

How to notify the Food Safety Authority of Ireland.

Article 10 of the Directive requires that a model of the label of any product requiring notification be forwarded to the competent authority of the Member State where the product is to be marketed. In Ireland, the competent authority is the FSAI.

The FSAI has developed a form that manufacturers and importers may use to help them with their notification. This is available on our website: ⁹ http://www.fsai.ie/legislation/notif_forms/food_supp_not_form.pdf. Please notify us by forwarding a completed form along with a model of the product label, any associated literature (e.g. advertising, consumer information leaflets, websites etc.) and a covering letter detailing contact details from where additional information may be requested. The addresses to which notifications should be sent are given at the end of these Guidance Notes.

⁹ Consult Annex 1 for a copy of this form.

This notification is acknowledged with an indication of the approximate timescale within which the notification will be processed, normally 8 weeks.

On completion of the processing of the notification, the notifier will receive a letter with regards to the outcome.

- In the event of a positive outcome, the applicant company will receive a letter stating compliance with the legislation.
- In the event of a negative outcome, the applicant company is informed by letter, detailing reasons of same and advised how to become compliant with the legislation.

Further information required by the Food Safety Authority of Ireland.

The FSAI may require the manufacturer (or where appropriate, the importer) to produce the scientific work and data establishing the product's compliance with the definitions for 'food supplement' together with information on the particular elements of the qualitative and quantitative composition or the special manufacturing process which gives the product its particular nutritional characteristics. If such work is contained in a readily available publication, reference to this publication will suffice. Failure to produce such information without reasonable excuse is an offence under the Regulations.

All submitted information during the notification process on a product will be kept confidential except in the case where the product may be considered a medicine and therefore it is the duty of the FSAI to notify the IMB of the case for their opinion.

The processing of this additional information could take up to a further 6 weeks on receipt of this extra information.

Responsibility for notification to the Food Safety Authority of Ireland.

It is the responsibility of the manufacturer or importer based in Ireland of a food supplement requiring notification to carry out this task. For food supplements requiring notification which are manufactured in the European Union and whose first marketing is in Ireland, it is the responsibility of the manufacturer to notify. For food supplements manufactured outside the European Union and whose first marketing is in Ireland, the responsibility falls to the importer.

Products already notified in another Member State.

A product, which has been notified in another Member State under the Directive, and subsequently, placed on the market in Ireland, is still subject to the notification requirements. The product must be notified to the FSAI by the manufacturer or, where appropriate, the importer based in Ireland using a model of the label (see annex 2 for example of a compliant label) and details of the recipient competent authority of the first notification in the European Union.

Processing of notification provided to the Food Safety Authority of Ireland.

The FSAI will acknowledge receipt of notification and inform the relevant official agencies – who enforce the food Regulations – that the product has been notified in accordance with S.I. 539 of 2003. The FSAI may require further information about a particular product (see Section 11 of these guidance notes).

Details about the notification, such as the product label, date of notification and contact details of the notifier, will be kept centrally and in confidence by the FSAI.

The FSAI will list food supplements notified under these Regulations on its website for use by official agencies and all other interested parties. However this listing will only include the name of the product and the manufacturer/distributor. Prior to the advent of the Directive and S.I., notification was not required for food supplements being placed on the market.

Checking for compliance by the Food Safety Authority of Ireland for food supplement labelling.

It is the responsibility of the manufacturer/importer to ensure that a food supplement complies with the relevant legislation. Products must not be placed onto the Irish Market unless it has satisfactorily presented itself as meeting the requirements of the legislation and failure to do so, is an offence under the Regulations.

After notification and submission of a proposed label, the FSAI will check the product for compliance with regards to labelling and provide appropriate advice. However, the notification of a food supplement under these Regulations should not be viewed in any way as FSAI 'approval'. The label cannot contain any statements suggesting such an approval.

In general, the FSAI will acknowledge receipt of the notification and product label within a week of submission. Assessment of labels would

normally take up to 8 weeks. Should any additional information be sought, it may take up to a further 6 weeks before an opinion is given by the FSAI.

In the event that the requirements of the Regulations are met, there will be no restrictions on placing the product on the Irish market. The FSAI will issue a letter stating such.

Warranty through the chain.

It is the responsibility of the retailer to ensure that the products being sold on their premises are compliant with the legislation. In order to be certain that the products are of a high standard, the certificate of analysis and where relevant, the letter from the FSAI with regards to notification procedure and labelling compliance should be made available to the retailer by the importer/distributor.

The retailer also needs to ensure that they have a traceability system in place back to their supplier and forward to their customers, in cases of selling on to other retailers.

Food supplements containing vitamin and mineral compounds not listed by the Directive.

If a product contains vitamins and minerals that are not currently listed in the Directive and the substance in question was used in one or more food supplements marketed in the Community on 12 July 2002, it can be placed on the Irish market. However, the labelling will need to be compliant with the legislation by July 2005 and a safety dossier on the compounds in question will need to be submitted to the European Food Safety Authority for assessment by 31 July 2005 also.

By way of derogation from paragraph (1) of this Regulation, the use of vitamins and minerals not listed in schedule 1 or in forms not listed in schedule 2, is permitted and until 31 December 2009. FSAI may allow in Ireland the use of vitamins and minerals not listed in Annex 1, or in forms listed in Annex 2, provided that:

(a) the substance in question was used in one or more food supplements marketed in the Community on 12 July 2002 and

(b) the FSAI after consultation with the Minister has either (i) submitted a dossier (on behalf of the industry), supporting the use of the substance, or its use in that form or (ii) indicated, in writing, its approval of a dossier submitted by another Member State, and such dossier or written approval has been sent to the Commission by 12 July 2005.

Where (a) and (b) are satisfied, the substance in question may be used until 31 December 2009, or until the European Food Safety Authority has given an unfavourable opinion in respect of the use of that substance, or its use in that form, in the manufacture of food supplements, whichever is earliest.

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)². This document should be read in conjunction with "Guidance on submissions for the safety evaluations of sources of nutrients or of other substances used as 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.

Marketing food supplements without notification.

If the product is subject to the notification requirements then it must be notified in line with the Regulations. Failure to do so is an offence and subject to fine.

However if the product was on the market prior to the advent of the Directive or Regulation, it can remain on the market provided the labelling complies with the legislation by July 2005. [The European Food Safety Authority will be making assessments of compounds not currently listed in the Directive and substances used as ingredients will be restricted to those which have not been given a negative outcome for use in food supplements.]

However, there will be a reasonable sell through period of based on a product's shelf life allowed in order to use stock with existing labels which may not fully comply with the requirements. It is envisaged that this sell through period will facilitate manufacturers to make a single label change in order to be compliant with a number of pieces of legislation at the one time.

If products have been notified in another Member State, a letter from the Competent Authority in that Member State will be accepted as proof of compliance. However the FSAI will still request a copy of the label.

Enforcement of food supplements Directive

Enforcement of food law is the responsibility of Health Service Executive, usually through environmental health officers. The food supplement legislation is food law and has the following offences set out.

¹²Offences Offences include:

1. Fail to comply with the Regulations.
 - a. Place product on market for the first time without prior notification
 - b. Place product on the market for the first time with non-compliant labelling
 - c. Place product on market for the first time containing vitamins and minerals not listed in Annex 1 and 2
2. To issue or forge the certificate of analysis or other documents.
3. To alter and issue a certificate of analysis or other documents.
4. Be unlawfully in possession of a forged document or an altered document.
5. Tamper with anything to misrepresent the substance sampled.
6. Tamper or interfere with any sample taken.

A person who is guilty of an offence under these Regulations shall be liable on summary conviction to a fine not exceeding €3,000 or at the discretion of the Court to imprisonment for a term not exceeding 12 months or both.

¹² Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 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.

The Health Service Executive will be directed, through arrangements of the service contracts, on the priority of enforcement of the Regulations and as part of routine and co-ordinated sampling programmes on the sampling and analysis of food supplements to check for compliance.

Contact details

Notification of foods supplements subject to these Regulations should be forwarded to:

Chief Specialist in Public Health,
Food Safety Authority of Ireland,
Abbey Court, Lower Abbey Street,
Dublin 1.
Telephone: +353 – 1 – 817 1300
Fax: + 353 – 1 – 817 1301

Copies of the legislation mentioned in these Guidance Notes are available from:

Statutory Instruments:

Government Publications Sales Office,
Sun Alliance House,
Molesworth Street,
Dublin 2.
Phone: (01) 679 3515.

EU documents:

European Commission Representation in Ireland,
European House,
Dawson Street,

Dublin 2.

Tel: 353 (01) 634 1111.

Fax: 353 (01) 634 1112.

Alan Hanna,

270, Lower Rathmines Road,

Dublin 6.

Ph.: 496 7399

There are also websites as which such information can be found:

Irish Statute Book <http://193.120.124.98/front.html>

European Law <http://europa.eu.int/eur-lex/>

FSAI <http://www.fsai.ie/legislation/index.asp>

Food Safety Authority of Ireland, April 2005.

Annex 1: Notification form for food supplements

Important Notice:

1. **Notification** of food supplements is a statutory requirement under S.I. No. 359 of 2003, which cover the enforcement of food legislation in the area of food supplements.
2. Notification is required when a food supplement **placed on the market for the first time** in Ireland.
3. The term **food supplement** means food coming within the classification of food supplement for which the compositional and labelling requirements are laid down in Commission Directive 2002/46/EC on food supplements.
4. This form may be used to notify the **Food Safety Authority of Ireland (FSAI)** when a food supplement is placed on the Irish market for the first time. The duty to notify falls on the manufacturer if the product is manufactured in Ireland and on the importer if the product is imported into Ireland.
5. A **separate** form is required for each product.

Manufacturer Details:

Name: _____

Address: _____

Telephone: _____ Fax number: _____

E mail: _____

Importer Details:

Name: _____

Full Postal Address: _____

Telephone number: _____ Fax number: _____

E mail address: _____

Product details

Product Name: _____

Product Description: _____

What is the function of this product? _____

A model of the product label and accompanying product literature should be provided to the FSAI. Please tick here to confirm it has been included. _____

Signature: _____

Name in block letters: _____ Date: _____



ANNEX 2: EXAMPLE OF COMPLIANT LABEL

VITAMIN C TABLETS

Orange flavour

30 tablets

Nutritional analysis

Vitamin C 60mg

RDA

100% *

Ingredients

Vitamin C (L-ascorbic acid)

Directions for use:

Take 1 tablet daily with water.

- Do not exceed the recommended daily dose.
- Food supplements should not be used as a substitute for a varied diet.
- This product should be stored out of the reach of young children.

Net weight: 120g

Best before end: December 2005

Manufactured by (or imported by): Food Supplements Limited, 63, Food Supplements Road, Co. Dublin, Ireland.

* This value relates to the E.U. RDA as set out in the nutrition labelling Directive of 1990/496/EC.

ANNEX 3: FOOD SUPPLEMENTS DIRECTIVE

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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
(Text with EEA relevance)

DRAFT

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission ¹,

Having regard to the opinion of the Economic and Social Committee ²,

Acting in accordance with the procedure laid down in Article 251 of the Treaty ³,

Whereas:

- (1) There is an increasing number of products marketed in the Community as foods containing concentrated sources of nutrients and presented for supplementing the intake of those nutrients from the normal diet.
- (2) Those products are regulated in Member States by differing national rules that may impede their free movement, create unequal conditions of competition, and thus have a direct impact on the functioning of the internal market. It is therefore necessary to adopt Community rules on those products marketed as foodstuffs.
- (3) An adequate and varied diet could, under normal circumstances, provide all necessary nutrients for normal development and maintenance of a healthy life in quantities which meet those established and recommended by generally acceptable scientific data. However, surveys show that this ideal situation is not being achieved for all nutrients and by all groups of the population across the Community.
- (4) Consumers, because of their particular lifestyles or for other reasons, may choose to supplement their intake of some nutrients through food supplements.
- (5) In order to ensure a high level of protection for consumers and facilitate their choice, the products that will be put on to the market must be safe and bear adequate and appropriate labelling.

- (6) There is a wide range of nutrients and other ingredients that might be present in food supplements including, but not limited to, vitamins, minerals, amino acids, essential fatty acids, fibre and various plants and herbal extracts.
- (7) As a first stage, this Directive should lay down specific rules for vitamins and minerals used as ingredients of food supplements. Food supplements containing vitamins or minerals as well as other ingredients should also be in conformity with the specific rules on vitamins and minerals laid down in this Directive.
- (8) Specific rules concerning nutrients, other than vitamins and minerals, or other substances with a nutritional or physiological effect used as ingredients of food supplements should be laid down at a later stage, provided that adequate and appropriate scientific data about them become available. Until such specific Community rules are adopted and without prejudice to the provisions of the Treaty, national rules concerning nutrients or other substances with nutritional or physiological effect used as ingredients of food supplements, for which no Community specific rules have been adopted, may be applicable.
- (9) Only vitamins and minerals normally found in, and consumed as part of, the diet should be allowed to be present in food supplements although this does not mean that their presence therein is necessary. Controversy as to the identity of those nutrients that could potentially arise should be avoided. Therefore, it is appropriate to establish a positive list of those vitamins and minerals.
- (10) There is a wide range of vitamin preparations and mineral substances used in the manufacture of food supplements currently marketed in some Member States that have not been evaluated by the Scientific Committee on Food and consequently are not included in the positive lists. These should be submitted to the European Food Safety Authority for urgent evaluation, as soon as appropriate files are presented by the interested parties.
- (11) The chemical substances used as sources of vitamins and minerals in the manufacture of food supplements should be safe and also be available to be used by the body. For this reason, a positive list of those substances should also be established. Such substances as have been approved by the Scientific Committee on Food, on the basis of the said criteria, for use in the manufacture of foods intended for infants and young children and other foods for particular nutritional uses can

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¹ OJ C 311 E, 31.10.2000, p. 207 and C 180 E, 26.6.2001, p. 248.

² OJ C 14, 16.1.2001, p. 42.

³ Opinion of the European Parliament of 14 February 2001 (OJ C 276, 1.10.2001, p. 126), Council Common Position of 3 December 2001 (OJ C 90 E, 16.4.2002, p. 1) and Decision of the European Parliament of 13 March 2002. Council Decision of 30 May 2002.

also be used in the manufacture of food supplements.

- (12) In order to keep up with scientific and technological developments it is important to revise the lists promptly, when necessary. Such revisions would be implementing measures of a technical nature and their adoption should be entrusted to the Commission in order to simplify and expedite the procedure.
- (13) Excessive intake of vitamins and minerals may result in adverse effects and therefore necessitate the setting of maximum safe levels for them in food supplements, as appropriate. Those levels must ensure that the normal use of the products under the instructions of use provided by the manufacturer will be safe for the consumer.
- (14) When maximum levels are set, therefore, account should be taken of the upper safe levels of the vitamins and minerals, as established by scientific risk assessment based on generally acceptable scientific data, and of intakes of those nutrients from the normal diet. Due account should also be taken of reference intake amounts when setting maximum levels.
- (15) Food supplements are purchased by consumers for supplementing intakes from the diet. In order to ensure that this aim is achieved, if vitamins and minerals are declared on the label of food supplements, they should be present in the product in a significant amount.
- (16) The adoption of the specific values for maximum and minimum levels for vitamins and minerals present in food supplements, based on the criteria set out in this Directive and appropriate scientific advice, would be an implementing measure and should be entrusted to the Commission.
- (17) General labelling provisions and definitions are contained in Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs¹, and do not need to be repeated. This Directive should therefore be confined to the necessary additional provisions.
- (18) Council Directive 90/496/EEC of 24 September 1990 on nutrition labelling for foodstuffs² does not apply to food supplements. Information relating to nutrient content in food supplements is essential for allowing the

consumer who purchases them to make an informed choice and use them properly and safely. That information should, in view of the nature of those products, be confined to the nutrients actually present and be compulsory.

- (19) Given the particular nature of food supplements, additional means to those usually available to monitoring bodies should be available in order to facilitate efficient monitoring of those products.
- (20) The measures necessary for the implementation of this Directive should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission³,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

1. This Directive concerns food supplements marketed as foodstuffs and presented as such. These products shall be delivered to the ultimate consumer only in a pre-packaged form.

2. This Directive shall not apply to medicinal products as defined by 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 use⁴.

Article 2

For the purposes of this Directive:

(a) 'food supplements' means foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form, namely forms 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 and powders designed to be taken in measured small unit quantities;

(b) 'nutrients' means the following substances:

- (i) vitamins,
- (ii) minerals.

Article 3

Member States shall ensure that food supplements may be marketed within the Community only if

¹ OJ L 109, 6.5.2000, p. 29.

² OJ L 276, 6.10.1990, p. 40.

³ OJ L 184, 17.7.1999, p. 23.

⁴ OJ L 311, 28.11.2001, p. 67.

they comply with the rules laid down in this Directive.

Article 4

1. Only vitamins and minerals listed in Annex I, in the forms listed in Annex II, may be used for the manufacture of food supplements, subject to paragraph 6.
2. The purity criteria for substances listed in Annex II shall be adopted in accordance with the procedure referred to in Article 13(2), except where they apply pursuant to paragraph 3.
3. Purity criteria for substances listed in Annex II, specified by Community legislation for their use in the manufacture of foodstuffs for purposes other than those covered by this Directive, shall apply.
4. For those substances listed in Annex II for which purity criteria are not specified by Community legislation, and until such specifications are adopted, generally acceptable purity criteria recommended by international bodies shall be applicable and national rules setting stricter purity criteria may be maintained.
5. Modifications to the lists referred to in paragraph 1 shall be adopted in accordance with the procedure referred to in Article 13(2).
6. By way of derogation from paragraph 1 and until 31 December 2009, Member States may allow in their territory the use of vitamins and minerals not listed in Annex I, or in forms not listed in Annex II, provided that:
 - (a) the substance in question is used in one or more food supplements marketed in the Community on the date of entry into force of this Directive,
 - (b) the European Food Safety Authority has not given an unfavourable opinion in respect of the use of that substance, or its use in that form, in the manufacture of food supplements, on the basis of a dossier supporting use of the substance in question to be submitted to the Commission by the Member State not later than 12 July 2005.
7. Notwithstanding paragraph 6, Member States may, in compliance with the rules of the Treaty, continue to apply existing national restrictions or bans on trade in food supplements containing vitamins and minerals not included in the list in Annex I or in the forms not listed in Annex II.
8. Not later than 12 July 2007, the Commission shall submit to the European Parliament and the Council a report on the advisability of establishing specific rules, including, where appropriate, positive lists, on categories of

nutrients or of substances with a nutritional or physiological effect other than those referred to in paragraph 1, accompanied by any proposals for amendment to this Directive which the Commission deems necessary.

Article 5

1. Maximum amounts of vitamins and minerals present in food supplements per daily portion of consumption as recommended by the manufacturer shall be set, taking the following into account:
 - (a) upper safe levels of vitamins and minerals established by scientific risk assessment based on generally accepted scientific data, taking into account, as appropriate, the varying degrees of sensitivity of different consumer groups;
 - (b) intake of vitamins and minerals from other dietary sources.
2. When the maximum levels referred to in paragraph 1 are set, due account should also be taken of reference intakes of vitamins and minerals for the population.
3. To ensure that significant amounts of vitamins and minerals are present in food supplements, minimum amounts per daily portion of consumption as recommended by the manufacturer shall be set, as appropriate.
4. The maximum and minimum amounts of vitamins and minerals referred to in paragraphs 1, 2 and 3 shall be adopted in accordance with the procedure referred to in Article 13(2).

Article 6

1. For the purposes of Article 5(1) of Directive 2000/13/EC, the name under which products covered by this Directive are sold shall be 'food supplement'.
2. The labelling, presentation and advertising must not attribute to food supplements the property of preventing, treating or curing a human disease, or refer to such properties.
3. Without prejudice to Directive 2000/13/EC, the labelling shall bear the following particulars:
 - (a) the names of the categories of nutrients or substances that characterise the product or an indication of the nature of those nutrients or substances;
 - (b) the portion of the product recommended for daily consumption;
 - (c) a warning not to exceed the stated recommended daily dose;

(d) a statement to the effect that food supplements should not be used as a substitute for a varied diet;

(e) a statement to the effect that the products should be stored out of the reach of young children.

Article 7

The labelling, presentation and advertising of food supplements shall not include any mention stating or implying that a balanced and varied diet cannot provide appropriate quantities of nutrients in general.

Rules for implementing this Article may be specified in accordance with the procedure referred to in Article 13(2).

Article 8

1. The amount of the nutrients or substances with a nutritional or physiological effect present in the product shall be declared on the labelling in numerical form. The units to be used for vitamins and minerals shall be those specified in Annex I.

Rules for implementing this paragraph may be specified in accordance with the procedure referred to in Article 13(2).

2. The amounts of the nutrients or other substances declared shall be those per portion of the product as recommended for daily consumption on the labelling.

3. Information on vitamins and minerals shall also be expressed as a percentage of the reference values mentioned, as the case may be, in the Annex to Directive 90/496/EEC.

Article 9

1. The declared values mentioned in Article 8(1) and (2) shall be average values based on the manufacturer's analysis of the product.

Further rules for implementing this paragraph with regard in particular to the differences between the declared values and those established in the course of official checks shall be decided upon in accordance with the procedure referred to in Article 13(2).

2. The percentage of the reference values for vitamins and minerals mentioned in Article 8(3) may also be given in graphical form.

Rules for implementing this paragraph may be adopted in accordance with the procedure referred to in Article 13(2).

Article 10

To facilitate efficient monitoring of food supplements, Member States may require the manufacturer or the person placing the product on the market in their territory to notify the competent authority of that placing on the market by forwarding it a model of the label used for the product.

Article 11

1. Without prejudice to Article 4(7), Member States shall not, for reasons related to their composition, manufacturing specifications, presentation or labelling, prohibit or restrict trade in products referred to in Article 1 which comply with this Directive and, where appropriate, with Community acts adopted in implementation of this Directive.

2. Without prejudice to the Treaty, in particular Articles 28 and 30 thereof, paragraph 1 shall not affect national provisions which are applicable in the absence of Community acts adopted under this Directive.

Article 12

1. Where a Member State, as a result of new information or of a reassessment of existing information made since this Directive or one of the implementing Community acts was adopted, has detailed grounds for establishing that a product referred to in Article 1 endangers human health though it complies with the said Directive or said acts, that Member State may temporarily suspend or restrict application of the provisions in question within its territory. It shall immediately inform the other Member States and the Commission thereof and give reasons for its decision.

2. The Commission shall examine as soon as possible the grounds adduced by the Member State concerned and shall consult the Member States within the Standing Committee on the Food Chain and Animal Health, and shall then deliver its opinion without delay and take appropriate measures.

3. If the Commission considers that amendments to this Directive or to the implementing Community acts are necessary in order to remedy the difficulties mentioned in paragraph 1 and to ensure the protection of human health, it shall initiate the procedure referred to in Article 13(2) with a view to adopting those amendments. The Member State that has adopted safeguard measures may in that event retain them until the amendments have been adopted.

Article 13

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health

instituted by Regulation (EC) No 178/2002¹ (hereinafter referred to as 'the Committee').

2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof. The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

Article 14

Provisions that may have an effect upon public health shall be adopted after consultation with the European Food Safety Authority.

Article 15

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 31 July 2003. They shall forthwith inform the Commission thereof. Those laws, regulations and administrative provisions shall be applied in such a way as to:

(a) permit trade in products complying with this Directive, from 1 August 2003 at the latest;

(b) prohibit trade in products which do not comply with the Directive, from 1 August 2005 at the latest.

When Member States adopt these measures, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. The methods of making such reference shall be adopted by the Member States.

Article 16

This Directive shall enter into force on the day of its publication in the Official Journal of the European Communities.

Article 17

This Directive is addressed to the Member States.

Done at Luxembourg, 10 June 2002.

For the European Parliament
The President
P. COX

For the Council
The President
J. PIQUÉ I CAMPS

12.7.2002 L 183/55 Official Journal of the European Communities EN

ANNEX I

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

1. Vitamins

Vitamin A (µg RE)
Vitamin D (µg)
Vitamin E (mg α-TE)
Vitamin K (µg)
Vitamin B1 (mg)
Vitamin B2 (mg)
Niacin (mg NE)
Pantothenic acid (mg)
Vitamin B6 (mg)
Folic acid (µg)
Vitamin B12 (µg)
Biotin (µg)
Vitamin C (mg)

2. Minerals

Calcium (mg)
Magnesium (mg)
Iron (mg)
Copper (µg)
Iodine (µg)
Zinc (mg)
Manganese (mg)
Sodium (mg)
Potassium (mg)
Selenium (µg)
Chromium (µg)
Molybdenum (µg)
Fluoride (mg)
Chloride (mg)
Phosphorus (mg)

ANNEX II

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

A. Vitamins

1. VITAMIN A
 - (a) retinol
 - (b) retinyl acetate
 - (c) retinyl palmitate
 - (d) beta-carotene
2. VITAMIN D
 - (a) cholecalciferol
 - (b) ergocalciferol
3. VITAMIN E
 - (a) D-alpha-tocopherol
 - (b) DL-alpha-tocopherol
 - (c) D-alpha-tocopheryl acetate
 - (d) DL-alpha-tocopheryl acetate
 - (e) D-alpha-tocopheryl acid succinate

¹ OJ L 31, 1.2.2002, p. 1.

4. VITAMIN K	ferrous citrate
(a) phylloquinone (phytomenadione)	ferric ammonium citrate
5. VITAMIN B1	ferrous gluconate
(a) thiamin hydrochloride	ferrous fumarate
(b) thiamin mononitrate	ferric sodium diphosphate
	ferrous lactate
	ferrous sulphate
6. VITAMIN B2	ferric diphosphate (ferric pyrophosphate)
(a) riboflavin	ferric saccharate
(b) riboflavin 5'-phosphate, sodium	elemental iron (carbonyl+electrolytic+hydrogen reduced)
7. NIACIN	
(a) nicotinic acid	cupric carbonate
(b) nicotinamide	cupric citrate
	cupric gluconate
8. PANTOTHENIC ACID	cupric sulphate
(a) D-pantothenate, calcium	copper lysine complex
(b) D-pantothenate, sodium	
(c) dexpanthenol	sodium iodide
	sodium iodate
9. VITAMIN B6	potassium iodide
(a) pyridoxine hydrochloride	potassium iodate
(b) pyridoxine 5'-phosphate	
	zinc acetate
10. FOLIC ACID	zinc chloride
(a) pteroylmonoglutamic acid	zinc citrate
	zinc gluconate
11. VITAMIN B12	zinc lactate
(a) cyanocobalamin	zinc oxide
(b) hydroxocobalamin	zinc carbonate
	zinc sulphate
12. BIOTIN	
(a) D-biotin	manganese carbonate
	manganese chloride
13. VITAMIN C	manganese citrate
(a) L-ascorbic acid	manganese gluconate
(b) sodium-L-ascorbate	manganese glycerophosphate
(c) calcium-L-ascorbate	manganese sulphate
(d) potassium-L-ascorbate	
(e) L-ascorbyl 6-palmitate	sodium bicarbonate
	sodium carbonate
B. Minerals	sodium chloride
calcium carbonate	sodium citrate
calcium chloride	sodium gluconate
calcium salts of citric acid	sodium lactate
calcium gluconate	sodium hydroxide
calcium glycerophosphate	sodium salts of orthophosphoric acid
calcium lactate	
calcium salts of orthophosphoric acid	potassium bicarbonate
calcium hydroxide	potassium carbonate
calcium oxide	potassium chloride
	potassium citrate
magnesium acetate	potassium gluconate
magnesium carbonate	potassium glycerophosphate
magnesium chloride	potassium lactate
magnesium salts of citric acid	potassium hydroxide
magnesium gluconate	potassium salts of orthophosphoric acid
magnesium glycerophosphate	
magnesium salts of orthophosphoric acid	sodium selenate
magnesium lactate	sodium hydrogen selenite
magnesium hydroxide	sodium selenite
magnesium oxide	
magnesium sulphate	chromium (III) chloride
	chromium (III) sulphate
ferrous carbonate	

ammonium molybdate (molybdenum (VI))
sodium molybdate (molybdenum (VI))

potassium fluoride
sodium fluoride

DRAFT