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Guidance

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

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## Contents



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## Nutrition law

Following the UK's departure from the EU on 31 January 2020, the UK entered a time-limited transition period until 31 December 2020. Now the transition period has ended, Regulation is an autonomous matter for both the UK and EU as 2 separate legal and regulatory systems. The government remains committed to promoting robust food standards nationally and internationally, to protect consumer interests, and to ensure that consumers can have confidence in the food they buy.

Section 1 of this guidance outlines for businesses those changes relating to food supplements from 1 January 2021.

## Executive summary

## Introduction

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

On 1 January 2021 The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 and The Nutrition (Amendment etc.) (EU Exit) Regulations 2020 transferred responsibilities from EU organisations involved in the risk assessment and risk management processes covered by nutrition legislation to bodies in Great Britain (GB); and fixed inoperability's of retained Directive 2002/46/EC that would otherwise have arisen.

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

This guidance is due to be updated to fully incorporate the exit bulletin and any previous legislative changes. Section 1 of this guidance reflects changes to processes from 1 January 2021.

## Intended audience

This guidance is aimed at all companies that manufacturer, process, distribute, use, sell or import food supplements, and those local authorities who are responsible for enforcing the legislation in this area. Legislation on food supplements is implemented on a devolved basis, however this guidance applies across the UK.

## Purpose of the guidance

This guidance and its associated bulletins are designed to help you comply with the regulations.

## Important note

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

- The Food Supplements (England) Regulations 2003 SI 2003 No. 1387 (https://www.legislation.gov.uk/uksi/2003/1387/contents/made)
- The Food Supplements (Scotland) Regulations 2003 SSI 2003 No. 278 (https://www.legislation.gov.uk/ssi/2003/278/contents)
- The Food Supplements (Wales) Regulations 2003 WSI 2003 No. 1719 (W186) (https://www.legislation.gov.uk/wsi/2003/1719/contents)
- The Food Supplements (Northern Ireland) Regulations 2003 Statutory Rule 2003 No. 273 (https://www.legislation.gov.uk/nisr/2003/273/contents/made)

As amended by:

- The Food Supplements (England) (Amendment) Regulations 2007 SI 2007 No. 330 (https://www.legislation.gov.uk/uksi/2007/330/contents/made)
- The Food Supplements (England) and Addition of Vitamins and Minerals and Other Substances (England) (Amendment) Regulations 2009 SI 2009 No. 3251 (https://www.legislation.gov.uk/uksi/2009/3251/contents/made)
- The Food Supplements (Scotland) Amendment Regulations 2007 SSI 2007 No. 78 (https://www.legislation.gov.uk/ssi/2007/78/contents/made)
- The Food Supplements, Vitamins, Minerals and Other Substances (Scotland) Regulations 2009 SSI 2009 No. 438 (https://www.legislation.gov.uk/ssi/2009/438/contents/made)
- The Food Supplements (Wales) (Amendment) Regulations 2007 WSI 2007 No.1076 (W114) (https://www.legislation.gov.uk/wsi/2007/1076/contents/made)
- The Food Supplements (Wales) and Addition of Vitamins, Minerals and Other Substances (Wales) (Amendment) Regulations 2009 WSI 2009 No. 3252 (W282) (https://www.legislation.gov.uk/wsi/2009/3252/contents/made)
- The Food Supplements (Amendment) Regulations (Northern Ireland) 2007 Statutory Rule 2007 No. 116 (https://www.legislation.gov.uk/nisr/2007/116/contents/made)
- The Food Supplements and the Addition of Vitamins, Minerals and Other Substances (Amendment) Regulations (Northern Ireland) 2009 Statutory Rule 2009 No. 407 (https://www.legislation.gov.uk/nisr/2009/407/contents/made)

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 (https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex%3A32002L0046)
- Commission Regulation (EC) No. 1170/2009 amending Directive 2002/46/EC and Regulation (EC) 1925/2006 regarding the lists of vitamins and minerals and their forms that can be added to foods, including food supplements (https://eur-lex.europa.eu/legal-content/EN/ALL

/?uri=CELEX%3A32009R1170)

- Commission Regulation (EU) No. 1161/2011 amending Directive 2002/46/EC, Regulation (EC) 1925/2006, and Regulation (EC) No. 953/2009 as regards the lists of mineral substances that can be added to food (https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32011R1161)
- The Food Labelling Regulations 1996 (as amended) and relevant guidance notes that are available on the National Archive website (https://webarchive.nationalarchives.gov.uk/20100817075713/http:/www.food.gov.uk/foodindustry/guidancenotes/)
- The Food Labelling Regulations (Northern Ireland) 1996 Statutory Rule 1996 No. 383 (for Northern Ireland) (https://www.legislation.gov.uk/nisr/1996/383/contents/made)
- The Novel Foods Regulation (EC) No 258/97 (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A31997R0258)
- Regulation 178/2002/EC of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex%3A32002R0178) (implemented in the UK by the General Food Regulations 2004 SI 2004 No. 3279 (https://www.legislation.gov.uk/uksi/2004/3279/contents/made) and The General Food Regulations (Northern Ireland) 2004 Statutory Rule 2004 No. 505 (https://www.legislation.gov.uk/nisr/2004/505/contents/made) )
- The Consumer Protection from Unfair Trading Regulations 2008 (https://www.legislation.gov.uk/uksi/2008/1277/contents/made)

The examples in these notes are provided for illustration only. The guidance notes cannot cover every situation and you will need to familiarise yourself with the relevant legislation itself to see how it applies in your circumstances. The UK regulations have been amended several times, therefore you may find it useful to also consult EC Directive 2002/46/EC, which is available in consolidated form for ease of use. A copy of the consolidated Directive (https://www.legislation.gov.uk/eudr/2002/46/contents) is available.

Copies of the UK legislation are available from the Stationery Office (https://www.tsoshop.co.uk/Information/Contact-Us/)

Copies of the EU legislation are available on the European Commission website (http://eur-lex.europa.eu/en/index.htm).

## Section 1: guidance from 1 January 2021

## 1.1 Using this guidance

This section is to be read in conjunction with the remainder of the guidance which remains relevant and useful, with exception to any references to the EU, in helping businesses comply.

The Protocol on Ireland/Northern Ireland (NIP) means that EU legislation relating to nutrition, as detailed in Annex 2 to the NIP, continues to be directly applicable in Northern Ireland.

From 1 January, EU Regulations and tertiary legislation relating to nutrition have been retained under the powers contained within the European Union (Withdrawal) Act 2018 as UK law. That EU legislation is subsequently amended by the Nutrition (Amendment etc.) (EU Exit) Regulations 2019 and the Nutrition (Amendment etc.) (EU Exit) Regulations 2020.

The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 and the Nutrition (Amendment etc.) (EU Exit) Regulations 2020 transferred responsibilities from EU organisations involved in the risk assessment and risk management processes covered by nutrition legislation to bodies in Great Britain (GB).

They also made practical changes, that resulted from this transfer to: applications; frameworks for the scientific evaluation of applications/dossiers/files; and the factors taken into consideration when a risk management decision is required.

Businesses seeking to submit requests for change, scientific dossiers, or files in accordance with the legislation covered by this guidance for consideration in the GB market should prepare those requests in line with the advice in this section and submit them to the Department of Health and Social Care (DHSC). DHSC will ensure that all documents are shared with the appropriate authorities in Scotland, and Wales, and Northern Ireland and, once deemed valid, the applicable expert committees.

Information is shared with Northern Ireland as all nutrition issues continue to be considered on a 4-nation basis: and importantly, officials and ministers in Northern Ireland continue to play a vital role in policy development under the arrangements agreed in the UK-wide common framework for nutrition-related labelling, composition and standards (NLCS). Northern Ireland's full participation in risk assessment and risk management processes ensure that any decisions taken in GB (England, Scotland and Wales) account for the potential impacts across the UK.

## 1.2 Appropriate authorities

The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 transferred functions and powers previously held by the European Commission to legislate to give effect to a decision, such as whether to authorise applications for new health claims, to the following appropriate authorities.

The appropriate authorities are in:

- England: the Secretary of State
- Scotland: the Scottish ministers
- Wales: the Welsh ministers

Each appropriate authority may, therefore: make legislation equivalent to that which the European Commission would have made previously. However, the Nutrition (Amendment etc.) (EU Exit) Regulations 2019 also provide concurrent powers for the UK Secretary of State to legislate for the whole of GB where devolved administrations in Scotland and Wales agree.

Note: Functions and powers held by the European Commission have not been transferred to Northern Ireland. However, officials and ministers in Northern Ireland continue to play a vital role in policy development under the arrangements agreed in the UK-wide common framework for NLCS. Therefore, references are included in this guidance to 'appropriate UK authorities' where Northern Ireland officials and ministers are involved in risk assessment or risk management.

The Food Standards Agency (FSA) remains the designated Competent Authority in Northern Ireland.

## 1.3 Common Framework for NLCS

Officials from the UK government and the devolved administrations in Scotland, Wales, and Northern Ireland have jointly developed a UK-wide Common Framework for NLCS (https://www.gov.uk/government/publications/nutrition-labelling-composition-and-standards-provisional-common-framework-command-paper) in preparation for the end of the Transition Period.

As a devolved policy area NLCS is one of several identified in the UK government frameworks analysis (https://www.gov.uk/government/publications/frameworks-analysis) which required more detailed discussion to explore whether a common framework agreement was needed to manage potential divergence within the UK after EU Exit; and the governance and decision-making processes required for effective joint working and implementation.

Officials across all 4 nations have worked together to develop the NLCS Common Framework, which was provisionally agreed at the Joint Ministerial Committee (EN) on 3 September 2020.

**Risk assessment and risk management (policy development) mechanisms**

NLCS risk assessments consider the impact on a UK-wide basis aiming to deliver a consistent approach and process for businesses and enforcement authorities across the UK (with capacity maintained for nation specific assessments where appropriate).

Decisions based on both scientific opinion and those wider risk management considerations are made by the appropriate authority (namely the Secretary of State, Scottish, Welsh, ministers or as appropriate with consent from the devolved administrations) through the establishment of 4-nation working arrangements which build on existing consensus-based policy making.

While ministers retain the right to take individual decisions for their nation on areas within the scope of the NLCS Framework, the opportunity for consistency of approach across administrations is always sought in the first instance and where agreed, common policy recommendations made.

The ability to diverge where appropriate and proportionate is, while taking account of the impact on consumer safety and confidence, and the functioning of the UK internal market in reaching a final

decision.

**Dispute prevention and dispute resolution**

Every effort is made at working level to resolve any disagreements in difference of approach. It is anticipated that the need for dispute resolution in areas within scope of the Nutrition Framework is unlikely. However, should it be needed, the dispute resolution established by the NLCS Framework will come into play.

## 1.4 Lists and registers

Where the Regulations require a list or register to be established, each Appropriate Authority must produce and maintain a list or register.

Decisions made by the appropriate authorities as set out above, will result in the GB lists and registers needing to be updated periodically.

For convenience and clarity, GB lists and registers (https://www.gov.uk/government/publications/register-on-adding-vitamins-and-minerals-to-foods), which consolidate all lists produced and maintained by the appropriate authorities, are available on GOV.UK for food business operators and other interested parties.

Businesses may submit applications or dossiers in support of these lists being amended for consideration for use on the GB market to DHSC mailboxes, unless stated otherwise in this guidance. DHSC will centrally coordinate applications.

## 1.5 Northern Ireland

The Northern Ireland Protocol (NIP) was published in October 2019 as part of the Withdrawal Agreement to address the “unique circumstances on the island of Ireland”.

The UK government published a command paper (https://www.gov.uk/government/publications/the-uks-approach-to-the-northern-ireland-protocol/the-uks-approach-to-the-northern-ireland-protocol) on its approach to the NIP on 20 May 2020 and further information can be found there, in addition to business guidance on GOV.UK (https://www.gov.uk/transition).

The NIP was designed as a practical solution to avoiding a hard border on the island of Ireland, whilst ensuring that the UK, including Northern Ireland, could leave the EU as a whole. It therefore included, a number of special provisions which apply only in Northern Ireland, for as long as the NIP is in force.

The NIP means that EU legislation relating to nutrition, as detailed in Annex 2 to the NIP, continues to be directly applicable in Northern Ireland.

Section 2 of the nutrition legislation information sheet (https://www.gov.uk/government/publications/nutrition-legislation-information-sources/nutrition-legislation-information-sheet) remains relevant and useful in complying with the compositional and labelling requirements set out in EU law when read alongside the updates in this section relevant in Northern Ireland.

With regards to trade going from Northern Ireland to the rest of the UK: this has not changed. Northern Ireland businesses continue to be able to place their goods on the market throughout the

rest of the United Kingdom without new restrictions.

Businesses should note, however, that under the Protocol, in Northern Ireland, the FSA is not able to submit: scientific dossiers concerning the modification of the Annex of Directive 2002/46/EC (https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1600431719867&uri=CELEX:02002L0046-20170726) to the European Commission for consideration.

Businesses seeking to submit any of the aforementioned applications or scientific dossiers in respect to authorisation for the Northern Ireland or EU27 markets should forward them to the European Commission in accordance with the Modifying Annex of the Directive 2002/46/EC in the European Union and Northern Ireland.

Northern Ireland's full participation in risk assessment and risk management processes ensures that any decisions taken in GB (England, Scotland and Wales) account for the potential impacts across the UK.

## 1.6 Foods supplements within the EU from 1 January 2021

Food supplements are regulated by Regulations made in each part of the UK (The Food Supplements (England) Regulations 2003 in England; Food Supplements Regulations (Northern Ireland) 2003; The Food Supplements (Scotland) Regulations 2003; The Food Supplements (Wales) Regulations 2003). These Regulations cross refer to the Annex of retained Directive 2002/46/EC (https://www.legislation.gov.uk/eudr/2002/46/contents), which sets out rules for vitamins and minerals used in food supplements. The Directive contains a list of permitted vitamins and minerals in Annex 1 (https://www.legislation.gov.uk/eudr/2002/46/annex/I). The permitted forms of those vitamins and minerals is listed in Annex 2 (https://www.legislation.gov.uk/eudr/2002/46/annex/II).

The Directive contains a power for the EC to update the lists in the Annexes, to set purity criteria, and to set maximum and minimum amounts for vitamins and minerals that may be used in food supplements.

## 1.7 Changes to supplements from 1 January 2021

Minor changes have been made to the regulatory framework that governs food supplements by inserting the lists of vitamins and minerals that may be used in the manufacture of food supplements, contained as an Annex to retained Directive 2002/46/EC, into the Nutrition (Amendment etc) (EU Exit) Regulations 2019 as Schedules to ensure that they continue to have affect in GB. This guidance sets out how GB system works when accounting for those changes.

The remainder of this UK guidance on food supplements (https://www.gov.uk/government/publications/food-supplements-guidance-and-faqs) remains relevant and useful, with exception to any references to the EU therein, in helping food businesses to comply with the relevant regulatory framework for food supplements.

The NIP means that EU legislation relating to food supplements continues to be directly applicable in Northern Ireland.

Given this, the remainder of this UK guidance on food supplements (https://www.gov.uk/government/publications/food-supplements-guidance-and-faqs) remains relevant and useful in helping food

businesses to comply with EU regulations on food supplements, when read alongside the updates in this document relevant to Northern Ireland; such as modifying Annex of the Directive 2002/46/EC in the European Union and Northern Ireland.

## 1.8 Schedules of vitamins and minerals for use in food supplements

Details of vitamins and minerals, and vitamin and mineral substances, that may be used in the manufacture of food supplements were contained as an Annex to Directive 2002/46/EC. These lists have now been inserted into the Nutrition (Amendment etc) (EU Exit) Regulations 2019 as Schedules to ensure that they continue to have effect in GB.

Schedule 1: Vitamins and minerals which may be used in the manufacture of food supplements

Schedule 2: Vitamin and mineral substances which may be used in the manufacture of food supplements

### Supplementary information: schedule 1

The Annexes to retained Directive 2002/46/EC are inserted as schedules into the Nutrition (Amendment etc.) (EU Exit) Regulations 2019 with the footnotes to the Annex omitted. This is because the footnotes set out recommendations rather than legal requirements, consequently they have been included here for reference.

#### Folic acid (µg)

Folic acid is the term included in Annex I of retained Commission Directive 2008/100/EC of 28 October 2008 amending Council Directive 90/496/EEC on nutrition labelling for foodstuffs as regards recommended daily allowances, energy conversion factors and definitions for nutrition labelling purposes and covers all forms of folates.

### Supplementary information: schedule 2

The Annexes to retained Directive 2002/46/EC are inserted as schedules into the Nutrition (Amendment etc.) (EU Exit) Regulations 2019 with the footnotes to the Annex omitted. This is because the footnotes set out recommendations rather than legal requirements, consequently they have been included here for reference.

#### Vitamin E: (f) Mixed Tocopherols

alpha-tocopherol \< 20 %, beta-tocopherol \< 10 %, gamma-tocopherol 50-70 % and delta-tocopherol 10-30 %.

#### Vitamin E: (g) Tocotrienol Tocopherol

Typical levels of individual tocopherols and tocotrienols:

- 115 mg/g alpha-tocopherol (101 mg/g minimum)

- 5 mg/g beta-tocopherol (\< 1 mg/g minimum)
- 45 mg/g gamma-tocopherol (25 mg/g minimum)
- 12 mg/g delta-tocopherol (3 mg/g minimum)
- 67 mg/g alpha-tocotrienol (30 mg/g minimum)
- \< 1 mg/g beta-tocotrienol (\< 1 mg/g minimum)
- 82 mg/g gamma-tocotrienol (45 mg/g minimum)
- 5 mg/g delta-tocotrienol (\< 1 mg/g minimum)

**Vitamin K: (b) Menaquinone**

Menaquinone occurring principally as menaquinone-7 and, to a minor extent, menaquinone-6.

**Vitamin C: (c) Calcium-L-ascorbate**

May contain up to 2 % of threonate.

**Mineral: Selenium Enriched Yeast**

Selenium-enriched yeasts produced by culture in the presence of sodium selenite as selenium source and containing, in the dried form as marketed, not more than 2,5 mg Se/g. The predominant organic selenium species present in the yeast is selenomethionine (between 60 and 85 % of the total extracted selenium in the product). The content of other organic selenium compounds including selenocysteine shall not exceed 10 % of total extracted selenium. Levels of inorganic selenium normally shall not exceed 1 % of total extracted selenium.

**Mineral: Silicic Acid**

In the form of gel.

## 1.9 Modifying schedules

The Nutrition (Amendment etc) (EU Exit) Regulations 2019 provides for the appropriate GB authorities to make regulations to amend the schedules, set the purity criteria as well as maximum and minimum amounts of vitamins and minerals that may be added to food supplements.

Food business operators, or other interested parties, that wish for vitamin and mineral substances to be considered for inclusion in the Schedules to the Nutrition (Amendment etc) (EU Exit) Regulations 2019 may submit a scientific dossier concerning the safety and bioavailability of the individual substance for consideration for use in the GB market by the appropriate UK authorities to the DHSC mailbox (which centrally coordinates dossiers for all 3 GB nations).

The UK government and devolved administrations in Wales and Scotland therefore recommend that, until further notice, scientific dossiers supporting the addition of a vitamin or mineral to the Schedules continue to be completed in line with administrative guidance (https://ec.europa.eu/food/sites/food/files/safety/docs/sci-com_scf_out100_en.pdf) produced by the European Commission and submitted to the DHSC mailbox (which centrally coordinates dossiers).

## 1.10 Risk assessment

Scientific advice previously provided by the European Food Safety Authority in relation to food supplements will be sought from existing scientific advisory committees in GB.

Scientific advisory committees will be identified by the appropriate UK authorities as necessary depending on the nature of the scientific advice required.

## 1.11 Risk management

Risk management functions related to Food Supplements is assumed by the appropriate UK authorities.

## 1.12 Modifying Annex of the Directive 2002/46/EC in the European Union and Northern Ireland

From 1 January 2021 Great Britain has its own list of Vitamins and Minerals for use in Food Supplements and modification processes.

Food business operators wishing to add vitamins and minerals to food supplements in the EU or Northern Ireland following from 1 January 2021 must continue to comply with the un-amended requirements of Annex of the Directive 2002/46/EC and/or Food Supplements Regulations (Northern Ireland) 2003.

We recommend that food business operators who wish for the addition of vitamins and minerals and their sources to be included in the Annex of the Directive 2002/46/EC, which applies to the EU and Northern Ireland, from 1 January 2021 refer to the extensive Food supplements (https://ec.europa.eu/food/safety/labelling_nutrition/supplements_en), specifically administrative guidance on submissions for safety evaluation of substances added for specific nutritional purposes in the manufacture of foods.

## Section 2: introduction

The Food Supplements (England) Regulations 2003 SI 2003 No. 1387 (as amended) and equivalent regulations in Scotland, Wales and Northern Ireland1 , implement the provisions of Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements (as amended). Directive 2002/46/EC is referred to throughout these guidance notes as “the Directive” and the implementing UK regulations will be referred to collectively throughout these notes as “the Regulations”.

## Purpose

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

## Status

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

## Interpretation of the Regulations

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

The details of your nearest enforcement office can be obtained on the Food Standards Agency's website (https://www.food.gov.uk/contact/businesses/find-details/contact-a-food-safety-team).

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

## Section 3: organisation of the regulations

The Regulations are split into the following sections:

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

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

## Interpretation (regulation 2)

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

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

## Scope of Regulations (regulation 3)

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

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

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

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

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

This regulation was amended by The Food Supplements (England) and Addition of Vitamins and Minerals and Other Substances (England) (Amendment) Regulations 2009 (and equivalent Regulations in the devolved administrations). This amendment reflects the adoption of Commission Regulation (EC) No. 1170/2009, introducing the list of vitamins and minerals permitted for use in food supplements – as set out in the annexes of the Commission Regulation.

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

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

## Enforcement (regulation 8)

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

## Offences and penalties (regulation 9)

This creates offences and penalties in relation to the Regulations.

## Defence in relation to exports (regulation 10)

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

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

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

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

## Transitional provisions (Regulation 12)

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

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

## Section 4: regulations

## 4.1 Regulation 1

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

## 4.2 Regulation 2

### Food supplement defined

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 is both:

- a concentrated source of a vitamin or mineral or other substance with a nutritional or physiological effect, alone or in combination
- 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.

### Complying with 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 General Food Regulations 2004, the Food Labelling Regulations 1996 (as amended) and the Consumer Protection

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

**Normal diet**

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

## 4.3 Regulation 3

**Products**

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.

**Differentiating medicinal products**

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 2 categories.

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

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

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

The MHRA can advise on whether a product is medicinal and you should contact the Borderline Section for advice:

## 4.4 Regulation 4

**Understanding the ‘ultimate customer’**

In Regulation 2, “ultimate consumer” is defined as meaning any person who purchases otherwise

than:

- for the purpose of resale
- for the purposes of a catering establishment
- for the purposes of a manufacturing business

**Classifying as 'pre-packed'**

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

- it is ready for sale to the ultimate consumer or to a catering establishment and
- 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

## 5.5 Regulation 5

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

**Vitamins and minerals in food supplements**

Only the vitamins and minerals listed in the Annexes to the Food Supplements Directive may be used. A consolidated list is available on the European Commission's website (https://ec.europa.eu/food/safety/labelling_nutrition/supplements_en).

**Amendment of permitted vitamins and minerals in the Annexes to the Directive**

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

The Regulations were amended by The Food Supplements (England) and Addition of Vitamins and Minerals and Other Substances (England) (Amendment) Regulations 2009 SI 2009 No. 3251 (and equivalent Regulations in the devolved administrations). This amendment removed schedules 1 and 2 of the original Regulations, and replaced them with a reference to the Annexes of the Directive, as amended from time to time.

**Process of adding new nutritional substances to the list in the annex to the Directive**

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

Requests for the inclusion of a new nutritional substance in the Directive should be submitted to the European Commission. Guidance on the procedure that should be followed for the submission of requests for substances to be considered for inclusion in the permitted list is available on the Commission website (https://ec.europa.eu/food/safety/labelling_nutrition/supplements_en).

**Use of 'natural sources' of vitamins or minerals in food supplements**

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

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

**Procedure of adding a 'novel' source of a vitamin or mineral to Annex 2**

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

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

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

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

## 5.6 Regulation 6

**Has the term "food supplement" become a prescribed name?**

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

**Food supplement labelling**

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

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

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

**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 the labelling of vitamins or minerals with a nutritional or physiological effect appear in the same field of vision as “food supplement”. However, it would be useful to the consumer if they were together.

**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.

**Regulation 6(2)(c) states that labels should carry a warning not to exceed the stated recommended daily dose. Does this exact wording have to be used? In our view it is not necessary to use the exact wording used in regulation 6(2)(c).**

It would be acceptable, for example, for a statement to warn against exceeding the recommended daily “intake”. The important thing is that the message is clear to consumers.

**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.

**Regulation 6(2)(e) states that labels should carry a statement to the effect that the product should be stored out of the reach of young children. Does this exact wording have to be used? In our view it is not necessary to use the exact wording used in regulation 6(2)(e).**

It would be acceptable, for example, for a label to carry a caution to keep out of the reach of children. The important thing is that the message is clear to consumers.

## 5.7 Regulation 6(2)(f) and Regulation 6(3)(a to e)

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

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

**Annex 1 and 2 of the Directive uses the style "Vitamin B12" rather than "Vitamin B12". Can either style be used on the labelling?**

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

**Annex 1 to the Directive sets out the units that must be used in relation to the listed vitamins and minerals. May other units be used instead?**

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

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

Yes as in the case of a vitamin or mineral listed in Annex 1, the relevant unit specified must be used. These Regulations do not require any change to the way quantities of vitamins are calculated – see table below.

| Vitamin | To be calculated as |
|---|---|
| Vitamin A | retinol or retinol equivalent on the basis that 6$\mu$g β-carotene or 12$\mu$g of other biologically active carotenoids are equivalent to 1$\mu$g of retinol |
| Vitamin D | ergocalciferol (vitamin D2) or cholecalciferol (vitamin D3) |

| Vitamin | To be calculated as |
|---|---|
| Vitamin E | D-α tocopherol equivalent on the basis that 3.3 mg α tocotrienol or 10mg γtocopherol are equivalent to 1 mg D-α tocopherol |
| Vitamin C | Ascorbic acid or dehydroascorbic acid |
| Thiamin | thiamin |
| Riboflavin | riboflavin |
| Niacin | nicotinic acid or nicotinamide or niacin equivalent on the basis that 60mg of trytophan equal 1mg of niacin equivalent |
| Vitamin B6 | pyridoxine |
| Folic Acid | total folates |
| Vitamin B12 | cobalamines |
| Biotin | biotin |
| Pantothenic acid | D-pantothenic acid |

**What unit should be used for vitamins or minerals not listed in Annex 1 of the Directive or for non-vitamin or mineral ingredients of food supplements?**

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

**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.

**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.

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

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

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

No levels have been set at European level. In the meantime, the Expert Group on Vitamins and Minerals (EVM) is an independent expert advisory committee in the UK which was asked to advise on safe levels of intakes of vitamins and minerals in food supplements and fortified foods. The EVM was asked to consider only vitamins and minerals sold under food law and produced a final report (https://ec.europa.eu/food/sites/food/files/safety/docs/labelling_nutrition-supplements-responses-uk_en.pdf).

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

The recommendations in the table (https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/152368/dh_130240.pdf.pdf) 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.

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

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

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

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

and advertising of foodstuffs.

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

Yes. There are no exemptions for small packages.

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

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

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

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

## 5.8 Regulation 7

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

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

- on the packaging
- on a label attached to the packaging
- 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.

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

Food supplements may only be sold to the consumer in pre-packed form, however, these Regulations

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

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

- on a label attached to the food supplement
- on a ticket or notice which is readily discernible by the intending purchaser at the place where he chooses the food supplement
- 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.

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

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

## Appendix

## Sources of information

For further information about food safety please visit the Food Standards Agency (http://www.food.gov.uk/) website.

For further information about healthy eating advice please see the NHS website (http://www.nhs.uk/Pages/HomePage.aspx).

For further information about the enforcement of food law please visit the Local Government Association (https://www.local.gov.uk/) website

For further information about what is considered a medicine and their control please visit the Medicines and Healthcare products Regulatory Agency (http://www.mhra.gov.uk/) website.

## Contacts

The Department of Health and Social Care does not authorise or check the composition or labelling of individual products. For advice on specific products, including the checking of labels, please contact your local Trading Standards or Environmental Health office, the details of which can be obtained on

the Food Standards Agency (http://www.food.gov.uk/enforcement/enforceessential/yourarea/) website.

If you require further advice relating to these guidance notes, please contact:

**England**

Nutrition Legislation Team
Obesity, Food and Nutrition Branch
Population Health Directorate
Department of Health and Social Care
39 Victoria Street
London SW1H 0EU

Tel: 020 7972 4340
DHSC mailbox

**Scotland**

Food Standards Scotland
4th Floor
Pilgrim House
Old Ford Road
Aberdeen AB11 5RL

Tel: 01224 285126
Food Standards Scotland mailbox

**Wales**

Health Improvement Division
Welsh Government
Cathays Park
Cardiff
CF10 3NQ

Welsh Government mailbox

Email: Lifestyles@wales.gsi.gov.uk

Copies of the legislation mentioned in these guidance notes are available from The Stationery Office Ltd (https://www.tsoshop.co.uk/Society/Legislation/).

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