

Fortified Foods

*Guidance to compliance with European
Regulation (EC) No. 1925/2006 on the addition
of vitamins and minerals and certain other
substances to food*

This guidance applies to the whole of the UK and was prepared by the Department of Health in association with the Welsh Government, and Food Standards Agency in Scotland and Northern Ireland

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Intended audience

This guidance is aimed at all businesses that manufacturer, process, distribute, use, sell or import food voluntarily fortified with vitamins and minerals, and local authorities who are responsible for enforcing the legislation in this area.

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

Executive summary

On 30 December 2006 Regulation (EC) 1925/2006 of the European Parliament and of the Council of the European Union on the addition of vitamins and minerals and of certain other substances to food was published. This legislation sets out compositional and labelling requirements, including lists of vitamins and minerals, which can voluntarily be added to foods, such as breakfast cereals and soft drinks.

The information set out in this document aims to provide non-statutory guidance on the rules, which apply to fortified food under these Regulations and outline what businesses must do if they add vitamins and minerals and other substances to food.

Last updated – November 2011 to update references to legislation in this area and reflect the transfer of responsibility for nutrition policy in England from the Food Standards Agency to the Department of Health on 1 October 2010. No other significant changes have been made.

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

IMPORTANT NOTE

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

- Regulation (EC) No. 1925/2006 of the European Parliament and of the Council, on the addition of vitamins and minerals and of certain other substances to foods

As amended by:

- Regulation (EC) No 108/2008 of the European Parliament and of the Council of 15 January 2008 (OJ L 39 11 13.2.2008)
- Commission Regulation (EC) No 1170/2009 of 30 November 2009 (OJ L 314 36 1.12.2009)

The Regulations are implemented in the UK by:

- The Addition of Vitamins, Minerals and Other Substances (England) Regulations 2007 (SI 2007 No. 1631)
- The Addition of Vitamins, Minerals and Other Substances (Scotland) Regulations 2007 (SSI 2007 No. 325)
- The Addition of Vitamins, Minerals and Other Substances (Wales) Regulations 2007 (WSI 2007 No. 1984 (W165))
- The Addition of Vitamins, Minerals and Other Substances Regulations (Northern Ireland) 2007 (Statutory Rule 2007 No. 301)

As amended by:

- The Food Supplements (England) and Addition of Vitamins and Minerals and Other Substances (England) (Amendment) Regulations 2009 (SI 2009 No. 3251)
- The Addition of Vitamins, Minerals and Other Substances (England) (Amendment) Regulations 2010 (SI 2010 No. 1886)
- The Food Supplements, Vitamins, Minerals and Other Substances (Scotland) Regulations 2009 (SSI 2009 No. 438)
- The Addition of Vitamins, Minerals and Other Substances (Scotland) Amendment Regulations 2010 (SSI 2010 No. 308)
- The Food Supplements (Wales) and Addition of Vitamins, Minerals and Other Substances (Wales) (Amendment) Regulations 2009 WSI 2009 No. 3252 (W282)
- The Addition of Vitamins, Minerals and Other Substances (Wales) (Amendment) Regulations 2010 (WSI 2010 No. 2069 (W191))
- The Food Supplements and the Addition of Vitamins, Minerals and Other Substances (Amendment) Regulations (Northern Ireland) 2009 Statutory Rule 2009 No. 407

Guidance to compliance with European Regulation (EC) No. 1925/2006

- The Addition of Vitamins, Minerals and Other Substances (Amendment) Regulations (Northern Ireland) 2010 Statutory Rule 2009 No. 292

The notes are intended to be read in conjunction with:

- the Regulations listed above;
- The Food Labelling Regulations 1996 (as amended) and relevant guidance notes that are available on the National Archive website (<http://webarchive.nationalarchives.gov.uk/20100817075455/http://www.food.gov.uk/foodindustry/guidancenotes/>)
- The Food Labelling Regulations (Northern Ireland) 1996 Statutory Rule 1996 No. 383 (for Northern Ireland)
- The Novel Foods Regulation (EC) No 258/97
- Regulation 178/2002/EC of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. (Implemented in the UK by the General Food Regulations 2004 SI 2004 No. 3279 and The General Food Regulations (Northern Ireland) 2004 Statutory Rule 2004 No. 505.
- The Consumer Protection from Unfair Trading Regulations 2008

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

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

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

Section 1

Introduction and Summary

This guidance will tell you what you must do to comply with this Regulation if you choose to add a vitamin or mineral to your food product. It also explains how the Regulation will control the addition of other substances, which could pose a potential risk to health. This guidance is not designed to be read cover to cover, rather you should use it as a tool, following the steps relevant to you. Where you see a ★ you will need to select the appropriate statement to continue to the relevant section.

While only the courts can give a definitive interpretation of the law, in preparing this guidance we have had to interpret certain provisions, based on consultation with stakeholders and discussions with the European Commission and other Member States. The guidance is not legally binding and should therefore be read together with the relevant EU and national legislation listed in Appendix 2. Additional sources of advice and information that can help you comply with the law are detailed in Appendix 3.

Addition of vitamins and minerals

European Regulation (EC) No. 1925/2006 on the addition of vitamins and minerals and of certain other substances to food was published on 30 December 2006. This Regulation lists the vitamins and minerals that can **voluntarily** be added to food. If you plan to add a vitamin or mineral to your product you should consult your Home Authority or Primary Authority¹. In addition, you should familiarise yourself with EU Regulation 1925/2006 and use this guidance to ensure you meet with the requirements of the Regulation.

In addition the Regulation puts in place certain restrictions, most notably prohibiting the addition of vitamins and minerals to non-processed foods and beverages containing more than 1.2% by volume of alcohol. It also sets minimum amounts that must be present following addition and puts in place provisions to set maximum amounts.

If a vitamin or mineral is added to food you must also provide nutrition labelling as per Directive 90/496/EEC on nutrition labelling for foodstuffs.

The Regulation does not apply to mandatory addition or where addition is required by law. Nor does it apply to vitamin and mineral Food Supplements or the use of substances for additive purposes, which are controlled by specific legislation.

What do I need to do to add vitamins and minerals to my product?

¹ The Home Authority and Primary Authority schemes are described at Section 7.2 and 7.3

- Ensure the vitamin or mineral you wish to add is listed in Annex I of the Regulation.
- Ensure the vitamin formulation or mineral substance you wish to use is listed in Annex II.
- Ensure the amount present complies with maximum and minimum levels where these are set, or where none are set you should ensure a sufficient quantity is present to have the intended effect, and that no more is present than is safe to be consumed as part of a varied diet.
- Comply with the labelling requirements.
- Comply with the other conditions of the Regulation as outlined in Section 3 and 4 of this guidance.

Use of other substances

The Regulation puts in place a process to control other substances where it is considered that these could pose a potential risk to human health. This control will be by way of either a prohibition or restriction on the substance's use in food. Food business operators will need to check the Community Register² for updates to Annex III of the Regulation to ensure that the ingredients they use or plan to use are not controlled in this way. For further information please see Section 5.

Date of application

Although the Regulation applied from 1 July 2007 transitional measures mean that certain aspects of the Regulation will not apply until a later date. For further information on transitional periods please see Section 6.

² Link to the Community Register:

http://ec.europa.eu/food/food/labellingnutrition/vitamins/comm_reg_en.pdf

Section 2

Background and Scope

2.1 – Introduction

On 30 December 2006 a Regulation of the European Parliament and of the Council of the European Union on the addition of vitamins and minerals and certain other substances to food was published (AVM Regulation). This Regulation was published as (EC) No. 1925/2006 and is the first piece of specific legislation to deal with the voluntary addition of vitamins and minerals and certain other substances to food.

Prior to this Regulation becoming law the relevant UK legislation governing the voluntary addition of vitamins and minerals and certain other substances to food has been the Food Safety Act 1990³ and Article 14 of European Regulation 178/2002⁴, which make it an offence to render food injurious to human health or place on the market food that is unsafe. Other Member States of the European Union had different controls, some of which are more stringent, leading to barriers to trade. This legislation still, applies but is without prejudice to the specific rules laid down in Regulation 1925/2006.

The Regulation seeks to protect people from consuming quantities of any vitamin, mineral or other substance, which could be harmful to health. It also harmonises legislation across the European Union making it easier to trade.

2.2 – Addition of vitamins and minerals to food (Article 1)

The Regulation seeks to control the voluntary addition of vitamins and minerals to food. It recognises that vitamins and minerals are added to food for a variety of purposes, such as to improve the nutritional status of the population or to take into account vitamin deficiencies.

The Regulation does not affect existing national rules regarding the mandatory fortification of flour and margarine (Recital paragraph 3) or the use of trace quantities of vitamins or minerals in alcoholic drinks as authenticity markers (Recital paragraph 13). It will not apply to the use of vitamins and minerals in food supplements (Directive 2002/46/EC) or where they are required to be added to food under Directive 2009/39/EC relating to foodstuffs for particular nutritional uses. Where vitamins or minerals are added to a food for an additive purpose the Regulation

³ In Northern Ireland it is the Food Safety (Northern Ireland) Order 1991

⁴ Regulation 4 of the General Food Regulations creates offences for breaches of certain Articles in Regulation (EC) 178/2002, including Article 14(1) (food safety). Implemented in Northern Ireland by The General Food Regulations (Northern Ireland) 2004 Statutory Rule 2004 No. 505.

will not apply, however the addition will need to meet with the controls on the use of additives in Regulation (EC) No. 1333/2008.

The Regulation also recognises that vitamins and minerals may be added to food to restore levels lost during processing. Additions of this kind must, nevertheless, comply with the general conditions of the Regulation and be authorised substances from the Annexes, in a form that is bio-available to the human body, conform to the conditions on maximum amounts and where appropriate on minimum amounts. If a claim is to be made on a vitamin or mineral that has been restored after processing losses (such as 'contains', 'source of' etc), this must comply with the requirements in the annex to Regulation (EC) No. 1924/2006 on nutrition and health claims. However, where claims are not to be made, there may be good reason to restore with a lower minimum amount. Food business operators should be able to substantiate this.

2.3 – Other substances (Article 8)

In the past there has been no specific harmonised way for the European Community to control the use of ingredients that represent a potential risk to health. The Regulation puts in place a mechanism to allow such ingredients to be assessed, including a safety assessment by the European Food Safety Authority (EFSA), and where necessary prohibited or restricted. Detailed rules on how this will be implemented are yet to be adopted.

2.4 – Legislation controlling the addition of vitamins and minerals and certain other substances to food (Article 1)

For certain products specific legislation already exists that controls composition and in these cases both this and the AVM Regulation will apply. However, in some cases this legislation contains requirements for the addition of vitamins, minerals or certain other substances to food. In such cases these mandatory rules will take precedence over the AVM Regulation. Examples of products which are controlled by specific legislation are given below:

- Supplements
- Foods for particular nutritional uses (PARNUTS – e.g. infant formula, medical foods etc.)
- Novel foods and Novel food ingredients
- Genetically modified food
- Food additives and flavourings
- Oenological practices and processes

For full details of the legislation controlling these and where to find further information please see Appendix 2.

2.5 – Addition of vitamins and minerals vs certain other substances

The Regulation deals with the addition of vitamins and minerals and certain other substances to food in two distinct chapters, the guidance therefore follows the same approach.

★ If you wish to add a vitamin or mineral to your product please go to Section 3.

★ If you want to ensure that any other substance is not controlled by the Regulation please go to Section 5.

Section 3

Foods to Which Vitamins and Minerals Can Be Added

3.1 – Introduction

The Regulation on the addition of vitamins and minerals and certain other substances to food (AVM Regulation) controls the voluntary addition of vitamins and minerals to food. It lists the vitamins and minerals that can be added to food and puts in place minimum amounts and provisions to set maximum amounts in the future.

For certain products there are additional considerations or restrictions that should be taken into account before a vitamin or mineral can be added. Further details are given below and you should assure yourself that your product is not affected by these restrictions before proceeding.

3.2 – Voluntary and mandatory fortification

Under UK legislation the addition of vitamins and minerals to flour and margarine is mandatory and is not affected by the Regulation (Recital paragraph 3). Under the Regulation the Government is responsible for notifying the Commission of the requirements for mandatory fortification in the UK. For further information on mandatory fortification please see the following legislation. For full links to this legislation please see Appendix 2.

- The Bread and Flour Regulations 1998⁵
- The Spreadable Fats (Marketing Standards) and the Milk and Milk Products (Protection of Designations) (England) Regulations 2008⁶

While it is mandatory to fortify these products, it is also possible to voluntarily add additional vitamins and minerals. You must, however, ensure that you also meet with the requirements on the mandatory fortification as well as those for voluntary fortification.

3.3 – Foods to which vitamins and minerals cannot be added (Article 4)

- Vitamins and minerals cannot be added to unprocessed foodstuffs such as fruits, vegetables, meat, poultry and fish.
- Vitamins and minerals cannot be added to beverages that contain more than 1.2% by volume of alcohol. There is one exception to this requirement for certain traditional wines,

⁵ In Northern Ireland The Bread and Flour Regulations (Northern Ireland) 1998 (SR. No. 24)

⁶ In Scotland The Spreadable Fats, Milk and Milk Products (Scotland) Regulations 2008 (SSI 2008 No.216); in Wales The Spreadable Fats (Marketing Standards) and the Milk and Milk Products (Protection of Designations) (Wales) Regulations 2008; and in Northern Ireland The Spreadable Fats (Marketing Standards) and the Milk and Milk Products (Protection of Designations) Regulations (Northern Ireland) 2008 (SR. No. 239).

which could not be produced without the addition of certain minerals. There are specific conditions associated with this exemption, including a prohibition on claims, which are explained in full in Section 8, question 6 (on tonic wine).

The Regulation contains provisions that allow further specific restrictions to be set in future. These will be based on scientific evidence and will be set by the European Commission.

★ If your product complies with the requirements outlined above please go to Section 4 for further information about the addition of vitamins and minerals to food.

Section 4

Adding Vitamins and Minerals to Food

4.1 – Introduction

Having read Section 3 you should be confident that the restrictions in the Regulation will not affect the addition of vitamins and minerals to your product. We will now look at which vitamins and minerals, and forms of these, can be added to food.

The Regulation permits only those vitamins and minerals listed in Annex I to be added to food, and requires that these be in a bio-available form. You will need to check (using the link below) that the vitamin or mineral you wish to add is listed in the Annex.

http://ec.europa.eu/food/food/labellingnutrition/vitamins/comm_reg_en.pdf

- ★ If the vitamin or mineral you wish to add is listed please go to Section 4.2.
- ★ If it is not on this list please go to Section 4.3.

4.2 – Vitamins and minerals listed in Annex I (Article 3)

If the vitamin or mineral you wish to add is listed in Annex I, you will now need to verify that the chosen source, the vitamin formulation or mineral substance is also listed in Annex II. For example, if you wanted to add vitamin B1 to your product you can actually use either thiamin hydrochloride or thiamin mononitrate as ingredients, both of which are forms of vitamin B1. Please see the following website address for an up-to-date copy of Annex II and check to see if the vitamin formulation or mineral substance you want to add is listed.

http://ec.europa.eu/food/food/labellingnutrition/vitamins/comm_reg_en.pdf

★ If the vitamin formulation or mineral substance is listed in Annex II please go to Section 4.4. This section gives additional information to help you comply with the Regulation.

★ If the vitamin formulation or mineral substance that you wish to add is not on the list in Annex II please see Section 4.3.

4.3 – Vitamins and minerals not listed in Annex I or Annex II (Article 3)

Vitamins and minerals not listed in Annex I and vitamin formulations or mineral substances not listed in Annex II cannot be voluntarily added to food (please see Section 6 for details of

transitional periods). It is, however, possible to make additions to the Annex (Article 3(3)). This will be done by the European Commission, which is required by the Regulation to consult with interested parties including food business operators and consumer groups on any changes. For further information and advice on making additions to the Annex, the Commission has published administrative guidance for applicants and a Community Register at the web link given below:

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

Once the vitamin, mineral, vitamin formulation or mineral substance has been added to the Annex and is permitted for use in food, the product will need to comply with the additional conditions outlined in Section 4.4.

4.4 – Further conditions on the addition of vitamins and minerals to food

If you have reached this section your product should comply with the restrictions in Section 3 and the vitamin or mineral you want to add is listed in Annex I and is in a form listed in Annex II. Detailed below are several other aspects of the Regulation that you will need to comply with to add the vitamin or mineral to your product.

4.5 – Minimum amounts (Article 6(6))

To ensure that fortification is beneficial to health, the Regulation requires that the final food contain a significant amount of a vitamin or mineral, as defined by Directive 90/496/EEC on nutrition labelling of foodstuffs, which defines a significant amount as 15% of the RDA per 100 g or 100ml. Minimum amounts will apply to the total level of the vitamin or mineral, including amounts already present in the food.

Where vitamins and minerals are added to food to restore levels lost during processing and a claim is to be made on a vitamin or mineral that has been restored after processing losses (such as 'contains', 'source of' etc), this must comply with the requirements in the annex to Regulation 1924/2006 on nutrition and health claims. However, where claims are not to be made, and where there is good reason, it is possible to restore with an amount below 15% of the RDA. Food business operators should be able to substantiate this.

The Regulation contains provisions allowing different minimum amounts to be set for specific foods or categories of food where these are considered necessary. An up-to-date list of minimum amounts that differ from the significant amount will be published in the Community Register, available at the following website address. We would strongly advise you check this to ensure you comply with the correct minimum amount.

http://ec.europa.eu/food/food/labellingnutrition/vitamins/comm_reg_en.pdf

4.6 – Maximum amounts (Article 6)

In addition to the setting of minimum amounts the Regulation also puts in place provisions that require the European Commission to set maximum levels to avoid over-consumption of vitamins or minerals, which might have an adverse effect on health. The European Commission is required by the Regulation to take into account the following information when doing this:

- the 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 groups of the population; and
- the intake of vitamins and minerals from other dietary sources, including supplements and foods subject to mandatory fortification.

Where the intake of a vitamin or mineral is already close to the upper safe level only a limited amount will be available for voluntary addition. Only in these cases will the following information be considered when deciding to which products addition should be allowed and by how much:

- the contribution of individual products to the overall diet of the population in general or to sub-groups of the population;
- the nutrient profile of the product established as provided for by Regulation (EC) No 1924/2006 on nutrition and health claims made on foods.

Once maximum levels have been set they will be published in the Community Register at the website address below. Vitamin or minerals should not be added at levels that exceed the maximum amounts. It is worth noting that, just as with minimum levels, maximum levels will apply to the total amount of a vitamin or mineral in the product after addition and will take into account naturally present levels.

http://ec.europa.eu/food/food/labellingnutrition/vitamins/comm_reg_en.pdf

4.7 – Labelling (Article 7)

The Regulation requires nutrition labelling to be provided whenever a vitamin or mineral has been voluntarily added to a product. Nutrition labelling should be that specified in Article 4(1), group 2 of Directive 90/496/EEC and should include the total amounts of the vitamins and minerals that have been added to the food together with the amount already (naturally) present in the food.

The labelling of the product must not state, suggest or imply that appropriate amounts of vitamins and minerals cannot be provided within a balanced and healthy diet. It should also not mislead or deceive consumers about the true nutritional merit of a food.

If you wish to make a claim referring to the vitamin or mineral content of the products please consult Regulation (EC) No 1924/2006.

4.8 – Purity criteria (Article 5)

Purity criteria define the chemical characteristics of each of the vitamin and mineral substances listed in Annex II. They define in law the chemical structure and properties of each formulation or substance. Only formulations or substances that meet with the conditions of the purity criteria can be added to food.

Where purity criteria already exist in European legislation, these will apply to the substances in Annex II. For example Directive 2008/84/EC, laying down specific purity criteria on food additives other than colours and sweeteners, includes purity criteria for ascorbic acid, an additive used to regulate acidity in foods. L-ascorbic acid is also listed in Annex II as a vitamin formulation for vitamin C. When L-ascorbic acid is voluntarily added to food as a source of vitamin C the purity criteria in Directive 2008/84/EC will apply.

Where purity criteria do not already exist in European legislation the Regulation requires such criteria to be set. Until this is completed any purity criteria recommended by international bodies, such as Codex, shall apply. The Regulation will also allow national rules to apply during this period, some of which may set stricter criteria. There are currently no purity criteria that are specific to the UK; however, if you are planning on exporting your products to other Member States, you will need to consider any purity criteria they have in place.

Figure 1. Checklist for adding vitamins and minerals to food

You will need to be able to tick all the following boxes in order to add vitamins and minerals to your product:

- My product is not an unprocessed foodstuff.
- My product is not an alcoholic beverage containing more than 1.2% by volume of alcohol.
- Existing legislation does not already control the addition of vitamins and minerals to my product, for example compositional requirements under PARNUTS legislation.
- I am not adding the vitamin or mineral to my product for any reason other than to restore or to supplement the nutritional benefit of the product (if it is being added for any other function it may be controlled by additives legislation).
- The vitamin or mineral I want to add is listed in Annex I.
- The vitamin or mineral substance I want to add is listed in Annex II.
- The vitamin or mineral will be present in the product at a significant amount after addition, unless for restorative purposes, which I can substantiate and no claim is made.

- The levels I wish to add are within maximum levels for vitamins and minerals where specified.
- There are no product specific restrictions for the addition of vitamins and minerals.
- I have provided nutrition labelling (group 2) including details of the vitamin or mineral added.
- There is no indication in the labelling of the product that appropriate levels of the vitamin or mineral could not be gained from a healthy balanced diet.
- The labelling does not mislead the consumer about the true nutritional benefit of the product.
- Any claims made about the vitamin or mineral content comply with the conditions set out in Regulation (EC) No 1924/2006 on nutrition and health claims.

Section 5

Addition of Certain Other Substances to Food

5.1 – Introduction

The Food Safety Act 1990⁷ and Article 14 of European Regulation 178/2002⁸, make it an offence to render food injurious to human health or place on the market food that is unsafe, but they do not put in place controls on specific ingredients for which there may be safety concerns. As no legislation exists to control such ingredients at a European level, Member States have had to take individual action. For example, in the UK the Kava Kava in Food Regulations 2002 prohibits the use of this substance in foods.

The AVM Regulation will be available for possible future control, at the European level, of a wide range of ingredients, which could represent a potential risk to consumers. This control will be carried out on a case by case basis as and when the need arises. The control of certain other substances will be in all foods, including food supplements. When the Regulation was adopted there were no proposals to control any specific substances.

It is worth noting that this is not the only piece of legislation that controls the addition of substances to food. European legislation does exist which controls the composition of certain categories of food, for example jam (Directive 2001/113/EC). While this indicates that a distinction can be drawn between ingredients in some foods and certain other substances controlled by this Regulation, the definition of “substances other than vitamins and minerals that have a nutritional or physiological effect” is broad and could include food ingredients. You will need to ensure that you comply with all relevant legislation.

5.2 – How will other substances be controlled by the Regulation? (Article 8)

The Regulation will only control other substances that present a potential risk to consumers' health. The Regulation defines “other substances” as a substance other than a vitamin or mineral that has a nutritional or physiological effect. The substance must also have been added to a food or used as an ingredient in a food, which results in more of that substance being ingested than under normal conditions or via a balanced diet.

If there is concern that a substance may represent a potential risk to consumers the European Food Safety Authority (EFSA) will carry out an assessment of available information. Based on

⁷ In Northern Ireland it is the Food Safety (Northern Ireland) Order 1991

⁸ Regulation 4 of the General Food Regulations creates offences for breaches of certain Articles in Regulation (EC) 178/2002, including Article 14(1) (food safety).

this assessment the European Commission will take a decision on its use in food, which will fall into one of the following four categories:

- i. The substance or ingredient containing the substance is deemed to have a harmful effect on health and its addition to food or its use in the manufacture of foods is prohibited. These substances will be listed in Part A of Annex III.
- ii. The substance or ingredient containing the substance is deemed to have a harmful effect on health and its addition to food or its use in the manufacture of foods will only be allowed under the conditions specified. These substances and the conditions of use will be listed in Part B of Annex III.
- iii. The substance or ingredient containing the substance could have a harmful effect on health, but there is some uncertainty. These substances and the conditions on their use will be listed in Part C of Annex III. See Section 5.3 for further information.
- iv. The substance or ingredient containing the substance is deemed safe and can continue to be used in food without control.

Once these rules are established, you must ensure you do not add substances, or ingredients containing substances, listed in Part A of Annex III, or if they are in Part B or C that they meet any conditions imposed.

5.3 – Other substances listed in Annex III, Part C (Article 8)

Part C of Annex III will include other substances where scientific uncertainty exists over the possibility that they represent a risk to health. This is a temporary listing to allow for further scientific data to be gathered.

Having been added to Part C, there will be a four-year time limit during which EFSA will issue an opinion on the substance and the Commission will reach a decision on its future use in food. During this period food business operators or any other interested parties can submit scientific data to EFSA demonstrating the safety of the substance. The resulting EFSA opinion will be taken into account when the Commission decide whether the substance can continue to be allowed to be used in food or restricted by adding it to Part B of Annex III or prohibited by adding it to Part A. We understand that there will be no restrictions on use during this scrutiny period.

Section 6

When Do I Need To Comply With The Regulation?

6.1 – Introduction

In order to help industry comply with the Regulation, some of its requirements do not take immediate effect. It is therefore important to familiarise yourself with the following transitional periods and key dates, by which time you will need to comply with the various requirements of the Regulation.

6.2 – Transitional periods (Article 17 and 18)

The Regulation came into force on 19 January 2007. This is the date on which the Regulation officially became law and which will trigger other time periods and transitional periods in the Regulation.

The requirements of the Regulation applied from 1 July 2007. From this date products should meet the requirements of the Regulation, unless there are specific transitional measures in place. Further information about transitional periods and when specific elements of the Regulation will take effect are given below.

6.3 – Transitional period for vitamins and minerals not in the Annex

Vitamins and minerals not listed in Annex I or forms not listed in Annex II can continue to be used until 19 January 2014, as long as they were used in food that was marketed on 19 January 2007 and a dossier in support of their use was submitted, via a Member State, before 19 January 2010. If, before 19 January 2014, the Commission reach a negative decision on its use it will no longer be permitted to be added to food.

During this period Member States can continue to enforce national restrictions or bans on the trade of products to which it has been added. Once it is included in either Annex I or Annex II Member States must permit it on their market (Article 17(2)).

6.4 – Transitional period for maximum and minimum levels

Member States can continue to apply existing national provisions on maximum and minimum levels until these are set at the European level (Article 17(3)).

Section 7

Enforcement

7.1 – Enforcement

The enforcement of food law in the UK is the responsibility of Local Authorities and in some instances Port Health Authorities. In each of the UK countries a domestic Regulation or Statutory Instrument⁹ is required to designate “competent authorities” who will enforce the requirements of the legislation as well as put in place enforcement and penalties. In the UK it is Trading Standards Departments or Environmental Health Departments or equivalent in the Local Authority of the food business operator that are responsible for enforcing the requirements of the Regulation.

Trading Standards Officer (TSOs) and Environmental Health Officers (EHOs) or any other authorised officer of the Local Authority (as appropriate) would initiate any legal proceedings in connection with a product that they consider to be in breach of the Regulation.

For advice on specific products, including the checking of labels, please contact your local TSO or EHO, the details of which can be obtained on the Food Standards Agency’s website by using the on-line search engine at:

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

7.2 – Home Authority Principle

The Home Authority Principle allows local authorities to work with a business to provide consistent and coordinated Trading Standards and food enforcement services across the UK. It assists these businesses that have outlets in more than one local authority and distribute goods and/or services beyond the boundaries of one local authority. Further information about the Home Authority Principle can be found on the Local Authorities Coordinators of Regulatory Services website (www.lacors.gov.uk), which is now the responsibility of Local Government Regulation (LGR).

⁹ Statutory Instrument 2007 No. 1631, The Addition of Vitamins and Minerals and Other Substances (England) Regulations 2007 (as amended)
Statutory Instrument 2007 No. 325, The Addition of Vitamins and Minerals and Other Substances (Scotland) Regulations 2007 (as amended)
Statutory Instrument 2007 No. 1984 (w.165), The Addition of Vitamins and Minerals and Other Substances (Wales) Regulations 2007 (as amended)
Statutory Rules 2007 No.301, The Addition of Vitamins and Minerals and Other Substances (Northern Ireland) Regulations 2007 (as amended)

7.3 – Primary Authority Scheme

The Government's statutory Primary Authority scheme came into force on 6 April 2009 and introduces provisions for businesses, charities or other organisations that operate across more than one site to enter into a partnership agreement with a single authority for it to become that organisation's Primary Authority. The existing Home Authority principle will continue to operate across the UK, particularly in Scotland and Northern Ireland where the Primary Authority scheme does not apply to food law enforcement functions which are devolved. Further information about the Primary Authority scheme can be found on the website of the Local Better Regulation Office at www.lbro.org.uk/.

7.4 – Safeguard measures (Article 13)

The safeguard measures give Member States powers to temporarily suspend or restrict a product that they strongly believe endangers human health, despite it complying with this Regulation. If any such action is taken the Member State must inform the Commission and other Member States.

Where appropriate, EFSA will give an opinion on the suspension or restriction. The Commission, via the Standing Committee, will then reach a decision on whether the suspension or restriction should apply at EU level. If the decision is that such action is not necessary the original Member State must stop its national suspension or restriction.

Section 8

Questions and Answers

8.1 – Scope

1. *Does the Regulation apply to supplements?*

Use of vitamins and minerals in food supplements are controlled by Directive 2002/46/EC relating to food supplements (Article 1). However, the use of ‘certain other substances’ in supplements is controlled by this Regulation.

2. *Does it cover the use of fortified ingredients?*

No. The Commission has confirmed that the Regulation will only apply to the direct addition of vitamins and minerals to food, not the use of a fortified ingredient. However, when the vitamin or mineral is initially added to the ingredient it will need to comply with the requirements of the Regulation.

3. *Does it cover the addition of fluoride to tap water?*

No. The Regulation applies to the addition of vitamins and minerals to food as defined by European Regulation 178/2002. Under this definition water is only a food after the point of compliance as defined by Directive 98/83/EC (as amended). As water only becomes a food when it emerges from the tap, is put into the bottle or container or when it is added to a food, the addition of fluoride before this stage is not controlled by the Regulation.

4. *Does the Regulation apply to the use of sodium chloride as an ingredient?*

No. Recital paragraph 10 clarifies that the use of sodium chloride as an ingredient will not be covered by the AVM Regulation.

5. *Does this Regulation apply to the use of authenticity markers?*

No. Recital paragraph 13 clarifies that the Regulation does not apply to the use of vitamins and minerals in trace quantities as authenticity markers in alcoholic drinks.

8.2 – Restrictions and requirements

6. *Vitamins and minerals are fundamental to the production of tonic wine, as this is an alcoholic drink can it still be produced?*

Yes. Article 4 states that products referred to in Article 44(6) and (13) of Council Regulation (EC) No 1493/1999, on the common organisation of the wine market, can have vitamins and minerals added to them. This will only apply to products which were on the market prior

to the adoption of the Regulation and as long as the Commission has been notified. These products, which include tonic wine, are not permitted to make any nutrition or health claims.

7. *What if a vitamin or mineral is not covered by Directive 90/496/EEC and nutrition labelling cannot be provided?*

For vitamins and minerals where no Recommended Daily Allowance (RDA) is established under Directive 90/496/EC, in order to comply with the labelling requirements in Regulation 1925/2006, food business operators must be able to substantiate the amount added for the purposes required and label with the total vitamin and mineral content.

8. *How and when will maximum levels be set?*

This is outlined in Article 6 which requires the upper safe level and the levels of vitamins and minerals already consumed via the diet to be considered. This will include vitamins and minerals consumed from food, but also food supplements. When food supplements legislation was adopted in 2002 it put in place provisions to set maximum and minimum levels for supplements. In order to set appropriate maximum and minimum levels for both fortified foods and supplements the Commission intend to set them at the same time and issued a discussion paper to start this process. To see a copy of this discussion paper, please see the Commission's website at http://ec.europa.eu/food/food/labellingnutrition/supplements/discus_paper_amount_vitamins.pdf

Sections 4.5 and 4.6 of this guidance gives further information about the setting of minimum and maximum levels respectively.

9. *What will happen if a vitamin or mineral is not in the Annex of this Regulation, but has been added to the list in the supplements Directive?*

Although the list of vitamins and minerals in the Annex was originally taken from the Supplements Directive 2002/46/EC, any additions will now need to be assessed independently. If you would like to have a vitamin or mineral added to the Annex please visit the European Commission's website, which includes administrative guidance on how this should be done.

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

8.3 – Authorisation process

10. *How will substances be added to the Annexes?*

The Commission will take advice from EFSA and propose additions to the Annexes to Standing Committee, where decisions are taken on qualified majority voting. The European Parliament may scrutinise decisions taken here.

11. Who is the competent Authority in the UK?

The Department of Health is the competent Authority in England and Wales and represents the UK in EU negotiations. The Food Standards Agency is the competent authority for policy decisions in Scotland and Northern Ireland. Enforcement is the responsibility of local authorities (see Section 7).

12. Will any vitamin, mineral, vitamin formulation or minerals substance ever be taken off the list in the Annex?

Article 3(3) of the Regulation does allow for the list to be amended, with decisions made by the Standing Committee. The European Parliament may scrutinise decisions taken here.

13. Article 4 says that vitamins and minerals cannot be added to unprocessed foods. What is meant by an unprocessed foodstuff?

Recital paragraph 12 explains that the Regulation prohibits the addition of vitamins and minerals to unprocessed foods to prevent consumers from being confused about the natural nutritional value of fresh foods. Regulation (EC) 853/2004 on hygiene of foodstuffs defines processing as "any action that substantially alters the initial product, including heating, curing, maturing, drying, marinating, extraction, extrusion or a combination of these processes" and unprocessed products as "products that have not undergone processing, and includes products that have been divided, parted, severed, sliced, boned, minced, skinned, ground, cut, cleaned, trimmed, husked, milled, chilled, frozen, deep-frozen or thawed". Therefore, in the majority of cases it should be easy to distinguish between products that are unprocessed and so cannot have vitamins or minerals added to them, such as fruit, vegetables and meat, and products that are processed, such as bread, flour, margarine and most breakfast cereals.

Appendix 1

Summary Guide to the Regulation

Section	What it means/Guidance
Recital 1	<ul style="list-style-type: none"> • Sets the purpose of the Regulation - to harmonise legislation on the addition of vitamins and minerals and certain other substances to food.
Recital 2	<ul style="list-style-type: none"> • Clarifies that national rules on the addition of other substances to food can apply where Community rules do not exist.
Recital 3	<ul style="list-style-type: none"> • Justifies why mandatory fortification cannot currently be controlled at the Community level.
Recital 4	<ul style="list-style-type: none"> • Clarifies that certain products and processes require vitamins and minerals to be added to food and are not controlled by the Regulation.
Recital 5	<ul style="list-style-type: none"> • Clarifies that the Regulation should not apply to food supplements, which are already controlled by European legislation.
Recital 6	<ul style="list-style-type: none"> • Gives additional reasons why vitamins and minerals could be added to food.
Recital 7	<ul style="list-style-type: none"> • Explains the benefits of fortified foods.
Recital 8	<ul style="list-style-type: none"> • Explains why additional vitamins and minerals may be required.
Recital 9	<ul style="list-style-type: none"> • Clarifies why there needs to be a positive list of vitamins and minerals that can be added to food.
Recital 10	<ul style="list-style-type: none"> • Clarifies the need for a positive list of vitamin and mineral substances. It also clarifies that the use of sodium chloride as an ingredient is not covered by the Regulation.
Recital 11	<ul style="list-style-type: none"> • Explains why revisions to the lists should be done by the Commission.
Recital 12	<ul style="list-style-type: none"> • Explains why the addition of vitamins and minerals to certain foods should be restricted.
Recital 13	<ul style="list-style-type: none"> • Clarifies that the Regulation will not apply to the use of trace quantities of vitamins and minerals as authenticity markers.
Recital 14	<ul style="list-style-type: none"> • Justifies the need for maximum levels.
Recital 15	<ul style="list-style-type: none"> • Sets the criteria that should be considered when setting maximum levels.
Recital 16	<ul style="list-style-type: none"> • Justifies the need for minimum levels.
Recital 17	<ul style="list-style-type: none"> • Explains that the Commission should be responsible for setting maximum and minimum levels.
Recital 18	<ul style="list-style-type: none"> • Explains that the Labelling Requirements in this Regulation will apply in addition to Directive 2000/13/EC and without prejudice to Regulation (EC) No 1924/2006.
Recital 19	<ul style="list-style-type: none"> • Explains why nutrition labelling should be compulsory where vitamins and minerals have been added to food.

Recital 20	<ul style="list-style-type: none"> Explains why the Regulations should be available to control other substances.
Recital 21	<ul style="list-style-type: none"> Highlights the need for additional means of monitoring the addition of vitamins and minerals to food.
Recital 22	<ul style="list-style-type: none"> Clarifies that the Regulation complies with Article 5 of the treaty.
Recital 23	<ul style="list-style-type: none"> Explains how the Commission should be given the necessary powers to implement the Regulation.
Article 1	<ul style="list-style-type: none"> Sets the objective of the Regulation and the products and instances of addition to which it does not apply.
Article 2	<ul style="list-style-type: none"> Defines “Authority” and “other substance”.
Article 3	<ul style="list-style-type: none"> The vitamins and minerals that can be added to food and the reasons why these can be added.
Article 4	<ul style="list-style-type: none"> Foods to which vitamins and minerals cannot be added.
Article 5	<ul style="list-style-type: none"> Requirements and mechanism for setting purity criteria.
Article 6	<ul style="list-style-type: none"> Requires fortified products to comply with maximum and minimum levels and dictates how these will be set.
Article 7	<ul style="list-style-type: none"> Labelling requirements.
Article 8	<ul style="list-style-type: none"> Puts in place provisions to control with the use of other substances, which could pose a risk to human health.
Article 9	<ul style="list-style-type: none"> Dictates the role and content of the Community Register.
Article 10	<ul style="list-style-type: none"> Prevents Member States adopting national legislation, which would prevent the free movement of goods that comply with the controls on the addition of vitamins and minerals in this Regulation.
Article 11	<ul style="list-style-type: none"> Member States are required to notify the Commission of relevant national legislation.
Article 12	<ul style="list-style-type: none"> The Commission’s requirements following notification under Article 11.
Article 13	<ul style="list-style-type: none"> Allows Member States to have national rules, controlling substances which they believe endanger human health and the requirements for controlling this at a Community level.
Article 14	<ul style="list-style-type: none"> Defines the Committee procedure.
Article 15	<ul style="list-style-type: none"> Allows Member States to request manufacturers notify of new foods to which vitamins, minerals or other substances in Annex III have been added.
Article 16	<ul style="list-style-type: none"> Requires the Commission to provide a report on the effects of implementing the Regulation.
Article 17	<ul style="list-style-type: none"> Transitional measures.
Article 18	<ul style="list-style-type: none"> Entry into force and application dates.

Guidance to compliance with European Regulation (EC) No. 1925/2006

Annex I	<ul style="list-style-type: none">• List of permitted vitamins and minerals.
Annex II	<ul style="list-style-type: none">• List of permitted vitamin and mineral substances.
Annex III	<ul style="list-style-type: none">• List of controlled other substances.

Appendix 2 Associated Legislation

The following table gives details of other legislation, associated with this Regulation and where to find more information.

Legislation	Further information	Website
Regulation (EC) No 1925/2006 of the European Parliament and of the Council of the European Union on the addition of vitamins and minerals and of certain other substances to foods (as amended)	Full copy of the text	http://eur-lex.europa.eu/LexUriServ/site/en/oj/2006/l_404/l_40420061230en00260038.pdf
Regulation (EC) No 1924/2006 of the European Parliament and of the Council of the European Union on nutrition and health claims made on foods	Full copy of the text	http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2006R1924:20080304:EN:PDF
Food Safety Act 1990 (as amended)	Full copy of the text	http://www.legislation.gov.uk/ukpga/1990/16/contents#end
Food Safety (Northern Ireland) Order 1991	Full copy of the text	http://www.legislation.gov.uk/nisi/1991/762/contents
Food Labelling Regulations 1996 (as amended)	Food Labelling Regulations 1996 Guidance Notes	http://www.food.gov.uk/multimedia/pdfs/Fguidnot1.pdf
Directive 2009/39/EC (formerly Directive 89/398/EEC) relating to foodstuffs intended for particular nutritional uses	Food for Particular Nutritional Uses: Guidance Notes	www.food.gov.uk/foodindustry/guidancenotes/laberegsguidance/parnutsguidancenotes
Directive 90/496/EEC on nutrition labelling for foodstuffs	Nutrition Labelling Guidance Notes	http://www.food.gov.uk/multimedia/pdfs/nutlabel2.pdf
Regulation (EC) No 258/97 concerns the placing on the market of novel foods or novel food ingredients.	Information on the Novel Process from the European Commission website, FSA website and FSA guidance	http://ec.europa.eu/food/food/biotechnology/novelfood/index_en.htm
Regulation (EC) No 1829/2003 and Regulation (EC) No 1830/2003 GM legislation	Information on GM and GM legislation from the European Commission website, FSA website and FSA guidance	http://ec.europa.eu/food/food/biotechnology/gmfood/index_en.htm

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Additives legislation	Food Additives Legislation Guidance Notes	http://www.food.gov.uk/foodindustry/guidancenotes/foodguid/foodadlegguid
Council Regulation (EC) No 1493/1999 on the common organisation of the market in wine	Full copy of the text	http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31999R1493:EN:HTML
The Bread and Flour Regulations 1998	Full copy of the text	http://www.legislation.gov.uk/ukSI/1998/141/contents/made
The Bread and Flour Regulations (Northern Ireland) 1998	Full copy of the text	http://www.legislation.gov.uk/nisr/1998/24/contents/made
The Spreadable Fats (Marketing Standards) and the Milk and Milk Products (Protection of Designations) (England) Regulations 2008	Full copy of the text	http://www.legislation.gov.uk/ukSI/2008/1287/contents/made
The Spreadable Fats, Milk and Milk Products (Scotland) Regulations 2008	Full copy of the text	http://www.legislation.gov.uk/ssi/2008/216/contents/made
The Spreadable Fats (Marketing Standards) and the Milk and Milk Products (Protection of Designations) (Wales) Regulations 2008	Full copy of the text	http://www.legislation.gov.uk/wsi/2008/1341/contents/made
The Spreadable Fats (Marketing Standards) and the Milk and Milk Products (Protection of Designations) Regulations (Northern Ireland) 2008	Full copy of the text	http://www.legislation.gov.uk/nisr/2008/239/contents/made
Directive 2002/46/EC relating to food supplements	Food Supplements Guidance notes	http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_130237

Appendix 3

Sources of Information

- Guidance to compliance with European Regulation (EC) No 1924/2006 on nutrition and health claims made on foods. A copy of the guidance is available here:
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_130972
- For further information about food standards and safety please visit the Food Standards Agency website at: www.food.gov.uk
- For further information about the enforcement of food law and advice on individual products please visit the Food Standards Agency's website to find our local Trading Standards or Environmental Health Department at:
<http://www.food.gov.uk/enforcement/enforceessential/yourarea/>

Contacts

The Department of Health 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's website by using the on-line search engine at:

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

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

In England:

Customer Service Centre

Department of Health

Richmond House

79 Whitehall

London SW1A 2NS

Tel: 020 7210 4850

<http://www.info.doh.gov.uk/contactus.nsf/memo?openform>

In Scotland:

Alison Taylor
Healthy Eating and Food Standards Branch
Food Standards Agency in Scotland
6th Floor, St Magnus House
25 Guild Street
Aberdeen AB11 6NJ
e-mail: Alison.Taylor@foodstandards.gsi.gov.uk
Tel: 01224 288356
www.food.gov.uk/scotland/

In Wales:

Alison Black
Food & Physical Activity Branch
Health Improvement Division
Department for Public Health and Health Professions
Welsh Government
Cathays Park
Cardiff, CF10 3NQ
e-mail: Alison.Black@wales.gsi.gov.uk
Tel : 029 2082 5953
wales.gov.uk

In Northern Ireland:

Mervyn Briggs
Senior Policy Officer
Food Standards, Incidents and Science Team
Food Standards Agency in Northern Ireland
e-mail: Mervyn.Briggs@foodstandards.gsi.gov.uk
Tel: 028 9041 7742

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

Appendix 4 Glossary

Annex I	The list of vitamins and minerals that can be added to food.
Annex II	The list of vitamin and mineral substances that can be added to food.
Annex III	The list of certain other substances controlled by the Regulation.
AVM Regulation	The European Regulation on the addition of vitamins and minerals and of certain other substances to food.
Commission	European Commission
Community	European Community
Community Register	Centralised source of information about the Regulation, including the list of vitamins and minerals that can be added to food.
Department	Department of Health
EFSA	European Food Safety Authority (referred to as the Authority in the Regulation)
EU	European Union
Food Business Operator	The natural or legal persons responsible for ensuring that the requirements of food law are met within the food business under their control.
Mandatory Fortification	Where the addition of vitamins and minerals to food is required by law
Nutrition Claim	Any claim which states, suggests or implies that a food has particular beneficial nutritional properties due to the energy it provides, provides at a reduced or increased rate, does not provide or the nutrients or other substances it contains, contains in reduced or increased proportions or does not contain.
Other Substance	A substance other than a nutrient that has a nutritional or physiological effect.

Guidance to compliance with European Regulation (EC) No. 1925/2006

Scope	The products and type of addition the Regulation controls.
Standing Committee	European Commission's Standing Committee on the Food Chain and Animal Health (SCoFCAH).
Transitional Period	A period of time set by the Regulation, during which its requirements will not apply.