

**EUROPEAN REGULATION (EC) NO 1925/2006 ON THE
ADDITION OF VITAMINS AND MINERALS AND CERTAIN
OTHER SUBSTANCES TO FOODS**

**FOOD STANDARDS AGENCY
GUIDANCE TO COMPLIANCE VERSION 1
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Note : To be revised and updated with the adoption of minimum
and maximum levels.

Foreword

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 of certain other substances to food was published.

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, and these remain the considered view of the Agency, 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.

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Section 1

Introduction and Summary

Addition of vitamins and minerals

A new European Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and certain other substances to food has recently been published. This Regulation lists the vitamins and minerals and the vitamin formulations and mineral substances that can voluntarily be added to food. If you plan to add a vitamin or mineral to your product you should consult your Home Authority¹, as well as using 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 it is obligatory to provide nutrition labelling.

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?

- 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 no more 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

¹ The Home Authority scheme is described at Section 7.2

will either be by way of 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 1990 and Article 14 of European Regulation 178/2002³, 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.

The new Regulation seeks to protect consumers from ingesting 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 89/398/EEC relating to foodstuffs for particular nutritional uses. Where vitamins or minerals are added to a food for an additive purpose the Regulation will not apply, however the addition will need to meet with the controls on the use of additives in Directive 89/107/EEC.

The Regulation also recognises that vitamins and minerals may be added to food to restore levels lost during processing. Additions of this kind must,

³ Regulation 4 of the General Food Regulations creates offences for breaches of certain Articles in Regulation (EC) 178/2002, including Article 14.

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. In the Agency's view, if a claim is to be made on a vitamin or mineral that has been restored after processing losses, there must be a significant amount in the food as sold as defined in Directive 90/496/EEC. 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 new Regulation will put 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.

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
- 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. Likewise they are dealt with separately in the guidance.

- ★ 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) will control the voluntary addition of vitamins and minerals to food. It lists the vitamins and minerals and the vitamin formulations and mineral substances that can be added to food and puts in place minimum amounts and provisions to set maximum amounts.

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 will not be affected by the new Regulation (Recital paragraph 3). Under the Regulation the Agency 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 1998
- The Spreadable Fats (Marketing Standards) Regulations 1995

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 can not 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. The composition of these products depends on the addition of certain minerals and without such addition these products could not be produced. There are specific conditions associated with this exemption, including a prohibition on claims, which are explained in full in Section 8, question 7.

The Regulation contains provisions that allow for 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's 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 can not 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 please check the Community Register at the web link given above in 4.2 or contact either the Agency or your trade association. Contact details for the Agency can be found in Appendix 3.

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. Although at the time of writing a significant amount was defined as 15% of the RDA per 100 g or 100ml, nutrition labelling rules are under review and we would advise you check the latest position. 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, the Agency takes the view that if a claim is to be made on a vitamin or mineral that has been restored after processing losses, there must be a significant amount in the food as sold as defined in Directive 90/496/EEC. 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 to set maximum levels to avoid over-consumption of vitamins or minerals which might have an adverse effect on health. The European Commission is currently working on setting maximum levels and 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.
- 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. Before adding a vitamin or mineral to your product you will need to check to ensure you meet with 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 amounts of the vitamins and minerals that have been added to the food together with the amount already 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 formulations 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 96/77/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 96/77/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, it is worth considering this if you are planning on exporting your products to other Member States, who may have purity criteria 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's 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 formulation 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.

- There are no maximum limits that apply to the addition of that vitamin or mineral to my product or the levels I wish to add are within these maximum levels.
- There are no product specific restrictions as a result of maximum limits.
- 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 couldn't 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.

Section 5

Addition Of Certain Other Substances To Food

5.1 – Introduction

The Food Safety Act 1990 and Article 14 of European Regulation 178/2002⁴, 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). 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 this assessment the European Commission will take a decision on its use in food, which will fall into one of the following four categories:

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

- 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.

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 are added in line with 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 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 its use is 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 Instrument⁵ 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.

To ensure that your product complies with the Regulation we would strongly recommend you contact your local TSO or EHO for advice.

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

7.3 – 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.

⁵ Statutory Instrument 2007 No. 1631, The Addition of Vitamins and Minerals and Other Substances (England) Regulations 2007
Statutory Rules 2007 No.301, The Addition of Vitamins and Minerals and Other Substances (Northern Ireland) Regulations 2007
Statutory Instrument 2007 No. 325, The Addition of Vitamins and Minerals and Other Substances (Scotland) Regulations 2007
Statutory Instrument 2007 No. 1984 (w.165), The Addition of Vitamins and Minerals and Other Substances (Wales) Regulations 2007

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 continue at an 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. Rules on the labelling of compound ingredients is currently under review and food business operators should check these labelling rules.

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 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 can't be provided?*

The Commission has started the process to review and amend Directive 90/496/EEC. One of the amendments to be considered is an up-date to the Annex of vitamins and minerals and the setting of associated RDAs, with reference to significant amounts. Until this has been completed, 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 has recently 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 contact the Agency or your trade association for further information.

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 Food Standards Act 1999 makes the Food Standards Agency the competent Authority in the UK for policy decisions. Enforcement is the responsibility of local authorities (see Section 7).

12. *Will the 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 can't 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) 852/2004 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 formulations 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 can not 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.
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 formulations 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	Full copy of the text	http://eur-lex.europa.eu/LexUriServ/site/en/oj/2006/l_404/l_40420061230en00260038.pdf
Corrigendum to 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/site/en/oj/2007/l_012/l_01220070118en00030018.pdf
Food Safety Act 1990 (as amended)	Full copy of the text	www.opsi.gov.uk/acts/acts1990/Ukpga_19900016_en_1.htm#end
Food Labelling Regulations 1996 (as amended)	Food Labelling Regulations 1996 Guidance Notes	www.food.gov.uk/foodindustry/guidancenotes/labregsguidance/foodlabregsguid
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/labregsguidance/parnutsguidancenotes
Directive 90/496/EEC on nutrition labelling for foodstuffs	Nutrition Labelling Guidance Notes	www.food.gov.uk/foodindustry/guidancenotes/labregsguidance/nutlabelguid
Novel foods legislation	Information on the Novel Process from the European Commission website	http://ec.europa.eu/food/food/biotechnology/novelfood/index_en.htm
GM legislation	Information on GM and GM legislation from the European Commission website	http://ec.europa.eu/food/food/biotechnology/gmfood/index_en.htm

Additives legislation	Food Additives Legislation Notes	Additives Guidance	www.food.gov.uk/safereating/chemsafe/additivesbranch/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		www.opsi.gov.uk/si/si1998/19980141.htm
The Spreadable Fats (Marketing Standards) Regulations 1995	Full copy of the text		www.opsi.gov.uk/si/si1995/Uksi_19953116_en_1.htm
Directive 2002/46/EC relating to food supplements	Food Regulations	Supplements 2003: Guidance notes	www.food.gov.uk/foodindustry/guidancenotes/foodguid/foodsupguidance

Appendix 3 Sources Of Information

- For further information about food standards and safety please visit the Food Standards Agency website at: www.food.gov.uk
- For further information about healthy eating advice please see the Agency's eatwell website at www.eatwell.gov.uk
- For further information about the enforcement of food law please visit the Local Authorities Coordinators of Regulatory Services website at www.lacors.gov.uk.
- Guidance to compliance with European Regulation (EC) No 1924/2006 on nutrition and health claims made on foods. [insert web address when published]

For further information and advice on the Regulations or the guidance notes please contact the Agency at:

Fortification and Claims Unit
Nutrition Division
Food Standards Agency
125 Kingsway
London
WC2B 6NH

addition-of-nutrients@foodstandards.gsi.gov.uk

Appendix 4 Glossary

The Agency	The Food Standards Agency
Annex I	The list of vitamins and minerals that can be added to food.
Annex II	The list of vitamin formulations 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.
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.

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

Appendix 5 Interested Parties List

The Agency holds electronic databases of all contacts who are interested in receiving information from us on particular issues. These databases are confidential and are only used to contact you about issues that may be of importance to you.

If you wish to receive further information and up-dates on any of the following please tick the relevant box(es) and fill in your details and return to the address below.

- Addition of vitamins and minerals to food
- Development of purity criteria
- Development of maximum and minimum amounts
- Use of certain other substances

Name:.....

Company:.....

Address:.....

.....

Postcode:.....

E-mail address:.....

Telephone number:.....

Fax number:.....

Where possible the Agency will contact you by e-mail to save valuable resources. If you do not want to be contacted by e-mail please tick the following box and we will contact you by post .

If you are already on our database but wish to up-date your details or subject areas for which you receive information please fill in the above. If you want any previous details to be removed from the system please fill in the following section*.

Details to be removed from our system:

Name:.....

Company:.....

Address:.....

.....

Postcode:.....

E-mail address:.....

Telephone number:.....

Fax number:.....

*any up-dates will apply to all interested parties lists held by the Agency. Please note that if you no longer wish to receive up-dates from the Agency your details will only be removed from the lists that apply to the addition of vitamins and minerals and certain other substances to food.