

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

**DRAFT FOOD STANDARDS AGENCY GUIDANCE TO
COMPLIANCE**

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 foods 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 it remains 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 EC 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: Small Business Quick Guide

Addition of Vitamins and Minerals

A new European Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods has recently been published. This Regulation lists the vitamins and minerals (and the corresponding 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 these guidelines 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 to 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 applies without prejudice to addition which is required by law. It does not apply to 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 of the Regulation.
- 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 a benefit to consumers, 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 Section 4 of these guidance notes.

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 either be by way of a prohibition or restriction on the substance's use in food. Food business operators will need to check Annex III of the Regulation

¹ The Home Authority scheme is described at Section 7.2

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 will apply 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.

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 of certain other substances to foods was published (AVM Regulation). The AVM Regulation was published as (EC) No 1925/2006 and is the first piece of specific EC legislation to deal with the voluntary addition of vitamins and minerals and certain other substances to food. A copy of this Regulation can be found at the following website address:

http://eur-lex.europa.eu/LexUriServ/site/en/oj/2006/l_404/l_40420061230en00260038.pdf

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 178/2002², which make it an offence to render food injurious to human health or place on the market food that is unsafe. Other countries of the European Community (Member States) have 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 Community 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 as authenticity markers (Recital paragraph 13). It will also not apply to the use of vitamins and minerals in food supplements (Directive 2002/46/EC) and applies without prejudice 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

² Regulation 4 of the General Food Regulations (SI 2004/3279) creates offences for breaches of certain Articles in Regulation (EC) 178/2002, including Article 14.

the addition will need to meet with the controls on the use of additives in Directive 89/107/EEC.

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 that also apply to the addition of vitamins, minerals or certain other substances to food. In such cases these requirements 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.

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). You will need to ensure that you comply with all relevant legislation.

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 this 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 of certain other substances to foods (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 will be 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 1999

Although subject to mandatory fortification, if the product meets with the conditions of the Regulation, it is possible to also voluntarily add additional vitamins and minerals to flour and margarine. You must, however, ensure that you also meet with the requirements on the mandatory fortification in the above legislation.

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

- The Regulation does not allow vitamins and minerals to be added to unprocessed foodstuffs such as fruits, vegetables, meat, poultry and fish.
- The Regulation does not allow vitamins and minerals to 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 8.2 – Restrictions and requirements Q7.

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 is not likely to be affected by 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 that Annex.

http://eur-lex.europa.eu/LexUriServ/site/en/oj/2006/l_404/l_40420061230en00260038.pdf

- ★ If the vitamin or mineral you wish to add is listed please go to 4.2 – Vitamins and minerals listed in Annex I (Article 3).
- ★ If it's not on this list please go to 4.3 – Vitamins and minerals not listed in Annex I or Annex II (Article 3).

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

As the vitamin and mineral you wish to add is listed in Annex I you will now need to look at Annex II, which lists the vitamin formulations and mineral substances that the Regulation permits to be added to food. 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.

[insert website address and link]

- ★ If the vitamin formulation or mineral substance is listed in Annex II please go to 4.4 – Further conditions on the addition of vitamins and minerals to food. 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 4.3 – Vitamins and minerals not listed in Annex I or Annex II (Article 3).

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

The Regulation prohibits vitamins and minerals not listed in Annex I and vitamin formulations or mineral substances not listed in Annex II from being

voluntarily added to food (please see Section 6: When do I need to comply with the Regulation? for details of transitional periods). The Regulation does, however, allow additions to be made to the Annexes (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. To have a vitamin, mineral, vitamin formulation or mineral substance added to the annexes a submission must be made to the European Commission. A link to Commission guidance on making such submissions can be found below, together with a link to guidance on the compilation of a technical dossier. Although the Commission's guidance only mentions submissions covered by Article 17, it should also be used as a guide for applications for additions not captured by this Article.

Guidance on making submissions:

http://ec.europa.eu/food/food/labellingnutrition/nutritional/adm_guidance_safely_substances_en.pdf

Guidance on compilation of a Technical dossier:

http://ec.europa.eu/food/fs/sc/scf/out100_en.pdf

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 requirements 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 and Recital 16)

To ensure that fortification is beneficial to health, the Regulation requires that the final food contains a significant amount of the added vitamin or mineral. These minimum amounts will apply to the total level of the vitamin or mineral, including amounts already present, in the food. For the majority of vitamins and minerals Directive 90/496/EEC on nutrition labelling of foodstuffs applies and defines a significant amount as 15% of the RDA. This Directive is in the process of being reviewed and it is intended that during this process RDAs and associated significant amounts will be set for the rest of the vitamins and minerals in the AVM Regulation.

Food Business Operators may want to consider Regulation 1924/2006 on nutrition and health claims made on food, which also requires a significant amount to be present for a claim to be made.

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 the maximum and minimum amounts 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.

[insert website]

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 of 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.

[insert website address]

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. The figure stated should include the amount added together with the amount already present in the food.

The Regulation also states that the labelling of the product must also not state, suggest or imply that appropriate amounts of vitamins and minerals can not 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. Where these exist, the Regulation requires formulations or substances to meet with the conditions of the purity criteria to 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 it states that any generally accepted purity criteria recommended by international bodies, such as Codex, shall apply. The table below gives links to legislation, which puts in place purity criteria, and links to purity criteria recommended by international bodies.

The Regulation also allows 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.

Table 1 – Existing purity criteria

This table gives links to purity criteria, for vitamin formulations and mineral substances listed in Annex II, within Community legislation or recommended by generally accepted international bodies. Due to the nature of this guidance this table may not be up-to-date and so we advise Food Business Operators to contact their Local Authority to ensure they are complying with latest purity criteria.

Legislation or International Recommendation	Document Name	Website
EU Legislation	Commission Directive 95/45/EC laying down specific purity criteria concerning colours for use in foodstuffs	http://europa.eu/eur-lex/en/consleg/pdf/1995/en_1995L0045_do_001.pdf
EU Legislation	Commission Directive 96/77/EC laying down specific purity criteria on food additives other than colours and sweeteners	http://ec.europa.eu/food/food/chemicalsafety/additives/dir9677ec.pdf
Joint FAO/WHO Expert Committee on Food Additives' Recommendations	Compendium of food additive specifications	http://www.fao.org/ag/agn/jecfa-additives/search.html?lang=en

Figure 1 – Check list 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 in accordance with the AVM Regulation:

- 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 put in place specific controls on which vitamins and minerals can be added to my product, for example compositional requirements under PARNUTS legislation.
- I am not adding the vitamin or mineral to fulfil a technological function that is 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 (where this is defined in directive 90/496/EEC).
- 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

Although the Food Safety Act 1990 and Article 14 of European Regulation 178/2002³, make it an offence to render food injurious to human health or place on the market food that is unsafe, 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 Addition of Vitamins and Minerals and of Certain Other Substances (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. When the Regulation was adopted there were no proposals to control any specific substances.

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

The Regulation will only control other substances that are added to foodstuffs or used as ingredients which result in higher levels of consumption than would be expected through a normal diet and which 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:

- 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**

³ Regulation 4 of the General Food Regulations (SI 2004/3279) creates offences for breaches of certain Articles in Regulation (EC) 178/2002, including Article 14.

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 (substances under Community scrutiny) 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 (unless controlled through any other legislation).

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, the Regulation puts in place 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 Regulation requires the EFSA opinion to 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.

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 will apply from 1 July 2007. After this date products will need to 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

The Regulation allows vitamins or minerals not listed in Annex I or forms not listed in Annex II to continue to be used until 19 January 2014, as long as they were used in food that was on the market in the European Community on 19 January 2007 and a dossier in support of such 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, the Regulation will no longer permit the vitamin or mineral or particular form in question 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 unlisted vitamins and minerals (or substances or formulations) have been added. Once such a vitamin, mineral, formulation, or substance 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 it is SI number **[fill in]** which puts in place these provisions for this Regulation. It will be the Trading Standards Department or the Environmental Health Department in the local authority of the manufacturer that is responsible for enforcing the requirements of the legislation.

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 in the Regulation 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 immediately.

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. It may also be possible that, due to issues at the national level, the Commission will decide to allow the national suspension or restriction to remain. If you plan to export your products to other Member States, you will need to ensure there are no relevant national provisions.

It is also possible that the UK may introduce such safeguard measures if we strongly believe human health could be endangered. This would be done by Emergency Legislation under the Food Safety Act 1990. As such controls would be introduced based on safety concerns the Agency may not be in a position to carry out a full 12 week consultation. It is not unusual for legislation to be introduced in this way, when there is a serious risk to consumer safety, and the Agency will endeavour to consult as widely as possible.

Section 8: Questions and Answers

8.1 – Scope

1. *Does the AVM Regulation apply to supplements?*

No. The Regulation clarifies in Article 1(2) that supplements will continue to be controlled by Directive 2002/46/EC relating to food supplements.

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

No. The Commission has indicated that they agree with the Agency's interpretation that the AVM 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 AVM 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, in our view, the addition of fluoride before this stage is not controlled by the AVM Regulation.

4. *Does the AVM 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 Regulation.

5. *Does the AVM Regulation apply to the addition of vitamins and minerals to restore levels that may be lost during manufacture and processing?*

Yes. The Regulation covers any voluntary addition of vitamins and minerals to food. Although Article 3 lists particular reasons why vitamins and minerals can be added to food, it would appear to be a non-exhaustive list and as Recital 6 indicates that restoration is a reason for addition this practice, in our view, will need to comply with the Regulation.

6. *Does this AVM Regulation apply to the use of trace quantities of vitamins and minerals as authenticity markers?*

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

8.2 – Restrictions and requirements

7. *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 AVM 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.

8. *What if a vitamin or mineral is not covered by Directive 90/496/EEC and the RDA on the nutrition labelling therefore can't be provided?*

The Commission have 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.

Recital 19 of the AVM Regulation explains that nutrition labelling should be provided to enable consumers to judge the global nutritional quality of those products to which vitamins and minerals have been added. Therefore it is the Agency's view that until Directive 90/496/EEC has been reviewed and is consistent with the Regulation, Food Business Operators should be consistent with Recital 19 and ensure consumers have access to a full nutritional breakdown of the product including the vitamins and minerals that have been added.

9. *If I add vitamins and minerals to restore those lost during manufacture and processing do I have to ensure minimum amounts are present?*

Yes. Article 6(6) requires at least a significant amount to be present following fortification. For vitamins and minerals covered by Directive 90/496/EEC on nutrition labelling of foodstuffs (as amended) a significant amount is defined as 15% of the RDA.

10. *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 these guidelines give further information about the setting of minimum and maximum levels respectively.

11. *What will happen if a vitamin or mineral is not in the Annex of the AVM 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, The Regulation requires any additions to be assessed independently. If you would like to have a vitamin or mineral added to the Annex please see 4.3 – Vitamins and minerals not listed in Annex I or Annex II (Article 3).

8.3 – Authorisation process

12. *How will vitamins and minerals be added to the Annexes?*

The AVM Regulation requires the Commission to take account of advice from EFSA and then propose additions to the Annexes. A final decision will be taken by the Standing Committee, based on qualified majority voting.

13. *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.

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

Article 3 (3) of the AVM Regulation does allow for the list to be amended, after prior consultation with food businesses and consumer groups. Final decisions will be made by the Standing Committee.

15. *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 AVM 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, smoking, curing, maturing, drying, marinating, extraction, extrusion or a combination of those processes" and unprocessed products as "foodstuffs 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 fresh fruit, vegetables and meat, and products that are processed, such as bread, flour, margarine and most breakfast cereals.

However, for some dairy products the distinction may be less clear cut. For example, although cheese would generally be considered to be a processed product, there may be certain cream cheeses or curd cheeses that may be seen as unprocessed if they are made by methods of minimal intervention (such as simply allowing the curds to separate from the whey by the natural souring process and then draining off the liquid to leave the solid cheese), particularly if they are marketed as "fresh". In this case, consumers are likely to associate the natural nutritional value with that of unprocessed milk. Similarly, yoghurt that has had sugar or flavourings added to it could be considered to be a processed food, but natural yoghurt may be viewed as unprocessed. For the purposes of the AVM Regulation, we believe pasteurised milk would be seen as an unprocessed food, because the gentle heating involved in the pasteurisation process does not substantially alter the natural nutritional quality of the milk, which consumers would regard as a "fresh" food. For further information about the criteria for use of the terms "fresh", "pure" and "natural" please see the Agency's guidance at the following web address:

<http://www.food.gov.uk/multimedia/pdfs/fresh.pdf>

Appendix 1: Summary Guide to the Regulation

Section	Summary
Recital 1	<ul style="list-style-type: none"> Explains 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 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 is not intended to 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"> Explains 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 the subsidiarity principle in 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 subject matter and scope 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"> Establishes the Community Register and sets out its content.
Article 10	<ul style="list-style-type: none"> Prohibits Member States from 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"> Requires Member States to notify the Commission of relevant national legislation and proposals for new legislation
Article 12	<ul style="list-style-type: none"> The Commission’s requirements following notification of proposals 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 for the introduction of implementing measures under the Regulation.
Article 15	<ul style="list-style-type: none"> • Allows Member States to require manufacturers to notify foods placed on the market 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 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 on nutrition and health claims made on foods	Despite being called a corrigendum, this is in fact a 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/labelregsguidance/foodlabelregsguid
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/labelregsguidance/parnutsguidancenotes
Directive 90/496/EEC on nutrition labelling for foodstuffs	Nutrition Labelling Guidance Notes	www.food.gov.uk/foodindustry/guidancenotes/labelregsguidance/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 Guidance Notes	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=C ELEX: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 1999	Full copy of the text	http://www.opsi.gov.uk/SI/si1999/uksi_19992457_en.pdf
Directive 2002/46/EC relating to food supplements	Food Supplements Regulations 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 on European Regulation (EC) No 1924/2006 on nutrition and health claims made on foods at **[insert web address when published]**

For further information and advice on the Regulation 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 vitamin or mineral 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 (in certain circumstances) 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.