EU Food Supplements Directive

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Author: Dr Gavin Colthart
Section: Science and Environment Section

This note provides background information on European Directive 2002/46/EC relating to regulation of food supplements containing vitamins and minerals, including permitted contents and maximum levels. Additional information on the UK implementation of the Directive can be found in EU Bibliographies: Food Supplements Directive (SN/IA/05101).

Contents

1 Summary

The UK market for food supplements containing vitamins and minerals, estimated to be worth approximately £364 million per year, is regulated by Directive 2002/46/EC, known as the Food Supplements Directive. The Directive does not currently apply to food supplements other than vitamins and minerals or to any products that claim to restore, correct or modify the body's physiological functions. The latter are subject to medicines licensing procedures.

EU responsibility for implementation and monitoring lies with the European Food Safety Authority (EFSA). The competent UK authority was initially the Food Standards Agency (FSA) but legislative responsibility transferred to the Department of Health in October 2010.

The Directive deals with five main aspects of vitamin and mineral supplement regulation:

- specifying permitted vitamins and minerals
- setting maximum and minimum permitted amounts
- defining product labelling requirements
- prohibiting manufacturers from making therapeutic claims for their products
- prohibiting Member States from restricting trade in Directive-compliant products

Under a derogation clause, 375 food supplements containing substances not listed in the Directive were permitted to be sold in the UK until 31 December 2009, subject to satisfactory safety assessments by the EFSA. From 1 January 2010 all vitamins and minerals used as food supplements must be included in the Directive's list of 181 permitted substances. Supplements must also comply with the Directive's definitions of allowable levels, although these remain undefined.

UK Governments have broadly supported the Directive's intentions in ensuring public safety and reducing barriers to trade but has been subject to intense lobbying by supplement manufacturers and the public. Key concerns include the potential impact of the Directive on the availability of high dose supplements and on the profitability of suppliers. A challenge to the legality of the Directive was heard at the European Court of Justice in 2005 but despite a preliminary ruling in favour of the plaintiffs, the Court eventually upheld it.

Current controversy centres mainly on the issue of maximum permitted levels in supplements. The EFSA has been working with Member States since 2006 to prepare a draft list of permitted levels. The UK has already addressed this issue via the Expert Group on Vitamins and Minerals, which reported in 2003. Successive governments have argued that the approach used by this group is consistent with World Health Organisation (WHO) and Food and Agriculture Organisation (FAO) methods and that maximum levels should be based on risk of harm rather than reference to a theoretically adequate level of intake (such as the Recommended Daily Amount). They have also argued that regulation should be flexible for vitamins and minerals for which there is no evidence of adverse effects.

Although a draft proposal on permitted levels was expected in early 2009, its finalisation and publication have been repeatedly delayed and negotiations on this matter continue.

2 Background, scope and responsibilities

Directive 2002/46/EC, which relates to regulation of food supplements, was implemented in England by the Food Supplements (England) Regulations 2003, which came into force in August 2005. Equivalent legislation applies in the devolved administrations.

The Directive's main intent is to harmonise regulations on vitamin and mineral supplements across Europe and ensure that products on the market are safe, clearly labelled, and do not make claims to medicinal properties.

The Directive deals with five main aspects of vitamin and mineral supplement regulation:

- specifying permitted vitamins and minerals and their chemical sources, based on evaluation of their safety
- setting maximum and minimum permitted amounts of vitamins and minerals in supplements
- defining product labelling requirements
- prohibiting supplement manufacturers from making any therapeutic claims for their products
- prohibiting Member States from restricting trade in products complying with the Directive

The Directive only currently applies to food supplements that contain vitamins or minerals, although it may in the future regulate amino acids and other food supplement components. Article 4(8) of the Directive required the European Commission to report on the need for additional regulation of food supplements other than vitamins and minerals. This report, published in December 2008, concluded that existing legislation was adequate and there are no current proposals to extend the scope of the Directive.[1] [2]

The Directive is not applicable to products that claim to restore, correct or modify the body's physiological functions, which are subject to medicines licensing procedures. Food supplements are defined in Article 2 (a) of the Directive:

> For the purposes of the Directive, 'food supplements' means foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in a dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities where 'nutrients' means the following substances: (i) vitamins, (ii) minerals.

EU responsibility for implementation and monitoring lies with the Directorate-General Health and Consumers. The European Food Safety Authority (EFSA) is responsible for the scientific assessment of supplements considered for inclusion on the permitted list.

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1 European Commission, Report from the Commission to the Council and the European Parliament on the use of substances other than vitamins and minerals in food supplements, 5 December 2008

2 HC Deb 15 May 2009 c1077W

The previous competent UK authority was the Food Standards Agency (FSA) but for England this role transferred to the Department of Health in October 2010. The websites of the EFSA and the FSA (the archive version of the latter) include useful updates and background information on food supplement regulation. The Department of Health website now includes several recent guidance documents on the topic.

3 The permitted list

From 1 August 2005 trade in supplements containing substances not included in the permitted list has been prohibited. Under a derogation ending after 31 December 2009, the UK allowed additional ingredients to continue to be used as food supplements after 1 August 2005 providing they were on sale before July 2002 and a dossier containing safety data was submitted to the EFSA before 12 July 2005.

Evaluation of safety dossiers by the EFSA proved problematic, in part due to an inability to assess dossiers containing insufficient data. The following extract from the EFSA website outlines the process of dossier evaluation:

> EFSA was asked by the European Commission to evaluate the safety and bioavailability of nutrient sources proposed for addition to the list of permitted substances in Annex II of the food supplements Directive. In July 2009, EFSA completed the first comprehensive assessment of substances used as sources of vitamins and minerals in food supplements, which are currently sold in the EU.
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> Based on EFSA's work, the European Commission reviewed the list of permitted vitamin or mineral substances that may be added in food supplements.
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> Between 2005 and 2009 EFSA examined a total of 533 applications. Of these, 186 applications were withdrawn during the evaluation process, and EFSA received insufficient scientific evidence to be able to assess around half of the remaining applications. Possible safety concerns were identified in relation to 39 applications.
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> The evaluations were carried out by the Panel on food additives and nutrient sources added to food (ANS). The Panel's evaluations involved judging the safety of a nutrient substance at the intake levels suggested by the applicant based on best scientific knowledge available. The Panel also assessed the bioavailability of the nutrient from the source, which is the effectiveness with which the mineral or vitamin is released from the source into the tissues of the body. Previously the former Panel on food additives, flavourings, processing aids and materials in contact with food (former AFC) was responsible for this work.
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> Moreover, EFSA's NDA Panel has performed a comprehensive evaluation of the possible adverse health effects of individual micronutrients at intakes exceeding the dietary requirements and, where possible, established Tolerable Upper Intake Levels (ULs) for different population groups. ULs represent the highest level of chronic daily intake of a nutrient that is not likely to pose a risk of adverse health effects to humans.

Annex I of the Directive initially listed 28 permitted vitamins and minerals (for example, vitamin A and potassium) and Annex II listed 112 chemical forms in which these may be included in supplements (for example, retinol and potassium bicarbonate). Additional substances were added to Annex II by Directive 2006/37/EC and both Annexes were further augmented by Commission Regulation No 1170/2009. There are now more than 180 vitamin and mineral substances listed in the Annexes.

4 Permitted levels

The European Commission has been working with Member States since 2006 to prepare a draft list of permitted vitamin and mineral levels in food supplements but this issue has proved particularly contentious.

A discussion paper on levels was produced by the European Commission in June 2006, to which the previous UK Government responded, along with a number of UK-based supplement manufacturers and trade associations.

The Government noted that the UK had already addressed the issue of safe levels of vitamins and minerals via its own Expert Group on Vitamins and Minerals (EVM), which produced a comprehensive report in 2003. The response argues that the approach used by this group is consistent with World Health Organisation (WHO) and Food and Agriculture Organisation (FAO) methods and that maximum levels should be based on risk of harm rather than reference to a theoretically adequate level of intake (such as the Recommended Daily Amount). The response also argues that regulation should be flexible for vitamins and minerals for which there is no evidence of adverse effects.

In reply to concerns about the possible impact of maximum levels on availability of certain popular supplement products, Commissioner Kyprianou issued a collective reply in February 2007:

> In the context of the exercise for the establishment of maximum and minimum amounts of vitamins and minerals in foodstuffs and in particular in food supplements, several letters have been addressed to Commissioner Kyprianou. With this answer we provide a collective reply to all letters.
>
> First of all, the Directorate General Health and Consumer Protection would like to emphasize that the main aim of the food supplements Directive is to ensure that food supplements placed on the market are safe and provide a wide choice to consumers to supplement their diet.
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> Moreover, it is important to note that food supplements are regulated as food and are intended for supplementing the normal diet rather than having therapeutic effects. In fact, claims as to treatment, cure or prevention of disease would not be allowed for food supplements and would place the product under the legal framework of medicines.
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> We can confirm that we have initiated the works for the establishment of the maximum amounts of vitamins and minerals in food supplements, as foreseen by Article 5 of the abovementioned Directive, where the criteria to be considered in this exercise are also listed.
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> We have recently published a discussion paper on the establishment of maximum and minimum amounts of vitamins and minerals in foods where we have identified the issues to be considered and invited all interested parties to provide their view by 30 September 2006. We are currently analysing the answers received.
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> Furthermore, we can reassure that in this exercise of setting the maximum levels for vitamins and minerals in food supplements at Community level, we will consider with the utmost care all existing national rules and will endeavour to incorporate in the measures as much flexibility as is compatible with the principles of the internal market.

5 Reaction to the Directive

The Directive has been welcomed by some consumer groups and health commentators but strongly opposed by other health commentators, smaller manufacturers of supplements and some members of the public.

Opponents cite many concerns, including:

- the costs of proving the safety of some supplements could lead to their withdrawal from the market by smaller manufacturers
- the Directive is an example of unnecessary regulation as most vitamins and minerals are unlikely to be toxic even in high doses
- unfavourable findings by the EFSA could mean that certain popular high-dose vitamin and mineral supplements may no longer be available once the Directive is fully implemented
- the basis for some negative EFSA safety decisions (for example, regarding vanadium) does not take into account possible safety at low doses
- the scientific models used for calculating maximum doses are contradictory and do not distinguish between naturally occurring and synthetic forms

In 2004 opponents took a legal challenge to the European Court of Justice. The Advocate General at the European Court of Justice gave an initial opinion that the Food Supplements Directive was illegal, on the grounds of infringement of the principles of legal protection, legal certainty and administration. However, the Directive was later upheld by the Court. The full statement of opinion on case C-154/04 can be found on the European Court of Justice website.

There has been considerable lobbying from the UK supplements industry and health food retailers around implementation of the Directive, including the Save Our Supplements postcard and media campaigns promoted by the organisation, Consumers for Health Choice.

The organisation, Alliance for Natural Health, whose supporters include natural health practitioners, health advocacy groups, some smaller supplement manufacturers and health food trade associations is also active in trying to modify the Directive. Their website includes detailed briefings on some of their key philosophical and scientific differences with the EFSA.

Supporters of the Directive, including the British Dietetic Association and Which?, have argued that consumers have suffered adverse effects from certain supplements and that the new regulations will protect consumers from unsafe products, ensure they are clearly labelled, and prevent sale of those which make unsubstantiated claims.

6 Government policy

UK Governments have broadly supported the Directive's intentions in ensuring public safety and reducing barriers to trade, while consistently arguing that any restrictions on maximum levels should be based on an assessment of risk.

> **Anne Milton:** The Government believe that any regulation for food supplements should be based on safety and consumers having the right to make an informed choice. The European Food Supplements Directive was implemented in England in

> 2003 and came into force in 2005. The legislation contains a requirement to set maximum levels for vitamins and minerals in food supplements on the basis of science and safety. Discussions on this are expected to restart in 2011 and any proposal would need to be agreed by a majority of member states before implementation.[3]

The most recent Government comment on policy and progress in this area was made in May 2011:

> **Anne Milton:** I last met with European Commissioner for Health, John Dalli, on 19 November 2010, to discuss United Kingdom concerns about the setting maximum limits for food supplements. I pressed for any changes to the legislation to be based on scientific evidence of risk and not be unduly restrictive, so that the impact on UK industry is minimised while maintaining consumer choice. Commissioner Dalli has confirmed that he recognises the UK's concerns and will take this into account in developing proposals.
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> Departmental officials are actively involved in European discussions as part of the health claims authorisation process. The Government's objective is to ensure that health claims are assessed and authorised appropriately so that consumers can have confidence in claims made about foods, including food supplements. Officials have met with members of food supplement trade associations to discuss the impact of the legislation, and will continue to keep interested parties informed of progress in Brussels.[4]

7 Impact on SMEs

Since the Directive was first proposed there has been concern regarding its potential impact on UK small and medium-sized enterprises (SMEs) involved in producing and selling food supplements. Numerous PQs have been tabled on this issue and the current Government has said that an impact assessment will be completed prior to a public consultation once the proposal on maximum permitted levels is finalised:

> **Anne Milton:** [...] An impact assessment is being prepared according to cabinet office guidelines, which will include economic impact to UK businesses; the assessment will be completed when the [maximum] European Commission's proposal on permitted levels for vitamins and minerals is published. The impact assessment is made at the UK level and does not consider individual counties or towns separately. The impact assessment will form part of a public consultation on the proposals.[5]

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3 HC Deb 2 November 2010 c771W
4 HC Deb 9 May 2011 c1043W
5 HC Deb 24 June 2010 c326W