Food supplements

Label advisory statements and suggested reformulations

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

First published September 2011
Published to DH website, in electronic PDF format only.
http://www.dh.gov.uk/publications

Food supplements: label advisory statements and suggested reformulations

In 2004 a voluntary agreement was reached between government officials and the food supplements industry to include advisory statements on food supplements labels. The advisory statements and the substances they relate to are listed in the Annex below. In addition, some reformulations were suggested, to reduce the levels of certain nutrients. The advice is intended to protect consumers by providing information and alerting them to any potential adverse effects, enabling them to make informed choices.

The advice was based on the conclusions of the 2003 report of the Expert Group on Vitamins and Minerals (EVM). The EVM was a group of independent experts established in 1998 to review the safety of food supplements containing high levels of vitamins and minerals; their final report can be accessed at http://www.food.gov.uk/multimedia/pdfs/vitmin2003.pdf.

The majority of food supplement products on the UK market contain amounts of vitamins and minerals that are below the safe upper level guidelines established by the EVM. However, a small number of products contain higher amounts, which could cause adverse effects in some individuals. These are some products containing vitamin C, iron, calcium, magnesium, nickel[1], beta-carotene, nicotinic acid, zinc, manganese, phosphorus and vitamin B6. For these substances, it was considered necessary to provide consumers with information to enable them to make informed choices. A series of discussions between government officials and industry representatives resulted in the agreed advisory label statements, and, for three vitamins, suggested reformulations; these are listed in the Annex below.

The recommendations in the Annex were agreed on the basis of scientific evidence considered by the EVM and may be amended if new information on safe upper levels arises. This approach is an important element of the safety-based regulation of food supplements, as it demonstrates a risk management approach, which both protects consumer health and enables informed consumer choice.

This advice was sent to the European Commission, the European Food Safety Authority and other Member States in order to inform further EC discussions on safety-based regulation of food supplements. The Council for Responsible Nutrition, the Health Food Manufacturers Association, and the Proprietary Association of Great Britain have disseminated the advice to their memberships.

---

[1] **On 1 January 2010 the EU list of permitted vitamins and minerals was updated and national derogations for substances not on the list ended. The mineral nickel does not appear on the list of vitamins and minerals which are permitted for use in food supplements, its inclusion in this list is for information only.**

ANNEX: LIST OF ADVISORY STATEMENTS

Label advisory statements and re-formulations agreed with the FSA and industry, May 2004

Nutrient	**Threshold to trigger statement** (recommended daily amount)	**Label advisory statement/reformulation**
Vitamin C	> 1000 mg	'[This amount of Vitamin C]* may cause mild stomach upset in sensitive individuals.'
Iron	> 20 mg	'[This amount of Iron]* may cause mild stomach upset in sensitive individuals'
Calcium	> 1500 mg	'[This amount of Calcium]* may cause mild stomach upset in sensitive individuals.'
Magnesium	> 400 mg	'[This amount of Magnesium]* may cause mild stomach upset in sensitive individuals.'
Nickel	All nickel-containing products See footnote [1]	'[Nickel]* may cause a skin rash in sensitive individuals.'
Beta-carotene	1) >7 mg 2) See footnote[2]	1) Encourage reformulation to < 7 mg/day. 2) Label statement: '[Beta-carotene]* should not be taken by heavy smokers.'
Nicotinic acid	> 20 mg	1) Encourage reformulation to nicotinamide. 2) If nicotinic acid is used, label statement: '[This amount of Nicotinic acid]* may cause skin flushes in sensitive individuals'.
Zinc	> 25 mg	Label statement: 'Long term intake [of this amount of zinc]* may lead to anaemia.'
Manganese	See footnote[3]	Label statement: 'Long term intake [of this amount of manganese]* may lead to muscle pain and fatigue.'
Phosphorus	> 250 mg	Label statement: '[This amount of Phosphorus]* may cause mild stomach upsets in sensitive individuals.'[4]
Vitamin B6	> 10 mg > 100 mg	Label statement: 'Long term intakes [of this amount of vitamin B6]* may lead to mild tingling and numbness.' Encourage reformulation to lower daily amount.

Label advisory statement agreed with Department of Health and Ministry of Agriculture, Fisheries and Food (MAFF) in 1991

Vitamin A	> 800μg[5] of preformed vitamin A (as retinol, not beta-carotene)	Label statement: This product contains vitamin A. Do not take if you are pregnant or likely to become pregnant except on the advice of a doctor or antenatal clinic.

Notes on the table:

*** For single nutrient products, the words in square brackets may be deleted.**
[1] Nickel is not included on the lists of vitamins and minerals that are permitted for use in food supplements under the EU Food Supplements Directive; the substance is included here for information only.
[2] Government officials considered that the labels of all food supplements containing beta-carotene should carry the advisory statement '[Beta-carotene]* should not be taken by heavy smokers.' Industry considered that this should only be on products recommending a daily amount > 7mg. This footnote is for information only; it will not appear on labels.
[3] Government officials considered that the labels of all food supplements recommending a daily amount greater than 0.5mg manganese should carry this advisory statement. Industry considered that this statement could only be justified on products recommending a daily amount greater than 4mg. This footnote is for information here; it will not appear on labels.
[4] Government officials wanted a second sentence 'Long term intake [of this amount of phosphorus] may weaken bones' to be included in the advisory statement for phosphorus. Industry did not agree that inclusion of the second sentence was warranted. Officials asked the Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) to look in detail at the effects of phosphate intake on parathyroid hormone and bone metabolism including new data on phosphate regulation. The wording of the advisory statement will be reconsidered following receipt of COT advice. This footnote is for information here; it will not appear on labels.

The COT reviewed the issue and took into account the publication of new data. The outcome of this review can be found at the link below entitled 'COT statement on phosphate and the calcium parathyroid hormone axis'. In the light of the COT advice, there is insufficient data to proceed with an advisory statement on bone. Since the long-term effects of phosphate are unknown, the issue is currently unresolved and will be kept under review.
http://www.food.gov.uk/science/ouradvisors/cot/cotstatements/cotstatementsyrs/cotstatements2005/cotstatements2005phoscpha

[5] Department of Health advice is to avoid any supplements containing vitamin A during pregnancy.

Notes
a) No vitamins are completely stable and they deteriorate at different rates. Amounts of vitamins are added to food supplements during manufacture to compensate for losses during shelf life. For very unstable nutrients, such as vitamin C, the threshold values above refer to the declared amount and manufacturers will strive to use only the necessary quantities in the products to ensure 100 per cent of the declared value at the end of shelf-life.
b) All sources of nutrients in a product should be taken into account when declaring the quantities of nutrients and in deciding if the trigger level for an advisory statement has been exceeded.
c) These advisory statements are based on current evidence and are subject to change in the light of new evidence and advice.