

PRESS RELEASE
For immediate release
12th November 2009



FOOD SUPPLEMENT BAN IN 2010 MAY CONTRAVENE EU LAW

The Alliance for Natural Health (ANH) has informed the UK's food regulator, the Food Standards Agency (FSA), that the proposed ban on particular vitamin and mineral food supplements from 1 January 2010 flies in the face of the European Court of Justice ruling on the ANH's case in 2005.

In a recent consultation, the ANH, an international campaign organisation representing sectors of the natural products trade, practitioners and consumers, has raised major concerns over the FSA's proposed approach to 'rubber stamping' the European Commission's proposed draft Regulation on food supplements.

The natural products industry in the UK, as well as in other EU Member States, has been asked to approve changes even before the draft Regulation amending the EU Food Supplements Directive of 2002 has been ratified in Europe. The reason given for the rush is the desire to stick to the date given in the 2002 Directive, which states that the derogation phase expires on 31 December 2009. This means that any vitamin or mineral forms not complying with the new list of approved forms, as given in the draft Regulation as proposed by the European Commission, will be banned as of 1 January 2010.

The draft Regulation adds just 69 additional vitamin and mineral forms to the previous list of 112 forms. All other vitamin and minerals forms will be banned, this affecting hundreds of products that have been selling freely, under the derogation, in more liberal Member States such as the UK. Amongst the casualties are all food supplements containing vanadium or silver, as well as many mineral amino acid chelates.

In its submission to the FSA (download via link in Editor's Notes), the ANH has asserted that the ban on all forms of vanadium cannot be justified. This is especially the case given the opinion of the European Food Safety Authority (EFSA) that stated that vanadium pentoxide has about equivalent (relatively low) bioavailability as vanadium found naturally in foods (such as shellfish). The ANH points out that paragraph 73 of the ruling on its case in the European Court of Justice (*Alliance for Natural Health and others* (2004); Joined Cases C-154/04 and C-155/04) implies that a ban cannot be implemented by a competent authority unless a risk to public health following scientific risk assessment can be proven. The scientific literature has revealed that there is no evidence that certain forms of vanadium, such as vanadium pentoxide, pose any risk to health at commonly recommended dosages.

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The ANH said it was mystified why sulphur was excluded from the list of allowed minerals when the Directive already allowed a number of sulphate salts of minerals, all of which delivered sulphur to the body. The continued exclusion of sulphur means that key supplemental forms of sulphur, such as MSM (methyl-sulfonyl-methane) that is used to support, among other things, healthy joints, skin, nails and energy levels, cannot be properly legitimised in the EU.

The ANH submission also slammed the contrasting approaches to risk assessment used by the EU's scientific evaluation body for foods, EFSA. The ANH was surprised to see that selenious acid, a highly toxic form of selenium used in 'gun blue' solution that has been responsible for the death of a number of children following its consumption, had been approved. In contrast, selenocysteine, a naturally occurring form of selenium found in a variety of foods such as mushrooms, was not.

Robert Verkerk PhD, executive and scientific director of the ANH said, *"The lack of scientific rationale behind some of the approvals and rejections beggars belief. Member States need to review their decisions to implement the Commission's proposed draft Regulation in the light of existing European case law, including that relating to our case that was ruled on in 2005. Additionally, in order to not compromise consumer choice, the industry needs to get serious about submitting further dossiers including safety and bioavailability data for many of the ingredients that will be lost as of January next year. We also need to see much more transparency and a level playing field in the evaluation process used by EFSA, as well as the way in which opinions are interpreted by the European Commission and Member States."*

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EDITORS' NOTES

The EU Food Supplements Directive (2002/46/EC) harmonises allowed forms of vitamins and minerals EU-wide. Subsequently the Directive will be amended to harmonise both maximum and minimum dosages. Although the Directive was transposed into Member State laws from 2003, a ban on several hundred forms was avoided on 1 August 2005 because the derogation provision in the Directive allowed continued use of vitamin and mineral forms for which dossiers had been submitted to the European Commission.

The derogation provision, under Article 4(6) of the Directive, allows those forms that were already on the market at the time the Directive came into force (2003) to continue to be sold until the end of the derogation phase on 31 December 2009. The only exception to this is in cases where a negative opinion has been issued following evaluation of a dossier by the European Food Safety Authority (EFSA) in which case Member State competent authorities are required to instigate a ban.

The submission of over 500 dossiers for particular vitamins and minerals forms in 2005 prevented a ban on thousands of products containing those forms of nutrients in August 2005. However, the Commission's proposed draft Regulation mandates only an additional 69 vitamin and mineral forms over the 112 listed in the original Directive. As of 1 January 2010 all vitamins and minerals not complying with the revised positive list of allowed vitamin and minerals forms (Annex II) will be banned, unless the procedure fails to be fully accepted, or is delayed, by Member States or the European Parliament.

Download full ANH submission to the UK Food Standards Agency:

http://www.anhcampaign.org/files/091109_FSA-comments-re-SI-for-Food-Supps-Reg-2010_final.pdf

European Commission proposed draft regulation:

http://members.wto.org/crnattachments/2009/tbt/eec/09_2752_00_e.pdf

About the Alliance for Natural Health:

www.anhcampaign.org

The Alliance for Natural Health (ANH) is an international, non-governmental organisation, based in the UK. It was founded in 2002, and works on behalf of consumers, medical doctors, complementary health practitioners and health-product suppliers worldwide, to promote natural and sustainable health, using the principles of good science and good law.