

**COMMENTS RE PROPOSED NEW UK STATUTORY INSTRUMENT ON
FOOD SUPPLEMENTS, PARTICULARLY THE AMENDMENT OF ANNEXES**

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The following comments are submitted by the Alliance for Natural Health (ANH), an international science and law based non-governmental organisation that works in particular to help shape scientifically rational and legally proportionate regulatory frameworks for natural health. The ANH represents significant leading-edge interests reliant on advanced forms of food supplements, particularly through the ANH Innovators Club and through its support of practitioners (notably qualified clinical nutritionists [including medical doctors] and nutritional therapists), both in the UK and EU-wide.

The present comments refer almost exclusively to the proposed amended regulation of food supplements, rather than that for fortified foods. We are not commenting on the regulation of fortified foods because the ANH does not represent significant players in the fortified foods sector.

We learn from your request to interested parties that “short, informal, consultations were undertaken with stakeholders by e-mail on drafts of the Commission Regulation....” and we are deeply concerned that the ANH was not among the interests who were invited to submit comment. This is especially the case given that the ANH was party to a judicial review of Directive 2002/46/EC between 2003 and 2005.

The replacement of the original Annexes I and II of Directive 2002/46/EC with the proposed annexes of the draft Regulation essentially results in the addition of 69 (as opposed to the 67 indicated by the FSA) vitamin and forms to the ‘positive list’ of Annex II. Just two mineral groups are added to Annex I, namely boron and silicon. The inclusion of these additional sources is intended to reflect opinions of the European Food Safety Authority, which, under the terms of Directive 2002/46/EC, has evaluated several hundred sources that have been derogated for use since 1 August 2005.

The ANH comments are divided into two sections, Section A dealing with general comments and Section B, covering more specific concerns.

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A. General concerns

Following are some general concerns relating to the draft Regulation. These concerns have been overlooked by the European Commission and Standing Committee on the Food Chain and Animal Health (SCoFAH).

However, given it is the transposition of EU Directives into Member State laws that impacts food supplement suppliers and consumers, we consider it appropriate that the UK (and other Member State) statutory instruments be modified accordingly. Our concerns not only relate to the exclusion of particular nutrients and forms (that are known to be safe at typical recommended doses), they also relate to the inclusion of particular chemical forms owing to their acute toxicity (e.g., selenious acid) or the fact that the chemical form is not being used for nutritional purposes but rather for an apparent medicinal purpose (e.g., sodium monofluorophosphate to prevent tooth decay).

1. The lack of inclusion of two minerals in particular, namely sulphur and vanadium, to the proposed new Annex I is anomalous given the fact that both minerals are “found in and consumed as part of the diet”, this being the only criterion relevant to the inclusion in Annex I, as confirmed by the ECJ judgment on *Alliance for Natural Health and others* (2005), Joined Cases C154-04 and C155-04, paragraph 91.
2. Furthermore, paragraph 135 of the above ECJ judgment also confirms that the only vitamins and minerals that should be affected by the prohibition are those “which are not normally found in, or consumed as part of, the diet.” On this basis, the disallowance of sulphur and vanadium, along with a number of other minerals (e.g., strontium, silver, germanium, lithium) cannot be legally justified. Scientific references supporting the presence of these minerals in foods are given in Appendix 1 of this consultation response, these having been submitted by the ANH to the European Commission in 2007. The European Commission opted to not forward these dossiers to the EFSA given that accompanying Annex II submissions were not made alongside these minerals, with the exception of strontium.
3. The lack of inclusion of sulphur in Annex I is particularly anomalous given the presence of sulphur in mineral forms listed in both the original and proposed new Annex II, as sulphates. Sulphur is an important nutrient (being present particularly in brassica vegetables¹) and has been used in supplemental forms safely for decades, for example in the form of sulphate salts of various minerals and as methyl-sulfonyl-methane (MSM). The fact that sulphur is included only as a salt is not a valid reason to exclude it from Annex I; iodine,

¹ Koralewska A, Posthumus FS, Stuiver CE, Buchner P, Hawkesford MJ, De Kok LJ. The characteristic high sulfate content in Brassica oleracea is controlled by the expression and activity of sulfate transporters. *Plant Biol (Stuttg)*. 2007; 9(5): 654-61.

which is included on Annex I, is also included only as a salt (e.g., sodium iodide/iodate, potassium iodide/iodate).

4. The decision by the European Commission and the SCoFCAH to reject nutrient sources on the basis of so-called negative opinions by EFSA, and accept those on the basis of positive opinions by EFSA, creates an uneven playing field, especially when also compared with vitamin and mineral forms listed in the original Annex II of Directive 2002/46/EC. For example, the acceptance of selenious acid (an industrial chemical and key component of 'Super Blue' or 'gun blue' which is highly toxic and has caused several acute lethal cases of poisoning^{2,3}) and the rejection of selenocysteine (which occurs naturally in selenium rich foods such as certain types of mushroom⁴) has no logical scientific basis when comparative risk is evaluated from known data. Similarly, the rejection of calcium aspartate (based only on the fact that aspartate intake might exceed a level causing amino acid imbalance if calcium, magnesium and potassium were all consumed at the maximum level considered by petitioners) is irrational when EFSA could have indicated that calcium aspartate could be safely consumed on the condition that aspartate intake does not exceed 6 g/day). The inclusion of sodium and potassium fluoride on the original list is also irrational given their clear acute toxicity (sodium fluoride has been used for decades as an insecticide and rodent poison⁵). Finally, it is clear from the EFSA opinion that the intended use of sodium monofluorophosphate is to supply fluoride as a means of preventing tooth decay.⁶ The ANH has previously exposed significant problems with the EFSA opinion on sodium monofluorophosphate.⁷ This intended use is in fact medicinal and outside the scope of food supplement law as described in Article 2a of Directive 2002/46/EC.

² Lombeck I, Menzel H, Frosch D. Acute selenium poisoning of a 2-year-old child. *Eur J Pediatr.* 1987; 146(3): 308-12.

³ Quadrani DA, Spiller HA, Steinhorn D. A fatal case of gun blue ingestion in a toddler. *Vet Hum Toxicol.* 2000; 42(2): 96-8.

⁴ Falandysz J. Selenium in edible mushrooms. *J Environ Sci Health C Environ Carcinog Ecotoxicol Rev.* 2008; 26(3): 256-99. Review.

⁵ Rabinowitch IM. Acute Fluoride Poisoning. *Can Med Assoc J.* 1945 April; 52(4): 345-349.

⁶ EFSA opinion on sodium monofluorophosphate:
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902213175.htm.

⁷ ANH commentary on EFSA opinion on sodium monofluorophosphate:
http://anhcampaign.org/files/090126_ANH_EFSA-sodium-monofluorophosphate-opinion.pdf.

B. Specific comments

1. Vitamin E

While “tocotrienol tocopherol” may have been the name given by the petitioner and was the form of vitamin E containing various isomers of both tocopherols and tocotrienols that was evaluated by EFSA, the name is confusing. The double asterisk adjacent to the form in Annex II (section A.3) links to a ‘typical analysis’ containing various quantities of 4 isomers (α , β , δ and γ) of both tocopherols and isomers. These amounts were clearly reflective of the amounts present in the form submitted by the petitioner. We would contest in particular the level of γ -tocopherol, which could easily be present (in other forms of full spectrum vitamin E) in at least or greater quantities than the α -tocopherol isomer. We see no reason why the γ -tocopherol level or range (which is the predominant form in the diet) should not be at least equivalent to that for α -tocopherol. We also suggest that the term “tocotrienol tocopherol” which is scientifically incorrect and confusing, should be changed to “mixed tocopherols and tocotrienols”. This would also be in keeping with the “mixed tocopherols” form already listed in the new Annex II, the presence (or absence) of low levels of tocotrienols being the principal feature distinguishing the two forms.

2. Folate

While the calcium-L-methylfolate form has been added and refers to a proprietary form of folate produced by Merck, the generic polyglutamate form, which is typically the most abundant form of natural folate in diets rich in natural folates, should be added to Annex II, namely 5-methyltetrahydrofolate (or 5-methyltetrahydrofolic acid). Additionally, the other common form of natural folate, 5-formyltetrahydrofolate (also known as 5-formyltetrahydrofolic acid or folinic acid) should also be added, given its importance and health benefits. The safety and bioavailability of these forms have been well studied.

3. Sodium

Why does sodium chloride continue to be listed in Annex II when it is clearly associated with hypertension risk and the FSA itself has an ongoing salt awareness campaign.

4. Chromium

Given the extensive work by Diane Stearns and co-workers, showing the potential of chromium picolinate but not polynicotinate to cause DNA damage,^{8,9,10,11} it is of concern that chromium picolinate is allowed, while chromium polynicotinate is not.

⁸ Stearns DM, Wise JP Sr, Patierno SR, Wetterhahn KE. Chromium(III) picolinate produces chromosome damage in Chinese hamster ovary cells. *FASEB J.* 1995; 9(15): 1643-8.

5. Fluoride

Sodium and potassium fluoride continue to be listed on Annex II. The question is, where are the data demonstrating safe usage in supplements following full scientific risk analysis? Additionally, what is the evidence supporting the use of sodium monofluorophosphate for nutritional rather than medicinal purposes?

6. Vanadium

The EFSA opinion on vanadium¹² recognises that vanadium is normally consumed as part of the diet, the sole criterion required for inclusion on Annex I (ECJ Joined Cases C-154/04 and C-155/04). The EFSA opinion also makes clear that vanadium pentoxide has low bioavailability and approximately equivalent bioavailability of vanadium forms found in the diet. On this basis, there is no scientifically rational basis for banning all forms of vanadium, and especially not vanadium pentoxide.

Conclusion

There are some serious anomalous issues arising from the wholesale adoption of the Annexes I and II as proposed in the draft European Regulation. The ANH argues that adoption of these lists creates discrepancies that are not aligned with the principles given in paragraph 73 of the ECJ judgment (Alliance for Natural Health and others [2005], Joined Cases C-154/04 and C-155/04) as shown below:

An application to have a substance included on a list of authorised substances may be refused by the competent authorities only on the basis of a full assessment of the risk posed to public health by the substance, established on the basis of the most reliable scientific data available and the most recent results of international research. If the procedure results in a refusal, the refusal must be open to challenge before the courts (see, by analogy, Case C-24/00 *Commission v France* [2004] ECR I-1277, paragraphs 26, 27 and 36, and Case C-95/01 *Greenham and Abel* [2004] ECR I-1333, paragraphs 35, 36 and 50).

⁹ Stearns DM, Silveira SM, Wolf KK, Luke AM. Chromium(III) tris(picolate) is mutagenic at the hypoxanthine (guanine) phosphoribosyltransferase locus in Chinese hamster ovary cells. *Mutat Res.* 2002 Jan 15;513(1-2):135-42.

¹⁰ Manygoats KR, Yazzie M, Stearns DM. Ultrastructural damage in chromium picolinate-treated cells: a TEM study. *Transmission electron microscopy. J Biol Inorg Chem.* 2002; 7(7-8): 791-8.

¹¹ Coryell VH, Stearns DM. Molecular analysis of hprt mutations induced by chromium picolinate in CHO AA8 cells. *Mutat Res.* 2006; 610(1-2): 114-23.

¹² EFSA opinion on various forms of vanadium:
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178689480914.htm.

On this basis, many of the rejections, such as for vanadium pentoxide, selenocysteine and numerous mineral amino acid chelates, cannot be justified.

We therefore argue that it is incumbent on the UK, and other Member State competent authorities, to rectify such discrepancies and anomalies. This is necessary to ensure that any unnecessary and disproportionate impacts on suppliers and consumers of food supplements are not experienced, while at the same time consumers are not exposed to unnecessary risk.

The ANH would be very happy to engage in constructive consideration of these matters and would welcome a meeting with the FSA at the earliest mutually convenient time to discuss these issues on behalf of food supplement interests represented by the ANH.