# PETITION SEEKING URGENT REVIEW OF RISK ASSESSMENT AND MANAGEMENT OPTIONS UNDER CONSIDERATION BY THE EUROPEAN COMMISSION AND EUROPEAN FOOD SAFETY AUTHORITY FOR LIMITING CONSUMER ACCESS TO VITAMINS AND MINERALS

**Filed by:** Dr Robert Verkerk, on behalf of the Alliance for Natural Health

**Contacts:** Alliance for Natural Health, The Atrium, Curtis Road,
Dorking, Surrey RH4 1XA, United Kingdom
Tel: +44 (0)1306 646 600
Email: info@anhcampaign.org
Web: www.anhcampaign.org

**Intended beneficiaries:** consumers of higher dosage vitamin and mineral supplements; those who choose to use food supplements to increase their intake of vitamins and minerals; those with a genetic requirement for higher than average intakes of vitamins and minerals; practitioners of nutritional, functional and naturopathic medicine, who have used high dose vitamins and minerals for decades with little or no evidence of harm, and substantial evidence of benefit; the patients and clients of these practitioners; manufacturers, distributors and retailers of higher dose vitamin and mineral supplements, whose businesses would be severely damaged by a ban on such supplements.

**Petition Host:** Kathy Sinnott, Member of the European Parliament [MEP] from Ireland South

## Key purpose of the petition

The key purpose of this petition is to stimulate an urgent review of risk assessment and management approaches presently under consideration by the European Commission and the European Food Safety Authority (EFSA). If these approaches are not altered, it appears highly likely that consumer freedom of choice, at least in the UK, Ireland, the Netherlands and Sweden, will be dramatically curtailed and businesses reliant on sale of higher dose vitamin and mineral supplements will be adversely affected. These risk assessment and management approaches directly determine the maximum permitted levels (MPLs) for vitamin and mineral food supplements, which will be harmonised EU-wide. Given clear scientific flaws in present methodologies under consideration, which, if implemented, will lead to severe and disproportionate impacts on small to medium sized enterprises (SMEs), the review should be independent and take into account the latest scientific data and clinical experience. Risk management options emerging from this process should be proportionate to the risk of consuming individual nutrient forms and must be consistent with the known safety of these nutrients as consumed in the normal diet.

## Background

The Food Supplements Directive (Directive 2002/46/EC), under Article 5, indicates the intention to harmonise maximum (and minimum) levels of vitamins and minerals in food supplements. The EFSA is now at an advanced stage of considering maximum safe levels for supplements (and fortified foods). These levels are likely to be substantially less than those presently allowed in countries such as the UK, Ireland, the Netherlands and Sweden.

There is little or no evidence that present high dose usage of food supplements in these countries constitutes a risk to public health. The Irish Association of Health

Stores (IAHS) has previously filed a petition, which has been found admissible (March 2008) and is presently under consideration by the European Commission. The IAHS petition focuses in particular on the potential impact these proposed measures would have on Irish health food stores should they be implemented.

The present petition focuses solely on the methodologies used for determining risk management options. It is therefore complementary to the IAHS petition yet in no way overlaps with it.

There is great concern, particularly from medical and complementary medicine practitioners, that both the proposed risk categorisation of vitamins and minerals, as well as likely proposed MPLs, do not reflect the known safety of vitamins and minerals consumed either in supplements or the diet. Nor do they differentiate between the risk of different forms of vitamin and mineral, with the exception of two forms of vitamin B3, namely niacin (nicotinic acid) and niacinamide.

The primary justification for restrictive, harmonising regulation affecting doses of vitamins and minerals is that it facilitates the single market and is required to ensure a high level of consumer protection. However, harmonisation in itself does not warrant excessive restriction. Harmonisation, for this purpose, could just as well liberalise EU markets. An intention to achieve a high level of consumer protection, on the other hand, does, at least in theory, provide a justification for restriction, assuming the requirement for a precautionary approach. Despite the fact that it is almost impossible, using observational or epidemiological data, to demonstrate that existing use patterns in Member States with more liberal regimes (e.g., UK, Ireland, the Netherlands and Sweden) create any significant health risk, the protagonists of ultra-restrictive usage of vitamins and minerals have found a variety of ways of demonstrating risk on a theoretical basis.

Theoretical risk has been determined through a process referred to as 'scientific risk assessment'. In order to manage the risk, a second, discrete process—'risk management'—is used. The end result of risk management, as proposed under the terms of Article 5 of Directive 2002/46/EC, is dramatic restrictions on the usage of higher dosages of vitamins and minerals. The methodologies for determining how to enact this requirement are still under consideration by EFSA. This petition seeks to ensure that new evidence and concepts are considered as a matter of urgency in order to avoid the instigation of disproportionate risk management measures that could severely impact consumers, practitioners who supply such products and the SMEs that manufacture, distribute or sell them.

**An example: the case of vitamin C**

Risk assessment by EFSA (or its predecessor the EU Scientific Committee on Food [SCF]) produces an alleged Safe Upper Level (SUL) of 1000 mg for vitamin C, implying that this is the maximum dosage that can be consumed by 97.5% of the population without *any* type of adverse effect. In the case of vitamin C, the only known risk is the production of loose stools following consumption of large single doses. The risk management step typically involves subtracting the highest mean intakes in the diet from the SUL to produce a maximum daily dosage for regulatory purposes. The Federal Institute for Risk Assessment (BfR) in Germany have done precisely this and ended up with a figure of 225 mg as a maximum daily dosage for vitamin C. This dosage is well beneath that considered to be useful for health promotion by clinical nutritionists and other practitioners using vitamins and minerals. It is relevant that the German authorities are already implementing BfR levels as maximum levels for new products being introduced to the German market.

In the case of vitamin C, imposing a restriction on maximum levels of all forms of vitamin C at a given low dosage is far from the only risk management option. The following two options much better reflect the existing science and risk profile:

a) providing a warning statement on vitamin C products recommending that daily dosages above a given threshold should be divided (i.e. take *x* number of capsules, *y* times a day) to reduce the risk of loose bowels;

b) imposing different risk management options for different forms of vitamin C. For example, L-ascorbic acid generally produces loose stools at lower dosages than mineral ascorbates. Therefore, applying the same risk management option to all forms of vitamin C would result in disproportionate impacts.

**Other considerations**

Maximum levels emerging either from the BfR model, or an alternative industry model, named after the two European trade associations, EHPM and ERNA, produce levels that are well beneath those often used safely by practitioners. Some of the levels are even beneath the current EU Recommended Daily Amounts (RDA). In fact, most of these levels are substantially below those consumed by health-conscious consumers keen to take responsibility for their own health.

A recent survey by the ANH of US practitioner products sold in the UK revealed that around 100% of the top 30 selling products had more than one ingredient in excess of the BfR levels, while around 70% exceeded another set of maximum levels (proposed by EHPM/ERNA). A further 60% of products exceeded even the SULs! All of this, when practitioner products are not only doing no harm, but are benefiting substantial numbers of people—a fact that is completely, and deliberately, ignored by the over-zealous risk assessors and managers. This situation is not limited to the practitioner suppliers, but also involves many independent health stores who would be forced to close having had much of their stock effectively banned from sale (see IAHS petition).

**The Alliance for Natural Health's previous engagement with this issue**

The ANH acts as the key representative, at a European level, for the complementary medical practitioners using vitamin and mineral supplements as interventions in healthcare. The ANH has pioneered the deconstruction of these flawed risk assessment and risk management processes since 2004, when it first made a major submission to the FAO/WHO nutrient risk assessment project. The report was endorsed by a wide range of leading practitioners in the United States, Canada and the UK including Drs Jonathan Wright, Abram Hoffer, Jeff Bland, Julian Whitaker, Steve Levine, Alan Gaby, and others[1].

The ANH has made numerous submissions on this subject since this time, most recently responding to the European Commission's consultation in October 2007.[2]

---

[1] ANH submission to FAO/WHO nutrient risk assessment project (2004): http://www.anhcampaign.org/documents/anh-consultation-response-faowho-nutrient-risk-assessment-project.

[2] ANH Position Paper on Maximum Permitted Levels, October 2007: http://www.anhcampaign.org/files/071015_ANH_position_MPLs_final.pdf.

Dr Robert Verkerk, ANH's executive and scientific director, was an active participant at an EFSA colloquium in July 2006 and many of these concerns were accepted by the scientists present and were committed to the published proceedings of the meeting.[3]

The Netherlands-based HAN Foundation has published 6 papers in peer reviewed journals on this issue, the most recent and important paper having been accepted for publication in *Risk Analysis* in August 2008. This paper is of key relevance to the review recommended as part of the present petition. The paper demonstrates why the approach being considered by the European Commission to categorise risk of vitamins and minerals, which is reliant on the margin between the Recommended Daily Allowance (RDA) and the Safe Upper Levels (SULs), is scientifically invalid.

The ANH has determined that a relatively small number of changes to the existing models under consideration could dramatically improve the likely negative regulatory impact of EU harmonised MPLs. These factors, which should inform the final risk management options, include, in particular, the following:

a) the discrete risk profile associated with particular nutrient forms as opposed to applying the risk profile for the most toxic member of the nutrient group to all members of the same group;

b) factoring in the slope of the dose/response curve, which greatly impacts the consequences of exceeding the SUL;

c) the application of a risk factor which accounts for the type, severity and reversibility of the adverse impact.

According to the risk assessment, a diverse range of risk options should be considered, not simply the imposition of a legal maximum level, which would prevent large numbers of people accessing food supplements containing beneficial dosages. Options should include such things as division of daily dosages and provision of warning statement for susceptible groups. These approaches are already used in the food industry.

**Petition request**

The primary objectives of this petition, which requires the urgent attention of the European Commission, the European Parliament, the European Food Safety Authority and Member State governments, are summarised below:

1. To initiate a full review, conducted by a non-partisan committee of independent scientists, of risk assessment and management approaches for vitamin and mineral supplementation, ensuring that outputs are validated against known safety thresholds as established from observational studies and clinical experience;

2. The review should include the re-assessment of risk for individual nutrient forms, where it can be demonstrated that risk varies significantly between nutrient forms (e.g., vitamin D2 vs D3, iron sulphate vs iron bisglycinate, folic acid vs polyglutamate folates, etc.);

3. The review should take into account the nature of any potential adverse effect, by applying a weighting factor proportional to the severity of the effect

[3] EFSA report of 6th Colloquium on Risk Benefit Assessment of Foods: http://www.efsa.europa.eu/EFSA/ScientificOpinionPublicationReport/EFSAScientificColloquiumReports/efsa_locale-1178620753812_Risk-benefitAnalysisOfFoods.htm.

(e.g., the risk of a niacin flush or vitamin C induced loose bowel would be allocated substantially less weighting than ultra high dose vitamin A induced hepatotoxicity);

4. Consideration should be given to the severity of the risk if SULs are exceeded, a situation that can be accounted for by considering the slope of the dose/response curve and the nature of the adverse effect. For example, where the dose/response curve is shallow, as is the case for calcium, the effects of exceeding the SUL by say 30% are likely to be considerably less than exceeding the SUL of another nutrient with steep dose/response, such as selenium, particularly over longer term usage, could be considerably more problematic). Risk assessments often cite the absence of dose/response data in the published literature as a reason for ignoring their consideration. However, a comprehensive source of such data is available from clinical nutritionists, their medical records and from analytical laboratory data compiled specifically to inform the therapeutic protocols of these practitioners.

5. Development of a more sophisticated range of risk management options that go well beyond the binary 'allowed' or 'banned' approach. The use of carefully considered warning labels targeting susceptible groups would be key (e.g., rather than banning dosages of vitamin C in excess of 500 mg or 1000 mg, an obvious risk management option would be to stipulate the need for divided doses to reduce the risk of loose bowels in sensitive individuals);

6. Validation of all models and model outputs against reality i.e., what is known both from clinical practice and published observational and epidemiological studies. Remarkably, this important validation step has been ignored by EU risk assessors, and explains why BfR have issued maximum levels that represent inadequate intakes for many people.

**About the Alliance for Natural Health – www.anhcampaign.org**

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

The ANH's chief objective is to help develop an appropriate legal-scientific framework and environment for the development of sustainable approaches to healthcare, while also helping to promote natural health. Within this setting, consumers and health professionals should be able to make informed choices about a wide range of health options, and in particular those that relate to diet, lifestyle and non-drug-based or natural therapies, so that they may experience their benefits to the full while not exposing themselves to unnecessary risks.

The ANH has pioneered the concept of sustainability as applied to healthcare - a concept that is already the most acceptable long-term approach for a variety of other industries, including agriculture, energy, construction and tourism. But pharmaceutically based, orthodox western medicine has strenuously avoided associating itself with the notion of sustainability. Western healthcare is now considered to be the third leading cause of death in industrialised countries in the West, and it is increasingly threatening and continuing to replace long-established traditional systems of healthcare in regions of the world, including the Indian sub-continent, South-East Asia, Southern Africa and South America.