Solutions

- As previously clarified by a court case initiated by ANH-Intl (Joined Cases C-154/04 and 155/04), natural sources of vitamins and minerals that are naturally present within foodstuffs are outside the scope of the FSD – and should be used by manufacturers wherever possible
- Manufacturers should make more applications for new sources of vitamins and minerals under the simplified procedure referred to in the above court case – and legally challenge any rejections according to the procedure outlined in paragraph 73 of the same case
- Consumers and industry must work with EU Member States to ensure that as many botanicals and other non-vitamin and mineral substances as possible are included in food supplements, to avoid unnecessary classification as medicines or novel foods
- Maintain pressure on the European Commission, EFSA and EU Member States both to reform the draconian Nutrition and Health Claims Regulation and to use appropriate science[1, 2] to determine MPLs.

[1] Verkerk RH, Hickey S. Toxicology 2010; 278(1): 17–26.
[2] Verkerk RH. Toxicology 2010; 278(1): 27–38.

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Food Supplements in Europe

"Narrowing scope seriously threatens food supplement freedom of choice"

Relevant legislation

Food Supplements Directive (FSD; Directive 2002/26/EC, as amended); Nutrition and Health Claims Regulation (NHCR; Regulation 1924/2006, as amended); Novel Foods Regulation (NFR; Regulation 258/1997, as amended); Human Medicinal Products Directive (HMPD; Directive 2001/83/EC, as amended); Food for Particular Nutritional Uses Directive (PARNUTS; Directive 2009/39/EC)

How are food supplements regulated?

- Several pieces of European Union (EU) legislation (left) interact to regulate various aspects of food supplements
- **Medicine or food supplement?:** The HMPD's functional limb (Article 1.2(b)) of the definition of a medicine technically makes all foods, including food supplements, and cosmetics medicines – unless they are "clearly" (7th recital of amending Directive) foods, supplements or cosmetics. If in doubt, medicines law reigns supreme (Article 2.2), so regulators may declare any food supplement to be medicinal at any time
- **Ingredients:** The FSD's 'positive lists' (amending Regulation (EC) 1170/2009) harmonise EU-wide the vitamins and minerals that may be used in the manufacture of food supplements. In addition, the NFR requires pre-market authorisation of any food or food constituent considered not to have been used 'significantly' in the EU prior to 15th May 1997. This includes an altered profile of natural constituents in a botanical, for example, where a novel preparation method is introduced
- **Dosage:** European Commission proposals on maximum (and minimum) permitted levels (MPLs) of vitamins and minerals in food supplements (FSD Article 5) are imminent
- **Health claims:** Manufacturers' permitted claims about the health benefits of food supplements are governed by the NHCR
- **Quality control:** An emerging area of regulation, governed by national legislation in EU Member States

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Positive lists are an example of Napoleonic law, where everything is illegal unless specifically permitted

What are the issues?

- The positive lists are an example of Napoleonic law, where everything is illegal unless specifically permitted
- Several useful vitamin and mineral species are absent from the positive list, e.g. silver, vanadium and many amino acid-chelated minerals
- Because the positive lists derive from PARNUTS legislation – also referred to as 'dietetic foods' law – the permitted vitamin and mineral ingredients mainly comprise inorganic chemicals, rather than the organically complexed forms found in foods that are more compatible with metabolic processes
- Although it is theoretically possible to extend positive lists, applications are subject to a strict process, are very costly and are frequently rejected by the European Food Safety Authority (EFSA)
- As of 14th December 2012, food supplement manufacturers will only be able to make health claims that have been authorised by the European Commission following evaluation of substantiating evidence by EFSA. Authorised and non-authorised health (and nutrition) claims are published on the EU Register of health and nutrition claims [http://ec.europa.eu/nuhclaims]. EFSA has approved less than 250 claims that apply to around 70 foods and ingredients, while rejecting thousands, creating significant problems for the food supplement industry and consumers reliant on such products

The risk assessment methods being used to set MPLs are flawed[1, 2] and could prevent the sale of products with significant beneficial effects

- The risk assessment methods being used to set MPLs are flawed[1, 2] and could prevent the sale of products with significant beneficial effects
- The European Commission indicated in 2008 it does not intend to fully harmonise laws on botanicals, amino acids, essential fatty acids, probiotics and other non-vitamin and mineral substances used in food supplements. Accordingly, these will be regulated by national rules in individual Member States. But, in an effort to align national rules, EFSA has published guidance for risk assessment of botanicals in food supplements, entitled 'Compendium of botanicals reported to contain naturally occurring substances of possible concern for human health when used in food and food supplements'. This is likely to cause regulators to become suspicious of botanicals with a previous long history of safe use. Botanicals subsequently classed as 'herbal medicines' must then face the tortuous approval process offered by the Traditional Herbal Medicinal Products Directive (THMPD) before reaching the market. Examples of botanical species in the EFSA Compendium considered to contain potentially toxic principles are the immune system-enhancing herbs Astragalus spp. and Boswellia serrata, the traditionally used common sage (Salvia officinalis) and the stimulant guarana (Paullinia cupana)
- Because of the diverse range of ingredients found in food supplements, some EU Member State governments are applying unnecessarily tight quality control regimes. These frequently withhold products from the marketplace based on perceived problems with the ingredients and other constituents
- Overall, therefore, the EU food supplements landscape is problematic: botanicals and many useful vitamins and minerals are excluded; the NFR acts as a 'sticky trap' for an increasing number of substances; health claims have been decimated; quality control regimes pose an increasing threat; and European Commission proposals for MPLs can be expected to be unrealistically low.

[1] Verkerk RH, Hickey S. Toxicology 2010; 278(1): 17–26.
[2] Verkerk RH. Toxicology 2010; 278(1): 27–38.