

ANH PRACTITIONER'S SUMMARY: FOOD SUPPLEMENTS DIRECTIVE

Official 'Europa EU' Summary of Legislation
<http://europa.eu/scadplus/leg/en/lvb/l21102.htm>

ANH Position Paper on EU maximum permitted levels: October 2007
http://www.anhcampaing.org/files/071015_ANH_position_MPLs_final.pdf

Useful extracts from Summary of Directive re: 'Composition of food supplements':

'Food Supplements may only contain the vitamins and mineral salts laid down in Annex I, and the vitamin and mineral formulations listed in Annex II, singly or in combination. The Commission is responsible for...the maximum and minimum quantities authorised...

Until 31 December 2009, Member States may allow in their territory the use of vitamins and minerals not listed in Annex I, or in forms not listed in Annex II, provided that: the substance...is used in one or more food supplements (already) marketed in the Community, (and) the EFSA has not given an unfavourable opinion in respect of the use of the substance on the basis of a "scientific safety dossier"...'.

- **Vitamins and Minerals.** Any vitamin or mineral ingredient not on the positive list (which contains primarily synthetic forms of vitamins and inorganic forms of minerals) is effectively banned.

A temporary EU list of derogated vitamin and mineral forms can still be used, and it is hoped that the majority of these will be added to the positive list by the end of 2009.

However, as a result of the ANH legal challenge, and the subsequent European Court of Justice's ruling in April 2005, a diverse range of natural sources of vitamins and minerals are considered by the EC to be outside the scope of this directive, and will be regarded as foods.

- **Vitamin and Mineral Dosages.** In the near future, this directive will be applied to both maximum and minimum allowable dosages, at least for vitamins and minerals. Currently, it looks as if 'maximum permitted levels' (MPLs) will be set so low that they will be much less than that which might be consumed in the conventional diet, which is known to be already nutrient-depleted in many areas. e.g. the maximum permitted level for beta-carotene that is being considered might be less than that which you might consume in two carrots, while that for selenium could be less than that found in just two or three brazil nuts.

All forms of vitamin and mineral, including the natural forms, are being restricted on the basis of some, sometimes spurious, safety concerns with

synthetic forms, and yet these natural forms are not only very safe, but are also beneficial at dosages well above the proposed MPL. The ANH argues that these unnecessarily restrictive EU-wide methods of risk assessment/management, which are being used for the setting of MPLs, are scientifically flawed.

The MPL will likely be used as the borderline between products considered as food supplements and those considered as drugs.

- **Other Nutrients including Botanicals.** This directive will eventually be applied to supplements containing other groups of nutrients, such as essential fatty acids, amino acids, botanicals, etc. The ANH is very concerned that future positive lists for botanical, herbal and other products might be very limited.

The European Food Safety Authority (EFSA) is engaged in developing lists of botanicals with historical use in food supplements e.g. those with psychotropic potential, or those with a history of food or medicinal use, but the ANH believes that the selection process and criteria are not scientifically rational, and is proposing an approach that rectifies these deficiencies.