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ANH BRIEFING PAPER
FOOD SUPPLEMENTS DIRECTIVE: GENERAL

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ABOUT THE FOOD SUPPLEMENTS DIRECTIVE

- The Directive (2002/46/EC), and its related statutory instruments in Member States, aims to harmonise laws relating to food supplements for the purpose of facilitating free trade of food supplements within the European Union, while also protecting consumer health.

- The framework Directive came into force on 1 August 2003 (Article 15(a)). Derogations for products containing vitamin and mineral forms not included on the 'positive list' (Annex II) expire on 31 December 2009 (Art 4(6)).

- The European Food Safety Authority (EFSA) is continuing to evaluate dossiers submitted under this derogation scheme and many derogations have already been withdrawn, while a few have been given negative opinions (e.g. 6 forms of vanadium, vitamin E tocotrienols).

- The Alliance for Natural Health and others brought a Judicial Review of the Directive, initiated in the High Court in London in October 2003, which culminated in a ruling from the European Court of Justice on 12 July 2005 that provided important clarification and accordingly reduced legal uncertainty.

- It is intended that the Directive be applied subsequently to other groups of micronutrients used in food supplements, such as amino acids, essential fatty acids, fibre and botanicals (Recitals 6 and 7; Art 4(8)).

- The Directive will in the near future be amended to limit both maximum and minimum daily dosages of vitamins and minerals in food supplement products across the EU (Article 5). See separate ANH BRIEFING PAPER— FOOD SUPPLEMENTS DIRECTIVE: MAXIMUM PERMITTED LEVELS (MPLs) for further information.

ANH KEY CONCERNS

- **Vitamin and mineral bans in 2010**. There is a considerable risk that significant numbers of vitamin and mineral forms will be banned on 1 January 2010 owing to insufficient data being available to EFSA to verify both their safety and bioavailability. This would be a disproportionate measure if stakeholders who have filed dossiers for derogated nutrients are not given sufficient opportunity to file additional data if required.

- **Scientific basis of EFSA negative opinions**. The negative opinions on 6 forms of vanadium and vitamin E tocotrienols issued by EFSA in February 2008 are not scientifically or legally justifiable given that no exposure or dose level was stipulated—and that risk is clearly dose dependent. Given that safety is a key criterion for determination of eligibility to the 'positive list', a particular nutrient cannot be regarded as generally unsafe, but rather it may become unsafe to particular population groups at a given dosage. A similar legal approach is already taken for certain cosmetics and food additives where levels lower than a stipulated inclusion level are considered safe.

- **Directive scope: nutrients other than vitamins and minerals**. There is considerable uncertainty as to how or if the Directive will be applied to other nutrients (as proposed in Art 4(8)) or how Member States will choose to implement laws affecting these nutrients should EU harmonisation not proceed.

- **Validity of approach to determination of MPLs**. There are significant scientific weaknesses in most of the methods being considered by the European Commission for determination of Maximum Permitted Levels [MPLs] (as per Art 5). This issue is considered further in the separate daily dosages of vitamins and minerals in food supplement products across the EU (Article 5). See separate ANH BRIEFING PAPER— FOOD SUPPLEMENTS DIRECTIVE: MAXIMUM PERMITTED LEVELS (MPLs)

- **Impact of EU medicines laws**. There is legal uncertainty about which food supplements may be considered 'clearly' food supplements, and which may not, as per the wording given in Recital of amending Directive 2004/27/EC on Human Medicinal Products. This may give rise to unjustified medicinal classification of food supplements.