AESGP Position Paper on the European Commission Discussion Paper on the setting of maximum and minimum amounts for vitamins and minerals in foodstuffs

AESGP represents the manufacturers of non-prescription medicinal products and food supplements in Europe.

AESGP appreciates the opportunity to comment on the above-mentioned Discussion Paper.

AESGP would like to stress the importance of setting harmonised maximum and minimum levels for vitamins and minerals in foodstuffs and in food supplements as soon as possible. This would considerably reduce production costs as well as the bureaucratic burden on industry.

It should nonetheless be stressed that every change in legislation requiring reformulation and relabelling is costly and represents a huge internal administrative burden for companies. Therefore it might seem advisable to foresee implementation of harmonised maximum and minimum levels of vitamins and minerals at the same time as the technical revision of the nutrition labelling Directive.

AESGP would like to address the following questions as outlined in the Discussion Paper:

- **In the absence of scientifically established numerical tolerable upper intake levels for several nutrients what should be the upper safe levels for those nutrients that should be taken into account in setting their maximum levels?**

  The SCF and later the EFSA have conducted a thorough evaluation of the scientific data related to vitamins and minerals. In some cases they came to the conclusion that there is insufficient evidence to set a numerical tolerable upper intake level. AESGP believes that in the absence of an EFSA opinion, opinions of other scientific bodies such as the US IOM (FNB) or the UK EVM should be taken into account if upper levels were established by these bodies. These levels could then be regarded as approximate guidance levels for establishing maximum levels on a Community level.

- **For some vitamins and minerals the risk of adverse effects, even at high levels of intakes, appears to be extremely low or non-existent according to available data. Is there any reason to set maximum levels for these vitamins and minerals?**

  Although it seems logical not to set maximum levels for vitamins and minerals which are generally regarded as safe, it should be taken into consideration that Member States, in the absence of concrete Community rules for these vitamins and minerals, might set their own maximum levels for those vitamins and minerals. This would then again lead to a non-harmonised market in food supplements and fortified foods.

  For those nutrients for which a European tolerable upper intake level is missing and for which other bodies (such as US IOM and UK EVM) have set tolerable upper intake levels, levels established by these bodies could be taken as approximate guidance levels for establishing maximum levels on a Community level. In the consequence the same calculation model as the one used for all other vitamins and minerals can be used. AESGP is of the opinion that the most appropriate model for this calculation is the ERNA model as

cited in the Annex of the Discussion Paper.

For those nutrient for which no tolerable upper intake level has been set, because no adverse events were reported even at high dosages, experiences from practice, such as the highest dose marketed safely in a Member State over a long period of time, could be taken into account when setting a maximum level.

For those nutrients for which no tolerable upper intake level has been set but for which adverse events were reported, a tolerable upper intake level could be set close to the dose reported to have an adverse effect. In the consequence the same calculation model (ERNA model) as the one used for all other vitamins and minerals can be used.

- **Where we set maximum levels, do we inevitably also have to set maximum amounts for vitamins and minerals separately for food supplements and fortified foods in order to safeguard both a high level of public health protection and the legitimate expectations of the various food business operators? Are there alternatives?**

Food supplements, contrary to fortified foods, have a defined serving size (e.g., 1 tablet/day) and use. The consumer takes a food supplement with a special aim and deliberately. Fortified foods may also be bought because an added value is expected by the consumer. However, the serving sizes cannot be monitored as precisely as with food supplements and the intake might vary between different days. Moreover the addition of vitamins and minerals to "normal" foodstuffs is limited because of their technological and organoleptic properties.

Therefore AESGP definitely sees a need to set separate levels for fortified foods and for food supplements.

- **The Commission would appreciate receiving available information on intakes of vitamins and minerals or indications of the best sources providing such data at EU level.**

The AESGP membership provided AESGP with the following data of intake studies:

Ortega RM, Mena MC, Faci M, Santana JF, Serra-Majem L.
Vitamin status in different groups of the Spanish population: a meta-analysis of national studies performed between 1990 and 1999.
Public Health Nutr. 2001 Dec;4(6A):1325-9

Ortega RM, Aranceta J, Serra-Majem L, Entrala A, Gil A, Mena MC.
Nutritional risks in the Spanish population: results of the eVe study.
Eur J Clin Nutr. 2003 Sep;57 Suppl 1:S73-5

Joyanes M, Gonzalez-Gross M, Marcos A.
The need to review the Spanish recommended dietary energy and nutrient intakes.
Eur J Clin Nutr. 2002 Sep;56(9):899-905

Serra-Majem L, Ribas L, Ngo J, Aranceta J, Garaulet M, Carazo E, Mataix J, Perez-Rodrigo C, Quemada M, Tojo R, Vazquez C.
Risk of inadequate intakes of vitamins A, B1, B6, C, E, folate, iron and calcium in the Spanish population aged 4 to 18
Int J Vitam Nutr Res. 2001 Nov;71(6):325-31

UK National Diet and Nutrition Survey
Available for the years 2002, 2003, 2004 under the link:
http://www.food.gov.uk/science/101717/ndnsdocuments/

Nutrition Survey in the course of the German Health Survey of the Robert Koch Institute, 1998
http://www.rki.de/cln_006/nn_254456/DE/Content/GBE/Gesundheitsberichterstattung/GBEDownloadsB/was__essen__wir__heute,templateId=raw,property=publicationFile.pdf/was_essen_wir_heute

Dortmund Nutritional and Anthropometric Longitudinally Designed Study (DONALD-Study)
http://kunden.interface-medien.de/fke/index.php

Austrian nutrition report 2003
http://www.univie.ac.at/Ernaehrungswissenschaften/oeeb/OEB2003.htm

- **If such existing data refer only to the intake in some Member States, can they be used for the setting of legitimate and effective maximum levels of vitamins and minerals at European level? On the basis of what adjustments, if any?**

  There is a wide range of national intake data available across the European Union. As the data were collected in different ways, the comparability might be difficult to guarantee. Nonetheless the data could be compiled and a range of intakes in the EU could be established to the best estimate. It could be expected that this range also covers the intake in countries with no nutrition surveys.

  In the absence of harmonised European intake data this might be an appropriate compromise and way forward.

- **Should the intake from different population groups be taken into account in the setting of maximum levels of vitamins and minerals?**

  Food supplements are indicated for the healthy population and not for people with metabolism disorders, as foodstuffs destined for this population group are covered by the PARNUTS category. Therefore it is not necessary to set different levels for this population group.

  If it is envisaged to set different maximum levels for children it might be helpful to take into account available intake data from children and the corresponding tolerable upper intake level.

  Setting maximum levels for other population groups would unnecessarily complicate the procedure without any added value as there are no additional safety concerns (e.g. in elderly people).

- **Taking into account all the above-mentioned considerations, how far should PRIs/RDAs be taken into account when setting maximum levels for vitamins and minerals?**

  RDAs should not be used as the primary criterion for setting maximum levels. RDAs could be taken into account in case there is a safety concern at levels very close to the RDA level. Maximum levels should not be set below one RDA.

- **Should the minimum amount of a vitamin or a mineral in a food to which these nutrients are added be the same as the significant amount required to be present for a claim and/or declaration of the nutrient in nutrition labelling?**
- **Should different minimum amounts be set for certain nutrients in specific foods or categories of foods? If yes, on what basis?**
- **Should minimum amounts for vitamins and minerals in food supplements also be linked to the significant amounts that should be present for labelling purposes or should they be set in a different way?**

  Minimum levels should be harmonised throughout the European Union. AESGP believes that in setting minimum levels there is no need to differentiate between nutrients or between different categories of foodstuffs. The 'significant amount' as currently laid down in the nutrition labelling Directive (15%) seems appropriate.

Brussels, 30 September 2006