EUROMETAUX
EUROPEAN ASSOCIATION OF METALS

WVM
WirtschaftsVereinigung Metalle

Brussels, September 29 2006

Dear Madam,

Dear Sir,

We would like to thank the Commission for the opportunity that has been given to comment on this interesting discussion paper, also of significant relevance for the metals and minerals industry. We really appreciated the Commission's efforts and willingness to structure the document with thorough questions and the request for information.

Please find attached some answers provided by the copper industry (ECI and ICA). As a general note, we would like to stress that in the context of the ESR, several metals have gone or are currently going through a risk assessment (e.g. Copper, Zinc, Nickel, Lead, Cadmium). An important part of this exercise consists in collecting and assessing data on exposure, including intakes. We would therefore appreciate whether you could consider those risk assessments as a relevant source for information as they include a comprehensive and extensive review of the available data.

We would be pleased to further discuss this with you or to provide you with information if you wish so.

Finally, please accept our apologies for sending those comments so close to the deadline. Despite this late sending, we expect that those will be helpful.

Many thanks for taking those comments into consideration,

Violaine Verougstraete
Eurometaux

Martin Wieske
WirtschaftsVereinigung Metalle

Discussion Paper on the setting of maximum and minimum amounts for vitamins and minerals in foodstuffs (EC, June 2006)

Establishment of maximum amounts for food supplements and other foods (pg 10)

Where there is not yet a 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?

If the levels of certain minerals are too high, competition effects may occur, leading to deficiency of other minerals. Maximum levels should thus consider levels of other minerals. Examples for competition effects are zinc and copper: High levels of one metal lower the uptake of the other. Also, synergistic effects should be considered. Some nutrients interact, increasing the uptake of one of them. An example is the Vitamin C, which increases the absorption of iron.

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?

If there is no documented risk associated with a nutrient, and if there are no interactions with other nutrients, no maximum level needs to be set. Such a low-risk or no-risk nutrient should still be added to a supplement at a reasonable level, avoiding “mega-doses”. Please consider also the response to the previous question.

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?

Public health protection is the objective. An evaluation should be made of the need for this (how big are the current risks where such limits do not exist). Is public health in danger by not setting different limit values for minerals & vitamins in food supplements and additional levels in fortified food?
As mentioned in paragraph 22, unnecessary overregulation should be avoided as for example marketing aspects might also be considered. This means that not every

fortified food and food supplement will contain the maximum allowed amounts due to cost or technical constrains.

Intake of vitamins and minerals from dietary sources

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.

Such information is available in the ongoing EU-Risk Assessments (RA) (793/93/EEC) for Zn and Cu. In the Cu voluntary risk assessment (Cu-VRA) RA for example a comprehensive review has been made of all existing diet studies (market basket and duplicate diet studies) performed in the EU member states till 2004. Data were first screened for their quality. Good quality data were retained for 10 EU countries geographically spread over Europe (Norway, Sweden, Spain and West-EU). Influence of sex and age were investigated. Further, the exposure through drinking water and alcohol was investigated in detail.
The Cu-VRA is currently under discussion by the EU-TCNES (coordinated by the ECB in Ispra). A copy of the report will be sent.

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?

If data are available for a limited number of countries, an evaluation should be made of the representativeness of the diet habits of those countries for the EU. Also, geographic differences need to be taken into account (e.g., soil-deficiencies in certain regions, proximity to the ocean, etc)

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

Yes, where possible. And the same should be done for setting minimum levels. This might especially be important for minerals and vitamins where the range between max and min recommended daily intakes is narrow.

Reference intakes of vitamins and minerals

Taking into account all the above-mentioned considerations, how far should PRIs/RDAs be taken

PRIs should be considered for the reason given in paragraph 42 (to avoid that maximum levels set could lead to risks of intakes lower than the PRI) especially where different PRIs exist for different sub-groups.
Please note that for Cu, an evaluation of the PRI has been made in the Cu-VRA. A PRI has been derived for the general population and for elderly people (identified as a sub-population requiring higher levels). A copy of this evaluation will be sent for consideration by EFSA.

MINIMUM AMOUNTS

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?

For some nutrients (e.g., selenium), the "therapeutic window" is very narrow, meaning that deficiency and toxicity levels are not very far apart. Adding such a nutrient to a supplement at a level at which a claim can be made may generate a risk of over-exposure. It should be allowed that nutrients with very small therapeutic windows can be added to supplements at an amount smaller than needed for a certain health-claim.

Should different minimum amounts be set for certain nutrients in specific foods or categories of foods? If yes, on what basis?

Minimum amounts should consider potential interactions of some food-contents with the uptake of a certain nutrient, e.g., inhibition if zinc and iron uptake by phytate, bran and certain starches, etc. In this example, if iron and zinc are added to a food rich in starch, phytate or bran, the minimum amount of iron and zinc should be adjusted.