CHIEF PUBLIC HEALTH OFFICER OF THE CZECH REPUBLIC
AND VICEMINISTER
MINISTRY OF HEALTH OF THE CZECH REPUBLIC
Palackého nám. 4, 128 01 Prague 2

Prague, October 10, 2006
OVZ-3500-9.10.06-41594

Dear Ms. Coggi,

I am writing in reply to your letter of June 5, 2006 Ref. No. SANCO/E4:FDA/eo/D 540345 (2006) concerning Discussion Paper on setting maximum and minimum amounts for vitamins and minerals in foodstuffs. In the annex please see the opinion of the Czech Republic enclosed.

Yours sincerely,

MUDr. Michael Vít, PhD.

Annex

Ms Paola Testori Coggi
Director
Directorate E: Safety of the food chain
Commission européene
B-1049 Bruxelles

The Czech Republic agree with the commentary of the Confederation of the Food and Drink Industries in the EU (CIAA) on this discussion material and are simultaneously enclosing the supplementary commentary of the Czech Republic.

1. 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?
We are of the opinion that no maximum level should be set for these nutrients. This holds if no doubts have been demonstrated as to their safety and the EFSA has not set an upper limit for intake (UL).
No proof of undesirable effects exists for most nutrients for which an upper intake limit has not been set. It holds for vitamins B1, B2, B12, biotin, pantothenic acid, vitamin K and trivalent chromium that, at the current levels in foodstuffs, enriched foodstuffs and food additives, they do not constitute a risk for human health.

2. 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?
We are of the opinion that, if the risk of undesirable effects from certain vitamins and mineral substances is extremely small, there is no reason to set maximum levels for these vitamins and mineral substances.
However, if certain maximum levels were to be set in these cases, then this should be at a level that reflects current practice and would not require reformulating the products on the market.

3. 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?
We are convinced that it is necessary to stipulate various maximum levels for food supplements and for enriched foodstuffs, following evaluation of each individual nutrient. Nutrients can be classified on the basis of scientific evaluation into groups according to the seriousness of the risk following from potential exceeding of the upper intake limit. The models prepared by ERNA, ILSI and also the Danish and German models agree on this procedure.

4. 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.
As far as we are aware, no document is available in the CR that would deal comprehensively with intake of vitamins and minerals derived from normal foodstuffs; however sources providing information on intake are available in Europe:

- the Irish Universities Nutrition Alliance (IUNA),
- the North-South Ireland Food Consumption Survey 2001, Gezondheidsraad,
- Enkele belangrijke ontwikkelingen in de voedselconsumptie (2002),
- Turrini A, Saba A, Perrone D, Cialfa E & D'Amiels A (2001) Food consumption patterns in Italy (to be extended).

On-going projects:

- EFSA project[1]

- EFCOSUM project
- Revision of the ERNA/EHPM project

[1]Phillippe Verger, Research Unit INRA;. Met@risk: EFSA Colloquium No 3, Brussels, April 2005

5. 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?
Analysis of existing data from various countries does not reveal major deviations. It thus follows that data on intake from some Member States can be used throughout the EU.

6. Should the intake from different population groups be taken into account in the setting of maximum levels of vitamins and minerals?
We consider it to be advantageous to establish different maximum levels for adults and for children.

7. 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?
In setting the maximum amounts of vitamins and mineral substances, the PRI/RDA values should be only auxiliary information.
PRI/RDA could be employed as indicators of the range of safe intake and in characterizing risks.

8. 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?
Unless this is part of a statement, no minimum amount should be set for a nutrient. Vitamins are frequently also added in small amounts as auxiliary substances or anti-oxidants to protect active substances and, in these cases, it is not possible to meet the requirement of a minimum amount (e.g. vitamin E in lipophilic formulae, vitamin C in hydrophilic combination tablets, etc.).
If this were part of a statement, then it would apparently be advantageous to use a minimum amount set as 15% RDA per 100 g / 100 ml.

9. 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 labeling purposes or should they be set in a different way?
The minimum amount should be in a certain relationship to RDA.

The submitted material contains several models for determining the maximum level of vitamins and mineral substances. The CR has long cooperated with the European Responsible Nutrition Alliance (ERNA) and considers the Risk management for intake of vitamins and minerals created by this alliance for the CR to be acceptable. However, the CR considers that it is necessary to extend this model to include the child population.