

ILSI Europe a.i.s.b.l.*
Comments to the Discussion Paper on the setting of maximum and minimum amounts for vitamins and minerals in foodstuffs

Page 11 Questions on which the Commission seeks comments:

- 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?

Comment:

In the absence of clear data, an expert judgement must be made by weighing all known relevant factors, including the quality of available evidence, as well as the nature and severity of potential adverse effects. ILSI Europe has coordinated the development of new methodology to assist the risk assessor and risk manager in making such decisions (Renwick et al, 2004). The tool helps the risk manager to estimate acceptable intakes based on the risk of both low and high intakes.

Further work in progress on this topic includes guidance to the risk manager on interpretation and use of upper levels as well as how to deal with nutrients for which no upper level has or can be set. This will be published in a peer-reviewed scientific journal during 2007.

Page 12 Questions on which the Commission seeks comments:

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

ILSI Europe is coordinating a team of experts in micronutrient nutrient intake to identify the best available sources in European countries. Available national intake data will be compiled and analysed in a structured format to help form a sound and informed comparison of national intakes across Europe. Data collected (where available) will include 95th centile micronutrient intakes in children and adults; the contribution of foods and fortified foods; food supplements together with the level of nutrients they contain and frequency of consumption. The intention

* All comments submitted by ILSI Europe a.i.s.b.l. are based on peer-reviewed work commissioned by the ILSI Europe Addition of Nutrients to Food Task Force (and executed by independent academic experts together with Task Force members). Members of this Task Force are Ajinomoto, BASF, Campina, Coca-Cola European Union Group, DSM, Friesland Foods, GlaxoSmithKline, Groupe Danone, Kellogg, Kraft Foods, Nestlé, PepsiCo International, and Unilever.

is to have preliminary data available during the first half of 2007. It is planned to publish the final outcome the project in a peer-reviewed scientific journal.

Page 14 Question on which the Commission seeks comments:

- 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?

Comment:

In addition to acceptable upper intake levels (ULs), yardsticks of adequate intakes such as PRIs/RDAs are also crucially important factors in setting maximum levels for vitamins and minerals. The risk manager also needs to consider the probability of increasing potential risk of inadequate intakes in nutritionally compromised population subgroups, in the process on capping addition levels of key nutrients.

The work coordinated by ILSI Europe and published by Renwick et al (2004) describes a new approach which can provide advice for risk managers in a form that will allow the risk of deficiency to be weighed against the risk of toxicity. The article is available at <http://europe.ilsa.org/NR/rdonlyres/A5F53E6F-D0F7-4F97-ACEE-0CD8169524C3/0/RiskBenefitFCT2004.pdf>

Reference:

Risk-benefit analysis of Micronutrients; Renwick et al. 2004. *Food and Chemical Toxicology*, 42 (12) 1903-1922.