Confédération des industries agro-alimentaires de l'UE
Confederation of the food and drink industries of the EU

CIAA Comments to

DG SANCO Discussion Paper on the setting of maximum and minimum amounts for vitamins and minerals in foodstuffs

SETTING OF MAXIMUM AMOUNTS

CIAA welcomes the DG SANCO initiative to consult on the setting of maximum and minimum amounts for vitamins and minerals in food, and offers the comments detailed below.

General Points

- Fortified foods and supplements have been safely consumed in Europe for several decades. There are no known safety problems with current customs & practices for the levels of vitamins and minerals currently used in fortified foods and supplements.
- CIAA endorses the view that any approach to set maximum and minimum levels for vitamins and minerals should be evaluated on the basis of safety and sound science.
- The models included in the discussion paper show a significant consensus on risk assessment categorisation of micro-nutrients. CIAA believes that such a categorisation and characterisation has merit. It is important to highlight and focus on the vitamins and minerals having the highest risk.
- The importance of the diet for a healthy life has been amply demonstrated. Fortified foods and supplements do have a role to play in a healthy balanced diet (FAO/UNICEF/WHO).

Avenue des Arts, 43 • B-1040 Bruxelles
Tel.: +32 2 514 11 11 • Fax: +32 2 511 29 05 • E-mail: ciaa@ciaa.be • Web: http://www.ciaa.be

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?

Where there is no demonstrable safety concern, no maximum level should be set.

EFSA has not derived any ULs for the following nutrients:

- Thiamine, riboflavin, biotin
- Vitamin K, vitamin $B_{12,}$ chromium,
- Pantothenic acid
- Iron, manganese, beta-carotene, vitamin C, sodium, potassium, chloride, phosphate.

The U.S. Food and Nutrition Board (FNB) also has not derived any ULs for the aforementioned nutrients, with the exception of iron, manganese and vitamin C.

The reasons why a UL is lacking vary from case to case, and thus CIAA maintains that a differentiated approach is necessary:

- For some nutrients, no adverse effects were identified (thiamine, riboflavin, biotin);
- For other nutrients, not enough data is available to permit derivation of a UL. At the same time, no adverse effects have been observed in connection with certain amounts far in excess of the usual intake levels (vitamin K 10 mg, vitamin $B_{12,}$1-5 mg, chromium 1 mg);
- For gram doses of pantothenic acid, adverse effects are thought to be possible, but not enough data was available for UL derivation;
- For manganese, beta-carotene, vitamin C, sodium, potassium, chloride, phosphate and iron, adverse impacts have been identified, but EFSA maintains that the available data with regard to dose-impacts relationships is not adequate for UL derivation.

The decisive aspect with regard to further steps is that neither Directive 2002/46/EC, nor the proposal for fortification, refers exclusively and expressly to the EFSA's ULs; instead, both refer to "upper safe levels of … vitamins and minerals, as established by scientific risk assessment based on generally acceptable scientific data".

In CIAA's view, this means that EFSA experts' opinions are relevant even for cases in which no UL has been derived. The reason for this is that these opinions often contain references to safe levels (see above) and provide indications regarding the nature/ intensity of the adverse effects. They thus provide a basis for a suitable qualitative approach.

As a result, for some nutrients, no maximum levels need to be derived – either because no adverse impacts have been identified (thiamine, riboflavin, biotin) or because such impacts occur only at doses far in excess of those obtained via food (including fortified foods and food supplements) (vitamin K, vitamin $B_{12,}$ chromium, pantothenic acid).

In cases in which adverse effects were identified, the ULs of other scientific bodies [1] may be used:

[1] For a comparative discussion of derived ULs and of identified adverse effects, see Annex 1 of Annex 3 of the following report: FAO/WHO (2006): A Model for Establishing Upper Levels of Intake for Nutrients and Related Substances. Report of

- Iron UL (FNB) = 45 mg
- Manganese UL (FNB) = 11 mg
- Vitamin C UL (FNB) = 2000 mg

In the case of beta-carotene, neither the FNB nor the SCF have established a UL; at the same time, the risk assessments carried by these bodies point to certain adverse effects that require risk-management measures. Therefore, a voluntary self-restriction of adding only a certain minimal amount of beta-carotene to foodstuffs could be an appropriate solution.

In using ULs to set maximum levels, it is important that proper expert judgment be used to take account of the actual health hazard upon which it is based. For example gastrointestinal discomfort at high levels of consumption presents a different risk from more severe adverse effects.

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?*

CIAA believes that there is no reason to set maximum levels for nutrients unless there is a demonstrable safety concern.

Currently there has been no evidence of excessive intake of any micronutrient, even nutrients with low or non-existent adverse effects. This applies even to countries with a long-standing liberal approach. In a liberal fortification regime, such as that of the UK, which also has mandatory white flour and margarine fortification, there is no evidence that fortified foods or dietary supplements pose any risk regarding unsafe levels of intake, based on the evidence of foods that people actually select for their diet. The only area of concern relates to excessive retinol intakes for those who regularly eat liver.

Experience to date from other parts of the worlds shows no adverse health effects from the addition of nutrients to food.

Research shows that fortified foods contribute to improving nutritional intake and status. Indeed micronutrient intake through food fortification will be naturally limited by the energy these foods provide, as well as by the volume of food that can be consumed in one day.

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?*

When setting the maximum levels, a realistic and actual intake from all the sources, including supplements, should be taken into consideration. One should take into account the several risk assessment models that identified the nutrients listed in category C (Zinc,

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a Joint FAO/WHO Technical Workshop on Nutrient Risk Assessment. Geneva, 2-6 May 2005 (http://www.who.int/ipcs/highlights/full_report.pdf

Iron, Copper, Iodine, Calcium, Retinol). For these nutrients CIAA agrees on setting maximum levels.

It is important that maximum levels are set on the basis of safety and sound science and should be set on a case-by-case basis.

The mandatory fortification in some member states (Vitamin A and D and some other vitamins) should be taken into account.

INTAKE OF **V**ITAMINS AND **M**INERALS FROM **D**IETARY **S**OURCES

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.

The responsibility for these data provision should fall with National Authorities. However, these data have been collected using different methodologies. CIAA believes that efficient monitoring; data analysis and collection of dietary intake (Pan-European dietary intake surveys) are urgently needed to assess the nutritional status of EU citizens. Such study would also be needed for monitoring intake data of micronutrients from fortified foods.

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?

Maximum safe levels should be developed on the basis of safety. Given that there are not demonstrable differences in the metabolism or sensitivities of populations within Europe, it would be reasonable to assume maximum safe levels should be set by extrapolation of the best data available in individual Member States.

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

Fortified foods are foods destined to be consumed by general population. Therefore, if there are specific concerns related to the consumption of a certain nutrient by specific subgroups, these should be addressed through consumer information.

For PARNUTS products as regulated by Framework Directive 89/398/EEC minimum and maximum levels should be allowed to differ from the general foodstuffs in order to meet special dietary requirements of the specific population groups they are addressed to.

It is important that any approach is of practical application; setting a number of different maximum levels may cause confusion for manufacturers and consumers.

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?

The setting of maximum levels should be based on scientific risk assessment. The use of arbitrary multiples or fractions of RDAs/ PRIs to set ULs are no longer acceptable from the scientific risk assessment point of view or as an objective approach to risk management. UL is the appropriate unit for this.

However, the RDA can be used as an indicator to help establish the extent of the range of safe intake and could form an approach to help clarify the relative safety of each nutrient for the population. If the UL and RDA are closer together, the safe range of intake is relatively small. Where the UL and RDA are further apart, the safe range of intake is relatively large. The RDA as an 'indicator' can therefore be taken into account in establishing the breadth of the range of safe intake and for risk characterisation.

Fortified foods play an important role in reducing the risk of underconsumption in many population sub-groups. The main application of RDA is in the estimation risk for marginal micronutrient intakes, which is important to considering limitations on nutrient addition to foods.

MINIMUM AMOUNTS

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?

For claims for nutrients in conventional and fortified foods, there is a need for consistency across several legislative instruments, namely the Nutrition Labelling Directive (under review), the Addition of Vitamins and Minerals and certain other substances in food, and the legislation on nutrition and health claims made on foods. Claims on fortified foods tend to reflect the criteria for 'source' and 'high' in the specified nutrient. It seems appropriate to maintain consistency for the 15% RDA supplied by:

- 100g or
- 100ml or
- per portion, where the portion is indicated by the manufacturer on the package, or
- per serving as quantified on the label, or
- per package, if the package contains only a single portion should be taken into consideration in deciding what constitutes a significant amount.

However for foods and beverages with low content of dried matter, e.g., liquids, fruits and vegetables, soups and milk, 7.5% of the recommended allowance per quantity as indicated above shall be considered as a significant amount for nutrition labelling.

Alternatively, 5% of the RDA per 100 kcal to be considered as a significant amount for the purpose of nutrition labelling.

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

In general, minimum levels should equally apply to all the foods and food groups.

In some cases minimum amounts are set for certain nutrients in specific foods. An example is the addition of sodium to sports' drinks. The SCF report (28/2/2001) indicates that the addition of sodium stimulates carbohydrate and water uptake and helps to maintain extra-cellular fluid volume so that a minimum level of sodium is recommended in such products. Carbohydrate electrolyte solutions should contain 460-1150 mg (20-50 mml) sodium/l as indicated in the Working draft Document of the Commission Directive on foods intended to meet the expenditure of intense muscular effort, especially for sportsmen.

In certain food categories the addition of nutrients is mandatory and it should be allowed as it is currently, even if it does not meet the minimum requirements.

10. *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?*

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