MINISTRY OF TRADE AND INDUSTRY

29 September 2006

SUBJECT:

View of a Finnish expert group on the Discussion paper on the setting of maximum and minimum amounts for vitamins and minerals in foodstuffs.

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?**

Since no upper safe levels (UL) have been set for nutrients, we should make use of the best available scientific research data and findings to set upper safe levels and the maximum amounts specified on their basis. Moreover, it is necessary to utilise experiences of long-term use and the intake of vitamins or minerals for the purpose of making such judgements. Where no upper safe levels have been established, mathematical models can use guidance levels (GLs) instead, which have been set by expert groups, for example in the UK and Denmark or by the IOM.

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 those vitamins and minerals?**

It is not necessary to set maximum amounts for vitamins and minerals if consumer groups have no evidence that they can be consumed excessively, or if even a high intake of those nutrients has not shown any adverse health effects. If the maximum amounts cannot be set due to lack of knowledge, we should take a precautionary approach. When new scientific research data becomes available, we should also be able to set or change upper safe levels and the maximum amounts based on them, where necessary.

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?**

Maximum amounts must be set for both food supplements and fortified foods. The amounts of vitamins or minerals in food supplements are known and food labelling guide consumers with respect to their use. The amounts of fortified food consumed are not so well known because a number of factors affect the amounts consumed. Consequently, a higher risk is associated with vitamin and mineral intake from them than from food supplements. For this reason, maximum levels of food supplements may be higher than those of foods, but it is necessary to take account of their intake from ordinary food and other dietary sources when setting the maximum levels. Consumption of foods is distributed differently

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amongst the population to that of food supplements. Therefore, it is necessary to take account of those consumer groups who are potentially most vulnerable when setting maximum levels for foods. Furthermore, it is also necessary to pay attention to any other sources (water, consumables).

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

The data must be based on information on food consumption at individual level. The EFCOSUM project, aimed at defining a European-wide food consumption monitoring method, proposed that two non-consecutive, 24-hour recalls (based on interviews with consumers) should be used as the measurement method. Methods up to this standard can be found in some EU member states. In its intake measurement, Finland uses the Finravinto survey; a 48-hour recall of food consumption, taking weekends into account and based on interviews with some 2,000 adults. These data can be analysed by sex, region, age group and education.

Finland has also performed risk assessments of the intake of certain nutrients, based on simulation models, with the above Finravinto survey used for intake calculation and supplementary data on the consumption of fortified foods. Simulation studies on adults are available on iron, vitamin B (report in Finnish, including an abstract in English on page 6, attached), calcium and vitamin D (report in Finnish, including an abstract on pages 7-8 in English, as well as an article on the efficacy and safety of fortification with calcium, in English[1]).

The contents and sales volumes of fortified foods and food supplements could be used to assess changes in their intake at population level. In this respect, cooperation between the food industry and the authorities is important.

5. Can a member state's national intake data be used as the basis for setting maximum levels at European level? Does this require adjustments?

A certain Member State's model for intake calculation can be used as a basis for setting maximum levels at EU level provided that certain criteria are fulfilled (for ex. EFCOSUM) The criteria should be agreed upon at EU level. If a certain model does not fulfil the criteria, it is possible to use factors to correct this. Also, we should establish a geographically representative sample and be able to sort out potentially vulnerable population groups (such as children and pregnant women) in the measurements. Carrying out validation analyses of the suitability of a single method for setting maximum levels would be of particular importance.

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

Basically, foods should suit the entire population. Basic foods must be completely safe for the most vulnerable population groups too, especially children. For this reason, these population groups' intake of nutrients should contribute to setting the maximum amounts for fortified foods.

[1] Hirvonen T. *et al.*, Efficacy and safety of food fortification with calcium among adults in Finland, *Public Health Nutrition* (2006) 9: 792-797.

Since food supplements are not classified as basic foods, the special groups' intake of nutrients should not affect the setting of maximum amounts for food supplements. However, package labels should suggest the right consumer groups for the product, taking potentially vulnerable consumer groups into consideration. When setting maximum amounts, it is necessary to pay attention to people's total intake from a normal diet and other dietary sources. When setting maximum amounts for food supplements, it is also necessary to take account of the vitamin's or mineral's medicinal, pharmacological, immunological or metabolic effects.

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

The reference intake values cannot be directly taken into account in setting maximum amounts based on risk assessments. This might be appropriate if the maximum levels are below the intake level, as stated in section 42 of the Commission's Paper. The intake has already been indirectly taken into account in setting upper safe levels.

8. Should the minimum amounts of nutrients added to a food be the same as the significant amount required for a claim and/or declaration of the nutrient in labelling? Could different minimum amounts be set for certain vitamins or minerals in specific foods or food categories?

For reasons of public health, it may be necessary to set minimum amounts lower than the significant amount defined in the Directive on nutrition labelling. It is likely that fortification is safest and most effective when added to a vast amount of foods in small concentrations. Vitamin D-fortified liquid milk products in Finland – based on 0.5 µg/100g representing 5 per cent of recommended daily allowances – serve as a good example. The effect of this enrichment policy has been evaluated (report in Finnish, including a summary on pages 7-8 in English, attached). As a result, the intake and levels of vitamin D have considerably increased among the Finnish population. Fortifying food with a small amount of a nutrient may also be reasonable if the presence of one nutrient makes the other work as intended (e.g. vitamin D and calcium).

If nutrition and health claims are made with respect to the food's nutritional content, the food must contain a significant amount of that nutrient in order not to mislead consumers. At Community level, it appears appropriate that the significant amount (one value), as defined in the Directive, would apply to all food categories.

10. Should minimum amounts of nutrients in dietary 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 amounts can be set for food supplements, based simply on RDA, because nutrients are sold in doses and consumers are guided by package labels with respect to their use. In our opinion, however, Codex's 15 per cent of the intake reference value is too low because food supplements are sold as concentrated sources of certain vitamins or minerals.
According to Finnish rules on food supplements, selling dietary supplements as sources of vitamins and minerals is misleading if their daily intake is less than 30 per cent of the EU's daily intake reference values. Should the amount of a vitamin or mineral in terms of daily doses be a minimum of 15 per cent of the daily intake reference value, this amount may appear on labelling, but the package labelling may not highlight the vitamin or mineral, for example in the name of the food product.

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When the EU makes decisions on minimum levels of dietary supplements at Community level, we should bear in mind that non-EU countries import dietary supplements whose minimum levels may be lower than ours. This may cause problems in the movement of goods.