Comments by JIHFS[1] on the Discussion Paper on the setting of maximum and minimum amounts of vitamins and minerals in foodstuffs

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The Japanese Institute for Health Food Standards (JIHFS) has a great respect for the endeavors of the European Commission for the setting of maximum and minimum levels for food supplements and fortified foods which is a global challenge for securing the safety and significance of these products for the human health. JIHFS has kept deep interest to this issue and would therefore like to forward our comments to the questions raised by the Commission.

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?

JIHFS believes that tolerable upper intake levels for nutrients should be determined based on the risk analysis. Where scientific evidence on safety has not been obtained, upper safe intake level has not been established. While numerical upper level is not derived owing to insufficient scientific data, from the practical point of view, the upper safe level of nutrient is necessary for the public understanding of the safe use of food supplements and fortified foods. However, there is no room for doubt as to that the upper safe level of nutrient should not be identified based on the evidences reported in the exiguous number of papers published in the scientific journals.

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[1] The Japanese Institute for Health Food Standards (JIHFS) was founded for authorizing GMP of health foods. The JIHFS GMP standard complies with the GMP guideline established by the Ministry of Health, Labor and Welfare of Japan for health foods which are considered similar to food supplements having dosage forms such as tablet, capsule, powder or liquid, etc. and defined in the EU Directive 2002/46/EC.

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In one case, the extensive survey of references reporting the safety of the particular nutrient in human has been carried out and found that there was nothing to exhibit the evidence of toxicity of the nutrient except a single paper published in a scientific journal. The safety committee identified the upper safe level of the nutrient based on the toxicity data reported in the unique paper, though any other evidences supporting the sole data have not been published. In this case, the reliability of the evidence has not been confirmed, because of no other paper reporting the toxicity of the particular nutrient in human clinical studies.

In the situation where there is not yet a scientifically established numerical tolerable upper intake levels for several nutrients, JIHFS supports the approach of IADSA to establish Observed Safe Levels (OSL). This procedure could be considered as practically useful tools for identification of upper safe level.

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?

As JIHFS wrote in the comment on the question 1, the information for consumers to judge the upper intake levels of nutrients is practically necessary, even though the risk of adverse effects of vitamins and minerals, even at high levels of intakes, appears to be extremely low or non-existent according to available data. To prevent excess and unnecessarily large amount of intakes, the practical indication of the upper level of intake must be shown on a label. To determine the upper levels of vitamins and minerals, the approach of IADSA to establish Observed Safe Levels (OSL) is practically available tools.

When looking at the texts recently adopted and developed by the global organizations affecting this process, the 2005 Codex Guidelines for Vitamin and Mineral Food Supplements and the 2006 FAO/WHO Report on the Risk Assessment of Vitamins and Minerals, it seems clear that the direction taken to establish maximum amounts for supplement ingredients is through a sound scientific risk assessment.

It is therefore hoped that this approach is also followed by the European Union when setting maximum levels for fortified foods and food supplements and that a rational approach, based on science not politics, can be achieved that could become a model for other countries addressing this issue across the world.

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?

JIHFS believes that the different maximum amounts for vitamins and minerals should be separately set for food supplements and fortified foods, respectively, according to the case by case scientific assessment, dominantly based on the risk analysis.

In Japan, most of adverse reactions in which symptoms including gastrointestinal disorders, allergic reactions, and others were observed have occurred associated with supplements (health foods with shapes of tablet and capsule). Accordingly, the maximum amounts for vitamins and minerals should be carefully determined for food supplements separately from fortified foods. However, food supplements can be ingested over a lifetime. Therefore, the maximum level of nutrient taken from food supplements should also be determined by considering the influence of intake from foods other than food supplements. Further, the nutrient to nutrient interactions should also be concerned.

If the scientific evidences for the determination of a safety of particular vitamin or mineral are not available, the approach of IADSA to establish Observed Safe Levels (OSL) could be the practical tool for setting the maximum levels of vitamin and mineral separately for food supplements and fortified foods.

JIHFS does not have appropriate evidences to comment on both of question 4 and 5, as follows;

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.

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?

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

JIHFS believes that the most sensitive groups of the general population are necessary to be protected from the adverse reactions when high amount of essential nutrition is taken. The sensitive groups such as pregnant women, lactating women, infants, aged people, and high risk people should be taken into account in the setting the upper safe levels of vitamins and minerals, based on applying the specific measures in consideration of characteristic for the individual physiological, pharmacokinetic and/or biochemical conditions. If the appropriate models of the above sensitive groups are not available, RDA is thought to be one of practical measures.

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?

RDAs/PRIs should be considered as the levels of lower margin of the safe intakes of individual vitamin and mineral, but can not be used to estimate the upper safe levels. RDA is thought to be the amounts of vitamins and minerals to fulfill the essential requirement for most of population.

The maximum levels of vitamins and minerals are related to the amount of intake expecting the specific function and efficacy where the intakes are included in the safe range of the nutrient. The upper safe level should be established based on the risk analysis. Accordingly, RDAs/PRIs and maximum levels are different concepts each other. How far between RDAs/PRIs and maximum levels depend on the individual physiological characteristics of ingredient

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 reference, the Ministry of Health, Labour and Welfare of Japan (MHLW) enforced the regulation of "Food with Nutrient Function Claims". According to this rule, the health claims for 13 vitamins (to except Vitamin K and to add beta-carotene) and 5 minerals (calcium, iron, magnesium, copper, and zinc) are permitted to explain their specific function, when the daily intake is included between the minimum and maximum daily dose of individual ingredient determined by the MHLW. The minimum daily dose of the individual nutrient is decided by the applying 30 % of NRV. The health claims of vitamin and mineral are decided by the MHLW individually. Regardless of food supplement and fortified food, vitamin and mineral are permitted to use for "Food with Nutrient Function Claims".

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 labelling purposes or should they be set in a different way?

The same information written for the question 8 might also be our comments for this question.