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"DG SANCO Discussion Paper on the setting of maximum and minimum amounts for vitamins and minerals in foodstuffs, June 2006"

GlaxoSmithKline Nutritional Healthcare Response

GlaxoSmithKline (GSK) is one of the world's leading research-based pharmaceutical and health care companies. We develop and manufacture prescription medicines, vaccines, over-the-counter medicines and oral care and nutritional health care products under the brands Horlicks, Lucozade and Ribena. Our headquarters are in the UK and we employ people right across the EU.

GSK has already contributed to the consultation responses submitted by the European Food Industry; therefore this response concentrates on those areas where we are able to provide additional, specific material to address the Commission's questions.

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?***

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?***

GSK supports a scientific risk based approach to setting maximum levels. We therefore believe that setting artificial limits based on simple multiples of RDAs is inappropriate.

The requirement in the food supplement Directive and the forthcoming Regulation on the addition of vitamins, minerals and certain other substances to foods, requires maximum levels to be set based on "upper safe levels of vitamins and minerals, established by scientific risk assessment based on generally acceptable scientific data ...". We believe that in addition to looking at the numerical upper levels set, it is appropriate to consider the full review and analysis of the expert groups.

As outlined in the Commission paper, for some nutrients the SCF / EFSA was unable to set an upper limit, in some cases because of a lack of data and in others because the available data suggested that even at very high doses of intake no adverse effect from the nutrient could be found. Where there is no evidence to suggest adverse effects even at high levels of intake GSK believes that no upper limit need be set.

In addition GSK believe that it is appropriate for the Commission to also look at expert opinion from other International organisations e.g. the US Food and Nutrition Board to help set levels where the SCF / EFSA did not set a numerical limit.

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?***

Whatever the source of a micronutrient, the safe intake for the consumer is the same. However, defining a **robust** means of "splitting" maximum levels of micronutrients between fortified foods and supplements is unlikely.

Dietary patterns and the use of fortified foods and supplements vary between different population groups and between different member States. We believe that provided both fortified foods and food supplements are labelled responsibly and comprehensively, consumers should be free to choose how they consume additional vitamins and minerals. For example, consumers should have the choice to purchase either a drink fortified with vitamin C, or a vitamin C supplement to help meet their dietary needs. "Splitting" a maximum level between fortified foods and supplements is likely to result in the need to reformulate products in both market sectors, even when products do not contain excessive levels of micronutrients.

Rather than imposing an arbitrary split of the maximum level between product sectors, GSK believes that once a maximum level is defined this should be available to both product sectors. GSK does not believe that it will serve the interests of consumers to impose unnecessarily stringent maximum levels on either the food supplements or fortified food sectors. Both fortified foods and supplements have a long heritage of safe use, and we believe it would be inappropriate to set lower limits for food products than supplements, as technological constraints will automatically limit the range and amount of micronutrients added to many food products. However, where technology allows, consumers should be free to supplement their diets with fortified foods and not just pills and capsules.

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

In setting upper intake levels, the SCF/EFSA and other scientific bodies have already taken into account the needs of vulnerable sectors of the population such as the elderly and pregnant women. We therefore do not believe that it is necessary to consider setting separate maximum levels for every population group. There may be a case for setting separate limits for adults and children, given their different physiological requirements and dietary intakes.

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 or maximum levels is no longer acceptable from the scientific risk assessment point of view or as an objective approach to risk management.

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?*

In most cases GSK supports the view that the minimum amount of a nutrient added to a product should equate to the amount required to support a claim. Thus there is a need to ensure 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.

However, GSK supports a revision of what constitutes a significant amount. In the current nutrition labelling Directive a significant amount is defined as 15% RDA per 100g or 100ml or per serving for single serve packs. Thus the Directive requires that different formulations must be used for single serving and multi-serving packs of fortified drinks. For example, a single serve 250ml pack of a juice drink could state "contains vitamin C" with a vitamin C content of 15% RDA per pack. The "same" product sold in a 1 L pack containing four servings could only make a claim of "contains vitamin C" with a vitamin C content of 15% RDA per 100ml; each 250ml serving would therefore provide 2 and a half times the vitamin C of a single serve pack. Consumers are unaware of this and do not expect the products to be different.

Additionally drinks are consumed in larger amounts than solid foods (a typical serving of a drink being 200 to 250ml, in comparison to 30g or 40g for a breakfast cereal for example) making a lower level of addition appropriate to constitute a significant amount.

We therefore support changing the definition of a significant amount such that for drinks it should be 7.5% of the RDA per serving, regardless of it being a single or multi-serving pack.

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

It is important to note that for foods for particular nutritional uses (PARNUTS products) flexibility is already given in Article 1.3.(a) of the draft Regulation ***on the addition of vitamins and minerals and of certain other substances to foods*** : *"This Regulation shall apply without prejudice to specific provisions laid down in Community legislation concerning:*

(a) foods for particular nutritional uses and, in the absence of specific provisions, compositional requirements of such products rendered necessary by the particular nutritional requirements of the persons for whom they are intended;"

Whereas a minimum of 15% RDA per 100g might be appropriate for general foods, a particular vitamin or mineral may be needed for overall nutritional balance in a PARNUTS food, but at a lower level than this minimum. Therefore, it may be needed to included in § 20 & 44 of the Commission Discussion Paper the exact reference to PARNUTS foods and not only a reference to *"special categories of food".*

In particular, the situation with regard to the presence of electrolytes in sports drinks, should be recognised. Electrolytes are added both to optimize fluid uptake and retention and to replace the amounts lost in sweat. The levels added need to be appropriate for these purposes, which are lower than the current definition of a significant amount. In the absence of an EU directive on foods for intense muscular effort, recognition is required that sports drinks should be exempt from the requirement for a significant amount in respect to electrolyte content.

There should also be recognition that in some cases, such as where nutrients are added to restore those lost as a result of food processing (e.g. the addition of B vitamins to white flour) levels added may be lower than the current definition of a significant amount. Such practice should not be ruled out by determining that in all cases the minimum amount MUST be equivalent to the level required to support a nutrition claim.

10. *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?*

Although the Nutrition Labelling Directive does not apply directly to food supplements, certain elements, such as the reference labelling values in the annex of 90/496/EC do apply. It would seem appropriate that the minimum amounts for vitamins and minerals in food supplements also be linked to these reference values.