DG-SANCO DISCUSSION PAPER ON THE SETTING OF MAXIMUM LEVELS

Response from BioCare Limited September 2006

History
BioCare is a science-based company founded almost twenty years ago by a team of natural practitioners and scientists with many years' experience in nutrition and biological science. Their main objective was to create a range of innovative, high quality professional food supplements designed to meet the needs of the growing number of practitioners using nutritional supplements as part of their practice. These practitioners included medical doctors, nutritionists, osteopaths, chiropractors, medical herbalists and naturopaths. The majority of BioCare products are sold direct to practitioners and independent health store retailers however, as the natural healthcare market has grown a growing number of BioCare sales are made to the end consumer via direct-mail.

GENERAL COMMENTS

BioCare fully supports an approach in which maximum levels of vitamins and minerals are determined by scientific risk assessment based on current evidence and information. We fully approve of the UK Food Standards Agency approach which sets maximum levels as described above whilst also permitting additional guidance levels on a national basis as this will ensure continuing consumer choice which is essential for the UK market and specifically for BioCare customers.

The UK has a long history of safe use of dietary supplements. Available data for reported adverse reactions to food supplements show an average of one per annum and most of these reactions have been minor. There is also considerable scientific evidence that food supplements provide significant benefit in supplementing the diet and therefore we would like to continue to provide a wide range of products for our customers.

RESPONSES TO SPECIFIC QUESTIONS

Question 1 (page 11)
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?

BioCare believes that in these cases, the upper safe level should be that level which is believed to be safe without risk of adverse effects. However it is important to distinguish between vitamins and minerals for which there is evidence that high intakes are not associated with adverse effects and those for which there is inadequate evidence to set a firm upper level.

We support the ERNA-EHPM approach of setting an upper level via a qualitative risk characterisation on the basis of the available risk assessment by EFSA/SCF, which gives indications of the nature of the adverse effects and the potential risks in relation to existing patterns of intake.

Question 2 (page 11)

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?

BioCare believes that for these nutrients there should be no maximum levels set because there is no scientific evidence on which these levels can be based as the risk of adverse reactions is so low or non-existent.

Question 3 (page 11)

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 at a high level of public health protection and the legitimate expectations of the various food business operators? Are there alternatives?

It would be very difficult to separate levels for supplements and fortified foods because the intake of vitamin and minerals from fortified foods and food supplements will vary between individuals.

It is important to continue to allow consumer choice by providing consumers with the necessary information to make an informed choice rather than defining set maximum levels for supplements and fortified foods separately.

The UK EVM report was able to provide an upper safe level or a guidance level for supplemental intake alone and also the EHPM-ERNA approach to risk management, which BioCare supports, allows for increasing dietary intakes over time, including the potential for higher levels from fortified foods.

Question 4 (page 12)

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 UK National Diet and Nutrition Surveys provide nutrient intake data across a range of population groups (adults, older people, 1½ to 4 year olds, and 4 to 18 year olds).

However, there is much variation in the quality and standard of intake data available in different member states, due to many factors such as the use of different methodologies and whether food supplements were included or not.

It is therefore important in the future to undertake improved dietary surveys that include estimation of the contribution of vitamins and minerals from food supplements and from fortified foods.

Question 5 (page 12)

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?

No we do not believe they can be used because of the huge variation in dietary intakes between different Member States, related to issues such as food cultures, activity levels, consumption of convenience foods and therefore overall food intakes.

An alternative is to allow individual member states to allow higher levels of nutrients if accompanied by informative advisory statements approved by national experts.

Question 6 (page 12)

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

Setting maximum levels of vitamins and minerals for different population sub-groups would be difficult to apply, especially for food supplements, as these products are not always targeted at specific population groups.

But maximum levels for supplements for children could be very important.

As stated above, due to the variation in the quality and standard of intake data available in different member states BioCare do not believe that intake data should be taken into account to set maximum levels for different population groups.

Overall there should be one main set of maximum levels, although it may also be appropriate to set a separate set of maximum levels for supplements for children, which could be set on the basis of body weight which was the approach used by the SCF/EFSA and the EVM.

Question 7 (page 14)

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

The PRIs/RDAs are described incorrectly in the discussion paper as they represent “minimal” rather than “optimal” intake.

PRIs/RDAs are a useful tool for assessing the risk of exceeding the upper levels of intakes but should not form the basis on which maximum levels are set.

Question 8 (page 15)

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

Generally if we want to add a nutrient in order to make a claim, we would usually add up to the minimum amount in order to be able to make the claim, therefore we would answer yes to the 1st question.

Different (i.e. lower) minimum amounts could be set for certain nutrients, particularly those at high risk of exceeding the upper safe levels.

Question 9 (page 15)

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 they should be sent in a different way?

Since the Nutrition Labelling Directive 90/496/EC, which sets significant amounts for labelling purposes (currently based on 15% of the RDA per 100g or per 100ml), does not apply to food supplements, there is currently no legal basis for the label declaration of minimum quantities of vitamins and minerals in food supplements.

Therefore, for food supplements the minimum amount present and the significant amount for labelling purposes should be set at the same level (15% of RDA).

However, this amount should be different to the significant amount required for claims.