Statement on the: <u>Discussion paper on the setting of maximum ad minimum amounts</u> for vitamins and minerals in foodstuffs

For this discussion we would basically like to emphasise the original character of all ,dietary supplements' and ,fortified food'. As they shall only be seen as addition to our daily diet and not firstly have any pharmaceutical character.

Subsequently the comments concerning the open questions:

- 1. Establishment of maximum amounts for food supplements and other foods
 - It seems obviously that maximum levels of nutrients have to be fixed in their determination or should be dependent on their tolerable upper intake levels. Generally, however, dietary supplements shall only supplement the daily diet, i.e. not replace it à therefore the maximum level of nutrients in supplements and fortified food should be fixed at 100% RDA (100% RDA however only in those cases when products have a spezial aim declared and the concering nutrients are proven to be connected with this ,aim'). If there is neither a scientifically established UL nor a RDA-value maximum levels ought to be fixed on the average daily intake in each member state.
 - Even if there are not yet any advers effects scientifically known the intake by supplements or fortified foods should not exceed the above mentioned 100%-RDA-level. For example: beta-carotene had seemed not to cause any adverse reactions at all, until the results of the CARET-study came out.
 - It does not seem reasonable to set different maximum levels depending on the kind of foodstuff – because dietary supplements and fortified foodstuff are both aimed at supplementing the daily diet and not something else. For this 100% RDA are the reasonable maximum levels. Moreover, for setting the maximum levels of isolated nutrients and being responsible for nutrition professionals are educated best. Therefore we would very much recommend that companies are only allowed to develop and fabricate food supplements when employing a nutrition professional.

2. Intake of vitamins and minerals form dietary sources

On this we are not able to give some more detailed comments. However, both different gender, ethnic group and population should be taken into account when setting the maximum levels of vitamins and minerals. For instance it is absolutely conceivable that some nutrients are only allowed or differently set in their maximum levels for men and women (e.g. iron). For instance the national surveys on the average consumption in each member state should be taken into account (in Germany there ought to be one finished by 2007).

3. Reference intakes of vitamins and minerals

As we mentioned already above the maximum levels of vitamins and minerals shall not only be seen in the point of safety but even more in the basical meaning of the word ,dietary supplement'. They shall supplement the daily diet. This is to us the reason the see all maximum levels depentent on the RDA/PRI or on the average daily intake. In addition, the biological value / bioavailability of the used nutrient-compounds should enter the discussion, too. For high-quality nutrients (e.g. zinc-gluconate) compared to low-value nutrients the stimulation should be enhanced for companies to use them.

4. Minimum Amounts

Nutrients shall be added to foodstuff or food supplements in that significant amount that the name ,supplementation' is justified. That means, it has to be at least 15% of RDA for adding that specific nutrient at all (as required for the declaration of the nutrient in nutrition labelling). However, to claim on that nutrient or make it essential and most valuable for that specific product (e.g. QUID) it has to be added in an amount of at least 33% RDA.

Finally, we want to stress a further problem in the setting of maximum levels of food supplements and fortified food. As especially vitamins react on oxygen, sunlight or heat they degrade during their ,life time' in product. Therefore, to garantee the declared content of a specific vitamin until the expiration date it has to be ,overdosed'. Due to the market demand on long-life-products (pharmacies need at least 24 month) some vitamins are commonly overdosed – sometimes up to two or three times.

That is one reason more why we would recommend to fix the maximum at the 100%-RDA-Level.

Kind regards

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