

Appendix IV**PROPOSED DRAFT GUIDELINES FOR VITAMIN AND MINERAL SUPPLEMENTS****(At Step 3 of the Procedure)****PREAMBLE**

Most people who have access to a balanced diet can usually obtain all the nutrients they require from their normal diet. Because foods contain many substances that promote health, people should therefore be encouraged to select a balanced diet from food before considering any vitamin and mineral supplement. In cases where the intake from the diet is insufficient or where consumers consider their diet requires supplementation, vitamin and mineral supplements serve to supplement the daily diet.

1. SCOPE

1.1 These guidelines apply to vitamin and mineral supplements intended for use in supplementing the daily diet [if and where necessary] with vitamins and/or minerals. These Guidelines apply to vitamin and mineral supplements which are regulated as foods.

1.2 It is left to national authorities to decide whether vitamin and mineral supplements are drugs or foods. These Guidelines do not apply in those jurisdictions where products defined in 2.1 are regulated as drugs.

[1.3 Foods for special dietary uses as defined in the General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses (CODEX STAN 146-1985) are not covered by these Guidelines.]

2. DEFINITIONS

2.1 Vitamin and mineral supplements for the purpose of these guidelines derive their nutritional relevance primarily from the minerals and/or vitamins they contain. Vitamin and mineral supplements are [concentrated] sources of those nutrients alone or in combinations, marketed in capsules, tablets, powders, solutions etc., not in a conventional food form and do not provide a significant amount of energy. [They serve to supplement the daily diet with these nutrients in cases when the intake from food is insufficient or where the consumers consider their diet requires supplementation.]

[2.2 Vitamin and mineral supplements can serve special nutritional purposes, if their composition and contents of minerals and vitamins corresponds to particular dietary requirements that result from certain physical or physiological conditions and they are marketed for that particular purpose.]

3. COMPOSITION**3.1 SELECTION OF VITAMINS AND MINERALS**

3.1.1 Vitamin and mineral supplements shall contain vitamins/provitamins and minerals in conjunction with the relevant Codex standards whose nutritional value for human beings has been proven by scientific data.

3.1.2 The selection of admissible ingredient sources of nutrient or compounds should be based on criteria such as safety and bioavailability of the [FAO/WHO or Pharmacopoeias and national legislation].

[3.1.3 The use of individual vitamins and minerals in supplements can be [limited] for reasons of health protection and consumer safety, taking into account regional or national peculiarities concerning the supply situation of the population].

3.1.4 Vitamin and mineral supplements may contain all vitamins and minerals that comply with the criteria in 3.1.1, a single nutrient or an appropriate combination of nutrients.

[The suitability of a single nutrient or a combination of several nutrients in a vitamin and mineral supplement for the special nutritional purpose for which it is marketed should be proven by scientific data.]

3.2 CONTENTS OF VITAMINS AND MINERALS

3.2.1 [The minimum level of each nutrient contained in a vitamin and mineral supplement should be [15%] of the recommended daily intake or the estimated safe and adequate daily intake.]

3.2.2 [The maximum level of each nutrient contained in a vitamin and mineral supplement should not exceed [100%] of the recommended daily intake or the estimated safe and adequate intake per daily dose.]

3.2.3 [Supplements may contain vitamins and minerals up to a level that is considered safe on the basis of science-based risk assessment considerations, as determined by appropriate risk analysis methodology, taking into account all sources of nutrients in the diet.]

3.2.4 For vitamins and minerals with a narrow safety margin between the recommended daily intake and the adverse effect level, different maximum limits for the daily dose may be established at the national level.

4. PACKAGING

4.1 The product shall be packed in containers which will safeguard the hygienic and other qualities of the food.

4.2 The containers, including packaging material, shall be made only of substances which are safe and suitable for their intended use. Where the Codex Alimentarius Commission has established a standard for any such substance used as packaging material, that standard shall apply.

4.3 Vitamin and mineral supplements should be distributed in child-resistant packagings, if necessary.

5. LABELLING

5.1 Vitamin and mineral supplements are labelled according to the Codex Standard for the Labelling of Prepackaged Foods (Codex-Stan 1-1985, Rev. 1-1991) as well as according to the General Guidelines on Claims (CAC/GL 1-1979).

[5.2 The name of the product shall be "vitamin and mineral supplement" or "dietary mineral/vitamin preparation to supplement the diet with ...", with an indication of the nutrients contained therein or

" vitamin and mineral supplement in cases of ...", with an indication of the special nutritional purposes for products that meet the criteria of 2.2 and 3.1.4.]

[5.3 The amount of the vitamins and minerals present in the product shall be declared in the labelling in numerical form. The units to be used shall be units of weight.

5.4 The amounts of the vitamin and minerals declared shall be those per portion of the product as recommended for daily consumption on the labelling and per unit dose form, as appropriate.

5.5 Information on vitamins and minerals shall also be expressed as a percentage of the reference values mentioned, as the case may be, in the Codex Guidelines on Nutrition Labelling.]

5.6 The label must indicate the recommendations on how to take the product (quantity, frequency, special conditions).

5.7 The label must contain a warning statement [if the product contains a significant amount of a nutrient with respect to the toxicity level.]

[5.8 The label must contain a statement: supplements can not be used for the replacement of meals on long term basis.

5.9 All labels shall bear a statement that the supplement should be taken on an advice of a nutritionist, a dietician or a medical doctor.]