codex alimentarius commission



FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS WORLD HEALTH ORGANIZATION



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Agenda Item 4

CX/NFSDU 01/4-Add.1 September 2001

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

Twenty-third Session Berlin, Germany, 26-30 November 2001

PROPOSED DRAFT GUIDELINES FOR VITAMIN AND MINERAL SUPPLEMENTS - Comments at Step 4 of the Procedure -

Comments from: DENMARK, GERMANY

DENMARK

SCOPE

- 1.1 We wish to delete the text in the square brackets.
- 1.3 We agree with the wording in the brackets. Delete the square brackets.

DEFINITIONS

2.1 We think that it is important to underline that we are talking about concentrated sources. The wording in the second phrase should then be: "Vitamin and mineral supplements are concentrated sources of those nutrients alone or in combinations, marketed in capsules, tablets, powders, solutions etc. not in conventional food form and do not provide a significant amount of energy".

The last sentence in the paragraph is superfluous as it already appears from the preamble. Therefore, delete the text in the square brackets.

2.2 We wish to delete the whole paragraph.

3. Composition

3.1.2 We agree with the text in the square brackets and wish to keep it. Delete the square

3.1.3 Delete the section in square brackets and keep the text.

3.1.4. Keep the first section and delete the section in square brackets.

3. 2 Contents of vitamins and minerals

3.2.1 Requirements for the minimum level must be established to prevent practices, which may mislead or deceive the consumer. Therefore, delete the square brackets, but change the minimum amount. We think that 15 % of the recommended daily intake is too low. We would suggest minimum requirement to be 25% to 30 % of the RDA.

3.2.2 Concerning the maximum value we could accept 100 % of the RDA in general and for certain vitamins and minerals, a few multiple of the RDA.

As a consequence, the following paragraph 3.2.3 in square brackets should be deleted.

5. Labelling

5.2. We prefer that the name of the product should be "vitamin and mineral supplements" As a consequence of that - delete the rest of the paragraph.

Delete paragraph 5.3 paragraph 5.4 and paragraph 5.5.

5. 7. The wording should be: The label must contain a warning statement such as "store out of reach of children" and "Should only be used by pregnant women after consulting a doctor or a health visitor". Delete rest of the text.

Delete paragraph 5.8 and paragraph 5.9.

GERMANY

PREAMBLE

Germany agrees with the proposed preamble.

1. SCOPE

1.1 The square brackets should be deleted to be in accordance with the text of the preamble. Furthermore, the second sentence should be amended to:

"These Guidelines apply only to vitamin and mineral supplements that are regulated as foods by national authorities".

1.2 With the second sentence in 1.1, this paragraph is redundant and should be deleted.

1.3 The square brackets should be deleted and the statement be included in these guidelines.

2. **DEFINITIONS**

2.1 Germany proposes to remove the square brackets around "concentrated". Furthermore, the last sentence of this paragraph, which is currently in square brackets, should be removed, as it is already included in the preamble.

2.2 It can not be denied that vitamin and mineral supplements implicitly serve special nutritional purposes. However, they should not be marketed for that particular purpose. Germany proposes to delete section 2.2.

3. COMPOSITION

3.1 SELECTION OF VITAMINS AND MINERALS

3.1.1 Germany proposes to delete this section.

3.1.2 The square brackets should be removed and the contents amended to:

" The selection of admissible ingredient sources of nutrients or compounds should be based on criteria such as safety and bioavailability of the FAO/WHO, Pharmacopoeias or national standards or legislation."

3.1.3 Germany holds the view that national authorities should be permitted to limit or even prohibit the use of certain vitamins and/or minerals in dietary supplements in countries where national programmes exist that aim at an increased supply of certain nutrients for the population (e.g. water fluoridation, iodisation of salt). Such practice might also be required when the general nutritional behaviour of a population is characterised by high intakes of certain nutrients and the ingestion of additional nutrients through dietary supplements is thus considered hazardous. Taking this into account, Germany proposes to remove the square brackets around the sentence. Moreover, the square brackets around "limited" should be deleted and "or prohibited" be added. The paragraph should read as follows:

"The use of individual vitamins and minerals in supplements can be limited or prohibited 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 The first sentence of this section will have to be changed according to the German proposal to read:

"Vitamin and mineral supplements may contain all vitamins and minerals that comply with the criteria in 3.1.2 and 3.1.3, a single nutrient or a combination of nutrients."

Furthermore, as laid down in 1.3, vitamin and mineral supplements referred to in these guidelines shall not serve special dietary purposes. Thus, the second sentence of this paragraph should be deleted.

3.2 CONTENTS OF VITAMINS AND MINERALS

3.2.1 Germany proposes to delete the square brackets around section 3.2.1. The square brackets around "15%" should be retained.

3.2.2 Germany proposes to substitute the section 3.2.3 for 3.2.2 and delete the square brackets around the current 3.2.3.

5. LABELLING

5.2 Germany proposes to remove the square brackets and amend the sentence as follows:

"The name of the product shall be "vitamin and mineral supplement to supplement the diet with...", with an indication of the nutrients contained therein."

The second part of the paragraph should be eliminated in accordance with the deletion of section 2.2.

5.3 Germany supports the statement.

5.4 Germany supports the statement.

5.5 Information relating to the nutrient content in food supplements is essential for allowing the consumers to make an informed choice and use them properly and safely. In this regard and also in view of the fact that other dietary sources may contribute to the daily intake of vitamins and minerals it is considered important to express the amount of vitamins and minerals also as a percentage of the reference values.

It is proposed to delete the square brackets surrounding the three paragraphs, 5.3, 5.4 and 5.5.

5.7 Germany proposes to remove the square brackets and amend the sentence as follows:

"The label must contain a warning statement if the product contains a significant amount of a nutrient with a narrow safety margin".

5.8 This sentence is unnecessary, provided that the recommendations on how to take the product are carefully indicated (as requested in 5.6). It should be deleted.

5.9 It is stated in the Preamble that vitamin and mineral supplements serve to supplement the daily diet "in cases . . . where consumers consider their diet requires supplementation . . . ". Provided that the formulation of supplements is based on an appropriate risk assessment and good manufacturing practice, there should not be any risk of adverse health effects for consumers who decide to take vitamin and mineral supplements without prior consultation of their doctor or any other health specialist. The statement is therefore considered unnecessary and should be removed.