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**
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

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PROPOSED DRAFT GUIDELINES FOR VITAMIN AND MINERAL SUPPLEMENTS

- Comments at Step 4 of the Procedure -

Comments from:

AUSTRALIA
MALAYSIA
MEXICO
NEW ZEALAND
SOUTH AFRICA
SPAIN

CRN - Council for Responsible Nutrition
IADSA - International Alliance of Dietary/Food Supplement Associations
ISDI - International Special Dietary Foods Industries

AUSTRALIA

Australia regulates products that contain supplementary vitamins and/or minerals as therapeutic goods and consequently is not bound by the Codex Proposed Draft Guidelines (the Guidelines). The salient features of Australia's regulatory system for vitamin and/or mineral supplements have been previously described in CX/NFSDU 98/5-Add.1. The impetus for the progression of these Guidelines comes from a perceived need to introduce a Codex standard for vitamin and/or mineral supplements traded as foods.

DISCUSSION

This Guideline would benefit from considerable editing to streamline its minimum requirements. Australia therefore submits the following comments.

Section 1 Scope

1.1 This section could be reduced, given the context set by the preamble and without changing intended meaning to: "These Guidelines apply to vitamin and mineral supplements which are regulated as foods *by national jurisdictions*". The words in square brackets [if and where necessary] currently conflict with the context set by the preamble and should be deleted.

1.2 The language should refer only to products *not regulated as foods*. The current wording does not allow for third regulatory categories such as dietary supplements. Thus: "It is left to national authorities to decide whether vitamin and minerals supplements are foods *or not*. These Guidelines do not apply in those jurisdictions where products defined in 2.1 are *not regulated as foods*."

1.3 The inclusion of section 1.3 is supported as this clarifies the intended scope of the Guidelines.

Section 2 Definitions

2.1 [Concentrated] refers to a process rather than an outcome. It is preferable to regulate concentrations by setting upper and lower limits, therefore [concentrated] should be deleted. The [second sentence] states the purpose and is consistent with the preamble, and should remain.

2.2 Conflicts with [sentence in 2.1] and therefore should be deleted.

Section 3 Composition

3.1.1 The meaning of this sentence needs clarification and could be reworded to: "Vitamin and mineral supplements shall contain vitamins/provitamins and minerals whose nutritional value for humans has been proven by scientific data and whose status as vitamins or minerals is recognised by Codex standards."

3.1.2 Australia supports the use of scientific methodology to determine the vitamin and mineral safety and bioavailability according to recognised international and national references.

3.1.3 If the intention of this provision is to permit national authorities to depart from the compositional limits imposed by the Guidelines, then the provision sits better within section 3.2 Contents of Vitamins and Minerals, in which case 3.2.4 appears to be attempting to convey the same intent. It should be reworded to clarify intent.

3.1.4 [The sentence in square brackets relates to purpose and associated claims.] The composition of the product should fit the purpose, and any claims in relation to the product should be substantiated by rigorous scientific evidence. This sentence is similar to 2.2 and for the same reason as given under 2.2, should be deleted.

Section 3.2 Contents of Vitamins and Minerals

3.2.1 & 3.2.2 These options are not supported. There should be no prescribed, absolute minimum levels, however minimum levels could be set in association with criteria for content and function claims.

3.2.3 Australia supports this option. It implies that national or regional authorities will be making the final decisions including those nutrients referred to under 3.2.4 until international agreement is reached on appropriate risk analysis methodology.

3.2.4 This provision refers to 'different' which implies that maximum numerical limits will be set. It is superfluous if 3.2.3 is adopted.

Section 4 Packaging

4.3 Australia queries the need for the qualifier 'if necessary'. It is expected that all packaging should be child resistant.

Section 5 Labelling

5.2 The appropriate designation of the product should be confined to 'vitamin supplement'; 'mineral supplement'; or 'vitamin and mineral supplement'. Australia notes the provisions in the Codex General Guidelines On Claims that permit this Committee to regulate claims as to the suitability of a food for use in the prevention, alleviation, treatment or cure of a disease, disorder or particular physiological condition. Australia therefore does not disagree with the intention of the prescribed statements but believes that the exact wording does not need to be prescribed. It could be reworded as "The appropriate designation of the product shall be …..; the special nutritional purpose of the product may be stated on the label either in terms of its primary nutrient content, or the human condition to be addressed." This approach adds labelling flexibility to facilitate trade.

5.3 Australia supports the statement.

5.5 Australia believes this requirement should not be mandatory but voluntary. Also that the reference values for the labelling of vitamin and mineral supplements should be those adopted by national or international authorities rather than the Codex labelling reference values for general purpose foods. For example, a supplement intended for consumption during pregnancy or lactation could adopt the reference values relevant to that subgroup.

5.7 Australia supports label statements, where applicable, that warn consumers not to exceed a stated maximal dose or one-day quantity.

5.8 & 5.9 These statements are opposed because they conflict with the sentiments expressed in the preamble.

MALAYSIA

Section 1 Scope

Section 1.3

Malaysia proposes to remove the square brackets in section 1.3 and adopt the text contained in the brackets.

This section is to read :

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.

Section 2 Definitions

Section 2.1

Malaysia proposes to remove all the square brackets and adopt the texts contained in the brackets. It is very important to clearly state that vitamin and mineral supplements are concentrated sources of these nutrients, so as to avoid confusion with enriched or fortified foods. It is also important to clearly state in the definitions that vitamin and mineral supplements are required only in cases when the intake from food is insufficient and they should not be used to replace a balanced diet.

This section is to read :

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. This supplement should not be used to replace a balanced diet.

Section 3 Composition

Section 3.1.2

Malaysia proposes to remove the square brackets in section 3.1.2 and adopt the text contained in the brackets.

This section is to read :

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.

Section 3.1.3

Malaysia proposes to remove all the square brackets and adopt the texts contained in the brackets in section 3.1.3. The word “can be” before the word limited is proposed to be amended to “should be” so as to emphasize that the consumer has to practise caution and limit intake of certain of these nutrients, depending on the specific situation they are in.

This section is to read :

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

Section 3.1.4

Malaysia proposes to remove the square brackets in section 3.1.4 and adopt the text contained in the brackets. To avoid misleading the consumer, it is important that the suitability of use of the supplement should be scientifically proven and endorsed by internationally recognized bodies.

This section is to read :

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 and endorsed by internationally recognized body.

Section 3.2.1

Malaysia proposes to remove all the square brackets and adopt the texts contained in the brackets in section 3.2.1. To protect the interest of the consumer against fraudulent practice, it is important to have a minimum level stipulated for the vitamin and mineral supplement.

This section is to read :

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 intake per daily dose.

Section 3.2.2

Malaysia proposes to remove all the square brackets and adopt the texts contained in the brackets in section 3.2.2. The upper level of the supplement should be stipulated so as to ensure that the supplements are still within physiological dosages and thus reducing risk to excessive intakes.

This section is to read :

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.

Section 3.2.3

Malaysia proposes the deletion of the text in section 3.2.3 in view that this section is redundant with the statements in section 3.2.1 and 3.2.2. Without any specific lower and upper limits, the clause 3.2.3. is too general and will not benefit the consumer.

Section 5 Labelling

Section 5.2

Malaysia proposes to remove the square brackets in section 5.2 and the deletion of the statement in this sentence, i.e. *"…..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* , and replace with "…..*with an indication of the vitamin and/or mineral contained therein"*. This is to simplify the appropriate designation of the product on the label and to avoid claims being made on the label, especially with the 3rd option mentioned above.

This section is to read :

The name of the product shall be "vitamin and mineral supplement", with an indication of the vitamin and/or mineral contained therein.

Section 5.3

Malaysia proposes to remove the square brackets in section 5.3 and add the words "biologically active part of the" before the words ".vitamins and minerals". This is in view that the weight of the biologically active part is different from that of the whole compound. For example, in the supplement zinc sulfate, zinc is the biologically active part of this compound and the weight of zinc is of interest to the consumer and should be declared on the label, not the weight of zinc sulfate.

This section is to read :

The amount of the biologically active part of the vitamins and minerals present in the product shall be declared on the label in numerical form. The units to be used shall be units of weight.

Section 5.4

Malaysia would like to seek clarification on the word "per portion" in this sentence.

Section 5.5

Malaysia proposes to add the word 'Nutrient' before the word "…reference values" for clarity, ie Nutrient Reference Values.

Section 5.7

Malaysia proposes to remove the square brackets in section 5.7 and adopt the text contained in the brackets for the safety of consumers. It is important that the consumer be appropriately warned of the possible toxic effects when consumed above a certain level.

This section is to read :

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

Section 5.8 and 5.9

Malaysia proposes to remove the square brackets in section 5.8 and 5.9 and adopt the text contained in the brackets. In the first statement, the consumer should be clearly warned that supplements are for short periods of time when nutrient needs are not met and that the daily diet must be the ultimate source of nourishment. The

second statement is important as there is much concern that the sale of such supplements are being carried out by personnel not qualified to do so and may bring more harm than good to the consumer.

These sections are to read :

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

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

MEXICO

Irrespective of the fact that these products have been classified as medicaments in Mexico and are subject to special regulations, we duly state the following:

PREAMBLE

Concerning this section, we propose deleting or amending the part *"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."* since consumers are not always able to decide by themselves whether they need supplements, and their selection is generally based on advertising for these products. On the other hand, sections of the population who are not ensured appropriate nutrition will not be able to spend money in order to buy supplements either. This also applies to Section 2.1 concerning the definition. Therefore we propose in both cases either deleting the parts concerned or adding "where it is believed to be necessary on the advice of a specialist", so that the sentence reads as follows: *"In cases where the intake from the diet is insufficient and* ***where it is believed to be necessary on the advice of a specialist to supplement one's diet*** *, vitamin and mineral supplements serve to supplement the daily diet."*

1. SCOPE

- We propose deleting the brackets in Section 1.1 in order to emphasize that vitamin and mineral supplements should be taken in justified cases on the advice of a specialist, as suggested in the Preamble.

2. DEFINITIONS

- Section 2.2 should be deleted as the decision regarding the need for vitamins and minerals should be taken by a doctor on the basis of special physical or physiological conditions, and not by the consumer himself.

3. COMPOSITION

- We propose deleting the brackets in Section 3.1.2 and retaining the reference to FAO/WHO, pharmacopoeias and national legislation, since they are of fundamental importance for the individual governments given the fact that different requirements exist depending on race, habits and regional strategies.
- As nutritional and education conditions vary from country to country, Mexico requests that Section 3.1.3 in brackets be retained.
- Section 3.1.4 should state that in addition to the criteria of Section 3.1.1, those of Section 3.1.2 must also be met. Moreover, the brackets in the final paragraph containing the provision that the suitability of a nutrient or a combination of nutrients in a supplement should be proven by scientific data should be deleted.
- As many countries base their own legislation on Codex standards, we request information about the scientific basis of the stipulation that 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. Moreover, the document should define precisely what "safe and adequate daily intake" means, and how this differs from the recommended daily intake.

5. LABELLING

- With regard to Section 5.2, we do not agree that the labelling of the product should be allowed to be connected with the physical or physiological condition or the special nutritional purpose, as this could arouse false hopes in the consumer and lead to the self-medication of ailments resulting from a variety of causes which should be treated under medical supervision.
- Sections 5.8 and 5.9 in brackets should be retained and amended as follows:

  - "5.8 The label ..., supplements can not be used as a replacement for a meal (breakfast, lunch, dinner)."

  - "5.9 All labels shall bear a statement that the supplement should only be taken on the advice and upon prescription by a nutritionist, a dietician or a medical doctor."

NEW ZEALAND

Section 1 - New Zealand recommends that text be added to the scope of the guidelines to note that the use of other food substances in vitamin and mineral supplements is not addressed in these guidelines at this stage.

Section 1.1 - New Zealand recommends removing the square brackets [if and where necessary], as this duplicates information given in the preamble.

Section 1.3 - New Zealand supports retaining this section in square brackets, and also adding words to the effect that national authorities may decide to consider these guidelines appropriate for specific foods regulated as special purpose foods in their jurisdiction.

Section 2.1 - New Zealand supports the inclusion of [concentrated] in the definition. New Zealand also suggests rewording this section, as follows:

> "Vitamin and mineral supplements for the purpose of these guidelines are concentrated sources of those nutrients alone or in combinations, marketed in controlled dosage form as capsules, tablets, powders, solutions etc., not in a conventional food form."

New Zealand questions why vitamin and mineral supplements should not be able to provide a significant amount of energy, and recommends removing that phrase. We note that the last sentence is already covered in the preamble, and therefore suggest removing it.

Section 2.2 - New Zealand does not support the inclusion of this section in square brackets, as the supplements referred to are more likely to be considered therapeutic products. Also, reference is made to the need to market the products for their particular dietary purpose. However, there should be consistency with the regulation for health and related claims and such marketing could well be considered a health claim.

Section 3.1.3 - In this sentence, New Zealand suggests replacing the phrase "can be limited for reasons of" with the phrase "should be limited where there are issues of".

Section 3.1.4 - The square bracketed text ("[The suitability of a single nutrient…]") is not necessary, as the information is already addressed in section 3.1.1.

Section 3.2.1 – New Zealand agrees with the inclusion of a percentage of the recommended daily intake (RDI). New Zealand supports 10-15% of the RDI.

Section 3.2.2 - New Zealand does not agree with the blanket upper limit of 100% RDI, as this could differ with different nutrients. New Zealand supports a risk based approach where upper limits are established where there are issues of public health and safety.

Section 3.2.3 – New Zealand supports this section, noting that it may be in conflict with section 3.2.2, which New Zealand does not support.

Section 5.2 - New Zealand does not believe it to be necessary to include the term "vitamin and mineral supplement" in the name of the product, and recommends that this phrase be required to appear in the principal display panel instead.

Section 5.3 - New Zealand supports the inclusion of the text in square brackets in respect to labelling, and recommends that the units referred to be units of "amount" to cater for both solids and liquids.

Section 5.5 - New Zealand supports the inclusion of the text in square brackets and recommends replacing "information" with "declarations", to be more specific. Again, we seek clarification on the use of a country's RDI for NRV.

Section 5.6 - New Zealand recommends that the label include age groups, where appropriate.

Section 5.7 - New Zealand finds the wording about the warning statement unclear, as the term "significant amount" is ambiguous. We suggest rewording it to reflect a risk based approach where warning statements are required where there is a potential for public health concern.

Section 5.8 - New Zealand does not support the statement as written, as it could be taken to mean that supplements **can** be used to replace meals on a short term basis. New Zealand supports the inclusion of a statement that reflects the role of supplements in conjunction with diet where nutritional needs may be enhanced.

Section 5.9 - New Zealand supports the inclusion of a recommendation that consumers seek advice from health professionals on dietary supplement consumption, rather than a warning statement.

SOUTH AFRICA

PREAMBLE

No changes.

1. SCOPE

1.1 Remove the square brackets around [if and where necessary].

2. DEFINITIONS

2.1 Remove the square brackets around [concentrated].

3. COMPOSITION

3.1 Selection of Vitamins and Minerals

3.1.3 Remove the square brackets around the sentence and around the word [limited].

3.1.4 Remove the sentence in square brackets [The suitability of single*... scientific data].

3.2 Contents of Vitamins and Minerals

3.2.1 Remove the square brackets around the sentence and around [15%] and amend the wording of the sentence as follows: When a nutrient function claim is made for an individual nutrient, the minimum level of that nutrient contained in a vitamin and mineral supplement shall be not less than 15 % of the recommended daily intake or the estimated safe and adequate daily intake.

3.2.2 Delete this sentence from the text.

3.2.3 Remove the square brackets around this sentence.

4. PACKAGING

No changes.

5. LABELLING

5.7 Add the words "where appropriate" after the words "warning statement".

Remove the square brackets in this sentence.

5.8 Replace "must" with "may".

5.9 Replace sentence with the following: Labels may bear a statement that the supplement should be taken on the advice of a suitably qualified health professional.

SPAIN

Re Section 1. Scope

- As we agree with the content of the wording in brackets in Section 1.1, we propose that the brackets be removed.
- In the third line of para. 1, "…which are regulated as…" should be amended to "… which under national regulations are regulated as …".
- As we agree with the content of the wording in brackets in Section 1.3, we propose that the brackets be removed.

Re Section 2. Definitions

- We propose deleting the brackets in the third line of Section 2.1.
- In the third line of Section 2.1, "... marketed as capsules ..." should be amended to "... marketed in a form which permits precise dosage in capsules ...".
- We propose deleting the wording in brackets at the end of Section 2.1 as this is already contained in the preamble and is therefore no longer necessary.
- We propose deleting Section 2.2 as the Section headed "Scope" stipulates that foods for special dietary uses are excluded.

Re Section 3. Composition

- We propose adding "internationally recognized" at the end of Section 3.1.1.
- As we agree with the content of the wording in brackets in Section 3.1.2, we propose that the brackets be removed.
- To make Section 3.1.3 clearer, we propose rewording it as follows:

  "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 of the country in which the product is to be marketed."
- In the second paragraph of Section 3.1.4, "… by scientific data." should be amended by "... by internationally recognized scientific data."
- In the third line of the same paragraph "… que se lo comercializa." should be amended to " …que se comercializa."

- We propose that Section 3.2.1 be reworded as follows:

  "3.2.1. The minimum level of each nutrient contained in a vitamin and mineral supplement should be 15% of the recommended daily intake" since the estimated safe and adequate daily intake describes a particular characteristic of the recommended daily intake and therefore does not need to be mentioned.

- For the same reason, we propose rewording Section 3.2.2 as follows:

  "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."

- As in our opinion Section 3.2.3 is made superfluous by the proposed amendments to Sections 3.2.1 and 3.2.2, we propose that it be deleted.

- Furthermore, Section 3.2.4 should be deleted as the recommended daily intake in the form of a maximum limit for vitamins and mineral supplements has already been evaluated and ought not to have a harmful effect.

Re Section 5. Labelling

- We propose rewording Section 5.2. as follows:

  "5.2. The name of the product shall be 'vitamin and mineral supplement' with an indication of the nutrients contained therein."

- As we agree with the content of the wording in brackets in Section 5.3, we propose that the brackets be removed.

- We propose adding the following text to the end of Section 5.4: "The recommendation for intake may not exceed 100% of the recommended daily intake."

- As we agree with the content of the wording in brackets in Section 5.5, we propose that the brackets be removed.

- Section 5.7 should be reworded as follows:

  "The label must contain a warning statement concerning the toxicity and possible risks of exceeding the recommended dose."

- Section 5.8 should be reworded as follows:

  "The label must contain the following warning: 'Supplements cannot be used as a substitute for meals nor for a varied, balanced diet."

- Section 5.8 occurs twice. The numbering is to be corrected.

- As we agree with the content of the wording in brackets in Section 5.9, we propose that the brackets be removed.

CRN - Council for Responsible Nutrition

Comments are provided on specific sections of the proposed draft guideline.

1. PREAMBLE

The Preamble section should be omitted. If it is kept, it should be modified to be policy neutral about where and when dietary supplements are needed. Advice about who needs or does not need dietary supplements should not be part of the proposed draft guideline that is intended to be a regulatory tool for the issues identified in the titles of the remaining sections.

2. DEFINITIONS

2.1 The word [concentrated] is usually accurate, but is not needed and should be omitted. The last sentence in square brackets supplies no useful information and should be omitted

2.2 The phrase "and they are marketed for that purpose" is not literally true. They can serve the purpose describe whether or not they are marketed for that purpose. The phrase should be deleted.

3. COMPOSITION

3.1 SELECTION OF VITAMINS AND MINERALS

3.1.2 The wording in the square brackets should be kept, and the brackets should be removed.

3.1.3 The words "use of" should be replaced by "composition and labeling of." This change will make sure that the Guideline, when approved, will be a useful regulatory tool.

3.1.4 Acceptable, contingent upon 3.1.1 being retained in present form. The sentence in square brackets following 3.1.4 is a supplement labeling issue, as it refers to the "purpose for which it is marketed." Labeling is the only way to discern the purpose for which the product is marketed. Labeling claims should have scientific substantiation that meets guidelines and standards promulgated by the Codex Committee on Food Labeling. The sentence in square brackets should be modified by adding words after "by scientific data" so that the final phrase reads: "by scientific data that meet the requirements adopted by the Codex Committee on Food Labeling."

3.2 CONTENTS OF VITAMINS AND MINERALS

3.2.1 The sentence in square brackets should be retained if it is modified to eliminate specific problems. It should state that a minimum of15% of the recommended daily intake applies to vitamins and minerals added deliberately for nutritive purposes and to those for which a nutrition claim is made. This section should state that the minimum does not apply to the vitamins and minerals that are used only for technical reasons as food additives or that are present only as minor components of another nutritive ingredient.

3.2.2 This section should be dropped, and paragraph 3.2.3 used instead.

3.2.3 The square brackets should be removed, and safety adopted as the only basis for limits.

3.2.4 This section should be dropped, in order to prevent its misinterpretation and misuse to support unjustified technical barriers to trade, without providing any additional safety. The fact that the safety limit will be near the recommended intake for specific nutrients should not change the basis for the limit. The basis should be safety only. The current wording of this section invites policy preference to be used to define specific safety limits as being "near" the recommended intake, so that national preference for RDA-based limits can be used to evade the Codex guideline.

4. PACKAGING

4.1 This section is appropriate.

4.2 This section is appropriate.

4.3 This sentence should be modified by editing the last clause to read: "if necessary to reduce the risk of acute overdose to children who consume the product by mistake.

5. LABELLLING

5.1 This section is appropriate.

5.2 This section should be changed in accordance with recommended changes in sections 2.2 and 3.1.4.

5.3 The intent of this section is appropriate—to require quantitative declaration of product content. Codex guidelines should require declaration in units of weight, but should also allow local requirement of declaration in units of activity. For example, a vitamin E product could be labeled in milligrams and International Units.

5.4 This requirement is appropriate.
5.5 This requirement is appropriate.
5.6 This requirement is appropriate.
5.7 This section must be modified to prevent misinterpretation and arbitrary decisions on whether a warning is required. RECOMMENDED WORDING: The label must contain a warning statement if the product contains an amount of the nutrient that has been shown to contribute to adverse effects in consumers.
5.8 The wording could be improved. RECOMMENDED WORDING: The label must contain a statement: Supplements are intended to supplement the diet with specific nutrients, and cannot be used as meal replacements.
5.9 This section should be dropped.

The following comment provides background rationale for the specific comments and recommendations given above.

BACKGROUND

A discussion paper was developed by a voluntary working group consisting of representatives from Brazil, Canada, the European Commission, Mexico and the United States in their delegations to the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU). This paper provides a summarization of the issues raised in consideration of a Codex guideline for vitamin and mineral supplements. The paper was discussed at the last (22st) meeting of the CCNFSDU in 2000, and the issues are still valid in relation to the current proposed draft guidelines, Appendix IV of the CL 2000/22 NFSDU, July 2000.

CRN recommendations on issues in the Discussion Paper:

Government delegations should strongly support appropriate development of the CCNFSDU draft guideline on vitamin and mineral supplements, carefully taking into account certain elements of the Discussion Paper. The critical elements of the guideline would be to specify nutrient appropriate risk assessment as the only basis for maximum limits, and a negative list rather than a positive list to determine permissible ingredients.

The rationale for a Codex guideline on vitamin and mineral supplements includes:

1. The membership of Codex includes approximately 160 countries, and thus a Codex guideline would provide for truly international standards to protect consumer health and fair practices in trade.
2. The CCNFSDU should recognize that other organizations such as the European Commission and some individual countries such as the United Kingdom are considering guidelines for vitamin and mineral supplements. Such independent development of guidelines runs counter to the increasingly international character of consumer awareness and demands. This globalization of consumer expectations and markets requires truly international Codex guidelines and standards for health protection and fair practices in trade.

SPECIFIC ISSUES

Issue: PURPOSE AND USES OF VITAMIN AND MINERAL SUPPLEMENTS

There are two major viewpoints on the purpose and use of vitamin and mineral supplements:

(1) Consumers should have easy access to safe, well-made and properly labeled and promoted dietary supplements to assure sufficient intake of vitamins and minerals to meet needs related to (a) uncertain intake related to changes in diet, (b) decreased needs for food related to increasingly sedate lifestyle, (c) decreased efficiency of utilization of some nutrients by increasing numbers of elderly individuals, and (d) possible decrease in the risk of certain chronic diseases.

(2) Governments have the obligation to assure that (a) good dietary habits are not adversely affected by use of vitamin and mineral supplements, (b) use of supplements do not lead to detrimental imbalances of vitamins and minerals, (c) resources are not wasted on unneeded vitamin and mineral supplements.

CRN comment: Government delegations should recognize that:

(1) Vitamin and mineral needs may increase with changes in lifestyle, activity, and aging.

(2) Current scientific evidence is never complete, and recommended intakes are being continuously revised to account for increased data on nutrient requirements and/or to provide additional benefits not previously recognized.

(3) Governments and other bodies can enhance the public health and interest in health-enhancing self-care through nutrition education and regulations that assure vitamin and mineral supplement products are safe, well-made, and appropriately labeled and represented.

CRN urges Government delegations to support the maximum freedom of choice by consumers that can be safely exercised, and to support a Codex guideline on vitamin and mineral supplements that assures ready availability of products that are safe, well-made, properly labeled, and responsibly promoted.

Issue: PRODUCTS TO BE COVERED BY A GUIDELINE AND TERMINOLOGY TO DESCRIBE THE COVERED PRODUCTS

The primary issues identified address content and terminology. With regard to content, should the proposed draft guideline cover:

(1) Supplements that contain only vitamins and minerals?

OR

(2) Supplements that contain other ingredients in addition to vitamins and minerals?

If the first option is selected, should the guideline recognize that there are supplements that contain other nutrients, and the guidelines simply do not address those products? A narrow guideline that addresses only vitamins and minerals would lessen the burden and presumably hasten the work necessary to develop the guideline. Alternatively, should the CCNFSDU avoid developing a guideline that does not address a wide range of nutrients that are commonly included in supplements as the result of ethical scientific research and authoritative recommendations? Clearly, the wider scope would increase the work and slow the progress toward development of a guideline.

Even if the guideline is restricted to vitamin and mineral supplement, should the products be intended only for general use for the population at large, or may the be intended for particular nutritional requirements of specific groups such as pregnant women, infants, the elderly, or other persons with special dietary needs? Additionally, the guideline allows the supplements to be intended to meet special health needs, and the products would be foods for special dietary uses, rather than general food products.

With regard to terminology, the proposed guidelines originally addressed "dietary supplements," but this was changed to "vitamin and mineral supplements" at the 20th meeting of the CCNFSDU. Some have expressed concern about use of the term "dietary" as possibly sanctioning supplementation of any substance found in the diet, without regard to whether it provided any nutritive or other beneficial effect.

CRN comment: If supplement guidelines are to be developed, the initial objective for the CCNFSDU should be the development of a Codex guideline for "vitamin and mineral supplements." No doubt, a more general guideline that addresses other appropriate ingredients for "dietary supplements" or "food supplements" should follow the vitamin and mineral guidelines. The narrower initial focus for a guideline on "vitamin and mineral supplement" will expedite the work, and this process should provide guidance for development of a broader guideline that would cover all appropriate ingredients for "dietary supplements." The proposed draft guideline for vitamin and mineral supplements should recognize that this additional work is needed.

The term "vitamin and mineral supplements" is appropriate if other ingredients are not precluded. The guideline should simply state that other ingredients are not precluded but are not addressed at this time, but may be in the future.

If the broader guideline is proposed and appropriate definitions and descriptions are included, "dietary supplements" or "food supplements" could be an acceptable term.

Issue: POSITIVE AND NEGATIVE LISTS

This issue raises numerous questions, every one of which must be answered. If a positive list is developed, will the ingredient on the list be the nutrient itself or the chemical substance that includes the nutrient? How

will the list be amended? What criteria are needed for inclusion of an ingredient in the list? Will ingredients in current widespread use be "grandfathered" as safe and appropriate for the positive list? However a positive list is constructed, ingredients not on the list would not be permitted. If a negative list is developed, it also could address any component of a chemical substance.

A. Lists of nutrients

Positive list: For a positive list, a nutrient approach is much more flexible that a chemical compound approach. The basis of a positive list could be quite general and permissive, or quite narrow and restrictive.

Criteria that have been suggested for development of a positive list include: (1) clear scientific evidence that the vitamin or mineral is "essential" for human nutrition, and (2) limitation to the vitamins and minerals not normally found in "abundance" in the diet (i.e., those with a significant incidence of deficiency in the population).

Negative list: For a negative list, a chemical compound or chemical moiety might be the listed ingredient. The guideline would permit inclusion of any substance not included in the negative list. Thus, a negative list may be more flexible and versatile approach than a positive list represents.

CRN comment: A positive list of nutrients should be avoided because it will always be out of date in relation to accumulating and relevant scientific evidence. Certainly, **nutritional essentiality,** meaning essential to life, should not be construed to be synonymous with nutritional value or usefulness. For example, several decades of research have not shown definitively that fluoride is an essential element for humans, but there is overwhelming evidence that appropriate intake of this element is beneficial (in reducing the incidence of dental caries). Recent research has shown unique and beneficial effects of the common dietary carotenoid lutein in protecting against age-related macular degeneration. Again, there is no compelling evidence that lutein is essential to life, and the quantitative evidence is not sufficient to set an RDA.

Vitamin and mineral supplements should permit, at safe levels, substances that occur in the diet and provide nutritive value, regardless of whether they are essential to life. Substances that fit into another nutritional category, such as fatty acids and amino acids, should not be excluded from vitamin and mineral supplements, although labeling rules should prohibit describing them as vitamins and minerals.

In general, guidelines and criteria are more appropriate than lists, either positive or negative. If any list is to be developed, the CCNFSDU should adopt a negative list approach because it allows consumers a greater choice, and if employed appropriately would fully protect the public health. A positive list should be avoided because it is likely to be unnecessarily restrictive in a manner that will inhibit the research and innovation to identify and formulate new, beneficial and more effective products.

B. List of sources of nutrients

Positive list: A positive list would specify the ingredient permitted in vitamin and mineral supplements. Any source of nutrients not on the positive list would be prohibited. A positive list establishes the product category as a commodity list that may restrict free trade without the restriction providing any benefit to consumers.

CRN comment: Because a positive list may seem attractive at first glance, it is important to examine the features and likely impacts. **Substantial equivalence**, as recognized by Codex for many other purposes, is an appropriate and crucial concept in any consideration of a positive list.

The meaning and impact of application of substantial equivalence for a positive list of vitamin and mineral compounds for use as ingredients in vitamin and mineral supplements can best be illustrated through examples:

1) **Thiamin.** This B-vitamin does not occur as free thiamin, because it is an unstable, hygroscopic free base. Commonly used commercially available forms of thiamin include thiamin hydrochloride, thiamin mononitrate, and thiamin phosphate. These three chemicals are equally useful as substantially equivalent sources of thiamin (with only a minor adjustment for differences in molecular weight). If a positive list is adopted, thiamin should be the ingredient listed, and thus any of the specific chemical forms would be appropriate.

2) **Iron.** This essential element is available in numerous chemical forms that are substantially equivalent (with only molecular weight corrections) for use in vitamin and mineral supplements. Numerous iron compounds have the ferrous ion associated with a metabolizable organic anion such as gluconate, furmarate, lactate, and so on. Each of these compounds is equally effective and appropriate for inclusion in a positive list.

GENERAL PRINCIPLE: Essential mineral elements occur as either positively charged cations or negatively charged anions. Most essential minerals are cations. For these elements, the accompanying anion that is necessary to form an electrically neutral chemical compound can be interchanged with many others without any significant consequence to the nutritional value or safety of the substance. For example, commonly used sources of iron, including ferrous citrate, ferrous fumarate, ferrous gluconate and ferrous sulfate might be included in a positive list, but only one source of copper, cupric sulfate, might be included. There is a massive amount of scientific evidence and compelling rationale that these anions could be compounded with copper or another cationic essential element and be substantially equivalence to other forms of the same element. Hence, these substances should be permitted by a positive list that permitted a soluble chemical compound of cupric copper in combination with any non-toxic anion that is safe when combined with that essential element.. Combinations of an essential nutrient with another substance that rendered the compound unfit for human consumption would not be allowed—that is, it could be prohibited by a negative list. A compound of essential ferrous iron with the toxic anion cyanide, that is, ferrous cyanide, would not be allowed because of the toxicity of the cyanide, and more than micrograms quantities should be included in a negative list.

3) **Vitamin A.** If retinyl palmitate were the only vitamin A source on a positive list, retinyl acetate would not be allowed. Instead of an arbitrary and unneeded restriction, any form of vitamin A that has documented substantial equivalence (after correction for molecular weight) should be allowed as a substitute. If retinyl palmitate is useful and safe, there is doubt that retinyl stearate or retinyl oleate would be equally appropriate.

4) **Vitamin C.** Any positive list developed must be flexible enough to permit use of an appropriate plant extract concentrate as the source of a specified nutrient. For example, acerola cherry extract is a safe, useful, and appropriate source of vitamin C.

Negative list: A negative list would be a specified list of substances that would be prohibited for addition to (deliberate inclusion in) vitamin and mineral supplements. Any substance not on the list could be added to vitamin and mineral supplements.

CRN comment: A negative list would be only as useful and valid as the criteria and standards used to generate it. The main criterion for a negative list should be a lack of safety at the level added as shown by recognized scientific procedures and decision paradigms. Some substances may generally qualify for the negative list (e.g., cyanide salts of cationic minerals, but not cyanocobalamin which provides only submicrogram quantities of cyanide while providing nutritionally useful amounts of vitamin B12).

A negative list must not be constructed on criteria that are not valid as generalities. For example, it is impossible to categorize certain substances as having "inherent toxicity" and categorizing others as "safe." Such a perspective is false and scientifically naïve—it ignores Paracelsus' truthful axiom that "the dose makes the poison." Certainly, some vitamins and essential minerals have recognized toxicity at high intakes, but each has essential or beneficial effects at intakes that are well within the safe intake range for that substance. For example, up until about 40 years ago, the only recognized biological effects of selenium related to its well-established toxicity. Since then, however, selenium has been recognized as an essential trace element, and more recently selenium intakes that are approximately three times the usually recommended intake have been shown to have anti-cancer effects in humans. Any generalization that selenium "can be toxic" may be truthful in a narrow sense, but would be very misleading. Such a criterion for a negative list would do more harm that good.

Issue: MAXIMUM LEVELS

The discussion paper correctly points out that there are two main viewpoints on this issue. One is that maximum levels should be based on nutrient appropriate risk assessment, for which the only goal is safety. The other is that limits should be tied to RDA values. The goals behind RDA-based limits can be either to a

simplified but overly restrictive approach to safety, or to avoiding excessive intakes that hare not recognized to have nutritional value.

CRN comment: The RDA was not defined to address safety, and none of the data that are used to establish RDAs are pertinent to safety. Thus, any maximum limits based on the RDA will not have any meaningful relationship to safety. Of course, RDA intakes are safe (by experience, not by testing for that purpose), but most nutrients are safe at intakes far above the RDA. Currently, a true paradigm change is occurring whereby this matter is evolving toward expert recommendations for RDAs that are much higher intakes of certain nutrients than previous values.

RDA-based limits are arbitrary and not related to safety, and thus carry the potential to be harmfully restrictive. With the progress in nutrition research, any assumption that the RDA represents safety is, in effect, imposing limits based on current knowledge of the benefits related to higher intakes nutrients. Calcium, folic acid, and vitamins C and E are examples of nutrients with higher needs recently recognized by increased RDA from the U.S. National Academy of Sciences..

Much of the currently researched benefits relate to reduction in the risk of chronic diseases that do not originate primarily from nutrient deficiency but are, nevertheless, beneficially influenced by nutrient intake. Codex and national government policy should not establish guidelines that would preclude such benefits. The expanding scientific evidence that selenium intakes well above the RDA may reduce the risk of certain cancers make an excellent example of the folly involved in setting "safety limits" at or very near the RDA when such restrictions are not needed to assure safety. If limits are set, they should be based directly on genuine safety considerations. Risk assessment for safety accommodate nutritional need and benefits, in order to avoid setting unwarranted and unnecessary "safety limits" that preclude benefits of intakes above the RDA.

The U.S. National Academy of Sciences has adopted the use of direct risk assessment (the Tolerable Upper Intake Level, UL) rather than a simple multiple of the RDA as the most appropriate method to identify Upper Limits for nutrients. The uncertainty factors used in the NAS UL method are fully database-derived—that is, they avoid arbitrary default values such as multiples of 10 or 3. The NAS has not made the mistake of using excessive safety factors and then claiming that the restrictive limit was valid because it was "still above the RDA."

Many vitamins and some minerals are so nontoxic that setting safety limits would be an idle gesture. Others have well-recognized capacity for adverse effects at sufficiently high intakes. For example, thiamin, riboflavin, biotin, pantothenic acid, vitamin B-12, vitamin C, vitamin E, and vitamin K have either extremely low or no known toxic potential. In contrast, vitamin A, vitamin D, niacin, and pyridoxine have well recognized capability for causing adverse effects. The situation is more complex and variable for the minerals, but chromium (III) is extremely nontoxic, whereas iron, selenium, and zinc have relatively narrow margins of safety. With the patterns of intake and use in dietary supplements, limits are appropriate for vitamin A, niacin, and pyridoxine, and may be appropriate for some other vitamins and minerals, including vitamin D and selenium.

True safety limits must be established on the basis total daily intake, rather than the amount in the supplement. Thus, maximums for vitamin and mineral supplements should be based on the amount of product recommended for intake per day. The evidence for the daily intake limits must be based on the daily intake over a long term. There must be feasible limits on the duration of intake demanded in relation to the evidence for safety under indicated conditions of use. An ever-escalating demand for evidence from longer-term intakes or to provide an arbitrary and uneven level of proof could be used arbitrarily to declare any vitamin or mineral supplement or other product unsafe.

For some nutrients such as preformed vitamin A, unfortified conventional foods can provide a large intake in comparison with a reasonable maximum intake limit. For others such as pyridoxine, unfortified conventional foods can contribute only a small fraction of a reasonable maximum intake limit. The fraction of the maximum intake limits that would be reasonable in a supplement is different from one nutrient to another, and therefore no values are valid for all nutrients. Thus, maximum limits must be based on risk assessment and the range of likely intakes from food sources.

For the few safety limits that should be set for specific nutrients, international uniformity in methods, values, and nomenclature would facilitate consumer understanding and acceptance, and also avoid artificial barriers to trade.

In summary on maximum levels:

1. Limits should be based on risk assessment methods that are appropriate for nutrients– the US NAS UL method is the most appropriate of all currently available The UL is different from the Acceptable Daily Intake (ADI) and related methods used by various regulatory agencies for environmental contaminants in foods and food additives that have only technological uses, and the advantages of the UL method must no be ignored.
2. Risk assessment for nutrients should not preclude potential benefits at intakes above the currently recognized RDA – limits should be based only on genuine safety considerations and not on nutritional policy related to currently known benefits.
3. Limits should not be based on simple, low multiples of the RDAs – the RDAs are not defined or based on data that is appropriate to describe the limits of safe intakes. Use of the RDA to set limits is arbitrary, \ unscientific, and potentially harmful through denial of benefits.
4. Limits should not be based on ill-defined "physiological" levels of intake – there is no identifiable boundary between the intakes that are "physiological" and those that are "pharmacological," and vitamin C provides an excellent example. Vitamin C intakes from unfortified foods can range from nearly nil to more than 1,000 mg per day, depending on the choice of foods. Average choices of foods in diets that meet the frequently recommended five servings of fruits and vegetables per day will contribute approximately 225 mg per day. The physiological effects of vitamin C differ with intake: 10 mg per day will prevent scurvy, 60 mg is a common RDA but vitamin C RDA in the United States has just been increased., about 75 mg per day will maximally activate certain essential enzymes (such as dopamine betahydroxylase) and the vitamin C inhibition of the chemical synthesis of carcinogenic nitrosamines begins at intakes well below the RDA but does not approach 100 percent until the intake exceeds 1,000 mg. For this vitamin, it is impossible to define a difference between "physiological" and "pharmacological" intakes. The characterization of a nutrient as a drug must depend on an intended effect to treat or prevent a disease, and not on the amount of the vitamin or mineral in the product.
5. Appropriate methods and data are available to identify safe intakes of vitamins and minerals – such methods, available in the peer-reviewed literature, have been published by the US NAS. Thus, failure to identify scientifically based limits for nutrients that warrant them cannot be justified on the basis of inadequate methods or data.

Issue: MINIMUM LEVELS

An appropriate minimum for most micronutrients deliberately added may be 10 percent of the RDA for most vitamins and minerals, but this amount should not be a minimum for all vitamins and minerals. Some nutrients, such as calcium and magnesium, may be limited in multivitamin/mineral products because of their bulk. Other nutrients may be present because they are part of a natural product such as yeast that may contain substantial amounts of one vitamin but far lesser amounts of another. This section should be thoroughly reconsidered, with input from industry experts who know the technical difficulties that would ensue from the same minimum for all vitamins and minerals.

Issue: PURITY CRITERIA

The discussion paper indicates that many vitamin and mineral ingredients currently added to conventional foods or used in supplements already meet either pharmaceutical purity standards or have been approved for use as food additives. It can be argued that substances added to or used as foods should meet higher purity standards than pharmaceutical products, because of the prospect of long-term use.

CRN comment: Supplements should be manufactured to appropriate food purity standards. The standards must be feasible and cost effective, but also must ensure wholesome, safe, and useful products. The purity standards must protect the consumer, but also must be feasible.

The guideline on purity must avoid ambiguous language such as "to the maximum extent possible" in relation to avoidance of impurities such as heavy metals unless clear criteria are provided. Obviously, the products must not be adulterated, but they must also be possible to produce. The basis of purity criteria should toxicological information relevant to the safety of trace impurities.

Issue: GOOD MANUFACTURING PRACTICES (GMPs)

Nearly everyone agrees that vitamin and mineral supplements should be manufactured under GMPs. There is difference of opinion on whether food or drug GMPs are more appropriate.

CRN comment: Supplements should be manufactured under appropriate GMPs. GMPs must be feasible and cost effective, but also must ensure wholesome and useful products. GMPs should not be used to limit supplements to 100 percent of the recommended daily intakes, because the RDA is not defined to serve as a safety limit and no safety data are used to set the RDAs, and using GMPs to enforce such limits would preclude established benefits related to intakes of some nutrients in amounts above the RDA.

In recognition of typical supplement forms (tablets, capsules, soft gels, powders, and liquids), it recommended that GMPs should be developed for supplements in consultation with industry experts who are aware of the limits of source materials, manufacturing aspects, and possibly other characteristics such as disintegration and dissolution.

Issue: LABELING ISSUES

The discussion paper correctly identifies the main issues, namely ingredient identification, nutrition labeling (nutrient content), claims, and warnings.

CRN comment: All countries require on label identification of the product and ingredients. In the areas of nutrient content labeling and claims, the United States has developed regulations that could serve as a useful starting point for Codex deliberations. All labeling issues should be resolved in cooperation with the Codex Committee on Food Labeling.

Nutrition labeling: Nutrition labeling should be mandatory on vitamin and mineral supplements. Nutrient content descriptive term guidelines should be developed for vitamin and mineral supplements, and may need to be different from those for conventional foods.

Claims: Two general types of claim should be permitted: (1) structure or function claims, and (2) "health claims" that address disease or health/disease related conditions. All claims must be truthful and not misleading. Guidelines are needed for the required level of substantiation for claims. Descriptive definitions, guidelines and criteria are needed to distinguish between different types of supplement claims, and to distinguish between supplement claims and drug claims.

Special statements and warnings: Certain warnings or advice may be appropriate on some products, to help assure their safe and appropriate use. A few examples—preformed vitamin A supplements at certain levels may be safe for most adults, but may be contraindicated for pregnant women or those with liver disease; high potency calcium supplements may be inadvisable for those with kidney disease; products with large amounts of nicotinic acid may require advice to take only under a doctor's supervision; high-potency iron products should bear warnings about the potential for accidental pediatric poisoning. Some such statements should be compulsory but others could be voluntary. The need for these types of statements will depend on other components of the label, including the clarity of instructions for restriction of use to specific age and gender groups. A detailed, specific, and flexible guideline is needed.

Issue: PACKAGING

The purposes of packaging are appropriately described in the discussion paper. The acceptability of packaging materials and functional requirements differ among countries.

CRN comment: Packaging should use food quality materials and be designed to maintain hygiene, stability, and purity of the product. Special requirements such as child resistant containers (CRCs) and tamper-evident packaging should be considered for certain products when necessary. Products marketed for the elderly should have special packaging guidelines to facilitate physical access.

Allowable marketing practices must include the claims that are permitted under those guidelines. Marketing should provide consumers with informed choices that are safe. Marketing restrictions should not be used to reinforce invalid notions that supplements are likely to be without benefit or are inherently hazardous, or that the RDA is an appropriate basis for maximum levels.

Issue: MARKETING

The main issue is whether supplements may be marketed only in conformation with national surveys of nutritional status and need, or whether consumers should be allowed to make informed choices from a wide range of products.

CRN comment: Because of the variability in individual food choices and physiological needs for nutrients, consumers should have unhindered access to a wide range of supplement products. These products must be safe, properly made, and labeled with complete information allowing the consumer to make informed choices based on truthful and not misleading information.

IADSA - International Alliance of Dietary/Food Supplement Associations

§	CODEX GUIDELINES	IADSA comments
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.	▪ IADSA does not promote products as a replacement for food and supports the principle that 'people should be encouraged to select a balanced diet from food.' However, IADSA is concerned about the implication of the preamble, namely that supplementation detracts from good diet. Existing evidence suggests that supplement consumers are particularly conscious of their nutrient intake and supplement their diet with the aim of achieving an optimum state of health, rather than just preventing deficiency diseases. Moreover, studies validate that only a small percent of any population group actually obtains 100% of the essential nutrients from a normal diet.
1. Scope	1.1 These guidelines apply to vitamins and minerals 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.	Delete 'if and where necessary' as it is redundant.

	~~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.]	▪ The Codex Alimentarius mandate is limited to food products. However, it is also committed to removing existing barriers to trade. In some countries trade barriers are caused by the classification of food supplements as drugs. ▪ There is also the tacit assumption that supplements not considered foods are automatically classified as drugs. Governments, however, have shown a great tendency to state that some supplement products are not foods and then have failed to permit them access to the market as drugs. ▪ If the guidelines are to be of practical value, they should at least ensure minimum standards for opportunities to trade on a global basis. Any reference to national classification should therefore be removed from the 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 <u>foodstuffs that are</u> ~~[~~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.]	▪ Add ‘foodstuffs that are’ in between ‘vitamin and mineral supplements are ’and ‘concentrated sources of those nutrients alone or ….’ ▪ Delete ‘and do not provide a significant amount of energy’. ▪ Delete the purpose of vitamin and mineral supplements as this is already covered in the preamble.
3. Compo-sition	**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].~~	▪ Delete 3.1.2 as the selection criteria for vitamins and minerals are already defined in 3.1.1 according to Codex standards.
	[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].	▪ IADSA considers that limitations imposed on the use of individual vitamins and minerals for reasons of safety must be based on adequate scientific risk assessment, which for essential nutrients does not vary significantly based on regional or national 'peculiarities', with the exception of selenium.
	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.]~~	▪ Delete this paragraph as this is related to the scientific substantiation of claims and should therefore fall under the criteria on the scientific basis for health claims, which are being developed by CCNFSDU.
3. Compo-sition	**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.~~]~~	▪ In principle, IADSA considers that a minimum level of 15% of the labelling RDI should be established to allow the inclusion of the vitamin or mineral on the statement of nutritional content. However, Codex needs to consult with technical experts from the industry on the practical implications of the bulk effect of certain nutrients, such as calcium, magnesium, potassium and sodium.
	~~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.]~~	▪ Recommended daily intakes (RDI) have been established to indicate the intake required in order to avoid deficiency diseases. They do not take into account the growing body of scientific research that supports the health benefits of intakes considerably higher than the RDI. In order to provide a framework for the development of supplements that reflect the benefits of higher intakes, the maximum limit cannot be linked to 100% of RDI.

	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.~~]~~	▪ Specific risk assessment methods have been developed to establish upper safe levels for micronutrients, which need to be taken into account by Codex. Where the relevant scientific authorities identify the potential of adverse effects from nutrient intake at levels close to the RDI, upper levels should be established for those nutrients. These are based well below that at which a significant adverse effect has been responsibly reported. The approach based on specific risk assessment methods allows consumers to supplement their diet with higher levels of nutrients that provide additional benefits to health, whilst ensuring that the products on the market are safe.
	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, <u>only if the national authority can scientifically validate a lower level than that established by Codex.</u>	▪ Add 'only if the national authority can scientifically validate a lower level than that established by Codex' at the end of paragraph 3.2.4.
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 packaging~~s~~, if necessary, <u>based on appropriate scientific risk assessment</u>.	▪ Add 'based on appropriate scientific risk assessment' at the end of paragraph 4.3
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~~ labelling of the product shall ~~be~~ include '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.~~]~~	▪ Delete the brackets around paragraph 5.2. It is not necessary to include the word 'supplement' in the name of the product. It would be more appropriate to simply require the term 'supplement' to be included on the principal display panel (front) of the product.
	[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~~ amount.]	▪ Replace 'weight' by 'amount' to allow for liquids.
	~~[~~5.4 The amounts of the vitamins and minerals declared shall be those per portion of the product as recommended for daily consumption on the labelling ~~and~~ or per unit dose form, as appropriate.~~]~~ The amounts declared shall be those of the product as sold.	▪ Delete the brackets around paragraph 5.4 and replace 'and' by 'or'. Add 'The amounts declared shall be those of the product as sold' as both declarations on the same label are redundant and unnecessary.
	~~[~~5.5 ~~Information~~ Declarations 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.~~]~~	▪ Delete the brackets around paragraph 5.5. The word 'information' is insufficiently specific. IADSA proposes the word 'declarations' to clarify which information should be expressed as a percentage of the reference values mentioned.
	5.6 The label must indicate the recommendations on how to take the product (quantity, frequency, special conditions), otherwise referred to as 'suggestion of use' or 'usage suggestions'.	▪ Add 'otherwise referred to as 'suggestion of use' or 'usage suggestions' at the end of the sentence
	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.]~~ , where appropriate, based on the recommended portion for daily consumption.	▪ IADSA agrees with the need for appropriate consumer cautions and warnings, and recommends to delete 'if the product contains a significant amount of a nutrient with respect to the toxicity level' and replace it by 'where appropriate, based on the recommended portion for daily consumption'.
	[~~5.8 The label must contain a statement: supplements can not be used for the replacement of meals on long term basis.~~] 'The labelling of food supplements may not state or imply that these products are a substitute for a diversified diet.'	▪ IADSA agrees that supplements should not be used as a substitute for a diversified diet. However, crowded labels can possibly confuse the consumer. It would therefore be more useful to prohibit the use of any statement which implies that supplements may be a substitute for a diversified diet, rather than including the statement in 5.8.

	~~[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.]~~	▪ Delete 5.9. Under these Codex guidelines vitamin and mineral supplements will be regulated as safe food products which do not require advice that goes beyond that provided in labelling.

ISDI - International Special Dietary Foods Industries

General comments

1. ISDI welcomes a further development of guidelines for vitamin and mineral supplements marketed as foods to add to the reduction of the risk of barriers to international trade of these type of foods and to promote the safety of these foods for human consumption.
2. ISDI recognises that vitamin and mineral supplements are used by individuals to supplement their diet to (1) obtain an intake in compliance with recommended dietary allowances, and (2) to obtain health benefits at levels of intake which go beyond current RDAs.
3. Therefore, ISDI is of the opinion that vitamin and mineral supplements presented as foods should be allowed maximum levels of vitamins and minerals which are based on a nutrient appropriate scientific risk assessment.
4. In consideration of the above, ISDI sees no grounds for considering vitamin and mineral supplements as medicines, whether these supplements are intended for normal consumption or for special dietary use.

Specific comments

- Preamble

  This section does not recognise that a normal diversified diet can not provide certain population groups, such as pregnant women and elderly, with adequate amounts of certain micronutrients (e.g. folic acid; vitamin D). Therefore, these population groups should have access to food supplements or foods for special dietary use.

1. Scope

1.1. ISDI considers it should be made clear that these guidelines equally apply to supplements that also contain ingredients other than vitamins and minerals. ISDI does not consider the text "[if and where necessary]" a useful addition to the understanding of the scope, and therefore, suggests to delete it entirely.

1.2. Only if presented as such, ISDI agrees to consider a supplement as a drug. If a supplement complies with the proposed draft guidelines, it should always be considered a food.

1.3. ISDI proposes to delete the square brackets and to keep the text.

2. Definitions

2.1. ISDI proposes to delete in the third line the first square brackets resulting to read "concentrated sources of those nutrients". Furthermore, it is suggested to delete the last full sentence "[They serve to supplement ...]" entirely as it is covered by the preamble.

2.2. ISDI strongly recommends to delete this paragraph entirely as supplements serving special nutritional purposes are under the scope of standards for foods for special dietary uses.

3. Composition

3.1. Selection of vitamins and minerals

3.1.1. No comments

3.1.2. The reduce the potential of barriers to trade, ISDI recommends to develop an extensive and appropriate Codex list for vitamin compounds and minerals salts. This list should be in compliance with current practice and based on safety and bioavailability of these vitamin and mineral sources.

3.1.3. ISDI recommends to delete this entire section as the proposed draft guidelines have safety as their basis. Any national authority has always the power to limit the marketing of a food if public health is proven to be in serious danger.

3.1.4. ISDI considers that ingredients other vitamins and minerals are allowed in these type of supplements (see comment to section 1.1. of Scope).

As for section 2.2., ISDI recommends to delete the entire sentence in square brackets "[The suitability of a single ...]".

3.2. Contents of vitamin and minerals

3.2.1. ISDI agrees that a minimum amount of a vitamin or mineral should be present in a supplement as these type of foods are considered by the consumer as a significant source of vitamins or minerals. ISDI considers a level of 15% of the Nutrient Reference Value (NRV) a suitable minimum level provided this applies to the daily dose (serving) recommended for consumption. This is in agreement with the draft table of the conditions for nutrient contents (Part B) of Alinorm 99/26, Appendix II, at Step 8 of the Procedure.

3.2.2. ISDI considers that maximum levels for vitamins and minerals should be set per daily dose and on the basis of a nutrient appropriate scientific risk assessment. The Nutrient Reference Value (NRV) should not be used as the basis for these maximum values as the derivation of NRVs is not based on safety but on normal nutritional requirements to protect the vast majority of the population from nutrient deficiencies instead.

3.2.3. As a result of its comments to section 3.2.2, ISDI proposes to delete the square brackets and to keep the text as its stands.

3.2.4. ISDI is of the opinion that a national authority should be allowed to set a different maximum level for a vitamin or mineral only on the same basis as provided for in section 3.2.3.

4. Packaging

4.1. No comments.

4.2. No comments.

4.3. No comments.

5. Labelling

5.1. No comments.

5.2. ISDI agrees to delete the square brackets. However, in accordance with the comments given above, ISDI recommends to delete the second half of the sentence that refers to special nutritional purposes. As a result, section 5.2. would read:

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

5.3. ISDI agrees to delete the square brackets.

5.4. No comments.

5.5. ISDI agrees to keep the text and to delete the square bracket and the end of this section.

5.6. No comments.

5.7. ISDI considers it more suitable to label contra-indications where appropriate (such as a precautionary statement for pregnant women in the case of vitamin A (retinol) containing supplements).

Furthermore, it would also be appropriate to require a statement not to exceed the recommended daily dose indicated in the labelling.

5.8. ISDI considers this statement for vitamin ad mineral supplements unnecessary as these supplements are and have never been interpreted as products which can serve as meal replacements.

5.9. ISDI considers this statement not suitable for normal vitamin and minerals supplements as the composition of the supplements falling under the draft proposed guidelines are safe for human consumption.