codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

JOINT OFFICE: Viale delle Terme di Caracalla 00100 ROME Tel: 39 06 57051 www.codexalimentarius.net Email: codex@fao.org Facsimile: 39 06 5705 4593

Agenda Item 5 **CX/NFSDU 03/5**
September 2003

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES
Twenty-fifth Session
Bonn, Germany, 3- 7 November 2003

PROPOSED DRAFT GUIDELINES FOR VITAMIN AND MINERAL SUPPLEMENTS

- Comments at Step 3 of the Procedure -

Comments from:

AUSTRALIA
BRAZIL
GERMANY
MALAYSIA
NEW ZEALAND
SOUTH AFRICA
SPAIN

CRN - COUNCIL FOR RESPONSIBLE NUTRITION
IADSA - INTERNATIONAL ALLIANCE OF DIETARY/FOOD SUPPLEMENT ASSOCIATIONS

AUSTRALIA

INTRODUCTORY REMARKS

Australia regulates vitamin and mineral supplements as therapeutic goods (drugs) and therefore would not be bound by these Draft Guidelines. The impetus for the progression of these Guidelines comes from a desire to introduce a Codex standard for vitamin and/or mineral supplements traded as foods.

GENERAL COMMENTS ON GUIDELINES

- 'Guidelines' should be capitalised throughout the document.

- The term 'daily' has been applied throughout the Guidelines to diet, portion, intake, dose and consumption. Its use in most contexts implies consumption of supplements every day, which is inappropriate. In such cases, the term 'one-day' should be substituted when the context overtly refers to supplement consumption, but merely deleted when the diet is described. 'Daily' is appropriate when used to describe vitamin/mineral intakes in the context of reference values or the conventional diet. The following table details the changes.

'Daily' to be ….	Section
Deleted	**Preamble; 1.1; 2.1**
Substituted for 'one-day'	**3.2.1 first mention; 3.2.2 introduction; 3.2.3 second mention; 5.4**
Maintained	**3.2.1 second mention; 3.2.2(b); 3.2.3 first mention**

- 'Daily portion of consumption' is cumbersome and could be simplified by substituting *one-day dose* as similarly given in Section 3.2.3.

SECTION 1 SCOPE

1.2 The current wording does not allow for third regulatory categories such as dietary supplements. Australia therefore proposes:
'It is left to national authorities to decide whether vitamin and mineral supplements are *regulated as* foods *or not*. These Guidelines apply *only* in those jurisdictions where products defined in 2.1 are regulated as foods.'

SECTION 2 DEFINITIONS

2.1 This definition should be revised to provide a description of vitamin and/or mineral supplements, their purpose and, given that these supplements are considered within the meaning of food, their differentiation from conventional foods. Australia proposes deleting the first sentence as it is implicit in the second sentence and revising the second and third (currently in square brackets) sentences to become:
Vitamin and/or mineral supplements are concentrated sources of vitamins and/or minerals either singly or in combination that are marketed in dosage form as capsules, tablets, powders, solutions or similar and whose purpose is to supplement the intake of vitamins and/or minerals from the normal diet. These supplements are not presented as conventional foods or beverages, nor do they provide a significant amount of energy.

If discussion focuses on only the third sentence in square brackets, it should be deleted as the information is more appropriately given in the Preamble.

SECTION 3 COMPOSITION

3.1.1 Insert: *, either singly or in combination,* after 'contain'. This change renders paragraph 3.1.4 redundant.

3.1.2 Change 'the FAO/WHO' to *appropriate FAO/WHO references*. Retain text within square brackets, with the following insertion so to read: *and in the absence of criteria from these sources, national legislation*.

3.1.3 Paragraph 3.1.3 should be deleted as it refers to vitamin or mineral content that is more appropriately covered under Section 3.2. Furthermore, national adjustment is already accounted for in paragraph 3.2.3. If paragraph 3.1.3 is retained, 'use' should be substituted by *inclusion.* It is not clear what 'supply situation of the population' means; perhaps *dietary intake of the population* would clarify intent.

3.1.4 This provision is redundant if Australia's suggested revisions to the definition and paragraph 3.1.1 are adopted.

3.2.1 Minimum levels can be tackled either by setting an absolute minimum content or by setting criteria for quantitative label declaration, either expressed positively or negatively. This Committee recently recommended 15% Nutrient Reference Value (NRV) per serve or per 100g reference quantity as minimum criteria for claims of 'source' of vitamins or minerals, although it is recognised that the reference quantity does not necessarily equate to a one-day dose; perhaps per serve is the closest. As a principle, the minimum should not be set so high as to discourage lower dosage products from the market, and therefore limit consumer choice. Australia prefers the lower of the two options i.e. 15% NRV/ one-day dose.

Australia also prefers a more indirect labelling solution that would impose fewer burdens on manufacturers and potentially facilitate trade. If a labelling solution is supported, then this provision 3.2.1 could be deleted.

If an absolute minimum is retained, the Guidelines should also explicitly allow for the use of NRVs that apply to various age/sex groups or stages of the lifecycle based on FAO/WHO Recommended Nutrient Intakes (RNI) in cases where supplements are targeted to individual population groups. These NRVs could be incorporated into or listed in an Annex to this Guideline. At least *nutrient* should replace 'daily' in this provision when describing the FAO/WHO *recommended nutrient intakes*. Also, the reference to RNI in this provision should be further qualified by *for the population group to which the supplement is specifically directed*.

3.2.2 Australia supports the intent of the second option under paragraph 3.2.2 although, given that this option adopts a risk-based approach, the separate sentence following point (b) is confusing and should be deleted. If the sentence is retained, it should refer to FAO/WHO recommended nutrient intakes.

3.2.3 This provision is important particularly if paragraph 3.1.3 is deleted. However, it needs to refer to *daily dietary intake of vitamins and minerals* rather than 'recommended daily intakes'. Also 'adverse effect level' should be replaced by *upper safe levels* consistent with paragraph 3.2.2 (a). The amended paragraph would then read: 'For vitamins *and* minerals with a narrow safety margin between *the relevant daily dietary intake* and the *upper safe level*, different maximum limits for the *one-day* dose may be *nationally* established.'

SECTION 4 PACKAGING

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

SECTION 5 LABELLING

In the light of our comments made in relation to paragraph 3.2.1, Australia suggests that a new provision be inserted either to:
establish a minimum level for quantitative declaration e.g. 15% NRV/one-day dose, below which a quantitative declaration could not be made (ingredient listing would still apply), or
not restrict quantitative declaration but require a relevant statement linked to declarations below 15% NRV/one day dose to the effect that the supplement is not a significant source of those particular vitamins or

minerals. This requirement could be further refined to be consistent with the Codex Guidelines on Nutrition Labelling such that quantitative declaration not be permitted at all for amounts less than 5% NRV.

5.1 Replace 'are labelled' with *shall be labelled.*

5.2 The square brackets should be removed and the text amended to: 'the *labelling* of the product shall *include'*.

5.3 The square brackets should be deleted and the text amended to: the *weighted average* amounts of vitamins and minerals present in the product shall be declared in numerical form according to *metric* units of weight. This is consistent with the Codex Guidelines on Nutrition Labelling (para 3.4.4; 3.5.2).

Australia suggests that the amounts of vitamins and minerals present in the product be declared per one-day dose and, where different, per unit dose. The text could be tidied up to state: 'The amounts of vitamin*s* and minerals declared shall be those per *one-day dose, and where different,* per unit dose'.

5.5 'Information' at the beginning of the sentence should be described as *numerical* consistent with the Codex Guidelines on Nutrition Labelling (para 3.4.4).. Percentages above 100% are not readily understood by consumers, therefore the alternative of *or multiple* should be inserted. As written, this provision would also require declaration as a percentage NRV according to one-day dose and per unit dose where given. This is excessive and the labelling requirement should apply only to the one-day dose.

The Guidelines on supplements should not rely on the current Nutrient Reference Values (NRVs) given in the Codex Guidelines on Nutrition Labelling since only one value is listed per micronutrient, and the range of micronutrients is smaller (by 4 nutrients: biotin, pantothenate, and vitamins E and K) than the FAO/WHO revised list of Recommended Nutrient Intakes (RNIs) in the 2002 FAO-published report of a joint expert consultation on *Human Vitamin and Mineral Requirements.* However, we note that the FAO/WHO report does not address copper.

Instead a separate process should be undertaken by this Committee to establish appropriate NRVs derived from the FAO/WHO RNIs for the sole purpose of vitamin and mineral food supplement labelling. These values would cover different age groups, pregnancy and so on for use when supplements are targeted to individual population groups. These values could be listed in an Annex to this Guideline. A corollary to this process could be to update and extend the range of micronutrients given in the Guidelines on Nutrition Labelling.

All these amendments can be expressed as '*Numerical* information on vitamins and minerals *per one-day dose* shall also be expressed as a percentage *or multiple* of the *Nutrient* Reference Values *given in Annex 1 to this Guideline*.

5.7 Australia considers that this statement is not necessary if an appropriate risk assessment has been conducted. However Australia supports a label statement, where applicable, that warns or advises consumers not to exceed a stated maximal one-day dose. The conditions of use for this statement should be determined from the relevant risk assessment. The statement could therefore be modified to read: *Where appropriate and as determined by risk assessment, the label should advise consumers not to exceed the maximum one-day dose*.

5.8 Australia supports the intent of this provision but suggests that the text could be improved to state: *The label shall contain a statement to the effect that consumption of vitamin and/or mineral food supplements does not compensate for an adequate and diversified diet*.

5.9 This provision should be deleted as vitamin or mineral food supplements are not classified as foods for special dietary use (see 1.3 of the Scope).

BRAZIL

Suggestions:

We suggest to exclude the term: "food" of the title. The text would be read as follows:

Title: PROPOSED DRAFT GUIDELINES FOR VITAMIN AND MINERAL ~~FOOD~~ SUPPLEMENTS (At Step 3 of the Procedure)

Justification: The term "FOOD" SUPPLEMENTS" extends the scope application of the Proposed Draft Guidelines. The objective to establish the Guidelines for the vitaminic and mineral supplements will be deviate. Brazil emphasizes the comments of the Paragraph # 94 (ALINORM 03/26A-NFSDU).

PREAMBLE

Suggestions:
To keep the PREAMBLE and to eliminate the sentence of the last paragraph: "or where consumers consider their diet requires supplementation, vitamin and mineral supplements serve to supplement the daily diet". The text would be read as follow:

"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".~~

Justification: the last sentence allows the possibility of a without-control-consumption by consumers, and takes into consideration the individual capacity of supplementation, without the use of adequate parameters.

2. DEFINITIONS

Suggestions:

2.1

- To delete the square brackets of the item 2.1. and to eliminate the expression "or where the consumers consider their diet requires supplementation". The text would be read as follow*:*

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 sources in concentrated forms 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.~~].

Justification: the expression can allow the possibility of a without-control-consumption, and considers the consumer individual capacity of a diet without the use of adequate parameters.

3. COMPOSITION

3.1 SELECTION OF VITAMINS AND MINERALS

Suggestions:

3.1.2.

- To delete the square brackets of the item 3.1.2, keeping the text.

3.1.3

- To substitute the word “limited” by “based on scientific data”
- To delete the square brackets of item 3.1.3, keeping the text. The text would be read as follow:

3.1.3 The use of individual vitamins and minerals in supplements can be ~~limited~~ “based on scientific data” for reasons of health protection and consumer safety, taking into account regional or national peculiarities concerning the supply situation of the population.

3.2 CONTENTS OF VITAMINS AND MINERALS

3.2.1.

- To delete the square brackets of the expression “[15% to 33%]”.
- To include after FAO/WHO, the expression “taking into account the national Legislation”. The text would be read as follow:

3.2.1 The minimum level of each vitamin and/or mineral contained in a vitamin and mineral supplement per daily portion of consumption as suggested by the manufacturer should be 15% to 33% of the recommended daily intake as determined by FAO/WHO, “ taking into account the national Legislation”.

***Justification:* the minimal level to be established must be in accordance to the specific legislation of each country. However, we recommend to raise the minimum level to assure the best cost/benefit of the product.**

3.2.2.

- We suggest to keep the first item 3.2.2. and to delete all square brackets of the hole item. The text would be read as follow:

3.2.2 The maximum level of each vitamin and/or mineral contained in a vitamin and mineral supplement per daily portion of consumption as suggested by the manufacturer should not exceed 100% of the recommended daily intake as determined by FAO/WHO .

~~or~~

~~3.2.2 [Maximum amounts of vitamins and minerals in vitamin and mineral supplements per daily portion of consumption as recommended by the manufacturer shall be set, taking the following criteria into account:~~
~~(a) upper safe levels of vitamins and minerals established by scientific risk assessment based on generally accepted scientific data, taking into consideration, as appropriate, the varying degrees of sensitivity of different consumer groups;~~
~~(b) the daily intake of vitamins and minerals from other dietary sources. When the maximum levels are set, due account should be taken to the reference intake values of vitamins and minerals for the population.]~~

***Justification:* the Institute of Medicine, Food and Nutrition Board and the Health Canada set up the “Upper Limits”, and call the attention to the fact that the UL are not recommendations; additionally, there are no benefit evidences by ingesting over what is recommended (EAR, RDA and AI).**

3.2.3.

- We suggest to delete the item 3.2.3 , keeping the text.

***Justification:* The exclusion of the item keeps the coherence with the maximum limit of 100% of the RDA proposed in the item 3.2.2.**

5. LABELING

5.2.

- To delete the sentence “or dietary mineral/vitamin preparation to supplement the diet with ..."
- To delete the square brackets of the item 5.2., keeping the text. The text would be read as follow:

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.

Justification: ***the designation: “Vitaminic and Mineral Suplements” avoids a misunderstanding among consumers.***

5.3.

- To delete the square brackets of the item 5.3., keeping the text.

5.8.

- To delete the expression: “on long term basis”.
- To delete the square brackets, keeping the text. The text would be read as follow:

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

Justification: ***The supplements must not be considered as meals substitutes at long and short term.***

5.9.

- To delete the square brackets of the item 5.9. keeping the text.

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.]

GERMANY

1.2:
Germany suggests that all countries in the jurisdiction of which vitamin and mineral supplements are regulated as drugs should from now on refrain from participating in the discussion about these proposed draft guidelines. In section 1.2, it is explicitly emphasized that the guidelines shall only apply in countries in the jurisdiction of which these products are regulated as foods ("*These Guidelines do apply in those jurisdictions where products defined in 2.1 are regulated as foods.*"). The different regulations inevitably lead to diverging opinions about various points and thus considerably impede the progress of this discussion.

2.1:
The following sentence in square brackets is unnecessary and should be deleted:
[*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.*].

3.1.2:

The addition made in square brackets: *[and national legislation, where applicable]* takes into account EU Directive 2002/46/EC on the use of vitamins and minerals in food supplements. This is to be supported. The square brackets should be deleted.

3.1.3:
The sentence [*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.*] only makes sense in case that health risks in a country cannot be ruled out because of a particular supply situation. We suggest to reformulate the sentence as follows and to replace *'limited'* with *'restricted'*:
"Taking into account regional or national peculiarities concerning the supply situation of the population, the use of individual vitamins and minerals in supplements can be restricted for reasons of health protection and consumer safety."

3.2.1:
We suggest to delete the brackets around [15% to 33%] and to accept 15 %.

3.2.2:
Germany prefers the second alternative and suggests that the last sentence, beginning with *"When the maximum levels are set, . . . "* be included into the list as subsection c) (as it had already been proposed in the comment on the 24th session).

The section would then read as follows:
"Maximum amounts of vitamins and minerals in vitamin and mineral supplements per daily portion of consumption as recommended by the manufacturer shall be set, taking the following criteria into account:

a) upper safe levels of vitamins and minerals established by scientific risk assessment based on generally accepted scientific data, taking into consideration, as appropriate, the varying degrees of sensitivity of different consumer groups;
b) the daily intake of vitamins and minerals from other dietary sources.
c) the reference intake values of vitamins and minerals for the population."

With regard to this section, Germany would also like to comment that
- we doubt that it will be possible to agree on uniform maximum levels on a global scale and therefore suggest that the guidelines only define the criteria or a particular procedure for the setting of maximum levels. Concrete figures should not be specified;
- an appendix should be added to the guidelines listing all admissible vitamins and minerals. The list of nutrients in the Annex of EU Directive 2002/46/EC could serve as a basis for this (see also 3.1.2).

4.3:
In accordance with EU Directive 2002/46/EC, the sentence *" Vitamin and mineral supplements should be distributed in child-resistant packagings, if necessary.*" should be replaced with:
"Products should be stored out of the reach of young children."

5.2:
In accordance with EU Directive 2002/46/EC, the square brackets in this section should be deleted and the name ‘food supplement’ should be used. The sentence would then read as follows:
"The name of the product shall be 'food supplement', with an indication of the nutrients contained therein."

5.3, 5.4, 5.5:
We agree on these wordings and propose to delete the square brackets.

5.7:
Vitamin and mineral supplements should be non-toxic and suitable for long-term use as a matter of principle. Germany suggests to reformulate the sentence [*"The label must contain a warning statement [if the product contains a significant amount of a nutrient with respect to the toxicity level."*] as follows and to delete the square brackets:

"The label must contain a warning statement not to exceed the stated recommended daily dose."

5.8:
In accordance with EU Directive 2002/46/EC, the sentence ["*The label must contain a statement: supplements can not be used for the replacement of meals on long term basis.*"] should be formulated as follows and the square brackets should be deleted:
"The label must contain a statement to the effect that food supplements should not be used as a substitute for a varied diet."

5.9:
The sentence ["*All labels shall bear a statement that the supplement should be taken on an advice of a nutritionist, a dietician or a medical doctor*."] should be deleted.

MALAYSIA

Title
Malaysia prefers to retain the title and delete the word 'food'.

The title is to read:

"Proposed Draft Guidelines for Vitamin and Mineral ~~Food~~ Supplement"

Rationale: The word 'food' may contradict paragraph 1.2 mentioned in the Scope as the national authorities are to decide whether vitamin and mineral supplements are drugs or foods.

Section 2: Definitions
Paragraph 2.1
Malaysia proposes to remove the square bracket and adopt the text contained therein. It is important to clearly state in the definitions that vitamin and mineral supplements are required only in cases when the intake of these nutrients from food is insufficient and they should not be used to replace a balanced diet.

This paragraph is to read:

" …..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. <u>Supplements should not be used to replace a balanced diet</u> ."

<u>Section 3.1: Selection of Vitamins and Minerals</u>
Paragraphs 3.1.2 & 3.1.3
Malaysia proposes to remove all the square brackets and adopt the texts contained in all the brackets.

These paragraphs are to read:

3.1.2 "The selection of admissible vitamin and mineral sources should be based on criteria such as safety and bioavailability. In addition, purity criteria should take into account the FAO/WHO or Pharmacopoeias and national legislation, where applicable".

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".

Section 3.2: Contents of Vitamins and Minerals

Paragraph 3.2.1

Malaysia proposes to remove the square brackets and adopt the text contained in the brackets. 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 paragraph is to read:

"The minimum level of each vitamin and/or mineral contained in a vitamin and mineral supplement per daily of consumption as suggested by the manufacturer should be 15% of the recommended daily intake as determined by FAO/WHO".

Paragraph 3.2.2

Malaysia proposes to remove the square brackets in option 1 and adopt the text contained in brackets. 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 paragraph is to read:

"The maximum level of each vitamin and/or mineral contained in a vitamin and mineral supplement per daily portion of consumption as suggested by the manufacturer should not exceed 100% of the recommended daily intake as determined by FAO/WHO".

Section 5: Labelling

Paragraph 5.5

Malaysia proposes to add the word *"nutrient"* before the word "*reference values"* for clarity, i.e. Nutrient Reference Values.

This paragraph is to read:

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

Paragraphs 5,7,5.8 & 5.9

Malaysia proposes to remove all the square brackets in the above paragraphs and adopt all the texts contained in the brackets for the safety of consumers.

In paragraph 5.7, it is important that the consumer be appropriately warned of the possible toxic effects when consumed above a certain level.

In paragraph 5.8, the consumer should be clearly warned that supplements are for short periods of time when nutrient needs are not adequately met and that the daily balanced diet must be the ultimate source of nourishment.

Paragraph 5.9 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 consumers.

These paragraphs are to read:

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

5.8 "The label must contain a statement: supplements cannot 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".

NEW ZEALAND

The New Zealand Government would like to make the following comments:

New Zealand continues to support a risk-based approach to the development of guidelines for vitamin and mineral supplements.

New Zealand believes that there is considerable repeat of information in the *Preamble*, *Scope* and in some of the *Definition* of the draft guideline. Although there appears to be some concern that vitamin and mineral supplements may be used inappropriately in the diet, restating such concerns throughout the guideline is not appropriate. New Zealand supports a statement about the importance of a balanced diet and the potential role of vitamin and mineral of supplements where dietary intakes are inadequate.

Although it is not usual to have a *Preamble* in a Codex Guideline, New Zealand does support the inclusion of the *Preamble* in this guideline. However repetition of issues covered in the *Preamble* should be removed form other parts of the guideline.

1. Scope

New Zealand recommends removing the text in the square brackets as the issue of necessity of vitamin and mineral supplements has been addressed in the *Preamble.*

2. Definitions

New Zealand recommends removing the text in the square brackets [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] as this is already addressed in the *Preamble.*

New Zealand would also like to state that although it supports the development of these guidelines, an area of significant growth that these guidelines will not address is foods, in a conventional food form and not necessarily in tablets or powders, with added vitamins and minerals (and other substances).

3.1 Composition

3.1.2 New Zealand supports deletion of the square brackets so that national legislation can be used in the selection of appropriate vitamins and minerals, especially in the absence of other sources of data.

New Zealand does not support retaining section 3.1.3.

3.2. Contents of Vitamins and Minerals

3.2.1 New Zealand supports a lower level of 15% NRV per one day dose as the minimum level.

New Zealand supports option 3.2.2 which follows a scientific risk based approach. This approach recognises the differing needs of different population groups. It is recommended that the sentence following point (b) be deleted as it is confusing.

5 Labelling

- 5.2 : New Zealand supports labelling provisions that require the name of the product "vitamin and mineral supplement" on the label.
- 5.3: New Zealand supports the inclusion of the text in square brackets and recommends that the units referred to be units of "amount" to cater for both solids and liquids.
- 5.5: New Zealand recommends replacing "information" with "declarations" to be more specific. We also seek clarification on the use of a country's RDI for NRV?
- 5.6: New Zealand recommends that the label include age groups, where appropriate.
- 5.7: New Zealand finds the wording about the warning statement unclear as the term "significant amount" is ambiguous. We suggest rewording to reflect a risk based approach where warning statements are required where there is s potential for public health concern.
- 5.8: New Zealand does not support the inclusion of this statement.
- 5.9: New Zealand supports the inclusion of a recommendation that consumers seek advice from health professionals on the consumption of vitamin and mineral supplements.

SOUTH AFRICA

TITLE
South Africa proposes the deletion of the word "food" in the title and the addition of the words "regulated as foods" at the end of the sentence. The new title "Proposed Draft Guidelines for Vitamin and Mineral ~~Food~~ Supplements **regulated as foods**" will more accurately reflect the contents of these Guidelines.

PREAMBLE
South Africa proposes the following new wording in the preamble:

"Most people who have access to a balanced diet can usually obtain all the nutrients they require from their normal diet **to prevent deficiencies**. Because foods contain many substances that promote health **and prevent chronic diseases,** people should therefore be encouraged to select a **healthy** ~~balanced~~ diet ~~from food before considering any vitamin and mineral supplement~~ **and supplement this diet with those nutrients for which the intake from the diet is insufficient to meet the requirements necessary for the prevention of chronic diseases and/or for the promotion of health beyond the demands of preventing micronutrient deficiencies.**" ~~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~~

In the title of the following WHO document "WHO Technical Report on Diet, Nutrition and the Prevention of Chronic Diseases" (2003) the WHO acknowledges the fact that nutrition plays a role in the prevention of chronic diseases. It will therefore be regarded as double standards if the CCNFSDU objects to the inclusion of the words "prevention of chronic diseases" in a Codex Guideline and Standard.

Furthermore a diet can be balanced in terms of the Dietary goals e.g. 15 % protein, 55% carbohydrates and 30% fat, but not necessarily be healthy. The use of the words "healthy diets" is in line then with the Draft Guidelines for Use of Health and Nutrition claims ALINORM 03/22A Appendix IV (at Step 8).

1. Scope

1.1 Delete text after "supplementing the daily diet".
Motivation: Additional wording is redundant.

1.2 Delete the sentence "It is left to national authorities to decide whether vitamin and mineral supplements are drugs or foods", since it contradicts what is said in the second sentence, namely that these guidelines apply to supplements legislated as foods. It also creates a potential barrier to trade. The Codex mandate is to remove existing barriers to trade and to harmonize legislation globally.

2. Definitions

Delete the last sentence. It is superfluous since the purpose is already explained in the preamble.

Composition

3.1 Selection of Vitamins and minerals

3.1.3 Delete 3.1.3 since the motivation for the use of vitamins and minerals is already addressed in the Preamble (as amended according to this proposal).

3.2 Contents of vitamins and minerals

3.2.1 South Africa firmly believes that option 2 should be the only choice. It is our opinion that maximum levels should be based on nutrient appropriate scientific risk assessment where the only goal is safety.

This approach is in line with Codex policies.

Motivation for option 3.2.2: The South African Experience

Background:

The Codex position during the last few years has moved from a RDA position to a Scientific Risk Assessment position. That means that the RDA position was to eliminate prevention of clinical deficiencies, while the Scientific Risk Assessment model focuses on the promotion of wellness and optimum nutrition.
The Institute of Medicine in the USA has done a lot of work in recent years to establish the safety of vitamins and minerals. They have established new Dietary Reference Intakes (DRI's). Dietary Reference Intakes are reference values that are quantitative estimates of nutrient intakes to be used for planning and assessing diets for healthy populations. DRI's replace the periodic revisions of Recommended Dietary Allowances (RDA's), which have been published since 1941 by the National Academy of Sciences. In view of these developments South Africa has thus initiated preliminary work to develop new **draft** national legislation.

Goals of the proposal:

The South African proposal for the proposed new **draft** legislation had to address 4 important issues:

1. For the consumer, safety issues had to be addressed
2. ***For regulatory purposes, the development of an absolute amount for each vitamin and mineral, based on the available scientific data was an important issue. This meant that each vitamin and mineral had to be evaluated individually.***
3. For trade purposes, the proposal had to be fair to the industry (e.g. an exclusion level of 300 mg Vitamin C as per current legislation is not based on science and therefore not fair to the industry.)
4. For scientific purposes, the proposal had to be able to withstand the scrutiny of the clinical committee of the South African Medicines Control Council.

Discussion of Process:

South Africa has used the DRI's as the basis for the proposed new draft legislation on Nutritional Supplements. However, DRI's provision is for total intake (including food). In the risk assessment model, the next step was to evaluate the actual intake of every micronutrient in order to ascertain whether there was a real risk that any population group would exceed the tolerable upper intake levels. National food survey studies are useful to determine the nutritional status of a certain population. In South Africa we used the work that has been done by Prof H H Vorster on the Nutritional Status of South Africans (See bibliography). From this data we wanted to know what the average intake of individual nutrients from food was. It was a problem that food consumption data was not available for all nutrients.

We had to decide which consumer group required protection from products containing high levels of vitamins and minerals. When dealing with supplementation one has to consider primarily the group that uses supplementation on a regular basis. Any recommendations should not expose this group to excessively high levels. Thus, we looked at a population group who has complete household food security and with enough disposable income to afford the option of supplementation. In SA this is the middle and upper income

groups. Vitamins and mineral requirements in the population group with little or no household food security and not enough disposable income to make nutritional supplements an option, are addressed through fortification programs and not through supplementation. Therefore the lower income groups were not considered in this proposal because they are not at risk in terms of excessive vitamin and mineral supplementation.

The DRI's were used as follows:

We used UL's, which is the Tolerable Upper Intake Level and deducted the amount that is present in food for that specific nutrient. The UL is the highest level of a daily nutrient intake that is likely to pose no risk of adverse health effects for almost all individuals in the general population.

We considered that using the UL's and not the Lowest Observable Adverse Effect (LOAEL's) as the starting point for all calculations, a responsible decision. A proposal that disregards the Uncertainty Factor would be unacceptable to any regulatory authority, as consideration of the uncertainty of some of the research data is an integral part of the DRI approach.

For certain nutrients, no UL has been set. In order to arrive at an amount for the nutrient, it became necessary to source additional data. The publication Vitamins and Minerals – A Scientific Evaluation of the Range of Safe Intakes (2nd edition) prepared by Dr Derek Shrimptom was used.

Both the DRI levels and Shrimpton's recommended levels included nutrients from all sources, i.e. food plus supplements. The issue was how to account for the nutrients that are provided by the food component in the absence of food consumption data for that specific nutrient.

Where South African data for a nutrient was available it was used. Where there was no SA data for the nutrient, a cautious percentage of the UL was allocated. The final amount was then calculated according to the allocated percentage. For instance where no data was available for a fat-soluble vitamin the Technical Committee used 50% of the UL to determine the level. If it was a water-soluble vitamin, the Technical Committee used 100% of the UL. For minerals the trend showed that about 25% is derived from food. Therefore the Technical Committee used 75% of the UL for minerals where no data was available.
Example:
UL for folic acid is 1000 mcg (DRI) The SA intake of folic acid from food is 18 % of the UL. Therefore the exclusion for folic acid for supplements is 82% UL.

Current work is still ongoing to establish levels for children. Our criteria for efficacy can be found in the bibliography.

The Bibliography included the following: Martindale, USP, BP, the Australian TGA references, the DRI's of the Institute of Medicines in the USA, the Shrimpton report, The Nutritional Status of South Africans – a Review of the literature from 1975 to 1996 which was done by Prof H H Vorster of the University of Potchefstroom.

3.2.3 Add the following at the end of the sentence: "… if the national authority can show scientifically that a level lower than that established by Codex is appropriate."
Motivation: To stop regulatory authorities making unscientific barriers to trade.

4. Packaging

4.1 Add the word "sealed " to read as follows: "The product shall be sealed and packed in containers which will safeguard the hygienic and other qualities of the food."

5. Labelling

5.2 to 5.5 The [ ] around 5.2 to 5.5 should be deleted.

5.2 Replace 'name' with 'labeling' and 'be' with 'include' to read: "The labeling of the product shall include…." Motivation: "Supplement" does not need to be part of the name of a product but should be in the immediate vicinity of the product name as part of the label.

5.4 Replace 'and' with 'or' to read "…… on the labeling or per unit dose form, as appropriate". Motivation: It is unnecessary to have both forms on the label. Cluttered labels confuse the consumer.

5.5 South Africa proposes to delete 5.5 since the average consumer does not have the knowledge in the majority of cases to correctly interpret this information, and since safety is no longer a factor to consider, there remains no reason to cause unnecessary confusion for the consumer.

5.7 Amend the wording to read:
"Where it can be demonstrated that the use of a food supplement may lead to adverse effects for a particular population group, appropriate cautionary statements should be made."

5.8 Amend the wording to read: "The labeling of food supplements may not state or imply that these products are a substitute for a varied diet."

5.9 South Africa proposes to delete 5.9, since the product is safe as a food and therefore this type of statement is superfluous.

South Africa proposes to add the following to the text:

"6. Quality assurance

Supplements should be manufactured under appropriate GMP's."

SPAIN

2.-DEFINITIONS

The paragraph in square brackets should be deleted from the text as it is already included in the Preamble.

3.-COMPOSITION

3.1.2.

In our opinion the square brackets should be deleted and the wording should be retained.

3.1.3.

We support the text in square brackets; consequently, they should be removed.

3.1. CONTENTS OF VITAMINS AND MINERALS (Translator's note: to read 3.2)

3.2.1

In our opinion, the lowest level of intake of 15 % is more appropriate.

3.2.2.

We support the first proposal; consequently, all square brackets appearing in the text should be deleted.

5.- LABELLING

5.2.

*We support the following wording: "**5.2 The name of the product shall be 'vitamin and mineral supplement' with an indication of the nutrients contained therein".***

5.3.,5.4 and 5.5.

We support the text in square brackets; consequently, they should be removed.

5.7.

We suggest the following text: ***"The label must contain a warning statement regarding the consumption of the product: non-compliance with the instructions of the manufacturer may present a hazard to the health of the consumer".***

5.8

The current text should be deleted as the vitamin and mineral supplements do not replace meals.

We suggest the following text ***"The labelling, presentation and advertising of vitamin and mineral food supplements shall not include any mention stating or implying that a balanced and varied diet cannot provide appropriate quantities of nutrients in general".***

COUNCIL FOR RESPONSIBLE NUTRITION (CRN)

PREAMBLE

The preamble includes so many qualifiers and limitations to justify a vague recommendation against use of supplements that it should be either deleted or extensively revised.

The following points—related to the first sentence only—illustrate the flaws:

- The draft uses the term "most people." How many is that? Fifty-one percent? All but one in a million?
- The draft uses the phrase "who have access to a balanced diet," but does not address whether those who have "access" actually consume such a balanced diet. For example, most persons in developed countries have "access" to good diets but many do not actually consume such diets.
- The preamble uses the term "balanced diet" without defining it. Does "balanced" equal "adequate?"
- The preamble indicates that persons who consume "balanced diets" will "usually" obtain all the nutrients they require. What is the probability related to "usually?" Because of the statistical definition of the Recommended Dietary Allowance (RDA), if everyone in a population consumes exactly the RDA, the result is that 2.3 percent of the population would be consuming inadequate quantities of the nutrients.

The second sentence of the preamble properly emphasizes consumption of a variety of foods that constitute a balanced diet. The mistake is to see diet and supplementation as an "either/or" situation. The prudent decision for consumers to protect their health is to consume both a balanced diet and supplement on a rational basis.

The last sentence of the preamble suggests that no one should take a supplement without first doing a detailed dietary intake or nutritional status assessment. This suggestion is not feasible because of the technical or scientific input required. Most consumers are not qualified to do this for themselves. The economic resources available would be better spent on food and supplements, rather than individual nutritional assessments by a professional.

1. SCOPE

1. This sentence is offered, apparently, as an "escape valve" for countries that wish to regulate supplements as drugs. It is self-evident in the name that a guideline by the Codex Alimentarius would not apply to products regulated as drugs. It is not apparent that a country can decide to impose drug regulations as a non-tariff trade barrier on supplements without sanction by the World Trade Organization. This sentence should be deleted because it seems to encourage countries to evade the guidelines by opting for drug regulations for supplements.

2. DEFINITIONS

2.1 The sentence in square brackets reflects the same flaws as the Preamble. It should be deleted.

3.1 SELECTION OF VITAMINS AND MINEREALS

3.1.1 This paragraph is restrictive in a way that could compromise the consumer's health. The word "vitamin" together with the phrase "proven by scientific data" could easily be interpreted in a restrictive manner that could be detrimental to the consumer's health and benefit— the word "vitamin," if interpreted literally, would exclude substances lutein and lycopene. Also, these two substances are not "provitamins" but instead are best described as "vitamin like" because they provide nutritional benefits, although they are not "essential" in the usual, restrictive meaning of that word. Such exclusions would not serve the public interest or health.

3.1.2 The total provisions of the Pharmacopoeias must be recognized, including the common separate provisions for the vitamin and tablets or capsules that contain it. Purity criteria for the concentrated vitamin used as a source for it in the vitamin tablet or capsule must not be applied to the final product. For example, a bulk ingredient identified as ascorbic acid might be required to be 99 percent pure, but the content in an ascorbic acid tablet might be much lower, thereby allowing use of vitamin C sources other than purified ascorbic acid, such as rose hips and acerola cherry. The purity of a tablet is related to the amount of the vitamin stated on the label.

[3.1.3] This section is redundant with 3.2, and should be deleted from 3.1.

3.2 CONTENTS OF VITAMINS AND MINERALS

3.2.1 Some specified flexibility is needed for the minimum quantity—33 percent is reasonable for the nutrients required in very small quantities (such as vitamins B1, B2 and others) but not for those require in larger quantities (such as calcium). The 15 percent minimum is reasonable for those required in larger quantities. This flexibility is necessary because, for example, a supplement of 15 percent of the calcium requirement may be very beneficial, but is not feasible for multivitamin/mineral products because the limitations of tablet size.

3.2.2 <u>The first option</u> in square brackets for RDA based limits should be deleted. The RDA does not provide all benefits, known with reasonable certainty, for the vitamins and minerals, and the statistical definition of the RDA does not cover 2.3 percent of the population—a terrible public health policy. See the following excerpt from a CRN comment to the US Food and Nutrition Board, November 2002 (indented in *Italics*, below). Most importantly for consideration of maximums, the RDA is not defined or determined to consider safety issues. The second option for maximums based on risk assessment is the current state of the science and should be adopted by Codex.

<u>The Italicized section that follows is excerpted from a CRN comment to the US Food and Nutrition Board, November 2002</u>

RDA – RECOMMENDED DIETARY ALLOWANCE: What it IS, and What it is NOT

A theoretical risk from intakes near or above the UL is likely to be overemphasized if the risk of inadequacy with intakes near the RDA are not recognized. Consider the following scenario that clearly demonstrates that the RDA is not an ideal intake or an appropriate nutrient intake target for all individuals in a population:

> *If the mean requirement is known with certainty (by including all members of the population), and the statistical distribution around that mean is exactly Gaussian, thus providing exact quantification of the variance (standard deviation), the RDA identifies an intake that would be sufficient for 97.5 percent of the population—but also insufficient for 2.5 percent of the population. If every member of the population put complete confidence in the sufficiency of the RDA and consumed a diet that provided exactly the RDA level of intake, 2.5 percent of the population would have nutrient intakes that were, by definition, inadequate. A health policy that would result in 2.5 percent of the population having inadequate intakes cannot be justified as a goal—thus the RDA is not an appropriate target intake for the population.*

An ideal target intake for a population would be one that is a safe and convenient intermediate between the RDA and the UL. Such an intermediate level of intake could simultaneously provide safety from adverse effects of excess intakes and from risk of inadequacy resulting from insufficient intakes. For example, in contrast to the 2.5 percent inadequacy rate expected for intakes equal to the currently defined RDA, the mean requirement plus four standard deviations would identify intakes that protect all

individuals but 1 in 13,000. (Note: a risk of 0.0001 would occur an intake 3.88 SD above the EAR.) It should be recognized, however, that there is no number of SD above the mean that would provide certainty of covering everyone in a population with a true Gaussian distribution.

For adult males, the following would apply:

*Nutrient**	*EAR*	*RDA based on + 2SD (as rounded by FNB)*	*"RDA" based on +4SD (with rounding)*	*UL*
Folate (µg DFE)	*320*	*400*	*500*	*1000*
Vitamin A (as µg RE)	*625*	*900*	*1150*	*3000*
Vitamin B-6 (mg)	*1.4*	*1.7*	*2*	*100*
Vitamin C (mg)	*75*	*90*	*105*	*2000*
Vitamin E (mg αTE)	*12*	*15*	*18*	*1000*
Selenium (µg)	*45*	*55*	*65*	*400*
Zinc (mg)	*9.4*	*11*	*13*	*40*

** For the nutrients listed, the FNB assumed a 10 % CV, except retinol with a 20% CV.*

This scenario comparing the RDA and a value 4 SD above the EAR does not address the issue of whether the endpoints selected by the FNB to serve as the basis of the RDA are the most appropriate ones. If endpoints related to risk of chronic disease (e.g., increased folic acid intake lowering homocysteine levels and the related risk of heart disease, or increased selenium intake decreasing the risk of certain cancers) had been selected as the basis of the RDA (regardless of the 2 SD vs 4 SD issue) the separations of the RDA and the UL would be considerably different. In such a circumstance, these relationships would need to be reexamined.

3.2.2 The second option for maximums based on risk assessment is the current state of the science and should be utilized. The last sentence of the second option for section 3.2.2, however, reflects compromise language that is included in the European Commission Food Supplements Directive. This reference to "population reference intakes" (can this be anything other than the RDA?) seems to be a "back door" to RDA-based limits. From a risk management viewpoint, the range of actual intakes from conventional food sources is relevant to the safety of supplements, but the RDA is not. The last sentence of option 2 should be deleted because it overtly contradicts the method described in sentences (a) and (b) in option 2.

3.2.3 This section should be deleted because it provides an "escape valve" to avoid Codex guidelines. The CCNFSDU should recognize that the Codex Procedural Manual (13th Edition) permits member countries to select one of three levels of acceptance Codex standards—for the purpose of domestic policy. The third of these ("free distribution") would give the Codex standard no impact on domestic regulations, but it does not exempt the country from its obligations to comply with Codex standards under the international trade rules of the World Trade Organization. In the context of paragraph 3.2.3, maximums might be established as the national level for domestic purposes without input from Codex, but imports would be subject to the Codex guideline.

4 PACKAGING

4.3 The child-resistant provision is appropriate, but the "if necessary" qualifier should be expanded to acknowledge that easy-to-open containers are needed by many elderly consumers.

5 LABELLING

5.5 The requirement for labeling with percentages of the RDA should be optional because many consumers believe with considerable scientific justification that the RDA is not the relevant issues for many vitamins and minerals. Certainly, the percentage of the RDA has no meaning for safety.

5.7 The term "significant amount" is likely to be interpreted in a kaleidoscope of ways by different countries. Such warning statements are not needed unless the product exceeds the maximum identified through the second option in paragraph 3.2.2. This paragraph should be rewritten to read: "The label must contain a warning statement if the product exceeds the maximum identified through risk assessment as described in paragraph 3.2.2."

5.9 This paragraph should be deleted. Under Codex supplements are to be regulated as "food" and therefore there should be no requirement to seek professional advice before their use. Note that the label itself is professional advice.

IADSA - INTERNATIONAL ALLIANCE OF DIETARY/FOOD SUPPLEMENT ASSOCIATIONS

PREAMBLE:

Amend the first sentence to read as follows (new words underlined):

'Most people who have access to a balanced diet can usually obtain all the nutrients <u>required from their normal diet in order to avoid deficiency diseases</u>.'

Amend the end of the second sentence to read as follows (new words underlined):

'Because foods contain many substances that promote health, people should therefore be encouraged to select a <u>balanced and varied diet</u>.'

Delete the words "before considering any vitamin and mineral supplement".

Rationale: The dietary supplement industry does not promote products as a replacement for food and actively promotes the principle that 'people should be encouraged to select a balanced diet from food.' IADSA is therefore concerned about the implication of the preamble, namely that supplementation detracts from good diet. Existing evidence suggests that many consumers of supplements are particularly conscious of their nutrient intake and supplement their diet with the aim of achieving an optimum state of health, rather than just correcting nutrient deficiencies.

1. SCOPE:

1.1 Delete all text after 'supplementing the daily diet'.

Rationale: This additional wording is redundant.

1.2 Delete paragraph 1.2.

Rationale: It is unnecessary and could serve to increase rather than decrease barriers to trade.

2. DEFINITIONS:

2.1 Add the words 'whether from natural or synthetic sources' at the end of the first sentence. The first sentence of paragraph 2.1 would therefore read as follows (new words underlined):

'Vitamin and mineral supplements for the purpose of these guidelines derive their nutritional relevance primarily from the minerals and/or vitamins they contain, <u>whether from natural or synthetic sources.</u>

Rationale: Since both natural and synthetic sources are widely used in food supplements, these should be specified within the text of the Guideline to avoid any confusion.

Delete the square brackets from the last sentence.

3. COMPOSITION:

3.1 SELECTION OF VITAMINS AND MINERALS

3.1.3 Delete Paragraph 3.1.3.

Rationale: *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 Add at the end of the sentence 'with or without other ingredients with a nutritional or physiological effect'.

Rationale: *Although the Guidelines only cover vitamin and mineral supplements, it is important to clearly state within the text that other ingredients may be combined with vitamins and minerals.*

3.2 CONTENTS OF VITAMINS AND MINERALS

3.2.1 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 to prevent misrepresentation. However, the practical implications of the bulk effect of certain nutrients, such as calcium, magnesium, potassium and sodium, should be considered carefully before a decision is taken in this respect.

3.2.2 Option 1 should be deleted.

Rationale: Recommended daily intakes (RDI) were established to indicate the required levels in order to avoid deficiency diseases. They do not reflect significant scientific research supporting the health benefits of intakes much 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 the RDI, but can only be established by nutrient appropriate scientific risk assessment.

Option 2 of paragraph 3.2.2 should be amended as follows:

- The addition of the words "by the relevant scientific body taking into account:" after the words "shall be set".

- The section relating to the sensitivity of different consumer groups should be placed in brackets until the issues it seeks to address have been defined.

- The deletion of the final sentence of paragraph 3.2.2.(b).

Paragraph 3.2.2 would therefore read as follows (new words underlined):

'Maximum amounts of vitamins and minerals in vitamin and mineral supplements per daily portion of consumption as recommended by the manufacturer shall be set <u>by the relevant scientific body taking into account</u>;

a) upper safe levels of vitamins and minerals established by scientific risk assessment based on generally accepted scientific data, [taking into consideration, as appropriate, the varying degrees of sensitivity of different consumer groups].

b) the daily intake of vitamins and minerals from other dietary sources.'

3.2.3 Add 'only if the national authority can scientifically validate a lower level than that established by Codex' at the end of paragraph 3.2.3.

Rationale: This would preclude national authorities placing unscientific technical barriers to trade.

5. LABELLING:

5.2 Paragraph 5.2 should read as follows:

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.

Rationale: 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.

5.4 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 IADSA proposes the words 'quantitative declarations' to clarify which information should be expressed as a percentage of the reference values mentioned.

Rationale: The word 'information' is insufficiently specific.

5.6 Add 'otherwise referred to as "suggestion of use" or "usage suggestions" at the end of the sentence.

5.7 Amend paragraph to read as follows:

'Where it can be demonstrated that the use of a food supplement may lead to adverse effects for a particular population group, usage information appropriate to this group should be provided.'

Rationale: The current wording of 5.7 is unworkable. It is more appropriate for specific information to be included on a label for a specific population group which can be demonstrated to be at risk from higher level products.

5.8 Amend paragraph to read as follows:

'The labelling of food supplements may not state or imply that these products are a substitute for a varied diet.'

Rationale: IADSA agrees that supplements should not be used as a substitute for a diversified diet. However, it would be more useful to prohibit the use of any statement which implies that supplements may be a substitute for a varied diet, rather than including the statement in 5.8.

5.9 Delete 5.9.

Rationale: Under these Codex guidelines vitamin and mineral supplements will be regulated as safe food products for self-selection. The requirement to obtain advice from a nutritionist, dietician or medical doctor is impractical and inappropriate to this draft Guideline.