codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 6 **CX/NFSDU 02/6**
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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 3 of the Procedure

Comments from:

AUSTRALIA
BRAZIL
CUBA
GERMANY
HUNGARY
MALAYSIA
NEW ZEALAND
SOUTH AFRICA

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.

Now that the European Parliament has passed the EC Directive on food supplements, and there are similarities between the Directive and these draft Guidelines, it may be useful, where appropriate, to draw text from the

Directive into these Draft Guidelines. Australia has made reference to appropriate texts from the Directive in these comments.

Comments On Guidelines

'Guidelines' should be capitalised throughout the document. Reference to 'dietary intake' in these comments is to vitamin and mineral intake from consumption of conventional foods. 'Daily portion of consumption' is cumbersome and could be simplified by substituting 'one-day dose'.

Preamble

Australia believes that a Preamble that sets out the policy basis for regulation of vitamin and/or mineral supplements that includes reference to effectiveness and risk of consumption is appropriate. However, the text could be improved and the following revision is suggested:

> *Most people can usually obtain all the nutrients they require for health from a balanced diet as recommended by national authorities. Because conventional foods contain many substances that promote health, people should be encouraged to select a balanced diet before considering consumption of vitamin and/or mineral supplements. However, such supplements may be useful in cases where dietary intake of vitamins and/or minerals is inadequate to maintain health or where people choose to supplement their dietary intake from these sources.*

Note: 'adequate and diversified' could substitute for 'balanced' in the above text.

Section 1 Scope

1.1 Australia suggests substituting the term 'normal' for 'daily' as it implies that supplements are required daily. The words [if and where necessary] conflict with the context set by the preamble because they do not allow for consumer choice and so should be deleted. The second sentence is redundant because the intent is captured (better) in 1.2.

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 minerals supplements are 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 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 nor do they provide a significant amount of energy."*

Section 3 Composition

3.1.2 Australia suggests the intent of the second sentence be strengthened to *"…purity criteria should be established according to Pharmacopoeias or appropriate FAO/WHO references or, in the absence of relevant criteria from these sources, national legislation."*

3.1.3 The intent of this [3.1.3] is ambiguous because of the text " the use of individual vitamins and minerals in supplements can be limited..". 'Use' probably refers to the further restriction of maximum limits by national jurisdictions including setting such limits to zero, thus having the effect of narrowing the selection of permitted vitamins and minerals. If such restriction is the intent, then relevant text should be included in provision 3.2.2, and 3.1.3 be deleted.

It is not clear what "supply situation of the population" means. If this sentence is retained within the Guidelines, perhaps "dietary intake of the population" would clarify intent.

3.1.4 This provision is redundant because its intent is covered by the definition and 3.1.1.

Section 3.2 Contents of Vitamins and Minerals

3.2.1 Minimum levels can be tackled either by setting an absolute minimum content or by setting criteria for quantitative declaration on the label, either in the positive or negative. This Committee recently recommended 30% Nutrient Reference Value (NRV) per reference quantity as a minimum criterion for 'good source' of vitamins or minerals claim, although it is recognised that the reference quantity, i.e. serve, 100g etc, does not necessarily equate to a one-day dose. Australia prefers a more indirect labelling solution that would impose fewer burdens on manufacturers and potentially facilitate trade.

Two alternate options are suggested:

- establish a minimum level for quantitative declaration eg 30% NRV/one-day dose below which a quantitative declaration cannot be made (ingredient listing would still apply), or
- do not restrict quantitative declaration but require a relevant statement for declarations below 15% NRV/one day dose to the effect that the supplement is not a significant source of that (*) vitamin or mineral.

FAO/WHO are likely to determine recommended daily intakes for several age-sex categories and stages of the lifecycle and therefore a process similar to the determination of NRVs in the Codex Guidelines on Nutrition Labelling should occur to establish summary reference values eg for different age groups, which could be annexed to this Guideline. It is noted however that the list of reference values relevant to this draft Guideline is likely to be more comprehensive than the current (or revised) list of micronutrients in the Guidelines on Nutrition Labelling.

3.2.2 Australia supports the intent of the second option under 3.2.2 and suggests that the text be revised in line with the original intent, in accordance with the final text of Article 5 (1) from the European Directive on food supplements.

3.2.3 This provision would only apply if the first option of 3.2.2 were adopted as its intent is already encapsulated in the EC Directive on food supplements. As Australia supports the second option of 3.2.2, this provision should be deleted.

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

5.1 Section 3.4 of the Codex Guidelines on Claims prohibits 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 unless permitted in standards developed by this Committee or national laws. It is also noted that provision 7.4 of the Codex Guidelines for the Use of Nutrition Claims (CAC/GL 23 – 1997), which are not referenced by these draft Guidelines, states " a claim should not imply or include any statement to the effect that the nutrient would afford a cure or treatment for or *protection from* disease.

Australia notes that the European Directive on food supplements, Article 7, permits information about the need for supplementation of the diet of specific population groups where this has been established by generally accepted data. It would seem appropriate that if the preamble refers to 'such supplements may be useful in cases where dietary intake of vitamins and/or minerals is inadequate to maintain health', then there should be some latitude for products to be labelled with equivalent statements.

Thought should be given by either this Committee or the Codex Committee on Food Labelling on the appropriate parameters for claims about vitamin and/or mineral supplements to be included in these draft Guidelines.

5.2 It is suggested that the text from Article 6 (1) of the European Directive on food supplements be adopted with minor modification: *"The name of the product shall include the word "supplement" and the category name 'vitamin' and/or 'mineral' that characterises the product. The name of the either category may be completed or replaced by the specific name of the vitamin(s) and/or* mineral(s) characterising the product."

5.4 Australia suggests that the average amounts of vitamins and minerals present in the product be declared per one-day dose and, where appropriate per unit dose i.e. where the unit dose does not equal the one-day dose.

5.5 In the light of comments made under 3.2.1, Australia suggests either:

- establish a minimum level for quantitative declaration eg 30% NRV/one-day dose below which a quantitative declaration cannot be made (ingredient listing would still apply), or
- do not restrict quantitative declaration but require a relevant statement for declarations below 15% NRV/one day dose to the effect that the supplement is not a significant source of that (*) vitamin or mineral.

Given that FAO/WHO are likely to determine recommended daily intakes for several age-sex categories and stages of the life cycle, a process similar to the determination of NRVs in the Codex Guidelines on Nutrition Labelling should occur to establish appropriate reference values eg for different age groups, pregnancy and so on. This could be set out in an Annex to this Guideline. It is noted however that the list of reference values relevant to this draft Guideline is likely to be more comprehensive than the current (or revised) list of micronutrients in the Guidelines on Nutrition Labelling. It may not be appropriate then for reference to be made to the NRVs in the Codex Guideline on Nutrition Labelling.

Australia has no objection to permitting these declarations in graphical form (similar to European Directive Article 9 (2)).

5.7 Australia supports label statements, where applicable, that warn consumers not to exceed a stated maximal dose or one-day quantity. The conditions of use of this statement would be determined from the relevant risk assessment.

5.8 Australia supports the intent of this provision but suggests that the text of European Directive on food supplements Article 6 (3)(c) be substituted i.e. a statement to the effect vitamin and/or mineral supplements should not be used as a substitute for an adequate and diversified diet.

5.9 This provision should be deleted.

BRAZIL

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.~~

We suggest to maintain the preamble and to delete the last phrase "or where consumers consider their diet requires supplementation, vitamin and mineral supplements serve to supplement the daily diet".

Justification: *the last sentence allowed the possibility of consume without control by consumers, and took into consideration the individual capacity of supplementation, without the use of adequate parameters.*

1. SCOPE

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

- To delete the square brackets of the expression "if and where necessary".

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 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.]~~

- To eliminate the square brackets and to delete the expression "or where the consumers consider their diet requires supplementation".

Justification*: the expression should allow the possibility of* consume without control *by the consumers.*

3. COMPOSITION

3.1 SELECTION OF VITAMINS AND MINERALS

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].

- To delete the square brackets of the item 3.1.2

[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].

- To delete the square brackets of item 3.1.3

- To substitute the word "limited" by "based on scientific data"

3.2 CONTENTS OF VITAMINS AND MINERALS

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.

- To delete the square brackets of the expression "[15% to 33%]".

- To include after FAO/WHO, the expression "taking into account the national Legislation".

Justification*: the minimal level to be established must be in agreement with the specific legislation of the each country.*

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 accont should be taken to the reference intake values of vitamins and minerals for the population.]~~

- We suggest to keep the first item 3.2.2. Delete all square brackets of the hole item 3.2.2.

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 For vitamins an 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.~~

- We suggest to delete the item 3.2.3

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

5. LABELLING

[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.

- To eliminate the square brackets of the item 5.2., and to delete the sentence "or dietary mineral/vitamin preparation to supplement the diet with ..."

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

- To eliminate the expression: "on long term basis".

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

CUBA

Preamble, Scope and Definitions

We are of the opinion that the Preamble should be retained. It could be included in the Scope Section (as CODEX Guidelines usually do not have Preambles)

In Section 2.1 Definitions, the sentence in square brackets could be deleted or included in the Scope Section.

COMPOSITION:

In Sections 3.1.2 and 3.1.3, the square brackets should be deleted.

3.2 Contents of Vitamins and Minerals

3.2.1 We still think that 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 25% to 30% of the recommended daily intake as determined by FAO/WHO.

3.2.2 Maximum levels

Delete the square brackets around the second option. Keep the text contained in a) and b).

LABELLING:

Delete the square brackets around 5.2, 5.3 to 5.5, 5.7, 5.8 and 5.9. and retain the text.

GERMANY

PREAMBLE

Germany fully supports the existence of a Preamble and also its wording as it stands.

1. SCOPE

1.1 The square brackets should be deleted to be in accordance with the text of the Preamble.

2. DEFINITIONS

2.1 The sentence in square brackets should be deleted as it is of the same tenor as the Preamble.

3. COMPOSITION

3.1.2 The square brackets should be deleted.

3.1.3 Germany proposes to remove the square brackets around this sentence. Furthermore, the square brackets around “limited” should be deleted and "limited" be replaced by the word "restricted".

3.2 CONTENTS OF VITAMINS AND MINERALS

3.2.1 We propose to retain 15% as minimum level and to remove the square brackets.

3.2.2 We propose to retain the second alternative and delete the other.
In the second alternative, the square brackets should be deleted.

5. LABELLING

5.2 The sentence should be replaced by the following (which is in accordance with future regulations in EU): The name under which products covered by this Guidelines are sold shall be „food supplement“ with an indication of the categories of nutrients contained therein.

5.3 The square brackets should be deleted.

5.5 The square brackets should be deleted.

5.7 The sentence should be replaced by the following (which is in accordance with future regulations in EU). The label must contain a warning statement not to exceed the stated recommended daily dose.

5.8 The sentence should be replaced by the following (which is in accordance with future regulations in EU). **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 text should be deleted.

A further paragraph 5.9 should be added:

The label must contain a statement to the effect that the products should be stored out of the reach of young children.

A further paragraph 5.10 should be added:

The labelling, presentation and advertising of food supplements shall not include any mention stating or implying that a balanced and varied diet cannot provide appropriate quantities of nutrients in general.

HUNGARY

ad 3.1.2.:

Square bracket should be deleted.

ad 3.1.3.:

This point should remain, the square bracket is to be deleted in case of word „limited".

ad 3.2.1.:

The Hungarian Working Committee for NFSDU proposes the minimal value of 33 % of RDA in the dose recommended for daily consumption. We consider that normally three meals are consumed daily and a well balanced diet contains all of the nutrients needed for health. That is in an average one meal may contain 33 % of the daily nutrient intake. Daily portion of a preparation containing less than 33% of the RDA can hardly be considered as supplement.

ad. 3.2.2.:

We prefer the first variation for at least two reasons.

a.) From viewpoint of nutrition the RDA determined by FAO/WHO indicate the ideal supply of vitamins and minerals. Thus a supplement containing 100 % of RDA ensures the total amount of the nutrients needed for good health. (It can be thought that the meals consumed also contain minerals and vitamins, so the actual intake is somewhat higher than the recommended one.) Accordingly there is no reason to produce preparations containing any essential nutrients in higher daily dose than RDA.

b.) In viewpoint of legislation we think that it is better to fix the maximum level for each vitamin and mineral than allow to take other criteria into account.

ad 5.7.

The text in square bracket is not needed if the first variation of point 3.2.2. can be accepted.

ad 5.8.

The following sentence is proposed:

"The label must contain a statement: supplement can not be used for replacement of meals."

ad 5.9.:

The following sentence is proposed:

"All labels shall bear a statement that it is reasonable to ask for an advice of a nutritionist, dietetitian, pharmacist or a medical doctor."

MALAYSIA

SECTION 2: DEFINITIONS

Paragraph 2.1

Malaysia proposes to remove all the square brackets and adopt the text contained in the brackets. It is 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 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>."

SECTION 3: COMPOSITION

3.1 SELECTION OF VITAMINS AND MINERALS

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".

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 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".

Comments from BPFK:

BPFK currently has a list of various minerals and vitamins with a maximum daily permitted level for use as supplements, some of these values are beyond the 100% RDI. However, the BPFK regulates the products as drugs whilst guidelines being deliberated are for application to foods.

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 both 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 the paragraph 5.8, 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. 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 can not be used for the replacement of meals on long term basis.*

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

NEW ZEALAND

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

Preamble

Although it is not usual to have a *Preamble* section in a Codex guideline, New Zealand does support the inclusion of the proposed *Preamble* in this guideline. We note that there is considerable repeat of information in the *Preamble* in the later *Scope* and *Definition* sections, however. 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. This need only be stated once, in the *Preamble,* and should be removed form other parts of the guideline.

1. Scope

1.1: 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 text of the *Preamble.*

2. Definitions

2.1: New Zealand recommends deleting the text in the square brackets (the last sentence)

> "[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. Composition

3.1 Selection of Vitamins and Minerals

New Zealand suggests that 3.1.2 and 3.1.3 can be combined into one section. We propose the following wording:

"The selection of admissible vitamin and mineral sources should follow a risk based approach and should consider criteria of public health need, safety and bio-availability. Regional and national peculiarities should be considered as part of the risk based approach. In addition purity criteria should take into account the FAO/WHO or Pharmacopoeias and national legislation where applicable."

3.2 Contents of Vitamins and Minerals

New Zealand supports the option in section 3.2.2 (currently in square brackets), which follows a scientific risk based approach. This approach recognises the differing needs of different population groups.

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 also 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: warning statements should be required where there is 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

1. Scope

1.1 Delete [if and where necessary]. It is superfluous since it is already explained in the preamble.

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

Remove the square brackets around the last sentence.

3.2 Contents of vitamins and minerals

3.2.1 The minimum level of each vitamin and mineral should be 15%.

3.2.2 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. However, the goal is always to reach consensus. Therefore, South Africa proposes a compromise where both the two original main viewpoints are accommodated, but which avoids wording that may create a barrier to trade.

The main viewpoints are:

1 Maximum levels based upper safe levels as determined through scientific risk assessment principles which will accommodate the need to recognise current research benefits that relates to reduction of risk of chronic diseases; and

2 Where the ultimate purpose is to correct malnutrition as a result of nutrient deficiencies; maximum levels could be tied to RDA values. In this case the purpose would mainly be to correct those deficiencies.

Both approaches have merit and it should be reflected as such in the document as a way to reach consensus and to make progress with the document.

South Africa thus proposes the following wording for the text to accommodate the compromise:

"The maximum level of each vitamin and mineral contained in a vitamin and mineral supplement, intended to correct a specific nutrient deficiency, should not exceed 100% of the recommended daily intake"

AND

"Vitamin and mineral supplements, for the purpose of reduction of risk of degenerative diseases, may contain vitamins and minerals up to a level that is considered safe on the basis of science-based risk assessment consideration, as determined by appropriate risk analysis methodology, taking into account all sources of the nutrients in the diet."

4. Packaging

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

5. Labelling

a. South Africa proposes to delete paragraph 5.5 since it could be confusing for consumers in cases where the maximum daily level is used in a supplement and the upper safe level of that vitamin is very high. For example, Riboflavin's upper safe level minus intake from food is about 200mg. The nutrient reference value for riboflavin is 1.6mg, in other words 12 500% of the NRV or RDA. Since the consumer does not have the knowledge in the majority of cases to correctly interpret this information and safety is no longer a factor to consider, there remains no reason to cause unnecessary panic and confusion to the consumer.

b. The square brackets around paragraphs 5.2 to 5.5 should be deleted.

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

South Africa proposes the addition of the following new paragraph and text:

6. Quality assurance

"Supplements should be manufactured under appropriate GMPs."

IADSA -INTERNATIONAL ALLIANCE OF DIETARY/FOOD SUPPLEMENT ASSOCIATIONS

The most significant change to the Codex text is the addition of the second option for paragraph 3.2.2, which presents an approach to establishing maximum levels for vitamins and mineral supplements. For the purposes of creating an international framework for food supplements, IADSA believes that the wording does not provide a sound basis nor sufficient clarity on the process to be used in setting maximum supplement levels.

Specifically, reference intake values or recommended daily intakes may be useful markers to help the risk assessor in establishing the range of minimal safe intake (i.e. below these intakes there is an increased risk of deficiency). However, reference intake values have no direct relationship with the safety of supplemental

vitamins and minerals. For this reason option one of paragraph 3.2.2 is unacceptable and the proposed wording for option two should be amended, particularly through the deletion of the final sentence.

The setting of upper tolerable intake levels (UL) and maximum supplement levels, if and where necessary, is a nutrient appropriate scientific risk assessment which needs to be undertaken by the qualified FAO/WHO scientific bodies. In order to reduce barriers to trade, these assessments should not be subject to national interpretations unless dietary patterns in a certain country pose documented safety concerns.

A number of other elements also need to be addressed in the CCNFSDU in November 2002. Below is a summary of IADSA's specific comments on the individual paragraphs of the draft Guideline:

PREAMBLE:

We strongly recommend that the words "before considering any vitamin and mineral supplement" are deleted. The dietary supplement industry 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.' 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 preventing deficiency diseases.

1. SCOPE:

1.1 Delete all text after 'supplementing the daily diet'. All additional wording is superfluous.

1.2 Delete paragraph 1.2. It is unnecessary and could serve to increase rather than decrease barriers to trade.

2. DEFINITIONS:

2.1 Delete the square brackets from the last sentence.

3. COMPOSITION:

3.1 SELECTION OF VITAMINS AND MINERALS

3.1.2 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 Delete Paragraph 3.1.3. 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'. 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 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.

Therefore option 1 should be deleted.

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. to preclude national authorities placing unscientific technical barriers to trade.

5. LABELLING:

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. Paragraph 5.2 should therefore read as follows:

The ~~name~~ <u>labelling</u> of the product shall ~~be~~ <u>include</u> ‘vitamin and mineral supplement’ or ‘ dietary mineral/vitamin preparation to supplement the diet with …’, with an indication of the nutrients contained therein.

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 The word ‘information’ is insufficiently specific. IADSA proposes the words ‘quantitative declarations’ to clarify which information should be expressed as a percentage of the reference values mentioned.

5.6 Add ‘otherwise referred to as “suggestion of use” or “usage suggestions” at the end of the sentence.

5.7 IADSA agrees with the need for appropriate consumer cautions in certain cases, but considers that the word ‘warning’ should be replaced by the word ‘cautionary’. We also recommend the deletion of the phrase ‘if the product contains a significant amount of a nutrient with respect to the toxicity level’ and replacing it with ‘where appropriate, based on the recommended portion for daily consumption’.

5.8 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. The new paragraph would read as follows:

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

5.9 Delete 5.9. 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.