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Agenda Item 3

CX/NFSDU 14/36/4

JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

Thirty-sixth Session Kuta, Bali - Indonesia 24 - 28 November 2014

DRAFT REVISION OF THE GENERAL PRINCIPLES FOR THE ADDITION OF ESSENTIAL NUTRIENTS **TO FOODS (CAC/GL 9-1987)**

Comments of Australia, Brazil, Canada, Costa Rica, European Union, India, Mexico, New Zealand, Norway, Paraguay, Philippines, African Union, FoodDrinkEurope, ICBA, ICGA and IFT

COMMENTS OF AUSTRALIA

Australia wishes to provide the following comments with regard to CL 2014-27-NFSDU Request for Comments at Step 6 on the Draft Revision of the General Principles for the Addition of Essential Nutrients to Foods (CAC/GL 9-1987)

Australia generally supports the proposed draft Principles for the Addition of Essential Nutrients to Foods and offers the following comments, many of which aim to streamline the current wording of the document.

Specific Comments

INTRODUCTION

Para 3: Australia suggests that the 3rd paragraph could be streamlined by deleting reference to competent national and/or regional authorities (as it is mentioned in paragraph 1) so to read:

Competent national and/or regional authorities may also consult FAO/WHO publications may also **be consulted** for further guidance on the addition of essential nutrients.

SCOPE

Para 1: 'Without prejudice' is difficult language that is not readily understood. Australia suggests that this wording be replaced by 'or' and deleting the preceding comma so to read:

The Principles are intended to apply to all foods to which essential nutrients are added, not including vitamin and mineral food supplements¹, **or** without prejudice to the provisions in Codex standards and guidelines for foods for special dietary use.

DEFINITIONS²

Definitions 2.5 and 2.6 in square brackets: Australia considers that significant progress was made at the Committee's last session in relation to understanding the types of regulatory context in which voluntary fortification is framed. We therefore suggest that the definitions of mandatory nutrient addition and voluntary nutrient addition be retained with the following amendments:

2.5 Mandatory nutrient addition

Delete the square brackets [2.5 Mandatory nutrient addition] to retain the definition but update national authorities to competent national and/or regional authorities.

2.6 Voluntary nutrient addition

Delete the square brackets surrounding [2.6 Voluntary nutrient addition] and amend the definition to change perspective from governments to food manufacturers so to read:

Voluntary nutrient addition is when National Authorities permit food manufacturers choose to add specified essential nutrients to particular foods or food categories.

Australia also suggests that the explanatory text in footnote 4 to paragraph 3.1.2 be transferred to this definition and placed after the first sentence as an explanatory note. This is because the described approaches taken by competent authorities (although unusually long for a definition) are sufficiently important to appear in the main body of the text rather than as a footnote, particularly when a term such as

conditional voluntary approach, is subsequently mentioned in paragraph 4.1.1. Our suggestion for the revised definition would read:

2.6 Voluntary nutrient addition is when food manufacturers choose to add specified essential nutrients to particular foods or food categories.

Explanatory note: Internationally, there are different regulatory approaches to how voluntary addition of essential nutrients is legally framed and/or managed by competent national and/or regional authorities.....amounts for addition.

Footnote 2: Clarify the text to read:

Different types of addition of essential nutrients for the purposes described in these Principles may be described by the term 'fortification' in certain Member Countries.

Certain competent national and/or regional authorities may ascribe the term 'fortification' to one or more of the purposes outlined in section 3.1.1 of these Principles.

GENERAL PRINCIPLES

Para 3.1.1, last sentence: move to 3.5 Monitoring or revise tense?

We note the additional sentence at the end of para 3.1.1 is written in the past tense and refers to demonstration of fulfilment of the intended purpose. This could be interpreted as a monitoring statement and therefore may be better placed as the second sentence of paragraph 3.5.1 or alternatively, remain in 3.1.1 and be re-expressed as information needed to justify <u>intended</u> addition, in which case, the 'are fulfilled' could be written as 'could be fulfilled'.

- **Para 3.2.2, last sentence**: Refer to 'daily intake reference values' for consistency with NRV-R and relevant Codex standards including the Nutrition Labelling Guidelines.
 - 3.2.2 When the maximum levels are set, due account may be taken of the **daily intake** reference intake values of essential nutrients for the population.
- Para 3.2.4: Insert 'any' before restrictions since restrictions may not be necessary in every case, so to read:
 - 3.2.4 The severity of adverse effects on which inform **any** restrictions on the addition of essential nutrients to foods.
- Para 3.2.5: Streamline text, so to read:
 - 3.2.5 When competent national and/or regional authorities establish minimum amounts for the addition of essential nutrients to foods, they should ensure that these amounts are should be significant and in line with the intended purpose as identified in 3.1.1. In determining significant amounts, they may also consider conditions of use for 'source' claims in the Guidelines for Use of Nutrition and Health Claims may also be considered.
- **Para 3.3.1**: Delete single square bracket. Separate the two concepts into alignment with purpose, and taking account of dietary patterns, socioeconomic and need to avoid health risks, so to read:
 - 3.3.1 The selection of foods to which essential nutrients may be added should be in line with the intended purposes as identified in 3.1.1 and should take account of dietary patterns, socioeconomic situations and the need to avoid any risks to health.
- Para 3.3.2: Streamline text similar to the use of should in 3.3.3, so to read:
 - 3.3.2 Foods to which essential nutrients may should not be added may be determined by competent national and/or regional authorities.
- Para 3.5.1: See our comments on para 3.1.1

If the last sentence of 3.1.1 is intended to refer to 3.5 Monitoring, it could be moved to this paragraph as the second sentence.

It is important..... excessive intakes is minimised. Competent national and/or regional authorities may request scientific rationale and evidence demonstrating that one or more of the purposes listed above in paragraph 3.1.1 are fulfilled.

Para 3.5.2: With the suggested changes to para 3.5.1, we prefer to delete both options because the second option unduly restricts monitoring methods for evaluating impact or outcome and does not allow for methodological improvements. The first option is not clear as it does not specify the comparator for the equivalent methodology.

Heading 4.0 PRINCIPLES: Delete the 0 and upgrade the heading to upper case for consistency.

Subheading 4.1: Bold entire subheading for consistency. Refer to name of defined term: 'Mandatory nutrient addition' so to read.

- 4.1 Mandatory nutrient addition to address a demonstrated public health need
- Para 4.1.1, first and last sentences: Refer to name of defined term: 'Mandatory nutrient addition' and streamline text so to read.
 - (first) Where there is....authorities may decide that this may be accomplished by mandatory **nutrient** addition of essential nutrients.
 - (last)...**Although** While most addition to address a serious public health need **is generally** addressed through mandatory nutrient addition of essential nutrients, there may be some situations where a conditional voluntary approach may be used.
- **Paras 4.1.3, 4.14, 4.1.5:** We suggest that the selected food be referred to as the 'food vehicle' in light of the preceding text in 4.1.2 'the food selected as a vehicle'.
- **Para 4.1.5, square brackets**: Delete text in square brackets as cost effectiveness is a community concept that includes impacts on industry, government and consumers, rather than on intended consumers alone. Also, here is another example where the defined term could be used.

The cost effectiveness of the **mandatory nutrient** addition of essential nutrients should be considered.

Para 4.2.1: Clarify text of dot point criteria to explain that:

- 1) restoration could apply to one or more nutrients
- 2) the food need not significantly contribute to population intake of (impliedly all or most) essential nutrients
- 3) the food need not be a significant contributor of a nutrient before its restoration
- 4) both criteria apply prior to restoration
- 5) since loss may be interpreted as total loss, reduction is perhaps a better term.
- 6) it is noted that population is a defined term.

The text should read:

Prior to restoration:

- The food should be a significant contributor to the a population's intake of some essential nutrients in the population.
- The food prior to restoration would be subject to loss of reduction in one or more of its the
 essential nutrients it contains during processing, storage or handling.
- Paras 4.3.1: similar amendments to 4.2.1 for consistency
 - 4.3.1 Where nutritional equivalence......the counterpart food should be a significant contributor to the **a population's** intake of **some** essential nutrients in the population.
- **Para 4.3.3**: Delete this paragraph as para 3.2.1 already refers to the need to avoid health risks from excessive intake.

COMMENTS OF BRAZIL

General Comments

Brazil thanks for the opportunity to present the following comments about the Proposed Draft Revision of the General Principles for the Addition of Essential Nutrients to Foods (CAC/GL 9-1987).

Specific Comments

- [2.5 Mandatory nutrient addition is when National Authorities require food manufacturers to add specified essential nutrients to particular foods or food categories.]
- [2.6 Voluntary nutrient addition is when National Authorities permit food manufacturers to add specified essential nutrients to particular foods or food categories.]

Brazilian Comments

Since the voluntary addition was clarified in the explanatory note in section 3.1.2, Brazil agrees to delete the definition of voluntary in section 2.6 in order to reach a consensus.

[3.5.2 The assessment of the impact of the addition of essential nutrients should use an equivalent methodology.]

OR

Monitoring of total nutrient intakes should in principle use the same [method]/{approach} as used in deciding the addition of essential nutrients unless otherwise necessary for the specific nutrient concerned.

Brazilian Comments

Brazil suggests replacing the word 'equivalent' for 'appropriate' in the text of section 3.5.2 because we consider that the methodology to be used for the assessment of the impact of the addition of essential nutrients should be decided on a case-by-case basis.

- [3.5.2 The assessment of the impact of the addition of essential nutrients should use an <u>appropriate</u> methodology.]
- 4.1.5 The cost effectiveness of the addition of essential nutrients to foods [for the intended consumer] should be considered.

Brazilian Comments

Brazil agrees to delete the square brackets from "for the intended consumer".

[4.3.3 Where there is a clear public health reason to moderate the intake of a specific nutrient, the level of this nutrient need to be equivalent].

Brazilian Comments

Brazil agrees to delete the square brackets from section 4.3.3 as we consider that when a nutrient is related to risk of noncommunicable disease, its level does not need to be equivalent.

COMMENTS OF CANADA

I. General Comments

Canada is pleased that the principles were adopted at step 5 by the Commission at the 37th session. Canada has specific comments for consideration by the CCNFSDU at its 36th session as described below.

Specific Comments

Proposed Revised Text in CX/NFSDU 13/35/5, Appendix II	Comments from Canada
Footnote 2: ² Different types of addition of essential nutrients for the purposes described in these Principles may be described by the term 'fortification' in certain Member Countries.	Canada suggests including this footnote in the introduction rather than in the definition section as the footnote should be placed next to the word or clause to which it refers. We would suggest adding it right after the mention of the term "Addition of Essential Nutrients to Foods" as follows:
	The Principles for the Addition of Essential Nutrients to Foods ² (the Principles) are intended
[2.5 Mandatory nutrient addition is when National Authorities require food manufacturers to add specified essential nutrients to particular foods or food categories.]	Canada supports retaining this definition with minor edits.
	2.5 Mandatory nutrient addition is when competent national and/or regional authorities require food manufacturers to add specified essential nutrients to particular foods or food categories.
[2.6 Voluntary nutrient addition is when National Authorities permit food manufacturers to add specified essential nutrients to particular foods or food categories.]	Canada suggests deleting this definition since footnote 4 already provides information on voluntary addition.
3.1.3 Specific provision may be made in food standards, regulations or guidelines that identify the food(s) and essential nutrients for addition and, where appropriate, the minimum and /or maximum	Canada suggests adding information related to consideration of overages in this principle as it is an important point to consider when setting regulations on

amounts within which the essential nutrients should addition of essential nutrients. be present. 3.1.3 Specific provision may be made in food standards, regulations or guidelines that identify the food(s) and essential nutrients for addition. and, ₩Where appropriate, this would include identification of the minimum and /or maximum amounts within which the essential nutrients should be present and indication of whether or not overages are included. 3.2.1 The addition of an essential nutrient, including Delete 2 extra periods at the end of the sentence. the amount added, should be in line with one or more of the purposes identified in 3.1.1. The amount added should not result in either an excessive intake or an insignificant intake of the added essential nutrient(s), considering total daily intakes from all relevant sources including food supplements... 3.2.2 ... The maximum amounts mentioned above Canada suggests the following changes for consistency may be set taking into account with the Codex Nutritional Risk analysis principles for the use of the term "upper level of intake" in 3.2.2, 3.2.3 a) upper levels of intake of essential nutrients and 3.2.4. We propose that the term not be capitalized established by scientific risk assessment based on and followed by the abbreviation the first time it is used generally... and then the abbreviation should be used in the subsequent instances. 3.2.3 Where an Upper Level of Intake is not available, the scientific evidence to support the safe 3.2.2 ... The maximum amounts mentioned above may addition of ... be set taking into account a) upper levels of intake (UL) of essential nutrients established by scientific risk assessment based on 3.2.4 The severity of the adverse effect on which the generally... upper level of intake (UL) is based ... 3.2.3 Where an ULpper Level of Intake is not available, the scientific evidence to support the safe addition of ... 3.2.4 The severity of the adverse effect on which the upper level of intake (UL) is based ... 3.2.3 Where an Upper Level of Intake is not Canada proposes the following edits as per stated available, the scientific evidence to support the safe above and for better clarity. Also, an edit is proposed to addition of an essential nutrient should be clarify that while the HOI is one type of value that can considered including evidence for intakes that are be used, other values such as guiding levels can also unlikely to result in adverse health effects including be used. consideration of the Highest Observed Intake⁵. **3.2.3** Where an ULpper Level of Intake is not available, the scientific evidence to support the safe addition of an essential nutrient should be considered including evidence for intakes that are unlikely to result in adverse health effects such as including consideration of the Highest Observed Intake5. 3.2.5 When competent national and/or regional -Canada notes that there are superfluous dashes authorities establish minimum amounts for the between "minimum" and "amounts" and between addition of essential nutrients to foods they should "foods" and "they" that should be removed. We suggest ensure that these amounts are significant and in line adding a comma after foods. with the intended purpose as identified in 3.1.1. In -We also suggest adding "applying the" before determining significant amounts, they may also "conditions" in the second sentence. consider conditions of use for a 'source' claim in the Guidelines for Use of Nutrition and Health Claims 3.2.5 When competent national and/or regional (CAC/GL 23-1997). authorities establish minimum amounts for the addition of essential nutrients to foods, they ... "In determining significant amounts, they may also consider applying the conditions of use for a 'source' claim in the Guidelines for Use of Nutrition and Health Claims..." 3.3.1 The selection of foods to which essential Delete superfluous bracket before "be". nutrients may be added should [be in line with the

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intended purposes of nutrient addition as identified in 3.1.1, dietary patterns, socioeconomic situations and the need to avoid any risks to health.	
[3.5.2 The assessment of the impact of the addition of essential nutrients should use an equivalent methodology. OR Monitoring of total nutrient intakes should in principle use the same [method]/[approach] as used in deciding the addition of essential nutrients unless otherwise necessary for the specific nutrient concerned].	Canada supports the deletion of this principle since monitoring can involve purposes and approaches different from those used to gather evidence to inform decisions on the need for and amount of nutrient addition. If this principle is retained, Canada prefers option 2 with use of the word "approach" rather than method.
4.1.1 Where there is a demonstrated public health need for increasing the intake of an essential nutrient in the population, competent national and/or regional authorities may decide that this may be accomplished by mandatory addition of essential nutrients. This need may be demonstrated by evidence of clinical or subclinical deficiency, suboptimal or inadequate nutritional status using biochemical indicators, estimates indicating inadequate or potentially inadequate intake of nutrients, or evidence related to another health outcome	Canada suggests adding "causally linked to the nutrient" at the end of the second sentence for clarification. "This need may be demonstrated by evidence of clinical or subclinical deficiency, suboptimal or inadequate nutritional status using biochemical indicators, estimates indicating inadequate or potentially inadequate intake of nutrients, or evidence related to another health outcome causally linked to the nutrient. While most
4.1.2 The food(s) selected as a vehicle for the added essential nutrient(s) should be habitually consumed in sufficient amount by the target population.	Add an "s" after amount. 4.1.2 The food(s) selected as a vehicle for the added essential nutrient(s) should be habitually consumed in sufficient amounts by the target population.
4.1.3 The amount of the essential nutrient added to the food should aim to be sufficient to meetthe public health need. when the food is consumed in habitual amounts by the population at risk.	Canada supports the deletion of the end of the sentence and suggests adding a space between "meet" and "the public health need".
4.1.4 . The intake of the food selected as a vehicle should be stable and uniform and the [lower and upper levels of intake] distribution of the population intake of the food including the lower and upper percentiles should be known.	Canada agrees with the proposed changes to the text and suggests adding two commas in the sentence: 4.1.4. The intake of the food selected as a vehicle should be stable and uniform and the distribution of the population intake of the food, including the lower and upper percentiles, should be known.
4.1.5 The cost effectiveness of the addition of essential nutrients to foods [for the intended consumer] should be considered.	Canada supports retaining the text with deletion of the text in square brackets. Cost effectiveness refers to the cost/benefit which is the health authority's consideration, not the consumer's. It is the health authority who is deciding whether the extra cost that might be added to the retail product as a result of the mandatory addition of a nutrient is worth the benefit to society for reduced rates of deficiency and related ill-health and health care costs, lost productivity, etc
[4.3.3 Where there is a clear public health reason to moderate the intake of a specific nutrient, the level of this nutrient need not be equivalent.]	Canada supports retaining this principle and removing the brackets. A substitute food may not need to be equivalent in fat content (i.e. increasing the fat content of the substitute food to make it equivalent to its counterpart).

COMMENTS OF COSTA RICA

Costa Rica welcomes the opportunity to submit comments on step 6 of the procedure for the project of review of the General Principles for the Addition of Essential Nutrients to Foods. Below we provide details of our position with regard to the aspects that are still under discussion in the Committee:

- **[2.5 Mandatory nutrient addition** is when National Authorities require food manufacturers to add specified essential nutrients to particular foods or food categories.]
- [2.6 Voluntary nutrient addition is when National Authorities permit food manufacturers to add specified essential nutrients to particular foods or food categories.]

Costa Rica supports the preservation of both definitions, both of mandatory and voluntary nutrient addition. We think that it is necessary, despite addition of the footnote on page 4, to ensure both terms are well-defined when mentioning them throughout the document. We interpret the footnote as an example of the focuses used in some countries or regions, but not as a definition as such.

[3.5.2 The assessment of the impact of the addition of essential nutrients should use an equivalent methodology.

OR

Monitoring of total nutrient intakes should in principle use the same [method]/[approach] as used in deciding the addition of essential nutrients unless otherwise necessary for the specific nutrient concerned].

Costa Rica does not consider the text in point 3.5.2 to be necessary. We believe that the text of point 3.5.1 is sufficiently clear and that the competent national and regional authorities have their methods for carrying out monitoring and thus avoiding excessive intakes. Nevertheless, if the majority of countries opt to keep the text, the second option appears to us to be the clearer one.

4.1.5 The cost effectiveness of the addition of essential nutrients to foods [for the intended consumer] should be considered.

Costa Rica does not consider the phrase between square brackets to be necessary, given that not only consumers, but also all the costs associated with the public health measure must be taken into account when evaluating cost-effectiveness. Therefore we tend towards a general formulation.

[4.3.3 Where there is a clear public health reason to moderate the intake of a specific nutrient, the level of this nutrient need not be equivalent.]

Costa Rica considers that the text in 4.3.3 would not be necessary by virtue of what is established in point 4.3.1* because the addition of essential nutrients for nutritional equivalence must be attributable to an improvement of nutritional quality of the substitute food in relation to a public health need. There would be no point in adding nutrients that have been related to non-communicable chronic diseases to a food to be improved that is nutritionally equivalent to a counterpart.

*4.3.1 Where nutritional equivalence is to serve as a justification for the improvement of the nutritional quality of a substitute food, especially in relation to a public health need, the counterpart food should be a significant contributor to the intake of essential nutrients in the population.

COMMENTS OF EUROPEAN UNION

The European Union (EU) would like to express its gratitude to Canada and New Zealand for preparing the draft proposed revision of the Codex General Principles for the Addition of Essential Nutrients to Foods.

The EU has the following comments to make on the Draft Revision, as presented in REP14/NFSDU, Appendix II.

SECTION 2 - DEFINITION

Paragraphs 2.5 and 2.6

The EU does not agree to retain the definition for voluntary nutrient addition as the purposes and principles for nutrient addition are already clarified in Section 3 of the document. The different regulatory approaches to voluntary nutrient addition by different jurisdictions are described and clarified with numerous examples in the footnote to paragraph 3.1.2. This is a good compromise that was amply discussed in the previous meeting of the Committee.

The EU also does not agree with maintaining the definition for mandatory nutrient addition as sub-section 4.1, as currently drafted, gives enough explanations on this type of addition of essential nutrients.

SECTION 3 - GENERAL PRINCIPLES

Sub-section 3.5 Monitoring

Paragraph 3.5.2

The EU prefers the second option for paragraph 3.5.2 to ensure that there is consistency in the approach used for the addition of essential nutrients and for the monitoring of the result in total nutrient intakes.

COMMENTS OF INDIA

2. Definitions

2.5. Mandatory nutrient addition

India would like to add following text in the definition:-

Mandatory nutrient addition is when National Authorities require food manufacturers to add specified essential nutrients to particular foods or food categories based on the nutritional problem determined in the target population.

Rationale:- It is more explanatory.

India would like to add following text in the definition 2.6.

Voluntary nutrient addition is when National Authorities permit food manufacturers to add specified essential nutrients to particular foods or foods categories **as per the requirement of the population.**

Rationale:- It is more explanatory.

3.3 Selection of Foods

India would like to amend the 3.3.2 as follows:-

Foods to which essential nutrients **may not** to be added may be determined by competent national and/or regional authorities.

Rationale:- As the Proposed draft is for the principles for the addition of essential nutrients to the foods, hence, competent national and/or regional authorities should focus only to those food(s) where there is a public health need to add essential nutrients.

3.5 Monitoring

India would like to retain following text under 3.5.2:-

Monitoring of total nutrient intakes should in principle use the same approach as used in deciding the addition of essential nutrients unless otherwise necessary for the specific nutrient concerned.

Rationale:- It is more explanatory.

4.0 Principles for specific Types of Addition of essential Nutrients

India would like to amend 4.1.3

The amount of the essential nutrient added to the food should aim to be sufficient to **meet the** public health need.

Rationale: - Grammatical correction.

India would like to amend 4.1.4

The intake of the food selected as a vehicle should be stable and uniform and the **lower and upper levels** of intake of selected food(s) should be known among the population distribution of the population intake of the food including the lower and upper percentiles should be known.

Rationale:- It is more explanatory.

India would like to amend 4.1.5

The cost effectiveness of the addition of essential nutrients to foods for the target population intended consumer should be considered.

Rationale:- The "target population" is a more explanatory term.

COMMENTS OF MEXICO

Mexico welcomes the opportunity to comment on the Circular Letter **CL 2014/27-NFSDU** Request for Comments at Step 6 on the Draft Revision of the General Principles for the Addition of Essential Nutrients to Foods (CAC/GL 9-1987), corresponding to Topic 3 of the programme of the 36th CCNFSDU meeting.

DRAFT PRINCIPLES FOR THE ADDITION OF COMMENTS BY MEXICO **ESSENTIAL NUTRIENTS TO FOODS** SEPTEMBER 2014 (Step 5) 2. DEFINITIONS [2.5 Mandatory nutrient addition is when National Mexico supports inclusion of the definitions Authorities require food manufacturers to add specified contained in sections 2.5 and 2.6 and, essential nutrients to particular foods or food categories.] consequently, we suggest removing the square brackets from both definitions. [2.6 Voluntary nutrient addition is when National Authorities permit food manufacturers to add specified essential nutrients to particular foods or food categories.] 3.5 Monitoring [3.5.2 The assessment of the impact of the addition of essential nutrients should use an equivalent methodology. With respect to Section 3.5.2, we think it could be removed because it neither indicates nor <u>Or</u> recommends a set of methods in particular that Monitoring of total nutrient intakes should in principle use serves as orientation for governments to the same [method]/[approach] as used in deciding the evaluate the impact of adding essential addition of essential nutrients unless otherwise necessary nutrients. for the specific nutrient concerned]. 4.0 Principles for specific types of addition of essential nutrients 4.1 Mandatory addition of essential nutrients to address a demonstrated public health need In section 4.1.1, we believe the term "conditional **4.1.1** Where there is a demonstrated public health need for voluntary approach" is not defined in the increasing the intake of an essential nutrient in the document. It is mentioned in footnote number 4, population, competent national and/or regional authorities but it is not defined and mention is only made of may decide that this may be accomplished by mandatory some examples that could cause confusion, and addition of essential nutrients. This need may be which we believe are already considered in demonstrated by evidence of clinical or subclinical section 3.1 Fundamental principles. deficiency, suboptimal or inadequate nutritional status using biochemical indicators, estimates indicating inadequate or potentially inadequate intake of nutrients, or evidence related to another health outcome. While most addition to address a serious public health need is through mandatory addition of essential nutrients, there may be some situations where a conditional voluntary approach may be used. **4.1.2** The food(s) selected as a vehicle for the added With the aim of improving the translation into essential nutrient(s) should be habitually consumed in Spanish, we suggest substituting the phrase sufficient amount by the target population. "must aspire to be" in section 4.1.3 with "must have as its goal being" because it agrees 4.1.3 The amount of essential nutrient added to the better with the objectives of the document; we foodstuff must aspire to be sufficient to cover public health are in agreement with removing the last phrase. needs. when the foodstuff is consumed in habitual amounts by the population at risk. We are in agreement with the proposed modifications in section 4.1.4. 4.1.4. Intake of the foodstuff chosen as the vehicle must be stable and uniform and [the upper and lower intake levels] the distribution of intake of the foodstuff in the population We suggest removing the square brackets in must be known, including the upper and lower percentiles. section 4.1.5 to improve clarity in the text. 4.1.5 The cost effectiveness of the addition of essential nutrients to foods [for the intended consumer] should be considered.

4.3. Addition of essential nutrients for nutritional equivalence

[4.3.3 Where there is a clear public health reason to moderate the intake of a specific nutrient, the level of this nutrient need not be equivalent.]

Where there is a clear public health reason to moderate the intake of a specific nutrient, the level of this nutrient <u>in the substitute foodstuff</u> need not be equivalent <u>to its counterpart</u>.

We suggest adding the following text in section

4.3.3 to improve clarity:

As far as footnote number 4 is concerned, we believe it is very extensive and that it includes concepts that are already properly addressed in the document. We suggest keeping the footnote as follows:

Internationally, there are different regulatory approaches to how voluntary addition of essential nutrients is legally framed and/or managed by competent national and/or regional authorities. In all these approaches, some form of regulatory oversight is required. There are approaches whereby addition of essential nutrients is generally permitted within a regulatory framework that can restrict foods or categories of foods to which nutrients may be added and set specific limits for those nutrients. There are other approaches that may be described as conditional voluntary. In one example, the framework in place describes all the foods categories of foods to which manufacturers may choose to add nutrients, along with the nutrients and levels of nutrients. In another of these examples, if a manufacturer chooses to make a statement on the label indicating that a nutrient has been added, then certain nutrients are required to be added at specified levels. Also, in another example, if a manufacturer chooses to add an essential nutrient to certain foods, they must do so in accordance with policies on addition of nutrients and/or meet requirements in place in relation to the nutrients and amounts for addition.

The rest of the footnote could be removed because it is noted that each case described is considered in the numbered points of section 3.1 Fundamental principles, as is indicated below:

By contrast, there are other approaches that could be described as being "conditional voluntary".

- In one example, the framework in place describes all the foods or categories of foods to which manufacturers may choose to add nutrients, along with the nutrients and levels of nutrients. This paragraph is considered in **section 3.1.3** Specific provision may be made in food standards, regulations or guidelines that identify the food(s) and essential nutrients for addition and, where appropriate, the minimum and/or maximum amounts within which the essential nutrients should be present.
- In another of these examples, if a

FOOTNOTE

⁴ Internationally, there are different regulatory approaches to how voluntary addition of essential nutrients is legally framed and/or managed by competent national and/or regional authorities. In all these approaches, some form of regulatory oversight is required. There are approaches whereby addition of essential nutrients is generally permitted within a regulatory framework that can restrict foods or categories of foods to which nutrients may be added and set specific limits for those nutrients. There are other approaches that may be described as conditional voluntary. In one example, the framework in place describes all the foods or categories of foods to which manufacturers may choose to add nutrients, along with the nutrients and levels of nutrients. In another of these examples, if a manufacturer chooses to make a statement on the label indicating that a nutrient has been added, then certain nutrients are required to be added at specified levels. Also, in another example, if a manufacturer chooses to add an essential nutrient to certain foods, they must do so in accordance with policies on addition of nutrients and/or meet requirements in place in relation to the nutrients and amounts for addition.

manufacturer chooses to make a statement on the label indicating that a nutrient has been added, then certain nutrients are required to be added at specified levels. This paragraph is considered in section 3.2.5 When competent national and/or regional authorities establish minimum amounts for the addition of essential nutrients to foods they should ensure that these amounts are significant and in line with the intended purpose as identified in 3.1.1. In determining significant amounts, they may also consider conditions of use for a 'source' claim in the Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997).

• Also, in another example, if a manufacturer chooses to add an essential nutrient to certain foods, they must do so in accordance with policies on addition of nutrients and/or meet requirements in place in relation to the nutrients and amounts for addition. This paragraph is considered in section 3.1.3 Specific provision may be made in food standards, regulations or guidelines that identify the food(s) and essential nutrients for addition and, where appropriate, the minimum and/or maximum amounts within which the essential nutrients should be present.

COMMENTS OF NEW ZEALAND

New Zealand was very pleased to co-chair the electronic and physical working groups that lead to the progress made on these important draft principles. New Zealand is very pleased with the progress on the guidelines and supports the directions that provide clear guidance to countries considering both mandatory and voluntary addition of essential nutrients to foods. Such principles need to be firmly grounded in a sound scientific evidence base of safety of addition.

With respect to the text that still remains in square brackets we have the following comments:

2. Definitions:

We do support the inclusion of definitions for both mandatory nutrient addition and voluntary nutrient addition, and support the definitions as they are proposed – ie

- 2.5 *mandatory nutrient addition* is when National Authorities require food manufacturers to add specified essential nutrients to particular foods or food categories.
- 2.6 **voluntary nutrient addition** is when National Authorities permit food manufacturers to add specified essential nutrients to particular foods or food categories.

We also support the inclusion of the explanatory note (Footnote 4) clarifying the different regulatory approaches to how voluntary addition of essential nutrients are legally framed and/or managed by competent national and/or regional authorities.

At the 37th Session of the Codex Alimentarius Commission, two delegations proposed to include a statement that the addition of essential nutrients to energy dense and nutrient poor foods should be avoided, unless justified to meet national public health goals. This issue was previously discussed at length within the Committee at the 35th Session, highlighting the difficulties in interpreting "energy dense and nutrient poor foods" and that this should be left at the discretion of competent national and/or regional authorities. We consider that principles 3.1.1 and 3.3.2 enables competent national/and or regional authorities the ability to prevent the addition of essential nutrients to foods which would not maintain or improve health.

3.5 Monitoring:

New Zealand supports the second option of 3.5.2. This provides greater clarity as the first statement firstly appears incomplete and also does not recognise situations where it may not be feasible to use a similar

methodology for monitoring. Situations such as where national nutrition surveys have been used to inform the assessment for addition of essential nutrients to foods and such methodology is extremely expensive and could not be used on a more regular basis to support and inform monitoring. Many countries would have alternative data collection methods that would allow for a level of monitoring that is less onerous and costly than full blown national dietary intake/nutrition surveys. Therefore we support the second option ie:

3.5.2 Monitoring in principles should use the same approach as used in deciding the addition of essential nutrients unless otherwise necessary for the specific nutrient concerned.

4. Principles for Specific Types of Addition of Essential Nutrients

New Zealand considers that the final phrase of 4.1.3 is an integral component of any dietary modelling that would be required to be taken into account when considering mandatory addition of essential nutrients to foods. It may be considered inherent in first part of 4.1.3 but we would have no objection to the final phrase being kept if it provides greater clarity.

4.1.3 The amount of essential nutrient added to the food should aim to be sufficient to meet the public health need when the food is consumed in habitual amounts by the population at risk.

New Zealand does not consider that a reference to the cost effectiveness should be limited to consideration for the intended consumer, rather the cost effectiveness for the mandatory addition should be considered for government, industry and consumers.

4.1.5 The cost effectiveness of the addition of essential nutrients to foods [for the intended consumer] should be considered

4.3 Addition of essential Nutrients for Nutritional Equivalence

4.3.3 Where there is a clear public health reason to moderate the intake of a specific nutrient, the level of this nutrient need not be equivalent

New Zealand can support the inclusion of 4.3.3 into the Principles.

COMMENTS OF NORWAY

We appreciate this opportunity to comment upon the Proposed Draft Revision of the Codex General Principles for the Addition of Essential Nutrients to Foods (CAC/GL 9-1987) at Step 6.

Comment to section 3.2.2

Norway would like to underline that we are still of the opinion that from a public health perspective, nutrient addition to energy-dense and nutrient-poor foods – like desserts, chocolates and chips should be avoided and we would prefer that Codex' guidance on this could have been clearer.

However, we consider it important that national governments use food vehicles they deem effective (i.e. addition of iodine to salt, vitamin A to sugar, and vitamin D to margarine). To clearly encompass this in the principles, we would like to repeat our suggestion to add the following text in section 3.2.2, after the first sentence - such that it reads:

Nutrient addition to energy-dense and nutrient-poor foods should be avoided, unless such addition is nutritionally justified to meet national public health goals.

An alternative is to include our proposal to keep the (original) text which was deleted by the Committee: "...

"taking into account the nutritional value of foods."

COMMENTS OF PARAGUAY

Paraguay is grateful for the opportunity to express its comments with respect to the revision project mentioned and, to this end, issues the following comments:

Point 2.5

[2.5 Mandatory nutrient addition is when National Authorities require food manufacturers to add specified essential nutrients to particular foods or food categories.]

Comment: We support the removal of the brackets from this section due to the fact that our country, just like other countries, has programmes at its disposal for mandatory addition of nutrients such as iodine in salt and also iron and vitamins in flour.

Point 2.6

[2.6 Voluntary nutrient addition is when National Authorities permit food manufacturers to add specified essential nutrients to particular foods or food categories.]

Comment: We support the removal of the brackets and leaving the definition as it is, due to the need for the National Authorities to control in some way or another the increase in the addition of nutrients to food products on some occasions without justification.

Point 3.5.2

[3.5.2 The assessment of the impact of the addition of essential nutrients should use an equivalent methodology.

<u>Or</u>

Monitoring of total nutrient intakes should in principle use the same [method]/[approach] as used in deciding the addition of essential nutrients unless otherwise necessary for the specific nutrient concerned].

Comment: We agree with the second option, because nutrient deficiency could have been detected by a methodology that included more than one nutrient or deficiency, but monitoring could be done with a method that covers only one specific nutrient.

We propose the following formulation:

"Monitoring of total nutrient intakes should in principle use the same **approach** (*remove brackets*) as used in deciding the addition of essential nutrients unless otherwise necessary for the specific nutrient concerned."

Point 4.1.3

4.1.3 The amount of the essential nutrient added to the food should aim to be sufficient to meet the public health need. when the food is consumed in habitual amounts by the population at risk.

Comment: We agree to the removal of the text crossed out, due to the fact that it is already clear that the foodstuff is consumed in a certain quantity and the population must not be urged to consume an intake higher than what is habitual.

Point 4.1.4

4.1.4. The intake of the food selected as a vehicle should be stable and uniform and the *[lower and upper levels of intake]* distribution of the population intake of the food including the lower and upper percentiles should be known.

Comment: We agree to the removal of the text crossed out because the formulation is thus understood better.

Point 4.1.5

4.1.5 The cost effectiveness of the addition of essential nutrients to foods [for the intended consumer] should be considered.

Comment: We agree to the removal of the brackets because the cost of the foodstuff in the population for which it is intended must be taken into account.

Point 4.3.3

[4.3.3 Where there is a clear public health reason to moderate the intake of a specific nutrient, the level of this nutrient need not be equivalent.]

Comment: We support the removal of the brackets due to the fact that there are nutrients that must be moderated by the population and therefore there is no reason for their restitution in the foodstuff for nutritional equivalence.

COMMENTS OF PHILIPPINES

The Philippines expresses its appreciation to the previous work of electronic and physical working groups led by Canada and New Zealand in the current draft General Principles for the Addition of Essential Nutrients to Foods.

The Philippines supports the proposed draft revision of the Codex General Principles for the Addition of Essential Nutrients to Foods. The outlined principles are consistent with the Philippine regulations on mandatory and voluntary food fortification (Republic Act 8976 and Administrative Order No. 4-A s. 1995).

RATIONALE

The specific comments and rationale are outlined in each of the sections below:

Definition- Section 2.5 and 2.6

The Philippines supports the retention of the bracketed texts defining both mandatory and voluntary nutrient addition. These terms should be included in the Definition to establish distinction and clarity between mandatory and voluntary addition of nutrients to food. These definitions are consistent with the definitions outlined in WHO/FAO (2006). Governments legally oblige or require addition of nutrients to food products through mandatory addition of nutrients. Voluntary addition of nutrients occurs when governments give permit to food manufacturers to freely choose addition of nutrients to food products. Sakko and Tarasuk (2009) describes voluntary fortification as the addition of vitamins and minerals to foods at the discretion of the food manufacturer.

Section 3.3- Selection of Food

We believe that the bracketed text in the statement "The selection of foods to which essential nutrients may be added should be [in line with the intended purposes of nutrient addition as identified in 3.1], dietary patterns, socioeconomic situations and the need to avoid any risks to health" should be retained. Selection of foods for addition of nutrients should be consistent with the purpose of such addition. Effectiveness of nutrient addition depends on selection of appropriate food vehicle for nutrient addition among other factors (Engle-Stone, et al 2012).

General Principles-Section 3.5 Monitoring

We are in favor of deleting the bracketed statements on Section 3.5.2 "[The assessment of the impact of the addition of essential nutrients should use an equivalent methodology]. 'Monitoring of total nutrient intakes should in principle use the same [method]/[approach] as used in deciding the addition of essential nutrients unless otherwise necessary for the specific nutrient concerned]." We believe that the first statement "It is important that competent national and/or regional authorities monitor population intakes from all sources including the essential nutrients added to foods to assess the extent to which the purposes identified in 3.1.1 are addressed and to ensure that any risk of excessive intakes is minimized" is sufficient to cover the necessary aspects of monitoring addition of essential nutrients to foods. We are of the opinion that neither one of the bracketed statements provides additional points on what to monitor and detailed methods to assess the impact of adding essential nutrients to food.

Section 4.1.4

The Philippines supports inclusion of the phrase "the lower and upper percentiles" in the statement "The intake of the food selected as a vehicle should be stable and uniform and the distribution of the population intake of the food including the lower and upper percentiles should be known. The lower and upper limits of the population intake for the selected vehicle for nutrient addition is important in calculating the projected nutrient intake which will determine adequacy or excessive intake of such nutrient. The groups at greatest risk of inadequate or excessive nutrient intakes can be confirmed from the nutrient intake data (Allen, 2006). Snow (1998) listed similar criteria for selection of food vehicle for nutrient addition.

Section 4.1.5

The Philippines supports deletion of the bracketed text "for the intended consumer" in the statement "The cost-effectiveness of the addition of essential nutrients to foods [for the intended consumer] should be considered". We are of the opinion that cost effectiveness both on the part of consumer and manufacturer should be considered in adding nutrients to foods. Deleting the bracketed text would refer to consideration of consumer and manufacturer. Nutrient addition to foods for whatever purpose should consider all cost calculations. Cost calculations should include associated costs to the manufacture, distribution, quality control and quality assurance and marketing of foods with added nutrients. These costs are outlined in the WHO Guidelines in Fortification of Micronutrients.

Section 4.3.3

We are in favor of retaining the bracketed text in this statement "Where there is a clear public health reason to moderate the intake of a specific nutrient, the level of this nutrient need not be equivalent]. It is only reasonable not to aim equivalent nutritional composition for a particular nutrient with compelling reason to limit intake. We believe that it is important to include this statement in the criteria if the purpose of nutrient addition is nutritional equivalence of substitute food.

References

Administrative Order No. 4-A s. 1995. Guidelines on Micronutrient Fortification of Processed Foods. Bureau of Foods and Drugs-Department of Health.

Allen. L. New Approaches for Designing and Evaluating Food Fortification Programs J Nutr; 2006 136 (1): 41055-

Engle-Stone, R, Ndejebayi AO, Nankap M and Brown KH. Consumption of Potentially FortifiableFoods by Women and Young Children Varies by Ecological Zone and Socio-Economic Status in Cameroon.(2012)J. Nutr; 142 (3): 555-565

Republic Act 8976-An Act Establishing the Philippine Food Fortification Program and for Other Purposes". Philippine Department of Health

Snow, J. (1998). Fortification basics: choosing a vehicle. Opportunities for Micronutrient Interventions.

Sacco, JE and Tarasuk, V. Health Canada's Proposed Discretionary Fortification Policy Is Misaligned with the Nutritional Needs of Canadians, (2009) J Nutr; 139 (10): 1980-1986.

World Health Organization. Guidelines on food fortification with micronutrients for the control of micronutrient malnutrition. Geneva: World Health Organization, 2005

COMMENTS OF AFRICAN UNION

SECTION	AU POSITION	RATIONALE
General comment on item 3	AU supports the work to continue taking into considerations the comments on scope and definitions as outlined below.	The revision will update the document with current scientific advancements. The revised principles will go a long way in helping government update and/or develop and implement regulations for their programs.
Scope	AU support the adoption of the scope as drafted {These Principles are intended to apply to all foods to which essential nutrients are added, not including vitamin and mineral food supplements, without prejudice to the provisions in Codex standards and guidelines for foods for special dietary uses.	Is a general principle for all foods that require essential nutrients including foods such as infant formula
	The Principles are applicable, as appropriate, to both mandatory and voluntary addition of essential nutrients.}	
Mandatory Voluntary	AU supports the adoption of the definitions in clauses 2.5 and 2.6 and hence support removal of the brackets	Its critical governments ensure that fortification is done according to national legislations and/or the Codex standards so as to ensure safety and efficacy of the addition.

COMMENTS OF FOODDRINKEUROPE

FoodDrinkEurope would like to thank Canada, New Zealand and the Chair of CCNFSDU for their constructive work and for managing the discussions during the electronic Working Group (eWG) and the Physical Working Group, which gave the CCNFSDU committee the possibility to come to an agreement on an updated text.

We fully support this new text proposal as such and propose to accept all the texts as proposed in square brackets in order to finalise this important document.

However, we would recommend the deletion of point 3.5.2 in its entirety. Point 3.5.2 proposes the following two options:

[3.5.2 The assessment of the impact of the addition of essential nutrients should use an equivalent methodology.

OR

'Monitoring of total nutrient intakes should in principle use the same [method]/[approach] as used in deciding the addition of essential nutrients unless otherwise necessary for the specific nutrient concerned].'

In fact, point 3.5.1, which states "...monitor population intakes from <u>all sources</u> including the essential nutrients <u>added to foods</u>...", covers the necessary on the monitoring aspect and does not need to be completed by these points, which lack clarity.

COMMENTS OF ICBA - INTERNATIONAL COUNCIL OF BEVERAGES ASSOCIATIONS

ICBA has the following comments with respect to the Draft Revision of the General Principles for the Addition of Essential Nutrients to Foods (CAC/GL 9-1987), which is currently at Step 6.

General Comments

ICBA supports the revision of the General Principles. We agree that there is a need to update the current document based on new scientific understanding and prevailing practices. In particular, the current document does not recognize the potential of vitamins and minerals to contribute to optimum health, when consumed beyond levels that prevent deficiency.

ICBA supports the safe and rational addition of essential nutrients to foods and beverages. As such, additions should be based on scientifically validated benefits to public health, with any limits based exclusively on matters related to safety.

With the changes noted below, ICBA recommends that the draft be sent to the Codex Alimentarius Commission for adoption at Step 8.

Specific Comments

ICBA has limited its comments to those items in square brackets, as is appropriate for comments at Step 6.

2.0 Definitions

- 2.5: ICBA supports removal of the square brackets and accepting the definition for "mandatory nutrient addition."
- 2.6: ICBA supports deletion of the definition for "voluntary nutrient addition." Voluntary addition is explained in detail in the footnote that accompanies in 3.1.2.

3.5 Monitoring

• 3.5.2: ICBA supports removal of the square brackets, with deletion of the first option and acceptance of the second option. This approach would allow appropriate flexibility for governments:

{The assessment of the impact of the addition of essential nutrients should use an equivalent methodology.

OR

Monitoring of total nutrient intakes should in principle use the same [method]/[approach]-as used in deciding the addition of essential nutrients unless otherwise necessary for the specific nutrient concerned].

4.0 Principles for Specific Types of Addition of Essential Nutrients

 4.1.3: ICBA supports acceptance of 4.1.3, with deletion of the text as shown. The deleted text is already included in 4.1.2.

The amount of the essential nutrient added to the food should aim to be sufficient to meet the public health need. when the food is consumed in habitual amounts by the population at risk.

4.1.4: ICBA supports the text as proposed, with deletion of the text in square brackets and the
acceptance of the underlined text.

The intake of the food selected as a vehicle should be stable and uniform and the [lower and upper levels of intake] distribution of the population intake of the food including the lower and upper percentiles should be known.

4.3.3: ICBA supports removal of the square brackets and acceptance of the text.

[Where there is a clear public health reason to moderate the intake of a specific nutrient, the level of this nutrient need not be equivalent.]

COMMENTS OF ICGA - INTERNATIONAL CHEWING GUM ASSOCIATION

On behalf of the member companies of ICGA, we would like to submit respectfully the following comments which relate only to those paragraphs in the Principles where ICGA is proposing changes to the text.

Text proposed after CCNFSDU35 (2013) as included in Appendix II of the report of CCNSFDU35 (i.e. REP14/NFSDU)	ICGA comments in advance to CCNFSDU36 and in response to Circular Letter CX/CL 2014/27-NFSDU (September 2014)
PROPOSED DRAFT PRINCIPLES FOR THE ADDITION OF ESSENTIAL NUTRIENTS TO FOODS	
DEFINITIONS	
[2.5 Mandatory nutrient addition is when National Authorities require food manufacturers to add specified essential nutrients to particular foods or food categories.]	CCNFSDU36 may wish to change « National Authorities » to "Competent national and/or regional authorities" to be consistent with other amendments made during CCNFSDU35 throughout the text.
	Otherwise, the square brackets around the text could be deleted.
[2.6 Voluntary nutrient addition is when National Authorities permit food manufacturers to add specified essential nutrients to particular foods or food categories.]	CCNFSDU36 may wish to change « National Authorities » to "Competent national and/or regional authorities" to be consistent with other amendments made during CCNFSDU35 throughout the text.
	Otherwise, the square brackets around the text could be deleted.
GENERAL PRINCIPLES	
3.5 Monitoring	
[3.5.2 The assessment of the impact of the addition of essential nutrients should use an equivalent methodology.	ICGA members would prefer the second proposed wording reading:
OR	"Monitoring of total nutrient intakes should in principle use
Monitoring of total nutrient intakes should in principle use the same [method]/[approach] as used in deciding the addition of essential nutrients unless otherwise necessary for the specific nutrient concerned].	the same approach as used in deciding the addition of essential nutrients unless otherwise necessary for the specific nutrient concerned."
	Otherwise, the square brackets around the text could be deleted.

The above ICGA comments are without prejudice of the position that ICGA may take on the other parts of the draft Principles prior and/or during the 36th session of CCNFSDU.

We are looking for successful discussions at CCNFSDU36, so that the Committee may decide to move the revised Principles to step 8 of the Uniform Procedure, for its subsequent adoption by the next session of the Codex Alimentarius Commission in July 2015, as a Codex standard.

COMMENTS OF IFT - INSTITUTE OF FOOD TECHNOLOGISTS

Sections 2.5 and 2.6: IFT supports removal of square brackets.

Section 3.3.1: A square bracket appears in 3.3.1 but its closing bracket is not shown and so it is unclear what language is in question. However, the current sentence reads well and has clear intent and we would support removing the single square bracket.

Section 3.4.2: has an unfinished thought. IFT suggests addition of the following clause after deletion of the period. "...use, such that the amount of nutrient stated on the label is available to the consumer through the identified shelf life of the food product." The modified sentence would read:

"The added essential nutrient should be sufficiently stable in the food under customary conditions of processing, packaging, storage, distribution and use such that the amount of nutrient stated on the label is available to the consumer through the identified shelf life of the food."

Section 3.5.2: IFT favors the second option (after "OR") but with insertion of the phrase "necessity of" after "the" and before "addition" and removal of the square brackets around approach. The modified phrase would read:

"Monitoring of total nutrient intakes should in principle use the same approach as used in deciding the necessity of addition of essential nutrients unless otherwise necessary for the specific nutrient concerned."

We would also support the word "desirability" as an alternate to "necessity."

Section 4.1.3: IFT agrees with the deletion of the lined text and notes the need for a space between meet and the (meet the public).