codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 5 **ALINORM 04/27/7A**
Original Language Only

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

Twenty-seventh Session
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PROPOSED DRAFT STANDARDS AND RELATED TEXTS SUBMITTED AT STEP 5

COMMENTS ON PROPOSED DRAFT STANDARDS AND RELATED TEXTS SUBMITTED AT STEP 5

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CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS

PROPOSED DRAFT MAXIMUM LEVELS FOR CADMIUM (ALINORM 04/27/12; para. 182; Appendix XXIII)

Japan

For the reasons below, we support the decision of the 36th CCFAC and the adoption of the proposed draft MLs for cadmium in polished rice, wheat grain, potato, stem and root vegetables, leafy vegetables, and other vegetables at Step 5 by the Commission:

- It is stipulated in the third indent of the *Establishment of maximum levels for contaminants* in Annex I of the Codex General Standard for Contaminants and Toxins in Food (GSCTF) that MLs shall be set as low as reasonably achievable and that providing it is acceptable from the toxicological point of view, MLs shall be set at a level which is (slightly) higher than the normal range of variation in levels in foods that are produced with current adequate technological methods, in order to avoid undue disruptions of food production and trade. The MLs for cadmium should be set in accordance with this principle.
- The proposed draft ML of 0.4 mg/kg for polished rice was derived by the application of the ALARA principle on the cadmium surveillance data obtained in Japan. The 95th percentile dietary intakes calculated using probabilistic approach on a basis of this and other MLs are likely to be below the PTWI of 7 □g/kg-bw/wk. We believe that the proposed draft MLs can ensure the protection of the health of consumer and are in accordance with the principles stipulated in the GSCTF.

CODEX COMMITTEE ON FISH AND FISHERY PRODUCTS

PROPOSED DRAFT AMENDMENT TO THE STANDARD FOR SALTED FISH AND DRIED SALTED FISH OF THE *GADIDAE* FAMILY (ALINORM 04/27/18, para. 183 and Appendix VI)

United States of America

The United States submits the following comments on the Proposed Draft Amendment to the Standard for Salted Fish and Dried Salted Fish of the Gadidae Family of Fishes.

General Comment

As the Delegation of Canada informed the Committee at the 26th session, there is an AOAC method already in existence for the determination of water in fish, which is very similar to the one under discussion. It is unclear why the AOAC method could not be referenced in this standard. Regardless, the thickest part of the fish should be used for analyses because this is where potential problems with moisture and salt content related to pathogen presence would occur.

Section 7.4.6 Control analysis of whole fish

The sentence in this subsection appears incomplete. Clarification is needed.

CODEX COMMITTEE ON FRESH FRUITS AND VEGETABLES

PROPOSED DRAFT STANDARD FOR TOMATOES (ALINORM 04/27/35, para. 56 and Appendix IV).

Brazil

"1. DEFINITION OF PRODUCE"

Brazil understands that in the "DEFINITION OF PRODUCE", the inclusion of the "commercial types of the tomato" is not appropriate. Such parameters are used to characterize different formats, which are known in the market.

Brazil suggests that the "commercial types" be included in the Standard as "Groups", under item "2. PROVISIONS CONCERNING QUALITY", together with the "Classification" and "Sizing", as follows:

"2.2. CLASSIFICATION"

The tomatoes are classified in Groups, regarding its form; Category, regarding the incidence of defects in the fruits; and, Size, the diameter of the fruit.

2.2.1. Tomato groups are: Round when the length and the equatorial diameter ratio is among 0,90 to 1,15; Oblong when the length and the diameter equatorial ratio of the fruits, is larger than 1,15; and, Flat when the length and the diameter equatorial ratio of the fruits, is smaller than 0,90.

2.2.2. The Classes are: Extra ", I and II.

2.2.2.1. "Extra" Class.

2.2.2.2. Class I

2.2.2.2. Class II

2.2.3. Size is determined by the maximum diameter of the equatorial section of the fruit, in accordance with the following.

As a consequence of our previous proposals, Brazil would also like to suggest changing this item, as follows:

The minimum sizing settles down in 15 mm for the tomatoes "cherry", 35 mm for the "round" and "flat" tomatoes and 30 mm for the "oblong" tomatoes.

2.2.3.1. The minimum size set at 15 mm for "cherry tomato"; 30 mm for the oblong tomato; and 35 mm for the round and flat tomatoes.

Brazil suggests using only one sizing scale for all types of tomatoes. Brazil doesn't agree with the definition of special sizing scale for cherry tomatoes; if it is considered important, their characteristics may be defined, but outside the sizing scales (ex.: 15 mm of minimum diameter; maximum diameter of 29 mm; etc).

Caliber Code	Diameter mm	
	Maximum	Minimum
000	15	19
00	20	24

0	25	29
1	30	34
2	35	39
3	40	46
4	47	56
5	57	66
6	67	81
7	82	101
8	102	-

Brazil suggests excluding item below, since all Categories must observe the sizing scale.

~~Observance of the sizing scale is compulsory for "Extra", Class and Class I tomatoes.~~

This sizing scale is not applied to trusses of tomatoes.

"4. PROVISIONS CONCERNING COLOUR"

"5. PROVISIONS CONCERNING TOLERANCES"

5.1. QUALITY TOLERANCES

5.2 SIZE TOLERANCE

The tolerance should be restricted to the maximum percentage allowed (10%), however it should include fruits, that fit into the whole range of calipers planned for the classes right inferior and superior. Hence, the definition of minimum diameters is not appropriate.

As a consequence of our previous proposals, Brazil would also like to suggest changing this item. We suggest the following wording, which is underlined:

~~For all the classes: 10% by number or weight of tomatoes corresponding to the size immediately above and/or below that indicated on the package, with a minimum of 33 mm for "round" and "ribbed" tomatoes, and 28 mm for "oblong" tomatoes.~~

<u>For all the classes, it is admitted up to 10% in weight of the tomatoes that correspond to the caliber immediately inferior and superior to the indicated in the packing.</u>

CODEX COMMITTEE ON METHODS OF ANALYSIS AND SAMPLING

PROPOSED DRAFT GUIDELINES FOR EVALUATING ACCEPTABLE METHODS OF ANALYSIS (ALINORM 04/27/23; Appendix V)

<u>Brazil</u>

On item "Scope"

We suggest the definitions utilized in document will be the same of harmonized document about terminology that will be deliberated by work group that was formed by Austria, USA, AOAC, AOCS and Brazil.

We suggest that the documents "Proposed draft guidelines for evaluating acceptable methods of analysis" and "Consideration of fitness-for-purpose approach to evaluation methods of analysis" are present in a single document named for example: **"Working instructions on the implementation of the criteria approach for Codex Committees".**

On item "Applicability**" to present an explanatory text about the Youden test its criteria and application.**

At the second paragraph of the item "Limit of detection" **sub item estimation include the references relative to IUPAC and other.**

Including in the items that mention the number of the blind independent samples the following note in the squares "Detection limit" – Quick reference and Determination Limit – quick reference **"The number of the blind independent samples may be smaller or bigger than 10 and depend on analytical procedure and dispersion of results**.

Withdrawing the definitions of the criteria and inform that must be utilized the definitions contained in the document about terminology that is being elaborated.

On item "Recovery" in the square "recoveries" – quick reference, in the column 'analyse" first paragraph to substitute by following paragraph **"Blank matrixes or unfortified samples and fortified with the analyte of interest at working range concentrations".**

On item "Recovery" in the square "recoveries – quick reference, in the column "comments" second paragraph to substitute by following paragraph **"Recoveries from fortified samples or blank matrixes will usually be higher than real samples in the which the analytes is more closely bound".**

Item "Sensitivity" sub item "note" **if it were maintained the text the expression "capability of detection" must be defined.**

On item "selectivity" sub item "estimation" **rewording the expression "selectivity/specificity" by "selectivity".**

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

CODEX PROPOSED DRAFT GUIDELINES FOR VITAMINS AND MINERAL FOOD SUPPLEMENTS (ALINORM 04/27/26; para. 61 and Appendix II)

Argentina

Argentina no está de acuerdo con la incorporación del texto entre corchetes en el párrafo 2.1.

En el párrafo 3.2.2 se sugiere la eliminación de los corchetes.

En el párrafo 5.4 Argentina sugiere eliminar los corchetes.

China

ALINORM 04/27/26, Appendix IV	OUR COMMENTS
2. DEFINITIONS	
2.1 ~~**[They are designed to be taken as measured small unit quantities].**~~	Delete the brackets and bracketed text. Rationale: The forms such as capsules, tables, powders, solutions etc using in the vitamin and mineral supplements are generally not common food.

3. COMPOSITION	
3.1.1 Vitamin and mineral supplements should contain vitamin/provitamins and minerals whose nutritional value for human beings has been proven by scientific data and whose status as vitamin and minerals is recognised by FAO and WHO.	Suggest to find whether FAO and WHO have such approval lists on vitamin and mineral supplements.
3.1.2 ~~[~~natural or synthetic sources~~]~~	Delete the brackets. The sources of vitamin and mineral supplements should include natural or synthetic compounds. For the natural source, purity criteria must take into account the prepared methodology and safety evaluation data.
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% <u>(limit to Ca and Mg) ~33%</u>** of the recommended daily intake as determined by FAO/WHO.	China does not agree to take the 15% as the minimum level except the Ca and Mg, because 15% nutrient intake from supplement can not play important role in improving health status and can not meet the recommended daily intake as determined by FAO/WHO for some nutrients.
3.2.2 ~~[~~When the maximum levels are set, due account should be taken to the reference intake values of vitamins and mineral for the population.~~]~~	Delete the brackets
5.4 ~~[~~and if different, the amount per single use~~]~~.	Delete the brackets
5.5 [Information on vitamin and minerals should also be expressed as a percentage of the nutrient reference values mentioned, as the case may be, in the Codex Guidelines on Nutrition Labelling.]	Keep the brackets and further look the NRV in the Helsinki Consultation.
5.7 The label shall contain advice to the consumer not to exceed the maximum one-day amount.	China agrees this item.

<u>Iran</u>

Preamble

Line 4 : where consumers, Preferlly upon the advice of a physician , nutritionist or dietiation , consider their diet…

2-Definitions

Delete the square bracket

3-Composition

3-1-2 Delete the square bracket

4-Packaging

4-1 This sentence correct as the following;

The product shall be packed in containers which will safeguard its hygienic and other qualities .

5-3 Line 2: Replace weight consistent with units of measurement .

5-4 Delete the square bracket

5-5 Delete the square bracket

5-8 This sentence correct as the following : the label should not state or imply that supplements can be used for the replacement of any foods, meals or a varied diet.

5-9 Replace young children with children

Malaysia

(i) Section 2: Definitions

(ii) Paragraph 2.1

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

" They are designed to be taken in small measured quantities"

Mexico

1. Del numeral 2.1 eliminar el punto relacionado a "son designados para ser tomadas en unidades de pequeñas cantidades".
2. Eliminar del punto 3.1.2. el corchete "natural a sintético".
3. Eliminar el corchete del numeral 5.4.
4. En el numeral 5.5 aparece un corchete, que en los textos en español y francés no aparece, por lo cuál, sugerimos eliminarlo del texto en ingles.

National Health Federation

PREAMBLE

There are a number of flaws and inconsistencies in the preamble. For example:

- The phrase 'who have access to a balanced diet' takes no account of the fact that many people who have access to a balanced diet may simply not be availing themselves of it. The UK National Diet and Nutrition Survey 2003, for example, clearly demonstrates that many UK citizens rely upon potato chips, beer and lager, soft drinks, savoury snacks, biscuits, buns, cakes, pastries, burgers, and kebabs as food sources in their normal daily diets.
- It is no longer true to say that people 'can usually obtain all the nutrients they require from their normal diet'. Research from the UK, the United States, Canada and Germany, to name but four countries, has shown that the mineral content of fruit and vegetables has fallen dramatically over the past sixty years. Indeed, the United States government has been aware of the reality of this for almost seventy years now. The following are extracts from U.S. Senate Document No. 264, recorded in 1936: *"The alarming fact is that foods now being raised on millions of acres of land that no longer contain enough of certain minerals are starving us - no matter how much of them we eat." "Laboratory test prove that the fruits, the vegetables, the grains, the eggs, and even the milk and the meats of today are not what they were a few generations ago." "No man today can eat enough fruits and vegetables to supply his stomach with the mineral salts he requires for perfect health, because his stomach isn't big enough to hold them!" "We know that vitamins are complex chemical substances which are indispensable to nutrition, and that each of them is of importance for normal function of some special structure in the body. Disorder and disease result from any vitamin deficiency. It is not commonly realised, however, that vitamins control the body's appropriation of minerals, and in the absence of minerals they have no function to perform. Lacking vitamins, the system can make some use of minerals, but lacking minerals, vitamins are useless."* As such then, if the CCNFSDU continue to insist that the statement 'Most people who have access to a balanced diet can usually obtain all the nutrients they require from their normal diet' is valid, then this would infer that our forefathers were obtaining far more nutrients than they actually needed, which is clearly illogical. Moreover, the phrase 'all the nutrients they require' simply begs the question: 'require for what purpose?' Given the literally thousands of scientific studies that now exist to show the effectiveness of nutritional supplements in preventing chronic diseases, it is no longer enough to say that avoiding outright nutritional deficiency diseases equates to obtaining sufficient levels of nutrients.

- It is of course true to say that 'foods contain many substances that promote health'. However, to then go on to say that people should be 'encouraged to select a balanced diet from food before considering any vitamin and mineral supplement' tends to suggest that the CCNFSDU believe there is something wrong with wanting to supplement ones' diet in the first place. Given that the mineral content of our fruit and vegetables has been diminishing for over sixty years now, as described above, this sentence also gives the misleading impression that the use of supplements does not confer any health benefits, when in fact quite the reverse is true.
- Given that none of us are getting the same level of minerals in our diets as were our forefathers, the phrase 'In cases where the intake from the diet is insufficient' is both unnecessary and misleading, as there is now more than adequate evidence to suggest that all of our diets are lacking sufficient quantities of nutrients to sustain optimum health. Similarly, to infer that consumers should only use supplements when they 'consider their diet requires supplementation' is also misleading, as it does not take account of the diminishing mineral content of our food. Therefore, any consumers who had been unable to avail themselves of information relating to the diminishing mineral content of our food could be forgiven for thinking that their diets do not require supplementation, when in fact quite the reverse is true.

The NHF therefore proposes the following new wording in the preamble:

~~Most people who have access to a balanced diet can usually obtain all the nutrients they require from their normal diet.~~ A healthy diet containing fruits and vegetables is usually capable of providing sufficient levels of nutrients to prevent nutritional deficiency diseases. ~~Because foods~~ **Foods** contain many substances that promote health, **but scientific research has shown that the overall nutrient content of our food has been diminishing for a considerable number of years, and that nutritional supplements are useful adjuncts in the promotion of optimum health.** ~~people~~ **Individuals** should therefore be encouraged to ~~select~~ **eat** a ~~balanced~~ **healthy** diet ~~from food before considering any vitamin and mineral supplement~~ **and supplement this diet with those nutrients for which their intake from food is insufficient to enable them to attain optimum health.** ~~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.~~

1. SCOPE

1.1 The NHF proposes that the first sentence should be rewritten as follows:

These guidelines apply to vitamin and**/or** mineral supplements intended for use in supplementing the daily diet ~~with vitamins and/or minerals~~.

Justification: The current wording is clumsy, and the additional use of the words 'vitamins and/or minerals' is not necessary to describe what the guidelines apply to.

1.2 . The NHF proposes that this sentence should be rewritten as follows:

These Guidelines ~~do~~ apply ~~in those jurisdictions where products defined in 2.1 are regulated as foods~~ to all WTO member countries.

Justification: The title of these guidelines indicates that vitamins and minerals are to be legislated as foods. As such, allowing some countries to continue regulating vitamin and mineral supplements as drugs would be contrary to the Codex mandate of removing existing barriers to trade and harmonising worldwide standards. Moreover, the current wording would allow some countries to avoid implementing the guidelines by choosing instead to regulate supplements as drugs.

2. DEFINITION**S**

2.1 The NHF proposes that the final sentence should be deleted.

Justification: From a legislative perspective the word 'small' has no meaning as it is an imprecise term that does not describe a quantitative amount. Given that the CCNFSDU has decided that upper limits will be based on scientific risk assessment, any reference in the definitions to words such as 'small' or 'quantities' are therefore unnecessary and inappropriate, because upper limits will be specified separately for each nutrient.

3. COMPOSITION

3.1.1 The NHF proposes that this sentence should be rewritten as follows:

Vitamin and mineral supplements should contain **those** vitamins/provitamins**/vitamin-like substances** and**/or** minerals whose ~~nutritional value~~ **safety** for human beings has been proven by **either** scientific data **or**

many years of safe use by virtue of their presence in foods and/or food supplements consumed by humans. ~~and whose status as vitamins and minerals is recognised by FAO and WHO.~~

Justification: In its current form this sentence could potentially restrict consumers from purchasing useful nutrients that they have been buying and consuming safely for many years. Examples of such substances include inositol, choline, para-aminobenzoic acid, alpha carotene, gamma carotene, lutein, lycopene, cryptoxanthin, zeaxanthin and capsanthin, The issue of 'nutritional value' (i.e. need) is an entirely separate matter however. If we are going to legislate out of existence everything that we don't need, then virtually everything in this modern world from lipsticks to televisions must logically be banned too. The CCNFSDU should be concerned with safety, and it is not within their mandate to make value judgements regarding the nutritional preferences and requirements of individual consumers.

3.1.2 The NHF proposes that this section should be rewritten as follows:

Vitamin and mineral supplements may contain ~~The sources of~~ vitamins**/provitamins/vitamin-like substances** and**/or** minerals ~~may be~~ from either ~~[~~natural or synthetic sources~~]~~ ~~and should be based on consideration such as safety and bioavailability~~. ~~In addition, purity~~ **Purity** criteria should take into account **appropriate** FAO/WHO standards~~,~~. ~~or if~~ **If appropriate** FAO/WHO standards are not available, **appropriate** international Pharmacopoeias or recognized international standards **should be taken into account**. In the absence of criteria from these sources, national legislation **or trade-industry standards** may be used.

Justification: The issue of safety is already addressed in 3.1.1 (as amended above). It is neither necessary nor appropriate to make any restrictions upon the sale of vitamin and mineral supplements other than to determine that they are safe for human consumption. FAO/WHO standards should only be utilized when they are appropriate, and extrapolations made from inappropriate standards should be strictly prohibited. Similarly, international Pharmacopoeias or recognized international standards should also only be taken into account when they are appropriate.

3.1.3 The NHF proposes that this sentence should be rewritten as follows:

Vitamin and mineral supplements may contain ~~all vitamins and minerals~~ nutrients that comply with the criteria in 3.1.1, either singly ~~a single vitamin and/or mineral~~ or **in** ~~an appropriate~~ combination ~~of vitamins and/or minerals~~. **This paragraph shall not be deemed to prohibit the inclusion of other nutrients in these products.**

Justification: Vitamin and mineral supplements should also be permitted to contain provitamins and vitamin-like substances, as described above in the amendments to 3.1.1. As such, use of the word 'nutrients' would be preferable to the term 'vitamins and minerals' in this sentence. Use of the word 'appropriate' in this context is not necessary, as it is suggestive of further unspecified restrictions. So long as vitamin and mineral supplements are safe there is no need to impose any additional limitations upon their sale.

The second sentence in this Paragraph is added to clarify the ambiguity introduced by the use in the second sentence of Paragraph 1.1 of the phrase "other ingredients" and later uses in these Guidelines of the term "nutrients."

3.2 Contents of vitamins and minerals

3.2.1 The NHF proposes that this sentence should be deleted.

Justification: Restrictions upon the minimum level of each nutrient contained in a vitamin and mineral supplement are impractical in the case of some minerals because of the limitations of tablet/capsule size. If the CCNFSDU were to insist upon a uniform minimum percentage level for each nutrient contained in a vitamin and mineral supplement, some manufacturers might choose to not include some important minerals in their multivitamin/mineral products on the grounds that tablets/capsules containing them would be difficult to swallow (and hence difficult to sell). Such an eventuality would not be in the best interests of public health or consumer safety.

In fact, by mandating any minimum levels of vitamins and minerals, the CCNFSDU will be ***jeopardizing*** the health of consumers because: (a) manufacturers will in many instances have to replace the small additional vitamins and minerals that would have been added to a capsule or tablet with useless inert fillers and excipients; and (b) minimum levels will prohibit those special formulations that make synergistic use of vitamins and minerals in smaller-than-minimum-level amounts.

The smarter and more pragmatic approach would be to adopt the position taken by the Delegation of Canada two years ago in its position paper where Canada had proposed that instead of setting minimum levels, the CCNFSDU simply prohibit any claims for those vitamins and minerals present in amounts below the threshold minimum level. The Canadian approach is a more direct and skillful way of accomplishing the CCNFSDU goal of avoiding inappropriate claims.

3.2.2 The NHF proposes that this section should be rewritten as follows:

Maximum amounts of vitamins and minerals in vitamin and mineral supplements per daily portion of consumption as recommended by the manufacturer shall be ~~set, taking the following criteria into account:~~

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

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

[When the maximum levels are set, due account should be taken to the reference intake values of vitamins and minerals for the population.]

Justification: Because vitamins and minerals are naturally-occurring substances that have been present in foods comprising the human diet for millennia and because the data cannot support findings of toxicity in humans except under very special and limited circumstances, the NHF does not support any maximum upper limits and instead supports deleting this paragraph 3.2.2 in its entirety.

However, if the CCNFSDU is inclined to retain this paragraph, then it should at least be modified as stated above, for the following reasons:

Unless the degrees of sensitivity of different consumer groups are precisely defined the text as it stands is open to a wide variety of interpretations. Moreover, issues relating to the sensitivity of particular consumer groups would be more appropriately dealt with under 5.6 in the labelling section of the Guidelines, in that these would more properly be defined as contraindications than as content specifications. Restricting the levels of vitamins and minerals contained in supplements for the general population - because of the sensitivity of small sub-sections of the population - is both disproportionate and unnecessary, and such issues could quite easily be dealt with by the addition of the appropriate labelling requirements

In addition, given that all subjects in risk assessment studies concurrently consume a diet containing vitamins and minerals it is not necessary to deduct any further amounts from the safe upper levels established under such studies.

5. LABELLING

5.1 The NHF proposes that this sentence should be rewritten as follows:

The ~~name of the~~ product **label** shall ~~be~~ **include the term**

"food supplement" **on the front of the container, and must also give** ~~with~~ an indication of the category(ies) of nutrients or of the individual vitamin(s) and/or mineral(s) contained in the product as the case may be.

Justification: The term "food supplement" is not a product name; it is a product category. It is not necessary to include the term "food supplement" in the name of every product covered by these Guidelines, and it would be quite sufficient for this description to be required to be displayed on the front of the container. Lists of nutrients contained in the product however are more appropriately displayed on the rear of the container.

5.4 The NHF proposes that this sentence should be rewritten as follows:

The amounts of the vitamin and minerals declared should be those per portion of the product ~~as~~ recommended ~~for daily consumption~~ on the labelling **for single use** ~~[~~and if different, the amount**s** per ~~single use]~~ **day**.

Justification: This wording would be more likely to ensure the safety of consumers than would the current wording. Single-use labelling permits the average consumer to more readily determine the quantity of any vitamin and/or mineral he or she is taking.

5.5 The NHF proposes that this sentence should be deleted, on the grounds that it misleadingly infers that the RDA is of a greater importance (in terms of nutritional sufficiency) than is suggested by the latest scientific research. Moreover, there would be no benefit to consumer safety were the CCNFSDU to insist upon its

inclusion. Indeed, the reverse may even be true, in that consumers are more likely to be confused, rather than helped, by cluttered labels.

5.6 The NHF proposes that this sentence should be rewritten as follows:

The label must indicate the recommendations on how to take the product (quantity, frequency, special conditions) **and should state any known situations or health conditions in which it would be inappropriate to take the product**.

Justification: This rewording would be more likely to ensure consumer safety, and would also be a more appropriate method of dealing with the issue of "the varying degrees of sensitivity of different consumer groups" than is the current wording of 3.2.2.

5.7 The NHF proposes that this sentence should be rewritten as follows:

The label shall contain advice to the consumer not to exceed the maximum one-day amount **unless directed by a healthcare practitioner**.

Justification: The recent decision by the CCNFSDU to delete the statement that supplements should only be taken upon the advice of a nutritionist, a dietician or a medical doctor is to be applauded. However, in some situations and/or health conditions, a physician might determine that it may be appropriate to take higher one-day amounts than is stated on the label.

New Zealand

Definitions

New Zealand does not believe that the text in square brackets [they are designed to be taken as measured small unit quantities] is not necessary and recommends removing this sentence.

Composition

3.1.1 New Zealand supports inclusion of the text [natural or synthetic].

Contents of Vitamins and Minerals

New Zealand supports a scientific risk based approach. This approach recognises the differing needs of different population groups. It is therefore recommended that the sentence following point (b) [when the maximum levels are set, due account should be taken to the reference intake values of vitamins and minerals for the population] is not necessary.

Labelling

5.4 New Zealand supports inclusion of the text in square brackets [and if different, the amount per single use].

Poland

Poland proposes adding the paragraph concerning limitation of harmful contaminants content in vitamin and mineral food supplements.

PROPOSED DRAFT REVISED STANDARD FOR INFANT FORMULA (ALINORM 03/27/26, para. 100 and Appendix V)

Argentina

En el párrafo 1.3, Argentina propone la eliminación de los corchetes, estando de acuerdo con la incorporación de la resolución WHA 55.25(2002) de la Asamblea Mundial de la Salud.

En el párrafo 2.1.2, es opinión de Argentina la eliminación de los corchetes.

En el párrafo 3.1.1, es opinión de Argentina la eliminación de los corchetes.

En el párrafo 3.6, Argentina considera que deben eliminarse los corchetes, teniendo en cuenta que estos productos no deberían contener grasas ni aceites hidrogenados comercialmente por su contenido en ácidos grasos trans y por no existir seguridad en su uso en lactantes.

Con relación al párrafo 4 Argentina considera conveniente esperar la opinión del JECFA a este respecto.

Asimismo, se considera que en los párrafos 9.1.5 y 9.6.6 los corchetes deben eliminarse, atento que estos alimentos no deberían contener leyendas nutricionales ni claims saludables para promocionar su venta, dado que es el médico pediatra es el que debe indicar que tipo fórmula infantil debería consumir el niño.

Con respecto al párrafo 9.1.6, Argentina estima conveniente considerar las dos opciones de declaración de hierro en el Estándar B, en el cual estarían definidos las fórmulas para propósitos médicos específicos, atendiendo que las fórmulas para lactantes sanos deberían cubrir los requerimientos de hierro fijados.

En relación a los párrafos 3.1.2 y 3.1.3, Argentina considera que estos puntos podrían aclararse una vez que la tabla de aporte de nutrientes fuese presentada a discusión.

Australia

While Australia supports the adoption of this draft standard at step 5, we are concerned with the large amount of text within square brackets. Australia looks forward to a full discussion and the opportunity to discuss in detail a number of issues at the next session of the NFSDU Committee.

China

ALINORM 04/27/26, Appendix V	OUR COMMENTS
TITLE	
Proposed draft revised standard for infant formula ~~[~~and formulas for special medical purposes intended for infants.~~]~~	Remove [ ], we agree with title. Rationale: As the format of the standard is based on the separation of the standard for infant formula and those for special medical purpose intended for infants, and this draft is for the standard for infant's formula only, it is not necessary to include the formula for special medical purpose intended for infants into this title of the standard.
PREAMBLE	
~~[~~This standard is divided into two sections: Section A refers to Infant Formula, and Section B deals with Formulas for special medical purposes intended for Infants.~~]~~	Delete all from the word "Preamble" to that of "Section A: 'infant formula'. Making a new standard for the Formulas for Special Medical Purpose Intended for Infants with a separated code of the standard. Rationale: Two different standards, one for Infant Formula and one for Formulas for special medical purposes intended for infants are favored because: – the compositional requirements are different – specialized products can be a health hazard to normal infants Discussions over this important issue took a long time and the present solution is a good compromise.
SECTION A: INFANT FORMULA	
1. SCOPE	
1.3 The application of this section of the Standard should take into account the recommendations made in the International Code of Marketing of Breast-milk Substitutes (1981), the Global Strategy for Infant and Young Child Feeding and World Health Assembly resolution WHA54.2 (2001)	Delete reference to WHA 55.25. Rationale : : WHA Resolution 55.25 requests that the Codex Alimentarius Commission takes WHO policy into consideration, in particular the Code of marketing of breast milk substitutes, Resolution WHA 54.2 and "other relevant resolutions of the World Health Assembly". The latest therefore includes future texts, to which CCNFSDU should not at this time commit.

~~and [WHA.55.25 (2002)]~~.	New resolutions relevant for CCNFSDU need to be discussed by the Committee before being referred to in a Codex Standard.
2.1 PRODUCT DEFINITION	
~~**2.1.2 [The safety and nutritional adequacy of infant formulas shall be scientifically demonstrated in meeting the nutritional requirements of the infants for whom they are intended.]**~~	Delete this section. Rationale: Although the principle laid down in this section is strongly supported, it is redundant with other sections of this standard. As the format of the standard is based on the separation of the standard for infant formula and those for special medical purposes intended for infants, and this draft is for the standard for infant formula only, it is not necessary to specify to whom it is intended. Furthermore, SPS and TBT agreements that provide guidelines of prudence for food safety and nutrition are observed during the drafting and revising the Codex standards. We suggest to delete this article and the article number for a concise text of the technical standard.
[3.1 ESSENTIAL COMPOSITION	
3.1.1 Infant formula is a product based on milk of cows or other animals and/or other ingredients, which have been proven to be suitable for infant feeding. ~~**[All ingredients and food additives used shall be gluten-free.]**~~	Delete the brackets and the bracketed text. Rationale: As the format of the standard is based on the separation of the standard for infant formula and those for special medical purposes intended for infants, and this draft is for the standard for infant formula only, it is not necessary to specify that all ingredients and food additives used are gluten-free.
3.1.2 Infant formula prepared ready for consumption in accordance with instructions of the manufacturer shall contain per 100 ml not less than 60 kcal (250 kJ) and not more than ~~[~~ 70 ~~or 75]~~ kcal (~~[~~ 295 ~~or 315]~~ kJ) of energy.	A maximum energy level of 70 kcal/100ml is supported. Rationale: The standard should reflect the latest scientific evidence on energy requirements as well as the concerns about energy intake during early life.
3.1.3 Infant formula prepared ready for consumption shall contain per 100 kcal **[100kJ]** the following nutrients within the following minimum and maximum levels.	Keep both of the 100 kcal and 100 kJ. Rationale: Both kcal and kJ are widely used concept for calculating food energy density. If possible, the table in this article should also be prepared in both per 100 kcal and kJ for reference.
a) PROTEIN	
3.1.3 a) Protein (i) Protein content = nitrogen content x ~~[6.25 or~~ 6.38~~]~~ **for milk proteins and their partial hydrolysates** **Protein content = nitrogen content x 6.25 for soya protein isolates and their hydrolysates**	A nitrogen conversion factor of 6.38 should be kept for milk proteins, whereas a nitrogen conversion of 6.25 should be applied for soya. Rationale: – The internationally applied conversion factors are different for milk and other protein sources. – A conversion factor of 6.38 is used for milk proteins by the present Codex Standard, and is consistent with those applied by the AOAC Official Methods and by the Joint ISO/IDF (International Dairy Federation) Standards for Milk Determination of Nitrogen Content as well as by most governmental bodies.

Protein content = nitrogen content x 6.25 for all other protein isolates and their hydrolysates	– Using a different conversion factor would imply that the definition of milk would be different depending on whether used as an ingredient for infant nutrition or not. – Switching to a factor of 6.25 would fail to recognize the nutritional quality of milk over other proteins and will result in an additional 2-3% higher protein intake by infant. Current paediatric opinion is to reduce protein in infant formulae, not to increase it. The nitrogen content of intact and moderate protein hydrolysates are not significantly different. Therefore the conversion factors should be similar. The possibility to use protein sources other than milk and soy should be maintained as in the current Codex STAN 72-1981. The conversion factor is 6.25, unless scientific evidence supports the use of a more appropriate conversion factor.
3.1.3 a) Protein (ii) For an equal energy value the formula must contain an available quantity of each essential and semi-essential amino acid at least equal to that contained in the reference protein (breast-milk as defined in Annex 1); nevertheless, for calculation purposes, the concentration of methionine and cystine, may be added together ~~**[unless the methionine to cystine ratio exceeds 2.0]**~~. **as well as of phenylalanine and tyrosine**,	Delete sentence in [ ] since no criteria should restrict the addition of methionine and cystine."**unless the methionine to cystine ratio exceeds 2.0".** Rationale: - All formula based on unmodified milk protein have a methionine to cystine ratio of about 3 and would be concerned by this criterium. - Casein-predominant infant formula, prepared from unmodified cow's milk protein, have been for many years on the market and make up a considerable part of the infant formula consumption in numerous countries. The long historical use of casein predominant formula has demonstrated that is supports adequate growth during early life. - Other expert recommendations (FAO/WHO, LSRO) agree with the addition of methionine and cystine for the calculation of protein quality. - Growth parameters do not differ between casein-predominant and whey-adapted formulae with the same protein content. Tyrosine can be derived from phenylalanine metabolically and thus the requirement for the two amino acids should be determined as the sum of both, as for methionine and cystine.
Footnote 1 ad a) Protein in the table of Nutrients: ~~1~~ ~~**1 Calculation of protein content : N x[6.25 or 6.38] ; [non-protein nitrogen (formulae made from intact protein) <15% of total protein]**~~	Delete entire footnote 1 Rationale: - Human milk contains 25% of non protein nitrogen (NPN) - NPN covers a broad range of different substances, including free amino acids and peptides, present in protein hydrolysates and soy-based formulas. All these factors will increase the NPN level. - Free amino acids, as well as choline and L-carnitine, are usually added to soy-based formulas. - No analytical method for the determination of NPN has been internationally validated. - As long as minima for essential amino acids are determined, an NPN criterium would not provide any additional safety to the nutritional value of the formula.

Nutrients (per 100 kcal, unless otherwise stated)	*Minimum*	*Maximum*	
~~**Cow's milk**~~ **Milk** protein **and its hydrolysates**	1.8[2]	3	Milk proteins commonly used to manufacture infant formulae (cow, buffalo, and goat) have similar nutritional quality and should be covered by the Standard. Add "its hydrolysates" since there is no scientific evidence to distinguish between intact milk proteins and their hydrolysates.
Soy protein **and its hydrolysates**	~~**[1.8 or**~~ **2.25]**	3	Add "its hydrolysates" for the same reasons as above. A minimum protein level of 2.25g/100 kcal for soy protein has a long history of safe use. Lower values have not been clinically tested.
~~**Protein hydrolysates**~~	~~**[1.8 or 2.25]**~~	~~**3**~~	Delete this sentence, see above.
Other protein and its hydrolysates	**2.25**	**3**	Introduce this new sentence which is in line with section 3.1.3 a (i)
L-carnitine [mg]	~~[~~≥ 1.2 ~~]~~	N.S. [3]	Acceptable, remove [].
~~**Addition of**~~ **Tt**aurine [mg]	~~[~~0 ~~]~~	~~[~~12~~]~~	Acceptable, remove [].
Nucleotides, if added [4] [mg]	~~[~~0 ~~]~~	~~[~~5~~]~~	Acceptable, delete []. The maximum level of 5mg is in accordance with available scientific evidence.
b) Fat and fatty acids			
Total fat [g]	4.4	~~**[6.0 or**~~ 6.5~~]~~	There are no reasons to change the maximum level for total fat set in the current Codex Standard. Therefore retain a maximum of 6.5 g/100 kcal. <u>Rationale:</u> A level of 55% of energy coming from total fat is considered appropriate.
~~[~~Phospholipids~~]~~	N.S.	~~[≤ 1~~ **2** g/L~~]~~	Maximum level for phospholipids should be 2g/l. <u>Rationale:</u> This level is needed in order to achieve a nutritionally relevant concentration of essential LCPUFA's (AA and DHA).
~~[~~Inositol~~]~~ [mg]	~~[4]~~ **N.S.**	~~[~~ 40 ~~]~~	No minimum recommended as there is no science to support it. Replace by N.S. We agree with the maximum level. Remove [].
~~[~~ Lauric and myristic acids~~]~~		~~[~~Together ≤ 20% of total fatty acids~~]~~	Agreement with the proposal. Remove [].

Linoleic acid [g]	~~[~~0.3 ~~or 0.5]~~	1.2	Support minimum linoleic acid (LA) level of 0.3 g/100 kcal. <u>Rationale:</u> - A minimum level of 300 mg/100 kcal, identical to the amount in the current Codex Standard, is well above that required to prevent deficiency. - No scientific evidence indicated that higher minimum LA levels are required.
~~*[Formulae without added LCPUFA]*~~			Delete this criteria. <u>Rationale:</u> - All infant formulae should comply with the same stringent criteria for nutritional adequacy, whether LCPUFA are added or not. - There is no science showing that there is a need to discriminate between the formula with or without LCPUFA. - The proposed subdivision would add unnecessary complexity to the Standard.
~~[~~*α*-linolenic acid~~]~~ [mg]	~~[~~**≥** 50 ~~or 100]~~	N.S.	Minimum level of α-linolenic acid (ALA) should be 50 mg/100 kcal. <u>Rationale:</u> - Most current formulas contain less than 100 mg ALA/100 kcal and result in adequate visual and psychomotor development. - Research is still in an early stage and the current scientific evidence does not show a need to set a higher minimum level.
Linoleic/α-linolenic ratio	5	~~15~~ **20**	Replace maximum 15 by 20. <u>Rationale:</u> - A ratio of 5-20 between LA and ALA ascertains a proper balance between the precursors of the respective n-6 and n-3 fatty acid series. - The proposed range sustains the nutritional requirements for both formulas with and without added LCPUFA.
~~*[Formulae with added LCPUFA]*~~			Delete, see above Rationale.
~~[α-linolenic acid]~~ [5]	~~[≥ 50 mg]~~		Delete this section and footnote, see above Rationale.
~~[Linoleic/α-linolenic ratio]~~ [5]	~~[5-20]~~		Delete, see above Rationale.
~~[~~ n-6 LCPUFA ~~]~~	**N.S.** ~~[≤2% of total fatty acids]~~	2% of total fatty acids	Minimum level set at N.S. Agreement with proposed maximum of 2%, which must appear in the "*Maximum*" not the "*Minimum*" column.
~~[~~ Arachidonic acid ~~]~~	**N.S**. ~~[≤1% of total fatty acids]~~	1% of total fatty acids	Minimum level set at N.S. Agreement with proposed maximum of 1%, which

			must appear in the "*Maximum*" not the "*Minimum*" column.
~~[~~ n-3 LCPUFA ~~]~~	**N.S. ~~[≤1% of total fatty acids]~~**	1% of total fatty acids	Minimum level set at N.S. Agreement with proposed maximum of 1%, which must appear in the "*Maximum*" not the "*Minimum*" column.
~~[~~ Ratio EPA/DHA (wt/wt) ~~]~~	~~[<1]~~	1	Agreement with proposed maximum 1 which must appear in the "*Maximum*" not the "*Minimum*" column.
~~[~~ Cottonseed/sesame oils ~~]~~	~~[No use of these type of oils]~~ **The use of sesame seed oil and cotton seed oil is prohibited.**		Rephrase the wording in order to avoid misinterpretation. It is suggested to include this section under 3.6 "Specific prohibitions"
~~[Conjugated linoleic acid(CLA)~~	~~No intentional addition]~~		Delete this section Rationale: - At the present moment, scientific data on the effects of CLA during early life are lacking. Therefore it is not suitable to add CLA to infant formulae. - However it should not be prohibited as such since ongoing research will add more scientific data on the safety and benefit of CLA and its interaction with LA and ALA may become available.
~~[~~*Trans* fatty acids	~~≤ 3 or 4% of total fatty acids]~~	4% of total fatty acids	Strong support for a maximum level of 4% of total fatty acids. Rationale: - No scientific data have established a causal relation between *trans* fatty acid intake and changes in early development. - Natural *trans* fatty acid level of cow's milk fat are often > 5% and vary geographically. - *Trans* fatty acids in human milk were reported to vary considerably (Spain: 1.3 - 7.2 % ; Canada: 0.1 – 17%) - Milk-based formulae with more than 60% of the fat as milk fat are not unusual. A maximum *trans* fatty acid level of 4% seems more appropriate and justified within the context of a global standard.
Erucic acid	**N.S**.	1% of total fatty acids	No minimum necessary, agreement with max. 1%.
c) Carbohydrates			
~~[~~ Lactose in ~~cows'~~ milk protein-and protein hydrolysates formulae [g]	**≥** 4.5 ~~]~~		Delete "*cows*'" for reasons indicated above, otherwise agreement, remove [ ].

~~[Lactose in soy protein formulae~~	~~No requirement]~~		This section is superfluous, delete.
~~[Saccharose~~	~~None in cows' milk protein and soy protein formulae~~ ~~≤ 20% of total carbohydrates in protein hydrolysates formulae]~~		Delete this section. Rationale: - There is no scientific evidence that the consumption of sweeter formulae would lead to greater weight gain. - There is no proof that the consumption of sweeter formulas would promote a preference for sugar in later life. - In many countries, saccharose is the only available superior quality source of carbohydrates.
~~[Fructose~~	~~None]~~		Delete this section as this criterium should appear in section 3.6 "Specific prohibitions"
~~[~~**Glucose**	No intentional addition to formulae. ~~based on intact proteins,~~ ~~≤ 2 g in formulae based on protein hydrolysates]~~		Glucose should not be added as such to infant formulae. Rationale: - Addition of glucose increases osmotic pressure of the formula and risk of Maillard reaction. A small amount of glucose may come from the use of glucose syrups.
~~[~~ Maltose, maltodextrins**, glucose syrup**	Unrestricted ~~]~~		Agreement with proposal, suggestion to add glucose syrups. Rationale: - Glucose syrup is used as a replacement for lactose in soya protein based infant formula, to assist with palatability.
~~[~~ Starches	30% of total carbohydrates (≤ 2 g/100 mL) as precooked or gelatinised naturally gluten-free starches No starches modified by enzymatic cross-linking or stabilisation ~~]~~		Agreement with proposal Remove [ ]

d) Vitamins			Agreement with the setting of minimum and maximum levels. Some modifications suggested. Rationale: - The range takes into account the natural variations in vitamin levels of the raw materials. - The proposed levels take into account losses during shelf life. - In general, vitamin requirements are similar for infant formulas and formulas for special medical purposes intended for infants. - The use of a single vitamin blend is also desirable for technological and safety reasons.
Vitamin E [mg α TE]	≥0.5 mg α TE/g PUFA ~~[~~(corrected for double bond, see footnote[9])~~],~~ but in no case less than 0.5/100 kcal	~~[~~5 ~~]~~	Delete part of the footnote ~~per g of polyunsaturated fatty acids, expressed as linoleic acid~~ because it is not meaningful.
Vitamin K [µg]	4	~~[~~ 20 ~~]~~	
Thiamin [µg]	~~[~~ 40 ~~or 60]~~	~~[~~ 300 ~~]~~	
Riboflavin [µg]	~~[~~ 60 ~~or 80]~~	~~[400]~~ **450**	
Niacin [µg]	~~[~~ 300 ~~or 800]~~	~~[~~1200~~]~~	
Vitamin B6 [µg]	35	~~[165]~~ **300**	
Vitamin B12 [µg]	0.1	~~[~~ 0.5 ~~]~~	
Pantothenic acid [µg]	~~[~~ 300 ~~or 400]~~	~~[~~ 2000 ~~]~~	
Folic acid [µg]	~~[~~ 4 ~~or 10]~~	~~[~~ 30 ~~]~~	
Vitamin C [mg]	~~[~~ 8 ~~or 10]~~	~~[30]~~ **40**	In agreement with proposed minimum level of 8 mg/100 kcal, but recommendation for a higher maximum level of 40 mg/100 kcal.
Biotin [µg]	1.5	~~[7.5]~~ **20**	
e) Minerals and Trace Elements			
Iron [mg]	**0.5**	**2.5**	We strongly favor a single level of iron for all infant formulas with the minimum at 0.5 mg/100 kcal and the maximum at 2.5 mg/100 kcal. Rationale: - A minimum 0.5 mg/100 kcal is appropriate to fulfill iron requirements of infants during the first six months of life. Although a min. level of 0.3 has proved sufficient it is considered prudent to provide a higher level to prevent risk of iron deficiency anemia. - A maximum level of 2.5 mg/100 kcal is necessary for countries where major iron deficiencies are encountered. This is in agreement with the AAP-CON recommendation (1993).

~~Cow's milk protein and protein hydrolysate formulae~~ ~~Soy protein formulae~~	~~[0.3 or 0.5]~~ ~~[0.45 or 1.0]~~	~~[1.3 or 1.5]~~ ~~[1.9 or 2.0]~~	Infant formula has a vitamin C to iron ratio enabling good iron absorption. Differentiation is not necessary between infant formulas.
Calcium [mg]	50	~~[~~ 140~~]~~	In agreement with the proposed maximum level.
Calcium/Phosphorus-Ratio	1.0	~~[2.0 or~~ 2.2 ~~]~~	High levels of phosphorus in infant formula are undesirable. **We strongly support max. Ca/P ratio of 2.2.** This value is physiological and is regularly found in breast milk.
Phosphorus [mg]	~~Cows' milk protein and protein hydrolysate formulae: 25~~ ~~Soy protein formulae: [30]~~ ~~[Bioavailable phosphorus, if measured: 20-70 mg]~~ **25**	~~90~~ ~~[100]~~ **100**	A single level of phosphorus is favored with the minimum at 25 mg/100 kcal and the maximum at 100 mg/100 kcal.
Chloride [mg]	50	~~[125 or~~ 160 **]**	Support for the maximum of 160 mg/100 kcal.
Potassium [mg]	60	[~~145 or 160]~~ **200**	The maximum for potassium should be 200 mg/100 kcal. Rationale: - It is important to retain for partial hydrolysates the maximum level of 200 mg/100 kcal for potassium as in current Codex Standard (72-1981). - This level of potassium is not harmful to infants, and is technologically necessary for the production of hydrolysed formula.
Manganese [µg]	~~[~~1 ~~or 5]~~	~~[~~100~~]~~	A minimum of 1 µg/100 kcal is justified. In agreement with maximum.
Fluoride [µg]	N.S.	~~[~~100~~]~~	In agreement with proposal.
Iodine [µg]	~~[~~ 5 ~~or 10]~~	~~[~~ 50 ~~]~~	A minimum of 5 µg/100 kcal is justified. In agreement with the maximum of 50µg/100kcal.
Selenium [µg]	~~[~~ N.S. ~~or 3]~~	~~[~~ 9 ~~]~~	We strongly oppose setting a minimum level and agree with NS. In agreement with max. of 9. Rationale: - Human milk Se ranges between 5-20 µg/l. - Infant formula Se ranges between 7 – 13 µg/l. - No clinical evidence has been reported sofar on selenium deficiency during infancy neither for breast- nor for formula-fed infants. - Unsupplemented formulas are widely available without any sign of deficiency.

Copper [µg]	~~[~~20 ~~or 35]~~	~~[80 or~~ 100~~]~~	
Zinc [mg]	**0.5**	**2.40**	We favour a single level of zinc for all infant formulas with the minimum at 0.5 mg/100 kcal and the maximum at 2.4 mg/100 kcal. Scientific data support above proposal.
~~**Cow's milk protein and protein hydrolysate formulae**~~	~~**0.5**~~	~~**[1.5]**~~	
~~**Soy protein formulae**~~	~~**0.75**~~	~~**2.40**~~	
f) Choline [mg]	7	~~**[30 or**~~ 50~~]~~	A maximum of 50 mg/100kcal is necessary in case of arachidonic acid (AA) supplementation
~~[~~ Nucleotide [mg] ~~]~~			Agreement with the proposal Remove [ ]
Cytidine 5'-monophosphate(CMP)	N.S.	2.50	
Uridine 5'-monophosphate(UMP)	N.S.	1.75	
Adenosine 5'-monophosphate(AMP)	N.S.	1.50	
Guanosine 5'-monophosphate(GMP)	N.S.	0.50	
Inosine 5'-monophosphate(IMP)	N.S.	1.00	

3.6 SPECIFIC PROHIBITIONS	
The product and its components shall not ~~[~~ contain commercially hydrogenated oils and fats and shall not ~~]~~ have been treated with ionizing radiations.	Delete the brackets and keep the bracketed text. Rationale: Commercially hydogenated oils and fats and ionizing radiation shall not be used in processing the infant foods.
4. FOOD ADDITIVES	
4.1 Thickening Agents	
4.1.2. INS 410: Carob bean gum (locust bean gum) 0.1 g in all types of infant formula ~~**REQUEST FOR 0.5G**~~	A level of 0.1 g/100 ml is sufficient for regular infant formula. Delete request.
4.2 Emulsifiers	
4.2.5 INS 472e: Diacetyltartaric and fatty acid of esters of glycerol GMP	Add new additive. Rationale: Retains homogeneity of liquid products and liquid reconstituted powder especially in formulas where whole proteins are not used. Has a high HLB, works well in combination with additive 322 and 471. Has a GRAS status in the US.
4.4 Antioxidant	
4.4.3 INS 309: Gamma-tocopherol **INS 308: Delta-tocopherol** **1 mg in all types of infant formula singly or in combination**	Add new additives. Alone or in combination to stabilise preparations containing fats and vitamins. Synergistic effect with additive 304. They are effective in preventing oxidation of vulnerable fatty acids.

4.5 CARRY-OVER OF FOOD ADDITIVES	
~~**[4.5 Carry-over of Food Additives**~~ ~~**No food additives shall be present as a result of carry-over from raw materials and other ingredients with the exemption:**~~ ~~**(a) of the food additives listed under Sections 4.1 to 4.4 of this standard within the limits of the maximum levels stipulated in this standard; and**~~ ~~**(b) of the carrier substances mentioned in the Advisory List of Vitamin Compounds for Use in Foods for Infants and Children within the limits of the maximum levels stipulated in that List]**~~ **Section 3 of the Principle relating to the Carry-Over of Additives into Foods shall apply.**	The issue of carry-over of additives in infant formulae is being readdressed. We support that the Principle relating to the Carry-over of additives shall apply to infant formula for the following reasons: – the amount of additives that are carried-over from an ingredient into the final product does not have a technological effect and does not affect safety – the exception to the carry-over principle for infant formula is not consistent with the General Standard for Food Additives. – the restriction on carry-over makes it difficult to develop new formula with certain desired beneficial qualities. Suggest adding the standard statement which should be used where reference to the applicability of the Carry-Over Principle is specifically made in a Codex Standard
9. LABELLING	
9.1.3 If 90% or more of the protein is derived from whole or skim cow's milk ~~is the only source of protein~~, the product may be labelled "Infant Formula Based on Cow's Milk".	Suggest to retain text of current Standard Infant Formula (72-1981).
9.1.5 ~~**[No health claims shall be made regarding the dietary properties of the product]]**~~ **Nutrition and health claims shall be permitted for the products covered by this standard, where they have been demonstrated beyond doubt in rigorous studies with adequate scientific standards, and the evidence has been accepted by an independent scientific body reviewing the data.**	Delete the whole article and the article number. Rationale: It is necessary to provide nutrition and/or health claim of some ingredients used in the foods for the sake of the consumer's right of knowing. We therefore recommend new wording. <u>Rationale:</u> – All claims that are scientifically substantiated, with the substantiation validated through independent scientific review, should be allowed. – There is no nutrition-based rationale for placing a severe restriction on claims for these products. These claims should be allowed as long as they are scientifically substantiated and are expressed in a manner that is understood by and is not misleading to the parent or caregiver. – Claims on products for infants and young children can provide parents and caregivers with important information about the composition and properties of a product that is specially designed for this age category. There is no justification for denying them information that is based on scientific substantiation.

9.1.6 ~~[~~ Products containing not less than 0.5 mg Iron (Fe)/100 kcal~~ories~~ shall be labelled "Infant Formula with added Iron" ~~]~~ ~~**or**~~ ~~**[Products containing less than 0.5 mg Iron (Fe)/100 kcal shall be labelled with a statement to the effect that when the product is given to infants over the age of four months, their total iron requirements must be met from other additional sources]**~~	Delete 'Or' and the brackets and the bracketed text. Rationale: Infants elder than 6 months shall be fed with complimentary foods, therefore, to make the text of this standard concise, it is no need to give instruction of feeding after the first 6 months of life.
9.3. DECLARATION OF NUTRITIVE VALUE	
(b) the total quantity of each vitamin, mineral, choline as listed in paragraph 3.1.2 of this Standard and any ~~**other**~~ **optional** ingredient as listed in paragraph 3.2 of this Standard per 100 grammes of the food as sold as well as per 100 mililiter of the food ready for use, when prepared according to the instructions on the label.	Using the wording "optional ingredient" is in line with section 3.2. Suggest "other ingredient" change to "optional ingredient", which can keep consistent with item 3.2.
9.5. INFORMATION FOR USE	
9.5.1 Directions as to the **appropriate** preparation and use of the food, and its storage and keeping after the container has been opened shall appear on the label or on the accompanying leaflet.	The word "appropriate" should be added for sake of clarity.
9.6. ADDITIONAL LABELLING REQUIREMENTS	
9.6.1~~**. d) Instructions for appropriate preparation**~~	This is redundant with section 9.5.1. Delete sentence.
9.6.4.Information shall appear on the label ..... and in any case from the age **of** ~~**over**~~ six months	The word "over" should be replaced by "of" for consistency with other Codex Standards.
~~**9.6.5. The products shall be labelled in such a way as to avoid any risk of confusion between infant formula, follow-up formula, and formula for special medical purposes.**~~	This provision is redundant with the requirements of 9.1. In addition there cannot be any risk of confusion between products which have different names, different Codex Standards, different composition, different labeling. Delete sentence.
~~**9.6.6 [No [nutrition and] health claims shall be made regarding the dietary properties of the product]**~~	Delete the whole article and the article number. Rationale: It is necessary to provide nutrition and/or health claim of some ingredients used in the foods for the sake of the consumer's right of knowing.

Czech Republic

ALINORM 04/27/26, Appendix V	OUR COMMENTS
PREAMBLE	
[This standard is divided into two sections: Section A refers to Infant Formula, and Section B deals with Formulas for special medical purposes intended for Infants.]	Remove [ ] Rationale: Two different standards, one for Infant Formula and one for Formulas for special medical purposes intended for infants are favoured because: – the compositional requirements are different – specialised products can be a health hazard to normal infants Discussions over this important issue took a long time and the present solution is a good compromise.
SECTION A: INFANT FORMULA	
1. SCOPE	
1.3 The application of this section of the Standard should take into account the recommendations made in the International Code of Marketing of Breast-milk Substitutes (1981), the Global Strategy for Infant and Young Child Feeding and World Health Assembly resolution WHA54.2 (2001) ~~and [WHA.55.25 (2002)]~~.	Delete reference to WHA 55.25. Rationale: WHA Resolution 55.25 requests that the Codex Alimentarius Commission takes WHO policy into consideration, in particular the Code of marketing of breast milk substitutes, Resolution WHA 54.2 and "other relevant resolutions of the World Health Assembly". The latest therefore includes future texts, to which CCNFSDU should not at this time commit. New resolutions relevant for CCNFSDU need to be discussed by the Committee before being referred to in a Codex Standard.
2.1 PRODUCT DEFINITION	
~~**2.1.2 [The safety and nutritional adequacy of infant formulas shall be scientifically demonstrated in meeting the nutritional requirements of the infants for whom they are intended.]**~~	Delete this section. Rationale: Although the principle laid down in this section is strongly supported, it is redundant with other sections of this standard.
[3.1 ESSENTIAL COMPOSITION	
3.1.1 Infant formula is a product based on milk of cows or other animals and/or other ingredients, which have been proven to be suitable for infant feeding. ~~**[All ingredients and food additives used shall be gluten-free.]**~~	Last sentence should be deleted since this provision is redundant at this stage.
3.1.2 Infant formula prepared ready for consumption in accordance with instructions of the manufacturer shall contain per 100 ml not less than 60 kcal (250 kJ) and not more than [70 ~~**or 75]**~~ kcal ([295 ~~**or 315]**~~ kJ) of energy.	A maximum energy level of 70 kcal/100ml is supported. Rationale: The standard should reflect the latest scientific evidence on energy requirements as well as the concerns about energy intake during early life.

3.1.3 Infant formula prepared ready for consumption shall contain per 100 kcal ~~**[100 kJ]**~~ the following nutrients within the following minimum and maximum levels.	Express nutrients "per 100 kcal". Rationale: Reference to energy is almost exclusively made in kcal and not in kJ.
a) PROTEIN	
3.1.3 a) Protein (i) Protein content = nitrogen content x ~~**[6.25 or**~~ 6.38~~]~~ **for milk proteins and their partial hydrolysates** **Protein content = nitrogen content x 6.25 for soya protein isolates and their hydrolysates** **Protein content = nitrogen content x 6.25 for all other protein isolates and their hydrolysates**	A nitrogen conversion factor of 6.38 should be kept for milk proteins, whereas a nitrogen conversion of 6.25 should be applied for soya. Rationale: – The internationally applied conversion factors are different for milk and other protein sources. – A conversion factor of 6.38 is used for milk proteins by the present Codex Standard, and is consistent with those applied by the AOAC Official Methods and by the Joint ISO/IDF (International Dairy Federation) Standards for Milk Determination of Nitrogen Content as well as by most governmental bodies. – Using a different conversion factor would imply that the definition of milk would be different depending on whether used as an ingredient for infant nutriton or not. – Switching to a factor of 6.25 would fail to recognize the nutritional quality of milk over other proteins and will result in an additional 2-3% higher protein intake by infant. Current paediatric opinion is to reduce protein in infant formulae, not to increase it. The nitrogen content of intact and moderate protein hydrolysates are not significantly different. Therefore the conversion factors should be similar. The possibility to use protein sources other than milk and soy should be maintained as in the current Codex STAN 72-1981. The conversion factor is 6.25, unless scientific evidence supports the use of a more appropriate conversion factor.

3.1.3 a) Protein (ii) For an equal energy value the formula must contain an available quantity of each essential and semi-essential amino acid at least equal to that contained in the reference protein (breast-milk as defined in Annex 1); neverthelesss, for calculation purposes, the concentration of methionine and cystine, may be added together **~~[unless the methionine to cystine ratio exceeds 2.0]~~**. **as well as of phenylalanine and tyrosine**,	Delete sentence in [ ] since no criteria should restrict the addition of methionine and cystine. Rationale: - All formula based on unmodified milk protein have a methionine to cystine ratio of about 3 and would be concerned by this criterium. - Casein-predominant infant formula, prepared from unmodified cow's milk protein, have been for many years on the market and make up a considerable part of the infant formula consumption in numerous countries. The long historical use of casein predominant formula has demonstrated that is supports adequate growth during early life. - Other expert recommendations (FAO/WHO, LSRO) agree with the addition of methionine and cystine for the calculation of protein quality. - Growth parameters do not differ between casein-predominant and whey-adapted formulae with the same protein content. Tyrosine can be derived from phenylalanine metabolically and thus the requirement for the two amino acids should be determined as the sum of both, as for methionine and cystine.
Footnote 1 ad a) Protein in the table of Nutrients: ~~1~~ ~~1 Calculation of protein content : N x[6.25 or 6.38] ; [non-protein nitrogen (formulae made from intact protein) <15% of total protein]~~	Delete entire footnote 1 Rationale: - Human milk contains 25% of non protein nitrogen (NPN) - NPN covers a broad range of different substances, including free amino acids and peptides, present in protein hydrolysates and soy-based formulas. All these factors will increase the NPN level. - Free amino acids, as well as choline and L-carnitine, are usually added to soy-based formulas. - No analytical method for the determination of NPN has been internationally validated. - As long as minima for essential amino acids are determined, an NPN criterium would not provide any additional safety to the nutritional value of the formula.

Nutrients (per 100 kcal, unless otherwise stated)	***Minimum***	***Maximum***	
~~Cow's~~ ~~milk~~ Milk protein **and its hydrolysates**	1.8[2]	3	Milk proteins commonly used to manufacture infant formulae (cow, buffalo, goat) have similar nutritional quality and should be covered by the Standard. Add "its hydrolysates" since there is no scientific evidence to distinguish between intact milk proteins and their hydrolysates.
Soy protein **and its hydrolysates**	**~~[1.8 or~~ 2.25~~]~~**	3	Add "its hydrolysates" for the same reasons as above. A minimum protein level of 2.25g/100

			kcal for soy protein has a long history of safe use. Lower values have not been clinically tested.
~~**Protein hydrolysates**~~	~~**[1.8 or 2.25]**~~	~~**3**~~	Delete this sentence, see above.
Other protein and its hydrolysates	**2.25**	**3**	Introduce this new sentence which is in line with section 3.1.3 a (i)
L-carnitine [mg]	~~[~~≥ 1.2 ~~]~~	N.S. [3]	Acceptable, remove [].
~~**Addition of T**~~taurine [mg]	~~[~~0 ~~]~~	~~[~~12~~]~~	Acceptable, remove [].
Nucleotides, if added [4] [mg]	~~[~~0 ~~]~~	~~[~~5~~]~~	Acceptable, delete []. The maximum level of 5mg is in accordance with available scientific evidence.
b) Fat and fatty acids			
Total fat [g]	4.4	~~[**6.0 or**~~ 6.5~~]~~	There are no reasons to change the maximum level for total fat set in the current Codex Standard. Therefore retain a maximum of 6.5 g/100 kcal. <u>Rationale:</u> A level of 55% of energy coming from total fat is considered appropriate.
~~[~~Phospholipids~~]~~	N.S.	~~[**≤ 1**~~ **2** g/L~~]~~	Maximum level for phospholipids should be 2g/l. <u>Rationale:</u> This level is needed in order to achieve a nutritionally relevant concentration of essential LCPUFA's (AA and DHA).
~~[~~Inositol~~]~~ [mg]	~~[**4**]~~ **N.S.**	~~[~~ 40 ~~]~~	No minimum recommended as there is no science to support it. Replace by N.S. We agree with the maximum level. Remove [].
~~[~~ Lauric and myristic acids~~]~~		~~[~~Together ≤ 20% of total fatty acids~~]~~	Agreement with the proposal. Remove [].
Linoleic acid [g]	~~[~~0.3 ~~**or 0.5]**~~	1.2	Support minimum linoleic acid (LA) level of 0.3 g/100 kcal. <u>Rationale:</u> - A minimum level of 300 mg/100 kcal, identical to the amount in the current Codex Standard, is well above that required to prevent deficiency. - No scientific evidence indicated that higher minimum LA levels are required.

~~*[Formulae without added LCPUFA]*~~			Delete this criteria. Rationale: - All infant formulae should comply with the same stringent criteria for nutritional adequacy, whether LCPUFA are added or not. - There is no science showing that there is a need to discriminate between the formula with or without LCPUFA. - The proposed subdivision would add unnecessary complexity to the Standard.
~~[~~α-linolenic acid~~]~~ [mg]	~~[~~≥ 50 ~~or 100]~~	N.S.	Minimum level of α-linolenic acid (ALA) should be 50 mg/100 kcal. Rationale: - Most current formulas contain less than 100 mg ALA/100 kcal and result in adequate visual and psychomotor development. - Research is still in an early stage and the current scientific evidence does not show a need to set a higher minimum level.
Linoleic/α-linolenic ratio	5	~~15~~ **20**	Replace maximum 15 by 20. Rationale: - A ratio of 5-20 between LA and ALA ascertains a proper balance between the precursors of the respective n-6 and n-3 fatty acid series. - The proposed range sustains the nutritional requirements for both formulas with and without added LCPUFA.
~~*[Formulae with added LCPUFA]*~~			Delete, see above Rationale.
~~[α-linolenic acid]~~ [5]	~~[≥ 50 mg]~~		Delete this section and footnote, see above Rationale.
~~[Linoleic/α- linolenic ratio]~~ [5]	~~[5-20]~~		Delete, see above Rationale.
~~[~~ n-6 LCPUFA ~~]~~	**N.S.** ~~[≤2% of total fatty acids]~~	2% of total fatty acids	Minimum level set at N.S. Agreement with proposed maximum of 2%, which must appear in the "*Maximum*" not the "*Minimum*" column.
~~[~~ Arachidonic acid ~~]~~	**N.S**. ~~[≤1% of total fatty acids]~~	1% of total fatty acids	Minimum level set at N.S. Agreement with proposed maximum of 1%, which must appear in the "*Maximum*" not the "*Minimum*" column.

~~[~~ n-3 LCPUFA ~~]~~	**N.S. ~~[≤1% of total fatty acids]~~**	1% of total fatty acids	Minimum level set at N.S. Agreement with proposed maximum of 1%, which must appear in the "*Maximum*" not the "*Minimum*" column.
~~[~~ Ratio EPA/DHA (wt/wt) ~~]~~	~~[<1]~~	1	Agreement with proposed maximum 1 which must appear in the "*Maximum*" not the "*Minimum*" column.
~~[~~ Cottonseed/sesame oils ~~]~~	~~[No use of these type of oils]~~ **The use of sesame seed oil and cotton seed oil is prohibited.**		Rephrase the wording in order to avoid misinterpretation. It is suggested to include this section under 3.6 "Specific prohibitions"
~~[Conjugated linoleic acid(CLA)~~	~~No intentional addition]~~		Delete this section Rationale: - At the present moment, scientific data on the effects of CLA during early life are lacking. Therefore it is not suitable to add CLA to infant formulae. - However it should not be prohibited as such since ongoing research will add more scientific data on the safety and benefit of CLA and its interaction with LA and ALA may become available.
~~[~~*Trans* fatty acids	~~≤ 3 or 4% of total fatty acids]~~	4% of total fatty acids	Strong support for a maximum level of 4% of total fatty acids. Rationale: - No scientific data have established a causal relation between *trans* fatty acid intake and changes in early development. - Natural *trans* fatty acid level of cow's milk fat are often > 5% and vary geographically. - *Trans* fatty acids in human milk were reported to vary considerably (Spain: 1.3 - 7.2 % ; Canada: 0.1 – 17%) - Milk-based formulae with more than 60% of the fat as milk fat are not unusual. A maximum *trans* fatty acid level of 4% seems more appropriate and justified within the context of a global standard.
Erucic acid	**N.S**.	1% of total fatty acids	No minimum necessary, agreement with max. 1%.
c) Carbohydrates			
~~[~~ Lactose in ~~cows'~~ milk protein-and protein hydrolysates formulae [g]	≥ 4.5 ~~]~~		Delete "*cows*'" for reasons indicated above, otherwise agreement, remove [ ].

~~[Lactose in soy protein formulae~~	~~No requirement]~~		This section is superfluous, delete.
~~[Saccharose~~	~~None in cows' milk protein and soy protein formulae~~ ~~≤ 20% of total carbohydrates in protein hydrolysates formulae]~~		Delete this section. Rationale: - There is no scientific evidence that the consumption of sweeter formulae would lead to greater weight gain. - There is no proof that the consumption of sweeter formulas would promote a preference for sugar in later life. - In many countries, saccharose is the only available superior quality source of carbohydrates.
~~[Fructose~~	~~None]~~		Delete this section as this criterium should appear in section 3.6 "Specific prohibitions"
[Glucose	No intentional addition to formulae. ~~based on intact proteins,~~ ~~≤ 2 g in formulae based on protein hydrolysates]~~		Glucose should not be added as such to infant formulae. Rationale: - Addition of glucose increases osmotic pressure of the formula and risk of Maillard reaction. - A small amount of glucose may come from the use of glucose syrups.
[Maltose, maltodextrins**, glucose syrup**	Unrestricted]		Agreement with proposal, suggestion to add glucose syrups. Rationale: - Glucose syrup is used as a replacement for lactose in soya protein based infant formula, to assist with palatability.
[Starches	30% of total carbohydrates (≤ 2 g/100 mL) as precooked or gelatinised naturally gluten-free starches No starches modified by enzymatic cross-linking or stabilisation]		Agreement with proposal Remove [ ]

d) Vitamins			Agreement with the setting of minimum and maximum levels. Some modifications suggested. <u>Rationale:</u> - The range takes into account the natural variations in vitamin levels of the raw materials. - The proposed levels take into account losses during shelf life. - In general, vitamin requirements are similar for infant formulas and formulas for special medical purposes intended for infants. - The use of a single vitamin blend is also desirable for technological and safety reasons.
Vitamin E [mg α TE]	≥0.5 mg α TE/g PUFA **[**(corrected for double bond, see footnote[9])**],** but in no case less than 0.5/100 kcal	**[** 5 **]**	Delete part of the footnote ~~per g of polyunsaturated fatty acids, expressed as linoleic acid~~ because it is not meaningful.
Vitamin K [µg]	4	**[** 20 **]**	
Thiamin [µg]	**[** 40 ~~**or 60]**~~	**[** 300 **]**	
Riboflavin [µg]	**[** 60 ~~**or 80]**~~	~~**[400]**~~ **450**	
Niacin [µg]	**[** 300 ~~**or 800]**~~	**[**1200**]**	
Vitamin B6 [µg]	35	~~**[165]**~~ **300**	
Vitamin B12 [µg]	0.1	**[** 0.5 **]**	
Pantothenic acid [µg]	**[** 300 ~~**or 400]**~~	**[** 2000 **]**	
Folic acid [µg]	**[** 4 ~~**or 10]**~~	**[** 30 **]**	
Vitamin C [mg]	**[** 8 ~~**or 10]**~~	~~**[30]**~~ **40**	In agreement with proposed minimum level of 8 mg/100 kcal, but recommendation for a higher maximum level of 40 mg/100 kcal.
Biotin [µg]	1.5	~~**[7.5]**~~ **20**	
e) Minerals and Trace Elements			

Iron [mg]	**0.5**	**2.5**	We strongly favour a single level of iron for all infant formulas with the minimum at 0.5 mg/100 kcal and the maximum at 2.5 mg/100 kcal. <u>Rationale:</u> - A minimum 0.5 mg/100 kcal is appropriate to fulfill iron requirements of infants during the first six months of life. Although a min. level of 0.3 has proved sufficient it is considered prudent to provide a higher level to prevent risk of iron deficiency anaemia. A maximum level of 2.5 mg/100 kcal is necessary for countries where major iron deficiencies are encountered. This is in agreement with the AAP-CON recommendation (1993).
~~**Cow's milk protein and protein hydrolysate formulae**~~ ~~**Soy protein formulae**~~	~~**[0.3 or 0.5]**~~ ~~**[0.45 or 1.0]**~~	~~**[1.3 or 1.5]**~~ ~~**[1.9 or 2.0]**~~	Infant formula have a vitamin C to iron ratio enabling good iron absorption. Differentiation is not necessary between infant formulas.
Calcium [mg]	50	~~**[**~~ 140~~**]**~~	In agreement with the proposed maximum level.
Calcium/Phosphorus-Ratio	1.0	~~**[2.0 or**~~ 2.2 ~~**]**~~	High levels of phosphorus in infant formula are undesirable. **We strongly support max. Ca/P ratio of 2.2.** This value is physiological and is regularly found in breast milk.
Phosphorus [mg]	~~**Cows' milk protein and protein hydrolysate formulae: 25**~~ ~~**Soy protein formulae: [30]**~~ ~~**[Bioavailable phosphorus, if measured: 20-70 mg]**~~ **25**	~~**90**~~ ~~**[100]**~~ **100**	A single level of phosphorus is favoured with the minimum at 25 mg/100 kcal and the maximum at 100 mg/100 kcal.
Chloride [mg]	50	~~**[125 or**~~ 160 **]**	Support for the maximum of 160 mg/100 kcal.

Potassium [mg]	60	[~~**145 or 160**~~] **200**	The maximum for potassium should be 200 mg/100 kcal. Rationale: - It is important to retain for partial hydrolysates the maximum level of 200 mg/100 kcal for potassium as in current Codex Standard (72-1981). - This level of potassium is not harmful to infants, and is technologically necessary for the production of hydrolysed formula.
Manganese [µg]	[1 ~~**or 5**~~]	[100]	A minimum of 1 µg/100 kcal is justified. In agreement with maximum.
Fluoride [µg]	N.S.	[100]	In agreement with proposal.
Iodine [µg]	[5 ~~**or 10**~~]	[50]	A minimum of 5 µg/100 kcal is justified. In agreement with the maximum of 50µg/100kcal.
Selenium [µg]	[N.S. ~~**or 3**~~]	[9]	We strongly oppose setting a minimum level and agree with NS. In agreement with max. of 9. Rationale: - Human milk Se ranges between 5-20 µg/l. - Infant formula Se ranges betweem 7 – 13 µg/l. - No clinical evidence has been reported sofar on selenium deficiency during infancy neither for breast- nor for formula-fed infants. - Unsupplemented formulas are widely available without any sign of deficiency.
Copper [µg]	[20 ~~**or 35**~~]	[~~**80 or**~~ 100]	
Zinc [mg]	**0.5**	**2.40**	We favour a single level of zinc for all infant formulas with the minimum at 0.5 mg/100 kcal and the maximum at 2.4 mg/100 kcal. Scientific data support above proposal.
~~**Cow's milk protein and protein hydrolysate formulae**~~	~~**0.5**~~	~~**[1.5]**~~	
~~**Soy protein formulae**~~	~~**0.75**~~	~~**2.40**~~	
f) Choline [mg]	7	[~~**30 or**~~ 50]	A maximum of 50 mg/100kcal is necessary in case of arachidonic acid (AA) supplementation
[Nucleotide [mg]]			Agreement with the proposal Remove [ ]
Cytidine 5'-monophosphate(CMP)	N.S.	2.50	
Uridine 5'-monophosphate(UMP)	N.S.	1.75	
Adenosine 5'-monophosphate(AMP)	N.S.	1.50	
Guanosine 5'-monophosphate(GMP)	N.S.	0.50	

Inosine 5'-monophosphate(IMP)	N.S.	1.00	

3.6 SPECIFIC PROHIBITIONS	
The product and its components shall not [contain commercially hydrogenated oils and fats and shall not] have been treated with ionizing radiations.	We fully support this prohibition. Remove [ ]
4. FOOD ADDITIVES	
4.1 Thickening Agents	
4.1.2. INS 410: Carob bean gum (locust bean gum) 0.1 g in all types of infant formula ~~**REQUEST FOR 0.5G**~~	A level of 0.1 g/100 ml is sufficient for regular infant formula. Delete request.
4.2 Emulsifiers	
4.2.5 INS 472e: Diacetyltartaric and fatty acid of esters of glycerol GMP	Add new additive. <u>Rationale:</u> Retains homogeneity of liquid products and liquid reconstituted powder especially in formulas where whole proteins are not used. Has a high HLB, works better in combination with additive 322 and 471. Has a GRAS status in the US.
4.4 Antioxidant	
4.4.3 INS 309: Gamma-tocopherol **INS 308: Delta-tocopherol** **1 mg in all types of infant formula singly or in combination**	Add new additives. Alone or in combination to stabilise preparations containing fats and vitamins. Synergistic effect with additive 304. They are effective in preventing oxidation of vulnerable fatty acids.
4.5 CARRY-OVER OF FOOD ADDITIVES	
~~**[4.5 Carry-over of Food Additives**~~ ~~**No food additives shall be present as a result of carry-over from raw materials and other ingredients with the exemption:**~~ ~~**(a) of the food additives listed under Sections 4.1 to 4.4 of this standard within the limits of the maximum levels stipulated in this standard; and**~~ ~~**(b) of the carrier substances mentioned in the Advisory List of Vitamin Compounds for Use in Foods for Infants and Children within the limits of the maximum levels stipulated in that List]**~~ **Section 3 of the Principle relating to the Carry-Over of Additives into Foods shall apply.**	The issue of carry-over of additives in infant formulae is being readdressed. We support that the Principle relating to the Carry-over of additives shall apply to infant formula for the following reasons: – the amount of additives that are carried-over from an ingredient into the final product does not have a technological effect and does not affect safety – the exception to the carry-over principle for infant formula is not consistent with the General Standard for Food Additives. – the restriction on carry-over makes it difficult to develop new formula with certain desired beneficial qualities. Suggest adding the standard statement which should be used where reference to the applicability of the Carry-Over Principle is specifically made in a Codex Standard

9. LABELLING	
9.1.3 If **90% or more of the protein is derived from whole or skim** cow's milk ~~**is the only source of protein**~~, the product may be labelled "Infant Formula Based on Cow's Milk".	Suggest to retain text of current Standard Infant Formula (72-1981).
9.1.5 ~~**[No health claims shall be made regarding the dietary properties of the product]**~~ **Nutrition and health claims shall be permitted for the products covered by this standard, where they have been demonstrated beyond doubt in rigorous studies with adequate scientific standards, and the evidence has been accepted by an independent scientific body reviewing the data.**	The sentence in square brackets must be deleted because nutrition and health claims will give essential information about the product. If justified, they should be allowed. Some legislations permit such claims, for example in Europe where the claim of hypoallergenic formulae is allowed. We therefore recommend new wording. Rationale: – All claims that are scientifically substantiated, with the substantiation validated through independent scientific review, should be allowed. – There is no nutrition-based rationale for placing a severe restriction on claims for these products. These claims should be allowed as long as they are scientifically substantiated and are expressed in a manner that is understood by and is not misleading to the parent or caregiver. – Claims on products for infants and young children can provide parents and caregivers with important information about the composition and properties of a product that is specially designed for this age category. There is no justification for denying them information that is based on scientific substantiation.
9.1.6 ~~[~~ Products containing not less than 0.5 mg Iron (Fe)/100 kcal~~ories~~ shall be labelled "Infant Formula with added Iron" ~~]~~ ~~**or**~~ ~~**[Products containing less than 0.5 mg Iron (Fe)/100 kcal shall be labelled with a statement to the effect that when the product is given to infants over the age of four months, their total iron requirements must be met from other additional sources]**~~	Agreement with the first alternative.
9.3. DECLARATION OF NUTRITIVE VALUE	
(b) the total quantity of each vitamin, mineral, choline as listed in paragraph 3.1.2 of this Standard and any ~~**other**~~ **optional** ingredient as listed in paragraph 3.2 of this Standard per 100 grammes of the food as sold as well as per 100 mililiter of the food ready for use, when prepared according to the instructions on the label.	Using the wording “optional ingredient” is in line with section 3.2.

9.5. INFORMATION FOR USE	
9.5.1 Directions as to the **appropriate** preparation and use of the food, and its storage and keeping after the container has been opened shall appear on the label or on the accompanying leaflet.	The word "appropriate" should be added for sake of clarity.
9.6. ADDITIONAL LABELLING REQUIREMENTS	
9.6.1**. ~~d) Instructions for appropriate preparation~~**	This is redundant with section 9.5.1. Delete sentence.
9.6.4.Information shall appear on the label ..... and in any case from the age **of ~~over~~** six months	The word "over" should be replaced by "of" for sake of consistency with other Codex Standards.
~~9.6.5. The products shall be labelled in such a way as to avoid any risk of confusion between infant formula, follow-up formula, and formula for special medical purposes.~~	This provision is redundant with the requirements of 9.1. In addition there cannot be any risk of confusion between products which have different names, different Codex Standards, different composition, different labelling. Delete sentence.
~~9.6.6 [No [nutrition and] health claims shall be made regarding the dietary properties of the product]~~	See comments on section 9.1.5 Delete sentence.

Iran

Title:

The dietary needs of infants with special medical conditions can be varied and by their very nature require specialist attention of their own. It is felt that infant formulas for special medical purposes is beyond the scope of its normal counterpart and hence should be covered by a separate standard altogether .

2-1-2 Delete the square bracket .

3-1-2 We accept not Less than 60 kcal and not more than 70 kcal of energy for 100ml .

3-1-3 a) we approved 6.38 because Infant formula based on Cows' milk .

3.1.3 a) (ii) Delete the square bracket .

Nutrients (per 1ookcal, unless otherwise stated)		
a) protein (g)	Minimum	Maximum
Soy protein protein hydrolysates	2.25	3
L-Carnitine mg	>= 0.7	N.S.
Taurine mg	15.8	24.6
Nucleotides , if added mg	0	5
b)Fat and fatty acids		
Total fat g Total saturated fatty acids g/100 g fat	4.4 40	6.0 45
Total Monounsaturated Fatty acids g/100g	37	40

fat		
Total polyunsaturated fatty acids g/100g fat	13	18
Inositol mg	4	40
Lauric and myristic acids		Together<= 20% of total fatty acids and contain 40% lauric acid and 60% myristic acid
Linoleic acid	0.3	1.2
Formula without added LCPUFA **α- Linolenic acid mg**	**>=50**	**N.S.**
Formula with added LCPUFA α – Linolenic acid mg Linoleic/α – Linolenic ratio n-6 LCPUFA Arachidonic acid n-3 LCPUFA Linseed because of containing over 50% Linolenic acid, safflower because it contains over 70% Linoleic acid, sesame seed oil because of the presence of phenolic compounds and Rapeseed oil because of the presence of Erucic acid and peanut oil because of high level in allergic agents and Arachidic acid	**>= 50** 5 <= 2% of total fatty acids <=1% of total fatty acids <=1% of total fatty acids	**20** No use of these type of oils
Hydrogenated oils **trans fatty acids** **Erucic acid**	**None** **<= 1% of total fatty acids** **none**	
C)carbohydrates **lactose in Cow's milk** **protein- and protein hydrolysates formulae g**	**>= 8.1** 90 % of total carbohydrates	
Saccharose Fructose Glucose Focus-Glucoseamine-Galactoseamine–polysaccharides contain nitrogen – Maltodextrins and oligosaccharides in human milk g Starches	**None** None None <,= 0.9 None	

d) Vitamins		
Vitamin A µgRE	75	180
Vitamin D µg	1	2.5
Thiamin µg	40	[300]
Riboflavin µg	60	[400]
Niacin µg	300	[1200]
Pantothenic acid µg	300	[2000]
Folic acid µg	4	[30]
Vitamin c mg	8	[30]
e) Minerals and trace Elements		
Iron mg		
Cow's milk protein and Protein hydrolysate formula	0.3	1.5
Soy protein formula	1.0	2.0
Calcium mg	60	140
Calcium/phosphorus-Ratio	1.0	2.0
Phosphorus mg	Cows milk protein - and protein hydrolysate Formula : 30	90
	20	
Sodium mg	50	35
Chloride mg	80	125
Potassium mg	5	145
Manganese µg	10	25
Iodine µg	1.5	50
Selenium µg	20	3
Copper µg	0.5	80
Zinc mg		1.5
Cow's milk protein		
And protein hydrolysate		
Formula		

3.6 Delete the sentence in the square bracket

4.1.2 Carob bean gum 0.1 g in all types of infant formula

4.5 We approve this section

5.2 Heavy metals = 0

7. Packaging 7.1 should be changed to read :

The product shall be packed in containers, with a Suitable functional recap, which will safeguard ….

Justification :

Some of the containers used for the packaging of infant formula do not unfortunately offer an adequate possibility of re- cap after opening . Much effort is made to ensure that such products are prepared in compliance with the highest hygienic standards: It would only be logical to also try to maintain that standard, to prevent product re- contamination during handling and after partial use of the packet contents .

9.1.5 Delete the square bracket

9.1.6 we approve each two sentences together

9.6.6 Delete the sentence in the square brackets

10- Methods of Analysis and sampling

In This section there aren't any refrence for Determination of Biotin, Iron, Magnesium, chloride, chromium, manganese, molybdenum, Fluorid, selenium, Copper, Zinc

Malaysia

Section 3: Essentian Composition and Quality Factors

Paragraph 3.6 Specific Prohibition

Malaysia proposes to remove the square bracket and adopt the text contained therein. This paragraph is to read:

"The product and its components shall not contain commercially hydrogenated oils and fats and shall not have been treated by ionizing radiation"

Section 9: Labelling

Paragraph 9.1.5

Malaysia proposes to delete the paragraph since this point has been stated under Paragraph 9.6.6.

Paragraph 9.6.6

Malaysia proposes to delete the words 'nutrition and' and adopt the text. This paragraph should read:

"No health claims shall be made regarding the dietary properties of the product"

Rationale:

Some nutrition claims could be permitted so as to provide nutrition information to the consumer. The current text implies that Nutrition Content Claims and Comparative Claims are also not permitted.

Mexico

1. Eliminar los corchetes del titulo de la norma.
2. En el punto 1.1, sugerimos cambiar el párrafo que dice: "as a substitute for human milk in meeting the normal nutritional requirements of infants", por: "to replace for the human milk". Pues consideramos que esta definición es más apropiada para describir a las formulas infantiles, pues son más bien un reemplazo no un sustituto.
3. Eliminar los corchetes del numeral 2.1.2.
4. 3.1.1 proponemos pasar este punto para la sección "B" de esta norma. Que es relacionado a que todos los ingredientes y aditivos para alimentos deben estar libres de gluten".
5. Punto 3.1.2, se toma no más de 75 kcal ó 315 kj d energía.
6. En el inciso a del punto 3.1.3. se toma como porcentaje de conversión de nitrógeno la cifra de 6.38.

De la tabla de nutrientes por 100 kcalorías:

7. En el inciso a, se deja gramos como medida y se toma el valor de 1.8 como valor mínimo de contenido de proteínas de varios tipos. Para L-carnitina y taurina, se deja el valor de referencia en mg.
8. En toda la tabla se acepta se quiten los corchetes para las unidades de medida.
9. En el inciso b, referente a ácidos grasos y grasa, se propone eliminar el rubro de fosfolípidos, derivado de que no se tienen establecidos niveles mínimos y máximos.
10. En el punto 5.1, referente a residuos de plaguicidas, sugerimos se elimine la frase que dice que los plaguicidas deben estar ausentes lo más posible en estas formulas, quedando de la siguiente manera: El producto debe ser preparado con mucho cuidado y apego a las Buenas Prácticas de Manufactura, tales que no deben contener residuos de plaguicidas que pueden ser utilizados durante la producción,

almacenamiento y procesamiento de materias primas y producto terminado o debe ser técnicamente inevitable.

11. Sugerimos se quite el corchete para el ácido Láurico y mirístico y se quite el corchete en sus valores máximos.
12. Para el ácido linoléico tomamos el valor mínimo de 0.5 gramos.
13. Sugerimos se quite el corchete para ácido araquidonico, se tome 2% del total de ácidos grasos como valor mínimo, para n-3LCPUFA se quite también el corchete y se deje como valor mínimo 1% del total de ácidos grasos.
14. Para ácidos grasos Trans, nuestra postura es dejar 3% del total de ácidos grasos como nivel mínimo y pedimos se establezcan niveles máximos para estos ácidos grasos.
15. Sugerimos quitar los corchetes al apartado de Hidratos de Carbono, excepto en el apartado de lactosa en formulas a base de proteína de soya, el cual proponemos se elimine.
16. En el apartado de vitaminas, estamos de acuerdo con las unidades de medida propuestas, en los valores mínimos, para: Tiamina, Riboflavina, Niacina y ácido pantoténico, estamos de acuerdo en los valores 40, 60, 300 y 300 respectivamente. Estamos de acuerdo en quitar los corchetes en los valores máximos en todas las vitaminas.
17. En el apartado de minerales y elementos traza, en la parte de hierro, sugerimos cuando la formula es a base de proteína de vaca o hidrolizado de proteína optamos por el valor mínimo de 0.5 mg y el valor máximo de 1.5 mg, cuando la formula es a base de proteína de soya, optamos por el valor mínimo de 1 mg y el valor máximo de 2 mg.
18. Sugerimos se quite el corchete en el valor máximo de calcio y en la relación calcio – fosforo optamos por el valor máximo de 2.
19. En la parte de fosforo, para formulas a base de proteína de soya, estamos de acuerdo en los valores mínimos y máximos.

New Zealand

New Zealand is supportive of two sections within the standard to address (A) infant formula; and (B) formulas for special medical purposes intended for infants. New Zealand is also very supportive of section A progressing to step 5.

Description

New Zealand does not believe that 2.1.2 adds any value to the draft standard and should be removed.

Essential Composition

3.1.3

Protein

New Zealand does not support a change in the nitrogen conversion factor from 6.38 to 6.25 as suggested by the EU Scientific Committee for Foods. We strongly believe that there is inadequate justification to support such a change, and if considered, it would require a change for all milk products and not just infant formula. The factor of 6.38 is consistent with the AOAC official methods recognised in Codex.

Adopting a conversion factor of 6.25 would underestimate the actual protein content of milk and require manufacturers of infant formula to add an additional 2 – 3% of protein to their formula.

Fat and Fatty Acids

The trans fatty acid content should be raised to “should not exceed 5% of the total fat content". Milk fat can contain up to 6 % trans fatty acids and it can be desirable to manufacture infant formula with a fat mix containing 80% milk fat. Long chain polyunsaturated fatty acids should remain optional additions.

Micronutrients

Selenium: New Zealand does not support the proposed levels for selenium. The proposed level is much higher than what would be acceptable in New Zealand and much higher than levels found in breastmilk.

New Zealand would support a minimum level of 0.2 μg/100 kJ (0.84 μg/100 kcal) as recommended by the LSRO report which is based on the estimated mean minus one standard deviation value for the selenium concentration of human milk in countries where selenium deficiency has been recognised.

Ca:P: New Zealand strongly supports a maximum calcium to phosphorus ratio of 2:2.

Sodium, Potassium and Chloride: The low maxima for potassium and chloride that have been proposed deviate from those recognised by many competent authorities including the levels stated in the Australia New Zealand Food Standards Code. The balance of these solutes is important for retaining essential fluid balance and disruption of the solute equilibrium could lead to either dehydration or oedema.

It is proposed that maximum sodium should be retained at 15 mg/100 kJ (63 mg/100 kcal). Potassium minimum should be 20 mg and maximum at 50 mg/100 kJ (84 and 209 mg/100 kcal respectively). Chloride maximum should be 35 mg/100 kJ (147 mg/100 kcal).

Iron: New Zealand questions the maximum level for iron of 0.36 mg/100 kJ (1.5 mg/100 kcal) and has recently set a maximum level of 0.5 mg/100 kJ (2.1 mg/100 kcal).

Labelling

Further consideration will need to be given to the labelling section following the outcome of discussions on the scope.

9.1.5

Reference to health claims can be removed as the Codex Committee on Food Labelling are dealing with this issue. The Draft Guidelines on Nutrition and Health Claims state that "nutrition and health claims shall not be permitted for foods for infants and children except where provided for in national legislation".

New Zealand recommends deletion of section 9.1.6 as the proposed minimum level of iron would require all infant formula to be labelled "with added iron".

Information for Use

This section contains only one paragraph and should therefore not be labelled 9.5.1.

Additional Labelling Requirements

9.6.6

New Zealand supports deletion of this paragraph as the issue of health and nutrition claims will be dealt with by CCFL and should only be addressed here if there was an express permission to use health and nutrition claims in infant formula.

Poland

5.2 Other Contaminants

Poland suggests establishing maximum levels for cadmium, mercury and arsenic in the products covered by the provisions of the Standard.

European Network of Childbirth Associations (ENCA)

Title

ENCA proposes to delete the square brackets in the title

Preamble

ENCA asks to delete the square brackets and keep the text to reflect the compromise agreed upon in Bonn at the last session

SCOPE of section A

1.2 delete the words “normal healthy” as they have no definition in Codex Alimentarius nor in WHO. The Scope of section B would further define the conditions of infants needing the products of section B, mutis mutandem this defines that section A covers all the other infants

1.3 Delete brackets and reword to read:

The application of the Standard shall be in conformity with the recommendations given to countries under the International Code of Marketing of Breast-Milk Substitutes(1981) the Global Strategy for Infant and

Young Child Feeding and World Health Assembly Resolution 54.2 (2001) and WHA Resolution 55.25 (2002).

2. DESCRIPTION

2.1.2 Reword to read:

"Infant formula shall be nutritionally adequate to ensure growth and development when used in accordance with its directions for use.

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1.1 The wording of the definition as in the previous draft with all possible ingredients named should be kept, as this gives the best information to consumers. Any shorter version is vague and hides information.

"Infant formula is a product based on milk of cows or other animals and/or other edible constituents of animal, including fish, or plant origin, which have been proved to be suitable for infant feeding. "

Delete brackets around "all ingredients and food additives used shall be gluten-free" and keep the text

Soy as a possible main ingredient should be reviewed.

After the report of the UK Committee on Toxicity (COT) and the report of the Scientific Advisory Committee on Nutrition (SACN) on Phytoestrogens and Health (http://www.food.gov.uk), regarding the potential risks of soy as a constituent of infant formula, we question the use of soy formula and request the CCNFSDU to review this ingredient.

Phytoestrogens in infant formula based on soy protein should be considered as a potential exposure of infants as they may be during the first six months the only nutritional intake and a major part of intake during the following year for an infant and young child. The effect of phytoestrogens will add to the exposure to endocrine disruptors occurred in the prenatal phase of life.

Here the references:

The SACN report states:

"Conclusion

20. Based on the evidence cited in the report, SACN is in agreement that the use of soy-based infant formulae is of concern. Whilst there is clear evidence of potential risk, there is no evidence that these products confer any health benefit or therapeutic advantage over products based on cow's milk protein isolates….there are no substantive medical or clinical indications for the use of soy-based formulae and, secondly on grounds of potentially important sequelae, principally amongst young infants. If the use of soy-based formula is to continue on "clinical" grounds, responsibility is placed upon health professionals rather than the industry and consumers. The issue appears to be one of consumer choice, but there must be an onus on industry to better inform firstly the general public and, secondly, through a health professional, parents actually using these products to feed their infants."

 Comité de nutrition de la Société française de pédiatrie: Préparations pour nourrissons et préparations de suit à base de protéines de soja : données actuelles. D. Rieu 2001

My translation of some quotes: For the moment there is no study on the endocrine development of infants and children raised or being raised on soy infant formula regarding their fertility in adult life. It seems to be safer to eliminate phytoestrogens from soy formula.

The report of the scientific committee on food on the revision of essential requirements of infant formulae and follow-on formulae (SCF/CS/NUT/IF/65 final from 18 may 2003) has not looked into the 2 previous reports as they are not quoted in the references. Nevertheless it stated this: http://europa.eu.int/comm/food/fs/sc/scf/outcome_en.html

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Soy protein is rich in isoflavones which can for example bind to oestrogen receptors and interact with enzyme systems influencing oestrogenic activity (Setchell, 2001). The total content in ready-for-use products in the USA was determined to be 20-47 µg/mL (Murphy *et al.*, 1997; Setchell *et al.*, 1998; Johns *et al.*, 2003), mainly the glycosides of genistein (65%) and daidzein. A four-month old infant fed such soy formula will receive 22 to 45 mg per day or 6 to 11 mg/kg body weight per day. Accordingly, plasma levels of daidzein and genistein in infants fed soy formula were significantly higher (654-1775 ng/mL), than in infants

fed cows' milk formula (9.4_1.2 ng/mL) after 4 months or human milk (4.7_1.3 ng/mL) (Setchell *et al.*, 1998). It is noted that adverse effects of soy-based formulae on reproduction, development, carcinogenesis and immunology have been observed in animals (Badger *et al.*, 2002; Essex, 1996; Newbold *et al.*, 2001; Setchell *et al.*, 1998; Yellayi *et al.*, 2002). To date, despite the wide-spread use of soy-based formulae for example in the USA, there are only limited data addressing the safety of soy-based infant formulae and follow-on formulae, other than noting the absence of case reports of adverse effects in those fed soy-based infant formulae. The limited epidemiological data available are described below.

Strom *et al.* (2001a) performed telephone interviews in 811 adults aged between 20 and 34 years who had participated as infants during the years 1965 to 1978 in feeding trials with soybased formula (n=248; 120 males) or cows' milk formula (n=563; 295 males). Data were collected in adulthood for self-reported height, weight, body mass index, pubertal maturation, menstruation, reproduction and education levels. Female subjects of the original soy group had a higher rate of regular use of antiasthmatic and antiallergic drugs (18.8% *vs.* 10.1%, p=0.047), while males showed a similar but non-significant trend (15.8% *vs.* 10.2%, p=0.08).

Females previously fed on soy formulae had a lower prevalence of sedentary activities (8.9+3.4 hours/week *vs* 9.6+3.5 hours/week, p=0.05) while there was no group difference for males. There were no differences in height, weight, incidence of thyroid disease (Strom *et al.*, 2001b) or pubertal development between the groups previously fed the two types of formuale. Duration of menstruation was slightly longer (by 0.37 days) and more painful in the soy-fed group. Pregnancies were reported by 42% of women fed soy-formula and by 48% of women in the cows' milk formula group. Outcomes of pregnancies were not different, neither were there differences in the occurrence of cancer, hormonal disorders, sexual orientation or birth defects in the offspring between the groups. No conclusions can be drawn on possible effects on fertility in men previously exposed to soy-based formula, considering their relatively young age at the time of the follow-up study. The Committee notes, however, that the potential effects of exposure to oestrogenic substances during infancy on subsequent male fertility need to be evaluated.

A retrospective epidemiological study by Fort *et al.* (1990) found that children with autoimmune thyroid disease were significantly more likely to have been fed soy formulae ininfancy: the frequency of previous feedings with soy based formulae in infancy was 31% in 59 patients with autoimmune thyroid disease, but only 12% in their 76 healthy siblings ($p<0.01$) and 13% in healthy nonrelated controls ($p<0.02$). There was no group difference in the frequency and duration of breast feeding. The aglucons of genistein and daidzein were demonstrated to inhibit the activity of thyroid peroxidase purified from porcine thyroid glands when present at concentrations of 1 to 10 µM, resulting in iodinated isoflavone compounds. Four months old infants fed soy protein formulae were shown to have plasma levels of isoflavones in the range of 1 to 4 µM/L (Setchell *et al.*, 1998). The presence of at least 150 µM of iodine per litre in the incubation mixture completely protected against the isoflavone mediated thyroid peroxidase inactivation (Divi *et al.*, 1997).

A preliminary report in abstract form did not indicate any oestrogenic hormonal effects in children fed soy formula (Businco *et al.*, 2000). *(ENCA's comment: This was research sponsored by infant formula manufacturers)*

Both cows' milk protein and soy protein isolate may be regarded as nutritionally adequate in infant formula. However, in view of some remaining uncertainties on the short- and the longterm effects of a high isoflavone intake in infancy and on the potential to influence allergic and autoimmune disease, the Committee is of the opinion that soy-based formula should be reserved for specific situations only and that cows' milk-based formula should be the standard choice.

(c) Carbohydrates

Lactose is the natural sugar found in breastmilk, therefore the lactose content in infant formula should be as optimal as possible.

The carbohydrate content should not be fixed in gram/100 kcal but related to their relative sweetness compared to lactose in breastmilk

3.2 Optional ingredients

3.2.1. Add: *Optional ingredients are mentioned in the ingredients list and give no right to make claims or use them in any promotional way to undermine breastfeeding*

3.2.2. Add: *The bio-availability of this substances to the infant should be proved before marketing*

3.5 Purity Requirements

Enterobacter contamination should be excluded

3.6. Specific Prohibition

delete brackets and retain text

3.7*. we support Brazil's comment published in CX/NFSDU 03/6 on GMO*

4. FOOD ADDITIVES

There is no need for thickening agents, emulsifiers and antioxidants in the preparation of infant formula with the exception of some special formulas where they may be necessary for product properties

4.1.Thickening agents: We oppose the use of thickeners because

- In the case of infant formula the product sold on the market is not compared to another product by an other producer who has to follow the same standard, but it is compared to a product produced naturally by the mothers body herself and foreseen as a unique nutritious mixture to satisfy by itself the needs of the infant. Nature has not planned to add thickeners to breastmilk as their unique composition is tailored to meet the need of the baby.

  For decades scientists, manufacturers and doctors have instaured doubts in women's ability to provide enough nutrition to her baby by breastfeeding. This doubts still persists in the head of people even now where new knowledge on the composition of breastmilk and lactation physiology is available and these doubts will be fueled by thickeners in infant formulae.

  This means that thickeners added to infant formula are misleading parents on the nutritional value of the product.

5. CONTAMINANTS

5.1 Reword to read:

"The product shall be prepared with special care under good manufacturing practices, so that residues of those plant protection substances which may be required in the production, storage and processing of the raw materials or the finished food ingredient do not remain, or if technically unavoidable, **do not exceed a maximum level of 0.01 mg/kg for each substance in the product as sold**."

This is in accordance with the European legislation

5.2 Delete current text and **reword** to read: "The product shall be free from residues of hormones, antibiotics, N-nitrosamines, nitrates, heavy metals, mycotoxins, as determined by agreed analysis, and free from other contaminants, especially pharmacologically active substances such as phytoestrogens."

Infant formula is the sole food for infants for the first six months of life and should be free from all contaminants, including residues of hormones and antibiotics. As hazardous levels for these substances are not known the current text linking permissible levels amounts which do not present a health hazard is impossible. Ideally infant formula should be totally free from such contaminants.

6. HYGIENE

6.1 Replace "it is recommended" by "shall be "prepared

Stating that the product shall be manufactured in accordance with these Codes of practice is stronger than a recommendation that the product be made in accordance with them.

6.2 Reword to read: "The product **shall** comply with any microbiological criteria established in accordance with the principles for the Establishment and Application of Microbiological Criteria for Foods (CAC/GL 21-1997; and shall be free from pathogenic microorganisms, parasites and any other poisonous or deleterious substances"

6.3 Add this new paragraph

The consumers should be informed that this is not a sterile product and that preparation shortly before feeding and discarding of left-over is needed to prevent multiplication of germs present in the product (cf. Joint FAO/WHO workshop on Enterobacter sakazakii and other microorganism in powdered infant formula)

Therefor the labelling section needs a special chapter on this: the label of each container has to have a clear, conspicious and easy readible and understandable message printed on it.

9. LABELLING

9.1 Add *"s" to language* **to read** *" languages" to reflect the linguistic situation in many countries*

9.1.4 Add the following: and must state the source of the protein content, i.e. Infant

Formula Based on Soya".

Consumers have the right to know the animal or plant source of the ingredients in infant formula.

9.1.5 Remove all square brackets and **read**:

"No health claims, shall be made regarding the dietary properties of the products."

Health claims are increasingly used by Infant formula manufacturers to market their products. They undermine breastfeeding and create a misleading perception that breastmilk and infant formula are similar or equal. In general, claims are used to idealize the product rather than to inform the consumer. This form of idealization is contrary to the International Code and therefore should not be permitted.

Example: currently claims for infant formula with LCPUFA are made by manufacturers to make health professionals and parents believe that this sort of formula enhances intellectual outcome or the view. ISDI says in CX/NFSDU 03/6 page 27 on LCPUFA "however it is not known if increases occur in neural tissues. Some studies do show a positive effect, where others were unable to measure such effects"

This example shows clearly how claims are based on inconclusive scientific evidence. The main aim seems to achieve marketing advantages by misleading consumers.

9.6.1.e) It is important to give consumers a rational why prepared formula should not be stored

Add this part of the sentence at the end:

because of possible contamination of the product during manufacturing or preparation with pathogen germs which grow in the prepared product and can cause illness in the baby. Be aware that this product as sold is not sterile.

9.6.2 Change to read: "The label shall have no pictures of infants and women nor any other picture or text which idealizes artificial feeding. The label **must** have graphics illustrating the method of preparation of the product and methods of feeding.

The label must have graphics so that mothers who cannot read have a better understanding.

9.6.4 Reword to read:

Information shall appear on the label to the effect that infants should receive **complementary** food in addition to infant formula from the age **over six months onward as advised by an independent health worker to satisfy their specific growth and development needs**.

9.6.5 Delete square brackets and retain the text to read:

No nutrition and health claims shall be made regarding the dietary properties of the product rationale see 9.1.5

International Dairy Federation

Introduction

During its last session held in Bonn (Germany), 3-7 November 2003, the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) advanced the Proposed Draft Revised Standard for Infant Formula to Step 5 of the Codex prodedure pending adoption by the 27th Session of the Codex Alimentarius Commission (July 2004).

The CCNFSDU also agreed that a Working Group would be convened before the next session of the committee to review the comments and proposals for compositional requirements in order to facilitate discussions at the plenary. (Codex ALINORM 04/27/26 , para. 100 – 102)

The present Proposed Codex Draft Revised Standard for Infant Formula at Step 5 contains the following provision (Appendix V to Codex ALINORM 04/27/26):

"3. Essential Composition and Quality Factors

[3.1 Essential Composition]

3.1.3 Infant formula prepared ready for consumption shall contain per 100 kcal [100 kJ] the nutrients within the following minimum and maximum levels. The general principles for establishing these levels are identified in Annex II of this standard.

a) Protein

(i) Protein content = nitrogen content x [6.25 or 6.38] ...”

Having followed the debate in CCNFSDU, IDF noted the suggestion to revise the established conversion factor for milk of 6.38 in favour of a universal nitrogen conversion factor of 6,25 x nitrogen as determined by the Kjeldahl method for all proteins, based on an "unweighted average" nitrogen content of many food proteins of ca 16%. In this regard reference was made to the EU Scientific Committee for Foods that has recommended application of a conversion factor of 6,25 for proteins in infant formulae and follow-on formulae for simplification purposes[1].

IDF position on proposed conversion factors for calculation of protein content based on determination of nitrogen by the Kjeldahl method

IDF recommends that the same nitrogen conversion factor for milk proteins i.e. N x 6.38 be used for the milk protein component in formula as is generally used in other Codex texts and as implemented in the dairy sector throughout the world. The rationales for this recommendation is further elaborated below and concerns:

1. The factor 6.38 is used by Codex and in national regulations for decades:
    a. in relation to mandatory compositional criteria for milk protein content;
    b. in relation to milk payment to farmers;
    c. in the price-setting of dairy products traded at the national and international market.
2. The factor 6.25 represents an underestimation of the actual milk protein content. Its use would de facto require that the milk protein content in infant formula be increased by 2-3%, if the compositional criterion for protein content was retained.

IDF supports the retention of the difference between the two categories of proteins and their respective conversion factors of 6.38 for milk protein and 6.25 for vegetable protein.

Scientific aspects

Determination of the protein content of milk or other foodstuffs is commonly done by analysis of total nitrogen according to reference method of Kjeldahl. Total nitrogen is the sum of that derived from amino acids, which generally represent the vast majority, and that from non-protein nitrogen (NPN) sources, generally minor in quantity, existing in the foodstuff. Total nitrogen derived from the analysis is converted into protein by multiplying by a factor which takes into account the nitrogen content of a known or average amino acid composition.

A conversion factor of 6,38[2] for milk and milk products, based on a total nitrogen content of 15,67%, has been widely accepted and is consistent with the AOAC Official Methods (1993 edition of "Methods of Analysis for Nutrition Labelling"), and with the Joint ISO/IDF Standards for Milk: Determination of Nitrogen Content, Part 1 to 5 (ISO 8968-1 - 5:2001 / IDF 20-1 - 5:2001). Soy protein has a protein nitrogen content of 17,5%, giving a conversion factor of 5,7[3]. Other proteins from vegetable sources have factors between 5 and 6[4]. It must be recognized that all these factors represent an approximation. The scientific approach would be to apply a specific conversion factor according to the true chemical composition of each protein. However, this would be extremely complicated to apply in practice.

[1] Report of the EU Scientific Committee on Food on the revision of essential requirements of infant formulae and follow-on formulae (May 2003).

[2] Hammersten,1883, Z Physiol Chemie 7:227.

[3] C.V. Morr 1982, J Food Science 47: 1751.

[4] J. Mossé 1990, Agric.Food Chem. 38:18.

Adopting a universal factor of 6,25 would obviously result in an underestimation by about 2% of the actual protein content of milk, and serious overestimation of the protein content of proteins from vegetable sources. In the case of soy protein the actual protein content would be overestimated by approximately 9%.

Regulatory and economic aspects

It must also be taken into consideration that two factors, 6,38 for milk, and 6,25 for all other proteins have been used in national regulations and standards as well as in the Codex Alimentarius for many years[5]. Revising this factor to 6,25 for all proteins would require a complete revision of most of these regulations and standards world wide, including food labelling and nutrition labelling, at national and international levels.

Besides, milk payment systems for farmers world-wide are based in part on the protein content of milk using the 6,38 factor.

In regard to the Proposed Draft Revised Standard for Infant Formula, it should be noted that a universal factor of 6.25 would fail to recognize the nutritional quality of cows' milk in comparison with other proteins and will require manufacturers of infant foods to add additional 2-3% protein to their formula in order to comply with the minimum protein content as stipulated in the table of section 3.1.3 of the present Codex proposed draft standard. Thus in the range of protein permitted, increases from 1.8 to 3.0 g/100kcal for N x 6.38 to the equivalent of 1.84 to 3.1g/100kcal if the factor of N x 6.25 was used.

International Special Dietary Foods Industries

ISDI PROPOSAL	JUSTIFICATION
TITLE: Proposed revised standard for infant formula ~~[~~and ~~formulas~~ **food** for special medical purposes intended for infants~~]~~	Replace "formula" by "foods" in order to be consistent with the Codex Standard for the labelling of and claims for foods for special medical purposes (CODEX STAN 180-1991)
PREAMBLE ~~[~~This standard is divided into two sections. Section A refers to Infant Formula, and Section B deals with ~~Formulas~~ **Foods** for special medical purposes intended for Infants~~]~~	"P" is missing in the title of this section Replace "formula" by "foods" in order to be consistent with the Codex Standard for the labelling of and claims for foods for special medical purposes (CODEX STAN 180-1991)
Section A: Infant Formula	

[5] Some examples of regulations referring to factor 6,38 for milk:

- Codex General Standard on food labelling [CODEX STAN 1-1985 (rev. 1-1991)]: new "class name" for milk protein: 50% of milk protein m/m in dry matter; milk protein content: Kjeldahl nitrogen x 6,38 (Report of the 26th session of the Codex Alimentarius Commission, ALINORM 03/41)
- Codex Guidelines on nutrition labelling, [CAC/GL 2-1985 (Rev. 1-1993)]
- Codex Stan A-18 (1995, Rev. 1-2001) for Edible Casein Products
- Codex Stan A-15 (1995, Rev. 1-2003)for Whey Powders
- Codex Standard for Fermented Milks (adopted 2003)
- EU Directive 85/503 on methods of analysis for edible caseins
- EU Directive 91/321 on infant formulae
- EU Directive 92/46/EEC on the hygiene of milk and milk products

1. SCOPE **1.3** The application of this section of the Standard should take into account the recommendations made in the International Code of marketing of breast-milk Substitutes (1981), the Global Strategy for Infant and Young Child Feeding and World Health Assembly resolution WHA 54.2 (2001) ~~and [WHA 55.25 (2002)].~~	Delete reference to WHA 55.25 WHA Resolution 55.25 asks Codex Alimentarius Commission to take into consideration WHO policy, in particular the Code of marketing of breast milk substitutes, resolutions WHA 54.2 and "other relevant resolution of the Health Assembly". The latest therefore includes future texts. ISDI believes that CCNFSDU can not commit to future texts that are not known. If there are new resolutions relevant for CCNFSDU, they need to be discussed by the Committee before being referred to in a Codex Standard.
2. DESCRIPTION **2.1. Product definitions** 2.1.2 [~~The safety and nutritional adequacy of infant formula shall be scientifically demonstrated in meeting the nutritional requirements of the infants for whom they are intended.~~]	Delete this section. While strongly supporting the principle laid down in this section, ISDI feels it is redundant with other sections. Indeed, an infant formula which complies with the standard should be safe and adequate. Section 3 on Essential composition ensures that a formula manufactured according to this standard meets the nutritional requirements of the infants, while sections 4, 5, 6 will cover the safety aspects linked with additives usage, contaminants and hygiene respectively.
3.1. Essential Composition 3.1.1 Infant formula is a product based on milk of cows or other animals and/or other ingredients, which have been proven to be suitable for infant feeding. ~~[~~All ingredients and food additives used shall be gluten free.~~]~~	Delete [ ]
3.1.2 Infant formula prepared ready for consumption, **with safe and suitable water,** in accordance with instructions of the manufacturer shall contain per 100 ml not less than 60 kcal (250 kJ) and not more than [70 ~~or 75~~] kcal ([295 ~~or 315~~] kJ) of energy.	Although mentioned in other sections of the standard, it should be made clear that formula should be prepared using safe and suitable water. ISDI supports a maximum energy level of 70kcal/100ml

a) Protein (i) Protein content = nitrogen content x [~~6.25~~ or 6.38] **for cow's milk protein and protein hydrolysate** **Protein content = nitrogen content x 6.25 for soya protein isolates and protein hydrolysate.** **Protein content = nitrogen content x CF for all other protein isolates and protein hydrolysates** **(CF: conversion factor to be determined by most up to date scientific data)**	- 6.38 is the nitrogen conversion factor for milk proteins has been used in national regulations and standards as well as in the Codex Alimentarius for many years[6] and is consistent with the AOAC Official Methods and with the Joint ISO/IDF (International Dairy Federation) Standards for Milk: Determination of Nitrogen Content. - switching to a factor of 6.25 would fail to recognize the nutritional quality of cows' milk over other proteins and will result in an additional 2-3% higher protein intake by infant, which goes against the current paediatric opinion. - The factor 6.38 is used throughout many worldwide legal texts for cows' milk protein and its protein constituents, whey and casein that are used in the manufacture of infant formulae and is also the conversion factor recognized in Codex Alimentarius standards (further justification in Annex:convfact) Section 3.1. allows the use of other protein sources. The conversion factor for these other protein sources needs to be appropriately chosen.

[6] Some examples of regulations referring to factor 6,38 for milk:

- Codex General Standard on food labelling [CODEX STAN 1-1985 (rev. 1-1991)]: new "class name" for milk protein: 50% of milk protein m/m in dry matter; milk protein content: Kjeldahl nitrogen x 6,38 (Report of the 26th session of the Codex Alimentarius Commission, ALINORM 03/41)
- Codex Guidelines on nutrition labelling, [CAC/GL 2-1985 (Rev. 1-1993)]
- Codex Stan A-18 (1995, Rev. 1-2001) for Edible Casein Products
- Codex Stan A-15 (1995, Rev. 1-2003)for Whey Powders
- Codex Standard for Fermented Milks (adopted 2003)
- EU Directive 85/503 on methods of analysis for edible caseins
- EU Directive 91/321 on infant formulae
- EU Directive 92/46/EEC on the hygiene of milk and milk products

3.1.3 a)(ii) For an equal energy value the formula must contain an available quantity of each essential and semi-essential amino acid at least equal to that contained in the reference protein (breast-milk as defined in Annex 1); nevertheless, for calculation purposes, the concentration of methionine and cystine may be added together ~~[unless the methionine to cystine ratio exceeds 2.0].~~ **as well as phenylalanine and tyrosine**	There should be no criteria for allowing the summing up of methionine and cystine: - Products concerned by such a criteria are all products in which the protein source is based exclusively on unmodified cows' milk protein (where the ratio is about 3) which represent in many countries a significant part of the infant formula market. This type of casein-predominant formulae have been used in infant feeding for more than 100 years, and have been proven to ensure adequate growth and health of the infant. - All other experts recommendations (FAO/WHO, LSRO, FNB 2002) agree with the addition of methionine and cystine for calculation of protein quality. - Several studies have compared growth and biochemical parameters in infants fed casein-predominant and whey-adapted formulae. For the same protein content, no study has ever been able to show differences in growth characteristics between casein-predominant and whey-adapted formulae. (Further justification in Annex:summethcyst) Regarding metabolic pathways of amino acids, tyrosine can be derived from phenylalanine and thus, these two amino acids should be added together as are methionine and cystine.
~~[non-protein nitrogen (formulae made from intact protein), <15% of total nitrogen]~~	Delete this criteria - As long as minima for essential amino acids are determined, ISDI wonders what a limitation on NPN content will bring in terms of additional safety or guarantee on the nutritional value of the formula - NPN in formula can be increased by the addition of free amino acids, choline, nucleotides, carnitine, taurine, all of which have a particular nutritional function therefore NPN should not be limited. ISDI questions the availability of a validated and feasible method for the analysis of NPN

Nutrients (per 100 kcal, unless otherwise stated)	***Minimum***	***Maximum***	ISDI comment
a) Protein[7] [g]			
~~Cow's~~ **all** milk protein **and their hydrolysates**	1.8[8]	3	There is no reason to have a separate category for protein hydrolysates based on milk compared to the intact milk protein

[7] Calculation of protein content: N x [6.25 or 6.38]; [non-protein nitrogen (formulae made from intact protein) <15% of total nitrogen]

[8] Infant formulae containing 1.8 g/100 kcal should be clinically evaluated

Soy protein and its hydrolysates ~~Protein hydrolysates~~	[~~1.8 or~~ 2.25~~]~~	3	The minimum level of 2.25 for soy protein has a long history of safe use
Other protein and their hydrolysat	**2.25**	**3**	This is in line with section 3.1.1
L-carnitine [mg]	~~[~~≥1.2 ~~]~~	N.S.[9]	
~~Addition of~~ taurine [mg]	~~[~~0~~]~~	~~[~~12~~]~~	
Nucleotides, ~~if~~ as added[10] mg	~~[~~0~~]~~	~~[5]~~ **16**	"as" instead of "if": nucleotides coming from raw material should be taken into account since they are not useful for the infants. Maximum should be increased to 16 mg/100 kcal. These levels are supported by extensive analytical and clinical data, and are in line with the LSRO (Life Sciences Research Office) recommendations (1998). (Further justification in Annex: nucleo)
b) Fat and fatty acids			
Total fat [g]	4.4	~~[6.0 or~~ 6.5~~]~~	ISDI does not see any reason to change the maximum levels and therefore wants to retain a maximum of 6.5
[Phospholipids]	N.S.	~~[≤ 1~~ **2** g/L~~]~~	If a maximum level is to be set for phospholipids for nutritional purposes, it should be 2g/l because it is the level needed in order to achieve the recommended minimum level of AA and DHA with the ingredient egg lecithin. (Further justification in Annex: lecithin)
[Inositol] [mg]	~~[~~4~~]~~	~~[~~ 40 ~~]~~	No minimum recommended as there is no science to support it.
~~[~~ Lauric and myristic acids ~~]~~		~~[~~Together ≤ 20% of total fatty acids~~]~~	
Linoleic acid [g]	~~[~~0.3 ~~or 0.5]~~	~~1.2~~	Min: 0.3 is the level in the present Codex Standard, there is no new scientific data justifying a change. Max: There are no safety concerns regarding high levels of linoleic acid

[9] N.S. = not specified
[10] Maximum content per nucleotide as specified in the text. (see end of table).

~~*[Formulae without added LCPUFA]*~~			There is no science showing that there is a need to discriminate between the formula with or without LCPUFA. Moreover it adds complexity to the Standard.
∝-linolenic acid [mg]	~~[≥ 50 or 100]~~	N.S.	The current state of science does not show a need to set a higher minimum level (further justification in Annex: ala
Linoleic/∝-linolenic ratio	5	15	Agree
~~*[Formulae with added LCPUFA]*~~			
~~∝-linolenic acid [mg]~~[11]	~~[≥ 50 mg]~~		Delete also the footnote
~~Linoleic/∝-linolenic ratio~~[11]	~~[5-20]~~		
~~[~~ n-6 LCPUFA ~~]~~	**N.S**. ~~[≤2% of total fatty acids]~~	**2% of total fatty acids**	
~~[Arachidonic acid]~~	~~[≤1% of total fatty acids]~~		There is no reason to set a maximum level for arachidonic acid because there is already a maximum level for n-6 LCPUFA which has C20 andC22 polyunsaturated fatty acids.
[n-3 LCPUFA]	**N.S**. ~~[≤1% of total fatty acids]~~	**1% of total fatty acids**	
~~[~~ Ratio EPA/DHA (wt/wt) ~~]~~	~~[<1]~~	**1**	
~~[~~ Cottonseed/sesame oils	~~No use of these type of oils]~~ **The use of sesame seed oil and cotton seed oil is prohibited**		Proposed wording avoids any misinterpretation. Moreover, such prohibition should be in section 3.6 "Specific prohibitions"
~~[Conjugated linoleic acid(CLA)~~	~~No intentional addition]~~		Although, at this moment, it is not suitable to add CLA, it should not be prohibited since research is ongoing on this matter and more scientific information on the safety and benefit of CLA and its interaction with PUFAs (LA and ALA) may become available.

[11] ~~If DHA content >0.2% of total fatty acids~~

~~[~~*Trans* fatty acids	~~≤ 3 or~~ 4% of total fatty acids]		Seasonal variation of trans fatty acid content in milk variation is very high. Furthermore, there is no solid evidence of detrimental effect of *trans* fatty acids in development and human milk fat contains up to 17% *trans* fatty acids (further justification in Annex: transfat)
Erucic acid	N.S.	~~[~~≤1% of total fatty acids~~]~~	
c) Carbohydrates			ISDI suggests to add "digestible" in front of the heading "carbohydrate"
Total carbohydrates [g]	9	14	
~~[~~Lactose in cows' milk protein-and protein hydrolysates formulae [g]	~~≥ 4.5]~~		
~~[Lactose in soy protein formulae~~	~~No requirement]~~		Superfluous
~~[Saccharose~~	~~None in cows' milk protein and soy protein formulae~~ ~~≤ 20% of total carbohydrates in protein hydrolysates formulae~~]		There is no scientific evidence to limit Saccharose in IF (further justification in Annex: sucrose)
~~[Fructose~~	~~None]~~		This criteria should be in section 3.6 "Specific prohibitions"
~~[~~Glucose	No intentional addition to formulae based on intact proteins, ~~≤ 2 g in formulae based on protein hydrolysates]~~	**2 g in formulae based on protein hydrolysates**	
~~[~~Maltose, maltodextrins, **glucose syrup**	Unrestricted~~]~~		Glucose syrup is used by many manufacturers as a replacement for lactose in soya protein based infant formula, to assist with palatability. The grades used, whilst having a dextrose equivalent of greater than 20, contain only very low levels of glucose and less disaccharides than human milk. The osmolality of formula containing glucose syrup is thus lower than most formula containing lactose as the carbohydrate source.

[Starches	30% of total carbohydrates (≤ 2 g/100 mL) as precooked or gelatinised naturally gluten-free starches No starches modified by enzymatic cross-linking or stabilisation]		
d) Vitamins	ISDI agrees with point 4 of the General principles for establishing min and max values, stating that for those nutrients without evidence of adverse effect, maximum levels shall be set for **guidance** purposes. The levels proposed, in bold, by ISDI take into account losses during shelf life and encompass variability of raw material, as also suggested in point 6 of the General Principles		
Vitamin A [µg RE][12]	60	180	
Vitamin D [µg][13]	1	2.5	
Vitamin E [mg α TE][14]	≥0.5 mg α TE/g PUFA [(corrected for double bond, see footnote [15])], but in no case less than 0.5/100 kcal	~~[~~5~~]~~	Delete part of the footnote "per g of polyunsaturated fatty acids, expressed as linoleic acid" because it is not meaningful.
Vitamin K [µg]	4	~~[~~20~~]~~	
Thiamin [µg]	~~[~~40 ~~or 60]~~	~~[~~300~~]~~	
Riboflavin [µg]	~~[~~60 ~~or 80]~~	~~[400]~~ **450**	
Niacin [µg]	~~[~~300 ~~or 800]~~	~~[~~1200~~]~~	As preformed niacin
Vitamin B6 [µg]	35	~~[165]~~ **300**	
Vitamin B12 [µg]	0.1	~~[~~0.5~~]~~	
Pantothenic acid [µg]	~~[~~300 ~~or 400]~~	~~[~~2000~~]~~	

[12] expressed as retinol equivalent (RE). 1 µg RE = 3.33 IU Vitamin A

[13] Calciferol. 1 µg calciferol = 40 IU Vitamin D

[14] Alpha-Tocopherol-Equivalent (TE)

[15] 0.5 mg α-TE/1 g linoleic acid (18:2n-6); 0.75 mg α-TE/1 g γ-linolenic acid (18:3n-3); 1.0 mg α-TE/1 g arachidonic acid (20:4n-6); 1.25 mg α-TE/1 g eicosapentaenoic acid (20:5n-3); 1.5 mg α-TE/1 g docosahexaenoic acid (22:6n-3)] or [~~per g of polyunsaturated fatty acids, expressed as linoleic acid]~~.

Folic acid [µg]	~~[~~4 ~~or 10]~~	~~[~~30~~]~~	
Vitamin C [mg][16]	~~[~~8 ~~or 10]~~	~~[30]~~ **40**	The maximum level of 30mg/100kcal is justified for infant formulae; however ascorbic acid is also used as an antioxidant in LCPUFA preparations (to protect LCP in liquid phase). Levels up to 75mg/l (or 11.2mg/100kcal) are permitted in the EU for this function. As one cannot distinguish between the different levels of vitamin C used for different functions, an upper limit of 36 mg/100 kcal rounded up to 40 mg/100kcal is needed.
Biotin [µg]	1.5	~~[7.5]~~ **20**	
e) Minerals and Trace Elements			
Iron [mg]			
Cow's milk protein and protein hydrolysate formulae	~~[~~0.3 ~~or 0.5]~~	~~[1.3 or 1.5]~~ 2.5	The maximum levels of 1.5 or 2 are rather low if they apply to countries where major iron deficiencies are encountered. ISDI supports the AAP-CON recommendation of 2.5 mg/100 kcal (1993) for the maximum level.
Soy protein formulae	~~[~~0.45 ~~or 1.0]~~	~~[1.9 or 2.0]~~ 2.5	
Calcium [mg]	50	~~[~~140~~]~~	
Calcium/Phosphorus-Ratio	1.0	~~[2.0 or~~ 2.2]	This value is safe and physiological and is regularly found in breast milk (Further justification in Annex: Ca_P_ratio)
Phosphorus [mg]	~~Cows' milk protein and protein hydrolysate formulae:~~ 25 ~~Soy protein formulae: [30] [Bioavailable phosphorus, if measured: 20-70 mg]~~	~~90~~ ~~[~~100~~]~~	ISDI does not believe there is a need to distinguish between these formulas, moreover, this adds unnecessary complication.
Magnesium [mg]	5	15	
Sodium [mg]	20	60	
Chloride [mg]	50	~~[125~~ or 160]	The low maxima for potassium and

[16] expressed as ascorbic acid

Potassium [mg]	60	[~~145 or 160~~] **200**	chloride, which have been proposed, deviate from the recommendations of several authorities including the U.S. Infant Formula Act (IFA), the Canadian requirements, as well as the current Codex infant formula standard. In these recommendations, the electrolytes have maxima of 200 mg/100 kcal for potassium and 150 mg/100 kcal for chloride.
Chromium [µg]	No recommended minimum and maximum levels		
Manganese [µg]	[1 ~~or 5~~]	[100]	
Molybdenum [µg]	No recommended minimum and maximum levels		
Fluoride [µg]	N.S.	[100]	
Iodine [µg]	[~~5 or~~ 10]	[50] ~~100~~.	A minimum level of iodine of 10 µg/100 kcal is justified by recently established recommendations for infants[17]. Max level: Agree with 50µg/100kcal
Selenium [µg]	[N.S.~~ or 3~~]	[9]	ISDI is opposed to the setting of a minimum level of selenium, but if it is to be set it should be 1µg/100kcal.
Copper [µg][18]	[~~20 or~~ 35]	[~~80 or~~ 100]	
Zinc [mg]			
Cow's milk protein and protein hydrolysate formulae	0.5	[1.5]	
Soy protein formulae	0.75	2.40	
f) Choline [mg]	7	[~~30 or~~ 50]	A max of 50 mg/100kcal is necessary in order to achieve the recommended arachidonic acid (AA) level (Further justification in Annex: choline)

[17] RDA examples to demonstrate that the minimum level should be higher than 5 µg/100 kcal are:
- Germany, Austria, Switzerland (2000): 40 µg/day for 0-4 months and 80 µg/day for 4-12 months old infants
- USA Food & Nutrition Board / Institute of Medicine: 110 µg/day for 0-6 months and 130 µg/day for 7-12 months old infants
- FAO/WHO (2001): 15 µg/kg body weight/day (equivalent to 15 µg/100 kcal assuming intake of 100 kcal/kg b.w.) for 0-6 months and 135 µg/day for 7-12 months
- LSRO (1998): 8 µg/100 kcal or 40 µg/day for 0-6 months old infants (although it is recognised that no studies have been carried out at this minimum level)

[18] [Adjustments may be needed in these levels for infant formula made in regions with a high content of copper in the water supply]

[Nucleotide [mg / **100kcal**]	**Minimum**	**Maximum**	
Cytidine 5'-monophosphate(CMP)	N.S.	~~2.50~~ **6.5**	See further justification in Annex: nucleo
Uridine 5'-monophosphate(UMP)	N.S.	~~1.75~~ **3.7**	
Adenosine 5'-monophosphate(AMP)	N.S.	~~1.50~~ **3.0**	
Guanosine 5'-monophosphate(GMP)	N.S.	~~0.50~~ **3.5**	
Inosine 5'-monophosphate(IMP)	N.S.	1.00	
Total Nucleotides	NS	16.0	

3.6 Specific prohibitions The product and its components shall not ~~[~~contain commercially hydrogenated oils and fats and shall not~~]~~ have been treated with ionizing radiations	ISDI agrees
4. <u>FOOD ADDITIVES</u> **4.1 Thickening agent** ~~4.1.1~~ INS 412 Guar gum ~~4.1.2~~ INS 410 Carob bean gum INS 410: Carob bean gum (locust bean gum) ~~0.1g~~ **0.5g** in all type of formula **INS 472e: Diacetyltartaric and fatty acid of esters of glycerol GMP** **INS 308: Delta-tocopherol** **INS 309: Gamma-tocopherol** **1 mg in all types of infant formula singly or in combination**	For simplification, the sub-numbering system for each additive can be deleted since they are already identified by their INS number. Change the level of INS 410 Non caloric thickening agent. Emulsion stabiliser, adjustment of viscosity. Used in some anti regurgitating formulas. If a lower level is used, the solution separates very quickly in phases. Carob bean floats to the upper level of the solution very quickly, so a minimum viscosity is needed to prevent this phenomenon. Addition of INS 472e Retains homogeneity of liquid products and liquid reconstituted powder especially in formulas where whole proteins are not used. Has a high HLB, works better in combination with additive 322 and 471. Has a GRAS status in the US Addition of INS 308 and 309 Alone or in combination to stabilise preparations containing fats and vitamins. Synergistic effect with additives 304 and 305. They are used as natural antioxidants and are much more effective in preventing oxidation of vulnerable fatty acids than alpha tocopherol

~~[~~ 4.5 Carry-over of Food Additives ~~]~~	Remove [ ] from the whole section
9. LABELLING **9.1.3** If cow's milk is the ~~only~~ **main** source of protein, the product may be labelled "Infant Formula Based on Cow's Milk" 9.1.5 ~~[No health claims shall be made regarding the dietary properties of the product]]~~ **Nutrition and health claims shall be permitted for foods for infants and young children where they have been demonstrated in rigorous studies with adequate scientific standards, and where they are accepted by or acceptable to the competent authorities of the country where the product is sold, as required by Section 7.1.2 of the Codex Guidelines for Use of Nutrition and Health Claims.**	Many other components may contain some protein, such as starches, maltodextrins. Therefore ISDI suggests changing the word "only" to "main". The sentence in square brackets should be deleted and replaced by the suggested wording in bold. It is of the utmost importance that information on the dietary properties of infant formula can be communicated as: • The lack of appropriate information on these adapted foods may orient the parent to choosing non-adapted and inappropriate foods for their infants and young children. Nutrition and health claims, being true statements/information regarding the dietary properties of the foods provide important information to parents. • ISDI is not aware of any study showing that parents of infants and young children are more readily persuaded by nutrition or health claims than other adults • Some countries already allow certain health and nutrition claims in labelling of formulas and weaning foods intended for healthy infants. • Provisions ensuring that claims for foods for special dietary uses are appropriately used, have already been detailed in Section 3.1 of Codex STAN 146-1985 (Codex General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses)[19]. Finally, there is no reason to prohibit the communication of relevant information through labelling and literature if it complies with the above mentioned criteria and as long as this communication remains in line with national practices and the WHO International Code on the Marketing of Breast-milk Substitutes. The aim of the Code on the Marketing of Breast-milk Substitutes is to "*contribute to the provision of safe and adequate nutrition for infants, by the protection and promotion of breastfeeding, and* ***by ensuring the proper use of breast milk substitutes, when these are necessary, on the basis of adequate information*** *and through appropriate marketing and distribution*".

[19] This section states that these foods may not be "*described or presented in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding their character in any respect"*.

9.3. Declaration of nutritive value. (b) the total quantity of each vitamin, mineral, choline as listed in paragraph 3.1.2 of this Standard and any ~~other~~ **optional** ingredient **if added** as listed in paragraph 3.2 of this Standard per 100 grammes of the food as sold as well as per 100 mililiter of the food ready for use, when prepared according to the instructions on the label.	Using the wording "optional ingredient" is in line with section 3.2. Including "if added" avoids misinterpretation.
9.5. Information for use 9.5.1 Directions as to the **appropriate** preparation and use of the food, and its storage and keeping after the container has been opened shall appear on the label or on the accompanying leaflet.	The word "appropriate" should be added for sake of clarity.
9.6. Additional labelling requirements **9.6.1. d)** ~~instructions for appropriate preparation~~	This is redundant with section 9.5.1 and should be deleted
9.6.4.and in any case from the age **of** ~~over~~ six months	Grammatical correction
9.6.5. ~~The product shall be labelled in such a way as to avoid any risk of confusion between infants formula, follow-up formula and formula for special medical purposes~~	This sentence is superfluous and should be deleted
9.6.6 [No [nutrition and] health claims shall be made regarding the dietary properties of the product]	See comments for section 9.1.5

ANNEX1

Essential and semi-essential amino acids in breast milk

For the purpose of this Standard the essential and semi-essential amino acids in breast milk, expressed in mg per 100kJ and 100kcal, are the following: .	The present table is inappropriate and should be reviewed.

ANNEX 2

General principles for establishing minimum and maximum values for the essential composition of infant formula

4. [Maximum values for nutrients with a documented risk of adverse health effects will be determined using a science-based risk assessment approach. Maximum values for those nutrients without evidence of adverse effects serve as guidance levels for manufacturers. The approach to setting maximum levels for guidance purposes shall be made transparent and comprehensible.]	Agree

5. When establishing minimum and maximum amounts, the following should be taken into account: a) bioavailability, processing losses and shelf-life stability from the ingredients and formula matrix, ~~b) total levels of a nutrient in infant formula, taking into account both naturally occurring nutrients in the ingredients and added nutrients,~~ ~~c) the inherent variability of nutrients in ingredients and in water that may be added to the infant formula during manufacture.~~ **b) total levels of a nutrient in infant formula, taking into account both naturally occurring nutrients and their variability in the ingredients and added nutrients**	Point 5b) and point 5c) address the same matter of ingredient variability,
7. In establishing minimum or maximum amounts of nutrients per 100 kcal (or per 100 kJ) of infant formula based on consideration of reference values for the nutrients expressed as units per daily intake or per kilogram of body weight, the following assumptions will be used: ~~a)~~ The mean intake of prepared formula for infants from birth to six months of age is 750 ml per day. This is based on the ~~following~~ assumptions **of** : ~~i)~~ a representative body weight for an infant over this period would be 5 kg and a representative caloric intake would be 500 kcal per day (or 100 kcal/kg/day) over the first six months; **resulting in a formula proving about 67 kcal/100 ml]** **[**~~ii) prepared formulas provide about 67 kcal/100 ml].~~ Modifications of the approach may be needed when there is justification for deviating from one or more of these assumptions with regard to the specific formula product or specific infant population group.	Editorial changes

More detailed justification for some ISDI comments:

<u>Protein</u>

<u>Conversion factor</u>

ISDI does not support the use of the same conversion factor 6.25 for both milk and soy protein and favours keeping the ones previously proposed i.e. 6.38 for milk proteins and protein partial hydrolysates and 6.25 for soy protein and protein partial hydrolysates.

- This recommendation to have one common factor 6.25 fails to recognize the nutritional quality of cows' milk over other proteins and will require manufacturers to add additional 2-3% protein to their formulae. Thus in the range of protein permitted, increases from 1.8 to 3g/100kcal for N x 6.38 to the equivalent of 1.84 to 3.1g/100kcal if the factor of N x 6.25 is used.

- The factor N x 6.38 for nitrogen conversion to protein is used for cows' milk protein and its protein constituents, whey and casein that are used in the manufacture of infant formulae throughout in throughout worldwide legislation including Codex Alimentarius Standards.

  Thus, all milk and milk protein products purchased for use in the manufacture of milk protein based products will be received with analytical data calculating the protein content using the factor N x 6.38 and this will have to be converted to N x 6.25 for the manufacture of infant formula and follow-on formulae.

Sum of methionine and cystine

ISDI is against the proposal to forbid the summing up of methionine and cystine if the methionine / cystine ratio is >2.

- Products concerned by such a criteria are all products in which protein source is based exclusively on unmodified cows' milk protein. This type of casein-predominant formulae have been used in infant feeding for more than 150 years, and have been proven to ensure adequate growth and health of the infant. They represent in many countries a significant part of the infant formula market (in France more than 90%).

  Although less scientifically advanced than whey-adapted formulae, they are prescribed for a number of "practical" advantages: slower gastric time ensuring a better feeling of satiety, well-formed stools with a colour and a consistency considered as more pleasant by the mother.

- Moreover this proposal goes against all other expert recommendations (FAO/WHO, FNB 2002), which all agree with addition of methionine and cystine for calculation of protein quality and at the same time does not provide the scientific justification for this threshold of 2.0

- Finally, several studies have compared growth and biochemical parameters in infants fed casein-predominant and whey-adapted formulae. For the same protein content, no study has ever been able to show differences in growth characteristics[20,21] between casein-predominant and whey-adapted formulae. Plasma amino acids profiles are different between casein-predominant and whey-adapted formulae, but they are equally different from breast-fed babies. Whereas casein-predominant – fed babies show higher levels of tyrosine and phenylalanine than breast-fed infants, infants fed whey-adapted formulae will present with higher levels of threonine, lysine, leucine and isoleucine. Plasma cystine levels do not show any difference between the two types of formulae[22,23,24] confirming that cystine is not a limiting factor in cows' milk protein based infant formulae.

Nucleotides

Justification for higher levels of nucleotides

The allowed levels of nucleotides that may be added to infant and follow on formula should be increased to the ones proposed below. These levels are supported by extensive analytical and clinical data, and are in line with the LSRO (Life Sciences Research Office) recommendations (1998).

	Minimum	Maximum	
		Mg/100 kJ	Mg/100 kcal
CMP	NS	1.56	6.5
UMP	NS	0.89	3.7
AMP	NS	0.72	3.0

[20] Harrison GG, Graver EJ, Vargas M, Churella HR, Paule CL. Growth and adiposity of term infants fed whey-predominant or casein-predominant formulas or human milk. J Pediatr Gastroenterol Nutr 1987; 6(5):739-747

[21] Lonnerdal B, Chen CL. Effects of formula protein level and ratio on infant growth, plasma amino acids and serum trace elements. II. Follow-up formula. Acta Paediatr 1990; 79(3):266-273.

[22] Janas LM, Picciano MF, Hatch TF. Indices of protein metabolism in term infants fed human milk, whey- predominant formula, or cows' milk formula. Pediatrics 1985; 75(4):775-784.

[23] Janas LM, Picciano MF, Hatch TF. Indices of protein metabolism in term infants fed either human milk or formulas with reduced protein concentration and various whey/casein ratios. Journal of Pediatrics 1987; 110(6):838-848.

[24] Jarvenpaa AL, Rassin DK, Raiha NC, Gaull GE. Milk protein quantity and quality in the term infant. II. Effects on acidic and neutral amino acids. Pediatrics 1982; 70(2):221-230.

GMP	NS	0.84	3.5
IMP	NS	0.24	1.0
Total Nucleotides	NS	3.8	16.0

Introduction

Breast-fed and formula-fed infants are known to differ in their rate of development of organ systems and in some functional outcomes. The development of the immune system in breast-fed infants has been shown to be enhanced relative to that of formula-fed infants. Breast-fed infants have shown more robust responses (higher antibody titres) to H. *influenza*e B (Hib) (Pabst and Spady, 1990), diphtheria toxoid and oral polio virus (Hahn-Zorick *et a*l., 1990). They have more rapid development of secretory IgA (Fitzsimmons, *et al*., 1994). Breast-fed infants also have lower diarrhoeal disease morbidity, even in developed countries.

Specific interest in nucleotides[25] derives from the knowledge that nucleotide levels in human milk are higher than bovine milk and bovine milk-based infant formulas and that the nucleotide patterns in the milks of various animals seem to have species specificity (Thorell *et a*l., 1996; Schlimme *et al*., 2000). Additionally, extensive animal and some human data pointed to a role for nucleotides in immune response[26].

(2) ANALYSIS OF NUCLEOTIDES IN HUMAN MILK

A comprehensive assessment of the nucleotide content of human milk was undertaken. A review of the literature indicated that:

- Sample sizes and the numbers of women from whom milk was collected and analysed were, with some exceptions, relatively small.
- Virtually every study used a slightly different method,
- Each method looked at selected different compounds in human milk that are sources of nucleotides, including complex ribonucleotides, nucleotides, nucleosides and other nucleotides-containing compounds.

Based on the above, a reanalysis of the content of nucleotides in human milk was undertaken. This led to the 1995 paper by Leach *et al*., (1995, "Leach") describing the total potentially available nucleosides in human milk.[27] Leach was unique in being the first paper to look at "all" forms and sources of ribonucleic acids in human milk *in the same study* using modern HPLC techniques coupled with simulated digestion. Leach recognized that after digestion, all of these forms were a potential dietary source of nucleic acids for the infant. Leach reported mean levels of approximately 10 -11 mg/100 kcal, with levels up to approximately 16 mg/100 kcal. In 1996, Thorell and colleagues, working in Stockholm and using a combination of HPLC and chemical methods, reported total nucleic acid content of human milk, including DNA, somewhat lower, "although within the same range" as Leach. They also reported that there were enzymes in human milk and in foetal intestinal homogenates capable of degrading nucleotides. A subsequent study by Tressler, *et al*. (2003, "Tressler") confirmed the data of Leach.[28].

The studies showed that nucleotide content changes little by stage of lactation and that the patterns of RNA, nucleotides, nucleosides and the nucleotide containing-adducts, as well as the purines and pyrimadines that

[25] In this document, the general term nucleotide will be used to refer to sources of nucleic acids in the diet except where specific papers or techniques require careful distinction of nucleotides and nucleosides. In general the discussion focuses on sources of ribonucleotides and ribonucleosides.

[26] Nucleotide-free diets lead to impaired T lymphocyte-related function (Van Buren *et al*., 1985), mice raised on nucleotide-free diets have increased mortality from Staphylococcal sepsis (Kulkarni *et al*., 1986), diets low in nucleotides negatively affected host resistance to Canadida (Fanslow *et al*., 1988), adult humans on total parenteral alimentation (without nucleotides) have decreased rejection of transplanted tissues, and rejection increases when a complete diet was introduced. This has been shown in animals to be an effect of nucleotides (Van Buren *et al*., 1983).

[27] Leach included RNA as a source of nucleotides in human milk. This inclusion was not new, as earlier analytical research shows. Uauy commented on RNA as a source of nucleotides in his chapter on nucleotides in Lebenthal's Textbook of Gastroenterology and Nutrition in Infancy in 1989 (Uauy, 1989).

[28] The Leach and Tressler studies were large – including substantially larger numbers of subjects than most previous studies – and comprehensive – examining effects of stage of lactation, race and diet. Overall, the higher levels of nucleotides in human milk were confirmed through the analysis of more than 200 women on three continents in seven countries at four stages of lactation.

comprise them, also are stable. In addition, nucleotide content is not greatly affected by diet or ethnic group - it is remarkably similar in Europe, Asia and the United States.

Thus, modern analytical approaches have shown that the levels of nucleotides in the diet of the exclusively breast-fed infant are substantially higher than previously thought. Based on these studies, Schlimme and Martin (see Schlimme 2000) have recommended that higher levels be allowed in infant formula and the expert group convened by LSRO (1998) at the request of the US FDA also made a similar recommendation.

b) Clinical research with formulas supplemented with nucleotides at 72 mg/L

Two trials of the effect of nucleotides in milk-based formulas on immune response were carried out (Pickering *et al*., 1998 – "Pickering"; Buck *et al*., 2004, "Buck"; Kuchan *et al*., 2004, "Kuchan). In both studies, immunisations were used as a tool to induce measurable endpoints – antibodies and changes in the T lymphocytes that produce them, thus probing the immune system response[29]. Changes at different time points were viewed as a reflection of the maturity of the immune system attributable to the dietary intervention. *The studies were not designed to show that infants fed nucleotide-supplemented formulas would have fewer episodes of the specific diseases against which they were being immunised*.

A total of 692 infants completed the two trials (222 control, 214 nucleotide-supplemented and 256 breast-fed). In Pickering (Trial 1), infants fed nucleotide-supplemented formula had significantly higher antibody responses to H. *influenza* type b (Hib) and Diphtheria vaccines relative to infants fed unsupplemented formula. These responses were not significantly different from those infants breast-fed for more than 6 months (about 40% of the breast-fed reference group). Infants breast-fed for less than 6 months and weaned to low nucleotides formula had lower responses. In the second trial (Buck/Kuchan), nucleotide supplementation had a significant effect only on the response to polio virus, which had not been seen in Pickering.

Notable differences occurred in both the vaccines and the immunisation schedules between the times that the two trials were conducted. During the interval between the two studies, the acellular pertussis vaccine was introduced, and other aspects of the vaccines were altered. A third polio immunisation also was added to the second trial.

These changes are important and explain why the vaccine antibody responses differed in the two trials. The acellular pertussis vaccine used in the Buck/Kuchan trial is less potent than the previously used whole cell pertussis vaccine. Use of acellular pertussis vaccines is known to result in reduced, but still protective, antibody responses not only to pertussis itself, but also to the diphtheria, tetanus and Hib vaccines (Decker and Edwards, 1999; Giuliano *et al*.,1998). In addition, Siegrist (2001) has pointed out, "…although neonatal immunisation does not generally lead to rapid and strong antibody responses, it may result in an efficient immunological priming [of T cells]..."

The cellular data make clear that the stimulation of the immune system by vaccines and other natural exposure to antigens was more than adequate to effect changes in the development of T-lymphocytes and that there was a notable effect of diet. Key findings are summarized in the table below. In general, infants fed formula supplemented with nucleotides (FN) had T cell subsets associated with more mature secondary immune responses (specific antibody production) and cell mediated immunity and not different from those of the breast-fed infant (HM). These responses were superior to those of infants fed unsupplemented formula (F).

[29] Both studies followed similar protocols. Formula-fed infants were randomised to formulas ± nucleotides, which were fed for a full year. Solid foods were allowed after 4 months of age. Breast-fed infants were enrolled concurrently and were studied under the same protocol. All infants were exclusively breast-fed for at least 2 months. At the discretion of the mother, the addition of commercially available infant formula (*unsupplemented* with nucleotides) to breast feeding was allowed thereafter; solid foods were withheld until after 4 months of age. Infants received their standard immunisations from single lots of vaccines, and in both trials the antibody response to the immunisations was determined at 6, 7, and 12 months of age. In addition, IgE (total IgE, IgE to cow milk proteins) was determined. Only limited, exploratory cellular data were obtained in the Pickering study, but one of the principal goals of the second study was an in-depth analysis of the effects of nucleotide supplementation on the maturation of the developing immune system based on an analysis of subsets of T lymphocytes.

Cell Types and Influence of Feeding

Cell Name	Function	Marker	Feeding group comparisons[1]		
			F vs HM[2]	FN vs HM[2]	FN vs F[3]
Memory/effector Th	**T helper cells which have encountered a specific antigen and proliferate, acquiring functional effector mechanisms and the ability to participate in secondary immune responses, or memory**	**CD4+CD45R0+**	**N.S**	**N.S**	F<FN
Memory/effector Tc	**T cytoxotic cells which have encountered a specific antigen and proliferate, acquiring functional effector mechanisms and the ability to participate in secondary immune responses, or memory**	**CD8+CD45R0+**	F<HM	FN=HM	F<FN
IFNγ +cells	**Cells producing IFNγ are classified as Type 1 cytokine producing cells. Type 1 responses are *generally* associated with cell-mediated immunity.**	**IFNγ+**	F<HM	FN=HM	F<FN
Tc1	**Cytotoxic T cells which produce IFNγ therefore *generally* involved in modulation of cell-mediated immunity.**	**CD8+ IFNγ+**	F<HM	FN=HM	F<FN
Th2	**Helper T cells which produce IL-4 therefore *generally* involved in modulation of humoral (antibody production) immunity.**	**CD4+IL-4+**	F<HM	FN=HM	F<FN

[1] HM = human milk, breast-fed; F = formula without added nucleotides; FN = formula with supplemented nucleotides. [2] 3-way analysis, [3] 2-way analysis. Results in bold were statistically significant. Differences between groups not detected at every time point tested.

Finally, an effect of nucleotide supplementation on the incidence of diarrhoea was found in Pickering. At the sites that prospectively collected data on diarrhoea (representing 35% of the infants studied), infants fed nucleotide-supplemented formula had significantly fewer episodes of diarrhoea than infants fed unsupplemented formula. This finding was confirmed in a later study carried out in Taiwan in 336 healthy term infants fed formulas with or without supplemented nucleotides (72mg/L) (Yau *et al*., 2003).

Conclusions

Newer analytical data show that the levels of nucleotides in breast milk are higher than previously thought. These higher levels have been endorsed by experts in the field such as Schlimme and Martin and the LSRO. Clinical trials have documented that there are beneficial effects in formula-fed infant who receive formulas supplemented with nucleotides at these levels, principally more rapid maturation of the developing immune system and a reduction in the incidence of diarrhoea, both important health outcomes.

The studies and post-marketing experience for the past 7 years in countries outside the European Union confirm that there are no safety issues[30].

Brief answer to some issues that were discussed in the report of the Scientific Committee on Food.

- **Nucleotides, nucleosides and the polymeric sources of nucleotides (especially RNA): Are these a by-product of milk production reflecting the metabolic activity of the mammary gland and the shedding of cells?**

This view is plausible based on what we know about milk production. Thorell, *et al*., summed up their views in 1996 as follows:

> Whether the nucleotides and nucleosides in human milk are actively secreted into the milk in response to a nutritional demand of the infant, or indirectly result from other metabolic events within the mammary secretory cell (i.e. synthesis of lactose, protein, and fat), is still not known. However, cellular metabolites are thought to enter milk by their secretion within Golgi vesicles, together with cytoplasmic fragments liberated during fat secretion and by diffusion across the apical membrane.

Schlimme (2000) also has been interested in whether ribonucleosides were secreted as such or formed by "post-secretory metabolic processes," but he did not reach a firm conclusion. It appears that both may occur.

It is fair to say that we do not know the precise source or regulation of many of the classical nutrients and other compounds that make human milk so unique. The most important point would seem to be: whatever the reason that nucleotides are present in human milk (active secretion, passive diffusion, cell shedding, or, most likely a combination of all of the above), they *are* present in reasonably controlled and reproducible amounts and, hence, are a normal part of the diet of all breast-fed in infants. They therefore have the potential to "exert beneficial effects in the breast fed infant" (SCF, 2003).

- **Are nucleotides from the complex sources in human milk bioavailable?**

Several lines of evidence support the proposition that complex nucleotides are digested and absorbed by the infant:

1) Enzymes are present in human milk that hydrolyze ribonucleotides.[31] (Chandon et al., 1968; Meyer et al., 1987; Ramaswami *et al.*, 1993)
2) The pancreas is known to secrete enzymes capable of digesting complex ribonucleotides. (Carver and Walker, 1995) There is no reason to think that infants are less able to digest ribonucleotides than other nutrients needing pancreatic enzymes for digestion, such as protein and fat. It is known that while not at an adult level early in life, exocrine pancreatic function in the infant is more than adequate.[32]

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[30] A discussion of several other issues that have been discussed in the Scientific Committee on Food are beyond the scope of this document. They are summarised briefly at the end of this section.

[31] This is one of the reasons that Thorell (1996) and Schlimme (2000) found it difficult to give a definitive answer to whether the free nucleosides in human milk were secreted as such or derived from post-secretory metabolism.

[32] This is so even in premature infants, who are able to digest and absorb amounts of protein, fat and carbohydrate sufficient to meet their increased requirements. The persistence beyond the early weeks of life of some degree of fat malabsorption in premature and most full infants is related to bile acid metabolism and not to an inability of pancreatic enzymes to hydrolyze dietary fat.

3) Enzymes that digest nucleotides have been found in foetal human small intestine (Thorell *et al*., 1996).

4) Soy protein isolates contain substantial levels of purine nucleic acids in the form of RNA. Infants fed soy formulas have serum uric acid levels that while within the normal range are higher than those of infants fed milk-based formulas with or without supplemented nucleotides or who were breastfed. In both randomised and cross-over studies, infants fed soy formulas with purine contents from RNA reduced to about 33% of that in standard soy formula had significant reductions in uric acid in serum and urine. (Kuchan and Ostrom, 2000) The logical explanation for these finding is that the purines from RNA in soy are digested and absorbed. If RNA were not digested and available to a significant degree, the uric acid levels in serum and urine would not have been affected.

- **Even if nucleotides are bioavailable, they represent a small percentage of the total nucleotide pool. Is a systemic effect likely?**

Nucleotides are considered to be semi-essential nutrients.[33] Both animal and adult human studies show that nucleotides may be semi-essential and may be beneficial in three specific circumstances: 1) periods of limited intake, 2) periods of rapid growth, and 3) during recovery from tissue injury. Normal full term infants fed formula not supplemented with nucleotides meet two of these conditions – limited intake and rapid growth. During recovery from diarrhoea, for example, the infant may meet all three.

The literature suggests that researchers in the field currently think the intestinal mucosa and lymphoid tissue in the intestine (the largest immune system "organ" in the body), are the sites of action of dietary nucleotides. One investigator has proposed that this effect on the mucosal barrier occurs through a yet to be identified mechanism involving purinergic signalling. (Grimble *et al*., 2001).

The intestinal mucosa has a high demand for nucleotides due to rapid cell proliferation and turnover. The small intestinal epithelium turns over completely every 3-6 days, and *de novo* synthesis of nucleotides in the small intestine is low to absent (LeLeiko *et al*., 1979; LeLeiko *et al*., 1983. Carver cites studies that suggest that like intestinal epithelial cells, lymphocytes in the intestinal tract may also have limited capacity for *de novo* synthesis of nucleotides and may have reduced salvage capacity as well. She concluded, "These studies suggest that proliferating lymphocytes require an exogenous supply of nucleotides for optimal function." (Carver, 1999)

Although the intake of nucleotides in breast milk is low relative to total nucleotide pools, the high requirements for and limited synthetic capacity of nucleotides by intestinal mucosa and lymphocytes point to a need for exogenous nucleotides to optimise function of these organs. The nucleotides in breast milk and in supplemented infant formula appear to be quite important for these organs. Extensive studies in animals and studies in human infants that included data on lymphocyte development, response to immunisations and effects of diarrhoeal disease morbidity are consistent with and supportive of this view.

- **Indications for relevant adverse effects of nucleotide addition at the proposed higher levels.**

The Protein-Calorie Advisory Group (PAG), 1975, concluded that the *addition* of 2 g/day and *total consumption* of 4 g/day by the adult was a reasonable upper limit for nucleic acid intake. The PAG was concerned about the relationship of purine intake to gout. We believe that the PAG built in a margin of safety in making their recommendations.

The PAG (Table II) used a 65 kg for reference adult male and calculated that an intake of single cell protein of 2 g/d equated to 30.8 mg/kg.[34] They then applied this same per kg intake to all age groups.[35] Thus, at an intake of nucleotides of 16 mg/kg (based on the proposed level), the infant would consume about half (52%) of the recommended upper limit. This still provides for a reasonable margin of safety over and above that

[33] "Nutrients may be considered semiessential if the endogenous supply is shown to be insufficient for fully normal function, but their lack does not lead to a classic clinical deficiency syndrome." (Uauy 1989)

[34] In making its calculations, the SCF used a 70 kg reference male, which lowered the per Kg intake from that in the PAG document.

[35] The PAG also stated in table II that they were assuming that intakes should be based on body weight across all ages. Without dwelling on this, it should be noted that nutrient intake recommendations are rarely constant by body weight across the spectrum of infant to adult. Two examples: protein – the suggested intakes for infants 0-6 month of life are about 1.52 g/kg/day compared with intakes of about 0.8 g/kg/day in the adult; energy – suggested intakes for the 5 kg reference infant in the SCF report are about 100 kcal/kg/day. This compares with energy intakes of adults of about 40 kcal/kg/day. Thus, a strict per kg translation of an adult recommendation to the infant may not be appropriate.

already built into the recommendation. Additionally, since formula would be the *entire* source of nucleotides during the first 4-6 months of life, it could be argued that the appropriate standard against which to judge nucleotide intake is that for *total* daily consumption recommended by the PAG – 4 G per day or 61.4 mg/kg. In this case, the infant consuming 16 mg/kg/day would be at 26% of the recommended maximum intake.

Clinical studies in infants, including milk-based formula studies and those with soy protein based formula supplemented with 72 mg/L of nucleotides (total intake 370 mg/L or 55 mg/kg), and the clinical experience around the world with formula supplemented at these levels over the past 7 years suggest there are no safety issues at the proposed levels.

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Fats

Maximum for phospholipids for nutritional purposes should be 2g/l.

In order to achieve the recommended minimum level of AA and DHA with the ingredient egg lecithin, approximately 2g phospholipids/l are needed (see model calculation below). With the limit proposed, it would not be possible to use egg lecithin for the supplementation with LCPUFA. Egg lecithin is successfully used for a long time on a big scale at levels higher than 1g/l (particularly in Germany, according to the "Munich consensus").

In addition it should be noted that there are several infant formulas with LCPUFA on the European market with a level up to 0,4 % AA in which egg yolk(phospho)lipids are the only source of AA and no adverse effects reported after consumption of these formulas.

Minimum level of alpha-linolenic acid

ISDI is opposed to the proposal from the SCF to increase the minimum level of alpha-linolenic acid to 100 mg/100 kcal. ISDI is in favour of retaining the current minimum of 50mg/100kcal in infant formulae and adopting also this level in follow-on formulae.

The recommendation to set a maximum of 100mg/100kcal comes from the European SCF report and is based on the scientific findings of the four reports of clinical trials referred to in the Lauritzen *et al* paper (2001)[36]. Of these, three were conducted with term infants and levels of ALA from 3.2 to 4.7% of the total fatty acids, with no fortification of the formula by LCPUFA, and there was no improvement in visual acuity. The fourth trial on very low birth weight infants showed only transient improvement and it could be argued that since the infants were all born preterm that this is not relevant to term infant formulae.

Moreover, these studies were small and lacked statistical power. They involved an average group size of 35 infants of which 33 were preterm, all of whom were fed formulae with ALA in excess of 2.7% of total fatty acids. In three of the four trials this level was obtained by the use of high ALA containing oils in the fat blend.

From these trials Lauritzen makes two conclusions:

- *At the present time, the data in term infants do not necessarily indicate that these infants need preformed 22:6n-3, merely that a formula with only 1.5 ALA% might not fulfil the needs for optimal development in visual function*. (Page 56 of the Lauritzen paper)
- *Furthermore, our presentation of the results indicate that an increase in 18:3n-3 intake also affects the functional development of infants, but that no trial yet has examined a large enough increase in the 18:3n-3 fatty acid intake above 2 FA% in a large enough group of infants to prove this. (Page 80)*

The European SCF report quotes the Lauritzen paper as one of the main recommendations for the increase in ALA, despite the fact that no benefit was seen in the few trials that added additional ALA at levels of up to 4.7 FA%, as well as stressing the importance of a proper balance between the precursors of the *n*-6 and *n*-3 fatty acid series, which is justified by their use of common enzymes for their metabolism to LCPUFAs.

For this reason ISDI believes that the current level of a minimum of 50mg/100kcal should be retained for infant formula, but that this should be reviewed as scientific knowledge in this field develops.

Trans fatty acids

Definition

Trans fatty acids are unsatured fatty acids that contain at least one double bond in the trans configuration. The *trans* configuration results in a greater bond angle than that of the cis configuration, which makes the carbon chain of *trans* fatty acids more extended than that of the corresponding *cis* fatty acid. As a consequence the properties of *trans* fatty acids are more comparable to that of saturated fatty acids.

Sources of trans fatty acids

Trans fatty acids are either from natural origin or produced as a result of technological processes.

A. Naturally occurring *trans* fatty acids:

Trans isomers of fatty acids occur naturally in the milk of ruminants as a result of biohydrogenation by bacteria in the rumen of animals. Since these *trans* fatty acids are of natural origin, very little, if anything, can be done from a technological point of view to reduce these naturally occurring levels.

B. Trans fatty acids generated by technological processes:

Trans fatty acids are present in variable concentrations in vegetable oils and marine oils that have been partially hydrogenated (hardened) by industrial processes. The industrial hydrogenation process generates primarily *trans* oleic acid ($C_{18:1,\ variable}$). A frequent point of confusion is the difference between partially and fully hydrogenated fats. Fully hydrogenated fats only contain saturated fatty acids, with only trace amounts of trans fatty acids. Partially hydrogenated fats on the other hand, are composed of a mixture of saturated and unsaturated fatty acids. Levels can be up to 60%.

Trans fatty acids can also be present as a result of refining techniques (deodorisation) applied to vegetable and marine oils. These *trans* fatty acid isomers formed are primarily those of the essential fatty acids linoleic acid ($C_{18:2,\ n\text{-}6}$) and α-linolenic acid ($C_{18:2,\ n\text{-}6}$).

[36] Lauritzen L, Hansen, HS, Jørgensen MH, Michaelsen KF (2001) The essentiality of long chain *n*-3 fatty acids in relation to development and function of the brain and retina. Progress in Lipid Research 40: 1-94

Natural trans fatty acid level of cow's milk fat often > 5%

Two publications have reported *trans* fatty acid levels in cow's milk above 5 % and up to 6.5%[37,38]. A third study[39] analysed the bi-monthly variation in *trans* isomer levels in whole milk powders produced in Brazil, Denmark, Indonesia and the Netherlands over a twelve month period in 1996/1997. Results showed that seasonal variation is very high and that, depending on the season and presumably on what they are eating, genetically similar animals generate milk with widely differing *trans* content. These results are summarised in table 2 below

Table 2: *Trans* fatty acids in whole milk powder (g/100 g total fatty acids)

	Denmark	Netherlands	Brazil	Indonesia
Jan/Feb	3.25	3.61	5.26	5.25
Mar/Apr	3.29	3.30	5.15	5.80
May/Jun	3.70	5.23	4.54	5.86
Jul/Aug	4.25	5.64	3.26	5.45
Sep/Oct	4.39	5.50	3.79	5.27
Nov/Dec	3.57	3.29	5.81	5.58

Most of these *trans* fatty acids (about 80 %) were *trans* oleic acid. *Trans* linoleic and *trans* linolenic acid were present only at low levels: milk fat is not a major source of these essential fatty acids.

A regulation limiting *trans* fatty acids automatically limits the use of milk fat in infant formula even though it is a good source of lipid for this purpose. Agricultural policies around the world support milk production in recognition of the nutritional importance of milk, but use of the fat, will be restricted.

A maximum *trans* fatty acid level of 3% is proposed, for a formula for which 40% of the fat is present as milk fat. Based on a similar reasoning, considering the important variations in the *trans* fatty acid levels of cow's milk and the fact that on a global scale formulae with more than 60% of the fat as milk fat are not unusual, a maximum *trans* fatty acid level of 4% seems more appropriate and justified from a global point of view.

Specific Effects of Trans Fatty Isomers

It is well known that the body has all the mechanisms for handling *trans* fatty acids – in fact *trans* fatty acids are a natural metabolite of normal lipid metabolism. Evidence is growing that different *trans* fatty acid isomers have different effects on metabolism. The *trans* fatty acid known as conjugated linoleic acid (CLA), for example has been implicated in anti cancer effects. More recent evidence has shown that dietary vaccenic acid (the *trans* isomer of 18:1) which is found in cow's milk can be converted into CLA by mice (Santora, 2000)[40].

*No solid evidence of detrimental effect of trans fatty acids in development.*In the past, some delegations have stated that *trans* fatty acids may be incorporated into brain and retina and alter optimal physiological function, without documenting scientifically this statement. A thorough review of the scientific literature by ISDI did not reveal any literature data on this point. In fact, to the contrary, studies in animals (these kinds of studies cannot be carried out in human infants) demonstrated that even at unrealistically high dietary *trans* fatty acid intake levels (up to 36% of calories which is equivalent to 5-12 times the average human intake),

[37] Wolf RL, Bayard CC, Fabien RJ. Evaluation of sequential methods for the determination of butterfat fatty acid composition with emphasis on *trans*-18-1 acids. Application to the study of seasonal variations in French butters. JAOCS 1995; 72:1471-83.

[38] Henninger M, Ulberth F. *Trans* fatty acid content of bovine milk fat. Milchwissenshaft 1994; 49:555-58.

[39] Dionisi F, Golay PA, Fay L.B. Influence of milk fat presence on the determination of *trans* fatty acids in fats used for infant formula. Analytica Chimica 21914 (2002) 1-13

[40] Santora JE, Palmquist DL and Roehrig KL 2000 *Trans* vaccenic acid is desaturated to conjugated linoleic acid in mice. J Nutr 130:208-215

very little *trans* fatty acid is incorporated into the brain and retinal tissues (0.0-0.5%)[41,42,43,44,45,46,47,48]. There have been no studies showing impaired neural functions due even to these extreme diets.

There is some evidence, particularly in tissue and cell cultures that *trans* fatty acids inhibit the enzymatic conversions to long chain polyunsaturated fatty acids. However it appears that this interaction is most relevant when essential fatty acid intake is low.

An Expert Panel composed of well-recognized specialists in the field of lipid nutrition in infants concluded: "*Existing data have not established a causal relation between trans fatty acid intake and changes in early development*"[49].

Human milk fat contains up to 17% trans fatty acids

A review of the literature on total *trans* fatty acids in human milk showed a range from 1.3 % in a group of 38 Spanish women to 7.2 for a group of 198 Canadian women, with a lowest value of 0.1 % and a highest value of 17 %.[50]. These levels are considerably higher than those originally considered by the European Scientific Committee for Food.

Conclusion

Limiting *trans* fatty acid levels in infant formula will necessarily restrict the use of cow's milk fat. *Trans* fatty acids are present in human milk and their content varies considerably with levels reported up to 17% of total human milk fat. No negative effects of *trans* fatty acid on metabolism nor on development have been established as long as sufficient essential fatty acids are available. It is therefore justified to propose a maximum *trans* fatty acid level for infant formula of 4% of total fatty acids. This level should not raise health concerns and will enable a reasonable use of milk fat in infant formula.

Carbohydrates

Sucrose

*ISDI believes the use of sucrose should not be prohibited***.**

- Sucrose may be helpful in camouflaging the bitter taste of protein hydrolysates, and soya protein is partially hydrolysed.
- Numerous international organisations such as the Infant Formula Act of the United States[51],[52], the American Academy of Pediatric's Committee on Nutrition[53], the Department of Health/Welfare of

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[41] Adlof RO, Emken EA. Distribution of hexadecenoic, octadecenoic and octadecadienoic acid isomers in human tissue lipids. Lipids 1986;21(9):543-7.

[42] Beyers EC, Emken EA. Metabolites of cis,trans, and trans,cis isomers of linoleic acid in mice and incorporation into tissue lipids. Biochim Biophys Acta 1991;1082(3):275-84.

[43] Grandgirard A, Bourre JM, Julliard F, et al. Incorporation of trans long-chain n-3 polyunsaturated fatty acids in rat brain structures and retina. Lipids 1994;29(4):251-8.

[44] Jones GP, Birkett A, Sanigorski A, et al. Effect of feeding quandong (Santalum acuminatum) oil to rats on tissue lipids, hepatic cytochrome P-450 and tissue histology. Food Chem Toxicol 1994;32(6):521-5.

[45] Opstvedt J, Pettersen J, Mork SJ. Trans fatty acids. 1. Growth, fertility, organ weights and nerve histology and conduction velocity in sows and offspring. Lipids 1988;23(7):713-9.

[46] Pettersen J, Opstvedt J. Trans fatty acids. 3. Fatty acid composition of the brain and other organs in the newborn piglet. Lipids 1989;24(7):616-24.

[47] Pettersen J, Opstvedt J. trans fatty acids. 5. Fatty acid composition of lipids of the brain and other organs in suckling piglets. Lipids 1992;27(10):761-9.

[48] Pettersen J, Opstvedt J. Trans fatty acids. 2. Fatty acid composition of the brain and other organs in the mature female pig. Lipids 1988;23(7):720-6.

[49]. Carlson SE,Clandinin MT,Cook HW,Emken EA,Filer LJ. *trans* Fatty acids: infant and foetal development. Am J Clin Nutr 1997;66:717S-736S

[50] Chen ZY,Pelletier G,Hollywood R,Ratnayake WMM.*trans* Fatty acids in Canadian human milk.Lipids 1995;30:15-21.

[51] Food and Drug Administration (1985a) Nutrient requirements for infant formulas. Fed.Reg. 50 (210): 45106-45108.

[52] Food and Drug Administration (1985b) Exempt infant formula. Fed. Reg. 50 (9):1833-1841.

Canada[54] and the Codex Alimentarius[55] support the safety of sucrose for infants. The levels requested are within those levels recommended by the European Society of Pediatric Gastroenterology, Hepatology and Nutrition[56,57] (ESPGHAN), an international authority on infant nutrition.

- Sucrose, a disaccharide consisting of glucose and fructose, is hydrolyzed in the small intestine by the enzyme sucrase. Because intestinal sucrase activities are fully developed at birth (Antonowicz & Lebenhal, 1977[58]; Auricchio et al., 1965[59]), sucrose-containing formulas are well tolerated by most term infants (AAP-CON, 1993b[60]).
- Sucrose is primarily used in soya protein-based formulas as a source of carbohydrate (alone or in combination with glucose polymers) for infants with indications of lactose intolerance (Klish, 1990[61]). Because of the absence of lactose, soya-protein formulas are frequently recommended for the management of galactosemia, primary lactase deficiency, or the recovery phase of secondary lactase intolerance (AAP-CON, 1983). Approximately 20% of infants in the United States are fed lactose-free soya isolate formulas (AAP-CON, 1993b).
- Finally, there is no proof that consumption of sweeter formulae by infants would promote a preference for sugar in later life. Human milk is inherently sweet.

Minerals

Ca/P ratio

During previous discussions of the ad hoc working group on the essential composition of infants formula, the French delegation provided in their submission the following scientific justification: "A certain number of arguments suggest that the upper limit for the Ca/P ratio could be increased to 2.2 (instead of 2). In breast milk the Ca/P is often higher than 2 with a standard deviation of about 20 % (Acta Paediatr Scand 1974; 63:347-50; Med Nutr 1993;29:183-71).

The UK Department of Health and Social Security published a report on *The composition of mature human milk* in 1977 published by HMSO. The values came from a sample of 97 mothers from 5 different regions and showed mean calcium level of 35mg/100ml and mean phosphorus level of 15mg/100ml. This on a w/w basis gives a ratio of 2.3:1. These values are still in use by the Department of Health today, and the UK recommendations prior to the EC Directive implementation were calcium to phosphorus ratio of 1.2:1 to 2.2:1 on a mg/mg (w/w basis).

The Swiss delegation provided a technical justification as follows: "The current footnote sets the maximum Ca: P ratio at 2.0. When this norm was agreed upon, products with low phosphorus content did not exist yet. A number of low P infant formulas are currently marketed in several countries all over the world. They provide advantages in comparison with the traditional formulae with higher phosphorus content. There is,

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[53] American Academy of Pediatrics. Committee on Nutrition (1983) Soya-protein formulas: recommendations for use in infant feeding. Pediatrics 72: 359-363.

[54] Department of National Health and Welfare. Canada (1995) Departmental Consolidation of the Food and Drug Act and of the Food and Drug Regulations with amendments to December 15, 1995. Minister of Supply and Services Canada, Ottawa, Ontario, Canada, 1981.

[55] Codex Alimentarius Commission. Joint FAO/WHO Food Standards Programme (1994) Codex Alimentarius. Vol 4. Food for Special Dietary Uses (Including Foods for Infants and Children). Part 2 – Foods for infants and Children. Food and Agriculture Organization and World Health Organization, Rome.pp. 15-75

[56] ESPGHAN Committee on Nutrition(1990a) Comments on the composition of cows' milk based follow-up formulas. Acta Paediatr. Scand.79:250-254

[57] ESPGAN Committee on Nutrition(1990b) Comments on the composition of soya protein based infant and follow-up formulas. Acta Paediatr. Scand.79:1001-1005.

[58] Antonwicz, I. & Lebenthal, E. (1977) Developmental pattern of small intestinal enterokinase and disaccharidase activities in the human fetus. Gastroenterology 72: 1299-1303.

[59] Auricchio, S., Rubino, A. & Murset, G. (1965) Intestinal glycosidase activities in the human embryo, fetus, and newborn. Pediatrics 35: 944-954.

[60] American Academy of Pediatrics. Committee on Nutrition (1993b) Carbohydrate and dietary fiber. In: Pediatric Nutrition Handbook. 3rd ed. (Barness, L.A. ed.). American Academy of Pediatrics, Elk Grove Village.pp.115-124.

[61] Klish, W.J. (1990) Special infant formulas. Pediatr.Rev. 12: 55-62.

however, a risk that these products exceed the Ca: P ratio of 2.0. We therefore propose to raise maximum allowed Ca: P ratio to 2.2. This value is safe and physiological. As a matter of fact, this value and even higher values are regularly found in breast milk."

Comments made by Germany were also in the same direction: "The reduction of the maximum amount of the calcium-phosphorus quotient should refer to the **molar** Ca: P ratio as indicated in the original". The molecular weight of Ca and P is 40 and 31 respectively, so the molar ratio = 2 becomes 2x [40:31] = 2.2 (weight/weight). This request is also supported and clearly expressed in the UK recommendations[62].

CHOLINE

ISDI believes the maximum level for choline should be 50 mg/100kcal in order to achieve the recommended arachidonic acid (AA) level, and not 30mg/100kcal as suggested

Model calculation for choline using a level of phospholipids of 2g/l (see previous comments on phospholipids above)

2g/l phospholipids

thereof 73 % = phosphatidylcholine = 1.46 mg phosphatidylcholine/l

thereof 23 % choline = 336 mg choline/l = 302 mg choline/680 kcal = **50 mg choline / 100kcal**

PROPOSED DRAFT REVISED STANDARD FOR CEREAL-BASED FOODS FOR INFANTS AND YOUNG CHILDREN (ALINORM 03/27/26, para. 130 and Appendix VI)

Argentina

En el párrafo 1.3, es opinión de Argentina la eliminación de los corchetes. Argentina está de acuerdo con la incorporación de la resolución WHA 55.25(2002) de la Asamblea Mundial de la Salud.

Con respecto al párrafo 3.6.1, Argentina considera conveniente resaltar que los valores de sodio deberían ser tan bajos como fuese posible y no superar los 100 mg/100 kcal, atento las de ingesta para este mineral que figuran en la guía de la Sociedad Argentina de Pediatría.

Con respecto al párrafo 3.7.1 este Argentina estima conveniente esperar los nuevos valores de ingestas diarias recomendadas de vitaminas y minerales antes de dar una opinión sobre este punto.

Argentina considera que deben eliminarse los corchetes en el párrafo 8.1.1, atento que estos alimentos no deberían contener leyendas nutricionales ni claims saludables para promocionar su venta, dado que es el médico pediatra es el que debe indicar que tipo fórmula infantil debería consumir el niño.

China

ALINORM 04/27/26, Appendix VI	OUR COMMENTS
1. SCOPE	
This standard covers processed cereal-based foods intended for feeding infants as a complementary food generally from the age of 6 months onwards, taking into account infants' individual nutritional requirements, and for feeding young children as part of a progressively diversified diet, in accordance with the Global Strategy for Infant and Young Child Feeding and World Health Assembly Resolution WHA54.2 (2001) ~~**and [WHA55.25 (2002)]**~~.	Delete reference to WHA 55.25 Rationale: WHA Resolution 55.25 requests that the Codex Alimentarius Commission takes WHO policy into consideration, in particular the Code of marketing of breast milk substitutes, Resolution WHA 54.2 and "other relevant resolutions of the World Health Assembly". The latest therefore includes future texts, to which CCNFSDU should not at this time commit. New resolutions relevant for CCNFSDU need to be discussed by the Committee before being referred to

[62] Report on Health and social subjects. 41, Dietary reference values for food energy and nutrients for the United Kingdom.

	in a Codex Standard.
2. DESCRIPTION	
Processed cereal-based foods are prepared ~~**primarily**~~ from one or more milled cereals, which should constitute at least 25% of the final mixture on a dry weight basis	Delete the word "primarily" as there are other very nutritive ingredients such as milk or pulses that can be used in these products.
3.1 ESSENTIAL COMPOSITION	
3.1.1 The four categories listed in 2.1.1 to 2.1.4 are prepared ~~**primarily**~~ from one or more milled cereal products, such as wheat, rice, barley, oats, rye, maize, millet, sorghum and buckwheat, **legumes (pulses), or oilseed**. They may also contain ~~**legumes (pulses),**~~ starchy root, (such as arrow root, yam, or cassava) or starchy stems ~~**or oil seeds**~~ in smaller proportions.	Delete "primarily" in accordance with section 2. Description. Rationale: – Legumes and pulses, such as soy and cowpea, are high quality and quantity protein ingredients and thus valuable sources of nutrition. – Moreover legumes historically have been covered by this standard and should remain so.

Editorial comment on Section **3.1 ESSENTIAL COMPOSITION**	Nutrient value is expressed either per 100 kcal or per 100 kJ, the corresponding value in brackets. Please ensure consistency. We recommend to use "per 100 kcal"
3.4 CARBOHYDRATES	
3.4.2 If sucrose, fructose, glucose, syrup or honey are added to products mentioned in points 2.1.1 and 2.1.4 - the amount of added carbohydrates from these sources shall not exceed ~~**2**~~ **1.2** g/100kJ **(~~8.~~ 4 5** g/100kcal)	The original proposal for this section was based on the European Directive which indicates a level of 1.2 g/100kJ. There must be a typing error in the Alinorm. Change accordingly.
3.6 MINERALS	
3.6.1. The sodium content of the products described in Sections 2.1.1 to 2.1.4 of this standard shall not exceed ~~[~~100mg/100kcal (24mg/100 kJ)~~]~~ of the ready-to-eat product~~. except in the case of products intended for children over one year of age, where the sodium content shall not exceed [200mg/100 kcal (48mg/100 kJ)].~~	A maximum sodium level of 100 mg/100 kcal is proposed for all processed cereal-based foods. Rationale: Reduction of the sodium level fully reflects efforts to reduce the salt intake during early life.
3.7 VITAMINS	
3.7.1. The amount of vitamin B1 (thiamine shall not be less than **60 µg/100 kcal ~~[(~~15 µg/100 kJ)~~]~~**	Agreement with proposed level. Remove [ ]

3.8 OPTIONAL INGREDIENTS	
3.8.3 Only L(+) producing lactic acid cultures may be used.	Add this new provision which reflects above request in 4.2.4. and which is consistent with the Standard for Infant Formula.
3.10.1 [spoon feeding]	Delete the brackets and keep the bracketed text.
4. FOOD ADDITIVES	
4.2 pH-adjusting agents **4.2.4 Request** for L(+) lactic acid producing cultures at GMP[3]	We fully support this request. As stated under footnote 3, cultures are not considered as food additives. Therefore they should appear under "Optional ingredients", see above comment under 3.8.3.
8. LABELLING	
8.1.1 ~~**The requirements of the Codex General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985 (Rev. 1-1991), Codex Alimentarius Volume 1) apply to this standard. With specific reference to section 7 of that Standard national jurisdictions may further restrict the use of pictorial devices**~~ ~~**or**~~ ~~**[No nutrition and health claims shall be made regarding the dietary properties of the products covered by the provision of this standard]**~~ **The requirements of the Codex General Standard for the Labelling and Claims for Prepackaged foods for special dietary uses (CODEX STAN. 146-1985) should apply to this standard.** **Nutrition and health claims shall be permitted for the products covered by this standard, where they have been demonstrated beyond doubt in rigorous studies with adequate scientific standards, and the evidence has been accepted by an independent scientific body reviewing the data.**	Delete the entire section and replace by the proposed wording. <u>Rationale:</u> – Reference to the Codex General Standard for the Labeling and Claims for Prepackaged foods for special dietary uses (CODEX STAN. 146-1985) is more specific. – The purpose of the Codex is to harmonise national practices and not to invite differences. – All claims that are scientifically substantiated, with the substantiation validated through independent scientific review, should be allowed. – There is no nutrition-based rationale for placing a severe restriction on claims for these products. These claims should be allowed as long as they are scientifically substantiated and are expressed in a manner that is understood by and is not misleading to the parent or caregiver. – Claims on products for infants and young children can provide parents and caregivers with important

	information about the composition and properties of a product that is specially designed for this age category. There is no justification for denying them information that is based on scientific substantiation.
8.6.2 For products covered by 2.1.1, directions on the label shall state **"milk or formula but no water shall be used for dilution or mixing"** or an equivalent statement.	"milk or formula but no water shall be used for dilution or mixing" is suggested to "milk or formula shall be used for dilution or mixing".
8.6.4 The label shall indicate clearly from which age the product is recommended for use. ~~**This age shall not be less than six months for any product. In addition, the label shall include a statement indicating that the decision when precisely to begin complementary feeding, including any exception to six months of age, should be made in consultation with a health worker, based on the individual infant's specific growth and development needs. Additional requirements in this respect may be made in accordance with the legislation of the country in which the product is sold.**~~	Delete the entire section. Rationale: Because a health worker is difficultly to defined in different countries.

Czech Republic

ALINORM 04/27/26, Appendix VI	OUR COMMENTS
1. SCOPE	
This standard covers processed cereal-based foods intended for feeding infants as a complementary food generally from the age of 6 months onwards, taking into account infants' individual nutritional requirements, and for feeding young children as part of a progressively diversified diet, in accordance with the Global Strategy for Infant and Young Child Feeding and World Health Assembly Resolution WHA54.2 (2001) ~~**and [WHA55.25 (2002)]**~~.	Delete reference to WHA 55.25 Rationale: WHA Resolution 55.25 requests that the Codex Alimentarius Commission takes WHO policy into consideration, in particular the Code of marketing of breast milk substitutes, Resolution WHA 54.2 and "other relevant resolutions of the World Health Assembly". The latest therefore includes future texts, to which CCNFSDU should not at this time commit. New resolutions relevant for CCNFSDU need to be discussed by the Committee before being referred to in a Codex Standard.
2. DESCRIPTION	
Processed cereal-based foods are prepared ~~**primarily**~~ from one or more milled cereals, which should constitute at least 25% of the final mixture on a dry weight basis	Delete the word "primarily" as there are other very nutritive ingredients such as milk or pulses that can be used in these products.

3.1 ESSENTIAL COMPOSITION	
3.1.1 The four categories listed in 2.1.1 to 2.1.4 are prepared ~~**primarily**~~ from one or more milled cereal products, such as wheat, rice, barley, oats, rye, maize, millet, sorghum and buckwheat, **legumes (pulses), or oilseed**. They may also contain ~~**legumes (pulses),**~~ starchy root, (such as arrow root, yam, or cassava) or starchy stems ~~**or oil seeds**~~ in smaller proportions.	Delete "primarily" in accordance with section 2. Description. Rationale: – Legumes and pulses, such as soy and cowpea, are high quality and quantity protein ingredients and thus valuable sources of nutrition. – Moreover legumes historically have been covered by this standard and should remain so.
Editorial comment on Section **3.1 ESSENTIAL COMPOSITION**	Nutrient value are expressed either per 100 kcal or per 100 kJ, the corresponding value in brackets. Please ensure consistency. We recommend to use "per 100 kcal"
3.4 CARBOHYDRATES	
3.4.2 If sucrose, fructose, glucose, syrup or honey are added to products mentioned in points 2.1.1 and 2.1.4 - the amount of added carbohydrates from these sources shall not exceed ~~**2**~~ **1.2** g/100kJ **(~~8.~~ 4 5** g/100kcal)	The original proposal for this section was based on the European Directive which indicates a level of 1.2 g/100kJ. There must be a typing error in the Alinorm. Change accordingly.
3.6 MINERALS	
3.6.1. The sodium content of the products described in Sections 2.1.1 to 2.1.4 of this standard shall not exceed ~~[~~100mg/100kcal (24mg/100 kJ)~~]~~ of the ready-to-eat product~~. except in the case of products intended for children over one year of age, where the sodium content shall not exceed [200mg/100 kcal (48mg/100 kJ)].~~	A maximum sodium level of 100 mg/100 kcal is proposed for all processed cereal-based foods. Rationale: Reduction of the sodium level fully reflects efforts to reduce the salt intake during early life.
3.7 VITAMINS	
3.7.1. The amount of vitamin B1 (thiamine shall not be less than **60 µg/100 kcal ~~[~~(15 µg/100 kJ)~~]~~**	Agreement with proposed level. Remove [ ]
3.8 OPTIONAL INGREDIENTS	
3.8.3 Only L(+) producing lactic acid cultures may be used.	Add this new provision which reflects above request in 4.2.4. and which is consistent with the Standard for Infant Formula.
4. FOOD ADDITIVES	
4.2 pH-adjusting agents **4.2.4 Request** for L(+) lactic acid producing cultures at GMP[3]	We fully support this request. As stated under footnote 3, cultures are not considered as food additives. Therefore they should appear under "Optional ingredients", see above comment under 3.8.3.

8. LABELLING	
8.1.1 ~~**The requirements of the Codex General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985 (Rev. 1-1991), Codex Alimentarius Volume 1) apply to this standard. With specific reference to section 7 of that Standard national jurisdictions may further restrict the use of pictorial devices**~~ ~~**or**~~	
~~**[No nutrition and health claims shall be made regarding the dietary properties of the products covered by the provision of this standard]**~~ **The requirements of the Codex General Standard for the Labelling and Claims for Prepackaged foods for special dietary uses (CODEX STAN. 146-1985) should apply to this standard.** **Nutrition and health claims shall be permitted for the products covered by this standard, where they have been demonstrated beyond doubt in rigorous studies with adequate scientific standards, and the evidence has been accepted by an independent scientific body reviewing the data.**	Delete the entire section and replace by the proposed wording. Rationale: – Reference to the Codex General Standard for the Labelling and Claims for Prepackaged foods for special dietary uses (CODEX STAN. 146-1985) is more specific. – The purpose of the Codex is to harmonise national practices and not to invite differences. – All claims that are scientifically substantiated, with the substantiation validated through independent scientific review, should be allowed. – There is no nutrition-based rationale for placing a severe restriction on claims for these products. These claims should be allowed as long as they are scientifically substantiated and are expressed in a manner that is understood by and is not misleading to the parent or caregiver. – Claims on products for infants and young children can provide parents and caregivers with important information about the composition and properties of a product that is specially designed for this age category. There is no justification for denying them information that is based on scientific substantiation.

Malaysia

Section 3: Essential Composition and Quality Factors

Paragraph 3.10.1

Malaysia proposes to remove the square bracket around the words 'spoon feeding' according to the adoption of the report of the 25th CCNFSDU.

Paragraph 3.11 Specific Prohibition

Malaysia proposes the text to be amended by using the same text in Draft Revised Standard for Infant Formula. The paragraph is to read:

"The product and its components shall not contain commercially hydrogenated oils and fats and shall not have been treated by ionizing radiation"

Section 8: Labelling

Paragraph 8.1.1 (second option)

Malaysia proposes to remove the square bracket and delete the words 'nutrition and'. A new number is to be given to the text and should read:

"8.1.3 No health claims shall be made regarding the dietary properties of the products covered by the provisions of this standard"

Rationale:

Some nutrition claims could be permitted so as to provide nutrition information to the consumer. The current text implies that Nutrition Content Claims and Comparative Claims are also not permitted.

(i) Malaysia proposes to remove all the square brackets and adopt the texts contained in all the brackets.

COMPONENT	CLAIM	CONDITIONS
B.		NOT LESS THAN
Dietary Fibre	Source	3g per 100g or 1.5g per 100kcal or per serving (liquid foods: 1.5g per 100ml)
	High	6g per 100g or 3g per 100kcal or per serving (liquid foods: 3g per 100ml)

Footnote: Serving size to be determined at national level

Mexico

1. En el punto 1 sugerimos se elimine el corchete a la resolución WHA 55.25 (2002).
2. En el punto 3.4.2 se sugiere se retire el corchete en la segunda viñeta.
3. En el punto 3.7.1 sugerimos se quite el corchete a 60 ug/100 Kcal.
4. En el punto 3.10.1 en corchetes esta la frase "spoon feeding", de la cual dado el texto sugerimos se quite la palabra spoon y quedaría….. a textura appropriatte for the feeding of infants or young childrens……..
5. En el punto 5.1 referente a residuos de plaguicidas, sugerimos se elimine la frase que dice que los plaguicidas deben estar ausentes lo más posible en estas formulas, quedando de la siguiente manera: El producto debe ser preparado con mucho cuidado y apego a las Buenas Prácticas de Manufactura, tales que no deben contener residuos de plaguicidas que pueden ser utilizados durante la producción, almacenamiento y procesamiento de materias primas y producto terminado o debe ser técnicamente inevitable.

New Zealand

New Zealand was most supportive of the progress made on this draft standard and fully supported its progression to step 5.

Essential Composition

3.6.1 New Zealand supports deleting the square brackets proposed for sodium levels and adopting the maximum levels of 24 mg/100 kJ (100 mg/100 kcal).

Consistency and Particle Size

3.10.1 New Zealand supports removing reference to spoon feeding as it is not relevant to all foods regulated by this standard such as rusks.

Labelling

New Zealand supports the first option of 8.1.1 which allows for national jurisdictions to restrict the use of pictorial devices and supports the general labelling provisions.

8.6.4 New Zealand does not support any labelling which makes reference to a set age. We support labelling that acknowledges the natural variation in the physiological development of infants.

Poland

5.2 Other Contaminants

Bearing in mind higher vulnerability of infants and young children to toxic effects of heavy metals, we suggest establishing maximum levels for lead, cadmium, mercury and arsenic in the products covered by the provisions of the Standard.

We would also like to stress the need to establish maximum limits for mycotoxins in the Proposed Draft Revised Standard for Infant Formula as well as in the Proposed Draft Revised Standard for Processed Cereal-Based Foods for Infants and Young Children.

International Special Dietary Foods Industries (ISDI)

ISDI PROPOSAL	JUSTIFICATION
1. SCOPE This standard covers processed cereal-based foods intended for feeding infants as a complementary food generally from the age of 6 months onwards, taking into account infants' individual nutritional requirements, and for feeding young children as part of a progressively diversified diet, in accordance with the Global Strategy for Infant and Young Child Feeding and World Health Assembly Resolution WHA54.2 (2001) ~~and [WHA55.25 (2002)].~~	WHA Resolution 55.25 asks Codex Alimentarius Commission to take into consideration WHO policy, in particular the Code of marketing of breast milk substitutes, resolution WHA 54.2 and "other relevant resolutions of the Health Assembly". The latest therefore includes future texts. ISDI believes that CCNFSDU can not commit to future texts that are not known. If there are new resolutions relevant for CCNFSDU, they need to be discussed by the Committee before being referred to in a Codex Standard.
2. DESCRIPTION Processed cereal-based foods are prepared ~~primarily~~ from one or more milled cereals, which should constitute at least 25% of the final mixture on a dry weight basis	The word "primarily" should be deleted. There are other very nutritive ingredients such as milk or pulses that can be used in these products.
3.1. Essential Composition **3.1.1** The four categories listed in 2.1.1 to 2.1.4 are prepared ~~primarily~~ from one or more milled cereal products, such as wheat, rice, barley, oats, rye, maize, millet, sorghum and buckwheat, **legumes (pulses), or oilseed**. They may also contain ~~legumes (pulses),~~ starchy root, (such as arrow root, yam, or cassava) or starchy stems ~~or oil seeds~~ in smaller	"primarily" should be removed because there are other very nutritive ingredients such as milk or that can be used in these products Indeed, pulses and pulses such as soy, are high protein content ingredients and thus are valuable sources of nutrition. Moreover legumes historically

proportions.	have been covered by this standard and should remain so.
3.4 Carbohydrates **3.4.2** If sucrose, fructose, glucose, syrup or honey are added to products mentioned in points 2.1.1 and 2.1.4 - the amount of added carbohydrates from these sources shall not exceed ~~2~~ **1.2** g/100kJ (~~8.4~~ **5** g/100kcal)	The original proposal for this section was based on the European Directive which indicates a level of 1.2 g/100kJ. There must be a typing error in the Alinorm;
3.5.2 Product categories 2.1**.**1 and 2.1.4 shall not exceed a maximum lipid content of 3.3g/100kcal (0.8g/100kJ)	Typing error, a "." Is missing in "category 2.11"
3.6 Minerals The sodium content of the products described **in this standard** ~~Sections 2.1.1 to 2.1.4 of this standard~~ shall not exceed ~~[~~100mg/100kcal (24mg/100 kJ)~~]~~ of the ready-to-eat product, ~~except in the case of products intended for children over one year of age, where the sodium content shall not exceed [200mg/100kcal (48mg/100kJ)].~~	
3.7 Vitamins The amount of vitamin B1 (thiamine shall not be less than ~~[~~15µg/100kJ~~]~~ ~~[~~(60 µg/100kcal)~~]~~	ISDI Agrees with the proposed level
3.8 Optional ingredients **3.8.1** In addition to the ingredients listed under 3.1, other ingredients suitable for infants who are more than 6 months of age **or as appropriate** and for young children can be used.	Add "or as appropriate" brings this section more in line with the scope of this standard.
3.9. Quality factors 3.9.1 All ingredients, ~~including optional ingredients~~, shall be clean, safe, suitable and of good quality.	"including optional ingredients" should be deleted since the wording "all ingredients" already cover them
3.10.1 When prepared according to the label directions for use, processed cereal-based foods should have a texture appropriate for the ~~[~~spoon feeding~~]~~ of infants or young children of the age for which the product is intended.	According to discussions at the last Committee session is was clear that the [ ] had been deleted
4. FOOD ADDITIVES **4.2 pH-adjusting agents** ~~4.2.4 request for L(+) lactic acid producing cultures at GMP~~[3] ~~4.4 Flavours~~	ISDI agrees with footnote 3: cultures are not considered as food additives, they are rather optional ingredients. Flavours are not considered food additives by CCFAC. JECFA is currently evaluating the safety of all flavouring substances Enzymes are processing aids they should not be in the additive section. They are currently are under consideration at CCFAC

~~4.5 Enzymes~~	
8. LABELLING **(current) 8.1.1**	
~~[The requirements of the Codex General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985 (Rev. 1-1991), Codex Alimentraius Volume 1) apply to this standard.~~ **In addition to the requirements of the Codex General Standard for the Labelling and Claims for Prepackaged foods for special dietary uses (CODEX STAN. 146-1985) the following specific provisions apply:**	Codex STAN 146-1985 contains a number of specific provisions, which apply to processed cereal-based foods. In addition, CODEX STAN 146-1985 extensively refers back to the General Standard for Labelling (CODEX STAN 1-1985) where appropriate. ISDI therefore believes it is sufficient to refer to CODEX STAN 146-1985 and seeks clarification from the Codex Secretariat on this matter.
~~With specific reference to section 7 of that Standard national jurisdictions may further restrict the use of pictorial devices].~~ ~~Or~~ ~~[No nutrition and health claims shall be made regarding the dietary properties of the products covered by the provision of this standard~~ **Nutrition and health claims shall be permitted for foods for infants and young children where they have been demonstrated in rigorous studies with adequate scientific standards, and where they are in accepted by or acceptable to the competent authorities of the country where the product is sold, as required by Section 7.1.2 of the Codex Guidelines for Use of Nutrition and Health Claims.**	This is already covered by Section 7 of Codex General Standard for the Labelling *for* Prepackaged foods (CODEX STAN. 1-1985 rev 1 –1991) with reference to section 3 of the same standard[63]. This sentence should be deleted and replaced by the wording proposed. • **The lack of appropriate information on these adapted foods may orient the parent to choosing non-adapted and inappropriate foods for their infants and young children** • **Nutrition and health claims, being true statements/information regarding the dietary properties of the foods provide important information to parents.** • **Some countries already allow certain health and nutrition claims in labelling of weaning foods intended for healthy infants.** **Provisions ensuring that claims for foods for special dietary uses are appropriately used, have already been detailed in Section 3.1 of Codex STAN 146-1985 (Codex General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses).**
8.1.2 The name of the food ~~Any indication required in the labelling should be made in the appropriate language(s) of the country in which the product is sold.~~	This is adequately covered in section 8 of CODEX 146-1985 and in section 8.2 of the General Standard (CODEX STAN 1-1985).
8.5 Date marking and storage instructions ~~**8.5.3.** Where practicable, storage instructions~~	This type of provisions is fully described in the

[63] Section 3.1 reads "*Prepackaged food shall not be described or presented on any label or in any labelling in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character in any respect.*"

~~shall be in close proximity to the date marking.~~	General Standard for the Labelling of and Claims for prepackaged Foods for Special Dietary Uses (CODEX STAN 146-1985) and is not needed here.
8.6 Information for utilization **8.6.2.** For products covered by 2.1.1, directions on the label shall state "Milk or formula but no water **alone** shall be used for dilution or mixing" or any equivalent statement.	The word "alone" should be added. Water is used in the reconstitution of infant formula, which is one of the nutritious liquids recommended for the dilution of cereals.
8.6.3. ~~"The presence or absence of gluten should be indicated on the label"~~	The labelling of the presence of ingredient containing gluten is already obligatory according to section 4.2.1.4 of Codex Standard CODEX STAN 1-1985 The absence of gluten is regulated by Codex Standard for Gluten free foods 118-1981 rev 1983.
8.6.4. The label shall indicate clearly from which age the product is intended for use. ~~This age shall not be less than 6 months for any product~~. In addition the label shall include a statement indicating that the decision when precisely to begin complementary feeding, including any exception to six months of age, should be made in consultation with a health worker, based on the infant specific growth and development needs. Additional requirements in this respect may be made in accordance with the legislation of the country in which the product is sold.	The second sentence should be deleted because this is already covered in the scope of this standard. In order to reflect the conclusion of the WHO Expert Consultation on "The optimal duration of exclusive breastfeeding" as referred to in the WHA Resolution 54.2., point 8.6.4 must be re-worded to ensure that the individual needs of all infants and young children are met.

International Wheat Gluten Association (IWGA)

Section 8.1.1 of the Proposed Draft Revised Standard specifies that the requirements of the Codex General Standard for the Labeling of Prepackaged Foods (CODEX STAN 1-1985 Rev. 1-1991) apply to this standard.

Section 8.6.3 specifies that *"the presence or absence of gluten should be indicated on the label"*.

The Codex General Standard for the Labeling of Prepackaged Foods as amended, provides for a list of foods and ingredients that are known to cause hypersensitivity and that shall always be declared. With the adoption in 1999 of these requirements, allergenicity and intolerance were adequately addressed by the Codex Alimentarius Commission, in a consistent way, as a horizontal measure.

The reference under Section 8.6.3 to the mandatory indication of the presence of gluten, therefore, is redundant. [If however the Committee wants to highlight the substances to be mandatory labelled for this category of products, in the context of allergen labeling, it should consider all substances known to cause hypersensitivity that can potentially be used in these products.]

The additional mandatory indication of the absence of one specifc substance, gluten, in a standard for a particular food not specially prepared to meet the dietary needs of persons intolerant to gluten as covered by the Codex Standard for "Gluten-Free Foods", is not consistent with the risk management option of Codex in the context of allergenicity and intolerance.

[The mandatory indication of the absence of allergens can be further considered from a general perspective if required.]

[If however the Committee decides that the additional mandatory indication of the absence of substances known to cause hypersensitivity in a specific product group is required, it should be considered from a general perspective, or it should consider at least all these substances that can potentially be used in these products.]

The International Wheat Gluten Association therefore asks the Codex Alimentarius Commission:

- To delete section 8.6.3 on the indication of the presence or absence of gluten;
- To consider if required the principle of additional mandatory indication of the absence of substances known to cause hypersensitivity from a more general perspective.