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codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 5 **ORIGINAL LANGUAGE ONLY**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

Twenty-ninth Session

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

(Comments submitted as of 31 May 2006)

A. CCNFSDU

(Codex Committee on Nutrition and Foods for Special Dietary Purposes / Comité du Codex sur la nutrition et les aliments / Comité del Codex sobre Nutrición y Alimentos para Regímenes Especiales)

PROPOSED DRAFT REVISED STANDARD FOR INFANT FORMULA AND FORMULAS FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS (SECTION B) (ALINORM 06/29/26, para 126 and Appendix IV B)

Australia

In response to Part C, Item 1 of Circular Letter CL 2005/53-NFSDU, Australia would like to provide the following comments with regard to Section B of the Draft Revised Standard for Infant Formulas for Special Medical Purposes Intended for Children.

Section B 3.1.1 Essential Composition

Australia notes that because of the structure of the Draft Revised Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants, the compositional requirements of Section A 3.1 also carries across to Section B. However, Australia notes that formula for special medical purposes intended for infants are highly formulated and may therefore require the addition of the essential minerals chromium and molybdenum to ensure nutritional adequacy for their particular special use. Therefore, Australia requests that Section B 3.1.1 includes minimum and maximum levels for chromium of 0.35 – 2.0ug/100kJ; and for molybdenum 0.36 – 3.0 ug/100kJ. These values are consistent with Australian and New Zealand regulations.

Australia notes that the current advisory list, CAC/GL 10-1979 does not list chromium and molybdenum forms for formula for special medical purposes intended for infants. However, the draft revised version of that

advisory list currently before CCNFSDU has now included permitted chromium and molybdenum forms. Australia has provided separate comments on the draft advisory lists, indicating that formula for special medical purposes intended for infants should indicate appropriate chromium and molybdenum forms.

Section B 9.5 Information for Use

Australia notes that the heading for Section 9.5 has not been provided, and requests that 'Information for Use' be inserted.

Section B 9.5 is cross-referenced to all provisions within Section A 9.5, however Australia considers that instances of "or in the accompanying leaflet" enclosed in square brackets in Section A 9.5.1 and A 9.5.2 are not applicable to Section B 9.5 and should be deleted from Section B. The directions for use and for storage after opening should be shown on the label and accompany the container at all times. If in due course, the text in square brackets in Section A 9.5.1 and A 9.5.2 is accepted for Section A, then the current cross reference should be replaced by modified text without the text in square brackets in Section B 9.5.

Section B 9.6 Additional Labelling Requirements

Australia does not support the inclusion of Section 4.4.3 of CODEX STAN 180-1991 in Section B 9.6.1, but instead requests that it be moved to Section B 9.6.3. The information covered by Section 4.4.3 of CODEX STAN 180-1991 is similar in nature to Sections 4.5.2 and 4.5.3 of that standard, and therefore should be similarly treated by location in Section B 9.6.3.

Bolivia

Observaciones generales

Bolivia considera importantes que para futuras revisiones de este y otros documentos se consideren un orden lógico de revisión, creemos que es importante circular primero las observaciones de la Sección A, de este documento para luego emitir observaciones a la Sección B que esta en función de la sección A.

Además creemos oportuno introducir todos los textos en extenso que se duplican de la Sección A a la Sección B, con el objeto de brindar mayor compresión a la lectura de la norma.

Observaciones a la traducción

Bolivia quiere hacer notar a la secretaría del comité algunos errores de traducción a la versión en español que cambian el sentido a la norma.

En el título, modificar la palabra "Preparados" por "Formulas", que es la traducción correcta de "*Formulas*"

En el punto 1.1 la frase "las necesidades nutricionales" debería modificarse por "los requerimientos nutricionales", de acuerdo a la versión original en inglés "The nutricional requirements"

En el punto 9.2.1 se solicita una revisión completa del párrafo, ya que la versión en español no tiene relación a la original en inglés

Observaciones a la norma

1. ÁMBITO DE APLICACIÓN

1.4 En la aplicación de esta sección de la Norma deberán tenerse en cuenta, según sea apropiado para los productos a los que se aplica esta sección y las necesidades especiales de los lactantes a los cuales se destinan, las recomendaciones incluidas en el Código Internacional de Comercialización de Sucedáneos de la Leche Materna (1981), así como la resolución WHA 54.2 (2001) **[WHA 55.25 y WHA 58.32]** de la Asamblea Mundial de la Salud sobre Estrategia mundial para la alimentación del lactante y del niño pequeño **[y posteriores aplicables a la lactancia materna].**

Justificación

Bolivia considera importante incluir en esta cita a manera de referencia las Resoluciones de la Asamblea Mundial de la Salud, para que la producción de las "Formulas para lactantes" sigan estos lineamientos.

2. DESCRIPCIÓN

2.1 Definición del producto

2.1.1 El Preparado para usos medicinales especiales destinados a los lactantes es un sucedáneo de la leche humana o los preparados para lactantes que se ajusta a la sección 2, Descripción, de la Norma del Codex para el Etiquetado y la Declaración de Propiedades de los Alimentos para Fines Medicinales Especiales (CODEX STAN 180-1991) y ha sido especialmente fabricado para satisfacer, ~~por sí sólo~~, las necesidades nutricionales especiales de los lactantes con trastornos, enfermedades o condiciones médicas específicas durante los primeros **[6]** meses de vida hasta la introducción de una alimentación complementaria apropiada.

Justificación

Bolivia sugiere eliminar el texto "por si solo", por que desalienta a la lactancia materna. Además creemos que es importante aclarar que la norma esta orientada a los primeros 6 meses de vida del lactante ya que si consideramos la definición 2.2, que incorpora lactantes de 0 a 12 meses, se crea una confusión el momento de aplicar la norma.

2.2 Otras definiciones

Véase la sección A 2.2 **[Entiéndase por lactante menor de 0-6 meses y lactante mayor de 6 a 12 meses de edad]**

Justificación

Esta sugerencia complementa la anteriormente vertida con el objeto de aclara más aún que esta norma esta orientada a los lactantes de 0 a 6 meses de edad.

9. ETIQUETADO

Además de las disposiciones que figuran en la Norma General del Codex para el Etiquetado de los Alimentos Preenvasados (CODEX STAN 1-1985 (Rev. 1-1991)), se aplicarán las siguientes disposiciones específicas

9.1 Nombre del alimento

9.1.1 El producto se denominará "preparado para usos medicinales especiales destinado a los lactantes" o cualquier otra denominación apropiada que indique la verdadera naturaleza del alimento, de conformidad con las costumbres del país.

Incluir los siguientes textos de la sección A

[9.1.1 El texto de la etiqueta y toda otra información que acompañe el producto deberán estar escritos en el idioma o los idiomas apropiados

9.1.3 En la etiqueta se indicará claramente el origen de las proteínas que contiene el producto

9.1.4 Si el origen de las proteínas es exclusivamente la leche de vaca, el producto podrá etiquetarse "preparados para lactantes a base de leche de vaca"]

Justificación

Se sugiere incorporar tres puntos de la sección A en extenso en esta Sección por las siguientes razones;

- *Es importante aclarar que la declaración debe ser exclusivamente en el idioma apropiado, en vista que un país como Bolivia que importa casi la totalidad de estos productos, no puede comercializar productos que no se etiqueten en el idioma español.*
- *Se debe declarar el origen de las proteínas porque estos productos están destinados a usos médicos especiales, donde la aclaración del origen de la proteína es una información importante para el prescripción de estos productos.*
- *El tercer punto complementa al anterior señalado*

9.5 Instrucciones de empleo

Véase la sección A 9.5

[Debe incluir una leyenda que indique "venta bajo prescripción médica"]

Justificación

Se sugiere la leyenda de "venta bajo prescripción médica" para evitar la venta y consumo sin control de estos productos.

9.6 Requisitos de etiquetado adicionales

9.6.2 En la etiqueta **[puede]** ~~deberá~~ figurar una declaración bien visible que indique que el producto está destinado a ser la única fuente de nutrición.

Justificación

Se sugiere modificar la palabra "deberá" por "puede", porque puede depender de la afección del lactante.

~~9.6.4 Las etiquetas y la información facilitada en impreso separado del envase no deberán desalentar la lactancia materna, a no ser que esté contraindicada por razones médicas para la enfermedad, trastorno o afección para cuyo tratamiento esté destinado el producto.~~

Justificación

Se sugiere eliminar este párrafo por desalentar a la lactancia materna.;

9.6.5 Véase la sección A 9.6.5

[9.6.6 No deberán hacerse declaraciones de propiedades nutricionales y saludables respecto de las propiedades dietéticas del producto]

Justificación

Solicitamos repetir el punto 9.6.6 de la Sección A en la Sección B, nos acogemos a lo que dice la norma de Uso de declaraciones nutricionales y saludables ", en lo que se refiere a declaraciones de propiedades nutricionales y saludables para alimentos para bebés indica;

"Declaraciones de propiedades nutricionales y saludables no serán permitidas para alimentos de bebés o para niños de corta edad a no ser que estén específicamente contempladas en Normas pertinente del Codex o la Legislación nacional"

La legislación Boliviana, para sucedáneos de la leche materna, prohíbe el uso de declaraciones nutricionales.

En Bolivia la inclusión de propiedades nutricionales y saludables en el producto podrían llevar a confusión y engaño del consumidor.

Brazil

Suggestion: Brazil maintains the same proposals presented on Section A.

Costa Rica

Costa Rica no enviará observaciones para la sección B norma revisada para preparados para lactantes y preparados para usos medicinales especiales dirigidos a niños: Sección B. (ALINORM 06/29/26 párrafo 129 y sección B del Apéndice IV). Lo anterior debido a que la sección B sólo hace referencia cruzada a ciertos puntos de la sección A de dicho documento, por lo cual las observaciones se plantearán oportunamente para el texto de la sección A.

Norway

1. Scope

In paragraph 1.1 and 1.2, Formula for Special Medical Purposes Intended for Infants is written with capital letters while this is written with small letters in paragraph 1.3. For consistency, it should be done in the same way in these paragraphs. This is also relevant for paragraph 3.2.3.

2. Description

When cross references are made to the standard's part A, is it is important to point out that it is the same paragraphs that applies, but that infant formula should be changed to Formula for Special Medical Purposes Intended for Infants. It is suggested to insert the following sentence where cross references are made;

2.1.2 The same provision as laid down in Section A, paragraph 2.1.2, is valid to Formula for Special Medical Purposes Intended for Infants.

New text is suggested for paragraph 2.2 for clarification purposes.

2.2 Other definitions

The same provisions as laid down in Section A, paragraph 2.2 apply to this section of the standard.

3. Essential composition and quality factors

New text is suggested for paragraph 3.3 to 3.6 for clarification purposes.

3.3 Vitamin Compounds and Mineral Salts

The same provisions as laid down in Section A, paragraph 3.3 apply to this section of the standard.

3.4 Consistency and Particle Size

The same provisions as laid down in Section A, paragraph 3.4 apply to this section of the standard.

3.5 Purity Requirements

The same provisions as laid down in Section A, paragraph 3.5 apply to this section of the standard.

3.6 Specific prohibitions

The same provisions as laid down in Section A, paragraph 3.6 apply to this section of the standard.

We support removing the square brackets around section 3 Essential composition and quality factors with the above mentioned changes included.

4. Food additives

New text is suggested for section 4 for clarification purposes.

4. Food additives

The same provisions as laid down in Section A, section 4, apply to this section of the standard.

The same changes as for section 4 are suggested to section 5 – 8, paragraph 9.2, 9.4, 9.5 and 9.6.5.

5. Contaminants

The same provisions as laid down in Section A, section 5, apply to this section of the standard.

6. Hygiene

The same provisions as laid down in Section A, section 6, apply to this section of the standard.

7. Packaging

The same provisions as laid down in Section A, section 7, apply to this section of the standard.

8. Fill of container

The same provisions as laid down in Section A, section 8, apply to this section of the standard.

9.2 List of ingredients

The same provisions as laid down in Section A, paragraph 9.2, apply to this section of the standard.

9.4 Date Marketing and Storage Instructions

The same provisions as laid down in Section A, paragraph 9.4, apply to this section of the standard.

9.5 Instructions for use

The same provisions as laid down in Section A, paragraph 9.5, apply to this section of the standard.

9.6.5 The same provisions as laid down in Section A, paragraph 9.6.5, apply to this section of the standard.

Peru

Perú está de acuerdo con el texto del Proyecto de Norma.

United States of America

The United States supports advancement of the Draft Revised Standard for Infant Formula and Formula for Special Medical Purposes Intended for Infants: Section B (ALINORM 06/29/26, Section B of Appendix IV) for adoption at Step 5 by the 29th Session of the Codex Alimentarius Commission. (See ALINORM 06/29/26 para 129.) We have several comments about the draft and the process for moving the draft revised standard forward.

I. General Comments

We support the concept of Section B for formulas for special medical purposes intended for infants. We also support the approach that the items in Section A serve as the model for Section B with modifications as needed for Section B.

3. Essential Composition and Quality Factors

3.1 Essential composition

Comment: While the entirety of Section 3.1 is in square brackets, we anticipate that many of the nutrients in Section A may be taken out of square brackets at the 28th Session of CCNFSDU, thereby providing an opportunity for consideration of levels for these nutrients for Section B.

4. Food Additives

The United States believes it is necessary for the CCNFSDU to establish working principles for establishing food additive provisions to guide a transparent decision-making process for the Committee and to facilitate progress on the food additive provisions of the standard. We expect to re-propose working principles for the Committee's consideration at its 28th Session.

9. Labelling

We anticipate that labels for formulas for special medical purposes intended for infants will need to be adapted according to the specific nature of these formulas. Provisions of the Codex Standard for the Labelling of and Claims for Foods for Special Medical Purposes (CODEX STAN 180-1991) will need to be incorporated, as appropriate, to reflect the medical purpose of these products.

Venezuela

PROPUESTA DE MODIFICACIÓN AL DOCUMENTO ALINORM 06/29/26 Sección B del Apéndice IV	
PROYECTO DE NORMA REVISADA ~~PARA~~ PREPARADOS PARA LACTANTES Y PREPARADOS PARA USOS ~~MEDICINALES~~ ESPECIALES DESTINADOS A LOS LACTANTES. Se leería: PROYECTO DE NORMA REVISADA **DE** PREPARADOS PARA LACTANTES Y PREPARADOS PARA USOS **DIETÉTICOS** ESPECIALES DESTINADOS A LOS LACTANTES. Otra alternativa sería sustituir "USOS MEDICINALES" por **REGÍMENES DIETÉTICOS.** **Se mantiene la observación en el texto completo del documento.**	Sustituir la preposición "para" por **de.** Cambiar la palabra "medicinales" por **dietéticos.** (Es de entender, la importancia entre el alimento y una condición relacionada con la salud, sin sugerir propiedades curativas o medicamentosas). (Implica la consideración de ajustes a ciertos principios necesarios para asegurar una alimentación suficiente, completa, armónica y adecuada.)
1. ÁMBITO DE APLICACIÓN	
1.1 Esta sección de la norma se aplica a los preparados para fines ~~medicinales~~ especiales destinados a los lactantes, en forma líquida o en polvo, destinados para el uso, cuando sea necesario, como sucedáneo de la leche materna [o de los preparados para lactantes] para satisfacer las necesidades nutricionales especiales consecuentes a trastornos, ~~enfermedad~~ o afección para cuyo ~~tratamiento~~ dietético haya formulado el producto.	Cambiar "fines medicinales" por alguna de las siguientes opciones: ….fines **dietéticos** especiales.. **usos dietéticos** especiales o **regímenes dietéticos** especiales…. Especificar lactantes **sanos** Eliminar corchetes. Completar …trastornos **fisiológicos….** Eliminar la palabra "enfermedad" Cambiar**…** "tratamiento" dietético por **régimen** dietético Incluir ….. **se** haya…. Debe decir: "Esta sección de la norma se aplica a los preparados para fines **dietéticos** especiales destinados a los lactantes **sanos,** en forma líquida o en polvo, destinados para el uso, cuando sea necesario, como sucedáneo de la leche materna o de los preparados para lactantes para satisfacer las necesidades nutricionales especiales consecuentes a trastornos **fisiológicos,** o afección para cuyo **régimen** dietético **se** haya formulado el producto".

	Mantener estas observaciones en el texto completo del documento.
2. DESCRIPCIÓN	
2.1 Definición del Producto	
2.1.1 El preparado para usos medicinales especiales destinados a los lactantes es un sucedáneo de la leche materna que se ajusta a la sección 2, Descripción, de la Norma del Codex para el Etiquetado y la Declaración de Propiedades de los Alimentos para Fines Medicinales Especiales (CODEX STAN 180−1991) y ha sido especialmente fabricado para satisfacer por sí solo, las necesidades nutricionales especiales de los lactantes con trastornos, enfermedades o condiciones médicas específicas durante los primeros meses de vida o hasta la introducción de una alimentación complementaria apropiada.	**Incluir a continuación de …. los "primeros" y antes de "meses" la palabra seis….** **Agregar la palabra oportuna, después de …introducción…** **Concretar después de apropiada con alguna de las siguientes opciones:** **…apropiada para su edad.** **…apropiada que lleve progresivamente a la consolidación de una dieta sana.** **o eliminar la palabra "apropiada" y señalar.. para asegurar una nutrición adecuada.** Debe decir: "El preparado para usos medicinales especiales destinados a los lactantes es un sucedáneo de la leche materna que se ajusta a la sección 2, Descripción, de la norma del Codex para el Etiquetado y la Declaración de Propiedades de los Alimentos para Fines Medicinales Especiales (CODEX STAN 180-1991) y ha sido especialmente fabricado para satisfacer por si solo las necesidades nutricionales especiales de los lactantes con trastornos, enfermedades o condiciones médicas específicas durante los primeros **seis** meses de vida o hasta la introducción **oportuna** de una alimentación complementaria **para asegurar una nutrición adecuada"**
3. COMPOSICIÓN ESENCIAL Y FACTORES DE CALIDAD	
3.1 Composición esencial	
3.1.1 El preparado para usos medicinales especiales destinado a los lactantes es un producto a base de ingredientes de origen animal y/o vegetal y/o de compuestos sintéticos adecuados para el consumo humano. Todos los ingredientes y aditivos alimentarios deberán ~~ser~~ exentos de gluten.	**Sustituir…. deberán "ser" exentos de gluten… por...deberán estar exentos de gluten**
3.2 Ingredientes facultativos	
3.2.3 [Solo podrán utilizarse cultivos productores de ácido láctico L(+) en los preparados para usos medicinales especiales destinados a los lactantes,	Eliminar corchetes y la última parte de este párrafo. (Redunda con la sección 3.2.2).

~~siempre y cuando se haya comprobado que son inocuos y adecuados para su uso en estas poblaciones vulnerables~~.]	

ILCA

1.1 Delete last part of first sentence "or infant formula"

This text is superfluous as a substitute of infant formula will stay a substitute of human milk.

Delete the word disorder *as it has no clear definition and may open the door to products that are not medically indicated but are only created to exploit parents concerns about infant behaviors like spitting, crying or sleeping disorders*.

Add: the product has to be used under medical supervision.

1.3 We propose to change the text 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)."

It is of critical importance that infants with special medical needs are not needlessly formula fed. Thus the necessity for compliance with the International Code is even more important to protect this specific population. The text presently in the draft as inserted on the proposal of the EU is weakening the application of the International Code.

2.1.1 Delete the word disorder (see 1.1) and add this sentence at the end.

"The product shall only been used when medically indicated under medical supervision of the infant".

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.

6.3 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"

(Infant Joint FAO/WHO workshop on Enterobacter sakazakii and other microorganisms in powdered infant formula) Therefore the labelling section needs a special chapter on this: the label of each container has to have a clear, conspicuous and easy readable and understandable message printed on it.

9.1 The Name of the Food

See our comments to section A

Para 9.1.1 of section A should be included or referenced here.

The text of the label and all other information accompanying the product shall be written in the appropriate language(s).

9.6 Additional Labelling Requirements

We would favour a text presentation of section 9.6. similar to section A with the specific labelling requirements for formulas for special medical purposes to be added at the end.

If there is no agreement on this proposal we want at least to have 9.6.1.c, 9.6.2 and 9.6.3 and 9.6.4 and 9.6.6 of section A repeated here.

Reinsert text 9.6.1.c of section A here:

A statement that the product should only be used on advice of a independent health worker as to the need for its use and the proper method of use.

Reinsert text 9.6.2 of section A here:

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

Reinsert text 9.6.3 of section A here:

The terms "humanized", "maternalized" or similar terms shall not be used

Reinsert text 9.6.4 of section A reworded in accordance to our comments in section A, here:

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**.

Reinsert text 9.6.6 of section A, where the square brackets have been deleted and the text retained to read:

No nutrition and health claims shall be made regarding the dietary properties of the product.

This product for special medical purposes should not bear health claims, this would be misleading or bear the danger that the product is used by infants who don't have the disease or medical condition for whose dietary management the product has been formulated. 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.

Comment to actual 9.6.2 This may unnecessarily restrict the use of the product as for some disease the feeding of the product will continue together with adequate complementary food adapted to the disease or medical condition.

Actual 9.6.4 Keep this text and insert **"totally"** before contraindicated as for some metabolic disease (for example some forms of PKU) partial breastfeeding is possible and should be recommended and supported. As this proposal of ILCA was not fully understood in **2005, we quote from:**

ILCA board could you please insert here a quote from a medical text book

ISDI

General comment:

ISDI would like to propose the cross references in the Section B to be removed and replaced by the entire text.

Rationale:

It would simplify the reading of the document and reduce risks of confusion/errors where the practical aspects of the Standard will be implemented, and will impact on consumers i.e. the labelling information.

Proposed text	ISDI comments and justification
1. Scope 1.1 This section of the standard applies to Formula for Special Medical Purposes Intended for Infants in liquid or powdered form intended for use, where necessary, as a substitute for human milk or infant formula in meeting the special nutritional requirements deriving from the disorder, disease or medical condition for whose dietary management the product has been formulated.	ISDI supports the proposed wording.
1.4 The application of this section of the Standard should take into account, as far as appropriate for the products	ISDI supports the proposed wording.

to which this section applies and the special needs of the infants for whom they are intended, 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).	
2. DESCRIPTION **2.1 Product definition** 2.1.1 Formula for Special Medical Purposes Intended for Infants means a substitute for human milk or infant formula that complies with Section 2, Description, of the Codex Standard for the Labelling of and Claims for Foods for Special Medical Purposes (CODEX STAN 180-1991) and is specially manufactured to satisfy, by itself, the special nutritional requirements of infants with specific disorders, diseases or medical conditions during the first months of life up to the introduction of appropriate complementary feeding.	ISDI supports the proposed wording.
3.1 Essential Composition 3.1.1 Formula for Special Medical Purposes Intended for Infants is a product based on ingredients of animal, plant and/or synthetic origin suitable for human consumption. All ingredients and food additives shall be gluten-free.	ISDI supports the proposed wording. However, ISDI would like to remind that Essential Composition in Section A is not final yet and therefore adjustments may need to be done in the future.
3.1.2 The composition of Formula for Special Medical Purposes Intended for Infants should be based on sound medical and nutritional principles **and** ~~Their use should have been demonstrated by scientific evidence, to~~ be safe**,** and beneficial in meeting the nutritional requirements of infants for whom they are intended.	Delete part of the second sentence Rationale: it is redundant.
4. Food Additives see Section A 4. The following additional food additives are permitted in the preparation of Formula for Special Medical Purposes Intended for Infants (**to be filled in**).	ISDI detailed comments have been previously provided to the delegation of Switzerland in charge of the revision of this section. Rationale: see annex
9.5 Information for Use see section A 9.5 ~~[Products in liquid form may be used either directly or prepared with safe water and previously boiled water before feeding according to directions for use. Products in powder form also require safe and previously boiled water for preparation.~~ **All products should be used according to instructions for use. Products in powder form and concentrated liquids should be prepared with safe and previously boiled water before feeding. Ready for consumption liquid formula may be used directly according to instructions for use.**	Reword and change the order of the sentence. Rationale: adds clarity and powdered formula are the most commonly used type of formula around the world.

9.6 Additional Labelling Requirements 9.6.1 Formula for Special Medical Purposes Intended for Infants shall be labelled with the additional information as specified in Sections 4.4.1, 4.4.3, 4.4.4, **and** 4.5.1 ~~and 4.5.5~~ of CODEX STAN 180-1991.	Delete the cross reference to section 4.5.5. Add "and" Rationale: it is redundant with section 4.5.3. which section 9.6.3. refers to.

ANNEX

Comments on Food Additives for FSMPs

(Section 4. Food Additives)

These comments are based on CX/NFSDU 05/27/6-ADD.1 the Proposed List of Food Additives for the Codex Draft Revised Standard For Infant Formula and Formulas for Special Medical Purposes Intended for Infants Prepared By the Swiss Electronic Working Group and ALN 06/29/26.

We support the additives proposed by the Swiss Electronic Working Group for Section A and the additional additives the Working Group as proposed for Section B, with the following comments:

Part 1: Additives listed in Appendix IV(A) where ISDI requests a different level for FSMPs (Section B) that the one proposed in Section A.

	INS no.			**Maximum level in 100 mL of the "ready for consumption" product**	**Technological Justification**
4.1	***Thickening Agents***				
4.1.2	410	Carob bean gum (Locust bean gum)		~~0.1 g in all types of infant formula~~ **REQUESTED at 0.5 g /100ml**	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. This can be obtained only by minimum concentrations from 0.4g/100ml.

	472e	Diacetyltartaric and fatty acid of esters of glycerol		**REQUESTED at GMP**	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
	308	Gamma-tocopherol		**REQUESTED at 1 mg in all types of infant formula singly or in combination**	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.
	309	Delta-tocopherol			

Part 2: Additives not listed in Appendix IV(A) that ISDI requests for FSMPs (Section B) in addition to those proposed in Section A.

	Thickening agents				
	401	**Sodium alginate**		**1g/l** **From four months onwards in special food products with adapted composition, required for metabolic disorders and for general tube feeding**	Used in some liquid formula containing fibre. When used in combination with additive 412, 401, 410, 415, the hydrocolloids in the mix prevent the separation of fibre in the liquid feed. It is important during the sterilisation process that the room temperature viscosity of the product is reduced otherwise the sterilisation effect will be impaired. At the same time, the same viscosity and gelling effect must be thermoreversible in order to hold the fibres together during feeding. Single hydrocolloids do not have the necessary effect and there are no other protein free additives available for this type of application.

	410	**Carob bean gum** **(Locust bean gum)**		**10 g/l** **From birth onwards in products for reduction of gastro-oesophageal reflux**	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.
	412	**Guar gum**		**10 g/l** **From birth onwards in products in liquid formulae containing hydrolysed proteins, peptides or amino-acids.**	Minimises and delays physical separation of the product, fat separation and fat globule coalescence. Guar gum is an excellent water binder, it does not form gel, which is an advantage in liquid products, it is cold water soluble and will not modify the thickening effect obtained by carrageenan.
	415	**Xanthan gum**		**1.2 g/l** **From birth onwards for use in products based on amino acids or peptides for use with patients who have problems with impairment of the gastro-intestinal tract, protein mal-absorption or inborn errors of metabolism.**	Thickening for semi solid preparation. Optimum viscosity is achieved when used in conjunction with other thickening agents.
	440	**Pectins**		**10 g/l** **From birth onwards in products used in case of gastro-intestinal disorders.**	Used a gelling agent in place of gelatine. Particularly efficient in presence of fruits and in acidic preparations. Thickening for semi solid preparation. Optimum viscosity is achieved when used in conjunction with other thickening agents.

	466	**Sodium carboxymethyl cellulose**		**10 g/l or kg** **From birth onwards in products for the dietary management of metabolic disorders.**	Better thickening, gel formation, solvation and a less "sandy" product is obtained with additive 466 compared to pectine. It disperses easily in water forming colloidal solutions; it can therefore be used as a suspending agent, an emulsifying agent and in the preparation of gels. Furthermore, it improves dispersion of other agents. Its technological functions are hardly influenced by temperature and metal salts have little effect on its viscosity.
	472c	**Citric and fatty acid esters of glycerol**		**7.5 g/kg for formulae sold as powder** **9 g/l for formulae sold as liquid**	Has an HLB value of10-12, is one of the most effective emulsifiers of oil in water emulsions. Produces a stable, milky white emulsion, giving the final product (usually products with superior stability, taste and organoleptic properties. Positive opinion on such usage has been expressed by the European Scientific Committee for Food in June 1997 and September 2002)
	1450	**Starch sodium octenyl succinate**		**20 g/l** **From birth onwards**	Viscosity and stability properties that native starch tend to lose when processed
	Emulsifier				

	471	**Mono- and diglycerides of fatty acids**		**5 g/l** **From birth onwards in specialised diets, particularly those devoid of proteins**	Natural stabiliser that retains homogeneity of liquid products and liquid reconstituted powder. Because it has an intermediate hydrophilic/lipophilic balance (HLB) value, it is suitable for emulsifying products containing fats which require intermediate HLB emulsifiers. It is a robust substance in that it can withstand harsh processing conditions, such a s spray drying and UHT processing. This property has been beneficial for the development of ready-to-feed UHT liquid products providing complete nutrition. It is also used extensively for emulsifying fat and carbohydrate components. Its resistance to ionic interactions make sit suitable for use in products containing mineral and trace element ions such as nutritionally complete products.

World Sugar Research Organisation (WSRO)

WSRO do not recommend the inclusion of the sentence '[sucrose, unless needed, and the addition of fructose particularly should be avoided in infant formula because of potential life-threatening symptoms in young infants with unrecognised hereditary fructose intolerance]' to the essential composition and quality factors of carbohydrates. It is unnecessary to highlight the potential effects of this condition in this way. WSRO suggest it is more appropriate to protect the affected group using current labelling requirements.

B. CCRVDF

(Codex Committee on Residues of Veterinary Drugs in Foods / Comité du Codex sur les résidus de médicaments vétérinaires dans les aliments / Comité del Codex sobre Residuos de Medicamentos Veterinarios en los Alimentos)

Australia

Australia welcomes the opportunity to comment on these matters to be adopted by the 29th Session of the Codex Alimentarius Commission (ALINORM 06/29/31, Appendices IV and VII).

The following is provided in response to Part A of CL2006/14-RVDF:

PROPOSED DRAFT MRLS FOR COLISTIN AND RACTOPAMINE (ALINORM 06/29/31, Para 77 and APPENDIX IV)

Australia supports progression of the MRLs for colistin and ractopamine by the Commission to Step 5.

PROPOSED DRAFT GUIDELINES FOR THE DESIGN AND IMPLEMENTATION OF NATIONAL REGULATORY FOOD SAFETY ASSURANCE PROGRAMMES ASSOCIATED WITH THE USE OF VETERINARY DRUGS IN FOOD PRODUCING ANIMALS (ALINORM 06/29/31, para 86 and Appendix VII)

Australia supports progression of this document by the Commission to Step 5.

C. WORK BY CORRESPONDENCE/TRAVAIL PAR CORRESPONDANCE/ TRABAJO POR CORRESPONDENCIA (REF. ALINORM 04/27/41, PARA 172)

PROPOSED DRAFT REVISED RECOMMENDED INTERNATIONAL CODE OF PRACTICE FOR THE PROCESSING AND HANDLING OF QUICK FROZEN FOODS (ALINORM 06/29/6 Add. 1)

Australia

Australia has the pleasure of submitting the following comments in response to Alinorm 06/27/6 Add 1 — Proposed Draft Recommended International Code of Practice for the Processing and Handling of Quick Frozen Foods. With the reservations expressed below, Australia supports the current iteration of the document and would like to see it progressed to Step 5.

Australia still has some concerns with the separation of food safety and food quality provisions particularly in Section 4 (safety) and Section 5 (quality). Because of the way the document has been constructed by considering mainly quality provisions, it is unclear to what extent the safety issues will eventually be covered off in the final document. What is important is that, because the DAP/quality provisions are **optional,** the HACCP/safety provisions must be sufficiently inclusive and stand-alone to ensure that safety is not compromised in the event that DAPs are not considered.

In Section 6.2 (Temperature Violation), Australia previously noted a concern that there was no explicit safety consideration mentioned for the case where unintended thawing of a product may lead to all or part of the product reaching a temperature which could facilitate pathogen growth. A corrective action is identified in Annex 2 but this is in the form of an optional DAP for a quality consideration. Australia's concerns were not incorporated in the latest draft of the document.

Australia would like to recommend additional wording to paragraph 2 as follows:

"Loads or parts of loads that are warmer than the temperature required for quick frozen food should be identified and sorted immediately. Delivery, removal and sale of these loads or parts of loads should be suspended **and appropriate corrective action should be taken (e.g. release or destroy) following assessment of the loads or part loads for safety and quality**".

Australia would like to point out a small number of minor editorial errors as follows:

2.1 Scope – to be consistent with the definition of a processing facility, food preparation should be part of the Scope i.e. "This Code of Practice applies to the **preparation**, processing, handling, storage, reception and distribution, and retailing of quick frozen food."

3.2.2 Cold Store Design – the wording of the last dot point should be consistent with that in the other dot points i.e. "leaks of any refrigerant ~~should be~~ **are** prevented".

3.3.4 Maintenance Regimes – "Proper maintenance **of,** and repair of any damage to**,** the cold store…"

5.6 Transport and Distribution – second paragraph - the recommended strikethrough should not include the word "of" i.e. the recommended wording should be "…not to impair the efficiency of ~~the freezing process~~ **temperature control**…"