June 2008

codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 4 **ORIGINAL LANGUAGE ONLY**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

Thirty-first Session,
International Conference Centre, Geneva, Switzerland, 30 June – 4 July 2008

COMMENTS ON DRAFT STANDARDS AND RELATED TEXTS SUBMITTED TO THE COMMISSION FOR ADOPTION

(Comments submitted as of 5 June 2008)[1]

CODEX COMMITTEE ON CONTAMINANTS IN FOODS
COMITÉ DU CODEX SUR LES CONTAMINANTS DANS LES ALIMENTS
COMITÉ DEL CODEX SOBRE CONTAMINANTES DE LOS ALIMENTOS

Draft Code of Practice for the Reduction of 3-Monochloropropane-1,2-diol (3-MCPD) during the Production of Acid-Hydrolyzed Vegetable Protein (Acid-HVPs) and Products that Contain Acid- HVPs (N09-2005) at Step 8 of the Procedure (ALINORM 08/31/41 para. 73 and Appendix IV)

Comments of Malaysia

Malaysia

Malaysia supports the adoption of the draft *Code of Practice for the Reduction of 3 Monochloropropane-1,2-Diol (3-MCPD) during the Production of Acid Hydrolyzed Vegetable Proteins (acid-HVPs) and Products that Contain acid-HVPs* by the 31st Session of the Codex Alimentarius Commission at Step 8.

Draft Maximum Level for Ochratoxin A in Raw Wheat, Barley and Rye at Step 8 of the Procedure (ALINORM 08/31/41 para. 112 and Appendix VII)

Comments of CIAA

CIAA (Confédération des industries agro-alimentaires de l'UE)

Supportive of the proposed draft maximum level.

Draft Maximum Levels for Total Aflatoxins in Almonds, Hazelnuts and Pistachios "For further processing" and "Ready-to-eat" at Step 8 of the Procedure (ALINORM 08/31/41 para. 127 and Appendix VIII)

Comments of Iran (Islamic Republic of) and CIAA

Iran (Islamic Republic of)

Iran's reservation, (Reference: ALINORM 08/31/41 Paragraphs 123 & 128), concerning the draft maximum level of 10 µg/kg for total aflatoxins in the case of almonds, hazelnuts and pistachios "ready-to-eat", that has been advanced at Step

[1] This document does not include comments to texts submitted to the Commission for adoption by CCPR, CCFA, CCFL and CCFFV due to the deadline of 15 June 2008 of relevant CLs. These comments will be compiled in CAC/31 LIM/3.

8 to the 31st Session of the Codex Alimentarius Commission for adoption, has two components: The first of which involves the 2007 JECFA risk assessment results as found in the WHO Food Additives Series number 59, under the section on Contaminants, pages 305-356, at: http://whqlibdoc.who.int/publications/2008/9789241660594_eng.pdf, as well as in the WHO Technical Report Series number 947, Subsection 5.1, pages 159-169, at: http://whqlibdoc.who.int/publications/2007/9789241209472_eng.pdf; The second concerns the application of the ALARA principle as a matter of practicality in the case of pistachios of Iranian origin. Both of the abovementioned points, as elaborated below, have lead us to the conviction that in the context of the Codex process, a more appropriate maximum level for total aflatoxins in the case of almonds, hazelnuts and pistachios "ready-to-eat" would be that of 12 µg/kg. This was the opinion expressed by Iran during the second meeting of the Codex Committee for Contaminants in Food, concerning this matter, and remains so at the time of this comment.

1) The 68th meeting of JECFA in 2007 and the two assessment reports derived there from, on the aflatoxin contamination levels in Tree nuts, referenced above, both conclude that: A fully enforced maximum level at 20 µg/kg in Almonds, Brazil nuts, Hazelnuts, Pistachios and dried Figs would have an impact on the relative contribution to dietary aflatoxin exposure in the five GEMS food clusters where contribution to total dietary exposure to aflatoxins is greater than 5%. This significant reduction of intake was also estimated for high-level consumers of the tree nuts. JECFA concluded further that: **The enforcement of any maximum level below that of 20 µg/kg, such as 15, 10, 8 or 4 would have little further impact on the overall dietary exposure to aflatoxins in any of the five highest exposed population groups.**

   In our view the JECFA assessment opinion would justify the setting of a higher maximum level for ready-to-eat pistachios than the proposed level of 10 µg/kg, without compromising consumer safety.

   JECFA has also acknowledged more recent data, which indicates that the roasting of pistachios can significantly reduce aflatoxin levels in pistachios. Roasting is a mandatory processing step for ready-to-eat open in-shell pistachios, (in contrast to other Treenuts which are also consumed raw). This provides an additional safety margin, since the aflatoxin levels used in the JECFA risk assessment came from raw pistachios.

2) For pistachios of Iranian origin specifically, the question of an optimal ML for aflatoxin contamination levels in the case of "ready-to-eat" Tree nuts, encounters a uniquely difficult question when attempting to comply with the Codex principle of "As Low as Reasonably Achievable" (ALARA). The main difficulty being the question of what is the lowest level of contamination in exported consignment of commercial pistachios from Iran, that could be reasonably expected, given the current **uniquely high background** (pre-harvest origin) levels of aflatoxin contamination in commercial lots of Iranian pistachios in the absence of a Codex Maximum Limit, which have been estimated by JECFA to be at a **mean level of** approximately **54 µg/kg.**

   Given the present socio-economic realities of pistachio production in, and export from Iran, (Reference: ALINORM 08/31/41 Paragraph 123 and CRD 7; subsections 2.1-2.6), the possibility that an ML of 10 µg/kg can be reasonably complied with on a nationwide basis, can be safely considered as improbable. It should be considered that such and attempt would result in the un-exportability of at least 49% of the total volume of this crop, according to the latest JECFA assessment on this topic. However, with an ML of 12 µg/kg, about 45- 47% of the total production amount would be deemed un-exportable. The latter of these two scenarios would seem to be more achievable than the former, at least as viewed from a producing nation's perspective. **According to the latest JECFA estimates, the mean AFT content in accepted pistachio lots under an enforced limit of 12 µg/kg, would be about 2.8 µg/kg, which is arguably a very low exposure risk level.**

Thus, it continues to be our opinion that a higher maximum level of 12 µg/kg would add only an insignificant additional risk for the consumers of the ready-to-eat Tree nuts, and we hope that the CAC will reconsider the current proposed level. Furthermore, we suggest that efforts and projects aimed at reducing the aflatoxin contamination in pistachios, be supported by the FAO, WHO and other Codex members, where appropriate, in order to help growers in those developing nations who will be obliged to cope with the adverse economic impact of the proposed Codex maximum level of 10 µg/kg on their production and export of pistachios. Such efforts could take the form of research projects aimed at developing a better understanding of the levels and frequency of aflatoxin contamination in pistachios, as well as the underlying causes of the observed and scientifically quantified levels of contamination. The above said information and data, when gathered, would help in finding ways of rectifying the present contamination problems at the source, rather than having to implement costly and counter productive draconian enforcement measures at the boarders of the importing nations.

CIAA (Confédération des industries agro-alimentaires de l'UE)

Supportive of the proposed draft maximum level.

Proposed Draft Aflatoxin Sampling Plans for Aflatoxin Contamination in Ready-to-eat Treenuts and Treenuts Destined for Further Processing: Almonds, Hazelnuts and Pistachios (N07-2004) at Step 5/8 of the Procedure with the omission of Step 6 and 7 (ALINORM 08/31/41 para. 142 and Appendix IX)

Comments of United States of America and CIAA

United States of America

We would like to note that the definitions for ³treenuts destined for further processing² given in the footnote in Appendix VIII, and in the ³Definitions² section of Appendix IX, while very similar, are not identical.

We would like to suggest the definitions in the two documents be aligned and that the definition given in the footnote in Appendix VIII be used in both documents.

CIAA (Confédération des industries agro-alimentaires de l'UE)

Supportive of the draft Sampling Plan.

Proposed Draft Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Dried Figs (N10-2007) at Step 5/8 of the Procedure with the omission of Step 6 and 7 (ALINORM 08/31/41 para. 163 and Appendix XI)

Comments of Malaysia and CIAA

Malaysia

Malaysia supports the adoption of the *Proposed Draft Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Dried Figs* by the 31st Session of the Codex Alimentarius Commission at Step 5/8.

CIAA (Confédération des industries agro-alimentaires de l'UE)

Supportive of the draft Code of Practice.

CODEX COMMITTEE ON FISH AND FISHERY PRODUCTS
COMITÉ DU CODEX SUR LES POISSONS ET LES PRODUITS DE LA PÊCHE
COMITÉ DEL CODEX SOBRE PESCADO Y PRODUCTOS PESQUEROS

Draft Code of Practice for Fish and Fishery Products (Live and Raw Bivalve Molluscs and Lobsters and relevant Definitions) at Step 8 of the Procedure (ALINORM 08/31/18, para. 62 and Appendix II).

Comments of Brazil and France

Brazil

In response to CL 2008/5-FFP, Brazil strongly disagrees with the following text:

SECTION 13 - PROCESSING OF LOBSTERS

13.1.2 Hygiene Control Programme

When an establishment has its own supply of fresh water or seawater or other water sources, and chlorine is used for water treatment, the residual content of chlorine should not exceed that of potable water.

Brazil suggests maintaining the original text, as follows:

13.1.2 Hygiene Control Programme

• *When in-factory chlorination of water is used, the minimum residual content of free chlorine should be maintained at the effective level for the use intended and at a concentration that would prevent chlorine tainting;*

• *Chlorinating systems should follow the Draft FAO/WHO Guide on the Use of Chlorination in Fish Processing and should not be relied upon to solve all hygiene problems.*

Justification: Since 70's, scientific texts have shown that water treatment based in chlorine could be used to wash seafood, as Connell, JJ. Control de la Calidad del Pescado, Editorial Acribia, 1978 and Bertullo, Victor, Tecnologia de los Productos y Subproductos de Pescados, Moluscos y Crustáceos, Editorial Hemisfério Sur, 1975.

Furthermore, the Discussion Paper on the Use of Chlorinated Water was presented at the twenty fourth session of the Codex Committee on Fish and Fisheries Products, in 2000. In this session, the Representative of WHO introduced the discussion paper which attempted to address two major issues: risks to consumers' health that may result from chlorine by-products arising from elevated levels of chlorine in water used for washing fish and fishery products; and gaps in knowledge concerning current practices at industry level in different countries. The Representative indicated that fish handling practices varied from country to country and from region to region. Chlorinated water up to 10mg/l was widely used in the fish processing sector, in direct contact with fish to prevent microbiological contamination and ensure the relevant sanitation. The Representative concluded that while additional work in this area was recommended, current scientific evidence did not warrant the change of the Codex recommended level of 10mg/l for water in direct contact with fishery products. This paper also concludes that "Consumer exposure to chlorine by-products from the consumption of fish that has been exposed to water treated with up to 10 mg chlorine is likely to be very low. This is based on the worst case risk assessment assumptions on chloroform exposure from poultry treated with 30 mg/l chlorine which indicated minimal, if any, additional cancer risk from this source; and on the exposure assessment calculations based on the results of exposing shrimp to 150 mg/l chlorine for 30 minutes and chlorine uptake. Consumer exposure to chlorine by-products primarily results from chlorinated process water and even if Iow levels are present in raw fishery products, most of these will be lost on cooking." This study confirms that the use of chlorinated water for washing fish is safe for consumers up to 10mg/l.

Huss, H. H., Ababouch, L and Gram, L. in Assessment and Management of Seafood Safety and Quality, FAO Fisheries Technical Paper 444, 2004, also, include the above reference to confirm this level's safety (page 111).

France

DSP / PSP / ASP / NSP

En français, les termes DSP, PSP, ASP et NSP ne sont jamais traduits en IPM, IAM, …. (ces abréviations ne sont pas connues en français). Les termes DSP, PSP, ASP et NSP sont toujours conservés en l'état dans les textes en français.

Traduction des termes « depuration »

Le point 71 de l'alinorm 07/30/18 indique que le remplacement de « purification » par « epuration » ne concerne que la version anglaise. Il est nécessaire de veiller à ce que, dans les versions françaises des documents relatifs aux mollusques bivalves, le terme « **depuration** » de la version anglaise soit traduit par « **purification** » et non par « ~~épuration~~ » comme c'est encore le cas dans les versions françaises dont nous disposons pour la norme et le code d'usage relatifs aux mollusques bivalves. La même attention doit être portée à cette traduction dans les documents relatifs aux coquilles Saint-Jacques et aux ormeaux.

point 7.1 1e ligne du dernier paragraphe

Le terme "live" a été omis

« *to be eaten live or raw* »

Draft Standard for Raw and Live Bivalve Molluscs (ALINORM 08/31/18, para112 and Appendix III).

Comments of France

France

p 74 : Noms scientifiques

Erreur dans le nom scientifique du Crabe de Tanner : le nom scientifique est *ChionoecEtes bairdi* et non ~~*Chionoectes bairdi*~~

- 3e ligne du second paragraphe,

- dernière ligne du XX.2.1.1 Potential Hazards

Erreur dans le nom scientifique du Crabe « red rock » : doit être *Cancer productUs* et non ~~*Cancer productis*~~

- dernière ligne du XX.2.1.1 Potential Hazards

p 67 : Tableau relatif aux biotoxines

Il manque « acid » dans la teneur pour l'OA : *0,16 mg of okadaic acid equivalent*

p 68 : Erreurs de numérotation dans le § I-8.2 :

Remplacer « in sections I-7.3 through I.7.5 » par « in sections I.8.3 through I.8.6 »

~~*in sections I-7.3 through I.7.5*~~

in sections I.8.3 through I.8.6

p 71 : Problème de mise en forme de II.8

Le paragraphe est à la suite du paragraphe I-7.4.2

p 71 : Erreurs de numérotation dans le § II-8.2 :

Remplacer « in sections II-7.3 through II.7.7 » par « in sections II.8.3 through II.8.8 »

~~*in sections II-7.3 through II.7.7*~~

in sections II.8.3 through II.8.8

p 71 : Erreurs de numérotation dans le § du II-8.3

Remplacer « in sections II-7.3.1 through II.7.3.5 » par « in sections II.8.3.1 through II.8.3.5 »

~~*in sections II-7.3.1 through II.7.3.5*~~

in sections II.8.3.1 through II.8.3.5

p 72 : Erreur de numérotation dans le § du II-8.8

Remplacer « refer to I.7.5 » par « refer to I.8.6 »

~~*refer to I.7.5 Determination of Biotoxins*~~

refer to I.8.6 Determination of Biotoxins

CODEX COMMITTEE ON FOOD HYGIENE
COMITÉ DU CODEX SUR L'HYGIÈNE ALIMENTAIRE
COMITÉ DEL CODEX SOBRE HIGIENE DE LOS ALIMENTOS

Proposed Draft Code of Hygienic Practice for Powdered Formulae for Infants and Young Children, at Step 5/8 of the Procedure, with the omission of Step 6 and 7 (ALINORM 08/31/13 para. 62 and Appendix II).

Comments of Brazil and ISDI

Brazil

Brazil has no comments and supports the adoption of the document at step 5/8.

ISDI (International Special Dietary Foods Industries)

The Proposed Draft Code of Hygienic Practice for Powdered Formulae for Infants and Young Children has been moved forward to Step 8 by CCFH at its latest session and hence is now sent to the Codex Commission for final adoption.

ISDI has had the opportunity during the various CCFH sessions to actively contribute to updating this Code of Hygienic Practice that exists since 1969 with the current industry practices and **therefore fully supports its final adoption by the CAC in July 2008**.

Indeed, ISDI notes that in the current Draft Code of Hygienic Practice for Powdered Formulae,

- The Title as proposed better reflects the scope of the Standard,
- The Scope clearly indicates the products covered by this Code of Hygienic Practice:
  - Powdered Infant formula,
  - Powdered Follow-up formula,
  - Formula for special medical purposes intended for infants (sole source of nutrition),
  - Formula for special medical purposes for infants and young children (not sole source of nutrition),
  - Human milk fortifier,
- The Design and Facilities section, the Control of Operation section as well as the Maintenance and Sanitation section give clear guidance on the recommended hygienic measures to apply to produce safe powdered formulae for infants and young children,
- The Product information and Consumer Awareness section as well as the Training section are important additions to the Code which provide guidance on appropriate preparation, handling and use of powdered formulae for infants and young children:
  - Through clear labelling of powdered formulae for infants and young children,
  - Through a good education of caregivers,

This new guidance notably in the Education section (9.4) on preparation, handling and use will also help to minimize risk of contamination from environmental sources which present the potential for significant public health concern.

- The Annex I specifies Microbiological criteria for powdered infant formula, formula for special medical purposes and human milk fortifiers:
  - *E. sakazakii* and *Salmonella*,
  - Mesophilic Aerobic Bacteria and Enterobacteriaceae as process hygienic indicators,

As a conclusion, ISDI fully supports the final adoption of the Proposed Draft Code of Hygienic Practice for Powdered Formulae for Infants and Young Children by the CAC in July 2008.

Proposed Draft Guidelines for the Validation of Food Safety Control Measures, at Step 5/8 of the Procedure, with the omission of Step 6 and 7 (ALINORM 08/31/13 para. 84 and Appendix III)

Comments of Brazil

Brazil

Brazil has no comments and supports the adoption of the document at step 5/8.

Proposed Draft Annex II on the Guidance on Microbiological Risk Management Metrics to the Principles and Guidelines for the Conduct of Microbiological Risk Management, at Step 5/8 of the Procedure, with the omission of Step 6 and 7 (ALINORM 08/31/13 para. 146 and Appendix IV).

Comments of Brazil

Brazil

Brazil has no comments and supports the adoption of the document at step 5/8.

CODEX COMMITTEE ON FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION SYSTEMS
COMITÉ DU CODEX SUR LES SYSTEMES D'INSPECTION ET DE CERTIFICATION DES IMPORTATIONS ET DES EXPORTATIONS ALIMENTAIRES
COMITÉ DEL CODEX SOBRE SISTEMAS DE INSPECIÓN Y CERTIFICACIÓN DE IMPORTACIONES Y EXPORTACIONES DE ALIMENTOS

Proposed Draft Appendix to the *Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification*, at Step 5/8 of the Procedure, with the omission of Step 6 and 7 (ALINORM 08/31/30, para. 44 and Appendix II).

Comments of Brazil, Colombia, Mexico and Peru

Brazil

Brazil would like to support the adoption of the Proposed Draft Appendix at step 5/8.

Colombia

Colombia agradece el trabajo realizado y presenta para consideración de los miembros de la Comisión, las siguientes observaciones a la versión en español del documento CL 2007/44-FICS **ANTEPROYECTO DE APÉNDICE A LAS DIRECTRICES SOBRE LA DETERMINACIÓN DE EQUIVALENCIA DE MEDIDAS SANITARIAS RELACIONADAS CON LA INSPECCIÓN Y CERTIFICACIÓN DE ALIMENTOS:**

El anteproyecto de apéndice tiene como objetivo aclarar y orientar la aplicación de algunos ítems del documento CAC/GL 53-2003 *Directrices para la determinación de Equivalencia de las Medidas Sanitarias relacionadas con los Sistemas de Inspección y Certificación de Alimentos* y por esta razón está presentado como un Apéndice del mismo. Adicionalmente, algunos de sus ítems remiten al documento CAC/GL 34 – 1999 *Directrices para la Elaboración de Acuerdos sobre Sistemas de Inspección y Certificación de Importaciones y Exportaciones de Alimentos.*

Comentarios:

1. Si bien, el anteproyecto de apéndice aporta algunas aclaraciones a las directrices contenidas en el documento CAC/GL 53-2003, varios de sus ítems son similares en redacción y contenido y podría verse como un documento repetitivo de aspectos incluidos en la citada directriz y de otros aspectos contenidos en las directrices CAC/GL 34 – 1999.

2. Lo anterior podría generar alguna confusión en su interpretación y haría difícil cumplir el objetivo que se busca de facilitar la aplicación de las directrices del documento CAC/GL 53-2003 con la adopción del citado apéndice.

3. Teniendo en cuenta que el citado documento surtió los trámites de procedimiento previstos, es importante que se avance y culmine su adopción en el CODEX y por ello, los anteriores comentarios deben tomarse en el contexto de la siguiente recomendación:

Se recomienda a la Comisión del Codex Alimentarius que una vez adoptado el APÉNDICE A LAS DIRECTRICES SOBRE LA DETERMINACIÓN DE EQUIVALENCIA DE MEDIDAS SANITARIAS RELACIONADAS CON LA INSPECCIÓN Y CERTIFICACIÓN DE ALIMENTOS, someta a la consideración del Comité del Codex sobre Sistemas de Inspección y Certificación de Importaciones y Exportaciones de Alimentos, la propuesta de revisión de estas directrices (documento CAC/GL 53-2003) para incorporar el contenido del apéndice en los ítems correspondientes y disponer de un sólo documento, que facilite aún más su aplicación por parte de los países.

Mexico

México agradece la oportunidad de emitir los siguientes comentarios al Anteproyecto de Apéndice a las Directrices sobre la Determinación de Equivalencia de Medidas Sanitarias Relacionadas con la Inspección y Certificación de Alimentos (N04-2204), "*Orientación Adicional para Asistir a los Países Importadores y Exportadores a llevar a cabo una Determinación de Equivalencia de Medidas Sanitarias":*

COMENTARIOS GENERALES.-

Los siguientes comentarios tienen el propósito de mejorar la redacción del texto en español y establecer una mejor concordancia entre éste y la versión del texto en inglés.

Párrafo 2.- En concordancia con el texto en inglés, se sugiere modificar de la siguiente manera: "Existe una amplia gama de circunstancias por las cuales un país exportador puede desear solicitar..."

Párrafo 3.- inciso f).- Se sugiere modificar como sigue: "El grado de preparación para llevar a cabo una determinación de equivalencia, ~~y~~ incluyendo que el país importador..."

Párrafo 4.- Modificar el texto de la siguiente manera: "Entre las etapas preparatorias que deberían ser consideradas se incluyen ~~lo~~as siguiente:"

Inciso a).- En el texto en inglés, se sugiere eliminar "The exporting country" (este texto no aparece en la versión en español"

Inciso d).- se propone redactar: "De corresponder, el país importador y el país exportador deberían elaborar, durante ~~la~~ una etapa ~~inicial~~ temprana del proceso..."

Párrafo 8.- Se sugieren las siguientes modificaciones: "En otras circunstancias, el ámbito de la determinación de equivalencia puede no ~~está~~ ser ~~muy~~ claro y la categorización..., puede ayudar~~ían~~ a establecer el ámbito de la determinación de equivalencia. Específicamente, la categorización puede ayudar a organizar las medidas sanitarias y a efectuar, donde sea apropiado, comparaciones detalladas..."

Párrafo 10.- Se sugiere redactar de la siguiente manera: ~~Un país importador considera~~ La experiencia, el conocimiento y la confianza en el sistema de inspección y certificación de los alimentos de un país exportador por parte de un país importador~~. Ello~~ incluye... ~~Entre los~~ Otros ejemplos que ~~podrían~~ pueden proporcionar información con respecto a la experiencia, conocimiento y confianza del país importador podrían ~~se~~ incluir~~ía~~ lo siguiente:

Inciso c.- Se sugiere modificar el párrafo: "Conocimiento ~~del sistema de control de los alimentos del país exportador y~~ de la implementación y aplicación de los principios de análisis de riesgos en el sistema de control de los alimentos del país exportador;"

Inciso d.- Modificar como sigue: "Inspecciones en el punto de entrada y resultados de ~~las~~ pruebas, registros de rechazos de importaciones y alertas ~~requeridos~~ por parte del ~~el~~ país importador...

Inciso i.- Modificar de la siguiente manera: "Datos de vigilancia referentes a las enfermedades transmitidas por los alimentos ~~y~~ relacionadas ~~al~~ con producto alimenticio en cuestión;"

Inciso n.- Cambiar como sigue: "~~Todo~~ cualquier sistema específico de control de las exportaciones que se halle en ~~funcionamiento~~ operación."

Párrafo 29.- Modificar el texto: "...La comunicación continua entre el país importador y el país exportador puede facilitar el proceso de determinación de equivalencia, entre otras cosas, para esclarecer puntos técnicos y ~~proporcionar~~ responder a la necesidad de información adicional.

Párrafo 31.- Se sugiere modificar el texto de la versión en inglés, ya que la redacción actual difiere de la idea expresada en español.

Título previo al párrafo 34.- Modificar como sigue: "La utilización de las ~~visitas~~ inspecciones in situ"

Párrafos 34.- Cambiar el término "visitas" por "inspecciones"

Párrafo 35, así como los incisos a y b del mismo.- Cambiar el término "visitas" por "inspecciones"

COMENTARIO ESPECÍFICO.-

Párrafo 3.- Existe discrepancia en los textos en español y en inglés. Los incisos a) y e) en español refieren al "sistema de inocuidad de los alimentos", en tanto que el texto en inglés cita "sistemas de control de los alimentos". Por otra parte del inciso d) en ambos idiomas hace referencia a los "sistemas de inocuidad de los alimentos". El contexto de ambos términos es muy diferente y conviene armonizar las versiones en todos los idiomas, tomando en cuenta lo siguiente:

El ámbito de las Directrices es la determinación de equivalencia de medidas sanitarias relacionadas con los sistemas de inspección y certificación de importaciones y exportaciones de alimentos. En ese contexto, las medidas sujetas a evaluación estarían limitadas a aquellas que permiten garantizar la inocuidad de los alimentos. No obstante, los sistemas de inocuidad de alimentos están comprendidos dentro de los sistemas de control de alimentos, por lo que no se considera que sean excluyentes estructural y operativamente. Por lo anterior se sugiere cambiar el término "inocuidad" por "control" en los incisos a), e) y d) -(en el texto en inglés cambiar el término "safety" por "control" en el inciso d)-

Cabe señalar que a lo largo del texto se hace referencia a los sistemas de control de alimentos: Párrafo 2; incisos a; c; g; k del párrafo 10; inciso c del párrafo 34.

Peru

El Perú agradece la oportunidad de expresar su opinión a la presenta Carta Circular, estableciendo su conformidad con la adopción del Texto avanzado del tramite 5 al 8.

CODEX COMMITTEE ON METHODS OF ANALYSIS AND SAMPLING
COMITÉ DU CODEX SUR LES MÉTHODES D'ANALYSE ET D'ÉCHANTILLONAGE
COMITÉ DEL CODEX SOBRE MÉTODOS DE ANÁLISIS Y TOMA DE MUESTRAS

Methods of Analysis in Codex, for adoption (ALINORM 08/31/23, paras 52-61 and Appendix III).

Comments of Australia

Australia

Australia endorses the work of the ad hoc Working Group and agrees with their recommendations.

CODEX COMMITTEE ON MILK AND MILK PRODUCTS
COMITÉ DU CODEX SUR LE LAIT ET LES PRODUITS LAITIERS
COMITÉ DEL CODEX SOBRE LA LECHE Y LOS PRODUCTOS LÁCTEOS

Draft Model Export Certificate for Milk and Milk Products, at Step 8 of the Procedure (ALINORM 08/31/11, para. 31 and Appendix III).

Comments of Egypt, Libyan Arab Jamahiriya, Malaysia, Peru, United States of America and Uruguay

Egypt

EOS supports the draft model export certificate for milk and milk products in Appendix III.

Libyan Arab Jamahiriya

Libya proposing re-editing the statement under section III title Destination of milk and milk products in page 32 and 33 of the document (proposed revision is underlined in the text below).

III- DESTINATION OF MILK AND MILK PRODUCTS

The country of destination and name of the importer may change during transport with advanced knowledge of importing country. Importing countries may or may not accept the provision of supplemantary information in such cases.

MODEL EXPORT CERTIFICATE FOR MILK AND MILK PRODUCTS

III. Destination of milk and milk products [3]

Country of destination: _____

Importer/Consignee Name and Address: _____

The country of destination and name of the importer may change during transport. Importing countries may accept the provision of supplementary information in such cases

~~[3] The country of destination and name of the importer may change during transport. Importing countries may accept the provision of supplementary information in such cases~~

Malaysia

Malaysia supports the adoption of the draft Model Export Certificate for Milk and Milk Products at Step 8 by the 31st Session of the Codex Alimentarius Commission. Malaysia is of the view that the Model Export Certificate serves as a guide for governments to provide adequate information for traceability, in addition to certification for complying public health requirements in the trade of milk and milk products to ensure consumer health.

Peru

a). El Certificado Sanitario Oficial de Exportación emitido por la autoridad competente de nuestro País es la DIGESA del Ministerio de Salud, teniendo modelos establecidos para la exportación de alimentos y bebidas industrializados. El modelo que se emite para productos lácteos o derivados lácteos está inmerso al de alimentos varios.

b). El modelo emitido para estos productos, consignan los puntos indicados en la propuesta del CODEX ALIMENTARIUS; sin embargo, se puede tener en cuenta lo siguiente:

- "The country of dispatch" es un dato importante que debería ir consignando junto con "Competent authority responsable for certification".
- "Presentation (cans, bottles, etc) es otro punto que debería incluirse en el punto I. details indentifying milk and milk products.
- En el Numeral "II. Provenance of milk and milk products, Country of dispatch" para ser más específicos se sugeriria incluir el término "Port and Country of dispatch", asimismo esta observación aplicaría para el numeral "III Destination of milk and milk products, Country of destination.
- Exporter or consignor" y "Name and Address", consignados en el punto II, se sugiere considerer: "Name and Address of dispatcher or exporter or consignor".
- En el Numeral "IV Attestation", para el caso nacional: únicamente se podría certificar que el producto ha sido elaborado" prepared or produced Ander good hygienic practice and an effective food safety control system, implemented within the context of HACCP.
- Adicionalmente, en el numeral IV, la autoridad competente, también debería certificar que los productos son " For human consumption".

United States of America

The United States fully supports the adoption the Draft Model Certificate for Milk and Milk Products at Step 8.

Uruguay

El Subcomité de Leche y Productos Lácteos de Uruguay está de acuerdo con lo recomendado. Cualquier cambio o enmienda debería ser discutida nuevamente.

Proposed Draft Amendment to the List of Additives of the Codex *Standard for Creams and Prepared Creams* (CODEX STAN A-9-1976) (N08-2006), at Step 5/8 of the Procedure, with the omission of Step 6 and 7 (ALINORM 08/31/11, para. 82 and Appendix V).

Comments of Libyan Arab Jamahiriya, New Zealand, Peru, United States of America and Uruguay

Libyan Arab Jamahiriya

All food additives listed under section Emulsifiers, of the ALINORM 08/31/11 Appendix V should be halal or from plant origin and should be declared on the label according to the Codex General Guidelines for Use of Term "Halal" (CAC/GL 24-1997).

New Zealand

Proposal to correct an omission in endorsement of additives requested for Codex Standard Creams and Prepared Creams (08/31/12 paras 55, 81 appendix VII)

The 40th Session of the Codex Committee on Food Additives agreed to endorse the proposal for the re-inclusion of INS 472e at a maximum level of 5000 mg/kg as a stabilizer/thickener for creams and prepared creams in the *Codex Standard*

for Creams and Prepared Creams. New Zealand notes that the final decision on the inclusion of the food additive will be made by the 31st Session of the Commission[2].

Background

At CCFA 40th session, the delegation of New Zealand, as the host country for CCMMP, provided information that the provision for *472e Diacetyltartaric and fatty acid esters of glycerol* was mistakenly deleted from the list of stabiliser/thickener additives for *Codex Standard for Creams and Prepared Creams (N08-2006)* as sent to CCFA 40 by the 8th meeting of CCMMP for endorsement at Step 5/8.

The omission can be found in CCFA 40 agenda item 4 (c), paper CX/08/40/4 page 19 immediately below the entry *516 Calcium sulphate.* The missing provision is:

472e - Diacetyltartaric and fatty acid esters of glycerol - 5000 mg/kg

This provision was included in the CCMMP 8 agenda paper CX/MMP 08/8/6 on page 4. CCMMP 8 made no decision to remove the entry for 472e and there is general agreement that this provision in CX/MMP 08/8/6 should have been included in the list for endorsement and that the omission is a mistake.

Therefore, New Zealand, as host country of CCMMP and on behalf of its Chairperson, proposed that:

> "CCFA 40 endorses *472e Diacetyltartaric and fatty acid esters of glycerol* at a maximum level of use of 5000 mg/kg as a stabiliser/thickener, in creams and prepared creams at Step 5/8 in Codex Standard for Creams and Prepared creams (N08-2006), with the final decision for inclusion in the standard being left to the CAC."

New Zealand therefore supports the re-inclusion of *472e Diacetyltartaric and fatty acid esters of glycerol* in the Codex General Standard for Food Additives.

Peru

Expresamos nuestra conformidad.

United States of America

The United States also agrees with the Codex Committee on Milk Products decision to subject Proposed Draft Amendment to the List of Food Additives of the Codex Standard for Creams to an accelerated elaboration procedure

Uruguay

El Subcomité de Leche y Productos Lácteos de Uruguay está de acuerdo con lo recomendado. Cualquier cambio o enmienda debería ser discutida nuevamente.

Maximum Levels for Annatto Extracts in Codex Standards for Milk and Milk Products, including consequential changes to the provision for beta-carotene (vegetable), for adoption (ALINORM 08/31/11, para. 17 and Appendix II).

Comments of Egypt, Peru and Uruguay

Egypt

EOS would like to emphasize the following information:

- The standardization of annatto in cheeses is not a straightforward matter as the colour is affected by Fat and water content and the acidity of the cheese.
- Annatto as a factor in cheese faults:

  The formula of annatto indicates, very susceptible of oxidation bleaching, therefore, any factor which leads to bleaching of annatto may cause discoloration in annatto cheese. Thus if lactobacilli or other bacteria produce hydrogen peroxide, sulphydryl or other compounds catalysing the oxidation (bleaching) of bixin and air obtained access through cracks in the cheese, discoloration may occur. Oxidation may cause bleaching, and drying out a darkening of the pigment. Copper and iron content in cheese and light accelerate the oxidation of annatto and light accelerate the oxidation of annatto by hydrogen peroxide and sulphydryl compounds.

Peru

Expresamos nuestra conformidad al texto.

[2] ALINORM 08/31/12 paragraph 55.

Uruguay

El Subcomité de Leche y Productos Lácteos de Uruguay encuentra altos los niveles máximos para los extractos de annato sugeridos en el Apéndice II de la Alinorm 08/31/11, por lo que sugiere una revisión de estos niveles. Los mismos serán sometidos a discusión según los criterios del Comité de Aditivos Alimentarios.

Food Additive Listings of the *Standard for Fermented Milks* (CODEX STAN 243-2003), for adoption (ALINORM 08/31/11, para. 93 and Appendix VI).

Comments of Libyan Arab Jamahiriya, Peru and Uruguay

Libyan Arab Jamahiriya

All food additives listed under section Emulsifiers, Flavour enhancers and Stabilizers and Thickeners of the ALINORM 08/31/11 Appendix VI should be halal or from plant origin and should be declared on the label according to the Codex General Guidelines for Use of Term "Halal" (CAC/GL 24-1997).

Peru

Nos abstenemos de opinión en razón que en el País no se realiza investigación sobre aditivos alimentarios.

Uruguay

El Subcomité de Leche y Productos Lácteos de Uruguay está de acuerdo con lo recomendado. Cualquier cambio o enmienda debería ser discutida nuevamente.

Updated List of Methods of Analysis and Sampling in Codex Standards for Milks and Milk Products for adoption (ALINORM 08/31/11, para. 107 and Appendix VII)

Comments of Egypt, Peru and Uruguay

Egypt

List of AOAC methods for milk and milk products Appendix VIII.

- In respect to ISO 3594/1972) IDF 54 : 1979/ AOAC 965 : 33.
- The glass and stainless steal column specified in these methods (GLC) for detecting adult ration of milk fat by vegetable fat are not available now, and not work well, so EOS suggests the replacement of glass or stainless steal column with capillary column.

Peru

Expresamos nuestra conformidad con los métodos de análisis y muestreo propuestos.

Uruguay

El Subcomité de Leche y Productos Lácteos de Uruguay considera referentes los Métodos de Análisis y muestreo utilizados por las normas FIL/ISO, no oponiéndose al uso de Métodos de la AOAC como alternativa luego de presentadas las observaciones y el estudio de la idoneidad correspondiente.

Se esta de acuerdo con el envío de la lista actualizada a CCMAS para su aprobación. Se sugiere la revisión por parte del CCMAS de la norma utilizada para la determinación de la Proteína total en los sueros en polvo, para que se aplique la norma FIL 20-1:2002 o FIL 20-2:2002 en vez de la FIL 92:1979 que es para caseínas y caseinatos

CODEX COMMITTEE ON NUTRITION AND FOOD FOR SPECIAL DIETARY USES
COMITÉ DU CODEX SUR LA NUTRITION ET LES ALIMENTS DIETETIQUES OU DE REGIME
COMITÉ DEL CODEX SOBRE NUTRICIÓN Y ALIMENTOS PARA REGÍMENES ESPECIALES

Draft Revised Codex Standard for Foods for Special Dietary Use for Persons Intolerant to Gluten, at Step 8 of the Procedure (ALINORM 08/31/26 para. 64 and Appendix III).

Comments of Canada, Iran and ISDI

Canada

Canada supports the recommendation of the 29th Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses to advance the **Draft Revised Codex Standard for Foods for Special Dietary Use for Persons Intolerant to Gluten** to Step 8 for final adoption by the 31st Session of the Codex Alimentarius Commission.

Iran (Islamic Republic of)

Item 4-Labeling 4.3 Iran suggest not to have the statement . "This food is by nature gluten -free " on the label, because the consumer may think that other brands of the same product do contain gluten. In other words ,such a statement may be a misleading statement.

ISDI (International Special Dietary Foods Industries)

The Draft Revised Codex Standard for Foods for Special Dietary Use for Persons Intolerant to Gluten has been moved forward to Step 8 by CCNFSDU at its latest session and hence is now sent to the Codex Commission for final adoption.

ISDI has had the opportunity during the various CCNFSDU sessions to actively participate to the discussions on the revision of this Standard that exists since 1981 and **therefore fully supports its final adoption by the CAC in July 2008**.

Indeed, ISDI notes that in the current Draft Revised Codex Standard,

- The Title as proposed better reflects the scope of the Standard,
- The Definition of the different products covered by this Standard is clearer and establishes the existence of two categories of Foods for Persons Intolerant to Gluten:
  - Gluten-free foods,
  - Foods specially processed to reduce gluten content to a level above 20 up to 100 mg/kg,
- The Essential Composition gives clear guidance on the content in gluten of the two categories of Foods for Persons Intolerant to Gluten:
  - Less than 20 mg/kg for Gluten-free foods,
  - Above 20 and up to 100 mg/kg for Foods specially processed to reduce gluten content to a level above 20 up to 100 mg/kg,
- The Labelling section clearly indicates that:
  - the first category of Foods for Persons Intolerant to Gluten is the only one that can be called *'gluten-free'*,
  - the labelling of the second category of Foods for Persons Intolerant to Gluten is left to the discretion of national authorities,
  - the labelling of normal foods that would be, by nature, suitable for Persons Intolerant to Gluten could bear the words *'this food is by nature gluten-free'*,
- The Methods of analysis section gives clear guidance on which method can be used to measure the gluten content of foods and ingredients,

As a conclusion, **ISDI fully supports its final adoption by the CAC in July 2008.**

Draft Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses Intended for Infants and Young Children, at Step 8 of the Procedure (ALINORM 08/31/26, para. 78 and Appendix IV).

Comments of Canada, AIDGUM and ISDI

Canada

Canada supports the recommendation of the 29th Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses to advance the **Draft Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses Intended for Infants and Young Children** to Step 8 for final adoption by the 31st Session of the Codex Alimentarius Commission.

AIDGUM (Association Internationale pour le développement des gommes naturelles – International Association for the Development of Natural Gums)

Aidgum submitted a comment on September 22, 2006 on this subject when it was proposed that the Gum Arabic/ gum Acacia level should be reduced from 100 to 10 mg/ kg in the Ready to Use Food.

JECFA has assigned Gum Acacia an "ADI not specified" status when used as an additive, meaning that it can be used for additive purposes according to good manufacturing practice (GMP) principles. The GSFA, Table 3, also recognizes acacia gum as a product that can be used according to GMP. In some countries, such as the USA, Gum Acacia is classified as a generally recognized as safe (GRAS) food component and in France AFSSA has recognized Gum Acacia (Arabic) as a soluble dietary fibre with pre biotic properties.

Aidgum confirms the need for 100 mg/kg of Gum Arabic (gum Acacia) when used as a coating agent to prevent oxidation or other deterioration of vitamins or other minor ingredients in foods for infants and young children. Use at 100 mg/kg as a coating agent is necessary for adequate protection of these minor ingredients, which are added to bulk and other ingredients of finished, packaged foods for infants and young children.

The level of acacia gum in the finished product will be well below 10 mg/kg, but Aidgum recommends that the level in the Advisory List should be related to the use of acacia gum for the food ingredient, rather than in the finished product to avoid confusion.

If CCNFSDU and Codex wish to specify levels of additives in the finished product, we believe that the report of the next CCNFSDU session that will consider this issue make clear that use of substances such as acacia gum for coating and protecting minor but important ingredients will require up to 100 mg/kg as a coating agent for these minor ingredients, resulting in a level of the substance in the finished product at less than 10 mg/kg.

ISDI (International Special Dietary Foods Industries)

The Draft Advisory List of Nutrients Compounds for Use in Foods for Special Dietary Uses Intended for Infants and Young Children has been moved forward to Step 8 by CCNFSDU at its latest session and hence is now sent to the Codex Commission for final adoption.

ISDI has had the opportunity during the various CCNFSDU sessions to contribute to the update of this List that exists since 1979 to reflect the current industry usages and **therefore fully supports its final adoption by the CAC in July 2008**.

Indeed, ISDI notes that in the current Draft Advisory List of Nutrients Compounds,

- Clear criteria have been set for the inclusion or for the deletion of nutrient compounds for the Advisory List including:
  - The need to demonstrate the safety and appropriateness of the nutrients as a nutrient source for the specific age group,
  - The biologically availability of the nutrient through appropriate animal and/or human studies,
  - The availability of purity criteria; either internationally or nationally recognised,
  - The need to demonstrate the stability of the nutrient in the particular foods for which it is requested,
- It has been clearly indicated that any Optional Ingredients could be added to Foods for infants and young children, even if they are not specifically mentioned in the Codex standards, with the condition that they fulfil the criteria of the Advisory List as described above.
- Mineral salts and trace elements, vitamin compounds, amino acids and other nutrients as well as food additives that can be used as nutrient carriers, for reasons of stability and safe handling of certain vitamins and other nutrients have been listed.

Note for correction

ISDI however would like to note that for *'1.22 L-Arginine L-aspartate'* the purity criterion 'FP' has been listed without having been listed in the Abbreviations. ISDI would like to indicate that FP 10 means French Pharmacopoeia Ed. 10th.

However, the monograph of L-Arginine-L-Aspartate has been suppressed from the French Pharmacopoeia in 2005 since it was part of the European Pharmacopoeia.

ISDI therefore suggests the CAC to modify the table as follows:

1.22 L-Arginine L-aspartate'		~~FP~~ Ph Eur	-	√				√

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

Draft Maximum Residues Limits (MRLs) for Veterinary Drugs (colistin and ractopamine), at Step 8 of the Procedure (ALINORM 08/31/31, paras 45, 47and Appendix II).

Comments of Australia, Brazil, China, Egypt, Iran (Islamic Republic of), Peru and IFAH

Australia

Colistin

Although Australia does not have a market authorisation for any products containing colistin, we support adoption of the colistin draft standards at Step 8 by the 31st session of the Codex Alimentarius Commission.

Ractopamine

Australia supports adoption of the ractopamine draft standards at Step 8 by the 31st session of the Codex Alimentarius Commission.

Brazil

Brazil supports the adoption of the Draft Maximum Residues Limits for Veterinary Drugs of Colistin and Ractopamine at Step 8.

China

As far as we have known from existing data, toxicology experiment on human long-term exposure to Ractopamine has not shown enough evidence that there is none negative effect on people who consume animal products fed by Ractopamine.

For instance, people suffering from chronic bronchitis tend to be more sensitive to Ractopamine than normal people. Besides, there is evidence showing Ractopamine makes negative impact on cardiovascular system, like speeding up heart rate.

In view of Chinese consumers' behavior and the characteristics of Ractopamine, further research regarding the influence (e.g. tissue distribution and residue) on animal internal organs (e.g. lung, stomach, intestine, etc.) and potential hazard is strongly recommended.

Therefore, China it is not suggested advancing MRL of Ractopamine further to Step 8.

Egypt

Colistin

About the committee agreement to advance the draft MRLs for Colistin in cattle, sheep, goat, pig, chicken, turkey and rabbit's tissues, in cattle and sheep's milk and chicken's eggs to step 8. We fully agree about this advancement to step 8 for the aforementioned MRLs of Colisting in tissues, milk and eggs.

Ractopamine

We disagree with the opinions of delegations of the Europ. Comm., Norway and Switzerland and we support the full agreement for the advance of the MRLs of Ractopamine to step 8 in cattle and pig tissues.

Iran (Islamic Republic of)

Ractopamin, injection colistin and injection erythromycin have not registered and used in Islamic Republic of Iran yet.

Peru

El Perú agradece la oportunidad de expresar su opinión a la presente Carta Circular relacionada a Proyectos y anteproyectos de límites máximos de residuos (LMR) para medicamentos veterinarios, estableciendo su conformidad para su aprobación en el trámites 8.

IFAH (International Federation for Animal Federation)

In response to CL 2007/37 – RVDF (Part A – Matters for Adoption by the 31st Session of the Codex Alimentarius Commission), the International Federation for Animal Health supports the adoption of the Draft Maximum Residue Limits for Colistin and Ractopamine at step .

Proposed Draft Maximum Residues Limits (MRLs) for Veterinary Drugs (erythromycin), at Step 5/8 of the Procedure, with the omission of Step 6 and 7 (ALINORM 08/31/31, para. 49 and Appendix III).

Comments of Australia, Brazil, Egypt, Peru and IFAH

Australia

Australia supports adoption of the erythromycin draft standards at Step 5/8 by the 31st session of the Codex Alimentarius Commission.

Brazil

Brazil supports the adoption of the Proposed Draft Maximum Residues Limits for Veterinary Drugs of Erythromycin at Step 5/8.

Egypt

Full acceptance of the committee agreement to the advancement of MRLs for Erythromycin in chicken and turkey tissues to step 5/8.

Peru

El Perú agradece la oportunidad de expresar su opinión a la presente Carta Circular relacionada a Proyectos y anteproyectos de límites máximos de residuos (LMR) para medicamentos veterinarios, estableciendo su conformidad para su aprobación en el trámites 5/8.

IFAH (International Federation for Animal Federation)

In response to CL 2007/37 – RVDF (Part A – Matters for Adoption by the 31st Session of the Codex Alimentarius Commission), the International Federation for Animal Health supports the adoption of the Proposed Draft Maximum Residue Limits for Erythromycin at step 5/8.

TASK FORCE ON FOODS DERIVED FROM BIOTECHNOLOGY
GROUPE INTERGOUVERNEMENTAL SPÉCIAL SUR LES ALIMENTS DERIVES DES BIOTECHNOLOGIES
GRUPO DE ACCIÓN INTERGUBERNAMENTAL ESPECIAL SOBRE ALIMENTOS OBTENIDOS POR MEDIOS BIOTECNOLÓGICOS

Comments of Colombia and European Community

Colombia

Colombia expresa su agradecimiento a todos los países que han trabajado en la generación y estructuración de los documentos: **Proposed Draft Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Animals, Proposed Draft Annex on Food Safety Assessment of Foods Derived from Recombinant-DNA Plants Modified for Nutritional or Health Benefits** y **Proposed Draft Annex on Food Safety Assessment in Situations of Low-level Presence of Recombinant-DNA Plant Material in Food,** manifestamos estar de acuerdo con el contenido de los tres documentos, considerando que los mismos son sólidos y han sido ampliamente discutidos, sin embargo y teniendo en cuenta la invitación que se hace a los países para enviar comentarios a los documentos antes citados, se presentan a continuación algunas recomendaciones que consideramos pueden aportar a la claridad de los proyectos de norma.

European Community - Communauté européenne - Comunidad Europea

English

The European Community and its Member States (ECMS) wish to commend the Task Force on Foods derived from Biotechnologies for the excellent results achieved and Japan as hosting country of the TFFBT for the outstanding chairmanship.

The Task Force has fully met its mandate and, following its last meeting, the Codex Alimentarius Commission is now in the position to consider the adoption of three new documents on the Safety assessment of Foods derived from Biotechnology. The ECMS wish to submit specific comments related to these three draft documents.

Français

La Communauté européenne et ses États membres (EMCE) souhaitent féliciter le groupe de travail sur les aliments dérivés des biotechnologies pour les excellents résultats obtenus, et le Japon pour sa remarquable présidence en tant que pays hôte du groupe de travail.

Ce dernier a pleinement rempli son mandat et, depuis sa dernière réunion, la commission du Codex Alimentarius est en mesure d'envisager l'adoption de trois nouveaux documents relatifs à l'évaluation de la sécurité des aliments dérivés des biotechnologies. Les EMCE souhaitent formuler quelques commentaires à propos de ces trois projets de documents.

Español

La Comunidad Europea y sus Estados miembros desean felicitar al Grupo de acción sobre alimentos obtenidos por medios biotecnológicos por los excelentes resultados alcanzados, así como a Japón, en su calidad de país anfitrión del Grupo de acción, por su extraordinaria labor de presidencia.

El Grupo de acción ha cumplido plenamente su mandato y, tras su última reunión, la Comisión del Codex Alimentarius se encuentra en condiciones de considerar la aprobación de tres nuevos documentos sobre la evaluación de la inocuidad de alimentos obtenidos por medios biotecnológicos. La Comunidad Europea y sus Estados miembros desean presentar observaciones específicas relacionadas con estos tres proyectos de documento.

Proposed Draft Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Animals, at Step 5/8 of the Procedure, with the omission of Step 6 and 7 (ALINORM 08/31/34, para. 33 and Appendix II).

Comments of Colombia, European Community and United States of America

Colombia

Párrafo 9:

- Se solicita que en el documento final en español, se tenga especial cuidado con la traducción que se de al termino "Recombinant-DNA animal" con el fin de evitar posibles confusiones. Por lo anterior se solicita que en el texto en español el término empleado sea **Animal con ADN**, término que resulta claro y consistente con el contenido del proyecto de norma y las definiciones propuestas.
- Se solicita que en la definición de "Conventional Counterpart", se revise el empleo del termino "breed" (raza en español) por cuanto en español el termino "raza" no aplica para la variedad de animales para el cual esta propuesto el proyecto de norma. Por ejemplo no se habla de razas de peces o aves.
- Incluir la definición de "Biotecnología moderna", siguiendo la estructura que presentan las demás normas Codex sobre alimentos obtenidos de la biotecnología moderna. Para lo cual se propone tomar la definición establecida en la norma Codex CAC/GL 44-2003.

Párrafo 19 (B), pie de página 6:

- se solicita modificar el pie de página como sigue, a fin de dar mayor claridad al término "surrogate dam":
  "Not to be confused with a surrogate **or recipient of an embryo**".

Párrafo 22.

- Solicita incluir la frase "relative to its conventional counterpart", con el fin de dar mayor claridad. El párrafo quedaría redactado así:

  "The goal of each safety assessment is to provide assurance, in the light of the best available scientific knowledge, that the food does not cause harm when prepared, used and/or eaten according to its intended use, **relative to its conventional counterpart**. Safety assessments should address the health aspects for the whole population, including immunocompromised individuals, infants, the elderly and individuals with food hypersensitivities. The expected endpoint of such an assessment will be a conclusion regarding whether the new food is as safe as the conventional counterpart taking into account dietary impact of any changes in nutritional content or value. In essence, therefore, the outcome of the safety assessment process is to define the product under consideration in such a way as to enable risk managers to determine whether any measures are needed to protect the health of consumers and if so to make well-informed and appropriate decisions in this regard".

- USE OF ANTIBIOTIC RESSITANCE MARKER GENES, Párrafo 64 a 67: Colombia está de acuerdo con que se mantenga el texto de genes de resistencia a antibióticos como marcadores como se encuentra en este momento, no obstante solicita que en revisiones futuras se evalúe la pertinencia de continuar utilizando este tipo de marcadores de selección
- ANNEX: ASSESSMENT OF POSSIBLE ALLERGENICITY, Párrafo 8: se solicita eliminar la nota de pie de página número 14 y modificar la redacción del párrafo como sigue:

  "The purpose of a sequence homology comparison is to assess the extent to which a newly expressed protein is similar in structure to a known allergen. This information may suggest whether that protein has an allergenic potential. Sequence homology searches comparing the structure of all newly expressed proteins with all known allergens. Searches should be conducted using various algorithms such as FASTA or BLASTP to predict overall structural similarities. Strategies such as stepwise contiguous identical amino acid segment searches may also be performed for identifying sequences that may represent linear epítopes. The size of the contiguous amino acid search **should be done moving from 8 to 6 identical amino acid segments**. Validated search and evaluation procedures should be used in order to produce biologically meaningful results."

  Lo anterior se sustenta en el hecho de que existe evidencia experimental sobre la presencia de epítopes B de 6 aminoácidos en varios antígenos, incluyendo alérgenos. El empleo de este criterio en la evaluación de OGM se sustenta en que es posible que la concordancia en 6 aminoácidos contiguos encontrada entre la proteína en estudio y un alérgeno, coincida con una región reconocida por anticuerpos IgE, es decir, un epitope. Como es de esperarse, no todos los hallazgos positivos de similitud se relacionan con un verdadero epítope, generando así falsos positivos. Sin embargo, la utilización de una ventana de mayor tamaño reduce la utilidad de la predicción al permitir la ocurrencia de falsos negativos, lo cual es de mayor preponderancia por su repercusión en la salud humana. Además, la

existencia de un resultado positivo mediante esta evaluación no determina la decisión final en cuanto al potencial alergénico de la proteína en cuestión, sino que exige la realización de ensayos confirmatorios[3],[4],[5]

Apoyamos el tramite acelerado para el Anexo: Assessment of Possible Allergenicity, pero solicitamos se de la discusión con relación y se invite a continuar las consultas con relación a las evaluaciones de bioinformática en ventana de 8 a 6 secuencias de aminoácidos.

- SECTION 3.3. PEPSINE RESISTANCE, párrafo 12-13 y SECTION 4-SPECIFIC SERUM SCREENING, párrafo 14-15: Se solicita al Comité de Análisis y Muestreo del Codex incluir dentro de los temas en estudio los lineamientos de los protocolos sugeridos para la resistencia a la pepsina y los análisis de suero específicos, con el fin de armonizar los métodos de análisis, criterios de evaluación, estándares y parámetros a considerar, entre otros.

European Community - Communauté européenne - Comunidad Europea

English

The ECMS consider that this guideline will provide essential guidance for the safety assessment of foods derived from recombinant-DNA animals. The Codex task force on Biotechnology has, by its very nature, worked in an area where the experience of food safety assessment is, compared to the majority of the Codex activities, limited. This is even more the case for the present guideline. The Codex Alimentarius Commission might thus consider, with a view to identify the possible needs to review this guideline in the future, to pay particular attention to the development of experience by its members in the application of this guideline and new developments for the safety assessment of this type of foods.

The ECMS wish also to stress that, as adequately reflected in paragraph 2 of the draft guidelines, the development, raising and use of recombinant-DNA animals for human purposes, and in particular, for use for food, raise a variety of issues beyond food safety. Although these issues, while important, are not within the scope of this guideline, they are essential when considering, from an early stage, the use of recombinant-DNA animals for human purposes.

Considering the above elements, the ECMS fully support the final adoption at step 5/8 of this draft guideline with the omission of steps 6 and 7.

Français

Les EMCE estiment que cette directive apportera des conseils essentiels à l'évaluation de la sécurité des aliments issus d'animaux à ADN recombiné. Étant donné sa nature, le groupe spécial du Codex sur les biotechnologies a travaillé dans un domaine où l'expérience en matière d'évaluation de la sécurité sanitaire des aliments est limitée par rapport à la majorité des activités du Codex, et c'est d'autant plus vrai dans le cas de la présente directive. La commission du Codex Alimentarius pourrait donc envisager, afin de déterminer l'éventuelle nécessité de revoir cette directive à l'avenir, de veiller plus particulièrement au développement de l'expérience de ses membres dans l'application de ce texte, ainsi qu'aux nouvelles avancées dans le domaine de l'évaluation de la sécurité de ce type d'aliments.

Les EMCE souhaitent également souligner que, comme l'indique de manière adéquate le paragraphe 2 des projets de directives, le développement, l'élevage et l'utilisation des animaux à ADN recombiné à des fins humaines et, en particulier, pour la production d'aliments, soulèvent diverses questions dépassant la simple sécurité sanitaire des aliments. Bien que cette directive ne porte pas sur ces questions en dépit de leur importance, il est fondamental d'en tenir compte dès le départ lorsque l'on envisage d'utiliser des animaux à ADN recombiné à des fins humaines.

Compte tenu des éléments ci-dessus, les EMCE soutiennent pleinement l'adoption définitive à l'étape 5/8 de ce projet de directive avec omission des étapes 6 et 7.

Español

La Comunidad Europea y sus Estados miembros consideran que estas directrices proporcionarán orientaciones esenciales para la evaluación de la inocuidad de los alimentos obtenidos de animales de ADN recombinante. Por su propia naturaleza, el Grupo de acción del Codex sobre biotecnología ha trabajado en un ámbito en el que la experiencia en materia de evaluación de la inocuidad de los alimentos es limitada en comparación con la mayoría de las actividades del Codex. En el caso de las presentes directrices, esto es especialmente evidente. Por tanto, para identificar las posibles necesidades de revisar estas directrices en el futuro, la Comisión del Codex Alimentarius podría prestar especial

[3] Beezhold, D.H., et al., *Human IgE-binding epitopes of the latex allergen Hev b 5.* J Allergy Clin Immunol, 1999. **103**(6): p. 1166-72.

[4] Banerjee, B., et al., *Conformational and linear B-cell epitopes of Asp f 2, a major allergen of Aspergillus fumigatus, bind differently to immunoglobulin E antibody in the sera of allergic bronchopulmonary aspergillosis patients.* Infect Immun, 1999. **67**(5): p. 2284-91.

[5] Kleter, G.A. and A.A. Peijnenburg, *Screening of transgenic proteins expressed in transgenic food crops for the presence of short amino acid sequences identical to potential, IgE - binding linear epitopes of allergens.* BMC Struct Biol, 2002. **2**: p. 8.

atención a la experiencia adquirida por sus miembros en la aplicación de las directrices así como a las novedades respecto a la evaluación de la inocuidad de este tipo de alimentos.

La Comunidad Europea y sus Estados miembros también desean destacar que, tal y como se refleja adecuadamente en el apartado 2 del proyecto de directrices, la obtención, cría y utilización de animales de ADN recombinante para usos humanos, y en concreto para uso alimentario, plantea diversas cuestiones que van más allá de la inocuidad de los alimentos. Aunque dichas cuestiones, pese a ser importantes, no entran dentro del ámbito de aplicación de las presentes directrices, son esenciales cuando se considera, desde una fase temprana, el uso de animales de ADN recombinante para usos humanos.

Teniendo en cuenta los elementos anteriores, la Comunidad Europea y sus Estados miembros apoyan plenamente la aprobación definitiva, en el Trámite 5/8, de este proyecto de directrices, omitiendo los Trámites 6 y 7.

United States of America

The United States strongly supports adoption of the *Proposed Draft Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Animals* at Step 5/8. We believe this guidance document will provide very helpful information to countries with respect to the safety assessment of recombinant-DNA animals.

Proposed Draft Annex on Food Safety Assessment of Foods Derived from Recombinant-DNA Plants Modified for Nutritional or Health Benefits, at Step 5/8 of the Procedure, with the omission of Step 6 and 7 (ALINORM 08/31/34, paras 73, 74 and Appendix III).

Comments of Colombia, European Community and United States of America

Colombia

- SECTION 3 – FOOD SAFETY ASSESSMENT, Párrafo 6. Se solicita que en el pie de página 4, se cite el nombre completo de la norma Codex a la cual se refiere. Por lo tanto se sugiere la siguiente redacción, como se encontraba en la versión anterior del proyecto de norma:

  "Further guidance for susceptible and high-risk population groups is provided in paragraph 49 of CAC/GL 45-2003 -Guideline for the conduct of food safety assessment of foods derived from recombinant-DNA plants"

- Párrafo 7. Consideramos que se debe adicionar la frase "or counterparts" teniendo en cuenta que puede ser uno o varios comparadores. Por lo tanto se sugiere la siguiente redacción:

  "Rather than trying to identify every hazard associated with a particular food, the intention of a safety assessment of food derived from recombinant-DNA plants is the identification of new or altered hazards relative to the conventional counterpart **or counterparts**. Since recombinant-DNA plants modified for nutritional or health benefits result in food products with a composition that may be significantly different from their conventional counterparts, the choice of an appropriate comparator6 is of great importance for the safety assessment addressed in this Annex. Those alterations identified in a plant modified to obtain nutritional or health benefits are the subject of this safety assessment."

European Community - Communauté européenne - Comunidad Europea

English

The ECMS note that this new annex to the guideline for the conduct of food safety assessment of foods derived from recombinant-DNA plants, developed by the Task Force on Foods derived from Biotechnologies, was reviewed and endorsed by the Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU).

The ECMS fully support the final adoption at step 5/8 of this annex with the omission of steps 6 and 7.

Français

Les EMCE font remarquer que cette nouvelle annexe à la directive régissant la conduite de l'évaluation de la sécurité sanitaire des aliments dérivés de plantes à ADN recombiné, annexe élaborée par le groupe spécial sur les aliments dérivés des biotechnologies, a été éxaminée et approuvée par le comité sur la nutrition et les aliments diététiques ou de régime (CCNFSDU).

Les EMCE soutiennent pleinement l'adoption définitive à l'étape 5/8 de la présente annexe avec omission des étapes 6 et 7.

Español

La Comunidad Europea y sus Estados miembros señalan que este nuevo anexo de las directrices para la realización de la evaluación de la inocuidad de los alimentos obtenidos de plantas de ADN recombinante, elaborado por el Grupo de

acción sobre alimentos obtenidos por medios biotecnológicos, fue revisado y aprobado por el Comité sobre Nutrición y Alimentos para Regímenes Especiales (CCNFSDU).

La Comunidad Europea y sus Estados miembros apoyan plenamente la aprobación definitiva, en el Trámite 5/8, de este anexo, omitiendo los Trámites 6 y 7.

United States of America

The United States supports the adoption of the *Proposed Draft Annex to the Food Safety Assessment of Foods Derived from Recombinant-DNA Plants Modified for Nutritional or Health Benefits, at* Step 5/8. We believe this guidance document will provide helpful information to countries with respect to the safety assessment of recombinant-DNA plants modified for nutritional or health benefits.

Proposed Draft Annex on Food Safety Assessment in Situations of Low-level Presence of Recombinant-DNA Plant Material in Food, at Step 5/8 of the Procedure, with the omission of Step 6 and 7 (ALINORM 08/31/34, para. 106 and Appendix IV).

Comments of Colombia, European Community and United States of America

Colombia

No hay observaciones.

European Community - Communauté européenne - Comunidad Europea

English

The ECMS consider that this new annex to the guideline for the conduct of food safety assessment of foods derived from recombinant-DNA plants, will provide, for the Codex members who may wish to use it, useful guidance for Food Safety Assessment in Situations of Low-level Presence of Recombinant-DNA Plant Material in Food.

In order to be effective, this draft annex relies on the establishment and functioning of a data and information exchange mechanism and the ECMS wish to express their appreciation to FAO and OECD for their contribution and ongoing collaboration on the development of such a mechanism. It is important that this progress continues and that a functioning data and information exchange mechanism is in place in order to ensure that the guidelines can be effective. The ECMS look forward for the presentation by FAO, during the 31st session of the Codex Alimentarius Commission, on the functioning of the publicly accessible central database. Given the limited experience that will be gathered on the database before this session of the Codex Alimentarius Commission, ECMS suggest that FAO could also report during the 32nd session of the Commission the experience gained after more than one year of functioning.

Considering the above elements, the ECMS are ready to fully support the final adoption at step 5/8 of this draft annex with the omission of steps 6 and 7.

Français

Les EMCE estiment que cette nouvelle annexe à la directive régissant la conduite de l'évaluation de la sécurité sanitaire des aliments dérivés de plantes à ADN recombiné apportera des conseils utiles aux membres du Codex qui souhaitent s'en servir pour l'évaluation de la sécurité sanitaire des aliments en cas de présence à faible concentration de matériel végétal à ADN recombiné dans les aliments.

Afin de garantir son efficacité, ce projet d'annexe se fonde sur la mise en place et le fonctionnement d'un mécanisme d'échange de données et d'informations, et les EMCE tiennent à remercier la FAO et l'OCDE pour leur contribution et leur collaboration continue à l'élaboration d'un tel mécanisme. Il est essentiel de poursuivre ce progrès et d'assurer le bon fonctionnement d'un mécanisme d'échange de données et d'informations afin de garantir l'efficacité des directives. Les EMCE se réjouissent de la présentation que la FAO fera lors de la 31^{e} session de la commission du Codex Alimentarius à propos du fonctionnement de la base de données centrale accessible au public. Étant donné que l'expérience relative à cette base de données sera encore limitée lors de cette session de la commission du Codex Alimentarius, les EMCE proposent que la FAO rende également compte, lors de la 32^{e} session, de l'expérience acquise après plus d'une année de fonctionnement.

Compte tenu des éléments précédents, les EMCE sont disposés à soutenir pleinement l'adoption définitive à l'étape 5/8 du présent projet d'annexe avec omission des étapes 6 et 7.

Español

La Comunidad Europea y sus Estados miembros consideran que este nuevo anexo de las directrices para la realización de la evaluación de la inocuidad de los alimentos obtenidos de plantas de ADN recombinante proporcionará a los miembros del Codex que deseen utilizarla, una orientación útil para evaluar la inocuidad de los alimentos en situaciones de niveles bajos de presencia de material vegetal de ADN recombinante en los alimentos.

Para ser eficaz, dicho proyecto de anexo se basa en la creación y el funcionamiento de un mecanismo de intercambio de datos y de información, y la Comunidad Europea y sus Estados miembros desean agradecer a la FAO y la OCDE su contribución y su colaboración continua para la elaboración de dicho mecanismo. Conviene que continúen dichos avances y que funcione correctamente un mecanismo de intercambio de datos e información para garantizar que las directrices sean eficaces. La Comunidad Europea y sus Estados miembros esperan con impaciencia la exposición de la FAO, que tendrá lugar durante el trigésimo primer período de sesiones de la Comisión del Codex Alimentarius, sobre el funcionamiento de la base de datos central accesible para el público. Habida cuenta de que, antes del citado período de sesiones de la Comisión del Codex Alimentarius, la experiencia acumulada en la base de datos será limitada, la Comunidad Europea y sus Estados miembros proponen que la FAO informe también durante el trigésimo segundo período de sesiones de la Comisión sobre la experiencia adquirida tras más de un año de funcionamiento.

Teniendo en cuenta los elementos anteriores, la Comunidad Europea y sus Estados miembros están dispuestos a apoyar plenamente la aprobación definitiva, en el Trámite 5/8, de este proyecto de anexo, omitiendo los Trámites 6 y 7.

United States of America

The United States strongly supports the adoption at Step 5/8 of the *Proposed Draft Annex on Food Safety Assessment in Situations of Low-Level Presence of Recombinant-DNA Plant Material in Food.* We believe this guidance document will provide very helpful information to countries to permit them to assess the low level presence or recombinant-DNA plant material in which the r-DNA plant material has passed a food safety assessment according to Codex Plant Guideline in one or more countries but may be present in food in importing countries in which the food safety of the relevant r-DNA plants has not been determined.

TASK FORCE ON QUICK FROZEN FOODS
GROUPE INTERGOUVERNEMENTAL SPÉCIAL SUR LA TRANSFORMATION ET LA MANIPULATION DES ALIMENTS SURGELÉS
GRUPO DE ACCIÓN INTERGUBERNAMENTAL ESPECIAL SOBRE LA ELABORACIÓN Y LA MANIPULACIÓN DE LOS ALIMENTOS CONGELADOS RÁPIDAMENTE

Proposed Draft Code of Practice for the Processing and Handling of Quick Frozen Foods, at Step 5/8 of the Procedure, with the omission of Step 6 and 7 (ALINORM 08/31/25, para. 62 and Appendix II).

Comments of Brazil and Peru

Brazil

Brazil supports the adoption of the Code at Step 5/8.

Peru

Se expresa la conformidad al presente Anteproyecto en razón de que el Código de Prácticas para la Elaboración y Manipulación de los Alimentos Congelados Rápidamente describe un programa de requisitos previos que comprende lineamientos tecnológicos y los requisitos de higiene esenciales para la elaboración de productos alimenticios congelados rápidamente con la finalidad que sean inocuos para el consumo humano y satisfagan los requisitos de los consumidores.

El Código también contiene orientación para el uso del sistema HACCP, como país esto es importante en razón de que a partir del presente año es obligatoria la validación técnica oficial del Plan HACCP de las empresas que fabrican alimentos y bebidas industrializados y este código ofrece los lineamientos dentro de la línea de producción de alimentos congelados rápidamente.

El presente código resultará útil a quienes se dedican a la manipulación y elaboración de productos alimenticios congelados rápidamente o bien a quienes se ocupan de su almacenamiento, transporte, venta al por menor, exportación, importación y venta, para lograr productos seguros y sanos que puedan venderse en los mercados nacionales o internacionales y satisfagan los requisitos de acuerdo a las normativas sanitarias peruanas o en su ausencia a lo que establezca el *Codex Alimentarius*.

El Código no solamente propone tratar los aspectos relacionados con la inocuidad de los alimentos congelados rápidamente sino también otros aspectos de la producción, incluidas las disposiciones en materia de calidad, composición y etiquetado.