June 2009

codex alimentarius commission



FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS WORLD HEALTH ORGANIZATION



JOINT OFFICE: Viale delle Terme di Caracalla 00153 ROME Tel: 39 06 57051 www.codexalimentarius.net Email: codex@fao.org Facsimile: 39 06 5705 4593

Agenda Item 5

ORIGINAL LANGUAGE ONLY

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

Thirty-second Session

FAO Headquarters, Rome, 29 June – 4 July 2009

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

(Comments submitted as of 1 June 2009)¹

FAO/WHO COORDINATING COMMITTEE FOR ASIA COMITÉ FAO/OMS DE COORDINATION POUR L'ASIE COMITÉ COORDINADOR FAO/OMS PARA ASIA

Draft Regional Standard for Gochujang (N03-2004), at Step 8 of the Procedure (ALINORM 09/32/15, para. 31 and Appendix II)

Comments of Japan

<u>Japan</u>

Japan supports the adoption of the Draft Regional Standard for Gochujang (ALINORM 09/32/15 Appendix II) at Step 8, with following small amendments.

Regarding the **Section 2.1 (d)** (product definition: process to prevent spoilage) of the Draft Regional Standard for Gochujang, Japan would like to propose to add one comma between "manner" and "before".

2. DESCRIPTION

2.1 PRODUCT DEFINITION

(d) Processed by heat, in an appropriate manner, before or after being hermetically sealed in a container, so as to prevent spoilage.

(Rationale)

Japan recognizes the importance of prevention of spoilage of product. But spoilage of product can be prevented by other means such as using adequate preservatives. Japan is of the opinion that there is no need to limit the method to "heating".

In this regard Japan would like to draw the attention of the Commission to the fact that Codex Standard for Canned Bamboo Shoots (CODEX STAN 241-2003) has the same sentence under section 2.1(b) as follows;

¹ This document does not include comments to texts submitted to the Commission for adoption by CCPR, CCFL and CCRVDF due to the deadline of 15 June 2009 of relevant CLs. These comments, along with other late comments, will be compiled in CAC/32 LIM/3.

2.1 PRODUCT DEFINITION

Canned bamboo shoots is the product:

(b) processed by heat, in an appropriate manner, before or after being hermetically sealed in a container, so as to prevent spoilage.

Note: Proposed additions are underlined and deletions are struckthrough.

Draft Regional Standard for Ginseng Products (N01-2004), at Step 8 of the Procedure (ALINORM 09/32/15, para. 42 and Appendix III)

Comments of Japan

Japan supports the adoption of the Draft Regional Standard for Ginseng Products (ALINORM 09/32/15 Appendix III) at Step 8 with following small amendments.

The number of AOAC method should be amended as follows according to the report of 29th CCMAS (ALINORM 08/31/23, APPENDIX III, C, p37).

(Amended text of Appendix III)

7.1 DETERMINATION OF MOISTURE

According to AOAC 9245.45.

7.2 DETERMINATION OF SOLID

According to AOAC 9245.45 and calculated by subtracting the content of water from 100%.

Note: Proposed additions are underlined and deletions are struckthrough.

Proposed Draft Regional Standard for Fermented Soybean Paste (N02-2004), at Step 5/8 of the Procedure (ALINORM 09/32/15, para. 51 and Appendix IV)

Comments of Japan

<u>Japan</u>

Japan supports the adoption of the Proposed Draft Regional Standard for Fermented Soybean Paste (ALINORM 09/32/15 Appendix IV) Step 5/8 with following small amendments.

Regarding the **Section 2.1** (d) (product definition: process to prevent spoilage) of the Proposed Draft Regional Standard for Fermented Soybean Paste, Japan would like to propose to add one comma between "manner" and "before".

2. DESCRIPTION

2.1 PRODUCT DEFINITION

(d) Processed by heat, in an appropriate manner, before or after being hermetically sealed in a container, so as to prevent spoilage.

(Rationale)

Japan recognizes the importance of prevention of spoilage of product. But spoilage of product can be prevented by other means such as using adequate preservatives. Japan is of the opinion that there is no need to limit the method to "heating".

In this regard Japan would like to draw the attention of the Commission to the fact that Codex Standard for Canned Bamboo Shoots (CODEX STAN 241-2003) has the same sentence under section 2.1(b) as follows;

2.1 PRODUCT DEFINITION

Canned bamboo shoots is the product:

(b) processed by heat, in an appropriate manner, before or after being hermetically sealed in a container, so as to prevent spoilage.

Note: Proposed additions are underlined and deletions are struckthrough.

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 Acrylamide in Foods, at Step 8 of the Procedure (ALINORM 09/32/41, para. 64 and Appendix IV)

Comments of CIAA

CIAA (Confederation of the Food and Drink Industries of the EU)

The Confederation of the European Food and Drink Industries (CIAA) fully supports the text as it currently stands, and would like to bring only one point to your attention:

In paragraph 1 of the Code, a hypertext link to the CIAA Acrylamide Toolbox is given. As the Toolbox has since been updated, however (the latest version is Version 12), this link is no longer valid. The following link would give direct access to Version 12: <u>http://www.ciaa.be/documents/brochures/ac_toolbox_20090216.pdf</u>

Alternatively, perhaps you would prefer to include the following link in order to allow access to any future Versions of the Toolbox:<u>http://www.ciaa.be/asp/documents/brochures_form.asp?doc_id=65</u>

CODEX COMMITTEE ON FOOD ADDITIVES COMITÉ DU CODEX SUR LES ADDITIFS ALIMENTAIRES COMITÉ DEL CODEX SOBRE ADITIVOS ALIMENTARIOS

Draft and proposed draft Food Additive Provisions of the General Standard for Food Additives (GSFA), at Steps 8 and 5/8 of the Procedure (ALINORM 09/32/12, para. 109 and Appendix IV)

Comments of European Community, IADSA and IFAC

European Community

Erythrosine:

Erythrosine was allocated a very low ADI of 0.1 mg/kg bw/d both by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and the Scientific Committee on Food (SCF), respectively in 1990 en 1987.

The current proposal intends to authorise the use of erythrosine in a very large number of sub categories of foodstuffs at a maximum limit quite high, among which some are widely consumed by children (e.g. water based flavoured drinks, confectionary, dairy based drinks, breakfast cereals...). With an ADI of 0,1 mg/kg bw/d the proposed level at 300 mg/kg (for both foods and drinks), children will reach the ADI by consuming very low quantity of food or drinks (less than 7 ml or 7 g), which is clearly a safety concern.

The European Community (EC) is therefore strongly opposed, in general, to the proposed uses and use levels of Erythrosine mentioned in Appendix IV of CL 2009/7-FA. The ECMS suggest that the risk assessment undertaken by JECFA in 2000 on erythrosine (WHO food additives series 44) be refined on the basis of the updated principles and method developed by JECFA for the risk assessment of chemicals in food in order to ensure that the current proposed uses and use levels do not exceed the ADI, in particular for high consumer children. The EC is of the opinion that a refined exposure assessment is needed before endorsing any of the uses and use levels for erythrosine.

Fast Green FCF

The EC notes that this food additive is not permitted currently in the EU. However the EC can lift its reservation as the note 161 has been added to the various food categories for which the EC has got concern that consumers can be misled.

IADSA (International Alliance of Dietary/Food Supplement Associations)

IADSA welcomes the results of the work of the CCFA this year and, in particular, IADSA supports the food additive provisions as proposed for adoption for Allura Red AC, Caramel Colour-Class IV, Carotenoids, Chlorophylls-Copper Complexes, Erythrosine, Fast Green FCF, Grape Skin Extracts, Indigotine and Iron Oxides in relation to food supplements (food category 13.6). They are important food additives widely used in food supplements and sufficient information has been provided to the CCFA on their safe use in food supplements at the levels proposed for adoption.

IADSA would like to express its support for the final adoption of the above-mentioned provisions by the Codex Alimentarius Commission.

IFAC (International Food Additives Council)

IFAC supports the draft standards and related text including appendix IV, provided in the alinorm of the 41st Codex Committee on Food Additive (CCFA).

Proposed draft Amendments to the International Numbering System for Food Additives, at Step 5/8 of the Procedure (ALINORM 09/32/12, para. 125 and Appendix VII)

Comments of IFAC

IFAC (International Food Additives Council)

IFAC supports the draft standards and related text including appendix VII, provided in the alinorm of the 41st Codex Committee on Food Additive (CCFA)..

Proposed draft Specifications for the Identity and Purity of Food Additives arising from the 69th JECFA, at Step 5/8 of the Procedure (ALINORM 09/32/12, para. 131 and Appendix VIII)

Comments of IFAC

IFAC (International Food Additives Council)

IFAC supports the draft standards and related text including appendix VIII, provided in the alinorm of the 41st Codex Committee on Food Additive (CCFA).

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

Proposed Draft Microbiological Criteria for Listeria monocytogenes in Ready-to-Eat Foods (Annex II to the Guidelines on the Application of General Principles of Food Hygiene to the Control of Listeria monocytogenes in Ready-to-Eat Foods (CAC/GL 61-2007), at Step 5/8 of the Procedure (ALINORM 09/32/13, para. 70 and Appendix II).

Comments of ICMSF

ICMSF

Here is the text as it is printed in the report of the CCFH meeting in Guatamala City (ALINORM 09/32/13, Appendix II; PROPOSED DRAFT ANNEX II: MICROBIOLOGICAL CRITERIA FOR LISTERIA MONOCYTOGENES IN READY-TO-EAT FOODS; at Step 5/8): "8: 0.5 log is two times the estimated standard deviation (i.e. 0.25 log) associated the experimental enumeration viable counting/plate counts."

It may be that this error has been spotted and the language has been corrected.

When a correction is still possible, this is how it should read (note the additional words) : "8: 0.5 log is two times the estimated standard deviation (i.e. 0.25 log) associated with experimental enumeration using viable counting/plate counts."

Proposed Draft Microbiological Criteria for Powdered Follow-up Formulae and Formulae for Special Medical Purposes for Young Children (Annex II to the *Code of Hygienic Practice for Powdered Formulae for Infants and Young Children* (CAC/RCP 66-2008), at Step 5/8 of the Procedure (ALINORM 09/32/13, paras 45-47 and Appendix III)

Comments of ICMSF

ICMSF

Considering the CODE OF HYGIENIC PRACTICE FOR POWDERED FORMULAE FOR INFANTS AND YOUNG CHILDREN, there are updates of two footnotes outstanding that I would like to submit as editorial comments on behalf of the ICMSF.

This concerns:

- footnote 20 of annex I to the code (on page 19 in CXC_066e), and

- the footnote numbered 1 in ALINORM 09/32/26, Appendix III (to be annex II of the code)

Both give a reference to a Food Control article that today has been given full bibliographic details.

To reflect these, in both footnotes, the second part of the footnote needs to be completed with the text in bold/underlined to complete the reference:

Relating microbiological criteria to food safety objectives and performance objectives. M. van Schothorst, M.H. Zwietering, T. Ross, R.L. Buchanan, M.B. Cole and International Commission on Microbiological Specifications for Foods (ICMSF), Food Control 20 (2009) 967–979.

(the shaded text is already in the footnote; the <u>underlined text</u> needs to be added to the existing footnote)

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 Generic Model Official Certificate (Annex to Guidelines for Design, Production, Issuance and Use of Generic Official Certificate (CAC/GL 38-2001), at Step 5/8 of the Procedure (ALINORM 09/32/30, para. 65 and Appendix II)

Comments of Colombia, Mexico and United States of America

DOCUMENTOS	PROPUESTA DE POSICIÓN	OBSERVACIONES O COMENTARIOS
DOCUMENTOS ALINORM 09/32/30 APÉNDICE II. ANTEPROYECTO DE MODELO GENÉRICO PARA UN CERTIFICADO OFICIAL (ANEXO A LAS DIRECTRICES PARA EL DISEÑO, ELABORACIÓN, EXPEDICIÓN Y USO DE CERTIFICADOS OFICIALES GENÉRICOS (CAC/GL 38-2001) En el Trámite 5/8	PROPUESTA DE POSICIÓN Colombia apoya este anteproyecto de modelo de certificado oficial, como anexo a las directrices CAC/GL 38-2001, teniendo en cuenta que dicho formato es altamente coincidente con el certificado de inspección sanitaria que actualmente viene aplicando Colombia tanto para las exportaciones como las importaciones de alimentos, expedidos por la autoridad sanitaria competente: Instituto Nacional de Vigilancia de Medicamentos y Alimentos – INVIMA Por tanto, Colombia recomienda que una vez el modelo genérico sea adoptado por la Comisión del Codex Alimentarius, los países lo acojan como documento para certificar importaciones y exportaciones de alimentos.	 ✓ Numeral 15 - Identificación de los productos alimenticios: Región o compartimiento de origen: Consideramos que este asunto sólo concierne a los productos afectados por medidas sanitarias y fitosanitarias del Acuerdo MSF de la OMC. Es importante realizar esta claridad a la descripción del ítem, para mayor soporte. ✓ Numeral 15 - Identificación de los productos alimenticios: Identificación del lote: Este dato de orden sanitario debería ser un requerimiento dentro del certificado. Por tanto, consideramos importante que se revise la expresión "*de corresponder". Los siguientes documentos Codex refieren la importancia del LOTE: Codex Stan 1-1985 Norma general para etiquetado de los alimentos preenvasados (considera que la etiqueta de los alimentos preenvasados deberá contener información entre Países sobre Casos de Rechazo de Alimentos Importados y CAC/GL 50-2004 Directrices Generales sobre Muestreo. ✓ En el mismo numeral 15 - Identificación de la Fecha de Vencimiento, como opcional. ✓ El modelo genérico debería incluir la fecha de realización y el número del la fecha de realización y el número del as realizón de la fecha de realización y el número del seria incluir la fecha de realización y el número del seria incluir la fecha de realización y el número del as realizón y el
	acojan como documento para certificar importaciones y exportaciones de alimentos.	 los alimentos preenvasados (conside que la etiqueta de los alimento preenvasados deberá conter información como Número de La (numeral 4.6)), CAC/GL 25-19 Directrices para el Intercambio Información entre Países sobre Casos Rechazo de Alimentos Importados CAC/GL 50-2004 Directrices Genera sobre Muestreo. En el mismo numeral 15 - Identificaci de los productos alimenticios: Tambid debería incluirse la declaración de Fecha de Vencimiento, como opcional. El modelo genérico debería incluir fecha de realización y el número documento (acta) mediante el cual realizó la inspección correspondien como soporte para la expedición de certificado.

Mexico

Se propone el siguiente texto como Anexo a las Directrices para el Diseño, Elaboración, Expedición y Uso de Certificados Oficiales Genéricos (CAC/GL 38-2001).

<u>Ámbito del Anexo</u>

El documento "Anexo" tiene como objetivo proporcionar orientación adicional a las autoridades competentes en base a los principios descritos en la Sección 4 y ampliar la información de las Secciones 8 y 9, cuando la Comisión del Codex Alimentarius establezca otros modelos de certificado oficial para propósitos específicos, los países deberían consultar dichas orientaciones.

Aunque la materia principal de los certificados son cuestiones sanitarias, podrían dar cabida a otros aspectos relacionados con las prácticas leales en el comercio de alimentos cuando dichos aspectos hayan sido objeto de certificación por parte de organismos de certificación.

El presente modelo de certificado podría abarcar múltiples productos múltiples en un mismo certificado.

Notas explicativas al modelo genérico para un certificado oficial

Aspectos generales:

El certificado debería cumplimentarse en forma legible.

<u>Si el consignatario, punto de entrada o pormenores del transporte se modifican después de que el certificado ha sido expedido, Ee</u>l importador tiene a responsabilidad de informar a la autoridad competente del país importador acerca de cualquier modificación posterior a la expedición del certificado relativa al consignatario, punto de entrada o pormenores del transporte. Dicha modificación no debería dar lugar a <u>un requerimiento de reemplazo del certificado emitido.</u> la expedición de un certificado sustitutivo.

El modelo de certificado, en su versión actual, incluye una numeración que <u>facilita el enlace entre</u> remite en una sección particular a y la nota explicativa correspondiente. <u>No se pretende que</u> <u>Dd</u>ichos números no deberían aparecer aparezcan en el certificado expedido por el organismo de certificación.

Aspectos específicos

<u>**Tipo de certificado:**</u> el certificado debería exhibir la indicación "ORIGINAL", "COPIA" o <u>"SUSTITUTIVO"</u> <u>"REEMPLAZO"</u>, según corresponda.

<u>**País**</u>: nombre del país que expide el certificado, posiblemente acompañado de logotipo o membrete<u>, con e</u>El objeto objetivo es de identificar claramente el país responsable de expedir el certificado.

1. <u>Consignador/Exportador</u>: nombre y dirección (vía/calle, ciudad y región /provincia/estado, según corresponda) de la persona o entidad física o jurídica que realiza el envío.

2. <u>Número de certificado</u>: número único de identificación para cada certificado, autorizado por la autoridad competente del país exportador. En caso de certificados de múltiples páginas, véase el párrafo 38 del documento (CAC/GL 38-2001).

3. Autoridad competente: nombre de la autoridad competente del país responsable de la certificación.

4. Organismo de certificación: nombre del organismo de certificación cuando difiera de la autoridad competente.

5. <u>Consignatario/Importador</u>: nombre y dirección de la persona o entidad física o jurídica en el país de destino a quien se le realiza el envío, en el momento de expedirse el certificado

6. <u>País de origen¹</u>: nombre del país de producción, elaboración o envasado de los productos.

7. País de destino¹: nombre del país de destino de los productos.

8. <u>Lugar de carga</u>: nombre del puerto, aeropuerto, terminal de carga, estación de ferrocarril o cualquier otro lugar donde se carguen los productos en el medio utilizado para su transporte.

9. <u>Medios de transporte</u>: por avión, buque, tren, carretera u otro, según corresponda y la identificación de los mismos (nombre o número) de estar disponibles o documentación pertinente de referencia.

10. <u>**Punto de entrada declarado**</u>: de requerirse y estar disponible, nombre del punto de entrada, autorizado por la autoridad competente del país importador, y el NU/LOCODE (*veáse* el Código de Localidades de las Naciones Unidas a efectos de comercio y transporte).

11. <u>Condiciones para el transporte/almacenamiento</u>: categoría <u>correspondiente a la de</u> temperatura <u>apropiada</u> (ambiente, refrigeración, congelación) u otros requisitos (por ej. humedad) <u>relativos al para el</u> transporte/almacenamiento del producto.

12. <u>Cantidad total</u>: peso o volumen de toda la remesa en <u>las</u> unidades adecuadas.

PAÍS:

13. <u>Identificación del contenedor o contenedores/Número o números de precinto</u>: se identificarán los contenedores y los números de precinto, de corresponder o si se conociera.

14. <u>Número total de bultos</u>: número total de bultos correspondiente a todos los productos de la remesa.

15. <u>Identificación de los productos alimenticios</u>: proporcionar información descriptiva y específica al <u>del</u> producto o productos objeto de la certificación.

Si fuera pertinente: naturaleza del alimento (o descripción del producto básico), código del producto básico (código HS), especie, propósito previsto, productor/fabricante, número de autorización del establecimiento (matadero, planta de producción, planta de almacenamiento (almacén frigorífico o no), región o compartimento compartimiento de origen, nombre del producto, identificación del lote, tipo de embalaje, número de envases, peso neto por tipo de producto.

- <u>Naturaleza del alimento (o descripción del producto)</u>: descripción del producto o productos lo más precisa posible para permitir la su clasificación de los productos en el Sistema Armonizado de la Organización Mundial de Aduanas, incluido el código del producto (código HS), de corresponder

- <u>Propósito previsto (o productos alimenticios certificados para un propósito determinado</u>): el certificado debería especificar el uso final del producto (por ej. consumo humano directo, elaboración procesamiento ulterior o muestras comerciales).

Cuando se <u>exige</u> <u>requiere</u> un certificado para muestras comerciales, la remesa de la muestra comercial de un alimento destinada a su evaluación, prueba o investigación en el país importador podría describirse usando un término tal como "muestra comercial". Debería indicarse claramente en el certificado o en el envase que la muestra no está destinada a la venta al por menor y que carece de valor comercial.

- <u>Región o compartimentos compartimiento de origen</u>: Si fuera pertinente: sólo concierne a los productos afectados por medidas de regionalización o por el establecimiento de zonas o <u>compartimientos</u> autorizadaos Θ compartimentos.

- <u>Tipo de embalaje</u>: identificar el tipo de embalaje de los productos según se define en la Recomendación N° 21 de CEFACT-NU (Centro de la Naciones Unidas de Facilitación del Comercio y las Transacciones Electrónicas).

16. <u>Atestados</u> <u>Declaraciones</u>: información que indica el cumplimiento de las normativas pertinentes de los países importadores o exportadores, con arreglo a las recomendaciones de la Comisión del Codex Alimentarius, de corresponder.

Los atestados serían Las declaraciones deberían ser el requisito mínimo exigido para los productos certificados a fin de garantizar la inocuidad de los alimentos y las prácticas leales en el comercio de alimentos. Los atestados Las declaraciones se aplicarían deberían se aplicables a todos los productos alimenticios certificados.

Los atestados Las declaraciones que no tienen aplicación se deberían ser excluidasrían o suprimidasrían.

Podría haber atestados declaraciones aplicables a otros temas (véase párrafo 7 del documento CAC/GL 38-2001).

17. Funcionario de certificación: nombre, cargo oficial, sello oficial (opcional), fecha de la firma y firma.

Los certificados se expedirían deberían ser expedidos con arreglo a lo dispuesto en la sección 9 del documento CAC/GL 38-2001.

Código ISO:(se podría utilizar el código de dos letras correspondientes al país de acuerdo con la norma internacional ISO 3166 alfa-2)

MEMBRETE/LOGOTIPO MODELO GENÉRICO PARA UN CERTIFICADO OFICIAL

TIPO DE CERTIFICADO

1. Consignador/Exportador:	2. Número del certificado:			
	3. Autoridad competente:			
	4. Organismo de certificación:			
5. Consignatario/Importador:				
6. País de origen:		Código ISO:		
7. País de destino:		Código ISO:		
8. Lugar de carga:				

9. Medios de transporte:			10. Punto de entrada declarado:				
11. Condiciones para el transporte/almacenamiento:		12. Cantidad total*:					
13. Identificación del contenedor o contenedores /Número o números de precinto:			14. Número total de bultos <u>*</u>				
15. Identificación de los productos alimenticios descriptos a continuación (se podrán usar varios renglones para productos múltiples)							
No.	Naturaleza del alimento, código del producto (código HS), de corresponder			Espec	Especie* Propósito previsto		
Se podrán usar varios renglones							
No.	Productor/Fabricante Número establecim		de autorización del iiento *		Región o compartimento <u>compartimiento</u> de origen		
No.	Nombre del producto	Identific	ación del lote	*	Tipo de embalaje	Número de bultos	Peso neto
16. Atestados Declaraciones:							
17. Funcionario de certificación:							
Nombre: Cargo oficial:							
Fecha:			Firma:				
Sello oficial:							

El modelo genérico para el certificado oficial deberá leerse con las notas explicativas

* De corresponder

United States of America

The United States supports the *Proposed Draft Generic Model Official Certificate* (Annex to the *Guidelines for Design, Production, Issuance and Use of Generic Official Certificates* - CAC/GL 38-2001) as developed by the Codex Committee on Food Import and Export Inspection and Certification Systems. We believe this additional guidance will be helpful to governments and recommend the adoption of the Annex as it appears in ALINORM 09/32/30, Appendix II by the Codex Alimentarius Commission at Steps 5/8 with the omission of Steps 6 and 7.

CODEX COMMITTEE ON FATS AND OILS COMITÉ DU CODEX SUR LES GRAISSES ET HUILES COMITÉ DEL CODEX SOBRE GRASAS Y ACEITES

Draft Amendment to the Standard for Named Vegetable Oil: Inclusion of Rice Bran Oil, at Step 8 of the Procedure (ALINORM 09/32/17, para. 30 and Appendix II)

Comments of Malaysia

<u>Malaysia</u>

Malaysia supports the Proposed Draft Amendment to be adopted at Step 8 by the 32^{nd} Session of the Codex Alimentarius Commission.

CODEX COMMITTEE ON GENERAL PRINCIPLES COMITÉ DU CODEX SUR LES PRINCIPES GÉNÉRAUX COMITÉ DEL CODEX SOBRE PRINCIPIOS GENERALES

Proposed draft Revised Code of Ethics for International Trade in Foods, at Step 5/8 of the Procedure (ALINORM 09/32/33, para. 43 and Appendix II)

Comments of Colombia and Mexico

<u>Colombia</u>

Colombia no está de acuerdo en avanzar para su aprobación en el trámite 5/8 por la 32 reunión de la Comisión del Codex Alimentarius con la omisión de los pasos 6 y 7. Propone que se siga el procedimiento uniforme para la elaboración de normas del Codex y textos afines, sin omitir los trámites 6 y 7, dando una mejor oportunidad a los países miembros para recabar sus comentarios y enriquecer el documento.

<u>Mexico</u>

México agradece la oportunidad de emitir comentarios al Anteproyecto de Código de Ética revisado para el Comercio Internacional de los Alimentos, reiterando la posición expuesta en la pasada reunión del CCGP, y considera que el paso de este documento al trámite acelerado (5/8), no debe ser aprobado. Debiendo continuar con el proceso normal de elaboración de norma Codex a efecto de que los gobiernos puedan analizar el alcance o las posibles implicaciones que pudieran existir en el documento, ya que tuvo modificaciones sustantivas que requieren un mayor estudio y análisis.

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

Draft Guidelines for Settling Disputes on Analytical (Test) Results, at Step 8 of the Procedure (ALINORM 09/32/23, para. 25 and Appendix II)

Comments of Brazil

Brazil

In the item 4. ANALYSING RESERVE SAMPLE

The Delegation of Brazil does not support the following text:

If the original test result of the importing country and the result of the reserve sample differ by less than the critical difference Δ that would be expected from measurement uncertainty of the results (see Annex), the importing country's original assessment of the lot shall stand, and the dispute is thus resolved.

And proposes to substitute by:

"If the analysis result of first reserve sample agrees with one of the two original results, or from importer country or from exporter country, considering measurement uncertainty, the dispute will be solved. Otherwise, if this result does not confirm the original results, it should proceed to the following step".

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

IADSA (International Alliance of Dietary/Food Supplements)

The International Alliance of Dietary/Food Supplements (IADSA) welcomes the results of the work of the 2008 Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) and supports the adoption of the provisions that the CCNFSDU agreed to advance for final adoption at Step 8 and Step 5/8 by the 32nd Session of the Codex Alimentarius Commission

Table of Conditions for Nutrient Contents (Part B: Provisions on Dietary Fibre) to the *Guidelines for Use of Nutrition and Health Claims* (CAC/GL 23-1997), at Step 8 of the Procedure (ALINORM 09/32/26 para. 54 and Appendix II)

Comments of Brazil, United States of America and IDF

<u>Brazil</u>

Brazil agrees with the document at step 8.

United States of America

Since 1992, the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) has discussed conditions for (dietary) fibre content claims (ALINORM 93/26, Appendix III). Early in these deliberations, it noted difficulties associated with the definition of (dietary) fibre and the methods of analysis for its determination (ALINORM 95/26, para 9). After many years of discussion, this Committee agreed to forward a Draft Table of Conditions for Nutrient Contents (Part B Provisions on Dietary Fibre) including a Codex definition on dietary fibre that was revised at the last CCNFSDU session to the 32nd Session of the Commission for adoption at Step 8 (ALINORM 09/32/26). The United States is not opposed to the adoption of these texts by the Commission.

IDF (International Dairy Federation)

SUMMARY

At the 30th CCNFSDU meeting in Cape Town/ South Africa November 2008, a definition for dietary fibre (Annex I) was discussed in the framework of the Codex Guidelines for the Use of Nutrition Claims² at step 7 and the Draft Table (Provisions on Dietary Fibre) including the definition on dietary fibre was forwarded to the 32nd Session of the Codex Alimentarius Commission for final adoption at step 8. The proposed definition covers polymers with 10 or more monomeric units and which are indigestible by endogenous enzymes in the small intestine of humans. A footnote was added which makes it possible for national authorities to include carbohydrates with a degree of polymerization between 3 and 9. This definition excludes indigestible disaccharides (DP of 2), which should according to the IDF be regarded as dietary fibres.

In defining dietary fibre at "Codex" the International Dairy Federation (IDF) considers it important not to lose sight of the USE of this definition, which is to confirm that food manufactures comply with the statements written on packages and used in their advertisements. In case of dietary fibre this means that food manufactures should be able to show their customers easily that their product contains fibres which contribute to general accepted heath benefits making it easier for consumers to make food choices.

The IDF supports the fact that intrinsic plant cell wall polysaccharides are regarded as an important source of dietary fibre as stated by FAO/WHO and that the intake of fruit and vegetables should indeed be stimulated to, for example, prevent disease onset or at least to minimize the severity of disease once it has developed. However, more recent scientific knowledge demonstrates that other sources of carbohydrates are able to contribute to the intake of dietary fibre. It is known that these latter types of indigestible carbohydrates are easily applicable in various types of food products and will thus provide a suitable way to improve the total dietary fibre intake and to contribute to general health.

The IDF is pleased that the current "Codex" definition (see Annex I) focuses on the chemistry of dietary fibres. However, IDF considers that this definition is not in line with the main purposes of the Codex Alimentarius namely; protecting health of the consumers and ensuring fair practices in the food trade, and promoting coordination of all food standards work undertaken by international governmental and non-governmental organizations. In relation to the second footnote IDF **persists to have this footnote changed** so that it refers to **degrees of polymerisation lower than 10** (**DP**<**10**) and that the decision be left to national authorities as to whether or not these substances could be classified as dietary fibre. IDF's position is based on the following reasons:

- The definition should cover all carbohydrates with dietary fibre-like properties.
- The definition should be in agreement with the definitions of dietary fibre found in the most recent scientific literature.
- Innovation of ingredients with dietary fibre-like properties should be maintained
- Nutrition declarations for carbohydrates with dietary fibre like properties should not confuse consumers with respect to both caloric as well as nutritional value.

With respect to the dietary fibre definition, this definition DOES NOT include digestible carbohydrates like lactose and glucose because of the specific mention that the monomeric units may not be hydrolysed by the endogenous enzymes in

² ALINORM 09/32/26

the small intestine of humans and that benefits should be demonstrated by generally accepted scientific evidence to competent authorities.

IDF proposes that the definition for dietary fibre then reads as follows:

Dietary fibre means carbohydrate polymers¹ with ten or more monomeric units², which are not hydrolysed by the endogenous enzymes in the small intestine of humans and belong to the following categories:

- o Edible carbohydrate polymers naturally occurring in the food as consumed,
- Carbohydrate polymers, which have been obtained from food raw material by physical, enzymatic or chemical means and which have been shown to have a physiological effect of benefit to health as demonstrated by generally accepted scientific evidence to competent authorities,
- synthetic carbohydrate polymers which have been shown to have a physiological effect of benefit to health as demonstrated by generally accepted scientific evidence to competent authorities

¹ When derived from a plant origin, dietary fibre may include fractions of lignin and/or other compounds when associated with polysaccharides in the plant cell walls and if these compounds are quantified by the AOAC gravimetric analytical method for dietary fibre analysis : Fractions of lignin and the other compounds (proteic fractions, phenolic compounds, waxes, saponins, phytates, cutin, phytosterols, etc.) intimately "associated" with plant polysaccharides are often extracted with the polysaccharides in the AOAC 991.43 method. These substances are included in the definition of fibre insofar as they are actually associated with the poly- or oligo-saccharides, they cannot be defined as dietary fibre. When combined with polysaccharides, these associated substances

may provide additional beneficial effects (pending adoption of Section on Methods of Analysis and Sampling).

² Decision on whether to include carbohydrates with monomeric units LOWER THAN 10 should be left to national authorities.

Table of contents:

- 1. The definition should cover all carbohydrates with dietary fibre-like properties.
- 2. The definition should be in agreement with the definitions of dietary fibre found in the most recent scientific literature.
- 3. Innovation of ingredients with dietary fibre properties should be maintained
- 4. Nutrition declarations for carbohydrates with dietary fibre like properties should not confuse consumers with respect to both caloric as well as nutritional value
- 5. Conclusion
- 6. References

Annexes

- Definition of dietary fibre as described in the Report of the 30th session of the Codex Committee on Nutrition and Foods for Special Dietary Uses; Cape Town, South Africa 3 - 7 November 2008
- II. Scientific data on the dietary fibre properties of Galacto-oligosaccharides.

1 THE DEFENITION SHOULD COVER ALL CARBOHYDRATES WITH DIETARY FIBRE-LIKE PROPERTIES

In defining dietary fibre, it should be taken into account that consumers are looking for the nutritional benefits fibres possess. The IDF considers it therefore to be important that the dietary fibre definition covers all carbohydrates which possess dietary fibre-like properties.

Nutritional benefits of dietary fibre:

The benefits of fibre do not arise from its assimilation by the body, but from its almost completely indigestible nature. This results in fibre being retained within the gastrointestinal tract. The presence of dietary fibre in the gastrointestinal tract as well as its fermentation by gut micro flora results in effects on gastrointestinal function that are important in health and to support the prevention and management of a variety of disease states.

Fibre in general

The principle components (monomeric units) in fibres are glucose, galactose, mannose and certain pentoses. Branching and substitution on the primary chains of carbohydrates can have major consequences with respect to physical properties. One of the main reasons behind the inability of mammalian enzymes to hydrolyze certain carbohydrates

even though they may consist of primary glucose residues is their primary chemical structure, which is determined by the conformation of the bonds between residues.

The most important characteristic of fibres with respect to upper gastrointestinal physiology is viscosity. With respect to the effect of fibres on the colon, the most important characteristic is the fibre's fermentability. An overview of the nutritional benefits of variable types of fibre are shown in the following table which was derived from *Jefferson and Cowbrough* (2005)

Fibre Component	Function	Potential health benefit	
Insoluble fibre (e.g. wheat bran)	Bulking of stools	Alleviation of constipation Increased transit time through gut. Decreases risk of colon cancer	
	Dilution of intestinal contents		
	Increase of dietary bulk Reduction of energy density	Increased satiety Aids weight management	
Soluble fibres (e.g. b-glucan, pectin)	Binding of cholesterol in gut Slowing of glucose absorption	Reduced blood cholesterol Reduced post-prandial glycaemia. Aids blood sugar control	
Functional fibres (e.g. variable oligosaccharides and resistant starches)	Source of fermentable carbohydrates for gut microbiota	Reduced incidence of pathogenic bacteria Improved immunity Enhanced digestive health	

The IDF agrees that the intrinsic plant cell wall polysaccharides in vegetables, fruit and cereals with a degree of polymerization higher than 10 are important sources for dietary fibre consumption. However *Stahl A et al* (2008) showed that two cross-sectional representative surveys with children aged 6-17 in Germany (1980-2006) indicated an increase in the consumption of vegetables/pulses and fruit/ nuts, but also indicated that the dietary fibre intake was still relatively low. A different study by *Buss C et al* (2008) with pregnant Brazil women concluded that about half of the pregnant women failed to meet the recommended fibre intake. Variable other studies indicate a low dietary fibre intake, meaning that national authorities and health care practitioners need to put effort in promoting the intake of food nutrients with fibre or carbohydrates with dietary fibre like properties. As was shown by *Stahl et al* (2008) an increase of vegetable and fruit intake does not immediately mean sufficient fibre intake. This implies that other substances will be needed to play a part in achieving the physiological benefits of dietary fibre.

Recent science shows that sources with degree of polymerization ranging from 2 to 10 are widely recognized and declared as dietary fibre, the so called "other fibres". Examples of these types of fibres are: Galactooligosaccharides (GOS), resistant starch, fructooligosaccharides (FOS), polyfructose, inulin, glucooligosaccharides, xylooligosaccharides (XOS), beta-cyclodextrins, resistant maltodextrins, polydextrose, modified celluloses, such as methyl- and hydroxypropylmethyl celluloses (*Gray*, 2006) and lactulose (Bouhnik et al, 2004a,b, Macfarlane et al., 2006, Ulla et al., 1999).

Other fibres

The above mentioned "other fibres", although containing DP lower than 10 and containing disaccharides (DP=2), are as a whole neither digested nor absorbed in the upper part of the gastrointestinal tract, they reach the last part (the large intestine or colon) virtually intact and thus should be regarded as a dietary fibre. Different scientific papers, describe all types of oligosaccharides containing disaccharides as indigestible and as beneficial for human health. *Asp* (1996) classifies oligosaccharides containing galactose, glucose and fructose as indigestible. *Ito* (1993) described the effects of transgalactosylated disaccharides in human supplementation. They concluded that these disaccharides resulted in a decrease in fecal pH, which can be explained by fermentation in the large intestine. These fermentation processes may serve dietary fibre properties like reducing the risk of cancer and decreasing constipation.

Macfarlane (2008) describes in a review different health-related effects of galacto oligosaccharides (DP 2-8), particularly in relation to their influence on mineral absorption, lipid metabolism, and anti-inflammatory and other immune effects such as atopic disease. This links a nutrient containing DP<3 to one of the most important properties of dietary fibre, namely being beneficial to human health.

In the colon variable types of oligosaccharides, with degree of polymerization ranging from 2 to 10, are mainly fermented by the health promoting *bifidobacteria*. These bacteria use e.g. galacto-oligosaccharides as a substrate, and are therefore stimulated to grow. This **fermentation** process contributes to a number of health benefits, including:

- Supports relief of constipation
- Supports natural defence
- Growth of colonic micro flora resulting in increased fermentation

Several studies were performed looking at the physiological benefits of oligosaccharides with a DP ranging from 2-10. One type of these oligosaccharides are galactooligosaccharides (GOS) of which scientific data is provided in Annex II.

As described the presence of fibre in the diet can have a considerable impact on many diseases and appears to promote a healthier gastrointestinal tract. Therefore, all people should strive to include more fibre in their diet to support the prevention of disease onset or at least to minimize the severity of disease once it has developed. With respect to declaration, national authorities need to be able to decide whether or not the chemical or physiological characteristics of dietary fibre need to be communicated to the consumer. IDF therefore persists in requesting that the decision for all carbohydrates with less than 10 monomeric units be left to national authorities, as long as the physiological behaviour of a constituent meets the definition of fibre.

2. THE DEFINITION SHOULD BE IN AGREEMENT WITH THE DEFINITIONS OF DIETARY FIBRE FOUND IN THE MOST RECENT SCIENTIFIC LITERATURE

In defining dietary fibre, it should be taken into account that multiple respectable organizations have published their definitions. These scientific definitions are applied in various countries. To have a reliable definition for dietary fibre, the IDF considers it important that the Codex definition would encompass these definitions.

Current definitions on dietary fibre

Various publications of respectable organizations have defined dietary fibre in a more broad perspective than the current Codex proposal for dietary fibre definition (AACC, 2001; *Gray*, 2006, Health Council of the Netherlands, 2006; IOM, 2002; *Jones et al.* 2004; *Asp*, 2004; *Tungland and Meyer*, 2002; *De Vries*, 2004) (see frame). The important **central element in all these definitions is the indigestibility** of dietary fibre in the human small intestine.

Current definitions of dietary fibre:

Respectable organizations

American Associations of Cereal Chemists (AACC, 2001):

"Dietary fibre is the edible parts of plants or analogous carbohydrates that are resistant to digestion and absorption in the human small intestine with complete or partial fermentation in the large intestine. Dietary fibre includes polysaccharides, oligosaccharides, lignin, and associated substances. Dietary fibres promote beneficial physiological effects including laxative effects and/or blood cholesterol attenuation, and/or blood glucose attenuation."

This definition of the AACC recently has been confirmed by the AOAC (De Vries, 2004)

Institute of Medicine of the National Academies (IOM, 2002):

"Dietary fibre consists of non digestible carbohydrates and lignin that are intrinsic and intact in plants. Functional fibre consists of isolated, non digestible carbohydrates and lignin that have beneficial physiological effects in humans. Total fibre is the sum of dietary fibre and functional fibre".

Health Council of the Netherlands (2006):

"Dietary fibre is the collective term for a group of substances that are not digested or absorbed in the human small intestines and which have the chemical character of carbohydrates, compounds analogous to carbohydrates, lignin, or substances related to lignin."

Superior Health Council Belgium(2006)

Dietary fibres are described as a group of very heterogenous nutrients as regards chemical structure, but which are characterised by their resistance to digestive enzymes secreted by or occurring in the human or animal gastrointestinal tract. Described examples of dietary fibres are e.g. pectins, oligosaccharides, resistant starch, cellulose and lignin.

Food Standard Australia and New Zealand (FSANZ Standard 1.2.8 Nutrition Information Requirements)

Dietary fibre means that fraction of the edible part of plants or their extracts, or synthetic analogues that- (a) are resistant to the digestion and absorption in the small intestine, usually with complete or partial fermentation in the large intestine; and- (b) promote one or more of the following beneficial physiological effects (i) laxation, (ii) reduction in blood cholesterol, (iii) modulation of blood glucose- and includes polysaccharides, oligosaccharides (degree of polymerisation>2) and lignins

Looking at these different definitions, it can be concluded that by changing the second footnote to DP < 10, the codex definition would not just be in line with the overall opinion of the FAO/WHO but would also be in agreement with the most recent scientific dietary fibre definitions.

3. INNOVATION OF INGREDIENTS WITH DIETARY FIBRE PROPERTIES SHOULD BE MAINTAINED

In defining dietary fibre it should be taken into account that, in most countries, the dietary fibre intake is substantially lower than recommended (e.g. *Papadaki, 2008; Sharma ,2008*). Especially for those countries, possibilities should be created to increase dietary fibre intake, which will eventually be beneficial for human health.

Although intrinsic plant cell wall polysaccharides are regarded as an important source of dietary fibre, these sources are not always available for or preferred by consumers. This is one of the reasons why research institutes and industry should always be driven to develop products/ ingredients which will improve human health by means of dietary fibre characteristics. If these products show similar physiological effects as dietary fibre, national authorities should be able to decide if the product/ ingredient should be considered as dietary fibre at their national level. This decision should be based on the most up-to-date scientific evidence, and not on chemical structure, leaving the possibilities open for further innovation.

With respect to the currently proposed footnote 2, national authorities do not have the possibility to define as fibre e.g. oligosaccharides with a degree of polymerization from 2 and higher, and which are shown to be totally indigestible and contribute to the physiological benefits of fibre.

4. NUTRITION DECLARATIONS FOR CARBOHYDRATES WITH DIETARY FIBRE LIKE PROPERTIES SHOULD NOT CONFUSE CONSUMERS WITH RESPECT TO BOTH CALORIC AS WELL AS NUTRITIONAL VALUE

In defining dietary fibre at "Codex", the IDF considers it important not to lose sight of the AIM and USE of this definition, which are to make sure that food manufacturers comply with the statements written on packages and used in their advertisements. In the case of dietary fibre, this means that food manufacturers should be able to show their customers easily that their product contains fibres which contribute to general accepted heath benefits making it easier for consumers to make food choices.

Most of the physiological benefits of dietary fibre are generally accepted by consumers, especially in Western societies. It is therefore important that consumers are aware of the products they consume and the nutritional properties they will provide. By not covering all the carbohydrates with dietary fibre properties in the dietary fibre definition, consumers are not entirely aware of the nutritional functionality of the product, making it more difficult to make the right decision.

With respect to nutrition declaration, there is no possibility according to the Codex Alimentarius to declare oligosaccharides containing a mixture of DP2 and higher which are indigestible and which have a caloric value of max. 2 kcal/gram. If these oligosaccharides, especially the DP 2 fractions, are not part of the dietary fibre definition, they will automatically adopt the caloric value of carbohydrates which is twice as high as their real caloric value. This will result in a deceived customer view on scientifically proven beneficial products, which eventually may lower the total dietary fibre intake instead of the needed improved intake.

The IDF is aware that not all consumers in all countries have the same knowledge level. Therefore IDF persists in requesting that the final decision as to whether or not to include any carbohydrates with scientifically proven dietary fibre properties with a **DP**<10 should be left to the national authorities.

5. CONCLUSION

IDF proposes to change the second footnote of the current Codex proposal for the definition of dietary fibre in relation to the monomeric units mentioned from:

3 to 9 monomeric units to LOWER THAN 10

It then reads as follows:

Decision on whether to include carbohydrates with monomeric units LOWER THAN 10 should be left to national authorities

The proposed second footnote:

- Is in line with the most recent scientific data
- Is in line with consumer acceptance
- Is in line with other scientifically based dietary fibre definitions
- Leaves possibilities for innovation which will contribute to the improvement of dietary fibre intake

The complete definition will then read as follows:

Dietary fibre means carbohydrate polymers¹ with ten or more monomeric units², which are not hydrolysed by the endogenous enzymes in the small intestine of humans and belong to the following categories:

o Edible carbohydrate polymers naturally occurring in the food as consumed,

- Carbohydrate polymers, which have been obtained from food raw material by physical, enzymatic or chemical means and which have been shown to have a physiological effect of benefit to health as demonstrated by generally accepted scientific evidence to competent authorities,
- synthetic carbohydrate polymers which have been shown to have a physiological effect of benefit to health as demonstrated by generally accepted scientific evidence to competent authorities

¹ When derived from a plant origin, dietary fibre may include fractions of lignin and/or other compounds when associated with polysaccharides in the plant cell walls and if these compounds are quantified by the AOAC gravimetric analytical method for dietary fibre analysis : Fractions of lignin and the other compounds (proteic fractions, phenolic compounds, waxes, saponins, phytates, cutin, phytosterols, etc.) intimately "associated" with plant polysaccharides are often extracted with the polysaccharides in the AOAC 991.43 method. These substances are included in the definition of fibre insofar as they are actually associated with the poly- or oligo-saccharidic fraction of fibre. However, when extracted or even re-introduced into a food containing non digestible polysaccharides, they cannot be defined as dietary fibre. When combined with polysacchrides, these associated substances

may provide additional beneficial effects (pending adoption of Section on Methods of Analysis and Sampling).

² Decision on whether to include carbohydrates with monomeric units LOWER THAN 10 should be left to national authorities.

6. REFERENCES

AACC (2001). The definition of dietary fibre. Report of the dietary fibre definition committee on the board of directors of the American Association of Cereal Chemists, vol 46; No.3: 112-126.

ALINORM 09/32/26; THE 30th SESSION OF THE CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES; CAPE TOWN, SOUTH AFRICA 3-7 NOVEMBER 2008.

Alles, MS & Schoterman HC (1999) Effects of fructo-oligosaccharides and galacto-oligosaccharides on breath hydrogen excretion and gastrointestinal wellbeing. Internal report. Research Centre Deventer, The Netherlands.

Asp NG (2004); Definition and analysis of dietary fibre in the context of food carbohydrates. In: Dietary fibre. Bioactive carbohydrates for food and feed. (Eds: Van der Kamp JW, Asp NG, Miller Jones J, Schaafsma G); pp 21 - 26. Wageningen Academic Publishers, The Netherlands.

Asp NG (1996); Dietary carbohydrates: classification by chemistry and physiology; Food Chemistry; 57 (1); 9-14

Ben XM, Zhou XY, Zhao WH, Yu WL, Pan W, Zhang WL, Wu SM, Van Beusekom CM, Schaafsma A. (2004) Supplementation of milk formula with galacto-oligosaccharides improves intestinal micro-flora and fermentation in term infants. *Chin Med J.* 117(6):927-931.

Boehm G & Stahl B, (2002) Oligosaccharides. In: Functional dairy products. Eds: Mattila-Sandholm T & Saarela M. Woodhead Publishing Limited. Cambridge England.

Bouhnik, Y, Raskine, L, Simoneau, G, Vicaut, E, Neut, C, Flourié, B, Brouns, F, Bornet, F.R. (2004a) The capacity of nondigestible carbohydrates to stimulate fecal bifidobacteria in healthy humans: a double-blind, randomised, placebocontrolled, parallel-group, dose-response relation study. *Am. J. Clin. Nutr.* 80:1658-64.

Bouhnik Y, Attar A, Joly FA, Riottot M, Dyard F, Flourié B. (2004b) Lactulose ingestion increases faecal bifidobacterial counts: a randomised double-blind study in healthy humans. *Eur J Clin Nutr.* 58(3):462-6.

Bouhnik, Y. Flourié, B., D'Agay-Abensour, L., Pochart, P., Gramet, G., Durand, M., Rambaud, J.C. (1997) Administration of transgalacto-oligosaccharides increases fecal Bifidobacteria and modifies colonic fermentation metabolism in healthy humans. *J. Nutr.* 127, 444-448.

<u>Buss C, Nunes MA, Camey S, Manzolli P, Soares RM, Drehmer M, Giacomello A, Duncan BB, Schmidt MI</u> (2008) Dietary fibre intake of pregnant women attending general practices in southern Brazil - The ECCAGE Study. <u>Public</u> <u>Health Nutr.</u> Dec 9:1-7. [Epub ahead of print]

Commission Working Paper for a proposal amending directive 90/496/EEC Nutrition Labeling of Foodstuffs, issued April 2008.

Codex Guidelines on Nutrition Labelling (CAC/GL 2-1985, Rev. 1 - 1993).

Deguchi Y., Matsumoto, K., Ito, A., Watanuki, M. (1997) Effects of beta 1-4 galacto-oligosaccharides administration on defecation of healthy volunteers with a tendency to constipation. *Japanese Journal of Nutrition*. 55(1), 13-22.

Gray J (2006); Dietary fibre. Definition, analysis, physiology & health. In: ILSI Europe Concise Monograph Series, ILSI Europe.

Ishikawa, F., Takayama, H., Matsumoto, K., Ito, M., Chonan, O., Deguchi, Y., Kikuchi-Hayakawa, H., Watanuki, M. (1995) Effects of β 1-4 linked galacto-oligosaccharides on human faecal microflora. *Bifidus*. 9, 5-18.

Ito, M., Deguchi, Y., Miyamori, A., Matsumoto, K., Kikuchi, H., Matsumoto, K., Kobayashi, Y., Yajima, T., Kan, T. (1990) Effects of administration of galacto-oligosaccharides on the human faecal microflora, stool weight and abdominal sensation. *Microb. Ecol. Health Dis.* 3, 285-292.

Ito, M., Kimura, M., Deguchi, Y., Miyamori-Watabe, A., Yajima, T., Kan, T. (1993a) Effects of transgalactosylated disaccharides on the human intestinal microflora and their metabolism. *J Nutr Sci Vitaminol.* 39, 279-288.

Ito, M., Deguchi, Y., Matsumoto, K., Kimura, M. Onodera, N., Yajima, T. (1993b) Influence of galactooligosaccharides on the human fecal microflora. *J Nutr Sci Vitaminol.* 39, 635-640.

Jefferson A and Cowbrough K (2005); Carbohydrates and fibre: a review of functionality and wellbeing; Food Science and Technology Bullitin: Functional Foods 2 (3) 31-38.

Macfarlane S, Macfarlane GT, Cummings JH. (2006) Review article: prebiotics in the gastrointestinal tract. Aliment Pharmacol Ther. 24(5):701-14.

Macfarlane G.T., Steed H and Macfarlane (2008); Bacterial metabolism and health-related effects of galactooligosaccharides and other prebiotics; Journal of Applied Microbiology Volume 104 Issue 2 Page 305-344.

Napoli JE, Brand-Miller JC, Conway P. (2003) Bifidogenic effects of feeding infant formula containing galactooligosaccharides in healthy formula-fed infants. *Asia Pac J Clin Nutr.* 12(Suppl):S60.

Papadaki A, Linardakis M, Codrington C, Kafatos A (2008); Nutritional intake of children and adolescents with insulindependent diabetes mellitus in crete, Greece. A case-control study; Ann Nutr Metab. 52(4):308-14.

Sako, T., Matsumoto, K., Tanaka, R. (1999) Recent progress on research and applications of non-digestible galactooligosaccharides. *International Dairy Journal*. 9, 69-80.

Santos, A., San Mauro, M., and Marquina Díaz, D. (2006). Prebiotics and their long-term influence on the microbial populations of the mouse bowel. Food Microbiology 23: 498-503.

Sharma S, Cao X, Harris R, Hennis AJ, Wu SY, Leske MC; Barbados National Cancer Study Group. (2008); Assessing dietary patterns in Barbados highlights the need for nutritional intervention to reduce risk of chronic disease; <u>J Hum</u> <u>Nutr Diet.</u> Apr;21(2):150-8.

Schoterman, H.C. (2001) Chapter 42 Galacto-oligosaccharides: Properties and health aspects. In: Advanced Dietary Fibre Technology. Eds: McCleary, B.V. & Prosky, L. Blackwell Science Ltd. 494-502.

Schoterman, H.C. & Timmermans, H.J.A.R. (2000) Galacto-oligosaccharides In: Prebiotics and Probiotics. LFRA Ingredients Handbook. G.R. Gibson & F. Angus, eds. Leatherhead Food RA Publishing. p. 19-46.

Shoaf K, Muvey GL, Armstrong GD, Hutkins RW. (2006) Prebiotic galacto-oligosaccharides reduce adherence of enteropathogenic Escherichia coli to tissue culture cells. Infect Immun. Dec;74(12):6920-8. Epub 2006 Sep 18.

Anna Stahl, Claudia Vohmann, Almut Richter, Helmut Heseker and Gert BM Mensink (2009); Changes in food and nutrient intake of 6- to 17-year-old Germans between the 1980s and 2006; <u>Public Health Nutr.</u> Feb 23:1-12.

Stipanuk MH; (2000); ISBN 0-72516-4452-X; Biochemical and Physiological Aspects of Human Nutrition.

Teuri, U., Korpela, R. (1998) Galacto-oligosaccharides relieve constipation in elderly people. *Ann Nutr Metabolism.* 42, 319-327.

Ulla, T, Vapaatalo, H, and Korpela, R. (1999) Fructooligosaccharides and lactulose cause more symptoms in lactose maldigesters and subjects with pseudohypolactasia than in control lactose digesters. Am J Clin Nutr 69:973–9.

ANNEX I: DEFINITION OF DIETARY FIBRE AS DESCRIBED IN THE REPORT OF THE 30th SESSION OF THE CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES; CAPE TOWN, SOUTH AFRICA 3-7 NOVEMBER 2008³

Definition:

Dietary fibre means carbohydrate polymers¹ with ten or more monomeric units², which are not hydrolysed by the endogenous enzymes in the small intestine of humans and belong to the following categories:

• Edible carbohydrate polymers naturally occurring in the food as consumed,

³ ALINORM 09/32/26

- Carbohydrate polymers, which have been obtained from food raw material by physical, enzymatic or chemical means and which have been shown to have a physiological effect of benefit to health as demonstrated by generally accepted scientific evidence to competent authorities,
- synthetic carbohydrate polymers which have been shown to have a physiological effect of benefit to health as demonstrated by generally accepted scientific evidence to competent authorities

Methods of Analysis for Dietary Fibre

To be agreed.

¹ When derived from a plant origin, dietary fibre may include fractions of lignin and/or other compounds when associated with polysaccharides in the plant cell walls and if these compounds are quantified by the AOAC gravimetric analytical method for dietary fibre analysis : Fractions of lignin and the other compounds (proteic fractions, phenolic compounds, waxes, saponins, phytates, cutin, phytosterols, etc.) intimately "associated" with plant polysaccharides are often extracted with the polysaccharides in the AOAC 991.43 method. These substances are included in the definition of fibre insofar as they are actually associated with the poly- or oligo-saccharide fraction of fibre. However, when extracted or even re-introduced into a food containing non digestible polysaccharides, they cannot be defined as dietary fibre. When combined with polysacchrides, these associated substances

may provide additional beneficial effects (pending adoption of Section on Methods of Analysis and Sampling).

² Decision on whether to include carbohydrates from 3 to 9 monomeric units should be left to national authorities.

ANNEX II: SCIENTIFIC DATA ON THE DIETARY FIBRE PROPERTIES OF GALACTO-OLIGOSACCHARIDES

Relief of constipation

Constipation is a frequently occurring problem among for instance the elderly and pregnant women. For these individuals, consumption of galacto-oligosaccharides (GOS) can offer relief of their complaints of constipation which is also a typical benefit of dietary fibre. In elderly suffering from constipation **frequency of bowel movement was increased** after consumption of 9 g GOS/day (Teuri & Korpela, 1998). Deguchi et al (1997) also found an **increase in bowel movement frequency** as well as **softer stools** after consumption of 5 and 10 g GOS a day in volunteers with a tendency for constipation.

Natural defence

There is increasing evidence that dietary fibres, such as GOS, can support natural defences of the human body via the gut microflora. For instance, an in-vitro study showed that galacto-oligosaccharides are able to inhibit adherence of E. Coli to tissue culture cells. This supports a possible anti-adhesive functionality of galacto-oligosaccharides. In this study other oligosaccharides have been tested as well. In comparison to these oligosaccharides, GOS showed the largest anti-adhesive activity (Shoaf, 2006). Another in-vitro study demonstrated that GOS inhibit adherence of Cholera toxin to human HT29 colonocytes (to be published). Santos et al 2006 showed a decrease in number of Clostridia after rats received a diet containing 1% galacto-oligosaccharides during 6 months.

A study with infants, receiving an infant formula with 1 g oligosaccharides per 100 ml, demonstrated that stimulation of bifidobacteria by the prebiotic oligosaccharides reduces the presence of clinically relevant pathogens (e.g. Staphylococcus aureus, Enterobacter, Streptococcus group B, Clostridium difficile and Bacillus subtilis) in the faecal flora. This indicates that oligosaccharides might have the capacity to protect against enteral infections.

Growth of colonic microflora

Infants

Ben et al (2004) showed that amounts of 0.24 g GOS per 100 ml infant formula, resulted in **levels of bifidobacteria and lactobacilli**, which were **significantly higher** compared with infants fed the standard infant formula without GOS. Napoli et al (2003) found similar effects in infants after consumption of an infant formula containing 0.7% GOS. In another study with infants an **increase in bifidobacteria** was seen after consumption of 0,5 g GOS/100ml. By showing growth of intestinal bacteria it can be concluded that GOS influence the bacteria present in the colon, as do other dietary fibres.

Adults

In addition to studies in infants, several studies with adults have shown that galacto-oligosaccharides **stimulate the growth of bifidobacteria and other beneficial bacteria**, such as lactobacilli (Schoterman, 2001; Sako, 1999; Schoterman & Timmermans, 2000). In a double blind study (Bouhnik, 2004a) consumption of 10 g galacto-oligosaccharides resulted in an increase in number of bifidobacteria in comparison to the placebo group. In the second part of this study, the effects of a daily dose of 2.5, 5.0, 7.5 and 10 g galacto-oligosaccharides were tested. Consumption of galacto-oligosaccharides increased bifidobacteria counts in all doses.

Bouhnik et al 1997 showed the effect of consumption of 10 g GOS a day, the faecal concentrations of **bifidobacteria** were significantly increased.

Provisions on Gum Arabic (Gum acacia) (Section D: Advisory List of Food Additives for Special Nutrient Forms) to the Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses Intended for Infants and Young Children (CAC/GL 10-1997), at Step 8 of the Procedure (ALINORM 09/32/26, para. 62 and Appendix III)

Comments of Brazil, Switzerland, United States of America and IADSA

<u>Brazil</u>

Brazil agrees with the document at step 8.

Switzerland

Switzerland welcomes the opportunity to send comments on the subject of provisions on Gum Arabic, as proposed in CL 2008/35-NFSDU. The Swiss comments relate to the Draft Advisory List of Nutrient Compounds for use in Foods for Special Dietary Uses Intended for Infants and Young Children: Section D: Advisory List of Food Additives for Special Nutrient Forms: Provisions on Gum Arabic (Gum Acacia) (ALINORM 09/32/26 para 62 and Appendix III).

First of all, Switzerland wishes to express full support for the adoption at Step 8 of the provisions on Gum Arabic which were advanced by the Codex Committee on Nutrition and Food for Special Dietary Uses (ALINORM 09/32/26 para 62). Nonetheless, Switzerland also wishes to point out that Gum Arabic has to be considered as a "carrier", in line with the definition provided in the Codex Guidelines CAC/GL 36-1989 where Gum Arabic has the status of a "carrier" for these applications. Endorsing the technological function of Gum Arabic as a "coating" agent, as proposed at the last session of the CCNFSDU (para 56 and 61, ALINORM 09/32/26) would differ from its common technological function in the manufacture of nutrient compounds for use in foods for special dietary uses intended for infants/young children.

Switzerland also wishes to refer to the discussions and conclusions on the issue which were held at the last session of the Codex Committee on Food Additives which took place in Shanghai, China (ALINORM 09/32/12, para 48 - 50).

United States of America

The United States supports the final adoption of the Draft Advisory List of Nutrient Compounds for Use in Foods for Special Dietary Uses Intended for Infants and Young Children: Section D: Advisory List of Food Additives for Special Nutrient Forms: Provisions on Gum Arabic (Gum Acacia) at Step 8.

IADSA (International Alliance of Dietary/Food Supplements)

IADSA supports advancing the provisions on Gum Arabic for adoption at Step 8 as agreed by the CCNFSDU. However, IADSA would like to stress that Gum Arabic should be endorsed as a "carrier" within the full meaning of the "carrier" definition as provided in Codex document CAC/GL 36-1989.

The technical function of Gum Arabic as a "carrier" was recognized and added to the original list by the CCNFSDU some time ago and endorsed by the Codex Committee on Food Additives (CCFA) and since then there has been no change in technological justification for the use of this substance in products for infants and young children.

Despite the fact that the use of gum arabic as a coating agent has been proposed, this would not be in line with its common technical use in the manufacture of nutrient compounds for use in foods for special dietary uses intended for infants/young children where it is used as a carrier.

In addition, the CCFA agreed at its meeting in March this year to endorse the proposed level of 10 mg/kg for use as a carrier (see ALINORM 09/32/12, para. 48-50 and Appendix III, page 45).

Draft Nutritional Risk Analysis Principles and Guidelines for Application to the Work of the Committee on Nutrition and Food for Special Dietary Uses, at Step 8 of the Procedure (ALINORM 09/32/26, para. 82 and Appendix IV)

Comments of Brazil, CRN, United States of America and IADSA

<u>Brazil</u>

Brazil agrees with the document at step 8.

United States of America

The United States supports the final adoption of the Draft Nutritional Risk Analysis Principles and Guidelines for Application to the Work of the Committee on Nutrition and Foods for Special Dietary Uses at Step 8.

CNR (Council for Responsible Nutrition)

When this Agenda Item was discussed at the last meeting of the CCNFSDU, there was some debate about the use and meaning of the term "hazard". The issue was whether "hazard" should be used to refer to an "agent" or "substance in food" or to the "adverse effect" that would serve as the basis for limiting the amount of a nutrient to be permitted.

There is wide acceptance by authoritative scientific bodies to use the term "hazard" to refer the adverse effect of significant concern. For example, the U.S. Institute of Medicine (IOM) uses "hazard" to mean the critical adverse effect selected as the basis of the Tolerable Upper Intake Level (UL) for a nutrient. This usage is also adopted by the European Commission Scientific Committee on Food (SCF) and the U.K.

Expert Group on Vitamins and Minerals (EVM0 and the Food and Agriculture Organization and World Health Organization (FAO/WHO) definition of the UL.

These usages by the IOM, SCF, EVM, and FAO/WHO are cited and quoted below.

In contrast to these uses, the Codex Procedural Manual, 17th Edition, includes different and perhaps ambiguous uses of the term "hazard." Specifically in the Procedural Manual, the primary use of the term "hazard" is to refer to a chemical or physical agent:

- 1. Page 43, referring to residues of veterinary drugs in foods, it describes the "hazard" as relating to the time and amount of the residue. Thus, in this usage "hazard" is not the agent but is effect that is dependent on the agent and amount of it.
- 2. Page 44 states, "A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect." In this usage, "hazard" seems primarily defined as an agent, and not an effect of an agent. On the other hand, the phrase "or condition of" in the same sentence could be interpreted as relating the term "hazard" to either the agent or to the potential of the food containing that agent to produce an adverse effect.

RECOMMENDATION:

Noting that,

- 1. The Procedural Manual uses a definition for "hazard" that is different from those in the authoritative scientific documents on nutrient risk assessment that were ited as the basis in this draft Risk Analysis guideline, and
- 2. The Procedure Manual will be seen as the final authority on the definition of terms used in Codex guidelines.

It is recommend that,

• Accompanying the definition of the term "nutrient-related hazard" in this guideline, a footnote should be inserted that acknowledges that the scientific references cited in the guideline use the word "hazard" as relating to an effect, whereas the Procedural Manual uses the term to refer to an agent. A suggested draft for the footnote follows:

FOOTNOTE: The reference documents and the section on risk assessment use the term *hazard* in a manner that differs from the

Procedural Manual, but these differences should not be seen as producing any conflict in application of the guideline.

References and supporting notes for discussion above:

1. Dietary Reference Intakes: A Risk Assessment Model for Establishing Upper Intake Levels for Nutrients Food and Nutrition Board, Institute of Medicine, (National Academy Press, Washington, DC, 1998:

Copied from page 8:

Steps in the Risk Assessment Process

The organization of risk assessment is based on a model proposed by the

NRC (1983, 1994); that model is widely used in public health and regulatory decision making. The steps of risk assessment as applied to nutrients are as follows (see also Figure 1):

• Step 1. *Hazard identification* involves the collection, organization, and evaluation of all information pertaining to the adverse effects of a given nutrient. It concludes with a summary of the evidence concerning the capacity of the nutrient to cause one or more types of toxicity in humans."

This statement on the first step in "hazard identification" describes the evaluation of all information pertaining adverse effects of a nutrient. Thus, this first publication on the UL method clearly refers to hazard as an effect, not an agent or substance. In this method, the agent is the nutrient, and the adverse effect is the hazard.

20

In summary, the UL method uses the term "hazard" to refer to an effect, but not to the agent producing the effect.

2. TOLERABLE UPPER INTAKE LEVELS FOR VITAMINS AND MINERALS

Scientific Committee on Food Scientific Panel on Dietetic Products, Nutrition and Allergies European Food Safety Authority, February 2006:

Copied from page 10:

The process of the risk assessment may be divided into a number of steps

(FAO/WHO, 1995; FNB,

1997, 1998, 2000):

Step 1. Hazard identification - identification of known or potential adverse health effects of a given nutrient. It involves the collection, organisation and evaluation of all information pertaining to the adverse effects of a given nutrient. It concludes with a summary of the evidence concerning the capacity of the nutrient to cause one or more types of adverse effect in humans. This usage of the term "hazard" by this European Commission Body is identical to that in the IOM document cited above.

3. Safe Upper Levels for Vitamins and Minerals, May 2003. Expert Group on Vitamins and Minerals (U.K.)

Copied from EVM report:

Approach taken by EVM

The EVM is concerned solely with risk assessment, which comprises:

- hazard identification;
- hazard characterisation (including dose-response assessment);
- exposure assessment; and
- risk characterisation.

The available database is reviewed and hazards (adverse effects) identified and characterised.

Thus, the EVM explicitly relates the term "hazard" to adverse effects.

4. A Model for Establishing Upper Levels of Intake for Nutrients and Related Substances

Report of a Joint FAO/WHO Technical Workshop on Nutrient Risk Assessment, WHO Headquarters, Geneva, Switzerland, 2-6 May 2005

Report issued (Internet) on 13 January 2006

Food [modification of IPCS, 2004a: 'hazard'].

hazard: inherent property of a nutrient or related substance to cause adverse health effects depending upon the level of intake.

As quoted above, the FAO/WHO nutrient risk assessment report clearly defines "hazard" as a property of a nutrient or related substances, not as the nutrient itself.

5. Procedural Manual, 17th Edition, Codex Alimentarius Commission

Page 43:

Codex maximum limit for residues of veterinary drugs (MRLVD) is the maximum concentration of residue resulting from the use of a veterinary drug (expressed in mg/kg or μ g/kg on a fresh weight basis) that is recommended by the Codex Alimentarius Commission to be legally permitted or recognized as acceptable in or on a food.

It is based on the type and amount of residue considered to be without any toxicological hazard for human health as expressed by the Acceptable Daily

Intake (ADI), or on the basis of a temporary ADI that utilizes an additional safety factor. It also takes into account other relevant public health risks as well as food technological aspects.

Page 44:

DEFINITIONS OF RISK ANALYSIS TERMS RELATED TO FOOD SAFETY

Hazard: A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect.

Risk: A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food.

Risk Analysis: A process consisting of three components: risk assessment, risk management and risk communication.

Risk Assessment: A scientifically based process consisting of the following steps: (i) hazard identification, (ii) hazard characterization, (iii) exposure assessment, and (iv) risk characterization.

6. ALINORM 8/31/26, Appendix VI—(before modification by the CCNFSDU at 30th Session in Cape Town)

Section 3, paragraph 10, last bullet

• advising on risk-risk analysis (e.g. risk associated with a significantly reduced or entirely avoided consumption of a nutritious, staple food in response to a dietary hazard such as a contaminant present in that food.

Section 4, paragraph 12

Nutritional risk – A function of the probability of an adverse health effect associated with inadequate or excessive intake of a nutrient or related substance and the severity of that effect, consequential to a nutrient-related hazard(s) in food.

The FAO/WHO report (2006) was used as the source of multiple definitions ("adverse health effects," "upper levels of intake," "highest observed intake," and "homeostatic mechanism") and a procedure ("nutritional problem formulation") for use in nutrient risk assessment, and is cited as footnote 4.

IADSA (International Alliance of Dietary/Food Supplements)

IADSA commends the overall text as it shares the principles and recommendations of the 2006 FAO/WHO nutrient risk assessment report and considers the draft Guidelines a solid framework for the potential future application of the risk assessment method by the CCNFSDU for the use of vitamins, minerals and other substances in food supplements.

IADSA considers that the Guidelines provide the potential for a sound foundation for ensuring consumer access to safe food supplements, based on scientific risk assessment.

Proposed draft Recommendations on the Scientific Basis of Health Claims (Annex to the Guidelines for Use of Nutrition and Health – CAC/GL 23-1997), at Step 5/8 of the Procedure (ALINORM 09/32/26, paras 102 and Appendix V)

Comments of Brazil, United States of America and IADSA

<u>Brazil</u>

Brazil agrees with the document at step 8.

United States of America

The United States supports the final adoption of the Draft Annex to the Codex *Guidelines for Use of Nutrition and Health Claims*: Recommendations on the Scientific Substantiation of Health Claims at Step 5/8.

IADSA (International Alliance of Dietary/Food Supplements)

IADSA welcomes the progress made on this text by the CCNFSDU over the last few years and considers that it takes into account the totality of the available relevant scientific data and weighing of the evidence to substantiate a health claim.

CODEX COMMITTEE ON PROCESSED FRUITS AND VEGETABLES COMITÉ DU CODEX SUR LES FRUITS ET LÉGUMES TRAITÉS COMITÉ DEL CODEX SOBRE FRUTAS Y HORTALIZAS ELABORADAS

General Comments

European Community - Food additive provisions for jams, jellies and marmalades and canned vegetables

The European Community (EC) would like to raise its concerns about the provisions on food additives as proposed in the draft standards for jams, jellies and marmalades and the draft Codex standard for certain canned vegetable. The EC can accept the food additive provisions in both standards at the condition that some modifications are inserted in the Appendix III of ALINORM 09/32/12.

RATIONALE

The EC would like to reiterate that Commodity Committees shall evaluate the technological justification for the use of individual food additives, and list the additives that really achieve the desired effect in the respective food categories.

This basic principle is enshrined in the Procedural Manual of the Codex Alimentarius dedicated to the relations between Commodity Committees and General Committees since one can read in section II that "All provisions in respect of food additives contained in commodity standards will require endorsement by the Codex Committee on Food Additives, on the basis of technological justification submitted by the commodity committees...".

Therefore, the EC would like to express its strong concern for inclusion by default into both draft Codex Standard for Jams, Jellies and Marmalades and draft Codex Standard for certain Canned Vegetables of all food additives listed under the functional classes colours, acidity regulators, antifoaming agents, firming agents, preservatives, thickeners and already listed in the Table 3 of the Codex General Standard for Food Additives.

In particular, the current proposal to authorise some of the acidity regulators and thickeners listed in Table 3 could mislead the consumer.

The EC is of the opinion that categories covering jams, jellies and marmalades but also certain canned vegetables should be added to the Annex to Table 3 of the GSFA as these categories of products are widely consumed and only need a very limited number of food additives from a technological point of view.

In addition, the EC is of the opinion that sorbates and benzoates are not technologically justified in jams, jellies and marmalades as the preservative action is adequately performed by the high concentration of sugar.

Finally, the EC is of the opinion that colours should be restricted in both standards due to potential intake concern.

Specific Comments

Draft Codex Standard for Jams, Jellies and Marmalades, at Step 8 of the Procedure (ALINORM 09/32/27, para. 34 and Appendix II)

Comments of Brazil, European Community, OEITFL

<u>Brazil</u>

Brazil supports the adoption of the proposed standards.

European Community

Extra jam/extra jelly

The EC regrets that the report of the 24th session of the Codex Committee on Processed Fruit and Vegetables did not retain specific criteria promoting a higher quality standard for extra jam and extra jelly. The ECMS still consider that the use of food additives in such products should be restricted.

The EC notes that only a very limited number of food additives are permitted in such products in the EU, namely INS 440, INS 270, INS 296, INS 300, INS 327, INS 330, INS 331 (i, iii), INS 333, INS 334, INS 335 (i, ii), INS 350 (i, ii) and INS 471.

<u>Colours</u>

Colours should not be permitted in extra jam/extra jelly. The higher quantity of fruit that are contained in extra jam/extra jelly should suffice by itself to ensure the colouring properties of the product. The addition of colours should not serve any technological purpose and could even mislead the consumer by masking the bad quality of the raw material.

Preservatives

Preservatives should not be permitted in such products because there is no technological justification. The high concentration of fruit is sufficient to ensure the adequate preservation of the product.

Jam/jelly/marmalades

Colours

Due to their very low numerical ADIs, the EC expresses its opposition to use Riboflavin (ADI: 0.5 mg/kg) and Iron oxides (allocated ADI of 0.5 mg/kg by JECFA) in jam, jellies and marmalades.

The EC notes that Allura Red (INS 129; ADI: 7 mg/kg) and Brilliant blue FCF (INS 133) are not authorised in jam, jellies and marmalades, according to the EU legislation.

In addition, the EC would like to note that fast green FCF is not currently permitted as food additive in the EU legislation.

The EC would like to stress that, based on a recent opinion issued by EFSA⁴ highlighting possible exceedance of the ADI in the EU, the EC is currently reviewing the use and use levels of lycopene.

EC position: In a spirit of compromise, the EC can accept the section 4.4 on "colours" as it stands if a specific footnote "Subject to national legislation of the importing country aimed, in particular, at consistency with Section 3.2 of the Preamble of the Codex General Standard for Food Additives (CODEX STAN 192-1995)" is assigned to the following food additives: Riboflavin, Iron oxide, Allura Red, Brilliant blue FCF, and Fast green FCF.

Preservatives

Bearing in mind that the scope of the draft Codex Standard for jams, jellies and marmalades does not cover low sugar products, the EC is opposed to authorise the use of sorbates and benzoates as preservatives in jams, jellies, and marmalades because it is not technologically justified under temperate climates. The preservative action is adequately performed by the high concentration of sugar itself.

EC position: In a spirit of compromise, EC can accept the section 4.5 "preservative" if the specific footnote "Subject to national legislation of the importing country aimed, in particular, at consistency with Section 3.2 of the Preamble of the Codex General Standard for Food Additives (CODEX STAN 192-1995)" is assigned both to Sorbates and Benzoates.

Acidity regulator

The EC is of the opinion that Fumaric acid (INS 297) which is assigned a low numerical ADI in the EU should be restricted to a limited number of applications. The EC notes that sodium Fumarate, while it is listed in Table 3, is not permitted in the EU legislation on food additives.

In addition, it should be kept in mind that the analytical calculation of percentage of fruit added in the jam may be undertaken through the dosage of potassium naturally present in the fruit. The EC would like to stress that the presence of potassium-based acidity regulators contained in the Table 3 of GSFA (e.g potassium lactate, potassium dihydrogen citrate, tripotassium citrate, potassium hydrogen malate) could artificially interfere with the dosage of potassium, leading to an artificial increase of the percentage of fruit contained in the final product. Consequently, the consumer could be misled. The EC is therefore of the opinion that these food additives should not be authorised in jam. For the same reason, the potassium tartrate (INS 336i) should not be authorised in jam.

EC position: In a spirit of compromise, the EC can accept the section 4.1 as it stands if the specific footnote "Subject to national legislation of the importing country aimed, in particular, at consistency with Section 3.2 of the Preamble of the Codex General Standard for Food Additives (CODEX STAN 192-1995)" is assigned at the end of the paragraph.

Thickeners

The EC would welcome further clarification regarding the technological need for adding by default all thickeners listed in the Table 3 of GSFA in the Codex Standard for jams while most of these food additives are not necessary in these products. Many of these food additives are intended to be used in the preparation of low sugar products which are outside the scope of the Standard.

In addition, a number of thickeners listed in the Table 3 of GSFA, e.g. starch-based food additives, cellulose-based food additives and polydextrose may substantially contribute to increase artificially the soluble solids contents in jam. Therefore the EC is of the opinion that such food additives should not be authorised in jam and jellies on the ground that the consumers could be misled.

EC position: In a spirit of compromise, the EC can accept the section 4.1 as it stands if the specific footnote "Subject to national legislation of the importing country aimed, in particular, at consistency with Section 3.2 of the Preamble of the Codex General Standard for Food Additives (CODEX STAN 192-1995)" is assigned at the end of the paragraph.

OEIFTL (Organization of European Indistries Transforming Fruit and Vegetable)

OEITFL represents the interests of the EU's fruit and vegetables processing industries. Our members are predominantly national associations representing over 500 companies in 13 European countries producing jams and preserves, canned fruit, frozen vegetables, canned vegetables and dehydrated vegetables.

After analysis of the Report of the 24th session of the Codex Committee on processed fruit and vegetables, and given that during the last meeting new proposals were made, we would like to submit comments on the *Draft Codex Standard for Jams, Jellies and Marmalades at Step 8 (CL 2008/31-PFV para34 and Appendix I)*:

1. Fruit spread (section 1.2. of Appendix II):

The current draft standard states in section 1.2 that" The terms "preserve", "conserve" or "fruit spread" are sometimes used to represent products covered by the Codex Standard. The use of the terms "preserve", "conserve" and "fruit spread" are thereby required to comply with the requirements for jam and/or extra jam as set out in this Standard".

⁴ Scientific Opinion of the Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food adopted on 30 January 2008 ;http://www.efsa.europa.eu/cs/BlobServer/Scientific_Opinion/afc_ej674_lycopene_op_en.pdf?ssbinary=true

According to section 3.2 the soluble contents for finished products (section 3.1.2 a - c) shall in all cases be between 60 to 65 % or greater. In the case of non citrus marmalade (section 3.1.2 d) the soluble content shall be 40 to 65 % or less.

As a consequence, a minimum of 60 % soluble content has to be applied for fruit spreads. In this case fruit spreads marketed in some EU countries (e.g Austria, Germany) do not comply with the FAO/WHO codex standard. Also export products would not comply and enormous costs result from changing packaging.

In particular in Austria, 24% of all jam-like products are sold as "fruit spreads" (while 76% of those products are sold as "jams, jellies, marmalades including "extra" products"). At the same time, products for the Non EU market are sold as fruit spreads because of the soluble solid content < 60%. For instance all jam-like products produced for the US-market are sold as "fruit spread", while this market represents - after the German and Italian market – one of the most important export markets for Austria. As a result, if fruit spreads have to meet the same requirements as jams (> 60% soluble solid), all the labels of products destined to USA will have to be changed.

In the case of Germany, fruit spreads represents just 30% of all jam-like and other breakfast spreads products. This represents an important part of the market in economic terms and will increase in the future given the current trends of consumption.

As a result OEITFL would oppose the proposed change and wishes "fruit spreads" to be deleted from section 1.2.

2. Tolerance for soluble solids (point 28 and 29 of the report):

During the last session in September 2008 the Codex Committee discussed about ± 3 or ± 0.5 refractometric degrees as a tolerance in the measurement of soluble solids in the final product. As a conclusion it was agreed to delete the sentence regarding refractometric tolerances.

Nevertheless the production of jams with a tolerance of ± 0.5 refractometric degrees is practically impossible in some cases since the product is subject to an unavoidable variation because of its natural characteristics (variations of soluble solids in natural products such as fruits and vegetables due to seasonal variations, soil conditions, etc). In this line, according to information of Austrian national authorities two out of three products do not comply with this tolerance.

It is worth noting that in Article 2.4 of EU Directive 2001/113/EC it is laid down that the labelling shall indicate the total sugar content by the words 'total sugar content ... g per 100 g', the figure indicated representing the value determined by refractometer at 20 °C for the finished product, subject to <u>a tolerance of \pm 3 refractometric degrees</u>.

Although during the last Codex session there was no consensus between the different members, in order to cover the concern above-mentioned OEITFL would like to propose **the addition of a sentence in point 8.3** *Fruit Quantity and Sugar Declaration* which reads as follows: "*If an indication of sugar content is given this should be in line with national requirements or legislation as regards tolerances*".

Draft Codex Standard for Certain Canned Vegetables (General Provisions), at Step 8 of the Procedure (ALINORM 09/32/27, para. 77 and Appendix III)

Comments of Brazil and European Community.

<u>Brazil</u>

Brazil supports the adoption of the proposed standards.

European Coomunity

Colours

As a general principle, the EC does not support the inclusion of any colours listed in the table of section 4.2 in the canned vegetables standard because their use could mislead the consumer except in a very limited number of cases, like INS 102 and INS 133 for processed mushy and garden peas⁵ only.

EC position: In a spirit of compromise, EC can accept the section 4.2 as it stands if the specific footnote "Subject to national legislation of the importing country aimed, in particular, at consistency with Section 3.2 of the Preamble of the Codex General Standard for Food Additives (CODEX STAN 192-1995)" is assigned to the heading "colours" in section 4.2 of appendix III in the draft standard for certain canned vegetables.

Colour retention agents

The EC would like to reiterate that due to the very low numerical ADI of EDTA (ADI: 2.5 mg/kg), this food additive should be restricted, and not permitted as a general rule to all canned vegetables because of potential intake concern. However, the EC supports the use of INS 385 only in canned and bottled pulses, legumes, mushrooms and artichokes.

INS 512 (stannous chloride) should be limited to canned or bottled white asparagus only.

⁵ Classified as "mature processed peas" in the draft Codex Standard for Certain Canned Vegetables.

EC position: In a spirit of compromise, the EC can accept the section 4.3 "colour retention agents" as it stands if the specific footnote "Subject to national legislation of the importing country aimed, in particular, at consistency with Section 3.2 of the Preamble of the Codex General Standard for Food Additives (CODEX STAN 192-1995)" is attached to 'Stannous chloride", "Calcium disodium ethylene diamine tetra acetate" and "Disodium ethylene diamine tetra acetate".

Proposed Draft Section 3.1.3 - provisions for packing media for certain canned vegetables (for inclusion in the draft Codex Standard for Certain Canned Vegetables), at Step 5/8 of the Procedure (ALINORM 09/32/27, para. 77 and Appendix IV)

Comments of Brazil

<u>Brazil</u>

Brazil supports the adoption of the proposed standards.

Proposed Draft Annexes specific to certain canned vegetables (for inclusion in the draft Codex Standard for Certain Canned Vegetables), at Step 5/8 of the Procedure (ALINORM 09/32/27, para. 77 and Appendix V)

Comments of Brazil

<u>Brazil</u>

Brazil supports the adoption of the proposed standards.