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codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD
HEALTH
ORGANIZATION



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Agenda Item 5

ORIGINAL LANGUAGE ONLY

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

*Twenty-eighth Session**FAO Headquarters, Rome, Italy, 4 – 9 July 2005*

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

CCFAC

**DRAFT RISK ANALYSIS PRINCIPLES APPLIED BY THE COMMITTEE ON FOOD ADDITIVES
AND CONTAMINANTS (ALINORM 05/28/33, Appendix II)**

Brazil

Brazil supports the adoption of this document at step 8.

United States

The United States supports the Risk Analysis Principles Applied by the Committee on Food Additives and Contaminants.

The U.S. notes that a number of committees are currently developing risk analysis guideline documents and that there is a degree of divergence among the various documents. The U.S. urges the relevant Codex committees to complete their work on risk analysis. The U.S. endorses the statement of the representative of WHO (para. 22, ALINORM 05/28/33) who noted that, when finalized, all documents require further consideration as to their overall consistency with the *Working Principles for Risk Analysis for Application within the Framework of Codex* and with one another, especially with respect to risk management.

**DRAFT CCFAC POLICY FOR EXPOSURE ASSESSMENT OF CONTAMINANTS AND TOXINS IN
FOODS OR FOOD GROUPS (ALINORM 05/28/33 Appendix III)**

Brazil

Brazil supports the adoption of this document at step 8.

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Yxxxx/E

United States of America

The United States supports the Policy for Exposure Assessment of Contaminants and Toxins in Foods or Food Groups, as developed by the Codex Committee on Food Additives and Contaminants.

CCFFP

PROPOSED DRAFT CODE OF PRACTICE FOR FISH AND FISHERY PRODUCTS (SHRIMPS AND PRAWNS; CEPHALOPODS; TRANSPORT; RETAIL; AND RELEVANT DEFINITIONS) AT STEP 5/8 (ALINORM 05/28/18; para. 91 and Appendix III)

Brazil

14.2.4 Chilled Storage

Brazil suggests the inclusion of the following bullet:

It should be avoided unnecessary delays during chilled storage in order to prevent quality deterioration.

United Kingdom

The UK has the following comments on Part A, Point 3 of CL 2005/14-FFP in respect of the Draft Code of Practice on Shrimps and Prawns advanced to Step 5/8 of the Codex procedure (Appendix III):

14.2.1 (p.43) - we suggest that clarification is given in respect of the mention of phytotoxins and that this applies specifically to head on products ;

14.2.3, third bullet (p.44) - for further clarification, we consider it useful to add, "to achieve a defrosted product at a temperature cooler than + 4^oC ; and,

14.2.9, fourth bullet (p.45) - typo "clearing" should read "cleaning". Also, insert "in" before "place".

CCFICS

PROPOSED DRAFT PRINCIPLES FOR ELECTRONIC CERTIFICATION AT STEP 5/8 (ALINORM 05/28/30, Appendix II)

Brazil

Brazil supports the adoption of this document at Steps 5/8.

Cuba

En relación con el Anteproyecto de Principios para la Certificación Electrónica (ALINORM 05/28/30, Apéndice II) opinamos que los países deberán crear las infraestructuras necesarias para dar respuesta a este sistema de certificación que debe caracterizarse por ofrecer la máxima seguridad y preparación para evitar complicaciones.

Nos preocupa en este sentido la situación que puedan presentar las Autoridades Nacionales Competentes de los países en vías de desarrollo respecto a la infraestructura que necesitan para dar respuesta a ese sistema de certificación

Este sistema debe funcionar correctamente de Autoridad Nacional a Agencia de Inspección – Proveedor – Banco.

Guatemala

Guatemala agradece el trabajo realizado por la delegación de Australia como país coordinador del Grupo de Trabajo. Consideramos que el documento, con las modificaciones realizadas y como un texto adicional del documento Directrices para Modelos Genéricos de Certificados Oficiales y para la Preparación y Expedición de Certificados, presenta una guía a tomar en cuenta en el momento en que las autoridades competentes implementen certificaciones electrónicas.

Mexico

México agradece la oportunidad de comentar que:

No tiene inconveniente en el avance del **ANTEPROYECTO DE PRINCIPIOS PARA LA CERTIFICACIÓN ELECTRONICA**, tal como aparece en el ALINORM 05/28/30, y su inclusión en el texto de las Directrices para Modelos Genéricos de Certificados Oficiales y para la Preparación y Expedición de Certificados (CAC/GL 38-2001).

United States of America

The United States concurs with the *Proposed Draft Principles for Electronic Certification* as they appear in Appendix II of ALINORM 05/28/30 and recommends their adoption by the Codex Alimentarius Commission at Steps 5/8 with the omission of Steps 6 and 7, for inclusion as an Annex to the *Codex Guidelines for Generic Official Certificate Formats and the Production and Issuance of Certificates* (CAC/GL 38-2001).

CCFO

PROPOSED DRAFT STANDARD REVISED TABLE 1 OF THE RECOMMENDED INTERNATIONAL CODE OF PRACTICE FOR STORAGE AND TRANSPORT OF EDIBLE FATS AND OILS IN BULK AT STEP 5 OF THE ACCELERATED PROCEDURE (ALINORM 05/28/17; para. 52, Appendix II)

Brazil

Brazil agrees with the minimum and maximum temperatures adopted in the 19^a Session of CCFO.

CCNFSDU

DRAFT GUIDELINES FOR VITAMIN AND MINERAL FOOD SUPPLEMENTS AT STEP 8 (ALINORM 05/28/26; para. 35, Appendix II)

Australia

Introductory Remarks

Australia is an example of a country that regulates vitamin and mineral supplements as therapeutic goods (drugs) and therefore it is expected that it would not be bound by these Draft Guidelines. The international impetus for the development of these Guidelines comes from a desire to introduce a Codex Standard for vitamin and/or mineral supplements traded as foods.

Section 1 Scope

1.3 Because not all countries regulate these products as foods, it is vitally important for the current sentence in this paragraph to remain so to recognise this global diversity and to indicate that it is not an international expectation that these products *should* be regulated as foods.

The sentence should have **ONLY** inserted to emphasise this point and to avoid merely being a self-evident statement for what is, after all, a Guideline about food supplements. It should thus read:

‘These Guidelines apply only in those jurisdictions where products defined in 2.1 are regulated as foods’.

Brazil

Brazil agrees to advance the Proposed Draft Guidelines on Vitamin and Mineral Supplements. However, manifest concern with the adoption of the safe maximum limits of vitamins and minerals, since there is not an international consensus about the criteria and values recommended to the different groups of the population.

Brazil recognizes the importance of the Nutrient Risk Assessment Project coordinated by FAO/WHO that has experts from various different countries aiming to establish on the scientific basis applicable internationally, pointing out only the deadline for finishing and publication of the documents and the current step of the norm advanced to step 8. The absence of accepted international criteria can delay the adoption of the norm.

China

ALINORM 05/28/26 Appendix II Draft Guidelines for Vitamin and Mineral Food Supplements (At step 8 of the procedure)	Our comments
<p>3. COMPOSITION</p> <p>3.1 Selection of vitamins and minerals</p> <p>3.1.1 Vitamin and mineral food supplements should contain vitamins/provitamins and minerals whose nutritional value for human beings has been proven by scientific data and whose status as vitamins and minerals is recognized by FAO and WHO.</p>	<p>Add a sentence “Countries and states could further decide categories of vitamins/provitamins and minerals that should be presented in food supplement depend on population’s own dietary habits in their territory, on the basis of provisions mentioned above” at the end of this paragraph.</p> <p>The reason is that with the big difference of dietary habits and life style between each country or state, the populations need to intake various vitamins/provitamins and minerals in various dosage. And the populations only need to intake deficient substance. So the special category of vitamins/provitamins and minerals in necessary shall be decided by the countries or states themselves.</p> <p>The concept of provitamins is too general. We suggest giving a specific definition or range for “provitamins”.</p>

Venezuela

Como los Complementos Alimentarios solo se refieren a vitaminas, minerales o mezclas de ellos Venezuela recomienda el título siguiente:

DIRECTRICES PARA COMPLEMENTOS ALIMENTARIOS DE VITAMINAS Y/O MINERALES

La expresión y/o se mantendrá en todo el documento.

Preámbulo:

Se recomienda:

Completar la frase de alimentación equilibrada con el término variada, eso implica que en la alimentación deben participar todos los grupos de alimentos.

En lugar de vitaminas y minerales debe decir: vitaminas y/o minerales

Eliminar la frase: ... “o los consumidores consideren que su alimentación requiere complementos”

En base a lo anterior la redacción propuesta sería:

“La mayoría de las personas que tienen acceso a una alimentación equilibrada y variada, suelen obtener de su alimentación normal todos los nutrientes que necesitan. Como los alimentos contienen muchas sustancias que promueven la salud, se deberá alentar a las personas a elegir una alimentación equilibrada y variada, antes de considerar la posibilidad de recurrir a cualquier complemento de vitaminas y/o minerales. En los casos en que la ingestión de nutrientes con los alimentos sea insuficiente, se recurrirá a los complementos alimentarios de vitaminas y/o minerales para completar la alimentación diaria”.

2.1 Se sugiere sustituir en la última frase a partir de por en y la redacción será:

A efectos de las presentes Directrices, la importancia nutricional de los complementos alimentarios de vitaminas y/o minerales. Su finalidad es complementar la ingestión de estos nutrientes en la alimentación diaria.

3.2.2 Se recomienda incluir el punto siguiente:

c) No debe alcanzar los niveles terapéuticos establecidos.

- Sobre el punto 5. Etiquetado, se hacen las siguientes observaciones:

Numeral 5.3 Sustituir la palabra deberán por deben, e indicar la expresión cuando proceda en UI.

Las unidades utilizadas deben ser unidades de peso o de volumen, por lo cual se sugiere el párrafo siguiente:

“La cantidad de vitaminas y minerales presentes en el producto debe figurar en la etiqueta en forma numérica y su equivalente en UI cuando proceda. Las unidades utilizadas deben ser unidades de peso o volumen, de conformidad con las Directrices del Codex para el Etiquetado Nutricional”.

Numeral 5.6: Reemplazar deberá por debe y sustituir condiciones especiales por particulares, ya que se entiende que son condiciones consumo y manipulación y a tal efecto debe decir:

“Debe indicarse en la etiqueta la modalidad de uso del producto (cantidad, frecuencia, condiciones particulares)”

Numeral 5.7, Sustituir deberá por debe y agregar al final del párrafo, la frase, sugerida por el

Fabricante, quedando redactado de la siguiente manera:

“En la etiqueta debe figurar una recomendación al consumidor de que no sobrepase la cantidad máxima diaria sugerida por el fabricante”.

Numeral 5.8: Reemplazar deberá por debe quedando la siguiente redacción:

“En la etiqueta no debe declararse o sugerirse que los complementos puedan utilizarse en sustitución de comidas o de una dieta equilibrada y variada.”

Numeral 5.9: Sustituir deberá por debe y eliminar pequeños al final del texto, ya que de acuerdo con la OMS, se consideran niños pequeños los niños de 1 a 3 años y la indicación debe cubrir hasta niños de más edad, por lo cual se sugiere la siguiente redacción:

“La etiqueta debe llevar la indicación de que el complemento debe mantenerse fuera del alcance de los niños”

Council for Responsible Nutrition (CRN)

The Codex Alimentarius Commission (CAC) should expeditiously approve and adopt this document because:

1. The Draft Guideline recognizes that vitamin and mineral food supplements can be appropriately regulated as food.
2. It recognizes that risk assessment is the only scientifically valid method for identifying maximums, and it adopts this approach.
3. The Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) considered and rejected the identification of maximums based primarily on population reference intakes (recommended dietary allowances) because such values do not relate to safety.
4. Valid, science-based guidelines are needed to eliminate unjustified non-tariff barriers to international trade in supplement products.
5. The draft guidelines will provide consumer protection in a manner that is minimally disruptive of international trade.

Discussion

1. The Codex Alimentarius is, by name and definition, a food code. The adoption of vitamin and mineral food supplement guidelines will overtly recognize that these products and their ingredients can be properly and effectively regulated as “food” if this guideline and other related guidelines, such as those on labeling, and standards, such as those on composition and purity, are followed. The adoption of Codex guidelines will allow the proper regulation and control of supplement products marketed and used as food without resorting

to more onerous and expensive regulations that could not only unnecessarily increase costs and decrease consumer choice and access but actually compromise consumer health by forcing regulatory officials to focus on extraneous matters that have no bearing on safety.

2. Several authoritative bodies (e.g., U.S. Institute of Medicine, European Commission Scientific Committee on Food and European Food Safety Authority, and U.K. Expert Group on Vitamins and Minerals) have adopted the application of risk assessment to the identification of the maximum quantities of vitamins and minerals that can be safely consumed. The Tolerable Upper Intake Level (UL) method has been developed, refined, and widely adopted for this purpose. The U.N. Food and Agriculture Organization and World Health Organization have a current project underway to establish an internationally accepted approach to nutrient risk assessment, and this approach should be available soon for use by Codex in the identification of maximums for vitamins and minerals in food supplement products.
3. The population reference intakes (PRI) and recommended dietary allowances (RDA) are based on nutritional need, and are not scientifically valid for assessing safety and setting maximums. The draft guideline at Step 8 recognizes these conclusions and recommends that maximums be set through a risk assessment process.
4. Members of the World Trade Organization are obliged to have trade (import) policies that conform to the Sanitary and Phytosanitary Standards (SPS Agreement). This agreement specifies that standards and guidelines for foods in international trade will be no more restrictive than necessary to protect the health of consumers. For this purpose, WTO recognizes the Codex Alimentarius as the international authority on food safety. Any national policy on imports more restrictive than Codex guidelines or standards could be contested under the SPS Agreement. A Codex Alimentarius guideline on vitamin and mineral food supplements would help eliminate the uneven and unjustified differences in trade standards now in place, while protecting consumer safety and health by focusing on appropriate issues.

Similarly, WTO members are obliged to have trade (import) policies that conform to the Technical Barriers to Trade Agreement (TBT Agreement). The objective of the TBT Agreement is to prevent the use of national or regional technical requirements, or standards in general, as unjustified technical barriers to trade. The agreement covers standards relating to all types of products and quality requirements for foods, except those requirements which are related to SPS measures. In essence, the TBT Agreement provides that all technical standards and regulations for imports must have a legitimate purpose and that the impact or cost of implementing the standard must be proportional to the purpose of the standard. It also states that if there are two or more ways of achieving the same objective, the least trade restrictive alternative should be followed. The agreement also places emphasis on international standards, specifically that WTO members are encouraged to use international standards in decisions on imported products, except where the international standard would be ineffective or inappropriate in the national situation. Arbitrary use of national PRI (or RDA)-based standards as maximums for supplements and other foods represent precisely the types of measures that the TBT Agreement meant to preclude. Such standards lack a legitimate purpose, so that their cost of implementation is by its nature disproportionate. If the objective is a healthy population, there are many more effective and less trade restrictive alternatives. Thus, the use of PRI (RDA)-based limits is inconsistent with both the spirit and the letter of the conclusions in favor of the risk assessment approach to maximums reached by the CCNFSDU at its past two meetings.

International Alliance of Dietary/Food Supplement Associations (IADSA)

After more than ten years of discussions in Codex, the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) agreed to advance the draft Guidelines for Vitamin and Mineral Food Supplements for final adoption at Step 8 by the 28th Session of the Codex Alimentarius Commission.

IADSA welcomes the results of the work of the CCNFSDU and considers the draft Guidelines a solid regulatory framework for the use of vitamins and minerals in food supplements.

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

IADSA would like to express its support for the final adoption of the draft Guidelines by the Codex Alimentarius Commission.

National Health Federation (NHF)

The National Health Federation considers that the drafting of the Guidelines for Vitamin and Mineral Food Supplements has not been carried out in full accordance with the rules set out in the Codex Procedural Manual (14th edition).

Paragraph (b) (page 57) of the section dealing with DRAWING UP OF CODEX STANDARDS (under GUIDELINES ON THE CONDUCT OF MEETINGS OF CODEX COMMITTEES AND AD HOC INTERGOVERNMENTAL TASK FORCES) states that:

.....all standards and related texts should have a preface containing.....a brief description of the scope and purpose(s) of the standard or related text,

This requirement was agreed at the 19th Session of the Codex Committee on General Principles, held in Paris between 17-21 November 2003, and adopted at the 27th Session of the Codex Alimentarius Commission (CAC), held in Geneva between 28th June and 2nd July 2004. The Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) subsequently met in Bonn from 1-5 November 2004 (26th Session) but did not take proper account of this requirement when considering the guidelines, as evidenced by both the CCNFSDU's report of its 26th session and the draft text of the guidelines themselves:

1. The CCNFSDU's report of its 26th Session gives no indication that the requirement for the preface to contain a description of the purpose of the text was even considered, despite the fact that the matter was raised at this session by the delegations of South Africa, Tanzania and the National Health Federation.
2. Neither the Preamble nor the Scope of the guidelines contain any statement to indicate the purpose(s) of the text. Given therefore that Codex texts have been used as the benchmark in international trade disputes, and moreover that it is expected that they will be used increasingly in this regard, we consider that it is of crucial legal importance that the question "What is the purpose of the guidelines?" should have a clear, easily understandable answer, and moreover that this should be provided in the text.

Bearing the above in mind, the National Health Federation believes that the 28th Session of the Codex Alimentarius Commission has no option but to refer the Guidelines for Vitamin and Mineral Food Supplements back to the CCNFSDU, in accordance with the GUIDE TO THE CONSIDERATION OF STANDARDS AT STEP 8 OF THE PROCEDURE FOR THE ELABORATION OF CODEX STANDARDS INCLUDING CONSIDERATION OF ANY STATEMENTS RELATING TO ECONOMIC IMPACT, as described on pages 26-27 of the Codex Procedural Manual (14th edition). As such, until such time as the CCNFSDU's written comments regarding this matter have been received and considered by the CAC the guidelines should not, and indeed, cannot, be advanced beyond Step 8 of the Procedure.

Mexico

Sin comentarios.

CCRVDF

PROPOSED DRAFT CODE OF PRACTICE TO MINIMIZE AND CONTAIN ANTIMICROBIAL RESISTANCE AT STEP 5/8 (ALINORM 05/28/31; Appendix VIII, para. 117)

Argentina

Argentina considera que el presente documento no reconoce que los antimicrobianos puedan resultar en un suministro de alimentos más inocuos. Por lo tanto, se deberían realizar los siguientes cambios a lo largo del documento: cambiar "basado en el riesgo" a "basado en el riesgo /beneficio" y "riesgos" a "riesgos y beneficios".

Por otro lado, del análisis de los párrafos 33, 34 y 35 de la ALINORM 05/28/31 AP VIII CL 2004/50 RVDF, debe observarse que, si bien conceptualmente se coincide en un todo con lo expresado, se encuentra que la puesta en práctica e implementación de tales conceptos en los países en desarrollo resultará muy difícil.

Australia

Australia supports the progression of this Draft Code of Practice to Steps 5/8, acknowledging the large number of changes adopted during the 15th meeting of CCRVDF.

Australia supports the proposal for a joint Codex/OIE Taskforce to address this issue and recommends that this Taskforce work towards developing risk assessment principles and procedures for antimicrobial resistance to be used within Codex.

Canada

Canada supports the final adoption, by the 28th Session of the Commission, of the proposed draft Code of Practice to Minimize and Contain Antimicrobial Resistance that was advanced to Step 5/8 by the 15th Session of the CCRVDF.

Canada is proposing the following changes to the text of the proposed draft:

§ Under **Responsibility of the Regulatory Authorities** Paragraph 9 last sentence: “and animals” should be deleted in order to be consistent with the description in Bullet 5 of Paragraph 8.

Egypt

The proposal looks to be satisfying the following objectives,

- 1- Responsibilities of the regulatory authorities.
- 2- Responsibilities of the veterinary pharmaceutical industry.
- 3- Responsibilities of the wholesale and retail distributors.
- 4- Responsibilities of veterinarians.
- 5- Responsibilities of producers

So, It is fully accepted.

We like to concentrate on,

- a- More concern have to be directed to the appropriate systems to ensure the control of veterinary drug manufacture, marketing, distribution, prescription and use which is weak in our country.
- b- These is a real stepwise approach for proper implementation of all the elements in item (a) by an authorized committee for the control of all previous items, acting through the Ministry of Agriculture and specifically the General Organization of Veterinary Services.
- c- The use of veterinary products specially the antibiotics have to be involved in the authorization, production, control, distribution and use of these drugs in food producing animal the human health welfare.

United States of America

The U.S. supports the adoption of the draft code.

DRAFT MAXIMUM RESIDUE LIMITS AT STEP 8 (ALINORM 05/28/31, Appendix II)

Australia

Cyhalothrin: Australia supports the recommendation to progress the draft MRLs to Step 8.

Flumequine: No further comment, not registered in Australia.

Neomycin: Australia supports the recommendation to progress the draft MRLs to Step 8.

Australia notes that JECFA should not be commenting on GAP/GPVD1 as this is not its role/remit and has already been determined by the member country. JECFA should be satisfied that GPVD is adequately described in the data submitted to verify the relevance of the residue data.

Dicyclanil: Australia supports the recommendation to progress the draft MRLs to Step 8.

¹ Good Practice in the Use of Veterinary Drugs (GPVD) is the official recommended or authorized usage, including withdrawal periods, approved by national authorities, of veterinary drugs under practical conditions, Codex Alimentarius Commission – 14th Procedural Manual.

Canada

Canada supports the final adoption, by the 28th Session of the Commission, of the draft MRLs recommended by the 62nd JECFA and advanced to Step 8 by the 15th Session of the CCRVDF, specifically:

Cyhalothrin for cattle, pig and sheep tissues and cattle milk.

Flumequine for cattle, chicken, pig and sheep tissues, and trout muscle.

Canada supports the final adoption, by the 28th Session of the Commission, of the draft MRLs recommended by the 60th JECFA and advanced to Step 8 by the 15th Session of the CCRVDF, specifically:

Neomycin for cattle liver and kidney, and cattle milk.

Dicyclanil for sheep tissues.

Egypt

It is accepted for:

Cyhalothrin	ADI of 0-5	µg/kg bw
Flumequine	ADI of 0-30	µg/kg bw
Neomycin	ADI of 0-60	µg/kg bw
Dicyclanil	ADI of 0-7	µg/kg bw

United States of America

Cyhalothrin: The U.S. supports the recommended MRLs in cattle, pig and sheep tissues because the ADI and MRLs are now permanent.

Flumequine: The U.S. supports the ADI and MRLs for cattle, chicken, pig and sheep tissues based on JECFA evaluation of new data indicating an absence of genotoxic potential.

Neomycin: The U.S. can support the draft standards for cattle liver, kidney and milk for international trade purposes. The U.S. has reviewed the animal and human food safety JECFA scientific conclusions and accepts their recommendation.

Dicyclanil: Although there are no U.S. approvals or MRLs for dicyclanil in sheep tissues, the U.S. supports the adoption of the draft standards.

PROPOSED DRAFT MAXIMUM RESIDUE LIMITS AT STEPS 5/8 (ALINORM 05/28/31, Appendix III)**Australia**

Imidocarb: Australia supports the recommendation to progress the draft MRLs to Steps 5/8.

Australia suggests improved precision for the definition of the marker residue as “sum of imidocarb as free base and conjugates, expressed as free base equivalents”.

Canada***Imidocarb***

Canada supports the final adoption, by the 28th Session of the Commission, of the proposed draft MRLs for imidocarb for cattle tissues and cattle milk recommended by the 60th JECFA and advanced to Step 5/8 by the 15th Session of the CCRVDF.

United States of America

Imidocarb: Although there are no U.S. tolerances, the U.S. supports adoption of the draft standards in cattle tissues and milk.