

# CODEX ALIMENTARIUS COMMISSION



Food and Agriculture  
Organization of  
the United Nations

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## Agenda Item 3



World Health  
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## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### CODEX ALIMENTARIUS COMMISSION

37<sup>th</sup> Session, CICG

Geneva, Switzerland, 14-18 July 2014

### AMENDMENTS TO THE PROCEDURAL MANUAL

(Comments submitted by 30 June 2014)

#### Codex Committee on Residues of Veterinary Drugs in Foods

Comité du Codex sur les Résidus de Médicaments Vétérinaires dans Les Aliments

Comité del Codex sobre Residuos de Medicamentos Veterinarios en Los Alimentos

Draft Provisions on Extrapolation of Maximum Residue Limits (MRLs) of Veterinary Drugs to Additional Species (for inclusion in the Risk Analysis Principles Applied by the CCRVDF) (REP14/RVDF para. 104 and App. VIII)

*Comments of Brazil, Canada, Costa Rica and Egypt*

#### BRAZIL

Brazil supports the adoption by the 37<sup>th</sup> Session of the Codex Alimentarius Commission.

#### CANADA

Canada strongly supports the adoption of draft provisions for inclusion in the Risk Analysis Principles Applied by the CCRVDF on extrapolation of MRLs of veterinary drugs to additional species.

#### COSTA RICA

Costa Rica apoya el anteproyecto de las disposiciones sobre la extrapolación de los LMRs de los medicamentos veterinarios para especies y tejidos adicionales ya que vendría a llenar un vacío o carencia de algunos LMR que hacen falta para algunas especies.

#### EGYPT

Egypt agrees on the decision as long as it is with species of combined physiological and anatomical characteristics as differences may play a big role in metabolism and excretion of drugs and their residues that is recommended to be transient till it is available for JECFA to put down precise ADI and MRLs for these drugs in different animals.

Draft Provisions of the Use of the Concern Form for the CCRVDF (for inclusion on the Risk Analysis Principles applied by the CCRVDF) (REP14/RVDF para. 121 and App. IX)

*Comments of Brazil, Costa Rica and Egypt*

#### BRAZIL

Brazil supports the adoption by the 37<sup>th</sup> Session of the Codex Alimentarius Commission. The use of the Concern Form by the CCRVDF is in line with the recommendations of the CCGP to all Committees and is an important tool to improve the quality of communication between the CCRVDF and JECFA, providing clarity and transparency when addressing scientific concerns.

**COSTA RICA**

Costa Rica apoya el uso del "formulario para expresar preocupaciones" porque considera que dicho formulario mejora la transparencia en la interacción con el JECFA y facilitaría la solución de diferencias; además su utilización no interferiría con el establecimiento de prioridades del Comité y sería útil para el JECFA ya que describiría claramente las preocupaciones o las inquietudes relativas a la evaluación de riesgo.

**EGYPT**

Egypt approves the use of a concern form for the CCRVDF to be referred to by JECFA to be included on the risk analysis principles applied by the CCRVDF.

**Codex Committee on General Principles**  
**Comité du Codex sur les Principes Généraux**  
**Comité del Codex sobre Principios Generales**

Definitions of Risk Analysis Terms related to Food Safety: hazard characterization and risk estimate (para. 13 and Appendix II)

*Comments of Brazil, Costa Rica, Egypt, Malaysia and Thailand*

**BRAZIL**

Brazil agrees with the proposed amendments to the Definitions of Risk Analysis Terms related to Food Safety: hazard characterization and risk estimate (para. 13 and Appendix II).

**COSTA RICA**

Costa Rica apoya la propuesta de enmienda de las definiciones de caracterización del peligro y estimación del riesgo para ser adoptadas en el 37º periodo de sesiones de la Comisión (Apéndice II del REP14/GP).

**EGYPT**

Egypt approves the above mentioned amendments.

**MALAYSIA**

Malaysia has no objection.

**THAILAND**

Thailand supports the adoption of the proposed amendments to the definitions of hazard characterization and risk estimate and agrees with the amendment in the Procedural Manual.

**Rationale:**

In general, we are of the view that the terms should be widely defined to cover their activities based on the risk analysis approach. Simultaneously, it should be flexible for new approaches and technologies in the future. Hence, we believe that the amended definition is appropriate to use in general for completion of hazard characterization and risk estimate for chemicals (pesticides, contaminants and veterinary drugs) and microorganisms.

Terms of Reference of the Committee on General Principles (para. 43 and Appendix III)

*Comments of Colombia, Costa Rica, Egypt, Ghana, Malaysia and Thailand*

**COLOMBIA****PROPUESTAS DE ENMIENDA AL MANDATO DEL COMITÉ SOBRE PRINCIPIOS GENERALES**

Téngase en cuenta lo siguiente: El texto nuevo se presenta subrayado; y el texto eliminado tachado.

Ocuparse de los asuntos de procedimiento y asuntos generales que le remita la Comisión del Codex Alimentarius o uno de sus órganos auxiliares y el Comité Ejecutivo.

Revisar y ratificar las disposiciones/textos de procedimiento previstos para ser incluidos en el Manual de Procedimiento remitidos por órganos auxiliares.

Proponer enmiendas al Manual de procedimiento de la Comisión del Codex Alimentarius.

~~"tales como el establecimiento de los Principios Generales que definen el objeto y la finalidad del Codex Alimentarius, la naturaleza de las normas del Codex y las formas de aceptación de las normas del Codex por parte de los países, la elaboración de directrices para los Comités del Codex, la elaboración de un mecanismo para el examen de todas las declaraciones sobre repercusiones económicas que presenten los gobiernos acerca de las posibles consecuencias que pudieran tener para su economía algunas de las normas o algunas disposiciones de éstas; el establecimiento de un Código de Ética para el Comercio Internacional de Alimentos."~~

Comentario 1: Fusionar y ordenar los dos primeros párrafos de la propuesta de mandato, cambiando el verbo ratificar por conceptuar. Lo anterior teniendo en cuenta que los dos primeros párrafos de la propuesta de enmienda al mandato hacen relación a una actividad similar, la que tiene que ver con tratar asuntos, disposiciones o textos de procedimiento, los cuales junto con los asuntos generales hacen parte del Manual de Procedimiento de la Comisión del Codex Alimentarius. De otra parte la función de ratificar podría entenderse como cierta autonomía del Comité sobre Principios Generales, por encima de las competencias de la Comisión.

El texto propuesto, producto de la unificación y ordenamiento de los dos primeros párrafos es:

Revisar y conceptuar sobre asuntos de procedimiento y asuntos generales que le remita la Comisión del Codex Alimentarius, el Comité Ejecutivo o uno de sus órganos auxiliares.

Comentario 2: Estamos de acuerdo con el tercer párrafo de la propuesta de mandato, debido a que establece, que el Comité sobre Principios Generales puede proponer enmiendas al manual de procedimiento, propuestas de enmiendas que deben surtir trámite ante la Comisión.

En resumen la propuesta de enmienda al mandato de acuerdo con nuestros comentarios sería:

- Revisar y conceptuar sobre asuntos de procedimiento y asuntos generales que le remita la Comisión del Codex Alimentarius, el Comité Ejecutivo o uno de sus órganos auxiliares.
- Proponer enmiendas al Manual de Procedimiento de la Comisión del Codex Alimentarius.

#### **COSTA RICA**

Analizando lo expuesto por el representante de la OMS en la 28<sup>a</sup> reunión del CCPG, Costa Rica desea presentar la siguiente enmienda:

Ocuparse de los asuntos de procedimiento y asuntos generales que le remita la Comisión del Codex Alimentarius o uno de sus órganos auxiliares y el Comité Ejecutivo.

Revisar y ratificar las disposiciones/textos de procedimiento previstos para ser incluidos en el Manual de procedimiento remitidos por órganos auxiliares.

#### **Proponer enmiendas al Manual de procedimiento de la Comisión del Codex Alimentarius.**

~~"tales como el establecimiento de los Principios Generales que definen el objeto y la finalidad del Codex Alimentarius, la naturaleza de las normas del Codex y las formas de aceptación de las normas del Codex por parte de los países, la elaboración de directrices para los Comités del Codex, la elaboración de un mecanismo para el examen de todas las declaraciones sobre repercusiones económicas que presenten los gobiernos acerca de las posibles consecuencias que pudieran tener para su economía algunas de las normas o algunas disposiciones de éstas; el establecimiento de un Código de Ética para el Comercio Internacional de Alimentos."~~

Justificación: Costa Rica solicita la eliminación del tercer punto del mandato ya que la CAC es la que realiza las enmiendas y el CCGP ratifica las enmiendas que le remite la CAC y los órganos auxiliares.

#### **EGYPT**

Egypt approves the above mentioned amendments

#### **GHANA**

"To deal with such procedural and general matters as are referred to it by the Codex Alimentarius Commission or one of its subsidiary bodies and the Executive Committee."

Ghana endorses the amendments but is of the opinion that the statement as it stands could be interpreted in two (2) ways:

Scenario 1: CAC working alone and submitting proposals to the CCGP or one of the Subsidiary bodies and the Executive Committee.

Scenario 2: CAC working with Executive Committee to submit proposals to the CCGP or one of its Subsidiary Bodies working with the Executive Committee.

Ghana would like to suggest that the statement:

*"To deal with such procedural and general matters as are referred to it by the Codex Alimentarius Commission or one of its subsidiary bodies and the Executive Committee."*

should be made clearer by putting a coma after Codex Alimentarius Commission and indicating whether the Subsidiary Bodies should send their proposals to the CCGP through the Executive Committee or with the approval of the Executive Committee.

Ghana's preferred statement could read:

*"To deal with such procedural and general matters as are referred to it by the Codex Alimentarius Commission, or one of its subsidiary bodies with the approval of the Executive Committee."*

#### **MALAYSIA**

Malaysia would like to propose editorial amendments for clarity purposes by inserting the words "as directed by the Commission" at the end of the second and third points as follows:

To deal with such procedural and general matters as are referred to it by the Codex Alimentarius Commission or one of its subsidiary bodies and the Executive Committee.

To review and endorse procedural provisions/ texts intended for inclusion in the Procedural Manual forwarded by subsidiary bodies **as directed by the Commission**.

To propose amendments to the Procedural Manual of the Codex Alimentarius Commission **as directed by the Commission**.

~~Such matters have included the establishment of the General Principles which define the purpose and scope of the Codex Alimentarius, the nature of Codex standards and the forms of acceptance by countries of Codex standards; the development of Guidelines for Codex Committees; the development of a mechanism for examining any economic impact statements submitted by governments concerning possible implications for their economies of some of the individual standards or some of the provisions thereof; the establishment of a Code of Ethics for the International Trade in Food.~~

#### **THAILAND**

Thailand supports the adoption of the amended Term of Reference of the Committee on General Principles proposed by the Committee.

#### **Rationale:**

In general, we are of the opinion that the term of reference should be in line with the current working procedures, practices and tasks that each Committee does and is responsible for. In addition, Thailand agrees with the evaluation of economic impact in the elaboration of Codex standard. Also, we are of the view that the evaluation should be taken into account by relevant subsidiary committees in each related steps. These has been already addressed in the Codex Procedural Manual. Thailand realizes that, in the elaboration of standards and related texts, Codex should firstly emphasize in two core principles that are food safety to protect consumer's health and facilitation of trade. However, the economic impact might be considered to enhance the implementation of Codex standards by countries. Based on the procedural manual, it is sufficient to allow Codex members to provide such information at the early stages of standard development as well as in all steps entirely done by the other subsidiary bodies.

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| Procedures for the Elaboration of Codex Standards and Related Texts (para. 98 and Appendix IV) |
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*Comments of Brazil, Costa Rica, Egypt, India, Malaysia and Norway*

#### **BRAZIL**

In regards to the proposed amendments to the Procedures for the Elaboration of Codex Standards and Related Texts (para. 98 and Appendix IV) Brazil does not support the amendments proposed. Brazil has already raised it concerns at the 28<sup>th</sup> CCGP meeting as stated in the referred meeting report.

#### **COSTA RICA**

El Manual de Procedimiento contempla de forma clara y completa el procedimiento de elaboración de normas y textos afines y por ello Costa Rica no está de acuerdo en realizar ninguna enmienda sobre este tema, máxime que el Secretariado del Codex asiste a todas las reuniones de los comités y está realizando esfuerzos para aumentar la comunicación entre los mismos.

Costa Rica considera que durante la 28<sup>a</sup> reunión del CCGP, no se debatió suficientemente el tema, no siendo la conclusión un reflejo fiel de lo manifestado en la plenaria. En este tema no hubo consenso para avanzar al siguiente nivel y mucho menos para que fuera enviado a la a la CAC.

Por lo anterior, Costa Rica solicita que la CAC no realice ninguna enmienda al Manual de Procedimiento o bien devuelva el tema al CCGP para finalizar el debate basado en el consenso

#### **EGYPT**

Egypt approves the above mentioned amendments.

#### **INDIA**

India would like to submit the following comments on the amendments regarding the Procedures for the Elaboration of Codex Standards and Related Texts as proposed by the 28th session of CCGP:

Amendment 1: Part 2. Critical Review – Para 1 (sixth bullet)

“Information on the relation between the proposal and other existing Codex Document as well as other ongoing Codex work”-

India accepts this amendment. The reason for that is it is always a good practice to take into account ongoing related Codex works in other committees to avoid duplicity which may result in differing or contradictory standards resulting into extensive discussions at CAC level. Even though this is the responsibility of Committee chairperson and Codex secretariat to avoid duplicity of work, but this proposed amendment will be an additional check to avoid that.

Amendment 2: Para 3 (after second bullet)

“Advice on the need for coordination of work between relevant Codex Subsidiary bodies”

India does not support this amendment as addition of this bullet will not have any additional benefit on the procedures. It is inherent in the whole process of standard setting process that the work should be coordinated between various Codex Committees. It is the duty of the concerned Codex Committee Chair to ensure coordination of work between the Committees. Therefore, this bullet seems redundant.

#### **MALAYSIA**

Malaysia has no objection.

#### **NORWAY**

We appreciate this opportunity to comment upon the proposed amendments in the Procedures for the Elaboration of Codex Standards and Related Texts, Part 2. Critical Review:

Para.1 (sixth bullet)

Information on the relation between the proposal and other existing Codex document as well as other ongoing Codex work:

We support the proposed amendment as it clarifies that also ongoing Codex work should be included in the information given when a proposal for new work is submitted.

Para.3 (after second bullet)

Advice on the need for coordination of work between relevant Codex subsidiary bodies;

We also support the inclusion of a new bullet (in para. 3 after second bullet) as it clarifies that the critical review also might give advice on the need for coordination of work between relevant Codex subsidiary bodies.

Both amendments are to clarify that when preparing and discussing new work, there is a need to have information on both adopted and ongoing work, and that it will be helpful if CCEXEC gives advice on coordination of work.

We would also like to underline that the intention of these amendments is to achieve better work management.

Risk Analysis Principles applied by the Codex Committee on Pesticide (para.163, Appendix XIII).

*Comments of Canada, Costa Rica and Japan*

**CANADA**

Item 4 (risk analysis principles applied by CCPR), paragraph 163 of the report of the 46<sup>th</sup> CCPR (REP14/PR): Canada supports to forward to the Commission, however, Canada also shares the concerns of the LAC region when there is no new scientific evidence that a pesticide could damage health, a CXL can be revoked, especially in light of the limited resources of JMPR.

**COSTA RICA**

Costa Rica welcomes the opportunity to express its comments and wishes to express its support for this document:**JAPAN**

Japan supports the adoption of revised *Risk Analysis Principles applied by the Codex Committee on pesticide Residues* (REP 14/PR, Appendix XIII) at the 37<sup>th</sup> Session of the Commission with the following editorial amendments on the numbering of sections for improving hierarchical structure of the document:

**5.2 SELECTION OF PESTICIDES FOR JMPR EVALUATION**

**5.2.2 Nomination requirements and criteria for the prioritisation and scheduling pesticides for evaluation by JMPR**

**5.2.2.1 New Pesticides**

**5.2.2.2 5.2.3 New Uses of Pesticides previously Reviewed by JMPR**

**5.2.2.3 5.2.4 Other Evaluations**

**5.2.2.4 5.2.5 Periodic Review**

**5.3 5.2.6 PERIODic REview PROCEDUREprocedure**

**5.4 5.3 ELABORATION PROCEDURE**

**5.4.1 5.3.1 Utilisation of the Accelerated Procedure for Elaboration of MRL (Step 5/8 – Procedure)**

**5.4.2 5.4 RevocationEVOCATION of CXLs**