comisión del codex alimentarius

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ORGANIZACIÓN DE LAS NACIONES UNIDAS PARA LA AGRICULTURA Y LA ALIMENTACIÓN

ORGANIZACIÓN MUNDIAL DE LA SALUD

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Tema 2 del programa **CX/RVDF 09/18/2**
Febrero de 2009

PROGRAMA CONJUNTO FAO/OMS SOBRE NORMAS ALIMENTARIAS

COMITÉ DEL CODEX SOBRE RESIDUOS DE MEDICAMENTOS VETERINARIOS EN LOS ALIMENTOS

Decimoctava reunión

Natal, Brazil, 11 al 15 de mayo de 2009

CUESTIONES REMITIDAS PARA EL COMITÉ EN LA COMISIÓN DEL CODEX ALIMENTARIUS Y EN OTROS COMITÉS DEL CODEX Y GRUPOS DE ACCIÓN[1]

CUESTIONES FORMULADAS EN LA 31ª REUNIÓN DE LA COMISIÓN DEL CODEX ALIMENTARIUS

A. Cuestiones informativas

Enmiendas al Manual de Procedimiento: "*Formato de las normas para productos" y "Relaciones entre los comités del Codex sobre productos y los comités de asuntos generales*"[2]

1. La Comisión aprobó las enmiendas al "*Formato de las normas para productos" y a las "Relaciones entre los comités del Codex sobre productos y los comités de asuntos generales*". Las enmiendas a estas secciones serán incluidas en la 18ª edición del Manual de Procedimiento.

Proyectos de normas y textos relacionados adoptados en los Trámites 8 y 5/8[3]

2. La Comisión adoptó los límites máximos de residuos (LMR) para medicamentos veterinarios (colistina y eritromicina), según lo propuesto por la 17ª reunión del CCRVDF.

Propuestas para elaborar nuevas normas y textos relacionados[4]

3. La Comisión aprobó la lista de prioridades de medicamentos veterinarios que requieren evaluación o reevaluación como nuevo trabajo por la 17ª reunión del CCRVDF.

Suspensión de trabajos[5]

4. La Comisión aprobó la suspensión de trabajos del proyecto y anteproyecto de LMR para la flumequina en el langostino pelágico y el langostino, según lo propuesto por la 17ª reunión del CCRVDF.

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[1] Este documento contiene las cuestiones planteadas o remitidas por la Comisión del Codex Alimentarius que tienen un interés específico para el Comité para su información (A) o su acción (B). El Secretariado del Codex informará verbalmente sobre las cuestiones de género horizontal apropiadas para la discusión del Comité.
[2] ALINORM 08/31/REP, párr. 54 y Apéndices III-IV
[3] ALINORM 08/31/REP, párrs 21/27-30 y Apéndice VII
[4] ALINORM 08/31/REP, párr. 92 y Apéndice X
[5] ALINORM 08/31/REP, párr. 109 y Apéndice XI

B. Cuestiones que necesitan una acción

LMR para ractopamina[6]

5. Tras un extenso debate la Comisión convino en retener en el trámite 8 los LMR para la ractopamina con el propósito de someterlos a nuevo examen en su 32º período de sesiones. Pidió a los miembros que presentaran la información pertinente sobre la disponibilidad de datos científicos en la 18ª reunión del Comité sobre Residuos de Medicamentos Veterinarios en los Alimentos (mayo de 2009), a fin de que el Comité pudiera adoptar una decisión sobre la inclusión de la ractopamina en la lista de prioridades para la evaluación/reevaluación de sustancias del JECFA. La Comisión acordó también que en su 32º período de sesiones tomaría una decisión sobre la adopción de los LMR para la ractopamina, que se basaría en el informe de la 18ª reunión del Comité sobre Residuos de Medicamentos Veterinarios en los Alimentos.

6. **Se invita** al Comité a transmitir a la 32ª reunión de la Comisión sus recomendaciones sobre la inclusión de la ractopamina en la lista de prioridades para la evaluación/reevaluación de sustancias el JECFA.

Recomendaciones sobre la gestión de riesgos respecto de medicamentos veterinarios sin IDA ni LMR debido a preocupaciones específicas sobre la salud humana[7]

7. La Comisión tomó nota de la propuesta de la Delegación de los Estados Unidos de América, tal como figura en CAC/31 LIM/15, de revisar el documento de proyecto con el objetivo de ampliar el alcance de los nuevos trabajos sobre decisiones en materia de gestión de riesgos, a fin de incluir también aquellas sustancias respecto de las cuales no se habían establecido IDA o LMR por no disponerse de la información necesaria para evaluar las preocupaciones sobre la salud humana. La propuesta recibió el apoyo de la Delegación de la Comunidad Europea. Habida cuenta de los cambios sustanciales del alcance de la propuesta, la Comisión decidió devolver al Comité sobre Residuos de Medicamentos Veterinarios en los Alimentos la propuesta de nuevos trabajos para su examen ulterior.

8. **Se invita** al Comité a examinar la propuesta de los Estados Unidos de América de revisar el nuevo trabajo sobre la gestión de riesgos (*véase* Anexo 1 a este documento[8]).

[6] ALINORM 08/31/REP, párrs 55-58
[7] ALINORM 08/31/REP, párr. 93
[8] solamente en inglés

Anexo 1

(CAC/31 LIM/15)

SUBMITTED BY UNITED STATES

PROJECT DOCUMENT NO. 1: PROPOSAL OF NEW WORK FOR THE DEVELOPMENT OF RISK MANAGEMENT RECOMMENDATIONS/GUIDANCE FOR VETERINARY DRUGS INCLUDING THOSE FOR WHICH NO ADI AND MRL HAS BEEN RECOMMENDED BY JECFA DUE TO SPECIFIC HUMAN HEALTH CONCERNS OR LACK OF INFORMATION NEEDED TO RESOLVE EXISTING HUMAN HEALTH CONCERNS

1. Purpose and Scope of the Standard

To provide risk management advice to national and regional authorities on veterinary drugs including those substances for which acceptable daily intakes (ADI) and maximum residue limits (MRL) cannot be recommended.

2. Relevance and Timeliness

In addition to providing specific ADI/MRL information on veterinary drugs it would be helpful to provide further pertinent risk management information on these substances, including , for example summaries of pertinent JECFA and CCRVDF comments and decisions..

For certain veterinary drugs, JECFA was is not able to propose an ADI and MRL due to specific human health concerns (e.g. toxicity to the human consumer, carcinogenicity) or to a lack of information needed to resolve existing human health concerns. It is therefore proposed that CCRVDF should take risk management decisions on those veterinary drugs in order to provide risk management guidance to Codex members. The objective is to protect consumers from residues of these veterinary drugs and to ensure a smoother functioning of international trade.

Various Codex members appreciate recognize certain the health concerns and thus have prohibited the use in food producing animals of respective some veterinary drugs. However, discrepancies in application these national regulatory decisions exist between some Codex members hampering international food trade. International standardization CCRVDF risk management guidance would therefore improve consumer protection and facilitate international trade in food. Providing summary information relating to decisions taken by JECFA and CCRVDF on veterinary drugs would assist in providing clear risk management guidance by Codex would be particularly helpful for developing countries to countries, particularly to countries without capacity to perform adequate safety reviews.

3. Main Aspects to be covered

The objective of the new work is to develop specific recommendations/guidance provide specific summary risk management information including recommendations/guidance on veterinary drugs as developed by CCRVDF or from risk assessment activities performed by JECFA, including those substances for which no ADI and MRL has been recommended by JECFA due to specific human health concerns or to a lack of information needed to resolve existing human health concerns.

The outcome of this proposal is not to establish a negative list, but to develop risk management recommendations. These recommendations may also suggest the use of substances with no ADI/MRL if their unavailability creates animal health concern.

This risk management information will consist of a single listing containing the following information:

- identification of specific risk assessment guidance developed by JECFA and risk management guidance developed by CCRVDF on veterinary drugs for which an ADI has been established or an MRL has been established or recommended and identification of specific risk assessment guidance developed by JECFA and risk management guidance developed by CCRVDF on veterinary drugs for which no ADI and MRL has been

established or recommended by JECFA or CCRVDF due to specific human health concerns or to a lack of information needed to resolve existing human health concerns; including:

- summarising ~~the~~ any specific concerns identified by JECFA and/or CCRVDF for each of those veterinary drugs;
- agreeing which veterinary drugs should or should not be used in food producing animals due to human health concerns related to their residues in food and provide~~ing~~ respective guidance to Codex members.

This risk management information will also consider options for communicating risk management recommendations ~~on such substances~~ for all veterinary drugs including those substances for which an ADI or MRL has been established or recommended and those for which no ADI or MRL has been established or recommended, for example by developing a Table that lists all compounds, their ADIs and MRLs if established and for others that no ADI or MRL has been established or recommended, and pertinent concerns/comments noted by JECFA and/or CCRVDF.

Example:

Chloramphenicol was evaluated by the 42nd and 62nd JECFA meetings. JECFA was unable to set an ADI or recommend an MRL because of specific concerns about human health, i.e. aplastic anaemia and carcinogenicity. Therefore, CCRVDF recommends that chloramphenicol should not be used in food-producing animals.

4. Assessment against the *Criteria for the Establishment of Work Priorities*

This proposal is consistent with the Criteria for the Establishment of Work Priorities. These recommendations will aim at ensuring better consumer protection from the point of view of health and food safety and fair practices in the international food trade.

In addition, the following criteria are also relevant:

- diversification of national legislations and apparent resultant or potential impediments to international trade;
- such work has not already been undertaken by other international organisations; and
- volume of consumption in individual countries and volume and pattern of trade between countries of concerned food products.

5. Relevance to the Codex Strategic Objectives

This proposal is congruent with the Codex Strategic Objectives 1 and 2.

Objective 1: Promoting Sound Regulatory Framework

This proposal will provide essential guidance for member countries and promote the development of national food control systems based on international principles and criteria for the reduction of health risk along the entire food chain.

Objective 2: Promoting Widest and Consistent Application of Scientific Principles and Risk Analysis

JECFA strictly follows the principles of risk analysis as regards risk assessment of veterinary drugs. Development of international standardisation on veterinary drugs proposed to be prohibited in food producing animals would promote the consistent application of risk analysis principles by Codex members in line with the Working principles for Risk Analysis developed by Codex.

6. Information on the relation between the proposal and other existing Codex documents

This guidance provided to Codex members will complement the MRL for veterinary drugs already adopted by the CCRVDF.

7. Identification of any requirement for and availability of expert scientific advice

These risk management recommendations/guidance will take into account evaluations made by JECFA and revised accordingly in the future.

8. Identification of any need for technical input to the standard from external bodies so that this can be planned for

None.

9. Proposed time-line for completion of the new work, including the start date, the proposed date for adoption at Step 5, and the proposed date for adoption by the Commission

- Circulation of a proposal elaborated by a working group at step 3 after adoption of new work by the CAC;
- Consideration of the proposed draft at the 18th Session of CCRVDF;
- Adoption at Step 5 by the following CAC;
- Consideration of the proposal at the 19th Session of CCRVDF;
- Final adoption by the following CAC.