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commission du codex alimentarius

ORGANISATION DES NATIONS UNIES POUR L'ALIMENTATION ET L'AGRICULTURE

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Point 2 de l'ordre du jour **CX/RVDF 09/18/2**
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PROGRAMME MIXTE FAO/OMS SUR LES NORMES ALIMENTAIRES

COMITÉ DU CODEX SUR LES RÉSIDUS DE MÉDICAMENTS VÉTÉRINAIRES DANS LES ALIMENTS

Dix-huitième session

Natal, Brésil, 11 -15 mai 2009

QUESTIONS DÉCOULANT DE LA COMMISSION DU CODEX ALIMENTARIUS ET D'AUTRES COMITÉS ET GROUPES SPÉCIAUX DU CODEX [1]

QUESTIONS DÉCOULANT DE LA TRENTE ET UNIÈME SESSION DE LA COMMISSION DU CODEX ALIMENTARIUS

A. Questions soumises pour information

Amendements au Manuel de procédure : "Plan de présentation des normes Codex de produits " et relations entre les comités s'occupant de produits et les Comités s'occupant de questions générales"[2]

1. La Commission **a adopté** les amendements au "Plan de présentation des normes Codex de produits " et aux " Relations entre les comités s'occupant de produits et les Comités s'occupant de questions générales". Les amendements effectués dans ces sections seront incorporés dans la dix-huitième édition du Manuel de procédure.

Normes et textes apparentés adoptés à l'étape 8 et 5/8[3]

2. La Commission **a adopté** les limites maximales pour les résidus (LMR) de médicaments vétérinaires (colistine et érythromycine) tels que proposés par le Comité sur les résidus de médicaments vétérinaires dans les aliments, à sa dix-septième session.

Approbation de nouvelles activités pour l'élaboration de nouvelles normes et de nouveaux textes apparentés[4]

3. La Commission a approuvé une liste prioritaire de médicaments vétérinaires pour évaluation ou réévaluation par le JECFA, telle que proposée par le Comité sur les résidus de médicaments vétérinaires dans les aliments, à sa dix-septième session.

Interruption d'activités[5]

4. La Commission **a approuvé** l'interruption d'un projet et avant-projet de LMR pour la fluméquine dans les crevettes tigrées et les crevettes, telle que proposée par le Comité sur les résidus de médicaments vétérinaires dans les aliments à sa dix-septième session.

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1 Dans ce document, figurent les questions découlant ou soumises par la Commission du Codex Alimentarius ayant un intérêt particulier pour le Comité pour son information (A) ou son action (B). Le Secrétariat du Codex fournira verbalement des renseignements sur des questions de nature horizontale, conformément au débat du Comité.

2 ALINORM 08/31/REP, par. 54 et Annexes III-IV

3 ALINORM 08/31/REP, par. 21 et 27-30 et Annexe VII

4 ALINORM 08/31/REP, par. 92 et Annexe X

5 ALINORM 08/31/REP, par. 109 et Annexe XI

B. Questions réclamant des mesures

LMR pour la ractopamine[6]

5. Après un débat prolongé, la Commission est convenue de maintenir les LMR pour la ractopamine à l'étape 8 pour examen plus approfondi à sa trente-deuxième session. Elle a demandé aux membres de soumettre des informations pertinentes sur la disponibilité de données scientifiques au Comité sur les résidus de médicaments vétérinaires dans les aliments à sa dix-huitième session (mai 2009), de façon que ce Comité puisse prendre une décision concernant l'inclusion de la ractopamine dans la liste des substances à évaluer ou à réévaluer en priorité par le JECFA. La Commission est convenue, en outre, qu'à sa trente-deuxième session, elle déciderait ou non d'adopter les LMR pour la ractopamine sur la base du rapport de la dix-huitième session du Comité sur les résidus de médicaments vétérinaires dans les aliments.

6. Le Comité **est invité** à adresser, à la trente-deuxième session de la Commission, ses recommandations à propos de l'inclusion de la ractopamine dans la liste prioritaire de substances pour évaluation ou réévaluation par le JECFA.

Recommandations en matière de gestion des risques pour les médicaments vétérinaires auxquels il n'a pas été attribué de DJA et/ou de LMR du fait de risques spécifiques pour la santé humaine (proposition de nouvelles activités)[7]

7. La Commission a noté la proposition de la délégation des États-Unis d'Amérique, figurant dans le document CAC/31 LIM/15, tendant à ce que le document de projet soit révisé afin d'élargir le champ d'application de la nouvelle activité sur les décisions de gestion des risques pour inclure aussi les substances auxquelles il n'a pas été attribué de DJA/LMR parce que l'on ne disposait pas des informations nécessaires pour évaluer les risques pour la santé humaine. La délégation de la Communauté européenne a appuyé cette proposition. Compte tenu de la modification importante apportée au champ d'application de la proposition, laCommission a décidé de renvoyer le projet de nouvelle activité au Comité sur les résidus de médicaments vétérinaires dans les aliments pour nouvel examen.

8. Le Comité **est invité** à considérer la proposition des Etats-Unis d'Amérique pour revoir le champ d'application des nouvelles activités par rapport aux décisions de gestion des risques (se référer à l'Annexe I de ce document[8]).

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6 ALINORM 08/31/REP, par. 55 à 58

7 ALINORM 08/31/REP, par. 93

8 en langue originale seulement

Annex 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~~ prohibit~~ed~~ 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.