



**Food and Agriculture  
Organization of  
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**World Health  
Organization**

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**REP11/RVDF**

## **JOINT FAO/WHO FOOD STANDARDS PROGRAMME**

### **CODEX ALIMENTARIUS COMMISSION**

*Thirty fourth Session*

*Geneva, Switzerland, 4-9 July 2011*

## **REPORT OF THE NINETEENTH SESSION OF THE**

### **CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS**

*Burlington, United States of America*

*30 August – 3 September 2010*

NOTE: This report contains Codex Circular Letter CL 2010/47-RVDF



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**CL 2010/47-RVDF  
September 2010**

**To:** Codex Contact Points  
Interested International Organizations

**From:** Secretariat,  
Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme  
Viale delle Terme di Caracalla  
00153 Rome, Italy

**Subject:** **Distribution of the Report of the Nineteenth Session of the Codex Committee on Residues of Veterinary Drugs in Foods (REP11/RVDF)**

The report of the Nineteenth Session of the Codex Committee on Residues of Veterinary Drugs in Foods will be considered by the 34<sup>th</sup> Session of the Codex Alimentarius Commission (Geneva, Switzerland, 4-9 July 2011).

## **PART A – MATTERS FOR ADOPTION BY THE 34<sup>TH</sup> SESSION OF THE CODEX ALIMENTARIUS COMMISSION**

### **Draft and Proposed Draft Standards and Related Texts at Steps 8 or 5/8 of the Procedure**

#### **1. Draft MRLs for narasin (pig tissues) and tilmicosin (chicken and turkey tissues) at Step 8 (see REP11/RVDF para. 49 and Appendix III)**

Governments and international organizations wishing to submit comment on the above texts should do so in writing, *preferably by e-mail*, to the Secretariat, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00153 Rome, Italy (e-mail: [codex@fao.org](mailto:codex@fao.org), fax : +39 06 57054593) **before 15 March 2011**.

## **PART B – REQUEST FOR COMMENTS AT STEP 3**

#### **2. Proposed Draft Sampling Plans for Residue Control for Aquatic Animal Products and Derived Edible Products of Aquatic Origin (Table C, Annex B of the *Guidelines for the Design and Implementation of National Regulatory Food Safety Assurance Programmes Associated with the Use of Veterinary Drugs in Food Producing Animals (CAC/GL 71-2009)*) (see REP11/RVDF para. 140 and Appendix VII)**

Governments and international organizations wishing to submit comment on the above texts should do so in writing, *preferably by e-mail*, to U.S. Codex Office, Food Safety and Inspection Service, US Department of Agriculture, Room 4861, South Building, 14<sup>th</sup> Independence Avenue, S.W., Washington DC 20250, USA (Telefax: +1 202 720 3157 ; or *preferably* E-mail: [CRVDF-USSEC@fsis.usda.gov](mailto:CRVDF-USSEC@fsis.usda.gov)), with a copy to the Secretariat, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, Viale delle Terme di Caracalla, 00153 Rome, Italy (Telefax: +39.06.5705.4593; E-mail: [Codex@fao.org](mailto:Codex@fao.org), *preferably*) **before 15 March 2011**.

## **PART C – REQUEST FOR COMMENTS**

#### **3. Proposed amendments to the *Risk Analysis Principles applied by Codex Committee on Residues of Veterinary Drugs in Foods* (see REPORT RVDF/19 para. 12 and Appendix VII); and**

#### **4. Proposed Amendments to the Terms of Reference of the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF) (see REP11/RVDF para. 113 and Appendix VIII)**

Governments and international organizations wishing to submit comment on the above texts should do so in writing, *preferably by e-mail*, to U.S. Codex Office, Food Safety and Inspection Service, US Department of Agriculture, Room 4861, South Building, 14<sup>th</sup> Independence Avenue, S.W., Washington DC 20250, USA (Telefax: +1 202 720 3157 ; or *preferably* E-mail: [CRVDF-USSEC@fsis.usda.gov](mailto:CRVDF-USSEC@fsis.usda.gov)), with a copy to the Secretariat, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, Viale delle Terme di Caracalla, 00153 Rome, Italy (Telefax: +39.06.5705.4593; E-mail: [Codex@fao.org](mailto:Codex@fao.org), *preferably*) **before 30 November 2011**.

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## SUMMARY AND CONCLUSIONS

The Nineteenth Session of the Codex Committee on Residues of Veterinary Drugs in Foods reached the following conclusions:

### Matters for Adoption/Consideration by the 34<sup>th</sup> Session of the Codex Alimentarius Commission

#### **Draft Standards and Related Texts for adoption at Step 8 of the Procedure**

The Committee forwarded:

- Draft MRLs for narasin in pig tissues and tilmicosin in chicken and turkey tissues for adoption at Step 8 (para. 49 and Appendix III);

#### **Other matters for approval (new work)**

The Committee forwarded:

- A project document on new work on the development of guidance on performance characteristics for multi-residues methods to be appended to the *Guidelines for the Design and Implementation of National Regulatory Food Safety Assurance Programmes Associated with the Use of Veterinary Drugs in Food Producing Animals* (CAC/GL 71-2009) (para. 65 and Appendix V);
- The priority list of veterinary drugs for evaluation or re-evaluation by JECFA (para. 83 and Appendix VI);

#### **Other matters for information**

The Committee agreed:

- To circulate the proposed amendments to the *Risk Analysis Principles for the CCRVDF* for comments and consideration at the next session (para. 12 and Appendix II);
- To retain the draft MRLs for narasin in cattle tissues at Step 7 for further consideration in the light of the JECFA assessment of the analytical method (para. 43 and Appendix IV);
- To revise the *Risk Analysis Principles applied by the CCRVDF* and the *Risk Assessment Policy for the Setting of MRLs for Veterinary Drugs* with special emphasis to: the revision of Section 3.2 “Evaluation of risk management options” (para. 101); developing risk management and risk communication recommendations for veterinary drugs for which no ADI and/or MRL has been recommended by JECFA either due to specific human health concerns or a lack of information (para. 116); and to consider the “concern form” used by the CCPR (para. 18);
- That the current definition of “hazard” should not be revised (para. 16);
- To consider the development of a policy for extrapolation of MRLs to additional species and tissues (para. 78);
- To continue maintaining the database on need for MRLs of developing countries (para. 87);
- To reiterate the request to FAO and WHO to convene an expert consultation on exposure assessment (para. 100);
- To circulate for comments proposed amendment to the terms of reference of the CCRVDF (para. 113 and Appendix VIII);
- To develop risk management recommendations for the veterinary drugs for which no ADI and/or MRL has been recommended by JECFA due to specific human health concerns (para. 116);
- To develop a policy for the establishment of MRLs or other limits in honey (para. 131).
- To circulate for comments at Step 3 the proposed draft Sampling Plans for Residue Control for Aquatic Animal Products and Derived Edible Products of Aquatic Origin (Table C, Annex B of CAC/GL 71-2009) (para 140 and Appendix VII);

### Matters Referred to Codex Committee and Task Forces

The Committee agreed:

- To ask the view of other relevant committees, such as the Committee on Pesticide Residues, on convening an expert consultation to provide scientific guidance on multi-residue analysis, taking into account technological updates and scientific research (para. 64).

**LIST OF ABBREVIATIONS USED IN THIS REPORT**

ADI	Acceptable Daily Intake
AGISAR	Advisory Group on Integrated Surveillance of Antimicrobial Resistance (WHO)
CAC	Codex Alimentarius Commission
CAC/GL	Codex Alimentarius Commission / Guidelines
CCGP	Codex Committee on General Principles
CCPR	Codex Committee on Pesticide Residues
CCRVDF	Codex Committee on Residues of Veterinary Drugs in Foods
CL	Circular Letter
CRD	Conference Room Document
CRP	Coordinated Research Project
EDI	Estimated Daily Intake
EHC	Environmental Health Criteria
EMPRES	Emergency Prevention Systems
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
GEMS/Food	Global Environment Monitoring System - Food Contamination Monitoring and Assessment Programme
GFN	Global Foodborne Infections Network
GIFSA	Global Initiative for Food-Related Scientific Advice
IAEA	International Atomic Energy Administration
JECFA	Joint FAO/WHO Expert Committee on Food Additives
MRL	Maximum Residue Limit
MRLVD	Maximum Residue Limit for Veterinary Drug
OIE	World Organization for Animal Health
PVS	Performance, Vision and Strategy
RILAA	Red Interamericana de Laboratorios de Analisis de Alimentos (Inter-American Network of Food Analysis Laboratories)
TDI	Tolerable Daily Intake
TMDI	Theoretical Maximum Daily Intake
TTC	Threshold of Toxicological Concern
UNIDO	United Nations Industrial Development Organization
USA	United States of America
VICH	International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products
WGAPFS	Working Group on Animal Production Food Safety (OIE)
WHO	World Health Organization

## INTRODUCTION

1. The Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF) held its Nineteenth Session in Burlington, Vermont (United States of America) from 30 August to 3 September 2010, at the kind invitation of the Government of the United States of America. Dr Steven Vaughn, Director of the Office of New Animal Drug Evaluation, United States Food and Drug Administration, Center for Veterinary Medicine, chaired the Session. The Session was attended by 172 delegates from 56 Member countries and one Member organization and Observers from 5 international organizations and FAO and WHO. The list of participants, including the Secretariat, is given in Appendix I to this report.

2. The Session was opened by Mr Roger Allbee, Secretary of Agriculture of the State of Vermont, who welcomed delegates and informed the Committee that agriculture was the main activity in the State of Vermont in terms of production and export, and that the development of food standards was very important in order to increase production and facilitate trade at the national and international level. Mr Allbee noted the heavy workload of the Committee and wished delegates all success in their debates. The session was also addressed by Mr Jim Douglas, the Governor of the State of Vermont. He noted that even with the focus in Vermont on locally-produced food the increased international attention to food safety had an important economic impact of food in the region. The Chairperson of the Committee recalled the importance of the work of the Committee especially for developing countries and invited delegates to address all the issues on the agenda with this important mission in mind.

### Division of Competence<sup>1</sup>

3. The Committee noted the division of competence between the European Union and its Member States, according to paragraph 5, Rule II of the Procedure of the Codex Alimentarius Commission, as presented in CRD 1.

### ADOPTION OF THE AGENDA (Agenda Item 1)<sup>2</sup>

4. The Delegation of Costa Rica proposed to consider the limit of detection to be applied in the case of veterinary drugs for which no ADI and/or MRL existed and which were not allowed, as the absence of a common interpretation of the zero tolerance created difficulties for inspection purposes and could create trade problems if the methodology and limits of detection applied in various countries were different. After some discussion, it was agreed to consider this question under Agenda Item 9.

5. In order to facilitate the discussion under Agenda Item 6, it was agreed to establish an in-session working group on methods of analysis, chaired by the Delegation of the United Kingdom and Canada and working in English, French and Spanish. In order to leave some time for delegates to consider the report of this working group, the Committee agreed to discuss the Agenda in the following order: Agenda Items 1 to 5, 10, 11, 7, 8, 9, 6, 12 and 13.

6. With these amendments, the Committee adopted the Provisional Agenda as its Agenda for the Session.

7. Noting the requests of some delegations to consider the issues related to capacity of developing countries to carry out research in relation to the work of the Committee and to apply its recommendations at the national level, the Committee noted that these questions could be considered when discussing FAO and WHO activities under Agenda Item 3 and OIE activities under Agenda Item 4.

### MATTERS REFERRED BY THE CODEX ALIMENTARIUS COMMISSION AND OTHER CODEX COMMITTEES (Agenda Item 2)<sup>3</sup>

8. The Committee noted that several matters were for information purposes or would be addressed under the relevant Agenda Items during the session, and discussed some specific items as presented below.

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<sup>1</sup> CRD 1 (Annotated Agenda – Division of competence between the European Union and its Member States)

<sup>2</sup> CX/RVDF 10/19/1, CRD 9 (Comments of Japan); CRD 12 (Comments of Panama)

<sup>3</sup> CX/RVDF 10/19/2; CRD 9 (Comments of Japan); CRD 12 (Comments of Panama)

**Codex Alimentarius Commission (33<sup>rd</sup> Session)**

9. The Committee recalled that the Commission, while considering future work on animal feeding had requested the relevant committees to review their policies and principles for risk analysis as to their applicability to animal feeding and, in particular, had asked the Committee to review the amendments to the *Risk Analysis Principles Applied by the CCRVDF* presented in Annex 1 of the working document.

10. The Delegation of Japan expressed the view that the current *Risk Analysis Principles* were appropriate to allow the Committee to address animal feeding in the framework of its terms of reference and, therefore, it was not necessary to amend them. Another delegation did not support the revision of the text at this stage as it required further consideration.

11. Several delegations supported the amendment referring to feed in order to reflect the consideration of animal feeding issues in the work of the Committee. The Committee agreed to amend paragraph 1a) of Annex 1 as proposed by the European Union for clarification purposes.

12. After some discussion, the Committee recognized that it would not be possible to finalise the revised text at the current session and agreed to circulate the proposed amendments to the *Risk Analysis Principles Applied by the CCRVDF*, as presented in Appendix II, for comments and consideration at the next session.

**Committee on General Principles (26<sup>th</sup> Session)****Risk Analysis Principles**

13. The Secretariat recalled that the Committee on General Principles had agreed to forward the review of the risk analysis policies of Codex committees (CL 2010/1-GP) to the committees concerned and had completed Activity 2.1 of the Strategic Plan *Review the consistency of risk analysis principles elaborated by the relevant Codex Committees*. It was for the Committee to decide how to undertake Activity 2.2 *Review risk analysis policies developed by relevant Code committees* which was an independent activity although it could take into account the recommendations put forward in the framework of Activity 2.1.

14. Several delegations, while recognizing that some discrepancies existed with the general *Working Principles for Risk Analysis*, expressed the view that current Risk Analysis Principles applied by the Committee should not be revised as they adequately addressed the purpose of risk analysis for residues of veterinary drugs.

15. The Committee noted that other questions related to risk analysis would be considered under Agenda Items 8 and 9 and those might require specific reviews of the risk analysis principles and agreed to defer the general decision until these items had been discussed (*see* Agenda Items 8, 9 and 12).

**Definition of “Hazard”**

16. The Committee considered the request for a revision of the “hazard” definition in the Procedural Manual forwarded by the CCGP. Several delegations expressed the view that the current definition was adequate in the context of risk analysis for residues of veterinary drugs and noted that the question put forward by the CCGP was rather specific to nutrition and would be more adequately addressed in the context of risk analysis applied to nutrition issues. The Committee, therefore, agreed that the current definition of “hazard” should not be revised.

**Executive Committee (64<sup>th</sup> Session)**

17. The Executive Committee, while considering the speed of Codex standards, had recommended that the CCRVDF consider using a concern form as in the Committee on Pesticide Residues (CCPR); to adhere to the Statements of Principles concerning the role of science, especially Statement 4; and to encourage data owners through the respective regulatory authorities to submit data.

18. The Committee discussed the concern form used in the CCPR and noted the conditions under which it was used. Some delegations noted that the use of a concern form was justified to facilitate the process in CCPR due to the large number of MRLs under consideration. However, in view of the limited number of MRLs under consideration in the CCRVDF, outstanding issues could be addressed on a case-by-case basis with the current procedure through comments and interaction with JECFA. Other delegations pointed out that the use of this form was not related to the number of MRLs under consideration but to ensure progress of MRLs would not be delayed by last minute objection at the session and proposed to use it on a trial basis. As the use of the concern form was described in the relevant risk analysis principles applied by CCPR, the

Committee agreed that a similar approach should be taken for veterinary drugs residues. It was, therefore, agreed that consideration of the concern form would be integrated into the work on the revision of the *Risk Analysis Principles applied by the CCRVDF* (see also Agenda Item 12).

19. The Committee noted the other recommendations of the Executive Committee.

#### **MATTERS OF INTEREST ARISING FROM FAO AND WHO (Agenda Item 3)<sup>4</sup>**

20. The FAO JECFA Secretary provided information on the process and conclusions of the evaluation of residues of ractopamine in pig tissues, requested by the 32<sup>nd</sup> session of the Commission and presented at the 33<sup>rd</sup> session of the Commission, and which had been published as an addendum to the residue monograph of ractopamine hydrochloride in FAO JECFA Monographs 9.

21. The Representatives of FAO and WHO, referring to document CX/RVDF 09/18/3, informed the Committee about activities carried out by FAO and WHO in the area of scientific advice to Codex and Member countries relevant to the Committee as well as other activities of interest to the Committee.

22. The Representative of FAO also provided information about the recent establishment of a new program on prevention and early warning system for food safety emergencies (EMPRES-Food Safety) within the existing Food Chain Crisis Management Framework for animal health and plant health. The program aims at responding to recent requests from countries for technical assistance in food safety emergencies, with focus on early detection of food safety issues, prevention and preparedness and rapid response.

23. The Committee noted the increased need expressed by FAO and WHO of extra-budgetary funding for implementation of activities related to the provision and dissemination of scientific advice and that to this end FAO has adopted a 4-year strategy for 2010-2013 for Science for Safe Food within the Global Initiative Food-related Scientific Advice (GIFSA) and the objectives and priorities of this strategy are available in several languages for countries interested in providing financial support.

24. FAO and WHO recently achieved the revision of Environmental Health Criteria for principles and methods for the risk assessment of chemicals in food. The document "EHC 240" is available on the web : <http://www.who.int/ipcs/food/principles/en/index.html>. The chapters 6 and 8, dealing respectively with dietary exposure assessment and establishment of Maximum Residue Limits for pesticides and veterinary drugs, are particularly relevant for the current meeting of the Committee.

25. The Representative of WHO informed the Committee on the activities of WHO GEMS/Food programme, which collects data on occurrence of chemicals in food and human food consumption all around the world. Food consumption data potentially of use to assess the safety of veterinary drugs consists in cluster diets based on FAO Food Balance Sheets and individual food consumption data to be provided by Member States.

26. The Representative of WHO informed the Committee of the activities of the two WHO programmes involved in foodborne antimicrobial resistance surveillance and control: (i) the Global Foodborne Infections Network (GFN) had been providing capacity building on foodborne disease surveillance, including antimicrobial resistance since 2000; and (ii) the Advisory Group on Integrated Surveillance of Antimicrobial Resistance (AGISAR), established in December 2008, to support WHO in promoting an integrated approach to antimicrobial usage and antimicrobial resistance monitoring, across the animal, food and human sectors. The Committee was also informed of ongoing activities in the four subcommittees (SC) of AGISAR: Usage monitoring SC; Antimicrobial resistance monitoring SC; Capacity building /Country pilot projects SC; and Software Development and Data management SC.

#### **FAO/IAEA Information on activities of the food and environmental safety sub-programme related to residues of veterinary drugs in foods**

27. The Representative of IAEA highlighted activities of the Joint FAO/IAEA Division of Nuclear Techniques in Food and Agriculture of interest to the CCRVDF as presented in document CX/RVDF 10/19/3 Add.1. The Committee was informed of the strengthening of the Division following the FAO reform process and progress of the Coordinated Research Project (CRP) on Analytical Methods to strengthen National Residue Control Programs focusing on areas of priority and concern to developing countries. The

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<sup>4</sup> CX/RVDF 10/19/3; CX/RVDF 10/19/3 Add.1; CRD 12 (Comments of Panama)



CRP was also investigating sources of natural antimicrobial compounds likely to impact the regulatory framework for veterinary drug residues. The Joint Division had initiated a new CRP that would help laboratories in member states to establish robust analytical techniques to determine origin of food through the assessment of isotopic and elemental composition of foodstuffs.

28. The Committee noted that IAEA continued to support developing countries in establishing national and regional residues control laboratories through technical cooperation projects.

29. The IAEA Representative informed the Committee of the work carried out in association with FAO, IFAH and UNIDO to address the problems associated with the use of counterfeit and low quality veterinary pharmaceutical products and to develop protocols for quality control/quality assurance for trypanocidal and other veterinary drugs.

30. The Committee noted that with reference to the discussions concerning methods of analysis for residues of veterinary drugs in foods (*see* Agenda Item 6) and to enhance the capabilities of developing countries to identify and implement suitable methods in support of residue monitoring plans, the Joint Division would include on its web pages a database of methods and protocols developed and validated through its activities and present it at the next session of Committee.

#### **REPORT OF THE OIE ACTIVITIES, INCLUDING THE HARMONIZATION OF TECHNICAL REQUIREMENTS FOR REGISTRATION OF VETERINARY MEDICINAL PRODUCTS (VICH) (Agenda Item 4)<sup>5</sup>**

31. The Observer from OIE, while referring to CX/RVDF 10/19/4, drew the Committee's attention to four main areas that were relevant to the work of the CCRVDF: the cooperation between the OIE and the Codex Alimentarius Commission; the OIE activities aiming at the improvement of capacity building of its members; antimicrobial resistance; and the OIE and VICH activities.

32. With regard to the first point, the Observer mentioned the ongoing and upcoming activities of the OIE Working Group on Animal Production Food Safety (WGAPFS), which also included experts from Codex, FAO and WHO. The work program for 2010 was detailed.

33. Concerning capacity building, the Observer underlined that the governance related to veterinary medicinal products was considered by the OIE as a priority regarding animal and public health. The strengthening of the actions in this field started with the adoption of Resolution No. 25 on veterinary products at the OIE General Session in May 2009. The OIE's Fifth Strategic Plan (2011-2016), adopted in May 2010, includes new fields of actions in particular good governance of veterinary services, the reinforcement of veterinary services capacities and infrastructure, including veterinary legislation and more generally the linkages between animal health, food safety and food security. Veterinary medicinal products are part of the Plan as they are considered as indispensable tools for any effective animal health and welfare policy.

34. The Observer informed the Committee on the implementation of the assessment of the veterinary services (OIE PVS tools), on the continuation of the laboratory twinning programme, on training session of focal points for veterinary medicinal products and on regional conferences organized in the field of veterinary medicinal products.

35. Regarding antimicrobial resistance, the Observer provided information on ongoing and upcoming activities and highlighted the collaboration between FAO, WHO and OIE for the benefit of animal and public health.

36. With respect to cooperation between VICH and OIE, the Committee was informed of the outcome of VICH steering committees and of the release of VICH guidelines including the draft Guidelines on metabolism and residue kinetics. The Committee was also informed of the outcome of the Fourth VICH public conference (VICH4), held in June in the OIE headquarters in Paris, and of the efforts to develop the VICH global outreach at a worldwide level in order to obtain a wider understanding of VICH standards and to encourage a wider harmonization of registration requirements and efficient use of resources.

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<sup>5</sup> CX/RVDF 10/19/4; CRD 12 (Comments of Panama)

**DRAFT MRL FOR VETERINARY DRUGS (at Step 7) (Agenda Item 5)<sup>6</sup>****Narasin**

37. The Committee recalled that at its 18<sup>th</sup> Session the proposed draft MRLs for narasin in chicken tissues had been forwarded to the 32<sup>nd</sup> Session for the Commission for adoption at Step 5/8. The other proposed draft MRLs (in pig and cattle tissues) had been advanced to Step 5 to allow more time for their consideration<sup>7</sup>.

38. The Delegation of the European Union did not have concern for the draft MRLs for narasin for cattle and pigs tissues because the draft MRLs did not raise concerns from a toxicological point of view. However, the Delegation reiterated their concerns for the draft MRLs as narasin was used in cattle and pigs primarily for growth promotion and the use of veterinary drugs for non-therapeutical purposes was not authorised in the European Union. This position was supported by the Delegations of Norway and Switzerland.

39. The Delegation of Nigeria did not support the advancement of the draft MRLs because of the potential risk of the use of this drug in animals to increase antimicrobial resistance. In this regard the JECFA Secretariat explained that narasin was extensively metabolised and that the metabolites exhibit little or no microbiological activity; furthermore, narasin represented a very low amount in the target tissue liver. In addition, the ADI for narasin was based on a toxicological endpoint and not on a microbiological endpoint.

40. Other delegations supported the advancement of the draft MRLs to Step 8.

41. The Committee also recalled that the draft MRLs for narasin in cattle tissues were temporary because of lack of a validated analytical method. In this regard it was noted that the method would be made available for assessment by JECFA at its next meeting (*see* Agenda Item 7).

42. The Committee agreed to forward the draft MRLs for narasin in pig tissue to the 34<sup>th</sup> Session of the Commission for adoption at Step 8. The Delegations of the European Union, Nigeria, Norway and Switzerland expressed their reservation to this decision.

43. The Committee also agreed to retain the draft MRLs for narasin in cattle tissues at Step 7 for further consideration in the light of the JECFA assessment of the analytical method.

**Tilmicosin**

44. The Committee recalled that at its 18<sup>th</sup> Session it had been agreed to advance the MRLs for tilmicosin in chicken and turkey tissues to Step 5 with the understanding that, if no new data would be submitted by the European Community to support JECFA re-evaluation, the MRLs would be advanced to Step 8 at its next session<sup>8</sup>.

45. The Delegation of European Union stated that they could support the draft MRLs for tilmicosin in view of their review of the new scientific data that indicated that the draft MRLs for tilmicosin did not represent a consumer safety concern as the TMDI calculated using the draft MRLs was below the ADI that would be established using the new data.

46. Other delegations supported the advancement of the draft MRLs.

47. The Committee also noted that due to the limited data it had not been possible for JECFA to recommend an MRL for tilmicosin in eggs and that such a request would be included in the database of drugs of potential interest from developing countries (*see* Agenda Item 6).

48. The Committee agreed to forward the draft MRLs for tilmicosin in chicken and turkey tissues to the 34<sup>th</sup> Session of the Commission for adoption at Step 8.

**Status of the Draft Maximum Residue Limits for Veterinary Drugs**

49. Draft MRLs to be forwarded to the 34<sup>th</sup> Session of the Commission for adoption at Step 8 are attached as Appendix III. Draft MRLs retained at Step 7 are attached as Appendix IV.

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<sup>6</sup> ALINORM 09/32/31 Appendix IV; CX/RVDF 10/19/5 (Comments of European Union, United States of America and IFAH); CX/RVDF 10/19/5 Add.1 (Comments of Philippines); CRD 5 (Comments of Kenya); CRD 12 (Comments of Panama); CRD 16 (Comments of Nigeria); CRD 19 (Comments of Indonesia)

<sup>7</sup> ALINORM 09/32/31 paras 65-66 and Appendix IV

<sup>8</sup> ALINORM 09/32/31 para. 72 and Appendix IV

**DISCUSSION PAPER ON METHODS OF ANALYSIS FOR RESIDUES OF VETERINARY DRUGS IN FOODS (Agenda Item 6)<sup>9</sup>**

50. The Committee recalled that its last session had agreed to establish an electronic working group to prepare a discussion paper addressing several issues related to methods of analysis. The Committee considered the recommendations of the discussion paper section by section, taking into account the outcome of the in-session working group chaired by the Canada and the United Kingdom, as presented in CRD 21, and made the following comments and recommendations.

**Recommendations on the evaluation of analytical methods provided by JECFA**

51. The Committee considered recommendations (a) to (e) in paragraph 3 of the discussion paper.

52. On the basis of recommendation (a), the Committee recommended that future JECFA evaluations take into account the single laboratory validation guidelines adopted at the 32<sup>nd</sup> Session of the Commission, recognizing that other possibilities existed and that the evaluations carried out by JECFA should not be limited by prescriptive recommendations.

53. As regards recommendation (b) suggesting that JECFA may wish to increase the expert representation for analytical method evaluation, the JECFA Secretariat recalled that the competence of experts was used in the best way possible for the purpose of the evaluations. The Delegation of Japan, as a general comment, pointed out that such suggestions were useful, however, the Committee should not make too prescriptive requests to JECFA and should more focus on its role in the consideration of methods as specified in its terms of reference.

54. Some delegations, while recognizing the competence of the experts, clarified that there may be a need to harmonise the procedures for the treatment of data in the evaluation of analytical methods. The Committee, therefore, recommended that JECFA may wish to apply criteria for evaluating analytical methods more uniformly.

55. The Committee considered recommendation (c) that, because standards of all marker residues are not routinely available to analytical laboratories, JECFA may take this into account when selecting marker residues especially for veterinary drugs that are no longer under patent protection and are not commercially available.

56. The JECFA Secretariat indicated that the criteria for the selection of marker residues were specified in EHC 240 and depended on the nature of the compound and the metabolism in the species concerned but were not related to the availability of the standards. Some delegations, however, supported this recommendation and the Committee agreed to retain it.

57. The Committee supported recommendation (d) and agreed that no further expert evaluation of analytical methods recommended by JECFA was required by the CCRVDF. The Committee also recalled its earlier decision that JECFA should be responsible for reviewing the methods for compounds on its agenda from its 15<sup>th</sup> Session (1998) onwards.

58. The Committee discussed recommendations (e) to consider how analytical methods might be made available to regulatory authorities and (f) on the availability of residue control methods for surveillance and monitoring purposes for substances for which JECFA could not establish an ADI or MRLs.

59. The Delegation of Brazil supported recommendations (e) and (f) and the recommendations for laboratories to share their methods among Codex members and for the development of a database listing national competent authority contacts related to residue control programmes. It also proposed that the Committee should develop a database containing complete information on the availability of standards in residue reference laboratories, in order to facilitate exchange of information and distribution of aliquots of such standards among member laboratories. The Delegation highlighted the difficulties in obtaining standards, especially for those compounds with no patent protection and those for drugs banned by national authorities, and also referred to the provisions in CAC/GL 71-2009, paragraphs 5 and 130 as regards technical assistance and cooperation between laboratories. These views were supported by other delegations.

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<sup>9</sup> CX/RVDF 10/19/6, CRD 3 (Comments of the European Union); CRD 12 (Comments of Panama); CRD 19 (Comments of Indonesia); CRD 21 (Report of the in-session working group on methods of analysis)

60. The Committee noted that its responsibility was to consider methods but that issues related to the availability of methods and of standards could rather be addressed through bilateral or regional cooperation between countries, or through the technical cooperation activities of international organizations.

61. The Committee noted that the reference laboratories in the European Union were ready to provide a list of methods and the list of reference standards and to cooperate with other countries and that the RILAA network in Latin America allowed an active exchange between public and private laboratories in that region.

62. The Representative of IAEA informed the Committee that, as was already the case with methods of analysis for pesticide residues, IAEA was ready to host on its website a database of available methods for residues of veterinary drugs, which could include the methods used by national authorities as well as by private companies. The Committee expressed its thanks to IAEA as this would be an important contribution to facilitate exchange of information on methods of analysis. The Committee also noted that IAEA would provide information on the work on the database in its report of activities at the next session.

63. Although it was noted that this proposal seemed to address the issue of availability of methods, the Committee agreed with the suggestion of some delegations to continue the discussion on this issue at the next session.

### **Guidance on the development of performance characteristics for multi-residue analysis**

64. The Committee noted that the discussion paper referred to the possibility of convening an expert consultation, of the same nature as the International Workshop on Principles and Practices of Method Validation held in Miskolc in 1999, in order to provide scientific guidance on multi-residue analysis, taking into account technological updates and scientific research. However, this could not be expected in the near future in view of technical and practical considerations, and the discussion paper provided some guidance in Annex II on the basis of available literature. The Committee agreed to ask the views of other relevant committees, such as the Committee on Pesticide Residues, on the proposed terms of reference for the consultation.

### **Validation of multi-residue methods**

65. The Committee agreed to propose new work on the revision of the *Guidelines for the Design and Implementation of National Regulatory Food Safety Assurance Programmes Associated with the Use of Veterinary Drugs in Food Producing Animals* (CAC/GL 71-2009) to include an Appendix on performance criteria for multi-residue analytical methods for veterinary drugs residues, as described in the project document in Appendix V.

66. For this purpose and to address the issue of availability of methods, the Committee agreed to establish an electronic working group chaired by Canada and the United Kingdom, working in English and open to all member and observers with the following mandate:

- To prepare a proposed draft Appendix on performance criteria for multi-residue analytical methods for veterinary drugs residues for inclusion in the *Guidelines for the Design and Implementation of National Regulatory Food Safety Assurance Programmes Associated with the Use of Veterinary Drugs in Food Producing Animals* (CAC/GL 71-2009); and
- To consider opportunities to facilitate communication with IAEA on the development of the database on analytical methods and reference standards.

67. The Committee expressed its appreciation to Canada and the United Kingdom for their constructive work between sessions and at the present meeting in order to facilitate the consideration of methods of analysis.

### **DRAFT PRIORITY LIST OF VETERINARY DRUGS REQUIRING EVALUATION OR RE-EVALUATION BY JECFA (Agenda Item 7)<sup>10</sup>**

68. The Delegation of Australia, as Chair of the physical working group held prior to the Session, introduced the report of the working group, as presented in CRD 13. The Committee noted that the

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<sup>10</sup> CX/RVDF 10/19/7; CX/RVDF 10/19/7 Add.1 (Comments of Brazil and Uruguay); CRD 4 (Comments of China); CRD 12 (Comments of Panama); CRD 16 (Comments of Nigeria); CRD 13 (Report of the physical Working Group on Priority); CRD 19 (Comments of Indonesia)

compounds included in the priority list recommended by the physical working group, namely monepantel, monensin and derquantel, were carried over from the list prepared by the 18<sup>th</sup> Session of the CCRVDF<sup>11</sup> and that had been approved by the 32<sup>nd</sup> Session of the Commission. The Committee further noted that ractopamine had been removed from the list as the assessment had already been carried out by JECFA and presented at the 33<sup>rd</sup> Session of the Commission (*see* Agenda Item 3) and that discussion on this assessment was outside the scope of the Committee's session.

69. The Committee agreed to the recommendations of the in-session working group on the inclusion in the priority list of apramycin, amoxicillin and narasin.

70. The Committee considered a request of the Delegation of China, as presented in CRD 4, referring to the studies from China that had been evaluated by JECFA to include ractopamine in the priority list due to concerns for the safety of residues in pig's lung and to consider the development of an MRL in pig's lung. The JECFA Secretariat informed the Committee that there were a few issues related to the studies carried out by China which made it difficult for JECFA to take up the request and to recommend MRL in lung tissue based on those studies. These included: (i) there was a high variability in all the data sets, as shown by the coefficients of variation; (ii) the hydrolytic step in the analysis had not been validated; (iii) the pharmacokinetics in lung tissue was variable between the studies and significantly different from other tissues; and (iv) data on consumption of lung tissues were lacking.

71. With regard to data on pharmacokinetics of ractopamine in lung tissues, the Observer from IFAH indicated that, if China was willing to agree, the company sponsor was willing to collaborate with China to explore the metabolism of ractopamine in lung. One delegation also noted that a validated analytical method should also be made available along with the other missing information.

72. One delegation pointed out the necessity to provide JECFA with appropriate tools for evaluating residues and recommending MRLs for non standard tissues. In this regard, the Committee recalled that at its 18<sup>th</sup> Session it had been agreed to request FAO/WHO to convene an expert consultation on dietary exposure assessment (*see* para. 100) as it relates to veterinary drug residues in food, which would also consider enlarging the scope of the "food basket" to include other tissues. The Committee noted the offers of the Delegations of United States of America and Canada to provide resources to FAO and WHO to enable the holding of such a consultation.

73. The Committee noted that the inclusion of this request for MRL for ractopamine in pig's lung should be considered separately from the ongoing consideration of the draft MRLs for ractopamine (in cattle and pig tissues) held at Step 8 by the 33<sup>rd</sup> Session of the Commission.

74. The Committee agreed to include in the priority list the request for MRL for ractopamine in pig's lung noting that the information gaps needed to be filled and that such evaluation would significantly benefit from the outcomes of the FAO/WHO expert consultation on dietary exposure assessment (*see* para. 100).

75. The Delegation of Brazil expressed their reservation to this decision.

76. In response to the need to establish MRLs for triclabendazole in goat tissues and the limited data available for the establishment of these MRLs, the Committee agreed to include in the priority list a specific question regarding the possibility to establish these MRLs by extrapolating the data that were used for recommending MRLs for cattle and sheep tissues. The Committee also noted the offer of the Delegation of the United States of America to contribute to the development of MRLs for triclabendazole in goat tissues with a search of relevant published information.

77. The Committee also agreed to consider the development of a policy for extrapolation of MRLs to additional species and tissues. In this regard the Committee noted the offer of the Delegation of the European Union to provide information on their 10 years experience that had allowed the establishment of a policy for extrapolation of MRLs. The JECFA Secretariat informed the Committee that chapter 8.5 of EHC 240 included principles for extrapolation of MRLs for veterinary drugs residues and pesticides.

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<sup>11</sup> ALINORM 09/32/31 Appendix VI

78. The Committee agreed to establish an electronic working group, led by the Canada and working in English only and open to all Codex members and observers, with the following tasks:

- (i) Collate and summarise all the available national and regional guidelines and documents and published literature pertinent to the extrapolation of MRLs;
- (ii) Prepare a list of substances with existing MRLs in a number of species/food matrices for which extrapolation is considered necessary and make a proposal for prioritization;
- (iii) Prepare recommendations for the CCRVDF to request JECFA to consider whether EHC 240 provides sufficient guidance for JECFA to develop a scientific framework for extrapolating MRLs between species and tissues, or whether additional scientific considerations are required; and
- (iv) Propose potential risk analysis policy for use by CCRVDF when considering extrapolating MRLs.

79. In response to the request of one delegation to consider the development of MRLs in skin of various animals, e.g. cattle, goat and sheep, the Committee agreed that this issue would be addressed in the FAO/WHO expert consultation on dietary exposure assessment (*see* para. 100) and in the policy on extrapolation.

80. The Committee considered requests to develop an MRL for ivermectin in cattle's muscle and to re-evaluate the ADI. Other delegations also requested to consider the development of MRLs for ivermectin in rabbit's muscle and in camel's tissues. Some delegations pointed out that MRLs for ivermectin had been established for fat and liver as these were the target tissues and the residue levels in muscle were very low. The Committee agreed to include the re-evaluation of the ADI of ivermectin in the priority list and, if necessary, the review of existing MRLs, while noting that data availability would have to be confirmed. In view of the lack of data on residues of ivermectin in rabbit and camel and the limited availability of data in cattle muscle, the Committee agreed to include these requests in the database on need for MRLs in developing countries.

81. One delegation proposed to include gentian violet in the priority list and offered to put together a data package similar to the one submitted for malachite green. In view of the need to accompany a request for inclusion in the priority list with a very specific request for JECFA and information on the availability of the data package, the Delegation agreed to resubmit the request at the next session of the Committee.

82. The Committee agreed to prioritise the list of veterinary drugs included in the priority list by assigning priority (1) to those compounds with clear indication of data availability and priority (2) to those compounds for which data availability was not yet confirmed.

83. The Committee agreed to forward the Priority List of Veterinary Drugs for Evaluation or Re-evaluation by JECFA to the 34<sup>th</sup> Session of the Commission, as attached in Appendix VI.

84. The Committee also agreed to establish a physical working group, which would meet immediately before its next session, under the chairmanship of Australia, to consider the replies to the Circular Letter requesting members and observers to provide comments and information on the priority list of veterinary drugs requiring evaluation or re-evaluation by JECFA and the report of the electronic working group on the database on need for MRLs of developing countries. The Committee reiterated the need to submit requests for inclusion in the priority list by following the procedures described in the "*Risk Analysis Principles Applied by the CCRVDF*"<sup>12</sup>.

#### **List veterinary drugs of potential interest for developing countries**

85. The Delegation of the United States of America confirmed their offer to continue maintaining the database on need for MRLs of developing countries. One delegation, while acknowledging the efforts of developing the database, stressed the importance of identifying mechanisms that would allow moving compounds from the database to the priority list of veterinary drugs for JECFA evaluation.

86. Many delegations expressed support for continuing the development of the database and the work of the working group, which assisted in better defining the needs for MRLs of developing countries and data

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<sup>12</sup> Procedural Manual of the Codex Alimentarius Commission

gaps and had started to give some results in terms of transferring veterinary drugs to the priority list. In view of the above discussion, the Committee agreed to establish an electronic working group, led by the United States of America and working in English only and open to all Codex members and observers, charged to: (i) continue developing and maintaining the database; (ii) identify data gaps and sources of data; and (iii) solicit support and identify potential sponsors to allow the inclusion in the priority list of veterinary drugs of interest for developing countries.

#### **FACTORS TAKEN INTO ACCOUNT IN CONNECTION WITH ESTABLISHING THE ADI AND THE CURRENT PROCESS OF RECOMMENDING MRLs (Agenda Item 8)<sup>13</sup>**

87. The last session of the Committee had agreed to consider further all relevant factors taken into account in the MRL setting process and, for this purpose, had established an electronic working group led by France to prepare a discussion paper, and a physical working group to consider the discussion paper and the comments received, to facilitate the discussion in the plenary session.

88. The Delegation of France presented the outcome of the physical working group that had considered the issues identified in the discussion paper: the “food basket” content; possible use of the full ADI; use of Estimated Daily Intake (EDI); and other considerations on how to proceed further.

89. The working group had not recommended the use of regional data for exposure assessment and had recognised the need for an FAO/WHO expert consultation on exposure assessment methodologies and model diets (*see* para. 100) to be used in the assessment of dietary exposure from residues of veterinary drugs, as already proposed at the last session. The working group had considered the “one meat+one egg+milk” approach proposed by the United States of America, more accurately described as “one meat+2 eggs+milk+honey”, which could be used without changing the foods listed in the present standard food basket. In the discussion, it had been noted that this approach might result in higher MRLs and that it could be helpful to incorporate tissues not listed in the current “food basket”.

90. As regards the possible utilisation of the full ADI, while some delegations expressed support, several concerns had been raised in the working group on this approach by delegations and by the JECFA Secretariat, who had clarified that if the estimated exposure exceeds the ADI, the MRLs first derived would have to be reconsidered, otherwise there was no justification to raise the MRLs in the absence of supporting data.

91. It had been noted that the EDI was applicable for substances exhibiting chronic toxicity and the TMDI or other approaches should be applied in the case of acute toxic effects and where the data sets did not allow estimation of the EDI.

92. The working group had suggested that a request could be forwarded to JECFA to provide for each recommended MRL a set of values derived from (i) using the TMDI approach, (ii) using the EDI approach, (iii) using calculations based on the current food basket and (iv) using the “one meat” approach, or (v) using a series of multiples of the recommended MRLs, based on the normal process of JECFA used to derive MRLs.

93. The Committee expressed its appreciation to the Delegation of France and to the working group for their excellent work in order to facilitate discussion on these complex issues.

94. The Delegation of the United States of America highlighted the differences between the current “food basket” and the “one meat+2 eggs+milk+honey” approach, noted that it could allow the evaluation of MRLs in other tissues not considered so far but might not be adequate without adjustment of consumption factors in an international setting, and proposed to consider the consequences of using as much as possible of the ADI, especially whether this would result in higher MRLs, and proposed to focus on these questions in further discussions.

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<sup>13</sup> CX/RVDF 10/19/8; CX/RVDF 10/19/8 Add.1 (Comments of Brazil, European Union, United States of America, Uruguay); CX/RVDF 10/19/8 Add.2 (Comment of the JECFA Secretariat); CRD 5 (Comments of Kenya); CRD 8 (Comments of Thailand); CRD 9 (Comments of Japan); CRD 11 (Comments of United States of America); CRD 12 (Comments of Panama); CRD 14 (Report of the physical working groups on Factors taken into account in connection with establishing the ADI and the current process of recommending MRLs); CRD 18 (Comments of IFAH)

95. The JECFA Secretariat pointed out that the degree of conservatism of such a model would have to be evaluated by experts, e.g. in the proposed expert consultation on exposure assessment (*see* para. 100).

96. The Representative of WHO indicated that the use of the full ADI approach would not be advisable in the case of antimicrobial substances due to their potential for inducing antimicrobial resistance.

97. The Delegation of Japan pointed out that MRLs should be established taking into account not only exposure from animal food consumption, but also from all other sources and, therefore, did not support the use of the full ADI, which may lead to establish higher MRLs. The Delegation also reiterated that the use of EDI should not be intended to replace the use of TMDI and suggested to develop clear criteria and condition of use of EDI to avoid unnecessarily high MRLs.

98. Some delegations suggested that JECFA should apply the different approaches considered in the discussion to a set of data and calculate the resulting MRLs. The JECFA Secretariat explained that confusion should be avoided as EDI was used as an estimate of chronic dietary exposure, and TMDI in other cases, and they should not be considered as alternative approaches. Therefore, it was not necessary to carry out such comparisons. The JECFA Secretariat also recalled that there should be a clear distinction between the responsibilities of risk assessors and risk managers and that it was the responsibility of the Committee, as risk manager, to establish MRLs. However, JECFA could consider requests for estimating the impact on exposure of different MRLs.

99. The JECFA Secretariat explained that dietary exposure assessment is recognised as a stepwise approach, each step requiring more data to be achieved. The EHC 240 specifies that each additional step should decrease the uncertainty around the estimation and ensure that the refined estimate is protective of consumers. The JECFA Secretariat recommended to keep the current “food basket” as a screening tool and to further develop refined models. Related data needs would be a task for the expert consultation on exposure assessment (*see* para. 100) and for JECFA. A number of delegations expressed some concerns about this two-step approach.

100. After some additional discussion, the Committee reaffirmed the request, made at its 18<sup>th</sup> Session<sup>14</sup>, to ask FAO and WHO to convene an expert consultation to address the following:

- Review of the current model diet (market basket) approach applied by JECFA;
- Possible simplification of the current food basket tool;
- Possibility to develop several model diets to reflect regional differences in consumption patterns; and
- Develop approaches for acute and sub-chronic dietary exposure assessment

101. The Committee also recalled that it was requested to review its principles and policies for risk analysis in the framework of the Strategic Plan and that any new or revised recommendations concerning policies for MRL setting should be integrated into the *Risk Analysis Principles*. The Committee, therefore, agreed to establish an electronic working group that would consider several aspects of risk analysis discussed at the present session (*see* also Agenda Item 9 and 12). As regards the issues discussed under the present item, the Committee agreed that special emphasis should be given to revising Section 3-2 ‘Evaluation of risk management options’ in order to provide JECFA with specific directions, together with their rationale, on how to generate and submit for consideration by the Committee a range of acceptable values for each MRL to be established. The detailed mandate and modalities of the working group, taking into account all decisions taken at the session, are presented under Agenda Item 12.

### **RISK MANAGEMENT RECOMMENDATIONS FOR VETERINARY DRUGS FOR WHICH NO ADI AND MRL COULD BE ESTABLISHED (Agenda Item 9)<sup>15</sup>**

102. The Delegation of the United States of America briefly introduced the report of the electronic working group charged to: (i) define the scope for the new work addressing risk management recommendations for veterinary drugs for which no ADI and/or MRL have been recommended by JECFA due to specific human

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<sup>14</sup> ALINORM 09/32/31 para. 150

<sup>15</sup> CX/RVDF 10/19/9; CRD 5 (Comments of Kenya); CRD 8 (Comments of Thailand); CRD 9 and Add.1 (Comments of Japan); CRD 10 (Comments of Cuba); CRD 12 (Comments of Panama); CRD 20 (Comments of Costa Rica)



health concerns or lack of information needed to resolve existing human health concerns; (ii) develop a process by which the Committee will promulgate risk management recommendations; (iii) make proposals on how to address the remaining veterinary drugs for which JECFA clearly identified human health concerns listed in Annex II of CX/RVDF 09/18/8; and (iv) propose procedures for conveying these risk management recommendations in the Codex standard setting process<sup>16</sup>.

103. The Committee recognised the importance for the CCRVDF to deal with the issues related to residues of veterinary drugs with no ADI and/or MRLs, which could be divided in two main groups: (i) substances for which no ADI and/or MRLs could be established due to specific health concern; and (ii) substances for which no ADI and/or MRLs could be established due to the lack of information. Some delegations were of the view that the differences in the characteristics of the two groups of substances required separate procedures for the development of risk management recommendations. Other delegations recognised the complexity of the issues and were of the view that it was important to formulate recommendations aiming at ensuring that substances for which no ADI and/or MRL could be established for specific health reason should not be used in food producing animals. Other delegations highlighted the need to identify a process to ensure timely and proper communication and to develop proper risk communication policies for these substances.

### **Policy and procedures for substance with no ADI and/or MRLs**

104. The Committee agreed that the recommendations related to the first two tasks of the electronic working group could be addressed in the framework of the revision of the *Risk Analysis Principles Applied by the CCRVDF*, as these recommendations were focusing on the development of a system of policy and procedures for addressing substances with no ADI and/or MRL rather than the outcomes of the Committee's work on these substances.

105. The Delegation of Costa Rica, referring to the written comments presented in CRD 20, highlighted the need to harmonize limits of detection for veterinary drug residues with no ADI and/or MRLs to the problems linked with the use of different analytical methods and the limits of detection that they could achieve.

106. One delegation also suggested that the Committee in collaboration with JECFA establish an internationally agreed threshold of concern for veterinary drugs with no identified human health concerns for which no data were available, and were not likely to become available, for conventional evaluation.

107. The Delegation of Japan suggested that, when no ADI and/or MRL was recommended by JECFA due to lack of information, the Committee might consider developing temporary MRLs taking into account regional and/or national MRLs, as recommended by the Bangkok workshop held in 2004.

108. In this regard the JECFA Secretariat clarified that the Threshold of Toxicological Concern (TTC) is a concept based on similar chemical structural classes to be considered and is extensively described in EHC 240. To date, the scientific basis for the establishment of such classes is not available for veterinary drugs. One factor that is important to note in this context is the wide variation in chemical structures of substances used as veterinary drugs. Establishment of risk-based thresholds would also require considerable amounts of scientific data, information and work.

109. One observer suggested that work on risk management recommendations should also address critically important antimicrobials and emphasised the importance to have in place a risk management communication strategy that would allow proper communication on substance with no ADI and/or MRLs due to specific health concern.

110. In view of the above discussion, the Committee agreed that the electronic working group that would consider several aspects of risk analysis discussed at the present session (*see* also Agenda Items 8 and 12) would develop risk management and risk communication recommendations for veterinary drugs for which no ADI and/or MRL has been recommended by JECFA either due to specific human health concerns or a lack of information. The detailed mandate and modalities of the working group, taking into account all the decisions taken at the session, is presented under Agenda Item 12.

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<sup>16</sup> ALINORM 09/32/31, para. 165

### **Terms of reference of the CCRVDF**

111. It was also noted that the terms of reference of the Committee might not cover the elaboration of risk management measures other than MRLs and codes of practice. It was suggested to amend the terms of reference of the Committee to allow for consideration of other matters. In this regard it was suggested to consider adding to the terms of reference of the Committee a new bullet point similar to point (e) “*to consider other matters in relation to the safety of food and feed containing pesticide residues*” of the terms of reference of the Committee on Pesticide Residues (CCPR).

112. Several delegations supported the proposed amendment to the terms of reference noting that it could be forwarded to the 34<sup>th</sup> session of the Commission for adoption and thus allow the Committee to elaborate other risk management measures than MRLs and codes of practice to address substances with no ADI and/or MRLs. Other delegations, while not objecting to the proposed amendment, considered it necessary to have more time to consider the amendment and the possible implication on the Committee’s work.

113. After some discussion, the Committee agreed not to forward at this time the proposed amendment to the terms of reference to the 34<sup>th</sup> session of the Commission for adoption and agreed to circulate the proposed amendment, as presented in Appendix VIII, for comments and consideration at the next session.

114. The Representative of FAO noted that to deliberate even further on the procedural amendments necessary to enable the Committee to make risk management recommendations in relation to the matters that had been already under discussion for several years, was not tenable. The Representative considered that this represented a step back and given the resources provided by FAO and WHO for the work of the Committee, as well as the resources and time put in by all others involved, urged the Committee to not delay this process any longer.

### **Remaining veterinary drugs for which JECFA clearly identified human health concerns**

115. The Committee had some discussion on the way to develop specific risk management recommendations for those veterinary drugs with no ADI and/or MRL for which JECFA had clearly identified human health risks. Some delegations were of the view that it was not possible for the Committee to make recommendations without a procedure and suggested to hold the decision on these compounds until work on the development of policy and procedures for veterinary drugs with no ADI and/or MRL has been completed. Other delegations were of the view that the Committee should start work on these recommendations and suggested to use the same approach of its 18<sup>th</sup> Session for malachite green and chloramphenicol (*see* ALINORM 09/32/31 para. 163) and to include a note in the report that these substances should not be used in food producing animals.

116. After some discussion, and in recognising the need to begin working on these recommendations, the Committee agreed to establish an electronic working group, led by the European Union and working in English only and open to all Codex members and observers, with the following terms of reference:

- (i) To develop risk management recommendations for the following veterinary drugs for which no ADI and/or MRL has been recommended by JECFA due to specific human health concerns: crbadox, chloramphenicol, chlorpromazine, malachite green, nitrofurans, nitroimidazoles, olaquinox, stilbenes (diethylstilbestrol);
- (ii) The risk management recommendations should be based on an evaluation of the information available through the JECFA reports and monographs and through dialogue with the JECFA secretariats; and
- (iii) The risk management recommendations should incorporate the decisions of the 18<sup>th</sup> Session of CCRVDF that chloramphenicol and malachite green should not be used in food producing animals.

### **Procedures for conveying risk management recommendations in the Codex standard setting process**

117. The Committee noted that Codex Veterinary Drug Residues in Food Online Database<sup>17</sup> included links to JECFA residues monographs in the FAO JECFA Online Edition: "Residues of some veterinary drugs in

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<sup>17</sup> <http://www.codexalimentarius.net/vetdrugs/data/index.html>

foods and animals”<sup>18</sup> and that plans were ongoing to create direct links between the Codex database and the WHO database of Evaluations of the Joint FAO/WHO Expert Committee on Food Additives (JECFA)<sup>19</sup>.

118. The Committee further noted that the Codex database only included adopted MRLs and it could be modified in the future to include other relevant risk management measures adopted by Codex.

### **DISCUSSION PAPER ON VETERINARY DRUGS IN HONEY PRODUCTION (Agenda Item 10)<sup>20</sup>**

119. The Delegation of the United Kingdom briefly introduced the report of the electronic working group charged to: (i) compile and analyse the information received in reply to CL 2009/21-RVDF (requesting information on veterinary drugs registered for honey production and bee health and data on honey consumption); and (ii) review the guidelines of good veterinary practice with respect to honey<sup>21</sup>.

120. The Committee noted the findings of the electronic working groups that: (i) there was a limited number of authorised active ingredients use in honey bee treatment with thymol being the most common; (ii) the limited number of data on honey consumption submitted seemed to support the JECFA proposal to revise the daily consumption data to 50g/day; and (iii) there was a number of national guidelines on good veterinary practice that covered several aspects of honey production.

121. The Committee considered the recommendations of the electronic working group as follows:

#### **Prioritization of active ingredients used in honey bee treatment**

122. In answer to a question on developing MRLs for substances for which an ADI was already available, the JECFA Secretariat explained that there were no specific recommendations and/or procedures that JECFA could follow for recommending MRLs and that JECFA could benefit from the development of specific guidance.

123. One delegation informed the Committee of their willingness to provide additional data on the substances used in bee treatment and to support further work on this subject. Another delegation pointed out that although a number of substances were registered for use in honey bees, they were not aware of any MRLs for these substances and that it was important to develop a risk assessment policy to establish these limits. This view was supported by other delegations.

#### **Honey consumption data**

124. The Delegation of United Kingdom pointed out that it was not likely that more data would become available on honey consumption than those submitted in reply to CL 2009/21-RVDF and that additional data most likely would not change the figure proposed by JECFA, which seemed adequate. In addition, the Delegation suggested that the cost and resources for generating new data did not justify such an effort.

125. The JECFA Secretariat indicated that the additional data collated by the working group seemed to give some confidence to the proposed figure for honey consumption of 50 g/day for a high consumer.

126. In view of this discussion, the Committee agreed to forward the additional data to the JECFA Secretariat and to support the revised figure proposed by JECFA. The Committee invited members to submit any additional consumption data to the JECFA Secretariat.

#### **Guidance document on good veterinary practice**

127. The Committee considered a project document for new work on the development of Guidelines on Good Veterinary Practice in Honey Production to Minimise and Control Residues of Veterinary Drugs in Honey, as presented in CRD 15.

128. One delegation indicated that some of the language used in the project document was inconsistent with the mandate of Codex and the Committee’s terms of reference. In addition, the delegation was of the view

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<sup>18</sup> <http://www.fao.org/ag/agn/jecfa-vetdrugs/search.html>

<sup>19</sup> <http://apps.who.int/ipsc/database/evaluations/search.aspx>

<sup>20</sup> CX/RVDF 10/19/10; CRD 6 (Comments of Brazil, European Union and Thailand); CRD 12 (Comments of Panama); CRD 15 (Project document for new work on preparation of Guidelines on Good Veterinary Practice in Honey Production to Minimise and Control Residues of Veterinary Drugs in Honey, prepared by United Kingdom); CRD 17 (Comments of Uruguay)

<sup>21</sup> ALINORM 09/32/31, para. 29

that it was premature to consider the development of guidelines before establishing a risk analysis policy for the establishment of MRLs for veterinary drugs in honey. This view was supported by other delegations which also indicated that good veterinary practices for use of veterinary drugs in honey production were better defined at country level.

129. Another delegation, while supporting initiation of new work, was of the view that the elaboration of good veterinary practice in honey production should focus on best practices for minimizing and control veterinary drug residues for the purpose of ensuring food safety and human health and that the guidelines should not cover aspects, such as bee husbandry for disease control and animal health, which were outside the mandate of Codex.

130. The JECFA Secretariat clarified that information on how veterinary drugs were used in honey bee production was important to develop procedures for establishing MRLs for honey.

### **Conclusion**

131. After some informal discussion on the scope of the new work and the need to develop a policy for the establishment of MRLs for honey, the Committee agreed that there was no need to develop a guidance document on good veterinary practice in honey production because the *Guidelines for the Design and Implementation of National Regulatory Food Safety Assurance Programmes Associated with the Use of Veterinary Drugs in Food Producing Animals* (CAC/GL 71-2009) provided adequate criteria for the selection of drugs and their use<sup>22</sup>. The Committee also agreed that it was more useful to develop a policy for the establishment of MRLs or other limits in honey taking into account relevant information on data and criteria used by national authorities for the authorization of veterinary drugs for use in honey bees.

132. Therefore, the Committee agreed to establish an electronic working group, led by the United Kingdom and working in English only and open to all Codex members and observers, to: (i) collate data from national authorities which have authorised veterinary drugs for use in bees from which honey is harvested for human consumption; (ii) to consider the criteria used by national competent authorities and identify common or related parameters used when authorising these treatments; and (iii) to propose a risk assessment policy for JECFA when the Committee would require its advice for setting appropriate limits for veterinary drugs in honey.

### **DISCUSSION PAPER ON SAMPLING PLAN FOR RESIDUE CONTROL FOR AQUATIC ANIMAL PRODUCTS AND DERIVED EDIBLE PRODUCTS OF AQUATIC ORIGIN (Agenda Item 11)<sup>23</sup>**

133. The Committee recalled that its last session had finalised the *Guidelines for the Design and Implementation of National Regulatory Food Safety Assurance Programmes Associated with the Use of Veterinary Drugs in Food Producing Animals* (CAC/GL 71-2009) and recognized that the sampling plans for aquatic animal products and derived edible products of aquatic origin included in Appendix B of the *Guidelines* required further consideration. For this purpose it had been agreed to establish an electronic working group chaired by the United States of America.

134. The Committee noted that the working group had revised the Table in the light of the comments received but that due to limited participation, some issues remained to be addressed and further input would be required in order to proceed with this task.

135. Several delegations supported further work on the sampling plan due to its importance for inspection purposes, while some delegations drew the attention of the Committee to their written comments and specific proposals to amend the Table.

136. The Committee considered a revised Table prepared by some delegations during the session and agreed that it should be circulated for further comments. The comments should be considered by an electronic working group with the mandate of preparing a revised table for aquatic products, including minimum quantity required for laboratory sample and instruction for collection, for future inclusion in the *Guidelines* after these concerns were addressed, and in particular:

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<sup>22</sup> CAC/GL 71-2009, paras 24-26

<sup>23</sup> CX/RVDF 10/19/11; CRD 7 (Comments of Brazil, Philippines); CRD 8 (Comments of Thailand); CRD 12 (Comments of Panama); CRD 19 (Comments of Indonesia)

- What is the appropriate minimum quantity required for laboratory sample in the context of current analytical technology; and
- The number and size of subsamples (increments) required.

137. In the process, the following aspects should be taken into account: the need for statistical input to ensure that the laboratory sample is representative of the entire lot; the difference between single source sampling and multi-source sampling; the fact that residue may vary in the different edible tissues; and the difference in import verification vs. domestic surveillance and compliance.

138. The working group would be chaired by the United States of America, would work in English and would be open to all members and observers.

139. Following some discussion on the scope of the work, the Committee agreed to clarify that the mandate of the electronic working group was to revise the content of Table C and not to consider issues related to sampling strategy, which were addressed in the current *Guidelines*.

**Status of the Proposed Draft Sampling Plans for Residue Control for Aquatic Animal Products and Derived Edible Products of Aquatic Origin (Table C, Annex B of the *Guidelines for the Design and Implementation of National Regulatory Food Safety Assurance Programmes Associated with the Use of Veterinary Drugs in Food Producing Animals* (CAC/GL 71-2009))**

140. The Committee agreed to circulate the Proposed Draft Table C, as amended at the present session, for comments at Step 3, review by an electronic working group as indicated above, further circulation for comments if time allowed, and consideration at the next session (*see* Appendix VII).

**OTHER BUSINESS AND FUTURE WORK (Agenda Item 12)**

141. In view of the decisions taken in relation to the discussion on the requests of the 26<sup>th</sup> Session of Committee on General Principles and of the 64<sup>th</sup> Session of the Executive Committee (*see* Agenda Item 2), on the revision of policies for the establishment of MRLs (*see* Agenda Item 8) and on policy and procedures for veterinary drugs with no ADI and/or MRL (*see* Agenda Item 9), the Committee agreed to integrate all these decisions in the revision of the *Risk Analysis Principles Applied by the CCRVDF* and the *Risk Assessment Policy in the setting of Maximum Limits for Residues of Veterinary Drugs in Foods*.

142. To carry out this work and pursuing activity 2.2 of the Strategic Framework, the Committee agreed to establish an electronic working group, co-chaired by France, Japan and the United States of America, working in English only and open to all Codex members and observers, to develop a working document:

- (i) Revising and updating, as appropriate, the current *Risk analysis principles applied by the CCRVDF* (p. 101 - Proc. Manual 19<sup>th</sup> ed.) and the risk assessment policy for setting MRLVDs (p.107);
- (ii) Special emphasis shall be given to:
  - Revising Section 3-2 'Evaluation of risk management options' in order to provide JECFA with specific directions, together with their rationale, on how to generate and submit for consideration by the Committee a range of acceptable values for each MRL to be established; and
  - Developing risk management and risk communication recommendations for veterinary drugs for which no ADI and/or MRL has been recommended by JECFA either due to specific human health concerns or a lack of information.

143. In carrying out this task, the electronic working group will take into consideration the discussion under Agenda Items 2, 8 and 9 and all written comments submitted under these agenda items.

144. In considering that activity 2.2 of the Strategic Framework should be completed by 2013 and the frequency of the CCRVDF sessions, the Committee encouraged the electronic working group to start working on the document as soon as possible so that it could be finalised and circulated well in advance of the next session of the Committee.

145. In order to facilitate its discussion and progress on the document, the Committee further agreed to establish a physical working group, co-chaired by France, Japan and the United States of America, which

would meet immediately before its next session, to consider the working document and the comments submitted.

### **CCRVDF CURRENT PROBLEMS AND SOLUTIONS (Agenda Item 12a)<sup>24</sup>**

146. The Chairperson introduced the document and recalled that the purpose of this agenda item was to have an open and informal exchange of views on problems that the CCRVDF was currently facing and possible solutions to these problems. He further noted that this was a continuation of the discussion initiated in the 18<sup>th</sup> Session by the previous Chair, which had been well received by the members and observers of the Committee.

147. The following is a summary of the main points of the discussion.

148. Several delegations expressed members' disappointment in the total number of adopted Codex MRLs that have been developed over the 19 sessions of CCRVDF. This disappointment was noted particularly in light of the Chair's reflection on the importance for the Committee to ensure consumer safety and develop trade particularly for developing countries. The Committee noted the list of 70 substances for which MRLs were needed by members countries (*see* Annex II of CX/RVDF 10/19/7). Some delegations noted the importance of sponsor companies providing data for risk assessment primarily through JECFA; and also the potential risk for these companies: (i) where MRLs have been previously established by national authorities; (ii) significant time is required for adoption of Codex MRLs; (iii) expiry of patent life occurs; and (iv) potential issues in the trade of commodities derived from treated animals.

149. Some delegations suggested giving consideration to a number of different approaches, taking into account the increasing demand on both human and funding resources. This included adopting national MRLs, which have been set in accordance with prevailing JECFA standards, and extrapolation of MRLs to minor species. Several ideas were expressed and discussed for possible approaches that can be considered by the Committee as it continues its work in the various electronic working groups established during the session.

150. The conversation was open and transparent and as such enabled many previously discussed concerns to be expressed. The Chair thanked the Committee for holding the discussion to facilitate further consideration of ideas for future work.

### **DATE AND PLACE OF NEXT SESSION (Agenda Item 13)**

151. The Committee noted that its 20<sup>th</sup> Session was tentatively scheduled to be held in approximately 18 months time, subject to further discussion between the Codex and United States of America Secretariats and taking into consideration the schedule and the availability of the report of the next JECFA meeting on veterinary drugs residues in foods.

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<sup>24</sup> CX/RVDF 10/19/12; CRD 12 (Comments of Panama); CRD 18 (Comments of IFAH)

## SUMMARY STATUS OF WORK

SUBJECT MATTER	STEP	ACTION BY:	DOCUMENT REFERENCE (REP11/RVDF)
Draft Maximum Residue Limits for: - narasin (pig tissues); and - tilmicosin (chicken and turkey tissues)	8	34 <sup>th</sup> CAC	Para. 49 and Appendix III
Draft Maximum Residue Limits for: - narasin (cattle tissues)	7	20 <sup>th</sup> CCRVDF	Para. 43 and Appendix IV
Proposed draft Sampling Plans for Residue Control for Aquatic Animal Products and Derived Edible Products of Aquatic Origin (Table C, Annex B of CAC/GL 71-2009)	3	eWG (United States of America) 20 <sup>th</sup> CCRVDF	Para. 140 and Appendix VII
Proposed draft Guidelines on performance characteristics for multi-residues methods (Appendix to CAC/GL 71-2009)	1,2,3	34 <sup>th</sup> CAC eWG (United Kingdom and Canada) 20 <sup>th</sup> CCRVDF	Para. 65 and Appendix V
Priority list of veterinary drugs requiring evaluation of re-evaluation by JECFA	1,2,3	34 <sup>th</sup> CAC 20 <sup>th</sup> CCRVDF	Para. 83 and Appendix VI
Proposed amendments to the <i>Risk Analysis Principles for the CCRVDF</i> for comments and consideration at the next session	-	20 <sup>th</sup> CCRVDF	Para. 12 and Appendix II
Proposed revision of <i>Risk Analysis Principles applied by the CCRVDF</i> and the <i>Risk Assessment Policy for the Setting of MRLs for Veterinary Drugs</i>	-	eWG (France, Japan and United States of America) 20 <sup>th</sup> CCRVDF	Paras 18, 101 and 116
Discussion paper on extrapolation of MRLs to additional species and tissues	-	eWG (Canada) 20 <sup>th</sup> CCRVDF	Para. 78
Database on need for MRLs of developing countries	-	eWG (United States of America)	Para. 87
Proposed amendments to the Terms of Reference of CCRVDF	-	20 <sup>th</sup> CCRVDF	Para. 113 and Appendix VIII
Risk management recommendations for the veterinary drugs for which no ADI and/or MRL has been recommended by JECFA due to specific human health concerns	-	eWG (European Union) 20 <sup>th</sup> CCRVDF	Para. 116
Discussion paper on policy for the establishment of MRLs or other limits in honey		eWG (United Kingdom)	Para.131

Appendix I

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LISTE DES PARTICIPANTS  
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Appendix II**PROPOSED AMENDMENTS TO THE RISK ANALYSIS PRINCIPLES APPLIED BY THE  
CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS****(for comments)**

Amendments are proposed only to the following sections. Proposed changes in *Italics and bold*

**1. PURPOSE – SCOPE**

1. The purpose of this document is to specify Risk Analysis Principles applied by the Codex Committee on Residues of Veterinary Drugs in Foods.

*a) This document also applies to residues of veterinary drugs in food originating from the use of veterinary drugs in feed<sup>1</sup> where it can affect food safety.*

.....

**3.1 Preliminary risk management activities**

1. This first phase of risk management covers:

- Establishment of risk assessment policy for the conduct of the risk assessments;
- Identification of a food safety problem *in the integrity of the food chain and determine if feed may be a source of the food safety problem;*
- Establishment of a preliminary risk profile;
- Ranking of the hazard for risk assessment and risk management priority;
- Commissioning of the risk assessment; and
- Consideration of the result of the risk assessment.

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<sup>1</sup> The term "feed" refers to both "feed (feedingstuffs)" and "feed ingredients" as defined in the *Code of Practice on Good Animal Feeding* (CAC/RCP 054 2004)

Appendix III**DRAFT MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS****(at Step 8 of the Elaboration Procedure)****Narasin** (antimicrobial agent)**Acceptable Daily Intake:** 0–5 µg/kg body weight on the basis of a NOAEL of 0.5 mg/kg body weight per day and a safety factor of 100 (70<sup>th</sup> JECFA, 2008).**Residue Definition:** Narasin A.

<b>Species</b>	<b>Tissue</b>	<b>MRLs (µg/kg)</b>	<b>Step</b>	<b>JECFA</b>	<b>ALINORM</b>
Pigs	Muscle	15	8	70	18IV
Pigs	Liver	50	8	70	18IV
Pigs	Kidney	15	8	70	18IV
Pigs	Fat	50	8	70	18IV

**Tilmicosin** (antimicrobial agent)**Acceptable Daily Intake:** 0-40 µg/kg body weight (47<sup>th</sup> JECFA, 1998).**Residue Definition:** Tilmicosin.

<b>Species</b>	<b>Tissue</b>	<b>MRLs (µg/kg)</b>	<b>Step</b>	<b>JECFA</b>	<b>ALINORM</b>
Chicken	Muscle	150	8	70	18IV
Chicken	Liver	2400	8	70	18IV
Chicken	Kidney	600	8	70	18IV
Chicken	Skin/Fat	250	8	70	18IV
Turkey	Muscle	100	8	70	18IV
Turkey	Liver	1400	8	70	18IV
Turkey	Kidney	1200	8	70	18IV
Turkey	Skin/Fat	250	8	70	18IV



Appendix IV**DRAFT MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS****(at Step 7 of the Elaboration Procedure)****Narasin** (antimicrobial agent)**Acceptable Daily Intake:** 0–5 µg/kg body weight on the basis of a NOAEL of 0.5 mg/kg body weight per day and a safety factor of 100 (70<sup>th</sup> JECFA, 2008).**Residue Definition:** Narasin A.

<b>Species</b>	<b>Tissue</b>	<b>MRLs (µg/kg)</b>	<b>Step</b>	<b>JECFA</b>	<b>ALINORM</b>
Cattle	Muscle	15 T <sup>a</sup>	7	70	18IV
Cattle	Liver	50 T <sup>a</sup>	7	70	18IV
Cattle	Kidney	15 T <sup>a</sup>	7	70	18IV
Cattle	Fat	50 T <sup>a</sup>	7	70	18IV

<sup>a</sup> The MRL is temporary. Before re-evaluation of narasin with the aim of recommending MRLs in tissues of cattle, the Committee would require a detailed description of a regulatory method, including its performance characteristics and validation data. This information is required by February 2011.

## PROJECT DOCUMENT

### **NEW WORK ON THE REVISION OF THE “GUIDELINES FOR THE DESIGN AND IMPLEMENTATION OF NATIONAL REGULATORY FOOD SAFETY ASSURANCE PROGRAMMES ASSOCIATED WITH THE USE OF VETERINARY DRUGS IN FOOD PRODUCING ANIMALS” (CAC/GL 71-2009) TO INCLUDE AN APPENDIX ON PERFORMANCE CRITERIA FOR MULTI-RESIDUE ANALYTICAL METHODS FOR VETERINARY DRUG RESIDUE ANALYSES**

#### **1. PURPOSE AND SCOPE OF THE NEW WORK**

The purpose of the new work is to update the existing general guidance document *Guidelines for the Design and Implementation of National Regulatory Food Safety Assurance Programmes Associated with the Use of Veterinary Drugs in Food Producing Animals* (CAC/GL 71–2009) in order to reflect important advances in veterinary drug residue analyses, whilst taking account of the recently published *Guidelines on Analytical Terminology* (CAC/GL 72-2009).

The scope of new work will involve:

- developing performance criteria for the validation and acceptability of multi-residue analytical methods employed in the detection and determination of veterinary drug residues in food producing animals and their products to bring this testing in line with the latest knowledge and practices.
- recognition of the importance of linking the development of performance criteria for multi-residue analytical methods with the need to develop validation requirements for such methods. This should build on the existing guidance in CAC/GL 71-2009 and be prepared as a further appendix to this guidance.
- providing guidance which will be “fit for purpose” and not be aimed at the highest standard achievable, recognising that different performance criteria may be appropriate for different analytical procedures and techniques.
- acceptance that any guidance developed must not be prescriptive in nature and choices to suit local needs should be included where possible.

#### **2. RELEVANCE AND TIMELINESS**

Testing food producing animals and their products for residues of veterinary drugs is routinely used by competent authorities and business operators to evaluate the safety of foods. To promote consistency in the use of analytical criteria, Codex Alimentarius introduced the *Guidelines for the Design and Implementation of National Regulatory Food Safety Assurance Programmes Associated with the Use of Veterinary Drugs in Food Producing Animals* (CAC/GL 71-2009). When this was introduced, it was recognised that rapid advances in analytical chemistry had meant that analytical laboratories were moving away from the use of dedicated single analyte methods for the detection and determination of veterinary drug residues.

With increased pressure on laboratories to be more efficient and productive, there is now an increasing movement towards the use of multi-residue analytical methods but there are no harmonised international guidelines to which laboratories can work to ensure that the new methods are both adequately validated and robust.

The current multi-residue analytical methods, which are used extensively by both competent authorities and industry, have different requirements, protocols, assumptions and interpretations that are not adequately covered by Codex guidance documents.

New work is proposed to reflect on this information and experience and it is proposed to update the existing guidance document to include specific guidance on this type of analytical method and produce guidance which is “fit for purpose” whilst recognising local needs where appropriate.

### 3. MAIN ASPECTS TO BE COVERED

Guidance will be introduced in the document to reflect current best practice regarding the utility of performance criteria for multi-residue analytical methods for veterinary drug residue analyses. The following aspects require attention:

- consideration of the application of multi-residue analytical methods, and their performance criteria, as applied in other areas with relevance to veterinary drug residue analyses, e.g. pesticide residue analyses,
- extending the existing principles for analytical method performance criteria in CAC/GL 71-2009 to cover the validation and use of multi-residue analytical methods for veterinary drug residue analyses and their use in residue control programmes,
- recognition of local analytical technology, where this does not compromise the integrity of the scientific need for robust veterinary drug residue analytical capacity,
- the appropriate roles of multi-residue method testing for verification of process control within the context of HACCP and validation of control measures.

### 4. ASSESSMENT AGAINST THE CRITERIA FOR THE ESTABLISHMENT OF WORK PRIORITIES

#### *General criterion*

This work is directed towards consumer protection from the point of view of food safety, quality and ensuring fair practices in food trade while taking into account the identified needs of developing countries. This new work will strengthen other guidance provided in general support of consumer protection in developing and developed countries. On a global scale, it will contribute to a reduction of human health issues arising from exposure to veterinary drug residues in excess of internationally agreed limits and simultaneously clarify issues which might impede the advancement of fair trading practices. This new work also supports the general goal of Codex Alimentarius to continually review and update its standards and guidance.

#### *Criteria applicable to general subjects*

*(a) Diversification of national legislations and apparent resultant or potential impediments to international trade:* this new work aims to provide general best practice guidance and update on new scientific and technical developments that are relevant for all countries and enable them to further refine their own risk management strategies.

*(b) Scope of work and establishment of priorities between the various sections of the work:* the most important parts of the work may be the update on the usefulness of performance criteria for analytical methods as applied to veterinary drug residue detection and the relationship with risk management.

*(c) Work already undertaken by other international organizations in this field and/or suggested by the relevant international intergovernmental bodies:* This new work does not duplicate any ongoing work undertaken by other (inter)national governmental organisations.

### 5. RELEVANCE TO CODEX STRATEGIC GOALS

The proposed work falls under all five goals of the Codex Strategic Plan 2008-2013.

#### *Goal 1: Promoting Sound Regulatory Frameworks.*

The results of this new work will further contribute to the development of sound food control and regulatory infrastructures and consequently will promote assurance of the safety of foods in general.

#### *Goal 2: Promoting Widest and Consistent Application of Scientific Principles and Risk Analysis.*

The new work updates the existing general guidance document with the latest thinking on the application of scientific principles and risk analysis and thus is essential to meeting this objective.

**Goal 3: Strengthening Codex work-management capabilities**

The new work strengthens an important aspect of Codex regarding the risk-based approach to food safety management and makes links to operational practice that are key to implementing the risk-based approach in day-to-day food industry practice.

**Goal 4: Promoting cooperation between Codex and other relevant international organisations.**

This work requires a close coordination between FAO, WHO and Codex, as well as competent authorities in countries and scientific organisations such as the IAEA.

**Goal 5: Promoting Maximum and effective Participation of members.**

The new work affects all members of Codex and may trigger further participation of both developing and developed countries with general interests in global trade of food and food ingredients.

**6. INFORMATION ON THE RELATION BETWEEN THE PROPOSAL AND OTHER EXISTING CODEX DOCUMENTS**

The proposed work concerns several general guidance documents, particularly CAC/GL 71-2009 and CAC/GL 72-2009 (*see above*).

**7. IDENTIFICATION OF ANY REQUIREMENT FOR AND AVAILABILITY OF EXPERT SCIENTIFIC ADVICE**

Although the new work can be undertaken with the scientific advice available within the CCRVDF, it would benefit from the outcome of a further expert meeting to review scientific progress on residue analyses since the Miskolc consultation organised by FAO/IAEA/AOAC in 1999..

**8. IDENTIFICATION OF ANY NEED FOR TECHNICAL INPUT TO THE STANDARD FROM EXTERNAL BODIES SO THAT THIS CAN BE PLANNED FOR**

None identified.

**9. PROPOSED TIMELINE FOR COMPLETION OF THE NEW WORK**

The following timeline is proposed for the completion of the work, preferably for final adoption in 2013. The timeline should not exceed four years (2014).

Date	Meeting	Progress
September 2010	19 <sup>th</sup> session CCRVDF	Agree on project documents and submit to 34 <sup>th</sup> CAC for approval of new work.
July 2011	34 <sup>th</sup> CAC	Approval of new work.
September 2012	20 <sup>th</sup> session CCRVDF	Consideration of the proposed draft guidelines at Step 4 and advance to 35 <sup>th</sup> CAC for adoption at Step 5.
July 2012	35 <sup>th</sup> CAC	Adoption at Step 5.
		Circulation for comments at Step 6.
2013	21 <sup>st</sup> session CCRVDF	Consideration of the proposed draft guidelines at Step 7 and advance to Step 8.
July 2013	36 <sup>th</sup> /37 <sup>th</sup> CAC (depending on the schedule of the 21 <sup>st</sup> session CCRVDF)	Final adoption.

**PRIORITY LIST OF VETERINARY DRUGS FOR EVALUATION OR RE-EVALUATION BY JECFA**

<b>Name of the Compound</b>	<b>Questions(s) to be answered</b>	<b>Data Availability</b>	<b>Proposed by</b>	<b>Comments</b>
Monepantel (1)	Request to establish ADI and recommend MRLs in sheep (tissues).	Company has advised that a data package is available that meets the JECFA requirements.	Australia	Registered in New Zealand.
Monensin (1)	Request to re-evaluate MRL in cattle (liver).	Company has advised that a data package is available that meets the JECFA requirements.	United States of America	MRL in cattle (liver) was adopted by 32 <sup>nd</sup> CAC (2009).
Derquantel (1)	Request to establish ADI and recommend MRLs in sheep (tissues).	Company has advised that a data package is available that meets the JECFA requirements.	United States of America	Currently registered in New Zealand.
Apramycin (1)	Request to establish ADI and recommend MRLs in cattle, pig, chicken and rabbit (tissues).	Company has advised that a data package will be available that meets the JECFA requirements by February 2011.	Australia	Currently registered in 43 countries.
Amoxicillin (1)	Request to establish ADI and recommend MRLs in cattle, sheep and pig (tissues) and cattle and sheep milk.	Company has advised that a data package will be available that meets the JECFA requirements by February 2011.	United States of America	Currently registered in many countries, including the United States of America.
Narasin (1)	Analytical method required for cattle tissues	Company has advised that a data package will be available that meets the JECFA requirements by February 2011.	United States of America	Temporary MRLs for narasin in cattle tissues are held at Step 7 pending JECFA assessment of the analytical method.
Ractopamine (2)	Request to recommend MRLs in pig's lung	Pharmacokinetics and residues studies in lung tissues and validated method will have to be made available	China	Currently registered in many countries, including the United States of America.
Triclabendazole (2)	Can MRLs for goat (tissues) be established by extrapolation considering data used for recommending MRLs for cattle and sheep (tissues).	JECFA has established MRLs for sheep and cattle and extrapolation would be based on the data packages available to the 70 <sup>th</sup> JECFA and literature review to be provided by the United States of America..	CCRVDF	Currently registered widely in sheep and cattle and in some countries in goats.
Ivermectin (2)	Request to re-evaluate ADI and, if necessary, recommend new MRLs.	Data availability will be confirmed as soon as possible.	United States of America	MRLs for ivermectin in cattle (liver, fat), pig (liver, fat) and sheep (liver, fat) were adopted by 20 <sup>th</sup> CAC (1993) and in cattle (milk) by 26 <sup>th</sup> CAC (2003)

(1) First priority; (2)Second priority

## Appendix VII

**PROPOSED DRAFT TABLE C “ AQUATIC ANIMAL PRODUCTS” OF THE *GUIDELINES FOR THE DESIGN AND IMPLEMENTATION OF NATIONAL REGULATORY FOOD SAFETY ASSURANCE PROGRAMMES ASSOCIATED WITH THE USE OF VETERINARY DRUGS IN FOOD PRODUCING ANIMALS*” (CAC/GL 71-2009)**

**(at Step 3 of the Procedure)**

**Table C: Aquatic animal products**

<b>Commodity</b>	<b>Instructions for collection</b>	<b>Minimum quantity required for laboratory sample</b>
<b>VII. Class B – Type 08</b> (Aquatic Animal Products)		
A. Packaged fish – fresh, frozen, smoked, cured, or shellfish (except oysters)	Collect 3 increments randomly for 1 sample. Minimum sample size is 1 kg and reduced to laboratory sample.	500g
B. Bulk fish 0.5 – 1.5 kg	Collect 3 increments randomly for 1 sample. Minimum sample size is 1 kg and reduced to laboratory sample.	500g
C. Bulk fish 1.5 – 2.5 kg	Collect 3 increments randomly for 1 sample. Minimum sample size is 1 kg and reduced to laboratory sample.	500g
D. Bulk fish > 2.5 kg	Collect 3 increments randomly for 1 sample. Minimum sample size is 1 kg and reduced to laboratory sample.	500g
E. Bulk Shellfish	Collect not less than 3 increments for 1 sample. Minimum sample size is not more than 1 kg and reduced to laboratory sample.	500g
F. Other fish and shellfish Products (including oysters)	Collect not less than 3 increments for 1 sample. Minimum sample size is not more than 1 kg and reduced to laboratory sample.	500g
<b>VII. Class E – Type 17</b> (Derived Edible Products of Aquatic Animal Origin)		
A. Canned fish and shellfish products (except oysters)	Collect not less than 3 increments for 1 sample. Minimum sample size is not more than 1 kg and reduced to laboratory sample.	500g
B. Other fish and shellfish products – fish flour and meal	Use sample schedule. Collect 1 kg per sample and reduced to laboratory sample.	500g

Appendix VIII**PROPOSED AMENDMENTS TO THE TERMS OF REFERENCE OF THE CODEX COMMITTEE  
ON RESIDUES OF VETERINARY DRUGS IN FOODS (CCRVDF)****(for comments)**Proposed changes in *Italics and bold*

Terms of reference:

- (a) to determine priorities for the consideration of residues of veterinary drugs in foods;
- (b) to recommend maximum levels of such substances;
- (c) to develop codes of practice as may be required;
- (d) to consider methods of sampling and analysis for the determination of veterinary drug residues in foods;
- (e) *to consider other matters in relation to the safety of food and feed containing residues of veterinary drugs.*