CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

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**Agenda Item 1** **CX/RVDF 12/20/1**

**JOINT FAO/WHO FOOD STANDARDS PROGRAMME**

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

**Twentieth Session**

***San Juan, Puerto Rico, 7-11 May 2012***

*The session will be held at the Hotel Sheraton Puerto Rico,*
*200 Convention Boulevard, San Juan, Puerto Rico*
*from Monday, 7 May at 10.00 hours to Friday, 11 May 2012*

*The meetings of the Working Groups on Priorities and on revision of the Risk Analysis Principles applied by the CCRVDF and the Risk Assessment Policy for the setting of maximum limits for residues of veterinary drugs in foods will be held at the same venue on*
*Sunday, 6 May 2012 from 09.00 to 12:00 and from 14:00 to 17:00, respectively*

**PROVISIONAL AGENDA**

| Agenda Item | Subject Matter | Document Reference |
|---|---|---|
| 1 | Adoption of agenda | CX/RVDF 12/20/1 |
| 2 | Matters referred by the Codex Alimentarius Commission and other Codex Committees and Task Forces | CX/RVDF 12/20/2<br>CX/RVDF 12/20/2-Add.1 |
| 3 | Matters arising from FAO/WHO and from the 75th Meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) | CX/RVDF 12/20/3 |
| | Activities of the Joint FAO/IAEA Division of nuclear techniques in food and agriculture relevant to Codex work | CX/RVDF 12/20/3-Add.1 |
| 4 | Report of the OIE activities, including the harmonization of technical requirements for registration of veterinary medicinal products (VICH) | CX/RVDF 12/20/4 |
| 5 | Proposed amendments to the Terms of Reference of CCRVDF | REP11/RVDF App. VIII |
| | • Comments to CL 2010/47-RVDF, part C (point 4) | CX/RVDF 12/20/5<br>CX/RVDF 12/20/5-Add.1<br>CX/RVDF 12/20/5-Add.2 |
| | Maximum Residue Limits (MRLs) for veterinary drugs | |
| 6 (a) | Draft MRLs for veterinary drugs (at Step 7) | REP11/RVDF App. IV |
| 6 (b) | Proposed draft MRLs for Veterinary Drugs (at Step 3) | CX/RVDF 12/20/6<br>CX/RVDF 12/20/6 Corrigendum |
| | • Comments at Step 3 | CX/RVDF 12/20/6 Add.1<br>CX/RVDF 12/20/6-Add.2 |

Working documents will be uploaded onto the Codex website: www.codexalimentarius.net/ or direct ftp-link: ftp://ftp.fao.org/codex/ccrvdf20
Delegates are kindly requested to bring with them to the meeting all documents which have been distributed, as the number of additional copies which can be made available at the session is limited.

| Agenda Item | Subject Matter | Document Reference |
|---|---|---|
| | CCRVDF Risk Analysis Principles | |
| 7 (a) | Proposed amendments to the *Risk Analysis Principles applied by the CCRVDF* | REP11/RVDF App. II |
| | • Comments to CL 2010/47-RVDF, part C (point 3) | CX/RVDF 12/20/7<br>CX/RVDF 12/20/7-Add.1 |
| 7 (b) | Proposed revision of *Risk Analysis Principles applied by the CCRVDF* and the *Risk Assessment Policy for the setting of maximum limits for residues of veterinary drugs in foods* | CX/RVDF 12/20/8 |
| | • Comments | CX/RVDF 12/20/8 Add.1 |
| | Methods of analysis for residues of veterinary drugs in foods | |
| 8 (a) | 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) | CX/RVDF 12/20/9 |
| | • Comments at Step 3 | CX/RVDF 12/20/9 Add.1<br>CX/RVDF 12/20/9-Add.2 |
| 8 (b) | Proposed draft Guidelines on performance characteristics for multi-residues methods (Appendix to CAC/GL 71-2009) (N01-2011) | CX/RVDF 12/20/10 |
| | • Comments at Step 3 | CX/RVDF 12/20/10 Add.1 |
| | Priority list of veterinary drugs requiring evaluation or re-evaluation | |
| 9 (a) | Draft priority list of veterinary drugs requiring evaluation or re-evaluation by JECFA (replies to CL 2010/50-RVDF) | CX/RVDF 12/20/11<br>CX/RVDF 12/20/11 Add.1 |
| 9 (b) | Database on need for MRLs for developing countries | CX/RVDF 12/20/12 |
| | Veterinary drugs with no ADI and MRL | |
| 10 | 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 | CX/RVDF 12/20/13 |
| | Discussion papers | |
| 11 | Discussion paper on the policy for the establishment of MRLs or other limits in honey | CX/RVDF 12/20/14 |
| 12 | Discussion paper on extrapolation of MRLs to additional species and tissues | CX/RVDF 12/20/15 |
| 13 | Other business and future work | |
| 13 (a) | CCRVDF current problems and solutions | CX/RVDF 12/20/16 |
| 14 | Date and place of next session | |
| 15 | Adoption of the report | |

**INFORMATION DOCUMENTS**

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|---|---|
| Information document for support of the discussion on the MRLs for veterinary drugs | RVDF/20 INF/01 |

**NOTES ON THE PROVISIONAL AGENDA**

**Item 1 - Adoption of the agenda (Doc. Ref. CX/RVDF 12/20/1) :** In accordance with Rule VII.2 of the Rules of Procedure, the first item on the Provisional Agenda shall be the adoption of the Agenda.

**Item 2 - Matters referred by the Codex Alimentarius Commission and other Codex Committees and Task Forces (Doc. Ref. CX/RVDF 12/20/2) :** The document includes matters related to the Committee arising from sessions of the Commission and the other Codex Committees and Task Forces.

**Item 3 - Matters arising from FAO/WHO and from the 75th Meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) (Doc. Ref. CX/RVDF 12/20/3)**: The document is a paper prepared by the FAO/WHO includes matters from FAO and WHO and from the 75th JECFA meeting referred to the Committee for action and information.

**Item 4 - Report on OIE Activities, including the harmonization of technical requirements for registration of veterinary medicinal products (Doc. Ref. CX/RVDF 12/20/4):** The document is a report on the relevant activities of the OIE and VICH.

**Item 5 - Proposed amendments to the Terms of Reference of CCRVDF (Doc. Ref. REP11/RVDF App. VIII):** The 19th CCRVDF agreed to circulate proposed amendments to its terms of reference which would allow the elaboration of risk management measures other than MRLs and codes of practice for comments and consideration at its 20th Session (*see* REP11/RVDF paras 111-114 and Appendix VIII). CX/RVDF 12/20/5 compiles comments submitted in response to CL 2010/47-RVDF, part C (point 4).

**Maximum Residue Limits (MRLs) for veterinary drugs**

**Item 6 (a) - Draft Maximum Residue Limits for veterinary drugs (at Step 7) (Doc. Ref. REP11/RVDF App. IV):** The 19th CCRVDF retained 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 (*see* REP11/RVDF para. 43).

**Item 6 (b) - Proposed Draft Maximum Residue Limits for Veterinary Drugs (at Step 4) (Doc. Ref. CX/RVDF 12/20/6)**: The Committee will consider the proposed draft MRLs recommended by the 75th Meeting of JECFA. CX/RVDF 12/20/6 Add.1 compiles comments at Step 3.

**CCRVDF Risk Analysis Principles**

**Item 7 (a) - Proposed amendments to the *Risk Analysis Principles applied by the CCRVDF* (Doc. Ref. REP11/RVDF App. II):** As it was not possible to finalise the amendments to the Risk Analysis Principles to address animal feeding, the 19th CCRVDF agreed to circulate the proposed amendments for comments and consideration at its 20th session (*see* REP11/RVDF paras 9-12). CX/RVDF 12/20/7 compiles comments in response to CL 2010/47-RVDF, part C (point 3).

**Item 7(b) - Proposed revision of *Risk Analysis Principles applied by the CCRVDF* and the *Risk Assessment Policy for the setting of maximum limits for residues of veterinary drugs in foods* (Doc. Ref. CX/RVDF 12/20/8)**: Document CX/RVDF 12/20/8 presents the report of the electronic Working Group established by the 19th CCRVDF to revise and update its Risk Analysis Principles and the Risk Assessment Policy for the Setting of MRLs with special emphasis to revising Section 3-2 and developing risk management and risk communication recommendations for veterinary drugs with no ADI and/or MRL (*see* REP11/RVDF paras 141-145). CX/RVDF 12/20/8 Add.1 compiles comments to the proposed revision.

**Methods of analysis for residues of veterinary drugs in foods**

**Item 8 (a) - 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) (Doc. Ref. CX/RVDF 12/20/9):** Document CX/RVDF 12/20/9 presents the report of the electronic Working Group established by the 19th CCRVDF 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 CAC/GL 17-2009 on the basis of the comments submitted in response to CL 2010/47-RVDF Part B (*see* REP11/RVDF paras 133-139). CX/RVDF 12/20/9 Add.1 compiles comments at Step 3.

**Item 8 (b) - Proposed draft Guidelines on performance characteristics for multi-residues methods (Appendix to CAC/GL 71-2009) (N01-2011) (Doc. Ref. CX/RVDF 12/20/10):** The 34th Session of the Commission approved new work on the development of an Appendix to CAC/GL 71-2009 on performance criteria for multi-residue analytical methods for veterinary drugs residues, as proposed by 19th CCRVDF (*see* REP11/CAC para. 131 and Appendix VI and REP 11/RVDF paras 65-67 and Appendix V). CX/RVDF 12/20/10 Add.1 compiles comments at Step 3.

**Priority list of veterinary drugs requiring evaluation or re-evaluation**

**Item 9 (a) - Draft priority list of veterinary drugs requiring evaluation or re-evaluation by JECFA (Doc. Ref. CX/RVDF 12/20/11)**: Document CX/RVDF 12/20/11 compiles replies to the CL 2010/50-RVDF "Request for Comments/Information on Priority List of Veterinary Drugs Requiring Evaluation or Re-evaluation".

**Item 9 (b) - Database on need for MRLs for developing countries (Doc. Ref. CX/RVDF 12/20/12)**: Document CX/RVDF 12/20/12 presents the report of the electronic Working Group established by the 19th CCRVDF 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 (*see* REP 11/RVDF paras 85-86).

**Veterinary drugs with no ADI and MRL**

**Item 10 – 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 (Doc. Ref. CX/RVDF 12/20/13):** Document CX/RVDF 12/20/13 presents the report the electronic Working Group established by the 19th CCRVDF with the task (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: carbadox, chloramphenicol, chlorpromazine, malachite green, nitrofurans, nitroimidazoles, olaquindox, 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 18th Session of CCRVDF that chloramphenicol and malachite green should not be used in food producing animals (*see* REP 11/RVDF paras 115-116).

**Discussion papers**

**Item 11 – Discussion paper on the policy for the establishment of MRLs or other limits in honey (Doc. Ref. CX/RVDF 12/20/14):** Document CX/RVDF 12/20/14 presents the report of the electronic Working Group established by the 19th CCRVDF 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 (*see* REP 11/RVDF paras 131-132).

**Item 12 – Discussion paper on extrapolation of MRLs to additional species and tissues (Doc. Ref. CX/RVDF 12/20/15):** Document CX/RVDF 12/20/15 presents the report of the electronic Working Group established by the 19th CCRVDF to: (i) collate and summarise all available pertinent documents; (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; (ii) prepare recommendations for the CCRVDF to request JECFA to consider whether EHC 240 provides sufficient guidance; and (iii) propose potential risk analysis policy for use by CCRVDF when considering extrapolating MRLs (*see* REP 11/RVDF paras 77-78).

**Item 13 - Other business and future work:** The Committee will discuss issues raised under Item 1.

**Item 13 (a) - CCRVDF current problems and solutions (Doc. Ref. CX/RVDF 12/20/16):** This item has been included in the provisional agenda by the Chairperson of the CCRRVDF to continue its discussion on new issues not currently covered by the work of the Committee.

**Item 14 - Date and place of next session**: The Committee will be advised of the tentative dates and place of the next Session.

**Item 15 - Adoption of the report**: In accordance with Rule X.1 of the Commission's Rules of Procedure, the Committee shall adopt the report of its Twentieth Session based on a draft provided by the Secretariat