# codex alimentarius commission





JOINT OFFICE: Viale delle Terme di Caracalla 00153 ROME Tel: 39 06 57051 www.codexalimentarius.net Email: codex@fao.org Facsimile: 39 06 5705 4593

Agenda Item 1

CX/RVDF 07/17/1 March 2007

### JOINT FAO/WHO FOOD STANDARDS PROGRAMME

## CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

**Seventeenth Session** 

Breckenridge, Colorado, United States of America, 3-7 September 2007

To be held at the "Village at Breckenridge" from Monday, 3 September at 10.00 hours to Friday, 7 September 2007

The meetings of the ad hoc Working Groups on Priority and on Methods of Analysis and Sampling will be held on Sunday 2 September starting at 09.00 hours and 14.00 hour, respectively

# PROVISIONAL AGENDA

| Agenda<br>Item | Subject Matter  | <b>Document Reference</b>   |
|----------------|---|---|
| 1              | Adoption of Agenda  | CX/RVDF 07/17/1   |
| 2              | Matters Referred by the Codex Alimentarius Commission and Other Codex Committees and Task Forces                                      | CX/RVDF 07/17/2   |
|                |   | CX/RVDF 07/17/2 Add.1   |
| 3              | Matters of Interest arising from FAO/WHO  | CX/RVDF 07/17/3   |
| 3 (a)          | 66 <sup>th</sup> Meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) (in English only)                            | http://whqlibdoc.who.int/publicat<br>ions/2006/9241209399_eng.pdf |
| 4              | Report of the OIE activities, including the Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products | CX/RVDF 07/17/4   |
| 5              | Consideration of Maximum Residue Limits (MRLs) for Veterinary Drugs   | CX/RVDF 07/17/5   |
| 5 (a)          | Draft MRLs for Veterinary Drugs (at Step 7)   | ALINORM 06/29/31, App. III  |
|                | • Information on registered use of Flumequine in Black tiger shrimp and in shrimps (CL 2006/14-RVDF, part C)                          | <u>CX/RVDF 07/17/6</u>  |
| 5 (b)          | Draft MRLs for Veterinary Drugs (at Step 6)   | ALINORM 06/29/31, App. IV   |
|                | • Comments at Step 6 (CL 2006/35-RVDF)  | CX/RVDF 07/17/7   |

Working documents will be uploaded onto the Codex website: <a href="www.codexalimentarius.org">www.codexalimentarius.org</a>
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.

CX/RVDF 07/17/1 2

| Agenda<br>Item | Subject Matter  | <b>Document Reference</b>       |
|----------------|---|---------------------------------|
| 5 (c)          | Proposed Draft MRLs for Veterinary Drugs (at Step 4)  | <u>ALINORM 06/29/31, App. V</u> |
| 5 (d)          | Proposed Draft MRLs for Veterinary Drugs (at Step 3)  | ALINORM 06/29/31, App. VI       |
|                | • Comments at Step 3 (CL 2006/14-RVDF, part C)  | CX/RVDF 07/17/8                 |
| 6              | Draft Guidelines for the Design and Implementation of<br>National Regulatory Food Safety Assurance Programmes<br>Associated with the Use of Veterinary Drugs in Food<br>Producing Animals | ALINORM 06/29/31, App. VII      |
|                | • Comments at Step 6 (CL 2006/35-RVDF)  | <u>CX/RVDF 07/17/9</u>          |
|                |   | CX/RVDF 07/17/9-Add.1           |
| 7              | Methods of Analysis for Residues of Veterinary Drugs in Foods   | CL 2007/04-RVDF                 |
|                | • Comments (CL 2007/04-RVDF)  | CX/RVDF 07/17/10                |
|                |   | CX/RVDF 07/17/10 Add. 1         |
|                | • Report of the <i>ad hoc</i> Working Group on Methods of Analysis and Sampling   | CRD 1                           |
| 8              | Priority List of Veterinary Drugs Requiring Evaluation or Reevaluation  |                                 |
|                | • Comments (CL 2006/52-RVDF)  | CX/RVDF 07/17/11                |
|                | • Report of the <i>ad hoc</i> Working Group on Priority   | CRD 2                           |
| 9              | Report of the physical Working Group on Residues of Veterinary Drugs without ADI/MRL  | CX/RVDF 07/17/12                |
|                | • Comments  | CX/RVDF 07/17/12-Add.1          |
|                |   | CX/RVDF 07/17/12-Add.2          |
| 10             | Discussion Paper on Risk Management Topics and Options for the CCRVDF   | CX/RVDF 07/17/13                |
|                | • Comments  | CX/RVDF 07/17/13-Add. 1         |
| 11             | Other Business and Future Work  |                                 |
| 12             | Date and Place of next Session  |                                 |
| 13             | Adoption of the Report  |                                 |

CX/RVDF 07/17/1

#### NOTES ON THE PROVISIONAL AGENDA

- **Item 1 Adoption of the Agenda (Doc. Ref. CX/RVDF 07/17/1) :** 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 07/17/2): The item includes matters related to the Committee arising from sessions of the Commission and the other Codex Committees including the Executive Committee, if there is any matter.
- Item 3 Matters of Interest arising from FAO/WHO (Doc. Ref. CX/RVDF 07/17/3): The document is an information paper prepared by the FAO/WHO.
- **Item 3 (a) 66<sup>th</sup> Meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA)**: The report of the 66<sup>th</sup> JECFA Meeting (Rome, Italy, 22-28 February 2006) and monographs are available online: 66<sup>th</sup> JECFA Report: Evaluation of certain veterinary drug residues in food:

http://whqlibdoc.who.int/publications/2006/9241209399\_eng.pdf;

Toxicological Monographs: Toxicological evaluation of certain veterinary drug residues:

http://whqlibdoc.who.int/publications/2006/9241660570 eng.pdf;

Residue monographs (FAO JECFA Monographs 2, 2006):

ftp://ftp.fao.org/docrep/fao/009/a0652e/a0652e00.pdf

- Item 4 Report on OIE Activities, including the Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (Doc. Ref. CX/RVDF 07/17/4): The document is a report on the relevant activities of the OIE and VICH.
- Item 5 Consideration of Maximum Residue Limits (MRLs) for Veterinary Drugs (Doc. Ref. CX/RVDF 07/17/5): The working document, prepared by the Codex Secretariat, is for information and support to the discussion on the Maximum Residues Limits for Veterinary Drugs.
- Item 5 (a) Draft Maximum Residue Limits for Veterinary Drugs (at Step 7) (Doc. Ref. ALINORM 06/29/31, App. III; CX/RVDF 07/17/6): The Committee will consider the draft MRLs for flumequine (in black tiger shrimp) and for melengestrol acetate, retained at Step 7 by its 16<sup>th</sup> Session (ALINORM 06/29/31, paras 54 and 73). The 16<sup>th</sup> Session of the Committee agreed to ask the Codex Secretariat to issue a Circular Letter (CL 2006/14-RVDF) requesting information on registered use of Flumequine in Black tiger shrimp and shrimps with the understanding that, if information is not provided, it will discontinue work on these MRLs at its next Session (ALINORM 06/29/31, para. 54). Information submitted in response to CL 2006/14-RVDF, part C, is summarised in working document CX/RVDF 07/17/6.
- Item 5 (b) Draft Maximum Residue Limits for Veterinary Drugs (at Step 6) (Doc. Ref. ALINORM 06/29/31, App. IV; CX/RVDF 07/17/7): The Committee will consider the draft MRLs for colistin and ractopamine, adopted at Step 5 and advanced to Step 6 by the 29<sup>th</sup> Session of the Codex Alimentarius Commission, as proposed by the Committee (ALINORM 06/29/41, para. 97 and Appendix V). Comments at Step 6, submitted in response to CL 2006/35-RVDF, are summarised in working document CX/RVDF 07/17/7.
- Item 5 (c) Proposed Draft Maximum Residue Limits for Veterinary Drugs (at Step 4) (Doc. Ref. ALINORM 06/29/31, App. V): The Committee will consider the proposed draft MRL for flumequine in shrimps, retained at Step 4 by its 16<sup>th</sup> Session (ALINORM 06/29/31, para. 54).
- Item 5 (d) Proposed Draft Maximum Residue Limits for Veterinary Drugs (at Step 3) (Doc. Ref. ALINORM 06/29/31, App. VI; CX/RVDF 07/17/8): The 16<sup>th</sup> Session of the Committee agreed to circulate the proposed draft MRLs for Erythromiycin and Triclabendazole for comments at Step 3 and further consideration at its next Session (ALINORM 06/29/31, paras 67 and 76). Comments at Step 3, submitted in response to CL 2006/14-RVDF are summarised in working document CX/RVDF 07/17/8.

CX/RVDF 07/17/1 4

Item 6 - Draft Guidelines for the Design and Implementation of National Regulatory Food Safety Assurance Programmes Associated with the Use of Veterinary Drugs in Food Producing Animals (Doc. Ref. ALINORM 06/29/31, App. VII; CX/RVDF 07/17/9): The Committee will consider the draft Guidelines adopted at Step 5 and advanced to Step 6 by the 29<sup>th</sup> Session of the Codex Alimentarius Commission, as proposed by the Committee (ALINORM 06/29/41, para. 115 and Appendix V). Comments at Step 6, submitted in response to CL 2006/35-RVDF, are summarised in working document CX/RVDF 07/17/9.

Item 7 - Methods of Analysis for Residues of Veterinary Drugs in Foods (Doc. Ref. CL 2007/04-RVDF; CX/RVDF 07/17/10; CRD 1): The 16<sup>th</sup> Session of the Committee agreed to ask the Codex Secretariat to issue a Circular Letter requesting that members and observers review the list of methods of analysis identified as suitable to support the MRLs for Veterinary Drugs; review and update any addresses of contact points for information; advise of any methods for which they are no longer able to provide information; and provide information on substances and matrices for which validated methods are still required. The Committee agreed to forward to the 29<sup>th</sup> Session of the Codex Alimentarius Commission the Compendium of Methods of Analysis Identified as Suitable to Support Codex MRLs. It further agreed to reconvene the *ad hoc* Working Group on Methods of Analysis and Sampling, under the co-Chairmanship of Canada and United Kingdom, prior to its next Session to continue work on the identification of suitable methods of analysis for residues of veterinary drugs in foods on the basis of information received in response to the Circular Letter (ALINORM 06/29/31, paras 119-121 and Appendix X).

The 29<sup>th</sup> Session of the Codex Alimentarius Commission noted the existence of the Compendium of Methods of Analysis as Suitable for Support to Codex MRLs developed by the Committee, without adopting it as a Codex text, and agreed that the Secretariat would make it publicly available is such a way as to make it most useful to Members. The Committee was invited to revise the Compendium regularly to keep it updated (ALINORM 06/29/41, para. 196).

Comments received in response to CL 2007/04-RVDF are summarised in CX/RVDF 07/17/10. Recommendations of the *ad hoc* Working Group will be summarised in Conference Room Document 1 (CRD 1).

- **Item 8 Priority List of Veterinary Drugs Requiring Evaluation or Re-evaluation (Doc. Ref. CRD 2; CX/RVDF 07/17/11)**: The 16<sup>th</sup> Session of the Committee agreed to convene the *ad hoc* Working Group on Priorities prior to its next session under the Chairmanship of Australia to consider: i) proposals for compounds to be evaluated to re-evaluated by JECFA; and ii) the report of the physical Working Group on Compounds with no ADI/MRL (see Agenda item 10) (ALINORM 06/29/31, para. 135). Comments and information on the Priority List of Veterinary Drugs Requiring Evaluation or Revaluation, submitted in response to CL 2006/52-RVDF, are summarised in document CX/RVDF 07/17/11. Recommendations of the *ad hoc* Working Group will be summarised in Conference Room Document 2 (CRD 2).
- Item 9 Report of the Working Group on Residues of Veterinary Drugs without ADI/MRL (Doc. Ref. CX/RVDF 07/17/12; CX/RVDF 07/17/12-Add. 1; CRD 2): The 16<sup>th</sup> Session of the Committee also agreed to re-establish the physical Working Group on Residues of Veterinary Drugs without ADI/MRL, led by the European Community, to consider Annex III of CX/RVDF 06/16/13 "Starting Point for a Priority List of veterinary Drugs Requiring Evaluation of Re-evaluation by JECFA". In particular the Working Group will: i) give further consideration to the prioritization on compounds on the list and update the list; ii) consider management option for compound to be evaluated by JECFA where a management option decision is pending; and iii) provide guidance on practical analytical methods suitable for use by national regulatory authority for these compounds (ALINORM 06/29/31, para. 134). The report of the physical Working Group and comments are contained in CX/RVDF 07/17/12 and CX/RVDF 07/17/12-Add.1, respectively.
- Item 10 Discussion Paper on Risk Management Topics and Options for the CCRVDF (Doc. Ref. CX/RVDF 07/17/13; CX/RVDF 07/17/13-Add.1): The 16<sup>th</sup> Session of the Committee agreed to establish an electronic Working Group, led by France, to prepare a Discussion Paper to identify risk management topics and options to be considered at the next Session of the Committee (ALINORM 06/29/31, para. 113). The report of the electronic Working Group and comments are contained in CX/RVDF 07/17/13 and CX/RVDF 07/17/13-Add.1, respectively.
- Item 11 Other Business and Future Work: The Committee will discuss issues raised under Item 1.

CX/RVDF 07/17/1 5

**Item 12 - Date and Place of Next Session**: The Committee will be advised of the tentative dates and place of the next Session.

**Item 13 - 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 Seventeenth Session based on a draft provided by the Secretariat