JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

Fortieth Session

CICG, Geneva, Switzerland

17 – 22 July 2017

REPORT OF THE TWENTY-THIRD SESSION OF THE
CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

Houston, Texas, United States of America

17 – 21 October 2016
TABLE OF CONTENTS

Summary and Status of Work ........................................................................................................................................ page ii
List of Abbreviations .................................................................................................................................................. page iii
Report of the Twenty-third Session of the Codex Committee on Residues of Veterinary Drugs in Foods ........................................................... page 1

Paragraphs

Introduction ........................................................................................................................................................................ 1
Opening of the Session .................................................................................................................................................. 2 - 4
Adoption of the Agenda (Agenda Item 1) .................................................................................................................. 5
Matters referred by the Codex Alimentarius Commission and other subsidiary bodies (Agenda Item 2) .......... 7 - 8
Matters of Interest arising from FAO/WHO and from the 81st Meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) (Agenda Item 3) ............................................................ 18 - 35
Matters of Interest arising from FAO/WHO and from the 81st Meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) (Agenda Item 3) ............................................................ 9 - 18
Diflubenzuron ............................................................................................................................................................. 10
Sisapronil ...................................................................................................................................................................... 11 - 14
Chronic dietary exposure assessment ........................................................................................................................................ 15
MRLs for generic fish species ........................................................................................................................................ 16 - 19
Acute Reference Dose (ARfD) for veterinary drugs ...................................................................................................... 20
MRLs in offal tissues ....................................................................................................................................................... 21 - 23
Processing of food containing residues of veterinary drugs ......................................................................................... 24 - 25
Coordination of the agendas of JECFA and JMPR ........................................................................................................ 26 - 27
Update of EHC 240 .......................................................................................................................................................... 28
Update on JECFA databases .......................................................................................................................................... 29
Guidance for the evaluation of veterinary drug residues in food by JECFA .................................................................... 30
Global Food Consumption database ....................................................................................................................................... 31
Updated on FAO/WHO activities on antimicrobial resistance (AMR) ........................................................................ 32 - 33
Activities of the Joint FAO/IAEA Division of Nuclear Techniques in Food and Agriculture relevant to Codex work ........................................................................................................ 34 - 36
Report of the OIE activities, including the Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) (Agenda Item 4) ........................................................... 37 - 44
Proposed draft RMR for gentian violet at Step 3 (Agenda Item 5) .................................................................................. 45 - 52
Proposed draft MRLs for ivermectin (cattle muscle) and lasalocid sodium (chicken, turkey, quail and pheasant kidney, liver, muscle, skin+fat) at Step 4 (Agenda Item 6.1) ................................................................. 53 - 60
Ivermectin ...................................................................................................................................................................... 53
Lasalocid Sodium ............................................................................................................................................................ 54 - 60
Proposed draft MRLs for ivermectin (cattle fat, kidney, muscle), teflubenzuron (salmon fillet, muscle) and zilpaterol hydrochloride (cattle fat, kidney, liver, muscle) at Step 3 (Agenda Item 6.2) .............. 74 – 89
Ivermectin ...................................................................................................................................................................... 61 - 62
Teflubenzuron ................................................................................................................................................................. 63 - 66
Zilpaterol hydrochloride .................................................................................................................................................. 67 - 74
Discussions paper on unintended presence of residues of veterinary drugs in food commodities resulting from the carry-over of drug residues into feed (Agenda Item 7.1) ........................................... 75 - 88

Discussion paper on the establishment of a rating system to establish priority for CCRVDF work (Agenda Item 7.2) .................................................................................................................................. 89 - 92

Global survey to provide information to the CCRVDF to move compounds from the database on countries’ needs for MRLs to the JECFA Priority List (Report of EWG) and Database on countries’ needs for MRLs (Agenda Item 8) .......................................................................................................... 93 - 104

Draft Priority List of veterinary drugs requiring evaluation or re-evaluation by JECFA (replies to CL 2015/18-RVDF) (Agenda Item 9) ........................................................................................................ 105 - 122

Other business and future work (Agenda Item 10) ........................................................................................................ 123 - 139

Proposal from Kenya on offal ........................................................................................................................................ 125 - 130

Proposal from Canada to revise the criteria for the use of multi residue analytical methods for the determination and identification of veterinary drugs in foods in CAC/GL 71-2009 ...... 131 - 132

Proposal from Argentina on pilot work for old compounds (e.g. ethion) ................................................................. 133 - 138

Chair’s report on the status of CCRVDF ....................................................................................................................... 139

Date and place of next session (Agenda Item 11) ........................................................................................................ 140

Appendices

Appendix I - List of Participants .............................................................................................................................. page 16

Appendix II - Proposed Draft Risk Management Recommendation for Residues of Veterinary Drugs (at Step 5) ............................................................................................................................. page 31

Appendix III - Proposed Draft Maximum Residue Limits for Veterinary Drugs (discontinued by CCRDVF23) ............................................................................................................................. page 32

Appendix IV - Proposed Draft Maximum Residue Limits for Veterinary Drugs (at Step 5/8) .................... page 33

Appendix V - Proposed Draft Maximum Residue Limits for Veterinary Drugs (at Step 4) ......................... page 36

Appendix VI - Priority List of Veterinary Drugs for Evaluation or Re-evaluation by JECFA (for approval) ............................................................................................................................ page 37
## SUMMARY AND STATUS OF WORK

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Members/CC EXEC73/CAC 40</td>
<td>Comments/Adoption</td>
<td>Proposed draft MRLs for: lasalocid sodium (chicken, turkey, quail and pheasant kidney, liver, muscle, skin+fat) (78th JECFA); ivermectin (cattle fat, kidney, liver, muscle) (81st JECFA); tebufenuron (salmon fillet, muscle) (81st JECFA);</td>
<td>CAC/MRL2 and Database of MRLs and RMR for residues of veterinary drugs in foods</td>
<td>5/8</td>
<td>60, 62, 66, App. IV</td>
</tr>
<tr>
<td>Members/CC EXEC73/CAC 40</td>
<td>Comments/Adoption</td>
<td>Proposed draft RMR for gentian violet</td>
<td></td>
<td>5</td>
<td>50, App. II</td>
</tr>
<tr>
<td>JECFA (2017) CCRVDF24</td>
<td>Scientific advice/Discussion</td>
<td>Proposed draft MRLs for zilpaterol hydrochloride (cattle fat, kidney, liver, muscle) (81st JECFA)</td>
<td></td>
<td>4</td>
<td>74, App. V</td>
</tr>
<tr>
<td>CAC40 JECFA (2017) CCRVDF24</td>
<td>Approval/Scientific advice/Discussion</td>
<td>Draft priority list of veterinary drugs requiring evaluation or re-evaluation by JECFA</td>
<td>Ongoing work</td>
<td>1/2/3</td>
<td>113, 138, App. VI Part A</td>
</tr>
<tr>
<td>Members PWG (Australia) CCRVDF24</td>
<td>Comments/Discussion</td>
<td>Draft priority list of veterinary drugs requiring evaluation or re-evaluation by JECFA</td>
<td></td>
<td>-</td>
<td>113</td>
</tr>
<tr>
<td>CAC40</td>
<td>Approval</td>
<td>Proposed draft MRL for ivermectin (cattle muscle) (78th JECFA)</td>
<td></td>
<td>-</td>
<td>Discontinuation 53, App. III</td>
</tr>
<tr>
<td>EWG (Norway and Japan) CCRVDF24</td>
<td>Drafting/Discussion</td>
<td>Discussion paper on MRLs for groups of fish species</td>
<td></td>
<td>18</td>
<td></td>
</tr>
<tr>
<td>FAO/WHO CCRVDF</td>
<td>Scientific advice/Discussion</td>
<td>Request for scientific advice to FAO and WHO to address the issue of unavoidable and unintended residues of approved veterinary drugs in foods resulting from carry-over of veterinary drugs residues in feed</td>
<td></td>
<td>86</td>
<td></td>
</tr>
<tr>
<td>CCRVDF23</td>
<td>Discontinued</td>
<td>Discussion paper on unintended presence of residues of veterinary drugs in food commodities resulting from the carry-over of drug residues into feed</td>
<td></td>
<td>88</td>
<td></td>
</tr>
<tr>
<td>CCEXEC73/ CCRVDF23</td>
<td>Discontinued</td>
<td>Discussion paper on the establishment of a rating system to establish priority for CCRVDF work</td>
<td></td>
<td>92</td>
<td></td>
</tr>
<tr>
<td>Members CCRVDF24</td>
<td>Comments/Discussion</td>
<td>Database of countries needs for MRLs</td>
<td></td>
<td>103</td>
<td></td>
</tr>
<tr>
<td>EWG (USA and Costa Rica) CCRVDF24</td>
<td>Drafting/Discussion</td>
<td>Analysis of the results of the Global survey to provide information to the CCRVDF to move compounds from the database on countries’ needs for MRLs to the JECFA Priority list</td>
<td></td>
<td>103, 104</td>
<td></td>
</tr>
<tr>
<td>Health for Animals CCRVDF24</td>
<td>Drafting/Discussion</td>
<td>Discussion paper on the evaluation of the rationale for the decline in new compounds to be included in the CCRVDF Priority List for evaluation by JECFA</td>
<td></td>
<td>115</td>
<td></td>
</tr>
<tr>
<td>EWG (Kenya) CCRVDF24</td>
<td>Drafting/Discussion</td>
<td>Discussion paper on edible offal tissues (possible definition and edible offal tissues of interest in international trade)</td>
<td></td>
<td>130</td>
<td></td>
</tr>
<tr>
<td>Canada CCRVDF24</td>
<td>Drafting/Discussion</td>
<td>Discussion paper on the revision of the criteria for the use of multi residue analytical methods for the determination and identification of veterinary drugs in foods in CAC/GL 71-2009</td>
<td></td>
<td>131</td>
<td></td>
</tr>
<tr>
<td>Abbreviation</td>
<td>Full Form</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>--------------</td>
<td>-----------</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADI</td>
<td>Acceptable Daily Intake</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ALARA</td>
<td>As Low As Reasonably Achievable</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AMR</td>
<td>Antimicrobial Resistance</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>APFSWG</td>
<td>OIE Working Group on Animal Production Food Safety</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ARfD</td>
<td>Acute Reference Dose</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>bw</td>
<td>body weight</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CAC</td>
<td>Codex Alimentarius Commission</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CCEXEC</td>
<td>Executive Committee of the Codex Alimentarius Commission</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CCRVDF</td>
<td>Codex Committee on Residues of Veterinary Drugs in Foods</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CCPR</td>
<td>Codex Committee on Pesticide Residues</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CL</td>
<td>Circular Letter</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CRD</td>
<td>Conference Room Document</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EHC</td>
<td>Environmental Health Criteria</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EU</td>
<td>European Union</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EWG</td>
<td>Electronic Working Group</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FAO</td>
<td>Food and Agriculture Organization of the United Nations</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>GAP</td>
<td>Good Agricultural Practice</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>GEADE</td>
<td>Estimated Acute Dietary Exposure</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>GL</td>
<td>Guidelines</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>GMP</td>
<td>Good Manufacturing Practice</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>GVP</td>
<td>Good Veterinary Practice</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IAEA</td>
<td>International Atomic Energy Agency</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>JECFA</td>
<td>Joint FAO/WHO Expert Committee on Food Additives</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>JMPR</td>
<td>Joint FAO/WHO Meeting on Pesticide Residues</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LOAEL</td>
<td>Lowest-Observed-Adverse-Effect Level</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MRL</td>
<td>Maximum Residue Limit</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NOAEL</td>
<td>No-observed-adverse-effect level</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>OIE</td>
<td>World Organization for Animal Health</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PCA</td>
<td>4-chloroaniline</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PVS</td>
<td>Performance of Veterinary Services</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PWG</td>
<td>Physical Working Group</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>R&amp;D</td>
<td>Research and Development</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RMRR</td>
<td>Risk Management Recommendation</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SPS</td>
<td>Sanitary and Phytosanitary</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>USA</td>
<td>United States of America</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>USDA</td>
<td>United States Department of Agriculture</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>VICH</td>
<td>International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>VOF</td>
<td>VICH Outreach Forum</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organization</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>WG</td>
<td>Working Group</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
INTRODUCTION

1. The Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF) held its Twenty-third Session in Houston, Texas, the United States of America, from 16 to 20 October 2016 at the kind invitation of the Government of the United States of America. Dr Kevin Greenlees, Senior Advisor for Science and Policy, United States Food and Drug Administration, Center for Veterinary Medicine, chaired the Session. The Session was attended by participants from 62 Member countries, one Member organization and 8 observer organizations and FAO and WHO. The list of participants, including the Secretariats, is given in Appendix I to this report.

OPENING OF THE SESSION¹

2. Mr Brian Ronholm, Deputy Under Secretary Food Safety USDA, opened the Session. In his remarks (CRD13) he welcomed the participants and underlined the importance of Codex being the preeminent international food standards setting body by elaborating standards that were science based, relevant worldwide and developed by consensus.

3. Mr Markus Lipp and Mr Philippe Verger, Representatives of FAO and WHO, Mr Mahamadou Sako (CRD7), Vice Chair of CAC and Mr Tom Heilandt, Secretary of CAC (CRD23), also addressed the meeting.

Division of Competence²

4. The Committee noted the division of competence between the European Union (EU) and its Member States, according to paragraph 5, Rule II of the Procedure of the Codex Alimentarius Commission.

ADOPTION OF THE AGENDA (Agenda Item 1)³

5. As decided at CCRVDF22, the Committee agreed to have a discussion under Item 10 on the issues and concerns that impact the ability of CCRVDF to efficiently perform its work. With this addition the Committee adopted the Provisional Agenda as its Agenda for the Session.

6. The Committee agreed to establish an in-session WG chaired by Australia to prepare recommendations on the Priority List of Veterinary Drugs for evaluation by JECFA (Item 9) for consideration by the Plenary.

MATTERS REFERRED BY THE CODEX ALIMENTARIUS COMMISSION AND OTHER SUBSIDIARY BODIES (Agenda Item 2)⁴

7. The Committee noted the information concerning the decisions and discussions of CAC38 and CAC39 related to the work of CCRVDF.

8. The Committee further noted that the request of CCEXEC70 to consider the need to develop an approach to manage its work would be considered under Item 7.2.

MATTERS OF INTEREST ARISING FROM FAO/WHO AND FROM THE 81ST MEETING OF THE JOINT FAO/WHO EXPERT COMMITTEE ON FOOD ADDITIVES (JECFA) (Agenda Item 3) ⁵

9. The Representatives of FAO and WHO introduced the paper and noted that some of the matters would be addressed when discussing the relevant items.

Diflubenzuron

10. The Representative of WHO summarized the conclusion of the 81st JECFA and confirmed that JECFA could not establish an ADI for diflubenzuron due to the absence of adequate data on the occurrence of 4-chloroaniline (PCA), a metabolite of diflubenzuron known to be carcinogenic and genotoxic. Consequently, JECFA was not able to recommend MRLs for diflubenzuron in fish.

¹ Opening remarks and other speeches (CRD7, CRD13 and CRD23)
² Annotated Agenda – Division of competence between the European Union and its Member States (CRD1)
³ CX/RVDF 16/23/1
⁴ CX/RVDF 16/23/2; Comments of Nigeria (CRD10), Senegal (CRD4), African Union (CRD5)
⁵ CX/RVDF 16/23/3; Comments of India (CRD15), Nigeria (CRD10), Senegal (CRD4), Trinidad and Tobago (CRD21), African Union (CRD5), HealthforAnimals (CRD9)
Sisapronil

11. The Representative of WHO reported the conclusion of the 81st JECFA and in particular that due to the absence of appropriate data for a long-term toxicity study in the presence of a prolonged plasma half-life, JECFA was not able to establish an ADI and recommend MRLs.

Discussion

12. The Observer from HealthforAnimals, referring to CRD9, supported the JECFA conclusion on the lowest NOAEL for sisapronil, which was the same recommended by the sponsor. However, the Observer reiterated their position regarding the possibility of using a safety factor of 100 to establish an ADI in the absence of additional uncertainties. With regard to the JECFA request for additional data, the Observer asked the JECFA Secretariat if other data might be generated, in lieu of a one-year dog study, which could allow the elaboration of an ADI.

13. The Representative of FAO replied that the JECFA Secretariat had always encouraged interactions with stakeholders and would consider the request for options to assess adequately the long-term effects of sisapronil.

Conclusion

14. The Committee noted that the JECFA Secretariat and the sponsor would continue discussions on approaches to satisfy the data needs to complete the evaluation of sisapronil.

General items

Chronic dietary exposure assessment

15. The Representative of WHO summarized the JECFA considerations and highlighted the importance of harmonizing the model to assess chronic dietary exposure in particular for compounds used both as pesticides and as veterinary drugs.

MRLs for generic fish species

16. The Representative of FAO introduced the matter and outlined the answers provided by the 81st JECFA in response to the questions by CCRVDF22. In particular, the conclusion that in order to properly address the issue of extrapolation of MRLs to fish species, JECFA required (in addition to the information identified by the 78th JECFA) further information on adequate groupings of fish species so that representative species could be identified from which MRLs could then be extrapolated to other similar species.

17. The 81st JECFA noted that several principles for grouping of fish species might be applied and that it would be critical to develop clear boundaries around each group and define the inclusion and exclusion criteria for each group.

Conclusion

18. To respond to the request of the 81st JECFA, the Committee agreed to establish an EWG, hosted by Norway and co-hosted by Japan, working in English only and using the pilot electronic platform for EWGs, to:

- Develop a discussion paper on the feasibility of establishing MRLs for groups of fish species for veterinary drugs being considered by JECFA/CCRVDF in the light of:
  i. Public health
  ii. international trade

- The paper should consider what grouping might be appropriate for finfish, crustaceans and molluscs.

19. The Committee noted that:

- Chile and Senegal had kindly offered to provide translations of relevant EWG documents to facilitate the participation of Spanish- and French-speaking countries.
- The report of the EWG would be made available at least three months before CCRVDF24.
Acute Reference Dose (ARfD) for veterinary drugs

20. The Representative of WHO reminded the Committee that JECFA had finalized the guidance for establishing ARfD for veterinary drugs. The document had been posted for public comments on the WHO website\(^6\), for transparency.

MRLs in offal tissues

21. The Representative of FAO introduced JECFA's response to the request of CCRVDF\(^22\) regarding the establishment of MRLs for zilpaterol hydrochloride in offal. He explained that JECFA had noted that several definitions for offal had been developed by various regulators or other institutions, and that these definitions, however, were not harmonized.

22. The 81st JECFA requested CCRVDF for further guidance on a defined list of tissues of offal of interest to CCRVDF with a view of setting MRLs in those tissues (see Item 10).

Discussion

23. The Committee noted that the development of a list of offal tissues for setting MRLs could be relevant to the work of CCPR and that it would be important to harmonise such lists. In this regard, it was also noted that CCPR was currently working on the revision of the Classification for Food and Feed, which included a section on animal products.

Processing of food containing residues of veterinary drugs

24. The Representative of FAO noted that during the evaluation of diflubenzuron by the 81st JECFA, the possibility of its thermal degradation to PCA, a metabolite of substantial toxicological concern, had been discussed.

25. It was further noted that, similarly to current practices applied by regulatory authorities involved in the assessment of veterinary drugs for use in food-producing animals, JECFA would not routinely assess, or seek to address, the effects of processing foods on residues of veterinary drugs. However, if there were evidence, or some other reason, to suspect that processing of foods containing residues of specific veterinary drugs could have toxicological implications, such as for diflubenzuron, the effect of processing would be taken into consideration in the assessment of that compound.

Coordination of the agendas of JECFA and JMPR

26. The Representative of WHO informed the Committee that a number of compounds were scheduled for evaluation or re-evaluation both as pesticides and as veterinary drugs leading to a waste of resources and possible confusion in case of different interpretations by JECFA and JMPR. The Representative emphasised the need to increase efforts to synchronize the toxicological evaluations by JECFA and JMPR.

Conclusion

27. The Committee agreed to the proposal of the Secretariat to add information on the registration of the compound as a pesticide and, where applicable, information on the JMPR evaluation to the form requesting information on compounds for evaluation by JECFA, attached to the CL requesting proposals for inclusion in the Priority List.

Update of EHC 240

28. The Representative of WHO mentioned that both JECFA and JMPR had a standing agenda item to update EHC 240 and the Secretariat should coordinate the future update of EHC 240 in agreement with the two expert bodies.

Update on JECFA databases

29. The Representative of FAO informed the Committee of the recently updated FAO JECFA databases. The new databases allowed for improved interconnectivity with other databases, such as the Codex database of MRLs and RMRs of veterinary drugs and the WHO summaries of JECFA evaluations. The new databases are available on the FAO JECFA web site\(^7\).

---

\(^6\) http://www.who.int/entity/foodsafety/chem/jecfa/ARfd/en/index.html

\(^7\) http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/en/
**Guidance for the evaluation of veterinary drug residues in food by JECFA**

30. The Representative of FAO informed the Committee that the JECFA Secretariat had revised the guidance documents for JECFA monographers and reviewers evaluating residues of veterinary drugs. While these guidance documents are intended primarily for JECFA experts who prepare residue and toxicological monographs for JECFA, they would also be useful to manufacturers who submit dossiers to JECFA and other parties interested in understanding the process followed in the evaluation of residues of veterinary drugs in food by JECFA. The revised FAO JECFA guidance is available on the FAO website.8

**Global Food Consumption database**

31. The Representative of WHO summarized the general consideration and reiterated the importance for Codex Members to contribute to the next call for data on individual food consumption to be launched in 2017.

**Updated on FAO/WHO activities on antimicrobial resistance (AMR)**

32. The Representative of FAO informed the Committee of the recent participation of the Director-Generals of FAO and WHO together with the Director General of OIE in a high level meeting of the UN General Assembly, which addressed the issue of AMR. At the meeting Member States agreed upon a strong political declaration that provided a good basis for the international community to move forward in addressing the issue of AMR.

33. The Representative also informed the Committee of the publication of the FAO Action Plan on Antimicrobial Resistance (2016-2020)9 in support of the implementation of the WHO Global Action Plan on Antimicrobial Resistance10. It was further stressed that FAO, WHO and OIE continue to work together to support the implementation of a One Health approach to AMR within the tripartite framework.

**Activities of the Joint FAO/IAEA Division of Nuclear Techniques in Food and Relevant to Codex Work**

34. The Representative of IAEA introduced the paper and drew attention to recent and current activities being managed by the Joint Division. He highlighted coordinated research projects and technical cooperation projects of interest to the Committee and work of the Joint Division related to capacity building, promoting laboratory networks and enhancing active participation of developing countries in Codex matters including occurrence data collection and involvement of laboratory scientists in Committee meetings. The Representative also reported on the Food Contaminant and Residue Information System database of analytical methods for veterinary drug and related residues, encouraging countries to continue to use and update the database with new methods.

35. A number of developing countries noted how the support had made a significant difference in their countries’ food control systems and boosted their participation in Committee meetings; they requested for continued support.

**Conclusion**

36. The Committee noted the report and thanked the Joint Division for their ongoing support and initiatives especially to developing countries.

**REPORT ON THE OIE ACTIVITIES, INCLUDING THE HARMONISATION OF TECHNICAL REQUIREMENTS FOR REGISTRATION OF VETERINARY MEDICINAL PRODUCTS - VICH (Agenda Item 4)**

37. The Observer from the OIE presented the paper and welcomed ongoing close collaboration with Codex also in the framework of the SPS Agreement of the WTO.

38. The Observer highlighted the importance placed by the OIE on food safety in an integrated food chain approach, recognising the contribution of animal health to food safety and the close cooperation with Codex, in particular through the work of the OIE APFSWG, in which Codex, FAO and WHO experts participate.

---

8 Module I: http://www.fao.org/3/a-bl002e.pdf
Module II: http://www.fao.org/3/a-bl003e.pdf
Module III: http://www.fao.org/3/a-bl004e.pdf

9 http://www.fao.org/3/a-i5996e.pdf

10 http://www.wpro.who.int/entity/drug_resistance/resources/global_action_plan_eng.pdf

11 CX/RVDF 16/23/3 Add.1; Comments of Nigeria (CRD10), African Union (CRD5)

12 CX/RVDF 16/23/4; Comments of Nigeria (CRD10), Senegal (CRD4), African Union (CRD5)
39. A key focus of the OIE remains AMR for which OIE works in close coordination with WHO and FAO in the tripartite framework. The Observer informed the Committee of the two resolutions on AMR adopted during the last General Sessions (2015 and 2016). One recommended to the OIE to collect and report standardised quantitative data on antimicrobial agents used in animals. This initiative had been launched at the end of 2015 and the first report would be published before the end of 2016.

40. The Observer noted the continued success of extending VICH activities to non-VICH Member Countries through the VOF and congratulated Uganda and the Kingdom of Saudi Arabia for joining the VOF.

41. The Observer reported on capacity building activities relevant to veterinary medicines, highlighting the PVS pathway as a means to assess and improve Member Countries' veterinary services, which was now offering the opportunity to improve veterinary legislation, including the regulation of veterinary medicines.

42. The Observer provided an update on the fourth cycle of training seminars for national focal points on veterinary products, involving 500 participants, which had addressed topics such as antimicrobial resistance, good quality of veterinary medicinal products and antiparasitic drugs and challenges.

43. In conclusion the Observer outlined the three major objectives of OIE's Sixth Strategic Plan (2016-2020) and announced the Second International Symposium on Alternatives to Antibiotics to be held in Paris (12-15 December 2016).

Conclusion

44. The Committee noted the report and expressed thanks to the OIE particularly regarding work on VICH.

PROPOSED DRAFT RMR FOR GENTIAN VIOLET AT STEP 3 (Agenda Item 5) 13

45. The Chair introduced the item and recalled that this recommendation had been considered at the last CCRVDF where delegations supported the establishment of a RMR for gentian violet. However, there were divergent views as to whether the inclusion of the last sentence of the RMR on the example of a risk mitigation measure to prevent residues of gentian violet in food (e.g. the non-use of this compound in food producing animals) should be part of the RMR. In view of this, the Committee had decided to circulate both options (i.e. with and without the example) at Step 3 for further consideration at the present session.

Discussion

46. Delegations reaffirmed their previous views in favour of Option 1 (with the example) and Option 2 (without the example) and noted that they had no further language to offer to assist CCRVDF in reaching a compromise solution.

47. Delegations in favour of Option 1 reiterated that: the risk associated with the use of this compound could not be ignored; JECFA had carried out the risk assessment; the RMR should be consistent with other RMRs on similar compounds (e.g. malachite green) recommended by the Committee; the language used in the last sentence of the RMR was flexible enough to allow national authorities to decide on the most appropriate measure to contain or minimize residues of gentian violet in food.

48. Delegations in favour of Option 2 reiterated that: the language used in the last sentence of the RMR was overly restrictive; could limit national authorities from applying other risk management measures they considered more appropriate; the application of the RMR as in Option 1 could introduce further expenses to national control programs; gentian violet was very efficient for the topical treatment of skin and eye lesions; Codex should provide broad guidance as the selection of specific risk management measures is in the remit of national authorities.

49. Delegations could not agree on compromise language, which attempted to bridge the two options by indicating that other suitable measures to prevent residues of gentian violet in food could be applied in addition to the non-use of gentian violet in food producing animals.

Conclusion

50. The Committee agreed to forward the RMR on gentian violet as in Option 1 to CAC40 for adoption at Step 5 (Appendix II).

13 REP15/RVDF Appendix III; Comments of Argentina, Costa Rica, Cuba, Ecuador, Egypt, European Union, Japan, New Zealand, Paraguay, Peru (CX/RVDF 16/23/5); Chile, El Salvador, Philippines, Thailand, African Union (CX/RVDF 16/23/5 Add.1); India (CRD15), Indonesia (CDR14), Mali (CDR12), Nigeria (CDR10), Panama (CDR19), Republic of Korea (CRD18), Senegal (CRD4), Trinidad and Tobago (CRD21)
51. The Committee acknowledged that this decision would allow Codex members to further reflect on the text of the RMR in order to make a final decision at its next session.

52. The United States of America expressed its reservation to the last sentence of the RMR (i.e. “This can be accomplished by not using gentian violet in food producing animals”).

PROPOSED DRAFT MRLS FOR IVERMECTIN (CATTLE MUSCLE) AND LASALOCID SODIUM (CHICKEN, TURKEY, QUAIL AND PHEASANT KIDNEY, LIVER, MUSCLE, SKIN+FAT) AT STEP 4 (Agenda Item 6.1) ¹⁴

Ivermectin

53. The Committee agreed to discontinue work on the proposed draft MRL for ivermectin in cattle muscle recommended by the 78th JECFA, in view of the new MRLs recommended by the 81st JECFA (Item 6.2) (Appendix III).

Lasalocid Sodium

54. The JECFA Secretariat drew the Committee's attention to the replies of the 81st JECFA to the concerns of Canada and the EU regarding the JECFA evaluation of lasalocid sodium. The 81st JECFA had provided all explanations on the calculation of the MRLs, which had remained unchanged, and had provided the explanation on the approach used to estimate exposure to be compared with the microbiological ADI.

Discussion

55. In view of the responses of the 81st JECFA to the concerns raised at CCRVDF22, delegations were in favour of advancing the MRLs in the Step procedure.

56. The EU expressed the reservation that in their view a risk to consumers could not be ruled out, as in the absence of a methodology for derivation of a microbiological acute reference dose there was no health-based guidance value with which to satisfactorily compare the acute exposure. As a consequence, the EU noted they could not support the proposed draft Codex MRLs.

57. The Committee noted the reservation of the EU for the reasons stated above.

58. In response to the EU concern, the Representative of WHO explained that a microbiological ADI for lasalocid sodium was much lower than a possible microbiological ARfD. Moreover, the acute dietary exposure would be below such an ARfD. Therefore, the Representative of WHO confirmed that the chronic dietary exposure was the appropriate model to be compared with the microbiological ADI, which had resulted in the absence of health concerns for this compound.

59. The Representative of FAO clarified that the 81st JECFA meeting had addressed the topic of setting a microbiological ADI and had noted the particular consideration necessary to evaluate exposure of the intestinal microbiota in the colon following acute and chronic oral doses of the veterinary drug residue in food. After a comprehensive review of the possible hazards and the relevant exposure of the intestinal microbiota in the colon, JECFA had determined that there was no additional risk to the consumer. He encouraged the members of CCRVDF to review the 81st JECFA report as it explained the scientific details.

Conclusion

60. The Committee forwarded the MRLs for lasalocid sodium to CAC40 for adoption at Step 5/8 (Appendix IV).

¹⁴ REP15/RVDF Appendix V; Comments of El Salvador, European Union, Philippines (CRD3), Argentina (CRD16), Ecuador (CRD17), India (CRD15), Panama (CRD19), Republic of Korea (CRD18), Trinidad and Tobago (CRD21).
PROPOSED DRAFT MRLS FOR IVERMECTIN (CATTLE FAT, KIDNEY, LIVER, MUSCLE), TEFUBENZURON (SALMON FILLET, MUSCLE) AND ZILPATEROL HYDROCHLORIDE (CATTLE FAT, KIDNEY, LIVER, MUSCLE) AT STEP 3 (Agenda Item 6.2) 15

Ivermectin

61. The JECFA Secretariat informed the Committee that the 81st JECFA had withdrawn the previous ADI and established a new ADI of 0-10 μg/kg bw on the basis of a NOAEL of 0.5 mg/kg bw per day for neurological effects (mydriasis) and retardation of weight gain in a 14-week dog study, and had recommended new MRLs for cattle fat, kidney, liver and muscle. An ARfD was established and acute exposure was also assessed.

Conclusion

62. The Committee agreed to forward the proposed draft MRLs for ivermectin to CAC40 for adoption at Step 5/8 (Appendix IV).

Teflubenzuron

63. The JECFA Secretariat informed the Committee that the 81st JECFA had established an ADI of 0-5 µg/kg bw. The chronic dietary exposure would correspond to 14 to 43% of the ADI. The JECFA also concluded that an ARfD was not necessary.

Discussion

64. A delegation noted that JMPR in the September 2016 meeting had evaluated teflubenzuron. JMPR had assigned the same ADI of the 81st JECFA and recommended several MRLs for agriculture commodities. The delegation also indicated that according to their calculation the sum of exposure from JMPR and JECFA would remain below the ADI.

65. One observer expressed concern for the negative impact of the use of teflubenzuron in agriculture on bees and was of the view that additional studies should be conducted to evaluate the impact of the pesticide on the insect population.

Conclusion

66. The Committee agreed to forward the proposed draft MRLs for teflubenzuron to CAC40 for adoption at Step 5/8 (Appendix IV).

Zilpaterol hydrochloride

67. The JECFA Secretariat informed the Committee that the 81st JECFA had reaffirmed the ADI of 0-0.04 µg/kg bw and established an ARfD of 0.04 µg/kg bw based on a LOAEL of 0.76 µg/kg bw for acute pharmacological effects observed in a single-dose human study, with application of an uncertainty factor of 20, comprising a default uncertainty factor of 10 for human individual variability and an additional uncertainty factor of 2 to account for use of a LOAEL for a slight effect instead of a NOAEL. The GEADE is 1.9 µg/day for the general population, which represents approximately 80% of the ARfD, and 0.57 µg/day for children, which represents approximately 94% of the ARfD. Based on this data JECFA was able to recommend MRLs for cattle kidney, liver and muscle.

Discussion

68. The Chair informed the Committee of the discussion between JECFA and the pharmaceutical sponsor on some limitations of the data previously submitted to the 81st JECFA (as noted in the JECFA report) and the offer of the sponsor to provide additional data to JECFA. In view of this, the Chair proposed to hold the MRLs at Step 4 so that JECFA could evaluate the additional data and thus provide the best risk assessment possible of the compound.

69. Delegations generally supported or did not object to the proposal to hold the MRLs at Step 4.

15 CX/RVDF 16/23/6; Comments of Brazil, Cuba, Philippines, HealthforAnimals (CX/RVDF 16/23/6 Add.1); European Union, Nigeria, Senegal, African Union (CX/RVDF 16/23/6 Add.2), Argentina (CRD16), Ecuador (CRD17), India (CRD15), Indonesia (CRD14), Mali (CRD12), Panama (CRD19), Republic of Korea (CRD18)
While generally supporting or not objecting to holding the MRLs at Step 4, the following comments were put forward by individual delegations: concern that non-compliance with GVP might expose populations at risk; the use of growth promoters is not allowed in a number of countries; it would be preferable to advance the MRLs to Step 5; the use of veterinary drugs should be restricted to therapeutic purpose; the use of growth promoters may lead to animal welfare concerns; literature references indicate an increase loss of cattle due to the use of zilpaterol and a potential risk of additional exposure through grazing in pasture contaminated by excreta (urine and faeces) of treated animals and possibly ground water and drinking water.

The EU, supported by some delegations and one observer, stated that they were opposed to the advancement of zilpaterol in the Step procedure and to the establishment of Codex MRLs for zilpaterol. The EU stated they did not believe that our resources were wisely spent on the assessment of growth promoters. It is a general policy in the EU to prohibit the administration of beta-agonists to healthy animals solely for the purpose of growth promotion.

The Representative of FAO thanked the members and observers for the discussion and the issues raised and encouraged all participants to forward all relevant information and data so that they could be considered by JECFA at its next meeting.

Members were encouraged to forward their concerns to JECFA using the concern form.

**Conclusion**

The Committee agreed to hold the MRLs for zilpaterol hydrochloride at Step 4 for consideration at its next Session in light of the JECFA evaluation of the additional studies (Appendix V).

**DISCUSSION PAPER ON UNINTENDED PRESENCE OF RESIDUES OF VETERINARY DRUGS IN FOOD COMMODITIES RESULTING FROM THE CARRY-OVER OF DRUG RESIDUES INTO FEED**

Coverage of the Code to manage the unavoidable and unintended residues of approved veterinary drugs in foods resulting from carry-over of veterinary drugs in feed, ("carry-over residues")

The Committee addressed the above points as follows:

Coverage of the Code to manage the unavoidable and unintended residues of approved veterinary drugs in foods resulting from carry-over of veterinary drugs in feed, ("carry-over residues")

The Committee noted the following views:

There is insufficient information to determine if the guidance in the Code is sufficient and if there is a need to include specific measures or to develop specific guidance as a separate document at this point in time.

CX/RVDF 16/23/7 identifies a large number of documents on how this matter has been addressed around the world, which could be used by countries in conjunction with the Code.

---

16 Risk Analysis Principles applied by the Codex Committee on Residues of Veterinary Drugs in Foods (Codex Procedural Manual)
17 CX/RVDF 16/23/7; Report of the PWG on unintended presence of residues of veterinary drugs in food commodities resulting from the carry-over of drug residues into feed (CRD2); Comments of Argentina (CRD16), Ecuador (CRD17), El Salvador (CRD6), India (CRD15), Mali (CRD12), Nigeria (CRD10), Senegal (CRD4), African Union (CRD5)
Before deciding on new work on the revision of the Code or the development of specific guidance, it would be important to investigate the root causes of carry-over residues; this would assist in determining the need for further guidance and/or for capacity development assistance to countries for implementing the Code.

The needs of countries and the different ways they are implementing the Code should be taken into account when considering further action on the revision of the Code or the development of separate specific guidance.

Elaboration of risk management recommendations to minimize carry-over residues

78. The Committee noted that the elaboration of risk management recommendations (either qualitative or quantitative or both) should be carried out based on the assumption that despite all relevant good practices (e.g. GAP, GMP, etc.) being fully followed, it was not possible to avoid the presence of low levels of certain veterinary drugs in feed that could then be transferred to food. This framework would ensure that the risk management recommendation would not be perceived as allowing non-compliance with relevant good practices but as a measure to protect consumer health and to ensure fair practices in trade.

79. The Committee noted that it was important to determine whether such low level presence of residues in food associated with unavoidable and unintended carry-over in feed: (i) would constitute a threat to human health; and (ii) would impact negatively on trade. It was also important to determine what risk management measures could be taken/were available to the Committee to address the issue and how the selected measure would be applied (i.e. as opposed to MRLs for veterinary drugs as described in the Procedural Manual).

80. The Committee also noted that there were only a few compounds presenting physical/chemical characteristics that would prompt unavoidable and unintended carry-over of certain veterinary drugs in feed that could be transferred to food.

81. Delegations noted that these low levels could possibly be addressed by setting numerical standards at a level that should be as low as reasonable achievable to protect consumer health while addressing the identified trade issue. One observer noted that another option was to ensure that any numerical standard remain consistent with the ADI, which would allow greater flexibility than ALARA.

82. The Committee further noted that the key issue was to determine whether there was a public health and/or trade issue associated with carry-over of veterinary drugs from feed into food that should be addressed by CCRVDF and the risk management options available.

83. Based on the above discussion, the Committee agreed with the criteria for requesting risk management recommendations/measures and the general considerations for risk management recommendations/measures, as proposed in CRD2.

84. In addition, the Committee agreed that the general considerations should also address the status of implementation of good practices and the investigation of the root causes of carry-over residues. This would assist in determining the need for further guidance and/or for capacity development assistance to countries for implementing the Code.

Definition of appropriate questions for scientific advice

85. The Committee agreed to request FAO and WHO to test the criteria for requesting risk management measures/recommendations as well as the general considerations for risk management measures/recommendations and to use lasalocid sodium in eggs as a case-study.

86. The Committee further agreed on the following set of questions that would constitute the Terms of Reference of the CCRVDF request for scientific advice to FAO and WHO:

Terms of Reference of CCRVDF request for scientific advice to FAO and WHO to address the issue of unavoidable and unintended residues of approved veterinary drugs in foods resulting from carry-over of veterinary drugs in feed:

The Committee requests scientific advice from FAO and WHO on the following, using residues of lasalocid sodium in eggs as a working example:

- Will the presence of residue of a veterinary drug in food at levels associated with unavoidable and unintended carry-over in feed constitute a risk to human health?
- Which risk management recommendations (e.g. limit, standards, etc.) could be established to address the trade issue while protecting human health?
Are additional measures to those in the Code of Practice on Good Animal Feeding (CAC/RCP 54-2004) available to minimise unavoidable and unintended carry over in feed?

In providing scientific advice, FAO and WHO will take into consideration the report of the PWG and discussion at CCRVDF23.

87. The Representative of FAO thanked the Committee for entrusting FAO and WHO with this request for scientific advice. The Representative further reminded the Committee that FAO/WHO would need inputs of Codex members, including surveillance data and information regarding the implementation of any national systems. He noted that according to the current budget and resource situation this work would probably not start before 2018.

Conclusion

88. The Committee agreed that all the issues around the unavoidable and unintended residues of approved veterinary drugs in foods resulting from carry-over of veterinary drug residues in feed raised in CRD2 had been addressed and that no further issues remained for discussion while awaiting the outcome of the FAO/WHO scientific advice on this matter.

DISCUSSION PAPER ON THE ESTABLISHMENT OF A RATING SYSTEM TO ESTABLISH PRIORITY FOR CCRVDF WORK (Agenda Item 7.2)18

89. France, as Host of the EWG, introduced CX/RVDF 16/23/8 and recalled that the EWG had been established at its previous session to prepare a discussion paper exploring the feasibility of adopting a rating type system to establish priorities for the work of the Committee.

90. The Host illustrated the steps of the tool that had been developed by the EWG and presented the options to proceed or otherwise with the tool that were now before the Committee.

Discussion

91. It was noted that the Committee did not currently have a workload that required a tool for prioritising its work, but that in the future, the tool presented could be useful should the work of the Committee increase.

Conclusion

92. The Committee agreed to discontinue consideration of this matter, but that the need for a prioritisation tool could be reconsidered if the workload of the Committee warranted it in the future. It further agreed to inform CCEXEC of this decision (see Item 2).

GLOBAL SURVEY TO PROVIDE INFORMATION TO THE CCRVDF TO MOVE COMPOUNDS FROM THE DATABASE ON COUNTRIES’ NEEDS FOR MRLS TO THE JECFA PRIORITY LIST (REPORT OF EWG) AND DATABASE ON COUNTRIES’ NEEDS FOR MRLS (Agenda Item 8)19

93. Costa Rica and the USA, as co-Hosts, introduced the report of the EWG on Countries’ Needs for MRLs. Responses of members to the global survey were summarized in Annex I of CX/RVDF 16/23/9 “Global survey database on MRL needs 2016”. The global survey database summary listed the veterinary drugs, which were considered to have the highest degree of importance by country and the widest agreement between countries in the active ingredients indicated. The database also included indications of use in each country regarding the amount and variety of food producing species and diseases of concern.

94. The EWG recommended the Committee to: (i) continue to develop and maintain the database of countries needs for MRLs; and (ii) establish a EWG to consider the results of the global survey in order to identify priority veterinary drugs and information gaps for a successful and comprehensive assessment by JECFA.

95. The Committee noted that the “Database on countries’ needs for MRLs” (Appendix 1 of CX/RVDF 16/23/9 Add.1) had been updated.

18 CX/RVDF 16/23/8; Comments of Argentina (CRD16), Ecuador (CRD17), El Salvador (CRD6), Nigeria (CRD10), Trinidad and Tobago (CRD21); Report of the side event (CRD24)

19 CX/RVDF 16/23/9; CX/RVDF 16/23/9 Add.1; Comments of Argentina (CRD16), Ecuador (CRD17), El Salvador (CRD6), India (CRD15), Mali (CRD12), Nigeria (CRD10), Panama (CRD19), Republic of Korea (CRD18), Senegal (CRD4), Thailand (CRD11), Trinidad and Tobago (CRD21), African Union (CRD5)
Discussion

96. With regard to the global survey database summary, delegations commented that: some of the compounds were used both as veterinary drugs and pesticides and might have been already evaluated by JMPR and therefore have MRLs relevant to animal products; since many countries were relying on Codex MRLs it was important to prioritise work on those substances which had never been evaluated or where the evaluation had been discontinued and those for which information was available in national agencies; and, the database should include information on veterinary drugs used for animal trypanosomiasis, in particular diminazene aceturate and isometamidium chloride, which is a major disease of livestock in Africa.

97. With regard to the inclusion of drugs used for animal trypanosomiasis, the co-Hosts, clarified that the global survey database summary presented in the report of the EWG was not a complete list gathered by the global survey and only included those drugs of high interest to members. Countries which had not replied to the survey would have an opportunity to provide information that would be considered when completing the analysis.

98. The Committee considered the recommendations of the EWG as follows:

Database of countries needs for MRLs

99. The Committee supported the recommendation to continue to develop and maintain the database. Delegations commented that this work was very important as countries were interested in having more Codex MRLs; that it was important to prioritise the veterinary drugs; to find mechanisms to fill the information gaps to allow their full evaluation by JECFA and to encourage industry and countries to provide these data.

EWG to consider the results of the global survey

100. The Committee supported the recommendation to establish an EWG.

101. The urgency to develop a comprehensive data package to allow the Committee to move top priority compounds from the database to the Priority List for JECFA evaluation was highlighted. In this regard the co-Hosts, noted that it might not be feasible by the next CCRVDF to move compounds from the database to the Priority List but more realistic to identify the ten top priority compounds and encourage countries, pharmaceutical industry and academia to fill the data gap.

102. The Committee noted the importance for African countries to include in the top priority list compounds used for animal trypanosomosis, in particular diminazene aceturate and isometamidium chloride, and strongly encouraged African countries to actively participate in the EWG by providing data and information.

Conclusion

103. The Committee agreed to:

- Continue to develop and maintain the “Database of countries needs for MRLs” by Circular Letter.
- Establish an EWG, co-hosted by the USA and Costa Rica, and working in English and Spanish and using the pilot electronic platform for EWGs, to consider the complete results of the global survey in order to identify priority veterinary drugs and identify information gaps for a successful and comprehensive assessment by JECFA.

104. The Committee:

- Noted that the report of the EWG would be made available at least three months before CCRVDF24.
- Encouraged interested countries to provide support for French translation of relevant EWG documents to facilitate the broadest possible participation in the EWG.

DRAFT PRIORITY LIST OF VETERINARY DRUGS REQUIRING EVALUATION OR RE-EVALUATION BY JECFA (Agenda Item 9) 20

105. Australia, Chair of the in-session WG, introduced CRD25, which included recommendations for the prioritization of veterinary drugs for evaluation or re-evaluation by JECFA. The WG had considered: (i) eight new proposals for the Priority List; and (ii) four compounds, listed in CCRVDF22 Priority List, but not yet evaluated by JECFA because data were yet available.

20 CL 2015/18-RVDF; Comments of Argentina, Chile, Cuba, European Union, New Zealand, Norway, Paraguay, United States of America, Uruguay (CX/RVDF 16/23/10); Peru, Philippines, Senegal, African Union (CX/RVDF 16/23/10 Add.1); Ecuador (CRD17), New Zealand (CRD22), Panama (CRD19), Thailand (CRD11), HealthforAnimals (CRD20); Report of In-session WG (CRD25)
106. Based on confirmation from Members of data availability for March 2017, the WG had made recommendations for inclusion in the Priority List for: (i) evaluation by JECFA in 2017 (Part A); and (ii) for evaluation by a future JECFA meeting (Part B), with the understanding that if data availability were not confirmed at CCRVDF24, the compound would be removed from the Priority List.

Discussion

107. The Committee agreed with the recommendations of the in-session WG to include in the Priority List the following new compounds:

- Part A (for evaluation by JECFA in 2017): bismuth sub-nitrate; flumethrin; halquinol; lufenuron; and monepantel.
- Part B (for evaluation by a future JECFA): ethion (see Item 10); fosfomicin; and triamcinolone (triamcinolona).

108. With regard to the previously listed compounds, the Committee made the following comments and decisions:

- **Amoxicillin**

109. In view of the confirmation by the Republic of Korea to provide data by March 2017, the Committee agreed to include amoxicillin in Part A of the Priority List.

- **Ampicillin**

110. The Committee noted the proposal of the Republic of Korea to consider an extrapolation of the ADI from amoxicillin to ampicillin. The USA, original sponsor of the evaluation of amoxicillin, having consulted with the pharmaceutical sponsor, agreed that the data package for amoxicillin could be accessed by JECFA. In light of this the Committee agreed to include ampicillin in Part A of the Priority List.

- **Ethoxiquin**

111. The Committee noting that the Philippines was continuing working with the pharmaceutical sponsor, agreed to include ethoxiquin in Part B of the Priority List, with the understanding that if data availability was not confirmed at CCRVDF24, the compound would be removed from the Priority List.

- **Others**

112. The Committee noted the issues faced by the JECFA Secretariat in scheduling the evaluation of compounds included in the Priority List, as reported in Part III of CRD25.

Conclusion

113. The Committee agreed to:

- Forward the Priority List of veterinary drugs for evaluation or re-evaluation by JECFA to CAC40 for approval (Appendix VI, Part A).
- Establish a PWG, chaired by Australia, and working in English, French and Spanish, which would meet immediately before its next Session, to consider the replies to the CL requesting comments and information on the Priority List of Veterinary Drugs requiring Evaluation or Re-evaluation by JECFA.

- **Others**

114. The Observer from HealthforAnimals informed the Committee of their consideration regarding the decreasing number of compounds submitted for evaluation by JECFA. In their view, this was due to different reasons, including:

i) A significant uncertainty and risk in passing a product through the entire Codex process. The growing influence of national legislation at Codex, coupled with the observation that JECFA MRLs and ADIs and assessments are sometimes more conservative than national levels, results in a conservative outcome – which sometimes determines whether a product is viable commercially, or not, in multiple markets. In general, where there is little flexibility and less certainty over a long time line, there is less incentive to put innovative products forward for review. Luckily we have recently seen some flexibility.

ii) Decisions that are taken today impact the product development pipeline for the next 30 years. This directly impacts the number of products that are put forward. These decisions also include countries’ lessening adherence to Codex adopted standards. Together, these observations send negative signals to innovative companies. Companies must see a reasonable return of investment and, therefore, given uncertainties for food animal products – whether in national regulatory processes or Codex reviews – and limited R&D resources, companies are and will increasingly invest more funds in other areas, such as companion animal products and vaccines, rather than food animal production.
challenges.

iii) The cost. The companies provide nearly 100 percent of the current data. It costs a company large amounts – sometimes over a million dollars to develop a complete data package specific to JECFA. That means that, increasingly, only the most interesting products with promising markets will be put forward and only the largest global companies can afford this process.

115. The Observer stated that the industry valued the role that Codex played in countries and was willing to work towards a possible solution to improve the outcomes of CCRVDF and Codex. Therefore, they proposed to prepare a discussion paper, which would systematically evaluate the rationale for the decline in new compounds to be included in the CCRVDF Priority List for evaluation by JECFA and include recommendations for the consideration of the Committee.

116. The Chair noting the difficulties of countries to obtain sufficient data and information to allow compounds to be evaluated by JECFA, proposed to have a discussion on innovative approaches to fill the data gaps. He suggested considering new approaches developed by the scientific community, such as the systematic literature review, developed for human medicine, which allowed to synthesize information from many sources and maximize the information. However, he cautioned that a systematic literature review was a complex and resource intense exercise.

117. The Representative of FAO confirmed the interest of JECFA to explore additional ways of working that addressed the needs of members in more immediate ways and expressed his support to consider a systematic review approach as a pilot study for an evaluation in the future. He cautioned the members that a systematic review required considerable resources and that these resources were not available in the immediate future unless members were able to provide them.

118. Delegations reiterated the importance of developing MRLs in particular for old compounds, which were widely used and for which there was no pharmaceutical sponsor, and to find innovative ways to use old data and thus accelerate the inclusion of these compounds in the Priority List for JECFA evaluation.

119. With regard to the possibility of generating data for JECFA evaluation, it was suggested that countries with the same needs in terms of MRLs might work together and sponsor the necessary data generation or seek financial support from international governmental or non-governmental organizations.

120. With regard to innovative approaches for making the work of the Committee more efficient, delegations put forward the following suggestions: to distinguish between residues of lower public health concern and to focus work on substances which represent a real risk; to focus work on compounds that are used for therapeutic purposes.

121. The Representative of FAO highlighted that FAO and WHO had multiple mechanisms at their disposal to give the scientific advice supporting the needs of members, but that it was the exclusive prerogative of the Committee to define the priority list of veterinary drugs and the exact nature of the scientific advice requested from JECFA. He stressed that while FAO and WHO were prepared to aid all those members who have questions regarding JECFA processes or to assist in interregional capacity building, the initiatives would need to originate at a country or regional level.

122. The Representative of WHO noted that, as mentioned in the JECFA call for data, the call is open to companies as well as to Members and to any institution willing to contribute any data to the risk assessment process. This means that JECFA is evaluating both the raw data submitted by the sponsors of the compound and the studies from the published literature. In case sufficient details are not available in published studies, the Committee might have to consider the use of additional safety factors in the derivation of the Health Based Guidance Values to account for that uncertainty. The FAO Representative further noted that also for the residue evaluation, JECFA would evaluate both the raw data submitted by the sponsors of the compound as well as the studies available from the published literature. In cases where the information available to JECFA proved not to be sufficient to recommend MRLs, JECFA would indicate the specific data needed to complete the evaluation.

OTHER BUSINESS AND FUTURE WORK (Agenda Item 10)

The Issues and concerns that impact the ability of CCRVDF to efficiently perform its work

123. The Chair recalled that CCRVDF22 had agreed to implement a discussion on this topic at every meeting of CCRVDF under Other Business.

124. The Chair began the discussion inviting delegations to put forward proposals for consideration at CCRVDF24.
Proposal from Kenya on offal

125. Kenya stated their wish to develop a discussion paper based on experiences in trade in offal tissue in the African region. The discussion paper would seek to define offal and specify which offal tissue was important for trade in the region and outside Africa. It would also aim to identify specific tissues that could be recommended to JECFA for work on establishing MRLs.

Discussion

126. The Committee noted that the proposal of Kenya was a follow up to the request of the 81st JECFA (see Item 3).

127. Delegations suggested that Kenya consider working by means of an EWG to widen possible participation and reflect the international aspect of trade in offal tissue; and that additional information and guidelines to support the work of the EWG could be sourced from VICH\(^{21}\), and global data through the IAEA.

128. The proposal received broad support. The discussion highlighted the need for the terms of reference for the EWG to be specific and precise whilst not being overly prescriptive in order to avoid pre-empting how the Committee might decide to use the resulting discussion paper from the EWG. It was further noted the need to limit the task of the EWG to exposure regarding offal tissues present in food for humans and not in animal feed or other areas (e.g. in sutures).

Conclusion

129. The Committee agreed to establish an EWG, hosted by Kenya, working in English only and using the pilot electronic platform for EWGs, to prepare a discussion paper in response to the request from 81st JECFA for CCRVDF to “provide a definition of edible offal”\(^{22}\). The discussion paper will propose a possible definition of edible offal tissue and specify edible offal tissues of interest in international trade.

130. The Committee:
- Noted that the report of the EWG would be made available at least three months before CCRVDF\(^24\).
- Noted the support of interested delegates and encouraged the broadest possible participation in the EWG.

Proposal from Canada to revise the criteria for the use of multi residue analytical methods for the determination and identification of veterinary drugs in foods in CAC/GL 71-2009

131. Canada recalled previous work in this area and that work completed in 2013 had substantially and significantly updated knowledge from 20 years ago. They proposed to lead an initiative to update CCRVDF on new criteria that have emerged as a result of this experimental work on determining and identifying residues of veterinary drugs in foods.

Conclusion

132. The Committee, noting that this initiative would signify new work, agreed to the proposal and indicated that the discussion paper and project document would need to be made available at least three months before CCRVDF\(^24\).

Proposal from Argentina on pilot work for old compounds (e.g. ethion)

133. Recalling the decision of the Committee to include ethion in Part B of the Priority List (Item 9), Argentina proposed a pilot project requesting JECFA to evaluate ethion making use of non-traditional data sources (e.g. data from scientific literature) and the residue data to be provided by Argentina and Uruguay.

Discussion

134. It was suggested that JECFA could consider the proposal and begin to evaluate older compounds in a more flexible manner, e.g. exploring the possibility to apply the ADI established by JMPR alongside studies from Argentina and Uruguay. If that data were insufficient JECFA could possibly identify what information they needed in order to be able to complete an evaluation.

135. In response, the Representative of WHO noted that whilst it might be possible to collect data and provide information on any data gaps, the timeframe for an evaluation could prove challenging. For JECFA to complete this work in 2017 piloting would have to be completed by March 2017, which was unrealistic.

---

\(^{21}\) VICH Guidelines 46 and 48
\(^{22}\) http://www.fao.org/3/a-bc313e.pdf
136. In response to questions raised on the feasibility of using the JMPR ADI, the Representative of WHO recalled that ethion had been identified for periodic evaluation by CCPR but that ethion had not been supported by the original sponsor and neither had countries expressed interest. The current evaluation was therefore very old and not useful for the proposed pilot exercise in CCRVDF.

137. It was suggested that ethion be added to the Priority list for JECFA evaluation in 2017 (Appendix VI Part A). Argentina and Uruguay should provide JECFA with a data package. JECFA should evaluate the data package, evaluate the compound if possible and or identify data gaps to complete the evaluation without placing any restrictions on the process.

Conclusion

138. The Committee:
- Requested JECFA to proceed with an evaluation of ethion based on available data and, if not possible to complete the evaluation:
  - i. identify additional data sources;
  - ii. provide advice on how the Committee could move work on the compound forward.
- Agreed to include ethion in Part A of the Priority List for approval by CAC40 (Appendix VI Part A).

Chair’s report on the status of CCRVDF

139. The Chair reviewed both the past achievements of the Committee and work completed at the current session. He recalled the efforts made to identify member needs for MRL development and the Committee’s willingness to take on difficult questions and press boundaries. He emphasised the challenges for the Committee in finding ways to address the data needs to bring veterinary drugs to JECFA for risk assessment or in finding ways to address the “risk” of a JECFA evaluation for pharmaceutical products already approved by national authorities. In conclusion he stressed the challenge of identifying ways forward when the Committee’s inability to reach agreement was due to a difference in core values.

DATE AND PLACE OF NEXT SESSION (Agenda Item 11)

140. The Committee noted that the next Session was tentatively scheduled to be held in April 2018, the final arrangements being subject to confirmation by the Committee Host and the Secretariat.

---

23 CRD26
LIST OF PARTICIPANTS
LISTE DES PARTICIPANTS
LISTA DE PARTICIPANTES

Chairperson: Dr Kevin Greenlees
Senior Advisor for Science and Policy, Chair,
CCRVDF
Center for Veterinary Medicine, HFV-100
U.S. Food and Drug Administration
7500 Standish Place
Rockville, Maryland
United States of America
Tel: +1-240-402-0638
Email: kevin.greenlees@fda.hhs.gov

Chair's Assistant: Mr Jon Scheid
International Programs
U.S. Food and Drug Administration
HFV220, Room 2676 7519 Standish Place
Rockville, MD
United States of America
Tel: +1 240 402 0762
Email: jon.scheid@fda.hhs.gov

MEMBERS NATIONS AND MEMBER ORGANIZATIONS
ÉTATS MEMBRES ET ORGANISATIONS MEMBRES
ESTADOS MIEMBROS Y ORGANIZACIONES MIEMBROS

ARGENTINA - ARGENTINE
Ms Laura Carina Sbordi
Supervisora Técnica.
Dirección Nacional de Agroquímicos, Productos Veterinarios y Alimentos.
SENASA
Av. Paseo Colón 439, 2°p
Ciudad de Buenos Aires
Argentina
Email: lsbordi@senasa.gov.ar
Ms Teresa Bianchi
SENASA
Buenos Aires
Argentina
Email: tbianchi@senasa.gov.ar
Mr Claudio Gustavo Cerati
Director Técnico
BEDSON S.A.A
Las Palmeras 2240
Pilar, Buenos Aires
Argentina
Tel: +54 9(11) 6940-1563
Email: claudio.cerati@bedson.com

AUSTRALIA - AUSTRALIE
Dr Dugald Maclachlan
Director, Chemical Residues and Microbiological Policy
Department of Agriculture and Water Resources
GPO Box 858 Canberra ACT 2601 Australia
Canberra
Australia
Tel: +61 2 6272 3183
Email: dugald.maclachlan@agriculture.gov.au
Mr James Deller
Senior Evaluator
Australian Pesticide and Veterinary Medicines Authority
18 Wormald Street
symonston
Australia
Tel: +61 416 605 998
Email: James.Deller@apvma.gov.au

AUSTRIA - AUTRICHE
Mr Thomas W. Kuhn
Head of Institute
Austrian Agency for Health and Food Safety
Spargelfeldstrasse 191
Vienna
Austria
Tel: +43(0) 50 555-32600
Email: thomas.kuhn@ages.at

BELGIUM - BELGIQUE - BÉLGICA
Mr Bruno Urbain
Senior Evaluator
DG pre authorization
Federal Agency for medicines and health products
Place Victor Horta 40/40
Brussels
Belgium
Tel: +3225284130
Email: bruno.urbain@afmps-fagg.be
BRAZIL - BRÉSIL - BRASIL

Mrs Suzana Bresslau
Official Veterinarian Inspector
Coordination of Special Programs / Department of Inspection for Livestock Inputs
Ministry of Agriculture, Livestock and Food Supply
Esplanada dos Ministérios, Bloco D, Anexo A, Sala 443
Brasília
Brazil
Tel: +55 61 3218 2438
Email: suzana.bresslau@agricultura.gov.br

Mrs Camila Brossi
Quality Assurance Specialist
Technical Board
Brazilian Association of Meat Exporters - ABIEC
Avenida Marginal Direita do Tietê, 500
São Paulo
Brazil
Tel: +55 11 39191498
Email: camila.brossi@jbs.com.br

Dr Clea Camargo
Manager
Regulatory Affairs
ABQUIFi
Av. Dr. Chucri Zaidan n°1240 – Ed. Diamond Tower – 4° floor
São Paulo
Brazil
Tel: +55-11 98467-9779
Email: clea.camargo@zoetis.com

Ms Stefani Faro De Novaes
Regulation and health surveillance expert
Food General Office
Brazilian Health Regulatory Agency
SIA trecho 5, area especial 57
Brasília
Brazil
Tel: +55 61 34625313
Email: stefani.novaes@anvisa.gov.br

Dr Silvana Górniak
Full Professor
Pathology
Federal Council of Veterinary Medicine
Av. Prof. Orlando Marques de Paiva, 87
São Paulo
Brazil
Tel: +551130917693
Email: gorniak@usp.br

Dr Cesar Lopes
Technology & Development Director
Technical
SINDAN
Av. Tancredo A. Neves 1063
Guarulhos
Brazil
Tel: +55 11 99379-4593
Email: cesar.lopes@pahc.com

Ms Fatima Machado Braga
Regulation and Health Surveillance Expert
Food General Office
Brazilian Health Regulatory Agency – ANVISA
SIA Trecho 5, Área Especial 57 - Bloco D, 2º andar
Brasília
Brazil
Tel: +55 61 34625313
Email: fatima.braga@anvisa.gov.br

Dr João Palermo-neto
Full Professor
Scholl of Veterinary Medicine
University of São Paulo
Av. Dr. Cardoso de Mello número 585, apto. 181B
São Paulo
Brazil
Tel: +55-11- 3071-27 28
Email: jpalermo@usp.br

Mr Wilkson Rezende
Federal Inspector
Division of Residues Monitoring / Secretariat of Animal and Plant Health and Inspection
Ministry of Agriculture, Livestock and Food Supply
Esplanada dos Ministérios, Bloco D, Anexo B, Sala 448
Brasília
Brazil
Tel: +55 61 3218 2329
Email: wilkson.rezende@agricultura.gov.br

CAMEROON - CAMEROUN - CAMERÚN

Mrs Colette Wolimoum Booto A Ngon
Coordonatrice régionale PCT
Direction Générale
Agence des Normes et de la Qualité
Yaoundé
Cameroon
Tel: 00237 699612471
Email: booto25@yahoo.fr

CANADA - CANADÁ

Dr Manisha Mehrotra
Director, Human Safety Division
Veterinary Drugs Directorate
Health Canada
11 Holland Ave
Ottawa
Canada
Tel: 613-941-8775
Email: manisha.mehrotra@hc-sc.gc.ca

Dr Joe Boison
Senior Research Scientist
Canadian Food Inspection Agency
CFIA Saskatoon Laboratory 116 Veterinary Road
Saskatoon
Canada
Tel: (306) 385-7843
Email: joe.boison@inspection.gc.ca

Dr Shiva Ghimire
Team Leader, Human Safety Division
Veterinary Drugs Directorate
Health Canada
14-11 Holland Ave, ADL 3000A
Ottawa
Canada
Tel: 613-618-0404
Email: shiva.ghimire@hc-sc.gc.ca
Ms Anne-Christine Poulin  
Senior Trade Policy Analyst  
Technical Trade Policy Division  
Agriculture and Agri-Food Canada  
1305 Baseline Road Tower 5, Floor 5, Room 343  
Ottawa  
Canada  
Tel: 613-773-3561  
Email: Anne-Christine.Poulin@AGR.GC.CA

CHILE - CHILI  
Mr Claudio Núñez Contardo  
Asesor Técnico  
División Asuntos Internacionales  
Ministerio de Agricultura  
Bulnes 140, piso 5  
Santiago  
Chile  
Tel: +56 223451183  
Email: c.nunez@sag.gob.cl

CHINA - CHINE  
Mr Yichun Dong  
Senior Researcher  
China Institute of Veterinary Drug Control  
No.8 Zhongguancun South Street,  
Beijing  
China  
Tel: +86-13910568855  
Email: peterdongyc693@163.com

Ms Hong Lin  
Senior Engineer  
Animal, Plant and Food Inspection Center, Jiangsu  
Entry-Exit Inspection and Quarantine Bureau  
99 Zhonghua Road, Nanjing, P.R. China  
Nanjing  
China  
Tel: +86-25-52345193  
Email: 13951600009@139.com

Ms So Mui Geraldine Luk  
Senior Veterinary Officer (Risk Assessment)  
Centre for Food Safety, Food and Environmental Hygiene Department, HKSAR  
3/F, 4 Hospital Road, Sai Ying Pun  
Hong Kong  
China  
Tel: +852-39622061  
Email: gsmluk@fehd.gov.hk

PROF Jianzhong Shen  
Professor/Dean  
China Agricultural University  
College of Veterinary Medicine, China Agricultural University  
Beijing  
China  
Tel: +86-10-62732803  
Email: sjz@cau.edu.cn

Ms Karina Wing Si Tam  
Veterinary Officer (ACVD)  
Centre for Food Safety, Food and Environmental Hygiene Department, HKSAR  
43/F, Queensway Government Offices, 66 Queensway, Hong Kong  
Hong Kong  
China  
Tel: +852-6160391  
Email: kwstam@fehd.gov.hk

COLOMBIA - COLOMBIE  
Dr Yenny Carolina Ponton Alvarado  
Profesional Especializado Medico Veterinario  
INVIMA  
CARRERA 10 NUMERO 64 - 28  
Tel: 2948700  
Email: jl pontona@invima.gov.co

COSTA RICA  
Dr Heilyn Fernández Carvajal  
Programa Nacional de Residuos de Medicamentos Veterinarios  
LANASEVE  
Servicio Nacional de Salud Animal - SENASA  
Barreal de Heredia, de Jardines del Recuerdo 1KM al oeste y 400 metros al Norte en el Camp  
Heredia  
Costa Rica  
Tel: 506-25871798  
Email: hfernandez@senasa.go.cr

DENMARK - DANEMARK - DINAMARCA  
Mrs Anne Rath Petersen  
Veterinary Adviser  
Danish Veterinary and Food Administration  
Stationsparken 31 - 33  
Glostrup  
Denmark  
Tel: +45 72276624  
Email: arp@fvst.dk

Mr Lars Holdensen  
Chief Adviser  
Organic Food and Farming  
Danish Agriculture and Food Council  
Axelborg  
Copenhagen V  
Denmark  
Tel: +45 3339 4007  
Email: lho@lf.dk

ECUADOR - ÉQUATEUR  
Mr Lenin Ernesto Moreno Gálvez  
Responsable de la Unidad de Gestión de Certificación de Producción Primaria y Buenas Prácticas  
Inocuidad de los Alimentos  
Agencia Ecuatoriana de Aseguramiento de la Calidad del Agro - AGROCALIDAD  
Avenida Eloy Alfaro y Amazonas  
Quito  
Ecuador  
Tel: 5932567232  
Email: lenin.moreno@agrocalidad.gob.ec
EGYPT - ÉGYPTE - EGIPTO
Mrs Reda Ismael
Food Standards Specialist
Food Standards
Egyptian Organization For Standardization And Quality
Cairo
Egypt
Tel: 20222845531
Email: reda nn mm@yahoo.com

EQUATORIAL GUINEA - GUINÉE ÉQUATORIALE - GUINEA ECUATORIAL
Mr Antonio Bonifacio Mba Ndong Obono
Medico Veterinario
Ministero De Agricultura Y Bosques
AVDA/HASAU II
Malabo
Equatorial Guinea
Tel: +240 222 685 855
Email: ambandong@yahoo.es

ETHIOPIA - ÉTHIOPIE - ETIOPIÁ
Dr Degaga Terzu Daya
Director General
Veterinary Drug and Animal Feed Administration and Control Authority
Ministry of Livestock and Fisheries
Cell phone +251-935-987-644 P.O.Box 31303
Addis Ababa
Ethiopia
Email: terzudaya@gmail.com

EUROPEAN UNION - UNION EUROPÉENNE - UNIÓN EUROPEA
Mr Marco Castellina
Policy Officer
DG Sante D 2
European Commission
Rue Froissart 101
Brussels
Belgium
Tel: +32 229-87443
Email: marco.castellina@ec.europa.eu

Ms Isaura Duarte
Head of Animal and Public Health
Veterinary Medicines Department
European Medicines Agency
30 Churchill Place | Canary Wharf |
London
United Kingdom
Tel: +44 (0)20 3660 8457
Email: isaura.duarte@ema.europa.eu

FRANCE - FRANCIA
Ms Louise Dangy
Official Veterinarian
General Directorate for Food
Ministry of Agriculture
251 rue de Vaugirard
Paris
France
Email: louise.dangy@ensv.velagro-sup.fr

GERMANY - ALLEMAGNE - ALEMANIA
Dr Sybille Hohenester
Deputy Head of Division
Ministry of Food and Agriculture
Rochusstr. 1
Bonn
Germany
Email: 326@bmel.bund.de

EUROPEAN UNION - UNION EUROPÉENNE - UNIÓN EUROPEA
Mr Marco Castellina
Policy Officer
DG Sante D 2
European Commission
Rue Froissart 101
Brussels
Belgium
Tel: +32 229-87443
Email: marco.castellina@ec.europa.eu

Ms Isaura Duarte
Head of Animal and Public Health
Veterinary Medicines Department
European Medicines Agency
30 Churchill Place | Canary Wharf |
London
United Kingdom
Tel: +44 (0)20 3660 8457
Email: isaura.duarte@ema.europa.eu

FRANCE - FRANCIA
Ms Louise Dangy
Official Veterinarian
General Directorate for Food
Ministry of Agriculture
251 rue de Vaugirard
Paris
France
Email: louise.dangy@ensv.velagro-sup.fr

Dr Olivier Debaere
Head of office veterinary drugs and residues
Directorate Generale for Food
Ministry of agriculture
251 rue de Vaugirard
Paris
France
Tel: 0033149555843
Email: olivier.debaere@agriculture.gouv.fr

GERMANY - ALLEMAGNE - ALEMANIA
Dr Sybille Hohenester
Deputy Head of Division
Ministry of Food and Agriculture
Rochusstr. 1
Bonn
Germany
Email: 326@bmel.bund.de

Dr Alexander Boettner
Executive Director Regulatory Affairs
MSD Animal Health Innovation GmbH
Zur Propstei
Schwabenheim
Germany
Tel: +49 6130 948 190
Email: alexander.boettner@msd.de

Dr Ludwig Klostermann
Head Global Policy & Public Affairs
Bayer HealthCare Animal Health
Alfred-Nobel-Str. 50 Bdgn. 6210
Monheim
Germany
Tel: +49 2173 38 3861
Email: ludwig.klostermann@bayer.com

Dr Monika Lahrssen-wiederholt
Head of Department Safety in Food Chain
Federal Institute for Risk Assessment
Max-Dohrn-Straße 8 - 10
Berlin
Tel: +49 30 18 412 2362
Email: monika.lahrssen-wiederholt@bfr.bund.de

Dr Wolfgang Radeck
Scientific officer
Federal Office of Consumer Protection and Food Safety
Mauerstr. 39 - 42
Berlin
Germany
Tel: +49 18445 7500
Email: wolfgang.radeck@bvl.bund.de
Dr Stefan Scheid  
Head of Unit  
Residues of Pharmacologically Active Substances  
Federal Office of Consumer Protection and  
Mauerstr. 39-42 D-10117 Berlin  
Berlin  
Germany  
Tel: +49 (0) 30 – 18 445 7500  
Email: stefan.scheid@bvl.bund.de

Dr Sabine Schueller  
Executive Director  
German Animal Health Industry  
Schwertberger Str. 14  
Bonn  
Germany  
Tel: +49 228 318296  
Email: s.schueller@bft-online.de

Mr Kwame Dei Asamoah-okyere  
Principal Regulatory Officer  
Agro Products and Biosafety  
Food and Drugs Authority  
P. O. Box CT 2783 Cantonments, Accra  
Accra  
Ghana  
Tel: +233 208 184188  
Email: kwamedei@hotmail.com

Mr Cheetham Lawrence Mingle  
Principal Regulatory Officer  
Laboratory Services  
Food and Drugs Authority  
P. O. Box CT 2783 Cantonments, Accra  
Accra  
Ghana  
Tel: +233 206 371954  
Email: tawa_gh@yahoo.com

Mr Ioannis Stamatekos  
Consulat of Greece in Houston  
2401 Fountain View Drive, Suite 850  
Houston  
Email: grcon.hou@mfa.gr

Ms Diaka Diallo  
Directeur General Adjointe  
Department of Control  
Ministry of Commerce  
Matoto  
Conakry  
Guinea  
Tel: +224622691230  
Email: diallodiaka@gmail.com

Mrs Marie Roberta Jean-baptiste  
Directeur  
Ministry of Trade and Industry  
Port-au-Prince  
Haiti  
Tel: +50934546588  
Email: jeanbaptiste_mr@yahoo.fr

INDIA - INDE
Dr Lokendra Kumar  
Assistant Director (T)  
Export Inspection Agency, Ministry of Commerce &  
Industry, Govt. of India  
India  
Email: ad.lkeiachennai@gmail.com

ITALY - ITALIE - ITALIA
Mr Ciro Impagnatiello  
Codex Contact Point  
Department of the European Union and Internationala  
Policies and of the Rural Development  
Ministry of Agricultural Food and Forestry Policies  
Via XX Settembre, 20  
Rome  
Italy  
Tel: +39 06 46654058  
Email: c.impagnatiello@politicheagricole.it

Ms Antonina Longo  
Dirigente Farmacista  
Direzione Generale della Sanità Animale e dei Farmaci  
Veterinari  
Ministero della Salute  
Via G. Ribotta, 5  
Roma  
Italy  
Tel: +38 06 59946124  
Email: an.longo@sanita.it

JAMAICA - JAMAÏQUE
Mr Errol Dakin  
Toxicologist/Analyst  
Vet Services Division  
Ministry of Agriculture  
193 Old Hope Road  
Kingston  
Jamaica  
Tel: +876-972-2489  
Email: eddakin@yahoo.com

JAPAN - JAPON - JAPÓN
Mr Ryota Nakamura  
Technical officer  
Standards and Evaluation Division  
Ministry of Health, Labour and Welfare  
1-2-2, Kasumigaseki, Chiyoda-ku, Tokyo  
Tokyo  
Japan  
Tel: +81-3-3595-2423(Ext.4289)  
Email: codexj@mhlw.go.jp

Dr Yuko Endo  
Director, Assay Division II  
National Veterinary Assay Laboratory  
Ministry of Agriculture, Forestry and Fisheries  
1-15-1 Tokura, Kokubunji  
Tokyo  
Japan  
Tel: +81-42-321-1843  
Email: yuko_endo700@mhlw.go.jp
Dr Shoko Iwamoto  
Technical Official  
Animal Health and Animal Products Safety Division  
Ministry of Agriculture, Forestry and Fisheries  
1-2-1, Kasumigaseki, Chiyoda-ku  
Tokyo  
Japan  
Tel: +81-3-3502-8097  
Email: shoko_iwamoto310@maff.go.jp

Dr Takatoshi Sakai  
Senior Researcher  
Division of Foods  
National Institute of Health Sciences  
Kamiyoga 1-18-1, Setagaya-ku  
Tokyo  
Japan  
Tel: +81-3-3700-1141  
Email: tasakai@nih.go.jp

Mr Kohei Sato  
Technical Official  
Animal Health and Animal Products Safety Division  
Ministry of Agriculture, Forestry and Fisheries  
1-2-1, Kasumigaseki, Chiyoda-ku  
Tokyo  
Japan  
Tel: +81-3-3502-8097  
Email: kohei_sato850@maff.go.jp

Dr Hajime Toyofuku  
Professor  
Joint Facility of Veterinary Medicine  
Yamaguchi University  
1677-1Yoshida  
Yamaguchi  
Japan  
Tel: +81-83-933-5827  
Email: toyofuku@yamaguchi-u.ac.jp

KENYA  
Dr Nathan Kipkorir Songok  
Head Of Veterinary Medicine  
Vet Medicine And Immuno-Biological Products Control  
Directorate Of Veterinary Services  
Private Bag Kangemi  
Nairobi  
Kenya  
Email: songoknat@yahoo.com

Dr Allan Azegele  
Senior Assistant Director Veterinary Services  
Directorate of Veterinary Service  
Central Veterinary Research Laboratory, Kabete  
Private Bag, Kangemi  
Nairobi  
Kenya  
Tel: +254729689898  
Email: ae_allan@yahoo.com

Mr Andrew Okwakau Edewa  
SMAP CONSULTANT  
NAIROBI  
Kenya  
Email: andrewedewa@gmail.com

LAO PEOPLE’S DEMOCRATIC REPUBLIC –  
RÉPUBLIQUE Démocratique Populaire Lao –  
REPUBLICA DEMOCRÁTICA POPULAR LAO  
Dr Syseng Khounsy  
Deputy Director General  
Livestock and fishery  
Ministry of Agriculture and forestry  
Department of Livestock and fishery, MAFF PO box 6644, Vientiane, Lao PDR  
Vientiane  
Lao People’s Democratic Republic  
Tel: +856-21-215242  
Email: laodff@gmail.com

MALAYSIA - MALAISIE - MALASIA  
Dr Marzuki Zakaria  
Head Section  
Section Of Zoonoses And Public Health  
Department Of Veterinary Services  
Department Of Veterinary Services Ministry Of  
Agriculture And Agro-Based Industries Wisma Tani,  
Block Podium, Lot 4g1 Precint 4, Federal Government  
Administration Centre  
Putrajaya  
Malaysia  
Tel: 603-88702028  
Email: marzuki@dvs.gov.my

MALI - MALÍ  
Dr Oumou Soumana Maiga  
Directrice Générale  
Ministère de la Santé et de l’Hygiène Publique  
Agence Nationale de la Sécurité Sanitaire des Aliments  
Centre Commercial, Quartier du Fleuve BPE :2362  
Bamako  
Mali  
Tel: +223 66717987 /+223 2020747  
Email: scodexamali@yahoo.fr

MAURITANIA - MAURITANIE  
Mr Lekweiri Heiba Leghrhae  
Cadre labo CQ aliments INRSP  
Ministère de la santé  
Email: lekwoiry86@yahoo.fr

MEXICO - MEXIQUE - MÉXICO  
Ms Ofelia Flores Hernandez  
Directora de Servicios y Certificación Pecuaria  
SAGARPA-SENASICA  
Av. Cuauhtémoc No. 1230 piso 10, Col. Santa Cruz  
Atoyac  
México, D.F.,  
Mexico  
Tel: (55) 59 05 10 00, Ext. 53222 y  
Email: ofelia.flores@senasica.gob.mx

Ms Martha Domínguez Mier  
SuKarne  
Tel: 045-6671420978  
Email: martha.dominguez@sukarne.com

Ms Bertha Iliana Giner Chávez  
Consultora de Asuntos Regulatorios y Corporativos,  
Investigación y Desarrollo Enriqueciendo la Vida  
ELANCO  
Tel: +52 871 193 5249  
Email: giner_bertha@elanco.com
Ms Edith Rangel Bustamante
Consejo Mexicano de la Carne
Tel: 01-55-5589-7771
Email: normas@comecarne.org

Ms Mildred Villanueva Martínez
Consejo Mexicano de la Carne
Tel: 01-55-8503-2096
Email: mvillanu@sigma-alimentos.com

**MOROCCO - MAROC - MARRUECOS**

Mr Sami Darkaoui
Chef du Service du Contrôle et des Expertises
Ministère de l'Agriculture et de la pêche maritime
National Food Safety Office
Rue Ikhlass, Cité yacoub ElMansour BP 4509, Akkari, Rabat Royaume du Maroc
Rabat
Morocco
Tel: + 212 6 73 99 78 25
Email: sami.darkaoui@onssa.gov.ma

**MOZAMBIQUE**

Ms Carla Maria Menezes
Directorate of Animal Sciences
Mozambique Agriculture Research Institute
Mozambique Ave PO Box 1922
Maputo
Mozambique
Tel: +25821475170
Email: carlamenezes786@gmail.com

**NETHERLANDS - PAYS-BAS - PAÍSES BAJOS**

Ms Susanne Waelen
Senior Policy Officer
Department of Plant Supply Chain and Food Quality
Ministry of Economic Affairs
PO Box 20401
The Hague
Netherlands
Tel: +31 6 2168 9866
Email: s.e.h.m.waelen@minez.nl

**NEW ZEALAND - NOUVELLE-ZÉLANDE - NUEVA ZELANDIA**

Dr Bill Jolly
Chief Assurance Strategy Officer
Ministry for Primary Industries
25 The Terrace
Wellington
New Zealand
Email: bill.jolly@mpi.govt.nz

Mr Warren Hughes
Principal Adviser
Ministry for Primary Industries
25 The Terrace
Wellington
New Zealand
Email: warren.hughes@mpi.govt.nz

**NIGERIA - NIGÉRIA**

Dr Abimbola Opeyemi Adegboye
Deputy Director
National Agency for Food and Drug Administration and Control
3/4 Oshodi Apapa Expressway, Oshodi Lagos
Nigeria
Tel: +2348053170810
Email: bimbostica@yahoo.com

Mrs Olabisi Bamidele Adepegba
Deputy Director
Federal Department of Fisheries
Federal Ministry of Agriculture and Rural Development
1 Capital Drive, Area 11, Garki, Abuja
Lagos
Nigeria
Tel: +2348023020382; +2348099820680
Email: beeseadepegba@yahoo.com

Dr Mabel Kamweli Aworh
Assistant Director (Veterinary Drugs Monitoring)
Department of Veterinary & Pest Control Services,
Federal Ministry of Agriculture & Rural Development
New Secretariat, Area 11, Garki, Abuja
Nigeria
Tel: +2348032377831
Email: mabelaworh@yahoo.com

Dr Ademola Adetokumbo Majasan
Deputy Director
Livestock
Federal Ministry of Agriculture and Rural Development
FCDA Secretariat, Area 11, Garki
Abuja
Nigeria
Tel: +2348033150343
Email: babatundehjn@gmail.com

Dr Omolara Ibiwumi Okunlola
Deputy Director
Standards Organisation of Nigeria
13/14, Victoria Arobieke Street, off Admiralty Way,
Lekki Phase I
Lagos
Nigeria
Tel: +2348023590639
Email: florence.arin@gmail.com
Mr Olumuyiwa Tunde Sigbeku  
Chief Regulatory Officer  
National Agency for Food and Drug Administration and Control  
Plot 1 Isolo Industrial Estate Oshodi Apapa Express Way Isolo  
Lagos  
Nigeria  
Tel: +234-8023194984  
Email: sigbeku.o@nafdac.gov.ng

Dr Bukar Ali Usman  
Director  
National Agency for Food and Drug Administration and Control  
Plot 1 Isolo Industrial Estate Oshodi Apapa Express Way Isolo  
Lagos  
Nigeria  
Tel: +2348035651540  
Email: bukar.usman@nafdac.gov.ng

Mr Waleed Saleh Al-qaisy Ahmed  
Senior Adviser  
Food Department  
Norwegian Food Safety Authority  
P.O.Box 383  
Brumunddal  
Norway  
Tel: +47 97773288  
Email: Waleed.Ahmed@mattilsynet.no

Mrs Christine Børnes  
Senior Adviser  
Fish and Seafood Department  
Norwegian Food safety Authority  
P.O.Box 383  
Brumunddal  
Norway  
Tel: +47 95749517  
Email: Christine.Bornes@mattilsynet.no

Mr Alamgir Ahmad Khan  
Joint Secretary  
Ministry of National Food Security and Research  
H#112(Cat II), St #14 I-81I  
Islamabad  
Pakistan  
Tel: +92-51-9208376  
Email: mafk22@yahoo.com

Ms Carmen Peralta  
Coordinadora de Equivalencia de Productos Cárnicos  
Oficina de Equivalencia de Productos Cárnicos  
Ministerio de Desarrollo Agropecuario  
Calle Manuel E. Melo, ALtos de Curundú, Edificio 571, Primer Alto,  
Panamá  
Panama  
Tel: (507) 507-0837/0826 Ext. 8837/  
Email: cperalta@mida.gob.pa

Dr Catya Martinez  
Jefa del Departamento de Registros de Medicamentos Veterinarios  
Departamento de Registros de Medicamentos Veterinarios  
Ministerio de Desarrollo Agropecuario  
vIA Tocumen, Río Tapiá,  
Panamá  
Panama  
Tel: (507) 220-2801/266-2303  
Email: cmartinez@mida.gob.pa

Dr Mercedes Lucia Flores Cancino  
Especialista  
Subdirección De Inocuidad Agroalimentaria  
Servicio Nacional De Sanidad Agraria  
Av. La Molina 1915 - La Molina - Lima - Peru  
Lima  
Peru  
Tel: 3133300 ANEXO 1479  
Email: mfflores@senasa.gob.pe

Ms Olivia Domingo  
Research Specialist  
National Food Authority  
Food Development Center  
Sugar Center Building North Avenue,Diliman, Quezon City  
City/Taguig City  
Quezon City  
Philippines  
Tel: 838-44-78  
Email: olivedomingo@yahoo.com

Ms Joanna Maryniak - Szpilarska  
Main Expert  
International Cooperation Department  
Agricultural and Food Quality Inspection  
30, Wspolna Str.  
Warsaw  
Poland  
Tel: + 48 22 623 26 50  
Email: jmaryniak@ijhars.gov.pl
REPUBLIC OF KOREA - RÉPUBLIQUE DE CORÉE - REPÚBLICA DE COREA

Mr Seong Keun Byun
Deputy director
Livestock Product Standard Division
Ministry of Food and Drug Safety
Republic of Korea
Tel: 0437193852
Email: byunsk@korea.kr

Mrs Ji Yoon Jeong
Deputy director
Pesticide and Veterinary Drug Residues Division
Ministry of Food and Drug Safety
Republic of Korea
Tel: 0437194203
Email: stopyoon@korea.kr

Dr Hyun-ok Ku
Senior Scientific Officer
Animal and Plant Quarantine Agency
Ministry of Agriculture, Food and Rural Affairs
177, Hyeoksin 8-ro, Gimcheon-si, Gyeongsangbuk-do, Gimcheon
Republic of Korea
Tel: 82-54-912-0571
Email: kuho@korea.kr

Ms Mihuyn Park
Codex researcher
Agro-Livestock and Fishery Products Policy Division
Ministry of Food and Drug Safety
Republic of Korea
Tel: 0437193209
Email: seehorse@korea.kr

Ms Somi Yun
Scientific officer
Livestock Product Standard Division
Ministry of Food and Drug Safety
Republic of Korea
Tel: 0437193861
Email: smyun@korea.kr

ROMANIA - ROUMANIE - RUMANIA

Mr Ponea Mihai
Vicepresident
National Sanitary Veterinary and Food Safety Authority
Bucharest
Romania
Email: poneamihai@ansvsa.ro

SAUDI ARABIA - ARABIE SAOUDITE - ARABIA SAUDITA

Mr Khalil Alswelem
Senior Microbiologist
Executive Dept. For Technical Regulations and Standards
Saudi Food and Drug Authority
Saudi Arabia North Ring Road - Al Nafal Unit (1)
Riyadh 13312 - 6288 (3292)
Riyadh
Saudi Arabia
Tel: +966112038222
Email: CODEX.CP@sfda.gov.sa

ROMANIA - ROUMANIE - RUMANIA

Mr Ponea Mihai
Vicepresident
National Sanitary Veterinary and Food Safety Authority
Bucharest
Romania
Email: poneamihai@ansvsa.ro

RUSSIAN FEDERATION - FÉDÉRATION DE RUSSIE - FEDERACIÓN DE RUSIA

Ms Daria S. Gracheva
Leading Expert
Department for Laboratory Control
Federal Service for Veterinary and Phytosanitary Surveillance (Rosselkhoznadzor)
Tel: +7(499) 975-59-42
Email: Koryolyova_AP@gsen.ru

SAUDI ARABIA - ARABIE SAOUDITE - ARABIA SAUDITA

Mr Khalil Alswelem
Senior Microbiologist
Executive Dept. For Technical Regulations and Standards
Saudi Food and Drug Authority
Saudi Arabia North Ring Road - Al Nafal Unit (1)
Riyadh 13312 - 6288 (3292)
Riyadh
Saudi Arabia
Tel: +966112038222
Email: CODEX.CP@sfda.gov.sa

SENEGAL - SÉNÉGAL

Mrs Astou Ndiaye
Chef De Section Chimie
Ministere Commerce
Laboratoire National D Analyses Et De Controle
Rue Parchappe Dakar
Dakar
Email: maguidadou@yahoo.fr

SLOVAKIA - SLOVAQUIE - ESLOVAQUIA

Dr Judita Hederová
Director
Institute for State Control of Veterinary Biologicals and Medicaments
Biovetská 34 P.O.Box 52c
Nitra
Slovakia
Tel: +421 904 835 695
Email: hederova@uskvbl.sk

SPAIN - ESPAGNE - ESPAÑA

Mrs Gema Cortes Ruiz
Head of Service on the Veterinary drugs department
Spanish Agency for Medicines and Medical Devices
Ministry of Health, Social Services and Equality
Calle Campezo 1 • Edificio 8
Madrid
Spain
Email: gcortes@aemps.es

SWEDEN - SUÈDE - SUECIA

Dr Viveka Larsson
Principal Regulatory Officer
National Food Agency
Box 622
Uppsala
Sweden
Tel: +46 709245588
Email: viveka.larsson@slv.se
SWITZERLAND - SUISSE - SUIZA
Ms Margrit Abel-kroeker
Scientific Officer
Food and Nutrition
Federal Food Safety and Veterinary Office FSVO
Bern
Switzerland
Email: margrit.abel@blv.admin.ch
Dr Maxim Bobkov
Early Warning Expert
Food Safety & Quality
Nestle Research Center
Lausanne 26
Switzerland
Tel: +41 21 785 82 44
Email: maxim.bobkov@rdls.nestle.com

THAILAND - THAILANDE - TAILANDIA
Dr Sujittra Phongvivat
Veterinarian, Expert
Bureau of Quality Control of Livestock Products,
Department of Livestock Development (DLD)
Ministry of Agriculture and Cooperatives
Tiwanond Rd., Bangkadi, Meuang
Patumthani
Thailand
Tel: 66-2-967-9705
Email: sujittrap@did.go.th
Dr Panisuan Jamnarnwej
Honorary Advisor of TFFA
Thai Frozen Foods Association
92/6 6th Floor, Sathornthani Building 2 North Sathorn Rd., Silom, Bangrak
Bangkok
Thailand
Tel: +6622355622
Email: panisuan@yahoo.com
Mr Charoen Kaowsuksai
Vice- Chairman of Food Processing Industry Club
The federation of Thai Industries
Queen Sirikit National Convention Center, Zone C, 4th Floor, 60 New Rachadapisek Rd., Klongtoey
Bangkok
Thailand
Tel: 662-9763088
Email: charoen@cpram.co.th
Ms Yupa Laojindapun
Expert in Agricultural Commodity and Food Standards
National Bureau of Agricultural Commodity and Food Standards (ACFS)
Ministry of Agriculture and Cooperatives
50 Phaholyothin Road, Ladyao Chatuchak
Bangkok
Thailand
Tel: (+66) 2561 2277 # 1458
Email: yupa@acfs.go.th
Dr Mintra Lukkana
Veterinarian
National Bureau of Agricultural Commodity and Food Standards (ACFS)
Ministry of Agriculture and Cooperatives
50 Phaholyothin Road, Ladyao Chatuchak
Bangkok
Thailand
Tel: (+66) 2561 2277 # 1430
Email: l.mintra@gmail.com

Ms Promporn Nagalaksana
Pharmacist
Thailand Food and Drug Administration
Ministry of Public Health
Thiwanon Rd., Nonthaburi
Nonthaburi
Thailand
Tel: +6625907058
Email: pp_naga@fda.moph.go.th
Dr Anurojana Punyawan
Technician
Thai Feed Mill Association
Thai Feed Mill Association
43 Thai CC Tower, 170 RM, 17th Fl., South Sathorn Rd., Sathorn
Bangkok
Thailand
Tel: +6626756263-4
Email: dr.max@cpf.co.th

Dr Somsajee Sivilaikul
Veterinarian, Practitioner Level
Animal Feed and Veterinary Products Control Division,
Department of livestock development
Ministry of Agriculture and Cooperatives
Phayathai Rd, Ratchaavee
Bangkok
Thailand
Tel: 66 2 159-0406
Email: rover0713@gmail.com

Mrs Supanoi Subsinserm
Food Technologist, Senior Professional Level
Department Of Fisheries
Ministry of Agriculture and Cooperatives
50 Kaset-Klang, Chatuchak
Bangkok
Thailand
Tel: 66 2 562 0600 -15 EXT 13300
Email: supanois@dof.mail.go.th

TRINIDAD AND TOBAGO - TRINITÉ-ET-TOBAGO - TRINIDAD Y TOBAGO
Mr Saed Rahaman
Director
Veterinary Public Health
Ministry of Health
Sackville Street
Port-of-Spain
Trinidad and Tobago
Tel: +8662859126
Email: saed.rahaman@health.gov.tt

TUNISIA - TUNISIE - TÚNEZ
Mrs Dalal Kamoun
Médecin vétérinaire inspecteur
Direction de la pharmacie et du médicament
Ministère de la santé
31, Rue de Khartoum 1002 Tunis - Belvédère
Tunis
Tunisia
Tel: (+216 ) 71 78 31 95
Email: dalel.kamoun@iaposte.net
TURKEY - TURQUIE - TURQUÍA
Ms Gulay Canga
Veterian
Food Establishments and Codex
Ministry of Food Agriculture and Livestock
Eskisehir yolu 9. km, Lodumlu
Ankara
Turkey
Tel: 00903122587712
Email: gulay.canga@tarim.gov.tr

UGANDA - OUGANDA
Dr Josephine Nanyanzi
Inspector of Drugs
National Drug Authority
Plot 46-48 Lumumba Avenue P.O. Box 23096,
Kampala
Kampala
Uganda
Tel: +256 712 110180
Email: jnanyanzi@nda.or.ug

UNITED KINGDOM - ROYAUME-UNI - REINO UNIDO
Mr Paul Green
Director of Operations
Veterinary Medicines Directorate
Woodham Lane, New Haw
Addlestone, Surrey
United Kingdom
Tel: +44 0 1932 338303
Email: p.green@vmd.defra.gsi.gov.uk

UNITED STATES OF AMERICA - ÉTATS-UNIS D'AMÉRIQUE – ESTADOS UNIDOS DE AMÉRICA
Ms Brandi Robinson
ONADE International Coordinator
Center for Veterinary Medicine
U.S. Food and Drug Administration
7500 Standish Place HFV-100
Rockville, MD
United States of America
Tel: +1 240 402 0645
Email: brandi.robinson@fda.hhs.gov

Mr Kyd Brenner
Senior Consultant
DTB Associates LLP
1700 Pennsylvania Avenue, NW Suite 200
Washington, D.C.
United States of America
Tel: +1202-684-2508
Email: kbrenner@dtbassociates.com

Dr Lynn Friedlander
Supervisory Physiologist & Team Leader
Center for Veterinary Medicine
U.S. Food and Drug Administration
7500 Standish Place, HFV – 151
Rockville, MD
United States of America
Tel: +1 240 402 0703
Email: lynn.friedlander@fda.hhs.gov

Ms Courtney Knupp
Deputy Director of International Trade Policy
Trade Department
National Pork Producers Council
122 C Street, NW., Suite 875
Washington, DC
United States of America
Tel: +1 202-347-3600
Email: knuppc@nppc.org

Ms Sara Kucenski
Agricultural Scientific Analyst
Foreign Agricultural Service
U.S. Department of Agriculture
1400 Independence Avenue, SW
Washington, DC
Tel: +12027206741
Email: sara.kucenski@fas.usda.gov

Dr Jessica Light
Veterinarian
COBTA
AVMA
15217 de la Pena Circle
Rancho Murieta, CA
United States of America
Tel: 916-502-6459
Email: Jessica.b.light@zoetis.com
Ms Mary Frances Lowe  
Manager, U.S. Codex  
U.S. Department of Agriculture  
U.S. Codex Office  
Room 4861 - South Building 1400 Independence Avenue  
Washington, D.C.  
United States of America  
Tel: +1 202 720 2057  
Email: MaryFrances.Lowe@fsis.usda.gov

Dr Mary Mcbride  
Director, Global Market Regulations and Standards Strategy  
Agilent Technologies  
5301 Stevens Creek Blvd  
Santa Clara, CA  
United States of America  
Tel: 408-553-2143  
Email: Mary.mcbride@agilent.com

Mrs Barbara Mcniff  
Senior International Issues  
Food Safety and Inspection Service; Office of CODEX  
U.S. Department of Agriculture  
1400 Independence Ave, SW  
Washington, DC  
United States of America  
Tel: +1-202-690-4719  
Email: Barbara.McNiff@fsis.usda.gov

Mr Sean Parker  
Director, Global Regulatory Affairs  
Phibro Animal Health Corporation  
Glenpointe Centre East, 3rd Floor 300 Frank W. Burr Bvd, Suite 21  
Teaneck, NJ  
United States of America  
Tel: +1 (201) 329-7377  
Email: sean.parker@pahc.com

Dr Charles Pixley  
Director  
Laboratory Quality Assurance Staff, USDA Food Safety  
U.S. Department of Agriculture  
Russell Research Center, 950 College Station Road  
Athens, Georgia  
United States of America  
Tel: +1 706 546 3559  
Email: charles.pixley@fsis.usda.gov

Mr Brian Ronholm  
Deputy Under Secretary for Food Safety  
Office of Food Safety  
U.S. Department of Agriculture  
1400 Independence Avenue, SW  
Washington, DC  
United States of America  
Tel: +1-202-720-0351  
Email: brian.ronholm@osec.usda.gov

Dr Kathryn Simmons  
Chief Veterinarian, NCBA  
DC Policy Office  
National Cattlemen's Beef Association  
1301 Pennsylvania Avenue., NW, Suite 300  
Washington, DC  
United States of America  
Tel: +1-202-879-9131 (work)  
Email: ksimmons@beef.org

Ms Caroline Smith Dewaal  
International Food Safety Policy Manager, International Affairs Staff  
Health and Human Services  
U.S. Food and Drug Administration  
5001 Campus Drive  
College Park, MD  
United States of America  
Tel: +1(240) 402-1242  
Email: Caroline.DeWaal@fda.hhs.gov

Ms Karen Stuck  
Principal  
KDS Associates  
148 North Carolina Ave.  
Washington, DC  
United States of America  
Tel: +1-202-544-0395  
Email: karenstuck@comcast.net

Dr Bettye Walters  
International Policy Analyst  
Center for Veterinary Medicine  
U.S. Food and Drug Administration  
7519 Standish Place  
Rockville, MD  
United States of America  
Tel: 240-447-7156  
Email: Bettye.walters@fda.hhs.gov

Mrs Leah Wilkinson  
Vice President of Legislative, Regulatory and State Affairs  
American Feed Industry Association  
2101 Wilson Blvd. Suite 916  
Arlington, VA  
United States of America  
Tel: 703-558-3560  
Email: lwilkinson@afia.org

Dr Dong Yan  
Biologist  
Center for Veterinary Medicine  
U.S. Food and Drug Administration  
7500 Standish Place, HFV -151  
Rockville, MD  
United States of America  
Tel: +1 240 402 0825  
Email: dong.yan@fda.hhs.gov

URUGUAY

Dr Graciela Oficialdegui  
Coordinadora Ejecutiva del Programa Nacional de Residuos Biológicos  
Ministerio de Ganadería, Agricultura y Pesca  
Dirección Ruta 8 km 17.500  
Montevideo  
Uruguay  
Tel: +5982220 4000 int 153108  
Email: oficialdegui@mgap.gub.uy

Dr Nancy Machado  
Directora  
Montevideo  
Laboratorio Microbióticos Uruguay  
Bypass Ruta 8 y 101 ramal José D’Elia  
Canelones  
Uruguay  
Tel: 2292 5325  
Email: nmachado@hotmail.com
VENEZUELA (BOLIVARIAN REPUBLIC OF) - VENEZUELA (REPUBLIQUE BOLIVARIENNE DU) - VENEZUELA (REPÚBLICA BOLIVARIANA DE)

Mr Jean Carlos Belandria Briceño
Instituto Nacional de Investigaciones Agrícolas
Apartado Postal 4001 Av. Los Haticos detrás del C.C Las banderas; Edif. INSOPESCA
Maracaibo, Zulia
Venezuela (Bolivarian Republic of)
Tel: 0058 261 7642324
Email: jbelandria.inia.zulia@gmail.com

OBSERVERS
OBSERVATEURS
OBSERVADORES

UNITED NATIONS AND OTHER RELATED ORGANIZATIONS - NATIONS UNIES ET AUTRES ORGANISATIONS APPARENTÉES - NACIONES UNIDAS Y OTRAS ORGANIZACIONES AFINES

INTERNATIONAL ATOMIC ENERGY AGENCY (IAEA)

Mr James Jacob Sasanya
Food Safety Specialist
Nuclear Sciences and Application (NA)
IAEA (Joint FAO/IAEA)
Vienna International Centre, PO BOX 100
Vienna
Austria
Tel: 00431260026058
Email: j.sasanya@iaea.org

INTERNATIONAL GOVERNMENTAL ORGANIZATIONS - ORGANISATIONS GOUVERNEMENTALES INTERNATIONALES - ORGANIZACIONES GUBERNAMENTALES INTERNACIONALES

AFRICAN UNION (AU)

Dr Raphael Coly
Coordinator Standards & Trade Secretariat
Drea
African Union
Kenindia Business Park
Nairobi
Kenya
Tel: +254739622183
Email: raphael.coly@au-ibar.org

INTER-AMERICAN INSTITUTE FOR COOPERATION ON AGRICULTURE (IICA)

Mrs Sacha Treilles
International Agricultural Health and Food Safety Specialist
Inter-American Institute for Cooperation on Agriculture (IICA)
Email: sacha.trellies@iica.int

World Organisation for Animal Health - Organisation Mondiale de la Santé Animale (OIE) – Organización Mundial de Sanidad Animal

Dr Jean-Pierre Orand
Director
OIE Collaborating Centre
Anses-ANMV 8 rue Claude Bourgelat PA de la Grande Marche Javené - CS 70611
FOUGÉRES
France
Tel: +33 2 99 94 78 71
Email: jean-pierre.orand@anses.fr

Dr Maria Szabo
Charge de mission for Veterinary Medicinal Products Science and New Technologies
OIE
12, rue de Prony
Paris
France
Tel: 33 (0) 1 44 15 18 14
Email: m.szabo@oie.int

INTERNATIONAL NON-GOVERNMENTAL ORGANIZATIONS - ORGANISATIONS NON-GOUVERNEMENTALES INTERNATIONALES - ORGANIZACIONES INTERNACIONALES NO GUBERNAMENTALES

INTERNATIONAL FEED INDUSTRY FEDERATION (IFIF)

Dr Karine Tanan
IFIF Regulatory Committee Chair
International Feed Industry Federation (IFIF)
P.O. Box 1340
Wiehl
Germany
Email: Karine_TANAN@cargill.com

NATIONAL HEALTH FEDERATION (NHF)

Mr Scott Tips
President
National Health Federation
P.O. Box 688
Monrovia
United States of America
Tel: 16263572181
Email: scott@monaco.mc

Ms Katherine Carroll
National Health Federation
P.O. Box 688
Monrovia
United States of America
Tel: 16263572181
Email: katacarroll@gmail.com

SAFE SUPPLY OF AFFORDABLE FOOD EVERYWHERE (SSAFE) (SSAFE)

Mr Mike Windisch
SSAFE
Email: mike_windisch@cargill.com

HEALTH FOR ANIMALS (HEALTHFORANIMALS)

Mr Anjulen Anderson
HealthforAnimals
Anjulen Anderson Elanco Animal Health 555 12 Street, NW Washington, DC 20004 USA
Email: Anderson.a@elanco.com
WHO
Dr Philippe Jean Verger
Scientist
Department of Food Safety and Zoonoses (FOS)
20, avenue Appia
Geneva 27
Switzerland
Tel: +41 22 791 3053
Email: vergerp@who.int

Ms Annamaria Bruno
Senior Food Standards Officer
Joint FAO/WHO Food Standards Programme
Viale delle Terme di Caracalla
Rome
Italy
Tel: +39 06 5705 6254
Email: annamaria.bruno@fao.org

Ms Gracia Brisco
Food Standards Officer
Joint FAO/WHO Food Standards Programme
Viale delle Terme di Caracalla
Rome
Italy
Tel: +39 06 5705 2700
Email: gracia.brisco@fao.org

Ms Takako Yano
Food Standards Officer
Joint FAO/WHO Food Standards Programme
Viale delle Terme di Caracalla
Rome
Italy
Tel: +39 06 5705 5868
Email: takako.yano@fao.org

Mr David Massey
Special Advisor
Joint FAO/WHO Food Standards Programme
FAO
Viale delle Terme di Caracalla
Rome
Italy
Email: David.Massey@fao.org

Mr Tom Heilandt
Secretary, Codex Alimentarius Commission, O-i-C
Joint FAO/WHO Food Standards Programme
Viale delle Terme di Caracalla
Rome
Italy
Tel: +39 06 5705 4384
Email: tom.heilandt@fao.org

HOST GOVERNMENT SECRETARIAT – SECRÉTARIAT DU GOUVERNEMENT HÔTE - SECRETARÍA DEL GOBIERNO ANFITRIÓN

Mr Kenneth Lowery
International Issues Analyst
U.S. Codex Office
1400 Independence Avenue SW Room 4861-South Building
Washington DC
United States of America
Tel: +1 202 690 4042
Email: kenneth.lowery@fsis.usda.gov

Ms Marie Maratos
International Issues Analyst
U.S. Codex Office, Food Safety & Inspection Service
U. S. Department of Agriculture
1400 Independence Avenue, SW Room 4861
Washington, DC
United States of America
Tel: +1-202-690-4795
Email: marie.maratos@fsis.usda.gov

Mr Juan Estrella
Senior Program Manager
Office of Capacity Building and Development
U. S. Department of Agriculture
1400 Independence Ave SW Room 3838-S
Washington DC
United States of America
Tel: 202 720 4940
Email: juan.estrella@fas.usda.gov

Ms Omoefe Ogbeide
U.S. Codex Office
1400 Independence Ave. SW
Washington, DC
United States of America
Tel: (202)7204752
Email: Omoefe.Ogbeide@fsis.usda.gov
PROPOSED DRAFT RISK MANAGEMENT RECOMMENDATION FOR RESIDUES OF VETERINARY
DRUGS
(at Step 5 of the Elaboration Procedure)

GENTIAN VIOLET (antibacterial, antifungal and anthelminthic agent)

JECFA evaluation: 78th (2013) JECFA

Recommended risk management measures

In view of the JECFA conclusions on the available scientific information, there is no safe level of residues of gentian violet or its metabolites in food that represents an acceptable risk to consumers. For this reason, competent authorities should prevent residues of gentian violet in food. This can be accomplished by not using gentian violet in food producing animals.
IVERMECTIN (antiparasitic agent)

**Acceptable Daily Intake (ADI):**  
0-1 µg/kg body weight (40th JECFA, 1992).

**Estimated Dietary Exposure (TMDI):**  
The 40th JECFA (WHO TRS No. 832, 1993) included an estimate of the potential intake from muscle. No further assessment of dietary exposure was undertaken at the current meeting.

**Residue Definition:**  
Ivermectin B1a.

<table>
<thead>
<tr>
<th>Species</th>
<th>Tissue</th>
<th>MRLs (µg/kg)</th>
<th>Step</th>
<th>JECFA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cattle</td>
<td>Muscle</td>
<td>4</td>
<td>discontinued</td>
<td>78</td>
</tr>
</tbody>
</table>
IVERMECTIN (antiparasitic agent)

Acceptable Daily Intake (ADI): 0-10 μg/kg body weight on the basis of a no-observed-adverse-effect level (NOAEL) of 0.5 mg/kg body weight per day for neurological effects (mydriasis) and retardation of weight gain in a 14-week dog study, with application of an uncertainty factor of 50 (5 for interspecies differences based on pharmacokinetic studies in dogs and humans and 10 for intraspecies differences). The previous ADI of 0-1 μg/kg body weight was withdrawn. (81st JECFA, 2015)

Acute Reference dose (ARfD): 0.2 mg/kg body weight, based on a NOAEL of 1.5 mg/kg body weight, the highest dose tested in a safety, tolerability and pharmacokinetics study in healthy human subjects, with application of an uncertainty factor of 10 for intraspecies variability. (81st JECFA, 2015)

Estimated chronic dietary exposure (GECDE): The estimated daily intake (EDI) is 38 μg/person per day, based on a 60 kg individual, which represents 6% of the upper bound of the ADI. The global estimate of chronic dietary exposure (GECDE) for the general population is 0.9 μg/kg body weight per day, which represents 9% of the upper bound of the ADI. The GECDE for children is 1.5 μg/kg body weight per day, which represents 15% of the upper bound of the ADI. The GECDE for infants is 1.3 μg/kg body weight per day, which represents 13% of the upper bound of the ADI. (81st JECFA, 2015)

Estimated Acute Dietary Exposure (GEADE): A combined analysis of all studies submitted showed that after 14 days, the maximum values of residues found at injection sites led to a Global Estimate of Acute Dose Exposure (GEADE) of 52 μg/kg bw for the general population and 87 μg/kg bw for children, corresponding, respectively, to 27% and 43% of the ARfD. (81st JECFA, 2015)

Residue Definition: Ivermectin B₁₆.

<table>
<thead>
<tr>
<th>Species</th>
<th>Tissue</th>
<th>MRLs (µg/kg)</th>
<th>Step</th>
<th>JECFA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cattle</td>
<td>Fat</td>
<td>400</td>
<td>5/8</td>
<td>81</td>
</tr>
<tr>
<td>Cattle</td>
<td>Kidney</td>
<td>100</td>
<td>5/8</td>
<td>81</td>
</tr>
<tr>
<td>Cattle</td>
<td>Liver</td>
<td>800</td>
<td>5/8</td>
<td>81</td>
</tr>
<tr>
<td>Cattle</td>
<td>Muscle</td>
<td>30</td>
<td>5/8</td>
<td>81</td>
</tr>
</tbody>
</table>

Keys for List of MRLs for Veterinary Drugs
Step: (r), revised MRL; (a), amended MRL; T, temporary MRL.
JECFA: Meeting number of the Joint FAO/WHO Expert Committee on Food Additives where the MRL was recommended/considered.
CCRVDF: Session number of the CCRVDF where the MRL was considered and Appendix number of its report where the MRL is contained.
LASALOCID SODIUM (antiparasitic agent)

**Acceptable Daily Intake (ADI):** 0-5 µg/kg body weight on the basis of a NOAEL of 0.5 mg/kg body weight per day from a developmental toxicity study in rabbits and a multigeneration reproductive toxicity study in rats, with application of an uncertainty factor of 100 for interspecies and intraspecies variability (78th JECFA, 2013).

**Estimated Dietary Exposure (EDI):** 80 µg/person per day was calculated, which represents approximately 27% of the upper bound of the ADI (78th JECFA, 2013).

**Residue Definition:** Lasalocid A.

<table>
<thead>
<tr>
<th>Species</th>
<th>Tissue</th>
<th>MRLs (µg/kg)</th>
<th>Step</th>
<th>JECFA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chicken</td>
<td>Muscle</td>
<td>400</td>
<td>5/8</td>
<td>78, 81</td>
</tr>
<tr>
<td>Chicken</td>
<td>Liver</td>
<td>1200</td>
<td>5/8</td>
<td>78, 81</td>
</tr>
<tr>
<td>Chicken</td>
<td>Kidney</td>
<td>600</td>
<td>5/8</td>
<td>78, 81</td>
</tr>
<tr>
<td>Chicken</td>
<td>Skin + Fat</td>
<td>600</td>
<td>5/8</td>
<td>78, 81</td>
</tr>
<tr>
<td>Turkey</td>
<td>Muscle</td>
<td>400</td>
<td>5/8</td>
<td>78, 81</td>
</tr>
<tr>
<td>Turkey</td>
<td>Liver</td>
<td>1200</td>
<td>5/8</td>
<td>78, 81</td>
</tr>
<tr>
<td>Turkey</td>
<td>Kidney</td>
<td>600</td>
<td>5/8</td>
<td>78, 81</td>
</tr>
<tr>
<td>Turkey</td>
<td>Skin + Fat</td>
<td>600</td>
<td>5/8</td>
<td>78, 81</td>
</tr>
<tr>
<td>Quail</td>
<td>Muscle</td>
<td>400</td>
<td>5/8</td>
<td>78, 81</td>
</tr>
<tr>
<td>Quail</td>
<td>Liver</td>
<td>1200</td>
<td>5/8</td>
<td>78, 81</td>
</tr>
<tr>
<td>Quail</td>
<td>Kidney</td>
<td>600</td>
<td>5/8</td>
<td>78, 81</td>
</tr>
<tr>
<td>Quail</td>
<td>Skin + Fat</td>
<td>600</td>
<td>5/8</td>
<td>78, 81</td>
</tr>
<tr>
<td>Pheasant</td>
<td>Muscle</td>
<td>400</td>
<td>5/8</td>
<td>78, 81</td>
</tr>
<tr>
<td>Pheasant</td>
<td>Liver</td>
<td>1200</td>
<td>5/8</td>
<td>78, 81</td>
</tr>
<tr>
<td>Pheasant</td>
<td>Kidney</td>
<td>600</td>
<td>5/8</td>
<td>78, 81</td>
</tr>
<tr>
<td>Pheasant</td>
<td>Skin + Fat</td>
<td>600</td>
<td>5/8</td>
<td>78, 81</td>
</tr>
</tbody>
</table>

Note: The 78th JECFA extended the MRLs in chicken to turkey and quail and extrapolated the MRLs in chicken to pheasant. No information was available for duck, including on approved uses. As the compound is not registered for use in laying hens, according to the sponsor, it is not appropriate to recommend MRLs for egg.
TEFLUBENZURON (insecticide)

Acceptable Daily Intake (ADI): 0.5 μg/kg body weight on the basis of a lower 95% confidence limit on the benchmark dose for a 10% response (BMDL10) of 0.54 mg/kg body weight per day for hepatocellular hypertrophy in male mice observed in a carcinogenicity study, with application of an uncertainty factor of 100 to account for interspecies and intraspecies variability. (81st JECFA, 2015)

Estimated chronic dietary exposure (GECDE): The EDI is 42.9 μg/person per day, on the basis of a 60 kg individual, which represents approximately 14% of the upper bound of the ADI. The GECDE for the general population is 1.6 μg/kg body weight per day, which represents 31% of the upper bound of the ADI. The GECDE for children is 2.1 μg/kg body weight per day, which represents 43% of the upper bound of the ADI. The GECDE for infants is 0.9 μg/kg body weight per day, which represents 18% of the upper bound of the ADI. (81st JECFA, 2015)

Residue Definition: Teflubenzuron.

<table>
<thead>
<tr>
<th>Species</th>
<th>Tissue</th>
<th>MRLs (µg/kg)</th>
<th>Step</th>
<th>JECFA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Salmon</td>
<td>Fillet&lt;sup&gt;a&lt;/sup&gt;</td>
<td>400</td>
<td>5/8</td>
<td>81</td>
</tr>
<tr>
<td>Salmon</td>
<td>Muscle</td>
<td>400</td>
<td>5/8</td>
<td>81</td>
</tr>
</tbody>
</table>

<sup>a</sup>Muscle plus skin in natural proportion.

Keys for List of MRLs for Veterinary Drugs
Step: (r), revised MRL; (a), amended MRL; T, temporary MRL.
JECFA: Meeting number of the Joint FAO/WHO Expert Committee on Food Additives where the MRL was recommended/considered.
CCRVDF: Session number of the CCRVDF where the MRL was considered and Appendix number of its report where the MRL is contained.
PROPOSED DRAFT MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS
(at Step 4 of the Elaboration Procedure)

ZILPATEROL HYDROCHLORIDE (β2-adrenoceptor agonist)

Acceptable Daily Intake (ADI): 0-0.04 μg/kg body weight established at the seventy-eighth meeting (WHO TRS No. 988, 2014) and reaffirmed at the eighty-first meeting. (81st JECFA, 2015)

Acute Reference Dose (ARfD): 0.04 μg/kg body weight based on a lowest-observed-adverse-effect level (LOAEL) of 0.76 μg/kg body weight for acute pharmacological effects observed in a single-dose human study, with application of an uncertainty factor of 20, comprising a default uncertainty factor of 10 for human individual variability and an additional uncertainty factor of 2 to account for use of a LOAEL for a slight effect instead of a NOAEL. (81st JECFA, 2015)

Estimated Acute Dietary Exposure (GEADE): 1.9 μg/day for the general population, which represents approximately 80% of the ARfD. The GEADE is 0.57 μg/day for children, which represents approximately 94% of the ARfD. (81st JECFA, 2015)

Residue Definition: Zilpaterol (free base) in muscle, liver and kidney.

<table>
<thead>
<tr>
<th>Species</th>
<th>Tissue</th>
<th>MRLs (µg/kg)</th>
<th>Step</th>
<th>JECFA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cattle</td>
<td>Kidney</td>
<td>3.3</td>
<td>4</td>
<td>81</td>
</tr>
<tr>
<td>Cattle</td>
<td>Liver</td>
<td>3.5</td>
<td>4</td>
<td>81</td>
</tr>
<tr>
<td>Cattle</td>
<td>Muscle</td>
<td>0.5</td>
<td>4</td>
<td>81</td>
</tr>
</tbody>
</table>
### Priorities List of Veterinary Drugs for Evaluation or Re-Evaluation by JECFA (for approval)

<table>
<thead>
<tr>
<th>Name of Compound</th>
<th>Question(s) to be answered</th>
<th>Data Availability / Timing</th>
<th>Proposed by</th>
<th>Comments</th>
<th>When will data package be available</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amoxicillin</td>
<td>Request MRL establishment in fin fish muscle and skin in natural proportions.</td>
<td>Nominator notes that relevant MRLs are established in a number of countries.</td>
<td>Republic of Korea</td>
<td>JECFA ADI of 0-0.7 μg/kg body weight on the basis of microbiological effects (2011). MRLs established in EU for all food producing species. Classified by WHO as a critically important antimicrobial in human medicine (CIA). Prudent use in animal husbandry recommended. Classified by OIE as a highly important antimicrobial in veterinary medicine (VCIA) with comments including: This class is very important in the treatment of many diseases in a broad range of animal species; Few economical alternatives are available.</td>
<td>Republic of Korea and USA confirm data availability at March 2017.</td>
</tr>
<tr>
<td>Ampicillin</td>
<td>Request ADI &amp; MRL establishment in fin fish muscle and skin in natural proportions</td>
<td>Nominator notes that relevant MRLs are established in a number of countries.</td>
<td>Republic of Korea</td>
<td>MRLs established in EU for all food producing species. Classified by WHO as a CIA. Prudent use in animal husbandry recommended. Classified by OIE as a VCIA with comments including: This class is very important in the treatment of many diseases in a broad range of animal species; Few economical alternatives are available.</td>
<td>No data to allow establishment of ADI. Republic of Korea confirms data availability at March 2017.</td>
</tr>
<tr>
<td>Bismuth sub-nitrate</td>
<td>Request ADI and MRL for cattle milk</td>
<td>Nominator notes has been evaluated by a number of countries.</td>
<td>New Zealand</td>
<td></td>
<td>Full package available by end March 2017</td>
</tr>
<tr>
<td>Name of Compound</td>
<td>Question(s) to be answered</td>
<td>Data Availability / Timing</td>
<td>Proposed by</td>
<td>Comments</td>
<td>When will data package be available</td>
</tr>
<tr>
<td>------------------</td>
<td>---------------------------</td>
<td>---------------------------</td>
<td>-------------</td>
<td>----------</td>
<td>-----------------------------------</td>
</tr>
<tr>
<td>Ethion</td>
<td>Request ADI and MRL for cattle tissues</td>
<td>Nominator notes that relevant MRLs are established in a number of countries. IFAH members unable to provide data. Argentina and Uruguay has method, residue, pharmacokinetic and monitoring data.</td>
<td>Argentina/Uruguay</td>
<td>ADI set by JMPR at 2 µg/kg bw (1990). An updated toxicological review required JECFA Pilot Study (see para. 138).</td>
<td>Residue, method, residue, pharmacokinetic and monitoring data will be available by March 2017. Toxicological data required but availability uncertain. Data on non traditional sources to be provided by March 2017.</td>
</tr>
<tr>
<td>Flumethrin</td>
<td>Request ADI and MRL establishment for honey</td>
<td></td>
<td>EU</td>
<td>ADI set by JMPR at 4 µg/kg bw (1996) Currently scheduled by CCPR for JMPR evaluation of tox in 2018.</td>
<td>Full data package (tox and residue) will be available by January 2017.</td>
</tr>
<tr>
<td>Halquinol</td>
<td>Request ADI and MRL establishment in swine tissues</td>
<td></td>
<td>USA and Philippines</td>
<td></td>
<td>Data will be available by end March 2017 Full data package (tox and residue).</td>
</tr>
<tr>
<td>Lufenuron</td>
<td>Request ADI and MRL establishment in fin fish (salmon/trout) muscle and skin in natural proportions</td>
<td>Nominator notes that relevant MRLs are established in a number of countries.</td>
<td>Norway and Chile</td>
<td>Finfish MRL established in EU. Lufenuron was evaluated by the 2015 JMPR which set an ADI (20 µg/kg bw) with ARfD unnecessary.</td>
<td>Full data package (tox and residue) will be available by January 2017.</td>
</tr>
<tr>
<td>Monepantel</td>
<td>Request MRL establishment in cattle tissues</td>
<td></td>
<td>New Zealand</td>
<td></td>
<td>Data will be available by December 2016 (residue data).</td>
</tr>
</tbody>
</table>

**Part B. Compounds for which data availability will be confirmed at the next CCRVDF**

<table>
<thead>
<tr>
<th>Name of Compound</th>
<th>Question(s) to be answered</th>
<th>Data Availability / Timing</th>
<th>Proposed by</th>
<th>Comments</th>
<th>When will data package be available</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethoxyquin (feed additive use)</td>
<td>Request to establish MRL in shrimp muscle</td>
<td></td>
<td>Philippines</td>
<td>From CCRVDF21 ADI 0-0.005 mg/kg bw (2005 JMPR). The ADI and the ARfD are applicable to ethoxyquin and its metabolites/degradation products methylethoxyquin (MEQ), dihydroethoxyquin (DHEQ), dehydromethylethoxyquin (DHMEQ) ARfD 0.5 mg/kg bw (2005 JMPR).</td>
<td>No data submitted in response to call for data. Data availability to be confirmed at CCRVDF24.</td>
</tr>
<tr>
<td>Name of Compound</td>
<td>Question(s) to be answered</td>
<td>Data Availability / Timing</td>
<td>Proposed by</td>
<td>Comments</td>
<td>When will data package be available</td>
</tr>
<tr>
<td>----------------------------------</td>
<td>---------------------------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------------------------</td>
<td>---------------------------</td>
<td>---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>----------------------------------</td>
</tr>
<tr>
<td>Fosfomycin (fosfomicina/ phosphomycin)</td>
<td>Request ADI and MRL establishment in chicken and swine tissues</td>
<td>Nominator notes that relevant MRLs are established in a number of countries.</td>
<td>Argentina/Paraguay</td>
<td>Classified by WHO as CIA. Prudent use in animal husbandry recommended. Classified by OIE as VCIA with comments: this antimicrobial is authorised only in a few countries. Fosfomycin has a limited number of alternatives in some fish infections. Critically important for fish.</td>
<td>Residue data available now but availability of toxicity data is uncertain. Data availability to be confirmed at CCRVDF24.</td>
</tr>
<tr>
<td>Triamcinolone (triamcinolona)</td>
<td>Request ADI and MRL establishment in cattle, sheep, goats and swine tissues</td>
<td>Nominator notes that relevant MRLs are established in Argentina.</td>
<td>Argentina</td>
<td>Need clarification as to availability of toxicology and metabolism data.</td>
<td>Residue data available now but availability of toxicity data is uncertain. Data availability to be confirmed at CCRVDF24.</td>
</tr>
</tbody>
</table>

**Part C. Continuing JECFA evaluations from 2016, for information**

<table>
<thead>
<tr>
<th>Compound</th>
<th>Question(s) to be answered</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diflubenzuron</td>
<td>Toxicity data for 4-chloroaniline (PCA)</td>
</tr>
<tr>
<td>Sisapronil</td>
<td>Additional data/scientific argument to enable ADI to be determined</td>
</tr>
<tr>
<td>Zilpaterol</td>
<td>Data on relative bioavailability</td>
</tr>
</tbody>
</table>