CODEX ALIMENTARIUS COMMISSION

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World Health Organization

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REP17/RVDF

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

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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

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LIST OF ABBREVIATIONS

ADI	Acceptable Daily Intake
ALARA	As Low As Reasonably Achievable
AMR	Antimicrobial Resistance
APFSWG	OIE Working Group on Animal Production Food Safety
ARfD	Acute Reference Dose
bw	body weight
CAC	Codex Alimentarius Commission
CCEXEC	Executive Committee of the Codex Alimentarius Commission
CCRVDF	Codex Committee on Residues of Veterinary Drugs in Foods
CCPR	Codex Committee on Pesticide Residues
CL	Circular Letter
CRD	Conference Room Document
EHC	Environmental Health Criteria
EU	European Union
EWG	Electronic Working Group
FAO	Food and Agriculture Organization of the United Nations
GAP	Good Agricultural Practice
GEADE	Estimated Acute Dietary Exposure
GL	Guidelines
GMP	Good Manufacturing Practice
GVP	Good Veterinary Practice
IAEA	International Atomic Energy Agency
JECFA	Joint FAO/WHO Expert Committee on Food Additives
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LOAEL	Lowest-Observed-Adverse-Effect Level
MRL	Maximum Residue Limit
NOAEL	No-observed-adverse-effect level
OIE	World Organization for Animal Health
PCA	4-chloroaniline
PVS	Performance of Veterinary Services
PWG	Physical Working Group
R&D	Research and Development
RMR	Risk Management Recommendation
SPS	Sanitary and Phytosanitary
USA	United States of America
USDA	United States Department of Agriculture
VICH	International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products
VOF	VICH Outreach Forum
WHO	World Health Organization
WG	Working Group

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 SESSION[1]

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 Competence[2]

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.

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[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 web site[6], for transparency.

MRLs in offal tissues

21. The Representative of FAO introduced JECFA's response to the request of CCRVDF22 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 web site[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 Resistance[10]. 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[11]

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)[12]

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.

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[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 (CRD10), Panama (CRD19), 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), TEFLUBENZURON (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)

70. 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

71. 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.

72. 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.

73. Members were encouraged to forward their concerns to JECFA using the concern form[16].

Conclusion

74. 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 (Agenda Item 7.1)[17]

75. The USA and Canada, as Co-chairs of the PWG, summarized the key points of discussion as contained in CRD2 and drew the attention of the Committee to the recommendations of the PWG as follows:

i) Coverage of the *Code of Practice on Good Animal Feeding* (CAC/RCP 54-2004), hereafter the "Code", to manage the unavoidable and unintended residues of approved veterinary drugs in foods resulting from carry-over of veterinary drugs in feed;

ii) Elaboration of risk management recommendations to minimize the unavoidable and unintended presence of residues of approved veterinary drugs in foods resulting from carry-over of veterinary drugs in feed; and

iii) Definition of appropriate questions for scientific assessment by FAO and WHO (including a case-study on a particular veterinary drug/commodity combination i.e. lasalocid sodium in eggs).

Discussion

76. 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")

77. 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 isometamedium 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 isometamedium 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 synthetize 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 on 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 CCRVDF24.
- 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 CCRVDF24.

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[23]

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

Appendix I

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LISTE DES PARTICIPANTS
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Appendix II

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.

Appendix III

PROPOSED DRAFT MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS

(discontinued by CCRVDF23)

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.

Species	Tissue	MRLs (µg/kg)	Step	JECFA
Cattle	Muscle	4	discontinued	78

Appendix IV

PROPOSED DRAFT MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS

(at Step 5/8 of the Elaboration Procedure)

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 B_{1a}.

Species	Tissue	MRLs (µg/kg)	Step	JECFA
Cattle	Fat	400	5/8	81
Cattle	Kidney	100	5/8	81
Cattle	Liver	800	5/8	81
Cattle	Muscle	30	5/8	81

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.

Species	Tissue	MRLs (µg/kg)	Step	JECFA
Chicken	Muscle	400	5/8	78, 81
Chicken	Liver	1200	5/8	78, 81
Chicken	Kidney	600	5/8	78, 81
Chicken	Skin + Fat	600	5/8	78, 81
Turkey	Muscle	400	5/8	78, 81
Turkey	Liver	1200	5/8	78, 81
Turkey	Kidney	600	5/8	78, 81
Turkey	Skin + Fat	600	5/8	78, 81
Quail	Muscle	400	5/8	78, 81
Quail	Liver	1200	5/8	78, 81
Quail	Kidney	600	5/8	78, 81
Quail	Skin + Fat	600	5/8	78, 81
Pheasant	Muscle	400	5/8	78, 81
Pheasant	Liver	1200	5/8	78, 81
Pheasant	Kidney	600	5/8	78, 81
Pheasant	Skin + Fat	600	5/8	78, 81

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.

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.

TEFLUBENZURON (insectide)

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.

Species	Tissue	MRLs (µg/kg)	Step	JECFA
Salmon	Fillet[a]	400	5/8	81
Salmon	Muscle	400	5/8	81

[a] Muscle plus skin in natural proportion.

Keys for List of MRLs for Veterinary Drugs
Step: (r), revised MRL; (a), amended MRL; T, temporary MRL.
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Appendix V

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.

Species	Tissue	MRLs (µg/kg)	Step	JECFA
Cattle	Kidney	3.3	4	81
Cattle	Liver	3.5	4	81
Cattle	Muscle	0.5	4	81

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.

Appendix VI

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

(for approval)

Name of Compound	Question(s) to be answered	Data Availability / Timing	Proposed by	Comments	When will data package be available
PART A: Compounds proposed for (re)evaluation by JECFA					
Amoxicillin	Request MRL establishment in fin fish muscle and skin in natural proportions.	Nominator notes that relevant MRLs are established in a number on countries. Some data in public domain. IFAH members unable to provide data. Korea has method, residue, pharmacokinetic and monitoring data.	Republic of Korea	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.	Republic of Korea and USA confirm data availability at March 2017.
Ampicillin	Request ADI & MRL establishment in fin fish muscle and skin in natural proportions	Nominator notes that relevant MRLs are established in a number of countries. Availability of sponsor data not clear. Some data in public domain. IFAH members unable to provide data. Republic of Korea has method, residue, pharmacokinetic and monitoring data.	Republic of Korea	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.	No data to allow establishment of ADI. Republic of Korea confirms data availability at March 2017.
Bismuth sub-nitrate	Request ADI and MRL for cattle milk	Nominator notes has been evaluated by a number of countries.	New Zealand		Full package available by end March 2017

Name of Compound	Question(s) to be answered	Data Availability / Timing	Proposed by	Comments	When will data package be available
Ethion	Request ADI and MRL for cattle tissues	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.	Argentina/Uruguay	ADI set by JMPR at 2 µg/kg bw (1990). An updated toxicological review required JECFA Pilot Study (see para. 138).	Residue, method, residue, pharmacokinetic and monitoring data data will be available by March 2017. Toxicological data required but availability uncertain. Data on non traditional sources to be provided by March 2017.
Flumethrin	Request ADI and MRL establishment for honey		EU	ADI set by JMPR at 4 µg/kg bw (1996) Currently scheduled by CCPR for JMPR evaluation of tox in 2018.	Full data package (tox and residue) will be available by January 2017.
Halquinol	Request ADI and MRL establishment in swine tissues		USA and Philippines		Data will be available by end March 2017 Full data package (tox and residue).
Lufenuron	Request ADI and MRL establishment in fin fish (salmon/trout) *muscle and skin in natural proportions*	Nominator notes that relevant MRLs are established in a number of countries.	Norway and Chile	Finfish MRL established in EU. Lufenuron was evaluated by the 2015 JMPR which set an ADI (20 µg/kg bw) with ARfD unnecessary.	Full data package (tox and residue) will be available by January 2017.
Monepantel	Request MRL establishment in cattle tissues		New Zealand		Data will be available by December 2016 (residue data).
Part B. Compounds for which data availability will be confirmed at the next CCRVDF					
Ethoxyquin (feed additive use)	Request to establish MRL in shrimp muscle		Philippines	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), dehydrimethylethoxyquin (DHMEQ) ARfD 0.5 mg/kg bw (2005 JMPR).	No data submitted in response to call for data. Data availability to be confirmed at CCRVDF24.

Name of Compound	Question(s) to be answered	Data Availability / Timing	Proposed by	Comments	When will data package be available
Fosfomycin (fosfomicina/ phosphomycin)	Request ADI and MRL establishment in chicken and swine tissues	Nominator notes that relevant MRLs are established in a number of countries.	Argentina/Paraguay	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.	Residue data available now but availability of toxicity data is uncertain. Data availability to be confirmed at CCRVDF24.
Triamcinolone (triamcinolona)	Request ADI and MRL establishment in cattle, sheep, goats and swine tissues	Nominator notes that relevant MRLs are established in Argentina.	Argentina	Need clarification as to availability of toxicology and metabolism data.	Residue data available now but availability of toxicity data is uncertain. Data availability to be confirmed at CCRVDF24.
Part C. Continuing JECFA evaluations from 2016, for information					
Diflubenzuron	Toxicity data for 4-chloroaniline (PCA)				
Sisapronil	Additional data/scientific argument to enable ADI to be determined				
Zilpaterol	Data on relative bioavailability				