CODEX ALIMENTARIUS COMMISSION

E

Food and Agriculture Organization of the United Nations

World Health Organization

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REP15/RVDF

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

Thirty-eighth Session

CICG, Geneva, Switzerland

6 – 11 July 2015

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

San José, Costa Rica

27 April – 1 May 2015

NOTE: This report includes Circular Letter CL 2015/14-RVDF

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CL 2015/14-RVDF
May 2015

To: Codex Contact Points
Interested International Organizations

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

Subject: Distribution of the Report of the Twenty-second Session of the Codex Committee on Residues of Veterinary Drugs in Foods (REP15/RVDF)

The report of the Twenty-second Session of the Codex Committee on Residues of Veterinary Drugs in Foods will be considered by the 38th Session of the Codex Alimentarius Commission (Geneva, Switzerland, 6-11 July 2015).

PART A – MATTERS FOR ADOPTION BY THE 38TH SESSION OF THE CODEX ALIMENTARIUS COMMISSION

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

1. **Proposed Draft Maximum Residue Limits for Veterinary Drugs** (REP15/RVDF paras 70, 75, 90 and Appendix IV);

2. **Proposed Draft Risk Management Recommendations for Residues of Veterinary Drugs:** (REP15/RVDF para. 92 and Appendix VII).

Governments and international organizations wishing to submit comments on the above texts should do so in writing ***by e-mail***, to the Secretariat, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00153 Rome, Italy (e-mail: codex@fao.org) **before 19 June 2015.**

PART B – REQUEST FOR COMMENTS AT STEP 3

3. **Proposed Draft Risk Management Recommendation for Gentian Violet** (REP15/RVDF para. 32 and Appendix III).

Governments and international organizations wishing to submit comments on the above texts should do so in writing, ***by e-mail***, to U.S. Codex Office, Food Safety and Inspection Service, US Department of Agriculture, Room 4861, South Building, 14th Independence Avenue, S.W., Washington DC 20250, USA (E-mail: CCRVDF-USSEC@fsis.usda.gov), with a copy to the Secretariat, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, Viale delle Terme di Caracalla, 00153 Rome, Italy (E-mail: Codex@fao.org) **before 31 July 2016.**

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

Matters for Adoption/Approval by the 38th Session of the Codex Alimentarius Commission

Draft and proposed draft Standards and Related Texts for adoption

The Committee forwarded:

- Proposed draft maximum residue limits (MRL) for derquantel (sheep tissues), emamectin benzoate (salmon and trout tissues) and monepantel (sheep tissues) and risk management recommendations (RMR) for dimetridazole, ipronodazole, metronidazole and ronidazole (paras 70, 75, 90, 92 and Appendices IV and VII).

Other matters for approval

The Committee forwarded:

- Draft and proposed draft MRLs for monepantel (sheep tissues) and derquantel (sheep tissues), recommended by the 75th JECFA, for discontinuation (para. 66 and Appendix VI);
- Priority List of veterinary drugs for evaluation re-evaluation by JECFA (para. 112 and Appendix VIII).

Other matters for information

The Committee:

- Provided replies regarding the status of implementation of selected activities of the Codex Strategic Plan 2014-2019 (para. 26 and Appendix II);
- Circulated for comments at Step 3 the RMR for gentian violet (para. 32 and Appendix III);
- Forwarded its discussion and conclusions on the 78th JECFA re-evaluation of recombinant bovine somatotropins (rbSTs) (paras 33-40);
- Held proposed draft MRLs for ivermectin (cattle tissues) and lasalocid sodium at Step 4 (paras 78, 84 and Appendix V).

Other Matters for FAO and WHO

The Committee:

- Forwarded requests to JECFA on (i) establishing MRLs for finfish, crustacean and molluscs or similar groups on the basis of data from one or more fish species; and (ii) extending the MRLs for emamectin benzoates to finfish in general or an appropriate sub-grouping (para. 110).

Other Matters

The Committee:

- Agreed to have discussions at every session on issues and concerns that impact the ability of CCRVDF to efficiently perform its work (para. 13)
- Established EWGs to prepare discussion papers: (i) a rating system to establish priorities for CCRVDF work (para. 13); and (ii) the unintended presence of residues of veterinary drugs in food commodity resulting from carry-over of veterinary drugs into feed (para. 85);
- Noting that CCRVDF has the latitude to put requests to JECFA for MRLs in honey, agreed to leave unaltered the *Risk Analysis Principles applied by CCRVDF* (para. 104);
- Agreed to add explanatory notes to the template attached to the Circular Letter requesting comments and information to the Priority List (para. 111);
- Established an EWG to implement a global survey to provide information to the CCRVDF to move compounds from the database on countries' needs for MRLs to the JECFA Priority List and agreed to continue to request inputs and maintain update the database (para. 120).

INTRODUCTION

1. The Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF) held its Twenty-second Session in San Josè (Costa Rica) from 27 April to 1 May 2015, at the kind invitation of the Governments of Costa Rica and the United States of America. Dr Steven Vaughn, Director of the Office of New Animal Drug Evaluation, United States Food and Drug Administration, Center for Veterinary Medicine, chaired the Session. The Session was attended by delegates from 62 Member countries and one Member organization, 9 international 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. His Excellency Mr Welmer Ramos Gonzalez, Minister of Economy and Commerce of Costa Rica opened the Session. In his remarks the Minister welcomed all the participants and underscored the value of the Codex process which brings together countries to develop international food standards based on science, that are subsequently used by countries as the basis for their national legislation.

3. Mr Luis Felipe Arauz Cavallini, Minister of Agriculture and Livestock of Costa Rica, Mr Brian Ronholm, Deputy Under Secretary for Food Safety U.S. Department of Agriculture, Mr Octavio Ramirez, FAO Representative ad interim of Costa Rica and Ms Angelika Tritscher, Food Safety and Zoonosis Department, WHO HQs, also addressed the delegates.

Division of Competence[2]

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

ADOPTION OF THE AGENDA (Agenda Item 1)[3]

5. The Committee adopted the Provisional Agenda as its Agenda for the Session and agreed to:

   - Establish an in-session Working Group, chaired by Australia and working in English, French and Spanish, to prepare recommendations on the Priority List of Veterinary Drugs for evaluation by JECFA (Item 8a) for consideration by the Plenary.

DISCUSSION PAPER REGARDING THE ISSUES AND CONCERNS THAT IMPACT THE ABILITY OF CCRVDF TO EFFICIENTLY PERFORM ITS WORK (Agenda Item 2)[4]

6. The Secretariat introduced the discussion paper and informed the Committee that comments received both before and after the formal presentation of the paper were available on the Codex ftp server[5].

7. The Chair reminded Members that the paper was the result of an initiative announced in CCRVDF21[6]. He stated that the paper intended to promote dialogue and discussion amongst Members, bringing them together, valuing differences, but developing alignment of thinking with a goal of working towards achieving consensus.

8. The Committee thanked the Chair for presenting a paper which allowed Members to recognise and address matters of critical importance. The close correlation with the responses prepared for the Strategic Plan questionnaire (Item 3) was noted.

9. Delegations spoke of the constant need for CCRVDF to operate in a timely, efficient and transparent manner (respecting Codex rules and procedures and the ultimate authority of the Commission) and to build capacity at the national level, as developing countries depended on the work of Codex to have standards in place to protect public health and ensure fair trade.

10. The role of JECFA, as the fundamental scientific basis for decision making in the Committee, was underlined as was the importance of CCRVDF Members conveying consensus reached in the Committee to their delegations attending the Commission in order to not simply re-debate issues.

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[1] Opening remarks and other speeches (CRD2).
[2] Annotated Agenda – Division of competence between the European Union and its Member States (CRD1).
[3] CX/RVDF 15/22/1.
[4] CX/RVDF 15/22/2.
[5] https://fao.ftp.org/Codex/meetings/CCRVDF/CCRVDF22
[6] REP14/RVDF para. 149.

11. The Representative of WHO recognised the constructive discussion and dialogue that had taken place and called on all parties to work together, including industry, in providing data to JECFA. The Representative acknowledged that the new way of listing priorities and forward planning was also an efficient way to increase transparency and that trusting the science provided by JECFA and using it fully were fundamental to the successful work of CCRVDF.

12. Several concrete proposals emerged from the discussion and these included:

- Establishing a rating system to set priorities for the Committee especially as meetings were held only every 18 months;
- Explore avenues such as using a Circular Letter addressed to drug companies seeking support to supply data in order to fill critical data gaps;
- Implementing scientific presentations and expanding the JECFA documentation included in meeting papers;
- Encouraging dialogue before meetings to promote a spirit of compromise; and
- Looking for opportunities to enhance communication and capacity building amongst delegations.

Conclusion

13. The Committee agreed to implement a discussion on this topic at every meeting of CCRVDF under Other Business. Noting the need to remain within the remit of CCRVDF the Committee further agreed to establish an electronic Working Group (EWG), led by France and working in English only, to prepare a discussion paper exploring the feasibility of adopting a rating type system to establish priorities for the work of the Committee.

MATTERS REFERRED BY THE CODEX ALIMENTARIUS COMMISSION AND OTHER CODEX COMMITTEES (Agenda Item 3)[7]

14. The Committee noted the information concerning the decisions and discussions of CAC37 related to the work of CCRVDF. The Committee also noted that several matters were for information purposes.

Codex Strategic Plan (2014-2019)

15. The Secretariat reminded delegates of the decision taken at CAC37 to establish a monitoring framework for the implementation of the Strategic Plan including mechanisms for systematic data collection via a template.

16. The Committee considered the responses on the implementation of the Strategic Plan based on a draft prepared by the Codex and the CCRVDF Secretariats, which took into account the comments submitted to this session.

17. The Committee made changes to the proposed responses and some editorial amendments to improve clarity. The following comments were also noted:

Activity 1.2.1

18. ~~A~~ systematic approach was required for identifying priorities in emerging risk and recommended a rating system similar to the one used in CCFH.

Activity 3.1.5

19. Other activities besides the use of multiple languages should be adopted to encourage participation and proposed that the Codex Secretariat enhance awareness (through the governments of Members) that participation in Codex meetings should be a high priority.

20. There are valuable advantages to working in two languages, however operating in this way is extremely labour intensive and has significant additional cost implications for the host countries.

Activity 3.2.3

21. The development of guidance and conduct of workshops are important to enhance the capacity of Members to develop and submit data for JECFA evaluation. Clearer guidance would contribute to enhance the participation of developing countries in the work of the Committee.

[7] CX/RVDF 15/22/3; Draft reply of CCRVDF22 on the Implementation of the 2014-2019 Strategic Plan (CRD3); Comments of Peru (CRD6); Gambia (CRD7); Costa Rica (CRD8); African Union (CRD9); Kenya (CRD10); Egypt (CRD16), Nigeria (CRD17); Indonesia (CRD19); Chile (CRD21).

22. Suggestions were made to:

- Seek technical assistance from JECFA to develop the capacity of Members to design, conduct and submit the required scientific studies to enable the submission of data to JECFA; and
- Continue to hold physical Working Groups (PWG) in conjunction with Committee meetings and not between.

23. The Chair, noting the importance of capacity building activities for CCRVDF, invited Members to propose and forward topics for future seminars and workshops to the Secretariats.

Activity 4.2.1

24. Examples of CCRVDF activities currently undertaken to facilitate consensus in the standard setting process:

- Working Groups as well as discussions on issues and concerns that impact the work of CCRVDF;
- The use of the concern form; and
- The informal meeting of the Chair with delegations and regions.

25. There should be monitoring and evaluation of adopted standards in terms of implementation by the Member. However, the Committee agreed not to include any specific examples in the reply as the list might not be comprehensive and balanced.

Conclusion

26. The Committee agreed to forward the responses to CCEXEC and CAC for consideration (Appendix II).

MATTERS OF INTEREST ARISING FROM FAO AND WHO AND FROM THE 78TH JECFA MEETING (Agenda Item 4) [8]

27. The JECFA Secretariat introduced the report and noted that some of the matters would be addressed when discussing the relevant agenda items.

Gentian violet

28. Regarding gentian violet, the 78th JECFA noted the structural similarity to malachite green and, based on a literature review, concluded that it was not appropriate to establish an ADI and recommend MRLs due to the toxicological mode of action, which is carcinogenic acting by a genotoxic mechanism.

29. Delegations supported the establishment of a Risk Management Recommendation (RMR) for gentian violet. However, there were divergent views as to whether the inclusion of the last sentence of the RMR for malachite green should also apply to gentian violet.

30. Views against the inclusion of the last sentence in the RMR reiterated the opinion that RMRs should provide guidance to governments and as such they should not be overly restrictive and limit national authorities from applying other risk management measures they considered most appropriate.

31. Views in support of the inclusion of the last sentence noted that this would ensure consistency between the two RMRs since both compounds (i.e. gentian violet and malachite green) were structurally related and that the last sentence provided flexibility for national authorities to decide on the best risk management option to contain the use of these compounds in food producing animals.

Conclusion

32. As no consensus could be reached on a text for the RMR, the Committee agreed to circulate the two options for the RMR for gentian violet for comments at Step 3 and further consideration at its next session (Appendix III).

[8] CX/RVDF 15/22/4; Comments of El Salvador (CRD4); India (CRD5); Peru (CRD6); Gambia (CRD7); African Union (CRD9); Kenya (CRD10); Brazil (CRD11); Egypt (CRD16); Nigeria (CRD17); Indonesia (CRD19); Ecuador (CRD20); Philippines (CRD22); China (CRD26); Canada (CRD27).

Recombinant bovine somatotropins (rbSTs)

33. The Codex Secretariat and the Chair reminded the Committee that the MRLs for rbSTs remained at Step 8 at the Commission and that the Committee had been requested to discuss the report of JECFA and provide recommendations on the outcome of the JECFA evaluation to CAC38 (REP13/CAC para. 84). The JECFA Secretariat reminded the Committee of the detailed Terms of Reference given by CAC35 to JECFA[9]. In order to address the request from CAC35 for the re-evaluation of rbSTs, JECFA had performed a systematic review of the literature. The details of the complex literature search are available on the JECFA website[10]. JECFA had also considered data submitted by a sponsor and two members in response to a public call for data. Detailed responses to each question are described in the JECFA report and monographs[11]. Based on this extensive review of all available information, the 78th JECFA had reaffirmed its previous decision and maintained the ADI and MRLs 'not specified' for somagrebove, sometribove, somavubove and somidobove.

Discussion

34. Delegations in support of the outcome of the JECFA evaluation expressed the view that JECFA had clearly and consistently addressed all the questions posed by CAC35 in a robust evaluation assuring the safety of rbSTs for human health. Therefore, these delegations were in favour of the adoption of the proposed MRLs at the Commission. One delegation, referring to CRD11, asked (based on the results of the JECFA evaluation), the Committee to recommend the Commission to stop holding the MRLs for rbSTs at Step 8. It was emphasized that JECFA had evaluated rbSTs three times and with 11 independent experts. Each evaluation had reaffirmed that rbSTs did not represent a risk to human health.

35. These delegations also noted that the concerns about antimicrobial resistance, related to the possible increase of mastitis and of the use of antimicrobials, had been carefully evaluated by JECFA. According to JECFA's report there was no increased incidence of mastitis between rbSTs treated and non-treated cows. It was reiterated that Codex must base its decisions on sound science and for rbSTs all scientific information available had been considered by JECFA. The Delegations in support of the outcome of the JECFA evaluation stated that the draft MRLs for rbSTs had been held at Step 8 since CAC23 (1999). The absence of any opposing scientific data was also noted.

36. Delegations having concerns with respect to the JECFA re-evaluation recognised the efforts of JECFA to consider aspects related to antimicrobial resistance associated with the use of rbSTs through the possible increased use of antibiotics to treat mastitis, in line with the mandate given to JECFA by CAC35. However, they expressed profound concern with respect to the fact that, as JECFA itself had pointed out, there was insufficient evidence (a lack of specific studies) to draw conclusions on the association between the use of rbSTs and the development of antimicrobial resistance. It was the view of these delegations that risks associated with antimicrobial resistance could therefore not be excluded. One delegation raised further concern because they had recent studies indicating that the incidence of mastitis increased due to the higher milk yields brought about through the use of rbSTs. It was further asserted that the direct link between the use of antibiotics in animals and increased levels of antimicrobial resistance in humans had been extensively demonstrated. Delegations highlighted that their concerns were particularly relevant given the global efforts underway to fight the growing threat of antimicrobial resistance which is widely recognised as a serious, global public health threat and which is receiving the fullest attention from Codex's parent organisations: FAO and WHO, amongst others.

37. These delegations highlighted furthermore, that it was expressly due to such concerns that CAC35 had specifically mandated JECFA to consider aspects of antimicrobial resistance (AMR) in its re-evaluation of rbSTs. Given the remaining scientific uncertainty in the JECFA re-evaluation, these delegations could not agree to move forward on this issue.

38. The Observer from NHF supported those delegations not agreeing to move forward on this issue and further noted that the JECFA review of rbSTs was incomplete in that it had failed to consider the industry's own data showing a marked increase in mastitis after rbSTs injection, which in turn led to increased antibiotic use to avoid pus and bacteria in milk.

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[9] REP12/CAC paras 79-85.
[10] Annex to rbSTs evaluation to describe in detail the systematic literature search process Annex file [438KB].
[11] http://www.who.int/foodsafety/publications/technical-report-series-988/en/index.html; http://www.who.int/iris/bitstream/10665/77763/1/9789241660679_eng.pdf?ua=1; http://www.fao.org/3/a-i3745e.pdf

39. In response to concerns raised regarding antimicrobial resistance, the JECFA Secretariat clarified that the aspects of mastitis and the risk to human health from the use of antimicrobials had been addressed in detail in the JECFA review. While previous publications indicated an increased incidence of mastitis, a systematic review of the literature published since the 50th JECFA did not find any significant difference in the incidence of mastitis between rbST-treated and untreated cows. JECFA had also reviewed data from a post-approval monitoring programme and concluded that the available evidence suggested that the approval of rbSTs did not lead to an increased incidence of non-compliant antimicrobial residues in bulk milk. The systematic search of the literature had not found specific studies correlating the use of rbSTs with the development of antimicrobial resistance in mastitis pathogens. JECFA concluded that there was no evidence to suggest that the use of rbSTs would result in a higher risk to human health due to the possible increased use of antimicrobials to treat mastitis or the increased potential for non compliant antimicrobial residues in milk. Based on the extensive review JECFA reaffirmed its previous conclusion that there was no need to establish numerical ADI and MRLs and confirmed the ADI and MRLs 'not specified'.

Conclusion

40. The Committee took note of the report from JECFA. The Committee agreed that JECFA had addressed all of the questions posed to it by the Commission, but that there were different opinions regarding the JECFA replies. As no agreement had been reached the above discussion was being forwarded by the Committee for consideration by CAC38.

Zilpaterol hydrochloride

41. An ADI was established by JECFA but data were insufficient to recommend MRLs. Further clarification has been provided on data needs to the sponsor and additional data have been received by the JECFA Secretariat which will be considered at the 81st JECFA (November 2015) with a view to completing the evaluation.

Dietary exposure to veterinary drug residues

42. In response to recommendations of previous JECFA meetings, as well as following the discussion held at CCRVDF18 and the request to JECFA to improve dietary exposure assessment methodologies for veterinary drug residues in food, a FAO/WHO expert meeting was held in conjunction with the 75th JECFA and new methods were recommended for acute and chronic dietary exposure estimates based on actual consumption data rather than a model diet. This approach was piloted at the 78th JECFA to explore the new methods and compare with the estimates using the model diet approach.

43. Dietary exposures were calculated for four veterinary drugs on the agenda of the 78th JECFA and details are reported in the FAO monographs and on-line[12]. Overall the outcomes were very similar between approaches but the new approach allows for more detailed exposure estimates. JECFA recommended that the new approach should be further tested in future JECFA meetings.

44. In order to further improve dietary exposure estimates, including for veterinary drug residues in food, based on realistic consumption figures, FAO and WHO continue to improve underlying data needs through the development of tools and by supporting countries and regions to undertake dietary surveys. A pilot project to collect individual food consumption data for use in nutrition and food safety has been initiated (FAO/WHO GIFT) and a global database has been established to collect chronic individual food consumption data (CIFOCOss). Furthermore a project is planned to collect, in a harmonized format, individual food consumption data in ASEAN countries.

45. One Observer pointed out that the global estimate of chronic dietary exposures (GECDE) and the global estimate of acute exposure (GEADE) approaches proposed by JECFA utilized significantly more of the available ADI than the estimate daily intake/theoretical maximum daily intake (EDI/TMDI) methodologies: at least 37% more for each substance evaluated for adults and up to 200% higher when infants and children are considered. Thus, caution was urged and it was suggested that continued extensive evaluation of this new approach was required before JECFA/CCRVDF should accept this approach as standard. The consequences of greater utilization of the ADI are lower MRLs and extended withdrawal times which may not be compatible with good veterinary practice or improve food safety.

[12] Annex Pilot of new approaches to estimate dietary exposure to veterinary drug residues Annex file [840KB]

Extrapolation of MRLs to minor species

46. The 78th JECFA had addressed the comments and questions of CCRVDF21 and prepared guidance on the criteria and principles applied by JECFA for extrapolation. It was further clarified that JECFA will use the term *extension* when sufficient depletion data are available for the minor species to permit the derivation of MRLs while the term *extrapolation* will be used when the depletion data are insufficient. The Committee was reminded that the details of the JECFA principles on extrapolation were stated in the 78th JECFA report (TRS 988)[13], and *FAO JECFA Monographs No. 15*[14].

Scope of MRLs established by JECFA relating to fish and fish species

47. The 78th JECFA had agreed that the term "fish" should be used when an MRL recommendation applies to multiple species of finfish. For other "seafood", the term "mollusc" should be used for species such as clams, oysters and scallops, and the term "crustacean" should be used when MRLs are recommended for species such as shrimp, prawn and crayfish. It was clarified that JECFA considered that it might be appropriate to also identify some representative "major species" of fish and seafood, and that this matter should be further discussed at future JECFA meetings.

Requests for scientific advice

48. In scheduling JECFA meetings and developing the agenda, the JECFA Secretariat takes into account the priorities requested by CCFA, CCCF and CCRVDF. In addition, the JECFA Secretariat also has to take into consideration several other factors including: the number of substances that can be evaluated in one meeting; the nature of the requests; specific issues related to each compound; the specific expertise needed to address these requests, and the resources available.

49. JECFA has made several efforts to respond to the requests of CCRVDF and to accommodate its needs in the most effective way and in a timely manner. However, in order to be able to function properly and use the limited available resources in the most efficient way, JECFA needs the full cooperation of data submitters. If a request for an evaluation is being prioritized, the JECFA Secretariat schedules meetings accordingly, with the understanding that there is a commitment to provide all necessary data and that this commitment will be respected. Only if all involved respect their responsibilities, can JECFA address CCRVDF requests in a timely and coordinated manner and the work of CCRVDF can proceed efficiently.

50. On the contrary, not respecting the commitment to submit data is very disruptive for the whole process. In this context, and to ensure that JECFA can meet the needs of CCRVDF in a timely and efficient manner, the JECFA Secretariat emphasised the importance of the prioritisation process and the commitment to submit the necessary data within the indicated time-frame. This is critical to ensure an efficient planning process.

FAO/WHO activities on antimicrobial resistance (AMR)

51. A Global Action Plan to combat antimicrobial resistance has been developed by WHO with active participation of FAO and OIE. The draft plan will be presented to the 68th World Health Assembly in May 2015 for adoption. The Plan, available on the WHO website[15], also aims at strengthening the FAO/OIE/WHO tripartite collaboration.

52. WHO continues to support Member States in their efforts to combat AMR through the development of training modules for national programmes on integrated surveillance; by updating the WHO list of critically important antimicrobials, and through specific country projects.

53. FAO also gives high importance to this topic and calls for AMR to be integrated in FAO work programmes on food safety and sustainable production systems. A resolution on AMR will be discussed at the FAO Conference in June 2015.

Response to specific requests from the CCRVDF21 on chlorpromazine

54. Following the request of CCRVDF21, the JECFA Secretariat had commissioned a targeted literature review on chlorpromazine to assess whether there were data to update the previous JECFA evaluation. While a significant number of publications on the compound had been identified, the available data were insufficient to establish the safety of chlorpromazine and considering the toxicological profile of the compound it was unlikely that the previous conclusion of JECFA (that this drug should not be used in food producing animals) would change.

[13] http://apps.who.int/iris/bitstream/10665/127845/1/9789241209885_eng.pdf?ua=1
[14] http://www.fao.org/3/a-i3745e.pdf
[15] http://apps.who.int/gb/ebwha/pdf_files/WHA68/A68_20-en.pdf

Next JECFA meeting on Veterinary Drug Residues

55. The 81st JECFA will be dedicated to the evaluation of veterinary drug residues in food, and will be held from 17 to 26 November 2015. No data on ethoxyquin have been received in response to the JECFA call for data, while for sisapronil - after follow up by the JECFA Secretariat - a dossier was submitted but no approved use of the compound could be confirmed. The JECFA Secretariat may consider additional substances for the 81st meeting if the data for the additional compounds are confirmed at the present session of the Committee and submitted to FAO and WHO JECFA Secretariats not later than 15 May 2015.

INFORMATION ON ACTIVITIES OF THE JOINT FAO/IAEA DIVISION OF NUCLEAR TECHNIQUES IN FOOD AND AGRICULTURE RELEVANT TO CODEX WORK (Agenda Item 4a) [16]

56. The Representative of IAEA reported on the Joint FAO/IAEA Division's continued efforts in building the institutional capacity needed to support Member Countries establish or strengthen residue monitoring programmes.

57. The Representative reported support provided to 36 countries since CCRVDF21 through 45 national and regional technical cooperation projects on veterinary drug residue testing. Up to 484 laboratory personnel had been trained for a period ranging from 1 week to 3 months since the last CCRVDF.

58. The Representative of IAEA further reported on coordination of inter-institutional research activities on veterinary drug residues in both terrestrial and aquaculture products, as a way to strengthen networking around the world, and as a platform to generate new methods of analysis for a database related to the *Guidelines for the Design and Implementation of National Regulatory Food Safety Assurance Programmes Associated with the Use of Veterinary Drugs in Food Producing Animals* (CAC/GL 71-2009). The Representative thanked CCRVDF members that had contributed methods to the database.

59. The CCRVDF Chair thanked the Joint Division for the continued collaboration with the Committee and for the relevant support to Members. This was echoed by the Delegation of Costa Rica, who also thanked the Joint Division for enhancing the capacity of the National Veterinary Services Laboratory (LANSEVE) to test veterinary drug residues and related hazards.

REPORT OF THE OIE ACTIVITIES, INCLUDING THE HARMONIZATION OF TECHNICAL REQUIREMENTS FOR REGISTRATION OF VETERINARY MEDICINAL PRODUCTS (VICH) (Agenda Item 5)[17]

60. Referring to document CX/RVDF 15/22/5 for the full report on OIE activities relevant to CCRVDF, the Observer from OIE highlighted key aspects of OIE work.

61. Noting the importance placed by OIE on food safety in an integrated food chain approach, recognising the contribution of animal health to food safety, the Observer commended the close cooperation with Codex, in particular through the work of the OIE Working Group on Animal Production Food Safety (APFSWG), in which Codex, FAO and WHO experts participate.

62. In close coordination with WHO and FAO a key focus of OIE remains antimicrobial resistance; the Observer presented recent updates to relevant OIE standards and guidelines, the contribution to the preparation of the WHO Global Action Plan on Antimicrobial Resistance, and OIE's new work on an approach to collect and report standardised quantitative data on antimicrobial agent use in animals; this latter work is included in a resolution to be presented to the World Health Assembly in 2015 in support of the international efforts on antimicrobial resistance.

63. Regarding VICH, the Observer noted the continued success of extending VICH activities to non-VICH members through the Outreach Forum and drew the attention of the Committee to the 5th Public Conference of VICH (taking place on 27 to 29 October 2015 in Tokyo, Japan), which provides an invaluable opportunity to find out more about VICH, its work and the VICH guidelines (see http://vich5.com).

64. The Observer reported on capacity building activities relevant to veterinary medicines, highlighting the Performance of Veterinary Services (PVS) pathway as a means to assess and improve Member countries' veterinary services, and which was now offering the opportunity to improve veterinary legislation, including the regulation of veterinary medicines.

65. The Observer confirmed that the third cycle of training seminars for national focal points on veterinary products had been completed and had addressed topics such as good governance of veterinary medicines, antimicrobial resistance, and updates on VICH. Lastly, the Observer noted that twinning Member Countries' laboratories with OIE Reference Laboratories had successfully improved Member Countries capacity.

[16] CX/RVDF 15/22/4 Add.1.
[17] CX/RVDF 15/22/5.

66. The Committee thanked OIE for its work. Several delegations reported on their own activities especially with regard to PVS evaluations and the work of VICH. Delegations were encouraged to commit to active participation in the work of VICH to widen support and generate further involvement. Members were also encouraged to inform OIE of their activities in this area.

MAXIMUM RESIDUES LIMITS (MRLS) AND RISK MANAGEMENT RECOMMENDATIONS (RMRS) FOR RESIDUES OF VETERINARY DRUGS IN FOODS (Agenda Item 6)[18]

DRAFT MRLs FOR MONEPANTEL AT STEP 7 (Agenda Item 6a)[19]

PROPOSED DRAFT MRLs FOR DERQUANTEL AT STEP 4 (Agenda Item 6b)[20]

67. In view of the new MRLs for monepantel and for derquantel in sheep tissues recommended by the 78th JECFA (Item 6c), the Committee agreed to discontinue work on the corresponding draft and proposed draft MRLs (recommended by the 75th JECFA), which were held at Step 7 and Step 4 by CCRVDF21.

PROPOSED DRAFT MRLS FOR DERQUANTEL, EMAMECTIN BENZOATE, IVERMECTIN, LASALOCID SODIUM AND MONEPANTEL, AT STEP 3 (Agenda Item 6c) [21]

Derquantel

68. The JECFA Secretariat informed the Committee that the 78th JECFA had maintained the ADI of 0-0.3 µg/kg bw established by the 75th JECFA and had recommended new MRLs on the basis of a withdrawal time of 6 days, rather than withdrawal time of 8 days used for the initial assessment. Data through Day 6 were used to determine the marker to total residues ratios.

69. The JECFA Secretariat further clarified that the difference of the MRL for fat recommended by the 75th JECFA (0.7 µg/kg) with that recommended by the 78th JECFA (7.0 µg/kg) was due to the change in the withdrawal time used, the rapid depletion of the residues in fat and the variability in the data (high standard deviations). More details could be found in the report and the residue monograph.

Conclusion

70. The Committee agreed to advance the proposed draft MRL for derquantel for adoption at Step 5/8.

Emamectin benzoate

71. The JECFA Secretariat informed the Committee that the 78th JECFA had confirmed the ADI of 0-0.5 µg/kg bw established by JMPR and had recommended MRLs on the basis of available published peer-reviewed scientific papers, evaluations from national agencies and the JMPR evaluation.

72. With regard to the MRLs for trout and salmon, it was observed that the common name used for fish, e.g. trout and salmon, did not always correlate with the scientific name of the species and, for example, in the case of trout corresponded to fish belonging to different orders, families and genera. Therefore, clarifications were needed on whether JECFA had considered and/or if it was possible to extrapolate the MRLs to finfish.

73. The JECFA Secretariat clarified that the data submitted to JECFA for emamectin benzoate were mainly for salmon and included a depletion study in trout. The MRLs for salmon had therefore been extended to trout. It was also noted that both fish have high fat content and that the issue of extrapolation of the MRLs to all finfish needed to be considered by JECFA.

74. Caution was advised when extrapolating MRLs too broadly (e.g. from salmon to all finfish) as finfish included a broad range of fish with different metabolic patterns (e.g. salt water and fresh water fish and warm and temperate water fish) and such extrapolation should be supported by science.

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[18] Information document for support of the discussion on the MRLs and RMRs for residues of Veterinary Drugs (RVDF/22 INF/01); Comments of NHF (CRD30).

[19] REP 14/RVDF App. II; Comments of India (CRD5); Gambia (CRD7); African Union (CRD9); Argentina (CRD14); Nigeria (CRD17); Indonesia (CRD19).

[20] REP 14/RVDF App. III; Comments of Gambia (CRD7); African Union (CRD9); Argentina (CRD14); Nigeria (CRD17); Indonesia (CRD19).

[21] CX/RVDF 15/22/6; Comments of Brazil, Chile, Costa Rica, Gambia, India, Iran, Kenya, United States of America, Peru, Philippines, African Union, IFAH (CX/RVDF 15/22/6 Add.1); El Salvador (CRD4); European Union (CRD12); Argentina (CRD14), Nicaragua (CRD15); Nigeria (CRD17); Ghana (CRD18); Indonesia (CRD19); Ecuador (CRD20); IFAH (CRD23); Canada (CRD27); Republic of Korea (CRD28); Thailand (CRD29); Concern form of the European Union on lasalocid sodium (CRD13).

Conclusion

75. The Committee agreed to advance the proposed draft MRL for emamectin benzoate for adoption at Step 5/8 and that the request on the possibility to extrapolate the MRLs to other types of fish would be addressed by the WG on Priority (Item 8a).

Ivermectin

76. The JECFA Secretariat informed the Committee that the 78th JECFA had conducted an evaluation of the data summarized in earlier residue monographs and had recommended an MRL for bovine muscle based on twice the Limit of Quantification (2 × LOQ) of the analytical method. It was further clarified that the dietary exposure calculation prepared by the 40th JECFA included an estimate of the intake from muscle and therefore, no further assessment of dietary exposure had been undertaken by the 78th JECFA.

77. A number of delegations commented that the proposed MRL for ivermectin in cattle muscle did not reflect approved Good Veterinary Practice (GVP). They noted that a request had been put forward for re-evaluation of the ADI and establishment of an MRL (Item 8a) and that the re-evaluation might lead to the establishment of new higher MRLs consistent with current good veterinary practices.

Conclusion

78. Noting the request for re-evaluation, the Committee agreed to hold the MRL for ivermectin at Step 4 for consideration at a future session. This consideration would take into account any new JECFA recommendations.

Lasalocid sodium

79. The JECFA Secretariat informed the Committee that the 78th JECFA had established an ADI of 0-5 µg/kg bw and recommended MRLs for chicken, turkey, quail and pheasant. An EDI of 80 µg/person per day was calculated, based on median residues, which represented approximately 27% of the upper bound of the ADI. The JECFA Secretariat further noted that no MRLs had been recommended for eggs since lasalocid sodium, according to the sponsor, was not registered for use in laying hens.

80. The Committee noted that the European Union had submitted a concern form on the approach used to estimate consumer short term exposure (CRD13). The Delegation of Canada also expressed concern that the proposed MRLs might expose consumers to residues of lasalocid higher than the ADI (CRD27).

81. The JECFA Secretariat clarified that these concerns referred to an on-going discussion at JECFA on the differentiation between chronic and acute risk assessments, which would be considered further by the 81st JECFA (November 2015). The ADI was the health-based guidance value for chronic exposures and the appropriate exposure estimate to compare was the EDI. JECFA was developing guidance on the setting of acute reference doses (ARfD), the health-based guidance value for acute exposures. The key question to be addressed in relation to the concern of the European Union was if the microbiological ADI was a valid proxy for an ARfD, and if the TMDI could be used as estimate of acute exposures if data were insufficient to apply the new approach for acute exposure assessment (GEADE).

82. With regard to MRLs for egg, some delegations and one Observer noted that these MRLs were necessary because there is a risk of potential cross contamination from feed for laying hens, which could result in a carry-over in eggs. It was noted that MRLs for eggs were already established in the. European Union and problems already existed in international trade which could result in the rejection of food. The Observer suggested considering the establishment of MRLs for eggs equivalent to those of the European Union and that JECFA consider the compatibility with the ADI.

83. The Committee discussed the need to develop a policy to address the issue of carry-over and cross-contamination from medicated feed and to allow for a certain flexibility in the procedure for the establishment of MRLs to address this type of trade issue. The Committee further reaffirmed the role of JECFA as the risk assessment body to provide the scientific basis for Codex MRLs.

Conclusion

84. Noting the need to address the concerns of the European Union and Canada, the Committee agreed to hold the MRL for lasalocid sodium at Step 4 for consideration at its next Session based on the recommendations of the 81st JECFA.

85. The Committee agreed to establish an EWG, led by United Stated of America and co-chaired by Canada and working in English only, with the following Terms of Reference:

Purpose:

To prepare a discussion paper for consideration by CCRVDF23 addressing the unintended presence of residues of veterinary drugs in food commodities resulting from carry-over of veterinary drugs into feed.

Work Objectives:

Elaborate a discussion paper articulating a policy to address situations under which a standard may need to be developed (and considerations for developing such standards) when there is carry-over of drug residues into feed, as a result of unintended exposure, resulting in residues in foods of animal origin.

The following points, among others, should be considered:

- Scope of what should be covered under this project? What is meant by unintended exposure/carry-over in the CCRVDF? What drug-commodity combination?
- Source of unintentional exposure at feed mill or farm level;
- Consider using existing policies/guidelines/codes of practice to establish these standards to the extent possible (example: *Code of Practice on Good Animal Feeding* (CAC/RCP 54 2004));
- Procedural changes that may be required to set these standards as these situations may not meet the current criteria for recommending MRLs;
- Nature of relevant data required for consideration for setting standards in these unique situations (example: monitoring data, GMP data);
- Source of data required, methodology consideration for detection of residues in feed as well as food.
- Consideration of relevant risk management measures from feed to food continuum .

86. The Committee agreed:

- To consider the establishment of MRLs in eggs at its next Session as guided by the agreed policy; and
- To establish a PWG at its next session to consider the report of the EWG.

Monepantel

87. The JECFA Secretariat informed the Committee that no new data or studies had been provided for the current evaluation and that JECFA had recommended new MRLs consistent with the shortest withdrawal time (i.e. 7 days) established in countries which have already approved the use of monepantel. The EDI was 446 µg/person per day, which represented approximately 37% of the upper bound of the ADI.

88. The Delegation of the European Union expressed concerns for the proposed MRLs which were equivalent to 118% of the European Union ADI when the consumer exposure was calculated using the TMDI approach.

89. With regard to the use of the TMDI approach, the JECFA Secretariat reminded the Committee that the CCRVDF18 had agreed that the EDI was an improvement relative to the TMDI for the evaluation of the risk from chronic exposure[22].

Conclusion

90. The Committee agreed to advance the proposed draft MRL for monepantel for adoption at Step 5/8. The Committee noted the reservation of the Delegations of the European Union and Norway for the reason stated above.

[22] ALINORM 09/32/31, para. 146.

PROPOSED DRAFT RMRS FOR DIMITRIDAZOLE, IPRONIDAZOLE, METRONIDAZOLE AND RONIDAZOLE, AT STEP 4 (Agenda Item 6d)[23]

91. The JECFA Secretariat informed the Committee that following the request of CCRVDF21 the Secretariat had commissioned an extensive review of the literature published since the last JECFA assessment of the four nitroimidazoles. Although a large number of publications had been identified, it was unlikely that the available data would fill the data gaps previously identified by JECFA. Considering the toxicological profile of the closely related compounds there was a clear health concern.

Conclusion

92. The Committee agreed to advance the proposed draft RMR for dimitridazole, ipronidazole, metronidazole and ronidazole for adoption at Step 5/8.

93. The Delegations of Australia, Brazil, New Zealand and United States of America, while recognizing the importance of JECFA's review and its conclusions, expressed their reservation on the inclusion of the last sentence ("*This can be accomplished by not using [name of compound] in food producing animals*") in the RMR because in their view it poorly communicated risk management advice to competent authorities and there should be a clear distinction between the role of Codex and the role of national competent authorities as risk managers.

Status of the Draft and Proposed Draft Maximum Residue Limits and Proposed Draft Risk Management Recommendation for Residues for Veterinary Drugs

94. Draft and proposed draft MRLs advanced at Step 5/8 and held at Step 4 are attached as Appendices IV and V respectively. Proposed draft RMRs advanced at Step 5/8 are attached as Appendix VII. Proposed draft MRLs recommended to be discontinued are attached as Appendix VI.

DRAFT PROVISIONS ON ESTABLISHMENT OF MRLs FOR HONEY (FOR INCLUSION ON THE *RISK ANALYSIS PRINCIPLES APPLIED BY THE CCRVDF*) (Agenda Item 7)[24]

95. The Codex Secretariat introduced the topic and referred delegates to Appendix XI of REP14/RVDF to discuss the proposed new wording for inclusion in the *Risk Analysis Principles Applied by the CCRVDF*.

96. The JECFA Secretariat reported on the outcomes of the 78th JECFA on the issue of MRLs in honey. Previous assessments by the 70th JECFA and by a CCRVDF working group had determined that the standard approach to developing depletion data for veterinary drugs used in food-producing animals did not provide reliable data when attempts were made to obtain depletion data for residues in honey. Reasons for this include: "between hive" and "between location" variability in residues, environmental variability, and the fact that depletion of residues in honey relates primarily to dilution and environmental factors causing chemical degradation. JECFA has therefore agreed that alternative approaches should be considered to develop the required data for such evaluations. Key issues identified by JECFA to be considered when evaluating a request for the recommendation of MRLs for a veterinary drug residue in honey include:

- MRLs for honey cannot be recommended based on extrapolation from MRLs for tissues, eggs or milk;
- Information on approved use (GVP) in one or more Codex member states is required;
- An ADI must be available (or data to derive an ADI);
- The presence of compounds resulting from degradation pathways in honey may require further toxicological evaluation;
- A marker residue must be identified for honey;
- Depletion data must be from hives treated under the approved GVP; these data may come from sources such as statistically based surveys or field trials conducted at multiple locations;
- An analytical method, suitable for regulatory use and validated for honey, should be available.

97. The JECFA Secretariat concluded that JECFA was aware of the guidance on depletion studies for honey currently being undertaken by VICH, and JECFA would continue to review approaches for such work as new information became available.

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[23] REP 14/RVDF App V; Comments of African Union (CRD9); European Union (CRD12); Argentina (CRD14); Nigeria (CRD17); Ecuador (CRD20); Philippines (CRD22); IACFO (CRD24); Thailand (CRD29).

[24] REP14/RVDF App. XI; Comments of Brazil, Chile, Costa Rica, European Union, Iran, FoodDrinkEurope (CX/RVDF 15/22/7); Argentina, El Salvador, India, Kenya, Peru, Philippines, African Union (CX/RVDF 15/22/7 Add.1); Egypt (CRD16); Indonesia (CRD19); Ecuador (CRD20); Thailand (CRD29).

98. There was some support in the Committee for not including any specific food commodity in the Procedural Manual and for removing the words "for honey" from the proposed text as this would still empower the Committee to take risk management decisions. But there were equal concerns on adopting such open-ended wording as it was felt issues could be resolved on case-by-case basis.

99. The Committee expressed support for establishing MRLs for honey but concerns were expressed regarding the adoption of an "alternative approaches" methodology to do so, as MRLs derived from national monitoring programmes that used residue monitoring could be inconsistent with GVP. This in turn could lead to a high number of MRLs that would not be practical for the approval of new veterinary products.

100. One Observer noted that the JECFA honey standard decision tree proposal required clarification. They stated that as the residues in honey were an incidental contaminant rather than a residue resulting from treatment of honey, and there was no metabolism and excretion of residues from honey, the residue data collection procedures were important to the risk assessment.

101. The Observer further noted that the approach taken to set MRLs by applying a statistical analysis to residue surveillance data, changing the portion of honey in the food basket, and in general the new EDI approach would all probably result in different Codex MRLs to the existing ones established by the competent authorities. Such different MRLs would hinder rather than facilitate trade and, in their opinion, CCRVDF should be aware of this risk.

102. One Delegation and one Observer added their concern, on technical grounds, to the JECFA proposed approach and repeated that the VICH was in the process of completing a Guideline for conducting residue studies in honey. They recommended that JECFA wait for these Guidelines to be available when reviewing honey residue data in the future.

103. Many delegations supported the proposal for waiting until VICH guidelines were complete in order to take a more informed decision on the matter.

Conclusion

104. Noting that CCRVDF has the latitude under its risk analysis principles to make requests to JECFA for MRLs for honey (and other commodities) using alternatives approaches , the Committee agreed to leave unaltered the current text of the *Risk Analysis Principles Applied by the CCRVDF*.

DRAFT PRIORITY LIST OF VETERINARY DRUGS REQUIRING EVALUATION OR RE-EVALUATION BY JECFA (Agenda Item 8a) [25]

105. The Committee considered the recommendations of the in-session WG as follows:

Priority List of Veterinary Drugs Requiring Evaluation or Re-Evaluation by JECFA

106. The Committee agreed to the Priority List and made the following comments and amendments:

107. The Committee agreed to:

- Retain in the Priority List those compounds for which data availability was not yet confirmed, e.g. ampicillin, because this information was useful for the JECFA Secretariat when planning future JECFA meetings; it was understood that if data availability were not confirmed at the CCRVDF23 these compounds would be removed from the Priority List;
- Amend the request for MRLs for amoxicillin for "flat fish" as opposed to "finfish" and to explore the possibility to extrapolate the MRLs to other finfish;
- Include the request to consider potential zilpaterol hydrochloride residues in animal lungs and other edible offal.

108. The JECFA Secretariat informed the Committee that ivermectin, sisapronil and lasalocid sodium would be evaluated by the 81st JECFA and that an addendum to the Call for Data on additional compounds to be evaluated by the 81st JECFA would be distributed by mid May 2015.

109. The Committee also agreed to have an annotation for critically important antimicrobials in the Priority List. The Committee further agreed that it was not necessary to include such annotation to MRLs established by the Committee.

[25] CL 2014/03-RVDF; CX/RVDF 15/22/8, Replies to CL 2014/3-RVDF of Algeria, Chile, Costa Rica, Norway, Unites States of America (CRD25); Comments of Peru (CRD6); African Union (CRD9); Kenya (CRD10); Argentina (CRD14); Nigeria (CRD17); Indonesia (CRD19); Ecuador (CRD20); Republic of Korea (CRD28); Report of the in-session WG on Priority (CRD31).

Request to JECFA on MRLs for Generic Fish Species

110. While recognising the ongoing activities of VICH in this area, the Committee agreed to forward the following requests to JECFA:

- To provide an assessment on whether on the basis of data from one or more fish species, it is possible to establish an MRL for finfish, crustaceans or molluscs in general, or for multiple similar groups.
- For emamectin benzoate, to provide an assessment as to whether there are any identified toxicological, dietary exposure modelling, or analytical methodology issues preventing extrapolation of the proposed MRLs to a general finfish MRLs or a more appropriate sub-grouping.

Template for Information Necessary for Prioritization by CCRVDF

111. The Committee agreed to add the explanatory notes "*This should include product labels or other evidence of official use authorisation*" to point 9 "Veterinary use pattern, including information on approved uses if available" and "*This should include a list of the data available with the full study titles*" to Point 14 "List of data (pharmacology, toxicology, metabolism, residue depletion, analytical methods)" in the "Template for Information necessary for Prioritization by CCRVDF" attached to the Circular Letter requesting comments and information of the Priority List to clarify the type of information available.

Conclusion

112. The Committee agreed to forward the Priority List of Veterinary Drugs for Evaluation or Re-evaluation by JECFA to CAC38 for approval (Appendix VIII).

ALTERNATIVE APPROACH TO MOVE COMPOUNDS FROM THE DATABASE ON COUNTRIES' NEED FOR MRLS TO THE JECFA PRIORITY LIST (REPORT OF THE EWG ON COUNTRIES' NEEDS FOR MRLS) (Agenda Item 8b)[26]

DATABASE ON COUNTRIES' NEED FOR MRLS (Agenda Item 8c)[27]

113. The Delegations of Costa Rica and the United States of America as Co-Chairs introduced the report of the EWG on Countries' Needs for MRLs and confirmed the belief of the EWG that they had found a vehicle with potential to provide information to the Committee that would allow CCRVDF to move compounds from the database on countries' need for MRLs to the JECFA Priority List.

114. The co-Chairs stressed that members would need to make a strong commitment to conduct the next phase of the survey for a more global representation should it be the will of the Committee to continue work. They outlined the possible activities of an EWG (composed of those members who are able and willing to contribute) where the members themselves would implement the survey. The EWG could also provide guidance to participants, based on the pilot, in order to encourage a robust response. The co-Chairs envisaged this EWG being able to report on a very preliminary sorting of information (collected through the survey) to the next session of CCRVDF and then providing an opinion with the results as to whether the initiative should continue. A successive working group could then attempt to interpret the data and make recommendations for compounds to be included in the Priority List.

115. The Delegation of the United States of America offered to continue updating the database on countries' needs for MRLs and to co-chair with Costa Rica the proposed EWG.

116. The Committee expressed its thanks to the EWG for the excellent work undertaken and offered full support for the continuation of the work.

117. In response to a question on possibly broadening participation in the global survey, the Secretariat confirmed that all Members of Codex and Observers would be invited to participate. It would be the responsibility of all Members to distribute the message and make others aware of this initiative.

118. The Representatives of FAO and WHO guaranteed continued assistance and guidance to countries taking part in the survey but also confirmed that now out of the pilot phase (which had been extremely labour intensive for FAO, WHO and OIE), the responsibility and ownership for working on the survey and acquiring the ground level data passed to the countries themselves.

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[26] CX/RVDF 15/22/9; Comments of El Salvador (CRD4); India (CRD5); Peru (CRD6); African Union (CRD9); Kenya (CRD10); Argentina (CRD14); Nigeria (CRD17); Indonesia (CRD19); Ecuador (CRD20).

[27] CX/RVDF 15/22/10; Comments of El Salvador (CRD4); Peru (CRD6); African Union (CRD9); Kenya (CRD10); Argentina (CRD14); Indonesia (CRD19); Ecuador (CRD20); Thailand (CRD29).

119. It was noted that the success of this survey would depend on the level of participation. A strong level of support would allow the Committee to truly examine countries' needs and make some priority recommendations (which species, tissues, drugs) on which requests to submit to JECFA and put on the Priority List in CCRVDF. A large number of countries participating would mean it would be possible to target the highest priority compounds.

Conclusion

120. The Committee agreed to:

- Establish an EWG, co-chaired by the United States of America and Costa Rica, and working in English and Spanish only, to implement a full global survey, as described above;
- Request inputs for the database on countries' need for MRLs through a Circular Letter; and
- Accept the offer of the United States of America to continue to maintain the database on countries' needs for MRLs on the basis of the replies to the Circular Letter.

OTHER BUSINESS AND FUTURE WORK (Agenda Item 9)

121. The Committee noted that no other business had been put forward.

DATE AND PLACE OF NEXT SESSION (Agenda Item 10)

122. The Committee noted that its 23rd Session was tentatively scheduled to be held in the United States of America in October 2016 the final arrangements being subject to confirmation by the Host Country and the Codex Secretariats.

SUMMARY STATUS OF WORK

SUBJECT	STEP	FOR ACTION BY:	DOCUMENT REFERENCE (REP15/RVDF)
Proposed draft MRLs for derquantel (sheep tissues), emamectin benzoates (salmon and trout tissues) and monepantel (sheep tissues)	5/8	CAC38	Paras 70, 75, 90 and App. IV
Proposed draft RMRs for dimetridazole, ipronidazole, metronidazole and ronidazole	5/8	CAC38	Para. 92 and App. VII
Draft RMR for gentian violet	3	CCRDF23	Para. 32 and App. III
Proposed draft MRLs for ivermectin (cattle muscle) and lasalocid sodium (chicken, turkey, quail and pheasant tissues)	4	CCRVDF23	Paras 78, 84 and App. V
Priority List of Veterinary Drugs requiring Evaluation or re-evaluation by JECFA	1,2,3	CAC38	Para. 112 and App. VIII
Proposed draft MRLs for derquantel (sheep tissues), and monepantel (sheep tissues) (recommendations of the 75th JECFA)	Discontinued	CAC38	Para. 66 and App. VI
Draft Provisions on establishment of MRLs for honey (for inclusion in the *Risk Analysis Principles applied by CCRVDF*)	Discontinued	---	Para. 104
Discussion paper on the establishment of a rating system to establish priority for CCRVDF work	---	EWG (France)	Para. 13
Discussion paper on unintended presence of residues of veterinary drugs in food commodities resulting from the carry-over of drug residues into feed	---	EWG (United States of America and Canada)	Para. 85
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)	---	EWG (United States of America and Costa Rica)	Para. 120
Database on countries' needs for MRLs	---	United States of America	Para. 120

Appendix I

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Appendix II

RESPONSES OF CCRVDF22 TO THE 2014-2019 STRATEGIC PLAN IMPLEMENTATION

Responses of CCRVDF22 are shown in **bold and underlined font**.

Strategic Goal	Objective	Activity	Expected Outcome	Measurable Indicators/Outputs
1: Establish international food standards that address current and emerging food issues.	1.1: Establish new and review existing Codex standards, based on priorities of the CAC	1.1.1: Consistently apply decision-making and priority-setting criteria across Committees to ensure that the standards and work areas of highest priority are progressed in a timely manner.	New or updated standards are developed in a timely manner	- Priority setting criteria are reviewed, revised as required and applied. - # of standards revised and # of new standards developed based on these criteria.
Question to the Committee: Is this activity relevant to the work of the Committee? **YES** Does the Committee use any specific criteria for standards development? **CCRVDF has developed specific criteria for including veterinary drugs in the Priority List for the establishment of MRLs (Section 3.1.2 Establishment of Priority List of the *Risk Analysis Principles applied by the Codex Committee on Veterinary Drugs in Foods* in the Procedural Manual).** Does the Committee intend to develop such criteria? **NO.**				
	1.2: Proactively identify emerging issues and Member needs and, where appropriate, develop relevant food standards.	1.2.1: Develop a systematic approach to promote identification of emerging issues related to food safety, nutrition, and fair practices in the food trade.	Timely Codex response to emerging issues and to the needs of Members.	- Committees implement systematic approaches for identification of emerging issues. - Regular reports on systematic approach and emerging issues made to the CCEXEC through the Codex Secretariat.
Question to the Committee: Is this activity relevant to the work of the Committee? **YES** How does the Committee identify emerging issues and member's needs? **Emerging issues are identified by Members, other committees, FAO/WHO and other international organizations with Observer status and are brought to the attention of the Committee.** Is there a systematic approach? Is it necessary to develop such an approach? **Currently there is no systematic approach; however, there might be a need to develop one should the current process be found to be insufficient.**				
		1.2.2: Develop and revise international and regional standards as needed, in response to needs identified by Members and in response to factors that affect food safety, nutrition and fair practices in the food trade.	Improved ability of Codex to develop standards relevant to the needs of its Members.	- Input from committees identifying and prioritizing needs of Members. - Report to CCEXEC from committees on how standards developed address the needs of the Members as part of critical review process.
Included in question to 1.2.				
2: Ensure the application of risk analysis principles in the development of Codex standards.	2.1: Ensure consistent use of risk analysis principles and scientific advice.	2.1.1: Use the scientific advice of the joint FAO/WHO expert bodies to the fullest extent possible in food safety and nutrition	Scientific advice consistently taken into account by all relevant committees during the standard setting process.	-. # of times the need for scientific advice is: - identified, - requested and, - utilized in a timely

Strategic Goal	Objective	Activity	Expected Outcome	Measurable Indicators/Outputs
		standards development based on the "Working Principles of Risk Analysis for Application in the Framework of the Codex Alimentarius".		manner.
Question to the Committee: Is this activity relevant to the work of the Committee? **YES** Does the committee request scientific advice in course of its work, how often does it request such advice? Does the committee always use the scientific advice, if not, why not? **The work of CCRVDF is based on the scientific advice provided by JECFA. The use by Members of the "Concern Form" is an additional tool, developed by CCRVDF, to bring scientific concerns to the attention of JECFA.** **The Committee may also develop codes of practice focussed on provision and more operational risk management advice to national authorities. Such codes are developed by the Committee taking into account the established risk analysis principles.**				
		2.1.2: Encourage engagement of scientific and technical expertise of Members and their representatives in the development of Codex standards.	Increase in scientific and technical experts at the national level contributing to the development of Codex standards.	- # of scientists and technical experts as part of Member delegations. - # of scientists and technical experts providing appropriate input to country positions.
Question to the Committee: Is this activity relevant to the work of the Committee? **YES** How do members make sure that the necessary scientific input is given into country positions and that the composition of the national delegation allows to adequately present and discuss this position? What guidance could be given by the Committee or FAO and WHO? **Members involve their scientific and technical experts (from within and outside government) to provide inputs and comments to the work of CCRVDF. Delegations include experts who have technical knowledge and expertise to participate in the discussion.** **Training and ad hoc workshops can contribute to strengthen technical participation of countries in the work of CCRVDF.**				
		2.1.3: Ensure that all relevant factors are fully considered in exploring risk management options in the context of Codex standard development.	Enhanced identification, and documentation of all relevant factors considered by committees during the development of Codex standards.	- # of committee documents identifying all relevant factors guiding risk management recommendations. - # of committee documents clearly reflecting how those relevant factors were considered in the context of standards development.
Question to the Committee: Is this activity relevant to the work of the Committee? **YES** How does the Committee ensure that all relevant factors have been taken into account when developing a standard and how are these documented? **In conducting its work in developing Codex standards, risk management principles and guidelines, CCRVDF is bound by the Procedural Manual and the Codex mandate. The Committee follows the *Working Principles for Risk Analysis* and the *Risk Analysis Principles applied by the Codex Committee on Residues of Veterinary Drugs in Foods* and ensures that only legitimate factors, as described in the Procedural Manual, are taken into account.**				
		2.1.4: Communicate the risk management recommendations to all interested parties.	Risk management recommendations are effectively communicated and disseminated to all interested parties.	- # of web publication/ communications relaying Codex standards. - # of media releases disseminating Codex standards.

Strategic Goal	Objective	Activity	Expected Outcome	Measurable Indicators/Outputs
Question to the Committee: Is this activity relevant to the work of the Committee? **YES** When taking a risk management decision, does the committee give guidance to members how to communicate this decision? Would more consideration of this be helpful to members? **Communication of the risk management recommendations are done through standards, guidelines and other related texts, which are posted on the Codex website. The development of an overarching Codex communication strategy that is fine tuned to the specific audience in each committee would be helpful to members.**				
3: Facilitate the effective participation of all Codex Members.	3.1: Increase the effective participation of developing countries in Codex.	3.1.5: To the extent possible, promote the use of the official languages of the Commission in committees and working groups.	Active participation of Members in committees and working groups.	- Report on number of committees and working groups using the languages of the Commission
Question to the Committee: Is this activity relevant to the work of the Committee? **YES** Is the use of official languages in working groups of the committee sufficient? **The Committee uses English, French and Spanish for its Working Groups (WGs) as much as possible.** What are the factors determining the choice of languages? How could the situation be improved? **The Committee determines the choice of language based primarily on the availability of resources and on the host of the WG. Expanding the use of languages in all WGs would enhance participation and inclusiveness; co-Chair arrangement can assist in this respect.**				
	3.2: Promote capacity development programs that assist countries in creating sustainable national Codex structures.	3.2.3: Where practical, the use of Codex meetings as a forum to effectively conduct educational and technical capacity building activities.	Enhancement of the opportunities to conduct concurrent activities to maximize use of the resources of Codex and Members.	-. # of activities hosted on the margins of Codex meetings.
Question to the Committee: Is this activity relevant to the work of the Committee? **YES** Does the Committee organize technical capacity activities or other activities in the margins of Committee sessions? If yes – how many and with which topics have been organized in the past. If no – could this be useful and what topics could be addressed? **Workshops for first time delegates have been organised in conjunction with CCRVDF.** **The following are possible topics for technical workshops to be organised in conjunction with CCRVDF sessions:** • **Procedure for risk assessments of veterinary drug residues in food (training by JECFA), including dietary exposure assessment;** • **Use of veterinary drugs in food producing animals and their impact on food safety;** • **Preparation of update procedural guidance for the submission of scientific and technical studies for risk assessment.**				
4: Implement effective and efficient work management systems and practices.	4.1: Strive for an effective, efficient, transparent, and consensus based standard setting process.	4.1.4: Ensure timely distribution of all Codex working documents in the working languages of the Committee/Commission.	Codex documents distributed in a more timely manner consistent with timelines in the Procedural Manual.	- Baseline Ratio (%) established for documents distributed at least 2 months prior to versus less than 2 months prior to a scheduled meeting. - Factors that potentially delay the circulation of documents identified and addressed. - An increase in the ratio (%) of documents circulated 2 months or more prior to meetings.

Strategic Goal	Objective	Activity	Expected Outcome	Measurable Indicators/Outputs
Question to the Committee: Is this activity relevant to the work of the Committee? **YES** Does the Committee have a mechanism in place to ensure timely distribution of documents? What could be done to further improve the situation? **The requirement for timely distribution of documents is stated in the Procedural Manual. Close monitoring of the activities of EWGs and adherence to deadlines (e.g. request for comments) would help ensuring more timely preparation and distribution of documents in all languages.**				
		4.1.5: Increase the scheduling of Work Group meetings in conjunction with Committee meetings.	Improved efficiency in use of resources by Codex committees and Members	- # of physical working group meetings in conjunction with committee meetings, where appropriate.
Question to the Committee: Is this activity relevant to the work of the Committee? **YES** Does the Committee hold physical working groups independent of Committee sessions? If yes – why is this necessary? **NO, PWGs are usually held in conjunction with the CCRVDF sessions either as pre-session or in-session WGs.**				
	4.2: Enhance capacity to arrive at consensus in standards setting process.	4.2.1: Improve the understanding of Codex Members and delegates of the importance of and approach to consensus building of Codex work.	Members and delegates awareness of the importance of consensus in the Codex standard setting process improved.	- Training material on guidance to achieve consensus developed and made available in the languages of the Commission to delegates. - Regular dissemination of existing material to Members through Codex Contact Points. - Delegate training programs held in association with Codex meetings. - Impediments to consensus being achieved in Codex identified and analysed and additional guidance developed to address such impediments, if necessary.
Question to the Committee: Is this activity relevant to the work of the Committee? **YES** Are there problems with finding consensus in the Committee? If yes – what are the impediments to consensus? What has been attempted and what more could be done? **The importance of animal derived food in trade, society and public health has caused problems on certain topics; however CCRVDF is making all efforts to ensure that its decisions are taken on the basis of consensus.**				

Appendix III

PROPOSED DRAFT RISK MANAGEMENT RECOMMENDATION FOR RESIDUES OF VETERINARY DRUGS

(at Step 3 of the Elaboration Procedure)

GENTIAN VIOLET (antibacterial, antifungal and anthelminthic agent)

JECFA evaluation: 78th (2013) JECFA

Recommended risk management measures

OPTION 1

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.

OPTION 2

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.

Appendix IV

PROPOSED DRAFT MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS

(at Step 5/8 of the Elaboration Procedure)

DERQUANTEL (anthelmintic agent)

Acceptable Daily Intake (ADI): 0-0.3 µg/kg body weight on the basis of a lowest-observed-adverse-effect level (LOAEL) of 0.1 mg/kg body weight per day for acute clinical observations in dogs, consistent with antagonistic activity on the nicotinic acetylcholine receptors. A safety factor of 300 was applied to the LOAEL (75th JECFA, 2011).

Estimated Dietary Exposure (TMDI): There were insufficient data to calculate an EDI, and the TMDI approach was used. Using the model diet and the MT:TR approach, these MRLs result in an estimated dietary exposure of 6.8 µg/person, which represents approximately 38% of the upper bound of the ADI (78th JECFA, 2013).

Residue Definition: Derquantel.

Species	Tissue	MRLs (µg/kg)	Step	JECFA
Sheep	Muscle	0.3	5/8	78
Sheep	Liver	0.8	5/8	78
Sheep	Kidney	0.4	5/8	78
Sheep	Fat	7.0	5/8	78

EMAMECTIN BENZOATE (antiparasitic agent)

Acceptable Daily Intake (ADI): ADI of 0–0.5 µg/kg body weight established by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) in 2011, based on an overall no-observed-adverse effect level (NOAEL) of 0.25 mg/kg body weight per day for neurotoxicity from 14- and 53-week studies in dogs, supported by an overall NOAEL of 0.25 mg/kg body weight per day from 1- and 2-year studies in rats. An uncertainty factor of 500 was applied to the NOAEL, which includes an additional uncertainty factor of 5 to account for the steep dose–response curve and irreversible histopathological effects in neural tissues at the lowest-observed-adverse-effect level (LOAEL) in dogs, as used by JMPR and confirmed by the current Committee (78th JECFA, 2013).

Estimated Dietary Exposure (EDI): 11 µg/person per day, which represents approximately 37% of the upper bound of the ADI (78th JECFA, 2013).

Residue Definition: Emamectin B1a.

Species	Tissue	MRLs (µg/kg)	Step	JECFA
Salmon	Muscle	100	5/8	78
Salmon	Fillet[a]	100	5/8	78
Trout	Muscle	100	5/8	78
Trout	Fillet[a]	100	5/8	78

[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.

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.

MONEPANTEL (anthelminthic)

Acceptable Daily Intake (ADI): 0-20 µg/kg body weight on the basis of a no-observed-adverse-effect level (NOAEL) of 1.8 mg/kg body weight per day considering liver effects in mice, and a safety factor of 100, with rounding to one significant figure (75th JECFA, 2011).

Estimated Dietary Exposure (EDI): Using the model diet and marker residue to total residue ratios of 1.00 for muscle and 0.66 for fat, liver and kidney, and applying a correction factor of 0.94 to account for the mass difference between monepantel sulfone (the marker residue) and monepantel, the EDI is 446 µg/person per day, which represents approximately 37% of the upper bound of the ADI (78th JECFA, 2013).

Residue Definition: Monepantel sulfone, expressed as monepantel.

Species	Tissue	MRLs (µg/kg)	Step	JECFA
Sheep	Muscle	500	5/8	78
Sheep	Liver	7000	5/8	78
Sheep	Kidney	1700	5/8	78
Sheep	Fat	13000	5/8	78

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 V

PROPOSED DRAFT MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS

(at Step 4 of the Elaboration Procedure)

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	3	78

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	4	78
Chicken	Liver	1200	4	78
Chicken	Kidney	600	4	78
Chicken	Skin + Fat	600	4	78
Turkey	Muscle	400	4	78
Turkey	Liver	1200	4	78
Turkey	Kidney	600	4	78
Turkey	Skin + Fat	600	4	78
Quail	Muscle	400	4	78
Quail	Liver	1200	4	78
Quail	Kidney	600	4	78
Quail	Skin + Fat	600	4	78
Pheasant	Muscle	400	4	78
Pheasant	Liver	1200	4	78
Pheasant	Kidney	600	4	78
Pheasant	Skin + Fat	600	4	78

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.

Appendix VI

DRAFT AND PROPOSED DRAFT MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS

(discontinued by CCRVDF22)

MONEPANTEL (anthelminthic)

Acceptable Daily Intake (ADI): 0-20 µg/kg body weight on the basis of a no-observed-adverse-effect level (NOAEL) of 1.8 mg/kg body weight per day considering liver effects in mice, and a safety factor of 100, with rounding to one significant figure (75th JECFA, 2011).

Estimated Dietary Exposure (EDI): Using the model diet and a ratio of marker residue to total residue of 100% for muscle and 66% for fat, liver and kidney, and applying a correction factor of 0.94 to account for the mass difference between the marker residue and monepantel, the EDI is 201 µg/person, which represents 17% of the upper bound of the ADI (75th JECFA, 2011).

Residue Definition: Monepantel sulfone.

Species	Tissue	MRLs (µg/kg)	Step	JECFA
Sheep	Muscle	300	7	75
Sheep	Liver	3000	7	75
Sheep	Kidney	700	7	75
Sheep	Fat	5500	7	75

DERQUANTEL (antiparasitic agent)

Acceptable Daily Intake (ADI): 0-0.3 µg/kg body weight on the basis of a lowest-observed-adverse-effect level (LOAEL) of 0.1 mg/kg body weight per day for acute clinical observations in dogs, consistent with antagonistic activity on the nicotinic acetylcholine receptors. A safety factor of 300 was applied to the LOAEL (75th JECFA, 2011).

Estimated Dietary Exposure (TMDI): As the ADI was based on an acute effect, the 75th JECFA (2011) did not calculate an EDI. Using the model diet of 300 g muscle, 100 g live, 50 g kidney, 50 g fat and 1.5 liter of milk with the MRLs recommended, the theoretical maximum daily intake (TMDI) is 8 µg/person, which represents 45% of the upper bound of the ADI (75th JECFA, 2011).

Residue Definition: Derquantel.

Species	Tissue	MRLs (µg/kg)	Step	JECFA
Sheep	Muscle	0.2	4	75
Sheep	Liver	2.0	4	75
Sheep	Kidney	0.2	4	75
Sheep	Fat	0.7	4	75

The 75th JECFA was not able to recommend a MRL for sheep milk, as no residue data were provided.

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 VII

PROPOSED DRAFT RISK MANAGEMENT RECOMMENDATION FOR RESIDUES OF VETERINARY DRUGS

(at Step 5/8 of the Elaboration Procedure)

DIMETRIDAZOLE (antiprotozoal agent and antibacterial agent)

JECFA evaluation: 34th (1989) JECFA

Recommended risk management measures

In view of the JECFA conclusions, although insufficient data were available or there was a lack of data to establish a safe level of residues of dimetridazole or its metabolites in food representing an acceptable risk to consumers, significant health concerns were identified. For this reason, competent authorities should prevent residues of dimetridazole in food. This can be accomplished by not using dimetridazole in food producing animals.

IPRONIDAZOLE (antiprotozoal agent and antibacterial agent)

JECFA evaluation: 34th (1989) JECFA

Recommended risk management measures

In view of the JECFA conclusions, although insufficient data were available or there was a lack of data to establish a safe level of residues of ipronidazole or its metabolites in food representing an acceptable risk to consumers, significant health concerns were identified. For this reason, competent authorities should prevent residues of ipronidazole in food. This can be accomplished by not using ipronidazole in food producing animals.

METRONIDAZOLE (antiprotozoal agent and antibacterial agent)

JECFA evaluation: 34th (1989) JECFA

Recommended risk management measures

In view of the JECFA conclusions, although insufficient data were available or there was a lack of data to establish a safe level of residues of metronidazole or its metabolites in food representing an acceptable risk to consumers, significant health concerns were identified. For this reason, competent authorities should prevent residues of metronidazole in food. This can be accomplished by not using metronidazole in food producing animals.

RONIDAZOLE (antiprotozoal agent and antibacterial agent)

JECFA evaluation: 34th (1989) and 42nd (1994) JECFA

Recommended risk management measures

In view of the JECFA conclusions, although insufficient data were available or there was a lack of data to establish a safe level of residues of ronidazole or its metabolites in food representing an acceptable risk to consumers, significant health concerns were identified. For this reason, competent authorities should prevent residues of ronidazole in food. This can be accomplished by not using ronidazole in food producing animals.

Appendix VIII

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 flat fish muscle and skin in natural proportions And explore extrapolation to other finfish.	Nominator notes that relevant MRLs are established in a number of countries. Some data in public domain. IFAH members unable to provide data. Republic of Korea has method, residue, pharmacokinetic and monitoring data (nomination and CRD 28).	Republic of Korea	JECFA ADI of 0–0.7 µg/kg body weight on the basis of microbiological effects (2011). MRLs established in the European Union for all food producing species. Classified by WHO as critically important antimicrobial in human medicine (CIA). Prudent use in animal husbandry recommended. Classified by OIE as critically 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 has data available, see CRD28. Could be submitted for 81st JECFA. The future Call for Data should include a request to submit all relevant GVPs so that JECFA can explore extrapolation to other finfish.
Ampicillin	Request ADI & MRL establishment in fin fish muscle and skin in natural proportions.	Nominator notes that relevant MRLs are established in a number on 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 (nomination and CRD 28).	Republic of Korea	MRLs established in the European Union for all food producing species. Classified by WHO as critically important antimicrobial in human medicine (CIA). Prudent use in animal husbandry recommended. Classified by OIE as critically 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.	No data to allow establishment of ADI. Leave on list, but not for 81st JECFA. Data availability will be confirmed at CCRVDF23.

Name of Compound	Question(s) to be answered	Data Availability / Timing	Proposed by	Comments	When will data package be available
Diflubenzuron	Request MRL establishment in finfish (salmon) muscle and skin in natural proportions.	Nominator notes pharmacokinetic, metabolism, residue depletion and method data available on request. Previous JMPR reports.	Norway	ADI of 0-0.02 mg/kg body weight previously established by JMPR (1985). In 2001 JMPR confirmed the ADI established in 1985. MRL established in the European Union for Salmonidae. Norway notes CVMP is considering toxicological significance of metabolite 4-chloroaniline.	Data are available.
Ivermectin	Request re-evaluation of the current JECFA ADI and re-evaluation of MRLs in all cattle tissues based on the revised ADI and other pertinent information.	Toxicity in dogs, human tolerance and other use information in humans. Residue depletion study. Sponsor confirmed data availability.	United States of America	JECFA ADI of 0-1 µg/kg body weight (1992). MRLs established by Codex and by many jurisdictions, including for all mammalian food producing species in the European Union. Cattle muscle MRL to be considered by CCRVDF22.	Data are available. Additional residue depletion and kinetic data available from Argentina.
Lufenuron	Request ADI and MRL in finfish (salmonoids) muscle and skin in natural proportions.		Norway and Chile	Finfish MRL established in the European Union. Lufenuron on JMPR schedule for toxicology evaluation in 2015.	Data will be available by June 2016. Full data package (toxicological and residue data).
Teflubenzuron	Request MRL establishment in finfish (salmon) muscle and skin in natural proportions.	Nominator notes data exists and that relevant MRLs are established in a number on countries.	Norway	ADI of 0-0.01 mg/kg body weight previously established by JMPR (1994). Proposed for periodic review by JMPR in 2016. MRL established in the European Union for Salmonidae.	Toxicological and residue data are available.
Sisapronil (formally known as phenylpyrazole)	Request ADI and MRLs in cattle tissues (liver, kidney, muscle and fat).		United States of America	From RVDF21	Tox and residue data have been submitted to JECFA Secretariat and will be considered by 81st JECFA; NOTE: currently no registration.
Ethoxyquin (feed additive use)	Request 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 will be confirmed at CCRVDF23.

Name of Compound	Question(s) to be answered	Data Availability / Timing	Proposed by	Comments	When will data package be available
Zilpaterol hydrochloride	Consider potential risks of residues in animal lungs and other edible offal		China	RVDF22/CRD26	Residue data have been submitted to JECFA Secretariat and will be considered by 81st JECFA.
PART B: Concern Forms and other General Considerations for JECFA					
Species definitions for fish for use in MRL setting and extrapolation (using emamectin benzoate as example)	Referred from plenary (see report para. 110).				To be considered at 81st JECFA.
Lasalocid sodium	Referred from plenary (see report para. 84): Concern form lodged by European Union (CRD13). Concern form to be lodged by Canada on basis of CRD27.				To be considered at 81st JECFA.