CODEX ALIMENTARIUS COMMISSION







Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - E-mail: codex@fao.org - www.codexalimentarius.org

Agenda Item 2

CX/RVDF 21/25/2(REV) July 2021

JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

25th Session (Virtual) 12-16 and 20 July 2021

MATTERS REFERRED BY THE CODEX ALIMENTARIUS COMMISSION AND/OR OTHER SUBSIDIARY BODIES

MATTERS FOR INFORMATION

Codex Alimentarius Commission

Amendments to the Procedural Manual

1. CAC41 (2018) **adopted** the amendment to the *Risk Analysis Principles applied by the Codex Committee on Residues of Veterinary Drugs* to clarify how CCRVDF could approach work to develop extrapolation of MRLs as a risk management decision.¹

Maximum residue limits and risk management recommendations adopted at Steps 8, 5/8 and 5

2. CAC41 **adopted** MRLs for veterinary drugs used in food-producing animals and RMR for Gentian Violet as proposed by CCRVDF24 (2018)² and noted the following in regard to the adoption of these standards:

Gentian violet

- 3. CAC41 noted reservations regarding the final sentence of the RMR, which delegations, while not opposed to the adoption, believed was overly prescriptive and went beyond the scope of CCRVDF and Codex. They noted that the existing language could be understood as limiting the capacity of national authorities to use other risk-management measures they may deem more appropriate. CCRVDF's interpretation of the text of the RMR, if read separately from it, could not assist Members in implementation. Delegations supporting adoption noted that the wording "can be accomplished" in the RMR text gave national competent authorities sufficient flexibility to determine risk-management measures most appropriate to their needs.
- 4. The JECFA Secretariat clarified that the text was intended to provide national authorities with risk-management options and noted that, since an RMR containing this text had already been adopted for malachite green, a compound similar in use and toxicity, it would be inconsistent to change the wording.
- 5. CAC41 **adopted** the RMR as proposed by CCRVDF24 (2018), noting that the text allowed Member countries to choose appropriate risk-management approaches to prevent residues of gentian violet in foods as clarified by CCRVDF24.³

Approval of new work for the elaboration of new standards and related texts

6. CAC41 approved the Priority List of Veterinary Drugs Requiring Evaluation or Re-evaluation by JECFA as proposed by CCRVDF24. 4

Standards held at Step 8 Draft MRLs for Bovine Somatotropins

7. CAC43 (2019) recalled that CAC38 had agreed to retain the draft MRL for bSTs at Step 8 to allow further time to facilitate consensus. CAC43 noted that these MRLs would continue to be held at Step 8.5

¹ REP18/RVDF, paras. 14-15, Appendix II

² REP18/RVDF, paras. 16-17, Appendices III and IV

³ REP18/CAC, paras. 48-51, Appendix III

⁴ REP18/CAC, Appendix VI

⁵ REP20/CAC, paras. 149-150

Other matters

Recognition of the Commission of the current situation and necessary actions between CAC43 and CAC44

8. CAC43 (2020)6:

- (i) **recognized** the challenges facing the Codex Alimentarius Commission in fulfilling its duties as the pre-eminent international food standards setting body due to the COVID-19 pandemic;
- (ii) **recognized** that while many Codex Committee meetings had to be postponed in 2020 this could not continue in 2021; and
- (iii) **supported** the use of modern tools and approaches by Codex subsidiary bodies in line with the Codex core values to ensure Codex work progressed in a timely and effective manner.

Procedural aspects

9. CAC43⁷:

- (i) **agreed**, on an exceptional basis in view of the circumstances surrounding the pandemic that, with respect to meetings and sessions of the Codex Subsidiary Bodies to be held in 2021, Rule XI (7) and (8) may be interpreted in a manner that includes a virtual setting;
- (ii) **agreed** on this basis, that Codex Subsidiary Bodies may be held virtually in 2021, if determined appropriate by FAO and WHO, in consultation with the host governments concerned and the Codex Secretariat.

Ongoing work of subsidiary bodies

10. CAC43 **recommended** to all subsidiary bodies and Members and Observers to make full use of existing remote working mechanisms such as EWGs and CLs and to plan their virtual committee meetings in such a manner as to optimize the possibility to complete their agendas.⁸

Executive Committee

Implementation of CAC42: Feedback on Changes and Proposals for Further Improvements

- 11. CCEXEC78 requested that Chairpersons of subsidiary bodies and CAC together with the Secretariat9:
 - (i) develop strategies to prevent or mitigate technical discussions at CAC on topics for which there was no consensus and communicate these strategies to Members. Such strategies may include short adjournments of the session for informal discussions or suspension of discussions on items that overrun the planned time limit; and
 - (ii) ensure that, at CAC meetings, written comments received were given due consideration and the technical basis of reservations were included in meeting reports.

Regular Review of Codex Work Management 2018-2019: Critical Review Process

- 12. CCEXEC78 concluded that the Critical Review was overall an efficient and effective work management tool and that there was no urgent need to revise it substantively while recognizing that improvements could be further discussed.
- 13. In this regard, CCEXEC78 also recognized that CCEXEC could provide guidance and advice to subsidiary bodies and that subsidiary bodies could also seek advice from CCEXEC and that such exchange could take place outside of the Critical Review process.¹⁰

Regular Review of Codex Work Management 2017-2018: Periodic Review of Codex Standards

14. CCEXEC78 concluded that the current approaches to standards review were working for active subsidiary bodies, and encouraged these bodies to continuously enhance their work management processes to consider the need for reviewing existing Codex standards.¹¹

⁶ REP20/CAC para 10

⁷ REP20/CAC para 20

⁸ REP20/CAC para 31

⁹ REP20/EXEC1, para. 30

¹⁰ REP20/EXEC1, paras. 46 and 51

¹¹ REP 20/EXEC1, para. 57

Regular Review of Codex Work Management 2017-2018: Use of References in Codex Texts

15. CCEXEC78 emphasized that while there may on occasion be merit in including references to standards of another standard setting organization, these should be kept to a minimum since they become an integral part of a Codex text and require life-long monitoring.¹²

Regular Review of Codex Work Management 2018-2019: Critical Review Process

Advice on the coordination of work

- 16. The Secretariat noted that there are ways to facilitate and promote cooperation between committees such as alignment of the meeting schedule and parallel EWGs such as those piloted between CCRVDF and CCPR.
- 17. CCEXEC78 **noted** that cross-committee cooperation including joint EWGs was important and should be encouraged and taken into account in future work planning.¹³

Codex virtual meetings in 2021

18. CCEXEC80 (2021) recognized that CAC43 had agreed on the possibility of holding virtual meetings in 2021 and endorsed the proposals from the sub-committee on Codex and the pandemic to operationalize this decision, noting that this did not at present require any change to formal Codex procedures.¹⁴

Codex work on foodborne antimicrobial resistance

Revision of the Code of practice to contain and minimize foodborne antimicrobial resistance (CXC 61-2005)

- 19. The 7th Session of the Codex Ad Hoc Intergovernental Task Force on Antimicrobial Resistance (TFAMR07, 2019) agreed to forward the revised COP to CAC for adoption at Step 5 and to establish an Electronc Working Group (EWG), chaired by the United States of America, to address the outstanding issues in square brackets and report back to the next session of TFAMR08 (2021). Further details on key points of discussions can be found in the report of the session.¹⁵
- 20. CCEXEC79 (2020) recommended that CAC43 (2020) adopt the revision of COP at Step 5; and that TFAMR08 focus its discussion on the issues that had not been extensively discussed to date and avoid reopening provisions to the extent possible. Further details on key points of discussions can be found in the report of the session. ¹⁶
- 21. CAC43 (2020) adopted the revised COP at Step 5. Further details on key points of discussions can be found in the report of the session. ¹⁷
- 22. The COP, as revised by the EWG, was subsequently circulated for comments through a circular letter CL 2021/32-AMR and considered by a virtual meeting of the WG/COP established by TFAMR07 (June 2021). The report of the EWG, together with the COP, would be issued in July and circulated for further comments and consideration by TFAMR08 (October 2021).

Development of Guidelines for integrated monitoring and surveillance of foodborne antimicrobial resistance

- 23. TFAMR07 agreed to return the proposed Guidelines to Step 2/3 for re-drafting and to establish an EWG, chaired by the Netherlands, to revise the document focusing on those areas that were not considered in the physical meeting of the working group (PWG) held prior to the session and not reopening definitions already agreed in the COP with a view to reporting back to the next session of TFAMR08 (2021). Further details on key points of discussions can be found in the report of the session.¹⁸
- 24. CCEXEC79 reiterated that the guidelines should focus on providing high level principles and guidance on the design and implementation of integrated monitoring and surveillance of foodborne AMR along the food chain, giving a framework under which every country could build their own specific monitoring and surveillance according to their capacity and needs and EWG and recommended that TFAMR08 do not reopen, to the extent possible, provisions common to both the code of practice and the guidelines, which have already been agreed by TFAMR during the consideration of the code of practice, recognizing that as the work progresses the guidelines may need to elaborate concepts not included in the code of practice text. Further details on key points of discussions can be found in the report of the session.¹⁹

¹² REP20/EXEC1, para. 64

 $^{^{13}}$ REP20/EXEC1, paras. 46 and 51

 $^{^{14}}$ REP21/EXEC1, para 35-36

¹⁵ REP20/AMR, paras. 13-127

¹⁶ REP20/EXEC2, paras. 42-43

¹⁷ REP20/CAC, paras. 96-113, Appendix III

¹⁸ REP20/AMR, paras. 128-133

¹⁹ REP20/EXEC2, paras. 44-46

25. The Guidelines, as revised by the EWG, was subsequently circulated for comments through a CL 2021/33-AMR and considered by a virtual meeting of the WG/GL established by TFAMR07 (June 2021). The report of the meeting, together with the COP, would be issued in July and circulated for further comments and consideration by TFAMR08.

Additional information

26. Information on Codex work on AMR can be found on the Codex dedicated website on TFAMR. ²⁰ Specific information related to the next session of TFAMR, including webinars providing an insight of the key issues for consideration in both documents to facilitate their finalization at the next TFAMR, can be found on the TFAMR08 website. ²¹

Codex work on zilpaterol hydrochloride

27. Background information on the consideration of MRLs for zilpaterol hydrochloride in CCRVDF, CCEXEC and CAC can be found in CX/RVDF 21/25/7 (Agenda Item 6.2).

MATTERS FOR ACTION

Coordination of work between CCPR and CCRVDF

Overall work

- 28. CCEXEC73 encouraged closer collaboration between CCRVDF and CCPR when considering MRLs for compounds used as both veterinary drugs and pesticides and invited the two Committees to explore innovative ways to foster such collaboration.²²
- 29. CCRVDF24 noted the recommendation of CCEXEC73 on closer collaboration between CCRVDF and CCPR when considering MRLs for compounds used as both veterinary drugs and pesticides.²³

Coordination of work on the definition of animal tissues including edible offal: Electronic working groups of CCPR/CCRVDF

- 30. CCEXEC75 recommended that the CCPR/EWG on the revision of the *Classification of Food and Feed* (CXM 4-1989), in addition to its existing terms of reference (ToRs), work closely with the CCRVDF/EWG on the definition of animal tissues (including edible offal) to develop a harmonized definition that would facilitate the establishment of MRLs for pesticides and veterinary drugs
- 31. CCEXEC75 further recommended that the CCRVDF/EWG on the definition of animal tissues, including edible offal, work closely with the CCPR/EWG on the revision of the *Classification of Food and Feed* to develop a harmonized definition that would facilitate the establishment of MRLs for pesticides and veterinary drugs.²⁴
- 32. This matter will be consider under Agenda Item 8.

Critical Review

33. CCEXEC77 **called** upon CCPR and CCRVDF to collaborate and synchronize work on issues of common interest to both committees to the extent possible to facilitate the establishment of maximum residue limits (MRLs) for pesticides / veterinary drugs for compounds with dual uses.²⁵

Timeliness of Codex working documents

34. CCEXEC78 requested that the Codex Secretariat bring the information ²⁶ on the timeliness of Codex working documents, reports and the availability of adopted standards to the attention of subsidiary bodies for their review and suggestions. ²⁷

²⁰ http://www.fao.org/fao-who-codexalimentarius/committees/committee/related-meetings/en/?committee=TFAMR

²¹ http://www.fao.org/fao-who-codexalimentarius/meetings/detail/en/?meeting=TFAMR&session=8

²² REP17/EXEC2, para. 19

²³ REP18/RVDF, paras. 7-9

²⁴ REP18/EXEC2-Rev.1, paras. 27-28

²⁵ REP19/EXEC2 para 19-20

²⁶ CX/EXEC 20/78/8

²⁷ REP20/EXEC1, para. 111

RECOMMENDATIONS FOR ENDORSEMENT BY CCRVDF

35. CCRVDF is invited to note:

- (i) the matters for information referred by CAC and CCEXEC (paragraphs 1- 15, 18)
- (ii) the innovative ways of working to facilitate and promote cooperation on cross-sectoral issues between committees will be considered as needed and in particular under Agenda Item 8 to advance work on items identified by CCRVDF (paragraphs 16 17)
- (iii) the matters of coordination of work between CCPR and CCRVDF will be considered under Agenda Item 8 (paragraphs 19 24)
- (iv) that the Codex Secretariat works closely with the Chair of CCRVDF, Chairs of Electronic Working Groups and the Host Country Secretariat on ways forward to improve work management of the Committee including the review of the information provided in CX/EXEC 20/78/8 (paragraph 25)