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Agenda Item 2

CX/RVDF 23/26/2

January 2023

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

26th Session 13-17 February 2023 Portland, Oregon, United States of America

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

MATTERS ARISING FROM THE CODEX ALIMENTARIUS COMMISSION AND ITS EXECUTIVE COMMITTEE

MATTERS FOR INFORMATION

Specific matters

Maximum residue limits adopted at Steps 8, 5/8 and 51

- 1. CAC44 (2021) adopted the following MRLs/texts:
 - MRL for flumethrin in honey at Step 8;
 - MRLs for diflubenzuron (salmon muscle plus skin in natural proportion) at Step 5/8;
 - MRLs for halquinol (swine muscle, skin plus fat, liver and kidney) at Step 5/8;
 - MRLs for ivermectin (sheep, pigs, and goats fat, kidney, liver and muscle) at Step 5 and endorsed extension of the timeline for completion of this MRL until CCRVDF26; and
 - Amendment to the *Glossary of Terms and Definitions* (*Residues of Veterinary Drugs in Foods*) (CXA 5-1993): Inclusion of a definition for edible offal.

Approval of new work for the elaboration of new standards and related texts²

2. CAC44 approved the priority list of veterinary drugs for evaluation or re-evaluation by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) as listed in REP21/RVDF25, Appendix VI-Part I.

Amendments to the Procedural Manual³

3. CAC44 adopted the Amendment to the PM by including the Approach for the extrapolation of MRLs for veterinary drugs to one or more species in the *Risk Analysis principles applied by CCRVDF*.

General matters⁴

Application of the Statements of Principle Concerning the Role of Science in the Codex Decision-Making Process and the extent to which other factors are taken into account (SoP)⁵

- 4. CCEXEC83 (2022) noted that the Subcommittee on the SoP had completed its work on guidance for the application of the SoP and therefore agreed to close the discussion on this topic while forwarding the draft guidance to CAC45 for further consideration.
- 5. CAC45 agreed to refer the draft Guidance for Codex Chairpersons and Members on the Application of the SoP to the chairpersons of Codex subsidiary bodies to facilitate deliberations on matters that fell within the scope of the SoP and urged members to take account of the draft guidance as appropriate during the process of standards development and advancement. CAC further requested the Codex Secretariat to issue a circular letter (CL) inviting Members and Observers to provide specific suggestions to improve the draft guidance, its finalization and its possible incorporation into guidance documents for Chairpersons and Members.
- 6. The draft guidance is available as an appendix to the report of CCEXEC83.6

¹ REP21/CAC44, para 61 & Apps III-IV

² REP21/CAC44 para 62 & App VI

³ REP21/CAC44 para 36 & App II

The adoption of the report of CAC45 is ongoing and the final report will only be published in February 2023 when adoption of the entire report would be completed. The information provided herein represents the content of the CAC45 report as adopted at the time of publication of this working document.

⁵ REP21/CAC44, paras 13-14; REP22/EXEC83, paras 81-84; REP22/CAC45, para 22

⁶ REP22/EXEC83, Appendix II

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Proposed draft MRLs on zilpaterol hydrochloride⁷

7. CAC44 requested the CAC Chairperson and Vice-Chairpersons (CVCs) to undertake informal consultations with all relevant parties to encourage and enable sustained effort to build consensus in advance of CAC45 in relation to the adoption of these MRLs. A report from the CVCs was presented to both CCEXEC83 and CAC45.⁸

- 8. CAC45 discussed the JECFA risk assessment of human health risks associated with residues of zilpaterol hydrochloride and agreed that such assessment provided a robust basis for the elaboration for MRLs in cattle liver, kidney and muscle.
- 9. The CCRVDF Chairperson confirmed that for other edible offal there had been a lack of data, but this would not preclude the committee requesting new advice when data became available, and also noted the ongoing work on extrapolation for edible offal tissues. She underlined that CCRVDF, as a technical committee, did not have further work to do on these MRLs at this time and requested that the MRLs would remain with CAC. She added that CCRVDF would welcome any new work proposals for the priority list for CCRVDF26 and noted that, with the adoption of the MRLs at Step 5, they would automatically be circulated for comments at Step 6. Any comments would be discussed at Step 7 by CAC46.
- 10. CAC45 adopted the MRLs for zilpaterol hydrochloride at Step 5 (by vote); agreed to retain the further elaboration of MRLs for zilpaterol hydrochloride in kidney, liver and muscle, in the Commission; advised CAC46 to note the discussions at CAC45; and welcomed the prospect of further informal consultation by the CVCs prior to CAC46 to facilitate consensus.

Codex and the pandemic⁹

- 11. CAC43 (2020) recommended to all subsidiary bodies and Members and Observers to make full use of existing remote working mechanisms such as Electronic Working Groups (EWGs) and CLs and to plan their virtual committee meetings in such a manner as to optimize the possibility to complete their agendas.
- 12. CAC44 recommended that Rule XI (7) and (8) continue to be interpreted in a manner that includes a virtual setting with respect to sessions of Codex subsidiary bodies, including CCEXEC, and that application of this should take into consideration the criteria¹⁰ outlined by CCEXEC80 (2021).

60th Anniversary of Codex 11

- 13. CAC44 agreed that the celebration of the Codex 60th Anniversary (2023) would be a wonderful occasion to raise awareness about food safety and quality and encouraged all Members and Observers to use the opportunity of the Codex 60th Anniversary to plan and implement activities to build awareness of Codex and to engage high-level political support for Codex work. CAC noted that Codex already had a number of tools at its disposal to facilitate engagement and planning for the Anniversary, including the FAO/WHO Coordinating Committees.
- 14. CAC45 encouraged Members and Observers to fully engage in the celebrations and to share information on their plans and activities directly and through the Codex Secretariat; and urged Members to commit to advocacy at all levels to ensure both the widest possible participation in the celebrations and the widest possible promotion of the work of Codex. Members and Observers are encouraged to send details of any activities and to celebrate Codex@60 to the Codex Secretariat at Codex@fao.org.

New food sources and production systems (NFPS)12

- 15. CCEXEC81 (2021) discussed a means to investigate potential mechanisms to address cross-cutting, overarching and emerging issues in Codex, such as edible insects and seaweed. There was consensus that, at the current stage, emerging issues should be addressed through existing mechanisms and committees, with the support of FAO and WHO for scientific advice as appropriate. FAO recalled that the challenge was how these issues could initially be introduced for consideration by Codex noting that these items did not naturally fall within the terms of reference (ToR) of existing committees. CCEXEC agreed to establish a subcommittee to investigate potential mechanisms to address cross-cutting, overarching and emerging issues in Codex.
- 16. CCEXEC82 recognized that ongoing work by CCEXEC on "new food sources" did not preclude committees from undertaking new work falling within their respective mandates and agreed that the subcommittee should continue its stepwise cosideration of the issue informed by an analysis of the information collected so far and the report of its session.

⁷ REP21/CAC44, para 29; REP22/CAC45, paras, 130, 134, 141

⁸ CX/EXEC 22/83/2-Add. 2

⁹ REP20/CAC43, para 31 (ii); REP21/CAC44, para 12(iii)

¹⁰ REP21/EXEC80, para 35

¹¹ REP21/CAC44 para 150; REP22/EXEC82, para 129; REP22/EXEC83, para 177; REP22/CAC45, para 220

¹² REP21/81, paras 105, 106, 110; REP22/EXEC82, para 85; REP22/EXEC83, para 100; REP22/CAC45, para 31

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17. CCEXEC83 recognized that this work had sensitized Codex to the challenges and opportunities arising in relation to NFPS and the potential role Codex could play in addressing any related food safety issues and facilitating fair trade of such commodities. CCEXEC also recognized the need to prepare guidance on how to apply existing procedures to ensure that Members do not perceive procedural obstacles to submitting new proposals for work in this and other areas of Codex.

- 18. CAC45 recognized the importance of Codex working in a flexible and timely manner to consider NFPS as an important topic in the development of international standards aimed at protecting consumer health and ensuring fair practices in the food trade. CAC encouraged Members to submit proposals related to NFPS using existing Codex mechanisms, and Codex subsidiary bodies to consider NFPS in their deliberations, and requested the Codex Secretariat to send a CL to Members and Observers to identify possible issues related to NFPS that the current structure and procedures could not address and options to address them for discussion at CAC46.
- 19. CAC45 further acknowledged the role of CCEXEC in ensuring cross-committee coordination, as part of the critical review, noting that this could be of particular relevance for any work on NFPS and strongly encouraged FAO and WHO to continue sharing information on NFPS with CAC and its subsidiary bodies through the agenda item on "Matters arising from FAO and WHO", to ensure Codex Members were fully aware of upcoming issues in this area and could consider them as appropriate.

Future of Codex¹³

- 20. CCEXEC82 agreed to establish a subcommittee to develop, in collaboration with the Codex Secretariat, a report including a proposed blueprint for the future of Codex for consideration by CCEXEC84, taking into consideration the views of Members and Observers, FAO and WHO, Chairpersons of Codex Committees, Regional Coordinators and Host Country Secretariats.
- 21. CCEXEC83 considered procedural issues related to nature of meetings (hybrid/virtual), development of new work and work of electronic working groups. CCEXEC recognized that virtual and hybrid meetings were essential tools for Codex and that practice in relation to these meeting modalities continued to develop; acknowledged the concerns expressed on the complexity of the process for developing new work; and noted the added value new tools provided to the deliberations of EWG. CCEXEC further agreed on a timeline for the way forward up to the publication of the blueprint by mid-May 2023.
- 22. CAC45 noted that work to date had focused on preparedness in terms of working modalities and the evolution of working practices within Codex related to meeting formats, meeting schedules and working groups, and other virtual informal working mechanisms. CAC further noted that the future of Codex was a work in progress and that there would be an opportunity in 2023 for all Members and Observers to engage on this topic; and noted the need, in due course, to review the PM to ensure that its provisions enabled and facilitated continued virtual and hybrid meetings.
- 23. CAC45 requested the Codex Secretariat to consult with the FAO and WHO Legal Offices on a possible amendment to the rules of procedure allowing the Commission to take place virtually if needed and to prepare a paper on this specific issue for consideration by the 33rd Session of the Codex Committee on General Principles (CCGP33, 2023) which in turn should advise CAC46.

Monitoring the use and impact of Codex Standards¹⁴

- 24. CCEXEC82 discussed a draft mechanism to monitor the use and impact of Codex texts (Goal 3 "increase impact through the recognition and use of Codex Standards") and
 - recognized the benefits and challenges in monitoring the use and impact of Codex texts, and the importance of engagement as the process evolved and of periodic review;
 - endorsed the proposed approach for building the Codex Monitoring and Evaluation (M&E) framework, noting that 2022 would be a pilot year for the re-designed survey approach and that the preliminary results would be reported at CCEXEC83 and CAC45;
 - encouraged Members and Observers to identify potential resources to support data gathering for this work, particularly through case studies which should be selected according to a set of pre-defined criteria and be clear in terms of scope and context.
- 25. CCEXEC83, noting the preliminary results of the 2022 pilot survey on the use and impact of Codex texts, and while requesting the Secretariat to further review and streamline the Codex SP monitoring framework, requested to consider the results of the survey in undertaking the elaboration of the next SP with the membership.

¹³ REP22/EXEC82, paras 99-100; REP22/EXEC83, paras 114, 118, 121-122; REP22/CAC45, para 41

REP22/EXEC1, para 121; REP22/EXEC2, para 165; REP22/CAC45, para 179

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MATTERS ARISING FROM OTHER SUBSIDIARY BODIES

Codex Committee on Pesticide Residues

Coordination of work between CCPR and CCRVDF

<u>Harmonization of meat mammalian MRLs between CCPR and CCRVDF: Harmonized definition for edible offal and other edible tissues¹⁵</u>

- 26. CCPR53 (2022) recalled its previous discussion on harmonization of terms/definitions for edible tissues of animal origin and further agreed to harmonize its definition for edible offal with that of CCRVDF25 as adopted by CAC44 (2021).
- 27. CCPR53 agreed to harmonize the definition of fat, meat and muscle with that of JECFA/CCRVDF as proposed by the Joint JECFA/JMPR WG including the definition for the portion of the commodity to which MRLs apply and which is analysed for fat and muscle. CCPR further agreed to forward the definitions for edible offal, meat, muscle and fat, including definitions for the portion of the commodity to which MRLs apply and which is analysed for fat and muscle, to CAC45 for adoption and to inform JMPR accordingly.

Mitigation of Trade Impacts Associated with the Use of Environmental Inhibitors in Agriculture 16

28. CCPR53 agreed that environmental inhibitors could be addressed on a case-by-case basis within its established procedures as described in the Risk Analysis Principles applied by CCPR and that environmental inhibitors administered directly to animals or via feed could be considered by CCRVDF. CCPR also agreed that in situations of multiple uses (e.g. dual-use compounds) the Joint CCPR/CCRVDF EWG could address these compounds to ensure harmonized approaches and appropriate mechanisms for the establishment of single/harmonized MRLs. CCPR agreed to inform CCEXEC and CAC that CCPR could consider environmental inhibitors on an ad hoc basis without changing the definition of pesticides, its procedures, or its ToR.

Joint CCPR/CCRVDF Working Group 17

- 29. CCRVDF25 agreed to request CCEXEC advice on a mechanism for cooperation between the Codex Committee on Pesticide Residues (CCPR) and CCRVDF on establishment of harmonized MRLs for dual use compounds. In supporting this request, CCPR52 (2021) also encouraged innovative ways of working to facilitate and promote cooperation on cross-sectoral issues between CCRVDF and CCPR as needed and to the extent possible. This was also relevant within the framework of the cooperation on edible offal.
- 30. CCEXEC81 recommended that CCRVDF and CCPR makes use of joint EWGs, including the use of virtual technology, to further advance the work on cross-sectoral issues between CCRVDF and CCPR.
- 31. CAC44 agreed to establish a Joint CCRVDF/CCPR EWG chaired by the United States of America, working with the support of the Joint FAO/WHO Expert Committee on Food Additives (JECFA), the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) and the Codex Secretariat to review work already done cooperatively between CCRVDF and CCPR and to identify, and if possible, prioritize areas of possible further collaboration between CCRVDF and CCPR and how this could be carried out (e.g. jointly, in parallel, etc.) so as to facilitate the consideration of compounds with dual uses by both committees and the possible harmonization of MRLs. This may include reflections on improved synchronization of work between CCPR and CCRVDF as well as collaboration between CCPR/CCRVDF and JMPR/JECFA. The Joint EWG would provide an update on their preliminary findings to CCRVDF26 and CCPR53.
- 32. The Joint EWG will continue its work as long as both CCRVDF and CCPR consider it useful. The Joint EWG will not replace the ongoing parallel cooperation between the established EWGs under CCRVDF (edible offal) and CCPR (revision of the Classification, food of animal origin) within their respective terms of reference.
- 33. CCPR53 noted the information on the work of the Joint CCPR/CCRVDF EWG on the status of work under their mandate, supported the activities of the Joint EWG and encouraged Members and Observers to actively participate in the work of the Joint EWG.
- 34. CAC45 welcomed harmonization of definitions for edible tissues of animal origin between CCPR and CCRVDF, which would facilitate the establishment of single MRLs for compounds with dual use and their subsequent uptake by Codex Member countries. CAC also commended the improved work management approaches in CCRVDF and CCPR to enhance coordination of work on matters of mutual interest such as the establishment of joint and parallel WGs between the committees to address compounds with dual use.

¹⁵ REP22/PR53, para 181

¹⁶ REP22/PR53, para 251

¹⁷ REP21/RVDF25, para 146; REP21/PR52, paras 12, 179, 185; REP21/EXEC81, paras 33-34; REP21/CAC44, paras 64-66; REP22/PR53, para 190; REP22/CAC45, paras 88-89

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RECOMMENDATIONS FOR ENDORSEMENT BY CCRVDF

35. CCRVDF is invited to:

- (i) note the matters for information referred by CAC and CCEXEC;
- (ii) encourage Members and Observers, on the occasion of the 60th anniversary of Codex, to plan and implement activities to build awareness of Codex and to engage high level political support for Codex work and to consider the implementation of a regional event to mark the 60th anniversary;
- (iii) encourage Members and Observers to actively engage in opportunities to contribute to the discussions in CCEXEC and CAC (i.e. the operationalization of the SoP; the future of Codex; new food sources and production systems, and monitoring the use of Codex standards) by providing replies to relevant CLs; and
- (iv) note that the matters of coordination of work between CCPR and CCRVDF will be considered under Agenda Item 9.