CODEX ALIMENTARIUS COMMISSION

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Food and Agriculture Organization of the United Nations

World Health Organization

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**Agenda item 3** **CX/RVDF 24/27/3**

**August 2024**

**JOINT FAO/WHO FOOD STANDARDS PROGRAMME**

**CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS**

**27th Session**
**21-25 October 2024**
**Omaha, Nebraska, United States of America**

**MATTERS OF INTEREST ARISING FROM FAO/WHO INCLUDING JECFA**

**Information from the 98th Meeting of the Joint FAO/WHO Committee on Food Additives (JECFA)**

1. Since the 26th Session of the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF26, 2023), four meetings of JECFA (i.e., JECFA 96th, 97th, 98th, and 99th) have been convened. These meetings addressed food additives (i.e., JECFA 96th, 97th, and 99th) and veterinary drug residues (i.e., JECFA98th). The reports and detailed monographs from these meetings are available at the relevant FAO[1] and WHO[2] web sites.

2. JECFA98 was held at FAO headquarters in Rome, Italy, on 20 – 29 February 2024 to evaluate residues of certain veterinary drugs in food. The full report of the meeting is published in the WHO Technical Report Series (TRS 1055)[3]. Toxicological monographs summarizing the data that were considered by the Committee in establishing Acceptable Daily Intakes (ADIs) will be published in the WHO Food Additives Series. Residue monographs summarizing the data that were considered by the Committee in recommending maximum residue limits (MRLs) will be published in the FAO JECFA Monograph series.

3. JECFA98 evaluated the safety of two veterinary drugs, clopidol and fumagillin dicyclohexachloride. The Committee also completed the safety evaluation of imidacloprid started at JECFA94. The MRLs recommended for these compounds will be discussed under Agenda item 6.

4. Although ethoxyquin was initially included on the list of substances to be evaluated, it was not assessed, as the sponsor did not submit any data.

5. JECFA98 also finalized a decision tree for evaluating veterinary drugs for which the dossier submitted by the sponsor is incomplete or outdated. It is available in the Technical Report Series TRS 1055, Annex 1—Guidance for the safety evaluation of residues of veterinary drugs with incomplete data packages.

**Guidance for the Safety Evaluation of Residues of Veterinary Drugs with incomplete data packages**

6. JECFA is sometimes asked to assess the risk of veterinary drug residues of compounds for which the data package is not comprehensive or is outdated. In such cases, generating a risk assessment of maximum utility for CCRVDF and other risk managers may require approaches different from those usually used by JECFA in assessing risk. JECFA first proposed the development of guidance to address such situations at JECFA66 (2006) and considered a first draft at JECFA70 (2008). Since then, the draft has been substantially revised and updated, including JECFA94 (2022). JECFA98 discussed the updated guidance and added relevant considerations for evaluation of toxicological, microbiological, residue, and dietary exposure. The Committee adopted the guidance and welcomes comments from CCRVDF.

**JECFA Toolbox for Veterinary Drug Residues Risk Assessment**

7. The process used by JECFA for assessing risks resulting from veterinary drug residues in food is based on sound scientific principles and procedures. For stakeholders and new JECFA experts to understand this process, FAO is developing a Toolbox for Veterinary Drug Residues Risk Assessment. The aim is to strengthen the understanding of JECFA procedures by stakeholders interested in veterinary drug residues in food, such as regulatory agencies responsible for veterinary drug approval or food safety standards, the pharmaceutical industry, producers in animal agriculture, and veterinary associations. The toolbox is designed for use by potential JECFA experts to broaden the pool of experts available for the JECFA roster and to ensure greater geographical representation, particularly from regions with previously low representation in FAO/WHO expert bodies. Additional sources of guidance listed in the Toolbox provide detailed information about the specific steps in the risk assessment process.

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1 http://www.fao.org/food-safety/resources/publications/en/

2 https://www.who.int/groups/joint-fao-who-expert-committee-on-food-additives-(jecfa)/publications

3 https://www.who.int/publications/i/item/9789240095533

8. The Toolbox is being finalized and is expected to be ready by the end of 2024. It will be publicly available on the FAO website, along with the guidance documents published in English, Spanish, and French.

**FAO's publication on the Food safety implications from the use of environmental inhibitors in agrifood**

9. At the end of last year, FAO released a report on the Food safety implications from the use of environmental inhibitors in agrifood systems[4]. The report has been developed within the activities of the FAO Food Safety Foresight Programme. As a forward-looking approach, foresight seeks to facilitate preparedness for food safety issues that may emerge in globalized and rapidly evolving agrifood systems. The challenge of feeding a growing world population while responding to the climate crisis requires developing practices and technologies that enhance agrifood systems' sustainability and reduce harmful environmental effects. Among those approaches, environmental inhibitors are used to improve the production efficiency of crops and livestock while reducing greenhouse gas emissions, such as methane, or limiting nitrogen loss from cultivated fields and pastures. An inadvertent presence of environmental inhibitors in food commodities can raise health concerns and trade disruption if standards are not established.

10. Challenges related to food safety risk assessment and management of these substances include the lack of internationally harmonized MRLs, an agreed definition for environmental inhibitors, and insufficient safety information for some compounds. This publication provides an overview of various synthetic and biological environmental inhibitors and analyzes possible food safety implications from their use. Regulatory frameworks relevant to environmental inhibitors in selected countries are presented as examples of current approaches being taken at the national or regional level. Finally, food safety-related knowledge gaps are discussed, together with some perspectives on how to move forward.

11. FAO organized a webinar on this subject on 9 May. The summary and the recording of the webinar are available online[5].

12. More information on FAO's work on foresight in food safety is also available online[6].

**Activities on antimicrobial resistance (AMR)**

13. This section provides a summary update on AMR activities carried out since the last session of CCRVDF.

***Quadripartite (FAO/United Nations Environment Program (UNEP)/WHO/World Organization for Animal Health (WOAH)) work on Antimicrobial Resistance***

14. The first quadripartite biennial report was published in 2023[7] and an updated progress report was published in 2024 outlining joint activities[8].

15. The Quadripartite has published an *Antimicrobial resistance: tool kit for media engagement*[9].

16. The Quadripartite Joint Secretariat (QJS) on AMR has established a technical group to support and coordinate integrated surveillance activities across the organizations (Quadripartite Technical Group on Antimicrobial Resistance and Use Integrated Surveillance (QTG-AIS)).[10]

17. The World Antimicrobial Awareness Week (WAAW) has been rebranded as World Antimicrobial Resistance Week. The World AMR Awareness Week (WAAW) 2024 theme is "Educate. Advocate. Act now."

18. The AMR Multi-Stakeholder Partnership Platform was launched. Established in 2023, this dialog aims to catalyze a global movement for action against antimicrobial resistance (AMR) by fostering cooperation between diverse stakeholders at all levels across the One Health spectrum.

19. Quadripartite Key Recommendations and Priorities for the 2024 United Nations General Assembly (UNGA) High-Level Meeting on Antimicrobial Resistance (AMR) are available.

20. The QJS on AMR published the One Health Priority Research Agenda for AMR in 2023, a guiding tool[11] for countries, research institutes, and funding bodies to support One Health AMR research, helping policymakers, researchers, and the multidisciplinary scientific community to work together across sectors on solutions that will prevent and mitigate AMR on a national, regional and global scale as further evidence on research strategies, interventions, and policies is required to understand what works, in which contexts and for whom.

4 https://openknowledge.fao.org/items/68ec6807-6934-48a3-a55d-6b22824f8a80
5 https://www.fao.org/food-safety/news/news-details/en/c/1698034/
6 https://www.fao.org/food-safety/scientific-advice/foresight/en/
7 https://iris.who.int/bitstream/handle/10665/375008/9789240074668-eng.pdf
8 https://www.qjsamr.org/docs/librariesprovider25/default-document-library/qjs-report-vf0571b0c0-8193-4612-b54e-f972a4f5d962.pdf?sfvrsn=7f91d0cf_1
9 https://iris.who.int/bitstream/handle/10665/376945/9789240093225-eng.pdf?sequence=1
10 https://www.qjsamr.org/technical-work/technical-group-on-integrated-surveillance
11 https://iris.who.int/bitstream/handle/10665/370279/9789240075924-eng.pdf?sequence=1

21. The QJS on AMR will be published in 2024. The One Health Legislative Assessment Tool for AMR (OHLAT) aims to assist countries in identifying and analyzing their AMR-relevant legislation across all sectors relevant to AMR based on existing international standards and agreed-upon good practices.

22. The AMR-Multi-Partner Trust Fund (AMR-MPTF) is a strategic, inter-sectoral, multi-stakeholder initiative inviting partnership and financing to leverage the Quadripartite convening and coordinating power as well as mandates and technical expertise to mitigate the risk of AMR by supporting the implementation of One Health AMR National Action Plans (NAPs). It is financially supported by Germany, Netherlands, Sweden, the United Kingdom, and the European Commission (Directorate-General for Health and Food Safety (DG Sante)). In 2023, new country projects were launched in Bangladesh, Madagascar, Mongolia, and Tunisia.

23. A new e-learning course is available for the evaluation and monitoring of national action plans for AMR[12].

***FAO's work on AMR***

24. The International FAO Antimicrobial Resistance Monitoring (InFARM) system is an FAO flagship initiative, supporting countries in collecting, collating, analyzing, visualizing, and effectively utilizing their AMR monitoring and surveillance data primarily from livestock, fisheries, and aquaculture, along with their associated food products. InFARM empowers countries to generate reliable evidence to measure the extent of AMR in animals and food at local, regional, and global scales, filling critical gaps in AMR data within agrifood systems. A *Manual for Implementation*[13] for the InFARM system was launched in 2024. The document introduces the InFARM system, provides the FAO's roadmap for implementation over the coming years, and serves as a guide for country officials, offering a step-by-step approach to support the implementation of InFARM. It provides specific steps and recommendations to guide national focal points in mobilizing country participation by collecting and sharing available AMR data, along with information on the implementation status of monitoring and surveillance activities. Through the InFARM system, FAO invites its Members to establish and strengthen operational national AMR surveillance systems.

25. In 2024, FAO launched a new flagship program to reduce the need for antimicrobials on the farm - Reduce the Need for Antimicrobials on Farms for Sustainable Agrifood Systems Transformation (RENOFARM).[14] This global initiative supports countries in developing policy, technical assistance, capacity building, and knowledge sharing to help reduce the need for antimicrobials in livestock production, prioritize animal health and welfare, mitigate environmental impact, and enhance food security and nutrition, thus helping to achieve the 2030 Agenda and its Sustainable Development Goals.

26. With funding from the Republic of Korea, progress continues on the "ACT" (Antimicrobial Codex Texts) project, a capacity-building project in six countries (Bolivia, Cambodia, Colombia, Mongolia, Nepal, and Pakistan). This project supports the beneficiary countries in complying with Codex texts on antimicrobial use and resistance through awareness raising, training in best practices, and surveillance support.

27. A new assessment tool for country-level capacity for analyzing and monitoring residues of veterinary drugs in food is being developed and piloted.

***WHO's work on AMR***

28. WHO published in February 2023 the WHO Medically Important Antimicrobial List (WHO MIA) to promote the responsible and prudent use of antimicrobials in all sectors. New approaches and categories have been established. https://cdn.who.int/media/docs/default-source/gcp/who-mia-list-2024-lv.pdf?sfvrsn=3320dd3d_2

29. WHO developed and published WHO Access. Watch. Reserve. (AWaRe) antibiotic book, which provides guidance on the choice of antibiotic, dose, route of administration, and duration of treatment for common infectious syndromes in alignment with the recommendations for antibiotics included in the WHO Model List of Essential Medicines and the WHO AWaRe classification of antibiotics.

12 https://openwho.org/courses/AMR-NAP-monitoring-evaluation?tracking_user=1YxcbGwNASSOvkZMTqBdHZ&tracking_type=news&tracking_id=7dYO1dZMiNT6ROqYBnU2MQ&tracking_course_id=bcdf9c76-a15c-4a07-a78a-a5a5ae790d0b

13 https://openknowledge.fao.org/bitstreams/c59c1b87-35ee-45fa-a463-e8d485e2d0b9/download

14 https://www.fao.org/antimicrobial-resistance/background/fao-role/renofarm/en/

***Global Leaders Group (GLG) on AMR***

30. In 2023 and 2024, the GLG on AMR released several publications:

i. A report, *Towards specific commitments and action in the response to antimicrobial resistance*[15];
ii. An associated annex[16];
iii. *Urgent call from the Global Leaders Group on AMR to Member States of the United Nations*[17]; and
iv. *GLG recommendations to address the antibiotic pipeline and access crisis in human health*[18].

**ACRONYMS USED IN THIS DOCUMENT**

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| ACT | Antimicrobial Codex Texts |
| ADIs | Acceptable Daily Intakes |
| AMR | Antimicrobial Resistance |
| AMR-MPTF | AMR-Multi-Partner Trust Fund |
| AWaRe | Access. Watch. Reserve. |
| CCRVDF | Codex Committee on Residues of Veterinary Drugs in Foods |
| DG Sante | Directorate-General for Health and Food Safety |
| FAO | Food and Agriculture Organization |
| GLG | Global Leaders Group |
| InFARM | International FAO Antimicrobial Resistance Monitoring system |
| JECFA | Joint FAO/WHO Expert Committee on Food Additives |
| MIA List | Medically Important Antimicrobial List |
| MRLs | Maximum Residue Limits |
| NAPs | National Action Plans for AMR |
| OHLAT | One Health Legislative Assessment Tool for AMR |
| QJS | Quadripartite Joint Secretariat |
| QTG-AIS | Quadripartite Technical Group on Antimicrobial Resistance and Use Integrated Surveillance |
| RENOFARM | Reduce the Need for Antimicrobials on Farms for Sustainable Agrifood Systems Transformation |
| TRS | Technical Report Series |
| UNEP | United Nations Environment Program |
| UNGA | United Nations General Assembly |
| WAAW | World Antimicrobial Awareness Week |
| WHO | World Health Organization |
| WOAH | World Organization for Animal Health (former OIE) |

15 https://www.amrleaders.org/docs/librariesprovider20/glg/glg-report-final.pdf?sfvrsn=1e2e2532_1&download=true
16 https://www.amrleaders.org/resources/m/item/annex-to-the-glg-report
17 https://www.amrleaders.org/docs/librariesprovider20/glg/glg-statement-unga-hlm-june-2024.pdf?sfvrsn=d0f71540_3&download=true
18 https://www.amrleaders.org/docs/librariesprovider20/glg/glg-discussion-paper-final.pdf?sfvrsn=864aab46_2&download=true