

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
United Nations



World Health
Organization

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Agenda item 10

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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

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

Comments in reply to CL 2024/66-RVDF

*Comments by Brazil, Chile, Costa Rica, Guatemala, Iran (Islamic Republic of),
New Zealand, Senegal, and United Arab Emirates (UAE)*

Background

1. This document compiles comments received through the Codex Online Commenting System (OCS) in response to CL 2024/66-RVDF¹ issued in August 2024. Under the OCS, comments are compiled in the following order: general comments are listed first, followed by comments on specific sections.

Explanatory notes on the Annex

2. Comments submitted through the OCS are annexed and presented in tabulated format. Comments on Part I are compiled according to the template for submission of requests for veterinary drugs for evaluation/re-evaluation by the Joint FAO/WHO Expert Committee on Food Additives (JECFA).

¹ <https://www.fao.org/fao-who-codexalimentarius/resources/circular-letters/en/>
<https://www.fao.org/fao-who-codexalimentarius/committees/committee/related-circular-letters/en/?committee=CCRVDF>

ANNEX**GENERAL COMMENTS**

COMMENT	MEMBER/OBSERVER
Response from Chile to CL 2024/66-RVDF Request for comments/information on the priority list of veterinary drugs for evaluation or re-evaluation by JECFA: Chile is grateful for the opportunity to submit comments on “Part I. Veterinary drugs for inclusion in the Priority List for JECFA evaluation/re-evaluation.” Chile is committed to submitting data on amoxicillin in broiler chickens. The data will be available before the deadline set out by JECFA’s call for contributions for its next meeting to evaluate veterinary drugs. The data package will contain the elements outlined in CL 2022/72-RVDF, including: • Amoxicillin depletion studies in liver, kidney, muscle, skin, and fat in natural proportions for broiler chickens; and • New analytical methodology, optimized and validated for liver, kidney, muscle, skin, and fat in natural proportions for broiler chickens.	Chile
Costa Rica is thankful and supports the work on the priority list; however, it would like to mention at this time that it not have data for any of the listed components. At the same time, it reaffirms support for JECFA’s parallel evaluation modality.	Costa Rica
1. Butylated hydroxytoluene: This medication is used in poultry as an antioxidant. 2. Simethicone: This carminative is consumed in cattle. 3. Dexpantenol: It is used in poultry as a supplement. 4. Benzyl Bezoate: This medication is used in cattle- goat- sheep- as an antifungal. 5. Florfenicol: This antibiotic is consumed in poultry extensively. 6. Bismuth Subcitrate: This disinfectant is used in cattle. 7. Amoxicillin Trihydrate: This medication is used in cattle- goat- sheep as an antibiotic. 8. Ceftiofur Sodium: This medication is consumed in cattle as an antibiotic. 9. Enrofloxacin: This medication is used in poultry as an antibiotic extensively. 10. Dihydrostreptomycin Sulfate: This medication is consumed in cattle- goat- sheep. 11. Doxycycline Hyclate: This medication is used in poultry as an antioxidant. 12. Flunixin Meglumine: This medication is used in cattle- goat- sheep as an analgesic. 13. Closantel Sodium: It is consumed in cattle as a anti parasite 14. Chlorhexidine Gluconate: It is used in cattle- goat- sheep as a disinfectant. 15. Pyrantel: This medication is consumed in horse as an anti-parasite. 16. Sulfadimethoxine Sodium: This medication is consumed in poultry as an antibiotic. 17. GNRH: This hormone is consumed in cattle. 18. Guaifenesin: This medication is used in poultry as an expectorant. 19. Amprolium: This medication is used in poultry as a coccidiostat. 20. Polymyxin B: This Antibiotic is used in cattle- goat- sheep as an antioxidant.	Iran (Islamic Republic of)

COMMENT	MEMBER/OBSERVER
21. Cyromazine: This medication is consumed in cattle- goat- sheep as an insecticide. 22. Maduramicin: This medication is used in poultry as a coccidiostat . 23. Glutaraldehyde: It is consumed in cattle- goat- sheeas a disinfectant. 24. Ambroxol: This medication is consumed in horse as an antibiotic. 25. Omeprazole: This medication is used in horse as an anti-acid. 26. Cloprostenol: This medication is used in cattle as a horomone. 27. Tulathromycin: This medication is consumed in cattle as an antibiotic. 28. Benzalkonium Chloride: This medication is used in cattle as a disinfectant. 29. Astaxanthin: This medication is used in aquatic as a supplement. 30. Glyoxal: This medication is consumed in cattle as a disinfectant. 31. Sodium tetraborate decahydrate: This medication is used in cattle as a disinfectant. 32. Atropine: This medication is consumed in cattle as a sedative. 33. Carprofen: This medication is used in cattle as an anti-inflammatory. 34. Niclosamide: This medication is used in goat- sheep as an anti-parasite. 35. Xylanase Enzyme Beta Glucanase: It is used in poultry as a supplement. 36. Marbofloxacin: This medication is used in cattle as an antibiotic. 37. Thiamethoxam: This medication is consumed in cattle as an insecticide. 38. Meloxicam: This medication is used in cattle as an anti-inflammatory. 39. Fosfomycin: This medication is used in poultry as an antibiotic. 40. Cefquinome Sulfate: This medication is used in cattle as an antibiotic 41. Furosemide: This medication is consumed in cattle, sheep as an antibiotic. 42. Bromhexine Hydrochloride: This medication is used in poultry as a mucolytic 43. Gonadorelin acetate: This medication is used in cattle as a horomone. 44. Aspirin: This medication is used in poultry as ananti-inflammatory. 45. Zinc sulfate: This medication is consumed in poultry as a supplement. 46. Canthaxanthin: This medication is used in poultry as a supplement. 47. Tiamulin Hydrogen Fumarate: This medication is consumed in poultry as an antibiotic. 48. Propetamphos: This medication is used in livestock as an insecticide and acaricide. 49. Benzoic acid: This medication is consumed in poultry as a supplement. 50. Tulathromycin: This medication is used in cattle as an antibiotic. 51. Silver nitrate: This medication is used in livestock as a disinfectant. 52. Rifaximin: This medication is used in buffalo, cattle as an antibiotic. 53. Cephapirin Benzathine: This medication is used in cattle as an antibiotic. 54. Bacitracin: This medication is used in poultry as an antibiotic. 55. Buserelin: This medication is used in cattle as a synthetic analogue of gonadotrophin-releasing hormone . 56. Clopidol: This medication is consumed in poultry as a coccidiostat. 57. Robenidine Hydrochloride: This medication is used in poultry as a coccidiostat .	

COMMENT	MEMBER/OBSERVER
58. Isoflupredone Acetate: This medication is used in cattle as an anti-inflammatory. 59. Triplenamine HCl: This medication is used in cattle as a central nervous system stimulator 60. Tetramethrin: This medication is used in livestock as an insecticide and acaricide 61. Fungal Protease: This medication is used in poultry as a growth promoter 62. Tylvalosin: This medication is used in poultry as as an antibiotic. 63. Prednisolonum anhydricum: This medication is used in poultry as an antibiotic. 64. Oxalic acid: This medication is consumed in honey bee as an anti-parasite. 65. Diminazene: This medication is used in livestock as an anti-parasite. 66. Enramycin: It is consumed in poultry as an antibiotic. 67. Toltrazuril: This medication is used in poultry as a coccidiostat. 68. Ofloxacin: This medication is consumed in poultry as an antibiotic. 69. Azamethiphos: This medication is used in livestock as an insecticide 70. Triclabendazole: This medication is used in livestock as an antioxidant anti parasite 71. Benzathine Cloxacillin: This medication is used in cattle as an antibiotic. 72. Sodium Dodecyl Benzene: This medication is used in livestock as a disinfectant 73. Fumagilline DCH: This medication is consumed in honey as an anti-parasite. 74. Trimethoprim: This medication is used in poultry as an antibiotic. 75. Kanamycin: This medication is used in livestock as an antibiotic. 76. Apramycin Sulphate: This medication is used in poultry as an antibiotic. 77. Prostaglandin: It is consumed in livestock as a hormone.	
United Arab Emirates acknowledges the work done by JECFA and CCRVDF and would like to mention that the requested data is currently not available. United Arab Emirates will provide the requested data when available	UAE

SPECIFIC COMMENTS**Part I. Veterinary drugs for inclusion in the Priority List for JECFA evaluation/re-evaluation**

COMMENT	MEMBER/OBSERVER
ADMINISTRATIVE INFORMATION - Member(s) submitting the request for inclusion: BRAZIL - Veterinary drug names: UMIFOXOLANER (INN) - Trade names: SOLECTUS® - Chemical names and CAS registry number: IUPAC (International Union of Pure and Applied Chemistry) Nomenclature: 4-[(5S)-5-[3-chloro-4-fluoro-5-(trifluoro-methyl)phenyl]-4,5-dihydro-5-(trifluoro-methyl)-3- isoxazolyl]-N-[2-oxo-2-[(2,2,2-trifluoroethyl)amino]ethyl]-1-naphthalene-carboxamide Synonyms: ML-3,032,878, ML-878 and MR-026, CLM2317 CAS number: 2021230-37-3 International Non-proprietary Name (INN): umifoxolaner - Names and addresses of basic producers: BOEHRINGER INGELHEIM ANIMAL HEALTH DO BRASIL LTDA, Avenida Doutor Roberto Moreira, nº 5005, Recanto dos Pássaros, CEP 13148-914, Paulínia/SP – Brazil PURPOSE, SCOPE, AND RATIONALE - Identification of the food safety issue (residue hazard): The food safety issue concerns the potential for residues of umifoxolaner to be remained in food products (cattle tissues) consumed by humans. Residues could pose health risks and therefore it is necessary to establish ADI (Acute Daily Intake), ARfD (Acute Reference Dose) and Maximum Residue Limits (MRLs) to ensure that any residue present in food are within safe levels for human consumption. Umifoxolaner is a novel veterinary drug that has not yet been evaluated by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) for use in veterinary medicine, and there is currently no established ADI, ARfD and MRLs for its residues in cattle tissues. - Assessment against the criteria for the inclusion on the priority list: The MAPA registration procedure will be performed in parallel to the JECFA/CCRVDF review. Currently the risk assessment for food safety dossier is under review at ANVISA. Umifoxolaner is intended to be registered in Brazil and other countries for use in cattle. Relevant data are available on toxicology, metabolism, pharmacokinetics, and residue depletion studies conducted with both radiolabeled and non-radiolabeled forms of the drug in the target species. A comprehensive dossier will be provided for the risk assessment. RISK PROFILE ELEMENTS - Justification for use: Treatment and control of infestations caused by single-host ticks.	Brazil²

² The nomination of the compound Umifoxolaner has been replaced for the correctness of the information provided.

COMMENT	MEMBER/OBSERVER
Treatment and control of infestations caused by chewing lice. 9. Veterinary use pattern, including information on approved uses if available (<i>this should include product labels or other evidence of official use authorization</i>): It is recommended to administer Solectus® in cattle, in a subcutaneous injection of 0.6 mg of umifoxolaner per kg of body weight (BW), equivalent to 1 mL of product per 100 kg of body weight (BW). Solectus® is indicated for beef cattle and can be given to all ages of animals including one-day-old calves. Do not use the product on dairy cows producing milk for human consumption. 10. Commodities for which Codex MRLs are required: Cattle Liver, kidney, fat, muscle. Specific request to risk assessors 11. Request for establishment of ADI, ARfD and MRLs for umifoxolaner for cattle muscle, liver, kidney and fat using the parallel review process. AVAILABLE INFORMATION 12. Countries where the veterinary drugs are registered: Under review by National Authorities in Brazil. 13. National/Regional MRLs or any other applicable tolerances: Review of the risk assessment for food safety dossier ongoing in Brazil (by ANVISA). 14. List of data (pharmacology, toxicology, metabolism, residue depletion, analytical methods) available (<i>this should include a list of the data available with the full study titles and whether the compound is also registered as pesticide and, as appropriate, has been evaluated or scheduled for evaluation or re- evaluation by JMPR</i>): The compound is not registered as pesticide and has not been evaluated or scheduled for evaluation by JMPR. The list of data is as follows: TOXICOLOGY - Genotoxicity Studies - Acute Toxicity studies - Subacute Toxicity - Chronic Toxicity Studies PHARMACOLOGY, METABOLISM and RESIDUES - Comparative Metabolism Study. - Pivotal Radio-Residue Metabolism and Depletion Study in Beef Cattle Following a Single Subcutaneous Injection at 0.6 mg/kg Body Weight. - Marker Residue Depletion Studies in Bovine Edible Tissues after a Single Subcutaneous Dose. ANALYTICAL METHOD 15. Date when data could be submitted to JECFA: December 2024	

COMMENT	MEMBER/OBSERVER
In response to the request for comments/information on the priority list of veterinary drugs for evaluation or re-evaluation by JECFA contained in the circular letter CL 2024/66-RVDF from July 2024 New Zealand would like to submit the following for discussion. With regards to Part I. Veterinary drugs for inclusion in the Priority List for JECFA evaluation/re-evaluation, New Zealand would like to draw the attention of the Working Group to the growing relevance and interest in environmental inhibitors and the likelihood of one or more compounds being submitted for evaluation by JECFA. Given the strategic significance of the use of environmental inhibitor compounds for advancing global interests around mitigating the impact of climate change, transforming food systems while advancing broader food security and sustainability goals, New Zealand believes that it would be appropriate for Working Group on Priorities and the CCRVDF to accord priority status for such compounds so that these may be considered expeditiously for risk assessment by JECFA. While there is no specific environmental inhibitor compound ready for prioritisation at this time, it is likely that a compound could be submitted to the JECFA between now and the next meeting of the CCRVDF, which will not be held again until 2026. New Zealand would like to propose that when an environmental inhibitor compound is submitted to the CCRVDF Committee, even intersessionally, it is given priority by the Working Group for the JECFA to fast track its consideration.	New Zealand

Part II. Veterinary drugs for which data availability should be confirmed at CCRVDF27

COMMENT	MEMBER / OBSERVER
Regarding Norfloxacin, Brazil has no relevant data/information for consideration at CCRVDF27.	Brazil
Codex members and observers wishing to support the evaluation of this compound are kindly invited to confirm the availability of relevant data/information for consideration at CCRVDF27, as indicated in REP23/RVDF26, Appendix IV, Part II, and to provide the data/information according to the template in the Appendix I to this document. It is agreed that revisions should continue as some countries already restrict or prohibit use.	Guatemala

Part III. Veterinary drugs for which additional data/information is necessary to complete the JECFA evaluation

COMMENT	MEMBER / OBSERVER
Brazil has no relevant data/information available on Ethion, Flumethrin, and Fosfomycin for consideration at CCRVDF27.	Brazil

Part IV. Parallel review: Evaluation of a new compound

COMMENT	MEMBER / OBSERVER
Brazil has no relevant data/information on Selamectin for consideration at CCRVDF27.	Brazil
Codex members and observers wishing to support the evaluation of these compounds are invited to confirm the availability of the required data/information for consideration at CCRVDF27, as indicated in REP23/RVDF26, Appendix IV, Part IV. Senegal recommends keeping this compound in part IV of the priority list.	Senegal

Part V. Extrapolation

COMMENT	MEMBER / OBSERVER
Brazil currently has no proposals for veterinary drugs to be added to the priority list for extrapolation of MRLs.	Brazil
MRLs for finfish should be explored.	Guatemala