CODEX ALIMENTARIUS COMMISSION







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Agenda Item 10

CX/RVDF 21/25/11 September 2020

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

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

DATABASE ON COUNTRIES' NEEDS FOR MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS IN FOODS

(Prepared by the United States of America and Costa Rica)

BACKGROUND

- 1. The 23rd Session of the Codex Committee on Veterinary Drugs in Foods (CCRVDF23, 2016) agreed¹ to establish an electronic working group (EWG) chaired by the United States of America (USA) and co-chaired by Costa Rica with the following Terms of Reference:
 - To consider the complete results of the global survey in order to identify priority veterinary drugs; and
 - To identify information gaps for a successful and comprehensive assessment by JECFA.
- 2. CCRVDF24 considered² the outcomes of the discussion³ in the EWG and the in-session WG that met in the margins of the plenary meeting and noted the following compound / commodity combinations identified as high priority needs and as feasible starting points for CCRVDF in the effort to address the database on countries' needs:
 - Amoxicillin in goats and poultry;
 - · Ampicillin in cattle, pig, horse, goats, sheep, fish and poultry,
 - · Diminazene in sheep and goats;
 - Imidocarb in horse,
 - Ivermectin in horse, goat, camel and poultry; and
 - Oxytetracycline in bees, camel, horse and goat
- 3. The following countries offered to develop dossiers to support JECFA evaluations:
 - Chile for Amoxicillin in poultry;
 - Costa Rica for Oxytetracycline in goat;
 - Argentina for Diminazene in sheep;
 - Côte d'Ivoire for Diminazene in cattle; and
 - Germany for Amoxicillin and Ampicillin in poultry.
- 4. Several countries pointed out the importance of keeping a reference to lists A⁴ and B⁵ of the database, in order to obtain data on those substances with a long history of use ("old compounds") and which may be provided to JECFA; because these drugs continue to be used in developing countries and the need to address this concern in the interest of consumer protection and strengthening fair trade practices. For this purpose, the support and commitment of industry and developed countries was necessary.
- 5. Countries and industry were thus encouraged to assist in the preparation of dossiers for the other identified priority compounds. At the same time, it was pointed out that there were many other compounds in the database for which data packages were needed and that commitment was needed from industry and countries to provide data packages to allow this work to move forward to a successful JECFA evaluation (refer to Agenda Item 11).

¹ REP16/RVDF, paras. 93-104

² REP18/RVDF, paras. 104-110

CX/RVDR 18/24/12 and RVDF24/CRD33.

Working documents, including the report of the session, are available on the CCRVDF24 webpage: http://www.fao.org/fao-who-codexalimentarius/meetings/detail/en/?meeting=CCRVDF&session=24

Top ten highest priority veterinary drugs in need of MRLs determined by analysis of individual country prioritizations

Top ten highest priority veterinary drugs in need of MRLs determined by analysis of cumulative country responses

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6. In addition, CCRVDF24 noted that some compounds with existing (adopted) Codex MRLs could be candidates for extrapolation following CCRVDF's decision to establish an EWG to develop a policy for extrapolation and to pilot extrapolation of MRLs to some species. In view of this observation, CCRVDF identified 10 compounds from the list of Codex MRLs for the pilot (refer to Agenda Item 7).

7. CCRVDF concluded that Costa Rica and the United States of America would continue to maintain the database, highlighting the compounds identified as high priorities in list A and B, which would be made available to members prior to the next session. No further requests for inclusion of additional compounds would be issued.

CONCLUSIONS

- 8. Following the discussions and decisions at CCRVDF24, USA and Costa Rica have updated the working paper prepared by the EWG (CX/RVDF 18/24/11) taking into account the recommendations made by the in-session WG (RVDF14/CRD33) and submit a revised document for consideration by CCRVDF25.
- 9. The Database on Countries' Needs for MRLs has been updated to highlight the compounds which were identified as high priorities in List A and List B and as more feasible by CCRVDF24. The updated Database is included in the Appendix of this document.
- 10. CCRVDF may assess the need to update the database in future depending on progress made on the establishment of MRLs for compound/commodity combinations currently identified in the database. If that would be the case, the prioritization criteria used to develop List A and List B should be considered by CCRVDF to include new compound/commodity combinations in the database.

RECOMMENDATIONS

11. It is recommended that the database on countries' needs for MRLs for veterinary drugs in foods be made available at every session of CCRVDF as an information document to inform the discussion on the priority lists of veterinary drugs for evaluation/re-evaluation by JECFA.

The INF/DOC will be updated [by USA and Costa Rica] after every session of CCRVDF following the outcomes of the discussion on the priority list of veterinary drugs for evaluation/re-evaluation by JECFA.

The INF/DOC should be made available to the Codex Secretariat contemporarily to the distribution of the Circular Letter requesting comments on the priority list of veterinary drugs for evaluation/re-evaluation by JECFA in order to facilitate submission of available relevant data / information that could enable the establishment of MRLs for the identified compound / commodity combinations.

- 12. It is recommended to encourage Codex member countries and observer organizations to submit relevant data / information to allow the evaluation of those compound / commodity combinations identified as high priority needs and as feasible starting points for establishment of relevant MRLs identified by CCRVDF24, in particular those for which support was expressed at CCRVDF24 (as described in paragraphs 2 and 3 of this document) for consideration by CCRVDF25 under Agenda Item 11 and to submit such data / information in reply to CL 2020/18-RVDF6
- 13. It is also recommended to encourage Codex member countries and observer organizations to submit relevant data / information to allow the evaluation of other compound / commodity combinations identified in the database on countries' needs for MRLs for veterinary drugs (besides those described in paragraphs 2-3) for consideration by CCRVDF25 under Agenda Item 11 and to submit such data / information in reply to CL 2020/18-RVDF.

⁶ Circular letters can be downloaded from the Codex website (dedicated page on Circular Letters or Circular Letters relevant to CCRVDF25) as follows:

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