CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 3 **CX/RVDF 12/20/3**
April 2012

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

Twentieth Session

San Juan, Puerto Rico, 7-11 May 2012

MATTERS ARISING FROM FAO/WHO AND FROM THE 75TH MEETING OF THE JOINT FAO/WHO EXPERT COMMITTEE ON FOOD ADDITIVES (JECFA)

1. This document provides information on FAO and WHO activities in the area of provision of scientific advice to Codex and Member countries, as well as other activities which are of potential interest for CCRVDF.

I. Provision of Scientific Advice from FAO and WHO

1. The 75th meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA)

1a. The meeting

2. The 75th meeting of JECFA was held 7-17 November 2011 in Rome, Italy, to evaluate the safety of residues of seven veterinary drugs in foods. The Technical Report Series (No. 969, 2012) report is now available at http://whqlibdoc.who.int/publications/2012/9789241209694_eng.pdf. The 75th meeting of JECFA also prepared comments on some general matters of interest noted below.

3. JECFA established acceptable daily intakes (ADIs) for four substances that were evaluated for the first time for the animal species of interest - amoxicillin, apramycin, derquantel and monepantel when they are administered to food producing animals in accordance with good practice in the use of veterinary drugs. Toxicological monographs were prepared for the four veterinary drugs evaluated for the first time and will be published in the WHO Food Additive Series.

4. Maximum residue limits (MRLs) were recommended as appropriate for the four new substances and for the three substances that were reassessed for residues only - monensin, narasin and triclabendzole. Specifically, narasin was reassessed for an analytical method in cattle tissues only and triclabendazole for consideration only of extending the MRLs in sheep tissues to goat tissues. The residue monographs will be published in the FAO JECFA Monographs series. The 75th meeting of JECFA recommendations for MRLs have been circulated for comments under CX/RVDF 12/20/6.

5. With regard to triclabendazole, the 75th meeting of JECFA concluded that the available database on the residues of triclabendazole in goat was too limited to allow a scientifically justifiable extrapolation of MRLs for cattle and sheep tissues to this species of animal.

6. The 75th meeting of JECFA also noted that no data on ivermectin had been submitted following the public request for data.

1b. Comments on documents under elaboration at CCRVDF

7. JECFA reviewed the draft report of the Electronic working group on the revision of the risk analysis principles applied by the CCRVDF and risk assessment policy for the setting of MRLVDs (Agenda Item 7b), especially as it relates to the work of JECFA. JECFA commented on some of the proposed revisions, for the JECFA Secretariat to bring into the discussion at the upcoming Twentieth Session of CCRVDF (May 2012). Regarding the draft Report of the electronic working group to develop risk management options for veterinary drugs for which no ADI and/or MRL has been recommended by JECFA due to specific human

health concerns (Agenda Item 10), JECFA emphasized that any requests for further assessments on such compounds to JECFA needed to be accompanied by a clear description of the specific request from CCRVDF and formulation of the risk management needs. Regarding the draft report of the CCRVDF electronic working group on extrapolation of MRLs for veterinary drugs to additional species and tissues (Agenda Item 12), JECFA provided comments on proposed risk analysis policy aspects, for the JECFA Secretariat to bring into the discussion at the upcoming Twentieth Session of CCRVDF.

1c. Information on registration/approval status of veterinary drugs

8. Nationally approved good practices in the use of veterinary drugs make an important contribution to the risk profile of a drug. For JECFA, it is important that all related information relevant for the risk assessment is available to JECFA when it evaluates substances with a view to recommending MRLs. In the past, information on registration/approval status of veterinary drugs and on approved conditions of use was not always available JECFA in time, leading to unnecessary difficulties in its discussions. JECFA therefore requested:

- that CCRVDF provide the Secretariat with information on registration/ approval status and the use pattern of veterinary drugs whenever it requests an evaluation by JECFA;
- that the JECFA Secretariat always include a request for submission of such information by the sponsors of the data into future calls for data.

1d. Extrapolation of MRLs

9. JECFA recognized the importance of using good science when extrapolating between food animal species to support the development of MRLs in additional food animal species and commodities. In addition, JECFA recognized the ongoing CCRVDF electronic working group that is collecting and evaluating information and developing recommendations on a risk analysis policy for use by CCRVDF when extrapolating MRLs. JECFA agrees that it is important to develop minimum criteria for information upon which to base extrapolation between food animal species and commodities. In view of the foregoing, JECFA recommended that the JECFA Secretariat establish an electronic working group to continue work commenced at the current meeting and to develop proposed minimum criteria for consideration at the next JECFA meeting for veterinary drugs.

2. Joint FAO/WHO ad hoc expert meeting on dietary exposure assessment for veterinary drug residues in food

2a. Approach

10. A joint FAO/WHO *ad hoc* expert meeting on dietary exposure assessment for veterinary drug residues in food was held in November 2011 in conjunction with the 75th JECFA meeting. The call for data was published at http://www.fao.org/ag/agn/agns/jecfa/JECFA_Call_for_data_food_consumption.pdf.

11. A draft report was prepared outlining proposed new approaches for acute and chronic dietary exposure assessment for veterinary drug residues, taking existing scientific approaches as well as concerns and recommendations of the stakeholders into consideration. Discussions and exchanges were organized between participants at both the meeting on dietary exposure assessment methodologies and the members of the 75th JECFA. Examples to compare the current model with proposed models were collaboratively developed.

2b. JECFA considerations for acute dietary exposure assessments

12. Acute dietary exposure estimates should cover a time period of food consumption over a single meal or 1 day and are intended to be used for comparison with acute reference dose (ARfD) values in a risk assessment process. JECFA emphasized that, depending on the health end-points for acute risk, acute exposure should be estimated for both the general population and children.

2c. JECFA considerations for chronic dietary exposure assessments

13. Chronic dietary exposure estimates cover food consumption over the long term and are intended to be used for comparison with a health-based guidance value based on chronic toxicity, such as an ADI, in a risk assessment process. At its 70th meeting, JECFA confirmed the use of the median residue level from depletion studies, with a correction for marker residue to total residue, instead of the MRL for long-term dietary exposure estimates, when supported by the available data.

2d. Main outputs of the expert meeting on dietary exposure assessment methodologies

14. Models were proposed to estimate both acute and chronic exposure to residues of veterinary drugs in food. JECFA noted that, compared with the current model, the proposed models use more detailed consumption data. The exploration of new approaches to the assessment of dietary exposure to veterinary drug residues is part of the ongoing process of ensuring that evaluations undertaken by JECFA incorporate available data as well as recent advances in methodology and scientific knowledge. When finalized, the proposed models should be considered as tools for potential use in the assessment of dietary exposure to residues of veterinary drugs. The report of the expert meeting will include the proposed new models for assessing acute and chronic dietary exposure to residues of veterinary drugs, the data on food consumption received and evaluated for use in the models and a summary of the input and views expressed at the stakeholder meeting.

2e. Current stage of the process

15. The report of the workshop was reviewed by JECFA experts, comments were integrated and the document was edited before being posted for public comment between 15/02/2012 and 15/03/2012. Public comments were received from national and regional authorities as well as from industry. As it is clearly stated in the report, the dietary exposure assessment is a component of the standard setting process but that the description of the complete process was beyond the scope of the workshop. There is a general agreement about the proposed approach for acute exposure. For the long term assessment, contradictory comments were submitted for both increasing the accuracy and simplifying the proposed model. The experts will discuss these comments and integrate as appropriate before finalization of the report. Additional comments by CCRVDF are welcome.

3. Global Initiative for Food-Related Scientific Advice (GIFSA)

16. GIFSA is a mechanism established by FAO and WHO to facilitate the provision of extra budgetary resources for scientific advice activities. Resources provided through GIFSA are allocated to activities in an independent and transparent manner, taking into consideration the criteria for prioritization of activities already agreed by Codex, FAO and WHO and the specific needs of FAO and WHO member countries. Contributions, which are accepted from governments, organizations and foundations in accordance with WHO and FAO rules continue to be received. FAO and WHO would like to express their appreciation to all donors for their contributions.

17. For additional information and advice on the procedure for making a donation/contribution please contact Ms Dominique Di Biase, Policy Assistance and Resources Mobilization Division (Dominique.DiBiase@fao.org; Tel: + 39 06 57055391) at FAO and Angelika Tritscher (tritschera@who.int) at WHO.

II. Other related initiatives underway in FAO and WHO

1. FAO and WHO activities on antimicrobial resistance (AMR)

18. The topic of the World Health Day 2011 (7 April 2011) was antimicrobial resistance and this was an opportunity for WHO to identify the main challenges as well as core actions for containment of antimicrobial resistance arising from use of antimicrobial agents in food-producing animals. More information at : http://www.who.int/world-health-day/2011/en/index.html

19. The third meeting of WHO-AGISAR was held in Oslo, Norway on 14-17 June 2011. The four AGISAR subcommittees (antimicrobial usage monitoring, antimicrobial resistance monitoring, capacity building and data management) are in the process of developing practical guidance documents to support WHO Member Countries in their efforts to implement a national program for integrated surveillance of antimicrobial resistance. More information at: http://www.who.int/foodborne_disease/resistance/agisar/en/index.html. The WHO list of Critically Important Antimicrobials for Human Medicine was revised during the third meeting of WHO-AGISAR . The WHO list and subsequent revised versions are available at http://www.who.int/foodborne_disease/resistance/cia/en/index.html.

20. FAO and WHO have initiated a series of activities aimed both at providing scientific advice and developing adequate capacities among the veterinary and food safety community to address the issues related

to non-human antimicrobial use at different steps of the food-chain, the emergence of resistant pathogens and associated human public health concerns.

21. FAO and WHO, in collaboration with a local partner, the Kenya Medical Research Institute (KEMRI), are implementing a project to strengthen national/regional policies, capacities and systems for the detection, monitoring, regulation and management of antimicrobial resistance risks in the poultry, beef and pig value chains. By addressing issues related to foodborne pathogen contamination and AMR in these value chains, the project will contribute to poverty alleviation, improved nutrition, household income, food security, and will also help to ensure that market opportunities are optimized.

22. FAO and WHO are carrying out a study in Cambodia to assess and manage in an integrated manner, the public health risks associated with foodborne pathogens (*Salmonella* spp., *Campylobacter* spp.) and AMR risks along the poultry value chain continuum. The collaboration is intended to foster sharing of information and data, to maximize synergies between the Organisations, and to ensure a more integrated approach that addresses microbiological contamination and AMR risks at all stages from primary production to consumption.

23. FAO and WHO are committed to work with key international partners, member governments, and food chain operators to combat AMR. Given the relative ease with which AMR can spread within countries and from one country to another in an increasingly globalized world, there is clearly a need for proactive actions to assist developing countries in strengthening systems to address AMR risks.

2. Development of a web-based decision support tool for the control of Campylobacter and Salmonella in chicken meat

24. Following the request of the 40th Session of the CCFH, FAO and WHO have developed a web-based risk management tool to support risk based approaches for the control of specific pathogens in chicken meat, as recommended in the Codex guidelines for the control of *Campylobacter* and *Salmonella* in chicken meat (CAC/GL 78/2011) This allows the consideration of control measures in three main areas: primary production, processing and, distribution and preparation. The tool allows users to characterize processes, assess the impact of interventions and provides a quantitative basis for estimating the net relative risk reduction of multiple user-specified interventions. The tool is freely available at http://www.mramodels.org/poultryRMTool/Default.aspx. Registration is required to use the tool as this allows users to save their work.

25. FAO and WHO welcome any feedback on the tool and any additional information/guidance countries might need to apply the tool. Delegates with an interest in this tool should follow up with the FAO/WHO JEMRA Secretariat (jemra@fao.org). FAO/WHO will continue to develop support materials to facilitate application of the tool in 2012.

3. FAO/WHO Guide for Application of Risk Analysis Principles and Procedures During Food Safety Emergencies

26. This document was developed to assist countries in understanding essential elements in the application of risk analysis during emergencies, within the framework of their Food Safety Emergency Response (FSER) plan. The principles and procedures may also apply to other food safety events that are not necessarily emergencies but that require action to be taken under time constraints and uncertainty. The guide outlines best practice for the application of risk analysis during food safety emergencies, and suggests practical ways of incorporating such processes into existing systems. The document can be found at: http://www.fao.org/docrep/014/ba0092e/ba0092e00.pdf and http://www.who.int/foodsafety/publications/fs_management/risk_analysis/en/.

4. FAO/WHO Expert Consultation on Parasites

27. The 42nd Session of the CCFH (December 2010) requested FAO and WHO to review the current status of knowledge of parasites in food to better assess the global problem associated with these, the commodities involved and the related public health and socio-economic/trade issues to identify parasite/commodity groups of greatest concern. An expert consultation to address foodborne parasites, approaches to their prioritization and options available for control and management measures has been convened for 3-7 September 2012, at FAO HQ in Rome, Italy.

5. FAO Activities on Wild Meat

28. FAO is developing a paper on a holistic methodology to support the implementation of the One Health approach in the development of national policies for the sustainable management of wildlife by local communities. The sustainable use of wildlife has traditionally contributed to food security in developing countries as it provides a protein source and generates income supporting the livelihoods of local communities. However extractive use of wild animals has increased rapidly over recent decades, moving from local use towards large-scale commercial enterprises, fostered by human population growth, urbanization and globalization. Sustainable use of wild animals and their products involves food, health, ecological, economic and cultural dimensions requiring a collaborative and multidisciplinary approach with science-based assessments.