CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - E-mail: codex@fao.org - www.codexalimentarius.org

Agenda Item 10 **CRD3**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

Twenty-fourth Session

DISCUSSION PAPER ON THE EVALUATION OF THE RATIONALE FOR THE DECLINE IN NEW COMPOUNDS TO BE INCLUDED IN THE CCRVDF PRIORITY LIST FOR EVALUATION BY JECFA

Comments from the joint FAO/WHO JECFA Secretariat

The decline in new compounds to be included CCRVDF Priority List is a critical issue affecting both the work of JECFA and CCRVDF. The JECFA Secretariat would like to thank Health for Animals for taking the initiative of preparing this discussion paper, and would like to offer the following clarifications and comments on some of the points made in the paper.

General comment

While it may not have been the intentions of the authors, the paper appears to imply that currently new requests to CCRVDF are withheld solely due to undesirable processes. At the same time, however, the paper makes reference to a diminishing pipeline in the number of new drugs that might fall under the purview of CCRVDF. In this context, it appears less clear to the joint JECFA secretariat how the suggested process improvements would lead to a substantial enough increase in the number of requested safety evaluations of residues of veterinary drugs in foods.

Updating the risk assessment methodologies applied by JECFA

Reference is made to paragraphs 7, 8, and recommendation 1 in the paper.

Providing sound assessments based on the best available science is one of the key principles of the FAO/WHO Scientific Advice Programme, and the elaboration/update of the Risk Assessment procedures is a core task of JECFA. While updating its methodologies, JECFA has continuously made substantial efforts to keep all the concerned stakeholders informed. The secretariat would like to offer some recent examples in the area of residues of veterinary drugs:

- New exposure assessment model

  In 2011 the Joint FAO/WHO Expert Meeting on Dietary Exposure Assessment Methodologies for Residues of Veterinary Drugs, recommended the use of a new model which is scientifically more robust and provides more refined estimates. JECFA piloted the new model (in parallel with the food basket model) for two consecutive meetings (JECFA 78th and JECFA 81st). CCRVDF was kept informed of the new approach and the pilot at its 21st, 22nd and 23rd sessions. Furthermore, during the last session of CCRVDF a specific side event was dedicated to the new exposure assessment approach.

- Acute reference dose (ARfD) for residues of veterinary drugs

  Following a recommendation of JECFA 75th, a working group was set up to elaborate principles establish Acute Reference Dose (ARfD) for residues of veterinary drugs. The guidance document was made available for public comments and following public consultation, was published in May 2017. The process was duly reported to CCRVDF23 (REP17/RVDF – para. 20)

- A review on latest methodological developments

  In order to reach out to a wider audience the review “Characterizing chronic and acute health risks of residues of veterinary drugs in food: latest methodological developments by the joint FAO/WHO expert committee on food additives” was recently published in Critical Review in Toxicology (Crit Rev Toxicol. 2017 Jul 10:1-15). The review describes in detail the consideration of acute and chronic effects, the estimation of acute and chronic dietary exposure, current approaches for including microbiological endpoints in the risk assessment, and JECFA’s considerations for the potential effects of food processing on residues from veterinary drugs.

While the above serve as an example for the considerable efforts we have made to be open and transparent about new method developments and providing opportunities for input in order to facilitate also uptake by regulatory authorities, we remain of course open to further suggestions.

Providing independent Risk Assessments

Reference is made to paragraphs 9, 16, 17, 19, and recommendations 6, 7, and 8 in the paper.

Through the procedural manual of the Codex Alimentarius Commission, JECFA is tasked to provide an independent risk assessment for all member countries of the Codex Alimentarius Commission. In providing independent risk assessment for its global constituents, JECFA comprehensively reviews all available data, including sponsors submissions, publicly available literature as well as assessments from national/regional agencies. In this context, it is important to note the following:

- JECFA makes substantial efforts to document its decision making process and provides a detailed rationale for its conclusions in the meeting reports and the monographs.
- In situations, where the information available to the Committee is found to be insufficient to conclude on possible health risks, additional data are requested. Any additional data are only requested in cases where they are indispensable to conclude on a health risk assessment. JECFA members and the secretariat are fully aware of the 3Rs Policy and the costs implications connected to any such request.
- Transparency is one of the trademarks and key values for the integrity of the UN system in general and Codex Alimentarius in particular. Following its mandate for transparency, JECFA will continue to make all reports, findings and evaluations publicly available in the most suitable manner.
- Members of JECFA as well as the secretariat are very well aware of the activities at VICH and use as appropriate the resources available. In addition, we note that work initiated by JECFA has also been often integrated into the work at VICH (e.g. microbiological ADI, Acute reference Dose etc.).
- Following its mandate, JECFA will not only perform a risk assessment, but also recommend suitable MRLs that are adequately health protective and demonstrably compatible with approved labels and GVPs to aid the risk managers at CCRVDF/CAC in their task to recommend Codex MRLs.

Interacting with the data sponsor

Reference is made to paragraphs 10 and recommendation 2 in the paper.

We fully agree with the notion of the critical importance of good interactions between the JECFA secretariat and the data sponsors. In particular, having the possibility to clarify any questions related to the submitted data greatly facilitates the work of the Committee. The JECFA secretariat would in this regard express its great appreciation for past support from data sponsors. To allow for a greater productivity of the Committee and an overall more efficient process, as well as allow for more time for data sponsors to answer potential questions, time lines have been shifted to earlier preparation of draft evaluations. In this context questions to sponsors are being identified and clarified well before the meeting. Having extensive discussion at the time of the meeting is simply too late to clarify sometimes complex matters. Should still questions arise during the meeting, contact has been made with the data sponsor and teleconferences scheduled.

Assessing compounds that are not yet approved in any member country

Reference is made to paragraph 11 in the paper.

The proposal of considering the possibility for JECFA to evaluate active substance even if they are not yet authorized in at least one country, is interesting and might benefit from further consideration. The reason for the requirement of registration is that a final product label, has been approved. It is important for JECFA to know the formulation, method of administration, dose regimen, target species and withdrawal period in order to be able to recommend MRLs.

Should draft labels change afterwards, the MRL assessment would have to be redone. In this context, the Secretariat would also like to recall that a similar proposal has already been piloted by JMPR and has not proven to be very useful as the draft label information differed too frequently from the final label information.

Trying new working arrangements

Reference is made to paragraphs 13-15 and recommendation 4 in the paper.

JECFA has made a variety of efforts to respond to the requests of CCRVDF and to accommodate its needs in the most effective and timely manner. Indeed some of the suggested working arrangements have already been tried in the past (e.g. electronic meeting for the evaluation of data on ractopamine residues in pig tissues). While the secretariat will continue to explore new working arrangements, it is important to note that a careful analysis and discussions with other stakeholder of the FAO/WHO scientific advice program will be essential to ensure that the integrity of the process is maintained.

Evaluating old compounds

Reference is made to paragraphs 22, and 27 and recommendation 10 in the paper.

We appreciate the report highlighting the complexity with regard to the evaluation of older compounds, for which often only very limited data are submitted. In an effort to collect a suitably comprehensive data package, JECFA has made several efforts to fill the existing data gaps by, e g., performing comprehensive literature searches (most recent examples can be found in JECFA 85th). Yet, regrettably, even with these additional efforts, in numerous cases it will still not be possible for JECFA to complete a toxicological assessment and recommend MRLs, as several critical data gaps remain. Lessons learnt from these experiences could be useful for CCRVDF in future similar situations.