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CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 9 **CX/RVDF 21/25/10-Add.1**

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

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

PARALLEL REVIEW OF A NEW VETERINARY DRUG BY JECFA AND NATIONAL REGULATORY AGENCIES

Comments on principles and procedures for the parallel review
of a new veterinary drug by JECFA and national regulatory agencies
in reply to CL 2021/5-RVDF:
Australia, Chile, Cuba, Egypt, European Union (EU), Iraq, Iran, Panama, Thailand
and HealthForAnimals

Background

1. This document compiles comments received through the Codex Online Commenting System (OCS) in response to CL 2021/5-RVDF issued in January 2021.

2. Under the OCS, comments are compiled in the following order: general comments are listed first, followed by comments on specific paragraphs.

3. The comments submitted through the OCS are, hereby attached as Annex I and are presented in table format.

GENERAL COMMENTS

Comments/Rationale	Member/Observer
Australia considers that the parallel review of a new veterinary medicine compound by JECFA and national regulatory agencies, with defined parameters, could assist in the timely establishment of Codex MRLs. We therefore appreciate that a pilot on a parallel review of a new compound (i.e. selamectin) was undertaken by JECFA88 and commend the work done in preparing principles and procedures detailed in this circular letter. Australia supports the concept of parallel review as a complement to the current process. It is considered that this process could expedite nomination of compounds onto the priority list and then assessment by the Joint FAO/WHO Expert Committee on Food Additives. National registration is currently a requirement for priority list nomination, and this proposal would allow a product which is submitted (or is expected to be submitted) to a national regulatory authority to commence the CCRVDF process for Codex MRLs.	**Australia**
Chile expresses its thanks for the proposal "Principles and procedures for the parallel approach to the evaluation of a new veterinary drug by JECFA and national regulatory bodies" developed by Canada with the support of Australia, the United States of America, the Secretariat of JECFA, and Health for Animals and is in agreement with its contents. Rationale: The proposal identifies important factors that can reduce the time necessary to establish an MRL for a veterinary drug. Likewise, Chile considers it important that countries as well as sponsors wishing to present materials under this procedure pay the utmost attention to the challenges identified in the "DISCUSSION PAPER ON PARALLEL REVIEW OF A NEW VETERINARY DRUG BY JECFA AND NATIONAL REGULATORY BODIES" (CX/RVDF 20/25/10) so that the different experts participating in that process have necessary and timely information, enabling them to make the most efficient use of the economic resources and time allocated to this.	**Chile**
Cuba expresses its appreciation for the opportunity to submit its comments on this circular letter, and in principle it supports what is proposed in the document.	**Cuba**
Egypt agrees and supports the proposed principles and procedure for the parallel approach to the evaluation of a new veterinary drug by JECFA and national regulatory authorities with no additional comments.	**Egypt**
Mixed Competence *European Union Vote* The European Union and its Member States (EUMS) generally support the proposed principles and procedure for parallel reviews as it could speed up the setting of Codex MRLs for new substances. However, the procedure remains to be tested as, according to JECFA, some data was lacking for the pilot substance selamectin. Moreover, EMA/CVMP did not get an application for setting MRLs for selamectin and therefore the EUMS are not in a position to comment on any specifics. As an editorial comment, the EUMS note that the document makes a number of references to "products" (eg, in phase 1 "…the product is identified as a candidate."; in phase 2 "At the following CCRVDF meeting, the product would be submitted (…) for inclusion on the prioirity list at CCRVDF (Step 1)."; in phase 3 "JECFA and the national assessor follow their normal processes of assessing the product"). But JECFA undertakes substance evaluations rather than product evaluations and CCRVDF similarly focuses on substances. So it would seem appropriate to refer to substances or veterinary drugs rather than to products.	**European Union**
Agree	**Iraq**
Iran support the parallel review of a new veterinary drug as an alternative or complement to the current process to assess new compounds by JECFA for the establishment of Codex MRLs by CCRVDF. We presume the text for the current principles could be further improved	**Iran**

Comments/Rationale	Member/Observer
Panama appreciates the work presented by the Secretariat of the Codex Alimentarius Commission and supports the parallel examination of a new veterinary drug as an alternative or complement to the current process of evaluation of new compounds by JECFA for the establishment of maximum residue limits (MRLs).) for Codex veterinary drugs by the CCRVDF, according to the procedure recommended in the document entitled: PRINCIPLES AND PROCEDURE FOR THE PARALLEL APPROACH TO THE EVALUATION OF A NEW VETERINARY MEDICINAL PRODUCT BY JECFA AND NATIONAL REGULATORY BODIES; without additional observations, according to the indications established in Circular Letter CL 2021/5 / OCS-RVDF. Similarly, Panama agrees with the format and general content of the proposed procedure CX / RVDF 20/25/10 September 2020 and in Circular Letter CL 2021/5 / OCS-RVDF. Panama, like many countries, depends on reference organizations such as Codex for the establishment of MRLs for veterinary drugs, which are part of the process and evaluation in the authorization of compounds for use at the national level, and we are sure that this procedure will reduce the time to establish MRLs in Codex, so that producers of food animals could more quickly access new and safe veterinary drugs worldwide; Not to mention that, at the same time, the risks to international trade in food of animal origin will be reduced.	**Panama**
In principle, Thailand has no objection to the principles and procedure for the parallel review. The approach is to be scientific evidence based, transparency and practical. Moreover, we strongly support that this proposed parallel review process should be applied primarily on the new veterinary drugs.	**Thailand**
HealthforAnimals thanks for the proposal and looks forward to a positive discussion at CCRVDF. The parallel review is a compliment to current national processes, and if conducted well, could allow more rapid access to products in markets around the world. This increases countries capacities to efficiently deal with animal disease.	**HealthForAnimals**

SPECIFIC COMMENTS

Comments/Rationale	Member/Observer
The three proposed principles of transparency, confidentiality and independence are supported. Australia agrees that national authorization process and JECFA process are two separate independent processes and should remain subject to their own independent decisions. Australia is supportive of the intent of the proposed four phase procedure. Steps 1 and 2 are supported but could be strengthen by clearly stating that a complete data package to address national regulatory requirements and draft Good Veterinary Practice (GVP) will be required prior to the JECFA assessment commencing. The independent assessment by JECFA and the national assessor is proposed to follow their normal processes of assessing the product at Phase 3 and this is supported by Australia. It is however recommended that care should be taken to maintain independence if one individual is both a national authority assessor and JECFA assessor. After JECFA assessment, it is proposed (Phase 4) that the draft ADI and MRLs proposed by JECFA and circulated for comment and then the current Codex process continues. This is supported by Australia but we recommend that a step for GVP verification be considered either at Phase 3 or Phase 4. A draft GVP, including a proposed WHO, is required to be submitted to JECFA to enable MRLs to be recommended. It is expected that the product will be approved by a national authority at some stage either during the JECFA assessment process or prior to consideration of the draft MRLs proposed by JECFA at CCRVDF. It is recommended that the approved GVP and the draft GVP assessed by JECFA are confirmed to be the same prior to discussion at CCRVDF. It is also recommended that a procedure is developed for situations where the approved GVP significantly differs from the draft GVP (which may warrant re-consideration by JECFA) or where the national authority did not approve the use pattern.	**Australia**
Panama supports and agrees with the principles and process proposed for the parallel review of a new veterinary drug by the Joint FAO / WHO Expert Committee on Food Additives (JECFA) and national regulatory bodies; therefore, it does not consider comments or additional provisions. Panama agrees with the objective of this proposal will reduce the time between the completion of the safety review by the national authority and the time the compound is included in the CCRVDF priority list for review by JECFA for establishment of MRLs.	**Panama**
<u>Specific comments</u>: Advantages of the proposed process: We have no objection to the advantages of the proposed process. - *Candidate selection and outcome*: We would like to support the establishment of selection criteria for candidate for parallel review. In addition, we are of the opinion that the last sentence under the 2nd bullet “There would never be any requirement that the expected outcome of any process that is developed has harmonized endpoints/MRLs” is not the challenges of the proposed process, whilst the independence is a principle of the process. - *Confidentiality and protection of intellectual property*: We fully support a strict implementation of confidentiality and protection of intellectual property during the parallel review process.	**Thailand**

Comments/Rationale	Member/Observer
We fully support a strict implementation of confidentiality and protection of intellectual property during the parallel review process. This proposed parallel review process should be applied primarily on the new veterinary drugs. We would like to support the establishment of selection criteria for candidate for parallel review. In addition, we are of the opinion that the last sentence under the 2nd bullet "There would never be any requirement that the expected outcome of any process that is developed has harmonized endpoints/MRLs" stated in CX/RVDF 20/25/10 is not the challenges of the proposed process, whilst the independence is a principle of the process.	
We support the three principles set out transparency, confidentiality, and independence. It may be worth having a discussion at CCRDDF whether a fourth principle could be added. That principle could be Cooperation, pointing to the advantages for many countries of working together. We agree with the phases set out. Under phase 3: Assessment it might be worth adding some text that suggests opportunities for JECFA and the national assessor to communicate during the process, whilst of course respecting confidentiality and other rules.	**HealthForAnimals**

OTHER COMMENTS

Comments/Rationale	Member/Observedr
- There are not missing points that need to be included but if we find out any critical and missing points we certainly will announce you. - In our viewpoint, the text for the current provisions are perfect and there is no need for improvement. - We agree with the overall format and content of the proposed procedure - We are of the opinion that additional principles could be taken into account	**Iran**
Panama has no additional observations or considerations to points a and b.	**Panama**