31.01.2023

CODEX COMMITTEE ON PESTICIDE RESIDUES

European Union comments on

Codex Circular Letter CL 2022/75-PR:

Request for comments on the need to enhance CCPR/JMPR and the associated opportunities and challenges

European Union Competence

European Union Vote

The European Union (EU) would like to thank the Electronic Working Group (eWG) on Enhancement of work management of CCPR and JMPR chaired by The United States of America and co-chaired Costa Rica, France, Germany and Uganda for the preparation of the discussion paper.

General comment

The EU notes that besides the present eWG, other eWGs are currently working on the issue of the workload of JMPR and CCPR (i.e. Establishment of CCPR schedules and priority lists, Management of unsupported compounds, National registration of pesticides). For efficiency purposes in time and resource management, the EU believes that this issue would benefit from a more integrated and consistent approach. The EU is concerned about the backlog of evaluations on new compounds, uses, and especially on periodic evaluations. Heavy backlogs show that the current system is not efficient enough to meet the demand today and in the future. The EU also notes that it is challenging to solve this immediately and that there is not one easy solution.

In that respect, as an overarching reflection on the model for the future Codex work, the Executive Subcommittee on the future of Codex could be a place that could effectively tackle some of the challenges currently faced by CCPR and JMPR.

Question 1. *Please comment on the need to enhance the operational procedures of CCPR/JMPR to (i) eliminate the backlog of compounds evaluations caused by the cancellation of JMPR meetings due to the COVID19 pandemic and (ii) expand its review capacity to meet the future demand.*

Currently, the annual JMPR Residue Meeting, hereafter referred to as “meeting”, lasts for 9 days (including weekends) with a typical agenda of 12 - 15 full compound assessments (new compounds or periodic reviews) and 15 - 20 compounds with additional uses for MRLs. Normally, significantly less than one day remains per compound for assessing all relevant endpoints, deriving the residue definitions, reviewing all supervised field trials, estimating

MRLs for plant and animal commodities, conducting long- and short-term dietary risk assessments and putting all this in written form.

Without changing the level of depth and independence of evaluations, increasing the capacity to review more compounds (e.g., by providing resources to recruit more experts) is not necessarily expected to increase the number of final outputs, since insufficient time to make scientifically sound joint decisions during the meeting is currently the bottleneck.

It would be helpful to task the FAO/WHO Secretariats to survey (e.g., by requesting JMPR experts' experience):

- the usual time required during meetings for the evaluation of a new compound and for evaluation of a substance under the periodic review program (assuming all relevant preparations have been completed before the meeting, such as preparing close to final, internally peer-reviewed evaluations and appraisal documents),
- the usual time required during meetings for new MRL assessments and
- the usual time required during meetings for general issues like responses to CCPR or General Items.

Based on this information, the workload and prioritization of the meeting agenda could be aligned with the available timeframe and required additional resources could be quantified and appropriate measures taken on that basis.

All these considerations apply also to the toxicological evaluation of compounds by WHO experts. An increase in the number of experts involved might increase the quality of monographs (if there are two monographers working on the same compound) and perhaps reduce the workload for individual monographers but will not necessarily increase neither the quantitative output of the meeting nor the quality of discussions.

Apart from the above considerations, the EU is strongly in favour of a stringent approach for deleting compounds from the system that are no longer supported by a manufacturer. The 4-year rule already exists for unsupported substances and the 25-year rule is laid down in the Codex procedural manual, but it is not implemented in CCPR in a strict way. Notably, the procedural manual clearly states that "*the proposed MRL is maintained for a period of no more than four years*" and that when "*there is no commitment to provide additional information, or no data are supplied despite a commitment being made in relation to the four-year-rule, the CCPR considers withdrawal of the draft MRL*[1].". The EU believes, that in such cases, a clear decision should be taken by CCPR to withdraw such substances. Consequent withdrawal of the corresponding CXLs will contribute to reducing the number of substances for which a periodic review is overdue.

In addition, the EU notes that the number of active substances with the reference "Awaiting advice on supported commodities" increases from year to year. In this regard, the EU would also like to call upon the data submitters to meet their commitments in a timely and comprehensive manner. Here too, a more stringent use of the rules laid down in the Procedural Manual would be necessary.

[1] *Risk analysis principles applied by the Codex committee on pesticide residues*, para 42.

Question 2. *Please comment on opportunities to enhance the operational procedures of CCPR/JMPR to improve the efficiency of the evaluation process and increase JMPR's evaluation capacity. Please consider both opportunities for enhancement (e.g., improvements to existing processes) and major reform (e.g., governance and structural changes) in your comments.*

Question 3. *For the opportunities you have identified, please comment on the anticipated challenges and propose possible solutions that may be implemented by CCPR and JMPR. This may include challenges related to resources, process and procedures, and governance*

The following reply covers question two and three.

Under the current expectations to provide independent and science-based recommendations to CCPR, capacity of JMPR has peaked. As outlined for Q1, the current bottleneck is the time during the meetings and not the capacity of experts in meeting preparation. Consequently, changes in data submissions will have limited impact on the efficiency. The utilization of remote sessions in advance of the annual JMPR meeting is already in place. However, this format does not provide the opportunity for in-depth discussions and is very inefficient when compared to physical meetings (see General Item 2.1 of the 2021 JMPR Report).

JMPR consists of experts from many different regulatory agencies and already takes note of National Review documents and data to support their conclusions. A decision on using National Reviews directly for establishing CXLs would be up to the risk managers. They also would have to define the circumstances under which such an approach would be acceptable for Codex Members.

One option could be the implementation of additional meetings of the JMPR. However, it seems very unlikely that experts already working for JMPR pro bono will be available for more than one meeting. Instead, a second group of experts and an overarching structure would be needed to keep the two expert groups connected and harmonize procedures and evaluations (otherwise, a lack of consistency is likely to occur).

Another option might be the participation of JMPR experts in joint national reviews.

Furthermore, as already stated above, under certain circumstances the direct use of final regulatory dossiers instead of preparing detailed evaluation documents by JMPR could be an option. However, while this scenario might reduce preparation efforts, it provides only limited benefit for the Annual Meeting. The time needed for discussions and decisions on each endpoint during the Meeting still remains the bottleneck.

Regarding the toxicological assessment, the following further considerations/observations are added:

- A general experience from the last years is the increasing demand for assessment of metabolites. Very often, it becomes clear only during the meeting which of the metabolites are in fact relevant for FAO evaluation resulting in pressure on WHO experts to perform a very quick and perhaps too superficial assessment that must be revised later. On the other hand, the WHO monographers might waste time by thoroughly assessing metabolites that are of no concern for residues evaluation. To the extent possible, communication between

FAO and WHO monographers should take place long before the meeting by exchange of available information on the metabolites and on possible needs for additional assessment.

- As it goes on now, the first half of the WHO experts' meeting is used for introduction of the substances to the auditory and the discussion on certain critical points. The number of discussion points, length and depth of discussions is very different, depending very much on the selection and preparations made by the respective monographer and the reviewer. Perhaps, sometimes, discussion of "not that important points" (e.g., not relevant for ADI/ARfD, for evaluation of CMR properties or on metabolites that are included in the residue definition) might take too much time whereas others are overlooked. Indeed, efforts have been made to improve this situation by assignment of two additional reviewers for each monograph just before the meeting. If this review would be scheduled earlier, the outcome could be used by the WHO secretariat to determine the issues that need to be discussed in the first week. The discussions would be expected to be more focused then. On the other hand, this approach could contradict that one taken in the second half of the eeting when the "Report items" must be agreed word by word, in a very time-consuming process. For this exercise, the complete toxicological profile of a substance under evaluation must be taken into consideration anyway. It might be worth thinking about changing the sequence, i.e., to start with general introduction of the substance, using the list of endpoints, the draft report item and considering the reviewers' comments. During these presentations, it would become clear which are really the critical points for each substance to be discussed in depth afterwards. The last step would be then to agree on final changes in the Report item.

Therefore, as a first step the EU suggests exploring and mapping all the possible non costly ways to enhance the operational procedures like improving templates and forms to enable expedited reviews and evaluation reports. The feedback could be also collected from the JMPR experts and industry to see which parts can be improved. The EU also highlights the importance from the industry's side to be more proactive and send complete data packages in order to ensure that assessments are carried out without delay. For periodic reviews, the industry already knows the schedule many years in advance and can commit themselves to prepare the data packages well in advance.

In parallel, a thorough analysis/impact assessment of the feasibility for more structural changes of the existing system should be carried out as it is unlikely that the steps proposed above will be sufficient on their own. The following are possible options to be evaluated:

- JMPR could consider using evaluations carried out by other risk assessment bodies as a first step in the evaluation process. This would free time of JMPR experts, and the number of evaluations could be increased.
- A pilot project could be set up on running a permanent risk assessment body for a certain period, i.e., 3 years. For this, an assessment of costs/benefits is needed, which would for instance compare the current costs of temporary JMPR meetings with the possible future ones on a permanent risk assessment body, considering also the expected savings in the long term due to faster procedures and the benefits for consumer health protection resulting in an expected decrease of health-related costs. The EU acknowledges that such an impact assessment and the funding for a possible pilot project should be discussed at the CAC level.

However, increasing the scientific production of JMPR alone would not be sufficient to extensively address the challenges faced, and CCPR would also need to undertake structural changes. In its zero draft[2], the Executive Subcommittee on the future of Codex notes in paragraph 3.2.2 that some committees, overloaded with work, could schedule extraordinary sessions focussing on specific agenda items in order to alleviate the timetable of the main ordinary meetings. In that perspective, the EU notes that CCPR would certainly benefit from such a "need-based approach".

Question 4. *Codex members and observers are requested to provide feedback on the focus of additional stakeholder workshops that aim to expand upon the virtual stakeholder workshop sponsored by CropLife International on March 31, 2022 and summarized in CX/PR 22/53/206. Please provide recommendations on key topics and themes for this follow-up workshop:*

The EU is of the view that to enhance the capacity of JMPR, some major procedural and structural changes will be necessary and should be seriously considered. While little improvements can be made immediately this will not address the structural problems arising from the fact that the JMPR is not a permanent structure supported by permanent staff. If a future workshop is organised, it should primarily focus on how to achieve major structural changes for the future´, e.g.by developing a roadmap for such a change.

Question 5. *Do you have any further proposals or recommendation that are not covered by the four previous questions?*

The current situation is caused by high customer demands, limited financial resources, limited work power and slow administrational procedures. Therefore, the feasibility of the of whole process in terms of available capacities, efficiency and restricting bottlenecks should be assessed and where possible improvements should be proposed.

[2] CX/EXEC 22/83/5, Annex I.