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Agenda Item 18

CX/PR 22/53/20 May 2022

JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COMMITTEE ON PESTICIDE RESIDUES

53rd Session (Virtual) 4-8 July and 13 July 2022

DISCUSSION PAPER ON

ENHANCING OPERATIONAL PROCEDURES OF JMPR AND CCPR TO ELIMINATE THE BACKLOG OF EVALUATIONS AND MEET THE FUTURE DEMAND OF ESTABLISHING CODEX MAXIMUM RESIDUE LIMITS FOR PESTICIDES

(Prepared by CropLife International)

BACKGROUND

- 1. For CCPR52 (2021), CropLife International prepared a conference room document CRD11 highlighting the backlog of evaluations with the Joint FAO/WHO Meetings on Pesticide Residues (JMPR) caused by the cancelation of the JMPR meeting in 2020 due to the COVID19 pandemic, and proposed possible solutions to catch-up. Since CCPR52, JMPR was able to convene, albeit virtually in 2021, with an understandably reduced output. Since that time, it has become clear that the Schedule of work for JMPR 2022 agreed by CCPR52 and CAC44 (2021) will not go ahead as planned and will likely be carried over to JMPR 2023, thus creating a "bow wave" of ongoing delays in JMPR evaluations if the current process and resources are maintained.
- 2. There is now clear evidence that the current system is unable to keep up with the demand for all three areas of work undertaken by JMPR i.e., evaluations on new active ingredients, new uses and other evaluations, and the perennially resource-challenged periodic re-evaluations.
- 3. Prior to COVID19, JMPR typically reviewed an average of 8.4 new active ingredients per year. CropLife International estimates that demand is likely to increase in the coming years to 10 new active ingredients per year, due to data sponsors bringing new innovations to the markets. For new uses and other evaluations, JMPR has typically undertaken 20 per year, and it is expected that this will need to increase to 30 per year to meet the demand.
- 4. Recent analysis by CropLife International indicates that as of the 1st of January 2022 Codex has over 6000 MRLs in place for 239 pesticide active ingredients. To re-evaluate these active ingredients on a fifteen-year cycle, 16 active ingredients need to be reviewed each year with an additional six re-evaluations needed in the first 10 years to catch-up on the 60 active ingredients which are currently overdue for re-evaluation (Table 1). This is a significant increase over the average of 3.6 re-evaluations conducted annually prior to COVID19.
- 5. The increased demand for evaluations is one part of the challenge. In addition, the work required to evaluate a dossier has also increased. The content of study reports and the areas addressed in a typical dossier has grown in recent years. A recent case in point is now the level of data required on metabolites. It is estimated that the "data density" of a typical submission has increased by 15% over the last ten years.
- 6. <u>Altogether, CropLife International therefore estimates that to meet the future demand for new active ingredients, new uses, and periodic review the output from JMPR needs to increase by a factor of three.</u>
- 7. It is important that innovation reaches the market as quickly as possible and Codex MRLs (CXLs) are an important step in this given the global nature of food and feed supply chains. At the same time, existing CXLs need to meet today's scientific requirements. CropLife International therefore advocates that more must be done for all areas of JMPR work.

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Table 1: The CropLife International analysis of pre-COVID19 output from JMPR and an estimate of what is needed to meet future demand

	Recent average (pre-COVID19)	Estimate of future needs
New AI evaluations	8.4	10 (22 for the next 2 years to catch-up on backlog caused by COVID19)*
New uses and other evaluations	20	30
Re-evaluations	3.6	16 (22 for the next 10 years to catch-up on overdue re-evaluations)

^{*} Carryover from JMPR 2020/21 = 9; Official schedule as agreed by CAC44 for JMPR 2022 = 6; current proposed schedule for JMPR 2023 = 7)

- 8. In addition to reducing the backlog and establishing a system that meets the future demands, processes need to be further refined to allow for the setting of thousands of more CXLs than the 6,000 currently in place. This is needed to facilitate even more trade and to provide an even more compelling reason for nations to adopt CXLs or to defer to Codex. Many countries have set tens of thousands of MRLs, and Codex needs to match those to remain the international MRLs standard.
- 9. In early 2022 CropLife International began a dialog with many Codex members, CCPR delegations, JMPR experts, FAO, WHO and CODEX, CCPR and JMPR Secretariats to share these capacity concerns. In those conversations options to enhance the CCPR/JMPR system to better meet the current and future demands whilst maintaining the independence, scientific rigor, and reputation of JMPR, CCPR and CODEX were explored. This culminated in a well-attended three-hour virtual workshop on the 31st of March with over 50 non-industry participants. The results of the workshop are available here.

OUTCOME

10. Through-out CropLife International's consultation, there is consistent high level of support for Codex and a strong desire to see it continue doing its great work. There was also consensus that the system is struggling to keep up with the demand and that "something needs to be done". The consultations also showed that there is not a single or simple solution to deliver the needed improvements. The desired enhancement can only be achieved considering the totality of the JMPR/CCPR process, and by joint and collaborative efforts from all involved in Codex. Below is a summary of some of the proposals raised during the consultation.

Data submissions

11. CropLife International received great feedback on how the quality of dossiers could be improved. CropLife International would like to continue the discussion to explore further means for improved templates and forms to enable expedited reviews and evaluation reports. CropLife International has taken this feedback on board and will share this with data submitters directly and via the next update of the CropLife International publication "Working with the JMPR and CCPR: A Manual for the Agrochemical Industry".

Increased sustainable funding

12. There was clear support that increased and sustainable funding of the FAO, WHO and JMPR is needed to make a significant difference in enhancing the Codex process, aligned with Objective 2.3 of the Codex Strategic Plan 2020-2025. Increased, predictable and long-term funding from Governments could clearly be used to hire permanent evaluation staff to be deployed within JMPR to best effect. Some options were proposed, and clearly additional discussion is needed to define the best model for when additional funds are available.

JMPR processes and resourcing

13. Many of the workshop delegates felt that increasing JMPR resources would make the biggest positive impact in enhancing the CXL setting process. JMPR experts are volunteers; industry and governments alike are grateful for their participation in the Codex process, however more experts are needed to expand the capacity of the JMPR panels.

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14. JMPR met twice virtually in 2021, an extra-ordinary meeting in May and the main meeting in September. Panel members pointed out that virtual meetings are more tiring and more difficult than face to face meetings (JMPR reports of May 2021 and September 2021, and CODEX 2021 – A year of virtual reality). Virtual meetings do not allow the same amount of output of CXL recommendations, and JMPR experts as volunteers only have a limited amount of time to devote to JMPR work (e.g., more JMPR meetings does not mean more available resource). However, virtual meetings have proved useful in better preparation of review materials by the experts.

- 15. Other options put forward to improve the process for consideration included:
 - Use national summaries of studies and evaluation of active ingredients as a starting point for the JMPR evaluation, whilst ensuring the independence of JMPR is maintained.
 - Conduct JMPR as an ongoing process, comparable to national regulatory agencies.
 - Make the JMPR secretariat assignments full time within WHO and FAO.
 - Consult with other Codex committees and expert panels to address these challenges, as they face similar issues.

RECOMMENDATIONS

- 16. The challenge to resolve the backlog and improve the existing system to meet current and future demands requires a multi-dimensional approach. The responsibilities must be shared across CCPR, JMPR, CAC, the Executive Committee (CCEXEC), FAO, WHO, national governments, and industry.
- 17. CropLife International recommends CCPR requests JMPR or the scientific panels of FAO and WHO undertake a review of processes and ways of working to assess if the output of JMPR could be enhanced through procedural efficiencies.
- 18. In parallel CropLife International also recommends establishing an electronic working group (eWG) or adjusting the terms of reference for an existing eWG within CCPR to address those issues that could be addressed within JMPR and CCPR. CropLife International proposes the following ToR:
 - i. Estimate the anticipated workload: currently pending; future new active ingredients; future new uses; periodic reviews;
 - ii. Estimate the resource needs (such as but not limited to human resources, expertise, meetings, budget, processes, and infrastructure) to respond to the anticipated demand for CXLs (new active ingredients, new uses and periodic reviews) for a sustainable functioning of JMPR and CCPR;
 - iii. Identify possible solutions that can be addressed within JMPR and CCPR: To identify and assess processes in JMPR and CCPR that could help increase the output, reduce the backlog and meet the demand for CXLs today and in the future, whilst maintaining the independence, scientific rigor and reputation of the Codex system; and
 - iv. Identify synergies with other ongoing work with CCPR eWGs such as parallel reviews, management of unsupported compounds, registration database, the schedule and priority list.
- 19. Based on the above considerations, the eWG would develop a discussion paper for consideration at CCPR54 (2023). The Codex enhancements coming from this effort have the potential to increase the capacity and efficiency of JMPR/CCPR leading to a direct benefit for all Codex members enabling global trade of agricultural commodities and balanced distribution of food and feed and will enable CCPR to be a key contributor to the delivery on the Codex Strategic Plan 2020-2025.