

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
United Nations



World Health
Organization

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Agenda Items 4a, 16

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Comments submitted by CropLife

Agenda Item 4a

Point 32 of CX/PR 21/3 states: CCPR is requested to decide if the Guideline should be updated and aligned on the EHC 240 or simply be withdrawn from the list of publications.

EHC 240 is a valuable collection of aspects and approaches to dietary risk assessment applicable to many sectors. This document is up to date and inclusive of many approaches and resources and is an excellent reference.

While some sections may be potentially outdated, the 1997 "Guidelines for predicting dietary intake of pesticide residues" contains specific guidance which is targeted in support of CXLs with worked examples for reviewers in Annexes 2 and 3.

Given the 1997 document targets a more specific purpose, in CropLife International's view, it would be more useful to update it rather than withdraw it.

Agenda Item 16

CropLife International's proposal for specific operational procedures to resolve CCPR backlog in MRL adoption, triggered by Covid-19 pandemic

Introduction

The global SARS-CoV 2 pandemic has caused millions of fatalities worldwide. It also has ongoing impact on the economic well-being of millions more, who have lost employment as a result. Affordable food prices are critical to social stability and are closely related to the production and international trade of agricultural commodities. In its 2020 - 2025 strategic plan, Codex Alimentarius sets important goals and deliverables that are highly relevant in addressing the (post)-pandemic crisis. For example, the first goal, "Address current, emerging and critical issues in a timely manner", states that the *'focus and needs of Codex Members are evolving, as is the environment in which Codex operates. Codex will need to be proactive and flexible and to respond in a timely manner to the opportunities and challenges that result.'*

The top priority of health protection for delegates and attendees forced cancellation and postponement of Codex meetings beginning in early 2020. In 2021 we are in the second year of an ongoing pandemic. Therefore, it is of utmost importance to take measures quickly to enable Codex and CCPR to regain its operational performance and prevent further delays in setting CXLs, by looking for efficiencies and process improvements.

Impact of Covid on back-log at CCPR

The CCPR is responsible to manage the development of the largest possible numbers of CXLs for approval by the CAC. Therefore, delays in procedures of CCPRs and its advisory joint meeting, the JMPR, have a substantial impact on overall Codex efficiency.

The table below provides an estimated overview on the expected delay of proposed standards advanced by 4 sessions of JMPR, since May of 2019.

Table 1: Estimated delays of pesticides MRLs in step procedure (worst case scenario)

Submissions	Type	JMPR	No of CXLs	CCPR
May 2018	New uses	2019 extra	436	CCPR-52 (July 2021) 436 delayed 1 year
Dec 2018	New uses, new compounds, reviews	2019 reg periodic		
Dec 2019	New uses	2020 (to 2021)	91	CCPR-53 (April 2022) 135 delayed 1 year
	New compounds		84	209 delayed 2 years
	Periodic reviews		34	
July 2020	New uses	2021 extra	35	
Dec 2020	New uses	2021 reg	~100**	
	New compounds *	2021 (to 2022?)	~100**	CCPR-54 (April 2023) 175 delayed 2 years
	Periodic reviews *	2021 (to 2022?)	~75**	300 delayed 1 year
Dec 2021	New uses, new compounds, reviews	2022 periodic	~300**	
Total			1,255***	

* It is uncertain at the current time; however, many periodic reviews scheduled for JMPR 2021 might be shifted to JMPR 2022.

** Conservative estimates based on CCPR performance over the last decade.

*** 1255 MRLs represent 24% of the existing database that would be delayed/backlog across 3+ years

Our analysis reveals a growing gap between the time of the setting of national MRLs, and the adoption and publication by Codex of global standards (CXLs) for new compounds. These compounds are developed based on state-of-the-art requirements and provide new tools for farmers in food production. They contribute to the adoption of Integrated Pest Management and other practices that will improve the sustainability and resilience of agriculture. In the absence of CXLs the use of these new compounds is often restricted by producers or other parts of the food and feed supply chain.

Secondly, our analysis appears to demonstrate that CXL standards for additional minor uses like on tropical fruits, vegetables, and other speciality crops, are also delayed. This matter can impact economies but has a disproportional impact on economies with low overall GDPs and high percentage of the population working in agricultural production, which depend heavily on export of agricultural commodities.

Thirdly, we believe the review program is delayed beyond the usual frequency. While not as key to trade enablement as CXLs for new compounds and uses, the periodic review program is an important element in updating standards to compliance with current safety requirements accounting for the availability of new data on the compound or risk assessment approaches employed by the JMPR expert panels.

While these delays as directly caused by the pandemic are a rare event, nevertheless this crisis opens an opportunity to review current procedures with two critically important objectives:

1. To develop immediate and pragmatic solutions to resolve the current backlog including identification and implementation of efficiencies and process improvements.

2. To enable Codex operations to become more resilient to future crises by implementing modern communication technologies and digital processes that support group or teamwork.

Meetings of committees have been proven as an important element for exchange of opinions and decision-making to find agreement on complex matters; the openness of the Codex Committee meetings have often been cited as a strength of the CXL standard system. However, Covid has helped to prove that many face-to-face meetings can often be supplanted, or even replaced by 'virtual meetings', based on the availability and workability of affordable modern communication technology. Certainly, the use of virtual meeting tools can make time zone differences challenging and might require unpopular activities like night shifts for some delegates; however, on the positive side, less business travel reduces stress of delegates, reduces costs, as well as the carbon-footprint of a large international meeting and would even potentially encourage participation of more members.

Therefore, CropLife International requests the CCPR-52 to re-consider with high priority the upcoming meetings to:

- set operational procedures to improve efficiency and implement process improvements and remove procedural obstacles,
- utilize modern communication tools and digital modernized systems for record retention and tracking of voting and commenting.

Opportunities for modernization of the Codex decision-making process

Crop Protection products are authorized continuously in countries worldwide. Since Codex has been established the numbers of CXLs has increased consistently, but the number of national authorizations is increasing at a significantly higher pace. Currently Codex has one of the shortest lists of CXLs for pesticides; many countries are establishing new national MRLs at a faster pace. There is need for a Codex Catch-Up Plan to address this ever-growing gap between CXLs and significantly larger national listed standards. More and more Codex member countries establish regulatory structures to improve the production of safe food according to modern standards. Often these improvements result in the establishment of national standards, where global standards will be deferred to, if they already exist. So far, about 70 of the 188 Codex members defer to the CXL, and with the implementation of an effective Codex Catch-Up Plan there could be a significant increase of Codex members deferring to the CXL standards. It is also of utmost importance that global standards are set with a minimum time period after the first national authorizations. Sponsors strive to make the first Codex submission soon after the first national use if approved for a pesticide. However, the rigid yearly schedules and resources limitations at JMPR and CCPR have resulted in lower productivity in comparison with national agencies, and a significant backlog in the Codex system has been the result. The general yearly process implies in the best case a 5-years process for a new compound to enter the Codex system: if a new compound has the first label approved before May of 'Year One', it can be scheduled by CCPR in 'Year 2', evaluated by JMPR in 'Year 4' and CXLs can be adopted in 'Year 5'. In practice depending on JMPR workload and possible additional requirements, the 5-year timeline can be longer. The current system needs improvement to reduce the 5 years period between first national regulatory approval and the adoption of an CXL, when the global trade of treated produce will potentially be limited, or restricted.¹

CropLife International is committed to collaborate with delegates, the Codex and FAO/WHO secretariats, and other involved stakeholders to identify and implement efficiencies and process improvements; and address ideas for procedural changes for the provision scientific advice (JMPR). CropLife International stands ready to participate in any established forum (e.g., a discussion paper, e-Working Group, webinar) to address the needs and to meet the objectives of Codex strategic goals.

CropLife Proposed Modification of Operational Procedures

1. We believe the CCPR could look for possible solutions that could have immediate impact toward resolving the backlog created by Covid. For example, decisions on CXL proposals could be expedited by utilizing a written procedure.

¹ It should be noted that discussions of process improvements have been active in an attempt to resolve this 5-year conundrum in the CCPR process, including the establishment electronic work groups (EWG); in particular, a national: JMPR 'parallel review' concept has been presented at CCPR-51 in 'DISCUSSION PAPER ON OPPORTUNITIES AND CHALLENGES FOR THE JMPR PARTICIPATION IN AN INTERNATIONAL REVIEW OF A NEW COMPOUND' (attached). Finally, it should be noted that other Codex Committee groups that conduct work similar to the JMPR and CCPR have developed principles and practices for 'parallel review'; in particular, the Joint FAO/WHO Expert Committee on Food Additives (JECFA) has released for public comment: 'Request for comments on the principles and procedure for the parallel review of a new veterinary drug by JECFA and national regulatory agencies' (attached)



Proposed standards not receiving any comments from delegates would proceed toward recommendation by the CCPR and to CAC for adoption. Using this approach, the CCPR virtual meeting that is operating on reduced schedule due to its virtual format could limit plenary discussion to those cases with noted reservations on the advancement of CXLs proposed by JMPR.

2. We also believe the CCPR should look for potential permanent solution for use in 2022 onwards. For example, a software-driven online or cloud-based collaborative site ('Portal') should be developed for the CCPR where proposed MRLs and draft standards are listed and comments, reservations and disagreements are posted and shared. Access to such a Portal should be limited to Codex staff, WHO/FAO joint secretaries, Codex members delegations, and accredited observers. A Portal solution would contribute to transparency and visibility of decisions and would facilitate tracking of previous dialogue and decisions. Improved transparency could also increase members confidence in development of standards and could encourage extended deferral to all members, or adoption by national regulations. Using such a digitally based approach, the CCPR process could also transform from an annual event, to become a more continuous process. Reviews of submissions could occur at established/agreed mileposts (2-4 times a year); having at least two deadlines where agreed recommendations are forwarded to the CAC for final approval. This could lead to a more robust and productive process.

In cases when members provide objections which do block advancement of standards, these standards should be discussed at the physical CCPR meeting. However, identifying and implementing a process like the one described above for all other non-controversial standards are sent to the CAC could limit the length of the physical CCPR meeting or expand the agenda of the physical meeting to include other relevant issues.

- Likewise, we encourage the CAC to establish mechanisms to adopt proposals on draft standards which are submitted by their committees more than once a year.
- Scheduling of substances for the provision of scientific advice. CropLife request that CAC and CCPR considers a reform of procedures and agree on a mechanism to take decisions on scheduling outside face-to-face meetings e.g. electronically in a Portal described above. The creation of workstreams where experts were included based on their resident time zone to continue the work of JMPR is a positive step in this direction.

Increased impact through the recognition and use of Codex standards

To support this strategic goal, we propose that reports on national measures of CXL adoption or their recognition for trade become a permanent item on CCPR's agenda to encourage as many countries as possible to follow these practices. Again, consideration of the EWG recommendations and principles and practices for 'parallel review' with affiliated Codex committees could be considered as an additional mechanism for broader acceptance of CXL standards.