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Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - Fax: (+39) 06 5705 4593 - E-mail: [codex@fao.org](mailto:codex@fao.org) - [www.codexalimentarius.net](http://www.codexalimentarius.net)

Agenda Item 13(a)

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## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### CODEX COMMITTEE ON PESTICIDE RESIDUES

43<sup>rd</sup> Session

Beijing, P.R. China, 4 - 9 April 2011

#### DISCUSSION PAPER ON JMPR RESOURCE ISSUES IN THE PROVISION OF SCIENTIFIC ADVICE TO CCPR

(Prepared by the United States with assistance from Cameroon and CropLife International)

#### Background

1. During the 42<sup>nd</sup> Session of the Codex Committee on Pesticide Residues (CCPR) it was agreed that the Delegation of the United States with assistance from the Delegation of Cameroon and CropLife International would prepare a discussion paper to address resource issues for the Joint FAO/WHO Meetings on Pesticide Residues (JMPR).<sup>1</sup> As reported during the 42<sup>nd</sup> CCPR meeting, five chemicals (dinotefuran, cyantraniliprole, ametoctradin, fluxapyroxad and clopyralid) that were originally scheduled for review during 2011 had to be rescheduled to 2012 and the 2012 schedule has already reached its quota and cannot accept further nominations. The demand is going up each year to schedule the review of chemicals thus pushing the review of a chemical further into the future. The resource constraints that limit the number of reviews are especially problematic for new active ingredients given the decision that has been made by the CCPR for the JMPR to have approximately a 50:50 review ratio for new compounds and periodic review compounds. Therefore, this has required the scheduling of nominated new chemicals to be pushed further out on the review schedule. This increase in demand is also now impacting the schedule for periodic review chemicals.

2. It is worth noting this increase in demand is indicative of the success of the process improvements that have been implemented in the past several years by the CCPR for the scheduling and review of chemicals by the JMPR, and the improved decision-making process in CCPR as related to the consideration of proposed MRLs. The work of the JMPR and CCPR serve an important role for the safety of the consumer, but also for the facilitation of world trade of food commodities. Therefore, in order to build on these successes and to remain relevant the CCPR is considering ways to increase the capacity for JMPR review. Three primary issues of concern have been identified: funding, the availability of expertise, and the timing/frequency of JMPR meetings.

#### Current Capacity

3. The JMPR meeting is held annually for two consecutive weeks in September. The FAO also has a one week pre-meeting during the week prior to the start of the JMPR meeting. Approximately 28 experts (14 from FAO and 14 from WHO) participate in the JMPR meeting and conduct the science reviews. These experts do not receive any remuneration for their work. Therefore, their participation in the JMPR meeting is largely based on the individuals and (if applicable) their employer's willingness to let them participate.

4. For WHO the maximum number of chemicals that can be considered for full evaluation during the yearly meeting is approximately 10 substances. This number varies for FAO depending on the number of commodities as well as the number of field trials that must be reviewed. However, it is not expected that completing full evaluations of more than 10 chemicals is feasible within the 10 day time-frame of the September JMPR meeting. Additionally, there are an increasing number of requests to review a larger number of residue studies for multiple commodities for chemicals being considered for both full evaluation as well as the follow-up evaluations for additional MRLs. This increase in the number of commodities being reviewed also impacts FAO resources.

5. Regarding the current financial situation, the FAO JMPR work is supported by FAO's regular program budget. However, FAO has continually had financial constraints in recent years regarding the regular program budget. Recent JMPR meetings have cost the FAO approximately \$240,000 which covers the travel and accommodations for the experts to participate in the pre-meeting and meeting as well as editing and printing costs for JMPR publications. However, this money does not cover the cost of staff including the Secretariat.

<sup>1</sup> ALINORM 10/33/24, paras. 167-173.

6. The financial situation for the WHO is significantly different than the situation at FAO. Only approximately 20 to 25% of the funding for the WHO (staff and activities) is allocated by the regular budget. The remaining 75 to 80% has to come from extra-budgetary resources. WHO is also anticipating a possible 20% cut in its regular budget and core voluntary contributions (non-specified funds) for 2011. The approximate cost for the WHO participation in the JMPR meeting is \$150,000 (+13% general WHO Program Support Cost, amounting to approximately \$170,000). This covers the cost for travel and lodging of the experts during the meeting, and the costs for editing and printing of reports and monographs. The \$150,000 does not cover the staff costs for WHO JMPR.

7. Based on discussions with pesticide manufactures, the increase in demand to schedule more chemicals for review is not expected to be just a temporary peak but is expected to be a sustained, long-term trend. Many registrants have been incorporating application for Codex MRLs early in development process of new crop protection products and new crop uses as a routine business practice, particularly for international joint reviews, which are becoming the norm. Customers (the growers) are more insistent that their crop protection practices afford them maximum marketing flexibility, particularly for export possibilities, and particularly when the market destination of the crop may not be known or knowable at the time that crop protection decisions are being made. This generally means that Codex MRLs must be in place along with MRLs in selected other national markets (where Codex MRLs may not be recognized) before the product can be used on some crops. Otherwise, many growers cannot afford to use the new chemistry if the intent is to export the commodity. Additionally, as a testament to the success of the JMPR/CCPR review process, there are now more Member States nominating chemicals for review. The table below illustrates the continued increase in demand. This information was taken from CCPR reports and the draft CX/PR 11/43/13 paper to be discussed during the 43<sup>rd</sup> CCPR meeting. The true workload might be slightly different but it appears that the trend is one of continued increase in demand. This picture may not be complete, since the schedules may not reflect all demands related to 'concern forms'.

Year	Number of New Compounds	Number of Periodic Evaluations (Sum of WHO and FAO Evaluations)	Follow-up Evaluations WHO	Follow-up Evaluations FAO	Comments
1990	1	7	2	11	
2000	2	13	3	6	
2001	3	13	3	5	
2002	3	11	5	7	
2003	4	9	3	6	
2004	3	11	6	8	
2005	5	12	7	3	
2006	5	9	6	15	
2007	4	13	7	8	
2008	6	6	2	13	
2009	4	10	2	12	
2010	8	12	0	9	3 new compounds had to be moved to 2011
2011	8	4	1	12	5 new compounds had to be moved to 2012
2012 Nominated	10	9	1	17	2-3 new compounds & 4 periodic re-evaluation compounds will need to move to 2013
2013 Nominated	10	9	0	13	5 new compounds & up to 9 periodic re-evaluation compounds will need to move to subsequent years
2014 Nominated	3	6		1	
2015 Nominated		6			
2016 Nominated		5			

### **Lack of Funding**

8. Currently, FAO and WHO receive very little specified financial support for JMPR from Member States. Therefore, the discussion to expand the capacity of JMPR should address if Member States are willing to increase the financial support contributed to FAO and WHO to realize this goal. One strategy in place for this purpose was the creation of the Global Initiative for Food-related Scientific Advice (GIFSA). However, GIFSA is intended to be more generic for submission of additional funds for scientific advice for food safety and nutrition in general, but it is possible to specify the use of GIFSA funds. Funding may also be sent directly to the FAO or WHO for JMPR support by sending a letter to the Secretary or Director explaining that additional funds are being sent, the amount being sent and the intended use. The money can then be deposited in the bank. JMPR can provide bank details for different accounts depending on the currency being sent. The rules prevent industry from providing funding to support JMPR so it really is incumbent on Member States to support such an effort.

### **Availability of Expertise**

9. As discussed, experts that participate in the JMPR meeting and conduct the science reviews do so based on their own or their employer's willingness to let them participate. Experts are expected to spend significant time prior to the meeting reviewing data for the chemicals assigned to them and preparing the draft evaluations for review at the meeting. They then travel and are away from the office for two or three weeks while attending the JMPR meeting. All of the work completed for JMPR is in addition to the core responsibilities of their job.

10. Given this, it is not likely that the current experts can be expected to provide yet more of their time in order to increase the number of chemicals reviewed by JMPR. Therefore, in order to increase the number of chemicals that JMPR reviews every year, additional competent experts would have to be available. Member States need to determine if they are willing to provide (additional) expertise to participate in the review process, and can assist the JMPR Secretariat to identify additional competent experts.

11. Yet, beyond just increasing the number of experts that participate in this process, worthy of discussion are alternative ways on how the experts participate in this process. One option suggested is for Member States to sponsor regional meetings prior to the JMPR meeting in September in order to complete some of the preliminary work on the review of these chemicals. This may be especially helpful in order to shorten the length of the FAO pre-meeting. Holding regional meetings for FAO would potentially allow for more experts to get involved and allow for experienced JMPR reviewers to work with and train new participants. Another suggestion would be to increase the number of experts that conduct primary reviews and consider relying on senior people currently involved in the process to complete secondary reviews and to participate in the meeting.

### **Options for Timing/Frequency of JMPR Meetings**

#### **1) Hold Two JMPR Meetings Each Year with both FAO and WHO Present**

12. Based on the existing cost to hold the current JMPR meeting, this option would require a considerable increase in funding. At a minimum an additional \$390,000 would be needed and this sum does not account for the staff costs of FAO and WHO. In order to extend JMPR activities by holding 2 meetings per year there will need to be additional staff resources, since staff is currently working at capacity of what can be managed with existing staff in the area of scientific advice (JMPR, JMPS, JECFA, JEMRA and ad hoc meetings) and for administrative staff. Currently, it takes staff 2 to 3 months to prepare for the JMPR meeting. This option would also require a substantial increase in the number of experts participating since it is not likely the current experts could be away from their office for 5 to 6 weeks out of the year to participate in both meetings plus provide the time to prior to the meeting reviewing data for the chemicals and preparing the draft evaluations.

#### **2) Hold a Second Meeting with FAO and have 1 or 2 WHO Experts Join the Second Meeting via Video Conference**

13. This option would also likely require an increase in the number of experts that participate but the increase in experts may only be needed for FAO. If there are two meetings a year the one in which both FAO and WHO are physically present could concentrate on the review of new active ingredients and chemicals due for periodic review. The second meeting in which the WHO experts participate by video conference could possibly be limited to the review of one or two new chemicals and review of chemicals that already have Codex MRLs with an existing ADI/ARd that are not scheduled for periodic review in the next five years. This approach could allow for more chemicals to be reviewed in a year without the entire cost of funding 2 meetings in which FAO and WHO are both physically in attendance. Further the second meeting could be held for 5 days with a possible need for a few days for a pre-meeting for the FAO experts. Shifting evaluations from new uses to an FAO-only meeting is expected to free up more time at the regular meeting for FAO reviewers. Based on the existing cost to hold the current JMPR meeting, this option would require an additional \$150,000 to fund FAO participants plus the staff considerations for both FAO and WHO. It is likely an additional \$200,000 would be needed to fund this option.

#### **3) Increase Capacity of JMPR to Add 1 or 2 More Experts and Review 1 or 2 More Chemicals**

14. As discussed, the current capacity for JMPR for full evaluation during the yearly meeting is approximately 10 substances. Reviewing an additional number of chemicals is not considered feasible within the 10 day time-frame of the meetings and with the current number of experts. However, extending the meeting for an additional few days may be possible if the FAO pre-meeting is shortened so experts are not away from their offices for longer than the current 3 weeks that FAO experts are away.

15. Is it possible to incorporate the use of electronic tools to do some of the work completed by FAO during the pre-meeting prior to the JMPR meeting? Could FAO use electronic tools to find agreement on metabolism issues, acceptable analytical methods, the residue definition and the impact on rotational crops for chemicals prior to the meeting by using electronic media such as conference calls or e-mail? It has been suggested that much of the evaluation/appraisal could be reviewed and approved in advance of the JMPR meeting via e-mails or use of a portal site where all documents are filed. This could be supplemented with regional, duplicative teleconferences (to accommodate time zone differences). If this could be done it is feasible to consider shortening the length of the pre-meeting by a few days to allow for additional time for the JMPR meeting to address 1 or 2 more chemicals.

16. The additional cost to increase the capacity of JMPR by adding 1 or 2 more experts and to review 1 or 2 additional chemicals would be considerably less than holding 2 full meetings a year. Based on the existing cost to hold the current JMPR meeting, FAO spends on average \$17,000 per person for the 15 day time-frame and WHO spends \$11,000 per person for the 10 day time-frame. Approximately an additional \$34,000 would be needed for FAO to fund 2 additional experts for 15 days. If the JMPR meeting were to meet for an additional two days, than WHO would need approximately \$28,000 to fund the current experts (assuming an additional \$2,000.00 per person per day) to extend their stay 2 extra days and an additional \$30,000 to fund participation of 2 additional experts. Approximately an additional \$100,000 would be needed to fund this idea. This alternative would likely be less resource demanding on staff support compared to the other options discussed.

#### **4) Organize A One Time Extra Meeting of JMPR**

17. It has been suggested that CCPR continue to follow the trend for the demand to evaluate more chemicals every year over a longer period of time before any changes are made to the current review process. However, considering the fact that capacity for review of new compounds has already been reached for 2012, 2013, and likely 2014 an extra-ordinary JMPR meeting could be organized over the period 2012-2014, provided the additional necessary resources are made available. This solution would also allow for more flexibility than the systematic organization of 2 annual JMPR meetings.

#### **Other Suggestions for Increasing Capacity**

18. It may not be feasible to easily find one solution which will allow JMPR to increase the number of chemicals reviewed in a given year. Budgetary and personal constraints may not be resolved quickly. Member States must consider if the needs of their growers outweigh the lack of capacity and determine if more money and experts can be made available to support the mission of the JMPR. In the meantime, there are some things that can be considered by the JMPR that may result in increased capacity without a large additional cost burden.

##### **1) Better Use of Electronic Tools**

19. Are there ways in which more work can be done using electronic media to reach agreement on the review of the ADI, metabolism issues, acceptable analytical methods, storage stability, the residue definition and the impact on rotational crops for chemicals prior to the meeting by using electronic media such as conference calls or e-mail? Even if the options discussed above are not implemented and the meeting remains as is it may be possible to review more than 10 substances a year if more work could be conducted prior to the meeting using electronic media.

##### **2) Consider Reliance on National Reviews**

20. An increasing number of the newer chemistries are reviewed by multiple national authorities at the same time as Global Joint Reviews. Therefore, there is greater collaboration and agreement between these national experts regarding the appropriate endpoints to use in risk assessment, the residue definition, the metabolites of concern and what is considered an acceptable analytical method. Given this international collaboration JMPR, to the extent possible, is relying on these reviews more when considering chemicals. Would having a discussion regarding the format of these international reviews be useful? Can a single format be used by OECD, JMPR and national governments that would help JMPR reviewers to better utilize national reviews? The use of reviews in which multiple national authorities have reached agreement on these issues may streamline the JMPR review process and allow for the review of a greater number of chemicals in a year.

##### **3) Rely on Data Extrapolation**

21. The CCPR has established an Electronic Working Group (EWG) for the Revision of the Codex Classification on Foods and Animal Feeds. This EWG has been identifying new commodities for the inclusion into the *Revision of the Codex Classification on Foods and Animal Feeds*. Also under consideration as part of this effort is the adoption of the *Principles and Guidance on the Selection of Representative Commodities for the Extrapolation of MRLs to Commodity Groups*. If the CCPR adopts these principles it will allow the JMPR to establish MRLs for crop groups and subgroups based on the review of data for representative commodities. This will allow for MRLs to be established on multiple commodities based on the extrapolation of residue field trial data for the representative commodity to other members of the crop group/subgroup. Relying on representative commodities to establish MRLs for multiple commodities will allow FAO to assess the pesticide exposure of a chemical on multiple commodities without having to review data for each commodity. This approach allows for the establishment of MRLs on many minor crops to facilitate trade while also ensuring a safe food supply. JMPR recognizes the importance of extrapolation to establish crop group MRLs (JMPR 2010 Report, General Item 2.4 and General Item 2.5).

### Conclusion

22. There has been an increased demand for JMPR to review new compounds. This increase in demand is indicative of the success of the process improvements that have been implemented in the past several years by the CCPR for the scheduling and review of chemicals by the JMPR, and the improved decision-making process in CCPR as related to the consideration of proposed MRLs. The work of the JMPR and CCPR serve an important role for the safety of the consumer, but also for the facilitation of world trade of food commodities.

23. Whether this is a permanent trend as many believe or requires further consideration before that determination can be made, there is an immediate need to address this issue in the short term since the review schedule for new chemicals is expected to be at capacity for 2012, 2013, and 2014 by the end of the 2012 43<sup>rd</sup> CCPR meeting. JMPR provided comments on some of the suggestions discussed in this document during the September, 2010 meeting. However, it would also be useful to ask that JMPR provide suggestions on how they propose this issue can be addressed. Further, it is unclear if FAO and WHO and Member States are willing to spend more resources on JMPR support, which leads to an almost unmanageable workload for the joint secretaries and involved staff. These resource constraints should be raised with FAO/WHO top management, perhaps at the CAC meeting, to determine if there is support of these proposals.