

codex alimentarius commission



FOOD AND AGRICULTURE
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Agenda Item 12

**CX/PR 02/14
March 2002**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON PESTICIDE RESIDUES

Thirty-fourth Session

The Hague, The Netherlands, 13 - 18 May 2002

OTHER BUSINESS AND FUTURE WORK: REVIEW OF THE WORKING PROCEDURES OF THE JOINT FAO/WHO MEETING ON PESTICIDE RESIDUES (JMPR)

Prepared by FAO and WHO

The Joint FAO/WHO Meeting on Pesticide Residues (JMPR) has, since its inception in 1963, updated on a regular basis the scientific principles and methods by which it assesses pesticides. However, its operating procedures and resources have remained static despite the huge increase in workload associated with the evaluation of pesticides today compared to forty years ago. As a consequence, JMPR has only limited capacity to fully serve the needs of the Codex Committee on Pesticide Residues (CCPR) or Member States, which adds to the already slow process of adopting Codex MRLs that may cause trade vulnerabilities. In recognition of this situation, the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) commissioned a report by a consultant, Mr S.J. Crossley, who was asked to perform a wide-ranging review and propose a strategy for redefining the current approach to the operation of the JMPR that includes proposals for addressing the constraints that exist. The report is available at the WHO web site,

<http://www.who.int/pcs/jmpr/jmpr.htm>,

or the FAO web site,

http://www.fao.org/ag/agp/agpp/pesticid/jmpr/pm_jmpr.htm.

Mr Crossley's report contains 29 recommendations to FAO, WHO, JMPR, and CCPR and a number of further options for consideration. The relevant recommendations are being considered by FAO and WHO and those directed to JMPR will be considered by the 2002 JMPR.

An executive summary of the report, Figures 1 and 2, and a consolidated list of recommendations are attached. The Thirty-fourth Session of CCPR is invited to address the relevant issues in the executive summary, including recommendations 3, 4, 6, 8, 9, 23, 24, 25, 26, 27, 28, and 29.

In responding to the report, it is extremely important that CCPR explains clearly what it expects to receive from the JMPR in view of the five options for the preparation of monographs outlined in the executive summary, i.e. use of national reviews of data, use of temporary advisers/resource experts, 'contracting out' of data reviews to scientific service companies, employment of full time FAO/WHO review staff and use of monographs written by sponsor companies. The use of national monographs or working jointly with regulatory authorities requires close coordination of schedules and priorities between CCPR and Member States (recommendation 24). FAO and WHO should be advised by governments through CCPR on how the whole process could be initiated. Such guidance from CCPR should include indications from countries on how to support and to cooperate, e.g. on a project basis, with FAO and WHO. Improving the timelines of JMPR evaluations has to be seen as a stepwise and long-term process, keeping in mind that any additional resources will need to be supplied by governments, and possibly industry (recommendation 9). CCPR also should suggest ways that additional resources could be made available for serving the needs of CCPR if it concludes that the work of JMPR continues to be essential.

EXECUTIVE SUMMARY OF CONSULTANT'S REPORT

BACKGROUND

The Joint Meeting on Pesticide Residues (JMPR) is an expert *ad hoc* body administered jointly by the Food and Agricultural Organization (FAO) and the World Health Organization (WHO). Although the JMPR is an independent body that can respond to requests for advice from a variety of sources, its primary function is in the provision of scientific advice to the Codex Committee on Pesticide Residues (CCPR). This advice relates to pesticide residues, including recommendations for Maximum Residue Limits (MRLs) and Acceptable Daily Intakes (ADIs).

Achievements of the JMPR

For over 40 years, the JMPR has consistently performed quality scientific assessments that are independent of national considerations with very few resources. In support of the work of the CCPR, approximately 200 pesticides have been evaluated and several thousand MRLs recommended. At the time of writing in February 2002, there were 94 published JMPR documents. The continuing dedication and integrity of the JMPR is internationally recognised and should be commended.

Demands and vulnerabilities of the JMPR

Since its inception in 1963, the demands on the JMPR have grown enormously. Whereas in the 1960s the JMPR monographs, which summarise the scientific data following a critical evaluation, were extremely brief in accordance with the standards of the time, the modern monographs are very detailed and extend to over one thousand pages for a particular Meeting. In addition, there has been a huge increase in the quantity of scientific data submitted for evaluation, and yet the JMPR only exists for two weeks of the year, in contrast to the situation at a national regulatory authority level. Furthermore, the JMPR now estimates a number of new end-points not previously considered, for example, the acute reference dose (acute RfD), the supervised trials median residue (STMR) and highest residue (HR), and also now publishes detailed dietary intake assessments. Despite these factors, the financial resources available for this work have not increased proportionally leading to the generation of a backlog of pesticides waiting for review.

The current JMPR system is also very vulnerable in that it relies on the goodwill of a limited number of individuals who work on a voluntary basis. These individuals, despite being internationally recognised in their fields, have to prepare the monographs without any financial reward and usually in their own personal time. Typically the Temporary Advisers of the WHO Core Assessment Group and Members of the FAO Panel have to spend the equivalent of 2-4 months full-time prior to the meeting preparing the monographs. The availability of suitable experts that are prepared to work on this basis is very limited.

Adoption of Codex MRLs and the Codex process

Despite the reference to Codex standards in the Sanitary and Phytosanitary (SPS) and Technical Barriers to Trade (TBT) Agreements, which formed part of the final act of the Uruguay round of the General Agreement on Tariffs and Trade (GATT), the level of acceptance of Codex MRLs remains low. Notably, the European Union (EU) and the United States of America (USA), although considering the presence of Codex MRLs in their establishment of national standards have not adopted the majority of Codex MRLs. This has led several sponsor companies and governments to question the value of the JMPR and the Codex MRL-setting system.

The periodic review procedure for re-assessing established pesticides (previously evaluated by the JMPR), has been successful. However, as the agenda of the JMPR has focussed more on periodic review chemicals, there has been a net loss of Codex MRLs. This has been due to the many recommendations for 'withdrawal' by the JMPR, on the basis that the existing CXLs (ie. MRLs that have been adopted by the CAC) have inadequate supporting scientific data by modern standards. A related problem has been the current lengthy JMPR/Codex MRL setting process. Typically, it takes up to eight years from the time that a pesticide is nominated for evaluation until the associated MRLs are adopted by the Codex Alimentarius

Commission (CAC). Whilst this is largely as a result of the lengthy Codex step procedure, the backlog of pesticides waiting for review by the JMPR also contributes significantly to this delay. These inefficiencies and the lack of reform in accordance with international requirements, has led some to question the appropriateness and value of the current Codex and JMPR process, despite the scientific judgements of the JMPR being well respected.

Critical review of the JMPR's working procedures

The considerable achievements of the JMPR in successfully performing quality scientific assessments over nearly 40 years are recognised. However, in the context of the background outlined above, a re-examination of the role of the JMPR is required to ensure that it complements other international activities as far as is practicable and is sufficiently responsive to the needs of the CCPR. Many changes to the working procedures of the JMPR have been implemented since its formation in 1963 taking into account scientific developments; this is particularly the case in the area of document preparation. However, the basic conditions of JMPR operation has not changed significantly and now appears unsustainable in its current form unless significant new resources become available. This has led to the commissioning of this report by the FAO and WHO.

CONSIDERATIONS

JMPR as an international peer review body

The current capacity of the JMPR is seriously limited by the pre-meeting preparatory time in writing the *global monographs* and *draft preliminary assessments*. It is proposed that the JMPR Members concentrate on undertaking international peer review of these *global monographs* and *preliminary assessments*, rather than being involved in this pre-meeting drafting. This would allow the JMPR to concentrate on producing an independent authoritative *final assessment* that would be published, as now, in the JMPR report. The *global monographs* and *draft preliminary assessments*, could be produced by one of five methods listed below in order of desirability.

- Option 1 – use of national reviews of data
- Option 2 – use of temporary advisers/resource experts
- Option 3 – ‘contracting out’ of data reviews to scientific service companies
- Option 4 – employment of full time FAO/WHO review staff
- Option 5 – use of monographs written by sponsor companies

The use of national reviews of data (option 1) by the JMPR would result in substantial pre-meeting time savings, while allowing the JMPR to concentrate on its own independent interpretation or ‘international risk assessment’. A quality assurance check, in which the national monographs would be cross-checked with a sample of the full study reports, would ensure the maintenance of accuracy and scientific quality. It is also recognised that some additional data evaluation of worldwide residue trials and Good Agricultural Practices (GAPs) would be required since these are not available in national or regional reviews. However, this additional evaluation could be added to the existing monograph and most of the residue chemistry data package eg. plant metabolism studies, are common to all data submissions.

The other options for the generation of the *global monographs* and *draft preliminary assessments* are explored further within the report. It is recommended though that monographs submitted by the sponsor (option 5) should not be used as the basis for the JMPR assessment, in the absence of the further development of substantial quality assurance criteria.

This “flexible international peer review model” for the future operation of the JMPR is outlined schematically in *Figure 1*. This model would retain the role of the JMPR as providing independent authoritative international assessments.

Number and nature of JMPR meetings

A further proposal to increase the capacity of the JMPR is to hold two meetings annually rather than the current single annual meeting. The success of this change would depend in part on the other changes to the working procedures of the JMPR. In particular, on whether the JMPR would concentrate on acting as an international peer review body, given that much of the current limit on the capacity of the meeting is associated with pre-meeting preparatory time. The removal of this preparatory work from the Members of the JMPR, may then allow JMPR Members to attend the Meetings, of up to two weeks each, at six month intervals. Given the need to ensure consistency and continuity in the work of the JMPR, it is recommended that where practicable each meeting is attended by the same Members, and that they consider both new and periodic review pesticides at each Meeting.

A possible timetable and consultative procedure, including this two annual meetings proposal, for the work of the JMPR, is presented in *Figure 2*. Other options, including that of inter-sessional work and the implementation of a pre-meeting, are also explored within the report.

Co-ordination with other international pesticide activities.

Whereas at the time of formation of the JMPR there was little or no international or regional co-ordination of pesticides registration and the associated scientific assessments, many governments are co-ordinating their pesticide regulatory activities at a regional trans-national level. In addition, countries of the Office of Economic Co-operation and Development (OECD), through the OECD Pesticide Working Group, have been working together since 1992 on harmonising regulatory approaches to registration, including detailed data requirements, risk assessment criteria and monograph guidelines for pesticides. Unfortunately though, this has led some of the participant government officials to question what ‘added value’ the JMPR offers.

An option for major reform of the JMPR, would be for the JMPR to work jointly with regulatory authorities on the preparation of monographs, rather than as an entirely separate international peer review body. For example, the JMPR could take an integral role in the trans-national pesticide review activities that are being undertaken in the EU and NAFTA region. However, ‘worksharing’ of this kind requires a high level of confidence and trust between the participating parties and would require the ongoing involvement of JMPR Members. The main drawback for the participation of the JMPR, would be that it may compromise the independence of its interpretation and recommendations.

It is, however, recommended that the JMPR should harmonise, as far as practicable, with other relevant internationally agreed protocols and guidelines, such as the dossier and monograph guidelines and assessment criteria that have been developed through the OECD Pesticide Working Group. In addition, it is recommended that the work on minimum residue data requirements, initiated by the European Commission and further developed by the OECD, should be finalised and formally proposed by one of these organisations to the CCPR for consideration by the JMPR. Furthermore, it is recommended that these minimum data requirements be implemented into the work of the JMPR wherever practicable.

Openness, transparency and the involvement of interested parties

The JMPR is perceived by some of those consulted as being like a “closed system” with little opportunity for governments or other interested parties to influence the broader *risk assessment policy*¹ in accordance with the Codex risk analysis paradigm. These issues need to be addressed to both facilitate the acceptance of the JMPR’s conclusions and to enhance public confidence.

For several years the JMPR has responded to calls for greater transparency by increasing the size of the monographs and reports. This has contributed to the current enormous demands on the time of the JMPR, since there is a trade-off between the size of monographs and output of the Meeting. However, it appears

¹ Risk assessment policy consists of the documented guidelines for scientific judgement and policy choices to be applied at appropriate decision points during risk assessment

that the calls from some of those consulted for “even greater transparency”, related not to the clarity and length of the current JMPR monographs and reports, but to the inability of these governments, through their delegates at the CCPR, to influence the *risk assessment policy* under which the JMPR works.

There have recently been further calls for the opening up of the work of the JMPR, including at the 33rd session of the CCPR. Three options for the further opening up of the work of the JMPR and enhancing the participation of interested parties are presented in this report, and are summarised below:

- Option 1 – allow the attendance of observers at the JMPR
- Option 2 – incorporation of an “interested party day” into the timetable of the JMPR
- Option 3 – consult with governments and other interested parties on a ‘preliminary assessment’, before finalisation by the next meeting of the JMPR.

In considering the best option, the commercial-in-confidence nature of the data that is evaluated needs to be taken into account. Each of the options would, to differing extents, reduce the perception that the JMPR process is a “closed system” and would ensure that all information and scientific perspectives on issues are considered by the JMPR. However, it should be recognised that some governments and other interested parties have not always taken full advantage of existing processes for the submission of information to the JMPR.

Funding of the JMPR

Given the serious resource constraints on the JMPR, sources of supplementary funding need to be further explored. National governments’ should make additional funds available to facilitate the work of the JMPR and to allow the implementation of the resource-dependent recommendations contained in this report. In the absence of significant additional national government funding, it is recommended that the FAO and WHO explore the possibility of securing additional funds from Crop Life International. These additional monetary resources would be placed into a trust account, administered by the JMPR secretariat, under conditions that would ensure the JMPR outcomes remained impartial. Although Crop Life International have expressed willingness to explore this option, it seems unlikely that these funds would be forthcoming unless the donors could be confident that an accelerated procedure would result. Other options for additional funding are explored in the report.

OTHER ISSUES

In addition to the considerations outlined above, this report also considers a number of other issues. Recommendations are presented for each of the issues listed below:

- Establishment of JMPR pre-meetings
- Geographical representation and expert capacity building
- Editing and timing of the JMPR monographs and report
- Appointment of an experienced peer reviewer for the FAO Panel
- Co-ordination between the FAO Panel and the WHO Core Assessment Group
- Dietary risk assessment
- Environmental fate and mammalian metabolism data
- Arrangements for interaction with sponsor companies
- Use of data submitted in an electronic format

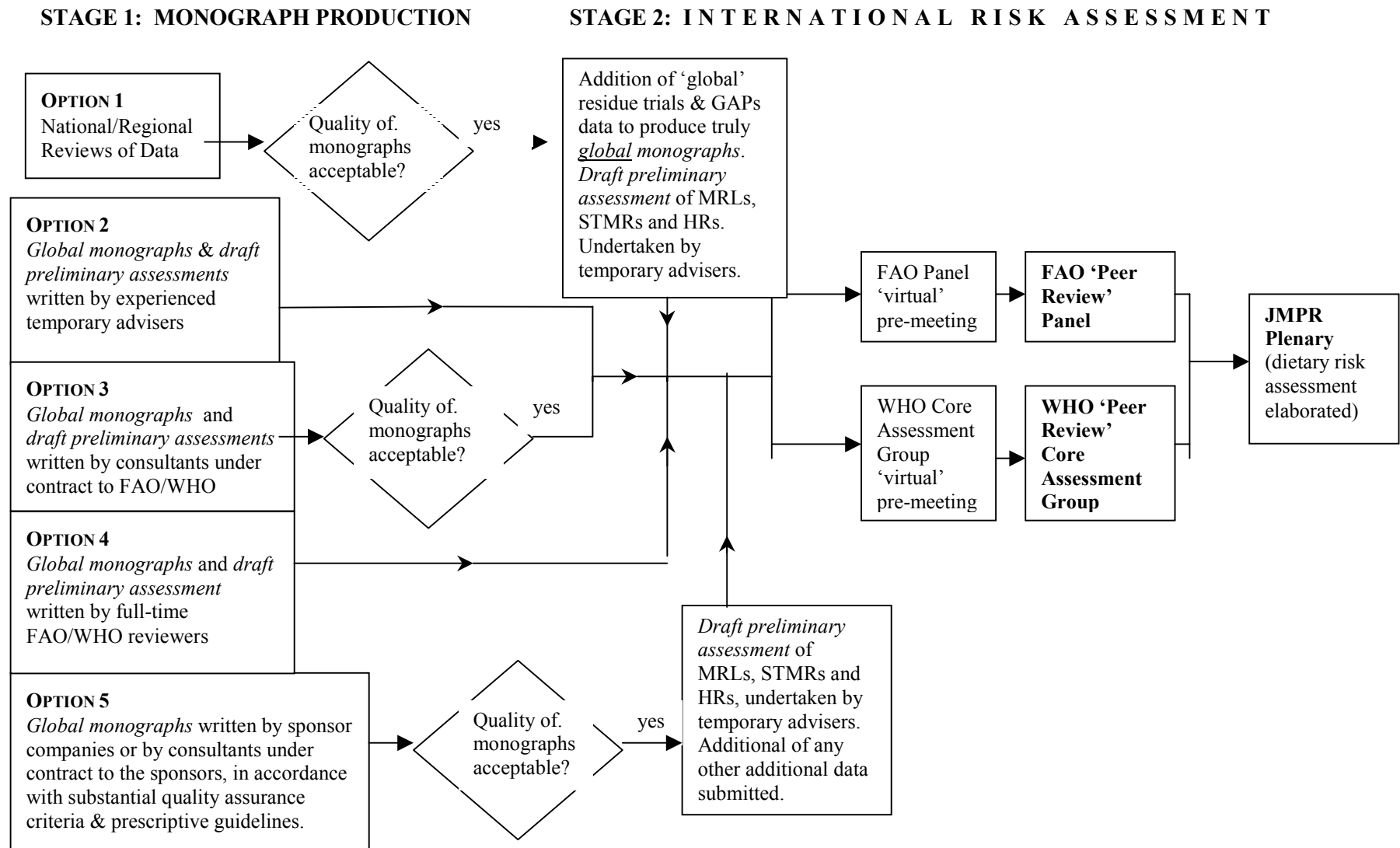
- Working language of the JMPR
- Naming in the monograph of the primary author
- Maintenance of the independence of the advice of the JMPR
- Submission of data to the JMPR
- Prioritisation of chemicals for the JMPR agenda
- Needs of developing countries
- Relationship between MRLs and GAP
- MRLs for both pesticides and veterinary drugs

CONCLUSION

There is clearly a need for an international body, that is substantially independent of national governments, to undertake quality science and evidence-based data assessments for standard setting bodies, such as the CCPR. For nearly 40 years the JMPR has successfully fulfilled this role; approximately 200 pesticides have been evaluated and several thousand MRLs recommended. However, the JMPR is currently under considerable strain, with inadequate resources and is arguably at a crossroads. To maintain its relevance and the support of governments and other interested parties, it needs to become more responsive to the needs of the CCPR. Some efficiency gains, within existing resources, could be made, by ensuring that the JMPR's work more effectively complements the pesticide assessment work that is being undertaken at the national and regional level. However, governments at the CCPR need to recognise that their full expectations will not be realised without additional financial and expert resources being made available.

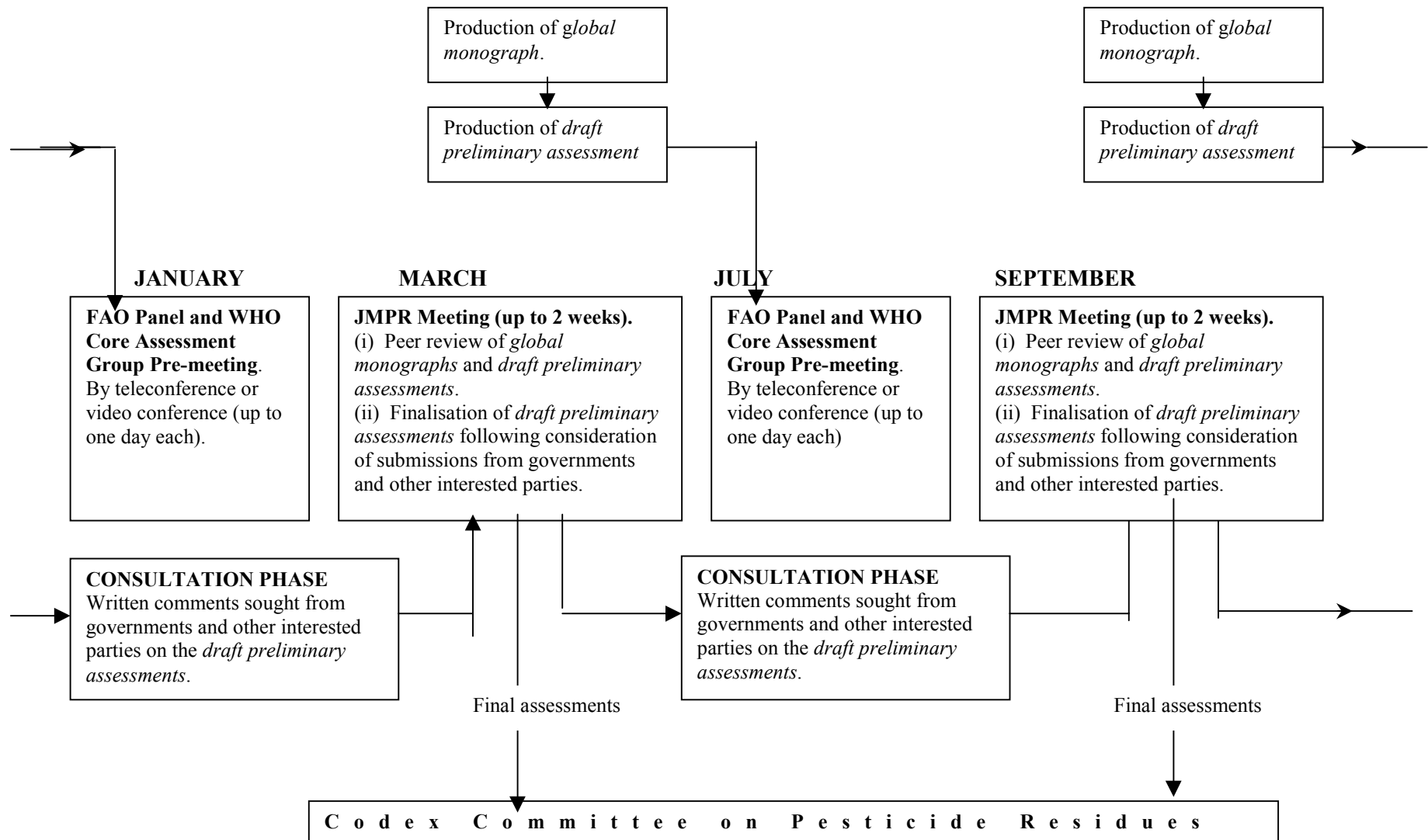
Figures 1 and 2 and a consolidated list of recommendations are attached.

Figure 1 - A possible flexible Jmpr “peer review” model for the future operation of the Jmpr



Note: In cases where the quality check indicates that the monographs are not of acceptable quality, then these would not be used. Where more minor inadequacies in the monographs are identified, then the monographs would be used after updating by a temporary adviser.

Figure 2 – Possible timetable and consultative procedure for the work of the JMPR



CONSOLIDATED LIST OF CONSULTANT'S RECOMMENDATIONS

[in the order they appear in the report]

1. That FAO and WHO consider paying the Temporary Advisers (otherwise known as resource experts) for their preparatory time prior to the meeting. Engaging the temporary advisor on a contract for 3-5 years should be investigated to ensure consistency and continuity.
2. That summaries of data (ie. monographs) submitted by the sponsor should not be used as the basis for the JMPR assessment in the absence of the further development of substantial quality assurance criteria.
3. That the “flexible international peer review model” for the future operation of the JMPR and associated options are put to the CCPR for their consideration.
4. That the minimum data requirements, initiated by the European Commission and further developed by the OECD, should be finalised and formally proposed by one of these organisations to the CCPR for consideration by the JMPR. That these minimum data requirements be implemented into the work of the JMPR wherever practicable.
5. That the JMPR further harmonise, as far as is practicable, with the dossier and monograph guidelines and assessment criteria that have been developed through the OECD Pesticide Working Group.
6. That a process be established to ensure a more comprehensive information exchange on *risk assessment policy* issues between the risk assessors (JMPR) and the risk managers (CCPR). The CCPR reports should explicitly state such policies in sufficient detail to ensure that the national governments and JMPR can apply them in their evaluations.
7. That the FAO and WHO further explore the practical considerations associated with undertaking some of the work of the JMPR on an inter-sessional basis.
8. That national governments’ make additional funds available to facilitate the work of the JMPR and to allow the implementation of the resource-dependent recommendations contained in this report.
9. That, in the absence of sufficient additional national government funding, the FAO and WHO explore the possibility of securing additional funds from Crop Life International, to be placed in a JMPR trust account, to allow the better resourcing of the JMPR.
10. That the FAO and WHO consider the introduction of a pre-meeting for the FAO Panel and the WHO Core Assessment Group respectively, to be held well before the JMPR. This would be conducted by telephone conference or by video-conference where facilities allow.
11. That in the consideration of attendees for technical expert committees, geographical representation should not be the primary overriding consideration. However, where a particular geographical region is consistently under-represented, then expert capacity building should be undertaken.
12. That the JMPR monographs no longer be edited allowing the CCPR to consider compounds one year earlier.
13. That if editing of the JMPR monographs is retained, and subject to resources, that a professional scientific editing company be engaged to undertake the publication of the JMPR monographs. The contract would include tight deadlines and penalties where these are not met.
14. That at least one experienced reviewer attends the FAO Panel meetings without review chemicals of their own, in order to provide an additional dedicated peer review role.

15. That the FAO Panel and the WHO Core Assessment Group consider compounds at the same meetings wherever possible. The identification of metabolites for the residue definitions, and the appropriateness of establishing an acute RfD, should be resolved prior to the JMPR by having a pre-meeting or by enhanced liaison between Members.
16. That additional expertise related to undertaking dietary intake assessments is brought into the JMPR.
17. That the FAO Panel of the JMPR only evaluate the environmental fate study reports, when it is directly required in the estimation of the maximum residue levels eg. in recommending MRLs for succeeding crops. That the mammalian metabolism data are only evaluated by the WHO Core Assessment Group.
18. That the JMPR should ensure that the best estimate of dietary intake, that is achievable at the international level with the available data, is agreed at the meeting. That the JMPR identify the uncertainties in the dietary intake assessment calculation and in particular identify those aspects that have led to an overestimate of dietary intake.
19. That there be increasing use of electronic means of submission of questions to the companies by the JMPR as and when the questions arise during the Meeting.
20. That the working language of the JMPR remains as English given the practical problems that would be associated with working with additional languages.
21. That the FAO Panel of the JMPR adopt the system in which the author of the first draft of the compound evaluation is attributed in the published monographs.
22. That the FAO and WHO consider making supplementary notes, or tape recordings, of the Panel and plenary discussions so that there is a supplementary record of involvement of Panel Members in the technical discussions. These notes, or tape recordings, would not be published, but would be available to the FAO and WHO in the future event of the integrity of an individual Panel member being questioned.
23. That national governments and other interested parties ensure that they submit all relevant data to the JMPR.
24. That there be better co-ordination between the JMPR timetables and that of national authorities undertaking significant data assessment and re-registration activity.
25. That the Joint Secretaries only accept technical questions (referrals) from the CCPR where these are clearly articulated and documented.
26. That the FAO/WHO consider initiating a questionnaire or consultants report specifically to investigate the needs of developing countries with respect to the JMPR and its written monographs and reports.
27. That the JMPR clearly document the GAP/GAPs on which the MRL is based in the appraisal. In situations where these defining GAPs are amended or removed at the national level, then this information should promptly be passed to the JMPR or the CCPR by the national government and/or sponsor company.
28. That the CCPR consider whether, once the capacity of the JMPR has been significantly enhanced, the JMPR evaluate some new compounds prior to the finalisation of national registration, consistent with the approach adopted for periodic review chemicals.
29. That the CCPR consider using a terminology other than 'MRL' for pesticides in the future, to enhance risk communication and to clearly differentiate between pesticide standards and those MRLs set by a different methodology for veterinary drugs.