codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

JOINT OFFICE: Viale delle Terme di Caracalla 00100 ROME Tel: 39 06 57051 www.codexalimentarius.net Email: codex@fao.org Facsimile: 39 06 5705 4593

Agenda Item 12 **CRD 3**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON PESTICIDE RESIDUES
Thirty-fourth Session
The Hague, The Netherlands, 13 - 18 May 2002

CONSULTANT'S REPORT: REVIEW OF THE WORKING PROCEDURES OF THE JOINT FAO/WHO MEETING ON PESTICIDE RESIDUES (JMPR)

UNITED STATES OF AMERICA

The US Delegation to the Codex Committee on Pesticide Residues (CCPR) congratulates the author of the subject report, Mr. Steve Crossley, for a comprehensive analysis of the JMPR issue and thanks him for having interviewed numerous US parties in the preparation of the document. The Delegation also commends the FAO and in particular the FAO Joint Secretary to the JMPR, Dr. Amelia Tejada, for the initiation of this most important project.

The US Delegation generally agrees with the recommendations of the report and wishes to offer comments and concerns on those recommendations (Annex 1 – Consolidated List of Recommendations).

The US notes that no recommendation was made from Section 6.7 of the Report: Openness, transparency and the involvement of interested parties. The US Delegation suggests that involvement by interested parties would strengthen the transparency and quality of the JMPR product by providing additional perspectives and strongly supports efforts to involve stakeholders in the JMPR process. Options, such as stakeholders' day and peer review, could be explored. Regardless of the mechanism(s) used to involve interested parties, great care must be taken (1) to avoid an unduly negative effect on the efficiency of the JMPR; (2) to maintain the integrity of the scientific deliberations of the expert panel; and (3) to protect the confidentiality of the data/studies provided by the manufacturers.

The following responses are numbered according to the scheme used in CX/PR 02/14. The reference in parenthesis refers to the full report.

1. ***Pay Temporary Advisers for a Fixed Contract Period for the Preparatory Time (6.2.2).***
Providing remuneration to the resource experts is one way of attracting and retaining additional competent experts. United States regulations prohibit Federal employees from accepting remuneration from external sources. Formal arrangements would be required between FAO/WHO and the US Government whereby the salaries would be given to the US Government. This option would have no net effect on the participation of US government personnel. It would not lead to additional personnel from the US Government being made available to the JMPR. The availability of Temporary Advisers from the US government is controlled by the

work priorities put upon a limited number of scientists, not by monetary considerations. Similar situations may exist for other national governments. However, this could be an excellent mechanism for obtaining the services of scientists from educational institutions and public scientific organizations, and independent consultants, such as former government and private industry individuals who have considerable expertise because of their prior employment.

2. ***Sponsor monographs should not be used as the basis for JMPR assessments in the absence of quality assurance criteria (6.2.5).***

The US concurs that monographs prepared by the sponsor cannot be used as the foundation of JMPR assessments and sees only a very limited use of the documents in the absence of a detailed validation. The time required to perform a proper validation might approach that required to do an independent review of the data submissions, as a detailed validation will require frequent reference to the original data sources. They may provide a general overview to the reviewer and may contain some extractable figures and summary tables.

Sponsor monographs could become the basis for JMPR deliberations if the monographs were carefully reviewed and validated by an independent source, such as temporary advisers. A JMPR panel member has informed the US Delegation that the quality of the sponsor monographs varies from excellent to worthless and that most fall in the middle. Data summary tables, GAP tables, and figures from the monographs often can be used by the reviewer, but they must be carefully checked against the original studies.

3. ***Flexible international peer review model (6.2.6).***

The flexible model envisions the use of national/regional reviews, sponsor-prepared monographs, and/or global monographs prepared by consultants or temporary advisers as the basis for JMPR deliberations. Consultants or temporary advisers would be needed to modify the national reviews to include worldwide residue trials and GAPs and to validate sponsor-prepared monographs.

The United States agrees with the concept of a flexible international peer review model and believes that the use of national/regional reviews and validated sponsor-prepared monographs could provide the foundation for most of the JMPR deliberations. The JMPR currently spends most of its valuable time redoing what has already been done at the national or regional levels. The outputs of the national governments or regional organizations should be utilized by the JMPR. These national/regional reviews can be augmented to include world-wide crop field trial data and registrations (labels). The original studies must be available to the JMPR, however, for reference in the event of questions or concerns.

The transition to the use of national/regional reviews and validated sponsor-prepared monographs should be carefully planned and possibly should start with a pilot project of one new and one periodic review compound. To be useful to JMPR the national/regional reviews must be in a standardized format, such as the OECD format, and must be sufficiently detailed as to permit the JMPR reviewer to reach an independent conclusion on the study without the need to refer frequently to the original study (raw data).

4. Minimum Data Requirements (6.4.2)

The Minimum Data Requirements developed by the EC and the OECD are incomplete in the areas of most need by the JMPR and cannot be used in their present form. For example, the OECD report specifies the minimum number of field trials required for a given commodity based upon the amount of consumption of that commodity and the importance of that commodity. However, neither of the factors (consumption, importance) have been defined quantitatively. Rudimentary crop groups and representative commodities were defined, but much remains to finalize the groups and to define translations among crops.

An OECD-sponsored workshop is currently crafting worldwide agricultural zones that can be used to gage the proper distribution of field trials and the equivalency of trials conducted in various areas. As currently proposed, the OECD zone maps are not compatible with the NAFTA agricultural zones, and this is or paramount concern to the US. Canada, Mexico, and the United States have invested years of effort in developing these zones based on climate, soil type, and crop types, and would suggest that OECD consider similar elements in developing its world-wide zones or incorporate the NAFTA zones into its scheme.

The US agrees that the JMPR should consider the implementation of the OECD Minimum Data Requirements, but those requirements first need to be fully developed and published in an official manner. Moreover, the US cautions that JMPR should use the information as a guideline only and not as an absolute requirement. Most of the data supplied to JMPR includes field trial data from only a few countries, and JMPR rarely has data that represent all the major growing regions for a particular crop. That is, JMPR does not receive field trial data for all the WHO diet groupings. The OECD Minimum Data Requirements should be useful to the JMPR in (1) determining the minimum number of trials required for a given commodity; (2) translating field trial data from one region to the GAP of a similar region (where GAP does not exist/was not provided for the trial region); and (3) translating field trial data to other crops. It should not be used to determine the proper distribution of field trials worldwide.

5. Harmonization with Dossier and Monograph Guidelines (6.4.3)

The US concurs with this recommendation for the monographs and notes that the US is implementing the standardized format with Canada for data review. The requirement for industry to use the dossier format may be an undue burden. Not all governments currently require this format, and requiring it for the JMPR may discourage US manufacturers from submitting studies to the JMPR. The use of standard formats would facilitate the use of national and regional reviews by the JMPR and should be encouraged, but not required at this time. Many elements of the dossier format may not be relevant to the JMPR, as that body does not rely upon the manufacturers' evaluations.

6. Comprehensive information exchange between risk assessors and risk managers (6.5).

Effective communication between assessors and managers is essential to provide coherent, credible risk analyses. As indicated in the Consultant's Report, JMPR sometimes appears to be operating on policies that some hold to be at odds with the wishes of CCPR. The CCPR has often been imprecise and/or cursory in its policy recommendations and questions to the JMPR. The US Delegation concurs that CCPR needs to be specific and detailed in its directives to JMPR. Otherwise, the JMPR uses its collective best judgment. The Delegation believes that it would be useful to establish an executive meeting between the CCPR and JMPR, where the decisions of CCPR could be carefully explained and where any differences and problems could be discussed. This meeting could be attended by the Chairman of the CCPR, the Joint Secretaries of the JMPR, and the chairs of the WHO and FAO JMPR panels well in advance of the JMPR.

The Consultant's Report indicates that JMPR currently pools "… GAP data from a variety of different GAPs to better reflect the world-wide use" and that such a policy can lead to an MRL based on one trial in each of five or more countries. The JMPR combines data from different GAPs only where the data are from similar uses and the residues are comparable. Thus, data from a postharvest dip treatment would not be combined with data from a foliar spray application. Likewise, data from foliar treatment in country X with residues from <0.1 – 3 mg/kg would not be combined with data from foliar treatment in country Y with residues ranging from 12 – 20 mg/kg. However, as the Report indicates, single data points from several countries might be pooled where the use patterns are generally similar and the values belong to the same population. This situation is of concern to some member countries, but the US considers this situation to be at least as reliable as basing an MRL estimate on 10 trials from one nation only. It must be remembered that the JMPR is not a regulatory authority, and it must deal with the data provided. It cannot request/require additional field trials.

The JMPR lacks explicit guidance on representative crops for crop groups and on the extrapolation of residue data from one crop to another. The US Delegation agrees that such guidance is needed, rather than the JMPR case-by-case approach, and suggests that the selection of representative crops and translations among crops might be tasked to the proposed commodity definition updating project.

7. *Inter-sessional work for JMPR (6.6.3)*

The US Delegation deems that inter-sessional work by the JMPR would place unreasonable demands upon individuals who are already more than adequately burdened by the workload of JMPR. Previous efforts were made to use a peer secondary review system before the Meetings, whereby members would review each

others assigned pesticide evaluations in advance of the Meeting. This system did not work, simply because members did not have the free time to review the work of other members. Certainly communications among members do occur between meetings, and these are encouraged. However, formal requirements for inter-sessional work are not reasonable, unless the workload is reduced by the addition of more personnel.

8. *Additional Funds for JMPR from National Governments (6.8.2).*

The US Delegation strongly supports this option, and notes that it currently provides significant supplementary funding to the WHO Panel of JMPR. Those options most likely to improve the JMPR and the overall MRL-setting process will require additional resources.

9. *Additional Funds from CropLife International (6.8.3).*

The members of CropLife International have a vested interest in supporting the promulgation of MRLs. The US supports the establishment of a JMPR trust fund to which CropLife International and other interested parties might contribute. Great care must be exercised to guarantee that there is no linkage between financial support and influence on the decisions of the JMPR and/or the prioritization of the pesticides for review. It must also be realized that such a fund would be at the mercy of the generosity of the interested parties. Neither Codex nor JMPR can establish mandatory contributions.

10. *JMPR Virtual Pre-Meeting (7.2)*

This concept has merit only if additional resources are provided to the JMPR. Otherwise, such a meeting merely adds to the burden of the current members.

11. *Geographical Representation on the JMPR and Expert Capacity Building* (7.3).

The FAO and WHO requirement that members must be from geographically diverse areas is obviously based on the desire to have representation from all segments of the world's population. Reality is that the expertise in pesticide regulation resides in several developed nations. The US believes that this rule should be relaxed to allow more than one member and an unlimited number of temporary advisers per country. The US proposes that the restriction should be that no more than 30% of each Panel's membership may be from any one country. Meanwhile, efforts should be launched to train competent scientists from developing nations to become members of the JMPR.

12 – 13. *Editing of the JMPR Monographs (7.4)*

Despite the best efforts of the Panel, technical errors do remain in the Monographs. While these errors generally do not alter the conclusions of the Report, they are a reflection upon the integrity of the JMPR and the entire Codex process and could potentially create problems for those who attempt to use the Monographs. The use of a professional scientific editing company that does not "delve into the technical and scientific issues" has little value. The world can live with less than perfect English, but the scientific and technical issues should be as correct as possible. The current editors have performed an invaluable service by unearthing discrepancies and technical errors prior to publication. Additional independent editors should be located or editing companies that will look for the technical and scientific problems should be employed, with strictly enforced deadlines.

14. *Peer Reviewer at JMPR* (7.5)

The US Delegation concurs.

***15. FAO and WHO Coordination (7.6*)**

Wherever practical, the toxicology and residue chemistry of a pesticide should be considered in the same year. The practice of considering toxicology one year before the chemistry is based on the premise that the FAO Panel must know the metabolites of toxicological concern and the necessity for an acute reference dose. Usually, this can be resolved before the Meeting by consultation between the respective WHO and FAO

reviewers. There are complicated cases, such as fipronil, where the WHO panel does not determine the metabolites of concern until late in the Session. Such complicated cases can often be identified in advance of the deliberations, and in such cases a staggered scheduling is appropriate.

16.Additional Expertise in Dietary Intake Assessment for the JMPR (7.7).

The development of dietary intake assessment policy by the introduction of additional experts in "food consumption, dietary modeling, uncertainty analysis, etc." is not a realistic proposal for a group that meets 2 weeks per year and is not supported by the US Delegation. The JMPR is preoccupied with the review of new and reevaluation pesticides and cannot give adequate time to the development of dietary intake procedures. International dietary risk assessment needs development in the areas of acute exposure and cumulative risk, and CCPR has recognized this need. The US supports policy development through CCPR and international independent consultations, such as the meetings that developed the current procedures used by JMPR for acute dietry risk assessment. These policies need to be developed in a forum with wider participation and expertise than JMPR and with focused tasks. Certainly JMPR panel members should be invited to participate in the consultations.

After the development of policy, the addition of appropriate new areas of expertise to the JMPR should be reconsidered. With policy guidance in place, new expertise might very well prove useful to the JMPR.

The US maintains that the need to introduce new expertise into the JMPR process is not limited to the dietary intake considerations. Experts in the various new aspects of toxicology, such as developmental neurotoxicology, should be considered for addition to the WHO Panel as advisors. Such experts for both the FAO and WHO panels should be sought in an open and transparent manner.

17. *Evaluation of Extraneous Data by JMPR (7.6)*

The US Delegation concurs with this recommendation. Only studies relevant to the estimation of MRLs and to dietary intake calculations should be evaluated. Environmental fate studies, with the exception of confined and field rotational crop studies, should not be evaluated. Manufacturers should be relieved from the requirement to submit environmental fate studies, with the exception of rotational crop studies. Likewise, only the WHO panel should consider lab animal metabolism in detail.

18. *Estimate of Dietary Intake by JMPR (7.7)*

The US Delegation certainly concurs that the JMPR should make the best possible estimates of dietary intake and indicate the uncertainties in the estimates. The JMPR is currently constrained in the chronic intake analysis by the use of "consumption" data based on agricultural production and lacking values for many important processed commodities. There is no information on real diets. Residue levels are based on STMRs from field trials. No use is made of residue monitoring data, primarily because the data is from one or two nations and certainly is not representative of all dietary regions. The situation is similar for the acute dietary intake considerations, where maximum field trial residues and maximum consumption values are used. The entire process needs reconsideration (see no. 16). To make use of the best available data, such as monitoring data and dietary consumption information, new methods of risk analysis need to be implemented and the consumption and monitoring data bases need to be expanded through new and increased efforts of national governments.

Given the constraints of the methods employed and the data available, the US Delegation believes that the JMPR is doing the best possible estimation of dietary intake. The methodology needs improvement.

19. *Increase Use of Electronic Means by the JMPR to Communicate with the Companies (7.9).*

The US Delegation concurs and understands that such media are currently being extensively used, both at the Meeting and by reviewers prior to the Meeting. The US Delegation further recommends that a mechanism be implemented to permit NGO's to submit electronically comments and/or data to the JMPR prior to the meeting. Perhaps this could be achieved through announcements on the FAO and WHO websites.

20. ***English as the working language of JMPR (7.11).***

The US concurs.

21. ***Acknowledgement of monograph authorship (7.12).***

Placing the primary authors name on the pesticide monographs is one small reward for the JMPR panel members and is important to those from an educational institution background. The US concurs, but sees this as a matter internal to the JMPR to be exercised as desired by the JMPR.

22. ***Detailed documentation of JMPR meetings (7.13.2).***

The US supports the use of recording devices at the JMPR. One of the most disturbing facets of the Vettorazzi issue was the lack of detailed documentation of the proceedings. Everything relied on the recollections of those present and on the official publications. Given modern technology, it is an easy matter to record the proceedings of the panel and plenary sessions. Such recordings should be maintained by the FAO and WHO as private files, not available to the public or to the panel members' employers. They would be referenced only in the event of an integrity issue. Supplementary written notes would be an archaic, time-consuming task, and they are unnecessary if electronic recordings are made.

23. ***Submission of All Relevant Data to JMPR (7.13.3)***

The JMPR lacks regulatory authority and can only request studies and data. The JMPR relies heavily upon the information submitted by the sponsor(s). Only one or two governments submit supplementary materials, and this is generally limited to label (GAP) information. A few developing countries have made efforts to provide additional data on field trials, but usually the submissions lack critical information and cannot be utilized. Both CCPR and the JMPR should work with developing countries to encourage and improve their submissions.

The US agrees that national governments and other interested parties, such as grower groups, be reminded and encouraged to submit supplemental data to the JMPR. They should use the FAO and WHO Guidance documents to ascertain the scope and depth of information required for a given topic. The US reminds CCPR that national governments are constrained in what they can provide the JMPR. For example, the US government can provide CCPR with the US review of field trial data on pesticide X, but it cannot provide the original studies. Thus, JMPR would be relying upon a national review.

The US maintains that the lack of worldwide data is not solely the fault of national governments and other interested parties. Manufacturers/sponsors have sometimes submitted only a partial database. While a manufacturer may have registrations in Europe, Australia, and the US, for example, they may submit field trial data from Europe only.

24. ***Coordination of JMPR and national timetables (8.1.1)***

The US supports improved coordination of JMPR and national timetables, specifically with reference to periodic reevaluations. While the US and other national/regional authorities can provide timetables of reregistration activities, those projections are often inaccurate with regard to the finalization of new labels (registrations). This creates the situation of JMPR reviewing field trial data for proposed labels. One possible manner to alleviate this situation is to schedule JMPR periodic reevaluations 2 – 3 years after the US or EC reregistration schedule completion dates. Those national authorities with reregistration programs should be requested to submit their schedules to the Priorities Working Group on an annual basis.

25. ***Referrals from CCPR to JMPR must be clearly articulated and documented (8.1.1)***

US Delegation has been informed by a member of the JMPR that the referrals from CCPR are sometimes very difficult to interpret, lacking both the specificity and background information to permit an intelligent response. Looking at recent Reports from the CCPR, the US Delegation must concur and suggests that more

diligence be exercised in the preparation of issues for the JMPR. Perhaps the Joint Secretaries of the JMPR, who are present at CCPR, could be tasked with note taking for the referrals.

26. ***Questionnaire or Consultants report to investigate the needs of developing countries with respect to the JMPR and its monographs and reports (8.2)***

As an initial effort, the US Delegation supports the development of a questionnaire from the CCPR to developing nations. Information should be solicited on what uses are currently made of the monographs and reports and what needs could potentially be met by the JMPR.

27. JMPR should clearly document the GAP/GAPs on which the MRL is based in the appraisal. *Pertinent changes in GAP should be promptly passed to JMPR or CCPR (8.3).*

The United States Delegation is of the opinion that the Appraisals usually clearly define the GAPs from which the residue data are derived and thus from which the STMRs and MRLs are derived. The Reports contain very detailed information and can be consulted in the event of uncertainty.

JMPR should be promptly informed of any changes in GAP for pesticides under consideration. Neither the companies nor the national governments, the US included, can be considered dependable in this matter. National governments are not tracking the sponsor submissions to JMPR and are not aware of possible GAP problems in those submissions. Companies must be relied upon to report the latest GAP information.

28. ***With increased capacity, the JMPR should evaluate some new compounds before finalization of the national registration (8.3)***

The US Delegation is opposed to the JMPR review of new compounds prior to a national registration under the current structuring of the Codex process. Some proposed national registrations never materialize, and CCPR could be confronted with proposed MRLs having no national registrations. Moreover, national registrations typically start with one or two major uses and are rapidly expanded to many uses after obtaining the first registration. Performance of a JMPR review early on in the national registration process could lead to Codex MRLs for only one or two of the commodities with national MRLs.

The national registration process for a new pesticide is a lengthy, iterative process, where studies are received and reviewed sequentially. A JMPR review before completion of the national registration would almost certainly exclude studies, some of which could be critical.

The US views introduction of a pesticide nomination into the Codex process before the completion of a national registration as a viable option only if JMPR were restructured into a nearly fulltime organization. JMPR personnel would be needed on a regular basis to interact with the national authority considering the registration. The US agrees that under this type of arrangement a Codex standard might be expected within 1 or 2 years of the national registration. However, it must be recognized that the JMPR would subsequently be burdened with additional studies for the same pesticide as new uses are added. The US reaffirms its position that, in the absence of an expanded JMPR with substantial new resources, the existence of a national registration should remain a requirement for nomination of a new pesticide for JMPR consideration.

29. ***CCPR should consider a terminology other than 'MRL' (8.4).***

Maximum Residue Limit (MRL) is a term well-understood by the member nations of the CCPR, although the public at-large may equate the value with the *maximum* safe dietary intake level. Use of a term such as "tolerance" will do nothing to change this misperception. In the US, many think of the tolerance value as the maximum amount that can be safely *tolerated* in the diet.

As to the different approaches used by JMPR and JECFA to arrive at MRLs, it is unlikely that the approaches can be harmonized. The current practice where there are both veterinary and food use MRL values is to defer to the higher MRL value (for animal commodities). Changing the name for the food use MRL will not alter the fact that there will be two values for chemicals used both as veterinary drugs and pesticides and that these two values should be harmonized. If a new name is selected for JMPR MRLs, then

there would need to be a policy of not setting values for animal commodities where veterinary drug uses exist, assuming that the JECFA will set MRLs.

CONSUMERS INTERNATIONAL

GENERAL COMMENTS

Consumers International welcomes the review of the working procedures of the Joint FAO/WHO Meeting on Pesticide Residues. As noted in CX/PR 02/14, the operating procedures and resources for the JMPR were developed in the early 1960's, and a review and update of those procedures is needed in order to keep pace with public expectations in the new millennium.

In our view, the most important issue for this review is ensuring that JMPR has the appropriate structures, resources and expertise to provide scientifically up to date, sound, unbiased risk assessment and scientific advice to CCPR. The consultant's report is largely focused on efficiency and other "quantity" issues and is largely silent on the key issues pertaining to scientific quality. Additional recommendations are needed to strengthen both the actual and the perceived transparency and quality of the advice provided to CCCPR.

Closely linked to the real and perceived scientific quality of JMPR products are issues relating to openness and transparency. While the report discusses these issues, no recommendations are provided. This is a serious omission, in our view; further consideration is needed to determine the most appropriate ways to make JMPR more open and transparent.

Also linked to quality issues is the need to ensure that the pool of experts represents a diversity of perspectives and disciplines, and that bias and possible conflicts of interest are managed properly.

Lessons Learned from CCFH and FAO/WHO

We note that the experiences of CCFH and FAO/WHO with regards to microbiological risk assessment and management provides CCPR/JMPR with an opportunity to see how another Codex group, one whose process has been developed since the adoption of a risk analysis approach by Codex, is tackling similar problems. Below are a few paragraphs from the last (34th) session of the CCFH that we believe contains some useful information relevant to the JMPR/CCPR experience:

> 67. The FAO and WHO Representatives outlined the lessons learned to date, including the need to take a multidisciplinary approach to risk assessment; the importance of clearly defining the scope of a risk assessment; the need for interaction between the risk assessors and the risk managers; the difficulty in generating global risk estimates; the possibility of generating risk assessment tools that can be used in the evaluation of risk management options; and, the identification of data gaps and research areas.
>
> 68. The Committee agreed that there was a need to clearly define the Scope of risk assessment through the development of risk profiles, to provide for interaction between risk assessors and risk managers, and to consider how the risk assessments could be used in the risk management activities of the Committee, and agreed to establish drafting groups as appropriate, and to consider the issue further (see also paras 73, 77, 78, 97). Some delegations mentioned that it was not always necessary to have a full risk assessment before risk management actions are taken

We believe that all of these "lessons learned" in the CCFH/microbiological risk context equally apply in the CCPR/JMPR/pesticides risk context, and if followed could greatly improve the quality of the process. The issue of needing to take a multidisciplinary approach to risk assessment, for example, is not really addressed by the Consultant's report. Ensuring that JMPR has the proper blend and balance of expertise to respond to CCPR's needs is a critical issue that should be a top priority for discussion. In addition, we believe that clearly defining the scope of risk assessment and the need for interaction between the risk assessors and the risk managers is important in the pesticide context as well as the microbiological context.

Add Recommendations to Address Openness, Transparency, and Involvement of Interested Parties

Section 6.7 of the report discusses some of the issues regarding openness, transparency, and the involvement of interested parties, and discusses several possible
options to address the problems. Option 1 is to allow observers at JMPR, option 2 is to incorporate an "interested parties day" into JMPR's timetable, and option 3 is to consult with governments and other

interested parties on a preliminary assessment. Yet no recommendations are made to address the issue, and the discussion does not give a very complete picture of how these issues could be addressed. These issues are fundamental to improving both the quality of the scientific advice to CCPR and the credibility, trust, and acceptance of that advice. We are very concerned that the problem and any potential solutions will be overlooked without a fuller discussion and a corresponding recommendation(s).

Furthermore, the different options need a more expanded discussion. Regarding option 1, allowing the attendance of observers, there are several sub-options: (a) that the observers would be non-participatory ("sit and listen"), or (b) that there would be an opportunity for observers to participate, as observers do at many other expert meetings sponsored by FAO/WHO, to cite just one example. The option as currently written is limited to sub option (a) and should be expanded to cover both options. It also may give some readers the misimpression that the US National Academy of Sciences and the UK use non-participatory observers in their development of scientific advice (this is not the case). Also, who gets to be an observer, and how they would be selected, has not been discussed. How many observers would be permitted? All of this needs further consideration.

In at least two models with which we are extensively familiar, individuals from consumer organizations, other "public interest" NGOs, and sometimes industry and other stakeholders, participate actively in the process, both as full-fledged members of the deliberative bodies, and as active observers (i.e. it is much more than "sit and
listen"). In addition, open meetings, workshops and informational sessions are held at which a wide range of scientific expertise and perspectives, beyond that available in the members of the committee itself, is brought into the process, enriching the information and expertise available. We think both of these mechanisms are viable for JMPR and should be seriously considered. These approaches would not only make the process more transparent and help interested parties to know what is going on, it would also expand the resources and expertise available to JMPR and help to strengthen the scientific quality of the work. It would be an excellent way to tap into expertise not represented on the committee itself and to get more diverse scientific perspectives on the evidence.

For example, in the recently published Food Standards Agency's review of scientific committees in the United Kingdom (see http://www.food.gov.uk/news/newsarchive/58746), paragraph 33 states:

> We endorse the conclusion in the Phillips Report that lay members can play a valuable role on expert committees. Non-specialists2 perform a vital function in providing a different perspective by, among other roles, challenging assumptions and ensuring that the committee's considerations meet the needs of, and are expressed in terms that can be understood by, consumers generally. We therefore welcome the fact that all of the committees that are the subject of this Review already include consumer experts and/or non-specialist members among their membership. To strengthen the current position, we recommend that each advisory committee should have at least two non-specialist members. Wherever possible at least one of these should have a background in consumer affairs.

Besides this recommendation for a non-specialist member with a background in consumer affairs, there are other recommendations related to training, support, and expectations for non-specialist and specialist members.

In at least some countries, a public hearing is held during the deliberations of expert committees, whereby the public (observers) listen to all or most the deliberations, and then a limited time for a public hearing is allowed. This would seem to be a combination of option 1(a) and 2, and be preferable to either option 1 or option 2.

Another consideration for whatever option or combination of options is selected is the ability of the option to enhance risk communication, the interactive exchange of information and opinions throughout the risk analysis process, as defined by Codex. As currently formulated, options 1 and 3 do not permit an interactive exchange, and so this would be a downside to those options.

We therefore urge that the following recommendation be added after recommendation 7:

> "That FAO and WHO commit to increasing openness, transparency, and the involvement of interested parties in JMPR, for example by opening the meeting to consumer representatives and/or other NGO observers, allowing for a "stakeholders day" at JMPR, and/or developing a consultation procedure."

Add Recommendations to Address Conflicts of Interest, Bias, and Influence

FAO and WHO have taken steps to address possible conflicts of interest, and this is to be commended. However, issues of bias and influence are not sufficiently addressed by these measures. Transparency also includes eliminating or at least revealing any biases and/or influences that impact the scientific assessment. Bias should be eliminated or minimized, and any introduced biases should be clearly identified. Ensuring a balance of perspectives and viewpoints amongst participants can also minimize bias. And, all assumptions used and the scientific rationale and data used to estimate the impact of the various factors influencing risks must be clearly stated. With regards to influence, the reports of JMPR should list all the individuals and organizations that submitted data, oral testimony, written comments or other information, and briefly describe the content of the submissions.

The National Academy of Sciences, to cite one example, requires its committee members fill out a form on "Potential sources of bias," and it explicitly asks for strongly held views and positions related to the issues the panel will study. This approach seems to work very well and elicits the right kind of responses. At the initial meeting, panel participants disclose both their financial interests and their stances on issues. After these discussions, the committee and staff discuss whether the panel has the right balance and sometimes they will agree that either additional expertise or people with another perspective are needed. We believe a similar approach should be considered for JMPR.

With regard to conflict of interest, it is common sense that scientists with conflicts of interest may attempt to conceal their conflict of interest. This was apparently the case with Dr. Vettorazzi. Individuals with conflicts of interest should not be permitted to participate, but some scientists may not be forthright about whether they have a conflict of interest or not. Making the declarations public (e.g., posting on a website) would increase the likelihood of discovery of a false disclosure, thus possibly discouraging such attempts, and would also foster greater public confidence.

We therefore believe that an additional recommendation should be added to the list:

> "That a declaration of expertise, potential conflicts of interest, and potential sources of bias be completed by each expert and that such declarations be made public."

Comments on Specific Recommendations

RECOMMENDATION 1: CONTRACT TEMPORARY ADVISERS

Consumers International does not object to paying Temporary Advisors for preparation of materials prior to the meeting, under certain conditions. In our view, adequate measures should be put in place to ensure that Temporary Advisors reveal their biases, and they should not be permitted to receive a profit from a third party, whether concurrently, prospectively, or retroactively, because of their work as a Temporary Advisor. However, we are concerned that relying too heavily on temporary advisers means too much of the work is done by someone with a comparatively narrow, one-discipline background and outlook; a process that fosters breadth of scientific inputs and interaction among multiple disciplines is needed.

RECOMMENDATION 2: DO NOT BASE JMPR ASSESSMENTS ON SPONSOR SUMMARIES

Consumers International agrees that summaries of data 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. In fact, we would further state that summaries of data submitted by the industry should never be used as the basis for a JMPR assessment or any independent assessment.

Recommendation 3: Use a flexible international peer review model in the future

This recommendation envisions JMPR as a peer review body which would review data and preliminary assessments generated by countries/regions, temporary advisors, consultants, full-time FAO/WHO reviewers, and/or sponsor companies or their consultants.

The issue of peer review is key. Currently, JMPR is not a peer review body, and its work is not peer reviewed. If something like the current system is used, we believe that JMPR conclusions and recommendations should be subject to peer review, just as are those of other expert bodies (e.g., the Royal Society in the UK, or the National Academy in the US). A peer review would enhance both the quality and the acceptance of JMPR results. The draft JMPR report should be circulated to some sel ected disinterested peer reviewers, to vet its scientific soundness. While it is true that JMPR does not do original research, but rather reviews work done by others, we do not agree with the idea that JMPR is itself a "peer review body" and therefore that its reports don't need review. JMPR and other similar expert bodies do come up with their own original findings--a synthesis of all the evidence they have reviewed and their own conclusions and recommendations, which represent the views of the JMPR experts--not those of the authors of the literature and data they reviewed. This product is a new scientific synthesis (with policy elements) and it should be reviewed.

Again, this concept has been raised in the CCFH context and the need for peer review has been accepted, at least in principle, in that Committee. The report from the last session of CCFH states, under discussion of the document, "PROPOSED DRAFT PRINCIPLES AND GUIDELINES FOR THE CONDUCT OF MICROBIOLOGICAL RISK MANAGEMENT":

Section 5.1.7 – Consideration of the Process and the Results of the Microbiological Risk Assessment

> 114. The Committee agreed in principle that the Guidelines needed to be examined, in particular at Section 5.1.5, to afford the opportunity for risk managers to resolve differences in risk assessments through a peer review process and in this regard, the Committee emphasized that this Section should be consistent with the Principles and Guidelines for the conduct of Microbiological Risk Assessment. The Committee therefore modified the 4th bullet of this section to indicate, “The risk assessment should be subject to a peer review. Any possible differences in the conclusions should be solved by the risk managers, with input from the risk assessors and stakeholders as appropriate” and left the text in square brackets.

Peer review is the sine qua non for assuring quality in science, and both peer and public review of JMPR's work products is essential for transparency and credibility, as well as soundness. The extra work and time required for a review process is offset
by the increased quality and the improved confidence in the soundness of the work.

If JMPR were to be restructured to become a peer review body that reviews MRLs and ADIs prepared by Temporary Advisers, consultants, national/regional bodies, or full-time FAO/WHO reviewers, this would require a complete restructuring of how JMPR currently operates. There would undoubtedly be a transition period where new roles and modes of operation were further developed and clarified, which might adversely impact the work of the JMPR. Presumably, a variety of MRL, ADI, and related estimates would be reviewed, and a process with specific criteria developed to assess the merits of the various proposals. Greater attention would be needed as to how those preparing draft proposed MRLs and ADIs would be identified, and how they would operate.

Consumers International is concerned that the system as described would not increase the scientific quality of the results. We believe that something significant would be lost in moving from an analysis performed by an expert panel to one performed primarily by an individual and then reviewed by an expert panel. An individual (consultant or technical advisor), no matter how competent and objective, has a relatively narrow disciplinary training and expertise, and a relatively narrow perspective and set of biases, compared to a multi-disciplinary, multi-perspective group of experts. We believe that a multidisciplinary and diverse group of experts with an opportunity for interaction can produce a better quality, better-balanced assessment of the evidence and its limitations than an individual. More diversity and more interaction are needed, not less. Both a multidisciplinary group and a peer review process are needed.

<u>Recommendation 5: Harmonize with OECD Data Guidelines and Assessment Criteria</u>

(no comment)

Recommendation 6: More Interaction between Risk Assessors and Risk Managers on Risk Assessment Policies

With regards to the specific recommendations in the Consultants report, we strongly agree with recommendation 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). In fact, we believe that this recommendation needs to go further, beyond information exchange; CCPR (with input from JMPR) needs to first identify what risk assessment policies need to be developed, then CCPR needs to develop them, using a process that allows an interactive exchange of information and opinions, and finally, a process for continued interactive exchange between risk assessors and risk managers and stakeholders needs to be developed. Effective communication between assessors and managers is essential to provide coherent, credible risk analyses.

CCFH has approached the same issue by forming "drafting groups" (open to any on the committee) to serve as a liaison between the risk assessors and risk managers, providing a forum where problems or questions that risk assessors may have can be discussed and risk management direction provided. While these drafting groups have just been established, and how well they will work is not yet known, we believe they provide a useful model and represent the first attempt that we are aware of in Codex to provide for better interaction and communication between risk assessors and risk managers.

Another recommendation to enhance risk communication and transparency would be to include a risk communication expert at the expert meetings, to help the risk assessment experts sort out where they need to be more explicit/clear about uncertainties in the science and the assumptions they are making.

Recommendation 7: Undertake Work Between Sessions
(no comment)

Recommendation 8: Governments Provide Additional Funds

Consumers International recognizes that additional funds are necessary to improve the scientific basis of Codex standard and supports this recommendation.

Recommendation 9: Pesticide Industry Provide Additional Funds

Should this recommendation be adopted, Consumers International cautions that clear “no strings attached” procedures must be in place to ensure that the industry can not influence which chemicals are reviewed by JMPR, which individuals are involved in the review, the review process, or the outcome of the review. We are very concerned that inappropriate influence in the work of JMPR could result. The procedures for such a funding mechanism would need to be developed in a clear and transparent manner and in a deliberative manner involving CCPR and/or the Commission to ensure the absence of any real or perceived improper influence. The Commission is grappling with similar issues as the FAO and WHO explore the establishment of a Trust Fund for developing country participation and this may be a useful model.

Recommendation 10: Hold Electronic Pre-Meeting
(no comment)

Recommendation 11: Flexibility for Geographical Representation

While some flexibility can be considered, Consumers International believes that geographical representation should continue to be a criterion that is considered in selecting JMPR participants. Surely experts can be found in different geographic regions of the world. CI does support the notion that expert capacity building be undertaken in regions where experts are scarce.

Recommendation 12-13: Editing of JMPR monographs

To the extent that editing corrects errors and improves the understanding of the text, Consumers International believes it should be retained. However, Consumers International believes that it is likely, given that the editor has been correcting scientific errors, that there may also be deeper errors, such as in the way questions are posed or the limited ways in which they are often answered, which requires a critical peer review process to address.

Recommendation 14: One reviewer Dedicated to Peer Review Role

While one would be better than none, having one person present at JMPR is not an adequate approach to peer review, in our view.

Recommendation 15: FAO and WHO Panels consider Same Compound
(no comment)

Recommendation 16: Additional Expertise

We strongly support recommendation 16, that additional expertise related to undertaking dietary intake assessments be brought into JMPR, and believe the recommendation needs to be expanded to ensure a more multidisciplinary approach and to provide a better balance in expertise and perspectives of scientists. As stressed earlier, however, the issue is much more fundamental: ensuring the appropriate expertise to do a scientifically up to date, sound, unbiased risk assessment is the primary, fundamental need for JMPR. Improving the basis for dietary intake assessments is just one small piece of the puzzle. It should be noted that risk assessment of pesticides in the 21st century requires expertise in several areas of toxicology that a decade ago did not exist, at least in the form recognized today: including neurodevelopmental toxicity, endocrine disruption, immunotoxicity, integration of effects of multiple residues with a common mechanism of toxic action, etc. There are not very many experts in emerging sub-disciplines available in the scientific community to begin with, and there is no mechanism for ensuring that their expertise is made available as needed for the work of JMPR. A special effort is required to obtain expertise from some of these emerging disciplines.

Recommendation 17: Limit Data Reviewed

This recommendation is for the FAO Panel of JMPR to only evaluate the environmental fate study reports when it is directly required to be able to recommend MRLs. Consumers International believes that environmental fate study reports should be evaluated whenever there is a concern that the pesticide's environmental fate could indirectly impact public and environmental health.

Recommendation 18: Agree on Best Estimate of Dietary Intake, and Identify Uncertainties, Particularly those that lead to an Overestimate of Intake

Where possible, JMPR should estimate dietary intake, although in some cases the data may be insufficient to do so. Such cases should be clearly indicated and data gaps identified. Consumers International agrees that uncertainties should be identified; however, we strongly disagree that there should be more emphasis on uncertainties leading to an overestimate of intake. The goal should be on producing an unbiased estimate that clearly identifies all the uncertainties and their impacts on the estimate of risk. Any overt bias (e.g., in the form of default assumptions) should, in the view of Consumers International, err in the direction of protecting health, given the objective of Codex standards to protect the health of the consumers. This should be addressed in risk assessment policy.

Recommendation 19: Increase Use of Electronic Means to Contact Industry

Consumers International favors increased use of electronic means to increase participation by all those with information and comments to contribute. We recommend that electronic communications permit two-way communications, so that any interested parties can submit comments/information electronically. The recommendation should not be limited to only one stakeholder.

Recommendation 20: Keep Working Language in English

(no comment)

Recommendation 21: Identify Authors of Monographs

We agree.

Recommendation 22: Record Discussions

Consumers International agrees that recordings and documentation should be kept. This is needed to investigate allegations of improper conduct, like the matter with Dr. Vettorazzi.

Recommendation 23: Submit All Data

We agree; all efforts should be made to encourage manufacturers and countries to submit all relevant data.

Recommendation 24: Coordinate JMPR and Country Timetables

(no comment)

Recommendation 25: Joint Secretaries Only Accept Documented and Clearly Articulated Referrals from CCPR

Rather than not accepting referrals that are unclear, there should be an opportunity for interaction between risk assessors (JMPR) and risk managers (CCPR) to clarify requests for scientific advice. This relates to our comments under recommendation 6.

Recommendation 26: Investigate Needs of Developing Countries Re: JMPR

We agree.

Recommendation 27: Document GAP and Communicate Changes In GAP
We agree.

Recommendation 28: Evaluate New Compounds Prior to Finalization of National Registration
Consumers International is concerned that this recommendation could slow down the process, since compounds sometimes do not get registered. If there were no national registrations, it would be a waste of time for JMPR to review the compound. However, in cases where a new compound offers significant advantages from a consumer health perspective compared to an existing compound, it might be worth taking this risk, in the interest of consumer protection.

Recommendation 29: Rename MRLs
We do not see any advantages at present to this recommendation.

We also wish to point out that the submission made in Annex 12 by Dr. Edward Groth was not made on behalf of Consumers International. While Dr. Groth has been actively involved in Codex and is certainly very familiar with positions taken by Consumers International, he was speaking on his own behalf, as Senior Scientist, Technology and Public Policy, with Consumers Union, a consumer organization that is a member of Consumers International.

WHO/FAO

A request by the Codex Committee on Pesticide Residues (CCPR) and member governments to speed up the evaluation process by the JMPR led to the commissioning of a critical review of the working procedures of the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO). The Consultant conducted interviews with grower/consumer associations, industries, international organizations and national governments from the US, the EU and Australia on their views of the current JMPR/CCPR process. The consultant's report

proposes a range of strategies for redefining the current approach to the operation of the JMPR in response to the changing needs of the CCPR and member governments. These comments are referring to CX PR 02/14.

The JMPR has a limited capacity to fully serve the needs of the CCPR and member governments as a result of the increasing complexities and modern data submissions on pesticide residues. This adds to the already slow process for establishing Codex MRLs, which may lead potential problems in trade. Action by FAO and WHO in response to the recommendations will depend upon clear feedback from CCPR on what is expected from JMPR and on the level of resources that are made available for its work. If CCPR considers the work of JMPR to be critical to the establishment of international standards, additional resources and support from governments, and possibly industry, will be required. While gains in efficiency are necessary, they will not obviate the need for increased resources if JMPR is to continue evaluating pesticides in a credible manner at an increased pace.

The report confirms the 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 CCPR .

Most of the options for major reforms recommended by the consultant (Annex 1 of the consultant's report) would require additional resources.

A. Major reforms in the production of preliminary assessments

The consultant proposed five options for the production of global monographs and draft preliminary assessments which may have the potential to increase the efficiency of the JMPR. Options 1 and 2 are the most feasible for the near term, and the benefits and risks of option 3 could be considered for the longer term.

- Option 1. Use of national reviews

Response: WHO has been making use of national reviews in its toxicological assessments for several years. One problem with the use of national reviews for residues assessments is that they do not cover worldwide good agriculture practices (GAPs), which JMPR must consider. However, a pilot project on worksharing has been initiated by FAO, WHO, OECD and national governments, which divides the work among two or more reviewers in national, regional or international organizations, each referring to the other's evaluation in its review. One of the goals of worksharing is globalization of pesticide reviews. However, the technical, scientific, and political conditions would have to be elaborated before worksharing could be accepted on a routine basis by JMPR.

- Option 2. Use of temporary advisers/resource experts for the preparation of working papers and monographs, which would give the members more time to concentrate on the peer review and risk assessment process.

Response: This procedure has been used by WHO for many years; extrabudgetary funds raised by the International Programme on Chemical Safety (IPCS) are used for this purpose. This procedure could also be adopted by the FAO, which would necessitate substantial quality assurance and the raising of additional funds.

- Option 3. ‘Contracting out’ of data reviews to scientific service companies

Response: This option is similar to option 2, with additional compensation and a formal contract with the evaluator. This option would require substantial quality assurance criteria and significant new resources.

- Option 4. Employment of full-time FAO/WHO review staff

Response: This option would give the parent organizations much more control over the preparation, timing, and editing of working papers and monographs, but would require a huge increase in resources.

- Option 5. Use of monographs written by sponsor companies

Response: FAO/WHO believe that reliance on global monographs produced solely by sponsor companies could undermine the credibility of the work of the JMPR, unless substantial quality assurance criteria and prescriptive guidance were developed.

When considering these options, it should be kept in mind that CCPR and Member States now have the opportunity to comment on the evaluations and to request re-evaluations of pesticides when significant information that has not been considered by JMPR is available. FAO and WHO see potential problems with the attendance of observers for a number of reasons, including the problem of controlling access to unpublished confidential data; without careful control of the number of observers, they could easily overwhelm the small number of members in attendance who make the decisions.

B. Data requirements

Recommendation 2: That summaries of data (i.e. 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.

Response: FAO and WHO agree that such summaries should not be used as the sole basis for the evaluation by the Panel members. Although JMPR evaluations are based on the full study reports, summaries provided by sponsors are helpful to the authors when preparing their working papers. When comparing company summaries with the study reports, it is usually clear when discrepancies arise, which is useful for quality control.
To be successful, the JMPR process requires participants to have a full and detailed understanding of the underlying data they have reviewed**.**

Recommendation 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.

Response: The JMPR has been actively involved in the OECD projects on pesticide residues and looks forward to publication of the final OECD Minimum Data Requirements for Establishing Maximum Residue Limits to facilitate worksharing
Recommendation 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.

Response: FAO and OECD are considering a proposal for a pilot project on worksharing of residue data and also on harmonizing the format for data submission for OECD and JMPR. WHO encourages the use of OECD formats for the preparation of toxicological monographs. FAO has developed its own Manual (FAO Plant Production and Protection Paper 167) format for the residue dossier which includes in Appendix 7 references to the relevant OECD dossier numbers.

Recommendation 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 e.g. in recommending MRLs for succeeding crops. That the mammalian metabolism data are only evaluated by the WHO Core Assessment Group.

Response: The assessment of environmental fate was a CCPR initiative in the late 1980s when environmental safety was brought back into the definition of GAP.

Recommendation 23: That national governments and other interested parties ensure that they submit all relevant data to the JMPR.

Response:

FAO and WHO agree that further efforts should be put into ensuring that all available relevant residue and toxicological data are provided. During the last years the number of countries providing such information to FAO and WHO has become less and less. WHO performs literature searches to identify relevant published information, and participants who are employed by regulatory agencies sometimes identify reports submitted to their agencies that were not submitted for review by JMPR. Sponsors and governments have the responsibility to provide all relevant data to JMPR for review.

C. Dietary intake and risk assessment

Recommendation 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.

Response: FAO and WHO agree that it is important that CCPR and JMPR should work together on defining risk assessment policy and that JMPR should include enough detail in its reports and evaluations so that the basis for risk assessment is clear.

Recommendation 16: That additional expertise related to undertaking dietary intake assessments is brought into the JMPR.

Response: FAO and WHO agree that further efforts must go into dietary intake assessments, which will require additional expertise and resources.

Recommendation 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.

Response: FAO and WHO will be further developing procedures for the assessment of intake in its *Project to update principles and methods for the safety assessment of chemicals in food*. This will provide a good opportunity to review recent advances, particularly in the area of probabilistic modelling, and to identify uncertainties and overestimates of dietary intake. The effects of processing on residue levels in food as consumed will also be considered.

D. Need for and identification of additional resources

Recommendation 1: FAO and WHO should consider paying the Temporary Advisers (otherwise known as resource experts) for their preparatory time prior to the meeting. Engaging the temporary adviser on a contract for 3-5 years should be investigated to ensure consistency and continuity.

Response: . FAO and WHO agree that multi-year contracts would help improve consistency and continuity, but this is accomplished now when Temporary Advisers participate in several Meetings. A possible way to put such a procedure in place would be to charge a standard fee for evaluating compounds, the proceeds of which would be placed in a trust fund that would be used to compensate resource experts for their JMPR work. This would facilitate also the increase of the number of reviewers and subsequently, could lead to additional sessions of the FAO Panel of JMPR to to overcome the present backlog to accommodate more compounds for evaluation in the future. While compensating scientists to do this work may be fairer than the present situation because scientists often do the work on their own time, governments may lose some of their commitment to the process if their scientists are not involved in the preparatory work.

Recommendation 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.

Response: Some governments now provide resources for JMPR under the IPCS umbrella to WHO only, which are essential for its functioning because the resources provided by the regular budget of WHO are extremely limited. FAO, on the other hand, funds JMPR from its regular budget, which has not been increased in the last 10 years. It will be nearly impossible for FAO or WHO to significantly increase its

funding for JMPR within their organizations in a short period of time. Every shift or budgetary increase of their regular funding would require support and approval from their governing bodies, meeting biannually only. Therefore, governments in their support of the work of JMPR should address the importance and relevance of the JMPR at the appropriate bodies of FAO and WHO in order to obtain adequate resources on the long-term from the organizations themselves. In the meantime additional resources to implement these recommendations and to initiate the necessary changes within the JMPR must come from other sources, including national governments**.**

Recommendation 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.

Response: FAO and WHO would consider this to be a possibility, so long as measures are put in place and ensure that there is no connection between the provisions of fundsand the specific evaluations, that the independence of JMPR would not be compromised and there would be no legal objections. When considering this option, it should be kept in mind that not all companies producing pesticides are members of an international association of chemical industries.

E. Inter-sessional work and pre-meetings

Recommendation 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.

Response: At the present time, a great deal of work, including information exchange and sharing of draft evaluations among participants, is done between Meetings. The possibility exists for extending this activity to teleconferences or videoconferences, but the logistics would be difficult considering the large number of people involved. Since JMPR exists only when it is in session, it would be difficult having Members 'sign off' on recommendations at other times without changing the structure of the Joint Meeting.

Recommendation 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 to do preliminary assessment and tentative recommendations prior to the meeting. This would be conducted by telephone conference or by video-conference where facilities allow.

Response: At present, the FAO Panel regularly holds a 5-day pre-meeting prior to the Meeting proper. If properly organized and executed, teleconferences or videoconferences held well before the Meeting could be useful. One salient feature would be that they would force adherence to time schedules. As noted in the response to Recommendation 7, the logistics could be difficult, but perhaps several smaller teleconferences could be held rather than one or two larger ones, since they could be used to resolve issues on specific pesticides.

F. Recommendations for consideration by CCPR

Recommendation 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.

Response: FAO/WHO believe that the "flexible international peer review model" entails certain risks, if the first part of the evaluation has not been done thoroughly and systematically. To maintain its high level of scientific recognition the JMPR process requires that the peer reviewers would have a full and detailed understanding also of the underlying data. When considering this recommendation, CCPR should keep in mind the implications of the various options in terms of maintaining the integrity of the scientific review process.

Recommendation 24:That there be better co-ordination between the JMPR timetables and that of national authorities undertaking significant data assessment and re-registration activity.

Response: FAO and WHO strongly encourage CCPR to coordinate its priorities with those of national governments. This would provide much more opportunity for JMPR to participate in worksharing activities and to make better use of national reviews.

Recommendation 25: That the Joint Secretaries only accept technical questions (referrals) from the CCPR where these are clearly articulated and documented.

Response: In view of the limited resources available to JMPR, FAO and WHO agree with this recommendation and will adhere to it.

Recommendation 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 it's written monographs and reports.

Response: FAO and WHO agree that feedback on this issue is important. Because developing countries are involved with CCPR's standard-setting activities, which have implications for them, efforts to obtain such feedback should be a joint FAO/WHO/CCPR activity.

Recommendation 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.

Response: The JMPR estimates MRLs based on all relevant information and residues arising from supervised trials according to authorized uses (GAP) worldwide. These are already summarized in the appraisals and in tables in the evaluations in which residues that are considered in the estimation of the MRLs are double-underlined. Repeating this information in the Annex 1 table would not be suitable for recording GAP. While FAO and WHO agree that MRLs should be reconsidered whenever GAP is changed at the national level, it is difficult to do this on a routine basis considering, e.g. the implications of changing MRLs to the dietary intake estimate and risk assessment, notwithstanding the already complex procedures they have undergone during their evaluation. CCPR should indicate the priority of this activity compared with its other priorities, including the evaluation of new pesticides and the re-evaluation of pesticides in the Periodic Review Programme.

Recommendation 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.

Response: It may be possible for toxicological evaluations to be performed on new compounds prior to finalisation of national registration, so long as preliminary national reviews are available. However, this approach would be difficult from a residue point of view, because MRLs recommended by JMPR are based on approved GAP. To base MRLs on pending GAP would not be efficient, because in many cases the proposals are either not finalised or are abandoned.

Recommendation 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.

Response: This is an issue for CCPR to consider. FAO and WHO will harmonize to the extent possible terms used in risk assessment in its Project to update principles and methods for the safety assessment of chemicals in food.

G. Evaluation schedules

Recommendation 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.

Response: FAO and WHO have adjusted their schedules so that the toxicity and residues of new pesticides are generally considered at the same Meeting. While liaison among Members before the Meetings could and should be improved, many issues relating to the definition of residues and whether an acute reference dose (acute RfD) should be established are judgement calls that can only be resolved at the Meeting.

H. Publications:

Recommendation 12: That the JMPR monographs no longer be edited allowing the CCPR to consider compounds one year earlier.

Response: While FAO and WHO recognize the need to publish the evaluations as soon as possible, they do not believe that the approach suggested in this recommendation is feasible. Both the residue and toxicological evaluations are very complex, which require quality assurance. It is impractical to consider the working documents to be ready for publication at the end of the Meeting. The editor always finds errors or omissions that would have created confusion if the documents had been published as originally prepared. In addition to being complex, the evaluations are very lengthy (in some cases more than 1000 pages), and a professional editor working full-time would not be able to complete the process in time for publication within 2-3 months after the Meeting. Considering these constraints, FAO and WHO strongly suggest that CCPR consider pesticides at Step 3 at its sessions in the year following their evaluation by JMPR on the basis of the report, recognizing that governments and NGOs will have an opportunity to comment on them before the next session on the basis of the published evaluations.

Recommendation 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.

Response: This approach would have the potential to shorten the time to publication, but as noted in the response to Recommendation 12, FAO and WHO do not believe that it would result in fast-enough publication for the evaluations to be available significantly before the next session of CCPR after JMPR is held. Editing by a professional scientific editing company would also require additional resources.

I. Other recommendations to FAO and WHO

Recommendation 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.

Response: Both FAO and WHO require reasonably balanced geographical distribution of participants, but they recognize the primary need for scientific expertise. Therefore, 'perfect' balance is never achieved. The importance of scientific expertise of experts invited to JMPR for ensuring the sound scientific basis of international standards should be emphasized by CCPR and Member States. Both FAO and WHO recognize the critical need for capacity-building, and are taking steps to address it. FAO has initiated a project proposal, which is awaiting clearance, for government assistance to support training for developing countries for MRL establishment and risk assessment for pesticide residues. WHO is using funds from an IPCS capacity-building fund to invite scientists from developing countries to participate in JMPR.

Recommendation 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.

Response: An expert, in addition to Panel members is usually invited to make a critical review of the evaluations and other general consideration items except in 2000, when an invited expert was not available.

Recommendation 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.

Response: Traditionally, the authors of draft appraisals (FAO) and draft working papers (WHO) ask questions of sponsors to clarify issues relating to the data. The draft appraisals and working papers, excluding the recommendations, are provided to sponsors prior to the Meeting so that they have an opportunity to check the summaries for accuracy. The questions that arise at the Meeting are the result of discussions that, in many cases, were not anticipated by the author. The questions are sent to the sponsors electronically approximately 2 days prior to their informal out-of-session meetings with the FAO Panel and the WHO Core Assessment Group. Meetings with sponsors have not always been as productive as they could have been because company specialists who could answer the questions have not always been present. This situation is improving in that sponsors increasingly recognize the need to have appropriate experts in attendance.

Recommendation 20: That the working language of the JMPR remains as English given the practical problems that would be associated with working with additional languages.

Response: While recognizing that its 'English language only' policy limits the expertise available, FAO and WHO have no alternative but to continue with it because of limited resources. Good reading, writing, and speaking skills in English are considred to be essential qualifications for the preparation of the reports and monographs by the reviewers. From limited experience, the Organizations have found that simultaneous interpretation does not work well for such highly technical discussions unless the interpreters have a technical background in the field of pesticide residues. In addition, translation services would lead to extended meeting time of the JMPR.

Recommendation 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.

Response: FAO is considering adopting the system used by WHO in which the author of the first draft of the working paper is attributed in the published monographs.

Recommendation 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.

Response: FAO and WHO do not agree that this is a practical recommendation. The resource implications are quite significant in that it would not be sufficient simply to tape the discussions; someone would have to go through the tapes later to identify the speakers 'for posterity', which would take a significant amount of time. If, instead, notes were taken, an expert would probably have to be invited as a full-time note-taker. If a record such as this had been available to respond to the 'tobacco report', the consequences could be quite troubling. It would have taken a long time for a person or group of people to go through the oral record, with likely disagreement on the interpretation as to 'what was meant'. In addition, there would have been pressure to make it public, which raises privacy issues. FAO and WHO believe that the report and evaluations provide an appropriate record of the deliberations of the group of competent and experienced scientists that reach consensus at JMPR.