


*REPORT*

# REVIEW OF THE WORKING PROCEDURES OF THE JOINT FAO/WHO MEETING ON PESTICIDE RESIDUES (JMPR)

WORLD HEALTH ORGANIZATION

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# REPORT

# REVIEW OF THE WORKING PROCEDURES OF THE JOINT FAO/WHO MEETING ON PESTICIDE RESIDUES (JMPR)

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# 1. Executive Summary

## 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* of the report. 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* of the report. 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.

Wheras 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 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:

[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

- Option 1 – allow the attendance of observers at the JMPR
- Option 2 – incorporation of a "stakeholder's 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.

A consolidated full list of recommendations is given in *Annex 1* of the report.

## 2. Introduction

### 2.1 Consultancy terms of reference and approach taken

This short-term consultancy was conducted in accordance with the terms of reference outlined in "*Annex 2 - Terms of Reference for the Review of the Working Procedures of the Joint FAO/WHO Meeting on Pesticide Residues"*. The consultancy was jointly funded by both the FAO and the WHO.

The consultancy conducted of two phases of 15 days and 10 days respectively. The first phase was a consultative phase in which the author interviewed a number of interested parties, in Australasia, Europe and North America. The second phase consisted of the report-writing.

The limited resources available to undertake this consultancy did not allow formal consultation with government representatives from developing countries. This aspect is discussed in "S*ection 8.2 Needs of developing countries*".

Two detailed written submissions were made on behalf of Crop Life International and Consumers International. These submissions, which were taken into account in undertaking this work, and are reproduced at "*Annex 11 - Submission by Richard Nielsson on behalf of Crop Life International (formerly the GCPF)"*, and at "*Annex 12 – Submission made by Edward Groth on behalf of Consumers International."*

In a development complimentary to this report, the CAC at its 24th Session (2001) "…requested FAO and WHO to convene a consultation to review the status and procedures of the expert bodies and to develop recommendations for consideration by the Directors-General on additional ways to improve the quality, quantity, and timeliness of scientific advice to the Commission."

### 2.2 General principles for the working procedures of the JMPR

The author proposes that the following general principles should apply to an international body (ie. JMPR) that is charged with reviewing scientific data relating to pesticide residues:

a) Capable of undertaking science and evidence-based data assessments that are responsive to the needs of standard setting bodies eg. the CCPR.

b) Recommendations substantially independent of [not unduly influenced by] national government positions.

c) Adequately funded to meet the expectations of standard setting bodies.

d) Containing expertise that encompasses different scientific/regional perspectives (eg. different agronomic, cultural and pest management practices understood) and be relevant to the data to be reviewed.

e) Assessment and recommendations are open and transparent and maintain the confidence of interested parties.

f) Members to be selected based on merit and in an open process.

g) Incorporation of capacity building mechanisms/succession planning to include developing countries.

h) Mechanisms to ensure the consistency of scientific assessment decisions and procedures between reviewers, meetings and across all chemicals eg. between new compounds or those resulting from the periodic review.

i) Submission of all relevant scientific data.

These general principles underpin the thinking within this report.

# 3. Role of Codex MRLs

## 3.1 The birth of the Codex Alimentarius Commission

Two landmark years in the foundation of the Codex Alimentarius were 1960 and 1961. In October 1960, the first FAO Regional Conference for Europe crystallised a widely held view when it recognised:

> "The desirability of international agreement on minimum food standards and related questions (including labelling requirements, methods of analysis, etc.) ... as an important means of protecting the consumer's health, of ensuring quality and of reducing trade barriers, particularly in the rapidly integrating market of Europe."

The Conference also felt that:

> "... co-ordination of the growing number of food standards programmes undertaken by many organisations presented a particular problem."

Within four months of the regional conference, FAO entered into discussions with WHO, the European Community, OECD and the Council of the *Codex Alimentarius Europeaus* with proposals that would lead to the establishment of an international food standards programme.

In November 1961, the Eleventh Session of the Conference of FAO passed a resolution to set up the CAC. In May 1963, the Sixteenth World Health Assembly approved the establishment of the Joint FAO/WHO Food Standards Programme and adopted the Statutes and Rules of Procedure of the CAC.

The Joint FAO/WHO Food Standards Programme and the CAC are primarily concerned with protecting the health of consumers and ensuring fair practices in the food trade.

## 3.2 Codex Committee on Pesticide Residues

Early in the work of the new CAC, the need to set Codex standards for pesticide residues was recognised leading to the establishment of the CCPR. This committee is now one of nine *General Subject Committees* and is hosted by the government of the Netherlands. It is referred to as a *General Subject Committees* because their work applies across the board to all commodity standards.

The CCPR, is therefore a subsidiary body of the CAC and is an intergovernmental meeting whose prime objective is to reach agreement between governments on MRLs for pesticides residues in food and feed commodities moving in international trade.

The FAO/WHO JMPR advises the CCPR on scientific matters. The JMPR estimates maximum residue levels and then recommends these as maximum residue limits (MRLs) to the CCPR.

The MRL proposals are considered by the CCPR as part of eight-step procedure that provides opportunity for discussion and comment by national governments and other

interested organisations. In an accelerated procedure, the number of steps required for the development of a standard varies from a maximum of eight to a minimum of five. In some circumstances, steps may be repeated. As discussed elsewhere in this report, most MRLs take a number of years to develop leading to frustration on the part of several interested parties. The CCPR recommends MRLs to the biennial meeting of the CAC, for adoption as Codex maximum residue limits, where they become CXLs.

## 3.3 SPS and TBT Agreements

The international status of Codex standards was significantly enhanced on the signing of the SPS and the TBT Agreement in 1994. These agreements were included among the Multilateral Agreements on Trade in Goods which formed part of the Final Act of the Uruguay Round negotiations of GATT. The importance of these Agreements with respect to Codex lies in the specific recognition of Codex standards, guidelines and recommendations within the SPS Agreement as well as the importance assumed by Codex standards in the Technical Regulations and Standards provisions contained in Article 2 of the TBT Agreement.

***The Agreement on the Application of Sanitary and Phytosanitary Measures*** acknowledges that governments have the right to take sanitary and phytosanitary measures necessary for the protection of human health. However, the SPS Agreement requires them to apply those measures only to the extent required to protect human health. It does not permit Member Governments to discriminate by applying different requirements to different countries where the same or similar conditions prevail, unless there is sufficient scientific justification for doing so.

***The Agreement on Technical Barriers to Trade*** seeks to ensure that technical regulations and standards, including packaging, marking and labelling requirements, and analytical procedures for assessing conformity with technical regulations and standards do not create unnecessary obstacles to trade.

The adoption of Codex standards as 'scientifically justified norms' by the SPS and TBT Agreements has stimulated additional interest in the activities of the CAC. Indeed, Codex standards have become an integral part of the legal framework within which international trade is being facilitated through harmonisation, and have already been used as the benchmark in international trade disputes.

## 3.4 Acceptance of Codex MRLs

The SPS agreement is of particular relevance to pesticide MRLs and references Codex MRLs as representing the international consensus. The agreement also places the onus on national governments to justify, based on a scientific *risk assessment*, sanitary measures (eg. lower MRLs) that they apply when they are more trade-restrictive than the Codex standard.

Despite these new obligations on national governments, the SPS Agreement does not appear to have led to a significant increase in the level of acceptance of Codex MRLs, which remains low. Notably, the EU and the USA, although considering the presence of Codex MRLs in their establishment of national standards, have not adopted the majority of Codex MRLs.

Although there have been a limited number of trade disputes relating to the SPS Agreement that have been taken to the WTO for resolution (eg. Canada/Australian salmon case), none of these have related to MRLs. It is the view of the author of this report that a significant increase in the rate of acceptance of Codex MRLs is unlikely to result until there has been a successful challenge relating to MRLs, brought before the WTO.

# 4. Historical perspective, current expectations and demands

## 4.1 Development and overview of the JMPR

In 1959 an FAO Panel of Experts on the Use of Pesticides in Agriculture recommended that FAO and WHO should jointly study the hazards to consumers arising from pesticide residues in and on food and animal feeds. Based on this recommendation, FAO and WHO convened the first JMPR in 1963.

Since the first meeting, the JMPR has met annually as an expert *ad hoc* body administered jointly by FAO and WHO. The JMPR evaluates pesticide residue chemistry and toxicology data for estimation of maximum residue levels, ADIs and acute RfDs. It is composed of two groups, the FAO Panel on Pesticide Residues in Food and the Environment (hereafter referred to as the FAO Panel), which estimates maximum residue levels, and the WHO Core Assessment Group (formerly WHO Expert Group on Pesticide Residues), which estimates ADIs and acute RfDs. The JMPR also estimated chronic and acute dietary intake.

The JMPR has evaluated pesticides for nearly 40 years with the aim of estimating the maximum residue levels in food and feed which are likely to result from legally permitted uses of pesticides. These estimates are the basis for recommendations to the CCPR on MRLs in food and feed commodities moving in international trade. 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 CCPR.

Both the FAO Panel and the WHO Core Assessment Group have striven to apply consistent scientific principles and data requirements in their respective areas over the years. However, over the years, these scientific principles and data requirements have generally been enhanced to higher standards, consistent with regulatory trends at the national level. The formats of the evaluations (monographs) have also been gradually revised and in particular have increased enormously in complexity and level of detail.

The JMPR consists of experts drawn from governments and academic circles. They attend as independent internationally-recognised specialists who act in a personal capacity and not as representatives of national governments or other organisations. The deliberations of the JMPR are summarised in the annual Report of the Meeting. The detailed evaluations of the residue (Evaluations Part I) and toxicology data (Evaluations Part II) are also published annually and circulated widely to member governments, international organisations and other interested parties. These evaluations are otherwise known as monographs and will be referred to as such in this report. Publication of all of these documents is part of the *FAO Plant Production and Protection Paper* series.

## 4.2 International Programme on Chemical Safety

The WHO Core Assessment Group also works within the framework of the International Programme on Chemical Safety (IPCS). The IPCS, established in 1980, is a joint programme of three Co-operating Organisations – International Labour Organisation (ILO), United Nations Environmental Programme (UNEP) and WHO,

implementing activities related to chemical safety. WHO is the Executing Agency of the IPCS, whose main roles are: (i) to establish the scientific basis for safe use of chemicals, and (ii) to strengthen national capabilities and capacities for chemical safety.

To improve the consistency and quality of its decision-making process, the IPCS sponsored the publication of Environmental Health Criteria no. 104, which consolidated and updated the JMPR's principles for the safety assessment[2] of pesticide residues to the late 1980s. Subsequent principles have been included in JMPR reports.

## 4.3 Successes of the JMPR

As already outlined in the Executive Summary, the JMPR has consistently performed quality scientific assessments that are independent of national considerations with very little resources; approximately 200 active ingredients have been evaluated and several thousand MRLs recommended. At the time of writing in December 2001, there were 94 published JMPR documents as is listed in "*Annex 10 - Reports and other documents produced by the Joint Meetings on Pesticide* Residues". The continuing dedication and integrity of the JMPR is internationally recognised and should be commended.

The historical strength of the JMPR lies in the quality of its expert participants and the independence of its assessments. Indeed, the credibility and acceptability of any conclusions and recommendations depend to a very large degree on the objectiveness, scientific skill and overall competence of the Members who formulate them. The selection of Members aims to identify those that are pre-eminent in their speciality, have the highest respect of their scientific peers, and be impartial and indisputably objective in their judgement. They are appointed in their own personal right - not as government representatives or as spokespeople for organisations - and their input is theirs alone. The need to ensure the maintenance of the advice of the JMPR is discussed further in "*Section 7.13.2 Maintenance of the independence of the advice of the JMPR*".

Although the JMPR often follows regulatory trends, it closely guards its scientific independence and has been at the forefront in the development of new scientific thinking, such as the concepts of the STMR and the acute RfD.

One further recent success is the development of the FAO Manual (FAO 1997) which lists as its aims to:

- clarify, update and consolidate the procedures used by the FAO Panel for the evaluation of experimental data and related information;
- improve transparency of the work of the FAO Panel
- define and provide guidance on the type, amount, quality and format of data submissions required for the estimation of maximum residue levels on which the Codex MRLs are based;
- facilitate the acceptance of Codex MRLs by the governments and their use within the WTO Agreement on the Application of Sanitary and Phytosanitary Measures;

[2] Primarily hazard identification and characterisation

- serve as a source of information and instruction for all those directly involved in the activities of the FAO Panel of the JMPR including data submitters and FAO Panel data reviewers; and
- assist member countries in evaluating residue data for the registration of pesticides and in developing their national evaluation systems.

A new and revised version of the FAO Manual will be published in 2002.

## 4.4 Current Demands on the JMPR

The high current demands on the JMPR are summarised in the Executive Summary and the points already made will not be repeated here. However, it should also be noted that considerable changes have also taken place in the procedures and complexity of assessments of chemicals in food since the inception of the JMPR. This increase in the complexity of assessments, has resulted from significant advances in chemical analysis, toxicological assessment, and risk assessment procedures, and has contributed to the increase in the JMPR's workload.

The introduction of the periodic review procedure for re-assessing established pesticides (previously evaluated by the JMPR), although being successful, has also added considerably to the workload of the JMPR. Even though the agenda of the JMPR is currently dominated by periodic review compounds, the capacity of the JMPR to undertake periodic reviews is also currently severely limited. This issue has been further discussed by the 1998 Meeting of the JMPR and is documented in *"Annex 3 – Relevant extract from the 1998 JMPR report"*. It is should also be acknowledged that the periodic review programme has depended on data generated for national re-registration/review.

In addition to the periodic review programme, there have also been other significant new demands from the CCPR to the JMPR, notably the routine consideration of dietary intake, including the derivation of acute RfDs and the calculation of acute dietary intake. These new issues have added further to the workload, for example, the estimation of dietary intake requires the estimation of STMR [and STMR-P] levels for processed items, which require more detailed reviews of residue trials, animal feeding studies, and food processing procedures than are needed for the estimation of MRLs alone.

Typical comments taken from unpublished notes of recent JMPR meetings are quoted below:

> *"Members were concerned with the workload prior to the meeting"*
>
> *"The meeting was a difficult one mainly because of the excessive workload"*
>
> *"…..circumstances may dictate a smaller workload, but also because of the loss of experienced Panel members from recent years and the increasing complexity of the work."*
>
> *"It is unreasonable to expect more work (from JMPR members) than can be completed in 2 months full time."*

*"It is very important for the Priorities Working Group and the FAO Secretary to match the workload with the capabilities and capacities of the Panel."*

*"Panel workload must be reduced. Excessive workload will encourage people to adopt shortcuts in evaluation or even to accept company summaries or conclusions."*

*"The current system of voluntary work is deteriorating. We have tried for 2-3 years to get governments to arrange for experts from their countries to have time to do the work. Generally the response has been fine words, but nothing else. In fact, it is becoming more difficult to get experienced people to participate."*

*"The system is not viable for much longer where it relies on voluntary workers. FAO needs to consider the need to pay members for the time spent on JMPR work."*

*"Our workload is excessive. The Panel spent an estimated 51hours per week in the meeting, and had to spend additional time on preparing revised drafts. Members coped with this workload because of dedication and high morale. Deadlines were achieved because meetings were held during the first weekend and members caught up on documents during weekend non-meeting time."*

The current backlog of work waiting for evaluation by the FAO Panel is up to 4 years. Whilst the availability of experts to undertake the work of the WHO Core Assessment Group appears to be a less serious problem than for the FAO Panel, a fundamental re-examination of the working procedures of the JMPR is considered timely.

## 4.5 Need for the JMPR

One question that needs to be asked before considering options and recommendations for change to the working procedures of the JMPR is "Is there a future need for the JMPR at all?".

During consultations prior to the drafting of this report, almost all of those questioned considered that there was a strong need for a body capable of undertaking science and evidence-based international data assessments to support standard setting bodies such as the CCPR. Whilst this body does not necessarily have to be the JMPR, the fact is that the JMPR is fully established, is respected for its scientific integrity and is substantially independent of national government positions. Indeed, the availability of independent scientific advice is an important consideration in the work of the CCPR. Although, groups of countries could agree on a scientific assessment and MRL recommendations between themselves and propose these to the CCPR, these recommendations are unlikely to be acceptable to other delegations at the CCPR.

The author of this report therefore believes that there is an important future role for the JMPR, although reform in line with the recommendations in this report is required. It is recognised, however, that the future of the JMPR is largely linked to the status and future of the CCPR and the specific reference to Codex standards in the SPS agreement. In this context, the statement arising from a recent paper (OECD 2001c) prepared for the OECD Working Group on Pesticides is notable. The paper states that "*based on the current experience, the workload of Codex is such that the value of Codex is increasingly being questioned. Unless there are organisational and process changes,*

*Codex may, in future, not be able to effectively act as the reference body under WTO arrangements. This may give further impetus to the development of standards within trade blocs and recognition of those standards in bilateral trade agreements."*

4.6 Level of support for the JMPR.

4.6.1 Support from national governments

Although governments of developed countries are generally supportive of the work of establishing MRLs at the CCPR, this commonly does not translate to support in releasing appropriate experts to work on the JMPR. A further problem is that many regulatory authorities in developed countries have moved to an Executive Agency/Statutory Authority model in which the regulator works on a cost-recovery basis. In these circumstances, the Executive Agency/Statutory Authority does not see the release of an appropriate expert to the JMPR in the context of the countries national contribution to the work of the FAO and the WHO. Rather they see little direct benefit to undertaking their statutory function other than the professional development opportunity attendance at the JMPR offers the staff officer.

The governments of developing countries are usually willing to support the work of the JMPR, however, some further training of their scientific experts is commonly required due to the complexity of the JMPR's evaluations.

The level of commitment by individual national governments to the JMPR/CCPR process is in part related to the relevance of these MRLs to their international trade in agricultural commodities. This may come down to the question "have growers/exporters had trade disrupted because of pesticide residues?" The rejection of shipments in international trade does occur but are limited in number relative to the enormous trade in agricultural commodities. This relatively low number of shipment rejections is related to the fact that most importing countries do not enforce the majority of MRLs. Where testing of imported food for compliance with MRLs is undertaken, this is usually at low frequency relative to the number of import consignments or may only include those analytes that can readily be included in multi-residue screen. This results in a reduced political will by national governments to 'do something' in the absence of Codex MRLs, despite the fact that there are likely to be many 'hidden' problems of pesticide residues in international trade.

A further issues is that many governments have also not co-operated with requests for data submission to the JMPR included in Codex circular letters; sometimes this has occurred even when a commitment was made in the previous year's CCPR plenary session.

4.6.2 Support from the chemical company sponsors

The current JMPR/CCPR process crucially depends on the voluntary submission of scientific data packages by the sponsor companies. Although some other information is also submitted by other interested parties, in particular details of Good Agricultural Practice (GAP) and residue monitoring by national governments, the bulk of data evaluated by the JMPR is submitted by the sponsor companies.

Sponsors have very little interest *per se* in Codex MRLs or in the elaboration of the JMPR monographs. Their interest lies in whether the elaboration of a Codex MRL, ADI or acute RfD gives them a commercial advantage in either the registration or the market share of their product. In this context some companies are questioning the relevance of the JMPR/Codex process and are not supporting the submission of data to the JMPR. Indeed it appears that two different views have developed by the sponsor companies which has led to some companies actively participating in the process, with others being more reluctant to engage with Codex and the JMPR. This view has been exacerbated by the slow pace of the process and the lack of reform in accordance with international trends, leading some to question the credibility of the current JMPR process.

Factors affecting the level of support from some sponsor companies include the following:

(i) the heavy workload associated with registration activities has led some companies to reduce their commitment to the submission of data to the JMPR. In particular, the reviews undertaken in the EU under Directive 91/414/EEC and in the USA under the *Food Quality Protection Act 1996* are stretching the resources of the chemical companies registration departments.

(ii) the reduced utilisation of the JMPR outcomes and monographs and outcomes by developed in support of national registrations. In addition, several developing countries are now making reference to registration in either the USA or EU as the basis for product approval, particularly where there are no Codex MRLs.

(iii) Frustration with the situation whereby Codex MRLs are not routinely accepted by many countries, notably the EU and the USA.

(iv) the lengthy and slow JMPR/CCPR system.

Despite the points at (i) to (iv) above, many sponsor companies do see value in having an established JMPR ADI/acute RfD for national registration purposes. In addition, grower groups or other interested parties, may encourage the sponsor companies to submit data to the JMPR to facilitate market access for their produce. This is particularly the case where the export markets are countries, such as Thailand, Malaysia and Chile which are reported to routinely accept Codex MRLs.

Finally it should be noted that the sponsor companies sometimes add to the slowness of the process. Some companies do not submit on time and data are frequently absent when notified; these data are then submitted at the last minute putting additional pressures on the data reviewers.

# 5. Current Operational Procedures of the JMPR

## 5.1 Overview

The historical development and nature of the JMPR is described in detail in "*Chapter 4. Historical perspective, current expectations and demands"*. This chapter will concentrate on describing the operational procedures of the JMPR.

As previously described, the JMPR evaluates pesticide residue chemistry and toxicology data for the estimation of maximum residue levels, ADIs and acute RfDs. It is composed of two groups, the FAO Panel on Pesticide Residues in Food and the Environment (hereafter referred to as the FAO Panel) which estimates maximum residue levels and the WHO Core Assessment Group (formerly the WHO Expert Group on Pesticide Residues) which estimates ADIs and acute RfDs.

The JMPR has met in September for many years, alternating the venue between the WHO headquarters in Geneva and the FAO headquarters in Rome. The two groups meet separately for most of the meeting.

## 5.2 Working procedures of the WHO Core Assessment Group

The WHO Toxicological Core Assessment Group is responsible for reviewing pesticide toxicological and related data and estimating pesticides ADIs for residues in food for humans. In addition, where appropriate, the Group also estimates acute RfDs.

For the WHO Toxicological Core Assessment Group, the data submission deadline for the provision of scientific study reports from the manufacturers is typically 15 months prior to the JMPR. Most of the monographs are produced by Temporary Advisers prior to the Meeting, with pre-Meeting peer review being undertaken where possible by a member of the Core Assessment Group.

At the JMPR, the Temporary Advisers presents the monograph (ie. critical summaries of the data) and their preliminary toxicological assessment to the Members of the WHO Core Assessment Group. Typically in any one year, the WHO Toxicological Core Assessment Group consists of approximately seven Members and twelve Temporary Advisers. Although technically the Members make the decisions in the Group, the other Temporary Advisers also take an active role in discussing each compound.

## 5.3 Working procedures of the FAO Panel

The FAO Panel is responsible for reviewing pesticide use (GAPs), data on the chemistry and composition of pesticides, environmental fate, metabolism in farm animals and crops, methods of analysis for pesticide residues and for estimating maximum residue levels and supervised trials, median residue values (STMRs) of pesticides in food and feed commodities. The toxicity of the active ingredient and its metabolites, evaluated by the WHO Toxicological Core Assessment Group, is taken into consideration in deciding if residues may or may not give rise to problems of public health. The maximum residue levels are recommended to the CCPR as suitable for use as Codex MRLs, to be adopted by the CAC.

For the FAO Panel, the data submission deadline for the submission of scientific study reports from the manufacturers is usually February of the year of the Meeting ie. six and a half months prior to the Meeting. The monographs and preliminary assessments (ie. the international risk assessments) are produced by the Members of the Panel prior to the meeting. In the first year of attendance, experts of the FAO Panel are nominally appointed as Temporary Advisers, however, they are not used in the same way as in the WHO Toxicological Core Assessment Group. In practise there is little distinction between the role of these Temporary Advisers and the established Members in the current working procedures of the FAO Panel.

Typically, the FAO Panel consists of just 7-8 Members who act as both primary evaluators and peer reviewers of the work of the other Members. A further difference to the procedures of the WHO Core Assessment Group is that the FAO Panel have a pre-meeting prior to the JMPR. The pre-meeting gives the FAO Panel further time to examine the monographs and preliminary assessments prepared by each of the Members.

## 5.4 Workload of the JMPR

The very heavy workload of the JMPR, relative to the available resources, has been described in detail in *"Section 4.4 Current Demands on the JMPR"*. In summary, it is the view of the author of this report, and many of those consulted, that radical reform needs to be considered to increase capacity and allow the JMPR to be sufficiently responsive to the needs of the CCPR.

The periodic review procedure for re-assessing established pesticides (previously evaluated by the JMPR), has been successful. However, the capacity of the JMPR to undertake periodic reviews is also currently severely limited as is described by the 1998 JMPR. Refer to *"Annex 3 – Relevant extract from the 1998 JMPR report"*.

The 1999 JMPR also drew attention to the issue of the increasing workload of JMPR participants. Refer to *"Annex 4 – Relevant extracts from the 1999 JMPR report"*. Of particular interest are the following recommendations made by the meeting:

(i) That the contribution of expertise and time of the JMPR Members be formally recognised as a contribution by national governments to the Codex/FAO/WHO system.

(ii) That national governments agree, when Members are appointed to the FAO Panel or WHO Core Assessment Group, to provide them with sufficient time and resources to complete their work to a standard expected of the JMPR.

The author of this report further endorses these recommendations. However, since the 1999 JMPR, the recommendations do not appear to have been adopted by national governments and there has therefore not been any significant subsequent improvements in the JMPR workload situation.

## 5.5 Factors that limit capacity of the JMPR

5.5.1 Institutional constraints and funding of the JMPR

Both the FAO and WHO are severely limited in the financial resources that they can make available for the work of the JMPR due to competing demands on their respective budgets.

The WHO Core Assessment Group is largely funded from extra-budgetary sources and costs approximately US$100,000 per meeting. The FAO fund the FAO Panel of the JMPR through their core budget, typically this is for the sum of US$160,000 over 2 years ie. US$80,000 per year. In addition to these costs are the salaries for the FAO and WHO secretaries to the JMPR.

In view of the significance and reputation of the work of the JMPR and the calibre of the international experts that participate, this is considered to be a very small budget by the author of this report. Further supplementation of the budget of the JMPR would allow the capacity of the JMPR to be expanded in line with some of the options outlined in this report.

5.5.2 Availability of experts

Over recent years, the FAO and WHO have had increasing difficulty in finding suitable experts that are willing to work on a voluntary basis in support of the work of the JMPR. This is particularly the case for the FAO Panel, where the pre-meeting workload in preparing the *draft global monographs* has become excessive and unsustainable as is further described in *"Section 4.4 Current Demands on the JMPR"*. It is understandable that there is only a limited number of suitable experts that are prepared to undertake a large amount of preparatory work during their own personal time (ie. at weekends etc.) without any financial reward.

Given that most of the work of the JMPR involves the assessment of scientific study reports that were generated for regulatory purposes, the international experts with most experience in critically evaluating these data reside in the national pesticide regulatory authorities. However, participation of these experts in the work of the JMPR, normally requires the agreement of the regulatory authority to release the expert. However, many national regulatory authorities in developed countries have moved to an Executive Agency/Statutory Authority model in which the regulator works on a cost-recovery basis. In these circumstances, the Executive Agency/Statutory Authority does not see the release of an appropriate expert to the JMPR in the context of the countries national contribution to the work of the FAO and the WHO. Rather they see little direct benefit to undertaking their statutory function other than the professional development opportunity, the attendance at the JMPR offers the staff officer. This is a further factor that has led to a greater reluctance to directly support the work of the JMPR by some regulatory authorities eg. the United Kingdom's (UK) Pesticide Safety Directorate (PSD).

5.5.3 Geographical Representation

In selecting Members for the JMPR, both the FAO and WHO are obliged to ensure that the FAO Panel and the WHO Core Assessment Group are geographically

representative. The following seven geographical regions are used as the basis for this assessment:

- Africa group
- Asia group
- European regional group
- Latin America and Caribbean group
- Near East Group
- North America group
- Southwest pacific group

Both the FAO and WHO also operate a gender requirement although it appears that this is not so strictly adhered to.

It was the view of all of those consulted in the preparation of this report that the obligation to ensure geographical representation in the selection of the FAO Panel and the WHO Core Assessment Group potentially limits the capacity of the JMPR. Highly qualified potential Members of the JMPR may have been excluded or overlooked, despite a shortage of suitable experts, purely on the basis that there is already (an) expert(s) from that geographical region. Given that the majority of suitable experts for the highly technical work of the JMPR reside in the regulatory authorities of the developed countries, this situation is likely to persist in the absence of a change of policy by the FAO and WHO.

The issue of Geographical Representation and the JMPR are explored further in *"Section 7.3 Geographical representation and expert capacity building.*

5.5.4 JMPR Secretariat resources

There is one staff member, the FAO/WHO Joint Secretarys' to the JMPR, within each of the FAO and WHO, which currently work in support of the JMPR. However, in addition to the JMPR, the WHO Joint Secretary is responsible for the Joint FAO/WHO Expert Committee on Food Additives (JECFA), which meets two times a year. Similarly, the FAO Joint Secretary has other responsibilities. The current staff resource within the FAO and WHO, is likely to be insufficient to support some of the options for increasing the capacity of the JMPR, that are outlined in this report.

# 6. Options for major reform of the working procedures of the JMPR

## 6.1 Overview

The background and the current demands on the JMPR are outlined previously in *"Section 4.4 Current Demands on the JMPR"*. In view of this background and the current demands, it is the view of the author of this report and many of those consulted that, whilst recognising the significant achievements of the JMPR, radical reform needs to be considered. This reform needs to ensure that the JMPR complements other international activities as far a practicable and is sufficiently responsive to the needs of the CCPR. It is recognised that many changes to the working procedures of the JMPR have been implemented since its formation in 1963; this is particularly the case in the area of document preparation. However, the broad JMPR model for the international assessment of pesticide residues data 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.

This chapter explores options for major reform in the work of the JMPR.

## 6.2 JMPR as a international peer review body

The work currently undertaken by the JMPR can be considered to fall into two stages:

*Stage 1* - Summarisation of the full study reports in producing a *monograph* ie. the monograph production.

*Stage 2* – Interpretation of the data to produce an independent assessment and recommendations ie. the international risk assessment, to produce a *final assessment*

*Stage 1* of the JMPR's work is undertaken prior to the meeting by Members or Temporary Advisers. The JMPR themselves normally concentrate either on S*tage 2* with Members having access to the full study reports, before the meeting (FAO Panel) or at the meeting (WHO Core Assessment Group).

It is the view of the author of this report that it is currently the enormous work associated with S*tage 1* that is largely limiting the work capacity of the JMPR. Indeed, in the case of the FAO Panel, this stage typically takes each reviewer the equivalent of 2-4 months full-time work.

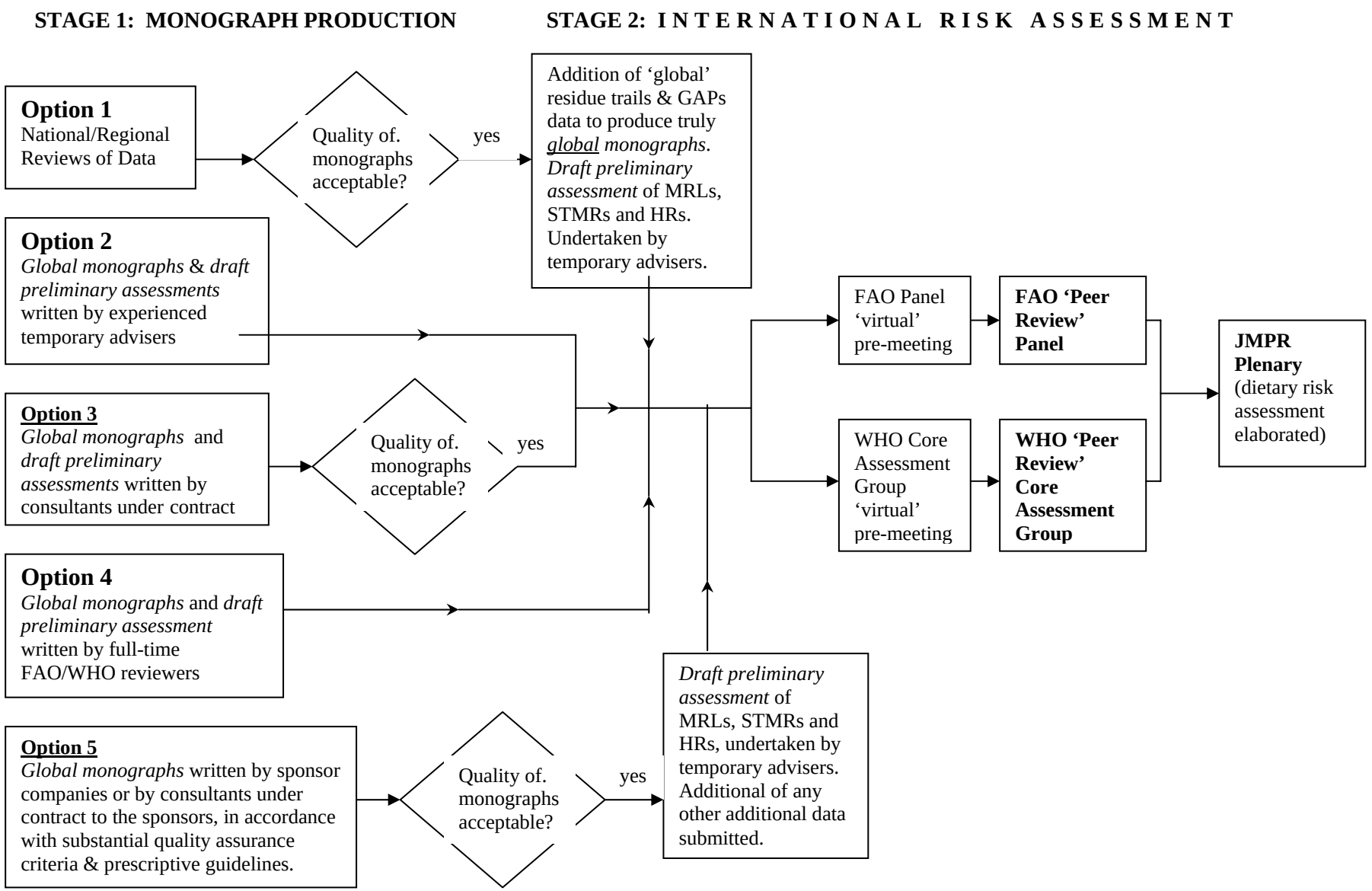
One proposal for major reform of the JMPR is therefore to remodel the JMPR to concentrate on undertaking *Stage 2*, the international risk assessment. The output of the meeting would still be an independent authoritative *final assessment* that would be published, as now, in the JMPR report. However, the meeting would concentrate on the international peer review of *global monographs* and *draft preliminary assessments.* These *global monographs* and *draft preliminary assessments,* would be produced by a variety of methods prior to the meeting.

Five methods for the production of the *global monographs* (Stage 1) and *draft preliminary assessments* are presented below. The author of this report has included

these broadly in order of preference ie. option 1 is the most favoured, with option 5 the least favoured. However, the intention is that the production of monographs would be undertaken in a flexible way so that more than one option would be utilised depending on the particular compound, the evaluation work already undertaken at a national level, and the financial resources available.

This flexible JMPR "peer review" model for the future operation of the JMPR is outlined schematically in *Figure 1* below.

Figure 1 - A possible "flexible international 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.

6.2.1 Use of national reviews of data

Several regulatory authorities are undertaking comprehensive reviews of both new chemicals and existing chemicals that are already on their markets. In view of the large size of the scientific data packages associated with these reviews, many of these reviews are being undertaken on a regional basis, notably within the EU and the North American Free Trade Agreement (NAFTA). Furthermore, countries of the OECD are now utilising common dossier guidelines (for use by the sponsor companies) and common monograph guidelines (for use by the regulatory authorities) in undertaking these reviews. Furthermore, these countries are commonly swapping their comprehensive critical summaries ie. monographs, written in a common format, to make more efficient use of regulatory resources. These developments are described in more detail in *"Section 6.4.3 OECD guidelines and assessment criteria."* and *"Section* 6.4.4 Regional reviews of pesticides*"*.

The first possible method (ie. option 1 in *Figure 1*) for the production of the *global monographs* is to base these on quality national reviews of residues and toxicological data. These national reviews of residues and toxicological data could then be used as the basis for the writing of the *draft preliminary assessment* by Temporary Advisers before the JMPR. The use of these national summaries of data 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'. These national reviews of data would preferably be submitted to the FAO and WHO by the national government, who would be willing to answer questions on their reviews if this proves necessary.

***Quality assurance check***

It is important that the quality of the national review of data is checked before it is used as the basis for a *draft preliminary assessment* for presentation to the JMPR. This task could be undertaken by either the FAO/WHO secretariat or by a small team of JMPR Members. Cross-checking of the monographs to a sample of the full study reports would be undertaken to identify any major shortcomings. Where major shortcomings in the national monograph are identified, it is proposed that these would not be used as the basis for the JMPR assessment. However, where only minor shortcomings are identified, then the national review could be updated as appropriate.

A further issue to be considered during the quality assurance check is the issue of the scientific quality of the evaluation. For example, was the national reviewer sufficiently knowledgeable, experienced and scientifically capable in order to allow a truly critical evaluation of the data? The cross-checking of the national review against a sample of the full study reports, would reveal where the sponsors conclusions have been routinely copied without checking the primary data or where the national reviewer has presented the data in a scientifically questionable manner.

Where more than one national review is submitted for consideration, the quality assurance check would also be used to make a decision on which to use to generate a draft preliminary assessment for consideration by the JMPR.

***Use of national reviews by the WHO Panel***

The issue of the use of national reviews was discussed at the 1999 Meeting of the JMPR as is documented in *"Annex 4 – Relevant extracts from the 1999 JMPR report"*. The Meeting recognised that "*the use of national evaluation documents aids the Meeting in its toxicological evaluations of the original reports of the studies and other pertinent information that are reviewed. Although the use of national documents does not eliminate the need to evaluate the original studies, it helps to identify the studies that are available to ensure that the full database has been evaluated*".

In the model that is proposed in this report, greater reliance would be placed on the national monographs, once a satisfactory quality assurance had been undertaken, that appears to currently be the case as described by the 1999 JMPR. However, in all cases the full study reports would be available to the JMPR Members for reference where necessary. In addition, the rapporteur (ie. original author of the national monograph) could be asked to present and explain the monographs, in order to ensure that a full and detailed understanding of the underlying data is available to the Meeting.

***Use of national reviews by the FAO Panel***

To date, the FAO Panel has not used national reviews of data as the basis for their assessments. The 1999 JMPR as documented in *"Annex 4 – Relevant extracts from the 1999 JMPR report"*, states that for the residue evaluation "*the use of national residue evaluation documents is generally of limited assistance, because national evaluations focus mainly on national uses and national data whereas the JMPR makes a detailed examination of labels from around the world and compares trials with the relevant GAP. This is a different process from national residue evaluation and registration. National residue evaluations will provide helpful additional information for some sections, e.g. farm animal metabolism and feeding, but the Meeting did not believe that the use of national evaluations would decrease the workload*."

It is recognised that any national monograph will need to be supplemented by 'global' residue trials and GAP. However, the author of this report believes that the 1999 JMPR statement reproduced above, overstates the problems in using national evaluations and underestimates the potential decrease in the workload that would result. These additional data summarises, could simply be added to the existing nationally-written monograph.

The FAO Panel of the JMPR currently review include the following data types:

- physico-chemical properties
- methods of analysis
- environmental fate
- mammalian metabolism
- metabolism in farm animals
- plant metabolism
- residue storage stability
- processing studies
- good agricultural practice
- animal feeding studies

- supervised residue trials

Of these data, only the supervised residue trials and GAP data are routinely likely to be significantly different in an international JMPR monograph, than those data summarised at the national level. In limited cases, it is recognised that the data on freezer storage and analytical methods contained in national monographs may not be adequate to support some of the supplementary 'global' supervised residue trials, for example, where a different analytical methods was used. In these cases, some further supplementary data in these areas may also need to be added to the national monograph.

### 6.2.2 Use of Temporary Advisers/resource experts

The second possible method (ie. option 2 in *Figure 1*) for the production of the *global monographs* is utilise the Temporary Advisers (sometimes also referred to as resource experts) to write both the *global monographs.* These Temporary Advisers can also write the *draft preliminary assessment* and present these to the Members of the JMPR. This is similar to the system currently operated by the WHO Core Assessment Group.

In order to increase the throughput of reviews available to be considered by the JMPR and in recognition of the considerable time required to write the *global monographs* and *draft preliminary assessments*, the FAO and WHO should consider paying the Temporary Advisers for the work. These Temporary Advisers could be engaged either on a review-by-review basis or on a long-term basis. Given the complexity involved in drafting the global monograph and the draft preliminary assessment and the need to ensure consistency and continuity, a contract with the temporary advisor of 3-5 years would appear appropriate.

Currently, monographs are not always ready prior to the meeting in time to send to a member of the JMPR for pre-meeting peer review and for the accuracy of the data summary to be checked by the sponsor company. An advantage with this direct payment of Temporary Advisers would be that the FAO and WHO could be more demanding with respect to the adherence to deadlines than is currently the case with volunteer reviewers.

**Recommendation: 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.**

It is not recommended that Temporary Advisers (or Members) would be paid to attend the actual JMPR, although they should get DSA and their travel expenses covered. In the event that Members undertake significant preparatory work, prior to the Meeting, then payment of Members for this time should be considered.

### 6.2.3 'Contracting out' of data review to scientific service companies

The third possible method (ie. option 3 in *Figure 1*) for the production of the *global monographs* is for the FAO and WHO to contract out the review of the study reports to recognised independent companies or consultants. The consultant could also write the

draft preliminary assessment or this could be undertaken by a temporary advisor (otherwise known as a resource expert), based on the consultant's *global monograph*.

Several regulatory authorities have used this model for some of their pesticide review activities. For example, the PSD in the UK, has utilised certain external consultants for a number of years. PSD's experience has proved that consultants can be used successfully. However, the quality of the monographs can be variable and consultants are expensive to engage.

The adoption of this method by the FAO and WHO, would increase the throughput of reviews available to be considered by the JMPR. However, where the consultant is inexperienced in the work of the JMPR, this approach may require additional supplementary work by an expert that is more familiar with the work of the JMPR. A quality assurance check, similar to that described in *"Section 6.2.1 Use of national reviews of data"* would need to be employed.

Given the high cost of this option, it may only be appropriate where no national critical reviews were available. An increase in the JMPR budget would be required, and great care would need to be exercised to insure that the primary review contractor had no conflicts of interest.

6.2.4 Employment of full time FAO/WHO review staff

The fourth possible method (ie. option 4 in *Figure 1*) for the production of the *global monographs* is for the FAO and WHO to employ full-time review staff. These staff would be based in Rome and Geneva, respectively, and would write the *global monographs* and the *draft preliminary assessments.*

This method would increase the throughput of reviews available to be considered by the JMPR and since permanent staff would be engaged in this work, consistency and continuity of assessments would be enhanced. Since the review staff would be directly accountable to the FAO and WHO management structure and be dedicated to this work, reviews are likely to be produced to deadlines.

This method would however, require considerable additional resources and would arguably turn the FAO and WHO into the international equivalent of a national regulatory authority. The FAO and WHO normally work on the basis that the experts are in the member governments, and may be reluctant to embrace this 'international regulatory authority' model.

6.2.5 Use of monographs written by the sponsor companies

The fifth possible method (ie. option 5 in *Figure 1*) for the production of the *global monographs* is for these to be by the sponsor companies. It is envisaged that this would usually be by an appropriate expert under contract to the sponsor company. Temporary Advisers (otherwise known as a resource experts), appointed by the FAO and WHO, would then write the *draft preliminary assessment*, based on the sponsor companies monograph.

The sponsor companies are already asked to produce and submit summaries of their data by the FAO Panel and the WHO Core Assessment Group. These data summaries are used as background documents, but are not used as the main basis for the JMPR's *global monographs;* these are usually written from the full study reports.

Given the relatively high level of resources available to the sponsor companies, this method would allow a major increase in the number of reviews available to be considered by the JMPR. In many cases the sponsor companies will have already produced these comprehensive summarises of their data for the EU or USA review process. With the addition of 'global' residue trials & GAPs, these monographs could be utilised by the JMPR.

The main drawback of this method for the generation of the *global monographs,* is that no independent critical review of the full study reports will have been undertaken. The sponsor companies have a vested interest in presenting their data in the 'best light'. Even in cases where the sponsor company had done a good job of critically reviewing their own data, the perception will remain that the company may not have been critical of their own data and that inadequacies in study reports may not have been highlighted.

The author of this report believes that the reliance on *global monographs* produced solely by the sponsor companies could undermine the credibility of the work of the JMPR, unless *substantial quality assurance criteria and prescriptive guidance* were developed for the development of such monographs. It is envisaged that *these substantial quality assurance criteria and prescriptive guidance* would aim to ensure that a critical summary of data was still presented and would include a mechanism for the validation of the monograph accuracy.

**Recommendation: 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.**

6.2.6 Consideration of the "flexible international peer review model" by national governments

It is currently unclear as to whether many national governments will accept Codex MRLs that arise from the "flexible international peer review model", presented in the section above, for the future operation of the JMPR. For example, what is the level of commitment from national governments to accept Codex MRLs that arise from the use of national monographs? This could be clarified with governments at the CCPR, before the introduction of the procedure. This would avoid the situation whereby a new procedure is implemented which is ultimately unacceptable.

**Recommendation: 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.**

6.3 Worksharing with national regulatory authorities

A further option for major reform would be for the JMPR to be integrally involved in worksharing activities with national regulatory authorities. For the purpose of this

report, worksharing is taken to be the situation where the FAO and/or WHO work jointly with regulatory authorities on the preparation of monographs. This differs from the options outlined in "*section 6.2 JMPR as a international peer review body*" in that the JMPR would no longer be working as an international peer review body but would be integrally involved in the writing of some of the monographs.

Some worksharing activities are already being undertaken between national regulatory authorities of the OECD countries. For example, the USA and Canada have been undertaking some data sharing assessments. In the EU, review of active ingredients are undertaken by one rapporteur member state and the assessment then used for the whole of the EU.

The 2001 JMPR considered the issue of sharing the work of agricultural pesticide reviews between the JMPR and national registration authorities as outlined in *"Annex 6 – Relevant extracts from the 2001 JMPR report"*. The Meeting "welcomed the activities of the OECD and recognised the value of work sharing as a means of reducing the workload of Members of the FAO Panel and WHO Core Assessment Group. Nevertheless, the Meeting considered that, before work sharing could be accepted on a routine basis in the work of JMPR, technical, scientific and political conditions would have to be elaborated." The Meeting also "recognised that harmonisation of procedures between JMPR, OECD and national governments is a prerequisite for successful implementation of the principle of work sharing at the international level".

Worksharing requires a high level of confidence and trust between the participating parties. The main drawback for the participation of the JMPR, is that it may compromise the independence of its interpretation and recommendations. Even if in reality this were the case, the fact that the JMPR was working jointly on a review with 'country X', could lead to the perception that the JMPR may have been unduly influenced in making its recommendations, by that country. In addition, worksharing would require JMPR members to work intermittently the whole year around. The upside to worksharing for the JMPR, is that its limited resources are pooled with those of national regulatory authorities allowing a significant increase in the output of the JMPR.

## 6.4 Harmonisation with other international pesticide activities

### 6.4.1 Overview

At the time of formation of the JMPR in the early 1960s there was little or no international or regional co-ordination of pesticides registration and the associated scientific assessments. As a consequence, the JMPR was the only international scientific assessment activity involving pesticide residues. Since this time many governments have been co-ordinating their pesticide regulatory activities at a regional level. In addition, countries of the 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. Further details of some of these activities are given in this section.

### 6.4.2 Minimum data requirements for establishing MRLs

In 1998, the European Commission initiated a project to "develop minimum data requirement for establishing MRLs and import tolerances". This work, which has been undertaken in co-operation with the OECD, was co-ordinated by the UK's PSD. The aim of the work was to harmonise the residue data components and approaches taken by national regulatory authorities and international/regional organisations in establishing pesticide MRLs.

This work culminated in an EU/OECD Workshop held in York, UK in September 1999. A draft report of a working group, established within the framework of this project, was presented to the 32nd session of the CCPR.

The 1999 JMPR considered the issue of the OECD working group on pesticides - workshop on developing minimum residue data requirements for estimating MRLs and import tolerances. In summary, the 1999 Meeting gave a cautious welcome to these international developments indicating that it looked forward to receiving information on developments in this area in the future. However, the Meeting also considered that the value of the recommendations in this area could be strengthened by the production of a scientific report justifying them. Refer to *"Annex 4 – Relevant extracts from the 1999 JMPR report"* for further details.

The OECD Pesticide Working Group has subsequently taken up some of the recommendations from the 1999 EU/OECD Workshop. In particular, in 2000 the OECD Pesticide Working Group established a small OECD/FAO expert Steering Group to develop a global zoning scheme to "define areas of the world where pesticide residue behaviour could be considered comparable, and therefore where residue trials data could be used with each zone for MRL-setting purposes, irrespective of national boundaries."

The 2000 JMPR also considered the issue of the development of minimum data requirements through the OECD as described in *"Annex 5 – Relevant extracts from the 2000 JMPR report"*. In summary, the JMPR indicated that they will "follow developments in this area with interest" and "looked forward to further updates" on a planned workshop relating to *residue trial zoning.*

The 33rd session of the CCPR also discussed this issue as outlined in *"Annex 7 – Relevant extracts from the Report of the 33rd CCPR, April 2001"*. The 33rd Committee "expressed its interest in the outcome of the project and recommended that JMPR should participate actively and make use of the results of the project." However, the JMPR understandably considers it improper to accept a draft report that has not yet been fully adopted by the OECD and will need a clear set of recommendations. Nevertheless, the extent to which the JMPR will utilise the final outcome of the project is still unclear. Traditionally, the JMPR has guarded against any erosion in the scientific discretion it applies, preferring to consider each situation on a 'case by case' basis. Whilst this might be justifiable on a purely scientific basis, it reduces the transparency and level of understanding the JMPR process and can erode the level of support granted to the JMPR by some national governments.

A further meeting of the OECD/FAO small expert steering group is to take place in May 2002 to finalise the proposed Zoning Scheme and to prepare a technical report to support this concept. It is envisaged that in the future the small expert steering group may consider other issues such as residue data extrapolation between crops and the number of residue trials required to support MRLs and import tolerances.

**Recommendation: 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.**

6.4.3 OECD guidelines and assessment criteria.

The OECD Pesticide Working Group, formerly known as the OECD Pesticide Forum, was established in 1992 and aims to help OECD countries to collaborate in the following areas:

- harmonisation of pesticide review procedures
- sharing of the work of evaluating pesticides, and
- finding new approaches to risk reduction.

Work towards these goals include the following activities:

- registration and re-registration
- testing and assessment
- risk reduction
- communication and information sharing

Perhaps the most important work that has arisen from the work of the OECD Pesticide Working Group is the agreement to guidelines establishing two formats:

- one for industry to use when making *data submissions*, otherwise known as *dossiers* (reference: OECDa).
- one for governments to use when writing their *evaluation reports*, otherwise known as *monographs* (reference: OECDb).

The formats do not require OECD countries to make the same regulatory decisions. Rather their purpose is to facilitate registration by minimising duplication of effort for both industry and governments.

The author of this report believes that the *monograph guidelines* (reference: OECDb) document is of particular relevance to the work of the JMPR. These guidelines were first approved by the 7th Meeting of the Working Group on Pesticides that took place in February 1998 at the Château de la Muette, Paris, and was endorsed by the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology in June 1998. A revised version, prepared to ensure its consistency with the revised Dossier Guidance document and dated March 2001,was approved by the 11 th Meeting of the Working Group that took place in November 2000.

The *monograph guidelines* were developed with the aim of facilitating the exchange of monographs between OECD countries with a view to achieving a sharing of the work

necessary for the evaluation of plant protection products and their active substances. In order to achieve that objective, the format is designed to help countries to prepare detailed monographs that are clear and transparent. This level of detail and transparency, facilitates the use of national monographs, produced to these guidelines, by the JMPR.

The development of these OECD dossier format is leading to a reduction in the different formats that sponsor companies are being asked to present their data. In addition, the OECD monograph format is enabling national regulatory authorities to use each other's reports more easily than in the past, saving time and resources. The monograph format also helps improve the quality of review reports by ensuring that they are clear, complete, well organised and transparent.

The OECD Pesticide Working Group have also been elaborating risk assessment criteria which member governments are encouraged to use in their national regulatory activities.

In view of the comprehensive work undertaken by the work to develop dossier and monograph guidelines and assessment criteria, it is recommended that the JMPR should further harmonise with these OECD documents. This would facilitate both the use of the monographs by governments and the agreement of the meeting's outcomes at the CCPR.

**Recommendation: 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.**

### 6.4.4 Regional reviews of pesticides

This section briefly outlines the co-ordination of pesticide regulatory activities that is underway at a regional level in the EU and the NAFTA region. Although these two regional activities do not represent the only co-ordination that is underway at a trans-national level, they appear to be the most comprehensive in terms of sharing the burden of data evaluation and assessment of review compounds. They are therefore of particular relevance to any attempt by the JMPR to complement the data review activities undertaken by national and trans-national regulatory authorities.

***The EU review and registration of pesticides***

The EC review programme is established under the provisions of Article 8.2 of Council Directive 91/414/EEC. The Directive requires that all pesticides used in products for plant protection purposes that were on the market within the EC on or before 26 July 1993 (or, in Austria, Finland, Iceland, Norway, Sweden or Liechtenstein, on or before 1 July 1994) be subject to review.

The Directive provides for the establishment of a positive list (Annex I to the Directive) of active substances that may be authorised for use within the Community. Only active ingredients that have been shown to be without danger to human or animal health or to the environment will be included in Annex I.

Individual Member States are responsible for the national approval of plant protection products containing active substances on Annex I. In order for existing active substances to be considered for inclusion on Annex I, a collaborative review programme has been established. The first stage of this review programme was the publication of the first review regulation, Commission Regulation (EEC) 3600/92, which was subsequently amended by Regulations 491/95, 1199/97, 1972/99 and 2266/2000.

The future stages of the review programme are set out in the second review regulation was published as Commission Regulation No. 451/2000 in the EC Official Journal on 29 February 2000. The regulation is in two main parts, it sets out:

- the action that approval holders need to take to support the 148 active substances in the second stage of the programme, and;
- what approval holders need to do in respect of all other existing actives substances which will be reviewed in the future (with some exceptions set out in Annex II of the regulation).

It was intended that, on an approximately annual basis, a list of active substances to be reviewed would be produced until the programme was completed. In the event progress with the review programme has been much slower than originally anticipated due the enormousness of the task of comprehensively reviewing all 800 existing active ingredients that were on the EU market. The European Commission's *Health and Consumer Protection Directorate General* website contains a list of existing active ingredients evaluated under the first regulation with the monographs downloadable in "pdf format". It has been estimated that of the 800 existing active substances that were on the EU market on 26 July 2003, only 300 will remain at the conclusion of the EU review process.

***NAFTA Joint Review Program***

The NAFTA Technical Working Group (TWG) on Pesticides was formed in 1996 with the mandate to develop a coordinated pesticides regulatory framework among NAFTA partners to: address trade irritants, build national regulatory/scientific capacity, share the review burden, and coordinate scientific and regulatory decisions on pesticides. Much of the TWG's work revolves around the NAFTA joint review program, which develops compatible review procedures for both conventional chemicals and biopesticides to facilitate the routine sharing of the work of pesticide regulation. Joint reviews increase the efficiency of the registration process, facilitate simultaneous registration in participating countries, and increase access to new pest management tools in participating countries. In addition to formal joint reviews, NAFTA countries also participate in "work share" projects, i.e., sharing reviews and risk assessments for pesticides which have not been simultaneously submitted for review and may be at different stages in the review process in each country.

Since its inception in 1997, nine new pesticides (7 conventional and 2 biopesticides) have been registered under the NAFTA Joint Review/Work Share Program. The first trinational review including Mexico was completed in July 2001 with the registration of Zoxamide, a fungicide for use on grapes and potatoes. At the time of writing in

February 2002 , twelve joint reviews/work shares (9 conventional chemicals and 3 biopesticides) were underway.

In the coming years, one of the priorities of the NAFTA TWG will be to facilitate Mexico's increased participation in the joint review process. Another priority is to develop a "NAFTA label", i.e. a single pesticide label that would meet the regulatory requirements of all three NAFTA countries. A joint review chemical currently underway is being used to pilot the development of a NAFTA label.

## 6.5 Risk assessment policy and the relationship between JMPR and CCPR

The JMPR is perceived by some of those consulted as being like a “closed black box” with little opportunity for governments or other interested parties to influence the broader *risk assessment policy* 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. The latest edition of the Procedural Manual (CAC 2001) defines risk assessment policy as “Risk assessment policy consists of the documented guidelines for scientific judgement and policy choices to be applied at appropriate decision points during risk assessment”.

The principles of risk assessment policy have recently been the subject of further discussion at the Codex Committee on General Principles. Document CL 2001/24-GP refers to the fact that “risk analysis is an iterative process” and that “interaction between risk managers and risk assessors is essential for its practical application”. The “determination of risk assessment policy should be included as a specific component of risk management.”

The author of this report believes that there is further scope for enhancing the communication between the JMPR (risk assessors) and the CCPR (risk managers). Put in simple terms, the CCPR needs to be more explicit with the JMPR as to “what it wants”. In addition, the JMPR should clearly describe the principles followed in its scientific risk assessments and ensure that issues that relate to *risk assessment policy* are referred to the CCPR.

Indeed it appears 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 lack of opportunity of governments, through their delegations at the CCPR, to influence the *risk assessment policy* under which the JMPR works.

Many governments of the EU disagree with the broad “rules” under which the JMPR select the residue data points from the trials data that are used to determine the MRL. Some of these rules are pseudo-scientific and highlight the fact that there is no clear dividing line between pure scientific assessment and *risk assessment policy*. One such “rule” operated by the JMPR might be:

> Is it appropriate for the JMPR to pool GAP data from a variety of different GAPs to better reflect the world-wide use of the pesticide, as is now the practice? At its most extreme, this could lead to a situation whereby MRL is based on the pooling of one GAP trial from each of Bolivia, UK, Australia, Canada, Japan and India. Or does at least one GAP need to be adequately supported in its own right?

Regulatory authorities have also established elaborate 'rules' for the assessment of residues data eg. in the extrapolation of residue data from one crop to a similar crop that is likely to have comparable residues, such as from apples to pears, and oranges to lemons. The FAO Panel of the JMPR has generally maintained that this approach is too rigid and that decisions should be made on a 'case by case' scientific basis in the absence of clear internationally agreed guidelines. Although, this approach is defendable in the absence of clear instructions from the CCPR, it has significant downsides: (i) lack of consistency (ii) reduction in the level of understanding of governments in the basis for the JMPR decisions (iii) outcome that differ significantly from that arising from national authorities. The CCPR should be asked whether they wish to have more explicit extrapolation rules applied whilst recognising that there may be cases where the JMPR decides that they are not appropriate. It should also be recognised that the JMPR have expressed willingness to consider the implementation of extrapolation 'rules' developed by an EU/OECD workshop, once these have been formally adopted by the OECD (see "*section 6.4.2 Minimum data requirements for establishing MRLs"*).

It is recognised that some of the 'rules' applied by the FAO Panel of the JMPR will need to be different from that applied on a national or regional level. One example of this is in the use of the 'critical GAP'[3] concept by some regional pesticide assessments (eg. EU) or implicitly within a country (eg. USA, Australia). In these cases, there may be more than one use patterns reflecting different pest and disease pressures, however, only one MRL is established based on the GAP that leads to the highest residues. If there are no residue trials data supporting the GAP that leads to the highest residues, then registration is not granted or an MRL not established. This approach is not possible for the JMPR who are not a registration authority. It would be unreasonable for the JMPR not to recommend an MRL for the pre-harvest use of country Y, simply because country Z has a post-harvest use for which they have submitted no data to the JMPR. In this circumstance it is reasonable for the JMPR to recommend an MRL to the CCPR based on country Y's GAP, despite recognising that it is unlikely to be high enough to encompass the critical worldwide GAP of country Z. The JMPR therefore works on establishing the MRL on the highest GAP for which adequate comparable trials data have been supplied; this is commonly not the critical worldwide GAP.

On some occasions, the JMPR has ventured into the area of *risk assessment policy*. One high profile example was in the consideration of the MRL for DDT in meat that was undertaken by 1995 JMPR. The meeting considered a wealth of monitoring data that were supplied by New Zealand. However, since these data formed a very wide distribution, the Extraneous Maximum Residue Limit (EMRL) that could have been proposed by the JMPR was crucially dependent on the "violation rate" on which the EMRL should be based. Different "violation rates" result in different EMRL values. The 1996 JMPR decided to use a violation rate of 0.2% leading to an EMRL of 5mg/kg. The point here is not that 0.2% is too high or too low, it is that "violation rate" is not a scientific decision and should have been left to the CCPR. To be fair to the JMPR, they were aware of this issue and an invitation to the CCPR was placed in the simultaneous report asking for "…the views of governments on the level of violation that are considered unacceptable". In the absence of clear advice from the CCPR, the 2000

[3] The critical GAP, identified from several different uses, is defined as the GAP that leads to the highest residues.

JMPR correctly amended the advice to the CCPR by giving a number of EMRL options depending on which violation rate is used.

One further area where there is a need for the enhanced communication between the JMPR (risk assessors) and the CCPR (risk managers) is in understanding the level of uncertainty and variability that are associated with the JMPR's recommendations.

**Recommendation: 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.**

## 6.6 Number and nature of JMPR meetings

The JMPR has met annually in September for many years, alternating the venue between the WHO headquarters in Geneva and the FAO headquarters in Rome. Options for major reform that involve the number and nature of the JMPR meetings are explored in this section.

### 6.6.1 Increasing the number of meetings

One option for reform of the JMPR would be to increase the number of annual meeting of the JMPR from one to two.

The success of this change would depend in part on the other changes to the working procedures of the JMPR, given that much of the current limit on the capacity of the meeting is associated with pre-meeting preparatory time (ie. the preparation of the *global monograph* and *draft preliminary assessment).* If reform of the JMPR were to lead to the *flexible JMPR peer review model* that is described in "*Section 6.2 JMPR as a international peer review body"*, then this would free up additional time for those JMPR Members that currently undertake pre-meeting preparatory work. This may then allow JMPR Members to attend the Meetings, of up to two weeks each, at 6 month intervals. In the view of the author of this report, it is highly preferable for each meeting of the JMPR to be attended by the same Members, rather than to have different experts at each meeting (ie. one set at the first meeting of the JMPR in the year and a different set at the second JMPR). To do otherwise, is likely to lead to inconsistencies and lack of continuity in the work of the Meeting. It is recognised that attending two meetings per year might not be possible for some Members, particularly those that are travelling from outside Europe. If it were not possible for each meeting to be attended by the same Members, then the Meetings should have the same chairpersons for both the FAO Panel and the WHO Core Assessment Group.

The further option of having one meeting devoted to periodic review compounds and another to new active ingredients is not favoured because the author believes that there should be an overriding desire to ensure that periodic review chemicals and new active ingredients are dealt with in a consistent way.

A possible timetable and consultative procedure, including this two annual meetings proposal, for the work of the JMPR, is presented in Figure 2. This procedure is

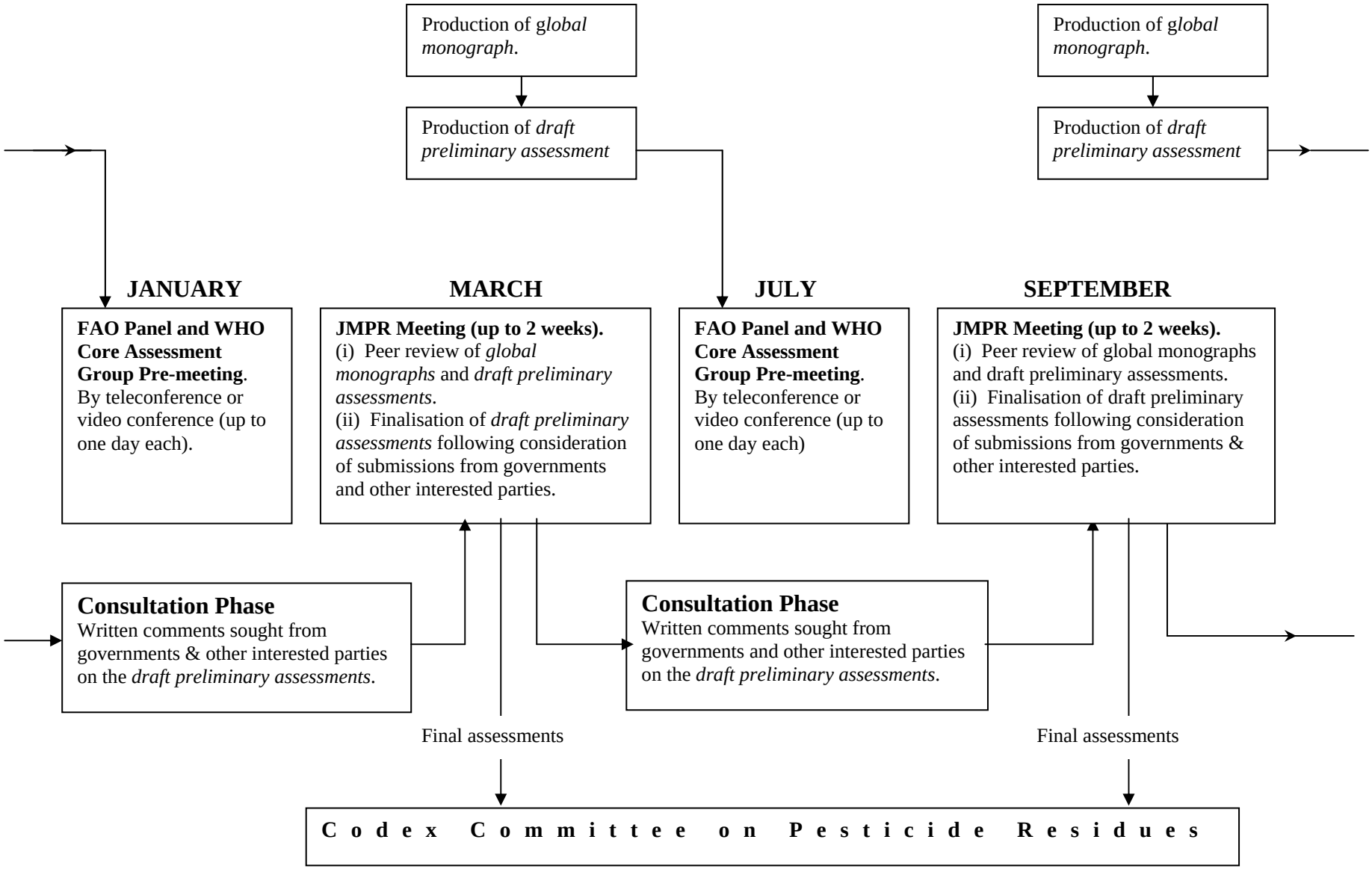
complementary to the *flexible JMPR peer review model* that was previously outlined in Figure 1.

6.6.2 Duration of JMPR meetings

Currently the JMPR meets for a period of two weeks. One further option increase the time span of the annual meetings of the JMPR from the current two weeks to three or four weeks.

This option does not appear a particularly viable one. The intense nature of the current meeting leaves many of the current Members exhausted after the current two weeks. It is unlikely that the Members of JMPR, who are usually fairly senior within their governments or organisations, with be able to attend the JMPR for a longer duration than the current two weeks.

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



6.6.3 Inter-sessional work

Currently the JMPR only exists for two weeks in the year. This leads to additional delays in the evaluation of data and the recommendation of MRLs to the CCPR. There appears to be no compelling reason why this should remain the case. One option would be for the full JMPR to meet by teleconference between face-to-face meetings. Alternatively, Members could be asked to 'sign-off' on recommendations out-of-session by correspondence or by e-mail. Yet another approach would be for the full JMPR to delegate inter-sessional decision making on some issues of a minor nature, to the chair of the meeting or to a core set of Members.

**Recommendation: 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.**

6.7 Openness, transparency and the involvement of interested parties

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.

Consistent with trends at the national level, there have recently been further calls for the opening up of the work of the JMPR. At the 33rd session of the CCPR, "several delegations and organizations expressed the importance of improving the transparency and accountability of FAO, WHO and Codex in their work including participation of all interested parties." as documented in *"Annex 7 – Relevant extracts from the Report of the 33rd CCPR, April 2001"*. In addition, some of those consulted in the writing of this report, particularly Non-Governmental Organisations (NGOs), called for greater openness and the involvement of interested parties.

There appears to be three main options for the further opening up of the work of the JMPR and enhancing the participation of interested parties. In considering the best option, the commercial-in-confidence nature of the data that is evaluated needs to be taken into account. It should be recognised that some interested parties have not always taken full advantage of existing processes for the submission of information to the JMPR. However, some interested parties do not fully understand the current working procedures of the JMPR.

***Option 1 – Allow the attendance of observers at the JMPR***

Interested parties, including NGOs, would be allowed to attend the JMPR as non-participatory "sit and listen" observers. Clear rules for the attendance of these observers would be developed, including the obligation to respect commercial-in-confidence data.

Allowing observers to attend the JMPR would eliminate the possible perception that decisions are being made in an inappropriate way "behind closed doors" and would facilitate greater understanding of the JMPR. This is the model that is used by the

USA's National Academy of Sciences (NAS) in their development of their independent scientific advice and by the UK Food Standards Agency. The experience of the NAS is that this has improved the quality of the scientific decision making. One difference though between the work of the NAS and that of the JMPR, is that in the case of the NAS the scientific data are usually already in the public domain.

On the downside, the presence of observers may inhibit candid discussion between Panel Members; consensus is sometimes only reached after vigorous debate. A further concern that has been expressed by one of those consulted is that information obtained by the observers may be used later at the CCPR to undermine the recommendations of the JMPR. Although requiring observers to sign confidentiality agreements could mitigate this concern, some problems could still occur where the observers disagree strongly with the position taken by the Meeting.

***Option 2 – Incorporation of a "stakeholder's day" into the timetable of the JMPR***

The JMPR would be opened up for a "stakeholder day" to allow interested parties to provide comments on the broader issues relating to pesticide residues eg. the potential sensitivity of infants and young children. Interested parties could be questioned on submissions that they may have made and to make short presentations relating to matters that are before the meeting. Although there would be direct interaction between interested parties and Members of the JMPR, this would not be a negotiating situation. In addition, although the JMPR would **take into account** the information and scientific views that they had heard, the final decision would be made by the JMPR in closed session.

This would reduce the perception that the JMPR process is a closed system and would allow interested parties to make a case directly to the JMPR. The JMPR may receive relevant scientific information or perspectives that they would not otherwise receive, thereby potentially improving the quality of the JMPR recommendations.

On the downside, this would take day out of the work of the JMPR and would take some organisation by the FAO and WHO secretariat.

***Option 3 – Consult with governments and other interested parties on a 'preliminary assessment'***

The *draft global monograph* and *preliminary assessment* would be subject to an official consultation procedure. It is suggested that a three month consultation period would be appropriate and that this would work best if the JMPR were held every six months. This approach is outlined in Figure 2, which was presented in *"Section 6.2 JMPR as a international peer review body"*.

Consultation on the *draft global monograph* and *preliminary assessment* would be *via* the FAO and WHO internet websites, with hard copies also being sent out by mail to governments. Written submissions would be accepted from all interested parties and these would be taken into account by the next meeting of the JMPR. It is envisaged that the majority (normally >90%) of the work would be undertaken at the first meeting, leaving the second meeting to concentrate on the submissions.

The advantages of this option are listed below:

- the scientific issues that are commonly the subject of comments at the CCPR would be considered at the JMPR. This could result in a speed up of the work of the CCPR as more MRLs would be able to utilise the "fast-track" procedure.
- enhance the commitment of governments and other interested parties
- reduce the perception that the JMPR is a closed system
- JMPR process would become more participatory.
- ensure that all information and scientific perspectives on issues are considered by the JMPR

On the downside, the initiation of formal consultation arrangements would require additional resources, particularly for the FAO and WHO secretariats, to administer the circulation of the *draft global monograph* and *preliminary assessment* and the compilation of the submissions received. It would also delay the passage of recommendations to the CCPR by an additional meeting of the JMPR (ie. an additional six months if meetings were held twice a year).

## 6.8 Additional sources of funding

### 6.8.1 Overview

Many of the changes to the working procedures of the JMPR that are recommended, or options presented, in this report would require the securing of additional sources of funding to implement.

### 6.8.2 National government contributions

National governments from developed countries spend a large amount of financial resource on their pesticide regulatory authority. In contrast the resources available to the JMPR are very limited, with very few countries providing direct financial support. At the same time, government delegations at the CCPR have expressed concern about the slow pace of the JMPR's work whilst recognising that the largest factor that contributes to these delays is the lack of resources available to the Meeting.

In the view of the author of this report, those national governments who currently do not provide any direct financial assistance to the JMPR, need to "put their money where their mouth is", and make additional funds available to facilitate the work of the JMPR.

**Recommendation: 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.**

### 6.8.3 Sponsor companies donation

Crop Life International (formerly GCPF) has indicated that they may be in a position to provide additional resources. However, these resources are unlikely to become available unless Crop Life International could be confident that the money would be result in an increase in the efficiency and timeliness of the work of the JMPR.

Rules on the use of additional funding from industry would be needed to ensure that the industry could not influence the outcome of an individual JMPR assessment, would need to be developed. The FAO and WHO could hold the money in a trust account dedicated to use on the work of the JMPR. In the view of the author, it would be also preferable for any funding to come from the peak worldwide industry body, the Crop Life International, rather than from individual sponsor companies. Otherwise, the perception might be that the sponsor companies could exert influence on individual compound assessments.

**Recommendation – 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.**

It is recognised that one of the concerns of Crop Life International is that small companies that may not be members, and manufacturers of generic chemicals would benefit from an enhanced JMPR process but would not contribute to the additional funding. The author of this report has no solution to this problem other than to point out that this is similar to the current Codex MRL system, in that the manufacturers of generic chemicals already benefit despite commonly submitting no data to the JMPR.

6.8.4 Direct charging

An alternative model for the securing of additional funds from industry would be for the JMPR to charge directly for the assessment of a pesticide active ingredient. This model would be consistent with that used by many national regulatory authorities. For example, in the UK, the Pesticide Safety Directorate has charged £120,000 (approx. US$ 170,000) since August 2000 for the full evaluation of one active ingredient under The Plant Protection Products (Fees) (Amendment) Regulations (Statutory Instrument No. 2119). Similarly, all other member states of the EU are required to charge fees for EU related evaluations in accordance with EU Regulation 451/2000.

The direct charging for evaluation by the JMPR, would allow the provision of additional resources that could be used to increase the capacity of the JMPR. On the downside, this system very closely links the money paid by an individual chemical company with a chemical assessment. This could affect the reputation and independence of the JMPR, though the perception that the sponsor companies could exert influence on individual compound assessments.

6.8.5 Other interested parties

The securing of additional funding for the JMPR from other interested parties could be further explored, such as grower groups, who directly benefit from Codex MRLs through facilitated exports. However, there appears to be no global peak body for grower groups and obtaining funding specifically from, for example, a national citrus growers organisation, would be difficult given the limit scope of their interest in the JMPR process (ie. citrus MRLs for just one or a limited number of chemicals). Furthermore, the belief that citrus growers from other countries may also benefit from

the MRLs that had been established, may inhibit these organisations in the provision of additional funding to the JMPR.

# 7. Improving the current working procedures of the JMPR

## 7.1 Introduction

This chapter explores more minor changes to the working procedures of the JMPR, than those described in "*Chapter 6. Options for major reform of the working procedures of the JMPR"*.

## 7.2 Establishment of JMPR pre-meetings

Presently there is some 'wasted' time at the current meetings of the JMPR due to the fact that reviewers' documents are not finalised prior to the meeting. For example, in the FAO Panel, a significant amount of time has been spent in recent years in the Members completing and updating their own evaluations. Members could spend this time more efficiently by concentrating on peer reviewing the work of others. Similarly, it was reported that in the WHO Core Assessment Group there have been some cases, where the assigned member has not had time to adequately peer review a temporary adviser's evaluation prior to the meeting. This has also led to discussions at the Meeting on issues that may have been able to be resolved beforehand. It is recognised that this 'wasted' time is a function of the extremely heavy pre-meeting workload on Members and Temporary Advisers and is not as a result of their lack of commitment and dedication.

Having regular pre-meetings of the FAO Panel and the WHO Core Assessment Group, well before the main Meeting, could save some of the time of the JMPR. Draft Preliminary assessments and tentative decisions could be decided prior to the official session. Major problems could be identified and addressed in advance. These pre-meetings could also be used for the secretariat to obtain information on progress with the drafting of the *global monographs* and the *draft preliminary assessments*. It is recognised that the FAO Panel already have a pre-meeting for the 3-4 days before the JMPR. However, this FAO pre-meeting, whilst being useful, is more like an extension to the main Meeting and is too late to address major issues and inadequacies in preliminary assessments prior to official session. It is suggested that pre-meetings might best be held 2 months before each of the meetings of the JMPR.

Pre-meetings could be held by telephone conference, or where facilities allow, by video-conference. These pre-meetings are included *in Figure 2 – A possible timetable and consultative procedure for the work of the JMPR*, which was included in *"Section 6.2 JMPR as a international peer review body"*. Some additional financial resources are likely to be required to implement pre-meetings into the work of the JMPR.

**Recommendation: 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.**

## 7.3 Geographical representation and expert capacity building

The issue of Geographical representation was introduced in *"Section 5.5.3 Geographical Representation"*. In summary, it was the view of all of those consulted in the preparation of this report that the obligation to ensure geographical representation in the selection of the FAO Panel and the WHO Core Assessment Group potentially limits the capacity of the JMPR.

In implementing their policy on the ensuring geographical representation of participants in FAO and WHO meetings, it recommended that a distinction is made between policy and technical expert committees. Geographical representation should not be the primary overriding consideration in the selection of technical expert committees. Indeed, geographical balance in the selection of experts must not compromise the scientific excellence of the reviews. However, where a particular geographical region is consistently underrepresented, then it is recommended that expert capacity building is undertaken to ensure that this situation does not continue for a sustained period. The FAO are currently considering a proposal "*to accelerate the review of pesticides under the JMPR/CCPR process by training of additional scientists from developing countries as potential panel members for the FAO Panel of Experts. New members will be trained in the process of establishment of MRLs and in the estimation of dietary intake and risk to pesticide residues in food and the environment*". This development should be welcomed.

**Recommendation: 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.**

It is recognised that IPCS now invites a small number of scientists from developing countries to both the JECFA and the JMPR as Temporary Advisors using a development fund.

7.4 Editing and timing of the JMPR monographs and report

As the monographs have grown in size, the editing demands have also grown. One of the key sources for the delay in the publication of the JMPR monographs is the reliance on single 'traditional' editors that have reviewed the work of the Panels for a number of years.

Whereas this historic approach has provided the FAO and WHO with a cost-effective way of ensuing that the monographs are satisfactorily edited, this has recently been at the expense of the timely provision of the monographs to the CCPR. The JMPR report is normally available within a few months of the Meeting; the monographs are now not normally available until about 15 months after the Meeting. Since the CCPR requires the monographs for their consideration, this has led to a delay of typically 19 months between the JMPR and the first consideration of the JMPR's recommendations at the CCPR.

It is recognised that the editing of the JMPR report is extremely useful. However, the editing of the JMPR monograph (excluding the assessment section) arguably adds far less value, except perhaps for some non-English speaking evaluators. Indeed the monograph is a highly technical document and is already peer reviewed at the meeting

by the FAO Panel and the WHO Core Assessment Group. In addition, the sponsor checks the accuracy of the monographs prior to the meeting. Eliminating the editing of the JMPR monograph, as is largely the case for the FAO components of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) monographs, could potentially lead to a time saving of one year. Where necessary, additional assistance could be given to non-English speaking evaluators prior to the JMPR to ensure that post-Meeting editing of their monographs are not required. The Assessment section which is currently included in the monographs would be only included in the report under this proposal.

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

If professional editing of the monographs is retained, then subject to resources, a professional scientific publishing house could be engaged with tight deadlines, and penalties where these are not met, built into the contract. This editing would not delve into the technical and scientific issues within the monographs, as is currently the case with the editing of the monographs. It should be the role of the JMPR Members at the meeting to ensure that the technical and scientific issues in the monographs are adequately peer reviewed.

**Recommendation: 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 adhered.**

7.5 Appointment of an experienced peer reviewer for the FAO Panel

Under the current arrangements, the FAO Panel Members not only peer review the work of the other Members, but also write and present at least one *comprehensive global monograph* and *draft preliminary assessment* to the Meeting. If this system is to be retained, it is recommended 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. The experienced reviewer should be identified as either Members, Consultants or staff, in order to clarify their status, including whether they are entitled to vote, at the Meeting.

**Recommendation: 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.**

7.6 Co-ordination between the FAO Panel and the WHO Core Assessment Group

Recently the FAO Panel has considered the appropriateness of a one year delay between the consideration of a compound by the WHO Core Assessment Group and the FAO Panel. This is in recognition of a recent problem where at the JMPR, the Members of the WHO Core Assessment Group did not agree with the conclusions of the toxicological reviewer on the toxicological significance of certain metabolites. This information is needed by the FAO Panel prior to the Meeting to derive the residue definitions for the estimation of maximum residue levels and STMRs.

Similarly the preparatory work of the FAO Panel is also partly dependent on whether the WHO Core Assessment Group consider it appropriate to establish an acute RfD. An example of this issue arising was at the 2001 meeting, where the reviewer of spinosad recommended an acute RfD to the Meeting, but the WHO Core Assessment Group agreed that an acute RfD was "unnecessary". The pre-Meeting work by the FAO Panel reviewer, to identify HRs and present an acute intake assessment, was not necessary.

It is the view of the author of this report, that the FAO Panel and the WHO Core Assessment Group should consider compounds at the same meeting wherever possible. To facilitate this, a mechanism needs to be developed by the FAO and WHO secretariats to ensure that reliable information on the metabolites relevant to the estimation of maximum residue levels and STMRs and whether an acute RfD will be established, are passed to the FAO Panel reviewer prior to the Meeting. This mechanism could include enhanced dialogue between the two reviewers and discussion on the residues definitions in a pre-meeting of the WHO Core Assessment Group.

**Recommendation: 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.**

## 7.7 Dietary risk assessment

Recently, at the 33rd session of the CCPR "The Secretariat recalled that according to the *Statements of Principles Relating to the Role of Food Safety Risk Assessment*, health and safety aspects of Codex decisions and recommendations should be based on risk assessment, as appropriate to the circumstances. The establishment of MRLs for pesticides in the absence of such a risk assessment would not be consistent with the risk analysis principles applied throughout Codex and would significantly impair their relevance in international trade." This discussion is included in "*Annex 7 – Relevant extracts from the Report of the 33rd CCPR, April 2001."*

The JMPR have also recently developed many new general principles within the risk analysis paradigm eg. the concept of the STMR. The author of this report believes that dietary risk assessment will remain an integral and important part of the work of the JMPR and should be further enhanced.

**Recommendation: 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.**

Consideration should be given to enhancing the current capability of the JMPR to undertake dietary intake assessments. A third Panel in the work of the JMPR is not considered necessary by the author of this report. However, consideration should be given to bringing additional expertise into the JMPR eg. in food consumption, dietary modelling, uncertainty analysis etc.

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

7.8 Environmental fate and mammalian metabolism data

There is some duplication in the data that are evaluated by the FAO Panel and the WHO Core Assessment Group, in that both evaluate the mammalian metabolism data that is submitted by the sponsor company. The FAO Panel consider these data in order to obtain an understanding of the metabolism in animals other than ruminants and poultry. Many JMPR monographs therefore have two different summaries of the same mammalian metabolism study reports.

In the view of the author of this report, the mammalian metabolism data is somewhat peripheral to the estimation of MRLs for ruminants and poultry. The FAO Panel Members could obtain this information by reference to the toxicological monograph produced for the WHO Core Assessment Group, rather than a new evaluation of the same study reports. To help the FAO Panel reviewers, the WHO reviewer should report information on tissue disposition of the residue and issues of fat solubility, which may be important from a residue perspective.

The FAO Panel of the JMPR also evaluates a number of environmental fate data for the compound under evaluation, as listed below:

- metabolism and degradation in soil, identification of metabolites and degradation products, and an indication of their levels
- persistence of the parent compound and its metabolites or degradation products in soil under aerobic and anaerobic conditions
- mobility of the parent compound and its transformation products in soil
- adsorption by various soils
- hydrolysis rate and products
- photolysis on soil and plant surfaces
- crop uptake and bioavailability of parent compound and its major transformation products
- soil dissipation
- residue degradation and disposition in water-sediment systems.

Whereas these data can be relevant to the levels of residues in succeeding crops and in determining whether residues are “essentially zero” in root crops and seed treatments, the FAO Panel rarely directly uses these data in the estimation of maximum residue levels. Indeed these data are usually peripheral to the estimation of the maximum residue levels and not generally used by national regulatory authorities in their consideration of MRLs. In the context of the severe workload of the FAO Panel and backlog of work of the JMPR, the routine summarisation of these data in the monographs is not justified.

**Recommendation: 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.**

7.9 Arrangements for interaction with sponsor companies

The current practice of the JMPR is to sort out factual matters any anomalies in the documentation with the sponsor company prior to the Meeting. Improvements in this process have occurred over recent years and this is usually now done by e-mail.

However, points of interpretation and other matters arising during the JMPR discussions are raised with the sponsor company representative during the course of the Meeting. Occasionally, company representatives on 'standby' for one week in Rome or Geneva, are not asked a single question by either the FAO Panel or the WHO Core Assessment Group. In many other cases, the company representative has not been in a position to answer the question due to its highly technical nature and have had insufficient time to obtain further details from study directors or company scientists.

Traditionally, these questions have been handed over on pieces of paper and the representatives of the sponsor companies have then been formally 'interviewed' by either the FAO Panel or the WHO Core Assessment Group.

**Recommendation: 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.**

7.10 Use of data submitted in an electronic format

The submission of data at the national level is now largely in electronic format for many countries.

The use of electronic data submission of full study reports can provide time savings to the reviewers, where reviewers are familiar with working in this format. It is recognised that some reviewers will continue to wish to receive all the data in hard copies and indeed it is reported that the current FAO Panel reviewers' all request a hard copy. Nevertheless, the use of electronic versions of the data can still offer potential efficiency gains to the work of the JMPR.

**Recommendation: That all sponsor data submissions to be provided in electronic form, preferably in the form of a CD-ROMs. An additional hard copy would also be provided whenever the reviewer requires this.**

7.11 Working language of the JMPR

Recent experience with experts that are not conversant with using with the working language of the meeting (ie. currently English) indicates that there are practical problems associated with working with additional languages. In view of the limited resources available to the JMPR, and these practical problems, it is envisaged that the Meeting should continue to work in English.

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

7.12 Naming in the monograph of the primary author

The WHO Panel currently refers to the first author of the monograph for each of the compounds published. That is the monograph states "First draft prepared by …..". JECFA have adopted a similar practise for the publication of monographs on food additives, contaminants, and residues of veterinary drugs. The FAO Panel of the JMPR has not adopted this practice.

This attribution in the monographs to the first-draft author of the evaluation gives some recognition to the first author and is particularly favoured by those Members or Temporary Advisers who come from an academic background.

Given that attribution in the monograph may, in a small way, contribute to as increased willingness of participation by additional suitable experts, it is recommended that the FAO Panel also adopt this system.

**Recommendation: 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.**

7.13 Other issues

7.13.1 Accelerated procedure for uncontroversial issues

In consultations made in the preparation of this report, the idea of having a JMPR *accelerated procedure for uncontroversial issues* was raised. This is not favoured by the author of this report in that the JMPR is a scientific body and should not be placed in a position to make a judgement on the level of controversy that is associated with a particular issue or compound. Nevertheless, the option exists for the CCPR to ask the JMPR to give priority consideration to certain issues.

7.13.2 Maintenance of the independence of the advice of the JMPR

The JMPR at its 2000 Meeting commented on the issue of maintaining the independence of the JMPR decision-making process, as outlined in "*Annex 5 – Relevant extracts from the 2000 JMPR report*". This follows the publication of the document "*Tobacco Company Strategies to Undermine Tobacco Control Activities at the World Health Organization, Report of the Committee of Experts on Tobacco Industry Documents, July 2000*.

The 2000 Meeting recognised the seriousness of this accusation and acknowledged that the credibility of the JMPR had been damaged by the events of 1993. The 'tobacco report' alleges that Dr G. Vettorazzi, who served as a temporary adviser at the Meeting, specifically influenced the outcome of the toxicological evaluation of ethylenebisdithiocarbamates and ethylenethiourea at the 1993 Meeting.

Whilst it appears that Dr Vettorazzi had little influence on the outcome of the evaluation of ethylenebisdithiocarbamates or ethylenethiourea, the incident has highlighted the need to ensure that the integrity and scientific reputation of the Meeting is maintained. It is also important that the perception of JMPR as a body of integrity and scientific reputation of the JMPR is also maintained. In recognition of these issues, the 2000 JMPR made a number of recommendations.

In response to the 'tobacco report', the FAO and WHO have made two major changes to its procedures. Firstly, a revised procedure for the selection of experts for the JMPR has been implemented. The FAO-version of this procedure is given in "*Annex 8 - Call for submission of applications to establish a roster of experts as candidates for membership of the FAO Panel of the JMPR"*. The new procedure is more open and has resulted in a number of new potential Panel Members being identified. Secondly, all attendees at the JMPR are now asked to sign a revised 'Declaration of Interest Form' to identify any potential sources of bias or conflict of interest. The draft FAO-version of this form is given in *"Annex 9 – Draft FAO Declaration of Interest Form"*.

The investigations into the 'Vettorazzi affair' also highlighted that there was no record of 'what was said and by whom', other than in the overall meeting report. Investigation of the role and involvement of Dr Vettorazzi depended primarily on personal mental recollections.

**Recommendation: 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.**

The 33rd session of the CCPR also considered the 'Vettorazzi affair' as documented in *"Annex 7 – Relevant extracts from the Report of the 33rd CCPR, April 2001"*. The CCPR supported the recommendations of the 2000 JMPR and several delegations "expressed the importance of improving the transparency and accountability of FAO, WHO and Codex".

### 7.13.3 Submission of data to the JMPR

An additional issue that affects the evaluations undertaken by the JMPR is that currently very few national governments or other interested parties submit scientific data to the JMPR. As a consequence almost all of the data evaluated by the Meeting are derived from a single sponsor company for each pesticide. As a result, the Meeting commonly only has supervised residue trials data coming from only one or a few countries, even though the resulting MRL, if adopted by the CAC, will apply as a world-wide standard.

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

# 8. Further issues

## 8.1 Establishing the JMPR agenda

### 8.1.1 Prioritisation of chemicals for the JMPR agenda

A common theme though many of the consultations that were undertaken in the preparation of this report, was the need for the prioritisation of the JMPR agenda to be enhanced. This is currently undertaken by the Priorities working Group at the CCPR in co-ordination with the joint secretaries to the JMPR.

Recent experience has shown that the evaluation work schedule of the JMPR evaluations does not take sufficient account of the review activity being undertaken in countries with significant regulatory activity. For example, recent meetings of the FAO Panel of the JMPR has been presented with more than one GAP for countries of the European Union. One set of GAPs represented the current historical GAP and a further set represented the revised GAP proposed by the sponsor as part of the EU review procedure under directive 91/414/EEC. A significant number of data requirements are also frequently established as a result of national review activity. It is in the interests of the JMPR to dovetail with these national activities in order to ensure that the most up-to-date data and GAP information are available to the meeting.

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

Additional problems for the JMPR have arisen when the referrals from the CCPR to the JMPR on technical questions have not been adequately articulated. The brevity of the CCPR report has exacerbated this problem, which is not normally a sufficient basis for the JMPR to clearly identify the issue.

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

### 8.1.2 Priority given by the CCPR to important commodities

The consideration of compounds by the JMPR could be accelerated by priority being given, by the CCPR, to the consideration of ‘important commodities’. ‘Important commodities’ could be those that are major crops in global trade or major contributors to the diet. The question has been asked as to whether, with limited resources, the JMPR should spend time considering minor crops. eg. kohlrabi, whilst other more major crops eg. cereals, wait for the estimation of maximum residue levels.

However, care would have to be taken in identifying “important commodities”, since a fruit may be a minor commodity in one country but a major export commodity for another country. Criteria would therefore need to be developed for the ranking of commodities to ensure that those commodities that are ranked highly did not disproportionately favour particular countries or regions.

In the view of the author of this report, the consideration of some 'important commodities' over more 'minor commodities' by the JMPR, is unlikely to result in a major time saving for the meeting, due to the consideration of residue trials being only a small part of the overall monograph preparation.

8.1.3 Balance between new active ingredients and periodic review chemicals

At the 33rd session of the CCPR concern was expressed by several governments about the low number of new compounds that have been evaluated over recent years by the JMPR. Indeed, periodic review compounds have dominated the agenda of the JMPR over recent years. At the 33rd session, the Priorities Working Group recommended, and the CCPR concurred, at the 33rd Session (2001) that the priorities list would be 50% 'new'/50% 'old' pesticides. Thus, at least 50% of the review schedule is reserved for new nominations.

The approach endorsed by the 33rd session of the CCPR provides a sensible balance between 'new' and 'old' chemicals. The author of this report does not support an extension of this policy to give new pesticide nominations absolute priority, with any vacancies in the schedule being filled with periodic review pesticides. This policy could result in many old pesticides, which are not supported by adequate data, and for which the GAP on which the MRL was originally based having potentially changed, remaining in place for many more years.

8.2 Needs of developing countries

The limited resources available to undertake this consultancy did not allow formal consultation with government representatives from developing countries. However, it is recognised that the extent to which the JMPR monographs and reports meet the needs of the developing countries needs to be further investigated. Whereas several residue control laboratories in developing countries make reference to the analytical methods section of the monographs, it would appear that the rest of the monographs are less routinely utilised. Indeed it would appear that for some developing countries, the monographs have become less user-friendly and too detailed, as they have expanded in recent years.

**Recommendation - 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.**

Historically, both developed and developing countries referred to the JMPR monographs in their registration activity. However, many developed countries have developed their own comprehensive pesticide data evaluation capability. In recognition of this, some developing countries are basing their decisions on whether registration has been granted in either the USA or the EU, rather than solely on the JMPR monographs.

8.3 Relationship between MRLs and GAPs

Registration activity means that GAPs can change frequently. Where the GAP, on which the Codex MRL is based, is revoked or changed at the national level then there is no mechanism to initiate the review of the MRL that is based on that GAP. Logically,

the JMPR's MRL recommendation should be reconsidered whenever the defining GAP, on which the MRL is based, changes. This is a serious inadequacy in the current system.

**Recommendation: 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.**

The 1999 JMPR considered the related issue of Periodic review of residue data for compounds currently under national re-registration as outlined in *"Annex 4 – Relevant extracts from the 1999 JMPR report"*. The JMPR highlighted the problems associated with reviewing compounds under the CCPR Periodic Review Programme that are also undergoing re-registration by national or regional authorities. Of particular note is the invitation by the Meeting to the CCPR to consider an alternative approach in the case of periodic reviews of compounds for which GAP is being changed significantly to meet increased safety requirements. Namely that the JMPR should recommend MRLs on the basis of trials data reflecting the amended uses provided the notifying Government gives a clear statement that old labels will be withdrawn and by what date.

The willingness by the 1999 JMPR to consider a more flexible approach in estimating maximum residue levels for proposed GAPs (ie. new or amended uses) is welcomed by the author of this report. However, this approach was not fully endorsed by the CCPR and the issue was considered again by the 2000 JMPR as described in *"Annex 5 – Relevant extracts from the 2000 JMPR report"*. In summary, the 2000 Meeting decided that although maximum residue levels would be estimated for proposed uses, maximum residue limits would only be recommended for current uses. Recommendations for proposed uses would only be made when they become extant GAP.

Given the long delay in the JMPR/CCPR process, as described in detail in the USA drafted paper "Trade Vulnerabilities Resulting from the Lengthy Codex Process", a similar approach to proposed GAPs could be utilised by the JMPR for new compounds. That is, the JMPR could evaluate the new compound and estimate a maximum residue level prior to the granting of the registration. The maximum residue level would then only be recommended for use as a maximum residue limit by the JMPR, when the registration had been granted and confirmation of the GAP sent to the JMPR. In cases where the JMPR evaluation has already been carried out, the adoption of this approach could significantly reduce the period of trade vulnerability. It is recognised, however, that this could be an inefficient use of JMPR resources in that GAP may be changed prior to the granting of national registration or the national registration authority may refuse the GAP. For this reason this approach would only be appropriate if the capacity of the JMPR is significantly enhanced so that resources were not diverted from compounds with confirmed GAPs.

**Recommendation: 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.**

## 8.4 MRLs for both pesticide and veterinary drugs

Some chemicals have dual uses as pesticides and as veterinary drugs and may therefore be evaluated by both the JMPR and JECFA. These two committees both establish MRLs but do so in a fundamentally different way. Whereas the JECFA MRLs are commonly related to the ADI, the JMPR MRLs are based solely on the levels that arise from GAP.

The FAO and WHO have recently initiated a project to "update and consolidate principles and methods for the risk assessment of food additives, contaminants, residues of veterinary drugs, pesticide residues, and certain food components." This was in response to a recommendation from the *Conference on International Trade Beyond 2000: Science-based Decisions, Harmonisation, Equivalence and Mutual Recognition* held in Melbourne in October 1999.

Although one of the objectives of this recent FAO/WHO initiative is to harmonise the JMPR and JECFA mechanism for MRL setting as far as is practicable, it seems likely that two different systems for the establishment of MRLs will remain. This situation leads to confusion within the community about the role of MRLs and in particular on the public health significance when an MRL is exceeded. Although MRLs for pesticides are not direct safety limits, they are often perceived to be the level above which dietary intake is unsafe. This perception is reinforced by the use of the word "maximum". If harmonisation of the JECFA and JMPR mechanism cannot be reached, consideration should be given to using different terminology, given that other risk communication measures are unlikely to completely resolve this issue. For example pesticide MRLs could be renamed "tolerances" a term that is used in the USA and is fairly well understood.

**Recommendation: That the CCPR consider using a terminology other than 'MRL' in the future of pesticides, to enhance risk communication and to clearly differentiate between pesticide standards and those MRLs set by a different methodology for veterinary drugs.**

## 9. Future work

This report has outlined a number of options for major reform of the working procedures of the JMPR, which should be carefully considered by the FAO, WHO, the CCPR and other interested parties. In addition, this report contains a large number of individual recommendations, which also need to be carefully considered.

As previously described, the limited resources available to undertake this consultancy did not allow formal consultation with government representatives from developing countries. It is has therefore been recommended that further work be initiated to investigate the needs of developing countries with respect to the JMPR and it's written monographs and reports.

Subject to the agreement of the FAO and WHO, it would appear logical for this report to be presented to the CCPR and for the report to act as one of the input documents into the joint FAO/WHO Consultation considering the provision of scientific advice to Codex, planned for mid-2002. In addition, the planned FAO/WHO Consultation could discuss the following problems:

- the reasons for the low level of acceptance of Codex MRLs (notably by the USA and EU);
- funding of capacity building activities to enable the developing countries to provide data for JMPR assessment and to play an active role in the JMPR / Codex procedure;
- increase in the financial contribution of national governments and other stakeholders.
- increase in the submission of scientific data by national governments and other interested parties to the JMPR.

## 10. Glossary of Terms

| | |
|---|---|
| Acute RfD | Acute Reference Dose |
| ADI | Acceptable Daily Intake |
| CAC | Codex Alimentarius Commission |
| CXLs - | Maximum Residue Limits that have that have been adopted by the Codex Alimentarius Commission |
| CCPR | Codex Committee on Pesticide Residues |
| EMRL | Extraneous Maximum Residue Limit |
| EPA | Environmental Protection Agency |
| EU | European Union |
| FAO | Food and Agriculture Organization of the United Nations |
| GAPs | Good Agricultural Practices |
| GATT | General Agreement on Tariffs and Trade |
| HR | Highest residue |
| ILO | International Labour Organisation |
| IPCS | International Programme on Chemical Safety |
| JECFA | Joint FAO/WHO Expert Committee on Food Additives |
| JMPR | Joint FAO/WHO Meeting on Pesticide Residues |
| MRL | Maximum Residue Limit |
| NAFTA | North American Free Trade Agreement |
| NAS | National Academy of Sciences |
| NGO | non-governmental organisation |
| OECD | Office of Economic Co-operation and Development |
| PSD | Pesticides Safety Directorate |
| SPS | Sanitary and Phytosanitary Agreement |
| STMR | Supervised Trials Median Residue |
| TBT | Technical Barriers to Trade Agreement |
| UNEP | United Nations Environmental Programme |
| UK | United Kingdom |
| USA | United States of America |
| WHO | World Health Organization |
| WTO | World Trade Organization |

## 11. Acknowledgements and Interviewees

The following represents a list of the people that were interviewed during the development of this report. However, although taking into account the views of those consulted, this report represents the views of the author and not necessarily those of the interviewees.

11.1 Chairpersons of the CCPR and the JMPR

Denis ***Hamilton***, Chair of the FAO Panel of the JMPR, Queensland Department o Primary Industries, Brisbane, Australia

Wim ***Van Eck***, Chair of the CCPR, Ministry of Health, Welfare and Sport, The Hague, Netherlands

Jan ***Van der Kolk***, Former Chair of the CCPR, Ministry of Housing, Spatial Planning and the Environment, The Hague, Netherlands

11.2 Consumer Organisations

Edward ***Groth***, Consumers International, New York, USA

Lisa ***Lefferts***, Consumers International, Washington DC., USA

11.3 Independent Scientific Organisations

Penny ***Fenner-Crisp***, Member of the WHO Core Assessment Group of the JMPR, International Life Sciences Institute (ILSI), Washington DC., USA

Myron F. ***Uman***, US National Academy of Sciences, Washington DC., USA

11.4 Industry Consultants, Agrochemical Industry and Growers

Hugh W. (Wally) ***Ewart***, President, California Citrus Quality Council, Auburn, California, USA

Cecelia P. ***Gaston***, Novigen Sciences, Washington DC., USA

Richard J. ***Nielsson***, Consultant to Crop Life International (formerly the Global Crop Protection Federation)

Barbara ***Peterson***, Novigen Sciences, Washington DC., USA

Eric ***Rosenberg***, Bryant Cristy incorporated, Seattle, USA

Gabrielle ***Timme***, Bayer AG, Agrochemicals Centre Monheim, Leverkusen, Germany

11.5 International Organisations (ie. WHO and FAO)

John ***Hermann***, WHO Joint Secretary to the JMPR, WHO, Geneva, Switzerland

Masa ***Keto***, Evaluation Service, FAO, Rome, Italy

John ***Markie***, Evaluation Service, FAO, Rome, Italy

Jeronimus ***Maskeliunas***, FAO joint secretary to the CCPR, FAO, Rome, Italy

Bill ***Murray***, Pesticide Management Group, FAO, Rome, Italy

Manfred ***Luetzow***, FAO joint secretary to the JECFA, FAO, Rome, Italy

Amelia ***Tejada***, Pesticide Management Group, FAO, Rome, Italy

Gero ***Vaagt***, Pesticide Management Group, FAO, Rome, Italy

Nick ***Van der Graaf***, Head of Service, FAO, Rome, Italy

11.6 National Government or Supranational Organisation Representatives

Ann ***Backhouse***, Codex coordinator for the Australian government, Agricultural, Fisheries and Forestries - Canberra, Australia

Les ***Davies***, Chemicals Evaluation Unit, Therapeutic Drugs Administration, Department of Health and Aged Care, Canberra, Australia
Bas ***Drukker***, Pesticides Section, Health and Consumer Affairs Protection Division, Commission of the European Communities, Brussels, Belgium
David A. ***Egelhofer***, Foreign Agricultural Service, United States Department of Agriculture, Washington DC., USA
Steve ***Funk***, Member of the FAO Panel of the JMPR, Office of Pesticide Programs, Environmental Protection Agency, Washington DC., USA
Marion ***Healy***, Chief Scientist, Australia New Zealand Food Authority, Canberra, Australia
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## 11.7 Other acknowledgements

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## 13. List of Annexes

## Annex 1 - Consolidated List of 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. (section 6.2.2)

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. (section 6.2.5)

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. (section 6.2.6)

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. (section 6.4.2)

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. (section 6.4.3)

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). (section 6.5)

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. (section 6.6.3)

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. (section 6.8.2)

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. (see section 6.8.3)

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. (section 7.2)

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. (section 7.3)

12. That the JMPR monographs no longer be edited allowing the CCPR to consider compounds one year earlier. (section 7.4)

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 adhered. (section 7.4)

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. (section 7.5)

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. (section 7.6)

16. That additional expertise related to undertaking dietary intake assessments is brought into the JMPR. (section 7.7)

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. (section 7.6)

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. (section 7.7)

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. (section 7.9)

20. That the working language of the JMPR remains as English given the practical problems that would be associated with working with additional languages. (section 7.11)

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. (section 7.12)

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. (section 7.13.2)

23. That national governments and other interested parties ensure that they submit all relevant data to the JMPR. (section 7.13.3)

24. That there be better co-ordination between the JMPR timetables and that of national authorities undertaking significant data assessment and re-registration activity. (section 8.1.1)

25. That the Joint Secretaries only accept technical questions (referrals) from the CCPR where these are clearly articulated and documented. (section 8.1.1)

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. (section 8.2)

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. (see 8.3)

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. (section 8.3)

29. That the CCPR consider using a terminology other than 'MRL' in the future of pesticides, to enhance risk communication and to clearly differentiate between pesticide standards and those MRLs set by a different methodology for veterinary drugs. (section 8.4)

NOTE:
A number or additional options for reform of the JMPR are given in *"Chapter 6. Options for major reform of the working procedures of the JMPR"*.

## Annex 2 - Terms of Reference for the Review of the Working Procedures of the Joint FAO/WHO Meeting on Pesticide Residues

**Objective:** *A critical review of the operation of the Joint FAO/WHO Meeting on Pesticide Residues and identification of options on how the JMPR can continue to meet the requirements and expectations of governments and the Codex Alimentarius Commission.*

Under the technical supervision of the FAO Plant Protection Service and the WHO Programme on Chemical Safety, the consultant will:

1. Define and clarify the need for internationally harmonised and accepted trading standards for pesticide residues in food, impact of Codex MRLs at the national/international level, use by governments and other organisations.

2. Review the relationship of JMPR to the Codex Committee on Pesticide Residues (CCPR), the Codex Alimentarius Commission and FAO and WHO. Consider how JMPR started and why, how expectations have changed and the ability of the original operational structure to continue to meet increased demand/expectations of the CCPR

3. Critically review the current operational procedures of the JMPR and identify those critical points that limit capacity. This should also include a consideration of the institutional constraints within FAO and WHO including but not limited to: level of funding/resources, sources of funding (extra-budgetary and regular programme), availability of technical expertise (within the limitations of governmental institutions that provide it) and need for geographic distribution of participants.

4. Outline a strategy for redefining the current approach to the operation of the JMPR, that includes proposals for addressing, in the short and medium term, the constraints identified. The proposals should contain distinct recommendations for action to FAO/WHO and the CCPR and should at a minimum consider the following issues: priority setting – for both commodities and chemicals; use of national/regional reviews by the JMPR; new chemicals versus periodic reviews; development of a global residue data base - applicability of residue zones; and the role of dietary risk assessment in the work of the JMPR/CCPR.

5. Define the anticipated human and financial resource implications of the strategy and proposals for redefining the approach to the operation of the JMPR for FAO, WHO, governments and pesticide industry, commodity groups and other potential interested parties.

6. Application of the strategy and associated proposals to the existing backlog and explanation of how they would serve to avoid creation of further a backlog in future. This should include the role of: national governments and the CCPR, pesticide industry as well as commodity groups.

7. Identification of further issues that will need to be considered by FAO, WHO and governments through the CCPR and Codex Alimentarius.

This consultancy will be carried out in close cooperation with the two Joint Secretaries of the JMPR. It will involve direct communication and meetings with government officials, non-governmental officials (including public interest groups, commodity and grower groups and pesticide industry representatives), representatives of the secretariat to the Codex Alimentarius, JMPR Panel Members and others involved and experienced in the operation of the JMPR and CCPR. The review should focus on item nos. 3 and 4. Item no 5 should address in general the necessary steps for FAO and WHO and the other potential interested parties.

The following excerpts from recent reports provide some background information:

- JMPR reports 1998 and 1999
- Report of the 33rd CCPR, April 2001

## Annex 3 – Relevant extract from the 1998 JMPR report

2.1 The capacity of the JMPR to undertake periodic reviews

The increasing amount of data on pesticides and the desire for more transparency, both of which require the preparation of increasingly comprehensive reports and evaluations, put severe strain on the JMPR. Assessments of dietary risk that incorporate estimates of intake, which were included in the report for the first time at the present Meeting, necessitate the estimation of STMR [and STMR-P] levels for processed items, which require more detailed reviews of residue trials, animal feeding studies, and food processing procedures than are needed for the estimation of MRLs alone. In addition, the complexity of the evaluations is increased when pesticides are re-evaluated under the CCPR Periodic Review Programme because data have been produced over many years according to different guidelines, often with technical products that meet changing specifications, differing residue definitions, and considerable changes in GAP.

Participants in the JMPR are subject to severe time constraints both during the preparation of their draft evaluations and during the Meeting itself. In many cases the preparatory work is done in their own time because their employers (usually national regulatory authorities) do not provide time for this work during office hours. Related to this, their work is sometimes not recognised as being important for the support of decisions on national registrations and for establishing international food standards. International peer reviews of national assessments substantially enhance the efficiency and quality of the JMPR evaluations, clearly demonstrating the mutual benefits of active participation in the Joint Meeting to both JMPR and the national authority.

To respond adequately to these constraints, better co-ordination and additional resources are needed. For efficient co-ordination between the CCPR and the JMPR Joint Secretaries, information is required from national delegations to the CCPR on their review schedules. The setting of priorities should take into account the amount of information to be evaluated for each compound, which will help the Secretariat to distribute the workload equally among the reviewers.

# Annex 4 – Relevant extracts from the 1999 JMPR report

2.1 Increasing workload of JMPR participants

The 1999 CCPR, after considering the 1998 JMPR Report *The capacity of the JMPR to undertake periodic reviews*, requested the JMPR Secretariat to prepare a short paper for consideration at the next Session with practical proposals to address this issue (31st Session of the CCPR, ALINORM 99/24A, para 21).

The Meeting was pleased to note that the CCPR had recognised the problems for the JMPR participants associated with the increasing workload arising, as explained in the 1998 report, from the need for transparency and the increasing quantities of data being evaluated.

The amount of work required has increased because of the high level of detail in modern data submissions. For example, it may not always be apparent that many points must be checked in evaluating residue trials that are generally not recorded in the published evaluations, including plot areas, description of application equipment, application calibration, treatment dates, sampling and harvest dates, analysis dates, freezer storage periods and comparison with the periods in freezer storage studies, procedural recoveries, sample sizes, nature of the replications (if any), analyses of field control samples and weather and irrigation, all of which may influence residue levels. Similarly, details such as data on individual animals in toxicological studies must often be reviewed. Because of the necessity for clear communication of risk assessments, the reports and evaluations are becoming more detailed and complex.

The use of national evaluation documents aids the Meeting in its toxicological evaluations of the original reports of the studies and other pertinent information that are reviewed. Although the use of national documents does not eliminate the need to evaluate the original studies, it helps to identify the studies that are available to ensure that the full database has been evaluated. On the other hand, the use of national residue evaluation documents is generally of limited assistance, because national evaluations focus mainly on national uses and national data whereas the JMPR makes a detailed examination of labels from around the world and compares trials with the relevant GAP. This is a different process from national residue evaluation and registration. National residue evaluations will provide helpful additional information for some sections, e.g. farm animal metabolism and feeding, but the Meeting did not believe that the use of national evaluations would decrease the workload.

The work currently required by a JMPR member to evaluate the data before each JMPR is equivalent to up to 3 months full time. In many cases the situation that has developed is that members are not afforded sufficient time during working hours, but devote their personal time to the bulk of the work. Some members have advised that they cannot continue devoting so much of their personal time to the work required for the JMPR.

The value of a JMPR member's knowledge and experience to his or her own organisation and national government should not be underestimated even when the time is mainly oriented towards the establishment of international food standards. A working

knowledge of the JMPR/CCPR system is invaluable in aligning national and Codex standards and preparing data submissions to develop Codex MRLs.

The Meeting recommended

1. That the contribution of expertise and time of the JMPR members be formally recognised as a contribution by national governments to the Codex/FAO/WHO system.

2. That national governments agree, when members are appointed to the FAO Panel or WHO Core Assessment Group, to provide them with sufficient time and resources to complete their work to a standard expected of the JMPR.

2.5 OECD working group on pesticides - workshop on developing minimum residue data requirements for estimating MRLs and import tolerances

The Meeting welcomed a draft copy of the recommendations from the Workshop on Minimum Data Requirements for Establishing Maximum Residue Limits (MRLs), including Import Tolerances. This was an initiative funded by the European Commission to develop guidelines on the minimum or core data requirements. The terms of reference were outlined in the proposal presented and agreed by the November 1996 OECD Pesticide Forum. The primary objective was to examine those areas which represent the greatest obstacles to the establishment of national import tolerances and the acceptance of international MRLs.

The Meeting had previously noted the need for such work in 1994[4] and welcomed this initiative. It recognised that the workshop had promoted work in this area which should ensure that more relevant data would be available for evaluation by allowing comparabilities, particularly between countries. The recommendations were generally based on a compromise between national requirements but some, particularly on extrapolation, were a formalisation of current working practices. The Meeting considered that the value of the recommendations in this area could be strengthened by the production of a scientific report justifying them.

The Meeting was aware of the differences between the working practices of the JMPR and registration authorities; such authorities need to ensure that guidelines are rigidly applied to ensure consistency between registrants. However it noted that requirements for studies of plant and farm animal metabolism and animal transfer studies had shown a high degree of uniformity and acknowledged that their application would ease the work of the JMPR in evaluating studies in these areas.

It was acknowledged that the recommendations should be useful particularly with respect to minor crops, but that difficulties might arise owing to data being insufficient for statistical evaluation. The recommendations require few decline curve trials and the Meeting stressed the value of such trials, particularly in defining tolerances around GAP and so allowing data within a wider tolerance of GAP conditions to be used.

The Meeting looked forward to receiving information on developments in this area in the future.

[4] JMPR, 1994. General considerations 2.4. Data required for estimating maximum residue levels

2.10 Periodic review of residue data for compounds currently under national re-registration

The Meeting has noted when reviewing compounds under the CCPR Periodic Review Programme that further consideration needed to be given to the timing of these reviews and of the submission of the required data, in particular for compounds which are undergoing re-registration by national or regional authorities.

It appeared that in the framework of national or regional re-registration, the uses of several compounds were being substantially revised. For instance, reduced application rates and extended pre-harvest intervals should result in lower residues to meet more stringent safety criteria. In these cases the data submissions to the JMPR included current registered uses as well as labels awaiting approval by national Governments. Most of the field trial data submitted, however, were related to the envisaged new uses. In accordance with the Periodic Review procedure the Meeting could neither recommend new or amended MRLs nor recommend maintaining the existing MRLs. Situations also ocurred where old and revised labels existed simultaneously. The registered uses at higher rates on old labels precluded the evaluation of new data from trials at lower rates.

The Meeting was aware of the practical consequences of changing current agricultural uses, requiring a transitional period to withdraw existing registrations and introduce new labels. The situation affects the efficiency of the JMPR however as an additional review is warranted at such time as new labels come into force.

The Meeting recommended that this issue should be brought to the attention of the CCPR, so that Governments wishing to include compounds for periodic review in the priority list should be requested to give detailed information on the registration status at the time of notification and again later when the compound is actually scheduled for review by the JMPR in a specified year.

The Meeting invited the CCPR to consider an alternative approach in the case of periodic reviews of compounds for which GAP is being changed significantly to meet increased safety requirements, namely that the JMPR should recommend MRLs on the basis of trials data reflecting the amended uses provided the notifying Government gives a clear statement that old labels will be withdrawn and by what date.

# Annex 5 – Relevant extracts from the 2000 JMPR report

**"**2.5 Minimum data required for establishing maximum residue limits, including import tolerances

At its thirty-first session, the CCPR decided to refer to the JMPR the recommendations of a workshop organized by OECD and held at the Pesticide Safety Directorate, York, United Kingdom, in 1999 on minimum data requirements for establishing MRLs, including import tolerances, and asked for comments to be made available for the 2001 meeting of the CCPR.The JMPR in 1994 (Annex 6, reference 71) had noted the need for internationally agreed minimum data requirements from supervised trials for establishing MRLs, and the present Meeting welcomed the lead taken by the OECD in this area.

The guidance document was considered generally to reflect current JMPR practices. Comments on a draft copy of the document were provided to the CCPR by the 1999 Meeting (Annex 6, reference 86). The main purpose of the workshop was to facilitate harmonization of requirements for trials used for setting MRLs and import tolerances. The areas identified during the workshop as requiring harmonization were suitable climate zones for residue trials, criteria for determining the minimum number of trials required, and extrapolation of data on residues in one crop to support an MRL for a related crop. The comments of the Meeting on these points are as follows:

- *Climate zones*: The generation of maps of equivalent climate zones among which data from residue trials could be transposed, if based on sound science, could aid the JMPR in estimating MRLs. The Meeting agreed to consider carefully any outcomes of the OECD project on climate zones, the scientific basis (for evaluating residues), and how they might be used in evaluation at an international level.
- *Minimum number of trials*: In considering the minimum acceptable number of trials (conducted according to GAP) for estimating a MRL, the Meeting currently takes into account such factors as importance in trade and in the diet. The OECD document extended the considerations to take into account various climate zones. The Meeting agreed to consider the OECD workshop proposals when they were finalised.
- *Extrapolation between crops*: One difficulty in extrapolating information on residues in one crop to another at the international level has been lack of agreement on which extrapolations are acceptable. In this area, the Meeting has taken a conservative approach. Agreement on extrapolations that are possible in principle would be useful
- *Processing studies*: The OECD paper outlined the minimum requirements for processing studies, including possible extrapolation of processing factors from, e.g., one oilseed crop to another or carrots to tuber crops.

The JMPR will follow developments in this area with interest. The Meeting was aware of an OECD project for defining climate zones, and a meeting on this subject was held on 12–13 September 2000 in Geneva prior to the 2000 JMPR. Of particular interest to the Meeting was the plan to validate zone models on the basis of significant differences in residue levels. The Meeting looked forward to updates on follow-up to the OECD workshop.

2.6 Periodic review of data on residues of compounds currently being re-registered nationally

The 1999 Meeting noted that further consideration should be given to the timing of reviews within the CCPR periodic review programme and the submission of the required data, in particular for those compounds that are also being re-registered nationally. In national review programmes, current uses are frequently revised substantially to meet new requirements for the safety of human health and the environment. The data submitted to the Meeting therefore often include both current registered uses and labels awaiting approval by national authorities. Data from field trials, however, usually relate to new uses. In such cases, the Meeting cannot amend or recommend maintenance of existing MRLs. Furthermore, for some compounds, both old labels and revised labels stipulating lower rates exist simultaneously, and MRLs reflecting the adjusted uses cannot be established.

In 1999, the meeting recommended that this issue should be brought to the attention of the CCPR and invited the Committee to consider an alternative approach in the case of periodic review of a compound for which GAP is being changed significantly to meet safety requirements. For the sake of efficiency, the Meeting proposed to recommend MRLs on the basis of data reflecting the envisaged uses, provided that the notifying governments stated clearly that the old labels would be withdrawn and when the CCPR considered these recommendations at its thirty-second session (Alinorm 01/24, para 18), when it recognized that, in cases such as that described above, the JMPR could not finalize an evaluation at a given meeting. It could continue its review only when the revised GAP had been approved by national governments. The CCPR did not concur with the solution suggested by the Meeting. It considered that the current periodic review procedure should be maintained, but that countries should provide detailed information on the registration status of a compound at the time it was proposed for inclusion in lists of priorities and again when the compound was scheduled for review by JMPR. The CCPR considered that the amendment to the periodic review procedure proposed by the Meeting would not add to the transparancy of the process of establishing MRLs and that it would be difficult in practice to keep track of changes in GAP in registered uses. The present Meeting considered the issue again, in the light of its evaluation of several compounds within the periodic review procedure. In order to ensure the best review of data on residues, the Meeting recommended that the following information should be submitted to the FAO Joint Secretary for compounds notified for periodic review while undergoing re-registration by national authorities:

- current registered uses
- current registered uses that will be supported
- envisaged new or amended uses
- the status of the registration and an estimate of the date on which new or amended uses will become GAP
- an estimate of the date on which old registered uses will be revoked
- a clear description of the uses (new, amended, or current but not to be supported) to which the data from supervised trials of residues relate.

The Meeting decided that, as of 2001, reviews of such compounds should focus on new or amended uses or current uses that will be supported, giving full details of the evaluation. MRLs will be recommended only for current uses. MRLs will be recommended for new

and amended uses only when those uses have become GAP. Moreover, the Meeting recommended that periodic review of compounds be postponed until such time as national authorities can reasonably have finished their re-registration process.

2.7 Maintaining the independence of the JMPR decision-making process

The attention of the Meeting was drawn to a document, *Tobacco Company Strategies to Undermine Tobacco Control Activities at the World Health Organization, Report of the Committee of Experts on Tobacco Industry Documents, July 2000*, in which it is alleged that an individual exerted improper influence on the outcome of the toxicological evaluation of the ethylenebisdithiocarbamates and ethylenethiourea by the 1993 JMPR. The Meeting recognized the seriousness of this accusation and acknowledged that the credibility of the JMPR had been damaged by the events of 1993. *The 1993 toxicological review of the ethylenebisdithiocarbamates and ethylenethiourea* The *Report of the Committee of Experts on Tobacco Industry Documents* alleges that Dr G. Vettorazzi specifically influenced the outcome of the toxicological evaluation of ethylenebisdithiocarbamates and ethylenethiourea at the 1993 Meeting. Dr Vettorazzi served as a temporary adviser at the Meeting and compiled a dossier of past international decisions on these pesticides. He was not responsible for critically evaluating dossiers of submitted data or for drafting a working paper on any of the pesticides evaluated at that Meeting. Therefore, in accordance with JMPR procedures, he did not have prior access, via the JMPR, to the dossiers of data on these pesticides. Several persons who attended the 1993 Meeting as Members or as Temporary Advisers unanimously confirmed the view already put to the Committee of Experts, that Dr Vettorazzi had made little, if any, comment on the evaluations of ethylenebisdithiocarbamates or ethylenethiourea. While Dr Vettorazzi may have over-emphasized the extent of his influence, the assertion that he was able to exert an inappropriate influence on the outcome impugns the integrity and scientific reputation of the Members, who actually make the decisions at the JMPR. Implicit also in the Committee's report is the conclusion that the interpretation of the data on the carcinogenic and genotoxic potential of these pesticides was flawed because it differed from the conclusions reached in the 1989 review of ethylenebisdithiocarbamates by the US Environmental Protection Agency (EPA). However, it is not unusual for the Meeting to evaluate a scientific dossier and to draw conclusions different from those made by another reviewing body or regulatory agency, as the Meeting uses its own risk assessment paradigm. Indeed, it is one of the strengths of the system that the Meeting makes an independent review of the available scientific data.

The conclusions drawn by the 1993 JMPR about the potential carcinogenicity and genotoxicity of ethylenebisdithiocarbamates and ethylenethiourea, while differing from those of the US EPA, are in fact consistent with JMPR risk assessment principles (WHO, ?). The Meeting noted that its conclusions were similar to those reached by a number of national regulatory agencies that reviewed the data on these compounds independently at about the same time. For example, in 1993–94, the European Commission reviewed the data on ethylenethiourea and four ethylenebisdithiocarbamates that generate this metabolite. None of these substances (ethylenethiourea, mancozeb, maneb, metiram, or zineb) was classified as either carcinogenic or mutagenic. The Australian regulatory authorities reached a similar conclusion in relation to ethylenethiourea in 1992– 93. The present Joint Meeting acknowledged that the scientific bases of its evaluations were not as clearly described in the report published in 1993 as they are today. The transparency of its reports and monographs has been improved considerably since that time, and the Meeting will continue to strive to improve its performance in this area. On the basis of the above considerations, the Meeting concluded that the evaluations of the ethylenebisdithiocarbamates in 1993 were appropriate

and had not been influenced by the tobacco industry. Furthermore, the Meeting concluded that the toxicological database on ethylenebisdithiocarbamates and ethylenethiourea could not be reviewed from the perspective of 1993, because of intervening developments in the understanding of the mechanism of the toxicity of such compounds. *Independence of JMPR decisions and avoidance of improper influence.* The credibility of JMPR depends, among other things, on its independence and on avoidance of influence by interested parties. Members and Temporary Advisers are appointed to serve in their personal capacities and on the basis of their scientific reputations and expertise. They are not appointed to represent any government, institution, or special interest group. Since 1993, the processes for revealing conflicts of interest have been extended and strengthened, consistent with similar exigencies around the world. The JMPR will take all possible steps to avoid repetition of a situation in which any Member or Temporary Advisor could participate in any way in a Meeting without disclosing a real or potential conflict of interest.

The Meeting acknowledged that potential conflicts of interest may arise between participants' continuing obligations to employers and/or fiduciary relationships. The Meeting emphasized that the participants must act independently, and not be beholden to any government, institution, business, or special interest group. The responsibilities and role of each person at a Joint Meeting should be clear to all other participants, in order to increase transparency both within the Meeting and from a historical perspective.

*Recommendations*

- When significant new toxicological data on ethylenebisdithiocarbamates and ethylenethiourea become available, it would be appropriate to schedule their re-evaluation at a time consistent with the priorities of CCPR.
- The roles of categories of participants (Members, Temporary Advisers, consultants and the WHO and FAO Secretariats) should be clarified in a revision of the procedural guidelines.
- The responsibilities and roles of each participant at each Meeting should be listed, and the Joint Secretaries should maintain the list in the appropriate archives of FAO and WHO.
- Guidelines should be developed by FAO and WHO for the maintenance of original working papers, correspondence, and other documentation relating to meetings of scientific committees.
- FAO and WHO should prepare a code of ethics for JMPR participants.
- FAO and WHO should explain more clearly their procedures for selecting experts.
- FAO and WHO should provide more guidance to participants in making their declaration of interests, in order to take account of all real, potential, or apparent conflicts.
- JMPR participants should be requested to submit to the Secretariat copies of any written reports required by their employers on their attendance.

The Meeting fully endorsed the efforts of FAO and WHO in implementing appropriate procedures for increasing transparency in the selection of experts and for ensuring the excellence and independence of scientists who serve on scientific committees by developing ethical guidelines and revising the declaration of interests that all participants must sign."

# Annex 6 – Relevant extracts from the 2001 JMPR report

## 2.2 Sharing the work of agricultural pesticide reviews

Governments invest significant resources in evaluating agricultural pesticides before they are marketed, to ensure that they do not pose unacceptable risks to human health and the environment. They also re-evaluate pesticides that have been in use for many years to be sure that they meet current scientific and safety standards. International organisations like FAO and WHO are also involved in assessing the safety of pesticides, and other compounds, for the purpose of setting Codex standards for the protection of consumer health and the promotion of fair practices in international trade. Governments and international organisations have recognised the substantial benefits that can in principle accrue if the task of pesticide evaluation is shared, rather than work being duplicated. Improved efficiency in pesticide evaluations is important in light of limited, ever-diminishing resources, while at the same time there is increased pressure on governments and international organisations to speed up the process of reviewing pesticides and to make their decisions more quickly.

### *Background*

A workshop on sharing the work of agricultural pesticide reviews, organised by the OECD and co-hosted by the Commission of the European Union and the Environmental Protection Agency of the USA, was held in Brussels on 12–14 February 2001. The participants were unanimous that work was already occasionally being shared and that the process had improved both the consistency and the quality of reviews. Now is the time to change work sharing and to identify specific projects and goals so that active progress can be made. Efficient communication, planning and commitment are essential to establishing work sharing. Thus, the schedules and proposed activities of the various groups must be shared, and a proactive approach should be taken to work sharing.

In this context, 'work sharing' means dividing the work of reviewing a submission on a pesticide among two or more reviewers in different national or regional authorities or international organisations, each referring to the other's evaluation in making its review, while respecting the right of each country or organisation to finalise its own risk assessment and to make its own regulatory decision. The objective of work sharing is to reduce the workload. It should result in an assessment of similar or higher quality. The ultimate goal of work sharing is globalisation of pesticide reviews.

> Countries of the OECD, through the OECD Working Group on Pesticides, have been working together since 1992 to harmonise regulatory approaches to pesticide registration. The work has included the development and implementation of common formats for submissions of data from industry ('dossiers') and reviews from governments ('monographs')[5] as well as harmonisation of data requirements, test guidelines and risk assessment methods. As a result, there is now a basis for countries and organisations to share work on evaluating submissions on new and existing active substances of pesticides.

The Meeting welcomed the activities of the OECD and took note of the conclusions and recommendations of the above-mentioned workshop. It recognised the value of work sharing as a means of reducing the workload of FAO Panel and WHO Core Assessment Group Members. Nevertheless, the Meeting considered that, before work sharing could be accepted on a routine basis in the work of JMPR, technical, scientific and political conditions would have to be elaborated.

[5] Guidance documents are available on the OECD website at http://www.oecd.org/ehs/PestGD01.htm

The Meeting recognised that harmonisation of procedures between JMPR, OECD and national governments is a prerequisite for successful implementation of the principle of work sharing at the international level.

## Pilot project

The availability of national and regional evaluations in a standard format should facilitate the work of the expert groups that make up the FAO/WHO JMPR. The JMPR cannot, however, accept a national or regional pesticide evaluation uncritically. Moreover, an evaluation of data on residues at the international level inevitably follows different rules from a review at the national level. The JMPR considers worldwide data derived from Good Agricultural Practice (GAP) and on residues, and establishes MRLs, STMRs and HRs that may be different from those established in regional or national reviews. The parts of an evaluation that should in principle not pose problems for general or mutual use include those on toxicology, plant and animal metabolism, animal feeding, physico-chemical data and processing. Work sharing should focus on these components of an evaluation.

The Meeting welcomed the implementation of a formal pilot project on work sharing at the international level, in which differences and similarities between current procedures and approaches to toxicological and residue evaluations used by JMPR, OECD and national governments should be identified. It should include comparisons of formats, data requirements and risk assessment methods. Attention should be given to data confidentiality and its consequences for work sharing. Due attention should also be given to the question of whether work sharing should rely on officially approved evaluations only. The aim of the pilot project should be to identify any potential problems that would require further harmonization and to estimate the practical costs and the saving of time that could be expected. The Meeting recommended that one or two active substances be identified for evaluation as a test of work sharing and that the pilot project should be carried out as soon as possible, preferably in 2002. Experts from JMPR, OECD and national governments should be invited to participate in the project.

The Meeting was aware of experiences in work sharing at bilateral and regional levels during the past several years. It considered that formalization of work sharing at the international level would not be an easy exercise from which quick results could be expected. The proposed pilot project and subsequent steps should therefore be carefully planned. The pilot project should not be funded from the budgets available for regular JMPR activities.

The Meeting noted that not only technical and scientific aspects but also political issues are associated with the formalization of work sharing. It considered that the the CCPR should reflect at an early stage on the consequences of work sharing for the elaboration and adoption of Codex standards for pesticide residues in the long run.

The Meeting considered that harmonization of data requirements and standardization of formats would also facilitate the submission of dossiers by industry and ultimately make it easier for national governments to accept the assessments underlying the recommendations of JMPR.

The Meeting looked forward to publication of the final OECD Minimum Data Requirements for Establishing Maximum Residue Limits, to facilitate work sharing between JMPR and national governments or regional organizations. JMPR will follow with interest the discussions on items that are still in abeyance, such as the climate zoning project and extrapolation of the behaviour of residues between crops, and will contribute to such discussions in order to achieve agreement at the international level.

### *Co-ordination of evaluation programmes*

A further point of concern is co-ordination of the timing of reviews. Improved co-ordination is needed in setting priorities for compounds to be reviewed. The scheduling of national and regional evaluations and the availability of data to be submitted by their owners should be taken into consideration by the CCPR in setting priorities and by JMPR in scheduling the evaluation of new

compounds and those for periodic review. Currently, data owners probably have the best view of the scheduling of reviews of pesticides by governments and at the regional or international level.

### *Recommendations*

- The Meeting recommended that FAO and WHO implement a pilot project on work sharing in the evaluation of pesticides at the international level in close cooperation with the OECD, national governments and regional and sub-regional authorities.
- The Meeting recommended that the CCPR examine the implications of work sharing for the elaboration and adoption of MRLs for pesticide residues.
- The Meeting recommended that the CCPR, when setting priorities for review of pesticides by JMPR, take account of the scheduling of compounds for review at the national and regional levels.

## Annex 7 – Relevant extracts from the Report of the 33rd CCPR, April 2001

Concerns about the current lengthy JMPR/Codex MRL system.

"TRADE VULNERABILITIES RESULTING FROM THE LENGTHY CODEX MRL PROCESS

6. The Committee noted that this matter had been considered by the FAO/WHO Codex Coordinating Committee for North America and South West Pacific (CCNASWP) and that the CCNASWP agreed to bring this issue to the attention of the CCPR.

7. The Delegation of the United States while introducing the issue indicated that according to current practice the time between nomination of a pesticide for consideration and the actual establishment of MRLs resulted in an existing window of trade vulnerability of agricultural commodities. The Delegation pointed out that a number of new pesticides were registered at the national level, as there was a need for safer and more efficient pesticides to address new challenges such as resistance and the introduction of exotic pests. However, in the current system, it would take several years before these pesticides could be evaluated by JMPR and before Codex MRLs were adopted. As a result, growers were faced with serious difficulties to export their products, and the absence of Codex MRLs at the international level for new compounds was likely to create significant barriers to trade. The Delegation proposed a number of options to address these difficulties, including a reorientation of the priorities for JMPR and the establishment of "interim" MRLs that could be used as a reference with the understanding that they would be revised within a limited timeframe.

8. Several delegations and the Observer of the EC recognised the need for further discussion on this important matter; and noted that their exporters shared similar concerns, however, there was no consensus regarding the proposed conclusions.

9. The Delegation of Japan expressed concern with some recommendations in the paper, as they were not consistent with Codex procedures and the status of Codex standards under WTO, and pointed out that the document considered trade aspects and that there should be a balanced consideration of health protection and trade aspects in elaborating MRLs. The Observer of CI called attention to the referral to CCPR from CCNASWP to give attention to newer pesticides and that the newer does not necessarily mean safer.

10. The Secretariat recalled that according to the *Statements of Principles Relating to the Role of Food Safety Risk Assessment*, health and safety aspects of Codex decisions and recommendations should be based on risk assessment, as appropriate to the circumstances. The establishment of MRLs for pesticides in the absence of such a risk assessment would not be consistent with the risk analysis principles applied throughout Codex and would significantly impair their relevance in international trade.

11. The Delegation of Spain supported by some other delegations, indicated that it was essential to establish Codex MRLs that would be accepted by all countries.

12. The Committee agreed to acknowledge the existence of the problem and requested the Delegation of the USA with the assistance of Australia, Brazil, Canada, Chili, New Zealand, South Africa, EC and GCPF to prepare a paper for consideration by the next session of the Committee."

"REPORT ON GENERAL CONSIDERATIONS BY THE 1999 AND 2000 JOINT FAO/WHO MEETINGS ON PESTICIDE RESIDUES (Agenda item 4)[6]

13. The Committee noted the general consideration items in the 2000 JMPR: the progress on estimation of IESTI; the relevance of food processing questionnaires for JMPR evaluations; measures to be taken when estimated dietary intake exceeds the ADI; the feasibility of establishing maximum residue limits for genetically modified crops and for residues of metabolites; minimum data required for establishing maximum residue limits, including import tolerances; periodic review of data on residues of compounds currently being re-registered nationally; maintaining the independence of the JMPR decision-making process; information required for Good Agricultural Practice; harmonisation between JECFA and JMPR; the establishment of acute reference doses; and summaries of critical end-points. Discussion of most of these items was deferred to other agenda items."

Dietary risk assessment

"14. The Committee noted that JMPR is still improving the method of estimation of IESTI in the light of experience gained in its application. For example, the STMR/STMR-P in case 2a was changed to HR/HR-P as the previous calculation might not reflect the actual situation, in which the commodity available for consumption is likely to be derived from a single lot. Also, for the first time, the JMPR applied the calculation of the IESTI from data on animal commodities."

"16. The Committee noted the conclusion of JMPR on the proposal of some governments and manufacturers at the 32nd Session of CCPR on measures to be taken when estimated dietary intake exceeds the acceptable daily intake. The JMPR concluded that national determinations of dietary intake are useful only at the national level and can be used at that level to refine the estimates made by JMPR. It explained that the dietary intake calculations performed by manufacturers in support of compounds under periodic review or newly evaluated are of little relevance."

Submission of GAP information

"18. The Committee agreed on the recommendation of JMPR regarding GCPF's proposal that the requirements on GAP information (labels) be modified. The JMPR indicated that the original labels (and if necessary the translations) be provided only for those uses that are adequately supported by residue data according to FAO requirements. A full summary of information on GAP should still be submitted as the company may not always have a clear view of which extrapolations are valid. In such cases, the JMPR might be unable to propose an MRL for a commodity for lack of relevant GAP information, although such information exists but was not provided by the company."

Use of OECD work on minimum data requirements by the JMPR

"19. The Committee noted that JMPR agreed to consider the report of the OECD workshop on minimum data requirements when they were finalised. The JMPR was particularly interested in the OECD/FAO project in validating geographical zones where residue data can be extrapolated within the same zone. Several delegations expressed concerns on the

[6] Pesticide residues in food – 1999 (FAO Plant Production and Protection Paper 153, 1999) and 2000 (FAO Plant Production and Protection Paper 163, 2001); CRD 4; CRD 5.

parameters considered in the climate-based zoning. The Observer from EC expressed concern about the limited participation of JMPR in this activity and would like JMPR to be more responsible to the issues of minimum data requirements, extrapolation and zoning. The delegation of Chile explained that there are other factors to be considered aside from climates, e.g., GAPs. The Committee expressed its interest in the outcome of the project and recommended that JMPR should participate actively and make use of the results of the project."

Consideration of compounds that are being reregistered at the national level

"20. In regard to the periodic review of data on residues of compounds currently being re-registered nationally, the JMPR decided that, as of 2001, reviews of compounds should focus on new or amended uses or current uses that will be supported with data, giving full details of the evaluation. MRLs would be recommended for current uses but will be recommended for new and amended uses only when those uses have become GAP. Moreover, the JMPR recommended that periodic review of compounds be postponed until such time as national authorities can reasonably have finished their re-registration process. The Committee concurred with this recommendation."

Maintaining the independence of the work of the JMPR

"21. The section in the JMPR 2000 Report on maintaining the independence of the JMPR decision-making process discusses the document *Tobacco company strategies to undermine tobacco control activities of the World Health Organization, Report of the Committee of Experts on Tobacco Industry Documents*, which was released in August 2000. The document alleged improper influence on the outcome of the toxicological evaluations of the ethylenebisdithiocarbamates (EBDCs) and ethylenethiourea (ETU) by the 1993 JMPR through the involvement of a scientist who served as a WHO Temporary Adviser who had been receiving consulting fees from the tobacco industry at that time. After reviewing the document and the previous evaluations, the 2000 Joint Meeting concluded that the 1993 evaluations of these substances were appropriate and had not been influenced by the tobacco industry. The Meeting made a number of recommendations, most of which relate to increasing the transparency and integrity of the process. The WHO Joint Secretary also informed the Committee that a Working Group of the International Agency for Research on Cancer evaluated ETU along with a number of other thyrotropic agents in October 2000. The Working Group concluded that ETU is not genotoxic and that ETU would not be expected to produce thyroid cancer in humans exposed to concentrations that do not alter thyroid hormone homeostatisis. This is a similar conclusion to that reached by the 1993 JMPR."

Transparency and accountability in the work of the JMPR, Codex, the FAO and WHO

"22. Several delegations and organizations expressed the importance of improving the transparency and accountability of FAO, WHO and Codex in their work including participation of all interested parties. The Committee supported the recommendations in the report on procedures to increase the transparency and credibility of the process in the JMPR. It also supported the recommendation to review new data on these substances as they become available. The Committee also agreed with the 2000 JMPR that the evaluations of the EBDCs and ETU by the 1993 JMPR are valid and no action was required on Codex MRLs for dithiocarbamate."

"23. The Committee was of the opinion that the general issues could be better dealt by the Commission. The Committee noted of and supported the conclusions relating to information required for Good Agricultural Practice in section 2.8 of the 2000 JMPR Report."

Use of JMPR evaluations by national governments

"24. Since 1995 the Joint Meeting has been including in its toxicological evaluations a table identifying the end-points relevant for setting guidance values for dietary and non-dietary intake. The 2000 JMPR requested feedback on the usefulness of this table. Several delegations indicated that these tables are very useful, and the Committee encouraged JMPR to continue including them in its evaluations."

Compounds that are both pesticide and veterinary drugs

"25. The Committee noted that JECFA and JMPR will continue harmonization of issues related to compounds used both as pesticides and veterinary drugs. In the 2000 JMPR, the definition of abamectin for animal commodity was considered among others."

**Food and Agriculture Organization of the United Nations**

**World Health Organization**

# FAO/WHO Joint Meeting on Pesticide Residues (JMPR)
## Annex 8 - Call for submission of applications to establish a roster of experts as candidates for membership of the FAO Panel of the JMPR

### Background

The Joint FAO/WHO Meeting on Pesticide Residues (JMPR) has met annually since 1963 to conduct scientific evaluations of pesticide residues in food. It provides advice on the acceptable levels of pesticide residues in food moving in international trade. The JMPR consists of experts drawn from governments and academic circles. They attend as independent internationally recognized specialists who act in a personal capacity and not as representatives of national governments. One of the functions of the JMPR is to recommend Maximum Residue Levels to the Codex Committee on Pesticide Residues (CCPR) which then provide the basis for the establishment of Maximum Residue Limits (MRLs) by the Codex Alimentarius Commission and are now recognized as international reference points for international trade under the Sanitary and Phytosanitary (SPS) and Technical Barriers to Trade (TBT) Agreements of the World Trade Organization (WTO).

The FAO Panel of Experts considers available data on registered use patterns, fate of residues, animal and plant metabolism data, analytical methodology and residue data developed through supervised trials. Based on these data, maximum residue levels are proposed for individual pesticides in individual food and feed items or well-defined groups of commodities. The deliberations of the JMPR are summarized in the annual Report of the Meeting. The detailed evaluations of the residue (Evaluations Part I) and toxicology data (Evaluations Part II) are also published annually and circulated widely to member governments, international organizations and other interested parties. Copies of the Reports of the JMPR and the residue evaluations may be found on the FAO website: http://www.fao.org/WAICENT/FAOINFO/AGRICULT/AGP/AGPP/Pesticid/Default.HTM. The meetings of the FAO Panel of Experts are conducted in English only. The FAO Manual on the submission and evaluation of pesticide residue data for the estimation of maximum residue levels in food and feed provides detailed guidance on how Panel members are to prepare their evaluations. A copy of the manual may also be found on the above noted website.

The objective of this call is to identify additional experts as possible candidates for membership on the FAO Panel of Experts. In the interest of ensuring an open and transparent process for the selection of experts and to ensure that the message reaches as wide an audience as possible, it was decided to issue this general call for candidates. This approach parallels that used by the Codex Alimentarius Commission in selecting experts for scientific panels and by the WHO part of the JMPR.

Interested parties are invited to review the list of qualifications and to submit their curriculum vitae including a description of education, work experience and a list of peer-

reviewed publications (preferably by using the FAO Personal History Form, attached) to the FAO Joint Secretary to the JMPR (address below) before 31 August 2001.

Successful candidates will be invited to participate in one or more meetings of the JMPR and/or expert consultation on an issue related to the work of the FAO Panel of Experts prior to being invited to become a full member of the JMPR. Panel Members are expected to review a substantial amount of pesticide residue data, which are delivered to the Panel members by the end of February, and to present the appraisals and evaluations at the annual JMPR Meeting, which lasts for three weeks in September.

**Process for the Selection of Experts**

The curriculum vitae submitted will be reviewed by a selection panel composed of officials of FAO and independent, internationally recognized experts. The purpose of the selection panel's review is to determine whether the applicants meet the requirements indicated below. The list of qualified experts will be posted on the appropriate FAO website.

Candidates will also be required to declare any potential conflict of interest through completion of a standard form developed in FAO.

**Appointment of experts**

The experts are appointed by the Director-General as FAO Panel Members for four years. In appointing experts, in addition to scientific and technical excellence, FAO will consider diversity and complementarity of scientific backgrounds and representation from all geographical regions, including developing and developed countries. Experts will be invited to participate in their individual personal capacity. The expert shall not represent the position of the government of which he or she is an official, or of the institutions with which they are associated. The experts designated to participate in the JMPR will not receive any remuneration, but will be paid travel costs for the meetings and a subsistence allowance according to prevailing UN rates.

Successful candidates should fulfil the following qualifications:

- employee of government or semi-government organizations;
- holder of advanced university degree(s) in Pesticide Chemistry, Agricultural Sciences, Biological Sciences or other related field;
- experience in the review of residue data as the basis for pesticide registration at national / regional level;
- professional experience in the field of Pesticide Residues, Pesticide Chemistry or other related fields;
- familiarity with the JMPR/Codex processes;
- computer literacy is an essential requirement as the Members of the FAO Panel of Experts are required to submit their reports in electronic format (Word 6.0 and Excel 97);
- ability to work and write reports well in English;
- scientific excellence evidenced by publications in peer-reviewed specialized journals;

- experience in delivering scientific opinions at national or international level;
- ability to work with people from different cultural backgrounds;
- preferably be below 62 years old.

***For further inquiries, please contact:***

FAO Joint Secretary to the JMPR
Pesticide Management Group, Plant Protection Service
Plant Production and Protection Division
**Food and Agriculture Organization**
**of the United Nations (FAO)**
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## Annex 9 – Draft FAO Declaration of Interest Form

# DECLARATION OF INTERESTS

Public Health considerations have a primary importance in all FAO work on food safety. Measures need to be taken to ensure that the best possible assessment o scientific evidence is achieved in a independent atmosphere free from either direct or indirect pressures. Thus to assure the scientific integrity of FAO's work, it is necessary to avoid situations in which financial o other interests affect the outcome.

Each expert is therefore asked to declare any interests that could constitute a real, potential or apparent conflict of interest with respect to his/her involvement in a meeting, between (1) commercial entities and the expert personally, and (2) commercial entities and the administrative unit with which the expert has an employment relationship. "Commercial entity" refers to any company, association (e.g. trade association), organization or any other entity of any nature whatsoever, with commercial interests.

**What is a conflict of interest?**

Conflict of interest means that the expert or his/her partner ("partner" includes a spouse or other persons with whom he or she has a similar close personal relationship), or the administrative unit with which the expert has an employment relationship, has a financial or other interest that could unduly influence the expert's position with respect to the subject matter being considered. An apparent conflict of interest exists when an interest would not necessarily influence the expert but could result in the expert's objectivity being questioned by others.

Different *types of financial or other interests*, whether personal or with the administrative unit with which the expert has an employment relationship, can be envisaged and the following list, which is not exhaustive, is provided for your guidance.

For example, the following types of situations should be declared:

1. a current proprietary interest in a substance, technology or process (e.g. ownership of a patent) to be considered in, or otherwise related to the subject matter of, the meeting;
2. a current financial interest, e.g. shares or bonds, in a commercial entity with an interest in the subject matter of the meeting (except share holdings through general mutual funds or similar arrangements where the expert has no control over the selection of shares);

3. an employment, consultancy, directorship, or other position during the past 4 years, whether or not paid, in any commercial entity which has an interest in the subject matter of the meeting, or an ongoing negotiation concerning prospective employment or other association with such commercial entity;

4. performance of any paid work or research during the past 4 years commissioned by a commercial entity with interests in the subject matter of the meeting;

5. payment or other support covering a period within the last 4 years, or an expectation of support for the future, from a commercial entity with an interest in the subject matter of the meeting, even if it does not convey any benefit to the expert personally but which benefits his/her position or administrative unit, e.g. a grant or fellowship or other payment for the purpose of financing a post or consultancy.

With respect to the above, an interest in a competing substance, technology or process, or an interest in or association with, work for or support by a commercial entity having a direct competitive interest must similarly be disclosed.

**How to complete this Declaration:** Please complete this Declaration and submit it to the FAO Secretariat well before the meeting.

Any financial or other interests that could constitute a real, potential or apparent conflict of interest should be declared (1) with respect to yourself or partner, as well as (2) with respect to the administrative unit with which you have an employment relationship. Only the name of the commercial entity and the nature of the interest are required to be disclosed and no amounts need to be specified (though they may be, if you consider this information to be relevant to assessing the interest). With respect to items 1 and 2 in the list above, the interest should only be declared if it is current. With respect to items 3, 4 and 5, any interest during the past 4 years should be declared. If the interest is no longer current, please state the year when it ceased. With respect to item 5, the interest ceases when a financed post or fellowship is no longer occupied, or when support for an activity ceases.

**Assessment and outcome:** The information submitted by you will be used to assess whether the declared interests constitute a real, potential or apparent conflict of interest, and you will be informed accordingly before the meeting. A conflict of interest may, depending on its nature and extent, result in (i) you being asked not to attend the meeting; (ii) you being asked not to take part in that portion of the discussion affected by the interest; or (iii) you taking part in the meeting but with restrictions on your contribution at the discretion of the Chairperson. For example, you may be invited to take part in the discussion on the item in question but not to participate in any decision-making. Such decisions will be at the discretion of the Chairperson in consultation with the FAO Secretary.

All declared interests will be listed and made available to the meeting as a whole, and following the meeting will be made public, as will any actions taken as a result of the declarations.

Declaration: Have you or your partner any financial or other interest in the subject matter of the meeting in which you will be involved?

Yes: No: If yes, please give details in the box below.

| Nature of interest, e.g., patent, shares, employment, association, payment (include details on any compound, work) etc. | Name of commercial entity | Belongs to you, partner, or unit? | Current interest? (or year ceased) |
|---|---|---|---|
| | | | |

Is there anything else that could affect your objectivity or independence in the meeting, or the perception by others of your objectivity and independence?

_____

_____

_____

I hereby declare that the disclosed information is correct and that no other situation of real, potential or apparent conflict of interest is known to me. I agree to inform you of any change in these circumstances, including if an issue arises in the course of the meeting itself.
Signature:_____

Date:_____

Name:_____
Institution:_____

_____

Note: If more than one page is necessary use copies of this form
**December 2000**

## Annex 10 - Reports and other documents produced by the Joint Meetings on Pesticide Residues

1. Principles governing consumer safety in relation to pesticide residues. Report of a meeting of a WHO Expert Committee on Pesticide Residues held jointly with the FAO Panel of Experts on the Use of Pesticides in Agriculture. FAO Plant Production and Protection Division Report, No. PL/1961/11; WHO Technical Report Series, No. 240, 1962

2. Evaluation of the toxicity of pesticide residues in food; report of a Joint Meeting of the FAO Committee on Pesticides in Agriculture and the WHO Expert Committee on Pesticide Residues. FAO Meeting Report, No. PL/ 1963/13; WHO/Food Add./23, 1964.

3. Evaluation of the toxicity of pesticide residues in food. Report of the Second Joint Meeting of the FAO Committee on Pesticides in Agriculture and the WHO Expert Committee on Pesticide Residues. FAO Meeting Report, No. PL/1965/10; WHO/Food Add./26.65, 1965.

4. Evaluation of the toxicity of pesticide residues in food. FAO Meeting Report, No. PL/1965/10/1; WHO/Food Add./27.65, 1965, nos 1-44 on INCHEM.

5. Evaluation of the hazards to consumers resulting from the use of fumigants in the protection of food. FAO Meeting Report, No. PL/1965/10/2; WHO/ Food Add./28.65, 1965, nos 45-55 on INCHEM.

6. Pesticide residues in food. Joint report of the FAO Working Party on Pesticide Residues and the WHO Expert Committee on Pesticide Residues. FAO Agricultural Studies, No. 73; WHO Technical Report Series, No. 370, 1967.

7. Evaluation of some pesticide residues in food. FAO/PL:CP/15; WHO/ Food Add./67.32, 1967, nos 56-74 on INCHEM.

8. Pesticide residues. Report of the 1967 Joint Meeting of the FAO Working Party and the WHO Expert Committee. FAO Meeting Report, No. PL:1967/ M/11; WHO Technical Report Series, No. 391, 1968.

9. 1967 Evaluations of some pesticide residues in food. FAO/PL:1967/M/ 11/1; WHO/Food Add./68.30, 1968, nos 75-109 on INCHEM.

10. Pesticide residues in food. Report of the 1968 Joint Meeting of the FAO Working Party of Experts on Pesticide Residues and the WHO Expert Committee on Pesticide Residues. FAO Agricultural Studies, No. 78; WHO Technical Report Series, No. 417, 1969.

11. 1968 Evaluation of some pesticide residues in food. FAO/PL:1968/M/9/1; WHO/Food Add./69.35, 1969, nos 110-144 on INCHEM.

12. Pesticide residues in food. Report of the 1969 Joint Meeting of the FAO Working Party of Experts on Pesticide Residues and the WHO Expert Group on Pesticide Residues. FAO Agricultural Studies, No. 84; WHO Technical Report Series, No. 458, 1970.

13. 1969 evaluations of some pesticide residues in food. FAO/PL:1969/M/17/1; WHO/Food Add./70.38, 1970, nos 145-177 on INCHEM.

14. Pesticide residues in food. Report of the 1970 Joint Meeting of the FAO Working Party of Experts on Pesticide Residues and the WHO Expert Committee on Pesticide Residues. FAO Agricultural Studies, No. 87; WHO Technical Report Series, No. 474, 1971.

15. 1970 Evaluations of some pesticide residues in food. AGP:1970/M/12/1; WHO/Food Add./71.42, 1971, nos 178-204 on INCHEM.

16. Pesticide residues in food. Report of the 1971 Joint Meeting of the FAO Working Party of Experts on Pesticide Residues and the WHO Expert Committee on Pesticide Residues. FAO Agricultural Studies, No. 88; WHO Technical Report Series, No. 502, 1972.

17. 1971 Evaluations of some pesticide residues in food. AGP-1971/M/9/1; WHO Pesticide Residues Series, No. 1, 1972, nos 205-222 on INCHEM.

18. Pesticide residues in food. Report of the 1972 Joint Meeting of the FAO Working Party of Experts on Pesticide Residues and the WHO Expert Committee on Pesticide Residues. FAO Agricultural Studies, No. 90; WHO Technical Report Series, No. 525, 1973.

19. 1972 Evaluations of some pesticide residues in food. AGP:1972/M/9/1; WHO Pesticide Residues Series, No. 2, 1973, nos 223-252 on INCHEM.

20. Pesticide residues in food. Report of the 1973 Joint Meeting of the FAO Working Party of Experts on Pesticide Residues and the WHO Expert Committee on Pesticide Residues. FAO Agricultural Studies, No. 92; WHO Technical Report Series, No. 545, 1974.

21. 1973 Evaluations of some pesticide residues in food. FAO/AGP/1973/M/ 9/1; WHO Pesticide Residues Series, No. 3, 1974, nos 253-277 on INCHEM.

22. Pesticide residues in food. Report of the 1974 Joint Meeting of the FAO Working Party of Experts on Pesticide Residues and the WHO Expert Committee on Pesticide Residues. FAO Agricultural Studies, No. 97; WHO Technical Report Series, No. 574, 1975.

23. 1974 Evaluations of some pesticide residues in food. FAO/AGP/1974/ M/11; WHO Pesticide Residues Series, No. 4, 1975, nos 278-313 on INCHEM..

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## Annex 11 - Submission by Richard Nielsson on behalf of Crop Life International (formerly the GCPF)

# Review of the Working Procedures of the JMPR

**Contribution by CropLife International**

**1. Need for internationally harmonized and accepted trading standards for pesticide residues in food, impact of Codex MRLs at the national/international level, and use by governments and other organizations.**

Codex MRLs are identified in the General Agreement on Tariffs and Trade (GATT) as the trading standard for residues in food. As a result, such standards must account for all critical national approved uses, and, at the same time, must be considered to be safe for consumption. This latter element has been the subject of considerable debate within the CCPR, because the dietary intake estimates at the international level are very conservative, typically overestimating any actual intake situation. In addition, in cases in which there is an extensive listing of MRLs resulting in a calculated excessive intake, rarely, if ever, will any one national government have all of the MRLs approved for national use. Therefore, the overestimate of dietary intake is a perception only.

Previously, Codex MRLs were important to the industry in general to obtain registrations in countries, which did not have their own system for setting residue MRLs. In such cases, if a country did not have its own MRLs, it would defer to the Codex MRLs and would grant a registration if the commodity was included in the list of commodities for which there were approved Codex MRLs. For some companies, this is not considered to be the case today. National governments without their own system for establishing the safety of residues in foods normally defer to registration status in major developed countries, such as the US or the European Union. Therefore, the necessity of Codex MRLs to support registration applications by the industry is not as important to some companies today as it was several years ago.

Even if Codex MRLs are not necessarily important to obtain registrations, they have been cited as important for international trade in fruit and vegetable commodities, especially for countries which do not establish their own residue standards. In cases where there is a residue on an internationally traded commodity, and the residue is within the accepted Codex tolerance, importing countries will usually permit the food commodity to enter the country, especially if the importing country does not have its own system of establishing acceptable residue levels.

Another factor is the lack of acceptance of Codex MRLs by the major developed countries. Unfortunately, the US and the European Union do not automatically accept Codex MRLs, when they do not have residue levels established by their own procedures. In both cases, the legislation requires them to “consider Codex MRLs in establishing their own standards,” but there is no requirement to follow the Codex MRL in cases where there is no national MRL established, for example, in the case of MRLs for imported food commodities,. This detracts from the significance of Codex MRLs. When a country adopts an MRL different from that set by Codex, it is up to the country to justify the difference. In the case of the EU, where no EU residue tolerance exists, Member States will frequently defer to the Codex MRL for use as a national residue tolerance.

For the reasons given above, the importance of Codex MRLs to the industry varies

company to company. In some cases, companies consider the international review by the JMPR to be an advantage, to support registration applications and other defensive efforts for the product. In other cases, however, Codex MRLs are viewed on a strict cost/benefit basis. Where there is a defined need, that is, an importing country has specified the need for a Codex MRL, the company will consider whether the market justifies the time and expense. If so, the request for a Codex MRL will be submitted. Such decisions are individual company decisions, based on several factors, including but not limited to marketing strategies, market share, and competitive products. CropLife must respect such individual company decisions.

**2. Relationship of JMPR to the CCPR, the Codex Alimentarius Commission, and to FAO and WHO**

The JMPR is composed of two expert bodies, the FAO and WHO groups of experts, which provide independent recommendations to the CCPR. Policies regarding participation in Codex committees do not affect the expert bodies, since they establish their own procedures for participation. The position of CropLife International is that such expert bodies must remain independent from the Codex Alimentarius, and must be allowed to reach decisions according to their own standards. In addition, CropLife International is opposed to the admission of observers to the deliberations of the expert bodies. The expert consultations have traditionally been held in closed sessions, to permit the experts to openly discuss the issues and reach appropriate decisions. CropLife believes the presence of observers would hamper the ability of the experts to discuss issues openly and freely. In addition, there are concerns regarding protection of proprietary data, which could not properly be accounted for if the modus operandi were changed. CropLife wishes to emphasize, however, that this ban on observers should not extend to the sessions held with the submitters of data, to clarify elements of the data submitted. Such sessions with data submitters are essential in order for the panels to give the appropriate interpretation and significance to all data submitted for review.

**3. Current operational procedures of JMPR, identifying those critical points that limit capacity.**

Currently, JMPR meets one time per year, generally in the second or third week of September. Submissions for review by the WHO experts must be submitted in June of the year before the JMPR is held. This provides approximately 15 months for the WHO expert to review the toxicology and animal metabolism data and develop an appraisal characterizing the significance of the data.

For the FAO expert panel, submissions must be made in February of the year in which the JMPR is held. This provides the FAO expert with approximately 7 months to review the residue and crop metabolism data, and develop a summary of the commodity residue results. At the time of the JMPR meeting, the FAO expert panel, utilizing intake estimates developed by the GEMS/Food division of the WHO, conducts dietary intake estimates. On the basis of the dietary intake estimates, recommendations are formulated for the CCPR, regarding the acceptability of advancing all, or certain, MRLs for the compound in question.

The first element that limits the capacity of the JMPR is that meetings are held only once per year. This limit of one meeting per year is necessitated by the limitation of financial and human resources to support the work of the JMPR. However, this limitation, in turn, limits the amount of work that the JMPR is capable of doing. According to the current scheduling policies, each expert panel is capable of doing 8, at the most, full reviews per meeting. A full review is defined as a new or periodic review. In addition to the full reviews, each panel will have an additional number of evaluations, which are not clearly limited to a maximum number, because the extent of such

evaluations is so variable.

The WHO expert panel consists of a group of permanent experts, together with a group of temporary reviewers, who do the actual reviews of the data and develop the appraisals for review and discussion with the permanent experts. The FAO panel, on the other hand, consists only of the experts who conducted the data reviews. This difference accounts for some of the differences in problems between the two panels.

The activities of the WHO expert panel are limited in part by the long lead time for the submission of data prior to the time of the JMPR. This long time is necessary because all of the data is reviewed *de novo.*

The activities of the FAO expert panel are limited by the financial resources to support the meetings of the experts, and by the numbers of experts serving on the panel. While there has been an effort in the past to obtain a geographical distribution of experts, the competence of the panel members should be the main consideration. Generally, experts are government employees and are permitted by their governments to do JMPR work as part of their assigned duties. However, this is not always the case, and experts, who have had to do the JMPR evaluations on their own time, have had difficulties in serving the JMPR for any period of time. An additional problem is that panel meetings are conducted only in English. Consequently, the experts have to be fluent in English, in order to prepare their reviews and appraisals in English, and to participate in the panel meetings, which are conducted in English.

A new problem has arisen recently, namely, the residue review for a new compound is delayed one year after the toxicology review for that same compound. This was done because the FAO panel makes assumptions regarding the toxicology of a compound in conducting a preliminary dietary intake calculation, in order to determine the safety of certain MRL estimations. However, if the toxicological assumptions are incorrect, all of the calculations must be redone and the summaries revised, requiring extensive additional work, which may prevent the completion of the review in the initial JMPR meeting.

An additional problem is the time required to publish reports of JMPR meetings. The summary report of a JMPR meeting is generally not available until the time of the next CCPR meeting, that is, approximately 7 months after the JMPR meeting was held. The monographs require several more months. The CCPR will not discuss any review until governments have had the opportunity to study the monographs. This means, effectively, that no discussion of a review occurs in CCPR until the second year after the review occurred in the JMPR.

**4. Strategy for redefining the current approach to the operation of the JMPR, including proposals for addressing the limiting factors identified above.**

The most important element in changing the operation of the JMPR is to increase the expert capacity of the FAO expert panel. Currently, this panel is limited to 5-6 experts, which severely limits the amount of work the panel is capable of doing.

An issue discussed at the 2001 CCPR was the prioritisation of new versus periodic reviews. CropLife International believes that a priority should be accorded to the review of new compounds, because these are typically more specific in activity and will be the compounds to replace the older, less desirable compounds. Recognising, however, that there is a need to maintain a program of reviews of older compounds, CropLife recommended that the appropriate prioritisation should be 4 new and 4 periodic reviews per meeting. If there were not 4 new compounds recommended for evaluation, the space could tentatively be assigned to periodic reviews. If, however, at a later date, proposals for review of new compounds were forthcoming, the tentative schedules would have to be revised to accommodate the 4+4 formula.

Another consideration is to increase the number of JMPR meetings per year. Two meetings per year would permit the panel to review a total of 16 new and periodic reviews per year. Considering that in 2000 there were 184 compounds active in the CCPR system, completion of periodic reviews on all compounds would require 23 years, if only 8 reviews were conducted each year, and all reviews by the panels were periodic reviews.

In order to support more than one meeting per year, it may be necessary for FAO to contract time with reviewers for an extended period of time. This contract should be for an extended period, such as 5 years, and would support panel members based in their national authorities on a full time basis, to deal exclusively with JMPR evaluations and the CCPR meeting. Such contracts would facilitate the identification of experts, since they would not be required to do the work on their own time. The funding for such contracts could be supported by governments and industry. CropLife International has taken the position that it would not be appropriate for a company to fund a specific review for one of its compounds. Such an action could be interpreted as influencing the review, and CropLife maintains that the industry and JMPR must be above such perceptions. There may, however, be a way for individual companies to contribute voluntarily to a general JMPR fund, or for CropLife to contibute to such a fund on behalf of the industry.

Having suggested that industry could participate in funding the work of the JMPR panels, it is necessary to point out that there are several issues to consider in connection with funding by industry, for example, would the generic industry also be asked to contribute? Would there be a disadvantage for companies not contributing, in terms of scheduling compounds for review? Would companies have the opportunity to donate only for reviews of new compounds, as opposed to periodic reviews? Would there be any commitments from JMPR in return for the funding?

It is necessary to point out that, at this time, CropLife has not had the internal discussions necessary to commit for any specific contribution of any amount.

While the use of English as the only language of the JMPR is acknowledged to be a limiting factor for the identification of experts, it does not seem reasonable to consider methods to correct this problem. Translation of summaries and appraisals would be required, as well as translation of correspondence between the data submitter and the reviewer, in addition to the requirement for interpretation during the panel meetings.

Regarding the use of national/regional reviews by the JMPR, one of the limiting factors identified above was the fact that the JMPR panels conducted *de novo* reviews for all data submitted. The JMPR could use national/regional reviews of toxicology and metabolism data in a work-sharing exercise, and apply JMPR risk assessment procedures to the nationally/regionally reviewed data. Such an exercise would require some pilot projects initially to familiarise the panels and governments with the exercise, and to have both parties comfortable with the process.

Regarding dietary risk estimates, such calculations must be scientifically based. Currently, the estimations made at the international level are extremely conservative. CropLife International recommends that decisions recommending against the advancement of MRLs can be made only at the national/regional level, based on specific data on consumption available at the national/regional level. Such areas can be flagged at the international level, to highlight the necessity for specific national/regional calculations.

## Annex 12 – Submission made by Edward Groth on behalf of Consumers International

# "Improving the working procedures of JMPR

### Outline of Ideas—Ned Groth, Consumers Union of U.S.

Note: Many points are largely generic, apply to JECFA and other bodies as well as to JMPR.

**1. Reforms/improvements are needed for several reasons:**

a. To keep pace with increasing workload/expectations from Codex

b. To improve the scientific quality of the product (risk assessments)

c. To earn and/or maintain public confidence in the work of JMPR

**2. There are both issues of substance (i.e., the work has to BE highly competent and objective), and issues of appearance (i.e, it has to be PERCEIVED to be competent and objective.)**

a. On the issue of competence: I am not familiar with JMPR's work in detail; I have not read very many JMPR reports. I have some suspicions, based on my general sense of the state of risk assessments for pesticides and what I know about the pool of experts JMPR draws upon. For example, I suspect that JMPR has had a difficult time keeping up with cutting-edge science related to pesticide risk assessments: Developmental neurotoxicity; endocrine effects; etc. (The number of specialists in these fields is small and they don't seem likely to be available to serve on JMPR panels very often.) I would surmise that the average JMPR panel has insufficient expertise on those emerging critical risk issues, and that its reports may therefore address those questions less thoroughly and competently than is desirable. But that's not based on an objective analysis of JMPR reports, it's a surmise, as I said.

b. The issue of objectivity should be approached more broadly than focusing on the Vettorrazzi affair. There have been occasional embarrassing cases of overt bias and/or conflict-of-interest, and/or of improper access or influence by interested parties (e.g., FDA's influence over the BST assessments by JECFA—not a JMPR issue in that case), but I can't point to many specifics for JMPR. My main worry however is more subtle forms of bias. Choosing scientists who all share the view (which may well be the majority opinion among toxicologists, but that does not make it correct!) that all chemical exposures are harmless at low levels, for example, inevitably biases a panel towards dismissing inconclusive evidence of adverse effects at low doses. Panels need to have at least some members who are willing to argue that the inconclusive evidence needs to be taken seriously, and that in the absence of more convincing data that would enable the no-effect level to be defined precisely, a wider safety margin is called for.

**3. In terms of proposals for reform, more attention should be devoted to:**

a. Ensuring that all the expertise needed to do a competent risk assessment for a particular chemical or set of chemicals is adequately represented among the panel members.

b. Ensuring that there is a balance of scientific perspectives, so that issues where the evidence is debatable will in fact be thoroughly debated.

c. Expanding the diversity of backgrounds of scientists on the panels. JMPR needs to get away from relying primarily on government scientists, and expand its pool to include scientists from academia, NGOs, and even industry, under carefully defined conditions that would exclude significant conflicts of interest. (I stress here, this is my personal view, not CI's.)

**4. More emphasis is also needed on openness and transparency. Among other things:**

a. Public meetings, open to observers. Not necessarily every part of every panel's work, but certainly the major portion of the work should be done openly, not behind closed doors.

b. Opportunities for input from and interaction with scientists not on the panel, who may have data or useful perspectives to contribute (i.e., something like a public hearing).

c. More complete reports, spelling out clearly the basis for conclusions, prepared more quickly after the panel has met.

d. More explicit attention, in those reports, to uncertainties and their significance.

e. Possibly, inclusion of a "consumer observer" on each panel. (CI has proposed this.)

f. Ensuring that the process through which experts are recruited and selected to serve on JMPR panels is open and transparent.

g. Requiring experts who serve on panels to complete a "declaration of expertise and interests" and making those declarations, or a summary of their content with names removed, public. (See similar recommendations on points "f" and "g" in "Working Principles for Risk Analysis," draft now under discussion at CCGP.)

**5. Practical changes to help achieve some of these improvements:**

a. There probably need to be more panels, longer meetings, or both. Trying to get more assessments of more chemicals from the same amount of expert-days risks both burning out the experts and lowering the quality of the assessments. Something's got to give.

b. WHO in particular (assuming WHO Core Assessment Group continues to bear the responsibility for health risk evaluations) will need more professional staff to run JMPR panels. Perhaps they can look at the NAS/NRC and other bodies that do similar work to get a sense of how many reports per staff-year it's reasonable to expect. I suspect that by any objective measure, WHO is very seriously understaffed for this work.

c. Staff need training in the scientific/political skills required to put together a strong, unbiased panel, and to write clear, frank, scientifically rigorous reports. These skills don't necessarily come naturally, but they can be taught. Assuming new staff are hired, they need to be trained to be at least as good as the current staff at these skills.

d. Given the critical importance of recruitment/selection process for members of panels, staff need to build, maintain and utilize a much more extensive network of contacts with people in various governments and non-government interested party organizations who can suggest good candidates. To meet the goals outlined in part 3, a more inclusive, functioning network is needed, and a substantial amount of staff time may be required to assemble and use it.

e. Paying for improvements may require that governments that want "good science" put their money where their mouth is. Countries that benefit from Codex MRLs should be willing to pay a reasonable share of the costs of the system that produces them.

f. There may be other ideas for funding sources as well (such as an industry trust fund), but such proposals should be approached with caution. Although it is in theory possible to set up and administer a trust in ways that minimize any influence of the fund sources over the end results of the risk assessments they pay for, avoiding public suspicion that they may be some improper influence would be very difficult. The need for credibility of the risk assessments may preclude accepting chemical industry money, even though it certainly can be argued that pesticide manufacturers benefit from Codex standards for their products.

g. WHO is already building a database of eligible experts. This effort needs to be expanded, and ways need to be found to feed into it a wider range of experts from diverse backgrounds in all regions of the world.

h. Another practical approach might be to contract out much of the work of collecting and summarizing the data, so that the expert panel could focus on interpreting and making recommendations. If this approach is followed, however, care needs to be taken to make sure the consultant’s report is competent and thorough. This places additional burdens on the staff (to oversee consultants) and increases the value of interested party comments and/or peer review to critically assess the quality of the information provided to JMPR.

**6. More opportunities should be provided for peer review and input by interested parties.**

a. A draft summary of the evidence on a particular pesticide or pesticide family should be sent out to interested observers and interested parties for scientific review and comment. Industry and consumer/environmental NGOs could critically review the data and make inputs--additional data that had been omitted, perhaps, or comments on the significance of particular data. These inputs would then be considered by the JMPR panel.

b. The panel's report also should be peer-reviewed, or circulated for comments, or both, with an obligation to consider amending the report in response to review/comments.

c. There is a trade-off, of course--these review and comment processes would add to the time required to complete a risk assessment.

However, I think a better balance needs to be struck between expedience and openness. Current procedures are too much like a "black box;" at the end the Oracle has spoken, and CCPR is in effect stuck with whatever the Oracle said, whether it was right on target, or whether what it said could have been made much better with some timely critical scientific feedback. JMPR and the sponsoring agencies have tended to resist opening up the process out of fear that this would "politicize science," but in truth it's essential that scientific debates be done in the open, and that debatable points be adequately debated. The risk that political factors will improperly influence the outcome is far greater when the process goes on in secret and when review is short-circuited, than it is with open debate. Certainly the suspicion of undue influence is much harder to dismiss with a closed process. Making the risk assessment portion more open and transparent would significantly strengthen the entire Codex system.

7. **The role of CCPR needs to be considered as well.**

a. There needs to be more interaction between CCPR and JMPR, along the lines of developing Risk Assessment Policies. That would be an inherently open part of the process as well.

b. CCPR has to set priorities and determine how many chemicals it needs JMPR to review in a given period; these discussions are under way.

c. Ways to speed up the review of *new* pesticides (especially less toxic agents that would replace critical food uses of more hazardous older chemicals) need to be examined."