codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 5 (b) **CX/PR 01/4**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON PESTICIDE RESIDUES

THIRTY-THIRD SESSION
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THE HAGUE, THE NETHERLANDS

DIETARY EXPOSURE IN RELATION TO MRL SETTING

REVIEW OF THE PROCEDURE DEALING WITH CHRONIC DIETARY EXPOSURE CONCERN

(Prepared by Australia[1])

PURPOSE

1. To propose for the consideration of the Committee a number of measures that may be taken when the International Estimated Daily Intake (IEDI)[2] indicates that the Acceptable Daily Intake (ADI) may be exceeded, and to recommend further development of the science related to dietary exposure calculations at the international level.

INTRODUCTION

2. The refinement of dietary exposure calculations has progressed significantly in recent years, with the publication of revised guidelines for predicting dietary exposure to pesticide residues, based on five regional diets (WHO 1997)[3]. As a result, the Committee at its 29th session agreed to implement a procedure for dealing with chronic dietary intake concerns and also to review this after three years[4]. This procedure has worked quite well in recent meetings, but there are still situations coming before the Committee where the IEDI indicates that the ADI may be exceeded in one or more regional diets. This led to the decision of the 31st session that a paper be prepared to address this issue[5].

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1 In collaboration with Canada, New Zealand, United States of America, European Community and the Codex secretariat.

2 The term 'IEDI' is also used throughout this paper to cover those estimates which by necessity are partly based upon the old TMDI methodology as a result of incomplete data sets or non-periodic review situations.

3 Guidelines for Predicting Dietary Intake of Pesticide Residues (revised) (WHO/FSF/FOS/97.7) 1997, WHO, Geneva, Switzerland.

4 ALINORM 97/24A, para. 40, 7-12 April 1997, The Hague,.

5 ALINORM 99/24A, para. 75, 12-17 April 1999, The Hague,

3. Following discussions at the 32nd session, Australia was requested to prepare a paper for the 33rd session, in collaboration with several countries and responses to CL 2000/27-PR, Part 3A[6]. This paper examines some of the options available for resolving situations where the IEDI exceeds the ADI in one or more regional diets. The discussion in this paper is focused on compounds that are not acutely toxic.

CHRONIC DIETARY EXPOSURE CALCULATIONS: ROLE OF JMPR

4. In the normal course of events, JMPR considers data supporting proposals for new or amended MRLs for pesticides which have been included in the Priority List of Pesticides agreed by CCPR. This can be for new pesticides, or adding new MRLs to previously considered pesticides, or for pesticides under the periodic review programme. JMPR makes recommendations on the proposed MRLs to FAO, WHO, their Member countries, the Codex Alimentarius Commission/CCPR and any other interested parties. JMPR also undertakes chronic dietary intake calculations with a view to checking that the IEDI does not exceed the acceptable daily intake (ADI) in any of the agreed regional model diets. This IEDI calculation is undertaken according to a methodology agreed in 1997, using the best data available to the JMPR. The calculation covers all MRLs, both proposed and existing, for the pesticide under consideration.

5. JMPR now flags or highlights for CCPR those proposed MRLs for new or periodic review compounds where the IEDI indicates that the ADI may be exceeded. The 31st session of the CCPR welcomed the initiative of JMPR in flagging these situations, although it was not in full agreement with the proposed use of the term "MRLM" (Maximum Residue Limits for Monitoring. The 1999 JMPR considered the matter and agreed to use a footnote, instead of the term "MRLM", to indicate that the ADI may be exceeded. Its conclusions are reproduced at Appendix 1.

PAST PRACTICE WHEN THE IEDI INDICATES THAT THE ADI MAY BE EXCEEDED

6. When the IEDI indicates that the ADI may be exceeded in one or more regional diets, the Committee has in previous meetings been faced with difficult decisions concerning the proposed MRLs. To recommend the adoption of the proposed MRLs to the Codex Alimentarius Commission (CAC) would, on the basis of the calculations, lead to a perception of a potentially unacceptable risk to consumers in the affected regions.

7. This difficult decision has been dealt with at past sessions by either:

(a) consideration being delayed while further data are sought allowing refinements to be made in the dietary exposure calculations, or

(b) chemical companies volunteering to amend or 'withdraw' one or more of the uses which underpin proposed or existing MRLs for a pesticide before the Committee.

The latter has raised some controversy in recent meetings. A brief discussion on the Codex procedure for revision and revocation/withdrawal of MRLs at Appendix 2 may serve to clarify this matter.

THE NEED TO IMPROVE THE SCIENCE OF DIETARY EXPOSURE METHODOLOGY

8. In many respects, Codex, through the IEDI calculations, may be seen to have created an artificial concern regarding human health and safety of residues in food. We should remember that the Codex/JMPR procedures are normally expected to lead to an overestimate of dietary exposure

[6] Comments were received from the United States and New Zealand.

as assumptions of 100% crop treated and treatment at maximum good agricultural practice (GAP) are included in the method. The calculated exceedence may be an artificial problem created by the method and the assumptions, and we should do our best to develop the science and facilitate the provision of data to make the calculated IEDI as realistic as possible. In all cases, the best use should be made of all the available data.

9. Codex MRLs are only elaborated for chemicals already registered and used by a number of nations. At the time of registration of a chemical, national dietary calculations do not indicate a problem related to treated commodities but these same commodities when introduced into international trade may generate dietary exposure concerns. This would tend to suggest that our methodologies and assumptions at the international level require further refinement.

10. Before embarking on what would appear to be significant new work at the international level, we need also to consider whether the international community may be better served with a list of scientifically sound Codex MRLs (perhaps exceeding the ADI in a number of diets) that would serve as supporting information to risk management choices made by national governments. This option, which acknowledges the key responsibility of national governments for risk management decisions, is further explored in this paper.

POSSIBLE MEASURES FOR FURTHER REFINEMENT OF THE IEDI CALCULATION

11. The results of total diet studies and monitoring and surveillance data are provided to the JMPR, however they are not currently used at the international level for dietary risk assessment. Such data are mentioned for use at the national level in the WHO Guidelines for Predicting Dietary Intake of Pesticide Residues (Sections 4.2.1.4 and 4.2.1.3). Criteria for use of such data at the international level must be considered before the information can be used in a meaningful way.

12. Monitoring information generally shows that national intakes are substantially below the ADI. It could be that where the IEDI suggests that there is a potential problem, the next step would be to have national governments provide more detailed information, which either supports or does not support the "International" assessment.

13. Following the adoption of new procedures in 1997, the JMPR is using STMR values in estimating a more realistic dietary exposure where the data exist. Similarly there may be opportunity to use contemporary national reviews and dietary exposure calculations as an adjunct to JMPR assessments. The JMPR is invited to consider further the use of national reviews and dietary exposure calculations. It is recognized that this should not infringe on the credibility and independent nature of the JMPR assessments, or on the workload of the expert panel.

14. Where data are not available to enable estimations of STMRs (eg: for older Codex chemicals prior to a periodic review), it is known that some nations in Europe use a factor such as 1/3 of the MRL for chemicals applied pre-harvest in their national dietary intake calculation. It is understood that this factor is taken to represent a generally accepted statistical level at which STMRs occur relative to the MRL, and it is used as an estimate in lieu of the STMR. The scientific basis of this approach or whether this national approach could be usefully extended to international dietary intake calculations is referred to the JMPR for consideration.

15. The Committee may therefore wish to consider recommending that work be undertaken to explore how the methodology can be better improved to provide a more realistic estimate of exposure, approximating that of the national calculations. In developing this new methodology, experts from governments and industry and other non-government organizations should be utilised. A cooperative approach is seen as being most productive.

16. The levels of residues in food as consumed have been reported in the recent JMPR reports for new compounds and those under periodic review. Processing factors and estimates of residues in processed foods are developed by JMPR but cannot be used in the IEDI calculations because consumption information is lacking. For example, dietary information on fruit juices is generally missing from the GEMS Food Regional Diets, but residue levels in apple, orange and grape juices are regularly estimated. There is a need to obtain better consumption data to make best use of the residue information in making international estimates of dietary exposure. The Committee should request that Food Balance Sheets that form the basis of the GEMS Food Regional Diets be updated, in accordance with recommendations made at the Geneva Consultation, 1997[7].

17. In situations where proposed and adopted MRLs are both contributing to an IEDI calculation which indicates that the ADI may be exceeded (ie: in a non-periodic review situation), the Committee may consider requesting countries to provide the Committee with information concerning current good agricultural practice (GAP) relevant to existing and proposed MRLs. This could be requested via circular letter and could provide an opportunity for the Committee to recommend revocation of MRLs for uses that have been discontinued. However, revocation would require further consideration of other possible uses of the chemical, which could result in a lower MRL for the same commodity. Currently, this can only be achieved in a systematic way under the periodic evaluation process.

18. Where the IEDI calculations indicate that there is an issue in only one or two of the regional diets, the Committee may wish to invite government comments from countries in the 'affected' regional diets. If there are no objections to the proposed MRLs from the countries in the affected regions, then the MRLs could be recommended for advancement by the Committee. This might be on the basis that, although potential dietary intake concerns had been identified at the international level (using agreed methodology that is known to over-estimate actual intake), participating countries where these potential concerns could arise have assessed the proposed MRLs and can support them or not after conducting their own national intake calculations.

19. Where the above-mentioned approaches are not fruitful then consideration may be given to scheduling the chemical for periodic review to allow for submission of additional data and re-assessment of all MRLs via contemporary methodologies. It is expected that the periodic review procedure itself will be enhanced by the aforementioned advancement of the science related to improved dietary exposure estimates at the international level.

EFFECT OF SCHEDULING A PERIODIC REVIEW

20. In practice, dietary exposure calculations may indicate that the ADI may be exceeded when new MRLs are being sought either for a chemical new to Codex or for a chemical already in the Codex system. For the latter there may already be a number of MRLs for that chemical. Many of the existing MRLs may not have data to enable STMRs to be estimated and may also be for commodities that are staple foods. In a dietary model that uses a mixture of MRL levels for existing uses and STMR levels for uses supporting proposed MRLs, those existing MRLs thereby may contribute a disproportionately high amount to the IEDI and potential exceedence of the ADI. It has been suggested that this situation may be resolved by JMPR undertaking a periodic review of the pesticide and all its uses, so as to trigger the systematic submission of a comprehensive data package.

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[7] In the Geneva Consultation, it is recommended that the regional diets should be based on a 5 year average of food consumption data based on food balance sheets and that the diets should be updated every 10 years. *Food Consumption and Exposure Assessment of Chemicals*, Report of a FAO/WHO Consultation, Geneva, Switzerland 10-14 February 1997, p 18.

21. In a periodic review situation, there is greater opportunity for contemporary and comprehensive data to be submitted and the manufacturer is more likely to support only a limited range of commodities that will impact less heavily on the IEDI and potential for the ADI to be exceeded. This ultimately puts the decision of which uses are preserved in the hands of the pesticide companies. The companies will naturally be inclined to preserve and support those uses in the biggest pesticide markets (USA and Europe) and will tend not to support those in the smaller markets. It is clear that unless a use is discontinued at the national level, a pesticide company decision not to support a particular MRL in Codex does not reduce the exposure.

22. Furthermore, governments and growers through their governments may still submit GAP information and data for those uses that the manufacturer has not supported. It cannot, therefore, be assumed that the issue will be self-correcting due to selected uses not being supported.

23. It is in the interest of all to ensure that Codex decisions are based on science and not based on what could be perceived as ad hoc decisions regarding the revision or revocation/withdrawal of MRLs.

INTERNATIONAL DIETARY INTAKE ESTIMATES: THE BALANCE BETWEEN INTERNATIONAL AND NATIONAL LEVEL RISK MANAGEMENT DECISIONS

24. Since any regulatory measures to be applied will be applied at the national level, one can question whether Codex needs to restrict its MRL-setting activities because of potential problems with one or more diets. Where there is good information supporting a use and an MRL, is Codex right to refuse or revoke an MRL? Would we not be better off with a list of scientifically sound Codex MRLs (perhaps in total exceeding the ADI) that would serve as a backdrop to risk management choices made by national governments? To avoid trade problems the national decisions would need to be transparent and based on sound criteria.

25. We need to determine whether or not countries want to undertake the extra work suggested above in refining the international dietary intake estimates. This may be a never-ending process, as there does not appear to be a shared understanding of what can be realistically achieved at the international level. We may never be in a position to satisfy all country needs with respect to dietary intake assessment at the international level.

26. In fact Codex might be better served in assisting countries, particularly developing countries, at the national and/or regional level to undertake better dietary intake analysis to support regulatory decisions and enforcement at the national level. It is important to try to ensure that countries recognise that this is a different approach before we embark on what would appear to be significant new work through a series of working groups, expert meetings and other work aimed at improving international dietary intake assessments. This approach does not preclude advancing the science behind international dietary intake estimation, which may be usefully advanced at the same time.

27. The required detailed information on national diets may not become available unless there is some pressure put on national governments to develop the information either individually or regionally. If we say that Codex MRLs are based on sound science and that CCPR provides a ‘flag’ for possible intake concerns then it becomes the responsibility of national governments to make the appropriate MRL risk management decisions to suit their needs. This option acknowledges the key responsibility of national governments to make risk management decisions for their citizens.

28. There are continuing improvements in dietary intake assessment methodology including the use of probabilistic approaches being worked through in a number of countries at the national level.

The challenge is that these require extensive detailed information on uses, food consumption etc., in order to provide meaningful results. While this approach is scientifically valid and rigorous, it is not clear that it is feasible at the international level. CCPR needs to consider the option to limit what is done at the international level with the recognition that as countries further develop their processes the results will be brought forward to CCPR and/or JMPR for information.

SUMMARY OF POSSIBLE OPTIONS

29. To sum up, the range of broad options which could be considered by the Committee include:

(a) Limiting the emphasis placed on international dietary intake assessments in the advancement of proposed MRLs and leave it to governments to make their own risk management decisions regarding which Codex MRLs they accept.

(b) Limiting the emphasis placed on international dietary intake assessments in the advancement of proposed MRLs, but develop criteria for the valid use of national monitoring and survey data to further progress the methodology at the international level.

(c) Make greater use of available national dietary assessments, particularly those in 'affected regions', and make this information available to other participants in order that they be considered in their own assessment at the national level.

(d) Increase effort into ensuring that countries/regions, particularly developing countries, are in a position to make and enforce sound decisions with respect to food safety relevant to their conditions.

(e) Do not alter the status of international dietary intake assessments and develop the methodology to permit a detailed international assessment, which essentially precludes the need for a national assessment. This expresses the current trend for further refinement of the international dietary intake estimation methodology.

DISCUSSION

30. In situations where the initial IEDI calculations of JMPR indicate that the ADI may be exceeded in one or more regional diets, a range of possible options have been raised for consideration. These include consideration of improvements to the methodology of the dietary intake calculations and the consumption data currently available for the five regional diets.

31. A further option is to limit the emphasis placed on international dietary intake assessments in the advancement of MRLs. The Committee may wish to consider recommending the establishment of MRLs even when the IEDI indicates that the ADI may be exceeded in one or more regional diets, and flagging this to member governments so that they may make their own risk management decisions regarding which Codex MRLs they accept. This could be accompanied by Codex putting increased effort into ensuring that countries/regions, particularly developing countries, are in a position to make and enforce sound decisions with respect to food safety relevant to their conditions. This approach does not preclude advancing the science behind international dietary intake estimation and benefits may accrue from pursuing both approaches.

32. It is recommended that the Committee commit to continued development of the science related to dietary exposure calculations at the international level so as to provide a more realistic estimate of exposure. This work may include the development of criteria for the use of national monitoring and surveillance data, total diet surveys and better use of processing data. In

conjunction with this recommendation and a previous recommendation from the Geneva Consultation, the GEMS Food Regional Diets should be revised and updated.

33. Such work in the past has been much facilitated by the convening of an expert consultation. It is proposed that convening such a consultation be considered by WHO/FAO when the research has progressed sufficiently to warrant it.

34 Consideration needs to be given as to how such issues might be progressed within the Committee in future, and the Committee may wish to consider the need to convene an ad hoc working group meeting at several future sessions. Note that the approval of the Commission will need to be sought to create a standing working group.

RECOMMENDATION

35. It is recommended that the Committee consider:

- Continued development of dietary exposure calculations at the international level to provide a more realistic estimate of exposure, approximating that of the national calculations;

- Development of criteria for the use of national total diet studies, monitoring and surveillance data, percentage of crop treated, and the better and more consistent use of processing data;

- Requesting to WHO/FAO convene an expert consultation on dietary intake estimation when appropriate;

- Encouraging countries to submit data which could be used in the refinement of dietary intake calculations (as indicated in the reports of JMPR); and

- Limiting the emphasis placed on international dietary intake assessments in the advancement of MRLs.

- The Committee may also wish to consider recommending the establishment of MRLs even when the IEDI indicates that the ADI may be exceeded in one or more regional diets, and flagging this to member governments so that they may make their own risk management decisions regarding which Codex MRLs they accept.

APPENDIX 1

EXTRACT FROM THE REPORT OF THE 1999 JMPR:

"2.2 Maximum Residue Limits for Monitoring (MRLM)

The Meeting decided to abandon the use of the term MRLM, and adopted the use of a footnote on the pesticide for those cases where the available information does not indicate that the ADI is not exceeded and the use of one or more footnotes on the specific commodities of a pesticide where the available information does not indicate that the acute RfD is not exceeded. It was decided to implement the practice with the 1999 JMPR. The Meeting further agreed to continue the practice of clearly stating in the JMPR reports the information needed by the JMPR to refine its estimates of dietary intakes for chronic dietary intake exposure situations."

APPENDIX 2

CODEX PROCEDURE FOR REVISION OF MRLS

At the last two sessions, the Committee was informed by some manufacturers that they had changed the support of their compounds either in connection with pesticides the IEDI calculation of which indicates that the ADI may be exceeded, or not related to intake concerns. As these policy decisions of manufacturers may eventually lead to revocation or withdrawal of MRLs, or, in some cases, revision of the adopted MRLs, this has led to some comments concerning who should determine which Codex MRLs to be retained and which to be revoked/withdrawn. The following is to serve to clarify the procedure for revision and revocation of adopted MRLs and change or withdrawal of MRLs under elaboration.

Revision of Codex MRLs: The modification of the value of an adopted MRL is a "revision". Concerning the revision of Codex standards, including Codex MRLs, the *General Principles of the Codex Alimentarius contained* in *Codex Alimentarius Commission Procedural Manual* states:

"The Codex Alimentarius Commission and its subsidiary bodies are committed to revision as necessary of Codex standards and related texts to ensure that they are consistent with and reflect current scientific knowledge and other relevant information. When required, a standard or related text shall be revised or removed using the same procedures as followed for the elaboration of a new standard. Each member of the Codex Alimentarius Commission is responsible for identifying, and presenting to the appropriate committee, any new scientific and other relevant information which may warrant revision of any existing Codex standards or related texts."[8]

The *Guide to the Procedure for the Revision and Amendment of Codex Standards*[9] further stipulates the procedure. As stated above, the revision shall follow the same procedures as followed for the elaboration of a new standard. That is, to initiate work it is necessary to seek approval of the Commission or its Executive Committee as in the case of the initiation of work on new MRLs. In a normal scenario, the substance and commodity should be proposed by a government to be included in the Priority List of pesticides. A proposal may be made by the Committee itself. Then this proposal will be considered by the Committee. If agreed, the Priority List containing the agreed proposal will be forwarded to the Commission or its Executive Committee for approval. A typical example of initiating revision is to include a pesticide with old MRLs for review under the periodic review programme, although the adopted MRLs may be confirmed.

According to the Codex Elaboration Procedure, in the case of the elaboration of MRLs for pesticides, Codex secretariat distributes the recommendations of JMPR[10]. Therefore, it is quite likely that if the Committee agrees to review an MRL, it will ask JMPR to do so based on data provided to it. In the same manner as for new MRLs, proposed revised MRLs will be elaborated through the Codex Elaboration Procedure.

In the elaboration process, the delegations of Member countries and observers from international organizations can comment on these revised MRLs in accordance with the Codex *Rules of Procedure*[11] and the *Guidelines to Codex Committees*[12].

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8 *Codex Alimentarius Commission Procedural Manua*l, Eleventh Edition, Rome, 2000, pages 36-37.
9 *Codex Alimentarius Commission Procedural Manua*l, Eleventh Edition, Rome, 2000, pages 27-28.
10 *Codex Alimentarius Commission Procedural Manua*l, Eleventh Edition, Rome, 2000, pages 21 (Uniform Procedure) and 23 (Uniform Accelerated Procedure).
11 *Codex Alimentarius Commission Procedural Manua*l, Eleventh Edition, Rome, 2000, pages 6-18.
12 *Codex Alimentarius Commission Procedural Manua*l, Eleventh Edition, Rome, 2000, pages 51-59.

It should be noted that unrevised (or existing) Codex MRLs will remain the applicable Codex MRLs until the revised MRLs have been adopted by the Commission.

Revocation/Withdrawal of MRLs: If it becomes clear that no countries use the substance at all or on specific commodities and if it is subsequently agreed by the Committee, the Codex MRL(s) may be recommended to the Commission for revocation, without going though JMPR. When the JMPR withdraws its previous recommendations and the Committee agrees with the JMPR's recommendations, the Codex MRL(s) may also be recommended for revocation. For the recommendations of the Committee to revoke Codex MRLs, comments are sought from Member countries for consideration by the Commission. When the same information is available for MRLs under elaboration, the Committee may agree to withdraw them discontinuing their elaboration.

There have been cases where the Committee modified proposed MRLs at certain Steps of elaboration. In this case the approval of the elaboration had already been granted by the Commission and new recommendations mostly came from JMPR through its evaluations.