codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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

ALINORM 05/28/24

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

Twenty-eighth Session
Rome, Italy, 4 - 9 July 2005

REPORT OF THE THIRTY-SEVENTH SESSION OF THE CODEX COMMITTEE ON PESTICIDE RESIDUES

The Hague, The Netherlands, 18 - 23 April 2005

Note: This report includes Codex Circular Letter CL 2005/20-PR.

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CX 4/40.2 **CL 2005/20-PR**
April 2005

TO: - Codex Contact Points
- Interested International Organizations

FROM: Secretary,
Codex Alimentarius Commission
Joint FAO/WHO Food Standards Programme
Viale delle Terme di Caracalla,
00100 Rome, Italy

SUBJECT: DISTRIBUTION OF THE REPORT OF THE THIRTY-SEVENTH SESSION OF THE CODEX COMMITTEE ON PESTICIDE RESIDUES (ALINORM 05/28/24)

The report of the Thirty-seventh Session of the Codex Committee on Pesticide Residues will be considered by the 28th Session of the Codex Alimentarius Commission (Rome, Italy, 4 - 9 July 2005).

PART A: MATTERS FOR FINAL ADOPTION BY THE 28TH SESSION OF THE CODEX ALIMENTARIUS COMMISSION:

1. DRAFT MAXIMUM RESIDUE LIMITS FOR PESTICIDES AT STEP 8 (ALINORM 05/28/24, APPENDIX II); AND

2. PROPOSED DRAFT MAXIMUM RESIDUE LIMITS FOR PESTICIDES AT STEP 5/8 (ALINORM 05/28/24, APPENDIX III)

Member Governments and interested international organizations are invited to comment on the Draft MRLs and Proposed Draft MRLs at Steps 8 and 5/8 and should do so in writing, in conformity with the Guide of the Consideration of Standards of the Procedure for the Elaboration of Codex Standards Including Consideration of Any Statements Relating to Economic Impact (*Codex Alimentarius Procedural Manual*, Fourteenth Edition) to the Secretary, Codex Alimentarius Commission, Viale delle Terme di Caracalla, 00100 Rome, Italy (fax: +39 06 57054593; e-mail, codex@fao.org), **not later than 31 May 2005**.

3. PROPOSED DRAFT MRLS FOR SPICES (ALINORM 05/28/24, APPENDIX IV)

Member Governments and interested international organizations are invited to comment on the Proposed Draft MRLs at Step 5/8 and should do so in writing, in conformity with the Guide of the Consideration of Standards of the Procedure for the Elaboration of Codex Standards Including Consideration of Any Statements Relating to Economic Impact (*Codex Alimentarius Procedural Manual*, Fourteenth Edition) to the Secretary, Codex Alimentarius Commission, Viale delle Terme di Caracalla, 00100 Rome, Italy (fax: +39 06 57054593; e-mail, codex@fao.org), **not later than 31 May 2005**.

4. INTERIM CODEX MRLS FOR SAFER REPLACEMENT PESTICIDES (ALINORM 05/28/24, APPENDIX V)

Member Governments and interested international organizations are invited to comment on the Proposed MRLs to be adopted at Step 8 with an indication that they were Interim (I) MRLs, which should last not more than 4 years, and should do so in writing, in conformity with the Guide of the Consideration of Standards of the Procedure for the Elaboration of Codex Standards Including Consideration of Any Statements Relating to Economic Impact (*Codex Alimentarius Procedural Manual*, Fourteenth Edition) to the Secretary, Codex Alimentarius Commission, Viale delle Terme di Caracalla, 00100 Rome, Italy (fax: +39 06 57054593; e-mail, codex@fao.org), **not later than 31 May 2005**.

5. PROPOSED DRAFT GUIDELINES ON THE USE OF MASS SPECTROMETRY (MS) FOR IDENTIFICATION, CONFIRMATION AND QUALITATIVE DETERMINATION OF RESIDUES AT STEP 5/8 (ALINORM 05/28/24, APPENDIX X)

Member Governments and interested international organizations are invited to comment on the proposed Draft Guidelines at Step 5/8 and should do so in writing, in conformity with the Guide of the Consideration of Standards of the Procedure for the Elaboration of Codex Standards Including Consideration of Any Statements Relating to Economic Impact (*Codex Alimentarius Procedural Manual*, Fourteenth Edition) to the Secretary, Codex Alimentarius Commission, Viale delle Terme di Caracalla, 00100 Rome, Italy (fax: +39 06 57054593; e-mail: codex@fao.org), **not later than 31 May 2005**.

6. PROPOSED NEW CODES AND NUMBERS FOR COMMODITIES WITH ADOPTED MRLS (ALINORM 05/28/24, APPENDIX XI)

Member Governments and interested international organizations are invited to comment on the proposed new codes and numbers at Step 5/8 and should do so in writing, in conformity with the Guide of the Consideration of Standards of the Procedure for the Elaboration of Codex Standards Including Consideration of Any Statements Relating to Economic Impact (*Codex Alimentarius Procedural Manual*, Fourteenth Edition) to the Secretary, Codex Alimentarius Commission, Viale delle Terme di Caracalla, 00100 Rome, Italy (fax: +39 06 57054593; e-mail: codex@fao.org), **not later than 31 May 2005**.

7. WITHDRAWAL OF CODEX MAXIMUM RESIDUE LIMITS FOR PESTICIDES RECOMMENDED FOR REVOCATION (ALINORM 05/28/24, APPENDIX VIII)

Member Governments and interested international organizations are invited to comment on the proposed revocation (not including that of Codex MRLs replaced by the revised MRLs) and should do so in writing to the Secretary, Codex Alimentarius Commission, Viale delle Terme di Caracalla, 00100 Rome, Italy (fax: +39 06 57054593; e-mail, codex@fao.org), **not later than 31 May 2005**.

PART B: MATTERS FOR PROVISIONAL ADOPTION BY THE 28TH SESSION OF THE CODEX ALIMENTARIUS COMMISSION:

1. PROPOSED DRAFT AND PROPOSED DRAFT REVISED MAXIMUM RESIDUE LIMITS AT STEP 5 (ALINORM 05/28//24, APPENDIX VI)

Member Governments and interested international organizations are invited to submit comments including the implications which the Proposed Draft Maximum Residue Limits may have for their economic interest and should do so in writing in conformity with the Procedures for the Elaboration of Codex Standards and Related Texts (at Step 5) (*Codex Alimentarius Procedural Manual*, Fourteenth Edition) to the Secretary, Codex Alimentarius Commission, Viale delle Terme di Caracalla, 00100 Rome, Italy (fax: +39 06 57054593; e-mail, codex@fao.org), **not later than 31 May 2005**.

2. PROPOSED DRAFT MAXIMUM RESIDUE LIMITS FOR PESTICIDES FOR DRIED CHILI PEPPERS, INCLUDING PROPOSED DRAFT MRL FOR MEVINPHOS FOR SPICES AT STEP 5 (ALINORM 05/28/24, APPENDIX VII)

Member Governments and interested international organizations are invited to comment on the Proposed Draft MRLs at Step 5 and should do so in writing, in conformity with the Guide of the Consideration of Standards of the Procedure for the Elaboration of Codex Standards Including Consideration of Any Statements Relating to Economic Impact (*Codex Alimentarius Procedural Manual*, Fourteenth Edition) to the Secretary, Codex Alimentarius Commission, Viale delle Terme di Caracalla, 00100 Rome, Italy (fax: +39 06 57054593; e-mail, codex@fao.org), **not later than 31 May 2005**.

3. PROPOSED DRAFT GUIDELINES ON THE ESTIMATION OF UNCERTAINTY OF RESULTS AT STEP 5 (ALINORM 05/28/24, APPENDIX XII)

Member Governments and interested international organizations are invited to comment on the proposed Draft Guidelines at Step 5 and should do so in writing preferably by an email to the Secretary, Codex Alimentarius Commission, Viale delle Terme di Caracalla, 00100 Rome, Italy (fax: +39 06 57054593; e-mail: codex@fao.org), **not later than 31 May 2005**.

4. PROPOSED DRAFT RISK ANALYSIS PRINCIPLES APPLIED BY THE CODEX COMMITTEE ON PESTICIDE RESIDUES AT STEP 5 (ALINORM 05/28/24, APPENDIX XIII)

Member Governments and interested international organizations are invited to comments on the proposed draft risk analysis principles and should do so in writing preferably by an email to the Secretary, Codex Alimentarius Commission, Viale delle Terme di Caracalla, 00100 Rome, Italy (fax: +39 06 57054593; e-mail: codex@fao.org), **not later than 31 May 2005**.

PART C: REQUEST FOR COMMENTS AND INFORMATION ON:

1. DRAFT AND PROPOSED DRAFT MRLS AT STEPS 6 AND 3[1]

Member Governments and interested international organizations are invited to comment on the draft MRLs and proposed draft MRLs as contained in **Appendix IX** of this report at Steps 6 and 3. Comments should be sent in writing in conformity with the Uniform Procedure for the Elaboration of Codex Standards and Related Texts at Steps 3 and 6 including possible implications of the proposed draft MRLs for their economic interests (*Codex Alimentarius Procedural Manual*, Fourteenth Edition) preferably by an email to Dr Hans JEURING, Food and Consumer Product Safety Authority, Prinses Beatrixlaan 2, PO Box 19506,2500 CM Den Haag, Fax:+31 70 348 4061, E-mail: hans.jeuring@vwa.nl, with a copy to the Secretary, Codex Alimentarius Commission, Viale delle Terme di Caracalla, 00100 Rome, Italy (fax: +39 06 57054593; e-mail: codex@fao.org), **not later than 1 February 2006**.

2. PROPOSALS FOR ADDITIONS TO PRIORITY LISTS OF PESTICIDES SCHEDULED FOR EVALUATION OR REEVALUATION BY JMPR

Proposals are being requested from countries for pesticides to be added to the Codex Priority List of Pesticides, for subsequent recommendation to the Joint Meeting on Pesticide Residue (JMPR) for evaluation.

Those countries planning to submit proposals for consideration by the Codex Committee on Pesticide Residues at the next Session are invited to consult Appendices I and II of the CL 2002/1-PR, complete and send the completed Appendix II[2] to Dr Trevor DOUST, Manager – Chemistry and Residues Evaluation,

[1] For proposed draft MRLs to be proposed by the JMPR 2005 a separate CL will be issued.
[2] In completing Appendix II, only a brief outline is needed. The form may be retyped if more space is needed under any one heading provided that the general format is maintained.

National Registration Authority for Agricultural and Veterinary Chemicals, PO Box E 240, KINGSTON, ACT 2604, Fax: +61 2 6272 3551, Email: tdoust@nra.gov.au with copies to Dr Hans JEURING, Food and Consumer Product Safety Authority, Prinses Beatrixlaan 2, PO Box 19506,2500 CM Den Haag, Fax:+31 70 348 4061, E-mail: hans.jeuring@vwa.nl and the Secretary, Codex Alimentarius Commission, Viale delle Terme di Caracalla, 00100 Rome, Italy (fax: +39 06 57054593; e-mail: codex@fao.org), **not later than 1 December 2005**.

PART D: REQUEST FOR INFORMATION AND DATA TO BE SENT TO JOINT FAO/WHO MEETING ON PESTICIDE RESIDUES

RESIDUES AND TOXICOLOGICAL DATA REQUIRED BY JMPR FOR PESTICIDES SCHEDULED FOR EVALUATION OR PERIODIC RE-EVALUATION

Governments and interested international organizations are invited to send inventory of data for pesticides on the agenda of the JMPR. Inventories of information on use patterns or Good Agricultural Practices, residue data, national MRLs, etc. should be sent to Dr Amelia Tejada, Plant Protection Service, AGP, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy, Fax: +39 06 5705 6347 E-mail: amelia.tejada@fao.org well before **30 November** of a year before a JMPR meeting where a pesticide of concern is scheduled to be evaluated and, submission of residue data should be well before the **end of February** of the same year as the JMPR meeting. Toxicological data should be sent to Dr Angelika TRITSCHER, WHO Joint Secretary to JECFA and JMPR, International Programme on Chemical Safety, World Health Organization, 20 Avenue Appia, CH-1211 Geneva 27, Switzerland, Fax: +41 22 791 4848, E-mail: tritschera@who.int, not later than one year before the JMPR meeting (see Appendix XIV of ALINORM 05/28/24)**.**

Those countries specified under individual compounds in the ALINORM 04/27/24 concerning matters related to the FAO Panel of the JMPR (GAP, residue evaluation, etc.) on specific pesticide/commodity(ies) or concerning toxicological matters are invited to send information of data availability and/or toxicological data (for deadlines see the paragraph above).

While consulting Appendix I, please note that pesticide/commodity combinations which are already included in the Codex system or under consideration are found in a working document prepared for and used as a basis of discussion at each Session of the Codex Committee on Pesticide Residues; the most recent being CX/PR 05/5. Consult the document to see whether or not a given pesticide has already been considered.

SUMMARY AND CONCLUSIONS

The summary and conclusions of the 37th Session of the Codex Committee on Pesticide Residues are as follows:

MATTERS FOR APPROVAL BY THE 27TH SESSION OF THE COMMISSION

The Committee recommended to the Commission:

- Adoption of the draft and draft revised MRLs at Step 8 and proposed draft MRLs at Step 5/8 (Appendix II and Appendix III);
- Adoption of Interim Codex MRLs for safer replacement pesticides (Para. 202 and Appendix V);
- Revocation of certain existing Codex MRLs (Appendix VIII);
- Adoption of the proposed draft Guidelines on the use of mass spectrometry (MS) for identification, confirmation and qualitative determination of residues at Step 5/8 (Para. 228 and Appendix X);
- Adoption of proposed new codes and numbers for commodities with adopted MRLs (Para. 268 and Appendix XI);
- Adoption of the proposed draft MRLs for certain commodities at Step 5 (Appendix VI);
- Adoption of proposed draft MRLs for dried chili pepper, including MRL for mevinphos for spices at Step 5 (Paras 179, 188 and Appendix VII);
- Adoption of the proposed draft Guidelines for the estimation of uncertainty of results at Step 5 (Para. 235 and Appendix XII);
- Adoption of the proposed draft risk analysis principles applied by the Codex Committee on Pesticide Residues at Step 5 (Para. 221 and Appendix XIII).

The Committee agreed to ask the Commission to approve the following new work:

- Priority List for the establishment of MRLs for certain pesticides (Paras 240-256 and Appendix XIV);
- Amendment of the MRL elaboration Procedure (Para. 200).

OTHER MATTERS OF INTEREST TO THE COMMISSION

The Committee:

- generally agreed with the views and recommendations under the General Considerations of the 2004 JMPR and expressed its concern about the difficult financial situation currently faced by the WHO part of the JMPR work (Paras 10 - 49);
- welcomed the development of more accurate and relevant diets and looked forward to seeing the completed GEMS/Food Consumption Cluster Diets with worked examples at its next session (Para. 61);
- agreed to retain the current policy i.e., when the JMPR notes an Acute Reference Dose exceedance, the MRLs are not advanced to a higher Step of the Codex Procedure (Para. 76);
- decided that when commodities were returned to Step 6 for three times JMPR should be requested to examine residue data from alternative GAPs and to recommend MRLs which have no dietary intake concerns (Para. 81);
- agreed to consider further the revision of the list of methods of analysis for pesticide residues at the next session (paras 184 – 195);
- agreed not to propose new compounds for the Pilot Project and decided to consider the paper on the evaluation the Pilot Project at the next session (Paras 189-202);
- agreed to develop a discussion paper on criteria to clarify when the Committee may advance or hold recommended draft MRLs and to develop other proposals in order to improve the decision-making process in the CCPR (paras 204 – 205);
- agreed to consider further the policy to be followed in the establishment of MRLs for processed foods at its next session (paras 206 – 208); and
- agreed on the priority list of pesticides to be evaluated by JMPR (paras 240 – 251);

- agreed to send the draft revised Criteria for Prioritization Process to the Committee on General Principles for their review with the understanding that the revised version would be forwarded to the Commission for adoption and be included in the Codex Alimentarius Procedural Manual (Paras 252 – 256 and Appendix XV).
- **agreed to ask the JMPR**
  - to review the basis for ARfD for carbaryl (008) (Para. 86);
  - to re-evaluate ARfD and ADI for fenitrothion (037) (Para.93);
  - to review animal feeding studies for malathion (049) (Para.97);
  - to review GAPs that may result in lower MRL recommendations for disulfoton (074), fenamiphos-methyl (086), aldicarb (117) (Paras 104,107, 135);
  - to clarify overall intake assessment and a generic processing factor for dried chili peppers (Paras183-188).

MATTERS OF INTEREST TO OTHER CODEX COMMITTEES

CCGP

- in replying to the CCGP on food safety definitions, concluded that it did not disagree with the definitions on food safety and noted that their application to the establishment of MRLs for pesticides would require further consideration (Paras 6 – 7).

CCPFV

- in replying to the request from the CCPFV regarding establishing MRLs for processed commodities, agreed to confirm its present policy concerning the establishment of MRLs for processed commodities on the basis of the recommendations of the JMPR 2003 and consider a discussion paper on the use of processing studies and the establishment of MRLs for processed foods at its next session (Paras 8 – 9).

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LIST OF ABBREVIATIONS
(Used in this Report)

CAC	Codex Alimentarius Commission
CCFAC	Codex Committee on Food Additives and Contaminants
CCGP	Codex Committee on General Principles
CCMAS	Codex Committee on Methods of Analysis and Sampling
CCNFSDU	Codex Committee on Nutrition and Foods for Special Dietary Uses
CCPFV	Codex Committee on the Processed Fruits and Vegetables
CCPR	Codex Committee on Pesticide Residues
CCRVDF	Codex Committee on Residues of Veterinary Drugs in Foods
CLI	CropLife International
EC	European Community
FAO	Food and Agricultural Organization of the United Nations
JECFA	Joint FAO/WHO Expert Committee on Food Additives
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
OECD	Organisation for Economic Co-operation and Development
SPS Agreement	Agreement on the Application of Sanitary and Phytosanitary Measures
WHO	World Health Organization
WTO	World Trade Organization

ARfD	Acute Reference Dose
ADI	Acceptable Daily Intake
CXL	Codex Maximum Residue Limit for Pesticide
DIE	Daily Intake Estimate
GAP	Good Agricultural Practice in the Use of Pesticides
EMRL	Extraneous Maximum Residue Limit
IEDI	International Estimated Daily Intake
IESTI	International Estimated of Short-Term Intake
LOAEL	Lowest-Observed-Adverse-Effect-Level
MRL	Maximum Residue Limit
NOEL	No Observed Adverse Effect Level
PHI	Pre-harvest Interval
PTDI	Provisional Tolerable Daily Intake
STMR	Supervised Trials Median Residue
TMDI	Theoretical Maximum Daily Intake

INTRODUCTION

1. The Codex Committee on Pesticide Residues (CCPR) held its 37th Session in The Hague, The Netherlands, from 18 to 23 April 2005 at the kind invitation of the government of The Netherlands. Dr H.J. Jeuring of the Food and Consumer Protection Authority of The Netherlands chaired the Session. The Session was attended by 60 Member countries one Member Organization and 14 international organizations. The list of participants is attached as Appendix I to this Report.

OPENING OF THE SESSION

2. The Session was opened by Dr P.W.J. Peters, former Chief Inspector to the Dutch Food and Consumer Product Safety Authority. He welcomed the delegates to The Hague, and introduced a recently published report of the Health Council of the Netherlands, entitled: 'Pesticides in food: assessing the risk to children'. The report recommends that when MRLs are set for pesticides in food, explicit account should be taken of the possibility that children may be more sensitive to pesticides and of the higher levels of exposure to which children are subject. Although the number of toxicological studies need not be increased, improvements are required to existing research protocols. Amongst them are broader defined studies on reproduction toxicity, to allow for the identification of effects on the development of the nervous system, immune system and endocrine-regulated processes of development. If there are indications that developing organisms are more vulnerable than adult organisms, an additional safety factor could be appropriate when calculating the Acute Reference Dose (ARfD) and the Acceptable Daily Intake (ADI). Finally Dr Peters wished the delegates all success in their deliberations.

ADOPTION OF THE AGENDA (Agenda Item 1)[1]

3. The Committee adopted the Provisional Agenda as contained in CX/PR 05/37/1. The Delegation of the European Community presented CRD 16 (Annotated Agenda) on the division of competence between the European Community and its Member States according to paragraph 5, Rule II of the Procedure of the Codex Alimentarius Commission.

APPOINTMENT OF RAPPORTEURS (Agenda Item 2)

4. Mr. D. Lunn (New Zealand) and Dr C.W. Cooper (USA) were **appointed** as rapporteurs.

MATTERS REFERRED TO THE COMMITTEE BY THE CODEX ALIMENTARIUS COMMISSION AND/OR OTHER CODEX COMMITTEES (AGENDA ITEM 3)[2]

5. The Secretariat informed the Committee that a number of matters referred from the 27th Session of the Codex Alimentarius Commission (CAC), the 54th and 55th Sessions of the Executive Committee, and the FAO/WHO were presented for information purposes or would be discussed in more detail under the relevant Agenda Items. It also informed the Committee that 17 delegates were attending this Session of the CCPR with the support of the FAO/WHO Trust Fund. Additionally the Committee noted matters referred to the Committee including:

Food safety definitions

6. The Committee recalled that the last session of the Commission had adopted the definitions of "Food Safety Objective", "Performance Objective" and "Performance Criterion", and referred the definitions to all Committees involved in risk analysis for advice, with the understanding that the Committee on General Principles would reconsider the definitions if required in the light of any comments received.

7. Some delegations pointed out that the concepts reflected in the definitions had been developed for microbiological hazards and might not be directly applicable to chemical hazards. The Committee concluded that it did not disagree with the definitions and noted that their application to the establishment of MRLs for pesticide residues would require further consideration in the future.

Concentration factor used by the CCPR in establishing MRLs for processed commodities

8. In reply to request from the Codex Committee on Processed Fruits and Vegetables (CCPFV) regarding the concentration factor to be used for pesticide for residues in those Codex standards for processed fruits

[1] CX/PR 05/37/1; CRD 16 (Division of competence between the European Community and its Member States).
[2] CX PR 05/37/2; CRD 15 (Additional information on Matters Referred); CRD 10 (comments of the European Community).

and vegetables where the product is concentrated and re-diluted, the Committee informed the CCPFV and other Commodity Committees that its present policy in the establishment of MRLs for pesticides was based on the recommendations of the report of the JMPR 2003, i.e:

9. CCPR will only establish MRLs for processed commodities in which the residue is concentrated during the processing procedure (PF › 1) and for which there is an existing Codex commodity code. When the processing factor is ‹ 1, the MRL for the raw commodity also applies to the processed commodity. CCPR, however has the subject of establishing of MRLs for processed commodities on its Agenda for 2006 and may develop further guidance.

REPORT ON GENERAL CONSIDERATIONS BY THE 2004 JOINT FAO MEETINGS ON PESTICIDE RESIDUES (Agenda Item 4)[3]

2.1. Guidance on the establishment of acute reference doses (ARfDs)

10. The Committee was informed on the establishment of a guidance document on setting of acute reference doses (ARfDs) and that the short version of the document was published in the 2004 JMPR report. There are three main parts to the document, (1) general considerations on the derivation of ARfDs, (2) specific guidance considering relevant toxicological endpoints, and (3) considerations for a targeted single-dose study protocol. The full guidance document was accepted by a peer-reviewed scientific journal and will be published shortly. The single dose study protocol will be published on the JMPR website, and it is intended to be submitted to the OECD test guidelines programme for consideration.

11. The JMPR Secretariat encouraged national/regional authorities to take this guidance document into consideration when setting ARfDs, which will help in the international harmonization of ARfD setting.

12. To the request on the suggested 5 mg/kg cut-off point for consideration of setting an ARfD, the JMPR Secretariat clarified that this is not considered as firm cut-off point, but should be suitable for virtually all agricultural pesticides.

13. The Committee acknowledged the efforts of JMPR, recognized the importance of such a guidance documents and encouraged member countries to use them.

2.2. Definition of ‘overall NOAEL’

14. The JMPR Secretariat informed that the 2004 JMPR clarified the term ‘overall NOEAL’. This is used when several comparable studies are available but dose spacing may lead to different NOAELs (no-observed-adverse-effect levels) and LOAELs (lowest-observed-adverse-effect levels). The JMPR **agreed** that the studies could be considered together to derive an overall NOAEL.

2. 3. Interim acute reference dose

15. JMPR occasionally establishes ARfDs for compounds that were not scheduled for toxicological evaluation. The evaluation is based on data available from previous evaluations and the interim ARfD can be used in short-term dietary risk assessment. The Meeting **decided** to call these values ‘interim ARfDs’, in order to distinguish them from the ARfDs established for compounds that were scheduled for toxicological evaluation.

16. At the 2004 meeting an interim ARfD of 0.1 mg/kg body weight was established for propineb, and a brief description of the rational is given in the report.

17. To the request of the Delegation of Canada as to whether an extra safety factor is used for interim ARfDs, since the database may not be complete, JMPR Secretariat clarified that there is no default additional safety factor, but that one may be applied if judged necessary by the experts based on a case-by-case basis.

2.4. Progress report on the JMPR work-sharing pilot project on trifloxystrobin

18. The JMPR Secretariat informed the Committee, that a FAO/WHO/OECD pilot project on work-sharing was conducted to test whether national and regional evaluations of pesticide residues and toxicology could be used in order to facilitate and expedite JMPR work. Trifloxystrobin was selected and evaluations were

[3] Pesticide residues in food. 2004. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide residues in Food and the Environment and the WHO Core Assessment Group. FAO Plant Production and Protection Paper 178; CRD 10 (comments of the EC)

available from Australia, Canada, the USA and the European Commission. Original data were also provided by the manufacturer.

19. Experience in work-sharing on toxicological evaluations and on residue evaluations was briefly described.

20. JMPR noted that the same key toxicological studies on trifloxystrobin were available to all four agencies and to JMPR. In general, the national and regional reports described the methods and results of the studies sufficiently, however the level of detail differed substantially, and the differences in the formats of the national evaluations made comparisons difficult. A comparison of study description and selection of end-points revealed similarities as well as differences in interpretation. When differences were found, JMPR experts made an independent evaluation of the original data, which was only necessary in a few instances. The JMPR evaluator could concentrate on areas of disagreement, helping to focus the JMPR deliberations.

21. For residue evaluation, except supervised trials, which were not included in this pilot project, the data package provided to JMPR was not identical to those assessed at national and regional levels, with the exception only for studies on metabolism in farm animals. A JMPR evaluation and an appraisal were prepared on the basis of the original studies provided by the company and then compared with the evaluations of the studies in the national and regional reviews. A report on the comparisons is available on the FAO website. The formats of the national and regional residue evaluations differed significantly. Differences in procedures and approaches were noted, resulting in some divergence on conclusions, such as those for residue definitions and processing factors.

22. As JMPR considers the worldwide use of pesticides when recommending MRLs for food commodities in international trade, its approach is not necessarily the same as those of national and regional organizations, which operate within registration systems.

23. Some of the main conclusions and recommendations from this pilot project are:

- The availability of several national and regional evaluations was useful for both the WHO and the FAO evaluators, despite the problems encountered. FAO, WHO and OECD should thus consider means to facilitate the provision of national or regional evaluations to JMPR evaluators.
- Consideration of multiple national and regional evaluations should aid progress towards international harmonization of dossiers and evaluations.
- The evaluation process, including standardization of formats and guidelines, should be harmonized further internationally. Good progress has been attained in the toxicological evaluations, while more work is necessary to improve work-sharing for residue evaluations.

24. Some specific issues relevant to toxicological evaluations or to the residue evaluations were listed in the report.

25. The Committee noted that progress in the OECD work on harmonized al data requirements may resolve many of the barriers to work-sharing by JMPR.

2.5. Comparison of the JMPR recommendations and interim MRL recommendations from the CCPR pilot project

26. The 36th Session of the CCPR requested the JMPR to compare the suggested MRLs from the pilot project on Interim MRL and the JMPR MRL recommendations. The 2004 JMPR evaluated trifloxystrobin and fludioxonil and compared the result with the proposed interim MRLs. The result is shown in details in section 2.5 of 2004 JMPR Report.

27. The Committee was informed that significant differences were apparent because of the following: JMPR has access to a larger database of field trials and can thus make recommendations on the basis of wider use; an interim proposal for a maximum residue level in a commodity that is based on a national crop group might be significantly different from that based on a single commodity by the JMPR; the JMPR uses the average for replicate samples/analysis while the interim MRL proposals are based on maximum values.

28. The JMPR considers that when interim MRLs would be used extensively and it has a limit of only four years for JMPR to review it, it may impact of the periodic review compounds due to limit capacity in JMPR.

29. The JMPR was concerned over the word 'safer' for compounds that should be considered as alternatives for use on food and feed. The CCPR has included a number of safeguards in the process, the most important being analyses of long-term and short-term dietary intake based on JMPR methods.

2.6 Estimation of maximum residue levels of pesticides in or on spices on the basis of monitoring results

30. The Committee was informed that the 2004 JMPR evaluated the data on residues in spices on the basis of monitoring data, but emphasized that estimating MRLs does not necessarily mean that the use of those compounds on spices is approved. The approach taken to derive the MRLs is described in detail in section 2.6 of the 2004 JMPR Report.

31. The JMPR recommended that the CCPR accept the principle of setting MRLs for spices on the basis of monitoring results covering the 95th percentile of the residue occurrence at the 95% confidence level but to note that residue levels might exceed the MRLs in 5% of cases.

32. Monitoring results should not be used for estimating maximum residue levels that reflect post-harvest use, which results in much higher residue values than foliar application or exposure to spray drift.

33. The Committee recognized the efforts from JMPR, and **agreed** with the proposed procedure, as well as with the recommendation that this method should not be used for post-harvest use of pesticides in spices.

2.7. Revisited: MRLs for fat-soluble pesticides in milk and milk product

34. The Committee was informed that the 2004 JMPR revisited the MRLs for fat-soluble pesticides in milk and milk products because many pesticides have intermediate solubility in fat. The 2004 JMPR **decided** that, for fat-soluble pesticides, two maximum residue levels will be estimated, if the data permit: one for whole milk and one for milk fat. For enforcement purposes, a comparison can be made either of the residue in milk fat with the MRL for milk (fat) or of the residue in whole milk with the MRL for milk. When needed, maximum residue levels for milk products can then be calculated from the two values, by taking into account the fat content of the milk product and the contribution from the non-fat fraction.

35. The JMPR **requested** the CCPR ad-hoc Working Group on Methods of Analysis to give further guidance on analytical methods for measuring residues of fat-soluble pesticide in milk.

2.8. Revisited: Dietary burden of animals for estimation of MRLs for animal commodities

36. The Committee was informed that the 2004 JMPR had revisited the dietary burden of animals for estimation of MRLs for animal commodities.

37. The 1997 JMPR developed guidance for estimating maximum residue and STMR levels for products of animal origin when residues are transferred from feed items. As a result of experience gained since that time, the JMPR **agreed** that animals could be exposed for extended periods to certain commodities such as fodder, grain and feeds treated post-harvest which contain residues at the highest level. Thus, the assumption of the 1986 JMPR i.e. "that it was unrealistic to assume the theoretical maximum residue level would be achieved and maintained in the rations of food-producing animals receiving feeds produced on the farm" should no longer apply, simplifying the estimation of dietary burden.

38. A revision of the relevant text in the *FAO Manual*, taking the above into account, will appear on the FAO website.

2.9. Statistical methods for estimating MRLs

39. The Committee was informed that the JMPR had been advised of developments in the use of statistics to estimate the maximum residue level, by a group of experts involved in MRL setting in the countries of the North American Free Trade Association (NAFTA) and the European Food Safety Authority (EFSA). The method is still being developed. The JMPR expressed interest in receiving spreadsheets and documentation for evaluation, when available, and will await further developments.

2.10. Application of the recommendations of the OECD project on minimum data requirements to the work of the JMPR

40. The 2004 JMPR **agreed** that a pilot study would be conducted in which the effect of full implementation of the recommendations would be considered for evaluation of fludioxonil.

41. The Committee was informed that JMPR will continue to consider the recommendations of the York Workshop and Zoning Steering Group as auxiliary advice but that substantial additional work is required to make the recommendations generally applicable as guidance. The JMPR recalled the conclusion of the Zoning report that trials on a given commodity conducted at the same GAP with similar residues at zero day be considered equivalent regardless of geographic location. The 2004 JMPR recommended that hypothetical zones be developed based on crop type and good agricultural practices.

42. The Committee was also informed that an FAO Consultant has conducted a survey on the acceptability of the recommendations of the workshop on minimum data requirements (York workshop) and the zoning report. The result is posted in the FAO website.

2.11. Alignment of toxicological and residue evaluations for new and periodically reviewed compounds

43. The JMPR recommended that the toxicological and residue evaluations of new compounds or those undergoing periodic review be scheduled for the same year, when practical. When the residue definition is problematic, toxicological evaluation should be scheduled one year ahead of the residue evaluation.

Other matters of interest relevant to scientific advice

44. The WHO Joint Secretary drew the attention of the Committee to the difficult financial situation currently faced by the WHO part of the JMPR work. The basic principle for all programme work at WHO was explained, where a larger part of financial support for all activities is coming from specified extra budgetary contributions from Member Countries, and only a smaller part from regular WHO funds. The current situation at WHO is as such that the planned WHO part of the JMPR programme cannot be continued if additional funds are not made available. There are several reasons for this, one of them being decreased specified extrabudgetary contributions to the WHO JMPR programme. Other reasons are increased programme cost, e.g. for travel of experts, editing and printing. A letter from the WHO Joint secretary describing this situation and asking for increased support by Member States was handed out.

45. The representative of FAO informed the Committee on the initial reaction of FAO in response to the letter of WHO “Request for increased support of JMPR activities by national authorities”. FAO has continued to fund the JMPR programme through its Regular Programme budget on the basis of priorities set by its Governing Bodies and intends to continue in 2006/07 and beyond. It indicated that the appropriate forum to discuss this extreme financial situation would be the relevant WHO governing bodies, e.g. the coming WHO Health Assembly. Should this difficult situation persist at WHO, FAO intends to take this matter up at the appropriate management level of WHO to ensure continuation of the provision of scientific advice.

46. Some delegations asked about the previous proposal made about establishing a trust fund to also accept money from the private sector. The Committee was informed that WHO and FAO are pursuing this possibility, but that this is a rather lengthy process as it was necessary to ensure the independence of the provision of scientific advice within the legal frame work of the Organizations. This should be considered as a possible long-term solution only. Commitments from governments and from organizations within the food supply chain to contribute to the trust funds would be helpful.

47. The Observer of Crop Life International expressed its concern that the approval process to obtain Codex CXLs is too long leading to unpredictable timelines due to: insufficient JMPR resources to fund expert review of data and limited number of experts available; and the time required to publish reports and evaluations of JMPR meetings does not allow for consideration of the proposed MRLs with subsequent CCPR meeting.

48. The Secretariat of the JMPR indicated that this statement was not correct and mixed up the roles of JMPR and CCPR. The lengthy process was not only due to the JMPR but also due to the work of the CCPR and that the JMPR and the CCPR sessions were scheduled too close to each other. The Secretariat pointed out that the JMPR will make efforts to provide the draft evaluations at an earlier time possible.

49. The Committee expressed its concern about this situation and emphasized the importance of the work of JMPR for CCPR. It supported the WHO letter and **agreed** to bring this matter to the attention of their national authorities. The Chairman suggested to Member Countries when making financial contributions to WHO to consider having a part of this contribution specifically reserved for JMPR activities.

GEMS FOOD PROGRES REPORT OF DIETARY INTAKE (Agenda Item 5)[4]

50. The Committee recalled that at its 31st session of the Committee WHO presented its proposal to develop more representative diets as recommended by an FAO/WHO expert consultation on exposure assessment.[5] At its 35th Session, the Committee was informed of progress in developing the new diets and encouraged countries to cooperate in providing necessary data[6].

51. At this session, the WHO Representative reported that using a cluster analysis approach[7], 13 GEMS/Food Consumption Cluster Diets have been prepared based on average FAO Food Balance Sheet data for the period 1997-2001. The list of countries assigned to the various Consumption Cluster Diets and average per capita intake of commodities for these diets (in g/person/day) are given in Tables of document CX/PR 05/37/3. Further details are available on the WHO Website (http://www.who.int/foodsafety/chem/gems/en/)

52. Estimates are provided for the food commodities listed in the current GEMS/Foods Diets[8] as well as for FAO food codes that did not directly match these food commodities, but that were used in the derivation of estimates for these commodities. No match could be found in the FAO database for 58 of the almost 400 food commodities and food commodity groups listed in the GEMS/Regional Diets. Intake for these foods is listed "No match" in the Revised Regional Diets provided in Table 2. Note that while consumption amounts for some of these commodities were not available in the FAO database, the commodities themselves were included in a broader food group in the FAO database, e.g., the FAO database does not differentiate between the various types of lettuce.

53. To the remark that the list contained the names of departments/areas that were not countries in themselves, the WHO Representative noted that this was because FAO Food Balance Sheet data existed for these departments/areas, and indicated that these should be corrected for the purpose of these diets.

54. The Delegation of the EC raised a question about the processed products identified under entry "GC 640 Barley". The WHO Representative responded that the total barley consumption presented in the diets consisted of barley, pot barley, pearled barley and barley flour and grits. The table will be corrected to clarify this oversight.

55. In regard to the entry for "VD 72 Peas, dry", the Codex Classification for this commodity includes peas, dry, cow pea and field pea. The Representative of WHO explained that the FAO definition separates these different categories, therefore, the value given below the entry for "VD 72" is the consumption of peas, dry by the FAO definition. The table will be corrected to clarify this oversight.

56. The Delegation of France noted that the GEMS/Food Regional Diets were used by the Codex Committee on Food Additives and Contaminants (CCFAC) and **requested** clarification of the impact of going from 5 to 13 diets. The WHO Representative explained that under the Codex General Standard for Contaminants and Toxins in Food, the procedure provides a transparent and consistent approach for deciding whether a Codex Maximum Levels (ML) should be considered. This procedure uses the consumption values for commodities or commodity groups in the GEMS/Food Regional Diets to calculate exposure and to compare this to the toxicological reference, usually the Provisional Tolerable Weekly Intake (PTWI). If the 10% of the PTWI is exceeded in one regional diet or 5% of the PTWI is exceeded in two regional diets, establishment of a ML would be considered. It was likely that CCFAC would probably revisit these criteria if they **decided** to use the new GEMS/Food Consumption Cluster Diets. The WHO Representative stated that this matter would be brought to the attention of the CCFAC at its next session.

57. The Delegation of Brazil noted that new consumption data were available and would be provided to GEMS/Food.

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[4] CX/PR 05/37/3; CRD 10 (comments of the EC); CRD 24 (comments of India)
[5] Progress report by WHO on the revision of GEMS/Food Regional Diets, CX/PR 99/3, February 1999
[6] ALINORM 03/24A, para 33
[7] Barraj, L. and B. Petersen (1997) 'A method for revising and redefining regional diets for use in estimating intake of pesticides', Presented at the Joint FAO/WHO Consultation on Food Consumption and Exposure Assessment of Chemicals, 10-14 February 1997, Geneva.
[8] http://www.who.int/foodsafety/publications/chem/regional_diets/en/

58. The Delegation of India indicated that many foods commonly consumed in India were not included in the Consumption Cluster Diet applicable to India. The WHO Representative noted that the focus of the diets was on major food commodities in international trade and for which Codex MRLs may be established.

59. The Delegation of the Republic of Korea noted that the new diets did not contain data on VR 494 Radish although this was an important item in the Korean diet. The WHO Representative responded that this information was not included in the FAO Food Balance Sheets and that a number of data gaps existed in the current data base.

60. The Committee noted that before the GEMS/Food Consumption Cluster Diets can be further refined, countries would need to provide missing data for certain food items not included on their FAO Food Balance Sheets. This list of food items for which data are missing is available at http://www.who.int/foodsafety/chem/en/

61. The Committee welcomed the development of more accurate and relevant diets and looked forward to seeing the completed GEMS/Food Consumption Cluster Diets with worked examples at its next session. The Committee **agreed** that a Circular Letter would be sent to countries requesting to provide information on foods for which data were missing and to submit these to the GEMS/Food Manager, Department of Food Safety, WHO, Geneva, Switzerland.

DISCUSSION PAPER ON PROBABILISTIC MODELLING: MRLs HEALTH OR TRADE LIMITS (Agenda Item 6)[9]

62. The Committee recalled that it had considered issues related to probabilistic intake calculations and the policy to be followed by CCPR when acute exposure assessment exceeded acute RfD at its 34th, 35th, and 36th Sessions and that at its 36th Session it formulated questions regarding probabilistic intake assessment to be forwarded to the FAO/WHO Workshop on the Principles and Methods for Risk Assessment of Chemicals in Food. The Committee also recalled that it had **agreed** to consider the outcome of this Workshop at its 37th Session. Since the Workshop was rescheduled for May 2005 this consideration was not possible. The Committee had also **agreed** to come back to the question of enforcement at the next session.

63. On behalf of the Delegation of the Netherlands Dr B. Ossendorp introduced the document and drew the attention of the Committee to the fact that although most of the questions formulated by the 36th Session of the CCPR were questions to scientists/risk assessors, the first one, *"Advice should be provided on the circumstances under which a "total population approach" versus "consumers only approach" should be used in the probabilistic modelling of acute exposure to pesticide residues"*, should also be discussed by risk managers, since this question requires a decision on which population to protect, and a definition on what is safe. Dr Ossendorp pointed out that preventing health risks of consumption of a single food item requires a different approach than the estimation of health risks for a population at actual exposure.

64. Dr Ossendorp explained that the discussion "total population" versus "consumers only" does not equal the discussion "point estimate" versus "probabilistic approach" and that probabilistic intake calculations can be performed based on "consumers only", and point estimates can be made based on the "total population." She noted that when the interest lies in assessing the safety of actually eating a commodity, the "consumers only" approach should be used and if one is interested in the probability of eating the commodity and therefore in the probability of being at risk, one should use the total population approach. The latter approach may result in setting an MRL for a food item while accepting that every time one eats this food with a residue at the MRL he/she is at risk. However, since only a small percentage of the total population will eat this food, the methodology may lead to the conclusion that the risk is acceptable. Dr Ossendorp indicated that irrespective of the calculation method chosen, detailed information on food consumption data was needed for realistic intake calculations.

65. Finally Dr Ossendorp asked the Committee to decide whether it wants to define MRL safety based on the commodity at hand, or based on the population of interest. She also recommended that GEMS/Food should investigate the possibility of using the electronic platform on consumption databases as set up by SAFE FOODS (and any comparable initiatives) as a tool for JMPR intake assessments and that the WHO Core Assessment Group of JMPR should continue to refine the methodology used to set the ARfD.

[9] CX/PR 05/37/4; CRD 2 (Probabilistic modelling of dietary intake substances, Report 320011001/2005, MN Pieters, BC Ossendorp, MI Bakker, W Slob, RIVM).

66. The Delegation of Australia pointed out that defining the questions that need to be answered by risk assessors was very important as this question determines the methodologies which can be used and associated data requirements such as “consumers only” versus “total population” and was of the view that the methodology should not determine the risk management question, but rather the question should shape the methodology, as the methodology should provide the outcome that the Committee requires.

67. Recalling the current approach taken by the JMPR, the Delegation proposed that when the ARfD is exceeded for a particular GAP and chemical/commodity combination, the JMPR consider country GAPs until it locates the GAP resulting in the highest residue for which an MRL can be recommended and for which the point estimate of intake is below the ARfD, and this would then be the MRL that the JMPR recommends to the CCPR.

68. The Delegation indicated that this would be an amendment to the current JMPR Procedures, in that the recommended MRL would not always be based on the GAP that leads to the highest residues from supervised trials, but would be based on a different GAP that leads to lower residues for which adequate data are available. The modification would allow the recommendation of an MRL that can be used for trade purposes and is a practical way of removing the current “obstacle”, where limits are either being deleted or held up indefinitely.

69. The Delegation noted that irrespective of the methodology used for the risk assessment, it was essential that food containing residues at the level of the Codex MRL must be safe for the consumer. The Delegation supported further work in developing probabilistic methodology for addressing the issue on the likelihood of an exceedance of an ARfD and efforts to expand the availability consumption databases available for both deterministic and probabilistic methodologies. Many delegations supported the views expressed by the Australian Delegation.

70. The FAO Joint JMPR Secretary to the JMPR informed the Committee that the JMPR could consider and apply the proposals of Australia, if the Committee wished to change its policy to arrive to MRLs based on maximum GAP.

71. The WHO Joint JMPR Secretary to the JMPR drew the attention of the Committee to the fact that the JMPR **agreed** in 2003 to adopt a tiered approach to refine the short-term intake estimate in which the second tier could be probabilistic. However some limitations still existed in the development of such a second tier. The Representative also indicated that the second question regarding the probability that a residue intake presents health risks requires actual monitoring data on pesticide residues.

72. The Delegation of the Netherlands clarified that option II is not a second tier of option I, as a tiered approach may be developed for both options, and stated that the use of actual monitoring data has no relation to the establishment of MRLs for pesticides since monitoring data are a mixture of treated and untreated commodities.

73. The Representative of WHO indicated that the FAO/WHO Expert Consultation in May 2005 would provide clarification on the use of probabilistic methodology. However, an ARfD should not, in principle, be exceeded in order to prevent adverse health effects, some of which were serious and irreversible. In this regard, the terms “consumers only” and “total population” should be used with caution as they actually refer to eating occasions.

74. The Observer of Croplife International expressed his concern over the fact that JMPR uses 97.5 % consumption percentiles, without knowing anything about the underlying database. The Representative of WHO explained that this was the only information provided to GEMS/FOOD by the Member States and indicated that this matter might be addressed by the FAO/WHO Expert Consultation in May.

75. The Chairperson noted that when both MRLs and ARfD were exceeded in imported commodities the enforcement authorities in the Netherlands usually ordered the commodity to be destroyed.

76. The Committee concluded that food containing residues at the level of the adopted Codex MRL must be safe for the consumers and that the Committee retains the current policy i.e., when the JMPR notes an ARfD exceedance, the MRLs are not **advanced** to a higher Step of the Codex Procedure.

DRAFT AND PROPOSED DRAFT MAXIMUM RESIDUE LIMITS FOR PESTICIDES IN FOODS AND FEEDS, INCLUDING SPICES, AT STEPS 7 AND 4 (AGENDA ITEM 7A)[10]

GENERAL REMARKS

77. The Committee was informed by the EC about the adopted new Regulation (EC 396/2005) on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC.

78. The Committee was informed by the Delegation of Japan that their new Regulation in the area of pesticide residues would be enforced by May 2006 and the final draft on the provisional MRLs would be notified to the WTO in the near future.

79. The Delegation of the European Community (EC) recalled their reservation in CCPR 36 on a default variability factor of 3 as recommended by IUPAC, a recommendation taken over by the JMPR in 2003. The Committee was informed by the EC that the European Food Safety Authority (EFSA) had evaluated the same data as the IUPAC study and available EC data. On the basis of the study the EC expressed their reservation on a default variability factor of 3. The Committee was informed that for the time being the EC would maintain the variability factors as recommended by the JMPR in 2002. The Delegation of Australia strongly supported the default variability factor of 3.

80. The Committee **decided** to postpone discussions on the variability factor awaiting the discussion by JMPR 2005

81. The Committee **decided** that when commodities were **returned** to Step 6 for three times JMPR should be **requested** to examine residue data from alternative GAPs and to recommend MRLs which have no dietary intake concerns.

CAPTAN (007)

82. The Committee noted written comments of the EC which opposed the advancement of the MRLs beyond Step 6 for commodities with acute intake concerns.

83. The Committee was informed that the 2000 JMPR had evaluated data on GAP for apple and pear from many countries reflecting an MRL of 15 mg/kg for pome fruits to replace the CXLs of apple and pear. The Committee noted that the draft MRL of 20 mg/kg for apple should be withdrawn.

84. The Committee **decided** to advance the proposed draft MRLs for cucumber; nectarine and raspberries, red, black to Step 8 and to return the draft MRLs for cherries; dried grapes (=currants, raisins and sultanas); grapes; melons, except watermelon; peach; plums (including prunes); pome fruits; strawberry and tomato to Step 6.

CARBARYL (008)

85. The Delegation of Australia expressed their reservation on MRLs for stone fruits (except cherries), cherries and grapes for acute dietary intake concerns. The Delegation of the EC considered the database to be insufficient and expressed intake concerns for peaches and grapes.

86. The Committee **requested** the JMPR to review the basis for the ARfD of 0.2 mg/kg bw based on the written comments of Australia (CX/PR 05/37/5 Add 1).

87. The Committee **decided** to return the MRLs of cherries; citrus fruits; citrus juice; citrus pulp, Dry; dried grapes (currants, raisins and sultanas); grape juice; grape pomace, Dry; grapes; stone fruits to Step 6.

CHLORPYRIFOS (017)

88. The Delegation Republic of Korea expressed a reservation with regard to the MRL for rice. The Committee **decided** to advance the MRLs of cotton seed; cotton seed oil, refined potato; rice; soya bean (dry); soya bean oil, refined; tea, Green, Black) to Step 5/8. The entries for apple and pear were deleted as a CXL for pome fruit exist. The entry for chicken meat was also deleted as a CXL for poultry meat exist.

[10] CX/PR 05/37/5; CL 2004/16-PR; CL 2004/36-GEN; CX/PR 05/37/5-Add.1(comments); CX/PR 05/37/5-Add.2 (list of CXLs and MRLs with noted acute intake concerns); CRD 19 (comments of Korea); CRD 23 (comments of Morocco); CRD 24 (comments of India); CRD 25 (summary results of TMDI and IESTI calculations for dried Chili peppers); CRD 27 (comments of Morocco)

DIAZINON (22)

89. Noting that no new information from the U.S.A. had been received, the Committee **decided** to advance the MRL for cabbages, head to Step 8.

DIMETHOATE (27)

90. The Delegation of Australia and the Delegation of the EC expressed their reservation on proposed MRLs for dietary intake concerns. The Committee **decided** to recommend the deletion of CXLs for apple; grapes; onion, bulb; plums (including prunes) and sorghum and to withdraw the MRLs for grapes, plums (including prunes) and pome fruits.

91. Committee **decided** to advance the MRLS for artichoke, globe; Brussels sprouts; cauliflower; celery; mango; olives; peas (pods and succulent=immature seeds); sugar beet leaves or tops; turnip greens; turnip, garden; wheat; wheat straw and fodder, dry to Step 8 and to return the MRLs of barley; cabbages, head; citrus fruits; lettuce, head; peppers, Sweet; and tomato to Step 6.

92. The Chairman invited the Delegation of the EC to review their dietary intake calculations and provide the results of their review to the next session of CCPR.

FENITROTHION (037)

93. The Committee noted intake concerns for this compound. Following the proposal of the Delegation Australia, the Committee **decided** to request the JMPR to re-evaluate the acute RfD and ADI for fenitrothion.

94. The Committee **decided** to advance the MRLs for apple, cereal grains; edible offal (mammalian); eggs; meat (from mammals other than marine mammals); milks, poultry meat; rice bran, unprocessed; wheat bran, unprocessed to Step 5.

95. The Committee **decided** to withdraw the MRLs for cereal grains; and wheat bran; unprocessed at Step 7 and to recommend deletion of the CXL for wheat flour.

FOLPET (41)

96. The Committee noted concerns regarding the residue definition and **decided** to return all MRLs to Step 6. The Committee **requested** the Delegation of the EC to further specify its concerns regarding the use of variability factors and intake concerns and make it available for the next CCPR session.

MALATHION (49)

97. The Committee **decided** to advance the MRL for apple; citrus fruits; and grapes to Step 5 and to return all other MRL associated with animal feeds to Step 6 pending review by JMPR of animal feeding studies. The Committee **decided** to delete of the CXL for peach.

98. The Committee, noting the intake concern of the EC for grapes, **requested** the EC to report on this intake calculations for the next session of the CCPR.

PARAQUAT (57)

99. The Committee **decided** to advance all proposed MRLs to Step 5.

100. The Committee **decided** to consider for withdrawal the CXL for cattle kidney; cotton seed oil, edible; edible offal of cattle, pigs and sheep; meat of cattle, pigs and sheep; passion fruit, pig kidney; potato; rice; rice, polished; sheep kidney and soya bean (dry), sunflower seed oil, crude; sunflower seed oil, edible and vegetables (except as other wise listed) at its next Session.

PARATHION-METHYL (59)

101. The Committee noted that animal transfer studies were not available and **decided** to return all the draft MRLs to Step 6 (this includes the MRLs for pea hay or pea fodder (dry); pea vines (green), which were incorrectly listed as having a CXL).

THIABENDAZOLE (65)

102. The Committee noted that thiabendazole was on the agenda of the 2006 JMPR, for evaluation of both toxicology and residues. The Delegation of Morocco noted that they have sent data on citrus fruits to the JMPR and that they prefer an MRL of 5 mg/kg for citrus fruits. However, the Delegation of Morocco

informed that they sent data and suggested to take it at the next JMPR meeting. The FAO Joint Secretary to the JMPR informed the Committee that they have never received data on citrus fruit, that the manufacturer intends to submit data for the residues evaluation of the JMPR in 2006.

103. The Committee **decided** to advance the MRL for mushrooms to Step 8 and to return the MRL for citrus fruits to Step 6.

CARBENDAZIM (72)

104. The Committee **decided** to return all MRLs currently at Step 7 to Step 6, pending the evaluation of acute toxicity by the JMPR in 2005.

DISULFOTON (74)

105. The Committee **decided** to return all the MRLs currently at step 7 to step 6. Since this was the third time that the proposed MRLs have been **returned** to Step 6 for intake concerns, the Committee also **decided** to request the JMPR to review GAPs that may result in lower MRL recommendations.

DODINE (84)

106. The Committee **decided** to advance the MRLs for cherries; nectarine; peach and pome fruits to step 8 and recommend subsequent deletion of CXLs for apple; peach and pear. The Committee also **agreed** to recommend deletion of CXLs for grapes and strawberry.

FENAMIPHOS (85)

107. The Committee noted that acute intake concerns existed for peppers; tomato and watermelon.

108. The Committee **decided** to return these MRLs to Step 6. The Committee **decided** to delete the CXLs for carrot; grapes and pineapple. Since this was the third time that the MRLs were **returned** to Step 6 concerns, the Committee **decided** to request JMPR to review GAPs that may result in lower MRL recommendations.

PIRIMIPHOS-METHYL (086)

109. The Committee **decided** to delete the CXLs for all commodities for which the 2003 JMPR recommended withdrawal. The Committee **decided** to advance the MRLs for edible offal (mammalian); eggs; meat (from mammals other than marine mammals); poultry meat; poultry, edible offal of to Step 5/8 with subsequent deletion of the CXLs for eggs and meat (from mammals other than marine mammals) and to advance milks; cereal grains; wheat bran, unprocessed to Step 8 with subsequent deletion of existing CXLs.

CHLORPYRIFOS-METHYL (090)

110. The Committee **decided** to return the MRLs for barley; oats: and rice to Step 6 due to intake concerns.

METHOMYL (094)

111. The Committee **decided** to advance the MRLs for alfalfa fodder; alfalfa forage (green); barley; bean fodder; beans, except broad bean and soya bean; citrus pulp, dry; pea vines (green); soya bean forage (green); wheat; wheat bran, unprocessed; wheat flour; wheat germ to Step 8 and mint hay; peppers to Step 5/8 and to return apple; brassica vegetables; celery; fruiting vegetables; cucurbits; grapes; leafy vegetables and pear to Step 6 for intake concerns and to recommend deletion of the CXLs of sweet corn(corn-on-the-cob) and tomato.

112. The Committee **decided** to recommend subsequent deletion of the CXls for alfalfa forage (green); barley; mint hay; pea vines (green); peppers; soya bean forage (green) and wheat.

ACEPHATE (095)

113. The Committee **decided** to recommend deletion the CXLs for alfalfa forage (green); cabbages, head; cattle fat; cattle meat; cotton seed; lettuce, head; pig fat; pig meat; potato; sugar beet; sugar beet leaves or tops; tomato; tree tomato and to advance artichoke, Globe; edible offal (mammalian); eggs; meat (from mammals other than marine mammals); milks; poultry meat; poultry, Edible offal of; soya bean (dry) to Step 8.

114. The Committee **decided** to return the MRLs for beans, except broad bean and soya bean; flowerhead brassicas; mandarins; nectarine; peach; peppers; and pome fruits to Step 6 due to intake concerns.

115. The Committee also **decided** to recommend subsequent deletion of CXLs for eggs; milks; poultry meat and soya bean (dry).

CARBOFURAN (096)

116. The Committee was advised that the EC had established an ARfD ten times lower than that established by JMPR. The Delegations of Canada and the USA also informed the Committee that their national ARfD was much lower than the JMPR ARfD. The WHO Joint Secretary of the JMPR informed the Committee that the relevant information from the EC had been received and that JMPR considered another study to be the critical one.

117. The Committee **decided** to return the MRLs for cantaloupe, cucumber, mandarin, oranges (sweet, sour), potato, squash (summer) and sweet corn (corn-on-the-cob) to Step 6 due to intake concerns.

118. The Committee **advanced** the MRLs for maize; maize forage; sugar beet and sugar beet leaves or tops to Step 8.

119. The Delegation of Australia noted that in several instances the MRLs have been held at Step 6 even though the JMPR had not noted any intake concerns. The Delegate expressed their concern with such decisions of CCPR and made the point that while the concern of countries should be noted, the CCPR should nevertheless base its decisions on the JMPR Risk Assessment. The Chairman acknowledged that this was the case, but if the MRLs were to be recommended for advancement, the objections of member countries had to be taken into account.

METHAMIDAPHOS (100)

120. The German Delegation noted that the MRL values for fodder beet and fodder beet leaves and tops had been switched and the value were corrected accordingly.

121. The Committee **decided** to return the MRLs for beans (except broad bean and soya bean); cabbages, head; flowerhead brassicas; mandarins; nectarine; peach; peppers; pome fruits and tomato to Step 6 because of intake concerns.

122. The Committee **decided** to withdraw the CXLs for alfalfa forage (green); cattle fat; goat fat; lettuce, head; pig fat; sheep fat and tree tomato.

123. The Committee **advanced** the MRLs for artichoke, globe; cotton seed; edible offal (mammalian); eggs; fodder beet; fodder beet leaves or tops; meat (from mammals other than marine mammals); milks, potato, poultry meat, poultry edible offal of; soya bean (dry); sugar beet, sugar beet leaves or tops to Step 8 and the subsequent deletion CXLs for cotton seed; goat meat; milks; pig meat; potato and sheep meat.

PIRIMICARB (101)

124. The Committee was informed that an ARfD for pirimicarb was established by the 2004 JMPR and that the compound was scheduled for Periodic Review by JMPR 2006.

PHOSMET (103)

125. The Committee noted the comments of the European Community that the JMPR ARfD was not acceptable since it is based on human data.

126. The Committee **decided** to return the MRLs for apricot, blueberries, citrus fruits, nectarine, and pome fruits to Step 6 due to intake concerns.

DITHIOCARBAMATES (105)

127. The JMPR 2004 evaluated propineb and proposed MRLs for the use of propineb alone and for the use of dithiocarbamates including propineb in several commodities.

128. The Committee **decided** to withdraw the double MRL proposals for cucumber, edible offal (mammalian); eggs; onion; bulb; peppers, sweet; potato; poultry meat and poultry, edible offal of; which were proposed at a lower level for propineb alone. The Committee **agreed** not to establish separate MRLs for propineb as the residue definition applies to all dithiocarbamates.

129. The Committee **decided** to advance all other proposals to Step 5/8, except for cherries; peppers, sweet and tomato.

130. The Committee **decided** to advance the MRL for peppers, sweet to Step 5 due to an acute intake concern expressed by the Delegation of Australia.

131. The Committee also **decided** to advance the MRLs for cherries and tomatoes to Step 5 as these were recommendations of the 2004 JMPR and countries needed time to review the report

132. The Delegations of Morocco and Brazil recalled that the Committee at its last Session had agreed to include a footnote in the MRL list of dithiocarbamates because of analytical problems in several crops.

133. The Committee **decided** to place the remark in the note section of the data base.

PHORATE (112)

134. The Committee noted that the compound was scheduled for re-evaluation for residues by JMPR in 2005.

ALDICARB (117)

135. The Committee, noting that the acute RfD was exceeded, **decided** to return the MRLs for bananas and potatoes to Step 6 for the third time and **requested** JMPR to examine residue data from the alternative GAP.

OXAMYL (126)

136. The Committee noted that there are acute intake concerns for some commodities for the second time. The Committee **decided** to return all MRL to Step 6 and asked JMPR to inform the Committee about CXL and GAP for apple and tomato.

TRIADIMEFON (133)

137. The Committee noted that the compound was scheduled for periodic re-evaluation for residues by JMPR in 2006.

DELTAMETHRIN (135)

138. The Committee **decided** to advance the MRL for leafy vegetables to Step 8.

139. The delegation of the European Community reserved its position on the advancement of the MRL for leafy vegetables because of acute intake concerns.

140. The Committee **agreed** that the data base needed to be corrected by deleting the entries for brassica vegetables; bulb, vegetables, except fennel, bulb; mandarins; nectarine; oranges, sweet, sour; peach and plums (including prunes).

PROCHLORAZ (142)

141. The Committee noted that the 2004 JMPR had noted acute intake concerns for mushrooms.

142. The Committee **decided** to advance the MRL for mushroom to Step 5.

143. The Committee **decided** to advance all other MRLs to Step 5/8 and the subsequent deletion of the CXLs for avocado; banana; barley; barley straw and fodder; cattle fat; cattle meat; cattle edible offal of; mango; milks; oat straw and fodder, dry; oats; orange, sweet, sour, papaya; rape seed, rye, rye straw and fodder, dry; wheat and wheat straw and fodder, dry. MRLs for coffee beans and stone fruit will be considered for deletion next year.

CARBOSULFAN (145)

144. The Committee noted that the compound was discussed at the 2003 JMPR and that there were no intake concerns.

145. The Committee **decided** to advance all MRLs to Step 8. The Delegation of the European Community opposed the advancement to Step 8 of the MRLs for oranges, potato and mandarin because they were associated with MRLs for carbofuran, which are unacceptable.

ETHOPROPHOS (149)

146. The Committee noted that the compound was reviewed by JMPR in 2004 and that withdrawal was recommended for several commodities.

147. The Committee **decided** to consider for withdrawal the CXLs for beetroot; cabbages head; gherkin; grapes; lettuce head; maize; maize fodder; maize forage; onion bulb; peanut; peanut fodder; peas; peppers; pineapple; pineapple fodder; pineapple forage; soya bean dry and soya bean fodder at its next Session.

148. The Committee **decided** to advance to Step 5/8 the MRLs for banana; cucumber; edible offal (mammalian); meat; melons (except watermelon); milks; peppers sweet; potato; sugar cane; sweet potato and tomato and the subsequent deletion of the CXLs for banana; cucumber; melons, excepted watermelon; potato; sugarcane; sweet potato and tomato.

DIMETHIPIN (151)

149. The Committee noted that an ARfD was established in 2004 and there were no intake concerns.

GLYPHOSATE (158)

150. The Committee noted that a revised ADI was established by JMPR in 2004 and that an acute Rfd was not necessary.

PROPICONAZOLE (160)

151. The Committee noted that propiconazole was scheduled for periodic re-evaluation for residues by JMPR in 2007. The Committee noted that the 2004 JMPR established an ARfD.

TOLYLFLUANID (162)

152. The Committee noted that there are no intake concerns and **decided** to advance the MRL for lettuce, head to Step 8 and the subsequent deletion of the existing CXL.

OXYDEMETON-METHYL (166)

153. The Committee noted that there are short-term intake concerns for children for apple; cabbages head; grapes, oranges; sweet, sour and pear.

154. The Committee **decided** to withdraw the MRLs currently at Step 7 for barley; barley straw and fodder; potato; rye; rye straw and fodder; sugar beet; sugar beet leaves or tops; wheat and wheat straw and fodder, dry. The Committee **decided** to advance the MRLs for these same commodities which are currently at Step 4 to Step 5.

155. The Committee **decided** to return the MRL's for the other commodities currently at Step 7 to Step 6 and to advance the MRL for cauliflower to Step 5.

TRIADIMENOL (168)

156. The Chairman informed the Committee that the 2004 JMPR established an ADI and an acute RfD but did not perform an acute dietary intake calculation, as no STMRs and HRs could be estimated.

157. The Committee **decided** to postpone discussions awaiting the periodic re-evaluation by the 2006 JMPR.

BENTAZONE (172)

158. The Committee was informed that bentazone was evaluated for toxicology at the 2004 JMPR and that the establishment of an ARfD was not necessary.

FENPROPIMORPH (188)

159. The Committee was informed that the 2004 JMPR established an acute RfD and there are no intake concerns.

FENPYROXIMATE (193)

160. The Committee **decided** to return for the second time the MRLs for apple and grapes to Step 6 because of acute intake concerns for children and the general population (grapes only) and to advance the MRL for oranges, sweet and sour to Step 8.

HALOXYFOP (194)

161. The Committee **decided** to return all MRLs currently at Step 4 to Step 3 and all MRLs currently at step 7 to step 6 because of chronic intake concerns.

162. The Committee **decided** to postpone discussions awaiting the 2006 JMPR risk assessment.

CHLORPROFAM (201)

163. The Committee **decided** to return all the MRLs to Step 6 because of acute intake concerns for potato (before peeling and cooking) and awaiting the toxicological evaluation by the 2005 JMPR.

SPINOSAD (203)

164. The Committee **decided** to advance the MRL for cattle milk to Step 8 and to advance the MRLs of cattle milk fat; cereal grains; dried grapes; edible offal; grapes; meat from mammals other than marine mammals (except cattle) and wheat bran, unprocessed to Step 5/8 with the subsequent deletion of CXLs for maize; sheep meat; sheep, edible offal and sorghum.

ESFENVALERATE (204)

165. The Committee was informed by the Observer from Crop Life International that in as many countries as possible the change from fenvalerate to esfenvalerate is in progress but that in some countries fenvalerate remains in use.

166. The Committee was informed by the Delegation of Morocco that fenvalerate residues are often found in imported green tea.

167. The Committee **decided** to return the MRLs for cotton seed; tomato and wheat to Step 6.

CYPRODINIL (207)

168. The Committee **decided** to advance all MRLs to Step 8 as there are no intake concerns.

FAMOXADONE (208)

169. The Committee **decided** to advance all MRLs to Step 8 as there are no intake concerns.

METHOXYFENOXIDE (209)

170. The Committee **decided** to return the MRL for spinach for the first time to Step 6 because of acute intake concern for children.

171. The Committee **decided** to advance all other MRLs to Step 8.

PYRACLOSTROBIN (210)

172. The Committee **decided** to advance all MRLs to Step 5 and noted the acute intake concern of the EC for grapes.

FLUDIOXONIL (211)

173. The Committee **decided** to advance all MRLs to Step 5, noting that the 2004 JMPR determined that the establishment of an ARfD was not necessary and there were no intake concerns.

METALAXYL-M (212)

174. The Committee **decided** to advance all MRLs to Step 5.

175. The Delegation of Japan recommended that the MRL data base should also include information on an ARfD when JMPR recommends an ARfD “unnecessary”.

TRIFLOXYSTROBIN (213)

176. The Committee **decided** to advance all MRLs to Step 5 as JMPR determined that an ARfD was not necessary and there were no intake concerns.

PROPOSED DRAFT RECOMMENDED MRLS FOR SPICES

177. The Chairman recalled that at previous Sessions of the Committee, there were discussions regarding the use of monitoring data to establish MRLs for spices because no GAP is available.

178. The Committee **decided** at its last Session to do this. In their evaluation the JMPR did not have individual spice consumption data and used the best estimates from the GEMS Food data base which is like to result in overestimates of consumption.

179. Noting that the dietary risk assessment by the 2004 JMPR had only indicated an acute intake concern for mevinphos the Committee **decided** to advance the MRLs for all pesticides except mevinphos to Step 5/8 and to advance the MRL of mevinphos to Step 5 (see Appendices IV and VII).

180. The Delegation of the United States informed the Committee that many of the pesticides were organophosphates which are being phased out.

181. The FAO Joint Secretary to the JMPR informed the Committee that the request for a schedule for a review of monitoring data on spices should not only be sent to the JMPR but also to the Working Group on Priorities.

182. The Committee noted the request of the Delegation of Thailand to establish MRLs for herbs based on monitoring data, however recalled that it had **decided** to apply this approach only for spices.

PROPOSED DRAFT MAXIMUM RESIDUE LEVELS IN/ON DRIED CHILI PEPPERS

183. The Delegation of Hungary informed the Committee that although in the 2004 JMPR report it is stated that 10% of the consumption figures for fresh peppers are used for dried chili peppers, this was not taken into account in the intake calculations. In CRD 25 the corrected intake calculations were presented showing that there were no remaining intake problems.

184. The Delegation Republic of Korea opposed the proposed MRLs for dried chili pepper for azinphos-methyl, chlorpyriphos and methomyl, because they have information that the processing factors for these compounds are much lower than the default factor of 10 that was used by JMPR. The Committee invited the Delegation of Korea to submit a full data package with the information on processing factors to the JMPR, according to the General Considerations 2.6 of the JMPR 2002.

185. The Committee **decided** to change the MRL for imidacloprid on dried chili pepper to 10 mg/kg, as the MRL for peppers of 1 mg/kg was based on a fresh weight basis.

186. The Committee noted that monocrotophos (54) was no longer in the system and that the MRL for pirimiphos-methyl (86) had been proposed for withdrawal. The Committee therefore **agreed** that no MRL should be proposed for dried chili pepper for these two compounds.

187. The Delegation of the European Community **requested** the JPMR to perform an overall intake assessment for each compound when the TMDI for dried chili peppers was > 5% of the ADI. The European Community noted that changes on CXLs for peppers should lead to changes in CXLs for dried chili peppers and therefore proposed to develop a generic processing factor for dried chili peppers.

188. The Committee **decided** to advance all remaining MRLs for dried chili peppers to Step 5 (see Appendix VII) and **requested** the JMPR to consider this matter once more taking into account the discussions at the present CCPR Session on the calculation of overall intake assessments and a generic processing factor.

PILOT PROJECT FOR THE EXAMINATION OF NATIONAL MRLS AS INTERIM CODEX MRLS FOR SAFER REPLACEMENT PESTICIDES (AGENDA ITEM 7 b)[11]

189. The Committee recalled that following the proposal of the 35th Session of the CCPR, the 26th Session of the Commission had approved the work on the Pilot Project for the examination of national MRLs as Interim Codex MRLs and that the 36th Session of the Committee had **agreed** that the Pilot Project Working Group would prepare draft proposals on refinements of the procedure, based on comments received for consideration by the next session of the Committee.

190. The Delegation of the United States introduced the document CX/PR 05/37/6-Add.1 containing the collation of comments and analysis received in response to the Codex CL 2004/ 48-PR and indicated that

[11] CL 2004/48-PR; CX/PR 05/37/6-Add.1 (Comparison of government comments in response to the CL 2004/48-PR); CX/PR 05/37/13-Add.1 (Working Group proposals to the 2005 CCPR on Interim MRL Process, prepared by the United States); CRD 1-Rev.1 (Report of the *ad hoc* Working Group on Establishment of Codex Priority Lists of pesticides); CRD 8 (comments of Argentina); CRD 11 (comments of the European Community); CRD 12 (comments of the JMPR Secretariat); CRD 19 (comments of Republic of Korea); CRD 24 (comments of India).

comments from member states on the specific proposed Interim MRLs focussed on: acknowledgement that exact proposals for interim MRLs would vary depending on the data considered and different technical interpretations. The highest proposed MRL value, supported by data that is demonstrated to be safe according to JMPR dietary intake calculations, would be selected as the MRL.

191. It was indicated that Attachment II contained the JMPR comparison on Interim MRL Values and JMPR 2004 recommendations and comments on difference. The Delegation drew the attention of the Committee to the fact that there were no intake concerns for compounds considered under the Pilot Project. The Delegation informed the Committee that comments received on the Pilot Process and generic responses to the comments were presented in CX/PR 05/37/13-Add.1. The Delegation also informed the Committee that Attachment III of CX/PR 05/37/13-Add.1 outlined various action steps on the Proposed Revised Interim MRL Process to be taken during the process of elaboration of the Codex Interim MRLs. The Delegation indicated that the Working Group on Priorities proposed to the Plenary some recommendations and among them to advance Interim MRLs for consideration at Step 8 (I).

192. The Committee had a lengthy debate on the procedure for establishment of Interim MRLs. While some delegations supported the process of elaboration of Interim MRLs, some other delegations questioned the necessity of the establishment of Interim MRLs, the meaning of "safer" and "reduced risk" chemicals and the status of Interim MRls in Codex. It was indicated that these definitions were quite broad and could be based on subjective estimation.

193. The Delegation of the United States clarified that the guidance on the criteria for "safer" and "reduced risk" pesticides was provided in their legislation and that consideration was given prior to the evaluation of substances as to whether they may reasonably reduce risk for human health, for non target organisms and for ground waters.

194. The Delegation of the EC recalled that the Pilot Project Working Group did not have a mandate to present recommendations on specific substances for adoption at Step 8 (I), which was not yet recognized in the Codex Procedure and that this should not be confused with Step 8 of the official Procedure. The Delegation suggested to seek guidance from the CCGP and the Commission in order to decide how to proceed, and in particular, whether to undertake new work under the Pilot Project for additional substances. The Delegation of the EC stressed that the main principle of risk analysis, the separation of risk assessment and risk management was not clear enough in the Proposed Project.

195. In reply to questions, the Secretariat clarified that following the request of the Commission the next Session of the CCGP will consider the proposal to clarify the term "Interim". The Secretariat also recalled that the Commission had approved new work on a pilot project concerning the development of MRLs but that no proposal had been made to amend the Codex Step Procedure. The Secretariat also noted that while proposed Interim MRLs did not formally fit for circulation at Step 3 of the Procedure, the proposed MRLs were circulated for government comments in CL 2004/48-PR. The Secretariat indicated that proposed Interim MRLs, if recommended by the Committee, should also be send for comments before adoption by the Commission.

196. The FAO Joint Secretary to the JMPR while referring to its written comments in CRD 12, drew the attention of the Committee to the fact that extensive use of the Interim MRLs might severely curtail the JMPR, as interim MRLs should be reviewed within 4 years and pointed out that the interim process would introduce inconsistencies in the process currently used by the Codex especially as regards independent data review. To mitigate the problems with interim MRLs, the Secretary suggested that it was better to use the proposed draft JMPR MRLs as the Interim MRLs and to be more flexible with the 50/50 ratio, of new compounds and periodic review compounds changing the priority to 70 and 30, if new less hazardous compounds were available for evaluation. Several delegations supported the proposal to use the proposed draft JMPR MRLs as Interim MRLs. It was indicated that in this case there will be no conflict with the separation of risk assessment and risk management and that there will be a possibility to comment and adjust MRLs which will also be adopted at Step 5.

197. The Committee **agreed** to attach Attachment III of document CX/PR 05/37/13-Add. 1 on the Proposed Revised Interim MRL Process to the report for comments in order to ensure transparency of the process (see Appendix XVI).

198. The Committee **agreed** not to propose new compounds for the Pilot Project and **decided** that the Pilot Project Working Group would prepare a paper containing the evaluation of the Pilot Project for consideration by the next Session of the Committee.

199. The Committee concluded that, in order to speed up the process of establishment of MRLs for safer replacement pesticides, there was a need to use the proposed draft JMPR MRLs for which there will be no intake concerns as Codex Interim/Temporary MRLs.

200. The Committee **agreed** to ask the Commission to approve new work on the amendment of the MRL elaboration procedure and that the JMPR and the Codex Secretariat with assistance of the Chairperson would prepare a document for consideration at the next Session with the understanding that these proposed draft MRLs will also follow the currently established Codex Step Procedure and will be adopted at Step 5.

201. The Committee noted that more flexibility was necessary in scheduling new safer pesticides for evaluation by the JMPR and **decided** that the ratio 50/50 for new/old compounds could be increased in favour of accommodating new safer compounds, if available.

202. The Committee **decided** to advance the proposed Interim MRLs for trifloxystrobin, fludioxonil and bifenazate, (noting some concerns of the Delegation of the EC on the sufficiency of database for proposed MRLs for bifenazate) for adoption at Step 8 with an indication that they were Interim (I) MRLs which should last not more than 4 years (see Appendix V).

203. The Delegation of the EC expressed its reservation on this decision.

Other matters

204. The Delegation of the United States noted that, while the Committee was considering proposals to accelerate the risk assessment process in JMPR, delays in the finalization of MRLs also occurred in the CCPR, in particular when objections based on national risk assessments were made to the adoption of MRLs that had been evaluated by JMPR. The Delegation therefore proposed to develop criteria for the advancement or not of JMPR MRL recommendations in the Codex Procedure. This proposal was supported by several delegations.

205. The Committee **agreed** that the Delegation of the United States, with the assistance of an electronic Working Group (Australia, Canada, European Community, Japan, New Zealand and Crop Life International), would develop a discussion paper on criteria to clarify when the Committee may advance or hold recommended draft MRLs and to develop other proposals in order to improve the decision-making process in the CCPR.

ESTABLISHMENT OF MRLS FOR PROCESSED AND READY-TO-EAT FOODS (Agenda Item 8)

206. The Committee recalled that its last session had **agreed** that the Delegation of the EC with the assistance of the Delegation of the United States would prepare a discussion paper on the use of processing studies and the establishment of MRLs for processed foods.

207. The Delegation of the EC informed the Committee that it had not been able to prepare a paper for the present session, but that it would prepare a discussion paper on the establishment of MRLs for processed and ready-to-eat foods for the next session, in cooperation with the Delegation of the United States.

208. The Committee **agreed** to confirm its present policy concerning the establishment of MRLs for processed commodities on the basis of the recommendations of the JMPR 2003 (See also Agenda item 3). This policy states that there is no need to establish a MRL for a processed food unless the process gives rise to a higher residue than that established for the raw agriculture commodity.

RISK ANALYSIS POLICIES USED BY THE COMMITTEE IN ESTABLISHING MRLs FOR PESTICIDES (AGENDA ITEM 9)[12]

209. The Committee recalled that its last session had considered a discussion paper on risk analysis policies and had **agreed** to initiate the development of Proposed Draft Risk Analysis Principles, to be drafted by the Chairperson with the assistance of the Delegation of Japan. This new work had subsequently been approved by the 27th Session of the Commission.

[12] CX PR 05/37/8; CRD 7 (comments of Thailand), CRD 10 (comments of the European Community),

210. The Committee considered the document section by section and made the following amendments and comments.

211. The Committee **agreed** to delete the Background section as it was provided only for information purposes.

Role of CCPR

212. In paragraph 13, the Committee noted that currently five regional diets were used to identify consumption patterns for exposure assessment and that the revision of regional diets would result in the establishment of 13 GEMS/Food Consumption Cluster Diets.

213. The Committee therefore **agreed** to refer to the "GEMS Food regional diets" in order to avoid confusion. A similar change was made in paragraph 24.

214. In paragraph15, the Committee **agreed** to add a reference to the Criteria for the Establishment of Work Priorities to the list of documents to be considered when preparing the priority list of compounds for JMPR evaluation.

Role of JMPR

215. The Committee **agreed** with the proposal of the JMPR Secretariat to add a new paragraph clarifying that one of the responsibilities of JMPR is to propose MRLs on the basis of GAPs.

Annex

216. The Committee **agreed** that the title of the Annex should refer to the "policies used by CCPR" in order to cover all the policies applied by the Committee.

217. The Committee **agreed** to add new text to paragraph (i) to clarify the policy and requirements for the establishment of MRLs for feeds and animal commodities.

218. Some delegations expressed their concern with the provisions of paragraph (o) as it specified how MRLs should be **advanced** when objections were made "by a government" and could introduce the notion of majority vote, whereas decisions should be generally taken by consensus within Codex. In addition, the Delegation of France noted that the last session of the Committee on General Principles had proposed to the Commission the abolition of the Acceptance Procedure and that the reference to acceptance in the present document would create confusion. After some discussion, the Committee **agreed** to delete the first two sentences of the paragraph. A consequential amendment was made to paragraph (q).

219. The Committee **agreed** to insert a paragraph on that the reconsideration by JMPR of MRLs which had been **returned** three times to Step 6.

Establishment of EMRLs

220. The Committee **agreed** to delete the provisions on the acceptable violation rate of 0.5% when considering the EMRL proposals of JMPR.

Status of the Proposed Draft Risk Analysis Principles Applied by the Committee on Pesticide Residues

221. The Committee **agreed** to forward the Proposed Draft Risk Analysis Principles to the 27th Session of the Codex Alimentarius Commission for adoption at Step 5 (see Appendix XIII).

222. The Committee noted that the document would be forwarded to the Committee on General Principles in order to ensure coordination and consistency with the *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius.*

MATTERS RELATED TO METHODS OF ANALYSIS FOR PESTICIDE RESIDUES (AGENDA ITEM 10)[13]

223. The Chair of the ad hoc Working Group on Methods of Analysis, Dr Piet van Zonen (Netherlands) introduced the report of the Working Group (CRD 3) and highlighted its main discussions and

[13] CX PR 05/37/9 (comments of Australia and the United States); CX PR 05/37/10 (comments of Australia and the United States); CX PR 05/37/11; CRD 3 (Report of the *ad hoc* Working Group on Methods of Analysis); CRD 18 (comments of Portugal); CRD 28 (comments of Thailand)

recommendations. The Committee considered the matters related to methods of analysis on the basis of the report of the Working Group and made the following decisions and comments.

Proposed Draft Guidelines on the Use of Mass Spectrometry (MS) for Identification, Confirmation and Qualitative Determination of Residues (Agenda Item 10a))

224. The Committee recalled that its last session had **agreed** to circulate the Proposed Draft Guidelines at Step 3 as an amendment to the *Guidelines on Good Practice in Pesticide Residue Analysis*.

225. The Committee noted that, although a proposal had been made to refer to document 96/23/EC in the draft guideline, the EC document applied to veterinary drugs and was not necessarily applicable or relevant to pesticide residue analysis.

226. The Committee noted that it had been proposed to include a paragraph discussing the comparative value of various mass spectrometric techniques. However, the Working Group had noted that emphasis on methods using high resolution or time of flight mass spectrometers might create difficulties for developing countries with limited or no access to such techniques; and that some of these methods were still mainly used in research and development laboratories. It was also noted however that the document on the use of mass spectrometry was not prescriptive and made sufficient provision for confirmation of residues by alternative techniques.

227. The Committee **agreed** that most of the changes made in the text were of an editorial nature and that there had been consensus in the Working Group for the finalization of the document.

Status of Proposed Draft Guidelines on the Use of Mass Spectrometry (MS) for Identification, Confirmation and Qualitative Determination of Residues

228. The Committee **agreed** to advance the Proposed Draft Guidelines to Step 5 with the recommendation that the Commission omit Steps 6 and 7 and adopt them at Step 8 for inclusion in the *Guidelines on Good Practice in Pesticide Residue Analysis* (see Appendix X).

Proposed Draft Guidelines on the Estimation of Measurement Uncertainty (Agenda Item 10b)

The Use and Implications of Measurement Uncertainty (Agenda Item 10c)

229. The Committee recalled that its last session had **agreed** to circulate the Proposed Draft Guidelines at Step 3 and to consider a discussion paper prepared by the Delegation of the Netherlands on the use and implications of measurement uncertainty.

230. The Committee noted that several amendments for clarification or editorial purposes had been made and that some of the comments proposed by Portugal had been incorporated. The main changes proposed by the Working Group concerned sections 6, 7 and 8.

231. In section 3. Procedures for Estimating Measurement Uncertainty it was **agreed** to refer to the "most commonly used procedures" rather the "preferred procedures" as other procedures might be used.

232. The Committee recalled that guidance on the use and implications of measurement uncertainty was necessary as there is general consensus about the estimation of uncertainty but there are widely different views and practices among members concerning the use of measurement uncertainty. It was **agreed** to include the recommendations on the use of uncertainty as Section 5 of the Proposed Draft Guidelines. Sections 5.1.1 and 5.1.2 were reformatted and simplified to provide guidance in both import and export situations.

233. The Committee noted that the Guidelines on Measurement Uncertainty developed by the Committee on Methods of Analysis and Sampling and adopted by the 27th Session of the Commission were of general application, and that the use of the analytical results in relation to measurement uncertainty and other factors was currently under discussion in the CCMAS.

234. The Committee noted that substantial changes had been made to the text and that it was preferable to consider it further at the next session before submitting the Proposed Draft Guidelines to the Commission for final adoption.

Status of the Proposed Draft Guidelines on the Estimation of Measurement Uncertainty

235. The Committee **agreed** to advance the Proposed Draft Guidelines for adoption by the Commission at Step 5 (see Appendix XII).

Proposed Draft Revision of the List of Methods for Pesticide Residue Analysis at Step 4 (Agenda Item 10 d)

236. The Committee recalled that its last session had **agreed** that a list of analytical of methods would be prepared and circulated for comments. However this had not been possible and document CX/PR 05/37/12 had not been prepared for the present session.

237. The Committee welcomed the offer of the Delegation of the Netherlands to review the list of methods and to identify the pesticides for which MRLs have been set but for which no suitable methods are available; to prepare an inventory of submitted methods; and to distribute the list in a Circular Letter requesting details of additional methods. It was also **agreed** that the methods would be submitted to IAEA with a view to their publication on the IAEA Training and Research Centre (TRC) website.

Other Matters Related to Methods of Analysis

238. The Delegation of Morocco referred to the discussion of the last session concerning false positives associated with Brassicae, and in particular capers, in the determination of dithiocarbamates and indicated that it used a HPLC method to determine several individual dithiocarbamates, in order to avoid the problem of false positives. The Delegation of Korea informed the Committee that it followed a similar approach at the national level and used HPLC methods. The Committee invited these delegations to provide the complete data on the methods used in reply to the Circular Letter, for consideration at the next session.

239. The Committee recalled the request arising from the 2004 JMPR Report concerning specific methods for fat-soluble pesticides in whole milk and milk fat. The Committee noted that there was not enough information or expertise available at this stage to address this request and that it could come back to this question when further information became available.

ESTABLISHMENT OF CODEX PRIORITY LISTS OF PESTICIDES (Agenda Item 11)[14]

240. The report of the ad hoc Working Group on Priorities was presented by its Chair, Mr Ian Reichstein (Australia) who highlighted the main issues discussed and the amendments proposed to the tentative lists of scheduled compounds.

241. The Committee **agreed** with the proposals of the Working Group and amended the schedule as described below and listed in Appendix XIV. This tentative schedule considered the recommendation of the 2004 JMPR to realign schedules of toxicological and residue evaluation at least within one year. Full alignment has been achieved for new compounds, and for compounds scheduled for periodic review alignment within one year was achieved for all but one compound.

242. The Committee also **agreed** that further efforts be made at the 2006 Priorities Working Group meeting to achieve full re-alignment, where appropriate.

243. **2006:** For new compounds dimethomorph (previously 2006) was ex**changed** with boscalid (previously 2007) and thiacloprid was added. Pyraclostrobin and thiabendazole were added to the tentative schedule for additional residue evaluation. Thiabendazole is already scheduled for acute toxicological evaluation. Fenamiphos, disulfoton and aldicarb were added for review of GAPs for MRL proposal.

244. The Committee **agreed** to advance aminopyralid from the 2007 to the 2006 schedule for evaluation of new compounds. In consequence, procymidone and profenofos are rescheduled for toxicological evaluation and propiconazol for residue evaluation within the periodic review program in 2007 instead of 2006.

245. **2007:** For new compounds dimethomorph and difenoconazole were scheduled in addition pyrimethanil and zoxamide. In regard to periodic re-evaluations, the Committee **agreed** to re-schedule flusilazole from 2008 to 2007 and to conduct both toxicological and residue evaluations on that compound. Benalaxyl, cyfluthrin/beta cyfluthrin, cyromazine and profenofos were **advanced** from the 2008 tentative schedule. The periodic reevaluation of triforine was deferred from 2007 to 2012 on the request of the company.

246. Fentin was deleted from the tentative schedule (toxicological evaluation 2007 and residue evaluation 2009) because it is no longer supported. Tebuconazole was added to the schedule for evaluation seeking

[14] CL 2004/16-PR; ALINORM 04/27/24, Appendix XI; CX/PR 05/37/13 ; CRD 1-Rev.1 (Report of the *ad hoc* Working Group).

additional MRLs. Fenitrothin was scheduled for toxicological evaluation. Carbaryl was added to the schedule for review of the basis of setting of ARfD and alternative GAPs.

247. **2008:** Azinphos-methyl and vinclozolin were **advanced** for periodic re-evaluation from the 2009 tentative schedule for residue evaluation.

248. **2009:** Bioresmethrin, buprofezin, chlorpyrifos-methyl and hexythiazox were **advanced** for periodic re-evaluation from the 2010 tentative schedule for residue evaluation.

249. **2010**: Amitraz, bifenthrin, cadusafos, and chlorothalanil were **advanced** for periodic re-evaluation from the 2011 tentative schedule, and cycloxydim from the 2012 tentative schedule for residue evaluation.

250. **2011**: Aldicarb, dithianon and fenbutatin oxide were **advanced** for periodic re-evaluation from the 2012 tentative schedule, and dicofol from the 2013 tentative schedule for residue evalaution.

251. **2012**: Dichlorvos, diquat, etofenprox and fenpropathrin were **advanced** for periodic re-evaluation of residues from the 2013 tentative schedule, triforine was re-scheduled from the 2007 tentative schedule.

PROPOSED DRAFT CRITERIA FOR PRIORITIZATION PROCESS OF PESTICIDES (Agenda Item 11a[15])

252. The Committee recalled that its last session had considered a set of criteria for the prioritization of compounds for JMPR review and had **agreed** to circulate them as contained in Appendix X of ALINORM 04/27/24 for comments and consideration at its next session.

253. The Committee noted that the Working Group on Priorities had proposed amendments to the criteria based on written comments and comments introduced at the Working Group meeting which are included in document CRD 20. The amendments made were: separation of criteria from procedural matters; inclusion of the availability of current labels as a criterion for prioritising periodic re-evaluations; some editorial changes to improve the wording and provide more details to both criteria and explanatory notes in order to avoid confusion in the data submission process.

254. The Delegation of the EC indicated that their comments were taken into account during the revision of the document and this document would provide clear guidance in scheduling compounds for evaluation.

255. The Committee **agreed** with the opinion of the Joint JMPR Secretary that the criterion in relation to the intake and/or toxicity and public health was more important than the criterion regarding the length of time since the last periodic review for toxicology, and moved this criterion as number one of Section 2.2 Periodic re-evaluation. In this criterion a “high” level of public health concern was substituted by “some” level.

256. The Committee **agreed** to send the draft revised Criteria for Prioritization Process to the Committee on General Principles for their review with the understanding that the revised version would be forwarded to the Commission for adoption and be included in the Codex Alimentarius Procedural Manual (see Appendix XV).

Other matters

Work-sharing

257. The Committee noted that dossiers from the US, EC, Canada and manufacturers would be available for quinoxyfen and therefore **agreed** to propose this compound for the work-sharing Pilot Project in 2006.

258. The Joint JMPR Secretary of WHO indicated that the progress report on the JMPR work-sharing pilot project on trifloxystrobin including work-sharing experience on toxicological and residue evaluations was presented in the 2004 JMPR report and that the outcome of the pilot project on quinoxyfen would be available for the Committee’s consideration in 2007. However the Joint Secretary pointed out that the first experience showed that difficulties existed in achieving some time saving due to different formats of dossiers and that the 2004 JMPR report clearly indicated what kind of limitations existed.

[15] CL 2004/16-PR; ALINORM 05/27/13 Appendix X; CX/PR 05/37/13-Add.1; CRD 1-Rev.1 (Report of the *ad hoc* Working Group on Priorities); CRD 6 (comments of the United States); CRD 20 (Draft Revised Criteria for Prioritization Process, prepared by Australia, USA and Canada).

Deletion of unsupported compounds

259. The Committee noted that there was a need to consider the removal of unsupported compounds from the periodic re-evaluation schedule to make way for new compounds, and **agreed** to issue a Circular Letter seeking information on the revocation of compound registrations and the likelihood of future support for the compound.

260. The Committee **agreed** that the Working Group on Priorities should be reconvened prior to the next Session of the Committee.

PROPOSED DRAFT REVISION OF THE CODEX CLASSIFICATION OF FOODS AND ANIMAL FEEDS (Agenda Item 13)[16]

261. The Committee recalled that the 27th Session of the Commission had approved the limited revision of the Codex Classification of Foods and Animal Feed as new work and that a revised version of the Classification prepared by the Delegation of the Netherlands with assistance of the Delegation of Japan had been circulated at Step 3.

262. The Delegation of the Netherlands introduced the document and indicated that new commodity codes for commodities with MRL proposals were suggested and that new proposals for modifications not yet included in the Classification were presented in Appendix II of CX/PR 05/37/15. The Delegation indicated that the CCFAC, which is also using the Classification for MLs for contaminants, noted the need for some general product codes e.g., food in general, all fruits, all fishes, infant foods and specific products. They also needed codes for categories of processed products which had contaminant MLs such as vegetable juices, chutneys, canned meat products and that these proposals were presented in Appendix III. The Delegation proposed to advance for final adoption new codes for commodities for which MRLs were established and to give one more year for governments to propose new commodities to be included in the revised Classification.

263. The Delegation of the Netherlands indicated that the Commission had approved only a limited revision of the Classification and the Committee should carefully consider all proposals regarding expanding the Classification.

264. The Delegation of Japan drew the attention of the Committee to the fact that the purpose of this Classification is to ensure consistent expression of MRLs. The Delegation further noted that new commodities should be added to the Classification only if MRLs are likely to be established for them and they meet proposed criteria for selecting food commodities for which Codex MRLs or EMRLs should be established.

265. The Delegation of Japan indicated that it would be necessary to allocate codes and numbers not only for spice groups but also for subgroups, following the establishment of MRLs for spices.

266. The Committee noted that an international expert group under the auspice of the United States was working on crop grouping and that this work might be of interest to the Committee. The Committee also noted the ongoing work in some countries regarding the selection of representative crops for each crop group and on the extrapolation of MRLs and was of the view that more international efforts were necessary in this area.

267. The Committee **agreed** to inform the CCFAC of the work on the limited revision of the Classification.

Status of the proposed draft revision of the Codex Classification of Foods and Animal Feeds

268. The Committee **agreed** to advance the new commodity codes and numbers for which MRLs existed to Step 5/8 with the recommendation to omit Steps 6 and 7 for adoption by the next Session of the Commission (see Appendix XI).

269. The Committee **agreed** that the Delegation of the Netherlands would revise the Classification on the basis of comments submitted and discussions at the current session for circulation at Step 3 prior to the next session of the Committee.

[16] CX/PR 05/37/15; CRD 9 (comments of Canada); CRD 14 (comments of Thailand); CRD 26 (comments of Brazil); CRD 29 (comments of Costa Rica); CRD 31 (comments of Republic of Korea).

OTHER BUSINESS AND FUTURE WORK (AGENDA ITEM 13)

270. The Committee noted the information provided in CRD 30 on the activities of the Joint FAO/IAEA Division of Nuclear Techniques in Food and Agriculture of interest to the Committee, and in particular that the Joint Division had been cooperating with Codex for a long time in the areas related to food irradiation, methods of analysis for, residues of pesticides and veterinary drugs. It was noted that the Joint Division intended to strengthen its technical input as regards methodologies for veterinary drugs, pesticide residues and contaminants; training of trainers in the application of methods of analysis for compliance purposes; web-based programmes on sampling and analysis of food for contaminants and in additional research and training. The list of Codex methods for pesticide residues was being incorporated into the IAEA Food Contaminants and Residue Information System (INFOCRIS) and the database was being updated to include additional data on methods of analysis for veterinary drugs residues.

271. The Observer from IUPAC expressed appreciation for the updating of the Codex database of pesticide residue MRLs on the Codex website. The Committee noted that the database will be updated following the adoption of revised MRLs after each session of the Commission and placed on the website as soon as technically feasible.

DATE AND PLACE OF NEXT SESSION (AGENDA ITEM 14)

272. The Committee was informed that its 38th Session was scheduled to be held in Brazil, from 3 to 8 April 2006, the final arrangements subject to confirmation by the Host Country and Codex Secretariat.

Annex 1

SUMMARY STATUS OF WORK

Subject	Step	Action by	Reference
Draft and Revised Draft MRL s	8	Governments, 28th CAC	Paras 77- 213 and Appendix II
Proposed Draft and Revised Draft MRLs	5/8	Governments, 28th CAC	Paras 77 – 213 and Appendix III
Proposed Draft MRLs for Spices	5/8	Governments, 28th CAC	Paras 177 – 182 and Appendix IV
Proposed Draft Interim MRLs	8 (I)	Governments, 28th CAC	Paras 189 – 203 and Appendix V
Proposed Draft MRLs	5	Governments, 28th CAC	Paras 60-175 and Appendix VI
Proposed Draft MRLs for Dried Chili Peppers including the MRL for Spices	5	Governments, 28th CAC	Paras 179; 183 – 188 and Appendix VII
Codex Maximum Residue Limits Recommended for Revocation		Governments, 28th CAC	Paras 77-213 and Appendix VIII
Draft and Proposed Draft MRLs	6 / 3	Governments, 38 CCPR	Paras 77-213 and Appendix IX
Proposed Draft Guidelines on the Use of Mass Spectrometry (MS) for Identification, Confirmation and Quantitative Determination of Residues	5/8	Governments, 28th CAC	Para. 228 and Appendix X
Proposed New Codes and Numbers for Commodities with Adopted MRLs	5/8	Governments, 28th Session of the CAC	Para. 268 and Appendix XI
Proposed Draft Guidelines on the Estimation of Uncertainty of Results	5	Governments; 28th CAC; 38th CCPR	Para. 192 and Appendix XII
Proposed Draft Risk Analysis Principles Applied by the Committee on Pesticide Residues	5	Governments; 28th CAC; 38th CCPR	Para. 209 and Appendix XIII
Draft Revised Criteria for Prioritization Process of Compounds for Evaluation by JMPR		Governments, 28th CAC, 38th CCPR	Paras 252 – 256 and Appendix XV
Proposed Draft Revision of the Codex Classification of Foods and Animal Feeds	2/3	Netherlands, Governments, 38th CCPR	Para. 257 and Appendix IX
Proposed Draft Revision of the List of Methods for Pesticide Residue Analysis	2/3	Netherlands, Governments, 38th CCPR	Paras 236 - 237
Discussion papers			
Criteria to Clarify When the Committee may Advance or Hold Recommended MRLs and Proposals to Improve the Decision Making Process in the CCPR		USA[17], 38th CCPR	Para. 205
Establishment of MRLs for Processed or Ready-to-Eat Foods		EC, USA, 38th CCPR	Paras 206 - 208
New work:			
Priority List of Pesticides (New Pesticides and Pesticides under Periodic Review)	1	28th Session of the CAC, Governments, Australia, 38th CCPR	Paras 240 - 251 and Appendix XIV
Other: Proposed Draft Revised Interim MRL Process			Para. 197 and Appendix XVI

[17] With assistance of Australia, Canada, European Community, Japan, New Zealand, and Crop Life International.

APPENDIX I

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APPENDIX II

DRAFT MAXIMUM RESIDUE LIMITS FOR PESTICIDES

Advanced for adoption at Step 8

			MRL (mg/kg)		Step	Note
7	**Captan**					
VC	424	Cucumber	3		8	
FS	245	Nectarine	3		8	
FB	272	Raspberries, Red, Black	20		8	
22	**Diazinon**					
VB	41	Cabbages, Head	0.5		8	
27	**Dimethoate**					
VS	620	Artichoke, Globe	0.05		8	
VB	402	Brussels sprouts	0.2		8	
VB	404	Cauliflower	0.2		8	
VS	624	Celery	0.5		8	
FI	345	Mango	1	Po	8	
FT	305	Olives	0.5		8	
VP	63	Peas (pods and succulent=immature seeds)	1		8	
AV	596	Sugar beet leaves or tops	0.1		8	
VL	506	Turnip greens	1		8	
VR	506	Turnip, Garden	0.1		8	
GC	654	Wheat	0.05		8	
AS	654	Wheat straw and fodder, Dry	1		8	
65	**Thiabendazole**					
VO	450	Mushrooms	60		8	
84	**Dodine**					
FS	13	Cherries	3		8	
FS	245	Nectarine	5		8	
FS	247	Peach	5		8	
FP	9	Pome fruits	5		8	
86	**Pirimiphos-Methyl**					
GC	80	Cereal grains	7	Po	8	
ML	106	Milks	0.01		8	
CM	654	Wheat bran, Unprocessed	15	PoP	8	
94	**Methomyl**					
AL	1020	Alfalfa fodder	20		8	
AL	1021	Alfalfa forage (green)	25		8	
GC	640	Barley	2		8	
AL	61	Bean fodder	10		8	
VP	61	Beans, except broad bean and soya bean	1		8	
AB	1	Citrus pulp, Dry	3		8	
AL	528	Pea vines (green)	40		8	

AL	1265	Soya bean forage (green)	40		8
GC	654	Wheat	2		8
CM	654	Wheat bran, Unprocessed	3		8
CF	1211	Wheat flour	0.03		8
CF	1210	Wheat germ	2		8

95 Acephate

VS	620	Artichoke, Globe	0.3		8
MO	105	Edible offal (mammalian)	0.05		8
PE	112	Eggs	0.01	(*)	8
MM	95	Meat (from mammals other than marine mammals)	0.05		8
ML	106	Milks	0.02		8
PM	110	Poultry meat	0.01	(*)	8
PO	111	Poultry, Edible offal of	0.01	(*)	8
VD	541	Soya bean (dry)	0.3		8

96 Carbofuran

GC	645	Maize	0.05	(*)	8
AF	645	Maize forage	0.2		8
VR	596	Sugar beet	0.2		8
AV	596	Sugar beet leaves or tops	0.3		8

100 Methamidophos

VS	620	Artichoke, Globe	0.2(Ac)		8
SO	691	Cotton seed	0.2		8
MO	105	Edible offal (mammalian)	0.01	(*)	8
PE	112	Eggs	0.01	(*)	8
AM	1051	Fodder beet	0.02		8
AV	1051	Fodder beet leaves or tops	30		8
MM	95	Meat (from mammals other than marine mammals)	0.01	(*)	8
ML	106	Milks	0.02		8
VR	589	Potato	0.05		8
PM	110	Poultry meat	0.01	(*)	8
PO	111	Poultry, Edible offal of	0.01	(*)	8
VD	541	Soya bean (dry)	0.1(Ac)		8
VR	596	Sugar beet	0.02		8
AV	596	Sugar beet leaves or tops	30		8

135 Deltamethrin

VL	53	Leafy vegetables	2		8

145 Carbosulfan

AB	1	Citrus pulp, Dry	0.1		8
SO	691	Cotton seed	0.05		8
MO	105	Edible offal (mammalian)	0.05	(*)	8
PE	112	Eggs	0.05	(*)	8
GC	645	Maize	0.05	(*)	8
AF	645	Maize forage	0.05	(*)	8

FC	206	Mandarin	0.1			8
MM	95	Meat (from mammals other than marine mammals)	0.05	(*)		8
ML	106	Milks	0.03	(*)		8
FC	4	Oranges, Sweet, Sour	0.1			8
VR	589	Potato	0.05			8
PM	110	Poultry meat	0.05	(*)		8
PO	111	Poultry, Edible offal of	0.05	(*)		8
AS	649	Rice straw and fodder, Dry	0.05	(*)		8
VR	596	Sugar beet	0.3			8
AV	596	Sugar beet leaves or tops	0.05			8

162 Tolylfluanid

VL	482	Lettuce, Head	15			8

193 Fenpyroximate

FC	4	Oranges, Sweet, Sour	0.2			8

203 Spinosad

ML	812	Cattle milk	1			8

207 Cyprodinil

AM	660	Almond hulls	0.05*	(*)		8
TN	660	Almonds	0.02*	(*)		8
FP	226	Apple	0.05	(*)		8
GC	640	Barley	3			8
VP	61	Beans, except broad bean and soya bean	0.5			8
VC	424	Cucumber	0.2			8
DF	269	Dried grapes (=currants, raisins and sultanas)	5			8
MO	105	Edible offal (mammalian)	0.01	(*)		8
VO	440	Egg plant	0.2			8
PE	112	Eggs	0.01	(*)		8
FB	269	Grapes	3			8
VL	482	Lettuce, Head	10			8
VL	483	Lettuce, Leaf	10			8
MM	95	Meat (from mammals other than marine mammals)	0.01	(*)	(fat)	8
ML	106	Milks	0.0004	(*)		8
VA	385	Onion, Bulb	0.3			8
FP	230	Pear	1			8
VO	445	Peppers, Sweet	0.5			8
PM	110	Poultry meat	0.01	(*)	(fat)	8
PO	111	Poultry, Edible offal of	0.01	(*)		8
DF	14	Prunes	5			8
FB	272	Raspberries, Red, Black	0.5			8
VC	431	Squash, Summer	0.2			8
FS	12	Stone fruits	2			8
AS	81	Straw and fodder (dry) of cereal grains	10			8

FB	275	Strawberry	2		8
VO	448	Tomato	0.5		8
GC	654	Wheat	0.5		8
CM	654	Wheat bran, Unprocessed	2		8

208 Famoxadone

GC	640	Barley	0.2		8
AS	640	Barley straw and fodder, Dry	5		8
VC	424	Cucumber	0.2		8
DF	269	Dried grapes (=currants, raisins and sultanas)	5		8
MO	105	Edible offal (mammalian)	0.5		8
PE	112	Eggs	0.01	(*)	8
AB	269	Grape pomace, Dry	7		8
FB	269	Grapes	2		8
MM	95	Meat (from mammals other than marine mammals)	0.5	fat	8
ML	106	Milks	0.03(F)		8
VR	589	Potato	0.02	(*)	8
PM	110	Poultry meat	0.01	(*)	8
PO	111	Poultry, Edible offal of	0.01	(*)	8
VC	431	Squash, Summer	0.2		8
VO	448	Tomato	2		8
GC	654	Wheat	0.1		8
CM	654	Wheat bran, Unprocessed	0.2		8
AS	654	Wheat straw and fodder, Dry	7		8

209 Methoxyfenozide

AM	660	Almond hulls	50		8
AB	226	Apple pomace, Dry	7		8
VB	400	Broccoli	3		8
VB	41	Cabbages, Head	7		8
VS	624	Celery	15		8
SO	691	Cotton seed	7		8
DF	269	Dried grapes (=currants, raisins and sultanas)	3		8
MO	105	Edible offal (mammalian)	0.02		8
PE	112	Eggs	0.01		8
FB	269	Grapes	1		8
VL	482	Lettuce, Head	15		8
VL	483	Lettuce, Leaf	30		8
GC	645	Maize	0.02	(*)	8
AS	645	Maize fodder	60		8
AF	645	Maize forage	50		8
MM	95	Meat (from mammals other than marine mammals)	0.05	(fat)	8
ML	106	Milks	0.01		8

VL	485	Mustard greens	30		8
VO	51	Peppers	2		8
FP	9	Pome fruits	2		8
FP	9	Pome fruits	2		8
PM	110	Poultry meat	0.01	(*)	8
PO	111	Poultry, Edible offal of	0.01	(*)	8
DF	14	Prunes	2		8
FS	12	Stone fruits	2		8
VO	447	Sweet corn (corn-on-the-cob)	0.02	(*)	8
VO	448	Tomato	2		8
TN	85	Tree nuts	0.1		8

APPENDIX III

PROPOSED DRAFT MAXIMUM RESIDUE LIMITS FOR PESTICIDES

Advanced for adoption at Step 5 and 8 with omission of Steps 6 and 7

			MRL (mg/kg)		Step	Note
17	**Chlorpyrifos**					
SO	691	Cotton seed	0.3		5/8	
OR	691	Cotton seed oil, refined	0.05		5/8	
VR	589	Potato	2		5/8	
GC	649	Rice	0.5		5/8	
VD	541	Soya bean (dry)	0.1		5/8	
OR	541	Soya bean oil, Refined	0.03		5/8	
DT	1114	Tea, Green, Black	2		5/8	
86	**Pirimiphos-Methyl**					
MO	105	Edible offal (mammalian)	0.01	(*)	5/8	
PE	112	Eggs	0.01		5/8	
MM	95	Meat (from mammals other than marine mammals)	0.01	(*)	5/8	
PM	110	Poultry meat	0.01	(*)	5/8	
PO	111	Poultry, Edible offal of	0.01	(*)	5/8	
94	**Methomyl**					
AM	738	Mint hay	0.5		5/8	
VO	51	Peppers	0.7		5/8	
105	**Dithiocarbamates**					
VC	424	Cucumber	2		5/8	
MO	105	Edible offal (mammalian)	0.1		5/8	
PE	112	Eggs	0.05	(*)	5/8	
FB	269	Grapes	5		5/8	
MM	95	Meat (from mammals other than marine mammals)	0.05	(*)	5/8	
VC	46	Melons, except watermelon	0.5		5/8	
ML	106	Milks	0.05	(*)	5/8	
VA	385	Onion, Bulb	0.5		5/8	
TN	672	Pecan	0.1	(*)	5/8	
FP	9	Pome fruits	5		5/8	
VR	589	Potato	0.2		5/8	
PM	110	Poultry meat	0.1		5/8	
PO	111	Poultry, Edible offal of	0.1		5/8	
FS	12	Stone fruits	7		5/8	
142	**Prochloraz**					
FI	30	Assorted tropical and sub-tropical fruits - inedible peel	7	Po	5/8	
GC	80	Cereal grains	2		5/8	
FC	1	Citrus fruits	10	Po	5/8	
MO	105	Edible offal (mammalian)	10		5/8	

PE	112	Eggs	0.1			5/8
SO	693	Linseed	0.05	(*)		5/8
MM	95	Meat (from mammals other than marine mammals)	0.5		(fat)	5/8
ML	106	Milks	0.05			5/8
HS	790	Pepper, Black, White	10			5/8
PM	110	Poultry meat	0.05	(*)		5/8
PO	111	Poultry, Edible offal of	0.2			5/8
SO	495	Rape seed	0.7			5/8
AS	81	Straw and fodder (dry) of cereal grains	40			5/8
SO	702	Sunflower seed	0.5			5/8
OR	702	Sunflower seed oil, Edible	1			5/8
CM	654	Wheat bran, Unprocessed	7			5/8

149 Ethoprophos

FI	327	Banana	0.02			5/8
VC	424	Cucumber	0.01			5/8
MO	105	Edible offal (mammalian)	0.01	(*)		5/8
MM	95	Meat (from mammals other than marine mammals)	0.01	(*)		5/8
VC	46	Melons, except watermelon	0.02			5/8
ML	106	Milks	0.01	(*)		5/8
VO	445	Peppers, Sweet	0.05			5/8
GS	659	Sugar cane	0.02			5/8
VR	508	Sweet potato	0.05			5/8
VO	448	Tomato	0.01	(*)		5/8

203 Spinosad

FM	812	Cattle milk fat	5			5/8
GC	80	Cereal grains	1		Po	5/8
DF	269	Dried grapes (=currants, raisins and sultanas)	1			5/8
MO	105	Edible offal (mammalian)	0.5			5/8
FB	269	Grapes	0.5			5/8
MM	95	Meat (from mammals other than marine mammals)	2	(fat)		5/8
CM	654	Wheat bran, Unprocessed	2			5/8

APPENDIX IV

PROPOSED DRAFT MRLS FOR SPICES[1]

Advanced for adoption at Step 5/8 with omission of Steps 6 and 7

Pesticide	Group or Sub-Group of Spices	Proposed MRL (mg/kg)	Step
Acephate (095)	Entire Group 028[2]	0.2(*)	5/8
Azinphos-methyl (002)	Entire Group 028[2]	0.5(*)	5/8
Chlorpyrifos (017)	Seeds	5	5/8
	Fruits or berries	1	
	Roots or rhizomes	1	
Chlorpyrifos-methyl (090)	Seeds	1	5/8
	Fruits	0.3	
	Roots/rhizomes	5	
Cypermethrin (118)	Fruits or berries	0.1	5/8
	Roots or rhizomes	0.2	
Diazinon (22)	Seeds	5	5/8
	Fruits	0.1 (*)	
	Roots or rhizomes	0.5	
Dichlorvos((025)	Entire Group 028[2]	0.1(*)	5/8
Dicofol (026)	Seeds	0.05(*)	5/8
	Fruits or berries	0.1	
	Roots/rhizomes	0.1	
Dimethoate (027)	Seeds	5	5/8
	Fruits or berries	0.5	
	Roots or rhizomes	0.1(*)	
Disulfoton (074)	Entire Group 028[2]	0.05(*)	5/8
Endosulfan (032) (total)	Seeds	1	5/8
	Fruits or berries	5	
	Roots or rhizomes	0.5	
Ethion (034)	Seeds	3	5/8
	Fruits or berries	5	
	Roots or rhizomes	0.3	
Fenitrothion (037)	Seeds	7	5/8
	Fruits or berries	1	5/8
	Roots or rhizomes	0.1(*)	5/8
Iprodion (111)	Seeds	0.05(*)	5/8

	Roots or rhizomes	0.1	5/8
Malathion (049)	Seeds	2	5/8
	Fruits or berries	1	5/8
	Roots or rhizomes	0.5	5/8
Metalaxyl (138)	Seeds	5	5/8
Methamidophos (100)	Entire Group 028[2]	0.1(*)	5/8
Parathion (058)	Seeds	0.1 (*)	5/8
	Fruits or berries	0.2	5/8
	Roots or rhizomes	0.2	5/8
Parathion-methyl (059)	Seeds	5	5/8
	Fruits or berries	5	
	Roots or rhizomes	3	
Permethrin (120)	Entire Group 028[2]	0.05 (*)	5/8
Phenthoate 128)	Seeds	7[c]	5/8
Phorate (112)	Seeds sub-group	0.5	5/8
	Fruits or berries	0.1(*)	5/8
	Roots or rhizomes	0.1(*)	5/8
Phosalone (060)	Seeds	2	5/8
	Fruits	2	5/8
	Roots/rhizomes	3	5/8
Pirimicarb (101)	Seeds	5	5/8
Pirimiphos-methyl (086)	Seeds sub-group	3	5/8
	Fruits sub-group	0.5	
Quintozene (064)	Seeds sub-group	0.1	5/8
	Fruits or berries	0.02	
	Roots or rhizomes	2	
Vinclozolin (159)	Entire spice group[2]	0.05 (*)	5/8

[1] The residue definitions remain the same as those recommended for the given pesticide in other plant commodities.

[2] The Group of A28 as modified by the 36th Session of CCPR.

APPENDIX V

PROPOSED DRAFT INTERIM MRLS ADVANCED FOR ADOPTION AT STEP 8 (I)

Bifenazate			
Letter code	**Number**	**Commodity**	**Interim MRL (mg/kg)**
AB	1230	Apple pomace, wet	2
SO	0691	Cottonseed	1
FP	0009	Pome fruits	1
FB	0269	Grapes	1
DF	0269	Grapes, dried	2
DH	1100	Hops	15
FS	0245	Nectarine	2
TN	0085	Tree nuts	0.2
FS	0247	Peach	2
HH	0738	Mint top	25
FS	0014	Plums	0.3
FB	0275	Strawberry	2
VC	0424	Cucumber	0.5
VC	0431	Squash	0.7
VC	0046	Melons (except watermelon)	0.3
VC	0432	Watermelon	0.3
VO	0051	Pepper	2
VO	0444	Chili pepper	2
VO	0442	Okra	2
VO	0448	Tomato	1
VO	0440	Eggplant	2
DT	1114	Tea	2
MM	095	Meat (from mammals other than marine animals)	0.1 (fat)
MO	0105	Edible offal, mammalian	0.01
ML	0106	Milks	0.01
PM	110	Poultry meat	0.01
PO	110	Poultry, edible offal of	0.01
PE	112	Eggs	0.01

Fludioxonil (211)			
Letter code	**Number**	**Commodity**	**Interim MRL (mg/kg)**
FS	12	Stone fruit	5 Po
FB	269	Grapes	2
FB	275	Strawberry	3
FB	272	Raspberry	5
FB	264	Blackberry	5
FB	20	Blueberry	2
VA	385	Onion	0.5
VA	389	Onion, spring (green)	5 (JMPR only)
VB	41	Cabbages, head	2
VB	400	Broccoli	0.7
VR	589	Potato	0.02
VR	577	Carrot	0.7

Fludioxonil (211)			
Letter code	**Number**	**Commodity**	**Interim MRL (mg/kg)**
VL	473	Watercress	10
VL	485	Mustard greens	10
HH	726	Herbs (fresh)	Basil 10 Chives 10
HH	726	Herbs (dried)	Basil, dry 50 Chives, dry 50
SO	495	Rapeseed	0.02
SO	691	Cottonseed	0.05
SO	702	Sunflower seed	0.01
SO	4723	Soya	0.01
TN	675	Pistachio	0.2
GC	0080	Cereal Grains	0.05
VO	447	Sweet corn (corn-on-the-cob)	0.01
MM	95	Meat (from mammals other than marine)	0.01
MO	105	Edible offal (mammalian)	0.05
ML	106	Milks	0.01
PM	110	Poultry meat	0.01
PO	111	Poultry, edible offal of	0.05
PE	112	Eggs	0.05

Trifloxystrobin (213)			
Letter code	**Number**	**Commodity**	**Interim MRL (mg/kg)**
FP	9	Pome fruits	0.7
FB	269	Grapes	3.0
DF	269	Grapes, dried	5.0
GC	640	Barley	0.5
GC	654	Wheat	0.2 (JMPR only)
VR	596	Sugar beet	0.05 (JMPR only)
ML	106	Milks	0.02
MM	95	Meat (from mammals other than marine)	0.05 (fat)
MO	105	Edible offal (mammalian)	
MO	98	Kidney	0.04
MO	99	Liver	0.05
PM	110	Poultry meat	0.04 (fat)
PO	111	Poultry, edible offal of	0.04
PE	112	Eggs	0.04

APPENDIX VI

PROPOSED DRAFT MAXIMUM RESIDUE LIMITS FOR PESTICIDES

Advanced for adoption at Step 5

			MRL (mg/kg)		Step	Note
37	**Fenitrothion**					
FP	226	Apple	0.5		5	
GC	80	Cereal grains	10	Po	5	
MO	105	Edible offal (mammalian)	0.05	(*)	5	
PE	112	Eggs	0.05	(*)	5	
MM	95	Meat (from mammals other than marine mammals)	0.05	(*)	5	
ML	106	Milks	0.01		5	
PM	110	Poultry meat	0.05	(*)	5	
CM	1206	Rice bran, Unprocessed	60		5	
CM	654	Wheat bran, Unprocessed	30	PoP	5	
49	**Malathion**					
FP	226	Apple	0.5		5	
FC	1	Citrus fruits	7		5	
FB	269	Grapes	5		5	
57	**Paraquat**					
AM	660	Almond hulls	0.01	(*)	5	
FI	30	Assorted tropical and sub-tropical fruits - inedible peel	0.01	(*)	5	
FB	18	Berries and other small fruits	0.01	(*)	5	
FC	1	Citrus fruits	0.02		5	
SO	691	Cotton seed	2		5	
MO	105	Edible offal (mammalian)	0.05		5	
PE	112	Eggs	0.005	(*)	5	
AV	1051	Fodder beet leaves or tops	0.2		5	
VO	50	Fruiting vegetables other than cucurbits	0.05		5	
VC	45	Fruiting vegetables, Cucurbits	0.02		5	
DH	1100	Hops, Dry	0.1		5	
VL	53	Leafy vegetables	0.07		5	
GC	645	Maize	0.03		5	
CF	1255	Maize flour	0.05		5	
AS	645	Maize fodder	10		5	
AF	645	Maize forage	5		5	
MM	95	Meat (from mammals other than marine mammals)	0.005		5	
ML	106	Milks	0.005	(*)	5	
FT	305	Olives	0.1		5	
FP	9	Pome fruits	0.01	(*)	5	

PM	110	Poultry meat	0.005	(*)	5	
PO	111	Poultry, Edible offal of	0.005	(*)	5	
VD	70	Pulses	0.5		5	
VR	75	Root and tuber vegetables	0.05		5	
GC	651	Sorghum	0.03		5	
AF	651	Sorghum forage (green)	0.3		5	
AS	651	Sorghum straw and fodder, Dry	0.3		5	
AL	541	Soya bean fodder	0.5		5	
AL	1265	Soya bean forage (green)	2		5	
FS	12	Stone fruits	0.01	(*)	5	
SO	702	Sunflower seed	2		5	
DT	1114	Tea, Green, Black	0.2		5	
TN	85	Tree nuts	0.05		5	
105	**Dithiocarbamates**					
FS	13	Cherries	0.2		5	
VO	445	Peppers, Sweet	7		5	
VO	448	Tomato	2		5	
142	**Prochloraz**					
VO	450	Mushrooms	40		5	
166	**Oxydemeton-Methyl**					
GC	640	Barley	0.02	(*)	5	
AS	640	Barley straw and fodder, Dry	0.1		5	
VB	404	Cauliflower	0.01	(*)	5	
VR	589	Potato	0.01	(*)	5	
GC	650	Rye	0.02	(*)	5	
AS	650	Rye straw and fodder, Dry	0.1		5	
VR	596	Sugar beet	0.01	(*)	5	
AV	596	Sugar beet leaves or tops	0.05		5	
GC	654	Wheat	0.02	(*)	5	
AS	654	Wheat straw and fodder, Dry	0.1		5	STMRs/STMRPs or HRs/HRPs were estimated based on new data submitted in 2004 JMPR
210	**Pyraclostrobin**					
AM	660	Almond hulls	2		5	
TN	660	Almonds	0.02	(*)	5	
FI	327	Banana	0.02	(*)	5	
GC	640	Barley	0.5		5	

VD	71	Beans (dry)	0.2		5
FB	20	Blueberries	1		5
VR	577	Carrot	0.5		5
FS	13	Cherries	1		5
FC	1	Citrus fruits	1		5
DF	269	Dried grapes (=currants, raisins and sultanas)	5		5
MO	105	Edible offal (mammalian)	0.05	(*)	5
PE	112	Eggs	0.05	(*)	5
AV	1051	Fodder beet leaves or tops	50		5
VA	381	Garlic	0.05	(*)	5
FB	269	Grapes	2		5
VD	533	Lentil (dry)	0.5		5
GC	645	Maize	0.02	(*)	5
FI	345	Mango	0.05	(*)	5
MM	95	Meat (from mammals other than marine mammals)	0.5	(fat)	5
ML	106	Milks	0.03		5
GC	647	Oats	0.5		5
VA	385	Onion, Bulb	0.2		5
FI	350	Papaya	0.05	(*)	5
AL	72	Pea hay or pea fodder (dry)	30		5
AL	528	Pea vines (green)	40		5
FS	247	Peach	0.5		5
AL	697	Peanut fodder	50		5
SO	703	Peanut, whole	0.02	(*)	5
VD	72	Peas (dry)	0.3		5
TN	672	Pecan	0.02	(*)	5
TN	675	Pistachio nuts	1		5
FS	14	Plums (including prunes)	0.3		5
VR	589	Potato	0.02	(*)	5
PM	110	Poultry meat	0.05	(*)	5
PO	111	Poultry, Edible offal of	0.05	(*)	5
VR	494	Radish	0.5		5
VL	494	Radish leaves (including radish tops)	20		5
VC	431	Squash, Summer	0.3		5
AS	81	Straw and fodder (dry) of cereal grains	30		5
FB	275	Strawberry	0.5		5
VR	596	Sugar beet	0.2		5
VO	448	Tomato	0.3		5
GC	654	Wheat	0.2		5

211 Fludioxonil

HH	722	Basil	10		5

DH	722	Basil, Dry	50			5
VD	71	Beans (dry)	0.07			5
VP	61	Beans, except broad bean and soya bean	0.3			5
VP	62	Beans, Shelled	0.03			5
FB	264	Blackberries	5			5
FB	20	Blueberries	2			5
VB	400	Broccoli	0.7			5
VB	41	Cabbages, Head	2			5
VR	577	Carrot	0.7			5
GC	80	Cereal grains	0.05	(*)		5
HH	727	Chives	10			5
HH	727	Chives (dried)	50			5
FC	1	Citrus fruits	7			5
SO	691	Cotton seed	0.05	(*)		5
VC	424	Cucumber	0.3			5
FB	266	Dewberries (including boysenberry and loganberry)	5			5
MO	105	Edible offal (mammalian)	0.05	(*)		5
VO	440	Egg plant	0.3			5
PE	112	Eggs	0.05	(*)		5
FB	269	Grapes	2			5
FI	341	Kiwifruit	15		Po	5
VL	482	Lettuce, Head	10			5
AF	645	Maize forage	0.03	(*)		5
MM	95	Meat (from mammals other than marine mammals)	0.01	(*)		5
VC	46	Melons, except watermelon	0.03			5
ML	106	Milks	0.01			5
VL	485	Mustard greens	10			5
VA	385	Onion, Bulb	0.5			5
VA	389	Onion, Spring	5			5
FP	230	Pear	0.7			5
VD	72	Peas (dry)	0.07			5
VP	63	Peas (pods and succulent=immature seeds)	0.3			5
VP	64	Peas, Shelled (succulent seeds)	0.03			5
VO	445	Peppers, Sweet	1			5
TN	675	Pistachio nuts	0.2			5
TN	675	Pistachio nuts	0.2			5
VR	589	Potato	0.02			5
PM	110	Poultry meat	0.01	(*)		5
PO	111	Poultry, Edible offal of	0.05	(*)		5
SO	495	Rape seed	0.02	(*)		5

FB	272	Raspberries, Red, Black	5		5
VC	431	Squash, Summer	0.3		5
FS	12	Stone fruits	5	Po	5
AS	81	Straw and fodder (dry) of cereal grains	0.06	(*)	5
FB	275	Strawberry	3		5
VO	447	Sweet corn (corn-on-the-cob)	0.01	(*)	5
VO	448	Tomato	0.5		5
VL	473	Watercress	10		5

212 Metalaxyl-M

FP	226	Apple	0.02	(*)	5
SB	715	Cacao beans	0.02		5
FB	269	Grapes	1		5
VL	482	Lettuce, Head	0.5		5
VA	385	Onion, Bulb	0.03		5
VO	445	Peppers, Sweet	0.5		5
VR	589	Potato	0.02	(*)	5
VL	502	Spinach	0.1		5
SO	702	Sunflower seed	0.02	(*)	5
VO	448	Tomato	0.2		5

213 Trifloxystrobin

AM	660	Almond hulls	3		5
FI	327	Banana	0.05		5
GC	640	Barley	0.5		5
AS	640	Barley straw and fodder, Dry	7		5
VB	402	Brussels sprouts	0.5?		5

APPENDIX VII

RECOMMENDED MAXIMUM RESIDUE LEVELS OF RESIDUES IN/ON DRIED CHILI PEPPERS[1] AND SPICES

Advanced for adoption at Step 5

Pesticide		MRL (mg/kg)	Step	Notes
177	Abamectin	0.2	5	
95	Acephate	50	5	
2	Azinphos-methyl	10	5	
155	Benalaxyl	0.5	5	
47	Bromide ion	200	5	
8	Carbaryl	50	5	
72	Carbendazim (based on chili peper)	20	5	
81	Chlorothalonil	70	5	
17	Chlorpyrifos	20	5	
90	Chlorpyrifos-methyl	5	5	
157	Cyfluthrin	2	5	
67	Cyhexatin	5	5	
118	Cypermethrin	5	5	
169	Cyromazine	10	5	
22	Diazinon	0.5	5	
82	Dichlofluanid	20	5	
26	Dicofol	10	5	
27	Dimethoate	50	5	
87	Dinocap	2	5	
105	Dithiocarbamates	10	5	
106	Ethephon	50	5	
149	Ethoprophos	0.2	5	(a)
192	Fenarimol	5	5	
185	Fenpropathrin	10	5	
119	Fenvalerate	5	5	
206	Imidacloprid	1	5	
49	Malathion	1	5	
138	Metalaxyl	10	5	
100	Methamidophos	20	5	
94	Methomyl	10	5	(b)
209	Methoxyfenozide	20	5	
54	Monocrotophos	2	5	
126	Oxamyl	50	5	
120	Permethrin	10	5	
61	Phosphamidon	2	5	
62	Piperonyl butoxide	20	5	
101	Pirimicarb	20	5	
86	Pirimiphos-methyl	10	5	(c)
136	Procymidone	50	5	
171	Profenofos	50	5	

148	Propamocarb	10	5	
63	Pyrethrins	0.5	5	
64	Quintozene	0.1	5	
203	Spinosad	3	5	
189	Tebuconazole	5	5	
196	Tebufenozide	10	5	
162	Tolylfluanid	20	5	
133	Triadimefon	1	5	
168	Triadimenol	1	5	
159	Vinclozolin	30	5	

053 Mevinphos	Seeds	5	5
	Fruits or berries	0.2(*)	
	Roots or rhizomes	1	

APPENDIX VIII

CODEX MAXIMUM RESIDUE LIMITS FOR PESTICIDES RECOMMENDED FOR REVOCATION

			MRL (mg/kg)		Step	Note
17	**Chlorpyrifos**					
SO	691	Cotton seed	0.05	(*)	CXL-D	To be revoked once the related MRL reaches Step 8
GC	649	Rice	0.1		CXL-D	To be revoked once the related MRL reaches Step 5/8
22	**Diazinon**					
VB	041	Cabbages, Head	2		CXL-D	To be revoked once the related MRL reaches Step 8.
27	**Dimethoate**					
FP	226	Apple	1		CXL-D	To be replaced by the MRL for pome fruits (1998 JMPR)
VB	402	Brussels sprouts	2		CXL-D	To be revoked once the related MRL(s) reach Step 8
VS	624	Celery	1		CXL-D	To be revoked once the related MRL(s) reach Step 8
FB	269	Grapes	1		CXL-D	
FT	305	Olives	1		CXL-D	To be revoked once the related MRL(s) reach Step 8
VA	385	Onion, Bulb	0.05	(*)	CXL-D	
VP	63	Peas (pods and succulent=immature seeds)	0.5		CXL-D	To be revoked once the related MRL(s) reach Step 8
FS	14	Plums (including prunes)	0.5		CXL-D	
GC	651	Sorghum	0.01	(*)	CXL-D	
AV	596	Sugar beet leaves or tops	1		CXL-D	To be revoked once the related MRL(s) reach Step 8
VR	506	Turnip, Garden	0.5		CXL-D	To be revoked once the related MRL(s) reach Step 8
37	**Fenitrothion**					
CF	1211	Wheat flour	2	PoP	CXL-D	Retained under 4 years periodic review procedure (36-88). JMPR 2004: Withdrawal receommended.
49	**Malathion**					
FS	247	Peach	6		CXL-D	JMPR 2004: Withdrawal recommended.
84	**Dodine**					
FP	226	Apple	5		CXL-D	2003 JMPR: Withdrawal recommended once pomefruit MRL reach Step 8
FS	13	Cherries	2		CXL-D	To be revoked once the related MRL(s) reach Step 8
FB	269	Grapes	5		CXL-D	2003 JMPR: Withdrawal recommended
FS	247	Peach	5		CXL-D	To be revoked once the related MRL(s) reach Step 8

FP	230	Pear	5			CXL-D	2003 JMPR: Withdrawal recommended once pomefruit MRL reach Step 8
FB	275	Strawberry	5			CXL-D	

85 Fenamiphos

VR	577	Carrot	0.2			CXL-D	
FB	269	Grapes	0.1			CXL-D	
FI	353	Pineapple	0.05	(*)		CXL-D	

86 Pirimiphos-Methyl

FP	226	Apple	2			CXL-D	2003 JMPR: Withdrawal recommended.
VB	402	Brussels sprouts	2			CXL-D	2003 JMPR: Withdrawal recommended.
VB	41	Cabbages, Head	2			CXL-D	2003 JMPR: Withdrawal recommended.
VR	577	Carrot	1			CXL-D	2003 JMPR: Withdrawal recommended.
VB	404	Cauliflower	2			CXL-D	2003 JMPR: Withdrawal recommended.
GC	80	Cereal grains	10		Po	CXL-D	To be revoked once the related MRLs reach Step 8
FS	13	Cherries	2			CXL-D	2003 JMPR: Withdrawal recommended.
FC	1	Citrus fruits	2			CXL-D	2003 JMPR: Withdrawal recommended.
VP	526	Common bean (pods and/or immature seeds)	0.5			CXL-D	2003 JMPR: Withdrawal recommended.
VC	424	Cucumber	1			CXL-D	2003 JMPR: Withdrawal recommended.
FB	278	Currant, Black	1			CXL-D	2003 JMPR: Withdrawal recommended.
DF	295	Dates, Dried or dried & candied	0.5		Po	CXL-D	2003 JMPR: Withdrawal recommended.
MD	180	Dried fish	8		Po	CXL-D	2003 JMPR: Withdrawal recommended.
PE	112	Eggs	0.05	(*)		CXL-D	To be revoked once the related MRL(s) reach Step 8
FB	268	Gooseberry	1			CXL-D	2003 JMPR: Withdrawal recommended.
FI	341	Kiwifruit	2			CXL-D	2003 JMPR: Withdrawal recommended.
VL	482	Lettuce, Head	5			CXL-D	2003 JMPR: Withdrawal recommended.
MM	95	Meat (from mammals other than marine mammals)	0.05	(*)		CXL-D	To be revoked once the related MRL(s) reach Step 8
ML	106	Milks	0.05	(*)		CXL-D	To be revoked once the related MRL(s) reach Step 8
VO	450	Mushrooms	5			CXL-D	2003 JMPR: Withdrawal recommended.
FT	305	Olives	5			CXL-D	2003 JMPR: Withdrawal

							recommended.
VA	389	Onion, Spring	1			CXL-D	2003 JMPR: Withdrawal recommended.
SO	697	Peanut	2		Po	CXL-D	2003 JMPR: Withdrawal recommended.
OC	697	Peanut oil, Crude	15		PoP	CXL-D	2003 JMPR: Withdrawal recommended.
OR	697	Peanut oil, Edible	15		PoP	CXL-D	2003 JMPR: Withdrawal recommended.
SO	703	Peanut, whole	25		Po	CXL-D	2003 JMPR: Withdrawal recommended.
FP	230	Pear	2			CXL-D	2003 JMPR: Withdrawal recommended.
VP	63	Peas (pods and succulent=immature seeds)	0.05	(*)		CXL-D	2003 JMPR: Withdrawal recommended.
VO	51	Peppers	1			CXL-D	2003 JMPR: Withdrawal recommended.
FS	14	Plums (including prunes)	2			CXL-D	2003 JMPR: Withdrawal recommended.
VR	589	Potato	0.05	(*)		CXL-D	2003 JMPR: Withdrawal recommended.
FB	272	Raspberries, Red, Black	1			CXL-D	2003 JMPR: Withdrawal recommended.
CM	1206	Rice bran, Unprocessed	20		PoP	CXL-D	2003 JMPR: Withdrawal recommended.
CM	649	Rice, Husked	2		PoP	CXL-D	2003 JMPR: Withdrawal recommended.
CM	1205	Rice, Polished	1		PoP	CXL-D	2003 JMPR: Withdrawal recommended.
CF	1251	Rye wholemeal	5		PoP	CXL-D	2003 JMPR: Withdrawal recommended.
VL	502	Spinach	5			CXL-D	2003 JMPR: Withdrawal recommended.
FB	275	Strawberry	1			CXL-D	2003 JMPR: Withdrawal recommended.
VO	448	Tomato	1			CXL-D	2003 JMPR: Withdrawal recommended.
CM	654	Wheat bran, Unprocessed	20		PoP	CXL-D	To be revoked once the related MRLs reach Step 8
CF	1211	Wheat flour	2		PoP	CXL-D	2003 JMPR: Withdrawal recommended.
CF	1212	Wheat wholemeal	5		PoP	CXL-D	2003 JMPR: Withdrawal recommended.
CP	1211	White bread	0.5		PoP	CXL-D	2003 JMPR: Withdrawal recommended.
CP	1212	Wholemeal bread	1		PoP	CXL-D	2003 JMPR: Withdrawal recommended.

94 Methomyl

AL	1021	Alfalfa forage (green)	10			CXL-D	To be revoked once the related MRL(s) reach Step 8

GC	640	Barley	0.5	CXL-D	To be revoked once the related MRL(s) reach Step 8
AM	738	Mint hay	2	CXL-D	To be revoked once the related MRL(s) reach Step 8
AL	528	Pea vines (green)	10	CXL-D	To be revoked once the related MRL(s) reach Step 8
VO	51	Peppers	1	CXL-D	To be revoked once the related MRL(s) reach Step 8
AL	1265	Soya bean forage (green)	10	CXL-D	To be revoked once the related MRL(s) reach Step 8
VO	447	Sweet corn (corn-on-the-cob)	2	CXL-D	Resulting from consideration of thiodicarb supervised field trial data. Confirmed (2001 JMPR). The information provided to the JMPR precludes an estimate that the dietary intake would be below the acute RfD (2001 JMPR)
VO	448	Tomato	1	CXL-D	Resulting from consideration of thiodicarb supervised field trial data. Confirmed (2001 JMPR). The information provided to the JMPR precludes an estimate that the dietary intake would be below the acute RfD. (2001 JMPR)
GC	654	Wheat	0.5	CXL-D	To be revoked once the related MRL(s) reach Step 8

95 Acephate

AL	1021	Alfalfa forage (green)	10	CXL-D	Withdrawal recommended (JMPR 2003)
VB	41	Cabbages, Head	2	CXL-D	Withdrawal recommended (JMPR 2003)
MF	812	Cattle fat	0.1	CXL-D	Withdrawal recommended (JMPR 2003)
MM	812	Cattle meat	0.1	CXL-D	Withdrawal recommended (JMPR 2003)
SO	691	Cotton seed	2	CXL-D	Withdrawal recommended (JMPR 2003)
PE	112	Eggs	0.1	CXL-D	To be revoked once the related MRL(s) reach Step 8
VL	482	Lettuce, Head	5	CXL-D	Withdrawal recommended (JMPR 2003)
ML	106	Milks	0.1	CXL-D	To be revoked once the related MRL(s) reach Step 8
MF	818	Pig fat	0.1	CXL-D	Withdrawal recommended (JMPR 2003)
MM	818	Pig meat	0.1	CXL-D	To be revoked once the related wider group MRLs reach Step 8
VR	589	Potato	0.5	CXL-D	Withdrawal recommended (JMPR 2003)
PM	110	Poultry meat	0.1	CXL-D	To be revoked once the related MRL(s) reach Step 8
VD	541	Soya bean (dry)	0.5	CXL-D	To be revoked once the related MRL(s) reach Step 8

VR	596	Sugar beet	0.1		CXL-D Withdrawal recommended (JMPR 2003)
AV	596	Sugar beet leaves or tops	10		CXL-D Withdrawal recommended (JMPR 2003)
VO	448	Tomato	1		CXL-D Withdrawal recommended (JMPR 2003)
FT	312	Tree tomato	0.5		CXL-D Withdrawal recommended (JMPR 2003)

96 Carbofuran

GC	645	Maize	0.1	(*)	CXL-D To be revoked once the related MRL(s) reach Step 8

100 Methamidophos

AL	1021	Alfalfa forage (green)	2		CXL-D 2003 JMPR: Withdrawal recommended
MF	812	Cattle fat	0.01	(*)	CXL-D 2003 JMPR: Withdrawal recommended
MM	812	Cattle meat	0.01	(*)	CXL-D 2003 JMPR: Withdrawal recommended
SO	691	Cotton seed	0.1		CXL-D To be revoked once the related MRL(s) reach Step 8
MF	814	Goat fat	0.01	(*)	CXL-D 2003 JMPR: Withdrawal recommended
MM	814	Goat meat	0.01	(*)	CXL-D To be revoked once the related wider group MRLs reach Step 8
VL	482	Lettuce, Head	1		CXL-D 2003 JMPR: Withdrawal recommended
ML	106	Milks	0.01	(*)	CXL-D To be revoked once the related MRL(s) reach Step 8
MF	818	Pig fat	0.01	(*)	CXL-D 2003 JMPR: Withdrawal recommended
MM	818	Pig meat	0.01	(*)	CXL-D To be revoked once the related wider group MRLs reach Step 8
VR	589	Potato	0.05		CXL-D To be revoked once the related MRL(s) reach Step 8
MF	822	Sheep fat	0.01	(*)	CXL-D 2003 JMPR: Withdrawal recommended
MM	822	Sheep meat	0.01	(*)	CXL-D To be revoked once the related wider group MRLs reach Step 8
VD	541	Soya bean (dry)	0.05		CXL-D To be revoked once the related MRL(s) reach Step 8
VR	596	Sugar beet	0.05		CXL-D To be revoked once the related MRL(s) reach Step 8
AV	596	Sugar beet leaves or tops	1		CXL-D To be revoked once the related MRLs reach Step 8
FT	312	Tree tomato	0.01	(*)	CXL-D 2003 JMPR: Withdrawal recommeded

105 Dithiocarbamates

VC	424	Cucumber	2		CXL-D To be revoked once the related MRL(s) reach Step 8
MO	105	Edible offal (mammalian)	0.1		CXL-D To be revoked once the related

							MRL(s) reach Step 8
PE	112	Eggs	0.05	(*)		CXL-D	To be revoked once the related MRL(s) reach Step 8
FB	269	Grapes	5			CXL-D	To be revoked once the related MRL(s) reach Step 8
MM	95	Meat (from mammals other than marine mammals)	0.05	(*)		CXL-D	To be revoked once the related MRL(s) reach Step 8
VC	46	Melons, except watermelon	0.5			CXL-D	2004 JMPR: Withdrowal recommended
ML	106	Milks	0.05	(*)		CXL-D	To be revoked once the related MRL(s) reach Step 8
VA	385	Onion, Bulb	0.5			CXL-D	To be revoked once the related MRL(s) reach Step 8
TN	672	Pecan	0.1	(*)		CXL-D	To be revoked once the related MRL(s) reach Step 8
FP	9	Pome fruits	5			CXL-D	To be revoked once the related MRL(s) reach Step 8
VR	589	Potato	0.2			CXL-D	To be revoked once the related MRL(s) reach Step 8
PM	110	Poultry meat	0.1			CXL-D	To be revoked once the related MRL(s) reach Step 8
PO	111	Poultry, Edible offal of	0.1			CXL-D	To be revoked once the related MRL(s) reach Step 8
FS	12	Stone fruits	7			CXL-D	To be revoked once the related MRL(s) reach Step 8

135 Deltamethrin

VL	53	Leafy vegetables	0.5			CXL-D	To be revoked once the related MRL(s) reach Step 8

142 Prochloraz

FI	326	Avocado	5		Po	CXL-D	To be revoked once the related wider group MRLs reach Step 8
FI	327	Banana	5		Po	CXL-D	To be revoked once the related wider group MRLs reach Step 8
GC	640	Barley	0.5			CXL-D	To be revoked once the related wider group MRLs reach Step 8
AS	640	Barley straw and fodder, Dry	15			CXL-D	To be revoked once the related wider group MRLs reach Step 8
MF	812	Cattle fat	0.5			CXL-D	To be revoked once the related wider group MRLs reach Step 8
MM	812	Cattle meat	0.1	(*)		CXL-D	To be revoked once the related wider group MRLs reach Step 8
MO	812	Cattle, Edible offal of	5			CXL-D	To be revoked once the related wider group MRLs reach Step 8
FI	345	Mango	2		Po	CXL-D	To be revoked once the related wider group MRLs reach Step 8
ML	106	Milks	0.1	(*)		CXL-D	To be revoked once the related MRLs reach Step 8
AS	647	Oat straw and fodder, Dry	15			CXL-D	To be revoked once the related wider group MRLs reach Step 8
GC	647	Oats	0.5			CXL-D	To be revoked once the related

							wider group MRLs reach Step 8
FC	4	Oranges, Sweet, Sour	5		Po	CXL-D	To be revoked once the related wider group MRLs reach Step 8
FI	350	Papaya	1		Po	CXL-D	To be revoked once the related wider group MRLs reach Step 8
SO	495	Rape seed	0.5			CXL-D	To be revoked once the related MRL(s) reach Step 8
GC	650	Rye	0.5			CXL-D	To be revoked once the related wider group MRLs reach Step 8
AS	650	Rye straw and fodder, Dry	15			CXL-D	To be revoked once the related wider group MRLs reach Step 8
GC	654	Wheat	0.5			CXL-D	To be revoked once the related MRL(s) reach Step 8
AS	654	Wheat straw and fodder, Dry	15			CXL-D	To be revoked once the related wider group MRLs reach Step 8
149	**Ethoprophos**						
FI	327	Banana	0.02	(*)		CXL-D	To be revoked once the related MRL(s) reach Step 8
VC	424	Cucumber	0.02	(*)		CXL-D	To be revoked once the related MRL(s) reach Step 8
VC	46	Melons, except watermelon	0.02	(*)		CXL-D	To be revoked once the related MRL(s) reach Step 8
GS	659	Sugar cane	0.02	(*)		CXL-D	To be revoked once the related MRL(s) reach Step 8
VR	508	Sweet potato	0.02	(*)		CXL-D	To be revoked once the related MRL(s) reach Step 8
VO	448	Tomato	0.02	(*)		CXL-D	To be revoked once the related MRL(s) reach Step 8
162	**Tolylfluanid**						
VL	482	Lettuce, Head	1			CXL-D	To be revoked once the related MRL(s) reach Step 8
203	**Spinosad**						
GC	645	Maize	0.01	(*)		CXL-D	To be revoked once the related MRL(s) reach Step 8
MM	822	Sheep meat	0.01	(*)	(fat)	CXL-D	To be revoked once the related group MRL(s) reach Step 8
MO	822	Sheep, Edible offal of	0.01	(*)		CXL-D	To be revoked once the related group MRL(s) reach Step 8
GC	651	Sorghum	1			CXL-D	To be revoked once the related group MRL(s) reach Step 8

APPENDIX IX

PROPOSED DRAFT AND DRAFT REVISED MAXIMUM RESIDUE LIMITS FOR PESTICIDES

Returned to Steps 6 and 3 respectively

MRLs returned to Step 6			MRL (mg/kg)		Step	Note
7 Captan						
FS	13	Cherries	25		6	
DF	269	Dried grapes (=currants, raisins and	50		6	
FB	269	Grapes	25		6	
VC	46	Melons, except watermelon	10		6	
FS	247	Peach	20		6	
FS	14	Plums (including prunes)	10		6	
FP	9	Pome fruits	15	Po	6	
FB	275	Strawberry	15		6	
VO	448	Tomato	5		6	
8 Carbaryl						
FS	13	Cherries	20		6	
FC	1	Citrus fruits	15		6	
JF	1	Citrus juice	0.5		6	
AB	1	Citrus pulp, Dry	4		6	
DF	269	Dried grapes (=currants, raisins and sultanas)	50		6	
JF	269	Grape juice	30		6	
AB	269	Grape pomace, Dry	80		6	
FB	269	Grapes	40		6	
FS	12	Stone fruits	10			
27 Dimethoate						
GC	640	Barley	2		6	
VB	41	Cabbages, Head	2		6	
FC	1	Citrus fruits	5		6	
VL	482	Lettuce, Head	3		6	
VO	445	Peppers, Sweet	5	Po	6	
VO	448	Tomato	2		6	
41 Folpet						
FP	226	Apple	10		6	
DF	269	Dried grapes (=currants, raisins and sultanas)	40		6	
FB	269	Grapes	10		6	

VL	482	Lettuce, Head	50	6
FB	275	Strawberry	5	6
VO	448	Tomato	3	6

49 Malathion

AL	1020	Alfalfa fodder	200	6
AL	1021	Alfalfa forage (green)	500	6
AL	1023	Clover	500	6
AL	1031	Clover hay or fodder	150	6
SO	691	Cotton seed	20	6
OC	691	Cotton seed oil, Crude	13	6
OR	691	Cotton seed oil, Edible	13	6
AF	162	Grass forage	200	6
AS	162	Hay or fodder (dry) of grasses	300	6
GC	645	Maize	0.05	6
AS	645	Maize fodder	50	6
AF	645	Maize forage	10	6
GC	651	Sorghum	3	6
GC	654	Wheat	0.5	6
CF	1211	Wheat flour	0.2	6
AF	654	Wheat forage (whole plant)	20	6
AS	654	Wheat straw and fodder, Dry	50	6

59 Parathion-Methyl

AL	1020	Alfalfa fodder	70	6
AL	1021	Alfalfa forage (green)	70	6
AL	1030	Bean forage (green)	1	6
SO	691	Cotton seed	25	6
OC	691	Cotton seed oil, Crude	10	6
OR	691	Cotton seed oil, Edible	10	6
AS	162	Hay or fodder (dry) of grasses	5	6
GC	645	Maize	0.1	6
CF	1255	Maize flour	0.05	6
OC	645	Maize oil, Crude	0.2	6
OR	645	Maize oil, Edible	0.1	6
AL	72	Pea hay or pea fodder (dry)	70	6
AL	528	Pea vines (green)	40	6
SO	495	Rape seed	0.05	6
OC	495	Rape seed oil, Crude	0.2	6
OR	495	Rapeseed oil, Edible	0.2	6
AV	596	Sugar beet leaves or tops	0.05 (*)	6
GC	654	Wheat	5	6
CM	654	Wheat bran, Unprocessed	10	6
CF	1211	Wheat flour	2	6
AS	654	Wheat straw and fodder, Dry	10	6

65 Thiabendazole

FC	1	Citrus fruits	3	Po	6

72 Carbendazim

VS	621	Asparagus	0.2 C		6
FI	327	Banana	0.2		6
GC	640	Barley	0.5		6
AS	640	Barley straw and fodder, Dry	2		6
VD	71	Beans (dry)	0.5		6
FB	18	Berries and other small fruits	1		6
VR	577	Carrot	0.2		6
MM	812	Cattle meat	0.05	(*)	6
FS	13	Cherries	10Th		6
PF	840	Chicken fat	0.05	(*)	6
VP	526	Common bean (pods and/or immature seeds)	0.5 Th		6
VC	424	Cucumber	0.05	(*)	6
MO	105	Edible offal (mammalian)	0.05	(*)	6
PE	112	Eggs	0.05	(*)	6
VP	529	Garden pea, Shelled	0.02		6
VC	425	Gherkin	0.05	(*)	6
FB	269	Grapes	3		6
VL	482	Lettuce, Head	5		6
FI	345	Mango	5 C		6
ML	106	Milks	0.05	(*)	6
FC	4	Oranges, Sweet, Sour	1		6
SO	697	Peanut	0.1*Th		6
AL	697	Peanut fodder	3 Th		6
VO	51	Peppers	0.1		6
VO	444	Peppers, Chili	2 C		6
PM	110	Poultry meat	0.05	(*)	6
SO	495	Rape seed	0.05	(*)	6
AS	649	Rice straw and fodder, Dry	15		6
CM	649	Rice, Husked	2		6
GC	650	Rye	0.05		6
VD	541	Soya bean (dry)	0.5 Th		6
VC	431	Squash, Summer	0.5 Th		6
VR	596	Sugar beet	0.1* Th		6
AV	596	Sugar beet leaves or tops	10 Th		6
GC	654	Wheat	0.05	(*)	6
AS	654	Wheat straw and fodder, Dry	1		6

74 Disulfoton

VB	400	Broccoli	0.1		6
VB	41	Cabbages, Head	0.2		6
VB	404	Cauliflower	0.05		6

VL	482	Lettuce, Head	1	6
VL	483	Lettuce, Leaf	1	6

85 Fenamiphos

VO	51	Peppers	0.5	6
VO	448	Tomato	0.5	6
VC	432	Watermelon	0.05 (*)	6

90 Chlorpyrifos-Methyl

GC	640	Barley	10 Po	6
GC	647	Oats	10 Po	6
GC	649	Rice	10 Po	6

94 Methomyl

FP	226	Apple	2	6
VB	40	Brassica vegetables	7	6
VS	624	Celery	3	6
VC	45	Fruiting vegetables, Cucurbits	0.1	6
FB	269	Grapes	7	6
VL	53	Leafy vegetables	30	6
FP	230	Pear	0.3	6

95 Acephate

VP	61	Beans, except broad bean and soya bean	5	6
VB	42	Flowerhead brassicas	2	6
FC	3	Mandarins	7	6
FS	245	Nectarine	2	6
FS	247	Peach	2	6
VO	51	Peppers	5	6
FP	9	Pome fruits	7	6

96 Carbofuran

VC	4199	Cantaloupe	0.2	6
VC	424	Cucumber	0.3	6
FC	206	Mandarin	0.5	6
FC	4	Oranges, Sweet, Sour	0.5	6
VR	589	Potato	0.2	6
VC	431	Squash, Summer	0.3	6
VO	447	Sweet corn (corn-on-the-cob)	0.1	6

100 Methamidophos

VP	61	Beans, except broad bean and soya bean	1(Ac)	6
VB	41	Cabbages, Head	1	6
VB	42	Flowerhead brassicas	0.5(Ac)	6
FC	3	Mandarins	0.5(Ac)	6
FS	245	Nectarine	0.5(Ac)	6
FS	247	Peach	0.5(Ac)	6
VO	51	Peppers	2(Ac)	6

FP	9	Pome fruits	0.5(Ac)	6
VO	448	Tomato	2	6

103 Phosmet

FS	240	Apricot	10	6
FB	20	Blueberries	15	6
FC	1	Citrus fruits	3	6
FS	245	Nectarine	10	6
FP	9	Pome fruits	10	6

117 Aldicarb

FI	327	Banana	0.2	6
VR	589	Potato	0.5	6

126 Oxamyl

FC	1	Citrus fruits	3	6
VC	424	Cucumber	1	6
VC	46	Melons, except watermelon	1	6
VO	51	Peppers	5	6

166 Oxydemeton-Methyl

FP	226	Apple	0.05	6
VB	41	Cabbages, Head	0.05 (*)	6
MF	812	Cattle fat	0.05 (*)	6
VD	526	Common bean (dry)	0.1	6
SO	691	Cotton seed	0.05	6
PE	112	Eggs	0.05 (*)	6
FB	269	Grapes	0.1	6
VL	480	Kale	0.01 (*)	6
VB	405	Kohlrabi	0.05	6
FC	204	Lemon	0.2	6
MM	97	Meat of cattle, pigs & sheep	0.05 (*)	6
ML	106	Milks	0.01 (*)	6
FC	4	Oranges, Sweet, Sour	0.2	6
FP	230	Pear	0.05	6
MF	818	Pig fat	0.05 (*)	6
PF	111	Poultry fats	0.05 (*)	6
PM	110	Poultry meat	0.05 (*)	6
MF	822	Sheep fat	0.05 (*)	6

193 Fenpyroximate

FP	226	Apple	0.3	6
FB	269	Grapes	1	6

194 Haloxyfop

PE	840	Chicken eggs	0.01 (*)	6
PM	840	Chicken meat	0.01 (*)	6
PO	840	Chicken, Edible offal of	0.05	6

SO	691	Cotton seed	0.2			6
OC	691	Cotton seed oil, Crude	0.5			6
AM	1051	Fodder beet	0.3			6
SO	697	Peanut	0.05			6
VP	63	Peas (pods and succulent=immature seeds)	0.2			6
VR	589	Potato	0.1			6
VD	70	Pulses	0.2			6
SO	495	Rape seed	2			6
OC	495	Rape seed oil, Crude	5			6
OR	495	Rapeseed oil, Edible	5			6
CM	1206	Rice bran, Unprocessed	0.02	(*)		6
CM	649	Rice, Husked	0.02	(*)		6
CM	1205	Rice, Polished	0.02	(*)		6
OC	541	Soya bean oil, Crude	0.2			6
OR	541	Soya bean oil, Refined	0.2			6
VR	596	Sugar beet	0.3			6
SO	702	Sunflower seed	0.2			6

201 Chlorpropham

MM	812	Cattle meat	0.1		(fat)	6
ML	812	Cattle milk	0.0005	(*)	F	6
MO	812	Cattle, Edible offal of	0.01	(*)		6
VR	589	Potato	30		Po	6

204 Esfenvalerate

SO	691	Cotton seed	0.05			6
VO	448	Tomato	0.1			6
GC	654	Wheat	0.05			6

209 Methoxyfenozide

VL	502	Spinach	50			6

MRLs returned to Step 3			**MRL (mg/kg)**		**Step**	**Note**

194 Haloxyfop

AL	1021	Alfalfa forage (green)	5	fresh	3	
MO	1280	Cattle kidney	1		3	
MO	1281	Cattle liver	0.5		3	
MM	812	Cattle meat	0.05		3	
ML	812	Cattle milk	0.3		3	
AV	596	Sugar beet leaves or tops	0.3	fresh	3	

APPENDIX X

PROPOSED DRAFT GUIDELINES ON THE USE OF MASS SPECTROMETRY (MS) FOR IDENTIFICATION, CONFIRMATION AND QUANTITATIVE DETERMINATION OF RESIDUES

Advanced for adoption at Step 5/8

Confirmatory Tests

When analyses are performed for monitoring or enforcement purposes, it is particularly important that confirmatory data are generated before reporting on samples containing residues of pesticides that are not normally associated with that commodity, or where MRLs appear to have been exceeded. Samples may contain interfering chemicals that may be misidentified as pesticides. Examples in gas chromatography include the responses of electron-capture detectors to phthalate esters and of phosphorus-selective detectors to compounds containing sulphur and nitrogen.

Analysis of pesticide residues with multi-residue methods generally consists of two phases: screening and confirmation. The process is schematically depicted in Fig. 2. The first phase comprises establishment of those pesticide residues that are likely to be present from interpreting the raw data, avoiding false negatives as much as possible. The second phase is the confirmation, which focuses on the pesticides found in phase 1. The use of the results to be reported, and consequent management decision determines the efforts put in the confirmatory process. The choice of the technique used for confirmation depends on their availability, time and cost. They are based on either further interpretation of chromatographic and mass spectrometric data, alternative methods using different physico-chemical properties of the compound, or a combination of various separation and detection methods. Some alternative procedures for confirmation are given in Table 6.

Whenever chromatographic techniques are used in screening or confirmation, proper settings of the retention time windows is pivotal. Care should be taken that the instrument is adjusted correctly before starting the analysis; a system suitability test should be performed prior to each batch of analysis[1]. Retention times data base should be adjusted for the current conditions[2]. In phase 1, tolerance intervals of 1.5 to 3% of the absolute retention time may be applied for capillary GC depending on the peak shape. For confirmation of the retention time, the absolute tolerance intervals will increase at higher retention time. The tolerance interval should be less than 1 sec for an RT less than 500 sec. For retention times between 500 and 5000 sec. an interval of 0.2% RRT is recommended. For higher retention times 6 sec. is a suitable interval.

Confirmatory tests may be quantitative and/or qualitative but, in most cases, both types of information will be required. Particular problems occur when residues must be confirmed at or about the limit of determination, although it is difficult to quantify residues at this level, it is essential to provide adequate confirmation of both level and identity.

The need for confirmatory tests may depend upon the type of sample or its known history. In some crops or commodities, certain residues are frequently found. For a series of samples of similar origin, which contain residues of the same pesticide, it may be sufficient to confirm the identity of residues in a small proportion of the samples selected randomly. Similarly, when it is known that a particular pesticide has been applied to the sample material, there may be little need for confirmation of identity, although a number of randomly selected results should be confirmed. Where “blank” samples are available, these shall be used to check the occurrence of possible interfering substances.

The necessary steps for positive identification are a matter of judgement on the analyst’s part, and particular attention should be paid to the choice of a method that would minimise the effect of interfering compounds. The technique(s) chosen depend(s) upon the availability of suitable instruments and expertise within the testing laboratory.

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[1] Soboleva E. Ambrus A., Application of system suitability test for quality assurance and performance optimization of a gas chromatographic system for pesticide residue analysis, J. Chromatogr. A. 1027. 2004. 55-65.

[2] Lantos J., Kadenczki L., Zakar F., Ambrus A. Validation of gas chromatographic Databases for qualitative identification of active ingredients of pesticide residues in Fajgelj A. Ambrus A. (eds) Principles of Method Validation, Royal Society of Chemistry, Cambridge, 2000, pp 128-137.

Gas Chromatography/Mass spectrometry (GC/MS)

Residue data obtained using mass spectrometry represents the most definitive evidence and, where suitable instrumentation is available, it is the confirmatory technique of choice. The technique is also used commonly for residue screening purposes (phase 1). Mass spectrometric determination of residues is usually carried out in conjunction with a chromatographic separation technique to provide retention time ion mass/charge ratio and abundance data simultaneously. Quantitative transmission of labile analytes through the chromatographic system is subject to problems similar to those experienced with other detectors. For quantification, the ions monitored should be those that are the most specific to the analyte, are subject to least interference and provide good signal-to-noise ratio.

When using selected ion monitoring (SIM), tolerance intervals of ion ratios and retention times based on injection of pesticide standard in pure solvent at the concentration close to the critical level should have been established at this point. The tolerance intervals for the ion ratios should be within the limits of ± 30 % of absolute ion abundances ratios. When 2 (or 3) selected ion ratios are within the established tolerance intervals the residue is confirmed[3]. For a small number of pesticides the mass spectrum may only exhibit one specific ion. In this case alternative confirmation should be sought.

When the ions detected still indicate the possible presence of a residue, the result may be reported as tentatively identified. However, when the result would lead to regulatory action, or results would be used for other purposes (e.g. dietary intake assessment) further confirmation of analyte identity shall be sought. This can be achieved with the same GC-MS instrumentation, by injecting matrix-matched standards of the suspected analyte, in order to compensate for matrix influence on ion ratios. In this case, subsequent injections of matrix matched standard and suspected sample has to be made. The deviation of RRT of analyte in standard and suspected peak in sample should typically be less than 0.1 %. Two ion ratios measured in a sample should be within the tolerance interval calculated based on the ion ratios in matrix-matched standard. The residue is considered to be confirmed if it complies with the general rule stated above. If the ion ratios are not within the tolerance intervals, additional confirmation of identity may be obtained by the use of alternative analytical techniques. Examples are listed in Table 6.

Further confirmation by mass spectrometry can be accomplished by acquisition of the complete electron-impact mass spectrum (in practice generally from m/z50 to beyond the molecular ion region). The absence of interfering ions is an important consideration in confirming identity. Additional confirmation of identity may be obtained by (i) the use of an alternative chromatographic column; (ii) by the use of an alternative ionisation technique (e.g. chemical ionization); (iii) by monitoring further reaction products of selected ions by tandem mass spectrometry (MS/MS or MS^n); or (iv) by monitoring selected ions at increased mass resolution.

Mass spectrometric determinations should satisfy similar analytical quality control criteria to those applied to other systems.

HPLC and HPLC-MS

Confirmation of residues detected following separation by HPLC is generally more problematic than where gas chromatography is used. If detection is by UV absorption, production of a complete spectrum can provide good evidence of identity. However, UV spectra of some pesticides are poorly diagnostic, being similar to those produced by many other compounds possessing similar functional groups or structures, and co-elution of interfering compounds can create additional problems. UV absorption data produced at multiple wavelengths may support or refute identification but, in general, they are not sufficiently characteristic on their own. Fluorescence data may be used to support those obtained by UV absorption. LC-MS can provide good supporting evidence but, because the spectra generated are generally very simple, showing little characteristic fragmentation, results produced from LC-MS are unlikely to be definitive. LC-MS/MS is a more powerful technique, combining selectivity with specificity, and often provides good evidence of identity. LC-MS techniques tend to be subject to matrix effects, especially suppression, and therefore confirmation of quantity may require the use of standard addition or isotopically-labelled standards. Derivatisation may also be used for confirmation of residues detected by HPLC (Table 6).

[3] Soboleva E. Ahad K. Ambrus A. Applicability of some MS criteria for the confirmation of pesticide residues, . Analyst, 129, 1123-1129, 2004.

Thin Layer Chromatography (TLC)

In some instances, confirmation of gas chromatographic findings is most conveniently achieved by TLC. Identification is based on two criteria, Rf value and visualisation reaction. Detection methods based on bioassays (e.g. enzyme -, fungal growth or chloroplast inhibition) are especially suitable for qualitative confirmation as they are specific to certain type of compounds, sensitive and normally very little affected by the co-extracts[4,5]. The scientific literature contains numerous references to the technique[6]. The quantitative aspects of thin-layer chromatography are, however, limited. A further extension of this technique involves the removal of the area on the plate corresponding to the Rf of the compound of interest followed by elution from the layer material and further chemical or physical confirmatory analysis. A solution of the standard pesticide should always be spotted on the plate alongside the sample extract to obviate any problems of non-repeatability of Rf. Over-spotting of extract with standard pesticide can also give useful information. The advantages of thin layer chromatography are speed, low cost and applicability to heat sensitive materials; disadvantages include (usually) lower sensitivity and separation power than instrumental chromatographic detection techniques and need for more efficient cleanup in case of detections based on chemicals colour reactions.

Derivatisation

When selecting ions for GC/MS confirmation based on a derivative, the selected ions must be structurally significant for the residue and not represent fragments of the derivatizing agent. Whereas derivatisation might be a valuable way to confirm the identity of a residue, it should be taken into account that it will also add an extra element to the uncertainty of a quantitative confirmation .

This area of confirmation may be considered under three broad headings.

(a) Chemical reactions

Small-scale chemical reactions resulting in degradation, addition or condensation products of pesticides, followed by re-examination of the products by chromatographic techniques, have frequently been used. The reactions result in products possessing different retention times and/or detector response from those of the parent compound. A sample of standard pesticide should be treated alongside the suspected residue so that the results from each maybe directly compared. A fortified extract should also be included to prove that the reaction has proceeded in the presence of sample material. Interference may occur where derivatives are detected by means of properties of the derivatising reagent. A review of chemical reactions which have been used for confirmatory purposes has been published by Cochrane, W.P. (Chemical derivatisation in pesticide analysis, Plenum Press, NY (1981)). Chemical reactions have the advantages of being fast and easy to carry out, but specialised reagents may need to be purchased and/or purified.

(b) Physical reactions

A useful technique is the photochemical alteration of a pesticide residue to give one or more products with a reproducible chromatographic pattern. A sample of standard pesticide and fortified extract should always be treated in a similar manner. Samples containing more than one pesticide residue may give problems in the interpretation of results. In such cases pre-separation of specific residues may be carried out using TLC, HPLC or column fractionation prior to reaction.

(c) Other methods

Many pesticides are susceptible to degradation/transformation by enzymes. In contrast to normal chemical reactions, these processes are very specific and generally consist of oxidation, hydrolysis or de-alkylation. The conversion products possess different chromatographic characteristics from the parent pesticide and may be used for confirmatory purposes if compared with reaction products using standard pesticides.

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[4] Ambrus[1]* Á.,. Füzesi[2] I.; Susán[2] M.; Dobi[3] D., Lantos[4] J., Zakar[5] F., Korsós[4] I., Oláh[3] J., Beke[3] B.B., and L. Katavics[5] A cost effective screening methods for pesticide residue analysis in fruits, vegetables and cereal grains, J. Environ Sci. Health B40, 297-339, 2005.

[5] Ambrus Á.; Füzesi I.; Lantos J.; Korsos I.; Hatfaludi T. Repeatability and Reproducibility of Rf and MDQ Values with Different TLC Elution and Detection Systems. J. Environ Sci. Health B39 **2004** *accepted for publication.*

[6] IUPAC Report on Pesticides (13) (Bátora, V., Vitorovic, S.Y., Thier, H.-P. and Klisenko, M.A.; Pure & Appl. Chem., 53, 1981, 1039-1049

Table 6. Detection methods suitable for screening (Phase 1) and confirmation (Phase 2) of residues.

		Phase 1 - Screening							
		GC with capillary column – ECD, NPD, FPD, PFPD	GC-MS	LC-MS	LC-DAD or scanning UV	LC-UV/VIS (single wavelength)	LC-fluorescence	GC with packed column – ECD, NPD, FPD	TLC – enzyme -, fungal growth or chloroplast inhibition
Phase 2, confirmation	GC – capillary column – ECD, NPD, FPD, PFPD	x[1]	x[1]	x	x	x	x	x	x
	GC-MS	x	x[1 2]	x	x	x	x	x	x
	LC-MS	x	x		x	x	x	x	x
	Full scan techniques	x	x	x	x	x	x	x	x
	$(MS)^n$, HRMS, alternative ionisation techniques	x	x	x	x	x	x	x	x
	LC-DAD or scanning UV	x	x	x		x	x	x	x
	LC-UV/VIS (single wavelength)	x	x				x	x	x
	LC-fluorescence	x	x		x	x		x	x
	TLC – enzyme, fungal growth or chloroplast inhibition	x	x	x	x	x	x	x	x[2 3]
	Derivatisation	x	x	x	x	x	x	x	x
	Specific isomers profile	x	x	x	x	x	x	x	

1 – Either the column of different polarity, which results in different elution order of the residues and contaminants eluting in the vicinity to the peak of interest, or another specific detector shell be used.

2- The same GC-MS technique can be used for the phase 2 (confirmation) if different ions are selected or tolerance intervals are established based on matrix matched solutions.

3 – Mobile or stationary phase of different polarity shall be used.

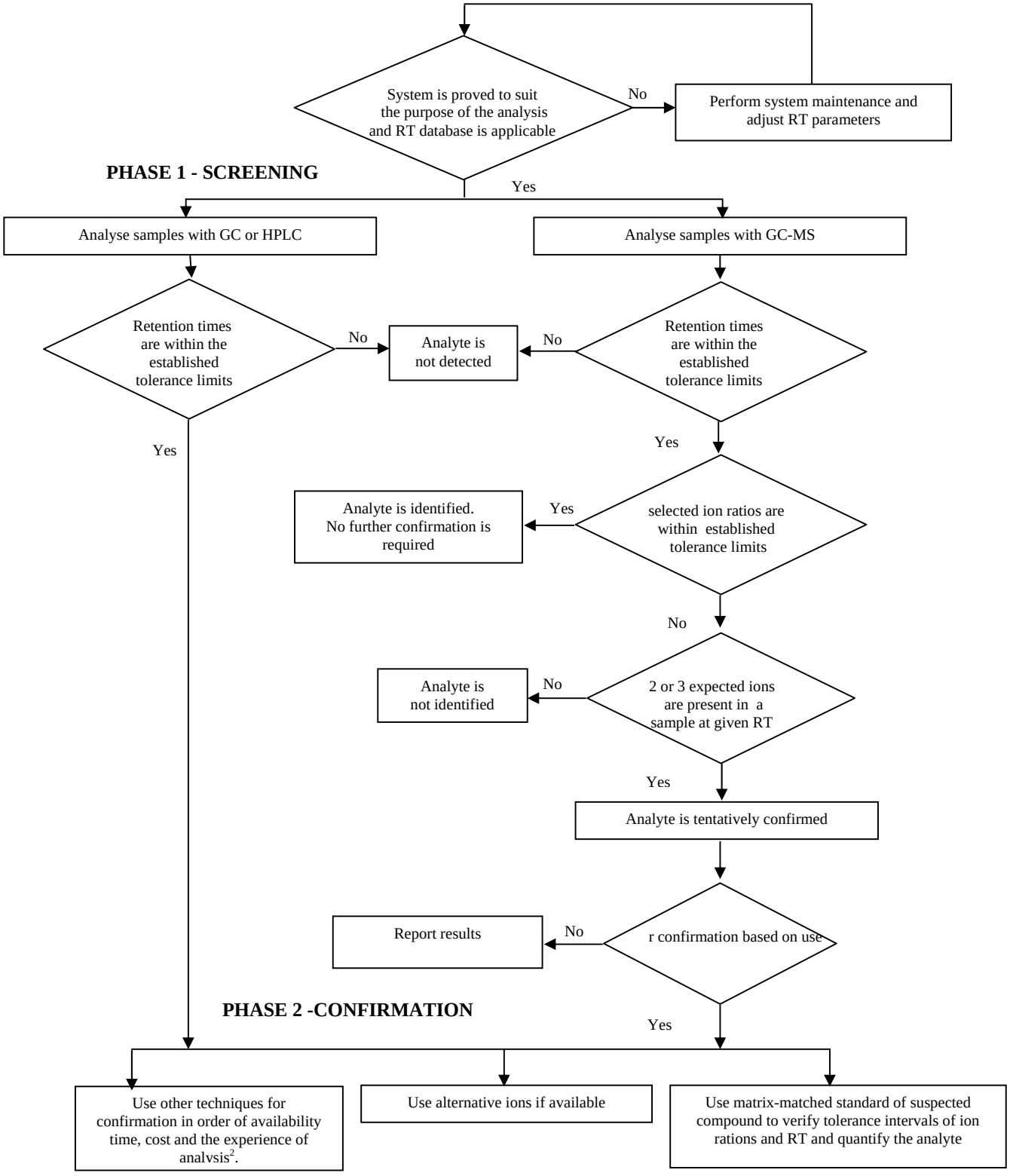

Figure 2. Schematic Representation of Screening and Confirmation (Phase 1 and Phase 2) for Pesticide Residues

1 - Unusual values including banned substances, MRL violation or study requirements as in e.g. exposure assessment

2 – Refer to table 6 for other means of confirmation

3 - For a small number of pesticides the mass spectrum may only exhibit one specific ion. In this case alternative confirmation should be sought.

APPENDIX XI

PROPOSED NEW CODES FOR COMMODITIES WITH ADOPTED MRLs

At Step 5/8 of the Procedure

Proposed food groups and letter codes:

Group 75: Manufactured Foods (single-ingredient) of fruit; Group letter Code: FW

Group 76: Manufactured Foods (single-ingredient) of vegetables; Group letter Code: VW

Group 77: Manufactured Foods (single-ingredient) of miscellaneous; Group letter Code: MW

Proposed commodity codes:

VW 0448 Tomato paste

AV 0495 Rape seed forage

AV 0702 Sunflower forage

AF 1053 Sorghum forage (dry)

CM 1207 Rice hulls

AB 0691 Cotton seed hulls

AB 1203 Cotton seed meal

AB 0541 Soya bean hulls

AB 1265 Soya bean meal

AB 0447 Sweet corn cannery waste

APPENDIX XII

PROPOSED DRAFT GUIDELINES ON ESTIMATION OF UNCERTAINTY OF RESULTS

Advanced for adoption at Step 5

1. INTRODUCTION

It is a requirement under ISO/IEC 17025 that laboratories determine and make available the uncertainty associated with analytical results. To this end, food testing laboratories operating under Revised Guidelines on Good Laboratory Practice in Pesticide Residue Analysis[1] should have available sufficient data derived from method validation/verification, inter-laboratory studies and in-house quality control activities, which can be applied to estimate the uncertainties particularly for the routine methods undertaken in the laboratory. These guidelines were prepared taking into account the general recommendations of the CCMAS

1.1 CONCEPT AND COMPONENTS OF UNCERTAINTY

Measurement uncertainty refers to the 'uncertainty' associated with data generated by a measurement process. In analytical chemistry, it generally defines the uncertainty associated with the laboratory process but may also include an uncertainty component associated with sampling.

The uncertainty 'estimate' therefore describes the range around a reported or experimental result within which the true value can be expected to lie within a defined level of probability. This is a different concept to measurement error which can be defined as the difference between an individual result and the true value. The reporting of uncertainty is intended to provide a higher level of confidence in the validity of the reported result.

Contributions to data uncertainty are manifold and described in detail in Tables 1and 2. The evaluation of uncertainty ideally requires an understanding and estimation of the contributions to the uncertainty of each of the activities involved in the measurement process.

2. IDENTIFICATION OF UNCERTAINTY SOURCES

In general, the uncertainty of measurements is comprised of many components, arising from activities involved with the sample. The uncertainty of an analytical result is influenced by three major phases of the determination:

- External operations: sampling (S_S), packing, shipping and storage of samples[2];
- Preparation of test portion: sub-sampling, sample preparation and sample processing (S_{Sp});
- Analysis (S_A): extraction, cleanup, evaporation, derivatisation, instrumental determination

The combined standard (S_{Res}) and relative (CV_{Res}) uncertainty may be calculated according to the error propagation law:

$$S_{Res} = \sqrt{S_S^2 + (S_{Sp}^2 + S_A^2)} \;;\; S_{Res} = \sqrt{S_S^2 + S_L^2} \qquad (1)$$

If the whole sample is analysed, the mean residue remains the same and the equation can be written as:

$$CV_{Res} = \sqrt{CV_S^2 + CV_L^2} \text{ and } CV_L = \sqrt{CV_{Sp}^2 + CV_A^2} \qquad (2)$$

Where CV_L is the relative uncertainty of the laboratory phase of the determination which may derive from the sub-sampling, sample preparation, sample processing and analytical steps.

[1] Report of the 35th Session of CCPR Appendix VI

[2] Packing, shipping, storage, and laboratory preparation of samples may have significant influence on the residues detected, but their contribution to the uncertainty can often not be quantified based on the current information. Examples of such errors are e.g, selection of sampling position, time of sampling, Incorrect labelling decomposition of analytes or contamination of the sample

It should be noted that a laboratory is normally only required to estimate the uncertainty associated with those processes for which it has control, that is, only those processes that take place in the laboratory if sampling is not the responsibility of the laboratory staff.

2.1 ERRORS IN ANALYTICAL MEASUREMENTS

In most measurements we can distinguish between three types of errors: gross, random and systematic errors.

Gross errors refer to unintentional/unpredictable errors while generating the analytical result. Errors of this type invalidate the measurement. Laboratory quality assurance procedures should minimize gross errors. It is not possible or desirable to statistically evaluate and include the gross errors in the estimation of uncertainty. They need no further discussion in this document.

Random errors are present in all measurements, and cause replicate results to fall on either side of the mean value. The random error of a measurement cannot be compensated for, but increasing the number of observations and training of the analyst may reduce the effects.

Systematic errors occur in most experiments, but their effects are quite different. The sum of all the systematic errors in an experiment is referred to as the bias. Since they do not sum to zero over a large number of measurements, individual systematic errors cannot be detected directly by replicate analyses. The problem with systematic errors is that they may go undetected unless appropriate precautions are taken. In practice, systematic errors in an analysis can only be identified if the analytical technique is applied to a reference material, the sample is analysed by another analyst or preferably in another laboratory, or by re-analysing the sample by another analytical method. However, only if the reference material matches identically in terms of analyte, matrix, and concentration does it meet the ideal conditions for determining the bias of the method. The bias of a method may also be investigated by recovery studies. However, recovery studies assess only the effects of analysis (S_A) and do not necessarily apply to naturally incurred samples, or components of the bias that may be introduced prior to the analytical step. In pesticide analysis, results are not normally corrected for the recovery, but should be corrected if the average recovery is significantly different from 100%. If the result has been corrected for recovery, the uncertainty associated with recovery should be incorporated in the uncertainty estimation of the measurement.

Some examples of sources of errors are illustrated in Tables 1 and 2 It should be noted that not all sources mentioned have to be evaluated in the uncertainty estimation. Some sources are already incorporated in the overall uncertainty, while others are negligible and may be disregarded. However, it is important to recognise and assess all sources before elimination. Further information may be obtained from published documents[1,2].

[1] EURACHEM Guide to Quantifying Uncertainty in Analytical Measurements, 2nd ed. 1999, http://www.measurementuncertainty.org

[2] Ambrus A. Reliability of residue data, Accred. Qual. Assur. 9, pp. 288-304. 2004.

Table 1: Sources of error in preparation of the test portion

	Sources of systematic error	Sources of random error
Sample preparation	The portion of sample to be analysed (analytical sample) may be incorrectly selected	The analytical sample is in contact and contaminated by other portions of the sample
		Rinsing, brushing is performed to various extent, stalks and stones may be differentially removed
Sample processing (S_{Sp})	Decomposition of analyte during sample processing, cross contamination of the samples	Non homogeneity of the analyte in single units of the analytical sample
		Non homogeneity of the analyte in the ground/chopped analytical sample
		Variation of temperature during the homogenisation process
		Texture (maturity) of plant materials affecting the efficiency of homogenisation process

Table 2: Sources of error in analysis (S_A):

	Sources of systematic error	Sources of random error
Extraction/Cleanup	Incomplete recovery of analyte	Variation in the composition (e.g. water, fat, and sugar content) of sample materials taken from a commodity
	Interference of co-extracted materials (load of the adsorbent)	Temperature and composition of sample/solvent matrix
Quantitative determination	Interference of co-extracted compounds	Variation of nominal volume of devices within the permitted tolerance intervals
	incorrect purity of analytical standard	Precision and linearity of balances
	Biased weight/volume measurements	Incomplete and variable derivatisation reactions
	Operator bias in reading analogue instruments, equipment	Changing of laboratory-environmental conditions during analysis
	Determination of substance which do not originate from the sample (e.g. contamination from the packing material)	Varying injection, chromatographic and detection conditions (matrix effect, system inertness, detector response, signal to noise variation etc.)
	Determination of substance differing from the residue definition	Operator effects (lack of attention)
	Biased calibration	Calibration

3. PROCEDURES FOR ESTIMATING MEASUREMENT UNCERTAINTY

Whilst there are a number of options available to laboratories for the estimation of measurement uncertainty, there are two preferred procedures described commonly as the 'bottom up' approach and the 'top down' approach[1].**The bottom-up method:**

The bottom up or component-by-component approach incorporates an activity-based process whereby the analyst breaks down all the analytical operations into primary activities. These are then combined or grouped into common activities and an estimate made of the contribution of these activities to the combined uncertainty value of the measurement process. The bottom up approach can be very laborious and requires a detailed knowledge of the whole analytical process. The benefit to the analyst is that this approach provides a clear understanding of the analytical activities which contribute significantly to the measurement uncertainty and which therefore may be assigned as critical control points to reduce or manage measurement uncertainty in future applications of the method.

The top-down method:

The top down approach is based on method validation and long-term precision data derived from laboratory control samples, proficiency testing results, published literature data and/or inter-laboratory collaborative trials. Uncertainty estimates based on inter-laboratory studies may also take into account the between-laboratory variability of the data and provides a reliable estimate of the method performance and the uncertainty associated with its application. It is important to acknowledge however that collaborative studies are designed to evaluate the performance of a specific method and participating laboratories. They normally do not evaluate imprecision due to sample preparation or processing as the samples generally tend to be highly homogenized.

Pesticide residue analytical laboratories normally look for over 200 residues in numerous commodities that lead to practically infinite number of combinations. Therefore it is suggested that, for estimating the uncertainty associated with multi residue procedures, laboratories use a properly selected range of analytes and sample matrices which represents the residues and commodities to be analysed in terms of physical chemical properties and composition according to the relevant parts of the *Revised Guidelines on Good Laboratory Practice* rather than establishing the uncertainty for each method/analyte/matrix combination. The selection of a representative range of analytes and matrices to provide an uncertainty estimate should be supported by validation data and studies on the selected matrix / analyte combination.

In summary, laboratories should use either their own long-term precision data or the activity-based procedure (component by component calculation) to establish and refine the uncertainty data.

In certain situations it may also be appropriate to estimate the uncertainty contribution due to sample variability. This will require an understanding of the analyte variability within the sample lot and is not readily available to the laboratory or the analyst The values obtained from the statistical analysis of over 8500 residue data (Table 4) provide currently the best estimate[1]. These estimates can be incorporated into the combined uncertainty value.
Likewise it may be necessary to take into consideration the stability of analytes during sample storage and processing if these are likely to result in analyte variability between analysts and laboratories.

3.1 UNCERTAINTY ESTIMATES OF RESULTS INVOLVING ANALYSIS OF MULTI-COMPONENTS

The estimation of uncertainty of results for multi-component residues arising from the application of technical mixtures including structural and optical isomers, metabolites and other breakdown products may require a different approach particularly where the MRL has been established for the sum of all or some of the component residues. The assessment of the random and systematic errors of the results based on the measurements of multiple peaks is explained in detail in a recent publication[2].

[1] Ambrus A and Soboleva E. Contribution of sampling to the variability of residue data, JAOAC. 87, 1368-1379, 2004.
[2] Soboleva E., Ambrus A., Jarju O., Estimation of uncertainty of analytical results based on multiple peaks, J. Chromatogr. A. 1029. 2004, 161-166

4. GUIDANCE VALUES FOR ACCEPTABLE UNCERTAINTIES

The establishment of the standard deviation of a series of tests ran by a single laboratory, as a measure of standard uncertainty, requires the results a large data-set that is not always available. However, for smaller amounts of data the true standard deviation can be estimated as follows:

Depending on the number of observations (n), the relation of the true (σ) standard deviations, calculated (S) standard deviations, and the expected range of the mean value ($\bar{x}$) at 95% probability are illustrated in Table 3. The multiplying factor, ***f***, provides the link between the estimated and true values as the function of the number of measurements.

Table 3 The values of *f* for calculation of expected ranges of standard deviation and mean values

n	$S_{min}=\boldsymbol{f}_1\sigma$	$S_{max}=\boldsymbol{f}_2\sigma$	$\bar{x} = \pm\boldsymbol{f}_3 S$
	$\boldsymbol{f}_1$	$\boldsymbol{f}_2$	$\boldsymbol{f}_3$
5	0.35	1.67	1.24
7	0.45	1.55	0.92
15	0.63	1.37	0.55
31	0.75	1.25	0.37
61	0.82	1.18	0.26
121	0.87	1.13	0.18

For instance: the repeatability of the laboratory operations, CV_L, was determined from 7 test portions drawn from a homogenised sample containing incurred residues. The average residue found was 0.75 mg/kg with a standard deviation of 0.2 mg/kg. The true residue of the processed sample can be expected between 0.75± 1.24*0.2 = 0.75±`0.248 mg/kg, while the true uncertainty of the measurement results is likely to be between 0.0696 (0.2*0.35) and 0.334 (0.2*1.67) mg/kg in 95% of the cases.

The guidance values for standard uncertainty, given in Table 4, are based on a large number of data and can be used to assess the reality of the estimated uncertainty in a laboratory in order to avoid an unreasonable high or low value.

Table 4. Typical expected uncertainties of major steps of pesticide residue analysis

Procedure	**Relative uncertainty**	**Comments**
Sampling of commodities of plant origin. Reflects the variation of mean residues being in composite samples taken randomly from a lot. It does not incorporate the errors of follow-up procedures.	Medium and small commodities. (Sample size ≥10)[a]: 26-30%[b]	For testing compliance with MRLs, the sampling uncertainty is 0, as the MRLs refer to the average residues in bulk samples.
	Large commodities. (Sample size ≥5)[a]: 36-40%[b]	
Sampling of animal products	The relation between the number of samples (n) to be taken for detection of a specified percentage of violation (β_p) with a given probability (β_t), is described by[a]: $1-\beta_t = (1-\beta_p)^n$	The primary samples should be selected randomly from the whole lot.
Sample processing Includes the physical operation performed for	Largely varying depending on sample matrix and equipment. No typical value can be given.	It may be influenced by the equipment used for chopping / homogenising the sample and the

Procedure	Relative uncertainty	Comments
homogenizing the analytical sample and subsampling , but excludes decomposition and evaporation of analytes.	The analysts should try to keep it[c] below 8-10%.	sample matrix, but it is independent from the analyte.
Analysis It includes all procedures performed from the point of spiking of test portions.	Within laboratory reproducibility: 16-53% for concentrations of 1µg/kg to 1 mg/kg[c]. Average between- laboratories reproducibility within 0.001-10 mg/kg: 25%[d]	The typical CV_A can be conveniently determined from the recovery studies performed with various pesticide-commodity combinations on different days and during the use of the method.

Notes:

(a) Codex Secretariat. Recommended method of sampling for the determination of pesticide residues for compliance with MRLs, ftp://ftp.fao.org/codex/standard/en/cxg_033e.pdf .

(b) Ambrus A. Soboleva E. Contribution of sampling to the variability of residue data, JAOAC, 87, 1368-1379, 2004;

(c) Codex Secretariat, Revised Guidelines on Good Laboratory Practice in Residue Analysis ftp://ftp.fao.org/codex/alinorm03/al03_41e

(d) Alder L., Korth W., Patey A., van der Schee and Schoeneweis S., Estimation of Measurement Uncertainty in Pesticide Residue Analysis, J. AOAC International, 84, 1569-1578, 2001

In addition to the estimated uncertainties made by the individual laboratories, regulatory authorities and other risk managers may decide on a default expanded uncertainty of measurements which can be used in judging compliance with MRLs (See section 5) based on between-laboratories reproducibility values. For instance, a 50% expanded uncertainty for CV_L is considered to be a reasonable default value.

5. USE OF UNCERTAINTY INFORMATION

If required, the result should be reported together with the expanded uncertainty, U, as follows

Result = $x \pm U$ (units)

The expanded uncertainty, U, may be calculated from the standard combined uncertainty (S_{Res}) with a coverage factor of 2 as recommended by EURACHEM or with the Student ***t*** value for the level of confidence required (normally 95%) where the effective degree of freedom is less than 20. The respective calculations for the expanded uncertainty are as follows

$$U = 2S_{Res} \quad \text{or} \quad U = t_{v,0.95}S_{Res} \qquad (3)$$

The numerical value of the reported results should follow the general rule that the last digit can be uncertain. Rounding the results should be done only when the final result is quoted since rounding at the initial stages of calculation may introduce unnecessary bias in the calculated values.

For the purpose of explication, it is assumed that the best estimate of the residue content is reported for a sample. How the results are interpreted depends upon the purpose of the testing. Typical reasons include testing compliance with the national MRL, certifying compliance with the Codex MRL of a commodity for export.

5.1 Testing compliance with an MRL

Figure 1 shows how the testing results can be displayed in terms of the measured value of the residue, the corresponding uncertainty interval, and the MRL.

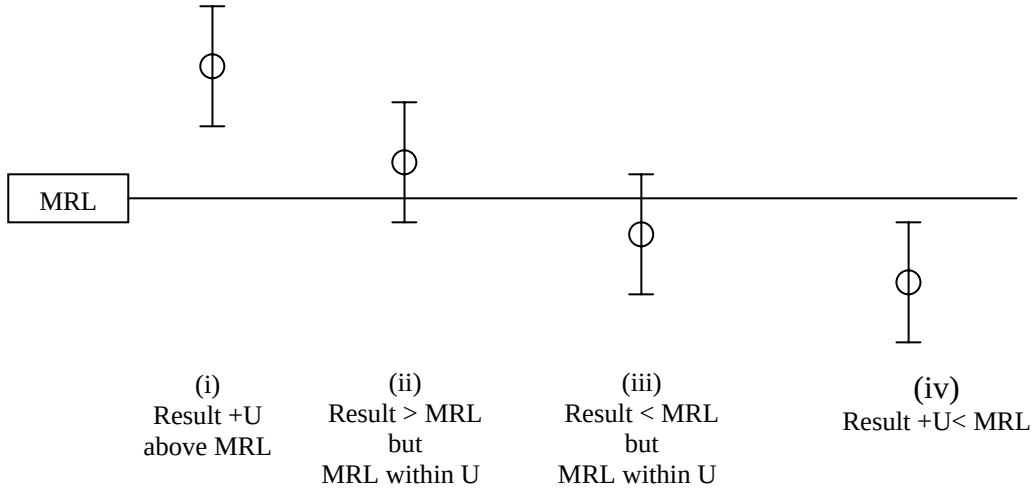

Figure 1. Illustration of the relationship of measured value expected uncertainty and MRL

Situation (i)

The analytical result bounded by the measurement uncertainty endpoints is greater than the MRL. The result indicates that the residue in the sampled lot is above the MRL.

Situation (ii)

The analytical result is greater than the MRL with the lower endpoint of the measurement uncertainty less than the MRL

Situation (iii)

The analytical result is less than the MRL with the upper endpoint of the measurement uncertainty being greater than the MRL.

Situation (iv)

The analytical result bounded by the expanded measurement uncertainty endpoints is less than the MRL.

5.2 Decision Environment

The examples given below are relevant for products of plant origin. The compliance of residues with MRLs for animal products should be decided following sampling plans based on distribution free statistics and examples given in the document on Recommended Methods of Sampling for the Determination of Pesticide Residues for Compliance with MRLS[1].

5.2.1 Testing of commodities for the domestic market

Since the residues in every sample that concurs with the minimum sample size and sample mass specified in the Codex Sampling Procedure should comply with the MRL, the expanded uncertainty should be calculated using S_L from equation 2 as $U = kS_L$.where $S_L = CV_L$* residue.

The decision-making in Situation (i) is clear. In order to avoid lengthy explanation of the uncertainty in a court case involving the performance of the analysis for testing compliance with the MRL at the national level in locally produced or imported commodities, the laboratory may report the results as the sample contains "not less than 'x – U' residues." Hence, action may be taken by enforcement authorities after the testing laboratory reports that the MRL was exceeded accounting for uncertainty. This satisfies the requirement that the MRL was exceeded beyond reasonable doubt should the results be challenged.

The same clarity is observed in Situation (iv). The sample should be considered compliant by all Enforcement Authorities.

[1] *ftp://ftp.fao.org/codex/standard/en/cxg_033e.pdf* .

The middle situations may be problematic for decision-makers. If the uncertainty of the result is not used in Situation (ii), the lot would be declared noncompliant which is an incorrect decision. Since the deviation from the MRL is within the uncertainty of the measurement, the sampled lot should be declared as being compliant with the MRL. In Situation (iii), the sampled lot would generally be considered as being compliant with the MRL by Enforcement Authorities.

5.2.2 Certifying compliance of a lot to be exported

The certification of compliance with the MRL of a lot based on composite sample(s) of specified size by the laboratory requires that the uncertainty of sampling is taken into account.

The coverage factor, k, required for the calculation of the expanded uncertainty depends on the number of effective degrees of freedom of the estimated standard uncertainty (S_{Res}) and the target percentage of compliance. To be on the safe side it should be selected at 99% probaility and confidence levels. Since the coverage is important on the upper end of the distribution: one sided tolerance factors may be used for calculation of the coverage factor.
The tested lot is compliant if the analytical result, X, plus the upper bound of the measurement uncertainty limit (situation iv) is less than the MRL. That is, $X+kS_{Res} < MRL$.

Table 6 Coverage factors for the calculation of expanded uncertainty $U= kS_{Res}$ [a]

Degree of freedom	t at 95%[b]	k at $\beta_p=0.95,\beta_t=0.95$[c]	k at $\beta_p=0.99,\beta_t=0.99$[c]
5	2.6	3.7	7.3
15	2.1	2.6	4.3
20	2.1	2.4	3.9
∞	2	1.65	2.3

Notes: (a) The expanded uncertainty uses S_{Res} from equation 1.
(b) This is recommended by EURACHEM.
(c) The coverage is important on the upper end of the distribution: one sided tolerance factors are included in the table.

Examples:

(a) For example, if the MRL is 1 mg/kg and the combined relative standard uncertainty of the pesticide result is 0.33 based on 20 degrees of freedom (one-sided coverage factor at 99% probability and a k value of 3.9), with the measured residue at 0.55 mg/kg. When the commodity is to be exported this ensures that 99% of the samples taken from the lot are compliant, the measured residue value of 0.55 mg/kg indicating that the lot should not be exported because in 99% of the cases up to 1.3 mg/kg residue may occur (0.55 + 3.9*0.33*0.55 = 1.258) as illustrated in situation (iii).

(b) The residue measured in one sample must be ≤0.43 mg/kg to certify compliance (0.43 + 3.9*0.43*0.33 = 0.983; 0.44+3.9*0.33*0.44=1.006 mg/kg).

(c) Where more than one sample can be taken and analyzed the uncertainty of the measured value can be reduced and higher average residue may be acceptable. It is emphasized, however, that none of the samples may contain residues above the MRL.

Glossary of terms used in the text[a]

Blank (sample, reagent)	(i) Material (a sample, or a portion or extract of a sample) known not to contain detectable levels of the analyte(s) sought. Also known as a matrix blank. (ii) A complete analysis conducted using the solvents and reagents only, in the absence of any sample (water may be substituted for the sample, to make the analysis realistic). Also known as a reagent blank or procedural blank.
Combined standard uncertainty	For a measurement result, y, the total uncertainty, $u_c(y)$ is an estimated standard deviation equal to the positive square root of the total variance obtained by combining all uncertainty components using the law of propagation of uncertainty (error propagation law)
Contamination	Unintended introduction of the analyte into a sample, extract, internal standard solution etc., by any route and at any stage during sampling or analysis.
Residue definition	The definition of a residue is that combination of the pesticide and its metabolites, derivatives and related compounds to which the MRL applies or which is used for dietary exposure assessment.
Determination system	Any system used to detect and determine the concentration or mass of the analyte. For example, GC-FPD, LC-MS/MS, LC with post-column derivatisation, ELISA, TLC with densitometry, or bioassay.
Level	In this document, refers to concentration (e.g. mg/kg, µg/ml) or quantity (e.g. ng, pg).
Lot	A quantity of a food material delivered at one time and known, or presumed, by the sampling officer to have uniform characteristics such as origin, producer, variety, packer, type of packing, markings, consignor, etc.
Matrix effect	An influence of one or more undetected components from the sample on the measurement of the analyte concentration or mass. The response of some determination systems (e.g. GC, LC-MS, ELISA) to certain analytes may be affected by the presence of co-extractives from the sample (matrix).
Procedural blank	See blank.
Reagent blank	See blank.
Response	The absolute or relative signal output from the detector when presented with the analyte.
Spike or spiking	Addition of analyte for the purposes of recovery determination or standard addition.
Standard uncertainty	Expressed as the standard deviation of an uncertainty component.
Unit (as part of sample)	A single fruit, vegetable, animal, cereal grain, can, etc. For example, an apple, a T-bone steak, a grain of wheat, a can of tomato soup.
Violative residue	A residue which exceeds the MRL or is unlawful for any other reason.

Note (a). The definitions given are based on the following references[1,2,3,4]. Additional definitions are given in the revised GLs on Good laboratory Practice in Residue Analysis[5]

[1] EURACHEM (2000) EURACHEM/CITAC Guide Quantifying Uncertainty in Analytical Measurements 2nd ed. http://www.measurementuncertainty.org

[2] Codex Secretariat. Recommended method of sampling for the determination of pesticide residues for compliance with MRLs, ftp://ftp.fao.org/codex/standard/en/cxg_033e.pdf

[3] Willetts P, Wood R (1998) Accred Qual Assur 3: 231-236

[4] , International Vocabulary of basic and general terms in Metrology, Geneva 1993

[5] Report of the 35th Session of CCPR Appendix VI

APPENDIX XIII

PROPOSED DRAFT RISK ANALYSIS PRINCIPLES APPLIED BY THE CODEX COMMITTEE ON PESTICIDE RESIDUES

Advanced for adoption at Step 5

SCOPE

1. This document addresses the respective applications of risk analysis principles by the Codex Committee on Pesticide Residues (CCPR) and the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) and facilitates the uniform application of the Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius[1].

ROLES OF CCPR AND JMPR IN RISK ANALYSIS

Interaction between CCPR and JMPR

2. In addressing pesticide residue issues in Codex, providing advice on risk management is the responsibility of the Codex Alimentarius Commission (CAC) and CCPR while conducting risk assessment is the responsability of JMPR.

3. CCPR and JMPR recognize that an adequate communication between risk assessors and risk managers is an essential requirement for successfully performing their risk analysis activities.

4. CCPR and JMPR should continue to develop procedures to enhance communication between the two committees.

5. CCPR and JMPR should ensure that their contributions to the risk analysis process are scientifically based, fully transparent, thoroughly documented and available in a timely manner to Member States[2].

6. JMPR, in consultation with CCPR, should continue to explore developing minimum data requirements necessary for JMPR to perform risk assessments. These criteria should be used by CCPR in preparing its Priority List for JMPR. The JMPR Secretariat should consider whether these minimum data requirement have been met when preparing the provisional agenda for meetings of JMPR.

Role of CCPR

7. CCPR is primarily responsible for recommending risk management proposals for adoption by the CAC.[3]

8. CCPR shall base its risk management recommendations, such as MRLs, to the CAC on JMPR's risk assessments of the respective pesticides.

9. In cases where JMPR has performed a risk assessment and CCPR or the CAC determines that additional scientific guidance is necessary, CCPR or CAC may make **a** specific request to JMPR to provide the scientific guidance necessary for a risk management decision.

10. CCPR's risk management recommendations to the CAC shall be based on JMPR's [quantitative] risk assessments and other legitimate factors relevant to the health protection of consumers and for the promotion of fair practices in food trade.

11. CCPR's risk management recommendations to the CAC shall take into account the relevant uncertainties and safety factors as described by JMPR.

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[1] ALINORM 03/26/6

[2] Submission and evaluation of pesticide residues data for the estimation of maximum residue levels in food and feed; FAO Plant Production and Protection Paper, 170, 2002, ISBN 92-5-104759-6

[3] Reports of CCPR sessions are available from the Codex Alimentarius web site: www.codexalimentarius.net.

12. CCPR shall consider maximum residue levels (MRLs) only for those pesticides for which JMPR has completed a full safety evaluation including a quantitative risk assessment.

13. CCPR shall base its recommendations on the GEMS/Food regional diets used to identify consumption patterns on a global scale when recommending MRLs in food. The GEMS/Food regional diets are used to assess the risk of chronic exposure. The acute exposure calculations are not based on those diets, but on the consumption data provided by some member countries.

14. When establishing its standards, CCPR shall clearly state when it applies any non-science-based considerations in addition to JMPR's risk assessment and specify its reasons for doing so.

15. CCPR shall consider the following when preparing its priority list of compounds for JMPR evaluation:

- CCPR's Terms of Reference;
- JMPR's Terms of Reference;
- The Codex Alimentarius Commission's Medium-Term Plan of Work;
- The Criteria for the Establishment of Work Priorities;
- The Criteria for Inclusion of Compounds on the Priority List;
- The Criteria for Selecting Food Commodities for which Codex MRLs or EMRLs should be Established;
- The Criteria for Evaluation of New Chemicals;
- The Criteria for Prioritising Chemicals for Periodic Re-evaluation; and
- A commitment to provide the necessary data for the evaluation in time.

16. When referring substances to JMPR, the CCPR shall provide background information and clearly specify the reasons for the request when chemicals are nominated for evaluation.

17. When referring substances to JMPR, the CCPR may also refer a range of risk management options, with a view toward obtaining JMPR's guidance on the attendant risks and the likely risk reductions associated with each option.

18. CCPR shall request JMPR to review any methods and guidelines being considered by CCPR for assessing maximum limits for pesticides.

Role of JMPR

19. JMPR is primarily responsible for performing the risk assessments upon which CCPR and ultimately the CAC base their risk management decisions[4]. JMPR also proposes MRLs based on Good Agricultural Practices (GAPs)/ registered uses.

20. JMPR should select scientific experts on the basis of their competence and independence, taking into account geographical representation where possible.

21. JMPR should strive to provide CCPR with science-based risk assessments that include the four components of risk assessment as defined by CAC and safety assessments that can serve as the basis for CCPR's risk-management discussions. JMPR should continue to use its risk assessment process for establishing ADIs and Acute Reference Doses where appropriate.

[4] JMPR reports and evaluation monographs are available from the FAO web site: www.fao.org/ag/agp/agpp/Pesticid/Default.htm

22. JMPR should provide CCPR with information on the applicability and any constraints of the risk assessment to the general population and to particular sub-populations and will as far as possible identify potential risks to populations of potentially enhanced vulnerability (e.g. children).

23. Recognizing that primary production in developing countries is largely through small and medium size enterprises, JMPR should strive to base its risk assessments on global data, including that from developing countries. These data may include monitoring data and exposure studies.

24. JMPR is responsible for evaluating exposure to pesticides. When evaluating intake of pesticides during its risk assessment, JMPR should take into account the GEMS/Food regional diets used to identify consumption patterns on a global scale. The GEMS/Food regional diets are used to assess the risk of chronic exposure. The acute exposure calculations are not based on those diets, but on the consumption data as provided by some countries.

25. JMPR should communicate to CCPR the magnitude and source of uncertainties in its risk assessments. When communicating this information, JMPR should provide CCPR a description of the methodology and procedures by which JMPR estimated any uncertainty in its risk assessment.

26. JMPR should communicate to CCPR the basis for all assumptions used in its risk assessments.

ANNEX: LIST OF RISK MANAGEMENT POLICIES USED BY CCPR

1. This part of the document addresses the risk management policy that is used by the Codex Committee on Pesticides Residues (CCPR) when discussing the risk assessments, the exposure to pesticides and the proposals for MRLs which are the outcomes of the Joint FAO/WHO Meeting on Pesticides Residues (JMPR).

ESTABLISHMENT OF MRLs/EMRLs

Procedure for Proposing Pesticides for Codex Priority Lists

2. CCPR has developed a policy document in relation to establishing a priority list of pesticides for evaluation or re-evaluation by JMPR[5].

3. Before a pesticide can be considered for the Priority List, it must:

- be available for use as a commercial product; and
- not have been already accepted for consideration.

4. To meet the criteria for inclusion in the priority list, the use of the pesticide must: give rise to residues in or on a food or feed commodity moving in international trade, the presence of which is (or may be) a matter of public health concern and thus create (or have the potential to create) problems in international trade.

5. When prioritising new chemicals for evaluation by the JMPR, the Committee shall consider the following criteria:

- if the chemical has a reduced acute and/or chronic toxicity to humans compared with other chemicals in its classification;
- the data nominated;
- the date that data will be submitted; and
- where possible, allocating new chemicals to be evaluated on at least a 50:50 basis with periodic re-evaluation chemicals to be evaluated.

6. When prioritising chemicals for periodic re-evaluation by the JMPR, the Committee shall consider the following criteria:

- chemicals that have not been reviewed toxicologically for more than 15 years and/or not having a significant review of maximum residue limits;
- the year the chemical is listed in the list for Candidate Chemicals for Periodic Re-evaluation – not yet scheduled;
- the date that data will be submitted and the availability of data;
- if the intake and/or toxicity profile indicate some level of public health concern;
- whether the CCPR has been advised by a national government that the chemical has been responsible for trade disruption;

[5] Draft Revised Criteria for Prioritization Process of Compounds for Evaluation by JMPR; ALINORM 04/28/24, Appendix XV.

- if there is a closely related chemical that is a candidate for periodic re-evaluation that can be evaluated concurrently; and

- allocating periodic re-evaluation chemicals to be evaluated on a maximum ratio of 50:50 with new chemicals to be evaluated.

7. Once the JMPR has reviewed a chemical, three scenarios may occur:

- the data confirm the existing Codex MRL, it remains in place, or

- a new MRL is recommended or an amendment of an existing MRL. The new or amended proposal enters at Step 3 of the Codex procedure. The existing MRL remains in place for no more than four years or

- insufficient data have been submitted to confirm or amend an existing Codex MRL. The Codex MRL is recommended for withdrawal. However, the manufacturer or countries may provide a commitment to the JMPR and CCPR to provide the necessary data for review within four years. The existing Codex MRL is maintained for a period of no more than four years pending the review of the additional data. A second period of four years is not granted.

MRLs for Commodities of Animal Origin

8. Farm animal metabolism studies are required whenever a pesticide is applied directly to livestock, to animal premises or housing, or when significant residues remain in crops or commodities used in animal feed, in forage crops, or in plant parts that could be used in animal feeds. The results of farm animal feeding studies and residues in animal feed serve also as a primary source of information for estimating maximum residue levels in animal products.

9. If no adequate studies are available, no MRLs will be established for commodities of animal origin. MRLs for feeds (and the primary crops) should not be established in the absence of animal transfer data. Where the exposure of livestock to pesticides through feeds leads to residues at the limit of quantitation, MRLs at the LOQ must be established for animal commodities. MRLs should be established for all mammalian species where pesticides on feeds are concerned and for specific species (e.g cattle, sheep) where direct treatments of pesticides are concerned.

10. Where the recommended maximum residue limits for animal commodities resulting from direct treatment of the animal, regardless of whether they are recommended by JMPR or JECFA and from residues in animal feed do not agree, the higher recommendation will prevail.

MRLs for Processed or Ready-to-eat Foods or Feeds

11. CCPR agreed not to establish MRLs for processed foods and feeds unless separate higher MRLs are necessary for specific processed commodities. However, this policy is under discussion at the moment.

MRLs for spices

12. CCPR agreed that MRLs for spices can be established on the basis of monitoring data in accordance with the guidelines established by JMPR.

MRLs for fat-soluble pesticides

13. [Under discussion at the moment]

Establishment of MRLs

14. The CCPR is entrusted with the elaboration of Maximum Residue Limits (MRLs) of pesticide residues in food and feed. The JMPR is using the WHO Guidelines for predicting dietery intake of pesticides

residues (revised)(1997)[6]. The JMPR is recommending MRLs establishing Supervised Trial Median Residues (STMRs) for new and periodic review compounds for dietary intake purposes. In cases the intake exceeds the Acceptable Daily Intake (ADI) in one or more of the regional diets, the JMPR, when recommending MRLs, flags this situation indicating the type of data which may be useful to further refine the dietary intake estimate.

15. When the ADI is exceeded in one or more regional diets, then the MRLs will not advance to Step 8 pending further refinement of the intake at the international level. If further refinement is not possible then MRLs (and CXLs) are withdrawn until the remaining MRLs and CXLs give no longer rise to intake concerns. This procedure should be reviewed at regular interval.

16. The JMPR is currently routinely establishing acute reference doses (ARfDs), where appropriate, and indicates cases where an ARfD is not necessary. The 1999 JMPR for the first time calculated the short-term dietary intake estimates following an approach using the International and National Estimates of Short-term Intake (IESTI, NESTI). The procedure allows for estimating the short-term risk for relevant subgroups of the population, like children. The JMPR flags cases when the IESTI for a given commodity exceeds the acute RfD.

17. When the ARfD is exceeded for a given commodity, then the MRLs will not advance to Step 8 pending further refinement of the intake at the international level.

18. When a Draft MRL has been returned to Step 6 three times, the CCPR should ask JMPR to examine residue data from other appropriate GAPs and to recommend MRLs which cause no dietary intake concerns if possible.

19. If further refinement is not possible then MRLs (and CXLs) are withdrawn. More sophisticated methodologies such as probabilistic approaches are under investigation at the moment.

20. The estimate of the short-term dietary intake requires substantial food consumption data that currently are only sparsely available. Governments are urged to generate relevant consumption data and to submit these data to the WHO.

Establishment of EMRLs

21. The Extraneous Maximum Residue Limit (EMRL) refers to a pesticide residue or a contaminant arising from environmental sources (including former agricultural uses) other than the use of the pesticide or contaminant substance directly or indirectly on the commodity. It is the maximum concentration of a pesticide residue that is recommended by the Codex Alimentarius Commission to be legally permitted or recognized as acceptable in or on a food, agricultural commodity or animal feed.

22. Chemicals for which EMRLs are most likely to be needed are persistent in the environment for a relatively long period after uses haven been discontinued and are expected to occur in foods or feeds at levels of sufficient concern to warrant monitoring.

23. All relevant and geographically representative monitoring data (including nil-residue results) are required to make reasonable estimates to cover international trade. JMPR has developed a standard format for reporting pesticide residues monitoring data[7].

24. The JMPR compares data distribution in terms of the likely percentages of violations that might occur if a given EMRL is proposed to the CCPR.

25. Because residues gradually decrease, CCPR evaluates every 5 years, if possible, the existing EMRLs, based on the reassessments of the JMPR.

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[6] Programme of Food Safety and Food Aid; WHO/FSF/FOS/97.7

[7] Submission and evaluation of pesticide residues data for the estimation of maximum residue levels in food and feed; FAO Plant Production and Protection Paper, 170, 2002, ISBN 92-5-104759-6

26. The CCPR generally agreed at the 30th Session on the potential elements for inclusion in a set of criteria for estimation of EMRLS while it also agreed not to initiate a full exercise of criteria elaboration.

Periodic Review Procedure

27. The Committee agreed on the Periodic Review Procedure, which was endorsed by the CAC and attached to the list of MRLs prepared for each session of the CCPR. Those Codex MRLs confirmed by JMPR under the Periodic Review shall be distributed to member countries and interested organizations for comments.

DELETING Codex MRLs

28. Every year new compounds are introduced. These compounds are often new pesticides which are safer than existing ones. Old compounds are then no longer supported/produced by industry and existing Codex MRLs (CXLs) can be deleted.

29. If information is delivered between two sessions of CCPR, that a certain compound is no longer supported, this information will be shared during the first coming session (t=0). The proposal will be to delete the existing CXLs at the following session (t=0+1 year).

30. It may happen that compounds are no longer supported in Codex, but are supported in some selected countries. If there is no international trade in commodities where the active compounds may have been used, CCPR will not establish MRLs.

MRLs AND METHODS OF ANALYSIS

31. JMPR needs data and information for their evaluations. Among these are methods of analysis. Methods should include specialized methods used in supervised trials and enforcement methods.

32. If no methods of analysis are available for enforcing MRLs for a specific compounds, no MRLs will be established by CCPR.

APPENDIX XIV

PRIORITY LIST OF CHEMICALS SCHEDULED FOR EVALUATION AND RE-EVALUATION BY JMPR

The following are the tentative schedules to be evaluated by the FAO/WHO Joint Meeting on Pesticide Residues (JMPR) for 2006-2012

TOXICOLOGICAL EVALUATIONS	Corresponding residue evaluation	RESIDUE EVALUATIONS	Corresponding toxicological evaluation
2006 JMPR			
New Compounds		**New Compounds**	
aminopyralid		aminopyralid	
bifenazate		bifenazate	
boscalid		boscalid	
quinoxyfen		quinoxyfen	
thiacloprid		thiacloprid	
Periodic re-evaluations		**Periodic re-evaluations**	
alpha and zeta cypermethrin	2006R	alpha and zeta cypermethrin	2006T
Cyfluthrin / beta cyfluthrin (157)	2007R	cypermethrin (118)	2004T (JECFA)
cyromazine (169)	2007R	pirimicarb (101)	2004T
		propamocarb (148)	2005T
		triadimefon (133) / triadimenol (168)	2004T
Evaluations		**Evaluations**	
haloxyfop (194) – acute and chronic toxicity	2001R	propargite (113)	2002R (4 year review)
pirimiphos-methyl (086) – acute toxicity	2004R	pyraclostrobin (210)	2003T
thiabendazole (065) – acute toxicity	2006R	thiabendazole (065) additional MRLs	2006T
thiophanate-methyl (077) – acute toxicity		fenamiphos – review of GAPs for MRL proposal	1997T
		disulfoton – review of GAPs for MRL proposal	1996T
		aldicarb – review of GAPs for MRL proposal	2002T

2007 JMPR			
New Compounds		**New Compounds**	
dimethomorph		dimethomorph	
pyrimethanil		pyrimethanil	
zoxamide		zoxamide	
difenoconazole		difenoconazole	
Periodic re-evaluations		**Periodic re-evaluations**	
azinphos-methyl (002)	2008R	benelaxyl (155)	2005T
lambda cyhalothrin	2008R	clofentezine (156)	2005T
flusilazole (165)	2007R	cyfluthrin/beta cyfluthrin (157)	2006T
procymidone (136)	2008R	cyromazine (169)	2006T
profenofos (171)	2007R	flusilazole (165)	2007T
vinclozolin (159)	2008R	permethrin (120)	1999T
		triazophos (143)	2002T
		profenofos (171)	2007T
		propiconazole (160)	2004T
Evaluations		**Evaluations**	
fenitrothion (review of ADI and ARfD)		tebuconazole – additional MRLs	1994T
Carbaryl – review of basis for ARfD setting		carbaryl – additional MRLs	2001T, 2002R

2008 JMPR			
New Compounds		**New Compounds**	
Periodic re-evaluations		**Periodic re-evaluations**	
bioresmethrin (93)	2009R	azinphos-methyl (002)	2007T
buprofezin (173)	2009R	lambda-cyhalothrin replacement of cyhalothrin	2007T
chlorpyrifos-methyl (090)	2009R	procymidone (136)	2006T
hexythiazox (176)	2009R	vinclozolin (159)	2007T
Evaluations		**Evaluations**	

2009 JMPR			
New Compounds		**New Compounds**	
Periodic re-evaluations		**Periodic re-evaluations**	
bifenthrin (178)	2010R	bioresmethrin (93)	2008T
cadusafos (174)	2010R	buprofezin (173)	2008T
chorothalanil (081)	2010R	chlorpyrifos-methyl (090)	2008T
cycloxydim (179)	2010R	hexythiazox (176)	2008T

Evaluations		**Evaluations**	
2010 JMPR			
New Compounds		**New Compounds**	
Periodic re-evaluations		**Periodic re-evaluations**	
aldicarb (117)	2011R	amitraz (122)	1998T
dicofol (026)	2011R	bifenthrin (178)	2009T
dithianon (028)	2011R	cadusafos (174)	2009T
fenbutatin oxide (109)	2011R	chorothalanil (081)	2009T
		cycloxydim (179)	2009T
Evaluations		**Evaluations**	
2011 JMPR			
New Compounds		**New Compounds**	
Periodic re-evaluations		**Periodic re-evaluations**	
dichlorvos (025)	2012R	aldicarb (117)	2010T
diquat (031)	2012R	dicofol (026)	2010T
etofenprox (184)	2012R	dithianon (028)	2010T
fenropathrin (185)	2012R	fenbutatin oxide (109)	2010T
Evaluations		**Evaluations**	

2012 JMPR			
New Compounds		**New Compounds**	
Periodic re-evaluations		**Periodic re-evaluations**	
triforine (116)	2012R	dichlorvos (025)	2011T
		diquat (031)	2011T
		etofenprox (184)	2011T
		fenpropathrin (185)	2011T
		triforine (116)	2012T
Evaluations		**Evaluations**	

APPENDIX XV

DRAFT REVISED CRITERIA FOR PRIORITIZATION PROCESS OF COMPOUNDS FOR EVALUATION BY JMPR

To be submitted to the Committee on General Principles and subsequent adoption by the Commission

1. GENERAL CRITERIA

1.1 CRITERIA FOR INCLUSION OF COMPOUNDS ON THE PRIORITY LIST

Before a pesticide can be considered for the Priority List it:

i must be registered for use in a member country;

ii must be available for use as a commercial product;

iii must not have been already accepted for consideration; and

iv must give rise to residues in or on a food or feed commodity moving in international trade, the presence of which is (or may be) a matter of public health concern and thus create (or have the potential to create) problems in international trade.

1.2 CRITERIA FOR SELECTING FOOD COMMODITIES FOR WHICH CODEX MRLS OR EMRLS SHOULD BE ESTABLISHED

The commodity for which the establishment of a Codex MRL or EMRL is sought should be such that it may form a component in international trade. A higher priority will be given to commodities that represent a significant proportion of the diet.

Note:
Before proposing a pesticide/commodity for prioritization, governments are recommended to check if the pesticide is already in the Codex system. Pesticide/commodity combinations that are already included in the Codex system or under consideration are found in a working document prepared for and used as a basis of discussion at each Session of the Codex Committee on Pesticide Residues. Consult the document of the latest session to see whether or not a given pesticide has already been considered.

2. CRITERIA FOR PRIORITISATION

2.1 New Chemicals

When prioritizing new chemicals for evaluation by the JMPR, the Committee will consider the following criteria:

1. If the chemical has a reduced acute and/or chronic toxicity risk to humans compared with other chemicals in its classification (insecticide, fungicide, herbicide);
2. The date nominated to the Chair, Priorities Working Group;
3. Commitment by the sponsor of the compound to provide supporting data for review with a firm date for data submission;
4. The availability of regional/national reviews and risk assessments, and coordination with other regional/national lists; and
5. Allocating new chemicals to be evaluated on at least a 50:50 basis, if possible, with periodic re-evaluation chemicals to be evaluated.

Note
In order to satisfy the criterion that the proposed new chemical is a "safer" or "reduced risk" replacement chemical, the nominating country is required to provide:

i the name(s) of the chemicals for which the proposed chemical is likely to be an alternative;
ii a comparison of the acute and chronic toxicities of the proposed chemical with other chemicals in its classification (insecticide, fungicide, herbicide);
iii a summary of acute and chronic dietary exposure calculations encompassing the range of diets considered by CCPR; and
iv other relevant information to support classification of the proposed chemical as a safer alternative chemical.

2.2 Periodic Re-Evaluation

When prioritizing chemicals for periodic re-evaluation by the JMPR, the Committee will consider the following criteria:

1. If the intake and/or toxicity profile indicate some level of public health concern;
2. Chemicals that have not been reviewed toxicologically for more than 15 years and/or not having a significant review of maximum residue limits for 15 years;
3. The year the chemical is listed in the list for Candidate Chemicals for Periodic Re-evaluation – Not Yet Scheduled;
4. The date that data will be submitted;
5. Whether the CCPR has been advised by a national government that the chemical has been responsible for trade disruption;
6. If there is a closely related chemical that is a candidate for periodic re-evaluation that can be evaluated concurrently; and
7. The availability of current labels arising from recent national re-evaluations.

2.3 Evaluations

When prioritizing proposed toxicological or residue evaluations by the JMPR the Committee will consider the following criteria:

1. The date the request was received;
2. Commitment by the sponsor to provide the required data for review with a firm date of submission;
3. Whether the data is submitted under the 4-year rule for evaluations; and
4. The nature of the data to be submitted, and the reason for its submission; for example, a request from CCPR.

Note:
Where a pesticide has already been evaluated by the JMPR and MRLs, EMRLs or GLs have been established, new evaluations may be initiated if one or more of the following situations arise:

i New toxicological data becomes available to indicate a significant change in the ADI or ARfD.
ii The JMPR may note a data deficiency in a Periodic Re-evaluation or New Chemical evaluation. In response, national governments or other interested parties may pledge to supply the information to the appropriate Joint Secretary of the JMPR with a copy to the Chair of the Working Group on Priorities. Following scheduling in the JMPR tentative Schedule, the data should be submitted subsequently to the appropriate Joint Secretary of the JMPR.

iii The CCPR may place a chemical under the four-year rule, in which case the government or industry should indicate support for the specific CXLs to the FAO Joint Secretary of the JMPR, with a copy to the Chair of the Working Group on Priorities. Following scheduling in the JMPR tentative schedule, any data in support of maintenance of the CXL(s) would be submitted to the FAO Joint Secretary of the JMPR.

iv A government member may seek to expand the use of an existing Codex chemical: that is, obtain MRLs for one or more new commodities where some CXLs already exist for other commodities. Such requests should be

directed to the FAO Joint Secretary of the JMPR and copied to the Chair of the Working Group on Priorities. Following scheduling in the JMPR tentative schedule, the data would be submitted to the FAO Joint Secretary of the JMPR.

v A government member may seek to review a CXL due to a change in GAP. For example a new GAP may necessitate a larger MRL. In this case the request should be made to the FAO Joint Secretary with a copy to the Chair of the Working Group on Priorities. Following scheduling in the JMPR tentative schedule, the data would be submitted to the FAO Joint Secretary of the JMPR.

vi The CCPR may request a clarification or reconsideration of a recommendation from the JMPR. In such cases the relevant Joint Secretary will schedule the request for the next JMPR.

vii A serious public health concern may emerge in relation to a particular Codex pesticide. In such csaes government members should notify the WHO Joint Secretary of the JMPR promptly and provide appropriate data to the WHO Joint Secretary.

APPENDIX XVI

PROPOSED REVISED INTERIM MRL ESTABLISHMENT PROCESS (2005 CCPR)

Action 1. The proposed chemicals and associated Interim MRLs must be nominated to the Chair, Ad Hoc Working Group on Priorities (WGP) by February 1st, for consideration at the next WGP meeting. The chemical must already be scheduled for review by the JMPR or be nominated simultaneously for consideration by the WGP. The nomination package should include (except where noted these documents are the product of and are supplied by the nominating country and not the manufacturer):

- The nomination form, which is the same as the one submitted to the WGP in the standard process. The nominating country will only propose interim MRLs which are established in their country (or established in other countries from which they have *already obtained* the relevant national government information).
- List of all of the established MRLs for nominated commodities in the countries where the chemical is registered (this may be the product of the manufacturer), together with the proposals for interim MRLs.
- Dietary intake calculations based on the nominating country's ADI or ARfD, the nominated interim MRLs, and the JMPR methodology.
- Justification for qualification as a new, safer, replacement pesticide[i]

Action 2. If the WGP (at its annual pre-CCPR meeting) agrees that the criterion for a new, safer, replacement pesticide is satisfied, then the nominations for Interim MRLs are to proceed to the CCPR for final decision.

Action 3. CCPR consideration and decision. CCPR may either decide to include the chemical on a list for consideration of interim MRLs at the next session or may decide to reject the chemical from further consideration in the Interim MRL Process.

Action 4. After the initial nomination process to the CCPR for a given chemical, and upon CCPR agreement, other national governments will have two months, until June 30, to supply the nominating country the relevant materials to nominate other uses of the approved chemical for interim MRLs or higher MRLs for commodities already nominated. Member countries wishing to add uses to the original list or support higher MRLs than those in the nominating country, should supply the nominating country with the following information, at a minimum (except where noted these documents are the product of and are supplied by the nominating country and not the manufacturer):

- A summary table of the health intake values (ADI and ARfD) used in their country
- A summary of residue trial data (not raw data) and an explanation of how the MRL was determined for the nominated commodities (see residue data requirements under Action 5 below)
- Chronic and acute dietary intake risk assessments performed in their country

Action 5. The nominating government would then include these additional (or higher) interim MRL proposals in the detailed information package it sends to all member states for review. The detailed information packages would be provided to the Codex Secretariat for posting on the web[ii] no later than August 1. The packages would be posted on the web no later than September 1. The complete detailed information package sent out for review and comment will include, at a minimum (except where noted these documents are the product of and are supplied by the nominating country and not the manufacturer):

- Summary of the information contained in the package and where it was obtained; noting, for example, if any additional or higher MRLs have been added by member states since the original nomination to the WGP and approval by CCPR.
- Summary of the reduced risk justification.

- List of all of the established MRLs for nominated commodities in the countries where the chemical is registered (this may be a product of the manufacturer), together with the proposals for interim MRLs.
- A summary table of the calculated dietary intake values from all countries where the chemical has been evaluated (this may be the product of the manufacturer).
- Summary reports of the toxicology (equivalent to OECD Tier II summaries). These summary reports of the toxicology database should also contain "summary" and/or "discussion" sections which explain how the health intake values (ADI and ARfD) were set, document the safety factors used, and comment on whether they are likely to be conservative or not. For example, was the ARfD based on an endpoint in a repeat-dose study because there was no adequate acute study in the toxicological database? Or was the endpoint a critical endpoint from a developmental toxicity study? Discuss whether (a) a LOAEL is used instead of a NOAEL and thus warranted the application of an additional factor and (b) indicate when the endpoint selected originated from a developmental neurotoxicity study or from a study which shows sensitivity of the young. .
- Summary reports of the residue chemistry. This would include summary evaluations for plant and animal metabolism, analytical methods (for enforcement), field trials (commodity, GAP, residue values in ranked order), and processing studies (as applicable), and a reasoned definition of residues for dietary intake calculation and for MRL enforcement.
- The nominating national government's assessment of the data in support of the interim MRLs. This would include the nominating national government's dietary intake risk assessment and chronic and acute dietary intake assessments per JMPR methodology, using the nominating government's health intake values and including all nominated commodities for all the regional diets considered by JMPR (FAO/WHO GEMS).
- In the case that other member states supplied additional information (as noted in Action 4 above) this would also be included with the source clearly marked.

Note: Full reports should be available from the nominating country on request. In addition, if a member state requests actual study data the nominating country will work with the manufacturer to try and supply this information.

Action 6. Comments by member states are to be posted on the web site by December 31. The interim MRL Group[iii] will prepare and submit a report to the Chair of the WGP by February 1 for comment and subsequent distribution to member states for consideration at the next meeting of the WGP. Commentors should remember:

- The commentor should explicitly state whether they support or oppose each specific proposed interim MRL.
- As with a standard JMPR review, many countries will have different MRLs established, but the *highest nominated* Interim MRL that is *supported by an adequate set of field trial data* and that is *demonstrated to be safe*, would generally be selected as the interim Codex MRL. It is not necessary to list the MRLs established in the commentor's country.
- Comments should not be based on residue data that are not included in the detailed information package. No additional residue data (and resulting alterations in the proposed interim MRLs) can be considered in the review of the detailed information packages. The only opportunity to provide additional residue data and propose different MRLs is in Action 4. Comments on the interpretation of the residue data provided in the detailed information packages and resulting suggested changes to interim MRLs are appropriate.

Action 7. The WGP, at its annual pre-CCPR meeting, will consider any technical issues raised and decide which Interim MRLs are proposed to CCPR for agreement at the plenary session.

Action 8. Proposed Interim MRLs agreed or refused by CCPR.

Action 9. Interim MRLs considered by the Codex Alimentarius Commission (CAC) for ratification at Step 8(I) or rejection.

Action 10. Upon CAC ratification, interim MRLs recognized as MRLs at Step 8(I), with the following conditions:

- The interim standard would have a four year lifetime. During the four years, the pesticide would be considered by the JMPR, and their recommendations would advance through the CCPR in the present Step fashion. The interim standard would be automatically withdrawn when the proposed standard in the normal process reaches Step 8.
- The interim values would continue until supplanted by the advancement of the JMPR values to Step 8 regardless of the values recommended by the JMPR.
- If JMPR makes unfavorable recommendations or cannot make MRL recommendations because of an insufficient data base, the subject interim MRLs will be automatically withdrawn at the next scheduled session of the CCPR.

Action 11. The adopted interim MRLs at Step 8(I) should be included in the annual listing (CX/PR) *Draft and Proposed Draft Maximum Residue Limits in Food and Feeds at Steps 7 and 4* or in whatever comprehensive, public listing that the Codex Secretariat may deem appropriate.

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[i] A new, safer, replacement pesticide is defined (CX/PR 03/14) as a pesticide that usually would have never had one or more Codex MRLs; would be shown to be an alternative to an existing pesticide or pesticide type within the Codex system; and would have demonstrated reduced acute and/or chronic risk to humans via dietary intake compared to the pesticide that it would supplant or compared to many other pesticides in its classification (insecticide, herbicide, fungicide).

[ii] The CCPR must give clear direction to Codex to provide an interactive web space for the nominating country to post documents and for other countries to post responses.

[iii] Membership of the Interim MRL Group, currently the Interim MRL Pilot Project Working Group, will need to be formalized if the pilot project is extended.