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 03/24A

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

Twenty sixth Session
Rome, Italy, 30 June - 05 July 2003

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

Rotterdam, The Netherlands, 31 March - 5 April 2003

Note: This report includes Codex Circular Letter CL 2003/15-PR.

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CX 4/40.2 **CL 2003/15-PR**
April 2003

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-FIFTH SESSION OF THE CODEX COMMITTEE ON PESTICIDE RESIDUES (ALINORM 03/24A)

The report of the Thirty-fifth Session of the Codex Committee on Pesticide Residues will be considered by the 26th Session of the Codex Alimentarius Commission (Rome, 30 June - 5 July 2003).

PART A: MATTERS FOR ADOPTION BY THE 26TH SESSION OF THE CODEX ALIMENTARIUS COMMISSION

The following matters will be brought to the attention of the 26th Session of the Codex Alimentarius Commission for final adoption:

1. DRAFT REVISED GUIDELINES ON GOOD LABORATORY PRACTICE IN RESIDUE ANALYSIS AT STEP 8 (ALINORM 03/24A, APPENDIX II);

2. DRAFT AND REVISED DRAFT MAXIMUM RESIDUE LIMITS FOR PESTICIDES AT STEP 8 (ALINORM 03/24A, APPENDIX III);

3. PROPOSED DRAFT MAXIMUM RESIDUE LIMITS FOR PESTICIDES AT STEP 5/8 (ALINORM 03/24A, APPENDIX IV);

Governments wishing to comment on the Draft Revised Guidelines on Good Laboratory Practice in Residue Analysis at Step 8 or on the Draft MRLs and Proposed Draft MRLs at Steps 8 and 5/8; 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*, Twelfth 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 25 May 2003**.

4. REVOCATION OF CODEX MAXIMUM RESIDUE LIMITS FOR PESTICIDES RECOMMENDED FOR REVOCATION (ALINORM 03/24A, APPENDIX VI)

Governments wishing to comment on the proposed revocation (not including that of Codex MRLs replaced by the revised MRLs) 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 25 May 2003**.

PART B: MATTERS FOR PROVISIONAL ADOPTION BY THE 26TH SESSION OF THE CODEX ALIMENTARIUS COMMISSION

1. PROPOSED DRAFT AND PROPOSED DRAFT REVISED MAXIMUM RESIDUE LIMITS AT STEP 5 (ALINORM 03/24A, APPENDIX V)

Governments wishing to submit comments including the implications which the Proposed Draft Maximum Residue Limits may have for their economic interest 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*, Twelfth 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 25 May 2003**.

PART C: REQUEST FOR COMMENTS:

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

Governments and interested international organizations are invited to comment on the draft MRLs and proposed draft MRLs as contained in Appendix VII 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*, Twelfth Edition) preferably by an email to Dr Hans JEURING, Inspectorate for Health Protection and Veterinary Public Health Ministry of Health, Welfare and Sport, PO Box 16108, 2500 BC Den Haag, Fax:+31 70 340 5435, E-mail: hans.jeuring@kvw.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 15 February 2004**.

2. REQUEST FOR 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, 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 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 December 2003**.

3. REQUEST FOR COMMENTS ON THE CRITERIA FOR THE PRIORITIZATION PROCESS OF COMPOUNDS FOR EVALUATION BY JMPR

Member Governments and interested international organizations are invited to comments on the set of criteria for the prioritization process of compounds for evaluation by JMPR (see paras 169 - 175 and Appendix IX). Comments should be sent in writing preferably by an email to Dr Hans JEURING, Inspectorate for Health Protection and Veterinary Public Health Ministry of Health, Welfare and Sport, PO Box 16108, 2500 BC Den Haag, fax:+31 70 340 5435, e-mail: hans.jeuring@kvw.nl), with a copy to

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[1] For proposed draft MRLs to be proposed by the JMPR 2003 (16 - 24 September 2003) 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.
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 03/5. Consult the document to see whether or not a given pesticide has already been considered.

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 15 February 2004**.

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, 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 S. Page, International Programme on Chemical Safety, WHO, CH-1211 Geneva 27, Switzerland not later than one year before the JMPR meeting **(see Appendix VIII of ALINORM 03/24A).**

Those countries specified under individual compounds in the ALINORM 03/24A 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).

SUMMARY AND CONCLUSIONS

The Thirty-fifth Session of the Codex Committee on Pesticide Residues reached the following conclusions:

MATTERS FOR APPROVAL BY THE 26TH SESSION OF THE COMMISSION

The Committee recommended to the Commission:

- Adoption of the Draft Revised Guidelines on Good Laboratory Practice in Residue Analysis at Step 8 (Appendix II);
- Adoption of the draft and draft revised MRLs at Step 8 and proposed draft MRLs at Step 5/8 (Appendix III and Appendix IV);
- Revocation of certain existing Codex MRLs (Appendix VI);
- Adoption of the proposed draft and proposed draft revised MRLs for certain commodities at Step 5 (Appendix V).

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

- Priority List for the establishment of MRLs for certain pesticides (Appendix VIII);
- Proposed draft Guidelines on the use of mass spectometry (MS) for identification, confirmation and qualitative determination of residues (para. 152);
- Review the existing texts relating to methods of analysis and sampling contained in Volume 2A at regular intervals (para. 153);
- Proposed draft Guidelines on the estimation of uncertainty of results (para. 156); and
- Proposed revision of criteria for the prioritization of compounds for evaluation by JMPR (paras 169 – 175).

FOR ADVICE OF THE COMMISSION

Interim MRLs

- In view of the lengthy process required for the elaboration of the MRLs for newly introduced, often safer, pesticides, procedure was proposed to use national MRLs as interim Codex MRLs. The proposed Procedure requires the Committee to notify the Commission about the proposed Interim (Step 8 (I)) MRLs, however it does not require the adoption of these MRLs itself. The Commission could only reject the proposed MRLs. Therefore the Committee is seeking advice on the proposed procedure of the elaboration of Interim MRLs (paras 176-186);

Reduction of an extraneous burden from the workload of JMPR

- In order to reduce an extraneous burden from the workload of JMPR, it was proposed that the JMPR should restrict its review of environmental fate to those areas specifically related to the estimation of dietary exposure and the estimation of MRLs. Therefore the Committee agreed to propose that the JMPR should proceed with consideration of environmental fate and to focus on those aspects that were most relevant to MRL setting (paras 210-213).

FOR INFORMATION TO THE COMMISSION

The Committee:

- Generally agreed with the views and recommendations under the General Considerations of the 2001 JMPR (paras 6 - 19);
- Agreed to prepare a paper considering the adoption of the probabilistic methodology for Codex purposes; (para. 31) and encouraged countries to submit missing data concerning certain commodities and processed foods (para. 33);
- Agreed to prepare a document outlining the risk analysis policies used in establishing Codex Maximum Residue Limits for Pesticides (paras 141 - 144);
- Noted that some compounds such as hexaconazole (170) (see para 118) and penconazole (182) (see

paras 120-123) were supported by manufacturers at national level, but not in the Codex system;

- Agreed to invite member countries to submit proposals for new analytical methods, especially for those pesticides were not covered by existing methods (para. 158);
- Clarified requirements for sampling for new tropical fruit and vegetable commodities (paras 159 – 161);
- Reconfirmed its decision to elaborate the MRLs for spices based on monitoring data and decided to revise the list of spices based on their growth classification; and agreed that for persistent organochlorine pesticides EMRLs but not MRLs should be established (paras 187 – 200);
- Agreed to initiate limited revision of the Codex Classification of Foods and Animal Feeds and decide which electronic data base would better suit for this purpose at the next session of the Committee (paras 201 – 205).

MATTER OF INTEREST TO OTHER COMMITTEES

Codex Committee on Methods of Analysis and Sampling CCMAS):

Following the request of the CCMAS, the Committee agreed to propose to the CCMAS to consider wording regarding the General Criteria for the Selection of Single-Laboratory Validated Methods of Analysis (paras 147 – 148).

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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
CCPR	Codex Committee on Pesticide Residues
CCRVDF	Codex Committee on Residues of Veterinary Drugs in Foods
CLI	CropLife International
CI	Consumers International
EC	European Community
FAO	Food and Agriculture Organization of the United Nations
JECFA	Joint FAO/WHO Expert Committee on Food Additives
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
SPS Agreement	Agreement on the Application of Sanitary and Phytosanitary Measures
WHO	World Health Organization
WTO	World Trade Organization

acute RfD	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
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 35th Session in Rotterdam, The Netherlands, from 31 March to 5 April 2003 at the kind invitation of the government of The Netherlands. Dr H.J. Jeuring of the Netherlands Ministry of Health, Welfare and Sport chaired the Session. The Session was attended by 51 Member countries and 11 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. R.J. Dortland, Director of the Department for Nutrition and Health Protection of the Ministry of Health, Welfare and Sport. He welcomed the delegates to Rotterdam, and recalled the discussion at the last CCPR session on the need to accelerate and improve the process of establishing Codex standards and the heavy workload of the JMPR. As a result of the discussion, the Committee would consider at the present session not only MRLs recommended by the 2001 JMPR, but also those by the 2002 JMPR. It would also consider a proposal to use national MRLs as interim Codex MRLs. He also mentioned the need to consider the importance of MRLs for some commodities in relation to the main objectives of Codex, for example, the elaboration of MRLs for spices. Finally, Dr Dortland suggested that the Committee could consider a possible future harmonization of the enforcement of Codex MRLs.

ADOPTION OF THE AGENDA (AGENDA ITEM 1)[3]

3. The Committee agreed to the proposal of the Chair to consider Agenda Item 18: *Removal of an Extraneous Burden from the Workload of the JMPR* after Item 4, and to consider Agenda Item 17: *Maximum Residue Limits for Processed or Ready-to-eat Food or Feeds* after Item 7. With these amendments the Provisional Agenda as contained in CX/PR 03/1 was adopted as the Agenda for the Session.

APPOINTMENT OF RAPPORTEURS (AGENDA ITEM 2)

4. Dr D. Lunn (New Zealand) and Dr Y. Yamada (Japan) were **appointed** as rapporteurs.

MATTERS REFERRED TO THE COMMITTEE BY THE CODEX ALIMENTARIUS COMMISSION AND/OR OTHER CODEX COMMITTEES (AGENDA ITEM 3)[4]

5. The Committee noted that matters arising from the 50th Session of the Executive Committee, the 17th Session of the Committee on General Principles (CCGP) and from the FAO/WHO Coordinating Committees for Near East and Asia were presented for information purposes or would be discussed in more detail under the relevant Agenda Items. The Committee also noted that the 25th Extraordinary Session of Codex Alimentarius Commission had considered the follow-up of the conclusions and recommendations of the Joint FAO/WHO Evaluation of Codex Alimentarius Commission and the proposal to establish a Trust Fund for participation of developing countries and countries in transition.

REPORT ON GENERAL CONSIDERATIONS BY THE 2002 JOINT FAO/WHO MEETINGS ON PESTICIDE RESIDUES (AGENDA ITEM 4)[5].

6. The report noted that the 34th Session of the CCPR had confirmed that the JMPR was essential to the continued independent international evaluation of pesticide residues (ALINORM 03/24).

7. As the JMPR is undergoing a very critical period with the current system of relying heavily on voluntary contributions by evaluators of their own time and with the increasing workload and complexity of

[3] CX/PR 03/1; CX/PR 03/1-Add.1.
[4] CX 03/2; CRD 4 (comments from the European Community).
[5] Report of the 2002 JMPR.

modern evaluations, the 2002 JMPR recommended that FAO, WHO and the Codex Alimentarius Commission prepare a strategic plan for JMPR to provide a framework for the proposed changes including: (a) a re-examination of the objectives of JMPR, its practices and its information and data requirements, (b) a description of the likely situation in 5 and 10 years time and what will be expected of JMPR, (c) an estimate of the resources needed for effective operation, and (d) an implementation process and recognition of implementation costs.

8. The 2001 JMPR had recommended the establishment of a WHO working group to develop a paper on the establishment of an acute reference dose (acute RfD). The 2002 JMPR considered the working paper prepared by this working group and confirmed the following points:

- The acute RfD of a chemical is an estimate of the amount of a substance in food and/or drinking water, normally expressed on a body-weight basis, that can be ingested in a period of 24 hours or less without appreciable health risk to the consumer on the basis of all known facts at the time of the evaluation.

- The establishment of an acute RfD should be considered for all substances. Preferably, only one acute RfD should be established for a chemical. Most of the scientific concepts applying to the establishment of ADIs apply equally to acute RfDs.

- A single exposure to a compound could result in a number of toxicological effects and the relevance of these effects should be considered on a case-by-case basis. The appropriate effect and the NOAEL should be based on the most relevant toxicological effects and the most relevant study in which these effects have been examined.

- the use of safety factors higher or lower than the default values of 100 and 10 could be justified in a number of cases on the basis of animal and human data, respectively.

- When available, human data should always be evaluated when deriving an acute RfD. However, when performing a risk assessment on a pesticide, the entire database should be considered and the most appropriate studies and safety factors used to derive acute RfDs.

- Establishing an ADI with a value higher than the acute RfD would be inappropriate.

- An acute RfD should not be established if there are no acute effects are seen at doses up to 500 mg/kg bw and no substance-related mortality is observed at doses up to 1000 mg/kg bw in single-dose oral studies. If mortality is the only trigger, the cause should be confirmed as being relevant to human intake of residues in food.

- If an acute RfD is not established, the reasons must be justified and explained.

9. The Committee was informed that the 2002 JMPR had reconsidered the acute RfDs for the following substances based on the new guidance, and had concluded:

- Bentazone: That insufficient information was available for reconsideration.

- DDT: The 2000 JMPR decision not to establish an acute RfD for DDT was confirmed.

- Dimethipin: That insufficient information was available to reduce the safety factor of 1000.

- Dodine: The 2000 JMPR decision to establish an acute RfD of 0.2 mg/kg bw was confirmed.

- Imazalil: That the establishment of an acute RfD for imazalil should be reconsidered when additional data on the toxicological alerts, including maternal toxicity, fetal deaths, and resorptions, are submitted.

- Fenpropimorph: That a full evaluation of the toxicological database is needed to determine the appropriate end-point and NOAEL for the establishment of an acute RfD.

- Permethrin: That an acute RfD of 1.5 mg/kg bw was established, based on the NOAEL of 150 mg/kg bw in rats, and safety factor of 100.

- 2-Phenylphenol: That an acute RfD is unnecessary for 2-phenylphenol, as decided by the 1999 JMPR.

- Propargite: That an acute RfD for propargite was unnecessary, as decided by the 1999 JMPR.

10. In order to evaluate the impact of developmental neurotoxicity studies on the establishment of acute RfDs and ADIs, the 2002 Meeting considered a working paper comparing the critical NOAELs identified in developmental neurotoxicity studies with those identified from the conventional data packages. The Committee noted that this comparison showed that, in general, the majority of the developmental neurotoxicity studies did not identify significantly lower NOAELs and LOAELs compared to those of the other related studies. The Committee also noted that the 2000 JMPR had identified several critical issues and concerns in conducting developmental neurotoxicity studies, including the introduction of artifacts due to stress and believed that should the toxicological profile of a chemical indicate a concern for developmental neurotoxicity end-points, appropriate testing parameters should be incorporated into a multigeneration reproductive toxicity study.

11. The Committee was advised that JMPR would be considering the final report of the Zoning project once it has been adopted by the OECD Working Group and the 2002 JMPR had indicated that the other recommendations from the 1999 York Workshop on Developing Minimum Data Requirements for Elaborating MRLs and Import Tolerances could be of relevance to JMPR and expressed the hope that these minimum data requirements could be finalized and made available for consideration.

12. The Committee noted the advice from the 2002 JMPR that several governments had submitted residue data derived from supervised trials often without the essential details needed for their evaluation and supported the JMPR invitation that national governments consult the relevant sections of the revised FAO Manual on the '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, http://www.fao.org/waicent/FAOINFO/ AGRICULT/AGP/AGPP/Pesticid/default.htm). Chapter 3 of the manual for provides guidance on data requirements.

13. The Committee was informed of the JMPR 2002 response to the request for guidance for the submission of monitoring data for setting MRLs or EMRLs for spices (ALINORM 03/24 para 209), in particular:

- that both exporting and importing Member governments submit their monitoring data on pesticide residues following the data requirement on the 'Estimation of extraneous maximum residue levels' in Chapter 5 of the revised FAO manual.

- that submissions should contain all relevant information on the current and past uses of pesticides in spices.

- that when the CCPR agrees to establish MRLs based on monitoring data, JMPR would evaluate the data submitted and would prepare guidelines for performing selective field surveys to support elaboration of MRLs for spices for which sufficient data are not currently available.

- that CCPR should provide information on the number of monitoring data and the geographical spread that could be considered acceptable by the members for estimating maximum residue levels.

- that CCPR should indicate if it is acceptable to use the current GEMS/Food total spice-consumption data for risk assessment of those spices not specifically listed.

14. The Committee **noted** that the 2000 JMPR had welcomed the initiative of the OECD Secretariat and the Working Group on Pesticides to contribute to the development of a statistically based approach for the estimation of MRLs but had recognized the difficulties of the statistical treatment of scattered small data sets and presently did not see the ways for proceeding further with this approach.

15. The Committee also **noted** the 2002 JMPR conclusion that a variability factor of 3 would properly represent the variability of residues in head lettuce and head cabbage and had recommended this factor for calculation of acute exposure for these commodities.

16. The Committee was informed that the JMPR had concluded that the mixed 20% fat / 80% muscle values for cattle and other mammalian animals and the mixed 10% fat/90% muscle values for poultry should be used for dietary intake calculations for meat in order to provide a more realistic estimation of the dietary exposure of consumers.

17. It was also noted that the 2002 JMPR had decided in general to use cattle feeding studies to recommend maximum residue levels for mammalian commodities to cover the potential exposure of an animal to a pesticide in the diet and that it was also reasonable to extrapolate from chickens to poultry.

18. The Committee considered the question raised by the JMPR 2002 on whether to recommend MRLs at or about the LOQ; or not to recommend any MRL where residues are unlikely to occur. After some discussion it was agreed that in cases where residues are not expected, MRLs should be elaborated at the limit of quantification, but with a footnote to indicate no residues expected.

19. The Committee was informed of the pilot project on work sharing at national and international level, with the national evaluations for some new compounds being available to JMPR at the time of evaluation.

DIETARY EXPOSURE IN RELATION TO MRL SETTING: DISCUSSION PAPER ON THE PROPOSALS FOR IMPROVEMENT METHODOLOGY FOR POINT ESTIMATES (AGENDA ITEM 5)[6]

20. The Delegation of the Netherlands introduced the paper and informed the Committee that following the decision of the 34th Session of the Committee they had prepared a document containing proposals on the improvement of the current methodology used for point estimates and also proposed risk management options for MRLs with acute intake concerns.

21. The Delegation informed the Committee that an unpublished IUPAC report on acute dietary assessment had been used in the preparation of this paper. The paper identified that the methodology for acute intake assessment included a number of factors such as *variability of residues in units of food commodities, unit weights and edible part of product, processing effects and the size of large portion of food commodity consumption*; and used deterministic (point) estimates that could result in highly unrealistic residue intake estimates because worst-case scenarios and extreme values were often used.

22. The Committee noted that the proposal of The Netherlands to consider the possibility of introducing simple probabilistic calculations at the international level to provide better acute intake estimates and raised the question of what risk management options, such as acceptance of limited exceedence of the acute RfD, could be used when acute dietary exposure assessment showed that the acute RfD was exceeded.

23. A number of delegations supported the reconsideration of variability factors used for the calculation of acute exposure. The Committee was informed that in some countries no variability factors were applied to results obtained from field trials as residues found in samples taken in the marketplace rarely approached those found in supervised field trials.

24. Some delegations were of the view that when the acute exposure assessment using the best IESTI methodology exceed the acute RfD, the Committee should not proceed with the further advancement of MRLs until further refinements to the IESTI calculations demonstrating no intake concerns. It was also

[6] CX/PR 03/3; CRD 3 (comments from Australia); CRD 5 (comments from Crop Life International).

indicated that the risk assessment done by JMPR represented the worst international case scenario and that additional mitigation factors could be taken into account at the national level.

25. The Delegation of The Netherlands indicated that while there were models validated for use in Europe and some countries, the use of a probabilistic methodology might be difficult at international level as data and models were not readily available. The necessity of training personnel was emphasized in order to progress on this matter.

26. The WHO Representative noted that short-term exposure assessment was still under development by both JMPR and Member states. In implementing the current IESTI deterministic exposure assessment, he mentioned that in some cases the use of 97.5th percentiles for food consumption and residues might not be so conservative and that the acute RfD, unlike the ADI, should not in principle be exceeded.

27. The Observer of Crop Life International supporting the initiative to improve acute intake assessments indicated that the probabilistic approach could enable the CCPR to make more informed risk management decisions at the international level.

28. The Chair summarized the discussion that: (1) the possibility of accepting limited exceedance should not be considered at present time; (2) the possibility of using a tiered approach could be considered in the future; and (3) JMPR should be asked to mention the probabilistic aspects in the point estimates, when the results exceed the acute RfD.

29. The Committee encouraged Member countries to submit data on large portion size and percentage of eaters for better estimation of acute risk.

30. The Committee confirmed its earlier position not to proceed with the advancement of MRLS beyond Step 6 when acute dietary intake calculations showed exceedance of acute RfD. The Committee also requested JMPR to consider this paper especially in relation to the use of probabilistic aspects of point estimates.

31. The Committee also agreed to establish a Working Group[7] to prepare a paper considering the adoption of probabilistic methodology for the purpose of Codex MRL setting. This should include the worked examples of semi-probabilistic calculations for some compounds using supervised trial data where the IESTI is exceeding the acute RfD. The Working Group should also discuss and propose parameters to be used in probabilistic calculations at the international level, and that this paper would be considered by the next session of the Committee.

GEMS/FOOD PROGRESS REPORT OF DIETARY INTAKES (AGENDA ITEM 6)[8]

32. The Committee recalled that previous FAO/WHO expert consultations had recommended that the current five GEMS/Food Regional Diets be revised to make them more representative of the dietary patterns of the world's populations. The use of the cluster analysis method to develop the thirteen new GEMS/Food Consumption Cluster Diets had been presented to the 32nd CCPR which supported the approach and asked to be kept advised of significant further progress, and requested that examples of dietary intake estimates for fruits and vegetables, based on the proposed new diets be provided to the Committee.

33. The WHO Representative reported that the cluster analysis had recently been applied to all information available in the FAO Food Balance Sheet data for all countries. Major data gaps for many commodities had been encountered, particularly in developing countries. In addition, information on a number of important processed commodities were missing. Consequently, WHO would be contacting individual Member States with specific inquiries concerning certain commodities and processed foods. The Committee welcomed this progress and encouraged countries to respond promptly to these requests.

[7] Netherlands with assistance of Australia, Canada, Denmark, France, Germany, Sweden, WHO, and International Banana Association. The Committee noted that the Delegation of the US might also wish to participate.
[8] CX/PR 03/4.

34. In regard the "large portion" database maintained by GEMS/Food for acute hazard exposure assessment, the WHO Representative reported that several new entries have resulted from data provided by South Africa. In addition, he reported that a revised submission of 97.5th percentile consumption data for the general population and children ages 6 and under had recently been received from the USA and this may also result in changes.

35. In reference to the typical unit weight and edible portion database, the WHO Representative noted that revised data had been provided by the UK and that new data had been received from Sweden and Belgium.

DRAFT AND PROPOSED DRAFT MAXIMUM RESIDUE LIMITS FOR PESTICIDES IN FOODS AND FEEDS AT STEPS 7 AND 4 (AGENDA ITEM 7)[9]

GENERAL REMARKS

36. The Chairman referred to the written comments from USA relating to their reservations over the advancement of MRLs for organophosphorus pesticides, because their cumulative risk analysis for these compounds was still being refined.

37. The Observer of the European Community speaking on behalf of the Member States present at the current session (Observer of the EC) expressed general reservations on the lack of statistical methods used for MRL-setting, on MRL's based on non specified PHI's and the mixing of pre- and post-harvest data. The Observer indicated that their comments were preliminary as the JMPR 2002 Evaluations were not available.

CAPTAN (007)

38. Several delegations expressed concern over the lack of an acute RfD and the Committee noted that the 2002 JMPR concluded that the establishment of an Acute RfD might be necessary.

39. In reply to a question concerning the extrapolation of data concerning peaches to nectarines, the Joint FAO JMPR Secretary informed the Committee that JMPR had considered this issue and evaluated data on peach and nectarine separately. However, JMPR had recognized that governments currently extrapolated MRLs and had therefore decided to leave this risk management decision to the CCPR. The Committee did not agree to extrapolation because the GAPs supporting the MRLs for the two commodities were significantly different.

40. The Observer of the European Community, speaking on behalf of the Member states, drew the attention of the Committee to the fact that there were no clear criteria for extrapolation.

41. The Delegation of France expressed the opinion that the metabolite THPI might be included in the residue definition for intake assessment purposes and taken into account when considering residues in processed food. Animal feeding studies should have been taken into account.

42. The Committee **decided** to return all draft MRLs for apple, cherries, cucumber, dried grapes, grapes, melons, except watermelon, nectarine, peach, plums, pome fruits, raspberries, red, black, strawberry and tomato to Step 6 and await the 2004 JMPR toxicological evaluation.

CARBARYL (008)

43. Several Delegations expressed their reservations on MRLs based on extreme residue values in the residue database. The Committee noted that the JMPR had indicated acute intake concerns with some commodities. The Committee noted that the evaluation of the available database by the JMPR provided no grounds for JMPR to discard these values. The Observer of the EC noted that within the EC, statistical methods were used to set MRLs and that there was a need for the development of minimum data requirements.

[9] CL 2002/16-PR; CL 2002/35-PR; CL 2003/1-PR; CX/PR 03/5; CX/PR 03/5-Add.1; CRD 6

44. The Committee was informed by the Delegation of Australia that data for pome fruits would become available and **decided** to retain the CXLs for apple and pear, pending the evaluation of this new data.

45. The Committee **decided** to advance the proposed MRLs to Step 5 for rice hulls; sorghum forage (dry); Soya bean hulls; sunflower forage; sweet corn cannery waste; tomato paste; almond hulls; asparagus; beetroot; carrot; cherries; citrus fruits; citrus juice; citrus pulp, dry; dried grapes (= currants, raisins and sultanas); egg plant, grape juice, grape pomace, dry; grapes; kidney of cattle, goats, pigs & sheep; liver of cattle, goats, pigs & sheep; maize; maize fodder; maize forage; maize oil, crude; meat (from mammals other than marine mammals); milks; olive oil, virgin; olives; peppers, sweet; rice bran, unprocessed; rice straw and fodder, dry; rice polished; sorghum forage (green); soya bean (dry); soya bean fodder; soya bean forage (green); soya bean oil, crude; stone fruits; sunflower seed; sunflower seed oil, crude; sweet corn (corn-on-the-cop); sweet potato; tomato; tomato juice; tree nuts; turnip, garden; wheat; wheat bran, unprocessed; wheat flour; wheat germ; wheat straw and fodder, dry.

46. Since the Delegations of Japan and Korea indicated that the MRL for rice is not needed because rice is traded in the form of polished rice or husked rice and a separate MRL is recommended for polished rice, the Committee **decided** to consider deletion of the CXL for rice next year and to return the proposed MRL to Step 3.

47. The Committee **decided** to consider next year, the deletion of the remaining CXLs recommended for withdrawal by JMPR 2000.

48. Recognizing the acute intake concerns with some commodities, the Chairman suggested that carbaryl could be a candidate for consideration by the working group established to evaluate options for using semi-probabilistic analysis in acute intake risk assessment at the international level (see para 31).

49. The Committee also agreed to delete the footnote relating to the period of validity (1999-2003) of the temporary CXLs.

CHLORMEQUAT (15)

50. The Observer from the EC expressed concern over the variability and the small number of processing studies on wheat. The Committee was informed that JMPR considered these processing factors to be comparable. The Committee **decided** to recommend revocation of the CXLs for barley straw and fodder dry; oat straw and fodder dry; rye; rye straw and fodder dry; wheat, wheat straw and fodder dry; and pear. The Committee **agreed** to advance the draft MRLs for rye; rye bran unprocessed; rye flour; straw and fodder (dry) of cereal grains; triticale; wheat; wheat bran unprocessed; wheat flour; and wheat wholemeal to Step 8, noting that the existing CRLs for rye and wheat would be replaced[10].

CHLORPYRIFOS (17)

51. The Committee **decided** to advance all draft MRLs to Step 8. The Committee further **decided** to recommended revocation of the CXL for apple and pear, since these MRLs will be replaced by the MRL for pome fruits. The Committee also **decided** to recommend revocation of the CXLs for chicken meat and turkey meat, since these MRLs will be replaced by the MRL for poultry meat. While noting that the CXL for rice was recommended for withdrawal by the 2000 JMPR, the Committee **decided** to retain it, awaiting the submission of data to JMPR by the manufacturer.

2,4-D (20)

52. The Committee **decided** to withdraw the draft MRLs for grapefruit; and oranges, sweet, sour as a newer MRL had been proposed for citrus fruits by the 2001 JMPR. The Committee **decided** to advance the proposed draft MRL for citrus fruits to Step 5.

DIAZINON (22)

[10] The same procedure applies to all relevant cases where amended or revised MRLs were advanced to Step 8 or 5/8

53. The Committee **decided** to return all draft MRLs to Step 6, awaiting new information from the USA and Australia on cabbages, head.

DICOFOL (26)

54. The Delegation of Japan informed the Committee that the CXL for tea, green, black was based on the use pattern of Japan, but that this use had been changed after the JMPR evaluation so that much lower residues were to be expected. The Committee **agreed** to consider withdrawal of this CXL at its next session.

DIMETHOATE (27)

55. The Chairman informed the Committee that dimethoate was on the agenda of the 2003 JMPR for the establishment of an acute ARfD and for residue evaluation. The Committee noted the written comments of the EC and the United States concerning acute intake concerns. The Committee **decided** to return all MRLs to Step 6.

DIPHENYLAMINE (30)

56. The Committee **decided** to advance the MRLs for apple, apple juice, cattle kidney, cattle liver, and cattle meat to Step 5/8. The Delegation of Spain informed the Committee that it had provided GAP information and trial data on the use of this compound on pears in support of an MRL of 10 mg/kg. The Committee **decided** to advance the MRL for pear to Step 5.

57. The Committee **decided** to advance the MRL for cattle milk to Step 5 and requested JMPR in clarify whether fortification was done in whole milk or milk fat in the recovery experiments. The Committee noted that the residue definition should indicate that the compound is fat-soluble.

ENDOSULFAN (32)

58. The Chairman informed the Committee that this compound was on the 2005 JMPR agenda for period review and that there were no intake concerns. The Committee decided to advance the MRLs for broccoli; cabbage; savoy; cabbages; head and cauliflower to Step 8 and all remaining MRLs to Step 5/8.The Committee also **agreed** to revote the general CXLs for fruits (except as otherwise listed) and vegetables (except as otherwise listed).

ETHION (34)

59. The Committee was informed that the use of ethion was no longer supported and **decided** to consider deletion of the CXL for citrus fruits at its next Session.

FENITROTHION (37)

60. The Committee at its 34th Session **decided** to retain the CXL for cereal grains for 1 year pending further information from the Delegation of Australia and the manufacturer. In June 2002 support for cereal grains was confirmed. The Committee therefore **decided** to retain the existing CXLs awaiting the periodic review by the 2003 JMPR.

FOLPET (41)

61. The need for an acute RfD for folpet would be re-evaluated by the JMPR in 2004. The Observer from the EC and the Delegations of France and Chile expressed their concerns on the residue evaluations for apple, dried grapes, grapes, lettuce head, strawberry and tomato. Therefore the Committee **decided** to return these MRLs to Step 6 waiting JMPR evaluation and to advance the MRLs for cucumber; melons except watermelon; onion; bulb; and potato to Step 8.

MALATHION (49)

62. The Committee noted the concerns of a number of countries over the lack of an acute RfD. The European Community also expressed concern at the lack of animal feeding studies. The Committee **decided** to return all draft MRLs to Step 6 awaiting the 2003 JMPR evaluation of the acute RfD and the calculation of acute intake estimates.

MEVINPHOS (53)

63. The Committee **decided** to recommend revocation of the CXLs for common beans (pods and/or immature seeds) and leek. The Delegation of Australia informed the Committee that they would supply new data to support the CXL for cabbages, Head.

MONOCROTOPHOS (54)

64. The Committee **decided** to recommend revocation of all CXLs as there was no longer support for this compound.

OMETHOATE (55)

65. The Committee **decided** to withdraw all draft MRLs as there was no longer support for this compound.

66. The Committee was informed that although omethoate residues can result from uses of dimethoate, these had been taken into account in the dietary risk assessments for dimethoate and that residue definition for exposure assessment was dimethoate and omethoate expressed as dimethoate.

2-PHENYLPHENOL (056)

67. The Committee **decided** to advance the MRL for pears to 5/8 and to revoke the existing CXL.

PARATHION-METHYL (059)

68. The Committee noted the remarks of Australia, the EC and the USA opposing the progression of MRLs for animal feeds since no animal transfer studies were available.

69. The Delegation of Canada expressed acute intake concerns and noted that the US cumulative risk assessment was incomplete. The Committee therefore **decided** to return all the MRLs to step 6 and to discuss the proposal again at its next session.

PHOSALONE (060)

70. The Committee **decided** to advance the MRL for pome fruit and stone fruit to Step 8, noting that the CXL for apple will be revoked.

PHOSPHAMIDON (061)

71. The Committee noted that at its last session this compound was no longer supported and therefore **decided** to withdraw all CXLs.

PIPERONYL BUTOXIDE (062)

72. The Committee **decided** to advance all MRLs to Step 5/8 and to delete the term “fat” from the entry for meat from mammals other than marine mammals, noting the reservations of the Delegation of France, who considered that the database was insufficient and informed the Committee that this compound is used as synergist to pyrethrins, which are compounds used in organic agriculture. The Committee noted that the CXL for wheat would be revoked when the cereal grains MRL is adopted.

PYRETHRINS (063)

73. The Committee **decided** to advance the MRLs for dried fruits and pulses to Step 8 and noted that the compound is on the agenda of the 2003 JMPR for residue and toxicological evaluation.

THIABENDAZOLE (065)

74. The Committee **decided** to advance the MRLs for Advocado, Cattle kidney, Cattle liver, Cattle milk, Mango, Papaya, Pome fruits and Potato to step 8, noting that the CXL for edible offal, apple and pear will be revoked

75. The Delegations of Morocco and Israel stated that they were of the opinion that the MRL for citrus fruit is too low. The Committee therefore **decided** to return the MRL for Citrus fruit to step 6 requesting the Delegation of Morocco to submit data to the JMPR. The Committee **decided** to return the MRL for mushrooms to Step 6 awaiting more data from the USA. The Committee will consider the withdrawal of the MRLs for melons and strawberry at its next session, since they are no longer supported.

CARBENDAZIM (072)

76. The Committee **decided** to return the MRLs for berries and other small fruits, Lettuce Head and peppers to step 6 awaiting an Acute RfD from the 2003 JMPR.

77. The Delegation of Australia reminded the Committee of its decision at its last session to change the residue definition to include benomyl, carbendazim and thiophanate-methyl to be expressed as carbendazim. The Committee also noted the remarks from Germany that benomyl is no longer supported in the EU and the USA, but was also advised that benomyl still had uses in Autralia. The Delegation of Germany also pointed out that the majority of MRLs came from the use of benomyl and that in its opinion all the MRLs should be reconsidered.

78. The Committee noted that carbendazim was being evaluated for residues by the 2003 JMPR.

DISULFOTON (074)

79. The Committee noted that for a number of commodities there is an acute intake concern and agreed this could be a candidate for consideration by the ad hoc Working Group on acute intake. The Committee therefore **decided** to return the MRLs for broccoli, cabbages head, cauliflower, lettuce head and lettuce leaf to Step 6 since for these commodities there were acute intake concerns identified. The Committee **decided** to advance all the other MRLs to Step 8, revoking the CXL for maize. The Committee will consider the withdrawal of the CXLs for potato and Japanese radish at its next years session since it was informed that these commodities were no longer supported. The Committee will delete the CXLs for cereal grains and vegetables when the proposals for the relevant individual commodities reach Step 8.

DICHLOFLUANID (082)

80. The Committee **noted** that the CXLs for blackberries and egg plant were no longer supported and therefore **recommended** the revocation of these CXLs, and to consider revocation of the remaining CXLs if no longer supported.

FENAMIPHOS (085)

81. The Committee **noted** that the 2002 JMPR had established an acute reference dose of 0.003 mg/kg bw. The Committee was **informed** that the EC opposed advancement of the proposed MRLs in view of acute intake concerns for peppers, tomatoes and watermelon. The Committee **decided** to return all draft MRLs to Step 6 awaiting more refined acute intake calculations.

82. The Committee also **noted** that this compound could be a candidate for consideration by the Working Group on Acute Intake.

DINOCAP (087)

83. The Committee **decided** to advance the proposed MRL for grapes to Step 8.

CHLORPYRIFOS-METHYL (090)

84. The Committee **noted** that the proposed MRLs for barley and oats reflected Australian GAP. The Observer of the EC and the Delegations of France and Spain opposed the advancement of these commodities in view of the fact that the proposed levels need to be in line with the results from feeding studies, leading to very low MRLs for products of animal origin. The Delegation of Korea **informed** the Committee that a MRL of 10 for rice was not acceptable, because of dietary intake concerns.

85. The Committee **decided** to return the draft MRLs for barley, oats and rice to Step 6, awaiting review by the JMPR, but noted the view of the Delegation of Australia and New Zealand that, in principle, MRLs should be advanced once all data requirements had been met.

METHOMYL (094)

86. The Committee **noted** that the JMPR had identified serious acute intake concerns for several commodities.

87. The Representative of WHO drew the attention of the Committee to the fact that acute dietary intake exceeded acute RfD more then 7000%. If was noted that clear policy should be established when the acute RfD was exceeded.

88. The Committee **decided** to return the draft MRLs to Step 3 for alfalfa fodder; alfalfa forage (green); barley; bean fodder; beans, except broad bean and soya bean; brassica vegetables; celery; citrus pulp, dry; fruiting vegetables, cucurbits; grapes; leafy vegetables; pea vines (green); soya bean forage (green); wheat; wheat bran, unprocessed; wheat flour and wheat germ.

89. The Committee **decided** to advance the MRLs to Step 5 for cotton seed, hulls; cotton seed, meal; rape seed forage; soya bean hulls; soya bean meal; apple; beans (dry); common bean (pods and/or immature seeds); cottonseed; cotton seed oil, edible; edible offal (mammalian); eggs; maize; maize forage; maize oil, edible; meat (from mammals other than marine mammals); milks; nectarine; oats; peach; pear; plums (including prunes); potato; poultry meat; poultry, edible offal of ; rapeseed; soya bean fodder; soya bean oil, crude; soya bean oil, refined; straw, fodder (dry) and hay of cereal grains and other grass-like plants.

90. The Committee **decided** to recommend the revocation of CXLs as recommended by the 2001 JMPR for barley straw and fodder, dry; egg plant; hops, dry; oat straw and fodder, dry; onion, welsh; peanut; peanut forage (green); peas shelled (succulent seeds); pineapple; sorghum; soya bean (immature seeds); squash, summer and sugar beet.

91. The Committee **decided** to postpone discussions awaiting the outcome of refined acute intake calculations - including existing CXLs - by the new Working Group on acute intake.

CARBOFURAN (96)

92. The Committee was informed that new data on maize will be submitted to the JMPR. The Committee therefore **decided** to revoke the CXLs for carrot; egg plant; oats, onion, bulb; soya bean (dry); sugar beet; sugar beet leaves or tops; sweet corn (kernels); tomato and wheat as recommended by the 1997 JMPR.

93. The Committee noted that the JMPR 2002 had performed acute intake calculations based on only two commodities. Taking into account the intake concerns expressed by the Delegation of Australia and the Observer of the EC, the Committee asked the WHO GEMS/FOOD to perform a full acute intake assessment based on all commodities.

94. Awaiting the outcome of these calculations and the evaluation of the new residue data on maize by JMPR 2003, the Committee **decided** to advance all draft MRLs for cottonseed; rapeseed ; rice straw and fodder, dry; and rice, husked to Step 5 and return all draft MRLs to Step 6.

METHAMIDOPHOS (100)

95. The Committee **decided** to return the MRLs for peach, pome fruits and tomato to Step 6, awaiting the periodic review evaluation and acute intake calculation by the 2003 JMPR.

PHOSMET (103)

96. The Committee noted that the 2002 JMPR considered that the Acute RfD is conservative and might be refined.

97. The Committee **decided** to advance the draft MRLs for blueberries; citrus fruits; nectarine; pome fruits and tree nuts to Step 5 and to return the draft MRL for apricot to Step 6.

ETHEPHON (106)

98. The 2002 JMPR noted acute intake concerns for children for cantaloupe, peppers, pineapple and tomato, but not for dried grapes. The Committee **decided** to advance the draft MRL for dried grapes to Step 8 and suggested this compound could be a candidate for consideration by the Working Group on acute intake.

PROPARGITE (113)

99. The Committee **agreed** to consider deletion of CXLs as recommended by the 2002 JMPR at its next session.

100. The Observer of the EC opposed group MRLs for citrus because of insufficient documentation and pointed out the necessity of minimum data requirements for extrapolation and group tolerance.

101 The Committee **decided** to advance all proposed draft MRL proposals to Step 5, noting the concern of the EC about intake risks to children via grape juice.

ALDICARB (117)

102. The Observer of the EC informed the Committee that this substance is to be taken from the market in the EU where only essential uses will be permitted for a limited time

103 The Committee **decided** to advance the draft MRL for banana to Step 5 and to return the draft MRL for potato to Step 6 and noting the acute intake concerns for banana and potato, considered this compound to be a candidate for consideration by the Working Group on Acute Intake.

OXAMYL (126)

104 The Committee **decided** to advance all proposed draft MRLs to Step 5 and to consider at its next Session, deletion of the CLXs as recommended by the 2002 JMPR.

DIFLUBENZURON (130)

105 The Delegation of France expressed its concern on the residue definition, because two important metabolites may not have been taken in account, particularly in processed products. The Delegation also expressed its concern that no adequate animal feeding studies have been taken into account in the evaluation.

106. The Committee **decided** to advance the proposed draft MRLs to Step 5, and to consider deletion of the CXLs for Brussels sprouts; cabbages, head; cottonseed; plums (including prunes); soya bean (dry) and tomato at its next Session.

DELTAMETHRIN (135)

107. The Committee noted the acute intake concerns for leafy vegetables and that the EC had a different residue definition for parent compound.

108. The Committee **decided** to advance all proposed draft MRLs to Step 5 and to consider at its next Session deletion of the existing CXLs as recommended by the 2002 JMPR.

BENDIOCARB (137)

109. The Committee was informed that this compound may not be longer supported and agreed to consider the deletion of all CXLs at its next Session.

BITERTANOL (144)

110. The Committee noted that the CXL of apricot of 1 mg/kg had been confirmed by the 2002 JMPR, and therefore CXL was retained.

CARBOSULFAN (145)

111. The Committee **decided** to return all draft MRLs to Step 6 awaiting the acute risk assessment by the 2003 JMPR.

METHOPRENE (147)

112. The Committee **decided** to recommend deletion of the CXL of mushrooms and peanut, as these CXLs are no longer supported by the manufacturer. The Delegation of Australia informed the Committee that they will be supplying data for S methoprene to support the CXLs for cereal grains, wheat bran, unprocessed, wheat flour and wheat whole meal.

113. The Committee agreed to retain the CXLs for eggs and maize oil, edible because thes are linked to the above cereal products.

DIMETHIPIN (151)

114. The Committee **decided** to advance all proposed draft MRLs to Step 5/8 and to revoke the associated CXLs, together with those for linseed, sunflower seed oil, crude and sunflower seed oil, edible.

PACLOBUTRAZOL (161)

115. The Committee noted at its last Session that the manufacturer no longer supported this compound and therefore **decided** to revoke all existing CXLs.

TOLYLFLUANID (162)

116. The Committee noted the concerns of the Delegations of France and Canada with regard to the unavailability of the JMPR 2002 monograph and **decided** to advance all proposed draft MRLs to Step 5. The Committee also **decided** to consider the withdrawal of the CXL for gherkin at its next session.

OXYDEMETON-METHYL (166)

117. The Committee **decided** to return all MRLs to Step 6 awaiting short-term intake calculations from the JMPR. The Committee was informed by the manufacturer that data will be submitted to the 2004 JMPR also to review the residue definition.

HEXACONAZOLE (170)

118. The Committee was informed at its last session that this compound was no longer supported by the manufacturer. However the Observer of the EC and the delegations of Spain and Canada informed the Committee that the compound was supported in the EU and Canada. The Delegation of Switzerland informed the Committee that the use is supported by the manufacturer in Member States but not in the Codex system.

119. The Committee **decided** to consider the deletion of all CXLs at its next session (see also 182), and to ask member countries for information of the status of this compound at the national level.

PENCONAZOLE (182)

120. The Committee was informed that the compound is no longer supported and therefore could consider the deletion of all CXLs at its next years session. The Observer of the EC informed the Committee that the manufacturer has notified the compound for evaluation within the Community and that it was used in all member states of the EU.

121. The Observer objected to the deletion of this compound. The Delegation of Switzerland informed the Committee that, as for hexaconazole (see 170), the use was no longer supported in the Codex system by the manufacturer.

122. Several Delegations expressed concern at this recent development, where compounds were being supported at the national level, but not in the Codex system.

The Committee noted that this could have implications on the accessibility and availability of data.

123. The Committee **decided** to consider the deletion of the CXLs at its next Session and also to address this issue in the policy paper to be elaborated by the Chair (see para 144).

CLETHODIM (187)

124. The Committee **decided** to advance all MRLs to step 8 noting that a method of analysis was now available which can differentiate the compound from sethoxydim.

FENPYROXIMATE (193)

125. The Committee **decided** to return the MRLs to Step 6 awaiting the 2004 JMPR toxicological evaluation for an acute RfD.

HALOXYFOP (194)

126. The Committee noted the concern from several delegations on the acute intake and therefore **decided** to return the MRLs for alfalfa forage (green); cattle kidney; cattle liver cattle meat; cattle milk; fodder beet leaves or tops and sugar beet leaves or tops to Step 3 and to return all other MRLs to Step 6 awaiting the 2004 JMPR to establish an Acute RfD. The Committee also noted the information from the Observer of the EC that the manufacturer will submit new residue data and that the residue definition for the racemic mixture will be replaced by the R-isomer.

TEBUFENOZIDE (196)

127. The Committee noted that the JMPR had indicated intake concerns and therefore **decided** to return the MRL for grapes to Step 6 and advance all other MRLs to Step 5.

128. The Committee noted that additional toxicological data would be submitted by the manufacturer to refine the acute RfD.

129. The Committee noted the request of the Delegation of Australia to the JMPR to consider the extrapolation of cattle commodities to all mammalian species.

KRESOXIM-METHYL (199)

130. The Committee **decided** to advance the MRLs for grapefruit; olive oil, virgin; olives and oranges, sweet, sour to Step 5/8.

CHLORPROPHAM (201)

131. The Committee noted that there were acute intake concerns for potatoes. Several Delegations expressed dietary intake concerns associated with the high MRL for potato.

132. The Committee noted that the MRL for potato was based on US data and US GAP, that the US acute RfD was significantly higher than that recommended by JMPR and that the commodity is also used as feeding stuff.

133. The Committee **decided** to advance all MRLs to Step 5 and to request JMPR to review acute toxicity again, taking into account the US assessment.

FIPRONIL (202)

134. The Committee **decided** to advance all proposed draft MRLs to Step 5/8.

SPINOSAD (203)

135. The Committee **decided** to advance all proposed draft MRLs to Step 5/8 with the exception of brassica vegetables, cattle milk and leafy vegetables, which were advanced to Step 5, noting the concerns from The Observer of the EC on the residue evaluations and of Delegation of France regarding the high MRL in milk (equivalent to 25 mg/kg in milk fat).

ESFENVALERATE (204)

136. The Delegation of Australia **noted** that fenvalerate and esfenvalerate both had the same residue definition, but had different MRLs for a number of commodities.

The Committee **decided**, in view of the above and pending the availability of the 2002 JMPR evaluation, to advance all proposals only to Step 5.

FLUTOLANIL (205)

137. The Committee **decided**, pending the availability of the 2002 JMPR evaluation, to advance all proposals to Step 5.

IMIDACLOPRID (206)

138. The Committee **decided**, pending the availability of the 2002 JMPR evaluation, to advance all proposals to Step 5.

DDT (021)

139. The Committee recalled that the Executive Committee returned the EMRL of 0.1-0.3 mg/kg for poultry meat to Step 3 on the basis of concerns expressed by the Regional Coordinator for Asia and that it was to the CCPR for further consideration. The Delegations of Thailand and Indonesia, were in favor of 0.3 mg/kg.

140. The Committee **decided** to advance the EMRL for poultry meat at the level of 0.3 mg/kg to Step 8.

RISK ANALYSIS POLICIES USED IN ESTABLISHING CODEX MRLS FOR PESTICIDES (AGENDA ITEM 8)[11]

141. The Committee recalled that it had agreed to consider risk analysis policies used in establishing Codex Maximum Residue Limits for Pesticides, following the Action Plan for the Risk Analysis in the Codex System adopted by the Commission in 1997 with the understanding that once the Codex-wide Working Principles had been adopted, relevant Committees would develop their own specific guidelines. The Codex Secretariat informed the Committee that the document had not been prepared due to practical difficulties and the need for clarification concerning the scope of the document in relation to policies and procedures.

142. The Committee was also informed that the Codex Committee on General Principles would consider *Draft Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius* and it was expected that the Codex Alimentarius Commission would give clear guidance after finalization of the above Principles, as to how Codex Committees should proceed with risk analysis policies in their respective areas.

143. It was pointed out that a clear CCPR policy framework document was necessary, that some general issues considered under agenda items 6 and 17 could be used for this purpose and that the relation between risk assessment and risk management should be clarified.

144. The Committee agreed that the Chair should prepare a paper on the risk analysis policies used by the Committee in establishing Maximum Residue Limits for Pesticides for consideration by the next session. The Committee also agreed that the paper should take into account the above-mentioned Working Principles and all relevant previous decisions of CCPR.

MATTERS RELATED TO METHODS OF ANALYSIS AND SAMPLING (AGENDA ITEM 9)[12]

145. The Chair of the Ad hoc Working Group on Methods of Analysis and Sampling, Dr Piet Van Zoonen (Netherlands), introduced the report of the Working Group (CRD 2) and summarized the discussions and conclusions of the group.

SINGLE LABORATORY VALIDATION OF METHODS AND ANALYSIS

146. The Committee recalled that the 24th Committee on Methods of Analysis and Sampling had considered the criteria for the selection of single-laboratory validated methods of analysis and had agreed to inform the CCPR of its discussions. The Committee agreed to propose to the CCMAS to consider the following criteria for inclusion in the Procedural Manual to reflect that single-laboratory validated methods could be selected under certain conditions.

General Criteria for the Selection of Single-Laboratory Validated Methods of Analysis (to be included after the General Criteria)

147. Inter-laboratory validated methods are not always available or applicable, especially in the case of multi-analyte/multi substrate methods and new analytes. The criteria to be used to select a method are included in the General Criteria for the Selection of Methods of Analysis. In addition the single-laboratory validated methods must fulfill the following criteria:

i. *the method is validated according to an internationally recognized protocol (e.g. the CCPR-Guideline on Good Laboratory Practice in Residue Analysis or the IUPAC Guideline);*

ii. *the use of the method is embedded in a quality assurance system in compliance with the ISO 17025 Standard or the principles of Good Laboratory Practice;*

[11] CX/PR 03/6.
[12] CRD 2.

148. The method should be complemented with information on accuracy demonstrated for instance with:

- *regular participation in proficiency schemes, where available;*
- *calibration using certified reference materials, where applicable;*
- *recovery studies performed at the expected concentration of the analytes;*
- *verification of result with other validated methods.*

149. The Committee noted that CCMAS had recommended the Harmonized IUPAC Guidelines for Single-Laboratory Validation of Methods of Analysis (with an amendment) for adoption by reference by the Commission.[13]

DRAFT REVISED GUIDELINES ON GOOD LABORATORY PRACTICE IN RESIDUE ANALYSIS AT STEP 7 (AGENDA ITEM 9(A)[14]

150. The Committee recalled that the Draft Guidelines had been adopted at Step 5 by the 50th Session of the Executive Committee and circulated for comments at Step 6 in CL 2002/35-PR. The Committee concurred with the recommendations of the Working Group to amend section 3.2.6 as proposed in the comments of Iran. Some minor amendments were also made to sections 3.2.6 and 4.2.2 for clarification purposes.

STATUS OF THE DRAFT REVISED GUIDELINES ON GOOD LABORATORY PRACTICE IN RESIDUE ANALYSIS

151. The Committee agreed to advance the Draft Revised Guidelines to Step 8 for adoption by the 26th Session of the Codex Alimentarius Commission (see Appendix II).

152. The Committee agreed to undertake new work on Guidelines on the use of mass spectrometry (MS) for identification, confirmation and quantitative determination of residues, subject to the approval of the Codex Alimentarius Commission. The first draft of the Guidelines would be prepared by the FAO/IAEA Training and Reference Center (TRC) in collaboration with the delegations of Australia, Belgium, Denmark, the Netherlands and the United Kingdom.

153. The Committee also agreed to review the existing texts relating to methods of analysis and sampling in Volume 2A of the Codex Alimentarius at regular intervals in order to incorporate new principles and practices, subject of approval of this approach by the Commission.

DISCUSSION PAPER ON THE ESTIMATION OF UNCERTAINTY OF MEASUREMENTS (AGENDA ITEM 9(B)

154. The Committee noted that document CX/PR 03/8 had not been prepared due to the unavailability of data and worked examples and agreed that this question would be considered in conjunction with the issues covered in Agenda Item 9 (c) at the next session.

155. The Committee was informed that the Codex Committee on Methods of Analysis and Sampling had advanced the Proposed Draft Guidelines on Measurement Uncertainty to Step 5.

[13] ALINORM 03/23; Appendices III and V

[14] ALINORM 03/24A, Appendix VI; CX/PR 03/7 (comments of Iran and Cuba); CX/PR 03/7-Add.1 (comments of the Netherlands); CRD 4 (comments of the European Community).

DISCUSSION PAPER ON MULTIPLE PEAKS FOR THE ESTIMATION OF UNCERTAINTY (AGENDA ITEM 9(C)[15]

156. The Committee noted that the document prepared by the Representative of FAO/IAEA on the estimation of uncertainty of results was a good basis for the development of specific guidelines, subject of approval of the Commission as new work. It welcomed the offer of the Representative of FAO/IAEA to prepare a revised document in collaboration with the delegations of Australia, Belgium, Denmark, the Netherlands and the United Kingdom, for consideration at the next session.

DISCUSSION PAPER ON THE REVISION OF THE LIST OF METHODS FOR PESTICIDE RESIDUE ANALYSIS (AGENDA ITEM 9(D)[16]

157. The Committee noted that the information provided by member countries in document CX/PR 03/10 would be made available on the website of the FAO/IAEA TRC and that a list of pesticides not covered by the current multi-residue methods would be prepared.

158. The Committee agreed that this list would be included in a Circular Letter inviting member countries to submit proposals for new analytical methods, especially for those pesticides that were not already covered by existing methods. A template prepared by FAO/IAEA TRC would be used to collect the information in a standard format and the Delegation of the Netherlands would compile the revised list for consideration by the next session.

PROPOSALS FOR NEW TROPICAL FRUIT AND VEGETABLE COMMODITIES (AGENDA ITEM 9E)[17]

159. The Committee noted the problems identified in some countries concerning the sampling of jackfruit and the sample preparation of coconut, durian and jackfruit and agreed with the recommendations of the Working Group that for generating residue data for establishing MRLs the juice and the flesh of coconut should be analyzed separately; and a number of representative segments of the whole fruit, cut in longitudinal direction, should be analyzed for jackfruit and durian.

160. In view of the high value and very large size/weight of these fruits, and low production volume of individual growers, the Committee agreed that a representative segment from each of 5 fruits might be selected randomly from the lot, provided that any contamination and or the deterioration of residues in the sample are avoided.

161. The Committee expressed its appreciation to Dr Van Zoonen and to the Working Group for their excellent work and the considerable progress achieved on several complex issues. The Committee agreed that the Working Group should convene at the next session under the chairmanship of Dr Van Zoonen.

ESTABLISHMENT OF CODEX PRIORITY LIST OF PESTICIDES (AGENDA ITEM 10)[18]

162. The Chairman of the *ad hoc* Working Group on Priorities, Dr T. Doust (Australia), presented the report of the Working Group and highlighted the main issues discussed by the group and the changes suggested for the tentative scheduling of the compounds.

163. A new chemical, *dimethomorph,* was proposed by France and tentatively scheduled for evaluation in 2006. Commodities for evaluation include grapes, potatoes, hops, tomatoes, onions peppers, litchee, and garlic. Data would be ready for submission in 2004/2005.

[15] CX/PR 03/8.
[16] CX/PR 03/9.
[17] CX/PR 03/11.
[18] CX/PR 03/12; CRD 1.

164. The tentative schedules for JMPR were modified on the basis of discussions of pesticides under Agenda Item 7 and other considerations. Included among these changes

were:

2003: *tebufenozide* for acute toxicity; *dodine* for periodic re-evaluation.

2004: *chlorpyrifos, bentazone*[19]*, dimethipin*[20]*, fenpropimorph*[21] for acute toxicity; *methomyl* (peppers), *folpet* (strawberries) and *carbofuran* (maize) for residues evaluation,

2005: *thiabendazole, chlorpropham*, and *carbendazim* for acute toxicity: *spinosad* (grapes and cereals)[22] for residues evaluation.

2007: *Lambda-cyhalothrin* for toxicological re-evaluation

165. It was agreed to delete penconazole (182) and ethion (034) as these compounds were no longer supported.

166. The Committee agreed with the proposed changes to the priority list and agreed to forward it to the Commission for approval as new work (see Appendix VIII).

167. On the concept of worksharing, it was suggested that worksharing between JMPR and national or multinational agencies could reduce the workload of JMPR reviewers. The Observer of Croplife International informed the Committee that recent EU and U.S. EPA evaluations for *trifloxystrobin, fenhexami, indoxacarb* and *bifenazate* could be made available to JMPR. It was proposed that JMPR would be provided with the normal data package for evaluation and copies of the national assessment reports and summary documentation prepared by the applicant from the original review.

168. The Committee **agreed** that an *ad hoc* Working Group on priorities should be convened at the next session under the chairmanship of Australia (Dr Doust).

CRITERIA FOR PRIORITISATION PROCESS (AGENDA ITEM 10(A))[23]

169. The Chairman of the *ad hoc* Working Group on Priorities, Dr T. Doust (Australia) informed the Committee that the Group had reviewed the criteria for the prioritisation of compound for evaluation by JMPR and had proposed a number of changes to these criteria.

170. The Observer of the EC supported by some delegations called for clear rules of procedure to be established for the Working Group on Priorities, that additional criteria should be added to the current list and, in particular, for removal of compounds form priority list. The Observer also proposed that as criteria for the evaluation of new compounds the Committee should consider adding the following criteria: availability of data; availability of international/national reviews and coordination with other national/international lists.

170. The Committee was also advised that, taking into account the heavy workload of JMPR, the Working Group had recognized that there would be considerable advantage for the proposal in Point 1 for periodic re-evaluations to be conducted every 15 years instead of every 10 years. The Delegations of Denmark and Australia supported this view in principle, but suggested that, where possible, the 10-year review cycle should be maintained.

[19] Originally scheduled for 2005.
[20] Originally scheduled for 2005.
[21] Originally scheduled for 2005.
[22] Originally scheduled for 2004.
[23] CX 03/13, CRD 1.

171. Pesticide specifications (JMPS) were not considered as a prioritization criterion as it was decided at the CCPR 34 that the development of specifications should not delay JMPR evaluations.

172. The Committee supported the proposal for candidate compounds for reevaluation to be selected on the basis of not having a major toxicological or residue review for 15 years, provided that Committee consider reverting to the 10 year period criterion once the JMPR backlog was removed.

173. The Committee agreed to circulate the revised set of criteria included as Appendix IX for comments and to consider this matter at its next meeting.

174. In responding to the request for consideration of the scheduling EMRLs for periodic re-evaluation, (ALINORM 03/24, paragraph 173), it was noted that although residue monitoring data were available from the Australia, EC, Norway and the USA, there was little or no recent toxicology data on EMRLs; that current CCPR policy was to re-evaluate every 5 years; and that the issue of violation rates had not yet been resolved.

175. The Committee agreed that, until a policy had been developed on how to deal with JMPR assessments on EMRLs, and the violation rate issue had been resolved, review of EMRLs should receive a low priority. The Chairman suggested that these two points and other relevant issues could be included in the risk analysis policy document being prepared for the next meeting (para. 144).

DISCUSSION PAPER ON THE PILOT PROJECT FOR THE EXAMINATION OF NATIONAL MRLS AS INTERIM CODEX MRLS FOR SAFER REPLACEMENT PESTICIDES (AGENDA ITEM 11)[24]

176. In the absence of the Delegation of the United States, the Chair introduced the document CX/PR 03/14 and recalled that the Committee had an extensive discussion at the last session on the issue of the lengthy process required for the elaboration of the Maximum Residue Limits for newly introduced, often safer, pesticides. The Committee had decided to explore the feasibility of using national MRLs as Interim MRLs in address trade vulnerability.

177. The Committee was informed that the criteria and procedures were proposed in the document to initiate a pilot project to establish Interim MRLs, and these included the following:

- The Interim standard would be used for a new pesticide that is a safer replacement for an existing one;
- The commodities of interest must be in international trade, and should be significant in the human diet;
- The interim standard would be designated as Step 8 (I) with the same status as a Step 8 MRL and would remain as an interim standard for a fixed time period unless and until rejected by the Codex Alimentarius Commission;
- The nomination of a pesticide to the Priorities Working Group of the Committee (PWG) must be through a national government and must include the required supporting documentation. The PWG will only provide a screening mechanisms and will make recommendations to the CCPR regarding the completeness of the submission. The proposed Step 8(I) MRLs to CCPR will be circulated to request comments from member governments. CCPR will note the nomination and schedule the pesticide for full consideration of interim MRLs at its next meeting.
- A proposal for an Interim Step 8(I) MRL for a given pesticide/commodity will be considered one time only;

[24] CX/PR 03/14, CRD 7 (comments by EC).

- CCPR will not need approval of the interim MRL concept by the Codex Alimentarius Commission before implementation. However, the Codex Alimentarius Commission should be consulted and informed of CCPR plans in this area;

178. Some delegations supported the proposed pilot scheme for the establishment of Interim MRLs, noting there were sufficient safeguards to protect the integrity of the scheme. The Observer from Croplife International also supported this proposal and indicated that the detailed procedure could be refined during the pilot of the project.

179. Several delegations, while not opposing the project in principle, expressed different views and concerns with respect to:

- practical difficulties where wide differences existed among national MRLs
- the need to separate and distinguish between risk assessment and risk management;
- the acceptance of Interim MRL concept by the Codex Alimentarius Commission and the legal status in the WTO-SPS;
- the level of independence and transparency associated with the elaboration of Interim MRLs;
- additional work required at the national level to assess Interim MRL submission;
- uncertainty as to how data protection requirements have been addressed;
- possible variability in the quality of the national assessments provided in support of Interim MRLs;
- How the success of the project would be evaluated.

180. The Observer from the European Community suggested that the Committee could achieve the same purpose through other measures such as mutual acceptance of national MRLs on a bilateral basis and concluded that the member countries of European Union could support the initiation of the pilot project provided that their concerns were addressed.

181. The Codex Secretariat indicated that Interim MRLs were not defined in the Codex Elaboration Procedure and therefore had no status in Codex. The establishment of Interim MRLs would require an amendment to the current procedure, for consideration by the Committee on General Principles and adoption by the Codex Alimentarius Commission. The Committee was also informed that paragraph 3(a) of Annex A - Definitions of the *Agreement on the Application of Sanitary and Phytosanitary Measures (SPS)* refers to "the standards, guidelines and recommendations established by the Codex Alimentarius Commission relating to food additives, veterinary drug and pesticide residues, contaminants, methods of analysis and sampling, and codes and guidelines of hygienic practice".

182. The Codex Secretariat was asked to seek and provide advice on the legal status of such interim MRLs should intended pilot scheme be progressed and for that advice to be provided to member countries before the next session of the CCPR. Advice on this matter was seen as an essential prerequisite for the commencement of a pilot project. The Secretariat indicated that such advice could be provided only by the Codex Alimentarius Commission.

183. In view of the substantial changes of the Codex Procedure put forward by the Working Group, the Delegation of France supported by several delegations, noted that the best way to deal with this issue, was to discuss it as part of the follow-up of the Codex evaluation. The Delegation of France added that this matter should not be pursued by the CCPR in isolation since this Committee was not only one in Codex to establish MRLs and that the comments from the other Committees concerned should be sought.

184. The Representative of FAO recalled that the 25th (Extraordinary) Session of the Commission had considered the *Joint FAO/WHO Evaluation of the Codex Alimentarius and Other FAO and WHO Work on*

Food Standards that included recommendations on scientific advice provided by FAO and WHO. The Commission had reasserted the essential importance of expert advice provided to Codex and to member countries and had supported an increase in the allocation of FAO and WHO to scientific risk assessment. The fragile situation of the JMPR in particular had been highlighted.

185. Referring to the proposed pilot project for the development of interim MRLs, he stated that after acceptance of such an approach, any member country could then request for an interim MRL based on a complete data submission. The Representative also addressed the need to avoid possible discrepancies, i.e. in relation to definitions or terminology, between the approach for interim MRLs and the normal procedure. To endure consistency he expressed the wish of the JMPR Secretariat to participate in the Drafting Group.

186. After further discussion, the Committee agreed in principle to initiate the project at the next session but to request preparatory work for that session. The Committee asked the Drafting Group established at the last session, with the addition of France, The Netherlands and the JMPR Secretariat, to revise the paper in the light of the above discussion so that it would be possible to initiate the project at the next session of the CCPR. The United States would be asked to coordinate this work. The Committee also agreed that advice of the Commission would be sought about this initiative.

CONSIDERATION OF THE ELABORATION OF MRLS FOR SPICES (AGENDA ITEM 12)[25]

187. The Delegation of South Africa introduced the document and informed the Committee that following the decision of the 34th Session of the Committee they had prepared a revised paper to provide further information on the definition of spices based on the Codex Classification (Group 028); the criteria to be applied for the use of monitoring data to establish MRLs for spices; and information on the type and origin of extraneous residues of persistent pesticides such as DDT, BHC and lindane.

188. Many delegations supported the use of monitoring data for the establishment of MRLs for spices in general.

189. The Delegation of China suggested to use the same approach to establish MRLs for tea which forms an important component in international trade, and the was only few MRLs established for this commodity, this can cause problems in international trade.. However, several delegations objected to this proposal and indicated that a decision had already been taken to limit the scope of discussion to spices.

190. Some delegations questioned the necessity of including such commodities as parsley, ginger root, caper buds or chili pepper is the "spices" category as in their opinion these were not regarded as "spices" .

191. Some delegations pointed out that MRLs already existed for chili peppers and that MRLs could be calculated to "dried chili peppers" by applying processing factor as it is done in processed vegetables. Other delegations were of the view that dried chili peppers were traded extensively and that because there were problems in trade, therefore the Committee should take a pragmatic approach in order to avoid trade disruptions. The EC suggested that MRLs from dried chili peppers could be calculated from fresh chili by using an appropriate processing/dehydration factor.

192. Some delegations pointed out that there was a need to group spices according to whether they were derived from seeds, roots and tubers, and leaves, as his might facilitate the elaboration of group MRLs.

193. The Committee noted that the residue levels in spices were not generally at comparable levels, depending on the characteristics of spices and also that there was a need to review and clarify the proposed number and distribution of residue data points.

194. Some delegations did not agree with one proposal contained in the document that MRLs instead of EMRLs be established for spices for persistent pesticides such as DDT and BHC as they were not registered for use in agriculture.

[25] CX/PR 03/15; CRD 3 (comments from Australia); CRD 4 (comments from the European Community); CRD 6 (comments from Thailand); CRD 8 (comments from Indonesia); CRD 10 (comments from India).

195. The WHO Representative informed the Committee that the Stockholm convention on Persistent Organic Pollutants, was intended to end production and use of certain organochlorine compounds, including DDT and BHC, but not lindane. Because of its public health importance, WHO had successfully argued for a 5 year extension of the use of DDT as a vector control agent for malaria to be applied on the interior walls of buildings. Consequently, the continued use of DDT for public health purposes should not result in contamination of the environment, including crops. No similar extension was requested for BHC.

196. The Observer of IOSTA indicated that currently they experienced difficulties in compiling the current list because some of the listed spices were not important, while others of importance were not in the list.

197. The Joint FAO Secretary of JMPR informed the Committee that guidance for submission of pesticide monitoring data on spices was provided in Section 2.7 of the 2002 JMPR Report and that the JMPR would prepare guidelines for performing selective field surveys to support elaboration of MRLs for spices for which sufficient data were not currently available, should the Committee agree to the use of monitoring data for setting spice MRLs.

198. The Committee reconfirmed its decision that the elaboration of MRLs on the basis of monitoring data should be restricted to spices, and that there was general agreement to consider sub-grouping of spices.

199. The Committee agreed that the Delegation of South Africa[26] would revise the paper on the basis of the above discussions. This revised paper should identify those spices of interest (irrespective of whether they were classified as spices in the Codex Classification system). The meeting agreed that this revised paper would be considered at the next session.

200. It was also agreed that for persistent organochlorine pesticides EMRLs but not MRLs should be established.

DISCUSSION PAPER ON THE NEED FOR THE REVISION OF THE CODEX CLASSIFICATION OF FOODS AND ANIMAL FEEDS (AGENDA ITEM 13)[27]

201. The Committee noted that the review of the Codex Classification of Foods and Animal Feeds had been considered at the last session and that there was general support for the revision. However, different views were expressed regarding the extent of the revision and therefore the Delegation of The Netherlands, at the request of the Committee, prepared the paper addressing this matter.

202. The Delegation of the Netherlands noted that comments were provided only by Australia and the USA. The Delegation pointed out that USA supported an extensive up-date of the classification and proposed suggestions for the re-grouping of raw commodities and processed commodities were proposed. Practical problems with electronic version of the classification could be solved by using either the Australian or the US electronic data base as the basis for further development. The Delegation of Australia proposed to investigate the possibility of posting an electronic version of the current classification on the Codex website as soon as possible to assist delegations identify suggested improvements in Codex Classification.

203. The Codex Secretariat suggested that if the Committee agreed to undertake a revision, the first step should be to ask a data base designer to evaluate the current Codex food and feed classification. It was indicated that the system must be capable of extension to new areas and capable of handling sub-sets of data.

204. The Committee was informed that the Delegation of the Netherlands favored a limited update of the classification and volunteered to take a lead in the revision. It was noted that this revision should not heavily affect the existing CXLs in a first stage.

205. The Committee agreed that the Delegation of the Netherlands with the assistance of other interested parties[28] would initiate work on the limited revision including potential re-grouping. The Working Group

[26] In cooperation with India, the Netherlands and IOSTA.
[27] CX/PR 03/16; CRD 9 (responses from Australia and the United States submitted to the CL 2002/16-PR).

would evaluate and propose which electronic data base would better suit this purpose and prepare a paper for consideration by the next session of the Committee.

MAXIMUM LIMITS FOR PROCESSED OR READY-TO-EAT FOODS OR FEEDS (AGENDA ITEM 17)[29]

206. In the absence of the Delegation of the United States, the Chair presented the paper prepared by the Government of the United States relating to past practices and policies of the Committee concerning the establishment of MRLs for processed or ready-to-eat foods. The paper noted that this issue had been considered several times in the CCPR and JMPR since 1981, and that there were inconsistencies in how these MRLs were elaborated.

207. When considering the conclusions on the paper, the Committee discussed in detail the First point relating to the decision of the 12th Session of this Committee, that "MRLs for raw agricultural commodities apply to all processed foods and feeds derived from them unless separate higher MRLs exist for specific commodities."

208. Some delegations supported this approach, commenting that consumer protection was adequately addressed in the dietary intake calculations, and that specific MRLs were not needed for processed foods unless residues concentrated during processing. Other delegations considered that it was important to elaborate MRLs for processed foods, irrespective of whether residues concentrated or not, in order to facilitate enforcement of GAP and to recognize that some commodities are mostly traded or consumed only after processing. It was also pointed out that the difference between pesticides used in pre- harvest and post-harvest applications should be taken into account.

209. Other points raised in the discussions included the possibility of different processing methods resulting in different residues, and that crops grown for processing might have different GAPs from those for grown for direct consumption. It was also suggested that a general approach on how to apply a MRL for raw agricultural commodity to processed products derived from it, as it exist in EU legislation, would cover all cases and be more efficient than case by case establishment of MRLs for processed products.

210. After further discussion the Committee agreed to invite the Delegation of the United States, with the assistance of the Delegation of the Netherlands, to redraft the paper concerning the policy to be followed in the establishment of MRLs for processed foods in the light of the above discussion.

REMOVAL OF AN EXTRANEOUS BURDEN FROM THE WORKLOAD OF THE JMPR (AGENDA ITEM 18)[30]

210. In the absence of the Delegation of the United States, the Chair presented the paper prepared by the Government of the United States to address some of the issues related to the excessive workload of the JMPR. The document recalled that the *Review of the Working Procedures of the JMPR*[31] considered by the last session of the Committee suggested that some of the data requirements for JMPR were unnecessary, including information on environmental fate. In response to this suggestion the United States proposed that the CCPR consider advising the JMPR to restrict its review of environmental fate to those areas specifically related to the estimation of dietary exposure and the estimation of MRLs.

211. Some delegations expressed their support for the proposal as it would streamline the work of JMPR. Other delegations, while recognizing the need to reduce the workload of JMPR, pointed out that some of the information on environmental fate was relevant in relation to crop rotation and for the purposes of

[28] Australia, Canada, Germany, Japan, New Zealand, Sweden, Codex Secretariat and WHO. The Committee noted that the Government of the United States might wish to contribute to the work of the above group.
[29] CX/PR 03/17, CRD 3 (comments of Australia)
[30] CX/PR 03/18.
[31] CX/PR 02/12.

establishing EMRLs when required. This information also provided an important reference for governments, especially for those countries that could not carry out such studies at the national level.

212. The Committee noted that consideration of environmental fate was part of the terms of reference of the JMPR and that to amend them would require consideration by the FAO Council. The Committee agreed that JMPR should proceed with the consideration of environmental fate but should focus on those aspects that were most relevant to MRL setting and that the current data requirements should be revised accordingly.

213. The FAO Joint Secretary of JMPR informed the Committee that JMPR would reconsider the requirements of Chapter 3 of the FAO *Manual on the Submission and Evaluation of Pesticide Residue Levels in Food and Feed* in line with the above decision.

OTHER BUSINESS AND FUTURE WORK (AGENDA ITEM 14)

Minimum data requirements

214. The Observer from the European Community informed the Committee that the reports EC/OECD Workshop on Minimum Data Requirements for Maximum Residue Limits and OECD/FAO Zoning Steering Group were available on the OECD/FAO website and proposed that there should be a follow-up activity on these important issues.

215. The Representative of FAO informed the Committee of a proposal that the FAO would contract a consultant, subject to availability of funds to review the reports and identify issues such as minimum number of trials, extrapolation between crops and processing studies on which there had been no international agreement and to prepare a paper for consideration by the next Session of the Committee.

AVE ATQUE VALE

216. The Committee noted the forthcoming retirement of Mr Bernard Declercq (France) and Dr Angel Yagüe Martinez de Tejada (Spain). It expressed its warmest appreciation for the outstanding contribution the Mr Declercq and Dr Yagüe had made to Committee's work over many years and wished them good health and all the best in their forthcoming life.

DATE AND PLACE OF THE NEXT SESSION (AGENDA ITEM 15)

217. The Committee was informed that India had invited the 36th Session be held in India from 19 to 24 April 2004, subject to confirmation of the host Government and the Codex Secretariat.

Annex 1

SUMMARY STATUS OF WORK

Subject	Step	Action by	Document Reference in ALINORM 03/24A
Draft Revised Guidelines on Good Laboratory Practice in Residue Analysis	8	26th Session of the CAC	Para. 163, Appendix II
Draft and Revised Draft MRLs	8	26th Session of the CAC	Paras. 51 – 155, Appendix III
Draft and Revised Draft MRLs	5/8	26th Session of the CAC	Paras 51-155, Appendix IV
Proposed Draft MRLs	5	26th Session of the CAC	Paras 51-155 Appendix V
Codex Maximum Residue Limits Recommended for Revocation		25th Session of the CAC	Paras 51-155 Appendix VI
Draft and proposed draft MRLs	6 / 3	Governments, CCPR 36	Paras 51 -155, Appendix VII
New work:			
Priority List of Pesticides (new pesticides and pesticides under periodic review)	1	26th CAC, Governments, Australia, 36th CCPR	Para. 166, Appendix VIII
Proposed Draft Guidelines on the Use of Mass Spectrometry (MS) for Identification, Confirmation and Quantitative Determination of Residues	1/2/3	26th CAC, FAO/IAEA TRC[32], Governments, 36th CCPR	Para. 152
Periodic Review of the Existing Texts Relating to Methods of Analysis and Sampling for the Determination of Residues for Compliance with MRLs	1/2/3	26th CAC, Governments, 36th CCPR	Para. 153
Proposed Draft Guidelines on the Estimation of Uncertainty of Results	1/2/3	26th CAC, FAO/IAEA, Governments, CCPR 36	Para. 156
Proposed Revised Criteria for Prioritization Process of Compounds for Evaluation by JMPR		26th CAC, Codex Secretariat, Governments, 36th CCPR	Para. 173, Appendix IX
Discussion papers on:			
Risk Analysis Policies Used in Establishing Codex MRLs		Chairperson, 36th CCPR	Para. 144
Estimation of Uncertainty of Measurements		FAO/IAEA	Para. 166
A Pilot Project for the Examination of National MRLs as Interim Codex MRLs for Safer Replacement Pesticides		26th CAC, US[33], 36th CCPR	Para. 186
Elaboration of MRLs for Spices		South Africa[34]	Para. 209
Revision of the Codex Classification of Foods and Animal Feeds		Netherlands[35], 36th CCPR	Para. 205
Establishment of Maximum Limits for Processed or Ready-to-Eat Foods and Feeds		United States, The Netherlands	Para. 210

[32] Australia, Belgium, Denmark, the Netherlands, and the United Kingdom.
[33] Argentina, Australia, Canada, Chile, Egypt, France, New Zealand, The Netherlands, South Africa, Sudan, European Community, JMPR Secretariat, Consumers International and CropLife International.
[34] South Africa, India, The Netherlands and IOSTA.
[35] Australia, Canada, Germany, Japan, New Zealand, Sweden, Codex Secretariat and WHO.

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APPENDIX II

DRAFT REVISED GUIDELINES ON GOOD LABORATORY PRACTICE IN RESIDUE ANALYSIS

(At Step 8 of the Codex Procedure)

FOREWORD

The Guidelines are intended to assist in ensuring the reliability of analytical results in checking compliance with maximum residue limits of foods moving in international trade. Reliable analytical results are essential to protect the health of consumers and to facilitate international trade.

In addition to the present Guidelines, other relevant Codex recommendations elaborated by the Codex Committee on Pesticide Residues (CCPR) in the field of enforcement of Codex maximum limits for pesticide residues are as follows:

1 Recommended Method of Sampling for the Determination of Pesticide Residues (CAC/GL 33-1999, Volume 2A, Part 1, Second Edition, Rome, 2000).
2 Portion of Commodities to which Codex Maximum Residue Limits Apply and which is analysed (CAC/GL 33-1999, Volume 2A, Part 1, Second Edition, Rome, 2000).
3 List of Codex Maximum Residue Limits for Pesticides (Codex Alimentarius, Wolume Two, Pesticide Resdues in Food, Rome, 1993.
4 Recommended Methods of Analysis of Pesticide Residues (CAC/GL 33-1999, Volume 2A, Part 1, Second Edition, Rome, 2000).
5 Codex Classification of Food and Animal Feed (Codex Alimentarius, Volume Two, Pesticide Residues in Food, Rome, 1993).

1. INTRODUCTION

It was considered that the ultimate goal in fair practice in international trade depended, among other things, on the reliability of analytical results. This in turn, particularly in pesticide residue analysis, depended not only on the availability of reliable analytical methods, but also on the experience of the analyst and on the maintenance of 'good practice in the analysis of pesticides'.

These guidelines define such good analytical practice and may be considered in three inter-related parts:

The Analyst (par. 2);

Basic Resources (par. 3);

The Analysis (par.4).

The requirements for facilities, management, personnel, quality assurance and quality control, documentation of results and raw data, and relevant subjects, which are considered as prerequisites for obtaining reliable and traceable results, are described in general in the ISO/IEC 17025 Standard (1999) and in a series of OECD GLP Guidance Documents, in the corresponding national laws and regulations. This Codex Guidelines, which are not exhaustive, outline the most essential principles and practices to be followed in the analysis of pesticide residues.

2. THE ANALYST

2.1 Residue analysis consists of a chain of procedures, most of which are known, or readily understood, by a trained chemist, but because the analyte concentrations are in the range μg/kg to mg/kg and because the analyses can be challenging, attention to detail is essential. The analyst in charge should have an appropriate professional qualification and be experienced and competent in residue analysis. Staff must be fully trained and experienced in the correct use of apparatus and in appropriate laboratory skills. In addition, each analyst using the method for the first time should complete the tests specified in sections 4.4.5 of Table 4 to demonstrate that they can use the method within the expected performance parameters established during method validation prior to analysis of samples. They must have an understanding of the principles of pesticide residue analysis and the requirements of Analytical Quality Assurance (AQA) systems. They must understand the purpose of each stage in the method, the importance of following the methods exactly as described and of noting any unavoidable deviations. They must also be trained in the evaluation and interpretation of the data that they produce. A record of training and experience must be kept for all laboratory staff.

2.2 When a laboratory for residue analysis is set up, the staff should spend some of their training period in a well established laboratory where experienced advice and training is available. If the laboratory is to be involved in the analysis for a wide range of pesticide residues, it may be necessary for the staff to gain experience in more than one expert laboratory.

3. BASIC RESOURCES

3.1 THE LABORATORY

3.1.1. The laboratory and its facilities must be designed to allow tasks to be allocated to well-defined areas where maximum safety and minimum chance of contamination of samples prevail. Laboratories should be constructed of, and utilise, materials resistant to chemicals likely to be used within them. Under ideal conditions, separate rooms would be designated for sample receipt and storage, for sample preparation, for extraction and clean-up and for instrumentation used in the determinative step. The area used for extraction and clean-up must meet solvent laboratory specifications and all fume extraction facilities must be of high quality. Sample receipt, storage and preparation should be handled in areas devoted to work at residue levels. Maintenance of sample integrity and adequate provisions for personal safety are priority requirements.

3.1.2 Laboratory safety must also be considered in terms of what is essential and what is preferable, as it must be recognised that the stringent working conditions enforced in residue laboratories in some parts of the world could be totally unrealistic in others. No smoking, eating, drinking or application of cosmetics should be permitted in the working area. Only small volumes of solvents should be held in the working area and the bulk of the solvents stored separately, away from the main working area. The use of highly toxic solvents and reagents should be minimised whenever possible. All waste solvent should be stored safely and disposed of both safely and in an environmentally friendly manner taking into account specific national regulations where available.

3.1.3 The main working area should be designed and equipped for utilisation of an appropriate range of analytical solvents. All equipment such as lights, macerators and refrigerators should be "spark free" or "explosion proof". Extraction, clean-up and concentration steps should be carried out in a well ventilated area, preferably in fume cupboards.

3.1.4 Safety screens should be used when glassware is used under vacuum or pressure. There should be an ample supply of safety glasses, gloves and other protective clothing, emergency washing facilities and a spillage treatment kit. Adequate fire fighting equipment must be available. Staff must be aware that many pesticides have acutely or chronically toxic properties and therefore, great care is necessary in the handling of standard reference compounds.

3.2 EQUIPMENT AND SUPPLIES

3.2.1 The laboratory will require adequate, reliable, supplies of electricity and water. Adequate supplies of reagents, solvents, gas, glassware, chromatographic materials, etc., of suitable quality are essential.

3.2.2 Chromatographic equipment, balances, spectrophotometers etc. must be serviced and calibrated regularly and a record of all servicing/repairs must be maintained for every such item of equipment. Calibration is essential for equipment performing measurements. Calibration curves and comparison with standards may suffice.

3.2.3 Regular calibration and re-calibration of measuring equipment must be done where the possible change in nominal value may significantly contribute to the uncertainty of the measurement. Balances and automated pipettes/ dispensers and similar equipment must be calibrated regularly. The operating temperatures of refrigerators and freezers should be continually monitored or be checked at specified intervals. All records should be kept up-to-date and retained.

3.2.4 Equipment used must be fit for purpose.

3.2.5 All laboratories require pesticide reference standards of known and acceptably high purity. Analytical standards should be available for all parent compounds for which the laboratory is monitoring samples, as well as those metabolites that are included in MRLs.

3.2.6 All analytical standards, stock solutions and reagents should be properly labelled including preparation date, analyst's identification, solvent used, storage conditions employed, and those compounds whose integrity could be influenced by degradative processes must be clearly labelled with an expiry date and stored under appropriate conditions. Reference standards must be kept under conditions that will minimise the rate of degradation, e.g. low temperature, exclusion of moisture and light. Equal care must be taken that standard solutions of pesticides

are not decomposed by the effect of light or heat during storage or become concentrated by solvent evaporation.

4. THE ANALYSIS

The methods applied for the determination of pesticide residues should generally satisfy the criteria given in Table 3.

4.1 AVOIDANCE OF CONTAMINATION

4.1.1 One of the significant areas in which pesticide residue analysis differs significantly from macro-analysis is that of contamination and interference. Trace amounts of contamination in the final samples used for the determination stage of the method can give rise to errors such as false positive or false negative results or to a loss of sensitivity that may prevent the residue from being detected. Contamination may arise from almost anything that is used for, or is associated with, sampling, sample transport and storage, and the analyses. All glassware, reagents, organic solvents and water should be checked for possible interfering contaminants before use, by analysis of a reagent blank.

4.1.2 Polishes, barrier creams, soaps containing germicides, insect sprays, perfumes and cosmetics can give rise to interference problems and are especially significant when an electron-capture detector is being used. There is no real solution to the problem other than to ban their use by staff while in the laboratory.

4.1.3 Lubricants, sealants, plastics, natural and synthetic rubbers, protective gloves, oil from ordinary compressed air lines and manufacturing impurities in thimbles, filter papers and cotton-wool can also give rise to contamination.

4.1.4 Chemical reagents, adsorbents and general laboratory solvents may contain, adsorb or absorb compounds that interfere in the analysis. It may be necessary to purify reagents and adsorbents and it is generally necessary to use re-distilled solvents. Deionised water is often suspect; re-distilled water is preferable, although in many instances tap water or well water may be satisfactory.

4.1.5 Contamination of glassware, syringes and gas chromatographic columns can arise from contact with previous samples or extracts. All glassware should be cleaned with detergent solution, rinsed thoroughly with distilled (or other clean) water and then rinsed with the solvent to be used. Glassware to be used for trace analysis must be kept separate and must not be used for any other purpose.

4.1.6 Pesticide reference standards should always be stored at a suitable temperature in a room separate from the main residue laboratory. Concentrated analytical standard solutions and extracts should not be kept in the same storage area.

4.1.7 Apparatus containing polyvinylchloride (PVC) should be regarded as suspect and, if shown to be a source of contamination, should not be allowed in the residue laboratory. Other materials containing plasticisers should also be regarded as suspect but PTFE and silicone rubbers are usually acceptable and others may be acceptable in certain circumstances. Sample storage containers can cause contamination and glass bottles with ground glass stoppers may be required. Analytical instrumentation ideally should be housed in a separate room. The nature and importance of contamination can vary according to the type of determination technique used and the level of pesticide residue to be determined. For instance contamination problems which are important with methods based on gas chromatography or high performance liquid chromatography, may well be less significant if a spectrophotometric determination is used, and vice versa. For relatively high levels of residues, the background interference from solvents and other materials may be insignificant in comparison with the amount of residue present. Many problems can be overcome by the use of alternative detectors. If the contaminant does not interfere with the residue determination, its presence may be acceptable.

4.1.8 Residues and formulation analyses must have completely separate laboratory facilities provided. Samples and sample preparation must be kept separate from the all residue laboratory operations in order to preclude cross contamination.

4.2 RECEPTION AND STORAGE OF SAMPLES

4.2.1 Every sample received into the laboratory should be accompanied by complete information on the source of the sample, on the analysis required and on potential hazards associated with the handling of that sample.

4.2.2 On receipt, a sample must immediately be assigned a unique identification code which should accompany it through all stages of the analysis to the reporting of the results. Samples should be subject to an

appropriate disposal review system and all records should be kept.

4.2.3 Sample processing and sub-sampling should be carried out using procedures that have been demonstrated to provide a representative analytical portion and to have no effect on the concentration of residues present.

4.2.4 If samples cannot be analysed immediately but are to be analysed quickly, they should be stored at (1 - 5 °C), away from direct sunlight, and analysed within a few days. However, samples received deep-frozen must be kept at ≤ -16 °C until analysis. In some instances, samples may require storage for a longer period before analysis. In this cases, storage temperature should be approximately - 20 °C, at which temperature enzymic degradation of pesticide residues is usually extremely slow. If prolonged storage is unavoidable, the effects of storage should be checked by analysing fortified samples stored under the same conditions for a similar period. Useful information on storage stability of pesticide residues can be found in the annual publications of FAO titled: Pesticide Residues - Evaluations prepared by the FAO/WHO JMPR, and in the information submitted by the manufacturers for supporting the registration of their pesticides.

4.2.5 When samples are to be frozen it is recommended that analytical test portions be taken prior to freezing in order to minimise the possible effect of water separation as ice crystals during storage. Care must still be taken to ensure that the entire test portion is used in the analysis.

4.2.6 The containers must not leak. Neither the containers used for storage nor their caps or stoppers should allow migration of the analyte(s) into the storage compartment.

4.3 STANDARD OPERATING PROCEDURES (SOPS)

4.3.1 SOPs should be used for all operations. The SOPs should contain full working instructions as well as information on applicability, expected performance, internal quality control (performance verification) requirements and calculation of results. It should also contain information on any hazards arising from the method, from standards or from reagents.

4.3.2 Any deviations from a SOP must be recorded and authorised by the analyst in charge.

4.4 VALIDATION OF METHODS[1]

4.4.1 Guidelines have been published for validation of analytical procedures for various purposes. The principles described in this section are considered practical and suitable for validation of pesticide residue analytical methods. The guidance is not normative. The analyst should decide on the degree of validation required to demonstrate that the method is fit for the intended purpose, and should produce the necessary validation data accordingly. For instance, the requirements for testing for compliance with MRLs or providing data for intake estimation may be quite different.

4.4.2 An analytical method is the series of procedures from receipt of a sample to the production of the final result. Validation is the process of verifying that a method is fit for the intended purpose. The method may be developed in-house, taken from the literature or otherwise obtained from a third party. The method may then be adapted or modified to match the requirements and capabilities of the laboratory and/or the purpose for which the method will be used. Typically, validation follows completion of the development of a method and it is assumed that requirements such as calibration, system suitability, analyte stability, etc., have been established satisfactorily. When validating and using a method of analysis, measurements must be made within the calibrated range of the detection system used. In general, validation will precede practical application of the method to the analysis of samples but subsequent performance verification is an important continuing aspect of the process. Requirements for performance verification data are a sub-set of those required for method validation.

Proficiency testing (or other inter-laboratory testing procedures), where practicable, provides an important means for verifying the general accuracy of results generated by a method, and provides information on the between-laboratory variability of the results. However, proficiency testing generally does not address analyte stability or homogeneity and extractability of analytes in the processed sample.

Where uncertainty data are required, this information should incorporate performance verification data and not rely solely on method validation data.

4.4.3 Whenever a laboratory undertakes method development and/or method modification, the effects of

[1] This section is based on the recommendations elaborated by an AOAC/FAO/IAEA Consultation held in Miskolc, Hungary, in 1999. The full document is available at www.iaea.org/trc and in A. Fajgelj & A. Ambrus Principles and Practices of Method Validation, Royal Society of Chemistry, 2000

analytical variables should be established, e.g. by using ruggedness tests, prior to validation. Rigorous controls must be exercised with respect to all aspects of the method that may influence the results, such as: sample size; partition volumes; variations in the performance of the clean-up systems used; the stability of reagents or of the derivatives prepared; the effects of light, temperature, solvent and storage on analytes in extracts; the effects of solvent, injector, separation column, mobile phase characteristics (composition and flow-rate), temperature, detection system, co-extractives etc. on the determination system. It is most important that the qualitative and quantitative relationship between the signal measured and the analyte sought are established unequivocally.

4.4.4 Preference should be given to methods having multi-residue and or multi-matrix applicability. The use of representative analytes or matrices is important in validating methods. For this purpose, commodities should be differentiated sufficiently but not unnecessarily. For example, some products are available in a wide range of minor manufactured variants, or cultivated varieties, or breeds, etc. Generally, though not invariably, a single variant of a particular commodity may be considered to represent others of the same commodity but, for example, a single fruit or vegetable species must not be taken to represent all fruit or vegetables (Table 5). Each case must be considered on its merits but where particular variants within a commodity are known to differ from others in their effects on method performance, analyses of those variants are required. Considerable differences in the accuracy and precision of methods, especially with respect to the determination step, may occur from species to species.

4.4.4.1 Where experience shows similar performance of extraction and clean-up between broadly similar commodities/sample matrices, a simplified approach may be adopted for performance validation. A representative commodity may be selected from Table 5 to represent each commodity group having common properties, and used for validation of the procedure or method. In Table 5, the commodities are classified according to the Codex Classification[2].

- Some examples of how far the validation data may be extended to other commodities are: **cereals**, validation for whole grains cannot be taken to apply to bran or bread but validation for wheat grain may apply to barley grain or wheat four;
- **animal products**, validation for muscle should not be taken to apply to fat or offal but validation for chicken fat may apply to cattle fat;
- **fruit and vegetables**, validation for a whole fresh product cannot be taken to apply to the dried product but validation for cabbages may apply to Brussels sprouts.

4.4.4.2 Similarly representative analytes may be used to assess the performance of a method. Compounds may be selected to cover physical and chemical properties of analytes that are intended to be determined by the method. The selection of representative analytes should be made based on the purpose and scope of analysis taking into account the following.

(a) The representative analytes selected should:

  (i) possess sufficiently wide range of physico-chemical properties to include those of represented analytes;

  (ii) be those which are likely to be detected regularly, or for which critical decisions will be made based on the results.

(b) As far as practicable, all analytes included in the initial validation process should be those which will have to be tested regularly and which can be determined simultaneously by the determination system used.

(c) The concentration of the analytes used to characterise a method should be selected to cover the accepted limits (AL, see Glossary) of all analytes planned to be sought in all commodities. Therefore the selected representative analytes should include, among others, those which have high and low ALs. Consequently, the fortification levels used in performance testing with representative analytes/representative commodities may not necessarily correspond to the actual ALs.

4.4.5 Where appropriate data are already available, it may not be necessary for the analyst to perform all the tests. However, all required information must be included or referred to in the validation records. Table 1 provides an overview of parameters to be assessed for method validation according to the status of the method to be validated. Specific parameters and criteria to be assessed are listed in table 2. Parameters to be assessed should

[2] Codex Alimentarius, Volume 2, 2nd ed., Pesticide Residues in Food, pp. 147-365, FAO, 1993

be restricted to those that are appropriate both to the method and to the purpose for which the particular method is to be applied. In many cases, performance characteristics with respect to several parameters may be obtained simultaneously using a single experiment. Test designs where different factors are changed at the same time (factorial experiment designs), may help to minimise the resources required. The performance of the analytical method should be checked, both during its development and during its subsequent use as indicated in section 4.5, according to the criteria given in Table 3.

4.4.6 Individual (single residue) methods should be fully validated with all analyte(s) and sample materials specified for the purpose, or using sample matrices representative of those to be tested by the laboratory.

4.4.7 Group specific methods (GSM) should be validated initially with one or more representative commodities and a minimum of two representative analytes selected from the group.

4.4.8 MRMs may be validated with representative commodities and representative analytes.

4.5 PERFORMANCE VERIFICATION

4.5.1 The main purposes of performance verification are to:

- *monitor the performance of the method under the actual conditions prevailing during its use;*
- *take into account the effect of inevitable variations caused by, for instance, the composition of samples, performance of instruments, quality of chemicals, varying performance of analysts and laboratory environmental conditions;*
- *demonstrate that the performance characteristics of the method are broadly similar to those established at method validation, showing that the method is under "statistical control", and the accuracy and uncertainty of the results are comparable to those expected of the method. For this purpose, data obtained during method validation may be updated with data collected from performance verification during the regular use of the method.*

The results of internal quality control provide essential information on the long term reproducibility and other performance characteristics of the method including the analytes and commodities which were incorporated during the extension of the method.

The basic performance characteristics to be tested and the appropriate test procedures are described in Table 2.

For effective performance verification, analyse samples concurrently with appropriate quality control analyses (blank and recovery determinations, reference materials, etc.). Control charts may be used to check for trends in performance of the method and to ensure that statistical control is maintained.

4.5.2 Construction and use of control charts

4.5.2.1 Control charts may be a useful tool for demonstrating the performance of a method and the reproducibility of its selected parameter. One example for that is the control chart for recoveries. Its application depends on the tasks of the laboratory. When a large number of the same type of sample is analysed for the same active ingredients the control chart is based on the mean recovery and its standard deviation obtained during the regular use of the method. When small numbers of each of a large variety of samples are analysed for a great number of analytes with a multi-residue procedure the control charts cannot be applied in the usual way. In such cases, initially a control chart is constructed with the average recovery (Q) of representative analytes in representative matrices and the typical within-laboratory reproducibility coefficient of variation (CV_{Atyp}), obtained as described below. . When the average recovery data and their coefficient of variation obtained during method validation for individual analyte/sample matrices are not statistically different, each can be considered as an estimate of the true recovery and precision of the method, and with their appropriate combination the typical recovery (Q_{typ}) and coefficient of variation (CV_{Atyp}) of the method can be established and used for constructing the initial control chart. The warning and action limits are $Q_{typ} \pm 2*CV_{Atyp}*Q$ and $Q_{typ} \pm 3*CV_{Atyp}*Q$, respectively.

4.5.2.2 When the method is applied for regular analysis of various analyte/matrix combinations represented during the validation of the method, the individual recoveries are plotted on the chart. The reproducibility of the method during its normal use may be somewhat higher than obtained at the validation of the method. Therefore, if some of the recoveries are outside the warning limits or occasionally the action limits, but they are within the ranges calculated from the CV_A values specified in Table 3, no special action is required.

4.5.2.3 Based on the additional 15-20 recovery tests performed during the regular use of the method, as part of performance verification, the mean or typical recovery and the CV_A shall be recalculated and a new control chart

constructed which reflects the long term reproducibility of the application of the method. The new parameters established must be within the acceptable ranges specified in Table 3.

4.5.2.4 If this is not achievable, for example in the case of particularly problematic analytes, results from samples should be reported as having poorer accuracy or precision than is normally associated with pesticide residues determination.

4.5.2.5 During the regular use of the method, if the average of the first ≥10 recovery tests for a particular analyte/sample matrix is significantly different (P=0.05) from the average recovery obtained for the representative analyte/sample matrices, the Q_{typ} and CV_{typ} are not applicable. Calculate new warning and action limits for the particular analyte/sample matrix, applying the new average recovery and the CV values measured.

4.5.2.6 If performance verification data repeatedly fall outside the warning limits (1 in 20 measurements outside the limit is acceptable), the application conditions of the method must be checked, the sources of error(s) identified, and the necessary corrective actions taken before use of the method is continued.

4.5.2.7 If performance verification data are outside the refined action limits established according to 4.5.2.1 to 4.5.2.3 section, the analytical batch involved (or at least samples in which residues found are ≥0.7 AL or 0.5 AL, for regularly and occasionally detected analytes, respectively) should be repeated.

4.5.2.8 Re-analysis of analytical portions of positive samples is another powerful way of performance verification. Their results can be used to calculate the overall within-laboratory reproducibility of the method (CV_{Ltyp}) in general or for a particular analyte/sample matrix. In this case, the CV_{Ltyp} will also include the uncertainty of sample processing, but will not indicate if the analyte is lost during the process.

4.6 CONFIRMATORY TESTS

4.6.1 When analyses are performed for monitoring or enforcement purposes, it is especially 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. As a first step, the analysis should be repeated using the same method, if only one portion was analyzed initially. This will provide evidence of the repeatability of the result, if the residue is confirmed. It should be noted that the only evidence supporting the absence of detectable residues is provided by the performance verification data.

4.6.2 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 but, although it is difficult to quantify residues at this level, it is essential to provide adequate confirmation of both level and identity.

4.6.3 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 randomly selected results should be confirmed. Where “blank” samples are available, these should be used to check the occurrence of possible interfering substances.

4.6.4 Depending upon the initial technique of determination, an alternative procedure which may be a different detection technique, may be necessary for verification of quantity. For qualitative confirmation (identity) the use of mass-spectral data, or a combination of techniques based on different physico-chemical properties, is desirable (see Table 6).

4.6.5 The necessary steps to 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 apparatus and expertise within the testing laboratory. Some alternative procedures for confirmation are given in Table 6.

4.7 MASS SPECTROMETRY

4.7.1 Residue data obtained using mass spectrometry can represent the most definitive evidence and, where suitable equipment is available, it is the confirmatory technique of choice. The technique can also be used for

residue screening purposes. 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 ion abundance data simultaneously. The particular separation technique, the mass spectrometer, the interface between them and the range of pesticides to be analysed are usually interdependent and no single combination is suitable for the analysis of all compounds. Quantitative transmission of labile analytes through the chromatographic system and interface is subject to problems similar to those experienced with other detectors. The most definitive confirmation of the presence of a residue is the acquisition of its "complete" electron-impact ionisation mass spectrum (in practice generally from m/z50 to beyond the molecular ion region). The relative abundances of ions in the spectrum and the absence of interfering ions are important considerations in confirming identity. This mode of analysis is one of the least selective and interference from contaminants introduced during the production or storage of extracts should be scrupulously avoided. Mass spectrometer data systems permit underlying interference (eg column bleed) signals to be removed by "background subtraction" but this technique must be used with caution. Increased sensitivity can usually be achieved by means of limited mass range scanning or by selected ion monitoring but the smaller the number of ions monitored (especially if these are of low mass), the less definitive are the data produced. Additional confirmation of identity may be obtained (i) by the use of an alternative chromatographic column; (ii) by the use of an alternative ionisation technique (eg chemical ionisation); (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. 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 ratios. Mass spectrometric determinations should satisfy similar analytical quality control criteria to those applied to other systems.

4.7.2 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 (paragraph 4.6.5.4).

4.7.3 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 groth 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. The scientific literature contains numerous references to the technique, the IUPAC Report on Pesticides (13) (Bátora, V., Vitorovic, S.Y., Thier, H.-P. and Klisenko, M.A.; Pure & Appl. Chem., 53, 1039-1049 (1981)) reviews the technique and serves as a convenient introduction. 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.

4.8 DERIVATISATION

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.

4.9 THE CONCEPT OF LOWEST CALIBRATED LEVEL (LCL)

4.9.1 When the objective of the analysis is to monitor and verify the compliance with MRLs or other ALs, the residue methods must be sufficiently sensitive to reliably determine the residues likely to be present in a crop or an environmental sample at or around the MRL or AL. However, for this purpose it is not necessary to use methods with sufficient sensitivity to determine residues at levels two or more orders of magnitude lower. Methods developed to measure residues at very low levels usually become very expensive and difficult to apply. The use of LCL (see Glossary) would have the advantage of reducing the technical difficulty of obtaining the data and would also reduce costs. The following proposals for LCLs in various samples may be useful in enabling the residue chemist to devise suitable methods.

4.9.2 For active ingredients with agreed MRLs, the LCL can be specified as a fraction of the MRL. For analytical convenience this fraction will vary and could be as follows:

MRL (mg/kg)	LCL (mg/kg)
5 or greater	0.5
0.5 up to 5	0.1 increasing to 0.5 for higher MRLs
0.05 up to 0.5	0.02 increasing to 0.1 for MRLs
less than 0.05	0.5 x MRL

When the MRL is set at the limit of determination of the analytical method, the LCL will also be at this level.

4.10 EXPRESSION OF RESULTS

For regulatory purposes, only confirmed data should be reported, expressed as defined by the MRL. Null values should be reported as being less than lowest calibrated level, rather than less than a level calculated by extrapolation. Generally results are not corrected for recovery, and they may only be corrected if the recovery is significantly different from 100%. If results are reported corrected for recovery, then both measured and corrected values should be given. The basis for correction should also be reported. Where positive results obtained by replicate determinations (e.g. on different GC columns, with different detectors or based on different ions of mass spectra) of a single test portion (sub-sample), the lowest valid value obtained should be reported. Where positive results derive from analysis of multiple test portions, the arithmetic mean of the lowest valid values obtained from each test portion should be reported. Taking into account, in general, a 20-30% relative precision, the results should be expressed only with 2 significant figures (e.g.: 0.11, 1.1, 11 and 1.1×10^2). Since at lower concentrations the precision may be in the range of 50%, the residue values below 0.1 should be expressed with one significant figure only.

Figure II.1. Overview of Method Validation

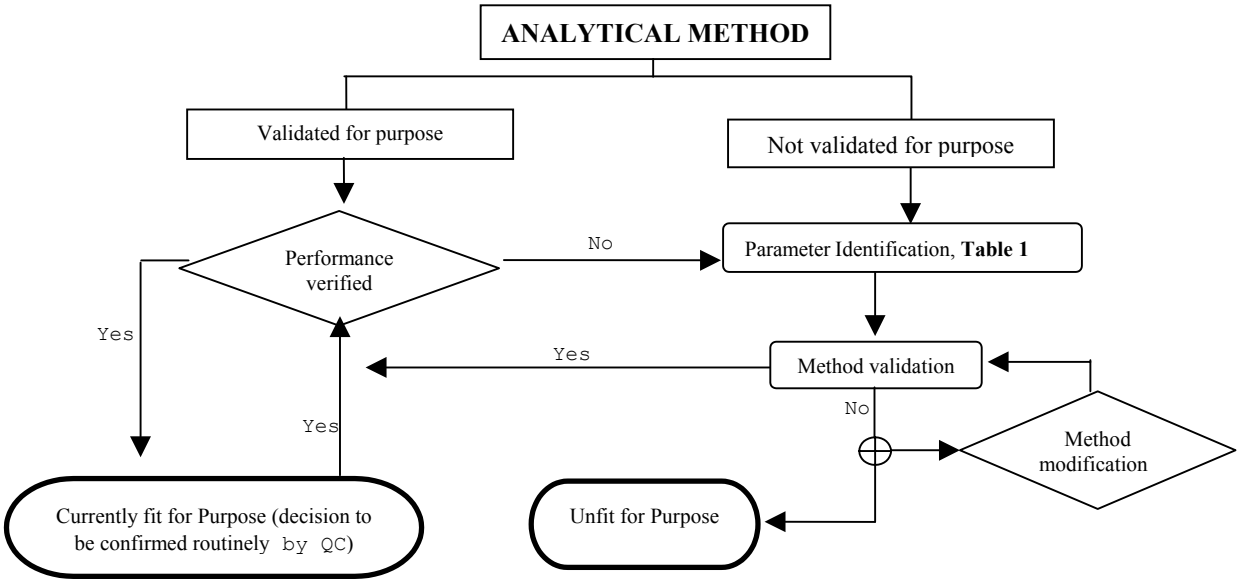

Figure II.2. Verification of Analyte Stability

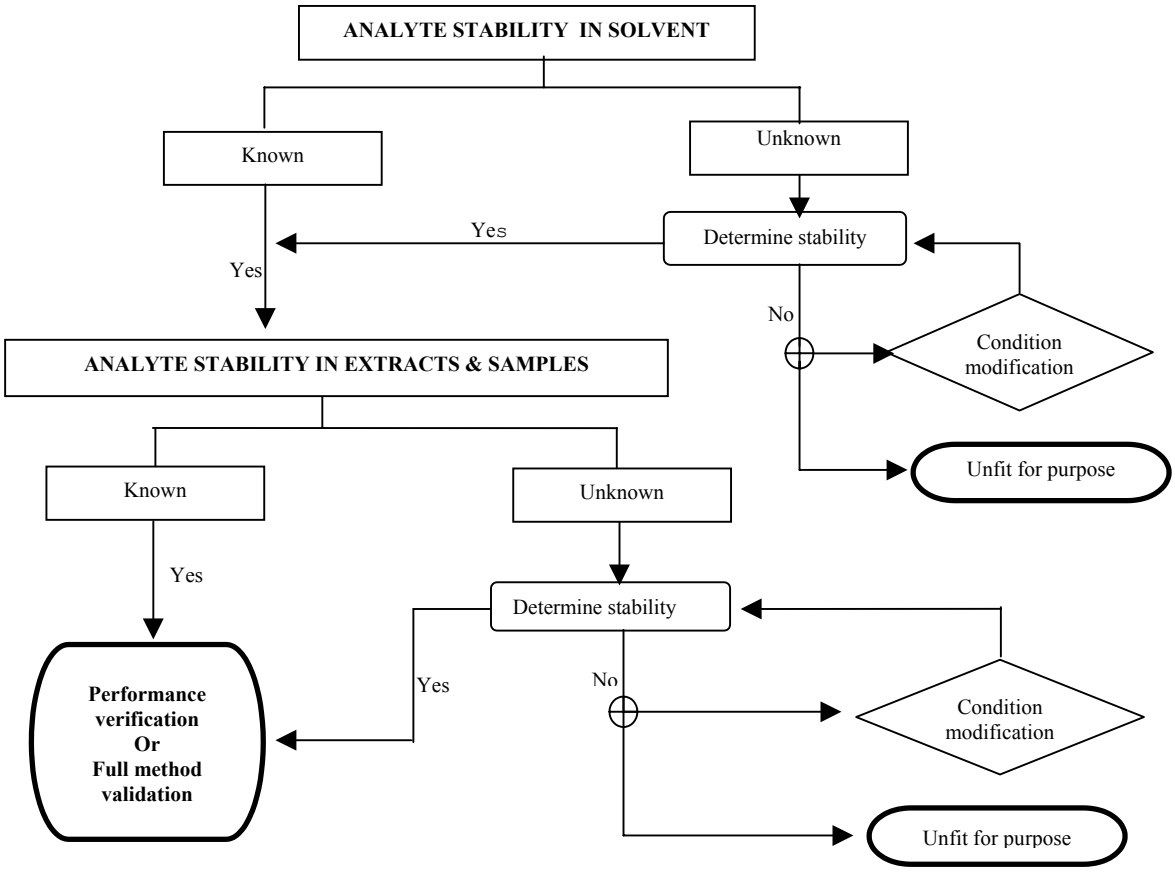

Table 1 Summary of parameters to be assessed for method validation

Parameters to be tested	Existing analytical method, for which previous tests of the parameter have shown that it is valid for one or more analyte/matrix combinations					Modification of an existing method	New method, not yet validated	Experiment types which may be combined
	Performance verification*	Additional matrix	Additional analyte	Much lower concentration of analyte	Another laboratory			
Specificity (show that the detected signal is due to the analyte, not another compound)	No (provided criteria for matrix blanks and confirmation of analyte are met)	Yes, if interference from matrix is apparent in QC	*Yes*	Yes, if interference from matrix is apparent in QC	Rigorous checks not necessary if the performance of the determination system is similar or better	Yes or No. Rigorous checks may be necessary if the determination system is fundamentally different or where the extent of interferences from the matrix is uncertain	Yes. Rigorous checks may be necessary if the determination system is different or where the extent of interferences from the matrices are uncertain, compared with existing methods	
Analytical Range, Recovery through extraction, clean-up, derivatisation and measurement	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Calibration range Analytical range LOD/LOQ Matrix effect
Calibration range for determination of analyte	No	No	Yes	Yes	Yes, for representative analytes	Yes, for representative analytes	Yes, for representative analytes	Linearity, reproducibility and signal/noise
LOD and LOQ	No	Yes, (partial if matrix is from a represented class)	Yes, partial for represented analytes	Yes	Yes	Yes	Yes	Lowest calibrated level, and low level spike recovery data
Reporting Limit, LCL	Yes	No	No	No	No	No	No	
Analyte stability in sample extracts* †	No	Yes, unless matrix is from a represented class	Yes, unless the analyte is represented	Yes	No	No, unless extraction/final solvent is different, or the clean-up is less stringent	Yes, if extraction/final solvent is different from that used in an existing method, or the clean-up is less stringent, compared with existing methods used.	

Parameters to be tested	Existing analytical method, for which previous tests of the parameter have shown that it is valid for one or more analyte/matrix combinations					Modification of an existing method	New method, not yet validated	Experiment types which may be combined
	Performance verification*	Additional matrix	Additional analyte	Much lower concentration of analyte	Another laboratory			
Analyte stability during sample storage*✪	Yes	Yes	Yes,	Ideally	No	No	No	
Extraction efficiency*◆	No	Ideally	Ideally	Ideally	No	No, unless different extraction conditions employed	Yes, unless previously tested extraction procedure is used.	
Homogeneity* of analytical samples	Yes✠	No, unless the matrix is substantially different	No	No	No, unless the equipment is changed	No, unless the equipment is changed	Yes, unless a previously tested sample processing procedure is used	See below
Analyte stability in sample processing*	No	Yes, unless a represented matrix	Yes, unless a represented analyte	Ideally	No	No, unless procedure involves higher temperature, longer time, coarser comminution, etc.	No, unless procedure involves higher temperature, longer time, finer comminution, etc. than validated procedures.	Repeatability, reproducibility

* On-going quality control

* If relevant information is not available

† Representative analytes may be chosen on the basis of hydrolysis, oxidation and photolysis characteristics

✪ Stability data in/on representative commodities should provide sufficient information. Additional tests are required, for example, where:

a samples are stored beyond the time period tested (eg. stability tested up to 4 weeks and measurable analyte loss occurs during this period, samples not analyzed until 6 weeks),

b stability tests were performed at ≤ -18 °C, but the samples are stored in the laboratory at ≤ 5 °C;

c samples are normally stored at ≤–15°C, but storage temperature rises to +5 °C).

◆ Information on efficiency of extraction may be available from the manufacturer or company that is registering the compound.

✠ Occasionally with repeated analysis of test portions of positive samples.

Table 2 Parameters to be assessed for method validation in various circumstances

Parameter	Level(s)	No. of analyses or type of test required		Criteria		Comments
			Quantitative method	Screening method		
1. Within-Laboratory (single laboratory) performance of optimised method						
1.1 Analyte stability in extracts and standard solutions	At ≤AL, or with well detectable residues	≥5 replicates at each appropriate point in time (including zero) and for each representative analyte/commodity. Fortify blank sample extracts to test stability of residues. Compare analyte concentration in stored and freshly made standard solutions.	No significant change in analyte concentration in stored extracts and analytical standards (P = 0.05)	At the end of the storage period, residues added at LCL are detectable		The test of stability in extracts is required if the analytical method is suspended during the determination process, and the material will likely be stored longer than during determination of precision, or if low recoveries were obtained during optimisation of the method. During method optimisation, recovery should be measured against both "old" and "freshly prepared" calibration standards, if the recovery extracts are stored. Storage time should encompass the longest period likely to be required to complete the analysis.
1.2 Calibration function Matrix effect	LCL to 2 (3) times AL	Test the response functions of all analytes included in the method with ≥2 replicates at ≥3 analyte levels plus blank sample. For non-linear response, determine response curve at ≥7 levels and ≥3 replicates. Test the matrix effect with all representative analytes and matrices. Apply the standards prepared in solvent and sample extracts randomly.	For linear calibration: regression coefficient for analytical standard solutions (r) ≥ 0.99, the SD of residuals ($S_{y/x}$) ≤ 0.1 For polynomial function (r) ≥ 0.98. The matrix effect is confirmed if the difference is significant at P = 0.05.	For linear calibration: regression coefficient (r) ≥ 0.98. SD of residuals ≤ 0.2 For polynomial function (r) ≥ 0.95		Calibration parameters may be established during optimisation of the procedure, determination of precision or detection capability. Prepare calibration solutions of different concentrations For MRM perform calibration with mixtures of analytes ("standard mixture"), which can be properly separated by the chromatographic system. Use matrix matched analytical standards for further tests if matrix effect is significant. The method validation may not give definite information for the matrix effect, because matrix effects change with time, with sample (sometimes), with column, etc.
1.3 Analytical range, accuracy, trueness	LCL to 2 (3) times AL*	Analyse representative analyte matrix combinations: ≥ 5 analytical portions spiked at zero, LCL, AL and ≥3 replicates at 2-3	LOQ should be fit for purpose. Mean recovery and CV_A see Table 3. Mean residue* measured	All recoveries are detectable at LCL		The analysts should demonstrate that the method is suitable for determining the presence of the analyte at the appropriate AL with the maximum (false negative and false

Parameter	Level(s)	No. of analyses or type of test required		Criteria		Comments
			Quantitative method	Screening method		
precision, limit of detection (LD), limit of quantitation (LOQ)		AL level. The recovery tests should be divided among the analysts, who will use the method, and instruments that will be involved in the analysis.	in reference material is not significantly different from the consensus value (P = 0.05).			positive) errors specified. For MRM, the fortification level of blank samples should cover the ALs of analytes represented. Consequently they may not correspond with the actual AL for the representative analytes. Fortify analytical portions with standard mixtures. The accuracy and precision ranges determined for representative analyte/matrix combinations can be considered typical for the method, and will be used as applicability criteria for extension to new analytes and commodities, as well as initial guidance for internal quality control of the method. Report uncorrected results, mean recovery and CV_A of replicates. CV_A is equivalent to the within laboratory reproducibility of analysis of samples. * Correct the results for mean recovery if it is significantly different from 100 %. Where the method does not permit recovery to be estimated, accuracy and precision are those of calibration.
1.4 Specificity and selectivity of analyte detection	At lowest calibration level (LCL)	Identify by mass spectrometry, by a similarly specific technique, or by the appropriate combination of separation and detection techniques available. Analyse ≥5 blanks of each representative commodity obtained preferably from different sources, Report analyte equivalent of blank response. Determine and report selectivity	Measured response is solely due to the analyte. Residues measured on two different columns should be within the critical range of replicate chro-matographic determinations.	The rate of false negative samples (β error) at AL should typically be < 5%.		Applies only to a specific combination of separation and detection technique. Samples of known treatment history may be used instead of untreated samples, for analytes other than that applied during treatment. Maturity of sample matrices may significantly affect the blank sample response. Blank values shall also be regularly checked during performance verification (see Section 4 below). Report typical peaks present in the extracts of blank samples.

Parameter	Level(s)	No. of analyses or type of test required		Criteria		Comments
			Quantitative method	Screening method		
		(δ) of detector and relative response factors (RRF) of representative analytes with specific detectors used..				The LCL should preferably be ≤ 0.3AL, except when the AL is set at or about the limit of quantitation. The test may be performed in combination with the determination of decision limit and detection capability and will also provide information for the relative RRts and RRFs of compounds. Alter chromatographic conditions if blank sample response interfere with the analyte or use an alternative detection system. Suitable combination of selective detectors increases specificity, because the amount of information about the analyte is increased.
1.5 Selectivity of separation	At AL	Determine RRt values for all analytes to be tested by the method (not only the reference compounds). When chromatographic techniques are used without spectrometric detection, apply different separation principles and/or determine RRt-s on columns of different polarity. Determine and report resolution (R_S) and tailing factors (T_f) of critical peaks.	The nearest peak maximum should be separated from the designated analyte peak by at least one full width at 10% of the peak height, or more selective detection of all analytes is required.	Tentative identification of all analytes tested. (Not all analytes need to be separated)		Unless the chromatographic separation and spectrometric detection is used in combination, report RRt values on columns of different polarity, which enable the separation (minimum R≥ 1.2) of all analytes tested. The test may be combined with the determination of calibration function and matrix effect (see. 1.7)
1.6 Homogeneity of analyte in analytical sample	At about AL or well detectable residues	Analyse ≥5 replicate test sample portions of one representative commodity from each group (Table 5), post-processing. Determine CV_{Sp} with analysis of variance. The analyte homogeneity should be checked with analytes known to be stable.	$CV_{Sp} \leq 10\%$.	$CV_{Sp} \leq 15\%$ For screening methods it may be desirable to take a portion in which residues can be expected to be highest (e.g. citrus peel) and achievement of homogeneity may be unnecessary.		Use preferably commodities with incurred stable surface residues or treat the surface of a small portion of the natural units (<20%) of laboratory sample before cutting or chopping to represent worst scenario of sample processing. Processing validated for use with any subsequent procedure. Validation applicable to other commodities with similar physical properties, and it is independent of the analyte. The test may be combined with testing stability

Parameter	Level(s)	No. of analyses or type of test required		Criteria		Comments
			Quantitative method	Screening method		
						of analyte (see Section 1.7 of this Table) Determine the sampling constant[3,4] to calculate the size of analytical portion required to satisfy quality criteria of $CV_{Sp} \leq 10\%$ specified. The CV_{Sp} may not need to be determined separately if the CV_L of the incurred residues are within the limits specified in Table 2.
1.7 Analyte stability during sample processing	About AL	Fortify commodities with known amounts of analytes before processing the sample. Analyse ≥5 replicates of each commodity, post-processing, Apply a stable marker compound together with the analytes tested For MRM and group specific methods, GSM, several analytes, which can be well separated, can be tested together.	The stability of the analyte need not be specified if the average overall recovery of analyte added before sample processing (including procedural recovery) and CV_A are within the ranges specified in Table 3. Quantify stability if the overall recovery and the procedural recovery is significantly different (P=0.05).	Analyte added at LCL remains detectable after processing		The temperature of the sample during processing may be critical. Processing validated for use with any subsequent procedure. Validation may be specific to analyte and/or sample matrix. For testing stability determine the mean recovery and CV_L of labile and stable marker compounds. Use these compounds for internal QA tests (see section 4). Express the ratio of average concentration of labile and stable compounds to indicate stability of residues. CV's of stable compounds will indicate the within laboratory repeatability as well.
1.8 Extraction efficiency	About AL or readily measurable residues	Analyse ≥5 replicate portions of samples or reference material with incurred residues. Compare the reference (or different) procedure with that under test. For MRM the analytes tested should preferably have a wide range of Pow values. Only to be determined using incurred residues.	For samples with incurred residues, the mean result obtained with the reference procedure and the tested procedure should not differ significantly at P=0.05 level applying CV_L in the calculation. Or, the consensus value of reference material and the mean residue should not differ significantly at P=0.05 level when calculated with CV_A of the	The mean incurred residues, known to be present at or about the LOQ or LCL, are actually detectable in the samples.		Temperature of the extract, speed of blender or Ultra Turrax, time of extraction and solvent/water/matrix ratio may significantly affect the efficiency of extraction. The effect of these parameters can be checked with ruggedness test. The optimised conditions should be kept constant as far as possible. Validation is generally applicable for commodities within one group and represented analytes of similar physical and chemical properties. Validation is independent from subsequent procedures in the method. The average recovery of each method shall be

[3] Wallace, D. and Kratochvil, B., Analytical Chemistry, **59**, 1987, 226.
[4] Ambrus, A., Solymosné, E.M. and Korsós, I., J. Environ. Sci. and Health, **B31**, 1996, 443.

Parameter	Level(s)	No. of analyses or type of test required		Criteria		Comments
			Quantitative method	Screening method		
			method tested. When the CV_A of the method is larger than 10%, the number of replicate analyses has to be increased to keep the relative standard error of the mean < 5%. Otherwise quantify and report the efficiency of extraction (excluding the recovery of analytical phase following the extraction).			determined from spiked analytical portions. Correct results with average recovery of analysis if it is significantly different from 100%. According to some regulations the ability of screening kits should be tested to detect a positive at 95% confidence.
1.9 Analyte stability during sample storage	About AL	Analyse freshly homogenised samples containing incurred residues, or homogenise and spike blank samples (time 0), and then analyse samples stored according to normal procedures of the laboratory (usually at ≤ -18 °C). The storage time should be ≥ than the longest interval foreseen between sampling and analysis. ≥5 replicates at each time point. When the stored portions are analysed ≥ 4 occasions, test ≥2 spiked portions, and ≥ 1 blank portion spiked at the time of analysis. Analytical portions should be thawed only immediately before or during extraction.	No significant loss of analyte during storage (P = 0.05)	Analyte added at lowest calibration level, LCL, remains detectable after storage		Storage is validated for use with any subsequent procedure. Validation is specific to analyte. However, generally storage stability data obtained with representative sample matrices can be considered valid for similar matrices. The matrices shall be selected taking into account the chemical stability (e.g. hydrolysis) of the analyte and the intended use of the substance. Useful information can be obtained on stability during storage from the JMPR evaluations[5] or from dossiers submitted for registration Report the initial residue concentration, the remaining residue concentration and the procedural recovery of the analyte. Unnecessary sample storage can be avoided by a careful planning for sampling and consequent analysis through administrative arrangement, which is not a part of analytical method.
2. Extension of the validated method						

[5] FAO, Pesticide Residues in Food – Evaluations; published annually in the series of FAO Plant Production and protection Papers

Parameter	Level(s)	No. of analyses or type of test required		Criteria		Comments
			Quantitative method	Screening method		
2.1 Analyte stability during sample storage, processing, and in extracts and standard solutions.	See 1.1, 1.2 & 1.9					Only if information on stability under the processing conditions and on the representative matrix is not already available
2.2 Calibration function, matrix effect	LCL to 2 (3) AL:	Three point calibration embracing AL with and without matrix matched analytical standards	For linear calibration: regression coefficient for analytical standard solutions (r) ≥ 0.99. SD of relative residuals ($S_{y/x}$) ≤ 0.1 For polynomial function (r) ≥ 0.98.	For linear calibration: regression coefficient (r) ≥ 0.98. SD of relative residuals ≤ 0.2 For polynomial function (r) ≥ 0.95.		The method validation may not give definite information for the matrix effect, because matrix effects change with time, with sample (sometimes), with column, etc.
2.3 Accuracy, precision, LD, LOQ	at AL	Planned in advance: (a) Analyse 3 analytical portions of representative sample matrices of interest fortified at AL Unexpectedly found: Fortify 2 preferably 3 additional portions of analytical sample approximately at the level of the new analyte. Calculate the recovery of added analyte. Use similar sample matrix for recovery test if appropriate amount of analytical sample is not available..	The residues recovered should be within the repeatability limits of the method: Three portions: $C_{max} - C_{min} \leq 3.3 CV_{Atyp} Q$ Two portions: $C_{max} - C_{min} \leq 2.8 * CV_{Atyp} Q$ CV_{Atyp} is the typical repeatability coefficient of variation of the method to be adapted. Q =average recovery of the new analyte, and it shall comply with Table 3.	Analytes added to blank samples at target reporting level should be measurable in all tests.		Use CV_{Atyp} established during method validation. The method should only be tested with commodities representing the intended use (possible misuse) of the analyte.
2.4 Specificity and selectivity of analyte	At LCL	Identify by mass spectrometry, or by the appropriate combination of separation and detection techniques available.	Measured response is solely due to the analyte. The detection system used should have equal or better	The rate of false negative samples (β error) at AL should be < 5%.		When the extension for a new analyte is planned, the applicability of the method shall be checked for all representative sample matrices in which the analyte may occur.

Parameter	Level(s)	No. of analyses or type of test required		Criteria		Comments
			Quantitative method	Screening method		
detection		Planned in advance: (a) Analyse one representative blank sample from each commodity group of interest (in which the new analyte is likely to be present). Analyse new matrix with representative compounds. Unexpectedly found: (b) Check response of blank sample (if available), or demonstrate that the response measured corresponds solely to the analyte, using the best technique available in the laboratory. Check δ and RRF of detection and RRts of representative analytes. Compare RRt and response of new analyte with other analytes tested during method validation and with blank responses obtained during extension of the method and the prior validation of the method.	detector performance than those applied during method validation. Residues measured on two different columns should be within the critical range of replicate chro-matographic determinations. Relative retentions of representative analytes obtained during method validation and measured should be within 2 % for GLC and 5 % for HPLC determinations.			When an analyte is unexpectedly detected, the performance check may be carried out for the actual matrix alone See also 1.4. The responses of blank sample(s) should not interfere with the analytes, which are likely to be measured in the sample. Report typical peaks present in blank extracts. The background noise of a new matrix extract should be within the range obtained for representative commodities/sample matrices. If the selectivity of detection does not eliminate the matrix response, use appropriate combination of chromatographic columns that enable the separation of analytes from the matrix peaks. See other options in Table 6.
2.5 Selectivity of separation	See 1.5	See 1.5	See 1.5	See 1.5		See 1.5 Only if information is not available
2.6 Extraction efficiency	See 1.8	See 1.8	See 1.8	See 1.8		See 1.8 Only if information is not available
3. Adaptation of the validated method in another laboratory						
3.1 Purity and suitability of chemicals, reagents and ad(ab)sorbents		Test reagent blank, applicability of ad(ab)sorbents and reagents. Perform derivatization without and with sample.	No interfering response above 0.3 LCL.	No interfering response above 0.5 AL		Some of the most common problems in method transfer involve differences in selection of reagents, solvents and chromatographic media, or in equipment capabilities. Whenever possible, try to confirm actual materials and

Parameter	Level(s)	No. of analyses or type of test required		Criteria		Comments
			Quantitative method	Screening method		
						equipment used by the method developer, if that information is not provided with the method or publication, as received. Substitutions can be tried after the method is working within your laboratory.
3.2 Analyte stability in extracts and standard solutions	See 1.10	See 1.1	See 1.1	See 1.1		This testing may be omitted if full information on analyte stability is provided with the method or if the method is replacing a previously used method for the analyte and the stability information has been previously generated for the previous method.
3.3 Calibration function Matrix effect	LCL to 2 (3) times AL	Test the response functions of representative analytes included in the method at ≥3 analyte levels plus blank. For non-linear response, determine response curve at≥7 levels and ≥3 replicates. Test the matrix effect with representative analytes and matrices.	For linear calibration: regression coefficient for analytical standard solutions (r) ≥ 0.99. The SD of relative residuals ($S_{y/x}$) ≤ 0.1 For polynomial function (r) ≥ 0.98.	For linear calibration: regression coefficient (r) ≥ 0.98. The SD of relative residuals ≤ 0.2 For polynomial function (r) ≥ 0.95.		Sees: 1.2
3.4 Analytical range accuracy and precision, limit of detection, limit of quantitation	Blank extract and or AL	Analyse representative analyte/matrix combinations: ≥ 5 analytical portions each of blank samples spiked at 0 and AL, and 3 portions spiked at 2 AL. The recovery tests should be divided among the analysts, who will use the method, and instruments that will be involved in the analysis.	Average recovery and CV_A should be within the ranges given in Table 3.	All recoveries detectable at LCL. Reference materials at AL: analyte detected.		See comments in 1.3.
3.5 Specificity and selectivity of analyte detection	At AL	Check performance characteristics of detectors used and compare them with those specified in the method. Check response of one blank of each	Measured response is solely due to the analyte. The detector performance (sensitivity and selectivity) should be equal or better	The rate of false negative samples (β error) at AL should typically be < 5%.		The relative response of specific detectors can substantially vary from model to model. Proper checking of specificity of detection is critical for obtaining reliable results. Compare blank response observed with typical

Parameter	Level(s)	No. of analyses or type of test required		Criteria		Comments
			Quantitative method	Screening method		
		representative commodity, otherwise perform test as described in section 1.4.	than specified in the method. See section 1.4			peaks reported in blank extracts See other comments under section 1.4.
3.6 Analyte "homogeneity"	At about AL or well detectable residues	Test two representative commodities of different nature	CV_{Sp}<10%	CV_{Sp}<15% For screening methods it may be desirable to take a portion in which residues can be expected to be highest (e.g. citrus peel) and achievement of homogeneity may be unnecessary.		The tests are performed to confirm similarity of application conditions and applicability of parameters obtained by the laboratory validating the method. When the test results in similar CV_{Sp} as reported, the conditions of sample processing may be considered similar and further tests are not required for the validation of the method.
3.7 Analyte stability in extracts and standard solutions	See 1.1	See 1.1	See 1.1	See 1.1		This testing may be omitted if full information on analyte stability is provided with the method or if the method is replacing a previously used method for the analyte and the stability information has been previously generated for the previous method.

Table 3. Within Laboratory Method Validation Criteria for Analysis of pesticide residues

Concentration	Repeatability		Reproducibility		Trueness[2,]
	CV_A% [3]	CV_L%[4]	CV_A% [3]	CV_L%[4]	Range of mean % recovery
≤1 μg/kg	35	36	53	54	50–120
> 1 μg/kg ≤ 0.01 mg/kg	30	32	45	46	60–120
> 0.01 mg/kg ≤ 0.1 mg/kg	20	22	32	34	70–120
> 0.1 mg/kg ≤ 1 mg/kg	15	18	23	25	70–110
> 1 mg/kg	10	14	16	19	70–110

1. With multi-residue methods, there may be certain analytes where these quantitative performance criteria cannot be strictly met. The acceptability of data produced under these conditions will depend on the purpose of the analyses e.g. when checking for MRL compliance the indicated criteria should be fulfilled as far as technically possible, while any data well below the MRL may be acceptable with the higher uncertainty.
2. These recovery ranges are appropriate for multi-residue methods. Stricter criteria may be necessary for some purposes e.g. methods for single analytes or veterinary drug residues (see Codex V3, 1996).
3. CV_A: Coefficient of variation for analysis excluding sample processing. The parameter can be estimated from tests performed with reference materials or analytical portions spiked before extraction. A reference material prepared in the laboratory may be used in the absence of a certified reference material.
4. CV_L: Overall coefficient of variation of a laboratory results, including up to 10% variability of residues between analytical portions (CV_{Sp}). Note: the variability of residues in between analytical portions can be calculated from the uncertainty of the measurement of replicate portions of samples (CV_L) containing residues; $CV_L^2 = CV_{Sp}^2 + CV_A^2$.

Table 4 Requirements for performance verification

Parameter	Level(s)	No. of analyses or type of test required		Criteria	Comments
			Quantitative method	Screening method	
4. Quality control (performance verification)					
4.1 Methods used regularly					
4.1.1 Suitability of chemicals, adsorbents and reagents		For each new batch: Test reagent blank, applicability of ad(ab)sorbents and reagents Perform derivatization without sample.	No interfering response ≥0.3 LCL.	No interfering response ≥ 0.5AL.	Alternately, if the sample blank, calibration and the recovery are satisfactory then the suitability of reagents etc. are confirmed.
4.1.2 Calibration and analytical range		Single point calibration may be used with standard mixtures, if the intercept of calibration function is close to 0. Apply multi point calibration (3x2) for quantitative confirmation.	The analytical batch may be considered to be under statistical control if the analytical standards and sample extracts are injected alternately, and the calculated SD of relative residuals is ≤0.1.	Analyte is detected at LCL.	Standard solution and samples should be injected alternately. Bracketing with appropriate standard injections may provide a time saving alternative to multi point calibration especially if auto sampler is not available. As system response often changes multi point calibration shall be performed regularly to confirm that the intercept is close to zero. Multi point calibration is not necessary for quantitative confirmation if the calibrant is very close in concentration to that of the sample.
4.1.3 Accuracy and precision	Within analytical range	Include in each analytical batch ≥1 sample either fortified with standard mixture, or the reanalysis of a replicate portion of a positive sample.	The performance of detector and chromatographic column shall be equal or better than specified in the method. Preferably all recoveries should be within the warning limit of control chart constructed according to section 4.5.2. On a long run one of every 20 or 100 samples may be outside the warning and action limits, respectively. The analytical batch should be repeated if any of the recoveries falls outside the action limits, or the results of the replicate analyses of the positive sample exceeds the critical range. $C_{max} - C_{min} > 2.8 * CV_{Ltyp} Q$ Q is the average residue obtained from the replicate measurements, the CV_{Ltyp} is the measure of within laboratory reproducibility, which includes the combined uncertainty of sample processing and analysis.		*Fortify analytical portion with standard mixture(s). Alter standard mixtures in different batches to obtain recoveries for all analytes of interest at regular intervals. Perform alternately recovery studies at AL as well as at LCL and 2 times AL, as appropriate, to confirm applicability of the method within the analytical range. The frequency of recovery studies at AL should be 2 to 3 times higher then those at other levels.* Repeated analysis of positive samples may replace the recovery test in a particular batch. For MRM prepare commodity/sample specific standard mixtures from the analytes which may occur in a particular sample. The selection of analytes for one mixture should assure selective separation/detection without any problem.

					For tentative identification: prepare analytical batches containing the appropriate detection test mixture, and samples. For quantitative determination/confirmation include in the analytical batch the detection test mixture, appropriate number of calibration mixtures, fortified blank sample(s), or one repeated positive sample and the new positive samples Inject standards and samples alternately.
4.1.4 Selectivity of separation, Specificity of detection Performance of detectors		Include appropriate detection test mixture in each chromatography batch. Include untreated commodity (if available) in analytical batch. Use standard addition if no untreated sample (similar to those analysed in the batch) is available Confirm identity and quantity of each analyte present ≥0.7 AL level.	R_s, T_f of test compounds, and RRF and δ of the detection should be within the specified range. Relative retention should be within 2 % for GLC and 5 % for HPLC determinations. Detector performance should be within specified range. Sample co-extractives interfering with the analyte should not be present ≥ 0.3 LCL. The recovery of added standard should be within the acceptable recovery range of the analyte.	Detector performance should be within specified range. Analyte should be seen above LCL or CCα for banned compounds.	This is also sometimes referred to as a "system suitability" test. Prepare detection test mixture for each method of detection. Select the components of the mixture in order to indicate the characteristic parameters of chromatographic separation and detection. Adjust RRt database for the compounds of detection test mixture and analytes used for calibration. Define the RRF specific for the detection system. Perform quantitative confirmation with analytical standards prepared in blank matrix extract if matrix effect is significant.
4.1.5 Analyte homogeneity in processed sample	At well detectable analyte concentration.	Select a positive sample randomly. Repeat analysis of another one or two analytical portions.	The residues measured on two different days should be within the reproducibility limit of replicate analytical portions: C_{max}- C_{min} ≤ 2.8*CV_{Ltyp}Q Q is the average residue obtained from the replicate measurements, the CV_{Ltyp} is the combined uncertainty of sample processing and analysis obtained during method validation.		Perform test alternately to cover each commodity analysed. Test homogeneity at the beginning of growing season, or at the start of the analysis of the given type of samples. The acceptable results of the test also confirm that the reproducibility of the analyses (CV_A) was appropriate.
4.1.6 Extraction efficiency					The efficiency of the extraction cannot be controlled during the analysis. To ensure appropriate efficiency, the validated extraction procedure should be carried out without any

					change.
4.1.7 Duration of analysis			The samples, extracts etc. should not be stored longer than the period for which the storage stability was tested during method validation. Storage conditions should be regularly monitored and recorded.		Examples for the need of additional storage stability tests are given under Table 1.
4.2 Analyte detected occasionally					
Follow tests described in 4.1 with the following exceptions					
4.2.1Accuracy and precision	At around AL	Reanalyse another analytical portion; Use standard addition at the measured level of analyte.	The residues measured on two different days should be within the critical range: $C_{max}- C_{min} \leq 2.8*CV_{Ltyp}Q$ Q is the average residue obtained from the replicate measurements, the CV_{Ltyp} is obtained during method validation. The recovery following standard addition shall be within action limits.		Check accuracy if residue found at ≥0.5AL.
4.3 Methods used at irregular intervals					
Follow tests described in 4.1 with the following exceptions					
4.3.1 Accuracy and precision (repeatability)	At AL and LCL	Include one fortified sample at LCL and two samples at AL in each analytical batch. Use standard addition if untreated sample (similar to those analysed in the batch) is not available. Perform analysis with ≥2 analytical portions.	Minimum two recoveries shall be within warning limit, one may be within action limit. The residues measured in replicate portions should be within the critical range: $C_{max}- C_{min} \leq 2.8*CV_{Ltyp}Q$ or $C_{max}- C_{min} \leq f_{(n)}*CV_{Ltyp}Q$ Q is the average residue obtained from the replicate measurements, the CV_{Ltyp} is obtained during method validation, $f_{(n)}$ is the factor for calculation of extreme range depending on the number of replicate samples.		The acceptable results also prove the suitability of chemicals, adsorbents and reagents used. Confirm residues above 0.5AL. If performance criteria were not satisfied, the method shall be practised and its performance characteristics (Q, CV_{Atyp}, CV_{Ltyp}) re-established during partial revalidation of the method.
4.4. Changes in implementation of the method					
Change	Parameters to be tested		**For test methods and acceptability criteria see the appropriate sections of Appendix 1**.		
4.4.1 Chromatographic column	Test selectivity of separation, resolution, inertness, RRt values.		Performance characteristics should not be affected		Apply appropriate test mixtures to obtain information on the performance of the column.
4.4.2 Equipment for sample processing	Homogeneity of processed sample; Stability of analytes.		Test described in 1.6 and 1.7 shall be performed and they should give results conforming to the relevant criteria..		Homogeneity test is only necessary if the degree of comminution and/or mixing is inferior to that of the original equipment. The stability of analytes needs to be tested if the processing time and temperature are significantly increased.
4.4.3 Equipment for	Compare field incurred residue levels detected with the old and new equipment in ≥ 5		The mean residues should not be significantly different at p=0.05 level.		Test is necessary if a new type of equipment is used

extraction	replicates		
4.4.4 Detection	Test selectivity of separation and selectivity and sensitivity of detection	Performance characteristics should be the same or better specified in the description of the method.	Test also detectability separately with new detection reagents.
4.4.5 Analyst	≥5 recovery tests at each level (LCL, AL and 2 (3) AL), re-analysis of one blank sample and two positive samples (unknown to the analyst)	All results should be within the warning limits specified for the method in the laboratory. Replicate sample analysis shall be within the critical range.	This is a minimum requirement. Laboratories in some areas of residue work use a more detailed protocol which includes: (1) generation of standard curve within acceptability criteria; (2) minimum of 2 analytical runs for each matrix, containing representative analytes fortified by the analyst at a minimum of 3 levels in duplicate; (3) minimum of 1 analytical run containing fortified or incurred samples, 3 levels in duplicate, provided as unknowns to the analyst. All results must meet acceptability criteria, or be repeated.
4.4.6 Laboratory	Accuracy and precision ≥3 recovery tests at each level (LCL, AL and 2 (3) AL) by (different) analyst(s) on different days.	All results should be within the warning limits specified for the method in the laboratory.	The reproducibility of the method under the new conditions must be established and it has to be done by more than one analyst if available.

Table 5. Representative commodities/samples for validation of analytical procedures for pesticide residues

Commodity Group	Common properties	Commodity class[6]	Representative species
Plant products			
I.	High water and chlorophyll content	Leafy vegetables Brassica leafy vegetables Legume vegetables	spinach or lettuce broccoli, cabbage, kale green beans
II.	High water and low or no chlorophyll content	Pome fruits Stone fruits Berries Small fruits Fruiting vegetables Root vegetables	apple, pear peach, cherry Strawberry grape, tomato, bell pepper, melon mushroom potato, carrot, parsley
III.	High acid content	Citrus fruits	orange, lemon
IV.	High sugar content		raisins, dates
V.	High oil or fat	Oil seeds Nuts	avocado, sunflower seed walnut, pecan nut, pistachios
VI.	Dry materials	Cereals	wheat, rice or maize grains
		Cereal products	wheat bran, wheat floor
	Commodities requiring individual test		e.g. garlic, hops, tea, spices, cranberry
Products of animal origin			
		Meats	Cattle meat, chicken meat
		Edible offals	Liver, kidney
		Fat	Fat of meat
		Milk	Cow milk
		Eggs	Chicken egg

Note: The method should be validated with representative pesticides for each commodity group. Commodities which are difficult to analyse require individual tests.

[6] Codex Alimentarius, Volume 2, 2nd ed., Pesticide Residues in Food, pp. 147-365, FAO, 1993

Table 6. Examples of detection methods suitable for the confirmatory analysis of substances

Detection method	**Criterion**
LC or GC and Mass spectrometry	if sufficient number of diagnostic ions are monitored
LC-DAD or scanning UV	if the UV spectrum is characteristic
LC – fluorescence	in combination with other techniques
2-D TLC – (spectrophotometry)	in combination with other techniques
GC-ECD, NPD, FPD	only if combined with two or more separation techniques[1]
Derivatisation	if it was not the first choice method
LC-immunogram	in combination with other techniques
LC-UV/VIS (single wavelength)	in combination with other techniques

1. Other chromatographic systems (applying stationary and/or mobile phases of different selectivity) or other techniques.

Glossary of terms

Accepted Limit (AL)	Concentration value for an analyte corresponding to a regulatory limit or guideline value which forms the purpose for the analysis, e.g. MRL, MPL; trading standard, target concentration limit (dietary exposure assessment), acceptance level (environment) etc. For a substance without an MRL or for a banned substance there may be no AL (effectively it may be zero or there may be no limit) or it may be the target concentration above which detected residues should be confirmed (action limit or administrative limit).
Accuracy	Closeness of agreement between a test result and the accepted reference value.
Alpha (α) Error	Probability that the true concentration of analyte in the laboratory sample is less than a particular value (e.g. the AL) when measurements made on one or more analytical/test portions indicate that the concentration exceeds that value (false positive). Accepted values for this probability are usually in the range 1 to 5%.
Analyte	The chemical substance sought or determined in a sample.
Analyte Homogeneity (in sample)	Uniformity of dispersion of the analyte in matrix. The variability in analytical results arising from sample processing depends on the size of analytical portion. The sampling constant[7] describes the relationship between analytical portion size and the expected variation in a well mixed analytical sample: $K_S = w\ (CV_{Sp})$[8], where w is the mass of analytical portion and CV_{Sp} is the coefficient of variation of the analyte concentration in replicate analytical portions of w [g] which are withdrawn from the analytical sample
Analytical portion	A representative quantity of material removed from the analytical sample, of proper size for measurement of the residue concentration.
Analytical sample	The material prepared for analysis from the laboratory sample, by separation of the portion of the product to be analysed and then by mixing, grinding, fine chopping, etc., for the removal of analytical portions with minimal sampling error.
Applicability	The analytes, matrices and concentrations for which a method of analysis has been shown to be satisfactory.
Beta (β) Error	Probability that the true concentration of analyte in the laboratory sample is greater than a particular value (e.g. the AL) when measurements made on one or more analytical portions indicate that the concentration does not exceed that value (false negative). Accepted values for this probability are usually in the range 1 to 5%.
Bias	Difference between the mean value measured for an analyte and an accepted reference value for the sample. Bias is the total systematic error as contrasted to random error. There may be one or more systematic error components contributing to the bias. A larger systematic difference from the accepted reference value is reflected by a larger bias value.
Commodity Group	Group of foods or animal feeds sharing sufficient chemical characteristics as to make them similar for the purposes of analysis by a method. The characteristics may be based on major constituents (e.g. water, fat, sugar, and acid content) or biological relationships, and may be defined by regulations.

[7] Wallace, D. and Kratochvil, B., Analytical Chemistry, 59, 226-232, 1987

[8] Ambrus, A., Solymosné, E.. and Korsós, I. J. Environ. Sci. Health, B31, (3) 1996

Confirmatory Method	Methods that provide complete or complementary information enabling the analyte to be identified with an acceptable degree of certainty [at the Accepted Limit or level of interest]. As far as possible, confirmatory methods provide information on the chemical character of the analyte, preferably using spectrometric techniques. If a single technique lacks sufficient specificity, then confirmation may be achieved by additional procedures consisting of suitable combinations of clean-up, chromatographic separation(s) and selective detection. Bioassays can also provide some confirmatory data. In addition to the confirmation of the identity of an analyte, its concentration shall also be confirmed. This may be accomplished by analysis of a second test portion and/or re-analysis of the initial test portion with an appropriate alternative method (e.g. different column and/or detector). The qualitative and quantitative confirmation may also be carried out by the same method, when appropriate.
Decision Limit (CCα)	Limit at which it can be decided that the concentration of the analyte present in a sample truly exceeds that limit with an error probability of α (false positive). In the case of substances with zero AL, the CCα is the lowest concentration level, at which a method can discriminate with a statistical probability of 1 - α whether the identified analyte is present. The CCα is equivalent to the limit of detection (LOD) under some definitions (usually for α = 1%). In the case of substances with an established AL, the CCα is the measured concentration, above which it can be decided with a statistical probability of 1 - α that the identified analyte content is truly above the AL.
Detection Capability (CCß)	Smallest true concentration of the analyte that may be detected, identified and quantified in a sample with a beta error (false negative). In the case of banned substances the CCβ is the lowest concentration at which a method is able to determine the analyte in contaminated samples with a statistical probability of 1 – ß. In the case of substances with an established MRL, CCβ is the concentration at which the method is able to detect samples that exceed this MRL with a statistical probability of 1 - ß. When it is applied at the lowest detectable concentration, this parameter is intended to provide equivalent information to the Limit of Quantitation (LOQ), but CCβ is always associated with a specified statistical probability of detection, and therefore it is preferred over LOQ..
Detection Test Mixture	Mixture of analytical standards which are suitable to check the conditions of chromatographic separation and detection. The detection test mixture should contain analytes which provide information for the selectivity and response factors for the detectors, and the inertness (e.g. characterised by the tailing factor Tf) and separation power (e.g. resolution Rs) of column, and the reproducibility of RRt values. The detection test mixture may have to be column and detector specific.
False negative result	See beta error
False positive result	See alpha error
Group specific method	Method designed to detect substances having either a common moiety or similar chemical structure. E.g. phenoxy acetic acids, dithiocarbamates, methyl carbamates.
Incurred Residue	Residues of an analyte in a matrix arising by the route through which the trace levels would normally be expected, as opposed to residues from laboratory fortification of samples. Also weathered residue.
Individual Method	Method, which is suitable for determination of one or more specified compounds. A separate individual method may be needed, for instance to determine some metabolite included in the residue definition of an individual pesticide or veterinary drug.
Laboratory Sample	The sample as received at the laboratory (not including the packaging).

Limit of Detection (LD)	Smallest concentration where the analyte can be identified. Commonly defined as the minimum concentration of analyte in the test sample that can be measured with a stated probability that the analyte is present at a concentration above that in the blank sample. IUPAC and ISO have recommended the abbreviation LD. See also Decision Limit.
Limit of Quantitation (LOQ)	Smallest concentration of the analyte that can be quantified. Commonly defined as the minimum concentration of analyte in the test sample that can be determined with acceptable precision (repeatability) and accuracy under the stated conditions of the test. See also Detection Capability.
Lowest Calibrated Level (LCL)	Lowest concentration of analyte detected and measured in calibration of the detection system. It may be expressed as a solution concentration in the test sample or as a mass and must not include the contribution from the blank
Matrix	Material or component sampled for analytical studies, excluding the analyte.
Matrix Blank	Sample material containing no detectable level of the analytes of interest.
Matrix-matched Calibration	Calibration using standards prepared in an extract of the commodity analysed (or of a representative commodity). The objective is to compensate for the effects of co-extractives on the determination system. Such effects are often unpredictable, but matrix-matching may be unnecessary where co-extractives prove to be of insignificant effect.
Method	The series of procedures from receipt of a sample for analysis through to the production of the final result.
Method Validation	Process of verifying that a method is fit for purpose.
Multi residue Method, MRM	Method which is suitable for the identification and quantitation of a range of analytes, usually in a number of different matrices.
Negative Result	A result indicating that the analyte is not present at or above the lowest calibrated level. (see also Limit of Detection)
Performance Verification	Sets of quality control data generated during the analysis of batches of samples to support the validity of on-going analyses. The data can be used to refine the performance parameters of the method.
Positive Result	A result indicating the presence of the analyte with a concentration at or above the lowest calibrated level.
Precision	Closeness of agreement between independent test results obtained under stipulated conditions.
Quantitative Method	A method capable of producing results, expressed as numerical values in appropriate units, with accuracy and precision which fit for the purpose. The degree of precision and trueness must comply with the criteria specified in Table 3.
Recovery	Fraction or percentage of an analyte recovered following extraction and analysis of a blank sample to which the analyte has been added at a known concentration (spiked sample or reference material).
Reagent Blank	Complete analysis made without the inclusion of sample materials for QC purpose.
Reference Material	Material one or more of whose analyte concentrations are sufficiently homogeneous and well established to be used for the assessment of a measurement method, or for assigning values to other materials. In the context of this document the term "reference material" does not refer to materials used for the calibration of apparatus.
Reference Method	Quantitative analytical method of proven reliability characterised by well-established trueness, specificity, precision and detection power. These methods will generally have been collaboratively studied and are usually based on molecular spectrometry. The reference method status is only valid if the method is implemented under an appropriate QA regime.
Reference Procedure	Procedure of established efficiency. Where this is not available, a reference procedure may be one that, in theory, should be highly efficient and is fundamentally different from that under test.
Repeatability	Precision under repeatability conditions, i.e. conditions where independent test results are obtained with the same method on replicate analytical portions in the same laboratory by the same operator using the same equipment within short intervals of time. (ISO 3534-1)

Representative Analyte	Analyte chosen to represent a group of analytes which are likely to be similar in their behaviour through a multi-residue analytical method, as judged by their physico-chemical properties e.g. structure, water solubility, K_{ow}, polarity, volatility, hydrolytic stability, pKa etc.
Represented Analyte	Analyte having physico-chemical properties which are within the range of properties of representative analytes.
Reproducibility	Closeness of agreement between results obtained with the same method on replicate analytical portions with different operators and using different equipment (within laboratory reproducibility). Similarly, when the tests are performed in different laboratories the inter-laboratory reproducibility is obtained.
Representative Commodity	Single food or feed used to represent a commodity group for method validation purposes. A commodity may be considered representative on the basis of proximate sample composition, such as water, fat/oil, acid, sugar and chlorophyll contents, or biological similarities of tissues etc..
Ruggedness	Ability of a chemical measurement process to resist changes in test results when subjected to minor changes in environmental and method procedural variables, laboratories, personnel, etc.
Sample Preparation	The procedure used, if required, to convert the laboratory sample into the analytical sample, by removal of parts (soil, stones, bones, etc.) not to be included in the analysis.
Sample Processing	The procedure(s) (e.g. cutting, grinding, mixing) used to make the analytical sample acceptably homogeneous with respect to the analyte distribution, prior to removal of the analytical portion. The processing element of preparation must be designed to avoid inducing changes in the concentration of the analyte.
Screening Method	A method used to detect the presence of an analyte or class of analytes at or above the minimum concentration of interest. It should be designed to avoid false negative results at a specified probability level (generally $\beta = 5\%$). Qualitative positive results may be required to be confirmed by confirmatory or reference methods. See Decision Limit and Detection Capability.
Selectivity	Measure of the degree to which the analyte is likely to be distinguished from other sample components, either by separation (e.g., chromatography) or by the relative response of the detection system.
Specificity	Extent to which a method provides responses from the detection system which can be considered exclusively characteristic of the analyte.
Standard Addition	A procedure in which known amounts analyte are added to aliquots of a sample extract containing the analyte (its initially measured concentration being X), to produce new notional concentrations (for example, 1.5X and 2X). The analyte responses produced by the spiked aliquots and the original extract are measured, and the analyte concentration in the original extract (zero addition of analyte) is determined from the slope and intercept of the response curve. Where the response curve obtained is not linear, the value for X must be interpreted cautiously.
Tailing Factor	Measure of chromatographic peak asymmetry; at 10% peak height maximum, the ratio of the front and tail segments of peak width, when separated by a vertical line drawn through the peak maximum.
Test Portion	See "Analytical Portion"
Test Sample	See "Analytical Sample"
Trueness	Closeness of agreement between the average value obtained from a large series of test results and an accepted reference value.
Uncertainty of measurement	Single parameter (usually a standard deviation or confidence interval) expressing the possible range of values around the measured result, within which the true value is expected to be with a stated degree of probability. It should take into account all recognised effects operating on the result, including: overall long-term precision (within laboratory reproducibility) of the complete method; the method bias; sub-sampling and calibration uncertainties; and any other known sources of variation in results.

ABBREVIATIONS

C_{max}	Highest residue detected in replicate analytical portions	MRM	Multi-Residue Method
C_{min}	Lowest residue detected in replicate analytical portions	RRF	Relative response factor
CV_{Atyp}	Typical coefficient of variation of residues determined in one analytical portion.	RRt	Relative retention value for a peak
CV_{Ltyp}	Typical coefficient of variation of analyses of portions of a laboratory sample.	Rs	Resolution of two chromatographic peaks
CV_{Sp}	Coefficient of variation of residues in analytical portions.	SD	Standard Deviation
GLP	Good Laboratory Practice	$S_{y/x}$	Standard deviation of the residuals calculated from the linear calibration function
GSM	Group Specific Method	WHO	World Health Organization
MRL	Maximum Residue Limit		

APPENDIX III

DRAFT AND REVISED DRAFT MAXIMUM RESIDUE LIMITS FOR PESTICIDES
(Advanced to Step 8 of the Codex Procedure)

			MRL (mg/kg)	Note	Step
15	**CHLORMEQUAT**				
GC	650	Rye	3		8
CF	1250	Rye flour	3		8
CM	650	Rye bran, Unprocessed	10		8
AS	81	Straw and fodder (dry) of cereal grains	30	dry	8
GC	653	Triticale	3		8
GC	654	Wheat	3		8
CM	654	Wheat bran, Unprocessed	10		8
CF	1211	Wheat flour	2		8
CF	1212	Wheat wholemeal	5		8
17	**CHLORPYRIFOS**				
AL	1020	Alfalfa fodder	5		8
AL	1021	Alfalfa forage (green)	20		8
TN	660	Almonds	0.05		8
FI	327	Banana	2		8
VB	400	Broccoli	2		8
VB	41	Cabbages, Head	1		8
VR	577	Carrot	0.1		8
MO	1280	Cattle kidney	0.01		8
MO	1281	Cattle liver	0.01		8
MM	812	Cattle meat	1	(fat)	8
VB	404	Cauliflower	0.05		8
SB	716	Coffee beans	0.05		8
VP	526	Common bean (pods and/or immature seeds)	0.01		8
DF	269	Dried Grapes (=currants, raisins and sultanas)	0.1		8
PE	112	Eggs	0.01	(*)	8
FB	269	Grapes	0.5		8
GC	645	Maize	0.05		8
AS	645	Maize fodder	10		8
AF	645	Mize forage	20		8
OR	645	Maize oil, Edible	0.2		8
ML	107	Milk of cattle, goats&sheep	0.02		8
VA	385	Onion, Bulb	0.2		8
AL	528	Pea vines (green)	1		8
FS	247	Peach	0.5		8
VP	63	Peas (pods and succulent=immature seeds)	0.01		8
TN	672	Pecan	0.05	(*)	8
VO	445	Peppers, Sweet	2		8
MM	818	Pig meat	0.02	(fat)	8
MO	818	Pig, Edible offal of	0.01	(*)	8
FS	14	Plums (including prunes)	0.5		8
FP	9	Pome fruits	1		8
PM	110	Poultry meat	0.01	(fat)	8
PO	111	Poultry, Edible offal of	0.01	(*)	8
MM	822	Sheep meat	1	(fat)	8
MO	822	Sheep, Edible offal of	0.01		8
GC	651	Sorghum	0.5		8

AS	651	Sorghum straw and fodder, dry	2		8	
FB	275	Strawberry	0.3		8	
VR	596	Sugar beet	0.05		8	
AV	596	Sugar beet leave or tops	40		8	
VO	447	Sweet corn (corn-on-the cob)	0.01	(*)	8	
TN	678	Walnuts	0.05	(*)	8	
GC	654	Wheat	0.5		8	
CF	1211	Wheat flour	0.1		8	
AS	654	Wheat straw and fodder, dry	5		8	
21	**DDT**					
PM	110	Poultry meat	0.3		8	
32	**ENDOSULFAN**					
VB	400	Broccoli	0.5		8	
VB	403	Cabbage, Savoy	2		8	
VB	41	Cabbages, Head	1		8	Except cabbage, Savoy
VB	404	Cauliflower	0.5		8	
41	**FOLPET**					
VC	424	Cucumber	1		8	
VC	46	Melons, except watermelon	3		8	
VA	385	Onion, Bulb	1		8	
VR	589	Potato	0.1		8	
60	**PHOSALONE**					
FP	9	Pome fruits	2		8	
FS	12	Stone fruits	2		8	
63	**PYRETHRINS**					
DF	167	Dried fruits	0.2	Po	8	
VD	70	Pulses	0.1	Po	8	
65	**THIABENDAZOLE**					
FI	326	Avocado	15	Po	8	
MO	1280	Cattle kidney	1		8	
MO	1281	Cattle liver	0.3		8	
ML	812	Cattle milk	0.2		8	
FI	345	Mango	5	Po	8	
FI	350	Papaya	10	Po	8	
FP	9	Pome fruits	3	Po	8	
VR	589	Potato	15	Po	8	
74	**DISULFOTON**					
VS	0621	Asparagus	0.02	(*)	8	
GC	0640	Barley	0.2		8	
VD	0071	Beans (dry)	0.2		8	
PE	0840	Chicken eggs	0.02	(*)	8	
VP	0526	Common bean (pods and/or immature seeds)	0.2		8	
SO	0691	Cotton seed	0.1		8	
VP	0528	Garden pea (young pods)	0.1		8	
VP	0529	Garden pea, Shelled	0.02	(*)	8	
GC	0645	Maize	0.02	(*)	8	
ML	0107	Milk of cattle, goats & sheep	0.01		8	
AF	0647	Oat forage (green)	0.5		8	
AS	0647	Oat straw and fodder, Dry	0.05		8	
GC	0647	Oats	0.02	(*)	8	

PM	0110	Poultry meat	0.02	(*)	8
VO	0447	Sweet corn (corn-on-the-cob)	0.02	(*)	8
VO	1275	Sweet corn (kernels)	0.02	(*)	8
GC	0654	Wheat	0.2		8
AF	0654	Wheat forage (whole plant)	1		8
AS	0654	Wheat straw and fodder, Dry	5		8

87 DINOCAP

FB	269	Grapes	0.5		8

106 ETHEPHON

DF	269	Dried grapes (=currants, raisins and sultanas	5		8

187 CLETHODIM

AL	1020	Alfalfa fodder	10		8
AL	61	Bean fodder	10		8
VD	71	Beans (dry)	2		8
VP	0061	Beans, except broad bean and soya bean	0.5	(*)	8
AL	1030	Bean forage (green)	5		8
SO	0691	Cotton seed	0.5		8
OC	0691	Cotton seed oil, Crude	0.5	(*)	8
OR	0691	Cotton seed oil, Edible	0.5	(*)	8
MO	0105	Edible offal (mammalian)	0.2	(*)	8
PE	0112	Eggs	0.05	(*)	8
VD	651	Field pea (dry)	2		8
AM	1051	Fodder beet	0.1	(*)	8
VA	0381	Garlic	0.5		8
MM	95	Meat (from mammals other than marine mammals)	0.2		8
ML	106	Milks	0.05		8
VA	0385	Onion, Bulb	0.5		8
SO	0697	Peanut	5		8
VR	0589	Potato	0.5		8
PM	110	Poultry meat	0.2	(*)	8
PO	0111	Poultry, Edible offal of	0.2	(*)	8
SO	0495	Rape seed	0.5		8
OC	0495	Rape seed oil, Crude	0.5	(*)	8
OR	0495	Rapeseed oil, Edible	0.5	(*)	8
VD	0541	Soya bean (dry)	10		8
OC	0541	Soya bean oil, Crude	1		8
OR	0541	Soya bean oil, Refined	0.5	(*)	8
VR	0596	Sugar beet	0.1		8
SO	0702	Sunflower seed	0.5		8
OC	0702	Sunflower seed oil, Crude	0.1	(*)	8
VO	0448	Tomato	1		8

APPENDIX IV

PROPOSED DRAFT MAXIMUM RESIDUE LIMITS FOR PESTICIDES
(Advanced at Steps 5/8 Steps of the Procedure with omission of Steps 6 and 7)

			MRL (mg/kg)	Step	Note
30	**DIPHENYLAMINE**				
FP	0226	Apple	10	Po 5/8	
JF	226	Apple juice	0.5	PoP 5/8	
MO	1280	Cattle kidney	0.01	(*) 5/8	
MO	1281	Cattle liver	0.05	5/8	
MM	812	Cattle meat	0.01	(*) (fat) 5/8	
32	**ENDOSULFAN**				
VP	552	Broad bean (green pods and immature seeds)	0.5	5/8	
SB	715	Cacao beans	0.1	5/8	
SB	716	Coffee beans	0.1	5/8	
VC	424	Cucumber	0.5	5/8	
FB	269	Grapes	1	5/8	
GC	645	Maize	0.1	5/8	
VC	46	Melons, except watermelon	0.5	5/8	
FC	4	Oranges, Sweet, Sour	0.5	5/8	
FS	247	Peach	1	5/8	
FI	353	Pineapple	2	Po 5/8	
SO	495	Rape seed	0.5	5/8	
VD	541	Soya bean (dry)	1	5/8	
VC	431	Squash, Summer	0.5	5/8	
SO	702	Sunflower seed	1	5/8	
VO	448	Tomato	0.5	5/8	
GC	654	Wheat	0.2	5/8	
56	**2-PHENYLPHENOL**				
FP	230	Pear	20	Po 5/8	
62	**PIPERONYL BUTOXIDE**				
MO	1280	Cattle kidney	0.3	5/8	
MO	1281	Cattle liver	1	5/8	
MM	812	Cattle meat	5	(fat) 5/8	
ML	812	Cattle milk	0.2	F 5/8	
GC	80	Cereal Grains	30	Po 5/8	
FC	1	Citrus fruits	5	5/8	
JF	1	Citrus juice	0.05	5/8	
DF	167	Dried fruits	0.2	Po 5/8	
PE	112	Eggs	1	5/8	
VC	45	Fruiting vegetables, Cucurbits	1	5/8	
MO	0098	Kidney of cattle, goats, pigs & sheep	0.2	5/8	Excluding cattle kidney
VL	483	Lettuce, Leaf	50	5/8	
MO	0099	Liver of cattle, goats, pigs & sheep	1	5/8	
OC	645	Maize oil, Crude	80	PoP 5/8	
MM	0095	Meat (from mammals other than marine mammals)	2	5/8	Excluding cattle meat
ML	0106	Milks	0.05	F 5/8	Excluding cattle milk
VL	485	Mustard greens	50	5/8	
AL	72	Pea hay or pea fodder (dry)	200	(dry) 5/8	

AL	528	Pea vines (green)	400	(dry)	5/8
SO	703	Peanut, Whole	1		5/8
VO	51	Peppers	2		5/8
PM	110	Poultry meat	7	(fat)	5/8
PO	111	Poultry, Edible offal of	10		5/8
VD	70	Pulses	0.2	Po	5/8
VL	494	Radish leaves (including radish tops)	50		5/8
VR	75	Root and tuber vegetables	0.5		5/8
VL	502	Spinach	50		5/8
VO	448	Tomato	2		5/8
JF	448	Tomato juice	0.3		5/8
CM	654	Wheat bran, Unprocessed	80	PoP	5/8
CF	1211	Wheat flour	10	PoP	5/8
CF	1210	Wheat germ	90	PoP	5/8
CF	1212	Wheat wholemeal	30	PoP	5/8

151 DIMETIPIN

SO	0691	Cotton Seed	1		5/8
OR	0691	Cotton seed oil, edible	0.1		5/8
MO	0105	Edible offal (mammalian)	0.01	(*)	5/8
PE	0112	Eggs	0.01	(*)	5/8
MM	0095	Meat (from mammals other than marine mammals)	0.01	(*)	5/8
ML	0106	Milks	0.01	(*)	5/8
PM	0110	Poultry meat	0.01	(*)	5/8
PO	0111	Poultry, Edible offal of	0.01	(*)	5/8
SO	0495	Rape seed	0.2		5/8
SO	0702	Sunflower seed	1		5/8

199 **KRESOXIM**

Fc	0203	Grapefruit	0.5		5/8
OC	0305	Olive oil, Virgin	0.7		5/8
FT	0305	Olives	0.2		5/8
FC	0004	Oranges, Sweet, Sour	0.5		5/8

202 **FIPRONIL**

FI	0327	Banana	0.005		5/8
GC	0640	Barley	0.002	(*)	5/8
VB	0041	Cabbages, Head	0.02		5/8
MO	1280	Cattle kidney	0.02		5/8
MO	1281	Cattle liver	0.1		5/8
MM	0812	Cattle meat	0.5	(fat)	5/8
ML	0812	Cattle milk	0.02		5/8
PE	0112	Eggs	0.02		5/8
VB	0042	Flowerhead brassicas	0.02		5/8
GC	0645	Maize	0.01		5/8
AS	0645	Maize fodder	0.1	dry wt	5/8
AF	0645	Maize forage	0.1	dry wt	5/8
GC	0647	Oats	0.002	(*)	5/8
VR	0589	Potato	0.02		5/8
PM	0110	Poultry meat	0.01	(*)	5/8
PO	0111	Poultry, Edible offal of	0.02		5/8
GC	0649	Rice	0.01		5/8
AS	0649	Rice straw and fodder, Dry	0.2	dry wt	5/8
GC	0650	Rye	0.002	(*)	5/8
VR	0596	Sugar beet	0.2		5/8
AV	0596	Sugar beet leaves or top	0.2	Dry wt	5/8
SO	0702	Sunflower seed	0.002	(*)	5/8
GC	0653	Triticale	0.002	(*)	5/8
GC	0654	Wheat	0.002	(*)	5/8

203 SPINOSAD

AM	0660	Almond hulls	2		5/8
TN	0660	Almonds	0.01	(*)	5/8
		Apple	0.1		5/8
MO	1280	Cattle kidney	1		5/8
MO	1281	Cattle liver	2		5/8
MM	0812	Cattle meat	3	(fat)	5/8
VS	0624	Celery	2		5/8
FC	0001	Citrus fruits	0.3		5/8
SO	0691	Cotton seed	0.01	(*)	5/8
OC	0691	Cotton seed oil, Crude	0.01	(*)	5/8
OR	0691	Cotton seed oil, Edible	0.01	(*)	5/8
PE	0112	Eggs	0.01		5/8
VC	0045	Fruiting vegetables, Cucurbits	0.02		5/8
FI	0341	Kiwifruit	0.05		5/8
VP	0060	Legume vegetables	0.3		5/8
GC	0645	Maize	0.01	(*)	5/8
AS	0645	Maize fodder	5		5/8
AF	0645	Maize forage	5	Dry wt	5/8
VO	0051	Peppers	0.3		5/8
VR	0589	Potato	0.01	(*)	5/8
PM	0110	Poultry meat	0.2	(fat)	5/8
MM	0822	Sheep meat	0.01(*)	(fat)	5/8
MO	0822	Sheep, Edible offal of	0.1	(*)	5/8
GC	0651	Sorghum	1		5/8
VD	0541	Soya bean (dry)	0.01	(*)	5/8
FS	0012	Stone fruits	0.2		5/8
VO	0447	Sweet corn (corn-on-the-cob)	0.01	(*)	5/8
VO	0448	Tomato	0.3		5/8
VO	0654	Wheat straw and fodder, Dry	1		5/8

APPENDIX V

DRAFT AND REVISED DRAFT MAXIMUM RESIDUE LIMITS FOR PESTICIDES
(Advanced to Step 5 of the Codex Procedure)

			MRL (mg/kg)		Step	Note
008	**CARBARYL**					
AM	0660	Almond hulls	50		5	
VS	0621	Asparagus	15		5	
VR	0574	Beetroot	0.1		5	
VR	0577	Carrot	0.5		5	
FS	0013	Cherries	20		5	
FC	0001	Citrus fruits	15		5	
JF	0001	Citrus juice	0.5		5	
AB	0001	Citrus pulp, dry	4		5	
DF	0269	Dried grapes (=currants, raisins and sultanas)	50		5	
VO	0440	Egg plant	1		5	
FB	0269	Grapes	40		5	
		Grape juice	30		5	
AB	0269	Grape pomace, dry	80		5	
MO	0098	Kidney of cattle, goats, pigs and sheep	3		5	
MO	0099	Liver of cattle, goats, pigs an sheep	1		5	
GC	0645	Maize	0.02	(*)	5	
AF	0645	Maize forage,	400	dry	5	
AS	0645	Maize fodder	250		5	
OC	0645	Maize oil, crude	0.1		5	
MM	0095	Meat (from mammals other than marine mammals)	0.05		5	
ML	0106	Milks	0.05		5	
FT	0305	Olives	30		5	
OC	0305	Olive oil, virgin	25		5	
VO	0445	Peppers, sweet	5		5	
CM	1206	Rice bran, unprocessed	170		5	
		Rice hulls	50		5	
AS	0649	Rice straw and fodder. dry	120		5	
CM	1205	Rice, polished	1		5	
AF	0651	Sorghum forage, green	20		5	
		Sorghum forage (dry)	50		5	
OC	0541	Soya bean oil, crude	0.2		5	
VD	541	Soya bean (dry)	0.2		5	
AL	0541	Soya bean fodder	15		5	
AL	1265	Soyabean forage (green)	30	Dry	5	
		Soybeans, hulls	0.3		5	
FS	0012	Stone fruits	10		5	
OC	0702	Sunflower seed oil, crude	0.05		5	
		Sunflower forage	5		5	
VO	0447	Sweet corn, corn on the cob	0.1		5	
		Sweet corn cannery waste	7.4		5	
VR	0508	Sweet potato	0.02	(*)	5	
SO	0702	Sunflower seed	0.2		5	
VO	0448	Tomato	5		5	
JF	0448	Tomato juice	3		5	
		Tomato paste	10		5	
TN	0085	Tree nuts	1		5	
VR	0506	Turnip, Garden	1		5	
GC	0654	Wheat	2		5	

CF	1211	Wheat flour	0.2		5
CF	1210	Wheat germ	1		5
CM	0654	Wheat bran, unprocessed	2		5
AS	0654	Wheat straw and fodder, dry	30		5

20	**2,4-D**				
FC	0001	Citrus fruits	1	Po	5
30	**DIPHENYLAMINE**				
ML	812	Cattle milk	0.0004	(*) F	5
FP	230	Pear	5	Po	5
94	**METHOMYL**				
Xx	2	[Cotton seed, hulls]	0.2		5
Xx	3	[Rape seed forage]	0.2		5
Xx	4	[Soya bean hulls]	1		5
Xx	5	[Soy bean meal]	0.2		5
FP	0226	Apple	2		5
VD	0071	Beans (dry)	0.05		5
VP	0526	Common bean (pods and/or immature seeds)	1		5
SO	0691	Cotton seed	0.2		5
OR	691	Cotton seed oil, Edible	0.04		5
MO	105	Edible offal (mammalian)	0.02	(*)	5
PE	112	Eggs	0.02	(*)	5
GC	0645	Maize	0.02	(*)	5
AF	0645	Maize forage	50		5
OR	645	Maize oil, Edible	0.02	(*)	5
MM	0095	Meat (from mammals other than marine mammals)	0.02	(*)	5
ML	0106	Milks	0.02	(*)	5
FS	0245	Nectarine	0.2		5
GC	0647	Oats	0.02	(*)	5
FS	0247	Peach	0.2		5
FP	0230	Pear	0.3		5
FS	14	Plums (including prunes)	1		5
VR	0589	Potato	0.02	(*)	5
PM	110	Poultry meat	0.02	(*)	5
PO	111	Poultry, Edible offal of	0.02	(*)	5
SO	495	Rape seed	0.05		5
AL	541	Soya bean fodder	0.2		5
OC	541	Soya bean oil, Crude	0.2		5
OR	541	Soya bean oil, Refined	0.2		5
AS	161	Straw, fodder (dry) and hay of cereal grains and other grass-like plants	10		5
96	**CARBOFURAN**				
SO	0691	Cotton seed	0.1		5
SO	0495	Rape seed	0.05	(*)	5
CM	0649	Rice, husked	0.1		5
AS	0649	Rice straw and fodder (dry)	1		5
103	**PHOSMET**				
FB	0020	Blueberries	15		5
FC	0001	Citrus fruits	3		5
FS	0245	Nectarine	10		5
FP	0230	Pome fruit	10		5
TN	0085	Tree nuts	0.2		5
113	**PROPARGITE**				
TN	0660	Almonds	0.1	(*)	5
AM	0738	Almond hulls	50		5

FP	0226	Apple	3		5
JF	0226	Apple juice	0.2		5
FC	0001	Citrus fruits	3		5
AB	0001	Citrus pulp, dry	10		5
SO	0691	Cotton seed	0.1		5
OR	0691	Cotton seed oil, Edible	0.2		5
DF	0269	Dried grapes (=currants, raisins and sultanas)	12		5
PE	0112	Eggs	0.1	(*)	5
FB	0269	Grapes	7		5
JF	0269	Grape juice	1		5
DH	1100	Hops, dry	100		5
CF	1255	Maize flour	0.2		5
OC	0645	Maize oil, crude	0.7		5
OR	0645	Maize oil, edible	0.5		5
MM	0095	Meat (from mammals other than marine mammals)	0.1	(*) (fat)	5
ML	0106	Milks	0.1	(*) F	5
MO	0105	Edible offal of (mammals)	0.1	(*)	5
JF	0004	Orange juice	0.3		5
OC	0697	Peanut oil, crude	0.3		5
OR	0697	Peanut oil, edible	0.3		5
PM	0110	Poultry meat	0.1	(*) (fat)	5
PO	0111	Poultry, edible offal of	0.1	(*)	5
FS	0012	Stone fruit	4		5
DT	1114	Tea, Green, Black	5		5

117 ALDICARB

FI	327	Banana	0.2		5

126 OXAMYL

VR	0577	Carrot	0.1		5
FC	0001	Citrus fruits	3		5
VC	0424	Cucumber	1		5
MO	0096	Edible offal of cattle, goats, horses, pigs & sheep	0.02 (*)		5
PE	0112	Eggs	0.02 (*)		5
MM	0095	Meat (from mammals other than marine mammals)	0.02 (*)		5
VC	0046	Melons, except watermelon	1		5
ML	0106	Milks	0.02 (*)		5
SO	0697	Peanut	0.05		5
AL	0697	Peanut fodder	0.2		5
VO	0051	Peppers	5		5
VR	0589	Potato	0.1		5
PM	0110	Poultry meat	0.02 (*)		5
PO	0111	Poultry, Edible offal of	0.02 (*)		5

130 DIFLUBENZURON

FC	0001	Citrus fruits	0.5		5
MO	0105	Edible offal (mammalian)	0.1	(*)	5
MM	0095	Meat (from mammals other than marine mammals)	0.1	(fat)	5
ML	0106	Milks	0.02	(*) F	5
VO	0450	Mushrooms	0.3		5
FP	0009	Pome fruit	5		5
PM	0110	Poultry meat	0.05	(*) (fat)	5
GC	0649	Rice	0.01	(*)	5
AS	0649	Rice straw and fodder, dry	0.7		5

135 DELTAMETRIN

FP	0226	Apple	0.2		5

VR	0577	Carrot	0.02		5
GC	0080	Cereal grains	2	Po	5
FC	0001	Citrus fruits	0.02		5
PE	0112	Eggs	0.02	(*)	5
VB	0042	Flowerhead brassicas	0.1		5
FB	0269	Grapes	0.2		5
TN	0666	Hazelnuts	0.02	(*)	5
Mo	0098	Kidney of cattle, goats, pigs and sheep	0.03	(*)	5
VL	0053	Leafy vegetables	2		5
VA	0384	Leek	0.2		5
VP	0060	Legume vegetables	0.2		5
MO	0099	Liver of cattle, goats, pigs and sheep	0.03	(*)	5
MO	0098	Kidney of cattle, goats, pigs and sheep	0.03	(*)	5
ML	0106	Milks	0.05 F		5
VO	0450	Mushrooms	0.05		5
FS	0245	Nectarine	0.05		5
FT	0305	Olives	1		5
VA	0385	Onion, Bulb	0.05		5
FS	0247	Peach	0.05		5
FS	0014	Plums (including Prunes)	0.05		5
VR	0589	Potato	0.01 (*)		5
PM	0110	Poultry meat	0.1	(fat)	5
PO	0111	Poultry, edible offal of	0.02 (*)		5
VD	0070	Pulses	1 Po		5
VR	0494	Radish	0.01 (*)		5
FB	0275	Strawberry	0.2		5
SO	0702	Sunflower seed	0.05 (*)		5
VO	0447	Sweet corn (corn-on-the-cob)	0.02 (*)		5
DT	1114	Tea, Green, Black	5		5
VO	0448	Tomatoes	0.3		5
TN	0678	Walnuts	0.02 (*)		5
CF	1211	Wheat flour	0.3 PoP		5
CF	1212	Wheat wholemeal	2 PoP		5

162 TOLYLFUANID

FB	0264	Blackberries	5		5
VC	0424	Cucumber	1		5
FB	0021	Currants, Black, Red, White	0.5		5
FB	0269	Grapes	3		5
DH	1100	Hops, dry	50		5
VA	0384	Leek	2		5
VL	0482	Lettuce, Head	0.2		5
VO	0445	Peppers, sweet	2		5
FB	0272	Raspberries, Red, Black	5		5
FB	0275	Strawberry	5		5
VO	0448	Tomato	3		5

196 TEBUFENOZIDE

AM	660	Almond hulls	30		5
TN	660	Almonds	0.05		5
FI	326	Avocado	1		5
FB	20	Blueberries	3		5
VB	400	Broccoli	0.5		5
VB	41	Cabbages, Head	5		5
MO	1280	Cattle kidney	0.02	(*)	5
MO	1281	Cattle liver	0.02	(*)	5
MM	812	Cattle meat	0.05	(fat)	5
ML	812	Cattle milk	0.01	(*)	5
FC	1	Citrus fruits	2		5

FB	265	Cranberry	0.5		5
DF	269	Dried grapes (=currants, raisins and sultanas)	2		5
PE	112	Eggs	0.02	(*)	5
VL	53	Leafy vegetables	10		5
HH	738	Mints	20		5
FS	245	Nectarine	0.5		5
FS	247	Peach	0.5		5
TN	672	Pecan	0.01	(*)	5
VO	0051	Peppers	1		5
PM	0110	Poultry meat	0.02	(*)	5
SO	0495	Rape seed	2		5
FB	0272	Raspberries, red, black	2		5
GS	0654	Sugar cane	1		5
VO	0448	Tomato	1		5

201 CHLORPROPHAM

MM	0812	Cattle meat	0.1	(fat)	5
ML	0812	Cattle milk	0.0005	(*) F	5
MO	0812	Cattle, Edible offal of	0.01	(*)	5
VR	0589	Potato	30	Po	5

203 SPINOSAD

FP	0226	Brassica vegetables	2		5
ML	0812	Cattle milk	1		5
VL	0053	Leafy vegetables	10		5

204 ESFENVALERATE

SO	0691	Cotton seed	0.05		5
PE	0112	Eggs	0.01	(*)	5
PM	0110	Poultry meat	0.01	(*) (fat)	5
PO	0111	Poultry, Edible offal of	0.01	(*)	5
SO	0495	Rapeseed	0.01	(*)	5
VO	0448	Tomato	0.1		5
GC	0654	Wheat	0.05		5
AS	0654	Wheat straw and fodder, dry	2		5

205 FLUTOLANIL

PE	0112	Eggs	0.05	(*)	5
MO	0098	Kidney of cattle, goats, pigs and sheep	0.1		5
MO	0099	Liver of cattle, goats, pigs and sheep	0.2		5
MM	0095	Meat (from mammals other than marine mammals)	0.05	(*)	5
ML	0106	Milks	0.05	(*)	5
PO	0111	Poultry edible offal	0.05	(*)	5
PM	0110	Poultry meat	0.05	(*)	5
CM	1206	Rice bran, unprocessed	10		5
AS	0649	Rice straw and fodder, dry	10		5
CM	0649	Rice, husked	2		5
CM	1205	Rice, polished	1		5

206 IMIDACLOPRID

FP	0226	Apple	0.5		5
AB	0226	Apple pomace, dry	5		5
FS	0240	Apricot	0.5		5
FI	0327	Banana	0.05		5
AS	0640	Barley straw and fodder (dry)	1	dry	5
VP	0061	Beans, except broad bean and soya bean	2		5
VB	0400	Broccoli	0.5		5

VB	0402	Brussels sprouts	0.5		5
VB	0041	Cabbages, head	0.5		5
VB	0404	Cauliflower	0.5		5
GC	0080	Cereals grains	0.05		5
FC	0001	Citrus fruits	1		5
AB	0001	Citrus pulp, dry	10		5
VC	0424	Cucumber	1		5
MO	0105	Edible offal (Mammalian)	0.05		5
VO	0440	Egg plant	0.2		5
PE	0112	Eggs	0.02	(*)	5
FB	0269	Grapes	1		5
DH	1100	Hops, dry	10		5
VA	0384	Leek	0.05	(*)	5
VL	0482	Lettuce, Head	2		5
AS	0645	Maize fodder	0.2	dry	5
AF	0645	Maize forage	0.5	dry	5
FI	0345	Mango	0.2		5
MM	0095	Meat (from mammals other than marine mammals)	0.02	(*)	5
VC	0046	Melons, except Watermelon	0.2		5
ML	0106	Milks	0.02	(*)	5
FS	0245	Nectarine	0.5		5
AF	0647	Oat forage (green)	5	dry	5
AS	0647	Oat straw and fodder, dry	1	dry	5
VA	0385	Onion, Bulb	0.1		5
FS	0247	Peach	0.5		5
FP	0230	Pear	1		5
TN	0672	Pecan	0.05		5
VO	0051	Peppers	1	dry wt	5
FS	0014	Plums (including prunes)	0.2		5
PM	0110	Poultry meat	0.02	(*)	5
PO	0111	Poultry, Edible offal of	0.02	(*)	5
VR	0589	Potato	0.5		5
SO	0495	Rape seed	0.05	(*)	5
AF	0650	Rye forage (green)	5	dry wt	5
AS	0650	Rye straw and fodder, dry	1	dry wt	5
VC	0431	Squash, Summer	1		5
VO	0447	Sweet corn (corn-on-the-cob)	0.02	(*)	5
VR	0596	Sugar beet	0.05	(*)	5
AV	0596	Sugar beet leaves or tops	5	dry wt	5
VO	0448	Tomato	0.5		5
VC	0432	Watermelon	0.2		5
CM	0654	Wheat bran, unprocessed	0.3		5
CF	1211	Wheat flour	0.03		5
AS	0654	Wheat straw and fodder, dry[a]	1		5

APPENDIX VI

CODEX MAXIMUM RESIDUE LIMITS FOR PESTICIDES RECOMMENDED FOR REVOCATION

			MRL (mg/kg)	Step	Note
15	**CHLORMEQUAT**				
AS	0640	Barley, straw and fodder, Dry	50		CXL-D
AS	0647	Oat, straw and fodder, Dry	50		CXL-D
FP	0230	Pear	3		CXL-D
GC	650	Rye	5		CXL-D
AS	0650	Rye, straw and fodder, Dry	50		CXL-D
GC	0654	Wheat	5		CXL-D
AS	0654	Wheat, straw and fodder, Dry	50		CXL-D
17	**CHLORPYRIFOS**				
FP	0266	Apple	1		CXL-D
VB	0041	Cabbages, Head	0.05	(*)	CXL-D
VR	0577	Carrot	0.5		CXL-D
MM	0812	Cattle meat	2	(fat)	CXL-D
VB	0404	Cauliflower	0.05	(*)	CXL-D
PM	0840	Chicken meat	0.1	(fat)	CXL-D
VP	0526	Common bean (pods and/or immature seeds)	0.2		CXL-D
DF	0269	Dried grapes (=currants, raisins and sultanas)	2		CXL-D
PE	0112	Eggs	0.05	(*)	CXL-D
FB	0269	Grapes	1		CXL-D
ML	0106	Milks	0.01	(*)	CXL-D
VA	0385	Onion, bulb	0.05	(*)	CXL-D
FP	0230	Pear	0.5		CXL-D
VO	0051	Peppers	0.5		CXL-D
MM	0822	Sheep meat	0.2	(fat)	CXL-D
VR	0596	Sugar beet	0.05	(*)	CXL-D
PM	0848	Turkey meat	0.2	(fat)	CXL-D
30	DIPHENYLAMINE				
FP	0226	Apple	5	Po	CXL-D
41	FOLPET				
VC	0424	Cucumber	2	T	CXL-D
VR	0589	Potato	0.02	(*)	CXL-D
32	ENDOSULFAN				
AO2	0002	Fruits (except as otherwise listed)	2		CXL-D
AO1	0002	Vegetables (except as otherwise listed)	2		CXL-D
53	**MEVINPHOS**				
VP	0526	Common bean (pods and/or immature seeds)	0.05		CXL-D
VA	0348	Leek	0.02	(*)	CXL-D

54	**MONOCROTOPHOS**				
FC	0001	Citrus fruits	0.2		CXL-D
VP	0526	Common bean (pods and/or immature seeds)	0.2		CXL-D
SO	0691	Cotton seed	0.1		CXL-D
OC	0691	Cotton seed oil, Crude	0.05	(*)	CXL-D
MO	0097	Edible offal of cattle, pigs and sheep	0.02	(*)	CXL-D
VO	0.2	Egg plant	0.2		CXL-D
PE	0112	Eggs	0.02	(*)	CXL-D
MM	0814	Goat meat	0.02	(*)	CXL-D
MO	0814	Goat, Edible offal of	0.02	(*)	CXL-D
GC	0645	Maize	0.05	(*)	CXL-D
MM	0097	Meat of cattle, pigs and sheep	0.02	(*)	CXL-D
AO3	0001	Milk products	0.02	(*)	CXL-D
ML	0106	Milks	0.002	(*)	CXL-D
VA	0385	Onion, bulb	0.1		CXL-D
SO	0697	Peanut	0.05	(*)	CXL-D
VP	0063	Peas (pods and succulent=immature seeds)	0.1		CXL-D
VO	0444	Peppers, Chili	0.2		CXL-D
VR	0589	Potato	0.05	(*)	CXL-D
PM	0110	Poultry meat	0.02	(*)	CXL-D
PO	0111	Poultry, Edible offal of	0.02	(*)	CXL-D
VP	0541	Soya bean (immature seeds)	0.05	(*)	CXL-D
VR	0596	Sugar beet	0.05	(*)	CXL-D
GS	0659	Sugar cane	0.02	(*)	CXL-D
VC	0432	Watermelon	0.1		CXL-D
GC	0654	Wheat	0.02	(*)	CXL-D
56	**2-PHENYLPHENOL**				
FP	230	Pear	25		CXL-D
60	**PHOSALONE**				
FP	0226	Apple	5		CXL-D
61	**PHOSPHAMIDON**				
FP	0226	Apple	0.5		CXL-D
VB	0400	Broccoli	0.2		CXL-D
VB	0402	Brussels sprouts	0.2		CXL-D
VB	0041	Cabbages, Head	0.2		CXL-D
VR	0577	Carrot	0.2		CXL-D
VR	0578	Celeriac	0.2		CXL-D
GC	0080	Cereal grains	0.1		CXL-D
FS	0013	Cherries	0.2		CXL-D
FC	0001	Citrus fruits	0.4		CXL-D
VP	0526	Common bean (pods and/or immature seeds)	0.2		CXL-D
VC	0424	Cucumber	0.1		CXL-D
VL	0482	Lettuce, Head	0.1		CXL-D
FS	0247	Peach	0.2		CXL-D
FP	0230	Pear	0.5		CXL-D
VP	0063	Peas (pods and succulent=immature seeds)	0.2		CXL-D
VO	0051	Peppers	0.2		CXL-D
FS	0014	Plums (including prunes)	0.2		CXL-D
VR	0075	Root and tuber vegetables	0.05	(*)	CXL-D
VL	0502	Spinach	0.2		CXL-D
FB	0275	Strawberry	0.2		CXL-D
VO	0448	Tomato	0.1		CXL-D

VC	0432	Watermelon	0.1		CXL-D
62	**PIPERONYL BUTOXIDE**				
GC	0654	Wheat	10	Po	CXL-D
63	**PYRETHRINS**				
DF	0167	Dried fruits	1	Po	CXL-D
65	**THIABENDAZOLE**				
FP	0226	Apple	10		CXL-D
ML	812	Cattle milk	0.1		CXL-D
MO	0096	Edible offal off cattle, goats, horses, pigs & sheep	0.1	(*)	CXL-D
VR	589	Potato	15		CXL-D
74	**DISULFOTON**				
GC	0080	Cereal grains	0.2		CXL-D
GC	0645	Maize	0.5		CXL-D
82	**DICHLOFLUANID**				
FB	0264	Blackberries	10		CXL-D
VO	0440	Egg plant	1		CXL-D
94	**METHOMYL**				
VO	0440	Egg plant	0.2		CXL-D
DH	1100	Hops, dry	10		CXL-D
AS	0647	Oats, straw and fodder	5		CXL-D
VA	0387	Onion, welsh	0.5		CXL-D
SO	0697	Peanut	0.1		CXL-D
AL	1270	Peanut forage (green)	5		CXL-D
VP	0064	Peas, shelled (succulent seeds)	0.5		CXL-D
FI	0353	Pineapple	0.2		CXL-D
GC	0651	Sorghum	0.2		CXL-D
VP	0541	Soya bean (immature seeds)	0.1		CXL-D
VC	0431	Squash, summer	0.2		CXL-D
VR	0596	Sugar beet	0.1		CXL-D
96	**CARBOFURAN**				
VR	0577	Carrot	0.5		CXL-D
VO	0440	Egg plant	0.1	(*)	CXL-D
GC	0647	Oats	0.1	(*)	CXL-D
VA	0385	Onion, bulb	0.1	(*)	CXL-D
VD	0541	Soya bean (dry)	0.2		CXL-D
VR	0596	Sugar beet	0.1		CXL-D
AV	0596	Sugar beet, leaves or tops	0.2		CXL-D
VO	1275	Sweet corn (kernels)	0.1	(*)	CXL-D
VO	0448	Tomato	0.1	(*)	CXL-D
GC	0645	Wheat	0.1	(*)	CXL-D
147	**METHOPRENE**				
VO	0450	Mushrooms	0.2		CXL-D
SO	0697	Peanut	2		CXL-D
151	DIMETHIPIN				
SO	0693	Linseed	0.2		CXL-D
OC	0702	Sunflower seed oil, Crude	0.1		CXL-D
OR	0702	Sunflower seed oil, Edible	0.02	(*)	CXL-D
OR	0691	Cotton seed oil, Edible	0.02	(*)	CXL-D
MO	0105	Edible offal (mammalian)	0.02	(*)	CXL-D
PE	0112	Eggs	0.02	(*)	CXL-D
MM	0095	Meat (from mammals other	0.02	(*)	CXL-D

		than marine mammals)			
ML	0106	Milks	0.02	(*)	CXL-D
PM	0110	Poultry meat	0.02	(*)	CXL-D
PO	0111	Poultry, Edible offal of	0.02	(*)	CXL-D
SO	0495	Rape seed	0.1		CXL-D
SO	0702	Sunflower seed	0.5		CXL-D
161		**PACLOBUTRAZOLE**			
FP	0226	Apple	0.5		CXL-D
FS	0012	Stone fruits	0.05		CXL-D

APPENDIX VII

DRAFT AND REVISED DRAFT MAXIMUM RESIDUE LIMITS FOR PESTICIDES
(Returned to Step 6 and Step 3 of the Codex Procedure)

			MRL (mg/kg)		Step	Note
007	**CAPTAN**					
FP	226	Apple	20		6	
VC	424	Cucumber	3		6	
FS	13	Cherries	25		6	
DF	269	Dried grapes (=currants, raisins and sultanas)	50		6	
FB	269	Grapes	25		6	
FS	245	Nectarine	3		6	
FSO	247	Peach	20		6	
FS	14	Plums (including prunes)	10		6	
FP	9	Pome fruits	15		6	
FB	272	Raspberries, Red, Black	20		6	
FB	275	Strawberry	15		6	
VO	448	Tomato	5		6	
VC	046	Melons, except watermelon	10		6	
008	**CARBARYL**					
GC	0649	Rice	50		3	
22	**DIAZINON**					
VB	41	Cabbages, Head	0.5		6	
MM	814	Goat meat	2	(fat)	6	
MO	98	Kidney of cattle, goats, pigs and sheep	0.03		6	
MO	99	Liver of cattle, goats, pigs and sheep	0.03		6	
MM	97	Meat of cattle, pigs and sheep	2	(fat)	6	
FP	9	Pome fruits	0.3		6	
27	**DIMETHOATE**					
GC	640	Barley	2		6	
VB	402	Brussels sprouts	1		6	
VB	404	Cauliflower	0.5		6	
FB	269	Grapes	2		6	
VL	482	Lettuce, Head	0.5		6	
VP	63	Peas (pods and succulent=immature seeds)	1		6	
FS	14	Plums (including prunes)	1		6	
FP	9	Pome fruits	0.5		6	
AV	596	Sugar beet leaves or tops	0.1		6	
VO	448	Tomato	2		6	
VR	506	Turnip, Garden	0.1		6	
VL	506	Turnip, Greens	1		6	
GC	654	Wheat	0.2		6	
AS	654	Wheat straw and fodder, Dry	10		6	
41	**FOLPET**					
FP	226	Apple	10		6	
DF	269	Dried grapes (=currants, raisins and sultanas)	40		6	
FB	269	Grapes	10		6(a)	
VL	482	Lettuce, Head	50		6	
FB	275	Strawberry	5		6(a)	
VO	448	Tomato	3		6	

49	**MALATHION**				
AL	1020	Alfalfa fodder	200		6
AL	1021	Alfalfa forage (green)	500	(dry)	6
VS	621	Asparagus	1		6
VP	61	Beans, except broad bean and soy bean	1		6
AL	1023	Clover	500	(dry)	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
VC	424	Cucumber	0.2		6
AF	162	Grass forage	200		6
AS	162	Hay or fodder *dry) of grasses	300		6
AS	645	Maize fodder	50		6
AF	645	Maize forage	10	(dry)	6
VL	485	Mustard greens	2		6
VA	385	Onion, Bulb	1		6
VA	0389	Spring onion	5		6
VO	447	Sweet corn (corn-on-the-cub)	0.02		6
JF	448	Tomato juice	0.01		6
VL	506	Turnip greens	5		6
AF	654	Wheat forage (whole plant)	20	(dry)	6
CF	1211	Wheat flour	0.2		6
AD	654	Wheat straw and fodder, Dry	50		6
FB	20	Blueberries	10		6
GC	645	Maize	0.05		6
GC	651	Sorghum	3		6
GC	654	Wheat	0.5		6

59	**PARATHON-METHL**				
AL	1020	Alfalfa fodder	70		6
AL	1021	Alfalfa forage (green)	70		6
FP	226	Apple	0.2		6
AL	1030	Bean forage (green)	1	Fresh wt	6
VB	41	Cabbages, Head	0.05		6
SO	691	Cotton seed	25		6
OC	691	Cotton seed oil, Crude	10		6
OR	691	Cotton seed oil, Edible	10		6
DF	269	Dried grapes (=currants, raisins and sultanas	1		6
FB	269	Grapes	0.5		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
FS	247	Peach	0.3		6
VD	72	Peas (dry)	0.3		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	0596	Sugar beat leaves or tops	0.05	(*) fresh wt	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,	10		6

		Dry				
65	**THIABENDAZOLE**					
VO	450	Mushrooms	60		6	
FC	001	Citrus fruits	3	Po	6	
VC	046	Melons, except watermelon	1		3	
FB	275	Strawberry	5		3	
72	**CARBENDAZIM**					
FB	18	Berries and other small fruits	1		6	Except grapes
VL	482	Lettuce, Head	5		6	
VO	51	Peppers	0.1		6	
74	**DISULFOTON**					
VB	0400	Broccoli	0.1		6	
VB	0041	Cabbages, Head	0.2		6	
VB	0404	Cauliflower	0.05		6	
VL	0482	Lettuce, Head	1		6	
VL	0483	Lettuce, Leaf	1		6	
85	**PENAMIPHOS**					
FP	226	Apple	0.05	(*)	6	
FI	327	Banana	0.05	(*)	6	
VB	402	Brussels sprouts	0.05		6	
VB	41	Cabbages, Head	0.05		6	
OC	691	Cotton seed oil, Crude	0.05	(*)	6	
MO	105	Edible offal (mammalian)	0.01	(*)	6	
PE	112	Eggs	0.01	(*)	6	
MM	95	Meat (from mammals other than marine mammals)	0.01	(*)	6	
ML	106	Milks	0.005	(*)	6	
OC	697	Peanut oil, Crude	0.05	(*)	6	
VO	51	Peppers	0.5		6	
PO	110	Poultry meat	0.01	(*)	6	
PO	111	Poultry, Edible offal of	0.01	(*)	6	
VC	432	Watermelon	0.05	(*)	6	
VO	448	Tomato	0.5		6	
90	**CHLORPYRIFOS-METHYL**					
GC	0640	Barley	10		6	
GC	0647	Oats	10		6	
GC	0649	Rice	10(a)		6	
94	**METHOMYL**					
AL	1020	Alfalfa fodder	20		3	
AL	1021	Alfalfa forage (green)	25		3	
GC	0640	Barley	2		3	
AL	61	Bean fodder	10		3	
VP	61	Beans, except broad bean and soya bean	1		3	
VB	0040	Brassica vegetables	7		3	
VS	0624	Celery	3		3	
AB	1	Citrus pulp, Dry	3		3	
VC	0045	Fruiting vegetables, Cucurbits	0.1		3	
FB	0269	Grapes	7		3	
VL	0053	Leafy vegetables	30		3	
AL	0528	Pea vines (green)	40		3	
AL	1265	Soya bean forage (green)	40		3	
GC	0654	Wheat	2		3	
CM	654	Wheat bran, Unprocessed	3		3	
CF	1211	Wheat flour	0.03		3	

CF	1210	Wheat germ	2		3
96	**CARBOFURAN**				
VC	4199	Cantaloupe	0.2		6
VC	0424	Cucumber	0.3		6
FC	0004	Oranges, Sweet, Sour	0.5		6
VC	0431	Squash, Summer	0.3		6
VO	0447	Sweet corn (corn-on-the-cob)	0.1		6
FC	0206	Mandarin	0.5		6
100	**METHAMIDOPHOS**				
FS	0247	Peach	1		6
FP	0009	Pome fruits	0.5		6
VO	0448	Tomato	1		6
103	**PHOSMET**				
FS	240	Apricot	10		6
117	**ALDICARB**				
VR	0589	Potato	0.5		6
145	**CARBOSULFAN**				
AB	0001	Citrus pulp, Dry	0.1		6
FC	206	Mandarin	0.1		6
FC	0004	Oranges, Sweet, Sour	0.1		6
166	**OXYMETON-METHYL**				
FP	0226	Apple	0.05		6
GC	0640	Barley	0.05	(*)	6
AS	640	Barley straw and fodder, Dry	2		6
VB	0041	Cabbages, Head	0.05	(*)	6
MF	0812	Cattle fat	0.05	(*)	6
VD	526	Common bean (dry)	0.1		6
SO	0691	Cotton seed	0.05		6
PE	0112	Eggs	0.05	(*)	6
FB	0269	Grapes	0.1		6
VL	0480	Kale	0.01	(*)	6
VB	0405	Kohlrabi	0.05		6
FC	0204	Lemon	0.2		6
MM	0097	Meat of cattle, pigs & sheep	0.05	(*)	6
ML	0106	Milks	0.01	(*)	6
FC	0004	Oranges, Sweet, Sour	0.2		6
FP	0230	Pear	0.05		6
MF	0818	Pig fat	0.05	(*)	6
VR	0589	Potato	0.05	(*)	6
PF	0111	Poultry fats	0.05	(*)	6
PM	0110	Poultry meat	0.05	(*)	6
GC	650	Rye	0.05		6
AS	650	Rye straw and fodder, Dry	2		6
MF	0822	Sheep fat	0.05	(*)	6
VR	0596	Sugar beet	0.05	(*)	6
AV	0596	Sugar beet leaves or tops	0.05	(*)	6
GC	0654	Wheat	0.05	(*)	6
AS	654	Wheat straw and fodder, Dry	2		6
193	**FENPYROXIMATE**				
FP	226	Apple	0.3		6
FB	269	Grapes	1		6
FC	4	Oranges, Sweet, Sour	0.2		6
194	**HALOXYFOP**				
AL	1021	Alfalfa forage (green)	5		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
PE	0840	Chicken eggs	0.01	(*)	6
PM	0840	Chicken meat	0.01	(*)	6
PO	0840	Chicken, Edible offal of	0.05		6
SO	0691	Cotton seed	0.2		6
OC	0691	Cotton seed oil, Crude	0.5		6
AM	1051	Fodder beet	0.3		6
AV	1051	Fodder beet leaves or tops	0.3	fresh wt	3
SO	0697	Peanut	0.05		6
VP	0063	Peas (pods and succulent=immature seeds)	0.2		6
VR	0589	Potato	0.1		6
VD	0070	Pulses	0.2		6
SO	0495	Rape seed	2		6
OC	0495	Rape seed oil, Crude	5		6
OR	0495	Rapeseed oil, Edible	5		6
CM	1206	Rice bran, Unprocessed	0.02	(*)	6
CM	0649	Rice, Husked	0.02	(*)	6
CM	1205	Rice, Polished	0.02	(*)	6
OC	0541	Soya bean oil, Crude	0.2		6
OR	0541	Soya bean oil, Refined	0.2		6
VR	0596	Sugar beet	0.3		6
SO	0702	Sunflower seed	0.2		6
AV	596	Sugar beet leaves or tops	0.3	fresh wt	3

196 TEBUFENOZIDE

FB	0269	Grapes	2		6

APPENDIX VIII

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 Pesticides Residues (JMPR) from 2003 to 2012

2003 JMPR

Toxicological evaluations	**Residue evaluations**
New compounds	***New compounds***
cyprodinil	cyprodinil
famoxadone	famoxadone
methoxyfenozide	methoxyfenozide
pyraclostrobin	pyraclostrobin
Periodic re-evaluations	***Periodic re-evaluations***
carbosulfan (145)	acephate (095)/methamidophos (100)
paraquat (057)	fenitrothion (037)
terbufos (167)	lindane (048)
	pirimiphos-methyl (086)
	dodine (084)
Evaluations	***Evaluations***
pyrethrins (063)	carbendazim (072)/thiophanate-methyl (077)
dimethoate (027) - acute toxicity	carbosulfan (145)
malathion (049) - acute toxicity	dimethoate (027)
tebufenozide - acute toxicity	dicloran (083)
	pyrethrins (063)

2004 JMPR

Toxicological evaluations	**Residue evaluations**
New compounds	***New compounds***
fludioxinil	fludioxinil
trifloxystrobin	trifloxystrobin
Periodic re-evaluations	***Periodic re-evaluations***
cyhexatin (067)/azocyclotin (129)	ethoprophos (149)
glyphosate (158)	metalaxyl-M
phorate (112)	paraquat (057)
pirimicarb (101)	prochloraz (142)
triadimefon (133) {should be evaluated	Propineb
triadimenol (168) {together	
Evaluations	***Evaluations***
captan (007) – acute toxicity	chlorpyrifos (017)
fenpyroximate (193) – acute toxicity	dithiocarbamates (105)
folpet (041) – acute toxicity	guazatine (114)
guazatine (114)	malathion (047)
haloxyfop (194)	methomyl (094)
phosmet (103) – acute toxicity	oxydemeton-methyl (166)
chlorpyrifos – acute toxicity	folpet (041)
bentazone (172) - acute toxicity	carbofuran (096)
dimethipin (151) – acute toxicity	
fenpropimorph (188) – acute toxicity	

2005 JMPR

Toxicological evaluations	**Residue evaluations**
New compounds	***New compounds***
dimethenamid-P	dimethenamid-P
fenhexamid	fenhexamid
indoxacarb	indoxacarb
novaluron	novaluron
Periodic re-evaluations	***Periodic re-evaluations***
benalaxyl (155)	alpha and zeta cypermethrin
clofentezine (156)	cypermethrin (118)
propamocarb (148)	cyhexatin (067)/ azocyclotin (129)
propiconazole (160)	endosulfan (032)
	glyphosate (158)
	methoprene (147)
	phorate (112)
	terbufos (167)
Evaluations	***Evaluations***
ethoxyquin (035)	ethoxyquin (035)
imazalil (110) - acute toxicity	methiocarb (132)
thiabendazole (65) - acute toxicity	spinosad (203)
chlorpropham (201) - acute toxicity	
carbendazim (72) - acute toxicity	

2006 JMPR

Toxicological evaluations	**Residue evaluations**
New Compounds	***New Compounds***
bifenazate	bifenazate
pyrimethanil	pyrimethanil
dimethomorph	dimethomorph
Periodic re-evaluations	***Periodic re-evaluations***
cyromazine (169)	pirimicarb (101)
flusilazole (165)	triazophos (143)
procymidone (136)	triadimefon (133) {should be evaluated
profenofos (171)	triadimenol (168) {together
Evaluations	***Evaluations***

2007 JMPR

Toxicological evaluations	**Residue evaluations**
New Compounds	***New Compounds***
Periodic re-evaluations	***Periodic re-evaluations***
azinphos-methyl (002)	clofentezine (156)
lambda-cyhalothrin	permethrin (120)
cyfluthrin/beta cyfluthrin (157)	propamocarb (148)
fentin (040)	propiconazole (160)
vinclozolin (159)	triforine (116)
Evaluations	***Evaluations***

2008 JMPR

Toxicological evaluations	**Residue evaluations**
New Compounds	***New Compounds***
Periodic re-evaluations	***Periodic re-evaluations***
bioresmethrin (93)	benalaxyl (155)
buprofezin (173)	cyromazine (169)
chlorpyrifos-methyl (090)	*lamba*-cyhalothrin (replacement of cyhalothrin)
hexythiazox (176)	flusilazole (165)
	procymidone (136)
	profenofos (171)
Evaluations	***Evaluations***

2009 JMPR

Toxicological evaluations	**Residue evaluations**
New Compounds	***New Compounds***
Periodic re-evaluations	***Periodic re-evaluations***
bifenthrin (178)	azinphos-methyl (002)
cadusafos (174)	cyfluthrin/beta cyfluthrin (157)
chorothalanil (081)	fentin (040)
cycloxydim (179)	vinclozolin (159)
Evaluations	***Evaluations***

2010 JMPR

Toxicological evaluations	**Residue evaluations**
New Compounds	***New Compounds***
Periodic re-evaluations	***Periodic re-evaluations***
dithianon (028)	bioresmethrin (93)
fenbutatin oxide (109)	buprofezin (173)
	chlorpyrifos-methyl (090)
	hexythiazox (176)
Evaluations	***Evaluations***

2011 JMPR

Toxicological evaluations	**Residue evaluations**
New Compounds	***New Compounds***
Periodic re-evaluations	***Periodic re-evaluations***
	amitraz (122)
	bifenthrin (178)
	cadusafos (174)
	chorothalanil (081)

Evaluations	*Evaluations*

2012 JMPR

Toxicological evaluations	**Residue evaluations**
New Compounds	***New Compounds***
Periodic re-evaluations	***Periodic re-evaluations***
	cycloxydim (179)
	dithianon (028)
	fenbutatin oxide (109)
Evaluations	***Evaluations***

ANNEX I
CANDIDATE CHEMICALS FOR PERIODIC RE-EVALUATION –NOT YET SCHEDULED
(confirmation of support required by November 2003)

aldicarb (117)	diquat (031)
bromopylate (070)	etofenprox (184)
dichlorvos (025)	fenpropathrin (185)
dicofol (026)	

ANNEX II

CHEMICALS PROPOSED FOR PRIORITY LISTING BUT FOR WHICH FURTHER CONSIDERATION IS REQUIRED BEFORE A DECISION CAN BE MADE.

DDT (EMRLs)
Gentamicin, oxytetracycline hydrochoride
MRLs for various pesticides on spices based on monitoring data.

Appendix IX

PROPOSED REVISED CRITERIA FOR PRIORITIZATION PROCESS[1]

PROCEDURE FOR PROPOSING PESTICIDES FOR CODEX PRIORITY LISTS

Member countries are required to nominate chemicals for the Priority List using the following procedure:

1. CRITERIA FOR INCLUSION OF COMPOUNDS ON THE PRIORITY LIST

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

(a) must be available for use as a commercial product; and

(b) must not have been already accepted for consideration.

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.

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 contain pesticide residues and form a component of international trade. A higher priority will be given to commodities that represent a significant proportion of the diet.

3. PROCEDURES TO BE FOLLOWED FOR COMMODITY/PESTICIDE COMBINATIONS WHICH MEET THE SELECTION CRITERIA

Governments are recommended to:

(a) check if the pesticide is already in the Codex system.

NOTE: 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. Consult the document of the latest session to see whether or not a given pesticide has already been considered.

If "YES", - proceed to section (b) below,

If "NO", - proceed as follows:

Prepare a proposal for evaluation by completing section on Pesticide Information for CCPR below.

IN THIS PROCESS:

(i) consult with the manufacturer(s) about the existence of sufficient toxicological and residue data and confirm that the manufacturer(s) would be willing to submit data to the JMPR, and in what year, and;

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[1] Criteria for consideration by the Ad Hoc Working Group on Priorities when establishing a Priority List of Pesticides for Evaluation or Re-evaluation by JMPR

(ii) submit the information to the Committee with a copy to the Secretary, Codex Alimentarius Commission using the form of Section "Pesticide Information for CCPR".

(b) where the pesticide has already been evaluated by the JMPR and MRLs, EMRLs or GLs have been established two situations may arise:

(i) interest exists in proposing MRLs for a new commodity. Consult the working document prepared for and used as a basis of discussion at each Session of the Codex Committee on Pesticide Residues to be sure that MRLs have not already been established or considered for the commodity/pesticide combination. Where interest exists in developing data for a new commodity, Governments are urged to discuss with Industry the possibility of collaborative programmes, e.g., manufacturers may be willing to analyze samples from supervised residue trials conducted in accordance with FAO Guidelines on Pesticide Residue Trials to Provide Data for the Registration of Pesticides and for the Establishment of Maximum Residue Limits. Proposals for new commodity/pesticide combinations and new residue data may be submitted directly to the FAO Joint Secretary of the JMPR.

(ii) in those cases where additional toxicological data has become available, Governments may wish to propose a pesticide for re-evaluation and to do so according to Section Pesticide Information for CCPR below. Where a serious public health concern exists in relation to a particular pesticide, Governments should notify the WHO Joint Secretary of the JMPR promptly and provide appropriate data.

CRITERIA FOR EVALUATION OF NEW CHEMICALS

When prioritising 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;
3. The date that data will be submitted; and
4. Where possible, allocating new chemicals to be evaluated on a 50:50 basis with periodic re-evaluation chemicals to be evaluated.

PRIORITISING CHEMICALS FOR PERIODIC RE-EVALUATION

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

1. 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 taking into account the heavy workload of JMPR];
2. The year the chemical is listed in the list for Candidate Chemicals for Periodic Re-evaluation –Not Yet Scheduled;
3. The date that data will be submitted;
4. If the intake and/or toxicity profile indicate a high level of public health concern.
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;

7. Allocating periodic re-evaluation chemicals to be evaluated on a 50:50 basis with new chemicals to be evaluated.

When prioritising proposed residue evaluations by the JMPR for food commodities, the Working Group on Priorities will consider the following criteria:

1. The date the request was received;
2. The date the data can be submitted;
3. Whether the data is submitted under the 4-year rule for evaluations of extra data; and
4. The nature of the data to be submitted.

PESTICIDE INFORMATION FOR CCPR

for evaluation _____

for reevaluation _____

1. NAME:
2. STRUCTURAL FORMULA:
3. CHEMICAL NAME:
4. TRADE NAME:
5. NAMES AND ADDRESSES OF BASIC PRODUCERS:
6. JUSTIFICATION FOR USE:
7. USES: MAJOR
   MINOR
8. COMMODITIES MOVING IN INTERNATIONAL TRADE AND LEVELS OF RESIDUES:
9. COUNTRIES WHERE PESTICIDE IS REGISTERED[2]:
10. NATIONAL MAXIMUM RESIDUE LIMITS:
11. COMMODITIES FOR WHICH THE NEED FOR ESTABLISHING CODEX MRLS IS RECOGNIZED:
12. MAJOR INTERNATIONAL USE PATTERN:
13. LIST OF DATA (TOXICOLOGY, METABOLISM, RESIDUE) AVAILABLE:
14. DATE DATA COULD BE SUBMITTED TO THE JMPR:
15. PROPOSAL FOR INCLUSION SUBMITTED BY (COUNTRY):

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[2] Countries should provide detailed information on the registration status at the time of proposing a compound for inclusion in priority lists and again when the compound is scheduled for JMPR review.