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 01/24A

JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX ALIMENTARIUS COMMISSION
Twenty-Fourth Session
Geneva, 2 - 7 July 2001

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

The Hague, 2 - 7 April 2001

Note: This report includes Codex Circular Letter CL 2001/14-PR.

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CX 4/40.2 **CL 2001/14-PR**
April 2001

TO: - Codex Contact Points
- Interested International Organizations

FROM: Secretary, Codex Alimentarius Commission
FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy

SUBJECT: DISTRIBUTION OF THE REPORT OF THE THIRTY-THIRD SESSION OF THE CODEX COMMITTEE ON PESTICIDE RESIDUES (ALINORM 01/24A)

The report of the Thirty-third Session of the Codex Committee on Pesticide Residues will be considered by the 24th Session of the Codex Alimentarius Commission (Geneva, 2 - 7 July 2001).

PART A: MATTERS FOR ADOPTION BY THE 24TH SESSION OF THE CODEX ALIMENTARIUS COMMISSION

The following matters will be brought to the attention of the 24th Session of the Codex Alimentarius Commission for adoption:

1. DRAFT AND DRAFT REVISED MAXIMUM RESIDUE LIMITS AT STEP 8 (ALINORM 01/24A, APPENDIX II); AND

2. PROPOSED DRAFT AND PROPOSED DRAFT REVISED MAXIMUM RESIDUE LIMITS AT STEP 5/8 (ALINORM 01/24A, APPENDIX III)

Governments wishing to propose amendments or to comment on the Draft MRLs and Proposed Draft MRLs, including revised MRLs, should do so in writing in conformity with the Guide to the Consideration of Standards at Step 8 of the Procedure for the Elaboration of Codex Standards Including Consideration of Any Statements Relating to Economic Impact (*Codex Alimentarius Procedural Manual*, Eleventh Edition, pp. 26-27) to the Secretary, Codex Alimentarius Commission, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy (fax, +39 06 57054593; e-mail, codex@fao.org), **not later than 31 May 2001**.

3. PROPOSED DRAFT AMENDMENTS TO THE CODEX CLASSIFICATION OF FOODS AND ANIMAL FEEDS (ALINORM 01/24A, APPENDIX V) AT STEP 5 OF THE ACCELERATED PROCEDURE

Governments are invited to comment on the above Proposed Draft Amendments to the Codex Classification of Foods and Animal Feeds (*Codex Alimentarius*, Volume 2, Section 4, pp. 75-78), including the revised definitions of “meat”, “mammalian fats”, “poultry fats” and “milks”, at Step 3 of the Accelerated Procedure. Comments should be sent to the Secretary, Codex Alimentarius Commission, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy (fax, +39 06 5705 4593; e-mail, codex@fao.org), **not later than 31 May 2001**.

3. PROPOSED DRAFT AND PROPOSED DRAFT REVISED MAXIMUM RESIDUE LIMITS AT STEP 5 (ALINORM 01/24A, APPENDIX V)

Governments wishing to propose amendments or to submit comments regarding 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,* Eleventh Edition, p. 22) to the Secretary, Codex Alimentarius Commission, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy (fax, +39 06 57054593; e-mail, codex@fao.org), **not later than 31 May 2001**.

4. REVOCATION OF CODEX MRLS (ALINORM 01/24A, 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, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy (fax, +39 06 57054593; e-mail, codex@fao.org), **not later than 31 May 2001**.

PART B: 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 Annex II 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,* Eleventh Edition, pp. 21-22) preferably by an email to Dr Wim H. Van Eck, Dr Ministery of Health, Welfare and Sport, Postbox 20350, 2500 EJ Den Haag, The Netherlands, (Fax: + 31 70 340 5554, e-mail: wh.v.eck@minvws.nl), with a copy to the Secretary, Codex Alimentarius Commission, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy (fax: +39 06 57054593; e-mail: codex@fao.org), **not later than 4 January 2002**.

2. DEVELOPMENTAL NEUROTOXICITY

While considering the appropriateness of the current ADI and MRL setting in relation to infants and children (see paras 67-82), the Committee concluded that the possible increased vulnerability of infants and children was an important issue which needed to be explicitly integrated into the work of the CCPR and JMPR and agreed to request Member governments to provide information to the JMPR Secretariat on the availability of studies on developmental neurotoxicity that have been submitted to them, along with contact details on the data owners. This information should be sent to Dr J.L. Herman, International Programme on Chemical Safety, World Health Organization, 1211 Geneva 27, Switzerland, (Fax: +41 22 791 4848, E-mail: herrmanj@who.int) with a copy to the Secretary, Codex Alimentarius Commission, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy (fax: +39 06 57054593; e-mail: codex@fao.org), **not later than 1 November 2001**.

3. REVISION OF THE CODEX CLASSIFICATION OF FOODS AND ANIMAL FEEDS

While considering the Discussion paper on the Need for the Revision of the Codex Classification of Foods and Animal Feeds (see paras 245 - 249), the Committee agreed to ask information to what extent the Classification should be updated and what new commodities should be added. This information should be sent to Dr Wim H. Van Eck, Dr Ministery of Health, Welfare and Sport, Postbox 20350, 2500 EJ Den Haag, The Netherlands, (Fax: + 31 70 340 5554, E-mail: wh.v.eck@minvws.nl), with a copy to the Secretary, Codex Alimentarius Commission, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy (fax: +39 06 57054593; e-mail: codex@fao.org), **not later than 30 November 2001**.

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[1] For proposed draft MRLs to be adopted by the 24th Session of the Commission (2-7 July 2001) and proposed draft MRLs allocated by JMPR 2000 a separate CL will be issued.

PART C: 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 J.L. Herrman, International Programme on Chemical Safety, WHO, CH-1211 Geneva 27, Switzerland not later than one year before the JMPR meeting (see Appendix IX of ALINORM 01/24A).

Those countries specified under individual compounds in the ALINORM 01/24A 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-third Session of the Codex Committee on Pesticide Residues reached the following conclusions:

MATTERS FOR APPROVAL BY THE 24TH SESSION OF THE COMMISSION

The Committee recommended to the Commission:

- Draft MRLs for adoption at Step 8, Proposed Draft MRLs at Step 5/8 and Proposed Draft MRLs at Step 5 (Appendices II, III and V);
- Proposed Draft Amendments to the Codex Classification of Foods and Animal Feeds for adoption at Step 5 of the Accelerated Procedure (Appendix IV);
- revocation of certain existing Codex MRLs (Appendix VI); and
- Priority List of Pesticides for new pesticides and periodic evaluations by the JMPR (Appendix IX).

MATTERS FOR CONSIDERATION BY THE 24TH SESSION OF THE COMMISSION

The Committee:

- decided to propose to the Commission an EMRL level for DDT of 5mg/kg and a level of 3mg/kg in square brackets and to ask the Commission to take a decision regarding the level, taking into account that the Committee would not be able to reach consensus by deferring consideration of this matter to a later session (para. 195);
- while considering the request of Mexico regarding the inclusion of some antibiotics to the priority list as they met criteria for inclusion, the Committee decided that it could not make a decision because of a lack of consensus at this time and referred the issue to the Codex Alimentarius Commission, requesting coordination among the other committees involved, including the Codex Committees on Residues of Veterinary Drugs in Foods and Food Hygiene (para. 222).
- deferred discussion on other legitimate factors in the framework of risk analysis until further progress had been achieved in the CCGP and Codex with the understanding that the Commission could provide general orientation to Codex committees concerning the role of other factors and the application of risk analysis principles in the decision process (para. 240).

FOR INFORMATION TO THE COMMISSION

The Committee:

- while reviewing the procedure dealing with chronic dietary exposure concern recognized that current procedures should be retained for the time being and reasserted its earlier decision that no MRL should be advanced to Step 8 when the ADI was exceeded in one or more of the regional diets (para. 43);
- noted general consideration items of 2000 JMPR, and the initiative and the new developments that pesticide specifications be developed and reviewed by FAO/WHO Joint Meeting on Specifications before a compound is evaluated by the JMPR and that this process will be initiated in 2003 giving the priority to compounds under the periodic review programme (paras 13-27);
- agreed that there was no need to develop an additional document on risk analysis at this stage and noted that future action would depend on the recommendations of the Commission in this area (para. 51);
- supported the development of the 13 revised regional diets and noted that further refinement of the diets would be required, including examples of calculation MRLs for fruits and vegetables, before recommending their use for the purposes of JMPR (para. 56);
- agreed to discontinue the collection of information through the questionnaire about processing studies while recognizing the importance of collection information by GEMS FOOD currently required by national governments (para. 62);
- agreed that a case by case approach should be followed in establishing MRLs for genetically modified crops and metabolite residues (paras 63-66), and for isomeric mixtures (para. 222)
- agreed to consider a position paper identifying the more important spice/pesticide combinations, the availability of GAP information and residue data (field trial and monitoring data) together with

information on trade problems and policy guidance on further steps in the establishment of MRLs/EMRL for spices (para. 234)

- agreed to apply procedures when establishing priorities as indicated in paras 211, 212 and 215;
- agreed to consider at the next session:
  - cumulative risk assessment especially in relation to the development of common understanding of methodology (para 78);
  - acute exposure assessment (paras 246-247);
  - to what extent the Codex Classification of Foods and Animal Feeds should be reviewed and updated and in what structure the updated version would be (paras 241-245);
  - establishment of priority lists; and review of the paper on the working procedures of JMPR to be prepared by the FAO/WHO Secretariat (para. 224); and
- requested JMPR to consider a number of matters of general nature (paras 33, 77).

MATTER OF INTEREST TO OTHER COMMITTEES

The Committee:

- following the referral from the CCNASWP regarding the Trade Vulnerabilities Arising from the Lengthy Codex MRL Process, agreed to acknowledge the existence of the problem and requested the Delegation of the USA with assistance of other interested Member states and international organizations to prepare a paper for consideration by the next session of the Committee (para. 12);
- further following the request of the CCNFSDU, and considering the appropriateness of ADI and MRL setting for infants and children concluded that ADIs and MRLs should cover all population groups including infants and children and that the possible increased vulnerability of infants and children was an important issue which needed to be explicitly integrated into the work of the CCPR and JMPR and therefore agreed that the development of cumulative risk assessment required further consideration, especially regarding the development of common understanding of methodology (paras 67-78).

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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
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
WHO	World Health Organization
WTO	World Trade Organization
EC	European Community
CI	Consumers International
GCPF	Global Crop Protection Federation
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 Short-Term Intake
MRL	Maximum Residue Limit
PHI	Pre-harvest Interval
PTDI	Provisional Tolerable Daily Intake
STMR	Supervised Trials Median Residue
TMDI	Theoretical Maximum Daily Intake
SPS Agreement	Agreement on the Application of Sanitary and Phytosanitary Measures

ALINORM 01/24A

REPORT OF THE THIRTY THIRD SESSION OF THE COMMITTEE ON PESTICIDE RESIDUES, THE HAGUE, THE NETHERLANDS, 2-7 APRIL 2001

INTRODUCTION

1. The Codex Committee on Pesticide Residues (CCPR) held its 33rd Session in The Hague, The Netherlands, from 2-7 April 2001. Dr. W.H. van Eck of the Netherlands Ministry of Health, Welfare and Sport chaired the Session. The Session was attended by 44 Member countries and 14 international organizations. The list of participants is attached as Appendix I to this Report.

OPENING OF THE SESSION

2. The Session was opened by Mr. A.W. Kalis, Director of the Public Health Department of the Ministry of Health, Welfare and Sport. He welcomed the Committee to The Hague, and acknowledged the increased significance of food safety in the work of Codex, especially in the context of the globalization of food production, the intensification of trade in foodstuffs and the increased consumer concern on food safety. He expressed his concern on the limited availability of data and methodology to assess acute dietary intake at the international level, and on the restricted capacity of the Joint Meeting on Pesticide Residues to (re-) evaluate pesticide dossiers, and considered it timely for a fundamental re-examination of the Joint Meeting's working arrangements.

ADOPTION OF THE AGENDA (Agenda Item1)

3. The Committee adopted the Provisional Agenda as contained in CX/PR 01/1.

APPOINTMENT OF RAPPORTEURS (Agenda Item 2)

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

MATTERS REFERRED TO THE COMMITTEE (Agenda Item 3)[2]

5. The Committee noted matters of interest arising from the 47th Session of the Executive Committee, the 15th Session of the Committee on General Principles (CCGP) and the 23rd Session of the Committee on Methods of Analysis and Sampling (CCMAS).

TRADE VULNERABILITIES RESULTING FROM THE LENGTHY CODEX MRL PROCESS

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

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

[2] CX/PR 01/2, CRD 3 (comments of US).

JMPR and the establishment of "interim" MRLs that could be used as a reference with the understanding that they would be revised within a limited timeframe.

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

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

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

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

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

REPORT ON GENERAL CONSIDERATIONS BY THE 1999 AND 2000 JOINT FAO/WHO MEETINGS ON PESTICIDE RESIDUES (Agenda item 4)[3]

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

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

15. The Committee discussed the relevance of food processing questionnaires to JMPR evaluations. It recognized that the questionnaire serves as a basis for defining appropriate processed commodities and recommended that GEMS/Food use the information from the questionnaire to revise or develop data on food consumption for assessing short-term and long-term dietary intake. The JMPR will continue to

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

evaluate processing data as described in the *FAO Manual.* No default factors will be applied and no new requirements will be imposed upon the data submitters.

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

17. The Committee noted the comments of JMPR on Canada's paper that no single approach is applicable in establishing maximum residue limits for genetically modified crops and for the residues of its metabolites and that a case-by-case approach should be used at present.

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

19. The Committee noted that JMPR agreed to consider the report of the OECD workshop on minimum data requirements when they were finalized. The JMPR was particularly interested in the OECD/FAO project in validating geographical zones where residue data can be extrapolated within the same zone. Several delegations expressed concerns on the parameters considered in the climate-based zoning. The Observer from EC expressed concern about the limited participation of JMPR in this activity and would like JMPR to be more responsible to the issues of minimum data requirements, extrapolation and zoning. The delegation of Chile explained that there are other factors to be considered aside from climates, e.g., GAPs. The Committee expressed its interest in the outcome of the project and recommended that JMPR should participate actively and make use of the results of the project.

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

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

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

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

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

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

26. Following the request of the 32nd Session of the CCPR on the recommendation of the 1999 JMPR that pesticide specifications be developed before a compound is evaluated by the JMPR, the Joint Secretaries informed the Committee that this process will be initiated in 2003. The schedule will be arranged in such a way that during the initial phase priority is given to compounds under the periodic review programme. The Committee was also informed that based on a recent Memorandum of Understanding FAO and WHO will develop pesticide specifications jointly leading to a Joint Meeting on Specification (JMPS) that should start in the year 2002. The new cooperation between the two organizations will enhance further the coordination and appropriate scheduling of compounds undergoing the JMPS and JMPR review process.

27. The Committee noted the initiative and the new developments.

DIETARY EXPOSURE IN RELATION TO MRL SETTING (Agenda Item 5)

PROGRESS REPORT BY WHO ON THE DEVELOPMENT OF DATABASES FOR ACUTE EXPOSURE ASSESSMENT (Agenda Item 5a)[4]

28. The Representative of WHO reported on the calculation of the International Estimated Short-Term Intakes (IESTI) prepared by the 2000 JMPR (Section 3.2 and Annex 4) and noted that the JMPR could not confirm that the IESTIs would be below the acute RfDs for chlormequat in pears; dinocap in grapes; and parathion in barley and apples. It was also noted that the 2000 JMPR included several corrections to the IESTI calculations performed by the 1999 JMPR (Annex IV).

29. In response to Circular Letter CL 2000/27-PR, Part 4 (A), information was provided by the United Kingdom and the United States on national approaches for estimating short-term intakes, which used deterministic and probabilistic approaches, respectively. The EU and Australia indicated that their approaches applied similar principles to those used by JMPR. South Africa reported that a total diet study was underway and that this data could be used as the basis for estimating short-term intake.

30. In regard to the request for additional data[5] to further develop the large portion databases 97.5 percentile food consumption (eaters only) data was received from Australia and New Zealand but were

[4] CL 2000/27-PR; CX/PR 01/3; 2000 JMPR Report, CRD 14 (comments from Global Crop Protection Federation).
[5] CL 2000/27-PR, Part 4 (B)

not expressed on a body weight basis. In addition, Sweden provided data on median weights and edible portion of a number of commodities.

31. Some delegations and the Observer from CI expressed the view that the existence of different procedures in member countries for acute exposure assessment would create problems and that approaches should be harmonized at the international level.

32. The Delegation of the Netherlands informed the Committee that guidance was under development at the national level on the criteria and procedures for the establishment of acute reference doses, and the Committee invited the Delegation to communicate these guidelines to JMPR for consideration by its next meeting in 2001.

33. Other member countries and international organizations were also invited to submit the result of their studies to JMPR to facilitate further consideration of this issue. This was especially important since current toxicological databases were not designed for establishing acute reference doses, as indicated in the JMPR Report (section 2.10).

34. The WHO JMPR Joint Secretary indicated that the role of JMPR was not to consider individual national acute RfDs but only develop criteria for their establishment at the international level; for that purpose, it was necessary to receive guidance from member countries on the methodology applied at the national level.

35. The Observer from the GCPF indicated that a project on variability of residues following single unit analysis had been conducted on the basis of supervised field trials and that the statistical analysis of the data was underway, and that it would be submitted to JMPR.

REVIEW OF THE PROCEDURE DEALING WITH CHRONIC DIETARY EXPOSURE CONCERN (Agenda Item 5b)[6]

36. The Committee recalled that the last session had considered how to proceed when the IEDI indicated that the ADI might be exceeded in one or more regional diets; that no consensus had been reached and the Committee had agreed that the Delegation of Australia would redraft its discussion paper for further consideration.

37. The Delegation of Australia highlighted the problems caused by the IEDI calculations as they might result in an overestimate of dietary intake, even when national dietary calculations demonstrated that the ADI would not be exceeded. The Delegation presented the recommendations put forward in the document to address this problem: continued development of dietary exposure calculations at the international level to provide realistic estimates; developing criteria for the use of national total diet studies; convening an expert consultation on this subject; encouraging countries to submit relevant data for dietary intake calculations; limiting the emphasis on international dietary intake while considering MRLs. It was also proposed to consider the establishment of MRLs even when the ADI was exceeded in one of the regional diets.

38. Several delegations supported the continued development of dietary exposure calculations at the international level, in order to provide a more realistic estimate of exposure and pointed out that member countries should provide additional data to improve the current process.

39. The Delegation of the United States supported the improvement of the chronic intake assessment since current practice resulted in overestimates, and indicated that MRLs might be finalized when the ADI was exceeded only in one regional diet. The Observer from GCPF expressed the view that the adoption of such MRLs would not result in a lower level of protection as IEDI calculations were too

[6] CX/PR 01/4, CRD 5 (comments of Consumers International), CRD 4 (comments of European Community).

conservative and created artificial problems as ADI calculations were very conservative and action taken would be addressing an artificial problem.

40. Several delegations and the Observer from Consumers International expressed their objection to a shift in emphasis from international to national dietary intake studies and to the adoption of MRLs when the ADI was exceeded in any regional diet. They stressed that it would not be consistent with Codex objectives since standards for the protection of consumers' health should be developed on a worldwide basis. Some delegations pointed out that this would create specific problems for developing countries because they relied on Codex recommendations when they could not carry out their own risk analysis.

41. Some delegations supported the proposal to convene an FAO/WHO expert consultation on dietary intake estimation to address this complex issue. Other delegations felt that it was difficult to give a clear mandate to such a consultation at this stage and that not enough relevant data appeared to be available for that purpose.

42. The Committee agreed that there was a need for improvement in international dietary estimates and that work should proceed in this area, and encouraged countries to generate relevant data in order to refine dietary intake calculations, as indicated in the JMPR report.

43. The Committee recognized that current procedures should be retained for the time being and reasserted its earlier decision that no MRL should be advanced to Step 8 when the ADI was exceeded in one or more of the regional diets.

RISK ANALYSIS PRINCIPLES AND METHODOLOGIES SO FAR APPLIED IN THE WORK OF THE COMMITTEE (Agenda Item 5c)[7]

44. The Chairman introduced the document prepared at the request of the last session of the Committee in order to consider the application of risk analysis principles and methodologies to MRL setting for pesticide residues.

45. The Chairman pointed out that considerable progress had been achieved concerning chronic intake, especially through the revision of the WHO *Guidelines for Predicting Dietary Intake of Pesticide Residues* (1997), and recalled the major issues considered by the Committee: clear distinction should be made between national and international approaches; MRLs could be finalized when the ADI was not exceeded in any of the regional diets; the current procedure had been maintained as there was no consensus on a review of dietary intakes calculations at the international level (see para 43). The Chairman also referred to recent developments as regards acute dietary intake, including the establishment of acute reference doses in JMPR and the consideration of acute toxicity as one of the criteria for MRL setting. However, this remained a difficult issue and would require further consideration, as appeared from earlier discussion (see Agenda Item 5a).

46. The Committee expressed its appreciation to the Chairman for this comprehensive document summarizing the integration of risk analysis in the work of the Committee. Several delegations, the Representative of WHO and the Observer from the EC supported the conclusions of the document and indicated that no further action was needed in the Committee.

47. The Delegation of Spain pointed out that further consideration should be given to variability factors, as it appeared from the JMPR Report (2000) that they were very high in some cases, especially for soil treatment, and this might lead to an overly conservative approach. The Representative of FAO/IAEA recalled that JMPR calculations were based on comprehensive residue data and that the variability factors used in IESTI accurately reflected the residues found in a wide range of products.

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7 CX/PR 01/5, CRD 5 (comments of Consumers International)

48. The Observer from Consumers International indicated that a comprehensive document on risk analysis was under preparation in the Committee on Residues of Veterinary Drugs in Foods, and proposed to follow a similar approach for pesticide residues. In particular, the Observer stressed the importance of addressing risk assessment policy, the relativenes between risk assessment and risk management, the use of other legitimate factors by both CCPR and JMPR and risk communication.

49. The Delegation of New Zealand supported this view and stressed the importance of defining risk assessment policy in the Committee, and addressing risk communication, especially as it was important to inform other Codex Committees of the approach taken by the CCPR in the establishment of EMRLs.

50. The Chairman noted that although the risk analysis procedures followed in MRL setting were not currently presented in a single document, they were reflected in several guidelines or related texts used by JMPR and CCPR, such as the FAO *Manual on Data Submission and Evaluation of Pesticide Residues Data for the Estimation of Maximum Residue Levels in Food and Feed*, the WHO *Guidelines for Predicting Dietary Intake of Pesticide Residues,* the agreed CCPR policy on EMRL setting, and the periodic review procedure.

51. The Committee noted that the Committee on General Principles was currently considering Proposed Draft Working Principles for Risk Analysis and that the 24th Session of the Commission would consider the reports from relevant Codex Committees on the integration of risk analysis in their decisions. The Committee agreed that there was no need to develop an additional document on risk analysis at this stage and noted that future action would depend on the recommendations of the Commission in this area.

REPORT ON THE REVISION OF REGIONAL DIETS AND INFORMATION ON PROCESSING (Agenda Item 5d)[8]

Regional Diets

52. The Committee at its last Session requested clarification on the possible impact of the revision of GEMS/Food Regional Diets on dietary exposure estimates undertaken by JMPR (ALINORM 01/24, para 38). The WHO Representative presented calculations of the TMDIs for a hypothetical pesticide using the existing 5 GEMS/Food Regional Diets and the 13 proposed GEMS/Food Consumption Cluster Diets. The results suggested that, on average, the proposed diets would slightly increase the exposure estimates, but that the range of values would increase. For the existing European-type diet, the 5 Consumption Cluster Diets that would replace it would result, in the worst case, in an increase of about 60% in the estimated exposure compared to the current diet.

53. The WHO Representative noted that the increase in exposure was expected because the current diets tend to average consumption of commodities among countries which have very different consumption patterns. For example, the consumption of maize in the existing African Region included countries which are both high and low consumers of maize. Consequently, the consumption of maize for that region is currently underestimated. Therefore, the Consumption Cluster Diets, when completed, would represent a more accurate description of the dietary patterns of Member countries. The full development of the diets to include about 250 commodities for which Codex MRLs exist or are proposed as well as certain processed commodities may take up to three years because consumption of many foods will need to be estimated. It was noted that the CCFAC and the JECFA are also using the existing 5 GEMS/Food Regional Diets in estimating exposure to contaminants and that JECFA welcomed the revision of the diets to more accurately estimate exposure.

54. The Committee also requested WHO to provide an estimate of the total consumption of food in order to assess potential differences among Cluster Diets. The estimated total food consumption ranged from 1156 g per person per day to 2337 g per person per day. The lower value was probably

[8] CX/PR 01/6

underestimated because food produced by subsistence farmers is not included in the FAO Food Balance Sheets.

55. In reply to some questions the Representative of WHO recalled that the definition of exposure assessment referred to exposure from all sources and confirmed that veterinary use was taken into account in the calculations of dietary intake. This appeared for example in the case of the IEDI calculations for thiabendazole included in Annex 3 of the 2000 JMPR report.

56. The Committee generally supported the development of the 13 revised regional diets and noted that further refinement of the diets would be required, including examples of calculation MRLs for fruits and vegetables, before recommending their use for the purposes of JMPR. The Committee agreed that it should be informed about significant further progress made in the framework of GEMS/Food on the finalization of the regional diets.

Information on Processing

57. The WHO Representative also reported that in response to CL2000/27-PR no additional information had been received from Governments on national food processing practices. It was noted that only Thailand had completed the processing questionnaire.

58. In reviewing the questionnaire (Section 2.2), the 2000 JMPR welcomed the use of the questionnaire to fill gaps in knowledge about typical methods of processing of raw agricultural commodities. In particular, information on significant differences in processing techniques from one region to another would be useful. The JMPR noted that information on important processed foods, such as various fruit juices, barley beer, maize meal and bran of rye and wheat was currently not available for use in dietary risk assessment.

59. The Committee was informed that GEMS/Food was reconsidering the questionnaire to focus on specific processed commodities of importance to exposure assessment. This would take into account information made available to Member countries based on actual national and regional requirements for data on the fate of pesticides during processing.

60. Some delegations expressed the view that the purpose of collecting processing information was not entirely clear, especially as it appeared that only a small portion of the ADI was used with current MRLs. Other delegations supported the development of such studies as it was important to demonstrate that the MRLs were safe on a worldwide basis.

61. The Committee recognized that no further progress could be made at this stage in CCPR as no additional data had been submitted on processing and noted that this would be considered further in the framework of GEMS/Food on the basis of the processing studies available at the regional and national level.

62. The Committee agreed to discontinue the collection of information through the questionnaire. However it recognized the importance of collection information by GEMS FOOD about processing studies currently required by national governments.

DRAFT AND PROPOSED DRAFT MAXUMUM RESIDUE LIMITS IN FOODS ANIMAL FEEDS (AGENDA ITEM 6)

FEASIBILITY OF ESTABLISHING MRLS FOR GENETICALLY MODIFIED CROPS AND METABOLITE RESIDUES (AGENDA ITEM 6A)[9]

63. The last session of the Committee had considered the feasibility of establishing MRLs for GM crops and metabolite residues and focused on matters related to residue definitions for control purposes. The Committee had agreed to seek information from governments on their approach to MRL setting for GM crops, to be compiled by the Delegation of Canada.

64. The Delegation of Canada indicated that the information received reflected the approach followed in Canada, Mexico and the United States since no other country had provided information. It appeared from the comments that the residue definition applied both to tolerant and other crops and that no separate MRLs were established for GM crops.

65. The Delegation of Germany indicated that a similar approach was followed at the national level; new metabolites occurring in GM crops were taken into account in the definition of residues on the basis of their toxicity and the level of residue, for example in the case of glufosinate for relevant commodities.

66. The Committee agreed that a case by case approach should be followed, taking into account national policies on enforcement for toxicity of metabolites, residue definitions and dietary intake estimations, and noted that this was also consistent with the conclusions of the 2000 JMPR (section 2.4) (see also para 13 above).

APPROPRIATENESS OF THE CURRENT ADI AND MRL SETTING IN RELATION TO INFANTS AND CHILDREN (Agenda Item 6 (b))[10]

67. The Delegation of the Netherlands introduced the document based on contributions received in response to the CL 2000/27-PR from the US, New Zealand, the European Community and Consumers International which focused on national policies related to the protection of infants and children. The Delegation indicated that the document provided a set of recommendations to acknowledge a possibility of additional vulnerability of infants and children; the necessity of clear confirmation of the applicability of ADIs and MRLs for all population groups including infants and children while clearly stating uncertainties; to make a primary screening of the lists of pesticides and pesticide/commodity combinations contained in contributions received, to clarify if they could be of concern to infants and children; to encourage the Committee to take an appropriate risk management decision in those cases where health concerns could not be addressed; and consider the need for an expert consultation to address the possible toxicological concerns of extra vulnerability and intake assessment of infants and children.

68. The Observer of Consumers International pointed out that there were four main matters to be addressed and proposed the following solutions as stated in CRD 5:

- In order to identify how pesticides that are really of concern, CI suggested three criteria: toxicity of pesticides to key developmental processes (if known), the presence of residues in foods that children eat in significant amounts and the frequency of exposure at toxicologically significant levels;

[9] CL 2000/27-PR (Part A), CX/PR 01/7

[10] CX/PR 01/8, CRD 11 (comments of US and Consumers International), Section 2.7 of the 1999 JMPR Report, CRD 4 (comments of the European Community), CRD 5 (comments of Consumers International),.

- CCPR was encouraged to take an appropriate risk management decision for cases where serious concerns for the health of infants and children might exist (as was the case for organophosphate insecticides as listed in CRD 5);

- An expert consultation should be convened to consider issues of toxicology and intake assessment in relation to infants and children, as there was no longer an international consensus that the current procedures were adequate, and

- The criteria used by JMPR to determine the adequacy of the database to assess risks to infants and children should be more transparent.

69. The Delegation of the United States clarified that Table 1 of CRD 11 was a list of pesticides that had been or were being evaluated and did not necessarily mean that they represented a greater risk for infants and children.

70. The Committee had an extensive debate on the recommendations contained in the document CX/PR 01/8. Many delegations agreed that the possible extra vulnerability of infants and children needed to be taken into account when performing risk assessment. However, it was pointed out that the situation should not be exaggerated.

71. The Observer of GCPF indicated that it did not believe that infants and children were generally more susceptible to chemicals, although this could occur occasionally at pharmaco-toxicologically active levels, this should not be the case with usual exposure from pesticide residues. The Observer did not support the concept of using default limits for residues or the use of additional uncertainty factors to ensure a reasonable protection of infants and children, and proposed that until new data become available JMPR continue working according to their current procedures in establishing ADIs and estimating MRLs.

72. Many delegations were of the view that the current process adequately addressed the sensitivity of infants and children and that ADIs and MRLs covered all population groups including infants and children and therefore there was no need to develop a new methodology.

73. The WHO Joint Secretary of JMPR indicated that the 1999 JMPR addressed the issue of susceptibility of infants and children and that the Meeting emphasized that possible differences between adult and developing mammals was currently addressed in the commonly performed studies of reproductive and developmental toxicity in various species. Therefore the Meeting concluded that it had no basis for changing its approach to addressing the susceptibility of developing mammals as compared with that of adult organisms in the toxicological evaluation of pesticides and that the routine use of safety factors in addition to those currently used was not justified on the basis of current information.

74. While it was acknowledged by some delegations that developmental neurotoxicity studies were valuable in assessing risks for infants and children, it was not clear whether the availability of those studies would lead to an adjustment of the ADI or MRLs. Some delegations indicated that additional scientific data in this area were needed, especially on the methodology of cumulative and aggregate risk assessment.

75. Some delegations were of the view that constructing a list of compounds that might give rise to concerns for infants and children would be costly and require extensive evaluation before any conclusive decision could be taken. The Committee agreed not to develop such a list at this time due to the lack of enough support from governments.

76. The Representative of WHO drew the attention of the Committee to the fact that there was not enough actual consumption data for some foods commonly consumed by children (e.g. apple or banana). It was not clear how much they were consuming expressed on a body weight basis which presented problems in conducting chronic risk assessment, at the international level. The Representative

indicated that WHO was planning to organize a Workshop on Total Diet Studies in Australia and that might assist countries, especially developing countries, to generate relevant data.

77. The Committee concluded that ADIs and MRLs should cover all population groups including infants and children. The Committee also concluded that the possible increased vulnerability of infants and children was an important issue which needed to be explicitly integrated into the work of the CCPR and JMPR and agreed by means of a Circular Letter to request Member governments to provide information to the JMPR Secretariat on the availability of studies on developmental neurotoxicity that have been submitted to them, along with contact details on the data owners. This information should be submitted by 1 November 2001, which should provide sufficient time for the Secretariat to obtain the data for consideration by the 2002 JMPR.

78. The Committee agreed that the development of cumulative risk assessment required further consideration, especially regarding the development of common understanding of methodology. Therefore, it requested the Delegation of the United States to prepare a paper on this matter for consideration by the next session of the committee. The Committee decided that it was premature to recommend convening an expert consultation on the various issues in relation to infants and children.

CONSIDERATION OF DRAFT AND PROPOSED DRAFT MAXIMUM RESIDUE LIMITS IN FOODS AND FEEDS AT STEPS 7 AND 4 (Agenda Item 6c)[11]

General comments

79. The Delegation of the United States indicated its preference for retaining proposed MRLs for OPs and carbamates at Step 6 until the results of a cumulative risk assessment are available.

80. The Observer from the EC considered it necessary that JMPR residue evaluations should be available at the latest in December the year after the JMPR evaluations. The Joint FAO Secretary of the JMPR indicated that 1999 JMPR evaluation was late; and noted, however, that usually the evaluations are available in time.

81. The Observer from the EC requested the clarification on the criteria used in proposing MRLs for bagged bananas (e.g. chlorothalonil (081)) or unbagged bananas (e.g. fenpropimorph (188)) and expressed the view that GAP in general should not be pooled. A member of the FAO panel of JMPR informed the Committee that JMPR can only propose an MRL on the basis of particular GAP that was supported by sufficient residue data. In most cases the MRL would be based on unbagged bananas since that was considered to be the most critical GAP. However, when data on unbagged bananas was lacking or insufficient and data only available on bagged bananas, then JMPR would only propose an MRL for bagged bananas.

82. The Observer of CI indicated that they could not support advancement of MRLs for organophosphorous compounds and other pesticides known to act on the nervous system whose database does not include a developmental neurotoxicity study, since there was not an adequate database for assessing their risks to infants and children, and since the CCPR procedures did not adequately account for the risks from multiple exposure to pesticide residues having a common mechanism of action.

83. The Observer of CI also indicated that it could not support the advancement of MRLs whose best estimate of chronic dietary intake exceeds the ADI or whose best estimate of short-term intake exceeds the Acute RfD for any population.

[11] CL 2000/49-PR; CX/PR 01/9; CX/PR 01/9-Add.1

84. The Committee noted that the designation V (allocated for MRLs that accommodate veterinary uses) should be replaced by a footnote according to the decision expressed in paragraph 48 of the 32nd session of the CCPR.

CHLORFENVINPHOS (014)

85. Since no new data had become available, the Committee **recommended** revocation of all existing CXLs.

CHLORMEQUAT (015)

86. Since several MRLs were re-evaluated by the JMPR 2000, the Committee would consider all proposed MRLs at its next session.

CHLORPYRIFOS (017)

87. The Committee would consider the proposed MRLs and the revocation of the existing CXLs as proposed by the 2000 JMPR at its next session.

DIAZINON (022)

88. The Observer of the EC expressed its reservation concerning the proposed MRLs for liver and kidney of cattle, goats, pigs and sheep since the compound is a fat-soluble compound. The EC recommended that the 2001 JMPR reconsider their methodology for setting an MRL for edible offal and fat soluble compounds.

89. The Committee **decided** to return the MRLs for goat meat, for kidney of cattle, goats, pigs and sheep, for liver of cattle, goats, pigs and sheep and for meat of cattle, goats, pigs and sheep to Step 6. New Zealand expressed concern that this decision was not based on JMPR and CCPR normal procedures and would again delay the progress of these MRLs.

90. Awaiting the evaluation of the acute RfD by the 2001 JMPR, the Committee **advanced** the proposed draft MRLs for cabbages, head and pome fruits to Step 5.

ETHOXYQUIN (035)

91. The Committee was informed that the required toxicology data would be available by 2004.

92. The delegations of Spain and France informed the Committee that they have uses on apples and pears as post harvest treatment.

93. The Committee **decided** to retain the existing CXL for pears for 4 years under the Periodic Review Procedure.

FENITROTHION (037)

94. The Committee noted that the 2000 JMPR had identified intake concerns.

95. The Committee was informed by the Observer from GCPF that information on which CXLS will be supported would be made available this year. The Committee **agreed** to consider deletion of commodities no longer supported at its next Session.

FENTHION (039)

96. The Committee **decided** to consider revocation of the CXLs for meat and milks at the next session, as the new data were insufficient.

FOLPET (041)

97. The Observer from EC requested for acute RfD. The Observer from GCPF indicated that an acute RfD for folpet was not necessary in view of the similar decision by the 2000 JMPR for captan. The Committee **requested** the manufacturer to provide detailed information on this item before the 1st of May.

98. The Delegation of France expressed reservations for MRLs of apple (GAP), grapes (metabolites in wine), and lettuce, head (insufficient database). The Delegation of Chile expressed reservations on MRL for grape (too high).

99. The Committee **decided** to advance the proposed draft MRLs to Step 5 and to retain the draft MRL for strawberry at Step 6.

LINDANE (048)

100. The Observer from the EC informed the Committee that they were withdrawing all authorizations for lindane. The Committee was informed that some existing CXLs were supported by the manufacturer. The Committee **decided** to recommend the revocation of all unsupported CXLs, except for carrot, eggs, poultry meat, rape seed, sugar beet and sugar beet leaves or tops.

MALATHION (049)

101. The Committee **decided** to recommend withdrawal of the CXLs as recommended by the 1999 JMPR, except for the commodities supported by the manufacturer (apple; broccoli; cabbages, head; grapes; peach; raspberries, red, black; root and tuber vegetables; strawberries; cereal grains; citrus fruits. The Observer of the EC expressed a general reservation (no acute RfD). The Committee **decided** to advance the draft MRLs to Step 5. The Committee also **decided** to retain the CXLs for supported compounds for 4 years under periodic review procedure.

MEVINPHOS (053)

102. The Committee requested JMPR to conduct intake calculation for cabbages, head, common bean, (pods and/or immature seeds) and leek. The Committee **decided** to consider revocation of the remaining CXLs as recommended by the 1997 and 2000 JMPR at the next session.

2-PHENYLPHENOL (056)

103. The Committee invited the Delegation of the Netherlands to send their specific and general comments on the necessity of establishing an acute RfD to the JMPR. The Delegation of Germany expressed a reservation on the extrapolation to all citrus fruits. The Committee had an exchange of view on the use of this pesticide and citrus producing countries indicated that is was used as a post harvest treatment on fruit intended for direct consumption; however in some cases, such fruit might be ultimately used for processing. The Committee noted that new residue data would be supplied by US growers organization in 2001.

104. The Committee noted the views of some delegations that for orange juice, as a processed commodity, normally no MRL should be established.

105. The Committee **decided** to add Po to citrus fruits and PoP to citrus pulp (dry) and orange juice. The Committee **decided** to advance all proposed draft MRLs to Step 5 and to retain the CXL for pear.

PARATHION (058)

106. The Committee **decided** to consider revocation of most CXLs at the next session as recommended by the 2000 JMPR, unless data are submitted.

107. The Observer from the EC informed the Committee that all uses had been withdrawn. The Committee **agreed** to consider an amended MRL for apple and a new MRL for barley, where JMPR 2000 had identified intake concerns, at it next session.

PARATHION-METHYL (059)

108. The Committee **decided** to consider revocation of most CXLs and MRLs, as recommended by the 2000 JMPR, at the next session. CXLs for beans, dry; cabbages, head; peas (dry); potato, and sugar beet will be maintained and MRLs for beans forage (green); hay or fodder (dry) of grasses; sugar beet leaves or tops; wheat; wheat bran unprocessed; and wheat straw and fodder, dry would be discussed at the next session.

PHOSALONE (060)

109. The Committee **decided** to advance the proposed draft MRLs for pome fruits to Step 5 and stone fruits to Step 5. The 2001 JMPR will establish an acute RfD. Almonds, hazelnuts and walnuts were advanced to Step 5/8 with the omission of Steps 6 and 7 for adoption by the 24th Session of the Commission.

110. The Observer from the EC expressed its reservation about advancement of MRLs for pome fruits and stone fruits (lack of acute RfD).

PYRETHRINS (063)

111. The Committee **decided** to consider revocation of all CXLs except dried fruits at its next session.

THIABENDAZOLE (065)

112. The Delegation of Spain informed the Committee that thiabendazole was also used in tropical fruits and will request the manufacturer to provide data. The Delegation of France drew the attention of the Committee to residue definition problems for animal products.

113. The Committee **decided to** advance the proposed draft MRL for eggs to Step 5/8 with the omission of Steps 6 and 7 for adoption by the 24th Session of the Commission.

114. The Committee **decided** to maintain the MRL for mushrooms at Step 3 as GAP was modified by the USA. The USA indicated that it would submit its new GAP to JMPR.

CYHEXATIN (067)

115. The Committee **recommended** revocation all CXLs, except CXLs for apple, citrus fruits, grapes, meat (from mammals other than marine mammals), milk products, milks, and pear. The Committee recommended withdrawal of the CXLs for common bean, cucumber, egg plant, gherkin, melons, except watermelon, peppers (sweet), strawberry and tomato.

116. All CXLs and MRLs being retained will be subject to full review in 2003 or 2004.

BENOMYL (069) / CARBENDAZIM (072) / THIOPHANATE-METHYL (077)

117. The Observer from the EC expressed concern about the residue definition for enforcement purposes. The Committee **agreed** to change the definition to 1998 JMPR wording. The Committee decided to consider the issue of the residue definition next session.

118. The Committee was informed that US GAP and GAP in the European Community for the use of benomyl in peaches, nectarines and apricots are identical. Extrapolation from peach to apricots and nectarines was supported by several delegations. The Committee therefore **decided** to change the MRL from 0.1 to 2 mg/kg for apricot and to advance the MRLs for apricot, nectarine, peach, plums (including prunes), pome fruits and tomato to Step 8.

119. The Committee agreed to return the proposed draft MRLs for berries and other small fruits, cereal grains, lettuce, head and peppers to Step 6.

DISULFOTON (074)

120. The Observer from CI, referring to the written comments of the USA and the EC, supported the view that MRLs should not be advanced until it is clearly demonstrated that they do not pose chronic or acute intake risks. The manufacturer informed the Committee that due to intake concerns MRLs for rice, sorghum and sorghum forage (green) will not be supported and that the Committee will be informed which uses will be supported before next year meeting.

121. The EC informed the Committee of a possible future revocation of all MRLs in the EC.

122. The Committee **agreed** to recommend revocation of the CXL for rice, and withdrawal of the proposed draft MRLs for sorghum and sorghum forage (green).

123. The Committee **decided** to return all remaining draft MRLs to Step 6 and would consider them at the next session. The Committee **requested** WHO to undertake intake calculations, especially acute intake for next years meeting.

PROPOXUR (075)

124. The Committee would consider the revocation of all CXLs, as the compound was no longer supported at its next session.

THIOPHANATE-METHYL (077)

125. The representative of the manufacturer informed the Committee that new residue data would become available for review by the 2002 JMPR including apricots, beans (dry), beans snap, beans forage & hay, celery, cherries, melons, peanuts, peanuts forage & hay, peppers, potatoes (seed treatment), sheep meat, soya beans, squash, and sugar beet roots & tops.

VAMIDOTHION (078)

126. Since no data had become available, the Committee **recommended** revocation of the existing CXLs.

CHLOROTHALONIL (081)

127. The Delegation of the USA expressed the view that a higher limit of determination was necessary for banana. As the proposal was based on residue data on bagged bananas the Committee invited the banana producing countries to submit data on unbagged bananas. The Committee **decided** to advance the draft MRL for banana to Step 8.

DICHLOFLUANID (082)

128. The representative of the manufacturer informed the Committee that the dossier of tolylfluanid would become available earlier for evaluation by the 2002 JMPR. The Committee requested the manufacturer to submit an overview on the registered uses of dichlofluanid. Based on this information the CCPR at its next Session would consider the revocation of CXLs for the commodities for which

there are no registered uses. The Delegation of France pointed out that dichlofluanid had not been evaluated toxicologically since 1985 and that GAP were obsolete, and proposed to revoke the CXL as soon as possible for consistency with the earlier decision on vamidothion.

129. The Committee **decided** to maintain the existing CXLs, nothing that the use of this compound will be replaced by tolylfluanid.

FENAMIPHOS (085)

130. The Committee noted acute intake concerns due to the low acute RfD.and that JMPR 2000 had revised the IESTI calculations. For several commodities, the acute RfD was exceeded even for commodities with residue levels at the LoD.

131. The representative of the Manufacturer informed the Committee that a new acute study in dogs would become available for evaluation of the Acute RfD by the end of this year.

132. The Committee **decided** to advance the proposed draft MRLs to Step 5 and **decided** not to advance the draft proposals beyond Step 7 until intake concerns were resolved.

133. The Committee **recommended** revocation of the CXLs for broccoli, cauliflower, coffee beans, coffee beans, roasted, kiwifruit, oranges, sweet & sour, potato, soya beans (dry), sugar beet and sweet potato as recommended by the 1999 JMPR.

134. The Committee **decided** to postpone further discussion on the draft MRLs and existing CXLs until its next Session and invited the Delegations to express their views on possible solutions.

DINOCAP (087)

135. The JMPR 2000 has reconsidered the acute RfD and established an RfD for the general population (excluding the subpopulation of women of child bearing age) and a separate acute RfD for women of child bearing age. New intake calculations were performed which showed that the IESTI is exceeded for grapes for children and for woman of childbearing age.

136. The representative of the manufacturer disagreed with the intake calculations based on the MRL/STMR for grapes because these were based on data on wine grapes grown in Northern Europe, which result in high residue levels. The residue levels of table grapes should have been used which are grown in Southern Europe, which result in lower residue levels. The Committee, noting that the proposed draft MRL for grapes was based on European GAP, **agreed** to consider this compound at its next session.

CHLORPYRIFOS-METHYL (090)

137. The Delegation of Australia introduced Addendum 2 to document CXPR01/9. Results of an estimated national daily intake (NEDI) showed that the Australian use according to GAP did not pose an intake concern. International dietary intake estimate for the 5 regional diets of the GEMS Food also showed that the intake of chlorpyrifos-methyl was below the ADI for all diets. Several delegations expressed concern, since an acute RfD was not established. The Delegation of the Republic of Korea expressed intake concerns (rice), Morocco expressed intake and trade concerns (cereal grains). The Committee **decided** to return all draft MRLs to Step 6, pending a full review by the JMPR.

CARBOFURAN (096)

138. The Committee noted the written comments of the EC (general reservation as no acute RfD had been established) and of Spain which supported extrapolation from mandarin and oranges, sweet and sour to citrus fruits. The Committee **decided** to advance the draft MRL for mandarin to Step 5.

139. The Committee **decided** to return the proposed draft MRLs to Step 6 pending the 2000 review of the JMPR.

METHAMIDOPHOS (100)

140. The Committee noted written comments of the EC requesting the setting of an acute RfD and estimation of the acute risk for all relevant consumer groups, before MRLs could be advanced beyond Step 6 and that the EC could not accept an MRLs for peach, pome fruits and tomato. The Committee also noted written comments of the USA requesting that the MRLs be held at Step 6 pending review by JMPR 2002 with special care for acute dietary intake. The Committee was informed that the CXLs or draft MRLs for pome fruits, peach, tomato, peppers (chili and sweet), cucumber, cauliflower, cabbages, head; potato, sugar beet, sugar beet leaves or tops, soya bean (dry), cotton seed are supported by the manufacturer and that there was no longer support for the CXLs or draft MRLs for celery, tree tomato, watermelon, lettuce, head; brussels sprouts, rape seed, and hops (dry).

141. The Committee **decided** to return the draft MRLs for peach, pome fruit and tomato to Step 6, pending review by the JMPR. The Committee also **decided** to retain the CXLs for cabbages, head, cauliflower, cotton seed, cucumber, peppers (chili and sweet), potato, soya bean (dry), sugar beet, sugar beet leaves and tops. Cattle fat and meat, sheep fat and meat, goat fat and meat, milks, alfalfa forage (green), lettuce, head; and tree tomato are being retained for two reasons, animal feed use and/or links to acephate uses.

PHOSMET (103)

142. The Committee **decided** to return the draft MRL for apricot to Step 6 pending review by JMPR. The Committee invited the US to submit written comments concerning combining apricot and nectarine residue data to support the CXL for nectarine and demonstrate that an MRL of 5 mg/kg is sufficient, taking into account written comments of the EC and Germany (acute dietary intake concern).

ETEPHON (106)

143. The Observer of the EC expressed reservations on MRLs grapes (lack of processing studies), peppers, pineapples and tomato (inadequate data base). The Delegations of France and Germany expressed their reservation on the MRL grapes (lack of processing studies).

144. The Committee **decided** to advance the draft MRL for dried grapes to Step 8 with omitting Step 6 and 7.

PROPARGITE (113)

145. The Committee invited the delegation of the Netherlands to submit their written comments concerning the acute RfD to the JMPR.

TRIFORINE (116)

146. The Committee **decided** to revoke the CXL for tree tomato, as it was not supported by the manufacturer.

ALDICARB (117)

147. The Committee **decided** to return the draft MRL for potato to Step 6 pending the review by the 2001 JMPR.

PERMETHRIN (120)

148. The Committee invited the Delegation of the Netherlands to submit their written comments concerning the acute RfD to the JMPR. The Observer of GCPF informed the Committee that thirty to forty commodities would be supported. The Observer of the EC informed the Committee that all registered uses would be withdrawn.

149. The Committee **decided** to retain all CXLs pending review at its next session.

AMITRAZ (122)

150. The Observer of the EC informed the Committee that acute RfD in EU did not significantly deviate from JMPR evaluations.

MECARBAM (124)

151. The Committee **decided** to consider revocation of the CXLs at the next session

AZOCYCLOTIN (129)

152. The Committee **decided** to retain the draft MRLs for apple; nectarine; peach; pear and plums (including prunes) and maintained the CXLs for citrus fruits; grapes; meat (from mammals other than marine mammals); milk products and milks. The Committee also **decided** to recommend revocation of the CXLs for common bean (pods and/or immature seeds); cucumber; egg plant; gherkin; melons, except watermelon; peppers, sweet; strawberry and the draft MRL for tomato.

METHIOCARB (132)

153. The Delegation of Germany expressed a reservation (data base concerns). The Observer from GCPF informed the Committee that studies on storage stability will be made available at the end of 2002 and data will be provided to support artichoke globe; rape seed; sugar beet and sweet corn (corn-on-the-cob).

154. The Committee **advanced** the draft MRL for strawberry and **decided** to recommend revocation of all CXLs.

BITERNATOL (144)

155. The Committee **decided** to maintain the CXL for apricot for 1 year in order to consider the extrapolation from peaches to apricots and the CXLs for banana; cucumber; nectarine; peach; plums (including prunes); pome fruits and to recommend withdrawal of CXLs of bean forage (green); common bean (pods and/or immature seeds); peanut and peanut forage (green). The Committee **advanced** the proposed draft MRLs to Step 5/8 with the deletion of the present CXLs except for tomato which was advanced to Step 5.

156. The Delegations of France and Germany expressed a reservation on the MRL for tomato (processing studies).

CARBOSULFAN (145)

157. The Committee noted the written comments from the EC expressing a reservation (lack of acute RfD).

158. The Committee **requested** the Delegation of Spain to provide GAP information on citrus fruits to the JMPR and **advanced** the proposed draft MRL for mandarin to Step 5. The Committee **returned** the draft MRLs for citrus pulp, dry and oranges, sweet, sour to Step 6.

DIMETHIPIN (151)

159. The Committee **requested** the Delegation of The Netherlands to refer its written comments relating to the estimation of the ADI to the JMPR.

FLUCYTHRINATE (152)

160. The Committee **decided** to recommend revocation of all CXLs.

PYRAZOPHOS (153)

161. The Committee **decided** to recommend revocation of all CXLs.

CYFLUTHRIN (157)

162. The Committee noted that the ADI established by JECFA was not agreed by the Observer from the EC at CCRVDF and that the Committee wold consider this compound again at its next session.

PACLOBUTRAZOL (161)

163. The Committee noted that support had not been confirmed.

ANILAZINE (163)

164. The Committee noted that this compound would not be supported and would consider revocation of all CXLs at the next session.

FLUSILAZOLE (165)

165. The Committee noted the request for supportive data and decided to consider this compound again at its next session.

OXYDEMETON-METHYL (166)

166. The Committee noted the written comment from the EC expressing a general reservation (lack of an acute RfD) and specific reservations on MRLs for grapes, lemon and oranges, sweet, sour (acute risk) and **decided** to return the draft MRLs to Step 6.

TERBUFOS (167)

167. The Committee **decided** to consider withdrawal of CXLs for barley; and straw and fodder (dry) of cereal grains as these uses were no longer supported at its next session.

HEXACONAZOLE (170)

168. The Committee noted the request for supportive data and decided to consider this compound again at its next session.

PROFENOFOS (171)

169. The Committee noted the absence of supportive data for brussels sprouts; cabbages, head; cauliflower; common bean (pods and/or immature seeds); oranges, sweet, sour; soya bean (dry); soya bean oil, refined; sugar beet and **decided** to consider the withdrawal of these CXLs at its next session.

BENTAZONE (172)

170. The Committee **requested** the Delegation of The Netherlands to refer its written comments on Acute RfD to the JMPR.

BUPROFEZIN (173)

171. The Committee noted written comments of Germany (insufficient processing data) and **decided** to advance the CXLs for oranges, sweet, sour to Step 8.

GLUFOSINATE-AMMONIUM (175)

172. The Committee **advanced** all draft MRLs to Step 5.

ABAMECTIN (177)

173. The Committee noted comments of the Delegation of Germany regarding the new residue definition for all crops and **advanced** all draft MRLs for commodities of animal origin to Step 8.

CLETHODIM (187)

174. The Committee was informed that the corrected version of the intake calculation would be published in the report of JMPR 2001.

175. The Committee was informed that the corrected version of the intake calculation would be published in 2001 report and that results did not exceed ADI. The Committee noted the absence of a suitable method of analysis and **advanced** all proposed draft MRLs to Step 5 and **returned** all draft MRLs Step 6. The Committee also **decided** to reconsider this compound at its next session with respect to the methodology of residue analysis with the understanding that without the method of analysis MRLs would not be advanced further.

FENPROPIMORPH (188)

176. The Committee noted the written comments from the EC expressing a reservation on the MRL for banana (lack of an acute RfD) and **advanced** the draft MRL for banana to Step 5 and all other proposed draft MRLs to Step 5/8 or Step 8.

FENPYROXIMATE (193)

177. The Delegation of France expressed a reservation on the MRL for grapes because of the possible transfer into wine. The Delegation of the Netherlands expressed its reservation on the MRL for apple as no acute RfD had been established.

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

HALOXYFOP (194)

179. The Committee noted the JMPR's review of this compound in 2001 and would consider this compound at its next session.

TEBUFENOZIDE (196)

180. The Committee noted that the 2001 JMPR would consider establishment of an acute reference dose and **returned** the draft MRL for grapes to Step 6.

AMINOMETHYLPHOSPHONIC ACID (AMPA) (198)

181. The Committee **decided** to delete the MRLs because they were no longer relevant.

KRESOXIM-METHYL (199)

182. The Committee **requested** the Observer from the EC to refer its written comments on animal products residue definition to JMPR.

PYRIPROXIFEN (200)

183. The Committee **decided** to change the draft MRL for citrus fruits from 1 to 0.5 on the basis of the USA database for grapefruits and extrapolation from present data for oranges and decided to advance the MRL to Step 8. The Committee also **decided** to delete cotton gin trash.

184. The Committee **advanced** all other proposed draft MRLs to Step 5.

185. The Delegation of Germany expressed its reservation for cotton seed oil, crude and cotton seed oil, edible (because of insufficient data on processing studies). The Delegation of France supported this view and indicated that no recovery factors should be applied to trial results.

DDT (021)

186. The Committee recalled that the 31st Session had considered the establishment of an EMRL for DDT on the basis of the 1999 JMPR evaluation. The Committee noted that JMPR had reevaluated DDT and established a new PTDI of 0.01 kg/kg bw.

187. The Committee had an exchange of views on the appropriate level for the MRL for meat (from mammals other than marine mammals). There were two different approaches within the Committee.

188. The delegation from New Zealand was in favor of an EMRL of 5 mg/kg. The Delegation advised that it had a pasture based economy, where under specific conditions, like droughts or floods, in certain years a level of 5 mg/kg is needed to accommodate the higher concentrations in an small percentage of animals resulting from such conditions. The Delegation stressed that this level did not represent any adverse effect on health as was confirmed by 2000 JMPR evaluation and was consistent with CCPR's policy on MRL setting and that lower level would create barriers to trade. The Delegation of Australia strongly supported the New Zealand's position stressing that an EMRL 5 mg/kg was justified by data evaluated and consistent with Codex procedure.

189. The Delegation of Sweden, speaking on behalf of the member states of the European Union, supported by Norway, Slovak and Switzerland, was in favour of an EMRL of 1 mg/kg. These delegations pointed out that their national monitoring data showed very low levels, which do not exceed 1 mg/kg and therefore there was no need for a higher EMRL, as 1 mg/kg corresponded to a violation rate of 0.5% based on Australia, Germany, Norway, Thailand,the United Kingdom and the USA data. The Delegation of Canada supported this view and informed the Committee that its position was based on a full national dietary risk assessment, including fish and that higher levels could result in a hazard to its consumers.

190. The Delegation of Sweden, speaking on behalf of the member states of the European Union, indicated that new monitoring data was available. The Delegation requested that more recent data than those used in the 1996 JMPR evaluation should be collected and evaluated in order to set an appropriate EMRL for DDT, however in order to find a solution at this stage the Delegation was willing to accept a level of 2 mg/kg. The Delegation of New Zealand stated that most up to date data was submitted at the time of request of 1996 JMPR evaluation.

191. The WHO Representative drew the attention of the Committee to the discussion on mycotoxins in the CCFAC and indicated that mycotoxins, and DDT both had a log normal distributions. JECFA had given the opinion that lowering of maximum levels on the tail of such distributions would only

result in a very marginal risk reduction on exposure. The Representative indicated that it was primarily a risk communication issue rather then a health problem.

192. The Observer of the AOAC, supported by some delegations proposed to split the residue definition into two parts in order to distinguish between misuses and environmental contamination. The Committee concluded that it would not be appropriate to undertake such a change during the meeting, as it required further consideration.

193. Some countries emphasized the negative implications higher levels of DDT could have for breastfeeding, and the desire to reduce contamination to the lowest level achievable. The Delegation of Australia was of the view that it was primarily risk communication issue which should be addressed at the national level.

194. The Chairman recalled that the monitoring data provided to JMPR originated partly from New Zealand and partly from other countries, and the data from New Zealand showed higher concentrations of residues. The Chairman also noted that the 2000 JMPR confirmed that from the intake calculation a level of 5 mg/kg was unlikely to present a hazard to the consumers and proposed a compromise level of 3 mg/kg, corresponding with a violation rate of 0.5% based on New Zealand data. The Committee also noted the comments from the USA recommending that a level of 3-5 mg/kg would be appropriate and should serve both to facilitate trade and to protect public health. This proposal was supported by Australia, the USA and South Africa although for Australia 5 mg/kg was preferred option. However the Committee could not come to a compromise.

195. The Committee decided to propose to the Commission an EMRL level of 5mg/kg and a level of 3mg/kg in square brackets and to ask the Commission to take a decision regarding the level, taking into account that the Committee would not be able to reach consensus by deferring consideration of this matter to a later session. The Committee also decided not to request a new evaluation of the monitoring data by the next meeting of JMPR.

196. The Delegation of Sweden, speaking on behalf of the member states of the European Union, expressed its strong reservation on this decision for the reasons indicated above. The delegations of Canada, Norway, the Slovak Republic and Switzerland opposed the decision, since they also supported a level of 1mg/kg.

HARMONIZATION OF MRL SETTING FOR COMPOUNDS USED BOTH AS PESTICIDES AND AS VETERINARY DRUGS: PROPOSED DRAFT AMENDMENTS TO THE CODEX CLASSIFICATION OF FOODS AND ANIMAL FEEDS (Agenda Item 7)[12]

197. The Committee recalled that at its last Session it had elaborated amendments to some animal products definitions commonly used by CCPR and CCRVDF and agreed to propose the use of the accelerated procedure for this work which was subsequently approved by the 47th Session of the Executive Committee.

198. The Delegation of Japan, supported by other delegations pointed out the importance of harmonization of animal product definitions in order to ensure consistency in Codex work and supported the proposed changes.

Status of the Proposed Draft Amendments to the Codex Classification of Foods and Animal Feeds

199. The Committee concurred with the proposed amendments for definitions on meat, mammalian fats, poultry fats and milks and agreed to forward them to the 24th Session of the Commission for final adoption at Step 5 of the Accelerated Procedure (see Appendix IV of this report).

[12] ALINORM 01/24, Appendix V, CX/PR 01/10.

MATTERS RELATED TO METHODS OF ANALYSIS (Agenda Item 8)

200. The Committee recalled that its last session had considered several issues concerning the selection of methods of analysis and agreed on further work relating to single-laboratory validation for pesticide residues, and to update current methods of analysis. It had also been agreed that a Working Group would consider these questions during the session in order to facilitate discussion.

201. Dr Van Zoonen (Netherlands), Chair of the Working Group, presented the discussions and recommendations of the WG presented in CRD 16. The WG had prepared a proposed revised draft of the Guidelines on Good Laboratory Practice in Pesticide Residue Analysis, including criteria for the assessment of the suitability of methods (Annex II of CRD 16), and a proposed revised draft of the Introduction section (Annex III of CRD 16), and had also considered how to revise the Recommended Methods of Analysis document.

202. The Committee noted the work underway in the CCRVDF on the definition of criteria for the establishment of methods of analysis and recognized the importance of harmonization throughout Codex. It was also noted that the CCMAS had reached a clear conclusion on the approach to the use of recovery factors and was currently developing recommendations on how to address the question of measurement uncertainty.

203. The Committee expressed its appreciation to Dr Van Zoonen and the WG for their considerable work on complex issues, agreed that it should convene again at the next session. The Committee concurred with the recommendations of the WG presented in CRD 16.

PROPOSED DRAFT AMENDMENTS TO THE GUIDELINES ON GOOD LABORATORY PRACTICE (Agenda Item 8a)[13]

204. The Committee recalled that the revision to the Guidelines had been approved as new work by the 47th Session of the CCEXEC and agreed that the Proposed Draft Revised Guidelines (Annex II to CRD 16) should be appended to the report and circulated for comments at Step 3 (see Appendix VII).

205. The Committee agreed that reference to measurement uncertainty should be deferred until its resolution in the CCMAS.

PROPOSED DRAFT AMENDMENTS TO THE INTRODUCTION SECTION OF THE RECOMMENDED METHODS OF ANALYSIS FOR PESTICIDE RESIDUES (Agenda Item 8b)[14]

206. The Committee recalled that the amendment to the Introduction section had been approved as new work by the 47th Session of the CCEXEC, in order to reflect the general acceptance of single laboratory method validation.

207. The Committee agreed that the Proposed Draft Amendment to the Introduction of the Recommended Methods of Analysis for Pesticide Residues should be appended to the report and circulated for comments at Step 3 (See Appendix VIII).

REVISION OF THE LIST OF METHODS OF ANALYSIS FOR PESTICIDE RESIDUES (Agenda Item 8c)[15]

208. The Committee agreed that an updated list of Recommended Methods of Analysis would be prepared on the basis of the criteria included in the revised text of the *Guidelines* and the *Introduction*,

[13] CX/PR 01/11, CRD 9 (Discussion paper) CRD 16 (Report of the Working Group on Methods of Analysis)
[14] CX/PR 01/12
[15] CX/PR 01/13

taking into account the information provided in reply to CL 1998/20-PR. The revised list of methods would be circulated for comments and consideration by the next session of the Committee.

PARAMETERS AND CRITERIA FOR THE ASSESSMENT OF THE SUITABILITY OF ANALYTICAL METHODS FOR CCPR PURPOSES (Agenda Item 8d)[16]

209. The Committee agreed to include the parameters and criteria in Table 3 of the Proposed Draft Revised Guidelines and in the Proposed Draft Revised Introduction of the Recommended Methods of Analysis.

ESTABLISHMENT OF CODEX PRIORITY LIST OF PESTICIDES (Agenda Item 9)[17]

210. The Chairman of the *ad hoc* Working Group on Priorities, Dr T. Doust (Australia), presented the report of the Group. The recommendations in the report were considered first.

211. The Committee **agreed** to that the following procedures should apply when establishing priorities:

- pesticides identified by JMPR for acute toxicity evaluation are to be added to the priority list as candidate compounds for assessment of acute toxicity;
- countries may nominate pesticides for assessment of acute toxicity; and
- acute toxicity is to be assessed for all new chemicals and those undergoing periodic re-evaluation.

212. Recognizing that flexibility will be necessary as urgent issues arise and to ensure that impact on health is an integral component of decisions, the Committee **supported** the recommendation that CCPR agree to new chemicals and re-evaluations being prioritised on a 50:50 basis, with appropriate flexibility where required and taking into consideration the impact on health.

213. Several delegations supported the use of national reviews by JMPR in its evaluations of pesticides. To increase the capacity and timeliness of the evaluations, the Committee encouraged governments to provide their national toxicological and residues reviews to JMPR before final national decisions have been taken. It was recognized that consultation with the manufacturer would be required in these situations.

214. To gain experience with the use of national reviews, the JMPR Secretariat asked governments to notify them of recent or ongoing national reviews of new compounds on the priority list that could be used for their evaluations. The JMPR Secretariat also informed the Committee that a paper will be prepared that considers working procedures and various options to increase the capacity of JMPR. The Committee looked forward to reviewing this paper and encouraged governments to provide information on their national reviews to the JMPR Secretariat.

215. The Committee considered additional criteria that should be applied when establishing priorities, and **agreed** that preference should be given to those pesticides:

- the intake and/or toxicity profile of which indicate a high level of public health concern;
- that are new and safer with a potential to replace existing pesticides of concern from a public health perspective (e.g., reduced risk pesticides);

[16] CX/PR 01/14
[17] CX/PR 01/15; CRD 2; CRD 10, CRD 12, CRD 13; CRD 15 (report of the *ad hoc* working group on priorities)

- on which national reviews are available;
- that are related to chemicals (parent and metabolites used as pesticides) scheduled for evaluation so that they can be reviewed concurrently; and
- that may be responsible for actual or potential losses owing to trade disruption (national governments must quantify these losses and provide the information to CCPR).

216. The Committee also agreed that lower priority should be given to pesticides that have received in recent years substantial toxicological and residues reviews short of a full periodic re-evaluation.

217. The Committee **requested** JMPR to review its requirements for periodic re-evaluation when certain components of the re-evaluation have not changed (e.g. such as analytical methods or the review of metabolism studies). The response of the Joint Meeting to this recommendation will be considered at the next session of the Committee when the report of the 2001 JMPR is reviewed.

Isomeric mixtures

218. In some cases purified isomers, which replace isomeric mixtures for which there is no longer support, have been placed on the priority list. The Committee **recommended** that, when CXLs exist for the isomeric mixture, CCPR, while retaining its flexibility to consider isomeric mixtures on a case-by-case basis, adopt a policy of maintaining the CXLs for the commodities supported by the manufacturer for the isomeric mixture until the MRLs for the purified isomer reach Step 8. If an isomeric mixture of a pesticide is not supported by any manufacturer, deletion of the CXLs will be recommended.

New compounds

219. Five new compounds were proposed for addition to the priority list: *cyprodinil*, *fludioxonil*, and *trifloxystrobin* (all proposed by Switzerland), *dimethenamid-P* (Germany), and *methoxyfenozide* (United States). The JMPR Secretariat stated that its policy is to evaluate both the toxicity and residues of new pesticides the same year, unless informed that complex issues relating to the toxicity of residues are likely to arise. In such situations toxicity will be evaluated before residues, as is generally done with pesticides undergoing periodic re-evaluation.

220. The Committee noted that *anilazine* and *propoxur* were not supported for periodic re-evaluation. No indication of support was provided for either *hexaconazole* or *paclobutrazol*. *Esfenvalerate*, which is scheduled for evaluation, is a purified isomer of fenvalerate. In this case the purified isomer and the unresolved isomers may coexist in the market, so a commitment for the support of *fenvalerate* should be sought by the next session.

221. All of the pesticides on the previous list that required assessments of acute toxicity have been scheduled for evaluation.

Antibiotics

222. Mexico had requested at the Thirty-second Session of CCPR that *gentamicin* and *oxytetracycline* be added to the priority list. However, at that time the Committee deferred the decision on their inclusion. At the present session the delegation of Mexico reiterated its request, stating that it complied with the criteria for inclusion on the priority list, that these agents are very effective and important for control of bacterial diseases on certain commodities, and that residue levels are very low when these substances are used according to GAP. A number of delegations and observers did not support their inclusion on the priority list because they did not consider the use of these antibiotics as pesticides to be appropriate, which could lead to the development of antibiotic resistance in humans. Other delegations stated that, although these antibiotics are not registered for such use in their own countries, these substances should be added to the priority list because the criteria were met; it is not

appropriate to take risk management decisions before a risk assessment has been performed. Because of a lack of consensus the Committee decided that it could not make a decision at this time and **referred** the issue to the Codex Alimentarius Commission, requesting coordination among the other committees involved, including the Codex Committees on Residues of Veterinary Drugs in Foods and on Food Hygiene.

Priority list

223. The priority list is attached as Appendix IX. It was noted that the schedules for 2003 and beyond will need to be reorganized to accommodate the decision taken at this session to evaluate new and periodic review pesticides on an approximately 50:50 basis, beginning with the 2003 Meeting. The JMPR Secretariat encouraged the submission of dossiers in electronic format, stating that three copies (two paper, two electronic) are needed for the toxicological reviews and two paper and two electronic copies are needed for the residues reviews.

224. The Committee **agreed** that an *ad hoc* Working Group on priorities should be convened at its next session under the chairmanship of Dr Doust. Activities will include consideration of the scheduling of pesticides by the 2002 JMPR and beyond, preparation of a document summarizing criteria for the prioritization process (including the criteria added at the present Session), and review of the paper to be prepared by the FAO/WHO Secretariat on the working procedures of JMPR.

CONSIDERATION OF ELABORATION OF MRLS FOR SPICES (AGENDA ITEM 10)[18]

225. The Delegation of South Africa introduced the document and informed the Committee that at the request of the 32nd Session of the Committee it was agreed to seek the relevant information from governments in order to consider the request of the Delegation of India to establish MRLs for spices. The Delegation pointed out that India, Mexico, Thailand and the USA submitted comments which indicated that:

- registered and unregistered pesticides were regularly used and detected on spices; therefore there was a need for the elaboration of MRLs/EMRLs on spices. Although a large number of pesticides were regularly used on many spices only the United States of America had officially established MRLs and that the many spice/pesticide combinations currently being used in spice-producing countries also added to the complexity of the problem;

- very little residue trial data were available and only one country had specific guidelines for spices which took into account that spices were produced and consumed in relatively small quantities;

- GAP and monitoring data could be made available to the JMPR for consideration in the elaboration of Codex MRLs; however at this stage it was difficult to determine which spice/pesticide combinations should receive priority or to express an opinion on the quality and quantity of the data that could be submitted.

226. The Committee had an extensive debate on how to proceed in this area. Due to the lack of GAPs and supervised trial data it would be not possible to fully apply the current MRL establishment procedures. It also appeared that in view of very small consumption of spices intake problems were not expected.

227. Several spice exporting and importing countries indicated that due to the lack of Codex MRLs there were problems in international trade.

[18] CX/PR 01/16.

228. The Delegation of Egypt informed the Committee that monitoring of residues had been carried out since 1995 and therefore residue data could be submitted. The Delegation suggested extending the scope of the discussion to aromatic plants and to establish MRLs for dry and fresh herbs. However, the Committee recalled that following the decision of the last session, priority should be given to spices.

229. The Delegation of India, while pointing out the complexity of the matter, proposed the elaboration of MRLs/EMRLs on the basis of monitoring data and indicated that monitoring data on residues of DDT, lindane and BHC could be submitted. This view was supported by several delegations. The Delegation of the Netherlands welcommed the collection of the monitoring data however suggested that in view of low intake of spices it might be unnecessary establish EMRLs unless it required to solve trade problems and indicated that the Netherlands did not establish EMRLs in order not to create trade problems.

230. The Delegation of Spain proposed to define groups of spices, to clarify intended uses of compounds as to whether it would be a field or postharvest treatment and suggested the extrapolation of data from one type of spice to another where possible.

231. The Delegation of Malaysia proposed that priority be given to establishment of EMRLs for DDT as several spice producing countries were facing residue problems of this insecticide.

232. The Representative of spice producing organization being part of the delegation of the Netherlands indicated that manufacturers were unlikely to support studies of residues or to provide data on the use of chemicals on those minor crops but it was nevertheless important that GAPs are developed as much as possible and offered its assistance for further work in this area.

233. The Committee noted concerns that some compounds should not be used on spices but recognized that the establishment of EMRLs might be necessary due to environmental contamination. However, due to the lack of data the Committee considered that referral to JMPR was premature.

234. The Committee agreed that the Delegation of South Africa with assistance of Egypt, India, Indonesia, and the spice trader associations would prepare a concise position paper to identify the more important spice/pesticide combinations, the availability of GAP information and residue data (field trial and monitoring data) together with information on trade problems. It was also agreed that the paper should consider policy guidance on further steps in the establishment of MRLs/EMRL for spices.

DISCUSSION PAPER ON OTHER LEGITIMATE FACTORS IN THE FRAMEWORK OF RISK ANALYSIS THAT HAVE BEEN OR ARE CURRENTLY BEING TAKEN INTO ACCOUNT IN THE WORK OF THE COMMITTEE (Agenda Item 11)[19]

235. The Committee recalled that the last session had been able to only briefly discuss other legitimate factors, following the request from the Committee on General Principles, and had agreed that the Delegation of Australia in collaboration with other delegations would prepare a discussion paper for consideration by the 33rd Session.

236. The Delegation of Australia, while introducing the document, indicated that all factors relevant to risk assessment and risk management had been considered, except those related to the scientific evaluation performed by JMPR insofar as they were relevant to risk analysis, in order to facilitate the debate. The Delegation noted that, for clarification purposes, the paper also mentioned the factors which were not taken into account by the Committee.

237. The Secretariat recalled the current status of discussions in the CCGP and other committees, with a reference to the "other factors" which had been considered in relation to risk management. The

[19] CX/PR 01/17, CX/PR 01/17-Add.1, CRD 5 (comments of Consumers International).

Committee noted that the next session of the CCGP would consider a document proposing a number of criteria for the consideration of other factors in relation to risk management[20].

238. The Observer from CI expressed the view that other factors were an important aspect of risk management decisions, and should be considered further as they were currently used in the work of the Committee. These factors should be considered in the wider context of risk analysis, in order to clarify the rationale for policy decisions which had an impact on health protection to ensure the scientific integrity of decision making and to make the process generally more transparent, efficient and consistent.

239. The Delegation of the Netherlands supported this view and indicated that in the light of the working documents and earlier discussions, it would be useful to consider the different steps of risk assessment and risk management followed in MRL setting from a broader perspective.

240. The Chairman recalled the importance of clarifying the use of other legitimate factors and risk analysis in the Committee and in the wider framework of Codex, and indicated that it might be useful to consider further the relationship between risk assessment and risk management in the future. However it was preferable to defer discussion in this area until further progress had been achieved in the CCGP and Codex. The Commission could provide general orientation to Codex committees concerning the role of other factors and the application of risk analysis principles in the decision process. The Chairman while referring to Agenda Item 5 indicated that the approach to these issues should be more concrete and focus on actual problems faced by the Committee. The Committee generally concurred with this approach.

DISCUSSION PAPER ON THE NEED FOR THE REVISION OF THE CODEX CLASSIFICATION OF FOODS AND ANIMAL FEEDS (Agenda Item 12)[21]

241. The Committee noted that at its last session there was support for the revision of the Codex Classification of Foods and Animal Feeds and that the Delegation of the Netherlands had been requested to prepare a short paper on this subject.

242. The Delegation of the Netherlands introduced CRD 17 regarding updating the Classification and indicated that it was expected that the revised Classification would promote harmonization of the terms used to describe commodities and would take into account new crops and varieties introduced on the market that were of relevance to the setting of MRLs. The Delegation pointed out that fish and fish products could also be revised, in view of the use of the classification by CCFAC. Furthermore the sections on the portions to which the MRL apply should be reviewed.

243. While there was general support to update the Classification, some delegations expressed the opinion that the work should be coordinated with the other Codex subsidiary bodies, eg the *ad hoc* Task Force on Animal Feeding and that the CCPR should be responsible for the revision of plant commodities section.

244. The Delegation of Japan drew the attention of the Committee to the fact that while the current Classification included detailed entries for the European fruits and vegetables, Asian fruits and vegetables were not well covered. The Delegation also questioned the need for too detailed entries in the classification.

245. The Committee agreed to ask information by a Circular Letter to what extent the Classification should be updated and what new commodities should be added, and requested the Delegation of the Netherlands with assistance of Japan, New Zealand, Sweden, the USA and WHO to prepare a paper for consideration by the next session of the Committee.

OTHER BUSINESS AND FUTURE WORK (Agenda Item 13)[22]

[20] CX/GP 01/5.
[21] CRD 17.

Acute Dietary Risk Assessment

246. Following earlier discussions on risk analysis, the Chairman proposed that the Committee should reflect further on the issues related to acute exposure assessment, especially the policy to be followed by CCPR when the acute dietary exposure exceeds the RfD, in order to facilitate the selection of appropriate risk management options. Also the feasibility of developing probabolistic methodology at international level should be explored.

247. The Delegations of the United States and the Netherlands, in view of their advanced experience in the development of acute dietary exposure assessment agreed to develop a discussion paper for consideration by the next session of the Committee. The Delegation of Australia and the Observers of CI and GCPF agreed to assist in the preparation of that paper, in order to provide guidance to the Committee in this area.

DATE AND PLACE OF NEXT SESSION (Agenda Item 14)

248. The Committee was informed that the 34th Session of the Committee would be held in the Hague, The Netherlands, from 13 to 18 May 2002 and the Ad Hoc Working Group on Priorities would meet on 11 May 2002, subject to confirmation by the host Government and the Codex Secretariat.

[22] CX/PR 01/14

SUMMARY STATUS OF WORK

Subject	Step	Action by	Document Reference in ALINORM 01/24
Draft MRLs	8	24th CAC	Appendix II
Proposed Draft MRLs	5/8	24th CAC	Appendix III
Proposed Draft Amendments to the *Codex Classification of Foods and Animal Feeds*	5[23]	24th CAC	Appendix IV
Draft MRLs	7	JMPR, CCPR	CX/PR 01/9
Proposed Draft MRLs	5	24th CAC, Governments, 34th CCPR	Appendix V
Draft and proposed draft MRLs	6 and 3	Secretariat, Governments, CCPR	Annex I
Proposed Draft Amendments to the Guidelines on Good Laboratory Practice in Pesticide Residue Analysis	3	Governments, International Organisations 34th CCPR	para. 204, Appendix VII
Proposed Draft Amendments to the Introduction Section of the Recommended methods of Analysis for Pesticide Residues	3	Governments, International Organisations CCPR	para. 207, Appendix VIII
New work: Priority List of Pesticides (new pesticides and pesticides under periodic review)	1	24th CAC, Governments, Australia, CCPR	Appendix IX
Revision of the List of Methods for Pesticide Residues Analysis	-	Netherlands	para. 208
Discussion Papers on:			
- Cumulative Risk Assessment		USA	para. 78
- Accute Exposure Assessment		**USA,** Australia, the Netherlands, CI, GCPF	paras 246-247
- Elaboration of MRLs for Spices			paras 225-234
- Revision of the Codex Classification of Foods and Animal Feeds		**Netherlands**, Japan, New Zealand, Swededn, USA, WHO	paras 241-245
- Trade Vulnerabilities Resulting from Codex MRL Setting Process		**USA,** Australia, Brazil, Canada, Chili, New Zealand, South Africa, EC, GCPF	paras 6-12

[23] of the Accelerated Procedure.

ALINORM 01/24A
ANNEX I

MAXIMUM RESIDUE LIMITS CONSIDERED AT THE SESSION

Commodity			MRL (mg/kg)		Step	Note
22	**DIAZINON**					
MM	0814	Goat meat	2		6	
MO	0098	Kidney of cattle, goats, pigs & sheep	0.03		6	
MO	0099	Liver of cattle, goats, pigs & sheep	0.03		6	
MM	0097	Meat of cattle, pigs & sheep	2(a)[1]		6	
35	**ETHOXYQUIN**					
FP	0230	Pear	3	Po	CXL	Withdrawal recommended (1999 JMPR). Retained for four years under the Periodic Review Procedure awaiting toxicity studies.
41	**FOLPET**					
FB	0275	Strawberry	5(a)		6	
49	**MALATHION**					
FP	0226	Apple	2		CXL	Withdrawal recommended (1999 JMPR). Retained for four years under the Periodic Review Procedure awaiting new residue data.
VB	0400	Broccoli	5		CXL	Withdrawal recommended (1999 JMPR). Retained for four years under the Periodic Review Procedure awaiting new residue data.
VB	0041	Cabbages, Head	8		CXL	Withdrawal recommended (1999 JMPR). Retained for four years under the Periodic Review Procedure awaiting new residue data.
FC	0001	Citrus fruits	4		CXL	Withdrawal recommended (1999 JMPR). Retained for four years under the Periodic Review Procedure awaiting new residue data.
FB	0269	Grapes	8		CXL	Withdrawal recommended (1999 JMPR). Retained for four years under the Periodic Review Procedure awaiting new residue data.
FS	0247	Peach	6		CXL	Withdrawal recommended (1999 JMPR). Retained for four years under the Periodic Review Procedure awaiting new residue data.
FB	0272	Raspberries, Red, Black	8		CXL	Withdrawal recommended (1999 JMPR). Retained for four years under the Periodic Review data.
VR	0075	Root and tuber vegetables	0.5		CXL	Withdrawal recommended (1999 JMPR). Retained for four years under the Periodic Review Procedure awaiting new residue data.

[1] (a) folowing MRL - the MRL is a proposed revision/amendment to a CXL.

56	**2-PHENYLPHENOL**					
FP	0230	Pear	25	Po	CXL	Withdrawal recommended (1999 JMPR). Retained for four years under the Periodic Review Procedure awaiting new residue data to be provided by US grower organisation.
106	**THIABENDAZOLE**					
VO	0450	Mushrooms	60		3	
106	**CARBENDAZIM**					
FB	0018	Berries and other small fruits	1	B,Th	6	
GC	0080	Cereal grains	0.5	B,C, Th	6	
VL	0482	Lettuce, Head	5	Th	6	
VO	0051	Peppers	0.1	Th	6	
74	**DISULFOTON**					
VS	0621	Asparagus	0.02	(*)	6	
GC	0640	Barley	0.2(a)		6	
VD	0071	Beans (dry)	0.2		6	
VB	0400	Broccoli	0.1		6	
VB	0041	Cabbages, Head	0.2		6	
VB	0404	Cauliflower	0.05		6	
PE	0840	Chicken eggs	0.02	(*)	6	
VP	0526	Common bean (pods and/or immature seeds)	0.2		6	
SO	0691	Cotton seed	0.1		6	
VP	0528	Garden pea (young pods)	0.1		6	
VP	0529	Garden pea, Shelled	0.02	(*)	6	
VL	0482	Lettuce, Head	1		6	
VL	0483	Lettuce, Leaf	1		6	
GC	0645	Maize	0.02(a)	(*)	6	
ML	0107	Milk of cattle, goats & sheep	0.01		6	
AF	0647	Oat forage (green)	0.5(a)		6	
AS	0647	Oat straw and fodder, Dry	0.05		6	
GC	0647	Oats	0.02(a)	(*)	6	
PM	0110	Poultry meat	0.02	(*)	6	
VO	0447	Sweet corn (corn-on-the-cob)	0.02	(*)	6	
VO	1275	Sweet corn (kernels)	0.02	(*)	6	
GC	0654	Wheat	0.2(a)		6	
AF	0654	Wheat forage (whole plant)	1(a)		6	
AS	0654	Wheat straw and fodder, Dry	5		6	
90	**CHLORPYRIFOS-METHYL**					
GC	0640	Barley	10		6	
GC	0647	Oats	10		6	
GC	0649	Rice	10(a)		6	
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		3	
100	**METHAMIDOPHOS**					
FS	0247	Peach	1		6	
FP	0009	Pome fruits	0.5		6	
VO	0448	Tomato	1		6	
103	**PHOSMET**					
FS	0240	Apricot	10(a)		6	
117	**ALDICARB**					
VR	0589	Potato	0.5(a)		6	
144	**BITERTANOL**					
FS	0240	Apricot	1		CXL	Withdrawal recommended (JMPR 1999). Retained for one year to consider extrapolation from nectarine.
145	**CARBOSULFAN**					
AB	0001	Citrus pulp, Dry	0.1		6	
FC	0004	Oranges, Sweet, Sour	0.1		6	
166	**OXYDEMETON-METHYL**					
FP	0226	Apple	0.05		6	
GC	0640	Barley	0.05	(*)	6	
VB	0041	Cabbages, Head	0.05	(*)	6	
MF	0812	Cattle fat	0.05	(*)	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	
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	
187	**CLETHODIM**					
AL	1020	Alfalfa fodder	10		6	
VD	0071	Beans (dry)	2		6	
VP	0061	Beans, except broad bean and soya bean	0.5	(*)	6	
MO	1280	Cattle kidney	0.2	(*)	6	
MO	1281	Cattle liver	0.2	(*)	6	
MM	0812	Cattle meat	0.5	(*)	6	
ML	0812	Cattle milk	0.1	(*)	6	

PE	0840	Chicken eggs	0.5	(*)	6
PM	0840	Chicken meat	0.5	(*)	6
SO	0691	Cotton seed	0.5		6
OC	0691	Cotton seed oil, Crude	0.5	(*)	6
OR	0691	Cotton seed oil, Edible	0.5	(*)	6
VD	0561	Field pea (dry)	2		6
AM	1051	Fodder beet	0.1	(*)	6
VA	0381	Garlic	0.5		6
VA	0385	Onion, Bulb	0.5		6
SO	0697	Peanut	5		6
VR	0589	Potato	0.5		6
SO	0495	Rape seed	0.5		6
OC	0495	Rape seed oil, Crude	0.5	(*)	6
OR	0495	Rapeseed oil, Edible	0.5	(*)	6
VD	0541	Soya bean (dry)	10		6
OC	0541	Soya bean oil, Crude	1		6
OR	0541	Soya bean oil, Refined	0.5	(*)	6
VR	0596	Sugar beet	0.1		6
SO	0702	Sunflower seed	0.5		6
OC	0702	Sunflower seed oil, Crude	0.1	(*)	6
OR	0702	Sunflower seed oil, Edible	0.05		6
VO	0448	Tomato	1		6

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PE	0840	Chicken eggs	0.01	(*)	6
PM	0840	Chicken meat	0.01	(*)	6
PO	0840	Chicken, Edible offal of	0.1		6
SO	0691	Cotton seed	0.2		6
OC	0691	Cotton seed oil, Crude	0.5		6
AM	1051	Fodder beet	0.3		6
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

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FB	0269	Grapes	1		6

APPENDIX I

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LISTE DES PARTICIPANTS
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DRAFT AND DRAFT REVISED MAXIMUM RESIDUE LIMITS FOR PESTICIDES

(Advanced to Step 8 of the Codex Procedure)

		Commodity	MRL (mg/kg)	Step	Note
72	**CARBENDAZIM**				
FS	0240	Apricot	2	B	
FS	0245	Nectarine	2	B	
FS	0247	Peach	2	B	
FS	0014	Plums (including prunes)	0.5	B	
FP	0009	Pome fruits	3	B,c,th	
VO	0448	Tomato	0.5	b,C	
81	**CHLOROTHALONIL**				
FI	0327	Banana	0.01(a)[1]	(*)	
106	**ETHEPHON**				
VC	4199	Cantaloupe	1		
FB	0269	Grapes	1		
VO	0051	Peppers	5		
FI	0353	Pineapple	2		
VO	0448	Tomato	2		
173	**BUPROFEZIN**				
FC	0004	Oranges, Sweet, Sour	0.5		
177	**ABAMECTIN**				
MF	0812	Cattle fat	0.1		
MO	1280	Cattle kidney	0.05		
MO	1281	Cattle liver	0.1		
MM	0812	Cattle meat	0.01	(*)	
ML	0812	Cattle milk	0.005		
MM	0814	Goat meat	0.01	(*)	
ML	0814	Goat milk	0.005		
MO	0814	Goat, Edible offal of	0.1		
188	**FENPROPIMORPH**				
GC	0640	Barley	0.5		
AS	0640	Barley straw and fodder, Dry	5		
AV	1051	Fodder beet leaves or tops	1		
AS	0647	Oat straw and fodder, Dry	5		
GC	0647	Oats	0.5		
GC	0650	Rye	0.5		
AS	0650	Rye straw and fodder, Dry	5		
VR	0596	Sugar beet	0.05	(*)	

[1] (a) folowing MRL - the MRL is a proposed revision/amendment to a CXL.

AV	0596	Sugar beet leaves or tops	1		
GC	0654	Wheat	0.5		
AS	0654	Wheat straw and fodder, Dry	5		
21	**DDT**				
MM	0095	Meat (from mammals other than marine mammals)	5 [3]	(fat)	The 33rd Session of the CCPR could not reach concensus on the proposed MRL at 5 mg/kg. The meeting decided to advance the proposel to Step 8 together with a compromise proposal at 3 mg/kg.

PROPOSED DRAFT AND PROPOSED DRAFT REVISED MAXIMUM RESIDUE LIMITS FOR PESTICIDES

(Advanced to Step 5 of the Codex Procedure with Omission of Step 6 and 7 for Adoption at Step 8)

Commodity			MRL (mg/kg)	Step	Note
60	**PHOSALONE**				
TN	0660	Almonds	0.1		
TN	0666	Hazelnuts	0.05	(*)	
TN	0678	Walnuts	0.05	(*)	
65	**THIABENDAZOLE**				
PE	0112	Eggs	0.1		
106	**ETHEPHON**				
DF	0269	Dried grapes (=currants, raisins and sultanas)	5		
144	**BITERTANOL**				
GC	0640	Barley	0.05	(*)	
AS	0640	Barley straw and fodder, Dry	0.05	(*)	
FS	0013	Cherries	1(a)[1]		
MO	0105	Edible offal (mammalian)	0.05	(*)	
PE	0112	Eggs	0.01	(*)	
MM	0095	Meat (from mammals other than marine mammals)	0.05	(*)(fat)	
ML	0106	Milks	0.05	(*)	
AF	0647	Oat forage (green)	0.05(a)	(*)dry wt	
AS	0647	Oat straw and fodder, Dry	0.05(a)	(*)	
GC	0647	Oats	0.05(a)	(*)	
PM	0110	Poultry meat	0.01	(*)	
PO	0111	Poultry, Edible offal of	0.01	(*)	
GC	0650	Rye	0.05(a)	(*)	
AF	0650	Rye forage (green)	0.05(a)	(*)dry wt	
AS	0650	Rye straw and fodder, Dry	0.05(a)	(*)	
GC	0653	Triticale	0.05	(*)	
AS	0653	Triticale straw and fodder, Dry	0.05	(*)	
GC	0654	Wheat	0.05(a)	(*)	
AS	0654	Wheat straw and fodder, Dry	0.05(a)	(*)	

[1] (a) folowing MRL - the MRL is a proposed revision/amendment to a CXL.

188	**FENPROPIMORPH**			
PE	0112	Eggs	0.01	(*)
MO	0098	Kidney of cattle, goats, pigs & sheep	0.05	
MO	0099	Liver of cattle, goats, pigs & sheep	0.3	
MF	0100	Mammalian fats (except milk fats)	0.01	
MM	0095	Meat (from mammals other than marine mammals)	0.02	
ML	0106	Milks	0.01	
PF	0111	Poultry fats	0.01	(*)
PM	0110	Poultry meat	0.01	(*)
PO	0111	Poultry, Edible offal of	0.01	(*)
200	**PYRIPROXIFEN**			
FC	0001	Citrus fruits	1	

PROPOSED DRAFT AMENDMENTS TO CODEX CLASSIFICATION OF FOODS AND ANIMAL FEEDS

(At Step 5 of the Accelerated Procedure)

Amend the definitions of "Meat", "Mammalian Fats", "Poultry Fats" and "Milk" contained in the *Codex Classification of Foods and Animal Feeds* as follows:

1. **Meat** (from mammals other than marine mammals)

Meats are the muscular tissues, including adhering fat issues such as intramuscular and subcutaneous fat from animal carcasses or cuts of these as prepared for wholesale or retail distribution in a "fresh" state. The cuts offered to the consumer may include bones, connective tissues and tendons as well as nerves and lymph nodes.

2. **Mammalian fats** (except fat from marine mammals)

Mammalian fats, excluding milk fats, are derived from the fat tissues of animals (not processed).

3. **Poultry fats**

Poultry fats are derived from the fat tissues of poultry.

4. **Milks**

Milk is the normal mammary secretion of milking animals obtained from one or more milkings without either addition to it or extraction from it, intended for consumption as liquid milk or for further processing.

PROPOSED DRAFT AND PROPOSED DRAFT REVISED MAXIMUM RESIDUE LIMITS FOR PESTICIDES

(At Step 5 of the Codex Procedure)

		Commodity	MRL (mg/kg)	Step	Note
22	**DIAZINON**				
VB	0041	Cabbages, Head	0.5(a)[1]	5	
FP	0009	Pome fruit	0.3(a)	5	
				5	
41	**FOLPET**				
FP	0226	Apple	10	5	
VC	0424	Cucumber	1(a)	5	
DF	0269	Dried grapes (=currants, raisins and sultanas)	40	5	
FB	0269	Grapes	10(a)	5	
VL	0482	Lettuce, Head	50	5	
VC	0046	Melons, except watermelon	3	5	
VA	0385	Onion, bulb	1	5	
VR	0589	Potato	0.1(a)	5	
VO	0448	Tomato	3	5	
				5	
49	**MALATHION**				
AL	1020	Alfalfa fodder	200	5	
AL	1021	Alfalfa forage (green)	500	5	
VS	0621	Asparagus	1	5	
VD	0071	Beans (dry)	2(a)	5	
VP	0061	Beans, except broad bean and soya bean	1	5	
FB	0020	Blueberries	10(a)	5	
AL	1023	Clover	500	5	
AL	1031	Clover hay or fodder	150	5	
SO	0691	Cotton seed	20	5	
OC	0691	Cotton seed oil, Crude	13	5	
OR	0691	Cotton seed oil, Edible	13	5	
VC	0424	Cucumber	0.2	5	
AF	0162	Grass forage	200	5	
AS	0162	Hay or fodder (dry) of grasses	300	5	
GC	0645	Maize	0.05(a)	5	
AS	0645	Maize fodder	50	5	
AF	0645	Maize forage	10	5	
VL	0485	Mustard greens	2	5	
VA	0385	Onion, Bulb	1	5	
VO	0051	Peppers	0.1(a)	5	
GC	0651	Sorghum	3(a)	5	
VL	0502	Spinach	3(a)	5	
VA	0389	Spring onion	5	5	
VO	0447	Sweet corn (corn-on-the-cob)	0.02	5	

[1] (a) folowing MRL - the MRL is a proposed revision/amendment to a CXL.

VO	0448	Tomato	0.5(a)		5
JF	0448	Tomato juice	0.01		5
VL	0506	Turnip greens	5		5
VR	0506	Turnip, Garden	0.2(a)		5
GC	0654	Wheat	0.5(a)		5
AF	0654	Wheat forage (whole plant)	20		5
AS	0654	Wheat straw and fodder, Dry	50		5

56 2-PHENYLPHENOL

FC	0001	Citrus fruits	10(a)	Po	5
AB	0001	Citrus pulp, Dry	60	PoP	5
JF	0004	Orange juice	0.5	PoP	5

60 PHOSALONE

FP	0009	Pome fruits	2(a)		5
FS	0012	Stone fruits	2		5

85 FENAMIPHOS

FP	0226	Apple	0.05	(*)	5
FI	0327	Banana	0.05(a)	(*)	5
VB	0402	Brussels sprouts	0.05(a)		5
VB	0041	Cabbages, Head	0.05(a)		5
OC	0691	Cotton seed oil, Crude	0.05	(*)	5
MO	0105	Edible offal (mammalian)	0.01	(*)	5
PE	0112	Eggs	0.01	(*)	5
MM	0095	Meat (from mammals other than marine mammals)	0.01	(*)	5
ML	0106	Milks	0.005	(*)	5
OC	0697	Peanut oil, Crude	0.05	(*)	5
VO	0051	Peppers	0.5		5
PM	0110	Poultry meat	0.01	(*)	5
PO	0111	Poultry, Edible offal of	0.01	(*)	5
VO	0448	Tomato	0.5(a)		5
VC	0432	Watermelon	0.05	(*)	5

96 CARBOFURAN

FC	0206	Mandarin	0.5		5

132 METHIOCARB

FB	0275	Strawberry	1		5

144 BITERTANOL

VO	0448	Tomato	3		5

145 CARBOSULFAN

FC	0206	Mandarin	0.1		5

175 GLUFOSINATE-AMMONIUM

MO	0105	Edible offal (mammalian)	0.1	(*)	5
PE	0112	Eggs	0.05	(*)	5
AS	0645	Maize fodder	10	(*)	5
AF	0645	Maize forage	5(a)		5
MM	0095	Meat (from mammals other than marine mammals)	0.05	(*)	5
ML	0106	Milks	0.02	(*)	5
PM	0110	Poultry meat	0.05	(*)	5
PO	0111	Poultry, Edible offal of	0.1	(*)	5

VD	0541	Soya bean (dry)	2(a)		5

187 CLETHODIM

AL	0061	Bean fodder	10		5
AL	1030	Bean forage (green)	5		5
MO	0105	Edible offal (mammalian)	0.2	(*)	5
PE	0112	Eggs	0.05	(*)	5
MM	0095	Meat (from mammals other than marine mammals)	0.2	(*)	5
ML	0106	Milks	0.05	(*)	5
PM	0110	Poultry meat	0.2	(*)	5
PO	0111	Poultry, Edible offal of	0.2	(*)	5

188 FENPROPIMORPH

FI	0327	Banana	2		5

193 FENPYROXIMATE

FP	0226	Apple	0.3		5
MO	1280	Cattle kidney	0.01	(*)	5
MO	1281	Cattle liver	0.01	(*)	5
MM	0812	Cattle meat	0.02	(fat)	5
ML	0812	Cattle milk	0.005	(*)F	5
FB	0269	Grapes	1		5
DH	1100	Hops, Dry	10		5
FC	0004	Oranges, Sweet, Sour	0.2		5

200 PYRIPROXIFEN

MM	0812	Cattle meat	0.01	(*)(fat)	5
MO	0812	Cattle, Edible offal of	0.01	(*)	5
SO	0691	Cotton seed	0.05		5
OC	0691	Cotton seed oil, Crude	0.01		5
OR	0691	Cotton seed oil, Edible	0.01		5
MM	0814	Goat meat	0.01	(*)(fat)	5
MO	0814	Goat, Edible offal of	0.01	(*)	5

CODEX MAXIMUM RESIDUE LIMITS FOR PESTICIDES RECOMMENDED FOR REVOCATION

Commodity			MRL (mg/kg)	Step	Note
14	**CHLORFENVINPHOS**				
VB	0402	Brussels sprouts	0.05		CXL-D
VB	0041	Cabbages, Head	0.05		CXL-D
VR	0577	Carrot	0.4		CXL-D
VB	0404	Cauliflower	0.1		
48	**LINDANE**				
FP	0226	Apple	0.5		CXL-D
VD	0071	Beans	1	Po	CXL-D
VB	0402	Brussels sprouts	0.5		CXL-D
VB	0403	Cabbage, Savoy	0.5		CXL-D
VB	0041	Cabbages, Head	0.5		CXL-D
SB	0715	Cacao beans	1		CXL-D
VB	0404	Cauliflauer	0.5		CXL-D
GC	0080	Cereal grains	0.5	Po	CXL-D
FS	0013	Cherries	0.5		CXL-D
DM	1215	Cocoa butter	1		CXL-D
DM	1216	Cocoa mass	1		CXL-D
FB	0265	Cranberry	3		CXL-D
FB	0279	Currant, Red, White	0.5		CXL-D
VL	0476	Endive	2		CXL-D
FB	0269	Grapes	0.5		CXL-D
VB	0405	Kohlrabi	1		CXL-D
VL	0482	Lettuce, head	2		CXL-D
MM	0097	Meat of cattle, pigs&sheep	2		CXL-D
MM	0106	Milks	0.01		CXL-D
FP	0203	Pear	0.5		CXL-D
VP	0063	Peas (pods and succulent=immature seeds)	0.1		CXL-D
FS	0014	Plums (including ptunes)	0.5		CXL-D
VR	0589	Potato	0.05		CXL-D
VR	0494	Radish	1		CXL-D
VL	0502	Spinach	2		CXL-D
FB	0275	Strawberry	3		CXL-D
VO	0448	Tomato	2		CXL-D
49	**MALATHION**				
FB	0264	Blackberries	8		CXL-D
VB	0404	Cauliflower	0.5		CXL-D
VS	0624	Celery	1		CXL-D
VL	0464	Chard	0.5		CXL-D
FS	0013	Cherries	6		CXL-D
VP	0526	Common bean (pods and/or immature seeds)	2		CXL-D
DF	0167	Dried fruits	8		CXL-D
VO	0440	Egg plant	0.5		CXL-D
VL	0476	Endive	8		CXL-D

VL	0480	Kale	3		CXL-D
VB	0405	Kohlrabi	0.5		CXL-D
VD	0533	Lentil (dry)	8		CXL-D
VL	0482	Lettuce, Head	8		CXL-D
AO5	1900	Nuts (whole in shell)	8		CXL-D
FS	0247	Peach	6		CXL-D
VP	0063	Peas (pods and succulent=immature seeds)	0.5		CXL-D
FS	0014	Plums (including prunes)	6		CXL-D
FB	0272	Raspberries, Red, Black	8		CXL-D
VR	0075	Root and tuber vegetables	0.5		CXL-D
CM	0650	Rye bran, Unprocessed	20	PoP	CXL-D
CF	1250	Rye flour	2	PoP	CXL-D
CF	1251	Rye wholemeal	2	PoP	CXL-D

67 CYHEXATIN

VP	0526	Common bean (pods and/or immature seeds)	0.2		CXL-D
VC	0424	Cucumber	0.5		CXL-D
VO	0440	Eggplant	0.1		CXL-D
VC	0425	Gherkin	1		CXL-D
VC	0046	Melon, except watermelon	0.5		CXL-D
VO	0445	Peppers, sweet	0.5		CXL-D
FB	0275	Strawberry	0.5		CXL-D
VO	0448	Tomato	2		CXL-D

74 DISULFOTON

GC	0649	Rice	0.5		CXL-D

78 VAMIDOTHION

GC	0080	Cereal grains	0.2		CXL-D
FB	0269	Grapes	0.5		CXL-D
FS	0247	Peach	0.5		CXL-D
FP	0009	Pome fruits	1		CXL-D
CM	0649	Rice, husked	0.2		CXL-D
VR	0596	Sugar beet	0.5		CXL-D

85 FENAMIPHOS

VB	0400	Broccoli	0.05	(*)	CXL-D
VB	0404	Cauliflower	0.05	(*)	CXL-D
SB	0716	Coffee beans	0.1		CXL-D
SM	0716	Coffee beans, Roasted	0.1		CXL-D
FI	0341	Kiwifruit	0.05	(*)	CXL-D
FC	0004	Oranges, Sweet, Sour	0.5		CXL-D
VR	0589	Potato	0.2		CXL-D
VD	0541	Soya bean (dry)	0.05	(*)	CXL-D
VR	0596	Sugar beet	0.05	(*)	CXL-D
VR	0508	Sweet potato	0.1		CXL-D

100 METHAMIDOPHOS

VB	0402	Brussels sprouts	1		CXL-D
VS	0624	Celery	1		CXL-D
DH	1100	Hops, dry	5		CXL-D
SO	0495	Rape seed	0.1		CXL-D
VC	0432	Watermelon	0.5		CXL-D

116 TRIFORINE

FT	0312	Tree tomato	0.02		CXL-D

129 AZOCYCLOTIN

VP	0526	Common bean (pods and/or immature seeds)	0.2		CXL-D
VC	0424	Cucumber	0.5		CXL-D
VO	0440	Eggplant	0.1		CXL-D
VC	0425	Gherkin	1		CXL-D
VC	0046	Melons, except watermelon	0.5		CXL-D
VO	0445	Peppers, sweet	0.5		CXL-D
FB	0275	Strawberry	0.5		CXL-D

132 METHIOCARB

VS	0620	Artichoke globe	0.05	(*)	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
VB	0404	Cauliflower	0.2		CXL-D
GC	0080	Cereal grains	0.05	(*)	CXL-D
FC	0001	Citrus fruits	0.05	(*)	CXL-D
PE	0112	Eggs	0.05	(*)	CXL-D
TN	0666	Hazelnuts	0.05	(*)	CXL-D
VL	0482	Lettuce, Head	0.2		CXL-D
VL	0483	Lettuce, Leaf	0.2		CXL-D
MM	0095	Meat (from mammals other than marine mammals)	0.05	(*)	CXL-D
ML	0106	Milks	0.05	(*)	CXL-D
PM	0110	Poultry meat	0.05	(*)	CXL-D
SO	0495	Rape seed	0.05	(*)	CXL-D
VR	0596	Sugar beet	0.05	(*)	CXL-D
VO	0447	Sweet corn (corn-on-the-cob)	0.05	(*)	CXL-D

144 BITERTANOL

AL	1030	Bean forage (green)	10		CXL-D
VP	0526	Common bean (pods and/or immature seeds)	0.5		CXL-D
SO	0697	Peanut	0.1	(*)	CXL-D
AL	1270	Peanut forage (green)	20		CXL-D

152 FLUCYTHRINATE

VC	0620	Artichoke globe	0.5		CXL-D
GC	0640	Barley	0.2		CXL-D
AS	0640	Barley straw and fodder, Dry	5		CXL-D
VD	0071	Beans (dry)	0.05		CXL-D
VB	0041	Cabbages, Head	0.5		CXL-D
SB	0716	Coffee beans	0.05		CXL-D
SO	0691	Cotton seed	0.1		CXL-D
OC	0691	Cotton seed oil, Crude	0.2		CXL-D
OR	0691	Cotton seed oil, Edible	0.2		CXL-D
VD	0561	Field pea (dry)	0.05		CXL-D
VB	0042	Flowerhead brassicas	0.2		CXL-D
FB	0269	Grapes	1		CXL-D
DH	1100	Hops, Dry	10		CXL-D
AS	0647	Oat straw and fodder, Dry	5		CXL-D
GC	0647	Oats	0.2		CXL-D
FS	0247	Peach	0.5		CXL-D
FP	0009	Pome fruits	0.5		CXL-D
VR	0589	Potato	0.05		CXL-D
VR	0591	Radish, Japanese	0.05		CXL-D
SO	0495	Rape seed	0.05		CXL-D

VR	0596	Sugar beet	0.05	CXL-D
AV	0596	Sugar beet leaves or tops	2	CXL-D
VO	1275	Sweet corn (kernels)	0.05	CXL-D
DT	1114	Tea, Green, Black	20	CXL-D
VO	0448	Tomato	0.2	CXL-D
GC	0654	Wheat	0.2	CXL-D
AS1	0654	Wheat straw and fodder, Dry	5	CXL-D

153 PYRAZOPHOS

FP	0226	Apple	1	CXL-D
GC	0640	Barley	0.05	CXL-D
AS	0640	Barley straw and fodder, Dry	5	CXL-D
VB	0402	Brussels sprouts	0.1	CXL-D
VR	0577	Carrot	0.2	CXL-D
VC	0424	Cucumber	0.1	CXL-D
DH	1100	Hops, Dry	10	CXL-D
VC	0046	Melons, except watermelon	0.1	CXL-D
FB	0275	Strawberry	0.2	CXL-D
GC	0654	Wheat	0.05	CXL-D
AS	0654	Wheat straw and fodder, Dry	5	CXL-D

PROPOSED DRAFT REVISED GUIDELINES ON GOOD LABORATORY PRACTICE IN RESIDUE ANALYSIS

(At Step 3 of the 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 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 (ref.: CAC/VOL XIII - Ed.2, Part VI or CAC/PR 5-1984), as amended with respect to meat and poultry (ALINORM 91/40; see also ALINORM 89/24A, Appd. II and ALINORM 91/24A Appd. VIII).

2 Portion of Commodities to which Codex Maximum Residue Limits Apply and which should be analysed (ref.: CAC/VOL XIII - Ed. l, Part V or CAC/PR6-1984).

3 Explanatory Notes on Codex Maximum Limits for Pesticide Residues (ref.: CAC/VOL XIII - Ed. 1, Part III).

4 Recommendations for Methods of Analysis of Pesticide Residues (ref.: CAC/VOL XIII Ed. 2 part VIII or CAC/PR 8-1984)

5 Codex Classification of Food and Animal Feed (ref.: CAC/PR4-1989)

CODEX GUIDELINES ON GOOD PRACTICE IN PESTICIDE RESIDUE ANALYSIS

1. INTRODUCTION

The Codex document ALINORM 76/24 Appendix IV (Report of the ad hoc Working Group on Methods of Analysis) contained the following statement:

"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 row data, and relevant subjects, which are considered as pre-requisites 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 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 applying the method for 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 being used, 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 members of 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 established 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 welldefined 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 in the area. 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 or chronically 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 protective manner taking into account the 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, gasses glassware, chromatographic materials, etc., of suitable quality are essential.

3.2.2 Chromatographic equipment, balances, spectrophotometers etc. must be serviced and their performance validated 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 recalibration of measuring equipment should only 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 checked at specified intervals. All records should be kept.

3.2.4 Although equipment may require periodic updating in order to keep up with developments, the equipment only needs to be sophisticated enough to do the job required.

3.2.5 All laboratories require an adequate range of reference pesticide standards of known and acceptably high purity. The range should cover 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 must be clearly labelled with an expiry date and stored under proper conditions. "Pure" reference standards must be kept under conditions that will minimise the rate of degradation, e.g. low temperature, exclusion of moisture, darkness. 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 owing to 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 of the final test solution.

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. De-ionised 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 gaschromatography 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 Residue 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 information on the sample, on the analysis required and on potential hazards associated with the handling of that sample.

4.2.2 On receipt of a sample it must immediately be assigned a unique sample identification code which should accompany it through all stages of the analysis to the reporting of the results. If possible, the samples should be subject to an appropriate disposal review system and 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 chill (1-5 °C) temperature, away from direct sunlight, and analysed within a few days. However, samples received deep-frozen must be kept at $\leq$ -16 ^{o}C until unalysis. In some instances, samples may require storage for a longer period before analysis. 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 used in the analysis.

4.2.6 Neither the containers used for storage nor their caps or stoppers should allow migration of the analyte(s) into the storage compartment. The containers must not leak. All samples should be labelled clearly with permanent labels and records must be kept. The extracts and final test solution should not be exposed to direct sunlight.

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 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 subset 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.

4.4.2 Whenever a laboratory undertakes method development and/or method modification, the effects of analytical variables should be established, e.g. by using ruggedness tests, prior to validation. Rigorous controls must be exercised in respect of all aspects of the method, which 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 relationships between the signal measured and the analyte sought is established unequivocally.

4.4.3 Preference should be given to methods having multi residue and or multi matrix applicability. The use of representative analytes or matrices is an important tool 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. Considerable differences in the accuracy and precision of methods, especially with respect to the determination step, may occur from species to species.

4.4.3.1 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;

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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.

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

- **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.

4.4.3.2 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 shall 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 AL-s 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 AL-s. Consequently, the fortification levels used in performance testing with representative analytes/representative commodities may not necessarily correspond to the actual AL-s.

4.4.3 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 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.

4.4.3.1 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.

4.4.3.2 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.

4.4.3.2 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 5.

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.

Control chart 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 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 number 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.

4.5.2.1 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 then 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.

4.5.2.2 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.

4.5.2.3 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.

4.5.3.4 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.

4.5.3.5 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.

4.5.3.6 If performance verification data are outside the refined action limits established according to 4.2.3, 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.

4.5.6.7 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 regulatory purposes, it is especially important that confirmatory tests are carried out before reporting adversely 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 gaschromatography 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 For qualitative confirmation, an alternative technique using different physicochemical properties and/or the use of spectral data is desirable. For quantitative confirmation at least one alternative procedure (which may be a different detection technique, additional ions monitored by mass spectrometry, etc.) should be used. The reported result depends on the methods applied:

- when a screening or semi-quantitative and quantitative methods are used report the result obtained with the quantitative method
- when the precision of the two methods are comparable and the two results are within the expectable extreme range of duplicate measurements, report the average result.

If the two results are outside the extreme range the validity of one of them shall be verified and the average of the two conforming results reported.

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 of 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 (e.g. 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 (e.g. 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 coelution 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, fungi spore, 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. Overspotting 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 Levels (LCL

4.9.1 When the objective of the analysis is to monitor and verify the compliance with MRLs or other accepted limits (AL), 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 registered 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

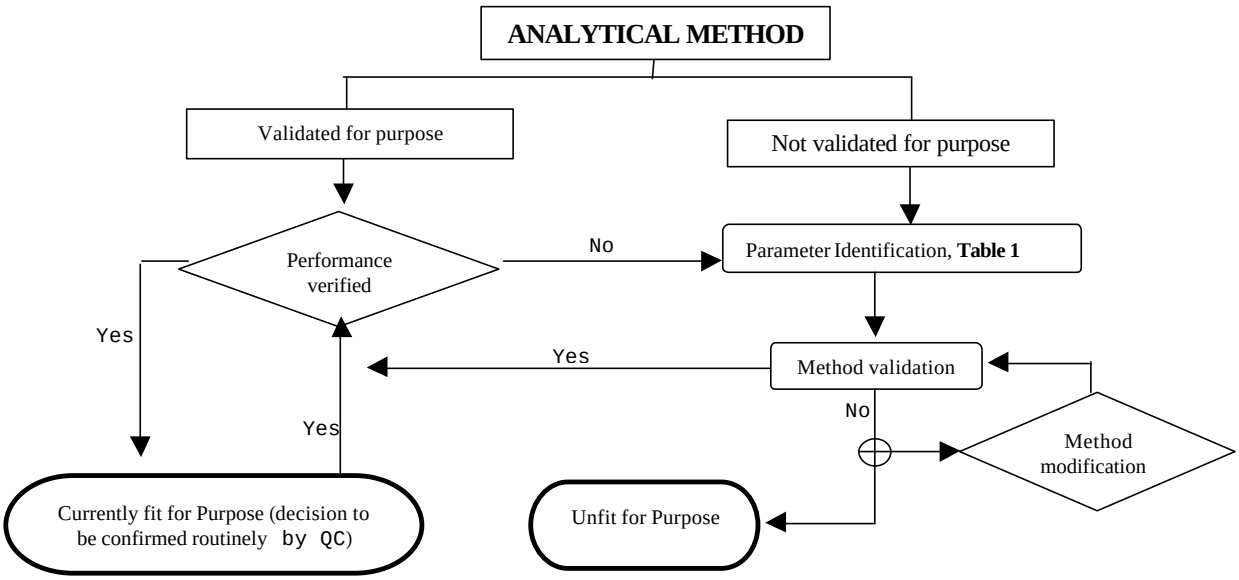

Figure II.2. Verification of Analyte Stability

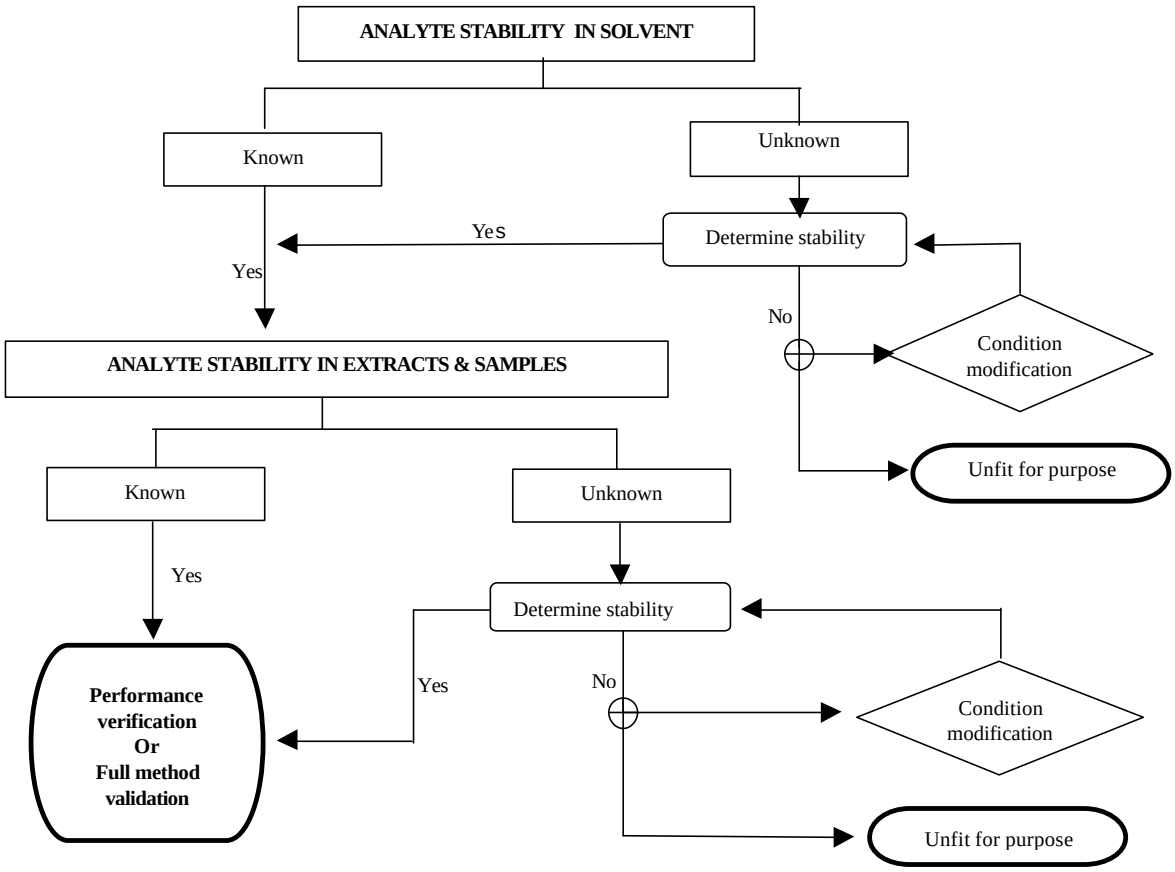

Table 1 Summary of parameters to be assessed for method validation

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

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			
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.	
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.	Repeatability, reproducibility

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			
							than validated procedures.	

* 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.

T**able 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. he 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	LCL to 2 (3)	Analyse representative analyte matrix combinations: ≥ 5	LOQ should be fit for purpose.	All recoveries are detectable at LCL		The analysts should demonstrate that the method is suitable for determining the

Parameter	Level(s)	No. of analyses or type of test required		Criteria		Comments
			Quantitative method	Screening method		
range, accuracy, trueness precision, limit of detection (LD), limit of quantitation (LOQ)	times AL*	analytical portions spiked at zero, LCL, AL and ≥3 replicates at 2-3 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.	Mean recovery and CV_A see Table 2. Mean residue* meaured in reference material is not significantly different from the consensus value (P = 0.05).			presence of the analyte at the appropriate AL with the maximum (false negative and false positive) errors specified. For MRM, the fortification level of blank samples should cover the AL's 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	Measured response is solely due to the analyte. Residues measured on two different columns should be within the critical range of replicate chromatographic	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

Parameter	Level(s)	No. of analyses or type of test required		Criteria		Comments
			Quantitative method	Screening method		
		obtained preferably from different sources, Report analyte equivalent of blank response. Determine and report selectivity (δ) of detector and relative response factors of representative analytes (RRF) with specific detectors used. .	determinations.			response. Blank values shall also be regularly checked during performance verification (see Section 5 below). Report typical peaks present in the extracts of blank samples. 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 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	At about AL or	Analyse ≥5 replicate test sample portions of one	CV_{Sp} ≤ 10%.	CV_{Sp} ≤ 15% For screening methods it		Use preferably commodities with incurred stable surface residues or treat the surface of

Parameter	Level(s)	No. of analyses or type of test required		Criteria		Comments
			Quantitative method	Screening method		
of analyte in analytical sample	well detectable residues	representative commodity from each group (Table 4), post-processing. Determine CV_{Sp} with analysis of variance. The analyte homogeneity should be checked with analytes known to be stable.		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.		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 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 notionally 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 2 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 5). 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.

[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		
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 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 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).	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 effect 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 determined from spiked analytical portions. Correct results with average recovery of analysis if its 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	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

Parameter	Level(s)	No. of analyses or type of test required		Criteria		Comments
			Quantitative method	Screening method		
		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.				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 avoid 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						
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 matix 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	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.

[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		
			(r) ≥ 0.98.			
2.3 Accuracy, precision, LOD, 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: $C_{max}- C_{min} \leq 3.3CV_{Atyp}Q$ 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 2.	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 detection	At LCL	Identify by mass spectrometry, or by the appropriate combination of separation and detection techniques available. 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 comounds. Unexpectedly found: (b) Check response of blank	Measured response is solely due to the analyte. The detection system used should have equal or better detector performance than those applied during method validation. Residues measured on two different columns should be within the critical range of replicate chromatographic determinations. RRts of representative analytes	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. 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

Parameter	Level(s)	No. of analyses or type of test required		Criteria		Comments
			Quantitative method	Screening method		
		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 RRt-s 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.	obtained during method validation and measured should be within 2 % for GLC and 5 % for HPLC determinations.			matrices. If the selectivity of detection does not eliminate the matrix response, use appropriate combination of chromatographic columns which enables the separation of analytes from the matrix peaks. See other options in Table 3.
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 equipment used by the method developer, if that information is not provided with the method or

Parameter	Level(s)	No. of analyses or type of test required		Criteria		Comments
			Quantitative method	Screening method		
						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 which will be involved in the analysis.	Average recovery and CV_A should be within the ranges given in Table 2.	All recoveries detectable at LCL. Reference materials at AL: analyte detected.		See comments in 1.3.
3.5 Specificity and	At AL	Check performance characteristics of detectors used and compare them with those	Measured response is solely due to the analyte. The detector	The rate of false negative samples (β error) at AL should typically be <		The relative response of specific detectors can substantially vary from model to model. Proper checking of specificity of detection is

Parameter	Level(s)	No. of analyses or type of test required		Criteria		Comments
			Quantitative method	Screening method		
selectivity of analyte detection		specified in the method. Check response of one blank of each representative commodity, otherwise perform test as described in section 1.4.	performance (sensitivity and selectivity) should be equal or better than specified in the method. See section 1.4	5%.		critical for obtaining reliable results. Compare blank response observed with typical 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 result, allowing up to 10% variability of sample processing.

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 4.2according to. 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.		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

			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.		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. RRt-s 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 relative retention data base 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 2.
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} ≤ 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	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} ≤ 2.8*CV_{Ltyp}Q or C_{max}- C_{min} ≤ $f_{(n)}$*CV_{Ltyp}Q		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

		available. Perform analysis with ≥2 analytical portions.	Q is the average residue obtained from the replicate measurements, the CV_{Ltyp} is obtained during method validation, $f_{(n)}$ if the factor for calculation of extreme range depending on the number of replicate samples.	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 with 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 need to be tested if the processing time and temperature are significantly increased.
4.4.3 Equipment for extraction	Compare field incurred residue levels detected with the old and new equipment in ≥ 5 replicates		The mean residues should not be significantly different at p=0.05 level.	Test is necessary if a new type of equipment is used
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. The detection test mixture may have to be column and detector specific.
False negative result	See beta error
False positive result	See alpha error
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 methods 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 β = 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_b	See Annex IV	MRL	Maximum Residue Limit
C_{max}	See Annex 4	MRM	Multi-Residue Method
C_{min}	See Annex 4	RRt	Relative retention value for a peak
CV_{Atyp}	See Annex 4	Rs	Resolution of two chromatographic peaks
CV_{Ltyp}	See Annex 4	SD	Standard Deviation
CV_{SP}	See Annex 4	$S_{y/x}$	Standard deviation of the residuals calculated from the linear calibration function
GLP	Good Laboratory Practice		
GSM	Group Specific Method		
		WHO	World Health Organization

PROPOSED DRAFT AMENDMENTS TO THE INTRODUCTORY SECTION OF THE RECOMMENDED METHODS OF ANALYSIS FOR PESTICIDE RESIDUES

(At Step 3 of the Procedure)

1. INTRODUCTION

1.1 Scope

The analytical methods listed are those which may, from practical experience of the Codex Committee on Pesticide Residues, be considered for the determination of pesticide residues for regulatory purposes. The list, given in par.2, is not exhaustive and methods not mentioned in the list can also be applied, provided that they can be shown to produce valid results, by the analyst using them.

1.2 Criteria for the selection of analytical methods

Whenever possible, the CCPR used the following criteria when selecting analytical methods:

i. Available through national or international standards organizations, books, manuals, open literature, the internet;

ii. collaboratively studied or known to have been validated in a number of laboratories. For single laboratory validated methods validation must have taken place according Guidelines on Good Practice in Pesticide Residue Analysis as a minimum;

iii. capable of determining more than one residue, i.e. multi-residue methods;

iv. suitable for as many commodities as possible at concentrations at or below the specified MRLs;

v. applicable in a regulatory laboratory equipped with generally available analytical instrumentation.

Preference was given to gas chromatography or high performance liquid chromatography as the separation step for the methods. Under certain conditions however, screening methods as defined in the Guidelines on Good Practice in Residue Analysis may be applicable. Screening methods are indicated in the list.

1.3 Application of methods

Before applying the methods it will always be necessary to validate the method and to demonstrate the competence of the analyst using it. T here is a further need for regular verification of the performance of the method during use. Validation and performance verification are described in the Guidelines on Good Practice in Residue Analysis.

PRIORITY LIST OF COMPOUNDS SCHEDULED FOR EVALUATION OR REEVALUATION BY JMPR

Following is the final list of compounds to be considered by the 2001 Joint FAO/WHO Joint Meeting on Pesticide Residues (JMPR) and the tentative schedule for the 2002 JMPR. Schedules for 2003 and beyond will need to be rearranged to accommodate the inclusion of more new compounds so that there is an approximately 50:50 split of new and periodic review chemicals.

2001 JMPR

Toxicological evaluations	**Residue evaluations**
New compounds	***New compounds***
	chlorpropham
imadocloprid	fipronil
spinosad	spinosad
Periodic re-evaluations	***Periodic re-evaluations***
lindane (048)	carbaryl (008)
methoprene (147)	diflubenzuron (130)
prochloraz (142)	dimethipin (151)
	diphenylamine (030)
	methomyl (094)/thiodicarb (154)
	propargite (113)
	piperonyl butoxide (062)
Evaluations	***Evaluations***
carbaryl (008)	aldicarb (117)
chlorpyrifos-methyl (090) – acute toxicity	2,4-D (020)
diazinon (022) – acute toxicity	haloxyfop (194)
diflubenzuron (130)	iprodione (111)
fenpropimorph (188) – acute toxicity	kresoxim-methyl (199)
imazalil (110)	tebufenozide (196)
methomyl (094)	
phosalone (060) – acute toxicity	
tebufenozide (196) – acute toxicity	

2002 JMPR

Toxicological evaluations	**Residue evaluations**
New compounds	***New compounds***
esfenvalerate (purified isomer of fenvalerate)	esfenvalerate (purified isomer of fenvalerate)
flutolanil	flutolanil
	imadocloprid
	thiophenatemethyl
Periodic re-evaluations	***Periodic re-evaluations***
acephate (095)	
metalaxyl-M (purified isomer of metalaxyl)	
methamidophos (100)	deltamethrin (135)
oxamyl (126)	oxamyl (126)
	pirimiphos-methyl (086)
tolylfluanid (162)	tolylfluanid (162)
triazophos (143)	
Evaluations	***Evaluations***
carbofuran (096) – acute toxicity	carbofuran (096)
ethephon (106) – acute toxicity	cyfluthrin (157)
fenamiphos (085) – acute toxicity	dithiocarbamates (105)
folpet (041) – acute toxicity	myclobutanil (181)
oxydemeton-methyl (166) – acute toxicity	phosmet (103)

2003 JMPR

Toxicological evaluations	Residue evaluations
New compounds	***New compounds***
cyprodinil	cyprodinil
dimethenamid-P	dimethenamid-P
famoxadone	famoxadone
methoxyfenozide	methoxyfenozide
	pyrochlostrobin
Periodic re-evaluations	***Periodic re-evaluations***
bendiocarb (137)	acephate (095)
carbosulfan (145)	ethoprophos (149)
cyhexatin (067)/azocyclotin (129)	fenitrothion (037)
glyphosate (158)	lindane (048)
paraquat (057)	metalaxyl-M (purified isomer of metalaxyl)
phorate (112)	methamidophos (100)
pirimicarb (101)	methoprene (147)
terbufos (167)	paraquat (057)
triadimefon (133) } should be evaluated	proclaraz (142)
triadimenol (168) } together	propineb
Evaluations	***Evaluations***
	carbendazim (072)
dimethoate (027) – acute toxicity	dimethoate (027)
malathion (049) – acute toxicity	dicloran (083)
	iprodione (111)

2004 JMPR

Toxicological evaluations	Residue evaluations
New compounds	***New compounds***
acibenzolar-S-methyl	*zeta*-cypermethrin
zeta-cypermethrin	fludioxonil
fludioxonil	trifloxystrobin
trifloxystrobin	
Periodic re-evaluations	***Periodic re-evaluations***
	endosulfan (032)
clofentezine (156)	bendiocarb (137)
flusilazole (165)	cypermethrin (118) – coordination required between JECFA and JMPR
propamocarb (148)	cyhexatin (067)/azocyclotin (129)
propiconazole (160)	glyphosate (158)
	phorate (112)
	pirimicarb (101)
	propiconazole (160)
	terbufos (167)
	triadmefon (133) } should be evaluated
	triadimenol (168) } together
	triforine (116)
Evaluations	***Evaluations***
guazatine (114)	guazatine (114)
	malathion (047)
	2-phenylphenol (056)
	triazophos (143)

2005 JMPR

Toxicological evaluations	Residue evaluations
New compounds	***New compounds***
quinclorac	quinclorac
	acibenzolar-S-methyl
Periodic re-evaluations	***Periodic re-evaluations***
benalaxyl (155)	clofentezine (156)
cyromazine (169)	flusilazole (165)
profenofos (171)	permethrin (120)
terbufos (167)	
Evaluations	***Evaluations***
ethoxyquin (035)	ethoxyquin (035)

2006 JMPR

Toxicological evaluations	Residue evaluations
New compounds	***New compounds***
Periodic re-evaluations	***Periodic re-evaluations***
procymidone (136)	benalaxyl (155)
	cyromazine (169)
	cyhalothrin (146)
	profenofos (171)
Evaluations	***Evaluations***

2007 JMPR

Toxicological evaluations	Residue evaluations
New compounds	***New compounds***
Periodic re-evaluations	***Periodic re-evaluations***
	procymidone (136)
Evaluations	***Evaluations***

ANNEX 1
CANDIDATE COMPOUNDS FOR PERIODIC RE-EVALUATION – NOT YET SCHEDULED
(confirmation of support required)

azinphos-methyl[1]
bioresmethrin[1]
buprofezin[1]
chlorpyrifos-methyl[1]
cyfluthrin (residues)[1]
dodine (residues)
fentin compounds[1]
fenvalerate
hexaconazole
hexythiazox[1]
monocrotophos[1]
paclobutrazol
phosphamidon[1]
vinclozolin[1]

[1]New candidate compound for periodic re-evaluation

ANNEX 2
CANDIDATE COMPOUNDS FOR PERIODIC ASSESSMENT OF ACUTE TOXICITY – NOT YET SCHEDULED

All such compounds have been scheduled.

ANNEX 3

COMPOUNDS PROPOSED FOR ADDITION TO THE PRIORITY LIST BUT FOR WHICH FURTHER CONSIDERATION IS REQUIRED BEFORE A DECISION CAN BE MADE

gentamicin
ddt (species)
lindane (species)
BHC (species)
oxytetracycline