

codex alimentarius commission

FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD HEALTH
ORGANIZATION

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ALINORM 93/24A

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

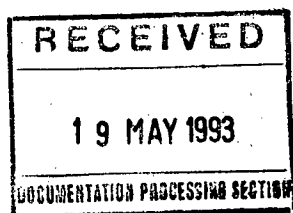
CODEX ALIMENTARIUS COMMISSION

Twentieth Session

Geneva, 28 June - 7 July 1993

**REPORT OF THE TWENTY-FIFTH SESSION OF THE
CODEX COMMITTEE ON PESTICIDE RESIDUES**

Havana, Cuba, 19 - 26 April



Note: This report incorporates Codex Circular Letter CL 1993/11 - PR

w/v0703

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CX 4/40.2

CL 1993/11 - PR
May 1993

TO: - Codex Contact Points
- Participants at the Twenty-fifth Session of the
Codex Committee on Pesticide Residues
- Interested International Organizations

FROM: Chief, Joint FAO/WHO Food Standards Programme, FAO,
Via delle Terme di Caracalla, 00100 Rome, Italy

SUBJECT: Report of the 25th Session of the Codex Committee on Pesticide Residues

The report of the 25th Session of the Codex Committee on Pesticide Residues (CCPR) (Ref. ALINORM 93/24A) will be considered by the 20th Session of the Codex Alimentarius Commission, to be held in Geneva from 28 June to 7 July 1993.

PART A: MATTERS OF INTEREST TO THE CODEX ALIMENTARIUS COMMISSION

The following matters will be brought to the attention of the 20th Session of the Codex Alimentarius Commission for adoption:

1. Draft MRLs and Draft Amendments to Codex MRLs at Steps 5 and 8

These are included in document ALINORM 93/24A - Add. 1 distributed separately.

2. Proposed Non-Substantial Changes to Codex Maximum Residue Limits

These are included in document ALINORM 93/24A - Add. 1 distributed separately.

3. Proposed Draft of "Method of Sampling for the determination of pesticide residues in milk, dairy product and eggs" at Step 5 (Appendix VI, ALINORM 93 /24)

Governments wishing to submit comments regarding the implications which the above matters or any provisions thereof may have for their economic interests should do so in writing in conformity with the Procedure for the Elaboration of Worldwide Codex Standards at Step 5 (see Codex Alimentarius Procedural Manual Seventh Edition) to the Chief, Joint FAO/WHO Food Standards Programme, FAO, Via delle Terme di Caracalla, 00100 Rome, Italy, no later than 20 June 1993.

PART B: COMMENTS AND/OR INFORMATION REQUESTED FROM GOVERNMENTS AND INTERESTED INTERNATIONAL ORGANIZATIONS

1. Inclusion of further pesticides in the Codex Priority Lists

Governments wishing to propose pesticides for inclusion in the Codex Priority List are requested to forward comments to Dr. Janet K. TAYLOR, Pesticide Directorate, Food Production and Inspection, Branch, Agriculture Canada, Ottawa, Canada K1A 0C6, with a copy to this office.

2. Specific Request for Residues and Toxicological Data Required for Evaluation by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR)

Information on use patterns, good agricultural practice, residue data, national MRLs, etc. should be sent to the FAO Joint Secretary, JMPR, Plant Protection Service, AGP, FAO, Via delle Terme di Caracalla, 00100 Rome, Italy.

Toxicological data should be sent to Dr. J.L. Hermann, International Programme on Chemical Safety, World Health Organization, 1211 Geneva 27, Switzerland.

(i) Pesticides scheduled for evaluation or re-evaluation by the JMPR (Annex I of Appendix V)

(ii) Pesticides for which the ADI was established from 1981 to 1982

Data on current GAP are requested for compounds included in para. 251 of the report (ALINORM 93/24A): Carbofuran, Chlorpyrifos, Cypermethrin, Deltamethrin, Propargite and 2, 4, 5 - T.

(iii) Pesticides for which MRLs are being elaborated

Azinphos-methyl (002) Scheduled for residue evaluation by the 1993 JMPR. Information on the commodities at Step 5 are requested (paras. 43-46).

Diazinon (002) Scheduled for toxicological and residue evaluation by the 1993 JMPR. Information on GAPs for barley, safflower seed, sunflower seed and wheat are requested (para. 52).

Ethion (034) Scheduled for residue evaluation by the 1993 JMPR. Information on residue data and GAP are requested of MRLs no more supported by manufacturer (para. 61).

Ethoxyquin (035) Scheduled for toxicological and residues evaluations by the 1994 JMPR. If data will not be provided, the deletion of MRLs would be recommended (para. 62).

Folpet (041) Scheduled for residue evaluation by the 1993 JMPR. Information on cherries and onions are requested (para. 66).

Formothion (042) Data on residue from trials based on the use of formation on citrus fruit are requested (para. 67).

Heptachlor (043) Reduction factors and monitoring data are requested for commodities for which an EMRL has been established (para. 68).

- Hydrogen cyanide (045) Information on agricultural applications are requested (para. 69).
- Inorganic bromide (47) Information on agricultural applications on fruits are requested (para. 70).
- Monocrotophos (054) Awaiting a full re-evaluation by the JMPR in 1994 national governments are requested to provide updated GAPs and residue data (para. 75).
- Omethoate (055) The Committee noted that there is still a registered use by several countries and decided to request information on current GAP and the manufacturer involved (para. 77).
- Ortho-phenylphenol (056) Information on data availability concerning the registered use and manufacturer involved are requested (para. 78).
- Piperonyl Butoxide (062) Data on cereals other than wheat are requested (para. 85).
- Pyrethrins (063) Delegations were invited to submit data in time for a tentatively scheduled review of 1994 JMPR and to inform about the manufacturer (para. 86).
- Bromopropylate (070) Scheduled for toxicological and residue evaluation by the 1993 JMPR. Data in support of the MRLs on banana, cherries nectarine and tea are requested (para. 93).
- Disulfoton (074) Requested information on residue definition and national intake (paras. 98 and 100).
- Dicloran (083) Governments are invited to submit data on current GAP because the compound will probably be recommended for deletion (para. 121).
- Chlorpyrifos-methyl (090) Governments are invited to inform JMPR on current GAP for all cereals, including barley, oats and rice (paras. 124-125).
- Methamidophos (100) Governments are requested to provide data on GAP and residues to the JMPR (para. 130).
- Fenbutatin oxide (109) The compound is on the agenda of the 1993 JMPR for periodic review. Governments are requested to provide any supporting data for gherkin, melons except watermelon and sweet peppers (para. 136).
- Amitraz (122) Governments are requested to submit information of national residue definitions (para. 146).
- Bendiocarb (137) Supporting data for mashrooms; rice straw and fodder dry and rice husked which are recommended for deletion (para. 168).
- Flusilazole (165) Governments are invited to submit information on current GAP and residue data on nectarine and peach which have a temporary status due to the limited availability of data (para. 183).

- Hexaconazole (170) Information are requested on methods of analysis for regulatory purposes (para. 190).
- Buprofezin (175) Additional data are requested for the compound scheduled for the 1994 JMPR (para. 194).
- Hexythiazox (176) Additional data on GAP and residues are requested by governments (para. 197).

3. Expression and Application of MRLs for fat soluble pesticides in meat, animal fat and edible offal

The Committee discussed several approach concerning the expression and application of fat soluble residues in animal products and decided to append the Working Paper prepared by The Netherlands to the Report of the 25th Session of the CCPR (ALINORM 93/24A) as Appendix II, requesting government comments (paras. 220-222).

Comments should be sent to Mr. D.G. Kloet, Ministry of Agriculture, Nature Management and Fisheries Department for the Environment, Quality and Nutrition, P.O. Box 20401, 2500 EK Den Haag, The Netherlands, with a copy to this office, preferably not later than 31 December 1993.

4. Methods of Analysis

Governments, manufacturers and concerned international organizations are requested to provide information on methods of analysis for: hexaconazole, buprofezin, cycloxydim, dithianon, clethodim, fenpropimorph, tebuconazole and telelofosmethyl.

Information are also requested on limits of determination for phorate and prochloraz.

Comments should be sent to the Chairman of the Working Group on Method of Analysis, Mr. L.G.M.Th. Tuinstra, Ministry of Agriculture, Natural Management and Fisheries, State Institute for Quality, Control of Agricultural Products, P.O. Box 230, 6700 AE Wageningen, The Netherlands, not later than 31 December 1993.

5. Identification of Problems Relative to Pesticide Residues in Foods in Developing Countries

Governments, manufacturers and concerned international organizations are solicited to provide information on impediment to the development and submission of residue data by developing countries and on specific pesticide/commodity combinations of interest to developing countries for food moving in international trade. Information are also requested on MRLs adopted by Codex which represent export/import problems for developing countries.

Comments should be sent to the Chief, Joint FAO/WHO Food Standards Programme, FAO, Via dell Terme di Caracalla, 00100 Rome not later than 31 December 1993.

SUMMARY AND CONCLUSIONS

The Twenty-fifth Session of the Codex Committee on Pesticide Residues (CCPR) reached the following conclusions during its deliberations:

Matters for Consideration by the Commission:

- Recommended the adoption of Draft MRLs and draft amendments to Codex MRLs at Step 5 and 8 as included in document ALINORM 93/24A - Add. 1.
- Recommended the adoption of proposed draft of "Method of Sampling for the determination of pesticide residues in milk, dairy products and eggs" as published in ALINORM 93/24 Appendix VI (paras. 223-227).
- The Committee also concluded that sampling procedures related to fish were of little interest to the CCPR as long as no MRLs for fishery product were elaborated.

Other Matters of Interest to the Commission:

- The Report of the 1992 Joint FAO/WHO Meeting on Pesticide Residues (JMPR) was discussed in detail (paras. 15-21). The Committee noted that the 1992 JMPR drew attention to some of the general considerations and specific problems such as data requirements under the periodic review programme, the general policy on the use of temporary MRLs and request for countries to provide information on their approach to requiring animal studies in relation to residues in animal feeds (paras. 15-21).
- The Committee received a report on the status of acceptance by member countries and was informed that several countries were currently in the process of notifying their position on acceptance of MRLs. The Committee also noted that MRLs at the limit of determination representing a non-residue situation could be easily accepted by member countries under "free distribution" (paras. 22-28).
- The Committee received a report from WHO on dietary intake estimates and it was stressed that the Estimated Maximum Daily Intakes calculated on those pesticides for which the Theoretical Maximum Daily Intakes exceeded the ADI did not contain all of the correction factors that might be justified and were still substantial overestimates of the true intake (paras. 29-38).
- Draft MRLs were considered in the light of comments received. The Committee decided to postpone discussion of individual proposals at Step 3 and some of the proposals at Step 6 arising from the 1992 JMPR in view of the fact that the 1992 Evaluations had not yet been published (paras. 39-200).
- The Committee received a report for combining limits of related compounds and expressed its preference to harmonize the residue definition and to combine MRLs for related compounds into a single list (paras. 201 - 209).
- The Committee supported the elaboration of a separate list of Extraneous Maximum Residue Limits (EMRLs) for pesticides and agreed that the list should continue to be updated regularly (i.e., every 5 years) as further monitoring data become available (paras. 210 - 214).

SUMMARY AND CONCLUSIONS (cont.d)

- The Committee considered the Guideline levels at Step 4 and decided to delete the guidelines levels for coumaphos because no information on agricultural uses were received (para. 215 - 219).
- The Committee examined different approaches for the expression and application of MRLs for fat soluble pesticides in meat, animal fat and edible offal and in view of the complexity of the solution proposed, decided to request comments from member countries and to continue the discussion on this issue at the next session of the CCPR (paras. 220 -222).
- The Committee endorsed the recommendation presented by the Working Group on Acceptances as contained in Appendix III and agreed that FAO and WHO Joint secretaries of JMPR should request national data and information to review global and regional diets, relationship between MRL's and dietary intake and national EDI calculations, in order to contribute to a review of Guidelines (paras. 228-233).
- The Committee made recommendations concerning the identification of pesticides and pesticide/commodity combinations of interest to developing countries, generation of specific regional GAP and procedures to generate data, identification of MRLs adopted by Codex which represented export/import problems for developing countries (paras. 242-247).
- Priority lists of pesticides were adopted for new compounds and for periodic review for the guidance of the JMPR, governments and industry regarding the generation of data and the evaluation of pesticides and their residues. A periodic review procedure (Appendix IV - Annex II) was adopted by the Committee (paras. 248-251).

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INTRODUCTION

1. At the invitation of the Cuban Government, the Codex Committee on Pesticide Residues held its 25th Session in Havana, Cuba, from 19-26 April 1993. Dr. W.H. van Eck, of The Netherlands Ministry of Welfare, Health and Cultural Affairs served as Chairman. The Session was attended by 35 Codex member countries and 6 international organisations. The list of participants is attached as Appendix I to this report.

OPENING OF THE SESSION (Agenda Item 1)

2. The Session was opened by Mr. Augusto Simoes Lopes, Permanent Representative of FAO in Cuba, Mr. Miguel Márquez, Permanent Representative of the Pan American Health Organisation in Cuba, Mr. Steven van Hoogstraten, on behalf of the State Secretary of the Ministry of Welfare, Health and Cultural Affairs of The Netherlands, and Mr. Carlos Pérez, Minister of Agriculture of Cuba.

3. Mr. Simoes Lopes, speaking on behalf of the Director General of the FAO, Mr. Edouard Saouma, thanked the Governments of Cuba and The Netherlands for making it possible to hold the 25th Session of the CCPR in Cuba. He emphasized the importance of the work of the Committee over the past 25 years to improve food quality and safety by establishing MRLs, as recognized by the Codex Alimentarius Commission. He mentioned the progress made within the GATT Uruguay Round of the Multilateral Trade Negotiations, and the role of international organisations such as FAO and Codex regarding facilitation of international trade. He wished the Committee the best of luck and success in its deliberations.

4. Mr. Márquez of the Pan American Health Organisation underlined the usefulness of the recommendations made by the Committee, and thanked the organizers and the Cuban Government for taking the opportunity to bring the Committee to Cuba this year.

5. Mr. van Hoogstraten, representing the State Secretary of Welfare, Health and Cultural Affairs of The Netherlands, congratulated the FAO, the WHO and the Committee on reaching this memorable milestone in its history. He mentioned the willingness of the Dutch Government to host future meetings of the CCPR and noted that holding this meeting in Havana underlines the importance The Netherlands attaches to the contribution of developing countries to the work of the CCPR. He mentioned that the first meeting of the Committee in The Hague in 1966 was attended by 16 countries and a few international organisations, and that since then participation has increased to almost 50 Governments and 12 international organisation. He also noted that subjects like the periodic review of old compounds and risk assessment of recommended MRLs are of particular importance, as both issues often hamper acceptance of CXLs. He also noted the growing demand to coordinate activities at the international level with regard to pesticide evaluations. Looking into the future, he emphasized the enormous task facing the CCPR, in the coordination of risk assessment strategies as well as the identification and resolution of the problems and needs of developing countries.

6. Mr. Pérez, Minister of Agriculture of Cuba, welcomed the Committee to Cuba. He referred to the importance of the work of the Codex Alimentarius Commission, mentioning in particular the benefits for developing countries, and noted the efforts made by the Government of Cuba to host this Session of the CCPR. He illustrated the progress made in Cuba in the field of public health,

especially in relation to the reduction of infant mortality. He also mentioned progress made in organizing the agricultural infrastructure in Cuba. The Cuban registration system assured that the use of pesticides was minimized by developing good agricultural practices and promoting the use of biological agents. He indicated that Cuba will continue to co-operate with international organisations like the CCPR and thanked the Dutch Government for the opportunity to organize, in close co-operation between both countries, the 25th Session of the CCPR in Cuba.

7. The Chairman thanked the speakers for their contributions to the opening of the 25th Session of the Committee, for their kind and interesting words, for the recognition from member countries and international organisations of the importance of the activities of the CCPR and for the opportunity to hold this 25th Session in Cuba. He also mentioned the receipt of a letter from a former chairman of the CCPR, Mr. J. Van der Kolk, who sent his best wishes on the occasion of the 25th Session of the Committee.

ADOPTION OF THE AGENDA (Agenda Item 2)

8. The Committee agreed to adopt the Provisional Agenda (CX/PR 93/1) as proposed.

APPOINTMENT OF RAPORTEURS (Agenda Item 3)

9. Mr. R. M. Parry, Jr. (United States of America) and Mrs. R. R. Hignett (United Kingdom) were appointed to act as rapporteur and as co-rapporteur to the Committee, respectively.

MATTERS OF INTEREST (Agenda Item 4)

Matters of Interest Arising from Other Codex Committees (Agenda Item 4(a))

10. The Committee had for its consideration document CX/PR 93/2 when discussing this agenda item, which summarized matters of interest arising from other Codex Committees as well as from the International Conference on Nutrition. It was noted that most of these issues were presented for information only or were scheduled for discussion elsewhere, the Committee focused its discussions on the following.

Alignment of Codex Elaboration Procedures

11. In response to concerns that priority lists developed by the CCPR at each of its Sessions would be subject to the step elaboration and approval process through the Commission (para. 41, Alinorm 93/33), the Committee was reassured that this proposal of the Codex Committee on General Principles simply reflected the current situation. When priority lists are appended to CCPR reports and the reports are then adopted by the Commission, this process reflected the actual de facto adoption of such lists.

Matters of Interest Arising from Other International Organizations (Agenda Item 4(b))

12. The Committee noted that the Netherlands was hosting the XIII International Plant Protection Congress in The Hague, from 2-7 July 1995.

13. The delegation of Canada informed the Committee that its previous publication concerning National Pesticide Residue Limits in Foods (1990) was now available in an updated computerized version in Wordperfect 5.1. It was indicated that among other issues, the diskettes included information on pesticide residue limits in 40 countries as well as Codex, which can be updated by individual countries as appropriate.

International Union of Pure and Applied Chemistry (IUPAC)

14. The Committee was informed of the IUPAC Workshop on the Assessment and Management of Risks from Pesticide Use in South East Asia, which was held in Thailand in November 1992. Other IUPAC activities include projects on the Effects of Storage and Processing on Pesticide Residues in Plant Products, a Glossary of Terms, Definitions and Abbreviations Related to Agrochemicals, and proposed projects on Dietary Intake of Pesticide Residues - Risk Assessment, Quality Standards for Residue Monitoring in Environmental Matrices and Pesticide Transformation in Soils in the Tropics. As a final matter, preparations for the 8th International Congress of Pesticide Chemistry (Washington, D.C., 4-9 July 1994) were also highlighted.

CONSIDERATION OF THE REPORT OF THE 1992 JOINT FAO/WHO MEETING ON PESTICIDE RESIDUES (Agenda Item 5)

15. The Report was briefly introduced by the JMPR Joint Secretaries and the Chairman of the 1992 JMPR.

16. The Report was published by FAO in February 1993 as FAO Plant Protection Paper 116. A total of 46 pesticides were considered. Seven pesticides were evaluated for the first time and nine were on the agenda on the basis of the periodic review programme.

17. The attention of the Committee was drawn to some of the general considerations and specific problems addressed in the Report. In particular data requirements under the periodic review programme and the general policy on the use of temporary MRLs were noted. Delegations were encouraged to refer to this information in preparing for future JMPRs.

18. The Committee was informed that only a single country had provided information on their approach to requiring animal studies in relation to residues in animal feeds as requested by the 1992 CCPR (Alinorm 93/24, para 189). Delegations were requested to provide this information to the FAO Joint Secretary by June 30, 1993 in order that a working paper might be prepared for the consideration of the 1993 JMPR.

19. It was noted that the workload of the JMPR reviewers had significantly increased as a result of the number of new compounds proposed for review and reevaluation and that the review of some compounds was postponed as a result. Efficiencies in the operation of the Joint Meeting have been introduced which have resulted in increased consistency in the presentation of the information in the evaluations and the Report. The delegations of several countries expressed their support for the work of the JMPR and the increased detail and clarity of the evaluations.

20. The representative of the EEC supported JMPR in its endeavour to clarify the data requirements for the periodic review programme, in particular the need to update GAPs after a 10 year period and to withdraw MRLs in the absence of data supporting them. However, changes in GAP can and do sometimes occur after

less than 10 years. Therefore, delegations should notify CCPR as soon as changes in GAP arise so that they can be considered as soon as possible. This was considered to be one way in which to increase the acceptance of Codex MRLs.

21. Countries and manufactures were requested to provide the JMPR with all relevant toxicology and residue data and GAP information for compounds scheduled for review.

REPORTS ON ACCEPTANCES BY GOVERNMENTS OF CODEX MRLs (Agenda Item 6)

Summary of Acceptance Received (Agenda Item 6 (a))

22. The Committee had before it document CX/PR 93/3 containing a summary of the status of Codex and draft MRLs in discussion at different steps of the Codex procedure. The document also included information on the number of Codex MRLs at or about the limit of determination, which represented 21 per cent of total Codex MRLs. It was noted that as such MRLs represented a non-residue situation, they could be easily accepted by member countries under "free distribution".

23. The Committee noted that Codex MRLs were often used as reference points for the establishment of national food standards and food laws. Several countries had also initiated procedures for acceptance of Codex MRLs for pesticides in food.

24. The delegation of the United States indicated that the proposal that MRLs at the limit of determination would be considered under "free distribution". They also hoped that information received recently could be included in the report to the Commission to improve the rather disappointing response in acceptances by countries.

25. The Committee also noted with interest that most of the countries which had notified of acceptance of Codex MRLs were developing countries, while only few notifications had been transmitted by developed countries.

Reports by Delegates (Agenda Item 6 (b))

26. The delegations of Brazil, Argentina and Cuba informed the Committee that reviews of Codex MRLs had been undertaken at the national level and that further notification of acceptance would be transmitted to the Codex Secretariat.

27. The delegation of Japan informed the Committee that MRLs for a number of pesticide/commodities combinations were under consideration in relation to the National Food Sanitation law, but that the general approach in Japan was that no Codex MRLs could be accepted if the TMDI or EMDI exceeded the ADI. The delegation also recommended that MRLs should be as low as possible.

28. The delegation of Norway stated that their country had not yet established national MRLs but Codex MRLs were followed as guideline levels. They were in the process of establishing national limits in line with EEC standards, but that Codex MRLs will be considered and implemented when no tolerance had been established by EEC.

CONSIDERATION OF INTAKE OF PESTICIDE RESIDUES (Agenda Item 7))

Progress Report by WHO on Dietary Intake Estimates (Agenda Item 7(a))

29. The Committee had before it CX/PR 93/4 (Progress Report by WHO on Prediction of Dietary Intake of Pesticide Residues) and CX/PR-93/4 Add.I, which provided details of the calculations and of the diets used in predicting these intakes. Theoretical Maximum Daily Intake (TMDI) and Estimated Maximum Daily Intake (EMDI) calculations, using the methods described in "Guidelines for Predicting Dietary Intake of Pesticide Residues" (WHO, 1989), had been performed on all of the pesticides evaluated by the 1992 Joint FAO/WHO Meeting on Pesticide Residues (JMPR). In addition, as requested at the Twenty-fourth Session of the CCPR, TMDI/EMDI calculations had been carried out for azinphos-methyl, benomyl, carbendazim, and thiophanate-methyl.

30. As described in the Guidelines, the TMDI is a gross overestimate of true pesticide intake because, among other reasons, very few of the crops treated with a pesticide contain the maximum residue level, residues are normally reduced through storage, preparation, commercial processing and cooking, and it is unlikely that each and every food for which an MRL is proposed will have been treated with the pesticide.

31. While the EMDI is a better estimate of intake than the TMDI, it is still an overestimate of the true pesticide residue intake because the proportion of a crop treated with a pesticide is usually far less than 100% and very few of the crops treated contain residue levels as high as the MRL, from which levels in the edible portion, processed and cooked commodities are derived.

32. In carrying out EMDI calculations, information on residue levels in the edible portion of the commodity and upon processing and cooking was seldom available. Thus, the EMDIs calculated on those pesticides for which the TMDIs exceeded the ADI did not contain all of the correction factors that might be justified and were still substantial overestimates of the true intake.

33. If the EMDI exceeds the ADI, it is necessary to try to estimate more closely the true intake by calculating the Estimated Daily Intake (EDI). Calculation of the EDI takes into account several reduction factors described in the Guidelines, which are available only at the national level. EDI predictions can be performed only on a national basis by those who have adequate information on food consumption, the use of a given pesticide locally, and the nature and the amount of imported food.

Report on Pesticide Residue Intake Studies through the Joint FAO/WHO/UNEP Food Contamination and Assessment Programme (Agenda Item 7(b))

34. The Committee had before it CX/PR 93/5, Report on pesticide residue intake studies through the Joint FAO/WHO/UNEP Food Contamination and Assessment Programme (GEMS/Food), which highlighted progress during the past year.

35. During 1991 and 1992, the latest in a series of analytical quality assurance (AQA) exercises were carried out for aflatoxin, organochlorine compounds and heavy metals (lead, mercury and cadmium) in cooperation with the International Agency for Research on Cancer (IARC), the National Food Authority of Sweden and the Ministry of Agriculture, Fisheries and Food of the United Kingdom, respectively. A report on the results of these exercises will be published in 1993. During 1992, two training courses were sponsored by GEMS/Food on the analysis of organochlorine residues in food, one in Guatemala and the other in Brazil.

36. In Europe, GEMS/Food has been greatly expanded by the establishment of GEMS/Food/EURO, which is administered by the WHO European Centre for Environment and Health in Rome. It is anticipated that GEMS/Food/EURO will contribute significantly to both the quality and quantity of data reported to GEMS/Food in the future.

Reports on Pesticide Residue Intake Studies by Delegations (Agenda Item 7(c))

37. The delegations of Australia, Finland, Spain, Sweden, United Kingdom, and United States reported on intake studies and market basket surveys which had been performed in their countries. In nearly all cases EDIs and other intake calculations based on these studies indicated that in practice dietary intakes of pesticides were very low, usually less than 1% of the ADI. The delegation of Belgium stated that a study was underway and that the results would be submitted to CCPR when available.

38. The representative of GIFAP announced the publication of a position paper on pesticide residues in food. An executive summary was distributed, and the position paper will be sent to all participants at the present Session of CCPR in the near future.

CONSIDERATION OF MAXIMUM RESIDUE LIMITS (Agenda item 8.1 (a), (b), (c) and (d))

39. The Committee had before it the following documents:

- CX/PR 93/6, 7 and 8 containing government comments on the MRL's under discussion;
- CX/PR 2-1993 "Status of Codex Maximum Residue Limits for Pesticides in Food and Animal Feed";
- CX/PR 3-1993 "Status of Pesticides for which Guide-line Levels have been set";
- CX/PR 93/6, 7, 8 add. 1 containing additional government comments and
- CX/PR 93/9 "Codex Maximum Limits for Fruit and Vegetables".

40. The Committee discussed the appropriate timing for discussions of proposals of the 1991 and the 1992 JMPRs. The Committee noted that the 1992 JMPR evaluations had not yet been published and therefore were not available to the meeting. The Committee also noted that the 1991 JMPR evaluations were published in October of 1992, but were not available to several governments until recently and that therefore, delegations may not have had sufficient time to give full attention to the report.

41. In view of this situation, the Committee decided to postpone the discussions on the proposals of the 1992 JMPR to the next Session of CCPR in 1994. The Committee also agreed to discuss at the current Session the proposals from the 1991 JMPR, but to give careful consideration to decisions on the advancement through the step procedure. If necessary, it would not advance the proposals but would allow for a second round of comments.

ALDRIN AND DIELDRIN (001)

42. The Committee decided to postpone decisions to the 26th CCPR.

AZINPHOS-METHYL (002)

43. The Committee noted that the 1991 JMPR had reevaluated both toxicological and residue data. The WHO carried out TMDI calculations for regional diets, showing that for the European diet the TMDI exceeded the ADI. The monitoring data available indicated, however, that there was less reason for concern. The representative of the manufacturer informed the Committee that residue data would only be available for cherries and grapes for the 1993 JMPR and the 1995 JMPR, respectively. Data for the other commodities requested by the 1991 JMPR were not expected.

44. Many delegations expressed their concern for the proposed MRLs of commodities (e.g., apple and pear) which show that the calculated TMDI exceeds the ADI. In addition the Representative of the EEC drew attention to the wide variation underlying GAPs and suggested that it should be possible to adjust the more extreme GAPs to lead to lower residue level. The Delegation of Germany was requested to perform EDI calculation for evaluation by the JMPR. Other delegations were of the opinion that some recommended MRLs, based on higher application rates and lower pre harvest intervals compared to their national uses, were too high. The Committee invited these delegations to submit the relevant data to the 1993 JMPR. The Delegation of France questioned the validity of some MRLs and was invited by the Committee to send their comments to the 1993 JMPR. The Delegation of the United States of America reserved their position in view of the re-registration procedure. The Delegation of Spain defended the use of extrapolation of data between similar commodities and was invited by the Committee to present the relevant data on GAP and residues including the method of extrapolation to the JMPR. The Delegation of Chile was invited by the Committee to give information on GAP and residue data for kiwifruit. The manufacturer informed the Committee that some uses would be dropped and other commodities would be supported in the United States of America re-registration process.

45. The Committee decided to postpone the deletion of CXLs for vegetables and fruits until the separate commodities reach Step 8. The Committee decided to recommend deletion of the CXLs for apricot, brussels sprouts, celery, citrus fruits, grapes, pea vines, kiwifruit, soya bean forage (green) and sunflower seeds because not supported by sufficient data. The manufacturer provided a list of commodities which will be supported with azinphos-methyl data in USA.

46. The Committee decided to advance the MRLs of the commodities at Step 3 to Step 5.

Status of MRLs

At Step 5: alfalfa fodder; alfalfa forage (green); almonds; apple; blueberries; cherries; clover hay or fodder; cranberry; cucumber; melons, except watermelon; nectarine; peach; pear; pecan; peppers, sweet; plums (including prunes); potato; soya bean (dry); sugar cane; tomato; walnuts; watermelon; wheat; wheat straw and fodder dry.

CARBOPHENOTHION (011)

47. Since the compound was no longer being manufactured and no information about registered uses had become available, the Committee decided to recommend deletion of all CXLs.

CHLORDANE (012)

Fruits and vegetables

48. The Committee noted that no action was required and maintained the EMRL at the limit of determination.

CHLORMEQUAT (015)

49. The Delegation of Sweden would try to provide data on GAP and residues for rye. Several other Delegations informed the Committee that they had registered GAP on a range of commodities. The manufacturer would be contacted to confirm data availability and the compound would be scheduled for consideration at a future JMPR.

CHLOROBENZILATE (016)

50. Since the compound was no longer being manufactured and no information about registered uses had become available, the Committee decided to recommend deletion of all CXLs.

COUMAPHOS (018)

51. As no new information on agricultural uses had become available since the 24th CCPR, the Committee decided to recommend deletion of all Guidelines Levels.

DIAZINON (022)

52. The Joint FAO Secretary informed the Committee that this compound was scheduled for toxicological and residue evaluation by the 1993 JMPR and that CXLs for barley, safflower seed, sunflower seed and wheat would not be supported by the manufacturer. If no new information on GAPs or relevant residue data were provided, the MRL's for these commodities would be recommended for withdrawal.

DICHLORVOS (025)

53. The Committee was informed that this compound was scheduled for toxicological and residue evaluation by the 1993 JMPR. The Joint FAO Secretary informed the Committee that the manufacturer had submitted a complete data package supporting all current uses in fruits. In addition some animal transfer studies were available.

DICOFOL (026)

54. Discussions on proposals at step 3 were postponed because the 1992 JMPR Residue Evaluations were not available at the meeting.

DIMETHOATE (027)

55. The Committee noted that dimethoate was scheduled for residue evaluation by the 1993 JMPR. For commodities that were held at step 7B data had become available from the United Kingdom (GAP and residue data on lettuce) and Italy (GAP for wheat and rice). Data on brussels sprouts, cabbages head and plums had been presented by The Netherlands but had not yet been received. For the

commodities at Step 7C the manufacturers would provide data generated in the mid-1960's since no further trials were planned and these would be re-evaluated in the light of current information on GAPs.

56. The Committee decided to maintain the proposals at steps 7B and 7C pending evaluation by the JMPR.

DIPHENYL (029)

57. The Committee agreed to recommend deletion of the CXL for citrus fruits.

DIQUAT (031)

58. The Committee noted that diquat was scheduled for toxicological and residue evaluation by the 1993 JMPR. The Committee agreed to maintain the CXL for vegetables since it was at the limit of determination.

ENDOSULFAN (032)

59. The Committee noted that endosulfan was scheduled for residue evaluation by the 1993 JMPR. Data had been submitted by Portugal, Finland and the manufacturer for those commodities for which MRLs were held at step 7B. Action on the general CXLs for fruits and vegetables was postponed pending the JMPR evaluation.

ENDRIN (033)

60. Discussions on the proposal at step 3 and the recommendation to withdraw a number of EMRLs were postponed because the 1992 JMPR evaluations were not available at the meeting.

ETHION (034)

61. The Committee noted that ethion was scheduled for residue evaluation by the 1993 JMPR. At the 1991 CCPR, GAP and relevant residue data were requested in order to reconsider the existing CXLs. Residue data will be provided by one manufacturer to support MRLs for the following commodities: apples, citrus fruits, maize, grapes, pear, plums, cucumbers, melons, squash, poultry meat and edible offal of poultry. No residue data were available for the other commodities for which CXLs have been set. Information on GAP had only been provided by Cyprus, Greece, Kenya and the United States of America.

ETHOXYQUIN (035)

62. The Committee noted that ethoxyquin was scheduled for toxicological and residue evaluation by the 1994 JMPR. The Joint FAO Secretary could not inform the Committee whether data would become available. The delegation of France asked what the position of the FAO and WHO would be if no data became available for the 1994 JMPR. The Joint WHO Secretary responded that in that case withdrawal of the CXLs would be proposed.

FENTIN (40)

63. The Committee decided to recommend deletion of the current CXLs for cacao beans, carrot, celeriac, celery and coffee beans because no new information was available.

64. The FAO Joint Secretary mentioned that the manufacturer had indicated that residue data for pecans and peanuts will be available in 1994 and the Committee decided to postpone their deletion.

65. The delegation of France stated that results from trials for hops (1991 Evaluations, p. 346) were lacking in sufficient clarity (real figures at 0.2 and 0.3 mg/kg, and others < 1.01 mg/kg). The delegation pointed out that MRLs should not be based on very variable data and suggested as being more appropriate an MRL of 0.5 mg/kg and agreed to provide written comments to JMPR. The delegation of Spain informed the Committee that the use of fentin in hops is forbidden for ecotoxicological reasons, as it has a negative impact on the environment. The representative of the EEC stated that the compound was recently evaluated. He pointed out that two of residues from trials reported at 1.01 by the JMPR should in fact read 0.01 mg/kg. An MRL of 0.5 mg/kg for hops, dry was agreed. The data will be sent to the 1993 JMPR. The Committee decided to advance the proposal for hops, dry to Step 5.

Status of MRLs:

At Step 5: hops, dry.

FOLPET (41)

66. The Committee was informed that the manufacturer provided information for all products with a TMLR, except for cherries and onions. It was on the agenda of the JMPR 1993 for toxicological and residue evaluation. The results of the long term studies are not yet available so the toxicological evaluation was likely to be postponed to 1994. The Committee agreed to keep the TMRLs for at least one year.

FORMOTHION (042)

67. The compound was removed from the 1993 JMPR schedule because insufficient data were available as confirmed by the manufacturer. The delegation of France informed the Committee that the MRL for dimethoate on citrus fruit was based on the use of formothion, and that the compound was not found as such. There was no reason for keeping an MRL for formothion. The delegation of the United States of America informed the Committee that some MRLs for dimethoate were based on formothion uses. The Committee was informed no further action would be taken until next year, giving delegations and individuals the opportunity to submit data. The Committee requested the JMPR to take into account formothion and also omethoate when dimethoate is evaluated.

HEPTACHLOR (043)

68. The compound was on the agenda of the 1991 JMPR for toxicological and residue evaluations. The Committee was informed that the TMDI is greater than the ADI and that no reduction factors were available. The Committee decided to postpone a decision while awaiting the 1993 JMPR evaluation.

HYDROGEN CYANIDE (045)

69. The delegation of Israel informed the Committee that there were no uses. The delegation of The Netherlands informed the Committee that there were registered uses on grain, nuts and several agricultural applications. The Committee agreed to consider the situation next year.

INORGANIC BROMIDE (047)

70. The 1992 JMPR did not make any recommendations with regard to the general MRL on fruit, since no further information was supplied. The Committee was informed that withdrawal of the MRL for fruit would be postponed until the next session of the CCPR.

MANCOZEB (050)

71. The dithiocarbamates, viz, mancozeb, maneb, propineb and their metabolites ethylene thiourea and prophylenethiourea were scheduled for periodic toxicological and residue re-evaluations and zineb for periodic toxicological re-evaluation. The Committee was informed that mancozeb was scheduled for periodic re-evaluation by the 1993 JMPR.

METHIDATHION (051)

72. The Committee noted that this compound was evaluated for toxicology and residue limits by 1992 JMPR and therefore postponed the discussion to its next Session.

METHYL BROMIDE (052)

73. See the discussion under Agenda Item 8.2 "Reconsideration of Guideline Levels" (para. 217).

MONOCROTOPHOS (054)

74. The Committee noted that the 1991 JMPR had re-evaluated the compound and lowered the ADI to 0.00005 mg/kg bw. JMPR also confirmed a number of MRLs. However, this evaluation could not be considered as a full evaluation of both toxicological and residue data. The Committee was informed that a toxicological review was scheduled for the 1993 JMPR. The Committee noted the very low ADI and expressed its concern with regard to the toxicity of the compound and its use in food crops. Many delegations therefore expressed a general reservation on its use and were of the opinion that it should only be used in those situations where it was indispensable and that only those limits which were at or below the limit of determination were acceptable. Giving its comments, the representative of the EEC, supported by several other delegations, noted the relatively high limit of determination and requested the manufacturer to investigate analytical methods with a lower limit. Several Delegations were also of the opinion that many CXLs were based on obsolete practices and that current uses of the compound were limited. The Delegation of the United Kingdom expressed its concern regarding the possible presence of the compound in tea brewed from treated leaves. The representative of a major manufacturer agreed to the deletion of MRLs for pears, apples and tomatoes. However, he informed the Committee that the compound is still approved for use in these and a number of other commodities in several countries. Several delegations informed the Committee that the compound was still registered in their country, but that they were aiming to reduce its use. The Delegations of Mexico and France emphasized that there were some important uses in their countries, but that they were reducing its use.

75. The Committee decided not to advance any MRL currently at Step 3 or to propose the deletion of the existing CXLs at this Session but to await a full re-evaluation by the JMPR in 1994 based on updated GAPs and residue data to be provided by national governments. It also agreed to send out a CL requesting Governments to inform the JMPR on registered uses in their countries and to

request submission of any relevant monitoring data. The Committee also requested national authorities to take note of the concerns expressed during the discussion and to review their registered uses in food crops at the national level. The Committee did not agree to a proposal from the Delegation of Sweden, supported by the Delegations of Norway and Finland that a recommendation should be made to the next Session of the CAC to withdraw a number of the existing MRLs. The Committee agreed to await the re-evaluation of all MRLs in 1994 and the toxicological evaluation of the 1993 JMPR. The Committee also agreed to a proposal from the Delegation of the United States of America that the 1993 JMPR should be requested to comment on the acute hazard from dietary intake posed by this compound in relation to cholinesterase inhibition.

OMETHOATE (055)

76. The representative of the manufacturer informed the Committee that a full data package would not be provided as was agreed at the twenty-fourth session of the CCPR. The compound was withdrawn from the schedule of the JMPR. The Delegation of the United States of America indicated that their dimethoate tolerance accommodates the omethoate residues.

77. The Committee noted that there is still a registered use by several countries and decided to request, by circular letter, information on current GAP and the manufacturer involved.

ORTHO-PHENYLPHENOL (056)

78. The Committee noted that ortho-phenylphenol was on the agenda of the 1994 JMPR for residue evaluation. The Committee decided to request, by circular letter, information on data availability concerning the registered use and manufacturer involved.

PARAQUAT (057)

79. The Committee noted that vegetables had an MRL at the limit of determination and no action was required.

PARATHION (058)

80. The Committee noted that parathion had been evaluated for residues by the 1991 JMPR and was scheduled for toxicological evaluation by the 1994 JMPR.

81. The Delegation of the United States of America indicated that the registered uses for some commodities were voluntarily cancelled. For other proposed MRLs based only on GAP in the United States of America it was noted that the current GAP of USA was still pending. The Committee agreed to add a footnote for cotton seed, maize, sorghum, soya bean (dry) and sunflower seed related to future review. The Delegation of Germany informed the Committee that the manufacturer will seek re-registration and indicated that a higher MRL for pomefruit was necessary. Several delegations noted that the use of parathion was discontinued or withdrawn. The Delegation of the United States of America reserved their positions in view of the re-registration. The Representative of the EEC reserved their position on the proposed MRLs considering that the ADI dated back to 1967 and the eminent JMPR toxicological review. The Delegation of Spain indicated that for olive oil the TMDI exceeded the ADI and was invited by the Committee to send these results to the JMPR.

82. The Committee decided to advance the MRLs of the commodities at Step 3 to Step 5. The Committee agreed to postpone the deletion of CXLs of citrus fruits, fruits and vegetables until the separate commodities reach Step 8.

Status of MRLs

At Step 5: apple; cotton seed; leek; lemon; maize; mandarin; olive oil, virgin; olives; oranges, sweet, sour; potato; sorghum; soya bean (dry); sunflower seed.

PARATHION-METHYL (059)

83. Discussions on proposals at Step 3 and the withdrawal of the MRLs as recommended by the 1992 JMPR were postponed. Additional toxicological and residue evaluations are scheduled for the 1994 JMPR.

PHOSALONE (060)

84. The FAO Joint Secretary of JMPR informed the Committee that phosalone was scheduled for toxicological evaluation by the 1993 JMPR and residue evaluation by the 1994 JMPR.

PIPERONYL BUTOXIDE (062)

85. Discussions on the proposal at Step 3 for wheat and the withdrawal of the MRLs as recommended by the 1992 JMPR were postponed until the 26th CCPR. It was noted that no residue data had been available for cereals except wheat. Delegations were invited to provide data on cereals other than wheat.

PYRETHRINS (063)

86. The compound was tentatively on the agenda of the 1994 JMPR for toxicological and residue evaluation, but residue data availability had yet to be confirmed. No residue information had yet been available for cereal grains except wheat. Delegations were invited to submit data in time and to inform the FAO Joint Secretary of JMPR about the manufacturer.

QUINTOZENE (064)

87. The Committee noted that quintozone was on the agenda of the 1995 JMPR for toxicological and residue evaluation.

THIABENDAZOLE (065)

88. The Committee was informed that JECFA evaluated this compound last year and established an ADI of 0.1 mg/kg (WHO Technical Report Series, No. 832.) Several delegations noted that a problem could arise if a compound is both used as pesticide as well as veterinary drug, and that the participants of both Committees should receive information of the evaluation data of both JMPR and JECFA. The Committee decided to request the JECFA and the JMPR to discuss this problem and advise both Codex Committees.

CYHEXATIN (067)

89. The Committee noted that cyhexatin, in conjunction with azocyclotin were scheduled for toxicological review by the 1994 JMPR. The Committee decided (Agenda Item 8.1 (e)) to harmonize the residue definition as the sum of azocyclotin and cyhexatin, expressed as cyhexatin. On a request of the

Delegation of Chile, three manufacturers of cyhexatin were identified. Several countries, including the EEC, expressed their concern on registered uses resulting in unnecessarily high MRLs in relation to the ADI, which was lowered by the 1991 JMPR to 0.001 mg/kg b.w.. The Delegations of the United States of America, Japan and Egypt informed the Committee that there were no longer registered uses in their countries.

90. Many delegations opposed the proposed MRL for apple, which was based on GAP in one country with a PHI of 3 days, therefore, the Committee decided to delete the proposed MRL and to maintain the existing CXL at 2 mg/kg. The Delegation of the Netherlands doubted whether the proposed MRLs for common bean and egg plant accommodate current GAP. The Delegations of France, Italy and the representative of the EEC were of the opinion that the available database was insufficient to recommend an MRL for peach; the Delegation of France and Italy had the same opinion on nectarine. The Delegations of the Netherlands and France and Italy opposed the draft MRL for plum, which was regarded as unnecessarily high. The delegation of Norway presented its opposition on nectarine and peach. The FAO Joint Secretary explained that stone fruits data provided mutual support.

91. The representative of the EEC and the delegations of The Netherlands and France asked if sufficient data were available on strawberries to propose an MRL. The Committee decided to recommend deletion of the MRL for tea, as recommended by the 1991 JMPR.

Status of MRLs

At Step 5: nectarine.

At Step 8: common bean; egg plant; grapes; peach; plums (including prunes); strawberry.

BENOMYL (69)

92. See carbendazim (072)(para. 94).

BROMOPROPYLATE (70)

93. The Committee noted that bromopropylate was scheduled for toxicological and residue evaluation by the 1993 JMPR. Consideration of the withdrawal of the MRL for vegetables was postponed pending the outcome of the 1993 JMPR. The FAO Joint Secretary informed the Committee that no data had become available in support of the CXLs on banana, cherries and nectarines. Data on tea were limited to only two trials and therefore, countries were requested to provide further data.

CARBENDAZIM (72)

94. The Committee noted that carbendazim, together with benomyl (069) and thiophanate-methyl (077), was re-scheduled for residue evaluation by the 1993 JMPR and scheduled for toxicological evaluation by the 1995 JMPR. The FAO Joint Secretary informed the Committee that requested data have become available from Hungary, The Netherlands and the EEC.

DEMETON-S-METHYL (73)

95. See oxydemeton-methyl (166)(para. 185).

DISULFOTON (074)

96. The compound had been evaluated by the JMPR in 1991 as part of the periodic review programme. The Committee was informed that deletion of the general MRLs for cereal grain, forage crops and vegetables would only take place when proposals for MRLs for the relevant individual commodities reached Step 8. The JMPR had been unable to recommend MRLs for celery and soya bean, dry and the Committee decided to recommend deletion of the CXLs for these commodities if GAP information and residue data were not made available before the next CCPR. The Delegation of the United Kingdom reported that in their experience the metabolite demeton-S and its sulphoxide and sulphone were not found in practice, and that therefore they should be deleted from the residue definition.

97. The Delegation of France stated that sulphone residues were found in animal products; the representative of the manufacturer agreed that demeton-S and its sulphoxide and sulphone are not found in practice. The Delegation of the United States of America informed the Committee that the methodology used in developing the residue trials data did not distinguish between the individual metabolites.

98. The Committee decided to leave the residue definition as currently drafted until more information was available from governments' monitoring programmes.

99. The Delegation of The Netherlands reserved its position on MRLs for barley; broccoli; cabbage, head; cauliflower; common beans (pods and/or immature seeds); lettuce, head; lettuce, leaf; sorghum and wheat because of concern over risk to consumers. The representative of the EEC expressed concern about the broad spectrum of use of a compound with such a low ADI. The Delegation of Finland had the same concern as The Netherlands, and found the CXLs for potato and rice extremely high in relation to the ADI, while the Delegation of Sweden found the high MRL for potato unacceptable for the same reason. The Delegation of Norway also expressed concern about the level of potential dietary intakes, referring specifically to high draft MRLs for lettuce, head and lettuce, leaf.

100. The Delegations of Finland and Sweden indicated they would submit their national intake calculations to the WHO; the representative of the EEC agreed to submit information based on dietary habits in the Community. The Delegation of Spain stated that because of the low ADI, countries should consider revising their authorizations. Delegations were invited to send their national intake calculations to WHO.

101. The Delegation of the United States of America said that for most cases it could not support the proposed MRLs, because the proposals were based on an incomplete residue package. The compound was under re-evaluation in the United States of America and additional data had been required and developed. The representative of the manufacturer agreed to ensure that a complete dossier, including all relevant old data, would be made available to the JMPR.

Alfalfa fodder

102. The Delegations of France and Germany questioned extrapolation from alfalfa fodder, green to alfalfa fodder, dry.

Barley straw and fodder, dry

103. The Delegation of France entered a reservation.

Cabbages, Head

104. The Delegation of France requested clarification of the GAP in the United States of America.

Chicken eggs

105. The Delegations of The Netherlands, the United Kingdom and Ireland found the limit of determination 0.001(*) unnecessarily low. It was felt that a 0.01 limit was more appropriate for use in enforcement. The Committee agreed to amend the proposal for chicken eggs to 0.01(*).

Lettuce, head

106. The representative of the EEC indicated its reservations because the level was too high, considering the consumption pattern and the ADI and the database was inadequate; in particular there were no data supporting the use of granular products considering that the majority of the authorization was for granular products.

Milk of cattle, goats and sheep

107. The Delegation of The Netherlands reserved its position for various reasons, including the high toxicity of the compound. A level of 0.01 would be more appropriate, since 0.02 was based on a high feeding rate of sorghum forage (green) with residues at the level of the proposed MRL which did not seem to be realistic. They were concerned about possible accumulation of residues in milk fat and in addition doubted whether extrapolation from cow's milk to milk of goats and sheep was valid. The Delegation of the United States of America reserved its position since no national decision had been taken on the likely feeding rate for cattle.

108. The Delegation of France said that the main residue in milk would be disulfoton-sulfone and that no residues were likely to be found in milk fat. The Committee asked for a re-evaluation by the JMPR. The delegations of the Netherlands and France were invited to send their comments and calculations when the compound was scheduled for JMPR evaluation. Both delegations were invited to send residue data to the JMPR and the Committee decided not to advance the MRL to Step 8 without a JMPR evaluation.

Pecan

109. The Delegation of the United States of America did not support the limit of 0.01(*) proposed by the 1991 JMPR since it did not take account of studies reflecting United States soil uses and the foliar use residue data examined by the JMPR did not reflect maximum GAP of USA.

Sorghum forage (green)

110. The Delegation of The Netherlands said that an MRL of 20 was so high that there might be toxicity to the animal itself. The Delegation of Chile expressed concern that the MRL was too high. The Delegation of the United States of America supported by France indicated that some of the data on which the proposal was based were aberrant and that a lower MRL was appropriate.

111. The Committee was informed that the JMPR should reevaluate the data and decided not to advance the proposed draft MRL to Step 8 without a JMPR evaluation.

Wheat

112. The Delegation of France pointed out that the compound was toxic and that an MRL of 0.1 was sufficient.

Status of MRLs

At Step 5: alfalfa fodder; asparagus; barley; barley straw and fodder, dry; beans, dry; broccoli; cabbages, head; cauliflower; chicken eggs; coffee beans; common beans (pods and/or immature seeds); cotton seed; garden pea (young pods); garden pea, shelled; lettuce, head; lettuce, leaf; maize; maize fodder; maize forage; milk of cattle, goats and sheep; oat forage (green); oat straw and fodder, dry; oats; pecan; poultry meat; radish, Japanese; sorghum; sorghum forage (green); sugar beet; sugar beet leaves or tops; sweet corn (kernels); sweet corn (corn on the cob); tomato; wheat; wheat forage (whole plant); wheat straw and fodder, dry.

PROPOXUR (075)

113. The Delegation of The Netherlands stated that 0.05 mg/kg was an appropriate limit of determination and to avoid different limits of determination the 0.02* should be changed. The Chairman of the JMPR noted that the 0.02* mg/kg limit was derived from the available database. The Committee decided to change the MRLs for broad bean and for carrot from 0.02* into 0.05* mg/kg.

114. The Delegations of The Netherlands and Germany stated that, based on the 1991 Evaluations, 0.1 mg/kg was a more realistic limit for garden pea. The Chairman of the JMPR referred that the JMPR had considered the result reported as 0.11 ppm as a result of contamination and should not influence the MRL.

115. The Delegations of The Netherlands and France noted the MRL for potato was based on very old data (1971-1975) with a rather high Limit of Determination. It was suggested that new data should be generated with a more appropriate Limit of Determination. The Representative of the manufacturer said that no additional studies were scheduled. The Delegation of France indicated a firm reservation against advancing potato to Step 5.

116. The general MRLs for root and tuber vegetables and for vegetables would be withdrawn when the MRLs for the individual commodities were advanced to Step 8.

Status of MRLs

At Step 5: broad bean (green pods/immature seeds); cabbage, savoy; carrot; common bean (pods and/or immature seeds); cucumber; garden pea (young pods); kohlrabi; leek; lettuce, head; onion, bulb; potato; spinach; tomato.

THIOPHANATE-METHYL (077)

117. See carbendazim (072)(para. 94).

VAMIDOTHION (078)

118. The Committee noted that the compound was evaluated by the 1992 JMPR for residues limits and therefore, decided to postpone discussions to its next Session.

AMITROLE (079)

119. The Committee noted that the compound was on the agenda of the 1993 JMPR for toxicology and residues limits.

CHLOROTHALONIL (081)

120. The Committee noted that the compound was evaluated by the 1992 JMPR for toxicology. A periodic review of all CXLs and grapes were on the agenda of the 1993 JMPR and therefore, decide to postpone discussions to its next Session. The Representative of the EEC informed the Committee that the Scientific Committee for Pesticides estimated an ADI of 0.01 mg/kg b.w., based on a NOAEL of 1.8 mg/kg b.w. for non neoplastic lesions in the long term rat study and using a safety factor of 200, which was different from the ADI established by the JMPR.

DICLORAN (083)

121. The Committee noted that the compound was on the agenda of the 1994 JMPR for toxicology and residues limits. The Committee was informed by the FAO Joint Secretary that residue data could not be expected from the manufacturer and that the compound therefore will probably be recommended for deletion. Governments were invited to submit data on current GAP.

PIRIMIPHOS-METHYL (086)

122. The Committee noted that the compound was evaluated by the 1992 JMPR and therefore, postponed discussions to its next Session.

DINOCAP (087)

123. The Committee noted that the 1992 JMPR had recommended the deletion of all temporary MRLs. The Delegations of France and Spain indicated that they were in favour of retaining these MRLs. However, the Committee agreed with the JMPR recommendation to delete the temporary MRLs.

CHLORPYRIFOS-METHYL (090)

124. The Committee noted that the 1992 JMPR confirmed the ADI of 0.01, but that the compound was on the agenda of the 1993 JMPR for the evaluation of processing studies on maize and rape seed. The Representative of the EEC informed the Committee that their Scientific Committee for Pesticides also estimated an ADI of 0.01 and that the Community was concerned about proposed MRLs at 10 mg/kg and reserved its position until processing studies for maize and rape seed had been examined. Several Delegations expressed a reservation on the proposed MRL for barley and oats, because they were of the opinion that a figure of 10 was too high.

125. The Committee was informed by the Chairman of the JMPR that the figure for barley was derived from the general GAP for cereals. The Committee decided to send out a Circular Letter (CL) inviting Governments to inform JMPR on current GAP's for all cereals, including barley and oats. The Committee also

followed a suggestion of the Delegations of France and the United States of America to include rice in the CL, since the existing MRL only covered pre-harvest use and in their opinion there was also a need for post harvest application. Governments who opposed an MRL of 10 were invited to submit their position to JMPR. The Delegation of France reserved its position because the proposed MRL was not supported by sufficient data. The Committee also advanced the temporary MRL for rape seed to step 5, but indicated that it was awaiting the outcome of the 1993 JMPR, which will evaluate data on processing studies indicating the possible concentration of the compound into the oil.

Status of MRLs:

At step 5: barley; dates; grapes; mushrooms; oats; oranges, sweet, sour; peppers; rape seed.

BIORESMETHRIN (093)

126. Bioresmethrin was on the agenda of the 1991 JMPR for toxicological and residue evaluation. The Delegation of Australia, in response to a question of the Delegation of The Netherlands, informed the Committee that an MRL of 1 mg/kg for wheat was acceptable. The Delegation of France was of the opinion that the MRL for wheat flour was too high in respect to the MRL for wholemeal wheat. The Chairman of the JMPR noted that the MRL for wheat flour was due to the variation of results in determining the residues. The Committee decided to move the proposals to Step 5.

Status of MRLs

At Step 5: all proposals.

METHOMYL (094)

127. The Committee noted the discussions arising from the 22nd and 23rd Sessions of CCPR and decided to postpone further considerations until information on grapes and pome fruits become available.

ACEPHATE (095)

128. The Committee noted that the compound was on the agenda of the 1994 JMPR for residue evaluation. The Committee was also informed that the manufacturers had been identified.

CARBOFURAN (096)

129. The Committee noted that the compound was on the agenda of the 1993 JMPR for residue evaluation and scheduled for the 1994 JMPR for toxicological evaluation.

METHAMIDOPHOS (100)

130. The Committee noted that methamidophos was on the agenda of the 1994 JMPR for residue evaluation. Governments were requested to provide data on GAP and residues to the JMPR.

PHOSMET (103)

131. The Committee noted that the compound was under periodic review and on the agenda of the 1994 JMPR for toxicological and residue evaluation.

DAMINOZIDE (104)

132. The Committee noted that the draft MRLs for this compound were withdrawn.

DITHIOCARBAMATES (105)

133. The Committee noted that maucozeb, maneb, propineb and their derivatives ethylene thiourea, propylene thiourea were scheduled for periodic re-evaluations of toxicology and residues of the 1993 JMPR. Metiram was scheduled for toxicology evaluation only in 1993. Metiram and thiram were scheduled to residue re-evaluation by the 1994 Joint Meeting in order to accomodate data under development. Ziram and ferbam were tentatively scheduled for residue re-evaluation by the 1995 JMPR pending the submission of data. The toxicological re-evaluation of these compounds had yet to be scheduled. No toxicological or residue data have been provided for Zineb. The manufacturer(s) have not been identified.

ETHEPHON (106)

134. The Committee noted that ethephon was scheduled for toxicological and residue evaluation by the 1993 JMPR.

ETHYLENETHIOUREA (ETU) (108)

135. The Committee noted that ethylenethiourea was scheduled for toxicological and residue evaluation by the 1993 JMPR.

FENBUTATIN OXIDE (109)

136. The Committee noted that fenbutatin oxide was on the agenda of the 1993 JMPR for periodic review. The manufacturer had provide limited data to support MRLs for gherkin, melons, except watermelon and sweet peppers. Delegations were requested to send any supporting data to the JMPR as soon as possible.

IMAZALIL (110)

137. The Committee noted that the 1991 JMPR had changed the ADI from 0.01 to 0.03 mg/kg.

IPRODIONE (111)

138. The Committee noted that iprodione had been on the agenda of the 1992 JMPR for toxicological and residue evaluation and was scheduled for the 1993 JMPR for residue evaluation.

PHORATE (112)

139. The Committee noted that the TMDI and the EMDI for a number of diets exceeded the ADI. The Delegation of the United Kingdom questioned the residue definition, since in their experience phorate oxygen analogue and its sulphoxide

and sulphone were not found in practice. After discussion and reference to the 1990 JMPR on residues evaluations the Committee agreed to maintain the present residue definition.

Carrot

140. The Delegation of the United Kingdom informed the Committee that they had provided information on revised GAP and residue data and that additional data would become available. The Delegation of Australia would provide information on its GAP. The Committee decided to maintain the proposal at Step 7C awaiting further information from the United Kingdom and Australia.

Potato

141. The MRL for potato had been changed from 0.05 mg/kg to 0.2 mg/kg by the 1990 JMPR. Discussions on this proposal were postponed because the 1992 JMPR residue evaluations were not available at the meeting.

Status of MRLs

At Step 5: maize; sweet corn (corn-on-the-cob).

At Step 6: potato.

At Step 7C: carrot.

At Step 8: maize forage; peanut.

TECNAZENE (115)

142. The Committee noted that tecnazene was scheduled for toxicological and residue evaluation by the 1994 JMPR.

TRIFORINE (116)

143. The Committee noted that triforine was scheduled for toxicological and residue evaluation by the 1994 JMPR, but would most probably be postponed to the 1996 JMPR at the request of the manufacturer.

ALDICARB (117)

144. The Committee noted that aldicarb was scheduled for a periodic review on residue data by the 1994 JMPR. The FAO Joint Secretary of JMPR informed the Committee that brussels sprouts would be reviewed by the 1993 JMPR.

PERMETHRIN (120)

145. The Committee decided to move the proposals at Step 6 to Step 8 and to move the proposal at Step 3 to Steps 5/8.

Status of MRLs

At Step 5/8: wheat germ.

At Step 8: wheat bran, unprocessed; wheat flour; wheat wholemeal.

AMITRAZ (122)

146. The delegation of France requested a revision of the residue definition. The Committee decided not to change the residue definition and reiterated its request to the delegation of France, the manufacturer and other countries to submit information of national residue definitions to the JMPR.

ETRIMFOS (123)

147. Since no data to support a MRL for head lettuce had been found, the Committee decided to propose the deletion of the MRL next year.

METHACRIFOS (125)

148. Several countries expressed their concern about the toxicity of the compound and made reservations on several proposals since the TMDI and EMDI exceed the ADI. The Representative of the manufacturer informed the Committee that the compound was primarily used in cereals. Uses in beans (dry); cacao beans; field pea (dry); peanut and peanut, whole were of minor importance and could be deleted. In view of the reservations made by several countries on cereal grains and related commodities, the representative of the manufacturer informed the Committee that their EMDI-calculations did not exceed the ADI after deletion of these commodities.

Cattle meat; cattle, edible offal of; cereal grains; wheat bran, unprocessed; wheat flour; wheat wholemeal

149. Discussion on the proposals at Steps 3 and 6 were postponed, because the 1992 JMPR evaluations were not available at the meeting.

Beans (dry); Cacao beans; field pea (dry); peanut; peanut, whole

150. The Committee decided to consider the possible deletion of the MRLs at its next Session since there was no current GAP supported by the manufacturer.

Poultry meat

151. The delegation of The Netherlands explained that methacrifos was correctly described as fat soluble because of its octanol water partition coefficient. Also animal transference studies (JMPR 1980) had shown methacrifos level in the fat to be much higher than in muscle tissues. Transfer studies showed that no residue could be expected in the muscle tissue at normal feeding level. The 1980 JMPR evaluations also showed that no residue had to be expected in poultry fat, so the proposed MRL for poultry meat could be changed into poultry meat (fat).

Eggs; milks; Poultry Meat

152. The Committee decided to add "(fat)" behind the figure of poultry meat and to advance the proposals to Step 8.

Status of MRLs

At Step 3: cattle meat, cattle edible offal of.

At Step 6: cereal grains; wheat bran, unprocessed; wheat flour; wheat wholemeal.

Plums

163. The Delegations of France, Sweden, Italy and The Netherlands were of the opinion that the available database would allow a lower figure than that proposed. The Chairman of the JMPR informed the Committee that data on other stone fruits had also been taken into account.

Status of MRLs

At Step 5: nectarine.

At Step 8: citrus fruits; common bean; cucumber; egg plant; gherkin; grapes; meat; melons except watermelon; milk products, milks; peach; pear; peppers, sweet; plums (including prunes); strawberry; tomato.

ISOFENPHOS (131)

164. The Committee noted that the compound had been on the agenda of the 1992 JMPR for residue evaluation and took note of the JMPR's recommendation that to harmonise the residue definition with the MRLs for meat and poultry meat the fat portion of the sample should be specified for analysis.

TRIADIMEFON (133)

165. The Committee noted that the compound was on the agenda of the 1992 JMPR for residue evaluation and decided to postpone further discussion until the next CCPR Session.

DELTAMETHRIN (135)

166. The Committee noted that the compound was on the agenda of the 1992 JMPR for residue evaluation and decided to postpone further discussion until the next CCPR Session.

PROCYMIDONE (136)

167. The Committee noted that the compound was on the agenda of the 1993 JMPR for residue evaluation.

BENDIOCARB (137)

168. The Committee noted that MRLs for mushrooms; rice straw and fodder dry; and rice, husked were temporary. It was indicated that the manufacturer will not submit data for these commodities. The Committee decided that the three Codex MRLs were candidate for deletion at the next CCPR Session if supporting data would not be provided.

METALAXYL (138)

169. The Committee decided to postpone discussions on lettuce, head; onion bulb, spinach; and strawberry to its next Session since they were evaluated by the 1992 JMPR, but agreed to advance the MRLs for broccoli, cabbages, head and cauliflower to step 8.

Status of MRLs

At step 8: broccoli; cabbages, head; cauliflower.

At Step 7B: beans (dry); cacao beans; field pea (dry); peanut; peanut, whole.

At Step 8: eggs; milks; poultry meat (fat).

AZOCYCLOTIN (129)

153. This compound had (partly) already been discussed in conjunction with cyhexatin (067) (paras. 89-91).

Apple

154. The Committee decided to delete the proposed figure of 5 mg/kg.

Citrus fruits

155. The Delegation of The Netherlands was of the opinion that the available database was poor and found the relationship to current GAP unclear.

Common bean

156. The Delegation of Germany informed the Committee that registration was pending in their country, and that a higher MRL would probably be needed; data would be made available to the JMPR.

Egg plant

157. The Delegation of The Netherlands doubted whether the proposed figure accommodated GAP in all countries.

Kiwifruit

158. The Committee decided to delete the draft MRL, as recommended by the 1991 JMPR.

Meat

159. The Delegations of France and The Netherlands expressed their reservations against the proposal; the Delegation of The Netherlands thought 0,1 mg/kg was probably sufficient, the Delegation of France felt that insufficient information was available on veterinary uses.

Nectarine

160. The Delegations of Sweden and Norway reserved their positions on this proposal for toxicological reasons.

Peach

161. The Delegations of Italy, Norway and Sweden reserved their position.

Pear

162. The Delegations of Italy, Sweden, Norway and The Netherlands expressed their reservation against this proposal, which was regarded as unnecessarily high.

PROCHLORAZ (142)

170. The Committee noted that the 1992 JMPR confirmed the proposals from the 1991 JMPR. The Delegation of the Netherlands, supported by the Delegations of Germany and France, expressed its disappointment that the JMPR did not make any amendments even though new data had been submitted. These delegations were of the opinion that figures for cattle fat, cattle meat, edible offal of cattle and milk were still too high. The Committee decided to advance the proposals to step 8, noting the reservations of these three countries. The Committee, however, also followed a suggestion of the delegation of the Netherlands to request the Working Group on methods of analysis to review the limit of determination for milk.

Status of MRLs

At step 8: cattle, fat; cattle, meat; cattle, edible offal of; milks.

TRIAZOPHOS (143)

171. The Committee noted that this compound was on the agenda for toxicology and residues evaluations by the 1993 JMPR.

CARBOSULFAN (145)

172. The Committee noted that this compound was on the agenda of the 1993 JMPR for residues evaluations.

PROPYLENETHIOUREA (PTU) (150)

173. The Committee noted that this compound was on the agenda of the 1993 JMPR for toxicology and residues evaluations.

FLUCYTHRINATE (152)

174. The Committee noted that this compound was on the agenda of the 1993 JMPR for residues evaluations.

PYRAZOPHOS (153)

175. The Committee noted that the 1992 JMPR estimated an ADI for the compound and converted the Guidelines to MRLs. It also noted that the compound was on the agenda of the 1993 JMPR for residues evaluations and therefore, postponed discussions to its next Session.

BENALAXYL (155)

176. The Committee noted that this compound was evaluated for residues limits by the 1992 JMPR and therefore postponed discussions to its next Session.

CLOFENTEZINE (156)

177. The Committee noted that proposals for citrus fruits and grapes were evaluated by the 1992 JMPR and postponed discussions on these two proposals to its next session.

CYFLUTHRIN (157)

178. The Committee noted that the compound was evaluated by the 1992 JMPR and therefore postponed discussions to its next session.

VINCLOZOLIN (159)

179. The Committee noted that the compound was evaluated by the 1992 JMPR and therefore postponed discussions to its next session.

PROPICONAZOLE (160)

180. The Committee noted that the proposed MRL for barley was due for discussion at the 1993 JMPR.

ANILAZINE (163)

181. The Committee noted that the compound was evaluated by the 1992 JMPR and therefore postponed discussions to its next session.

DEMETON-S-METHYLSULPHON (164)

182. (See oxydemeton-methyl (166)(para. 185).

FLUSILAZOLE (165)

183. The Committee noted that proposals for nectarines and peaches were on the agenda of the 1993 JMPR. The Committee was also informed by the FAO Joint Secretary that they had a temporary status, due to the limited availability of data. Governments were invited to submit information on current GAPs and residue data. The Committee advanced these two MRLs to Step 5, while noting reservations from The Netherlands regarding the inadequacy of the data bases.

184. The Committee also advanced the MRLs at Step 6 to Step 8, noting reservations from The Netherlands on rye and wheat and France on barley, rye and wheat, indicating that the limits are too high and should be lowered. The delegation of the Netherlands indicated that for regulatory purposes they would prefer a limit of determination of 0.05 mg/kg.

Status of MRLs

At Step 5: nectarine; peach.

At Step 8: barley; barley, straw and fodder, dry; cattle fat; cattle meat; cattle milk; cattle, edible offal of; rye; rye, straw and fodder, dry; wheat; wheat straw and fodder, dry.

OXYDEMETON-METHYL (166)

185. Discussions on all proposals were postponed because the 1992 JMPR evaluations were not available at the meeting. The Representative of the EEC pointed out that in order to complete the evaluations of oxydemeton-methyl it would be necessary to have similarly updated data packages for demeton-S-methyl and demeton-S-methylsulphon. The Representative of the manufacturer indicated that data had been submitted on demeton-S-methylsulphon and they will face out demeton-S-methyl which will be replaced by oxydemeton-methyl.

TRIADIMENOL (168)

186. Discussions on all proposals were postponed because the 1992 JMPR evaluations were not available at the meeting.

CYROMAZINE (169)

Cucumber

187. The Delegation of The Netherlands doubted whether 0.2 mg/kg was sufficient to reflect use with a PHI of 3 days, which was the proposed GAP in their country.

Mushrooms and Tomato

188. The Delegation of France expressed its reservations on these proposals, indicating that lower figures were appropriate. The Vice-Chairman of the 1990 JMPR informed the Committee that 5 mg/kg for mushrooms was the appropriate figure due to the variability of the data base.

Peppers

189. Discussion was postponed because the 1992 JMPR evaluations were not available at the meeting.

Status of MRLs

At Step 6: peppers.

At Step 8: celery; cucumber; eggs; lettuce, head; melons, except watermelon; milks; mushrooms; poultry meat; sheep meat; tomato.

HEXACONAZOLE (170)

190. The Delegation of Germany repeated their previous concern, about the availability of a method of analysis for regulatory purposes. The Committee noted that a method of analysis for animal products was not to be provided by the manufacturer due to the low level of MRL and therefore, the only commodity involved in a possible deletion of the MRL was wheat straw and fodder, dry. The delegation of The Netherlands, referring to the discussion on animal transference studies, remarked that in their view no animal transference studies were required in this case, because the residues in animal feeding were well below 1 mg/kg. The Committee decided to postpone discussion on this matter until information is available from countries on the requirement for animal transference studies.

Banana

191. The Committee decided to advance the proposal to Step 8.

Status of MRLs

At Step 8: banana.

PROFENOFOS (171)

192. Discussions on proposals at Step 6 were postponed because the 1992 JMPR evaluations were not available.

BENTAZONE (172)

193. The Committee noted that the compound had been on the agenda of the 1991 JMPR for toxicological and residue evaluation. The Delegation of Germany questioned the limit of determination, which was lower than the sum of limits of determination of the three compounds bentazone, 6-hydroxy-bentazone and 8-hydroxy-bentazone. The Committee agreed to refer this to the Ad Hoc Working Group on Methods of Analysis for discussion next year. The Delegations of France and The Netherlands indicated the preference of an MRL of 1 mg/kg for alfalfa forage (green) on the basis of the trials data evaluated by the JMPR. The Delegation of Germany indicated that their national GAP required a higher MRL for beans (dry), common bean (pods and/or immature seeds), field pea (dry) and garden pea (young pods). The delegations of The Netherlands and France remarked that the data in the 1991 JMPR residue evaluations did not support a figure of 3 mg/kg for maize fodder. The FAO Joint secretary agreed that this figure should be reviewed by the 1994 JMPR. The Delegation of The Netherlands preferred an MRL of 0,05(*) for potato and, supported by the Delegation of the United States of America, an MRL of 0.05(*) for rice. The Committee decided to advance all proposals to Step 5.

Status of MRLS

At Step 5: all proposals

BUPROFEZIN (173)

194. The Committee noted that the compound had been on the agenda of the 1991 JMPR for toxicological and residue evaluation and was scheduled for the 1994 JMPR for residue evaluation. The Delegation of The Netherlands expressed their reservations pending receipt of the information required by the JMPR on chemistry and on residues in three commodities. The Delegation of Japan indicated that they required MRLs of 1 mg/kg to reflect existing GAP in Japan for cucumber, oranges, sweet, sour and tomato. The Delegation of Spain requested an MRL for citrus fruit by extrapolation of results obtained for oranges. The Committee invited delegations to send additional data or comments to the 1994 JMPR and decided to advance all proposals to Step 5.

Status of MRLs

At Step 5: all proposals

CADUSAFOS (174)

195. The Committee noted that the compound was evaluated by the 1991 JMPR, but was also on the agenda of the 1992 JMPR for the method of analysis. The Committee advanced the MRLs for banana and potato to Step 5. The Delegation of Germany reserved its position on potato, indicating that the data were insufficient.

Status of MRLs

At step 5: banana; potato.

GLUFOSINATE-AMMONIUM (175)

196. The Committee noted that the compound was evaluated by the 1991 JMPR. The Delegation of The Netherlands was of the opinion that the residue definition should not include the metabolite, since it is considerably less toxic than glufosinate-ammonium itself. The Committee was informed by the representative of the manufacturer that new data on potato, currants, sunflower, banana, rape seed, citrus, kiwifruit and soyabean will be submitted to the 1994 JMPR and that they did not support use as a soyabean desiccant any longer. The Delegation of Germany will submit residue data on berries to the JMPR. The Delegations of Germany and The Netherlands made a reservation on the MRL for citrus fruits, because the available data did not include processing studies. The Delegation of France made a reservation on rape seed. The Delegation of Canada informed the Committee that new data will be submitted to the 1994 JMPR on lentils and for a higher GAP for rape seed. The Delegation of Germany made a reservation on sunflower seed. The Committee requested that the Ad Hoc Working Group on Methods of Analysis review limit of determination at the next Session. The Committee decided to advance the MRLs for banana, berries and other small fruits, citrus fruits, grapes, kiwifruit, maize, pomme fruit, potato, rape seed, soyabean (dry), stone fruits and sunflower seed to Step 5. The Committee also recommended to withdraw the MRL for soyabean (dry) at its next Session.

Status of MRLs

At Step 5: banana; berries and other small fruits; citrus fruits; grapes; kiwifruit; maize; pome fruits; potato; rape seed; soya bean (dry); stone fruits; sunflower seed.

HEXYTHIAZOX (176)

197. The Committee noted that the compound was examined by the 1991 JMPR for toxicological and residue evaluations. The Delegations of The Netherlands and France expressed their difficulties with the form in which the data were presented. The Chairman of the JMPR informed the Committee that it was indeed the current practice to present the data for the individual commodities instead of a presentation on the basis of a division in countries as was reported in some older monographs. The Delegations of France and Chile questioned the GAP in general. The Delegation of The Netherlands indicated that they doubted whether the proposals for apple, pear, peach, grapes, currant, red, white and tomato reflect GAP. The Delegation of Germany expressed reservations regarding the proposed MRLs for stone fruits, citrus fruits, grapes and tomatoes. The Delegation of France reserved their position for cherries, apples and citrus fruits. The Delegation of Japan preferred an MRL of 0.3 mg/kg for cucumber, and MRL of 2 mg/kg for plums (including prunes) and an MRL of 1 mg/kg for strawberry. The Delegation of the United States of America reserved their position for pears. They informed the Committee that their MRL of 0.3 mg/kg was based on the total residues of hexythiazox and its metabolites. The Committee requested delegations to provide additional data on GAP and residues and decided to advance all proposals to Step 5.

Status of MRLs

At Step 5: all proposals.

ABAMECTIN (177), BIFENTHRIN (178), CYCLOXYDIM (179), DITHIANON (180), MYCLOBUTANIL (181), PENCONAZOLE (182), PROPHAM (183)

198. Discussions on proposals at Step 3 were postponed because the 1992 JMPR evaluations were not available at the meeting.

CYCLOXYDIM (179)

199. The Committee was informed that the residue evaluation by the 1992 JMPR will be continued by the 1993 JMPR.

PROPHAM (183)

200. The Committee was informed that no residue data were provided to the JMPR. The Committee decided that if no new information became available propham should be recommended for deletion.

Consideration of Combined List of Compounds (Agenda Item 8.1 (e))

201. The Committee had before it a review of all cases in the Codex system of related compounds and relevant CCPR recommendations for combining limits, as summarized by the Codex Secretariat in document CX/PR 93/10. The Representative of the EEC suggested that when similar cases arise in the future, the related compounds should be also combined.

Cyhexatin (067)/Azocyclotin (129)

202. The Committee took note of the proposal of the 1991 JMPR to combine the lists for cyhexatin and also azocyclotin, and to indicate in the combined list the compound whose use results in the proposed MRL. The representative of the EEC and the Delegations of Finland, Sweden, Australia and The Netherlands indicated their preference for a combined list, while the Delegation of Brazil was in favour of maintaining separate lists.

203. The Committee decided to accept the proposal of the 1991 JMPR and to harmonize the residue definition as the sum of azocyclotin and cyhexatin expressed as cyhexatin.

Triadimefon (133)/Triadimenol (168)

204. At its 24th Session the CCPR had noted that a decision should be postponed until the 1992 JMPR evaluations were available.

Dimethoate (027)/Formothion (042)/Omethoate (055)

205. At its 24th Session the CCPR had decided to postpone a decision until the 1993 JMPR evaluations were available.

Benomyl (069)/Carbendazim (072)/Thiophanate-methyl (077)

206. At its 24th Session the Committee had agreed that no action was needed. MRLs for thiophanate-methyl would be recommended for deletion when MRLs for carbendazim reached Step 8.

Acephate (095)/Methamidophos (100)

207. At its 24th Session the Committee had agreed to postpone a decision until the 1994 JMPR evaluations were available.

Carbofuran (096)/Carbosulfan (145)

208. At its 24th Session the Committee had agreed to a harmonized residue definition and the establishment of 2 separate lists. The representative of the EEC was of the opinion that these compounds should be considered in conjunction with benfurecarb and furathiocarb, since the use of these pesticides also results in residues of carbofuran and 3-hydroxycarbofuran. The FAO Joint Secretary of JMPR informed the Committee that a future JMPR (after 1993) could consider this question, but that both compounds were not yet incorporated in the Codex system.

Methomyl (094)/Thiodicarb (154)

209. The Committee had agreed at its 24th Session to a combined list for both compounds.

Consideration of the Use of a Separate List for Codex Extraneous Maximum Residue Limits (Agenda Item 8.1(f))

210. The Committee had for its consideration documents CX/PR 93/ 11 and Add. 1 when discussing this agenda item, which summarized comments submitted by the governments of Australia, Norway, Sweden and the United States of America in response to CL 1992/12-PR, Part B.4. The Representative of EEC recommended that HCB and HCH be added to the list and that compounds lindane and fenitrothion be excluded as these compounds were still used as plant protection products.

211. The Committee was reminded that at its 24th Session discussions were held on a proposal to establish a separate list of Codex Extraneous Maximum Residue Limits (EMRLs) which would refer to pesticide residues arising from environmental sources as opposed to specific applications of a pesticide (paras. 202-204, ALINORM 93/24). It was noted that EMRLs were based on monitoring data as opposed to GAP and residue trials data.

212. The Committee noted that comments submitted by governments generally supported the establishment of a separate list of Codex EMRLs, with the understanding that such a list clearly referred to these limits as maximum parameters.

213. In relation to a suggestion that the establishment of maximum limits for pesticides arising from environmental sources should be coordinated with the Codex Committee on Food Additives and Contaminants and should take note of the principles and procedures which have been developed in the CCFAC for the establishment of Maximum Levels for Contaminants, the Committee strongly supported the continued examination of this subject by the CCPR. The Committee also agreed to several editorial revisions to the list of EMRLs in Appendix I of document CX/PR 93/11.

214. The Committee concluded its discussions by supporting the elaboration of a separate list of EMRLs for those pesticides which include only EMRLs and no remaining MRLs, with the understanding that this subject would continue to be handled exclusively by the CCPR. The Committee also agreed to a number of amendments to the current list, and noted that it should continue to be updated regularly (i.e., every 5 years) as further monitoring data become available.

RECONSIDERATION OF GUIDELINE LEVELS (Agenda Item 8.2)

215. The Committee had before it document CX/PR 3-1993 containing status of pesticides for which guideline levels have been set.

COUMAPHOS (018)

216. At its 24th Session, the CCPR decided to request information on agricultural uses and to delete the compound at the next session if no such uses were reported. The Committee decided to delete the guideline levels because no information on agricultural uses were received.

METHYL BROMIDE (52)

217. The compound was on the agenda of 1992 JMPR, however it was not cleared toxicologically. The Committee decided to postpone any action and maintain the guideline levels.

ETHEPHON (106)

218. This compound is on the agenda of the 1993 JMPR for periodic residue and toxicological evaluation. The Committee will consider ethephon after the JMPR evaluations become available.

PROPYLENETHIOUREA (PTU) (150)

219. This compound is on the agenda of the 1993 JMPR for periodic toxicological and residue evaluation. The Committee will consider PTU after the JMPR evaluations become available.

EXPRESSION AND APPLICATION OF MRLs FOR FAT SOLUBLE PESTICIDES IN MEAT, ANIMAL FAT AND EDIBLE OFFAL (Agenda Item 9)

220. The Committee had before it Conference Room Document 8 which concerned the Regulation of Fat-soluble Pesticides in Animal Products as prepared by Mr. Kloet (The Netherlands). In introducing the report, Mr. Kloet reminded the Committee that it had discussed the subject of fat soluble residues in animal products over a period of many years. It was noted that the document provided the Committee with a broad overview of the subject and an analysis of the different aspects for milk and milk products, meat and meat products, eggs and egg products and fishery products. The document presented several options on how to address these matters in the future in a consistent way, recommended transitional arrangements for the MRLs which are already established for these products and in particular recommended an improved approach for low fat animal products.

221. Several Delegations expressed their appreciation of the approach proposed in the document, but indicated that they needed more time to study the proposals in detail. The Delegation of Australia, supported by the Delegation of the United States of America, cautioned the Committee as to the complexity of the solution proposed in the document. In their view, the Committee should determine if in practice problems exist in international trade. The Delegation of China drew the attention of the Committee to the problem of low fat meat products such as rabbit, and expressed a preference for expressing residue limits in such cases on a whole byproduct basis.

222. The Committee decided to send out a Circular Letter inviting Governments to comment on the paper as attached to this report in Appendix II. The Committee also agreed to a suggestion from the Delegation of Australia to include in the paper a request for information on the fat content of animals in countries and for information on problems encountered under the existing arrangements.

The Committee also decided to continue discussion on the subject at its next Session and requested The Netherlands to prepare a revised paper on the basis of the comments received.

SAMPLING FOR THE DETERMINATION OF PESTICIDE RESIDUES IN MILK AND FISH FOR CONTROL PURPOSES (Agenda Item 10)

223. The Committee had for its consideration document CX/PR 93/13, which was based on the previous document circulated by the CCPR (Appendix VI, ALINORM 93/24), as well as those sections the CCRVDF was recommending for adoption by the Commission on procedures for the sampling of aquatic animal products, eggs and egg products. In addition, comments submitted in regard to the previous CCPR draft (Part B.5, CL 1992/12-PR) were summarized in document CX/PR 93/13-Add.1. The delegation of Australia had also provided written comments to the Secretariat.

224. The Committee recalled its previous discussions concerning this issue, in which the 24th CCPR had decided to circulate the proposed draft Codex Recommended Method of Sampling for the Determination of Pesticide Residues in Milk, Dairy Products and Eggs for government comments at Step 3. The Committee had also agreed that the proposed draft plan should be forwarded to the CCRVDF for discussion, and that governments should be requested to provide information on possible sampling procedures for aquatic animal products. In view of these CCPR decisions, the CCRVDF had agreed to include the CCPRs suggestions concerning dairy products into Appendix B of the CCRVDF Guidelines for the Establishment of a Regulatory Programme for Control of Veterinary Drug Residues in Foods.

225. The Committee focussed its discussions on the revised draft circulated at its previous Session and contained in CX/PR 93/13, and noted that the comments requested previously were limited to provisions concerning Instructions for Collection and Minimum Quantities Required (i.e., Table 1), as opposed to actual Sampling Procedures. Several revisions to the Sampling Guidelines were proposed in regard to the terms used and actual sample sizes required, especially in view of other terms and definitions elaborated by other international organizations, such as the ISO and IDF. The question was raised how to deal with existing sampling procedures that were established by other international organizations, that were often slighter different and more elaborate than Codex proposals. It was suggested to ask the opinion of the CCMAS on this matter. It was also remarked that in several cases the sampling procedures proposed in the Codex documents might be obsolete or irrelevant.

226. In regard to the consideration of sampling procedures related to fish, several delegations were of the opinion that such matters were under the primary responsibility of the Codex Committees on Veterinary Drug Residues in Foods and/or the Codex Committee on Food Additives and Contaminants and were of little interest to the CCPR as long as no MRLs for fishery products were elaborated. However, as it was also noted that pesticide use sometimes resulted in environmental contamination and consequently in residues in fish, the Committee accepted the offer of the delegation of Australia to prepare a paper for consideration at the next CCPR session concerning the apparent overlap of responsibilities between CCPR and other Codex Committees.

227. In view of this discussion, the Committee agreed to send the previously elaborated proposed draft Recommended Method of Sampling for the Determination of Pesticide Residues in Milk, Dairy Products and Eggs to the Commission for adoption at Step 5, as included in Appendix VI of ALINORM 93/24. This decision was made with the understanding that provisions related to the sampling of fish

would not be considered for the time being, and that oral and written comments presented at the current CCPR session would be considered to prepare a revised version of the Recommended Method of Sampling for the determination of pesticide residues in milk, dairy products and eggs. This revision would be re-circulated requesting further comments at Step 6 for consideration at the 26th Session of the CCPR. The delegation of France reserved its position regarding this proposal.

REPORT OF THE AD HOC WORKING GROUP ON ACCEPTANCES (Agenda Item 11)

228. The Report of the Ad Hoc Working Group on Acceptances was presented by its Chairman, Mr. Frank Hinsley (United Kingdom). The Committee focussed its discussions and agreed to the Revised Summary of Recommendations prepared by the Group, as contained in Appendix III and as follows.

229. In discussing what action should be taken when Estimated Maximum Daily Intakes (EMDIs) exceed the ADI, the Committee noted the difficulty in collecting good monitoring data based on clear criteria in order to make calculations as accurate as possible. In this regard, the WHO Joint Secretary advised that it was considering holding a new consultation to revise Guidelines for predicting dietary intake of pesticide residues. National inputs were requested before this could take place. The Representative of the EEC supported the concept of a core set of processing data and offered to forward its use to the JMPR. In relation to the revised recommendation 1, 4 and 6 (see Appendix III) the FAO and WHO Joint secretaries would issue a Circular Letter to remind governments on the opportunities to submit national data in order to contribute to the progress of this work.

230. Several delegations supported the elaboration of a procedure to consider JMPR proposals where the EMDI exceeds the ADI, as reduction factors and other calculations need to be performed before a EMDI calculation is made. It was also noted that the lowering of an ADI by the JMPR should give rise to an automatic review of existing CXLs if the TMDI or EMDI values as appropriate exceed the new ADI.

231. This proposal was supported by the Committee with the understanding that the Guidelines should be prepared well in advance of the 26th CCPR Session in order allow for their full consideration by governments. It was agreed that the Delegations of Australia, Finland, Sweden, the United States of America and the EEC would assist the United Kingdom in elaborating such Guidelines.

232. The Representative of the EEC requested procedures to examine GAP in case where the ADI might be exceeded by the best estimate of TMDI or EMDI dietary intake. Other delegations were reluctant to adopt amendments to the current determination of GAP and asked the working group on acceptances to draft guidelines to assist the Committee in processing draft MRLs through the step procedure.

233. The Committee thanked the Working Group and its Chairman and decided to set up a new *Ad Hoc* Working Group which would function until the end of the next session under the charmanship of Mr. F. Hinsley (United Kingdom).

CONSIDERATION OF THE REPORT OF THE WORKING GROUP ON METHODS OF ANALYSIS (Agenda Item 12)

234. The Committee was informed that a revised list for methods of analysis was elaborated by the Working Group for the 183 compounds which were included in the Codex system and that for four pesticides (hexaconazole, buprofezin,

cycloxydim and dithianon) no adequate methods of analysis could be recommended at the moment because published methods were not available. Governments, manufacturers and concerned international organizations were requested to provide information on methods concerning the above compounds as well as the new compounds scheduled to be included in the Codex system (clethodim, fenpropimorph, tebuconazole and tolclofos-methyl). A suitable method of analysis for the determination of clofentezine in products of animal origin was also requested.

235. The Committee noted that a full review of the text on "Good Practice in Pesticide Residue Analysis" had been finalized and that this document was scheduled for future publication as a Supplement to Volume 2 of the Codex Alimentarius.

236. The Committee was informed that limited information was received from countries on screening methods based on immunoassays, fungal growth or cholinesterase inhibition. It was noted that older methods based on fungal spores or cholinesterase inhibition were no longer used while new methods based on immunological techniques were not yet fully established. However, in view of the fact that such methods were considered to be of primary importance for regulatory purposes, the Committee agreed to follow the development of methods of analysis in this area.

237. The Working Group considered that there was a need to review the sampling definitions used by Codex for determining complaints with MRLs in view of their inconsistency with the glossary adopted by IUPAC on terms and definitions related to agrochemicals. The Committee agreed with this recommendation and supported a process of harmonization with definitions and guidelines arising from other international bodies such as IUPAC, ISO, IDF, CEN and AOAC as future work.

238. The Committee noted that a review of the document on "Storage Stability of Analytical Samples" prepared by GIFAP (ALINORM 93/24, App. III - Annex I) had been carried out by the Working Group and that it would be circulated again before the next CCPR Session.

239. The Working Group informed the Committee that Governments and concerned International Organizations should provide information on limits of determination for phorate and prochloraz for consideration at the next CCPR Session. The Committee also supported the recommendation of the Working Group that national and international organizations should make pesticide and metabolite standards available.

240. The Committee was also informed of concerns regarding the presence of ETU residues in processed food moving in international trade, as Codex MRLs do not apply to these foods. The Committee agreed to refer this matter to the attention of the JMPR for consideration.

Appointment of an Ad Hoc Working Group on Methods of Analysis

241. The Committee thanked the Working Group for its efforts and decided to set up a new Ad Hoc Working Group under the Chairmanship of Mr. L. Tuinstra (NL) and Vice-Chairmanship of Mr. P. van Zoonen (NL).

IDENTIFICATION OF PROBLEMS RELATIVE TO PESTICIDE RESIDUES IN FOODS IN DEVELOPING COUNTRIES (Agenda Item 13)

242. The Committee had for its consideration Conference Room Documents 3 and 5 when discussing this agenda item, which included the the report of the Ad Hoc Working Group on Pesticide Residue Problems in Developing Countries and a Secretariat Discussion Paper concerning this subject, respectively. The Report of the Working Group was presented to the Committee by its Chairman, Ms. Salwa Dogheim (Egypt).

243. The Committee, while supporting the report of the working group meeting, also expressed its appreciation to the Secretariat for the preparation of the discussion paper concerning this subject. It was agreed that the extensive information collected by the Group over the last several years highlighted the need to prepare specific pesticide/commodity lists for consideration by the CCPR Working Group on Priorities.

244. It was also noted that the generation of specific regional GAP data would be required, and that in those cases where data was not available, the Working Group on Developing Countries would need to determine procedures on how such data could be generated. In this regard, it was stressed that developing countries should focus on those products of interest to the region as an initial first step.

245. In regard to the expansion of Integrated Pest Management Procedures, the Committee supported assistance in this area through increased resources directed towards financing, education and training.

246. The Committee concluded that information should be solicited through a circular letter seeking information on impediments to the development and submission of residue data by developing countries for consideration by the JMPR and on specific pesticide/commodity combinations of interest to developing countries for foods moving in international trade. New terms of reference of the Working Group on Developing Countries should be elaborated to reflect the needs of developing countries in the area of MRLs for pesticides in foods. The Committee also agreed that MRLs adopted by Codex which represented export/import problems for developing countries should be identified. It was noted that such information should also be collected from developing country economic groups and other international organizations, as well as from other Codex Coordinating Committees.

247. The Committee agreed that the Ad Hoc Working group would continue the consideration of this information at the 26th CCPR under the Chairmanship of Ms. Salwa Dogheim (Egypt) with a view towards proposing priorities for review by the CCPR Working Group on Priorities.

CONSIDERATION OF THE REPORT OF THE WORKING GROUP ON PRIORITIES (Agenda Item 14)

248. The report of the Working Group on Priorities was introduced to the Committee by its Chairman, Mrs. J. Taylor (Canada). One new compound, flumethrin was suggested by Australia, with data to be provided by Bayer AG for the 1996 JMPR. In addition, two other pesticides, linuron and tebufenozide, were proposed by Sweden and New Zealand, respectively. It was agreed that these delegations will determine the availability of data on these pesticides before the next Session of CCPR.

249. With regard to reevaluation of older pesticides, no country and/or manufacturer had come forward to indicate continued GAP and/or willingness to provide data on carbophenothion or chlorobenzilate, and therefore, MRLs for these pesticides were recommended for deletion by the CCPR. Dicloran was scheduled for review by the 1994 JMPR, however, the manufacturer has indicated that no information would be provided of JMPR. Data availability for this pesticide, as well as for cartap and ethoxyquin, will be determined by the JMPR Secretariat. The delegation of Germany stated that deletion of CXLs should be recommended for ethoxyquin unless adequate toxicology data were available. The pesticides scheduled and agreed of JMPR review in 1993 through 1996 are listed in Appendix IV.

250. The procedure for the periodic review of pesticides was discussed at the Working Group meeting. Several amendments to the procedure included in ALINORM 93/24 were proposed by the Working Group, primarily related to criteria for identifying periodic review compounds. The major change suggested was that the primary criterion for considering the initiation of a periodic review would be that the compound at first had been reviewed more than 10 years ago as opposed to the last toxicological evaluation of greater than 10 years ago. The practical effect of this change would be that the list of pesticides that qualify for periodic review would be much larger than before.

251. The Committee decided to adopt the periodic review procedure, which is attached as Annex II of Appendix IV. Pending development of the list of pesticides that qualify for periodic review using the new criteria, information would be requested in the Circular Letter on the pesticides for which ADIs were established in 1981 and 1982, i.e. carbofuran, chlorpyrifos, cypermethrin, deltamethrin, edifenphos, ethiofencarb, etrimfos, fensulfothion, metalaxyl, pirimicarb, propargite, and 2,4,5-T. When developing priority lists of periodic review chemicals, the need was stressed to fully consider the JMPR review schedules in conjunction with those of national and international organizations, including OECD. Account should also be taken of the EEC re-registration exercise for plant protection products as provided by Directive 91/414/EEC. The Chairperson of the Working Group on priority informed the Committee that criteria for prioritizing reviews will be on their agenda for the 26th Session.

Appointment of a new Ad Hoc Working Group

252. It was decided to establish a new Ad Hoc Working Group which would function until the end of the next session under the Chairmanship of Ms. J. Taylor (Canada).

OTHER BUSINESS (Agenda Item 15)

253. The Committee was informed of the retirement of the former head of the United States Delegation, Mr. Stan Fertig, and expressed its gratitude to his outstanding contributions to the work of the CCPR over more than 10 years.

DATE AND PLACE OF NEXT SESSION

254. The Chairman informed the Committee that its 26th Session would be held in The Hague, The Netherlands, from 11-18 April 1994.

SUMMARY STATUS OF WORK

Recommendation	Step	For Action By:	Document Reference:
Proposed draft MRLs	5	CAC	ALINORM 93/24A-Add.1
Proposed draft MRLs	5/8	CAC	ALINORM 93/24A-Add.1
Draft MRLs	8	CAC	ALINORM 93/24A-Add.1
Draft MRLs	6	Governments	CX/PR 2-1993
Draft MRLs and matter arising from the 25th Session of CCPR	7	Governments JMPR	CX/PR 2-1993
Method of Sampling for the determination of pesticide residues in milk, dairy products and eggs	5	CAC	ALINORM 93/24 Appendix VI
Combined list of MRLs for related compounds	-	JMPR Secretariat	ALINORM 93/24A
Separate list of Extraneous Maximum Residue Limits (EMRLs)	-	Secretariat JMPR	ALINORM 93/24A
Expression of fat-soluble pesticides	-	Governments	ALINORM 93/24A Appendix II
Review of global and regional diets, national EDI and relationship between MRLs and dietary intakes	-	FAO/WHO Joint Secretaries of JMPR	ALINORM 93/24A
Publications of revised texts on GLP	-	Secretariat	ALINORM 93/24A
Consideration of the 1993 proposals for the Priority list	-	Government Industry, CCPR	
Review of Pesticides for which the ADI was established more than 10 years ago	-	Secretariat JMPR CCPR	ALINORM 93/24A
Identification of pesticides and pesticide/commodity combinations of interest to developing countries	-	Secretariat Governments International organizations	ALINORM 93/24A

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REGULATION OF FAT-SOLUBLE PESTICIDES IN ANIMAL PRODUCTS

1. Introduction

The fat-solubility of many pesticides has given rise to problems in setting and enforcing MRLs and therefore to specific solutions in the regulation of their residues. The general problem is that the residues are not evenly distributed in the animal tissues but accumulate in the fat, so that variations in the fat content of the animal as such, and the derived animal products, have a large effect on the pesticide concentration in the product. When these effects are not accounted for in the regulation of the residues, it may give rise to unjustified actions against products.

The problem was first encountered with the persistent and bio-accumulating organochlorine pesticides. The solution that was found in the CCPR and that was internationally accepted was the expression of the residue on a fat basis, both for meat and for milk. This already covers most of the problems that are encountered in practice. In a later phase however, some remaining issues, regarding the situation in low-fat milk products and regarding lean animals, were brought to the attention of the CCPR. This led to further adaptations. Also the question of the fat solubility of many other pesticide residues required much attention and led to adaptations in the expression of many MRLs. In 1990 the Netherlands drew the attention of the Committee to an EEC-Directive on the regulation of fat-soluble pesticides in meat, which contained a more refined approach regarding low-fat meat. Discussion of the matter in the CCPR in 1990 and 1991 and an evaluation by the JMPR in 1991 led to some further clarification regarding the fat-solubility of many pesticide residues and about the Codex MRLs that were involved, but a definitive solution was not reached. In the 1992 session of the CCPR the Netherlands agreed to draft a document on fat soluble pesticides for consideration at the next CCPR session. As a consequence, a discussion document regarding the issue is presented here.

2. Development of regulations for fat soluble pesticide residues in animal products and identification of remaining problems

2.1 Milk and milk products

Milks, also from the same animal species, can have a large variation in fat content. The fat is easily separated from the other milk components and there are many milk products on the market, with a fat content ranging from about 0.1% to near 100%. Therefore, after initial regulation on a product basis for milk only, MRLs for fat-soluble pesticide residues in milk and milk products were expressed on a fat basis. This seemed a satisfactory solution, until it was realised that this implies that when the MRL is exceeded in milk and the fat is removed, the MRL in the resulting low-fat product still exceeds the MRL, when this is expressed on a fat basis, because there is always some remaining fat. There may even be an effect of higher pesticide concentration found in the remaining fat, because there is often a preferential concentration in the smaller fat particles in the milk, which are less easily removed by centrifugation. It is obvious that it would be unjustified to condemn products which on a product basis contain only low amounts of pesticide residues, simply because the remaining residue is concentrated in the fat. Therefore, the CCPR decided in 1981 to introduce a system in which low-fat milk products, with a fat content of less than 2%, would be assessed on a whole product basis. It was also decided to

express MRLs for milk on a whole product basis (regardless of the fat content). Assuming that milk (raw or standardized whole milk) usually has a fat content of 4%, the previously existing fat-based MRLs were converted to product-based MRLs using a factor $\times 4 \backslash 100$. The product-based MRLs for low-fat milk products were then defined as half those specified for milk. The maximum residue limit for milk products with a fat content of 2% or more was defined as 25 times the MRL specified for milk, expressed on a fat basis.

Since this decision there have been no reports of problems with the application of this system. Probably the adaptations have resulted in more satisfactory and less costly solutions to local contamination problems. Some minor problems can be identified, however:

- The fact that MRLs for raw milk are set on a product basis implies that a milk with a higher fat content than 4% is only acceptable when the fat-based residue content is lower than 25 times the product-based MRL. This means that when a milk product is made from a milk which violates the MRL, without changing the fat content, it might become acceptable. In other words, the product-based and the fat-based MRLs do not fit together optimally. An alternative would be to judge milks with a higher fat content than 4% on a fat basis. This would cause a better fit between milks and their products, but would on the other hand imply that a higher amount of residues would be accepted in high-fat milks. In principle the problem also exists the other way round: raw milk with a fat percentage of 3% may have a 30% higher fat-based residue content and milk products derived from it could be therefore violate the fat-based MRL. The only real solution for these "fitting" problems would be to set the demarcation point from product-basis to fat-basis on a level which is either lower than all raw milks occurring in practice, with the consequence that all milks again would be judged on a fat basis, or higher than most milks (4 or 5%), which would retain a product-based approach for milks. In practice the mentioned possible problems probably can not be considered to be so serious as to necessitate another change here.
- The system has introduced some "irregular" figures in MRLs for milk, which are normally not accepted in the Codex MRL-system. This was caused by the calculation and the fact that original regular figures on a product basis were later magnified by a factor 25 to convert them to a fat-based MRL, rounded-off to remove the resulting irregularity of the rounding-off again. This was not felt to be a problem. Because it is only the case for some organochlorine pesticides, which are now forbidden and for which the resulting ERLs may be changed on the basis of monitoring results, it is probably only a matter of time before these irregularities will disappear.
- Because MRLs for fat-soluble pesticides in meat are still expressed on a fat basis, it is more difficult to see the consistency in the MRLs for pesticide residues between milk and meat, which is often valid because the residues are usually fairly equally partitioned in the fatty parts and products of the animal. Also, some psychological effects seem to be involved with MRLs on such different levels: expression on a product basis causes low levels, which sometimes raise doubt whether they still can be analyzed properly, and whether they are not too low. The same level, recalculated on a fat basis with a factor 25, results in high MRLs, raising doubts whether they are

acceptable. Therefore, it may be useful to discuss the various possibilities for expressing the MRLs and to investigate if greater consistency in the whole area of animal products could bring advantages.

2.2 Meat and meat products

Meats are the muscular tissues of animals, including adhering fatty tissues such as intramuscular, intermuscular and subcutaneous fat. MRLs for fat-soluble pesticides in meat are expressed on a fat basis and apply to the fat of the meat. As a rule, a portion of adhering fat is analyzed; for those commodities where the available fatty tissue is insufficient to provide a suitable sample, the whole commodity (without bone) is analyzed and the MRL applies to the whole commodity (e.g. rabbit meat) (ref. ALINORM 87/24, Appendix IV, paragraph 6).

The fat content of meat can vary widely, both within the carcass of one animal as between species. Lean meat of cattle and poultry usually has a low fat content, around 2%; for pigs and sheep this is usually somewhat higher, but still below 10% fat. The occurrence of meats with a higher fat content depends on the health and feeding status and the variety of the animal. Especially for pigs and sheep meats containing medium or high amounts of fat (20-30% fat) are common. These animals generally have a much higher total fat content in the body than more lean animals, such as cattle, poultry and especially rabbits. The total fat content of an animal is of course important for the concentration of fat-soluble pesticides in the fat, because when there is a specific dosage of the pesticide, it will be more concentrated in the small fat amount of a lean animal than in the larger fat amount of an animal containing high amounts of body fat. There are also influences from the production of milk and eggs, because with the fat-containing products, part of the residues will leave the animal and the remaining body burden will be diminished. Because of these effects, it will be evident that usually trial results with several varieties of producing animals and with different species are necessary to obtain a good judgment of the residue situation, and care should be taken not to set MRLs too easily for a whole range of animal products.

Generally the regulatory approach for fat-soluble pesticides in meat by specifying the MRL for fat will satisfy for most situations. However, when lean meat has to be judged, it will be clear that this, like in the case of low-fat milk products, may lead to the condemnation of a product which on a product basis does not contain an unacceptable amount of residues from a public health point of view. Especially for animals like rabbits, with a low total fat content of the body, this seems to be unjustified when the MRL was not based on a specific judgement of the situation for these animals, but was simply extended to cover e.g. all mammalian meats. The CCPR already decided that the best solution for lean animals is to develop a specific data base for these cases and to set specific MRLs based on this information. In practice, not much information seems to be forthcoming, and the question remains whether a more general approach, with a specific provision for low-fat meats and meat products, is justified here. In the case of animal meats for which fat-based MRLs have been set on a suitable basis of trials or monitoring results (for ERLs), the argument against such a proposal might be that evidently the animal as a whole was too highly exposed and that it is not necessary (with a view on the GAP concept) to make arrangements for low-fat products in such a situation. On the other hand, it might be argued that the background of samples is not always known, and that in the case of milk products the CCPR already took a decision with the same implication. Therefore, the CCPR might consider to make a general arrangement for lean meats and low-fat meat products, with the effect that these are judged on a

product basis. A suitable demarcation point might be 10% fat in the product, as is already incorporated in EEC-Directive 86/363 for pesticide residues in animal products.

2.3 Eggs and egg products

Codex-MRLs for eggs have always been on a product basis. In some countries, expression on a fat basis was preferred because this led to a consistent system for the MRLs for fat-soluble pesticides (especially the organochlorine compounds) for all animal products. The decision of the CCPR to revert to a product-based approach for milk made this argument invalid. Still, it can be argued that the product-based expression of the MRLs for eggs, next to the fat-based MRLs for meats, somehow blurred the visibility of the fact that a number of MRLs of especially organochlorine pesticides in eggs were much higher than those in poultry meat, a fact which was not justified because trial data show good consistency between residue levels in the meat of egg-laying animals and in the eggs, on a fat basis.

Poultry eggs usually have a fat content of 10-11%. The fat content in other eggs which are regularly marketed (e.g. from ducks and geese) can be somewhat higher. Increasingly, egg products are marketed, sometimes based on the whole product, dried or with additions like sugar and/or salt; sometimes based on only the egg white or the yolk, as such, dried or with added ingredients. The judgement of the acceptability of those derived products regarding pesticide residues can be difficult when not enough is known about the partition of the residue. In the case of fat-soluble residues, this information can be considered to be available and might be used by introducing a fat-based MRL for egg products with a higher fat content. In the EEC, this provision was introduced in a proposal for a Directive which is likely to be accepted soon. In the same proposal it was included that eggs with a higher fat content than 10% will also be judged on a fat basis.

2.4 Fishery products

Presently there is only one Code MRL for a fishery product. When ERLs would be contemplated for organochlorine pesticides, that occur in fish because of environmental contamination, the question of the fat solubility of the residues would become relevant. Available evidence shows that fish with a high fat content (e.g. eel) concentrate much more fat-soluble residues from the environment than other types of fish. Locally the levels of the residues can be high and there are some national regulations regarding organochlorine pesticide residue levels in fish. These regulations are always on a product basis, but do account for the mentioned concentration factors. Special products with a high fat content like cod liver and fish oil deserve special attention when MRLs are set. It will be apparent that further Codex attention to the matter of fat-soluble residues in fishery products is not necessary as long as no MRLs/ERLs are being developed for this product group.

3. Options for further Codex action regarding fat-soluble pesticide residues

3.1 General considerations

The present general Codex system for developing MRLs should be maintained and strengthened. This implies that all known relevant information is taken into account and that MRLs are set on the basis of generally accepted principles as GAP and the protection of public health and fair trade practices. In order to reach optimal transparency in the regulation of pesticide residues a consistent approach is

necessary, which takes account of complicating factors, such as concentration processes, by solutions which as much as possible are generally applicable and do not give rise to misunderstandings.

3.2 General options for regulating the fat-soluble pesticides

It is inevitable to have a mixed system with provisions for MRLs both on a fat basis and on a product basis, where they are justified. Still, choices have to be made how and where this is appropriate.

There are 3 general options:

- (a) Preserving the present situation and possibly introducing some adaptations to overcome problems that are encountered, e.g. a provision for low-fat meats.
- (b) Choosing for a more consistent approach for fat soluble pesticides, e.g. by adopting fat-based MRLs for all animal products, with a product-based approach for low-fat products.
- (c) Also a more consistent approach, but now choosing product-based MRLs as the ruling principle, with special provisions for products with a higher fat content.

Preserving the present situation and introducing some further adaptations where necessary is of course the most easy solution, certainly on a short term. There are some arguments however to contemplate a more consistent solution. In the first place, a more consistent system will enable a more general understanding of the principles involved and of the practical solutions. It may also help in avoiding the development of different approaches and therefore promote international harmonisation. A consistent system enables more easy data management and control. Therefore it seems worth while to investigate the merits and possible disadvantages of the options (b) and (c) more thoroughly.

Generally, much remains to be said in favour of the fat-based expression, option (b), because it is easily applicable to many products, is in line with usual analytical practices and shows the relationship between levels in various animal fats. However, there are also a number of arguments in favour of option (c). In the first place it creates better consistency with the majority of the MRLs, which are on a product basis. Secondly, it is better in line with previous Codex decisions, in which the fat-based MRLs for milk were reconverted to product-based MRLs, and with the existing situation for eggs. Thirdly, it would probably require less changes in MRLs because the conversion would be only for meats, and it would direct the attention again to the residue situation in the major product which is judged (meat), in stead of directing it to the fat which is more a by-product. Another argument is that it seems likely that application of the principle of expression on a fat basis is more difficult in intermediary cases, e.g. with a $\log P_{ow}$ between 3 and 4, or with metabolites which are more water-soluble. An intermediate solution might be to retain the MRLs for animal fats and to add MRLs for meats. More insight in the practical application aspects of the various options can be gained by looking at some examples. See Annex I.

4. Consideration of important aspects related to the regulation of MRLs for fat-soluble pesticides

4.1 Choice of the demarcation point from fat basis to product basis

For milk a demarcation point of 2% was chosen. This is justified because there are many milk products with a fat content around 3-4%, and also many products containing about 1.5% fat or lower. In this way "borderline" problems are mostly avoided and also the extent of allowing higher residues on a fat basis in low-fat products is moderate enough to be justified. A higher demarcation point, e.g. 4% or even 5%, to avoid "borderline" uncertainties about the MRL-type that should be applied, could in principle also be used, would strengthen the product-based approach, but would cause another change of residue policy, which does not seem really necessary.

For meat the EEC chose a demarcation point of 10% fat. Although borderline cases can not always be avoided here, the choice seems justified enough. A higher demarcation point (e.g. 20%) would have caused uncertainty because the effect on the judgement of carcass meats would be too high and might imply ineffectiveness of the MRL on a fat basis. A lower demarcation point (e.g. 5%) would have only insignificant effects and therefore would be without purpose. Therefore, when the CCPR would consider adopting a provision for low-fat meats, a demarcation point of 10% will be appropriate.

For egg products a demarcation point of 5% might be argued on the basis that this gives most clarity, is comparable to the milk situation and causes the product-based approach to apply only to egg white products. A choice for a demarcation point of 10% in order to reach the same approach as for meat is however also defensible. Practical problems will probably not be serious, only some whole egg products might need an extra determination of the fat content in order to see which type of MRL should apply.

An important general point related to the decision about the demarcation point between the fat-based and the product-based approach is whether the primary product is included in the fat-based approach. Milks are now fully product-based, high-fat meats are fat-based and eggs are fully product-based, but in the EEC a decision is pending to change eggs with a fat content higher than 10% (meaning in practice all eggs) to a fat-based approach. Arguments can be given for both possibilities; in any case it will be wise to avoid borderline problems by choosing the demarcation point either lower or higher than the usual fat content in the primary product. Because there are always problems involved with changing the system, especially when it would mean that analysis results have to be reported in another way, and in practice there seem to be no complaints, the best decision is probably to retain the present situation for milk, meat and eggs.

4.2 Residue levels near the limit of determination

Special considerations are necessary for product-based MRLs at a level which is considered to be a suitable level of determination for enforcement purposes. When the residue is fat-soluble and the MRL on a fat basis is above the level of determination this should be designated by not placing an asterisk (*) after the product-based MRL. It may be that calculating the fat-based MRL from the product-based MRL or vice versa with the usual factors (25 for milk and 10 for meat) is not justified in those cases. Where appropriate, more specific MRLs might be introduced.

In the EEC there is, besides the 10% demarcation level for meat, also a rule that for meat no lower levels are set than 0.01 mg/kg. This is done on the assumption that for meat (and also for all other products, except milk) it is not necessary for the protection of public health to aim at lower MRLs than 0.01 mg/kg. As a general rule, this seems acceptable also for Codex purposes (except possibly cases where the ADI is extremely low).

4.3 Classification and designation of fat-soluble pesticides

As the JMPR states in its 1991 Report, the log P_{ow} seems a suitable property for primary screening of the possible fat-solubility of a pesticide. It is evident that also the behaviour of metabolites has to be taken into consideration. The final decision obviously has to rely on the actual residue data base and must be taken on a case by case basis. In some instances where there is reason for doubt and the data base is insufficient or inconclusive, it may be necessary to ask for more data. Where fat solubility is evident this has to be designated next to the residue description and also with a suitable suffix following the MRLs for milk (e.g. F, as it is presently), but also for meat and eggs, when general provisions for high-fat products apply. See the suggested descriptions in Annex I.

4.4 Analytical aspects

It seems likely that analytical approaches are flexible enough to allow for the variations in the MRL-concept that are discussed here and it is not expected that the suggested changes will cause extra work or problems regarding this aspect, except perhaps some further attention to the fat content of products near the proposed new demarcation points. The fact that in the case of meats, fat remains the preferred sampling and analysis material and that results will be reported on a fat basis, seems a strong argument for retaining separate MRLs for meat fats in all cases. The Working Group on Methods of Analysis should look into this matter.

4.5 Identification of the work load involved with changing the MRLs for fat-soluble pesticides in animal products

It does not seem necessary to change the MRL-system for fat-soluble pesticides in animal products all at once. In many cases, it may be sufficient to recalculate and redefine the MRLs for meats and to add some appropriate notes. In a number of cases, it may be necessary to have a more thorough look at the data base, or even further data may be necessary. The JMPR shall have to be involved in these evaluations. Therefore, it is desirable to make an assessment of the possible consequences of the proposed changes and of the work load involved, before reaching a final decision.

5. Conclusions and recommendations

Evaluation of the situation regarding the Codex system for setting MRLs for fat-soluble pesticides in animal products gives rise to the conclusion that some improvements are desirable, especially regarding low-fat meat. Introduction of a more consistent system of MRLs for fat-soluble pesticides in animal products is recommended, preferably primarily presented on a product basis, but retaining the MRLs for meat fats. Provisions consisting of (calculated) MRLs on a fat basis for derived products with a high fat content can easily be introduced. Also further refinements

can be incorporated, related to MRLs at or below the lower limit of determination. It is recommended to investigate the work load involved with the proposed transition, before a final decision is taken. A gradual approach seems possible and advisable.

6. Necessary decisions

- 6.1 (a) Keeping present "mixed presentation" system for MRLs or
- (b) Change to more consistent presentation.
- 6.2 When 6.1.b was chosen:
 - (a) Preference for fat-based MRL-presentation or
 - (b) Product-based presentation.
- 6.3 When fat-based system is maintained for meat (fat):
Introduction of general provision for low-fat meat to be decided.
- 6.4 Decision about provision for high-fat egg products (in product-based system) or about low-fat egg products (in fat-based system).
- 6.5 When MRLs for eggs are presented on a product basis, and a fat-based provision is made for high-fat egg products, decision about including high-fat eggs in this provision.
- 6.6 When high-fat eggs (or, possibly even all eggs, depending on the demarcation point) will be judged on a fat basis, a decision is desirable about the question if this principle should also be extended to high-fat milks.
- 6.7 Decision about demarcation points:
 - (a) For meat: 10% proposed.
 - (b) For eggs: 10% or 5%, to be decided.
 - (c) For milk: 2% existing, no change proposed.
- 6.8 Decision about the desirability of introducing the principle of not setting MRLs lower than 0.01 mg/kg, except in the case of milk, and possibly in the case of an extremely low ADI.

EXAMPLES OF DIFFERENT POSSIBLE PRESENTATIONS OF MRLs OF FAT-SOLUBLE PESTICIDES

As a first example, the presentation of the different alternative systems (options a-c, page 5) for MRLs is given for CCPR-nr 1, aldrin and dieldrin.

<u>Option</u>	<u>Milks</u>	<u>Meat</u>	<u>Eggs</u>
a. Present CCPR-system	0.006 F	0.2 (fat)	0.1
b. All MRLs presented on a fat basis	0.15 F'	0.2 (fat)	1 F''
c. All MRLs presented on a product basis	0.006 F	0.02 F'''	0.1 F''''

REMARKS

a. Present CCPr system

This existing system is internationally widely accepted. It is a mixed system the MRLs for milks and for eggs being on a product basis and the MRL for meat being on a fat basis. Comparison of the MRLs is therefore less easy. The MRL for meat does not have a provision for low-fat meat, which implies that products from animals with a low total fat content in the body could more easily face problems because the MRLs for fat-soluble pesticides are violated. Low-fat meats might be condemned without enough justification from a public health point of view.

The suffix F after the MRL for milk means that the residue is considered to be fat-soluble and implies provisions for the calculation of the MRL for milk products from the product-based MRL for milk (raw milk and standardized whole milk). For milk products with a fat content less than 2% the MRL shall be on a product basis, at a level half that specified for milk. For milk products with a fat content of 2% or more the MRL shall be 25 times the MRL specified for milk, expressed on a fat basis.

The suffix (fat) after the product "meat" implies that the MRL applies to the fat of the meat.

Possible further additions to this system

A provision for low-fat meat could read as follows:

For meat which contains 10% fat (as a percentage on weight) or less, the residue is related to the total weight of the commodity (without bones). In that case the MRL is 1/10th of the MRL related to the fat.

Further refinements are also possible, e.g. introducing the provision that exists in EEC-Directive 86/363, with the effect that the residue level in low-fat meat is not set lower than 0.01 mg/kg on a product basis.

A fat-based provision might be envisaged for egg products; for a possible wording see under c.

b. System with MRL-presentation on a fat basis

This fat-based system would have the advantage of consistency and easy comparability of MRLs. E.g. the MRL for aldrin/dieldrin in eggs is shown to be much higher on a fat basis than the MRL for meats (including poultry meat). This will probably cause discussion about the justification of those higher MRLs, where they exist, and the necessity of further study of the data base. When MRLs for milk and eggs would have to be converted to a fat-based system, it would bring the necessity of many alterations in existing national regulations about pesticide residues. Within the Codex system, although the amount of work would be considerable, the change could still be seen as non-substantial.

Necessary and possible provisions for low-fat products

A suffix F' would be needed to introduce a product-based MRL for milk products with a fat content of less than 2%, with a magnitude of 1/50th of the fat-based MRL for milk.

A provision might be introduced to cover low-fat meat, in the same way as described under a.

A suffix F" might be introduced to make a product-based provision for low-fat egg products (when this is thought necessary, no serious problem is expected).

c. System with MRL-presentation on a product basis

This product-based system would have the advantage to optimal consistency between MRLs in the Codex system, everything primarily being expressed on a product basis. Provisions regarding fat-based MRLs for derived products with a higher fat content would be necessary, at least for milk and for meat, but a provision for egg products might also be appropriate. A disadvantage might be that the existing MRLs for fat-soluble pesticides in meat would have to be converted and that analysis results in the commodity fat which is preferentially analyzed in these cases could no longer be directly compared to the MRL but would have to be recalculated. An alternative solution might be to keep the MRLs for meat (fat) and gradually, after evaluation of the data base where necessary, to introduce MRLs for meat, which would in these cases have a suffix F and apply only to low-fat meat.

A double way of presentation (MRLs for meat next to MRLs for fat) could in particular be useful in intermediate cases of lipophilicity of the residues, where there is a preferential accumulation in the fat, but where residues in low-fat tissues are higher than is to be expected from the fat content and can not be ignored. A mixed MRL-system will then anyhow be necessary. A double presentation is in the product-based system also necessary when further refinements are desired, e.g. the introduction of a rule that the MRL in low-fat meat shall not be lower than 0.01 mg/kg.

In some cases where fat-soluble residues in milk, meat or eggs are considered to be below the limit of determination, it may be necessary to make a provision for residues in products with a high fat content, because these might be higher than the limit of determination. In that situation it seems advisable not to use the asterisk (*) next to the product-based MRL and to introduce a separate fat-based MRL for high-fat products at the appropriate level. A specific regulatory provision is then necessary for products with an intermediate fat content.

Necessary and optional provisions

An integrated system covering all mentioned options is presented here. It seems possible and advantageous, because it gives optimal clarity and easy application, to use the same suffix F to cover all provisions. See also the example further on in this Annex.

Note 1 is as already agreed in the CCPR.

Note 2 is the proposal which is already accepted in the EEC, only presented here for a primarily product-based MRL-system.

Note 3 is at present proposed in the EEC and likely to be accepted.

Note 4 is also contained in a recently proposed EEC-Directive.

Note 5 is necessary to cover adequately the gap between fat-based MRLs and product-based MRLs.

EXPLANATORY NOTES

F means fat-soluble residue. When this suffix is attached to an MRL, the following rules apply:

1. In the case of milk products, with a fat content less than 2%, the MRL shall be half of the MRL specified for milk. For milk products with a fat content of 2% or more the MRL shall be 25 times the MRL specified for milk, expressed on a fat basis.
2. The MRL for meat also applies to meat products with a fat content of 10% or lower. In the case of meat (including fat) and meat products with a fat content higher than 10%, the residue is related to the fat, with a maximum level of 10 times the product-based MRL.
3. The MRL for eggs also applies to egg products with a fat content of 10% or lower. In the case of [eggs] and egg products with a fat content higher than 10%, the residue is related to the fat, with a maximum level of 10 times the product-based MRL. [Optional: demarcation point of 5% fat and inclusion of eggs in the fat-based provision for the MRL. The EEC chose for a demarcation point of 10% and for a fat-based MRL for eggs with a higher fat content than 10%.]
4. Rules 1-3 do not apply regarding higher fat-related maximum levels or lower product-based maximum levels, when (only) the lower limit of analytical determination is indicated (*).
5. When a separate MRL is mentioned for (specified) fat in conjunction with a product-based MRL, the residue shall be related to the fat in products with a fat content which is higher than the ratio (as a percentage) between the product-based MRL and the fat-based MRL.

Special example with a double presentation of MRLs for meat

CCPR-nr 12, chlordane, presently has a fat-based MRL in meat of 0.05 mg/kg. Conversion to a product-based MRL would result in 0.005 in meat. When the rule is applied that no MRLs are set lower than 0.01 mg/kg (except for milk), retaining the fat-based MRL is necessary.

Application of rule nr 5 then is as follows:

The ratio between the product-based MRL of 0.01 and the fat-based MRL of 0.05 is 20%. Therefore, in meat (products) with a fat content of 20% or lower the MRL of 0.01 applies. For meat (products) with a fat content higher than 20% the fat-based MRL of 0.05 applies. This means for a meat (product) containing 30% fat that in the product maximally $30/100 \times 0.05 = 0.015$ mg/kg is acceptable.

The MRL presentation for chlordane then looks like this:

<u>Present CCPR-system</u>		<u>Proposed product-based system</u>	
Product	MRL	Product	MRL
Milks	0.002 E F	Milks	0.002 E F
Eggs	0.02 E	Eggs	0.02 E F
Meat	0.05 E (fat) Meat fat	Meat 0.05 E	0.01 E F

REPORT OF THE AD HOC WORKING GROUP ON ACCEPTANCES

1. The Ad Hoc Working Group on Acceptances met on 17 April 1993 to discuss issues that warranted further investigation with respect to their potential impact on the acceptance of Codex maximum residue limits (MRL's) by national governments. In particular the 24th CCPR asked the Ad Hoc Working Group on Acceptances to consider what action should be taken when Estimated Maximum Daily Intakes (EMDI's) exceed the ADI.
2. To aid this discussion a questionnaire on national consumer risk assessment procedures was circulated (on 27 October 1992) to all Codex member countries. Replies were received from 19 countries and a summary of these responses was presented to the meeting of the Ad Hoc Working Group, along with recommendations for procedures which could lead to increased transparency in consumer risk assessment procedures.
3. The summary of national procedures considered food consumption and residue concentration figures and how these data are combined to produce pesticide intake estimates used in risk assessments. The stepwise approach advocated in the WHO guidelines has achieved widespread acceptance. The responses to the questionnaire did show, however, that there are a number of significant differences in national approaches which merit discussion because they explain the difficulties which some delegations have in accepting some proposed MRL's.
4. Most countries used food consumption data generated nationally using a range of methods: diary and dietary recall methods generate data on eating habits of individuals while other methods (balance sheets and disappearance data) produce average data for households or whole populations. Average consumption data for adults was most commonly used in estimates of pesticide intakes, and several countries also prepared estimates for children and other population groups and/or measures of the top end of the distribution of food consumption behaviours.
5. The Ad Hoc Working Group supported a proposal that WHO global and regional diets should be reviewed on the basis of relevant information on national dietary habits made available to WHO. It was, however, recognised that it was unrealistic to expect the same quality of data in all regional diets and intake estimates should be treated with caution when based on less reliable consumption data.
6. It was agreed at the Ad Hoc Working Group that different measures of food consumption would be appropriate when estimating intakes of pesticides which may cause adverse health effects following single or short term exposure.
7. Almost all countries used MRL's as a measure of residue concentration in initial TMDI calculation. Most countries prepared EMDI's by incorporating reduction factors for the effects of processing and preparation before consumption.
8. It was recognised at the Ad Hoc Working Group that processing factors do not always lead to a reduction in exposure and that although processing factors may be useful on a national basis, it is sometimes less easy to use these data on a global basis.

9. It was agreed that a comparison of different national approaches may provide a basis for harmonization. Data should be made available by member countries to FAO with a view to investigation of how reduction, concentration and transformation factors are handled with a view to proposal of core data requirements and general rules for use of processing factors. It was pointed out to the meeting that useful information may be available from a paper on food processing from the working group on sampling.
10. When considering residue data, the Ad Hoc Working Group agreed that the definition of the residue was important. Occasionally the MRL could be based on a residue definition which did not include chemical(s) which were important for intake calculation and risk assessment purposes. This was fully justifiable, provided all documentation was clear.
11. In considering toxicological aspects of the risk evaluation the Ad Hoc Working Group agreed that the JMPR (WHO group) be requested to consider the definition of the ADI when the ADI was based on an adverse health effect following single or short term exposure.
12. Although the Ad Hoc Working Group recognised that there are many conservative assumptions included in allocation of ADI's and calculation of TMDI's and EMDI's, it was agreed that whenever the TMDI exceeded the ADI, this should remain a trigger for further action. As a first stage this should include refinement of intake estimates, where data are available, followed by measures to reduce intake where necessary.
13. It was, however, recognised that the use of MRL's in calculation of TMDI's leads to vast over estimates of pesticide intake. The Ad Hoc Working Group discussed proposals for modifying the methods of calculation of EMDI's - with the objective of making the best use of available trials data to derive a realistic intake estimate. There was no general agreement over changes to the currently accepted methods. It was pointed out that when the WHO guidelines for predicting pesticide intake were prepared, it was recognised that revision could be carried out in the light of experience.
14. Proposals for research work being considered by IUPAC were brought to the attention of the meeting. This work was intended to confirm the results of preliminary observations which suggest that the median residue at "maximum GAP" is around 20-40% of the MRL and to investigate ways of using this information in calculation of intake estimates. The meeting welcomed this approach and agreed that results of this project may be useful in review of guidelines for estimation of pesticide intake. The meeting agreed that WHO should revise the guidelines for estimation of pesticide intake, taking into account the IUPAC work and any other available information.
15. The meeting strongly supported a proposal that whenever a member country at CCPR commented that pesticide intake exceeded the ADI, then that member should be required to supply all the relevant residue, food intake and ADI data used in that calculation to the CCPR meeting.
16. The Ad Hoc Working Group agreed that national pesticide residue and dietary intake surveys could provide useful data for comparison of best estimates of pesticide intakes with TMDI's and EMDI's. It was suggested that if national data resulting in calculation of EDI's were submitted to WHO the information could be collated and evaluated before submission to CCPR.

17. In conclusion, the Chair of the ad hoc working Group thanked delegates for attending the meeting and contributing to a constructive discussion of ways of improving pesticide intake estimations and risk evaluation procedures. It was agreed that proposals to be taken forward from the working group to the plenary session should provide a useful basis for increasing acceptance of Codex MRL's by national governments.

18. The meeting was informed of the current status of a project started by the Ad Hoc Working Group at previous sessions of CCPR. It had been proposed that case studies of efficacy data should be developed as part of a pilot project to investigate the feasibility of forming an expert group on efficacy. However, as no information on efficacy data for the chosen pesticide/crop combinations had been received by the deadline set, it was concluded that the proposal had no support and therefore the formation of an expert group on efficacy will not be considered further.

AD HOC WORKING GROUP ON ACCEPTANCES
REVISED SUMMARY OF RECOMMENDATIONS

1. CCPR members should make information on national dietary habits available to WHO; WHO should continue to review global and regional diets on the basis of information submitted.
2. CCPR members should make information on processing data requirements and the development and use of factors (reduction, concentration and transformation) available to FAO; FAO should organise a review of this information as well as that from earlier reports of JMPR and the Working Group on Sampling, with a view to preparing core data requirements and general rules for development and use of processing data and factors.
3. JMPR (WHO group) should develop guidelines for assessing the toxicological significance of dietary exposure where adverse health effects may result from single or short-term exposure; JMPR (WHO group) should consider the definition of the ADI (or appropriate concept) in such cases.
4. The IUPAC representative should keep CCPR informed of the progress of the proposed project on the relationship between MRL's and dietary intakes; CCPR members should make any information on the relationship between MRL and median residue and the application of such relationships in calculation of dietary intakes available to WHO; WHO should review the guidelines for estimation of pesticide intake in the light of the IUPAC project and information submitted by CCPR members.
5. CCPR members asserting that intake exceeds the ADI should supply all relevant data (residue, food intake and ADI) supporting their assertion to CCPR.
6. CCPR members should make details of national EDI calculations and the pesticide residue and dietary intake monitoring and survey data on which they are based available to WHO; WHO should collate, evaluate and report to CCPR.

AD HOC WORKING GROUP ON PRIORITIES

COMPOUNDS SCHEDULED FOR EVALUATION OR RE-EVALUATION BY THE JMPR

1. The WHO Joint Secretary updated the Working Group on the 1993 and 1994 Agendas for the JMPR. Chlorpropham will be dropped from the agenda as the manufacturer will not be supplying data for the evaluation. With respect to the dithiocarbamates the manufacturer will be supplying some data for maneb but no data have been received for zineb.

2. The FAO Joint Secretary prepared and distributed complete documentation describing why each pesticide is on the upcoming JMPR agendas and why others such as propham and chlorpropham have been deleted. The Working Group expressed their appreciation for the effort that went into preparing this very helpful document. Members of the Group were invited to supply any further updates, corrections etc to the FAO Joint Secretary.

NEW COMPOUNDS PROPOSED FOR EVALUATION

3. The following new compound was proposed and tentatively scheduled for the 1996 JMPR.

PESTICIDE	COUNTRY	MANUFACTURER	JMPR*
Flumethrin	Australia	Bayer AG	1996

* Data can be supplied by the manufacturer in time for the JMPR indicated. The date has been confirmed with the Secretariat of the JMPR.

4. The following two additional pesticides were raised as possible candidates for first-time evaluation by the JMPR

4.1 Linuron - The delegate of Sweden indicated that linuron is registered for various uses in Sweden and residues had been found on both domestic and imported carrots. An effort will be made during the CCPR meeting to get some indication of whether data can be made available by the manufacturer for evaluation by the JMPR.

4.2 Tebufenozide - The delegate of New Zealand informed the Group that New Zealand would be interested in seeing this insecticide scheduled for evaluation. An effort will be made to contact the manufacturer (Rohm and Haas) to determine availability of data.

UPDATE ON RE-EVALUATION

5. Carbophenothion, Chlorobenzilate - Since the 1992 CCPR no country and/or manufacturer has come forward to indicate continued need for and/or willingness to provide data on the above two compounds. The Group therefore agreed to propose to plenary that a recommendation for deletion of CXLs should be put forward to the Commission.

6. Dicloran is scheduled for review by the 1994 JMPR. The manufacturer (Schering) has indicated that no information will be available to the JMPR. During the meeting it was indicated that there is some possibility of residue data being produced in the USA for apples. It was agreed that the status of data development on dicloran should be verified during the meeting if possible. If no data are forthcoming dicloran will be deleted from the schedule for 1994 and a recommendation will go forward for deletion of CXLs.

7. Cartap - The meeting was informed that toxicology data would be submitted in time for the 1995 JMPR. The availability of residue data and critical supporting studies has yet to be confirmed with the manufacturer.

PROPOSED PROCEDURE FOR THE PERIODIC REVIEW OF PESTICIDES

8. Two sets of comments on the above procedure were received since the 1992 CCPR. (Sweden and the USA). As the US comments were very substantive Mr Fred Ives was invited to make a presentation on the changes proposed by the US Delegation.

9. Discussion centered on the criteria for periodic review and on the time which should be allowed to elapse before a recommendation for deletion of CXLs is made to the Commission.

10. With respect to the former it was decided that the primary criterion for considering the initiation of a periodic review would be that the compound had been first reviewed (or reviewed as a part of the periodic review program) more than 10 years ago. Other criteria e.g dietary intake exceeding the ADI, were also discussed as possible criteria and may become more important as the number of candidate compounds increases.

11. To clarify the issue regarding timing for deletion of CXLs, a wording change is proposed to the draft provided by the Delegation of the USA (see attached). If the wording change is acceptable to the Working Group the procedure proposed by the USA will be taken to plenary with a recommendation for adoption.

Note: Since the Meeting of the Working Group on Priorities, the WHO Joint Secretary has made a preliminary estimation of the number of pesticides which might meet the newly proposed criteria for the periodic review. It appears that there could be a large number of pesticides coming forward for review in the next year. The estimation will be carefully checked after the CCPR meeting and the list will be included in the Circular Letter accompanying the Report of the CCPR meeting for 1993. If this preliminary estimation is accurate there will be a need at the next meeting of the Working Group to discuss criteria for a prioritization scheme. Such a scheme should take into consideration the current schedules of member countries and of the OECD in addition to other criteria such as intake.

PESTICIDES TENTATIVELY SCHEDULED FOR EVALUATION
OR RE-EVALUATION BY
THE JOINT FAO/WHO MEETING ON PESTICIDE RESIDUES

The following is the tentative list of compounds to be considered by the JMPR from 1993 to 1996.

Final Agenda of the 1993 Joint Meeting

Toxicological evaluations	Residue evaluations
<p>NEW COMPOUNDS</p> <p>etofenprox fenpropathrin metiram</p> <p>PERIODIC RE-EVALUATIONS</p> <p>Amitrole (079)</p> <p>Bromopropylate (070)</p> <p>Diazinon (022) Dichlorvos (025) Diquat (031)</p> <p>Phosalone (060)</p>	<p>NEW COMPOUNDS</p> <p>cycloxydim (179) etofenprox fenpropathrin</p> <p>PERIODIC RE-EVALUATIONS</p> <p>Amitrole (079) Benomyl(069)/carbendazim (072)/thiophanate-methyl (077)</p> <p>Bromopropylate (070) Chlorothalonil (081) Diazinon (022) Dichlorvos (025) Diquat (031) Ethephon (106) Ethion (034)</p> <p>Fenbutatin-oxide (109) Iprodione (111)</p>

Final Agenda of the 1993 Joint Meeting (cont.d)

Toxicological evaluations	Residue evaluations
<p><u>Dithiocarbamates</u> (105)</p> <p>mancozeb maneb propineb</p> <p>zineb</p> <p>Ethylenethiourea (108) Propylenethiourea (150)</p> <p>EVALUATIONS</p> <p>Captan (007)</p> <p>Ethephon (106)</p> <p>Monocrotophos (054)</p> <p>Folpet(041)</p> <p>Triazophos (143)</p>	<p><u>Dithiocarbamates</u> (105)</p> <p>mancozeb maneb propineb</p> <p>Ethylenethiourea (ETU) (108) Propylenethiourea (PTU) (150)</p> <p>EVALUATIONS</p> <p>Aldicarb (117) Azinphos-methyl (002) Benalaxyl (155)</p> <p>Carbofuran (096) Carbosulfan (145) Chlorpyrophos-methyl (090) DDT (021) Dimethoate (027) Endosulfan (032)</p> <p>Flucythrinate (152) Flusilazole (165) Folpet (041) Heptachlor (043) Hexaconazole (170) Procymidone (136) Profenofos (171) Propiconazole (160) Pyrazophos (153) Triazophos (143)</p>

Tentative schedule of the 1994 Joint Meeting

Toxicological evaluation	Residue evaluation
<p>NEW COMPOUNDS</p> <p>Clethodim Fenpropimorph Tebuconazole Teflubenzuron Tolclofos-methyl</p> <p>PERIODIC RE-EVALUATIONS</p> <p>Chlorfenvinphos (014) Chlormequat (015) 2,4-D (020) Dichloran (083) Ethoxyquin (035)</p> <p>Parathion (058) Parathion-methyl (059)</p> <p>Phosmet (103) Pyrethrins (063) Tecnazene (115)</p> <p>EVALUATIONS</p> <p>Azocyclotin (129)</p> <p>Captan (007) Carbofuran (096) Cyhexatin (067) 2,4-D (020)</p> <p>Folpet (041)</p> <p>Phorate (112)</p>	<p>NEW COMPOUNDS</p> <p>Clethodim Fenpropimorph Tebuconazole Teflubenzuron Tolclofos-methyl</p> <p>PERIODIC RE-EVALUATIONS</p> <p>Aldicarb (117)</p> <p>Chlorfenvinphos (014) Chlormequat (015) 2,4-D (020) Dichloran (083) Ethoxyquin (035) Ferbam Ortho-phenylphenol (056)</p> <p>Parathion-methyl (059) Phosalone (060) Phosmet (103) Pyrethrins (063) Tecnazene (115)</p> <p>Thiram Ziram</p> <p>EVALUATIONS</p> <p>Acephate (095) Azinphos-methyl (002)</p> <p>Bentazone (172)</p> <p>Captan (007)</p> <p>Disulfoton (074)</p> <p>Fentin (040) Glufosinate ammonium (175) Hexythiazox (176) Methamidophos (100) Moncrotophos (054)</p>

Tentative agenda of the 1995 Joint Meeting

Toxicological evaluation	Residue evaluation
NEW COMPOUNDS Fenarimol Fenpyroximate Haloxypop	NEW COMPOUNDS Fenarimol Fenpyroximate Haloxypop
PERIODIC RE-EVALUATIONS Benomyl (069)/Carbendazim (072)Thiophante methyl (077) Cartap (097) Fenthion (039) Malathion (049) Quintozene (064) Thiometon (076) Trichlorfon (066)	PERIODIC RE-EVALUATIONS Cartap (097) Fenthion (039) Malathion (049) Quintozene (064) Thiometon (076) Trichlorfon (066)
EVALUATIONS Piperonyl-butoxide (062) Vinclozolin (159)	EVALUATIONS Buprofezin (173)

Tentative agenda of the 1996 Joint Meeting

Toxicological evaluation	Residue evaluation
NEW COMPOUNDS Flumethrin	NEW COMPOUNDS Flumethrin
PERIODIC RE-EVALUATIONS Carbaryl (008) Dodine (084) Guazatine (114) Mevinphos (053) Thiabendazole (065) Triforine (116)	PERIODIC RE-EVALUATIONS Carbaryl (008) Dodine (084) Guazatine (114) Mevinphos (053) Thiabendazole (065) Triforine (116)
EVALUATIONS	EVALUATIONS

THE PERIODIC REVIEW PROCEDURE

The Periodic Review Procedure consists of two distinct phases as described below:

PHASE I

IDENTIFY PERIODIC REVIEW CHEMICALS AND SOLICIT DATA COMMITMENTS
(Year 1, April CCPR Meeting)

1. Identify Candidate Chemicals for Re-evaluation

On an annual basis the Working Group on Priorities lists chemicals meeting the following criteria:

- pesticide chemicals for which MRLs were first estimated more than 10 years ago or:
- pesticide chemicals for which a periodic review was conducted more than 10 years ago.

Tentative lists for several years may be prepared when feasible.

2. Notify Data Owners or Other Parties of Candidate List

GIFAP and governments represented at the annual CCPR Meeting expeditiously notify current data owners (or other interested parties) of the candidate list for periodic reviews, and when available, tentative lists for the following years. A copy of the most recent procedure for periodic review is also included.

3. Invite Commitment to Support Continued (or New) Codex CXLs.

With their notification to data owners (or other interested parties) on the candidacy of chemicals for periodic review, GIFAP and governments inquire of these parties their willingness to provide data for that review and as well as to advise them of the implications if they choose not to.

The invitation for a commitment will request a written response within six months to be provided to:

- Chairman, CCPR
- Chairman, Priorities Working Group
- JMPR Secretariats
- the requester (GIFAP or government representative)

(Names titles and addresses will be provided)

The invitation will request that the following information be provided in the response:

- a. A list of all commodities for which interested parties are willing to support CXLs.
 - b. A brief summary of all current GAP which they are willing to provide and which is pertinent to residue data they are willing to provide (e.g. commodities and countries for which detailed GAP summaries and representative labels can be provided).
 - c. A list of all chemistry (residue, metabolism, animal transfer, processing, analytical sample storage stability, analytical methods etc.) and toxicology studies and other data that they are willing to provide (regardless of whether previously provided) and the date they commit to make complete data package submissions to the JMPR. Comments on the status of registrations for the chemicals at the national level are encouraged, Data for which a submission is committed should be identified in the response by study or report title and number, author, date.
4. Repeat the Notification and Invitation

By means of a circular letter to accompany the report of the Meeting the Secretariat will repeat the notification and request. On receipt of the CL request, governments and GIFAP will immediately repeat their notification and invitation to identified interested parties who may not have been represented (e.g. by GIFAP) at the CCPR (they would not have received the report of the Meeting and the accompanying CL). Interested parties need only respond to one of the requests, but should copy addresses listed in item 3 above.

PHASE II

STATUS REPORT ON DATA COMMITMENTS AND CCPR FOLLOW-UP (Year 2, April CCPR Meeting)

1. Status Report on Data Commitments - The Priorities Working Group will provide a report and room document to the CCPR on the status of commitments received to provide data for each compound identified in year 1. This information will be used to schedule JMPR reviews or to make other recommendations such as withdrawal of CXLs.
2. Response to Data Commitments
 - a. If there is no commitment - to provide and identify or develop data to support current CXLs, the CXL(s) will be recommended by the CCPR for withdrawal by the next session of the Codex Commission.
 - b. If a commitment is made - to provide and identify or develop data to support current CXLs, the MRL(s) are scheduled for JMPR review, The JMPR review will result in one of the following scenarios:

- Sufficient data are submitted to confirm the CXL and it remains in place.
- Sufficient data are submitted to support a new proposed MRL and it enters the process at step 3(a) and the existing CXL is designated for automatic deletion after 4 years i.e. new proposal stands on its own.
- If insufficient or no data are submitted to confirm the existing CXL or to make a new recommendation and the JMPR recommends deletion, the CCPR may also immediately recommend deletion of the CXL.

The 4 years may be reconsidered in exceptional cases where a proponent has experienced unusual difficulty in producing the data in the time frame first indicated and has communicated the situation in writing to the individuals indicated in para 3 of Phase I.

- c. If a commitment to provide data to the JMPR by the specified times are not met the relevant CXLs may be recommended to the Codex Commission for deletion before the 4 year period is up without prejudice to a future submission. A future submission should be treated as a new chemical/CXL nomination and submitted to the Priorities Working Group for ranking.