codex alimentarius commission

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION
Sixteenth Session, 1985

REPORT OF THE FIFTEENTH SESSION OF THE CODEX COMMITTEE ON PESTICIDE RESIDUES

<u>The Hague</u> 3 - 10 October 1983

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^{*} To be distributed during 1984.

JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX ALIMENTARIUS COMMISSION

Sixteenth Session, 1985

THE CODEX COMMITTEE ON PESTICIDE RESIDUES The Hague, 3 - 10 October 1983

INTRODUCTION

The Codex Committee on Pesticide Recidues held its fifteenth Session in The Haque, The Netherlands, from 3 to 10 October 1983. Mr. A.J. Pieters, Public Health Officer of the Ministry of Welfare, Health and Cultural Affairs, Foodstuffs Division, acted as Chairman. The Session was attended by Government delegates. experts, observers and advisers from the following 39 countries:

Argentina
Australia
Austria
Belgium
Brazil
Cameroon
Canada
China, People's Republic
of
Costa Rica
Cuba
Czechoslovakia
Denmark
Egypt
Finland

France
German Democratic
Rep. (observer)
Germany, Fed.Rep. of
Greece
Hungary
Iran
Ireland
Israel
Italy
Japan
Korea, Democratic
People's Rep. of
Kuwait
Mexico

Netherlands
New Zealand
Nigeria
Norway
Philippines
South Africa,
Rep. of
(observer)
Spain
Sweden
Switzerland
Thailand
United Kingdom
United States of
America

The following International Organizations were also represented:
 Council of Europe (CE)
 European Economic Community (EEC)
 International Union of Pure and Applied Chemistry (IUPAC)
 International Federation of National Associations of Pesticide
 Manufacturers (GIFAP)
 International Dairy Federeration (IDF)

The list of participants, including officers from FAO and WHO, is attached as Appendix I to this Report.

OPENING OF THE SESSION BY THE CHIEF PUBLIC HEALTH OFFICER FOR FOODSTUFFS

2. The Fifteenth Session was opened by Mr. P.H. Berben, Chief Public Health Officer for Foodstuffs of the Ministry of Welfare, Health and Cultural Affairs of The Netherlands.
Mr. Berben described briefly the 15 years' activities of the Committee which had contributed considerably to mutual understanding in this area. He mentioned that pesticides were involved in the complex mechanism of production of foodstuffs and had contributed significantly and would continue to contribute in the struggle against hunger.
Mr. Berben also emphasized that the safety of foods treated by pesticides was to a considerable extent dependent on the outcome of the work of this Committee, which worked in close co-operation with the Joint FAO/WHO Meeting on Pesticide Residues. He hoped that all these

activities would contribute to a situation in which the role of pesticides was better understood by the general public.

ADOPTION OF THE AGENDA

The delegation of Argentina indicated that many of the documents had not been available in time, or had not been available in Spanish. They requested that all documents be distributed in Spanish at least 40 days prior to the meeting, because otherwise it was very difficult to prepare their participation properly. They, therefore, reserved their position on any decision that might be taken which could have negative effects on the export of foodstuffs from their country. The Secretariat agreed that a timely distribution of all papers in the three working languages of the Committee was of great importance, but indicated that time and manpower in the Codex Secretariat were not always sufficient to realise this aim. The Chief of the Joint FAO/WHO food Standard Programme would be informed of the request. The agenda was adopted by the Committee.

APPOINTMENT OF RAPPORTEURS

4. Ms. E. Campbell (United States of America) and Mr. A.F. Machin (United Kingdom) were appointed to act as rapporteurs to the Committee.

MATTERS OF INTEREST TO THE CODEX COMMITTEE ON PESTICIDE RESIDUES (a) Matters arising from the 15th Session of the Codex Alimentarius Commission

5. The Committee had before it document CX/PR 83/3 and an extract of the report of the 15th Session of the Commission which related to the 13th and 14th Sessions of the CCPR.

$\frac{\textit{Residues in food of chemicals used in animal husbandry and veterinary}{\textit{medicine}}$

The need to consider the question of residues in food of various chemicals arising from their use in animal husbandry and veterinary medicine had been raised not only by the Codex Committee on Pesticide Residues but also by the Codex Committee on Food Additives and the Codex Committee on Meat Hygiene.

The Commission had been of the opinion that the subject was urgent and timely and had agreed that the subject should first be examined by a Joint FAO/WHO Expert Consultation Group to be convened in 1984. The Commission would act on the recommendations of the Expert Consultation Group, and this might result in the establishment of a new Codex Committee.

$\begin{array}{c} \textbf{General discussion on temporary maximum residue limits and the} \\ \textbf{withdrawal of MRLs} \end{array}$

7. The Committee deferred discussion of this subject to Agenda Item 8.

(b) Matters arising from Codex Committee Sessions

Codex Committee on Fish and Fishery Products (15th Session)

8. The Committee was informed that there was increasing use of pesticides to prevent insect infestation of dried or smoke-dried fish and fishery products in tropical countries. Potentially dangerous situations could occur where pesticides were used without any quidance resulting in increased risk to the potential consumers. The Codex Committee on Fish and Fishery Products sought the guidance of CCPR for

overcoming such a problem. The Committee <u>suggested</u> that FAO, through its fisheries division should identify those insecticides, which could be used safely to control infestation by insects able to damage fish both during and after drying. The levels at which the insecticides could be used according to "GAP" and the resulting residue levels should be determined. As for the principles for selection of appropriate insecticides, some guidance could be obtained from the JMPR Evaluations 1981, FAO Plant Production and Protection Paper 42, page 550, which lists criteria for the selection of grain protectants. The Committee noted that the data being generated by the Tropical Development and Research Institute of the United Kingdom on the use of insecticides to control insect infestation of fish and fishery products in Northern Kenya would be most useful. Such data could also be evaluated by the JMPR for recommending maximum residue levels for such insecticides.

Executive Committee (30th Session)
Codex Maximum residue limits: Consequences of the withdrawal of temporary acceptable daily intakes

9. The Committee agreed that this subject might require the preparation of a detailed paper by the Secretariat for discussion at the next Session (See also para 73).

Codex Committee on Methods of Analysis and Sampling (13th Session)
Consideration of i) the need for confirmatory tests in selecting Codex
Methods of Analysis and ii) Limits of determination

10. The Committee agreed not to discuss the above in the plenary session but referred this subject to the Working Group on Methods of Analysis.

Codex Committee on Pesticide Residues (13th and 14th Session)

11. The discussion on environmental contaminants, arising from the last Sessions of the Codex Committee on Food Additives and of this Committee was deferred to Agenda item 14 (see paras 260-264).

- (c) Matters arising from International Organizations

 12. The delegation of the United Kingdom, speaking on behalf of the International Organization for Standardization, mentioned a discussion within ISO on the definition of lindane. Currently, lindane was defined as a product containing not less than 99% gamma-HCH. The Federal Republic of Germany had proposed to amend this description in such a way that lindane should contain at least 99.5% gamma-HCH. This proposal had not found a majority to favour it within ISO. The Committee was asked for its comments on the proposal. It was indicated that during more than 15 years, data on lindane and lindane residues had been collected with a product complying whith the current definition, i.e. containing 99% of gamma-HCH or more. A change would cause considerable confusion. The Committee expressed the opinion that the existing definition should be retained.
- 13. The delegation of GIFAP, recalling the previous issue of a booklet on the safe handling of pesticides, informed the Committee that a similar booklet, containing guidelines for the safe and effective use of pesticides had just been printed in English. It would soon be translated into French, Portuguese and Spanish. This booklet, as well as a poster on the same subject, were available at the GIFAP office in Brussels.

(d) Second Government Consultation on International harmonization of

- Pesticide Registration Requirements

 14. Mr. J.A.R. Bates, general rapporteur of the meeting held in Rome in October 1982, gave a brief overview of the main topics covered by this Consultation. A number of separate expert consultations had prepared draft guidelines in their areas. The emphasis had been on 4 aspects of the work: harmonization of data requirements, registration procedures, national control and international coordination. A large degree of agreement had been reached at the Consultation. It was now the task of registration authorities and industry to implement the conclusions.
- It was indicated that FAO was currently working on these guidelines and intended to publish them in a finalised form. Part of the material could also be included in future appropriate Codex publications.

As a consequence of the 1982 Consultation, another consultation had been planned for 1984 in order to finalize the documents from 1982. Governments would be asked to comment on these documents prior to the 1984 Consultation. The document on a model registration scheme would have to be revised and the scheme possibly simplified in order to meet the needs expressed in the $\overline{ ext{Ad}}$ $\overline{ ext{Hoc}}$ Working Group on Pesticide Problems in Developing Countries.

At the 1982 Second Government Consultation the proposal for a code of conduct on the distribution and use of pesticides had received wide support and was given high priority. A meeting held in Rome in September 1983 had discussed a new draft of this proposed code. Many of the provisions had already been accepted by a number of international organisations. It was hoped that final draft would be available for circulation to governments before the end of 1983. The 1984 Consultation would then discuss this draft on the basis of the comments received from governments.

CONSIDERATION OF THE REPORT OF THE 1981 AND 1982 JOINT FAO/WHO MEETING ON PESTICIDE RESIDUES (JMPR)

- The Committee had before it the Reports of the 1981 and 1982 JMPRs (FAO Plant Production and Protection Papers 37 and 46). The reports were introduced by Mr. Bates of the UK delegation, who had been involved in both meetings.
- Attention was drawn to paragraph 2.3 in the 1981 JMPR Report where the concept was outlined of the extrapolation of residue data from crops on which data had been obtained to related crop varieties or cultivars which could be covered by the same estimated maximum residue level.

The Committee endorsed this concept, indicating that it was not practicable to carry out residue trials with every variety within a family of crops. However, the commodities covered by a group MRL would have to be more clearly defined, in order to avoid a number of problems, particularly those related to the introduction of a computerized system and to acceptances. The ongoing work on the classification of commodities would help to clarify a number of problems in this field.

- 19. The 1982 JMPR Report contained mistakes on p.47, where thiophanate-methyl was erroneously included in a list of compounds without an ADI, and on p. 27 (section 4.24) where the third item of "further work or information" should have been listed as "desirable" rather than "required".
- 20. At the 1982 JMPR attention had been given to the difficulties caused by the lack of adequate information on good agricultural practice (Report, Para 2.3). It was agreed that every effort should be made to obtain this information to assist evaluations by the JMPR. All governments were strongly encouraged to provide data on GAP in their countries. As the basic manufacturer of a compound did not always have full information on the world-wide use pattern, other producers and distributors should be invited to provide additional information. It was suggested that FAO might undertake to revise their guidelines for the presentation of these data to the Joint Meeting. (see para 14.).
- 21. It was decided to consider the consequences of the conversion of a number of ADIs into temporary ADIs and the withdrawal of certain ADIs by the 1982 JMPR when discussing the individual compounds under agenda items 8 and 9.
- The delegation of The Netherlands pointed to the statement in the 1982 JMPR report (para 2.2) regarding ADIs, that the ADI "refers to 'man', a healthy adult male, and not to the chronically ill, or pregnant or lactating women, or others who may be more susceptible to the adverse effect of toxic chemicals than the healthy adult male". The delegation of The Netherlands indicated that toxicological studies included female animals, that data on reproduction and teratogenicity were required when estimating an ADI, and that toxicologists used a safety factor of 10 to allow for differences between healthy people and e.g., ill, young and old people. It was unreasonable that the ADI should apply only to a small proportion of the population. Such a limitation might be supposed to imply that MRLs should be similarly restricted. Several other delegations joined in the concern expressed by the delegation of The Netherlands. The Chairman also pointed to the glossary in the 1975 JMPR report, in which it was stated that the ADI applied during the entire lifetime. He indicated that if the limitations mentioned in the Report of the 1982 JMPR applied these definition should be reworded.
- 23. The representative of WHO replied that every JMPR was different from the others and might come to different conclusions. The 1982 JMPR had concluded that the ADIs it had estimated applied only to healthy adult males. ADIs were not established as well defined parameters, such as an LD_{50} value. As the ADI was an extrapolation of data obtained with healthy animals, one had to be careful in defining to what kind of subgroup of the population the ADI applied. Many of the ADIs which had been estimated previously had not been derived from data bases which had included reproduction studies. The extrapolation of the animal data was not a scientific exercise. He also indicated that in the 1977 Evaluations it had been an editorial mistake to use the word "human" instead of "man". Subsequent JMPRs had

been reluctant to accept the change from "man" to "human".

- As the Committee expressed great concern over this matter, the representative of WHO undertook to request the 1983 JMPR to reconsider it with a view to modifying the paragraph in the 1982 JMPR report.
- 25. The delegation of Sweden asked for clarification of the approach followed by the JMPR in re-evaluating pesticides the evaluation of which had involved IBT data. In some cases the existing ADI had been changed to a temporary ADI, while in others the ADI had been withdrawn.

It was indicated that the latter approach had been taken in those cases where the toxicological data had indicated potential adverse effects.

- 26. The attention of the Committee was drawn to paragraph 5.1. in the report, recommending the initiation of periodical reviews of the toxicological aspects of pesticides. In the case of older pesticides the JMPR had appreciated the difficulties of obtaining toxicological data that conformed to currently accepted scientific standards. This periodical review, therefore, would be a difficult undertaking.
- 27. The delegation of The Netherlands drew attention to a recent publication of IARC (volume 30), in which it was indicated that the data on a number of pesticides had been insufficient to evaluate their carcinogenicity for humans. Several of these pesticides however had full ADIs. This would be likely to give rise to confusion in the minds of those reading both publications. It was suggested that WHO should try to find the means to harmonize the conclusions of the JMPR and IARC.
- 28. It was indicated that IARC based its evaluations only on published data, while the JMPR had access to many unpublished reports. The set of data on which the JMPR could base its conclusions therefore included the data available to IARC. On the other hand, the JMPR was concerned only with oral exposure, while IARC also considered other routes.
- 29. It was noted that the ADIs of some compounds had been estimated long before IARC had evaluated their possible carcinogenicity. The findings of IARC might be one reason to initiate the periodical review mentioned above (para 26).
- REPORT ON ACCEPTANCES BY GOVERNMENTS OF CODEX MAXIMUM RESIDUE LIMITS 30. The Committee had before it a brief paper prepared by the Secretariat (CX/PR 83/4) on the status of acceptances of Codex MRLs and on developments as regards the issue of the Codex summary of acceptances of pesticide residue limits. The Secretariat pointed out that the Codex summary of acceptances (Ref. CAC/ACCEPTANCES PART II Rev. 2) had been prepared and was in the process of being finalized for printing. It contained some 17,000 notifications, which would have to be computerized so that the Secretariat could handle future acceptances of existing Codex MRLs as well as of new Codex MRLs to be issued shortly. It appeared from the acceptances that the concept of "limited acceptance", which recognized Codex limits for the purpose of checking imports, while applying more stringent MRLs within the country, was finding increasing favour among governments.

- 31. As regards the issue of the MRLs adopted by the Commission, the Secretariat informed the Committee that Volume XIII of the Codex Alimentarius, incorporating all Codex MRLs adopted by the Commission up to and including the 15th Session, had been finalized and would be issued to governments, together with a suitable "acceptance form", in the near future. This volume, together with the summary of acceptances, constituted the "Codex Alimentarius".
- 32. The representative of the EEC informed the Committee that an up-dated communication indicating the position of EEC countries regarding some 13 compounds, in addition to the original 16 already commented on, would be communicated to the Codex Secretariat around the middle of 1984. The Community response to Codex would be on the same basis as the previous response, i.e. an indication of the extent of free circulation within the Community of products complying with the Codex MRLs, for which Community provisions also existed.
- The delegation of Canada stated that, in view of recent changes in maximum residue limits for certain pesticides in Canada under the Canadian Food & Drug Regulations, it has been necessary to advise the Joint FAO/WHO Food Standards Programme of changes in Canada's position on three pesticides and to indicate "non-acceptance" in most cases. The three pesticides in question were binapacryl, captan and DDT and full details of Canada's reasons for non-acceptance had been outlined in their correspondence with the Commission.
- The delegation of Argentina informed the Committee that some 32 pesticides of those listed in the 4th and 5th Series of Codex MRLs were in use in Argentina. Acceptances of the MRLs in these Series had been communicated to FAO previously. It was the intention of Argentina to accept Codex MRLs as far as this was possible under GAP in that country.
- The delegation of Hungary stated that, as a principle, Codex MRLs would be given either "full" or "limited" acceptance by Hungary. "Limited" acceptance would be given where Codex MRLs were higher than national MRLs.
- The Committee was informed that Australia recognised the strong obligation on the part of participating countries in the Joint FAO/WHO Food Standards Programme to adopt Codex Standards domestically. Unfortunately constitutional factors complicated formal notification of acceptances by Australia. Before formal advice of Australian acceptance could be communicated to the Codex Secretariat, each State and Territory had to accept individually a particular MRL. Despite the relatively slow progress that is normally associated with legislative amendments, there were signs that the situation was improving. The Federal Government was actively pressing for Australian adoption of Codex MRLs and State Food Authorities were also generally convinced of this necessity. A comprehensive review was under way which would canvass the possibility of responding to the Codex Secretariat in terms of the four options outlined in the Procedural Manual of the Codex Alimentarius Commission. The majority of Australian States had already incorporated, or were in the process of incorporating, most of the 4th, 5th and 6th Series of Codex maximum residue limits for pesticides into their respective legislations and it was anticipated that notification of this would be forwarded to the Codex Secretariat in the not too distant future.

37. The delegation of Norway informed the Committee that a general legal provision giving recognition to Codex MRLs was in preparation in that country and would be promulgated towards the end of 1984.

INTAKE OF PESTICIDE RESIDUES

- Guidelines for the Study of Dietary Intake of Chemical Contaminants 38. The Committee had before it document CX/PR 83/6, prepared by the delegations of the United Kingdom and the United States of America, and the unedited final version of the Guidelines for the Study of Dietary Intakes of Chemical Contaminants (WHO-EFP/83.53; FAO-ESN/MISC/83/2) prepared under the joint sponsorship of FAO, WHO and UNEP. The Committee also had available to it a report of a Joint FAO/WHO meeting on the Guidelines for the Study of Dietary Intakes of Chemical Contaminants held in Rome, 16-21 December 1982 (FAO/ESN/MISC/83/1). (see also para 244).
- 39. In introducing this agenda item the Chairman stressed the importance of dietary intake studies, which alone can confirm that pesticide residues in food commodities do not endanger public health.
- 40. The Committee recalled that, at its 14th Session, it had agreed that guidelines for the study of the dietary intake of contaminants should be developed to stimulate and assist countries in carrying out studies to estimate actual dietary exposures of their consumers to pesticide residues. This decision had been based on the Committee's recognition of the importance of having such estimates for comparison with ADIs estimated by the JMPR in order to assess potential health risks from the use of pesticides in the production of food. Representatives of the Joint FAO/WHO Food Contaminant Monitoring Programme (FCM) who had been in attendance at the 14th Session of the Committee had indicated that they were planning to develop guidelines for conducting dietary intake studies for chemical contaminants and had agreed to cooperate in this project. This cooperation had resulted in the finalization of the above Guidelines, the first draft of which had been prepared by Dr. Jelinek of the United States and Dr. Lindsay of the United Kingdom.
- 41. The Guidelines provide detailed instructions for conducting three basic and practical procedures for estimating actual dietary exposures of consumers to chemical contaminants. The types of intake study described are:
 - (1) total diet or market basket studies;
 - (2) selective studies of individual foodstuffs; and
 - (3) duplicate diet studies.

The choice of which of these approaches to use will depend on the objectives of, and the resources available to, countries in assessing their consumers' dietary intake of chemicals. Although as stated in the Guidelines each approach has its own strengths as well as limitations, any one of these types of study can provide governments, including those of developing countries, with a means of obtaining information on actual dietary exposures to pesticide residues and chemical contaminants.

42. The Guidelines also contain procedures for countries to develop data on the food consumption patterns of their consumers, which

is a prerequisite to conducting a residue intake study. In addition, the Guidelines address other important aspects of conducting an intake study, including sample collection and preparation, analytical methods and techniques, laboratory quality assurance, and calculation and reporting of dietary intakes of pesticide residues and chemical contaminants.

- 43. The Committee was informed that a Joint FAO/WHO Expert group which had met in Rome in December 1982 had reviewed the Guidelines and had recommended that i) FAO/WHO publish the document as expeditiously as possible and give it the widest possible distribution; ii) governments give priority to dietary intake studies as an essential part of public health protection; iii) governments study the Guidelines and apply them in their national programmes in order to generate information on the intake of contaminants which should be made available to FAO/WHO and iv) FAO/WHO provide technical assistance to governments of developing countries to undertake intake studies.
- Dr. Lindsay of the United Kingdom, one of the Consultants who had prepared the Guidelines, expressed his opinion that the Guidelines met the needs of countries which had not yet undertaken any dietary intake studies. Where food consumption data were not available for economic and/or social reasons, the duplicate diet study offered a means of arriving at an estimate of intake. The Guidelines, in addition to describing methods for estimating intakes of the general population include methods for estimating intakes of special population groups such as infants.
- 45. The Committee considered the Guidelines as suitable for recommendation to Governments since they provided a number of useful methods for estimating the dietary intake of contaminants from which countries were free to select the method of their choice. That choice would depend on the country's resources and technical capabilities. No one method was suitable for the problems facing countries with widely differing resources, life-styles and food supply and distribution networks. The relative advantages, disadvantages and limitations of the various approaches had to be taken into account once the overall policy of a country's food safety programme has been determined.
- 46. The Committee noted that the expression "limit of quantitation", used in the Guidelines (paras. 8.3, 8.3.2), had a connotation which differed from that of "limit of determination". The Committee agreed that the latter was the appropriate expression in the context.
- 47. The Committee concluded that the Guidelines were a major contribution to the work of the CCPR and urged member governments to follow them if they wished to assess dietary exposures to pesticide residues in their countries. The Committee agreed to the suggestion of The Netherlands that it might be of great help to a number of countries if more precise guidance were given on what a minimum programme for the study of dietary intakes of contaminants should include, especially in circumstances where resources and technical capabilities were limited. A duplicate diet study appeared to be the minimum that a country should carry out when determining the dietary intake of contaminants by its population.

- Reports on pesticide residue intake studies in various countries
 48. The Committee had before it room document 6 and addendum 1
 detailing the pesticide residue intake studies carried out by various
 countries.
- 49. Australia had conducted a Market Basket Survey in 1981 to study the dietary intakes of lead, cadmium, sodium and organochlorine compounds including dieldrin, the intake of which had the theoretical potential to approach the ADI. The study indicated that the levels of organochlorine pesticide residues in the Australian food supply were satisfactory.
- 50. The Republic of Korea, with the assistance of FAO, had conducted studies to determine levels of pesticide residues and heavy metals in brown rice. This was an example of the assistance that could be obtained from international organizations by countries which wished to carry out studies on the dietary intake of contaminants.
- 51. The representative of GIFAP advised the Committee that it had been reviewing data on national pesticide residue intakes. The paper was now nearing completion. Whilst the survey could never be comprehensive, it had provided a reassuring picture. GIFAP would be pleased to make the information available to the Committee, if the Committee felt that such information could be helpful.
- In France studies had been carried out to determine dietary intakes of heavy metals, pesticides, PCBs, nitrates, nitrites and mycotoxins. The results indicated that the intakes of aldrin and dieldrin approached the ADI (for full details of the study see IUPAC Pesticide Chemistry- Human Welfare and the Environment- Pergamon Press 1983).
- 53. The United Kingdom had recently completed an analysis of total diet samples collected in 1981 which had included 20 food groups. The results of the study indicated that there was a continuing decline in the levels of pesticides in the diet. In addition a recent survey on fresh fruit and vegetables had indicated that some 40% of all the samples analysed contained no detectable residues of pesticides and less than 1% contained residues at the level of Codex MRLs. The Committee was informed that the United Kingdom had now published a report on monitoring studies undertaken between 1977 and 1981.
- In the United States the Food and Drug Administration had been conducting annually since 1965 total diet studies designed to estimate the actual dietary intake of pesticide residues and other chemicals in food as prepared for consumption. The studies had consisted of examining 20 market basket samples of food each year for a variety of chemical residues. The market basket samples, which were collected from retail stores in various regions of the United States of America contained approximately 120 individual food items and represented the typical diet of a 16-19 year old male. The results of the study indicated that pesticide residue intakes were substantially below the ADIs.
- In Czechoslovakia, the relative accumulation of HCB, β -BHC and DDT in human fat and mother's milk had been investigated. 173

Samples of butter, 40 samples of mother's milk and 33 samples of human fat had been analyzed.

- 56. Studies carried out in Finland had shown that the total pesticide residue intake was approximately 60 mg/person/year. Intakes from fish of PCBs, DDT and chlordane were about 1.0, 0.3 and 0.3 mg/person/year respectively. The average daily intake of DDT by a Finnish child weighing 5 kg exceeded the ADI.
- New Zealand was in the process of conducting a third dietary intake study. Contaminants and food additives to be investigated included heavy metals, preservatives, food colours and pesticides. Results of this study should be available to the next Session of the CCPR.
- In a study of cows' milk, powdered milk and human milk, Argentina had found human milk to be the most contaminated with pesticides while cows' milk and powdered milk contained lower levels. One conclusion drawn from the study was that educational efforts regarding good agricultural practice had led to a reductions in pesticide residues in milk products.

GENERAL MATTERS RELATING TO MAXIMUM RESIDUE LIMITS

- (a) Codex MRLs for Commodities established both on the Whole Product and the Edible Portion basis for the same Food
- 59. The Committee had before it document CX/PR 83/7 prepared by the Secretariat, containing a list of food commodities for which double MRLs had been set.

The Chairman of the Ad Hoc Working Group on Sampling, Mr. J.A.R. Bates, commented upon this document on the basis of a discussion about this matter in the above-mentioned Working Group. These comments, which were also included in Room Document CX/PR 83/7 Rev.1, were based on the two principles that (a) MRLs should only be set for commodities moving in international trade and (b) the classification and the definition of the portion of a commodity to be analysed should be followed. As an example he cited azinphos-methyl in kiwi fruit; the specification "in the whole fruit" in connection with the first MRL could be deleted and the second MRL expressed on the edible part could be deleted entirely because kiwi pulp was not an item moving in international trade. Most of the other items could be resolved similarly.

- 60. The delegate of The Netherlands opposed the proposal to delete MRLs for "whole peanuts", because this commodity moved in international trade and was used as such for animal feed purposes. Since peanut kernels without shell were also an item in international trade, it was agreed that in this case both MRLs should be maintained.
- 61. The Committee noted that the MRL for captafol was erroneously listed as captan in document CX/PR 83/7. As regards the MRL for carbaryl, in the pulp of bananas, this had probably been based on the analysis of bananas after removal of the skin. The delegation of The Netherlands questioned the existence of banana pulp as an item in international trade but indicated that dried banana pulp did move in commerce. It was agreed that the expression "in the pulp" was an instruction to the analyst and not a commodity description.

- The delegation of Israel pointed to the fact that governments might wish to be reassured with regard to the amount of residue in the edible part of products with inedible peel, where the MRL set for the product with peel might be quite high. The delegation of Spain urged that a thorough explanation of the Codex approach in this matter be disseminated widely and that the approach be adopted by all countries, because a system of double MRLs could give rise to more analytical work and uncertainties regarding the residue limits which should be enforced. The delegation of Australia mentioned that the wording of the Codex document ALINORM 83/24A, Appendix VIII, about the portion of banana to be analysed had already led to misunderstandings and needed revision. It was agreed that the CCPR approach should adhere to the principle that MRLs applied to the commodity as it moves in international trade and that separate MRLs should be established only where such products as pulp, juice, oil or other primary processed products were important items in international trade.
- 63. The delegation of the Federal Republic of Germany pointed to some specific MRLs that were not mentioned in the list, e.q. (089) sec-butylamine for citrus fruit, citrus juice, citrus molasses and dried citrus pulp; (033) endrin for cottonseed, cottonseed oil (crude) and cottonseed oil (edible), and (037) fenitrothion for processed and raw bran. The delegation of the United Kingdom added that the MRL for carbaryl in poultry (edible portion) also probably needed revision. Other substances were also mentioned. It was agreed that the matter needed further careful attention when considering individual MRLs.
- It was <u>decided</u> that, in principle, only one MRL should be established for one commodity, but that "double MRLs" could be established where agricultural commodities moved in trade in more than one form (e.g. whole peanuts and shelled peanuts).
- (b) Expression of MRLs and ERLs for fat-soluble Pesticides in Milk and Milk Products
- The delegation of the Federal Republic of Germany had prepared room document 8 in which it outlined the advantages of its proposal to modify slightly the approach agreed by the Committee at its 14th Session regarding the expression of MRLs and ERLs for fat soluble pesticides in milk and milk products (see para 237, ALINORM 83/24A). Without modifying the basic approach taken, the delegation proposed that the MRL for milk be expressed on a fat basis, instead of on a whole product basis. Assuming 4% fat in whole milk, the MRL for the whole product could, if desired, be derived easily by dividing the MRL on a fat basis by 25, and for milk products with 2% of fat or less, by dividing this MRL by 50. For all other milk products, the MRL on a fat basis would apply
- of The delegation of The Netherlands strongly supported this proposal, which, while in line with previous decisions of the Committee, would less easily lead to confusion and errors in the transcription of certain figures with two or more zeros after the decimal point. The delegation of the United Kingdom, supported by some other delegations, strongly opposed the proposal, as it was not in line with previous decisions and most of the data originally provided on milk had been based on the whole product.

without change.

The delegation of the Federal Republic of Germany reserved its position on the procedure adopted by the 14th Session of the Committee for the calculation of MRLs for whole milk.

- As no agreement could be reached on the proposed amendment, it was <u>decided</u> to refrain from modifying the decision of the fourteenth Session.
- (c) MRLs for Organochlorine Pesticides in Eggs and Egg Products The Committee had before it room document 7 containing a proposal from the delegation of The Netherlands to bring the MRLs for organochlorine pesticides in eggs in line with the MRLs established for these compounds in poultry. In the opinion of the delegation of The Netherlands there was sufficient scientific evidence that residue levels in eggs and in poultry were about the same when calculated on a fat basis. This was confirmed by monitoring data from The Netherlands. Furthermore, there were no important differences in the contamination of the feed for broilers and for laying hens. The established MRLs for eggs and poultry, however, differed so much that the false impression was given that eggs were more contaminated than poultry. The delegation was of the opinion that if the MRL in eggs were expressed on a fat basis it should be similar to the MRL for the fat of poultry meat. Since eggs contain about 10% of fat, this implied that the MRL for whole eggs multiplied by ten should not exceed the MRL for the fat of poultry meat. Expressing the MRL for eggs on a fat basis had also advantages for egg products. As egg-products might have a fat content which differed from whole eggs, the MRL applied to these products might be the same as that for whole eggs, if expressed on a fat basis, whereas the MRL to be applied on a whole product basis would have to be recalculated. This view was supported by the delegation of the Federal Republic of Germany. There would be no analytical problems. The delegation of the United Kingdom drew the attention of the Committee to the fact that the MRLs established for eggs had been based on experimental data relating to actual use of the compounds concerned. As the use of these organochlorine pesticides had virtually stopped, the MRLs for eggs probably could be lowered and converted to ERLs. These ERLs could then be based on monitoring data. The delegation was also of the opinion that the definition of eggs for the purposes of residue analysis should not be changed as it had taken a long time to agree on such definitions. This view was supported by the delegations of France and the United States of America.
- 69. It was <u>decided</u> not to amend the expression of the residue on a whole product basis, but to bring the questions of the Committee as to the appropriateness of the MRLs for eggs in relation to those for poultry to the attention of the JMPR.

CONSIDERATION OF AMENDMENTS TO CODEX MAXIMUM RESIDUE LIMITS (a) Consideration of draft amendments at Step 4 and 7 in the light of comments

70. Document CX/PR 83/9 contained those changes proposed by the 1982 JMPR to previous recommendations which affected Codex MRLs.

The Committee decided to discuss these proposals when considering the Draft Codex Maximum Residue Limits under the next agenda item.

- (b) Consideration of new amendments proposed by the 1982 Joint FAO/WHO Expert Meeting on Pesticide Residues
- 71. As the Evaluations of the 1982 JMPR were not yet available, the Committee <u>decided</u> to postpone the discussion on these amendments until its next Session.

CONSIDERATION OF DRAFT CODEX MAXIMUM RESIDUE LIMITS IN THE LIGHT OF COMMENTS AND RECONSIDERATION OF MAXIMUM RESIDUE LIMITS HELD AT STEP 7.1/

- 72. The Committee had before it the following documents:
 a. Part I of the Guide to Codex Maximum Limits for Pesticide Residues, containing all Codex Maximum Residue Limits and Draft Codex Maximum Residue Limits.
- b. A summary of written comments which had been received prior to the Committee's Session, CX/PR 83/8, 83/10 and add. 1 and 2 to this document.
- c. Document CX/PR 83/9, containing the changes to previous recommendations proposed by the 1982 JMPR.
- 73. The Committee noted that for a number of compounds the 1982 JMPR had either withdrawn the ADI or had converted the ADI to a temporary ADI, sometimes at a lower level. The Commission, at its 15th Session, had discussed the case of coumaphos, for which the 1980 JMPR had withdrawn the ADI. A number of Codex MRLs had been established for this compound and the Commission had asked the advice of both the CCPR and the JMPR as to how to deal with such situations. Although the Secretariat had not been able to prepare a paper which could serve as the basis for discussion, it was decided to have an exchange of views on the matter at this Session, while postponing a final conclusion to the next Session. (see para 9).
- 74. The Chairman, in introducing the subject, said that if Codex MRLs existed for a compound the ADI of which had been withdrawn, this would automatically lead to an amendment procedure. These amendments were to be considered substantial. In most cases, this would result in Codex MRLs being converted to Guideline Levels, while in some cases it might be appropriate to withdraw the Codex MRL altogether, e.g. because the product was no longer in use. It was decided to consider both possibilities when discussing the individual compounds.
- 75. An amendment procedure would have to be initiated also in cases where the ADI had been converted to a temporary ADI. In such cases the corresponding Codex MRLs should remain as such until a final decision on the temporary ADI had been taken, and draft MRLs at Step 8 should be held at that Step, pending the reinstatement or withdrawal of the ADI.
- 76. The following paragraphs reflect the discussions concerning individual maximum residue limits. Only those proposed MRLs on which discussions took place are referred to. Where no special indication is made, proposals were advanced from Step 4 to Step 5 or from Step 7 to Step 8, as appropriate. Discussion of MRLs advanced to Step 6 by the

^{1/} See ALINORM 85/24-ADD.1 to be distributed separately during 1984.

15th Session of the Commission was postponed to the next Session to allow governments an opportunity to comment. In view of the conclusion of the discussion on temporary ADIs at the previous Session, TMRLs for pesticides having a temporary ADI were not advanced beyond Step 7. It was $\frac{\text{decided}}{\text{to the Commission at Step 8 by the}}$ Secretariat as soon as an ADI had been estimated by the JMPR. The Secretariat was requested to make the necessary editiorial arrangements for easy identification of the proposals at Step 7 which were in this

The Committee noted that, for practical reasons, the consideration of "quideline levels" had been postponed to the 16th Session of the Committee.

BINAPACRYL (003)

77. The 1982 JMPR had withdrawn the ADI for this compound. Several delegations had received information that the manufacturer had no intention to replace the invalidated studies. It was indicated that the product was still used in a number of countries, although only on a moderate scale. It was, therefore, concluded that conversion of the Codex MRLs to Guideline Levels might be the best solution. The Committee decided to consider this compound again at its next Session, when more information about possible replacement studies and actual use patterns might be available.

BROMOPHOS (004)

78. The 1982 JMPR had proposed MRLs for many commodities which were higher than the existing Codex MRLs. Some countries were opposed to such increases. As the Evaluations of the 1982 JMPR were not yet available, the Committee postponed discussion of these MRLs to the next Session.

Kale

The delegation of the Federal Republic of Germany informed the Committee that GAP in that country required an increase in the MRL for kale from 0.5 mg/kg to 1 mg/kg and that manufacturers would supply data to the JMPR.

CAPTAFOL (006)

Referring to para 75 the delegation of the United States of 80. America informed the Committee that in the meantime sufficient toxicological information had become available and had already been sent to the JMPR for consideration.

CAPTAN (007)

81. Several delegations expressed their concern at the toxicity of the compound especially with respect to carcinogenicity. The Committee was however informed by the delegation of the United States of America that data at present under review in their country the evaluation of which would be completed in 1984, would be made available to the JMPR.

Cherries The delegation of the United States of America informed the 82. Committee of their tolerance of 100 mg/kg which was needed when using the compound both pre- and post-harvest. According to the delegation of The Netherlands a residue of 100 or even 50 mg/kg would be visible on the crop and would adversely affect its quality. The delegation of France drew the attention of the Committee to the fact that, while cherries and strawberries were similar commodities on which the same dosage of the compound was used, their MRLs differed greatly. The proposal was kept at Step 7.

83. The Committee <u>decided</u> to discuss this proposal when more toxicological data were available. The proposal was kept at Step 7.

CARBARYL (008)

84. The proposal for rye had been brought in line with the other proposals for grains. Accordingly it had been adopted as a Codex MRL and was not at Step 7 as mentioned in document CX/PR 83/2.

Bananas

85. The delegation of the United Kingdom had checked the original data for basanas as requested in the earlier discussion (paras 61,62). Data were apparently based on analysis of the peeled banana. It was decided to keep the original description, namely "banana' with an MRL of 5 mg/kg (in the pulp). Meanwhile however the JMPR should be asked to consider whether an MRL for whole bananas could be established. The representative of GIFAP indicated that residues data on bananas would be submitted to the JMPR.

Poultry

The original residue data for poultry were based on the use of carbaryl as a dusting powder. As a result high residues had been found on the skin of the poultry. The MRL had been established for the edible part. It was questioned however, whether this practice was still followed. Countries were invited to send data on the current use pattern to enable the JMPR to review the proposal.

CARBOPHENOTHION (011)

Most of the proposals before the Commission at Step 8 had been returned to Step 7 for review by the CCPR owing to concern about the wide use pattern and the low ADI. This problem had been discussed at previous Sessions of the Committee. The delegation of the United Kingdom stated that intake studies carried out over several years had shown that the intake was extremely low. The delegation of Australia was also of the opinion that, as the

compound was used only for selective purposes, there would be no likelihood of significant intake. It was agreed that, as the Committee had arrived at the same conclusions as had its 14th Session, this view should again be expressed to the Commission. All proposals were sent to Step 8.

CHLORDANE (012)

The Committee noted that the 1982 JMPR had changed the ADI to a temporary ADI at the same level. The maximum limits before the Committee were all ERLs, some of which were proposed amendments to existing MRLs, except those for root crops which were MRLs.

- ERLs
 89. The ERL of 0.05 mg/kq for a number of fruit and vegetable crops, meat, eggs, cereals etc., had been proposed by the 14th Session of the Committee and was intended to cover environmental contamination. The limit of 0.05 mg/kg was considered too high for most commodities of plant origin by the delegation of the Federal Republic of Germany, which preferred a limit not exceeding 0.01 mg/kg in view of the cumulative nature of chlordane.
- 90. The delegation of the United States of America was of the opinion that the limit of 0.05 mg/kg was rather arbitrary and that more information was needed on the uses of chlordane and residue levels in the environment. In any event Codex MRLs lower than 0.05 mg/kg should not be increased to 0.05 but should remain at their existing values. The delegation of Australia pointed out that 0.05 mg/kg represented the limit of determination and the presence in gas chromatograms of multiple peaks due to metabolites did not allow measurement at levels such as 0.01 and 0.02 mg/kg. Some other delegations did not share this view.
- 91. Opinion was divided as to what limit should be adopted. The Secretariat made the point that the foods now covered by the proposed ERL for chlordane of 0.05 mg/kg were only those foods which had originally been covered by MRLs established on the basis of GAP. Other foods would also be affected by an environmental contaminant such as chlordane. Furthermore, Codex ERLs should be based on appropriate data from monitoring from various parts of the world. The delegation of the United States of America will submit data from monitoring on meat and poultry.
- As regards the MRLs for chlordane in certain root crops it was noted that these were derived from residue data based on GAP. The delegation of the Federal Republic of Germany stated that most of the use patterns of persistent organochlorine compounds could not be considered as GAP.
- 93. The Committee decided that, where a Codex MRL was lower than the proposed ERL of 0.05~mg/kg, the conversion of the MRL to an ERL at the same level should be proposed to the Commission as a non-substantial amendment. Where the Codex MRL was higher than 0.05~mg/kg, it should be changed to an ERL at 0.05~mg/kg and be advanced to Step 5 as an amendment to the Codex MRL. All other ERLs should be returned to Step 6 so that they can be reconsidered by the Committee at its 16th Session. The MRLs for root crops, including the proposed amendment to the Codex MRL for sugar beets, would be held at Step 7 as the ADI is temporary.

CHLORPYRIFOS (017)

Kiwi fruit
94. The delegation of the United States of America informed the Committee that a tolerance of 2 mq/kg had been set for kiwi fruit in that country. The delegations of the Federal Republic of Germany and France had reservations on the proposed limit. The proposed MRL of 2 mq/kg was advanced to Step 5.

 $\frac{\text{Milk}}{95.}$ The Committee <u>decided</u> to retain only the amendment proposed by the 1982 JMPR, i.e. 0.01~mg/kg (*) in milk with the deletion of the

existing Codex MRL for milk products. It was agreed that the phrase "fat-soluble residue" should be added after the definition of the residue. It was agreed that the new amendment proposed by the 1982 JMPR should replace the previous one at the same Step (i.e. 7) but that it should be returned to Step 6 to allow comment by governments.

COUMAPHOS (018)

- The Committee noted that the 14th Session of the CCPR had requested the Commission to initiate the amendment of the temporary MRLs for coumaphos with a view to their conversion into guideline levels in view of the fact that the temporary ADI for this pesticide had been withdrawn by the 1980 JMPR. The Commission had in turn requested the CCPR to re-examine the question of the withdrawal of temporary ADIs and ADIs as a general issue (see also para 73).
- 97. The Committee was assured by the delegation of Israel that coumaphos had an application for cattle ticks as an alternative to lindane. The Committee then enquired about the availability of the toxicological information required by the JMPR. The representative of GIFAP informed the Committee that new information had been submitted to WHO in April 1982. The representative of WHO undertook to put this information before the 1983 JMPR.
- In view of these developments the Committee <u>decided</u> that the temporary Codex MRLs for coumaphos should be withdrawn, i.e. converted into guideline levels through the Codex Amendment Procedure, unless the 1983 JMPR reinstated either an ADI or a temporary ADI for coumaphos.

DDT (021)

The delegations of France and Italy expressed the view that it was necessary to have information on the use pattern of DDT. The Committee recalled that it had requested such information from governments. The delegation of Australia gave some information on the use of DDT as an insecticide. In reply to a question as to what was the meaning of the "conditional" ADI, the WHO representative referred to the report of the 1975 JMPR. The opinion was expressed that the concept of "conditional" ADIs was not a clear one.

Grapes

100. As the proposed MRL for grapes was at the same level as the general MRL for fruit, the Committee decided to delete the proposed MRL for grapes and also to delete the words "except grapes" in connection with the above general MRL. This change was referred to the Commission as a non-substantial amendment. The delegation of Greece indicated that, with the exception of lindane, the agricultural use of all organochlorine pesticides had been prohibited in that country since 1972, unless a special authorisation was given.

DIMETHOATE (027)

101. The delegation of The Netherlands drew the attention of the Committee to the agenda of the forthcoming JMPR in which dimethoate had been included. According to a previous agreement the compounds omethoate and formothion should also have been included. The Committee requested the JMPR to postpone the review of dimethoate to the 1984 Meeting, in order to be able to include omethoate and formothion in the review.

ENDOSULFAN (032)

102. The JMPR had been asked to reconsider the proposals for the compound but, because only very few data had been received, it had not been included in the agenda.

The Committee <u>agreed</u> that a new circular letter asking for information, especially on use patterns, should be sent to governments.

Meat, Milk

The proposals were kept at Step 7 to await the review of the compound by the JMPR.

104. The Committee <u>agreed</u> that the phrase "fat-soluble residue" should be added after the definition of the residue.

FENITROTHION (037)

Wheat flour (white)

105. The Committee noted that footnote 68 in the Guide should be deleted. Discussion on the proposal was postponed untill the next Session.

FENTHION (039)

- 106. The Committee noted that the Commission at its 15th Session had not adopted the MRLs referred to it at Step 8, mainly because of the low ADI and the possible health hazard from residues, and had asked the Committee to reconsider the MRLs at Step 7.
- 107. The Committee was informed of the continued use of the pesticide for fruit crops such as apples, cherries, bananas, citrus fruit, olives, peaches, plums and tomatoes and vegetable crops such as beans and cabbage to control infestation from the fruit fly, bean fly and cabbage maggot; the incidence of such use was limited. The pesticide is effective against developing larvae and doubt was expressed by some countries whether fenthion could be replaced effectively by any other pesticide.
- 108. The compound also had veterinary use.
- 109. The delegation of the United Kingdom advised the Committee that residues of fenthion had seldom been found in total diet studies. The Committee advanced the MRLs for all the commodities to Step 8.

PARAQUAT (057)

110. The Committee noted that the 1982 JMPR had recommended a change from a full ADI to a temporary ADI valid till 1985.

Sova beans

111. The 1981 JMPR had recommended that the existing Codex MRL of 0.1 mg/kg be increased to 0.2 mg/kg. Several countries expressed the opinion that the suggested increase in the MRL was not necessary. In view of the low consumption of soya beans in their country, the delegation of the Federal Republic of Germany dit not object to the MRL for soya beans. However, they objected in principle to MRLs greater than 0.05 mg/kg for this compound in foods of plant origin. The delegation of the United States of America reserved its position on the Step 3 proposal pending disposition of a petition currently under review.

112. The Committee advanced the MRL of 0.2 mg/kg for soya beans to Step 5.

THIABENDAZOLE (065)

113. The Committee advanced the MRL of 3 mg/kg for strawberries to Step 8 and agreed to consider the MRL for tomatoes at its next Session. The delegation of the Federal Republic of Germany indicated that its country was awaiting more detailed toxicological information on this pesticide from the manufacturer and expressed a reservation.

CYHEXATIN (067)

114. The delegation of the Federal Republic of Germany pointed out that the residue definition for azocyclotin included cyhexatin but that the definition of cyhexatin did not include azocyclotin and that, therefore, the MRLs for apples, beans and strawberries might be taken to apply separately to cyhexatin and azocyclotin. The delegation was of the opinion that a single MRL should cover combined residues of the two pesticides.

The Committee noted that the 1982 JMPR had amended the residue definition of both compounds. A discrepancy still existed between the CCPR and JMPR residue definitions of cyhexatin and the Committee agreed to refer the question to the Working Group on Methods of Analysis. (see para 201).

115. The delegation of Sweden expressed a general reservation against the acceptance of an MRL of 2 mg/kg for fruits since in its opinion such high MRLs might result in the intake of the pesticide exceeding the ADI.

Beans

The delegation of Canada was of the opinion that the proposal of 0.5 mg/kg for beans was not sufficiently supported by the data in the 1978 Evaluations, which indicated that 0.2 mg/kg was sufficient. The Committee agreed to keep the proposal at Step 7 of the Procedure pending a further review by the JMPR and to recommend that the JMPR consider a limit of 0.2 mg/kg.

Peaches

The Committee <u>decided</u> to keep the proposal of 2 mg/kg for peaches at Step 7 pending consideration by the JMPR of residue and GAP data which had been submitted.

Strawberries

The delegation of The Netherlands opposed the MRL of 2 mg/kg for strawberries and preferred a level of 1 mg/kg. However, the Committee advanced the MRL of 2 mg/kg to Step 8. The delegation of the United States of America indicated that a United States tolerance of 3 mg/kg existed for this commodity, but that it could support an MRL of 2 mg/kg.

DEMETON-S-METHYL (073)

The Committee noted that the 1982 JMPR had withdrawn the ADI. The delegation of the Federal Republic of Germany informed the Committee that this pesticide was registered in that country and that it was intended to review old and new toxicological information by 1985. Toxicological information had been forwarded to the JMPR.

120. The Committee <u>decided</u> to leave the temporary MRLs unchanged until the JMPR had evaluated the new toxicological data. The matter will be reconsidered at the 1984 Session of the Committee.

THIOMETON (076)

121. The delegation of the Federal Republic of Germany indicated that the ADI could not be accepted since, in its opinion, it was not based on a "no-effect level" and because no screening tests for mutagenicity had been reported. The Committee noted that the JMPR had used the same data base as the Federal Republic of Germany.

Maize (leaves, stalks and cobs)

122. Following verification by the Secretariat, the Committee noted that the above description referred to animal fodder consisting of the whole plant. The proposal would be considered by the Committee at its next Session.

VAMIDOTHION (078)

123. As the 1982 JMPR had established a temporary ADI for the compound, the guideline levels had been converted into TMRLs. Data on which the proposals were based, however, were from before 1973. Several delegations were of the opinion that consideration of the compound should await publication of the data on which a temporary ADI had been established by the 1982 JMPR. They were also of the opinion that the proposed TMRLs were too high in relation to the temporary ADI. The Committee decided to ask the JMPR to look at more recent residue data, of which some had already been provided by The Netherlands, and at the current GAP. Countries were encouraged to send data to the JMPR. The proposals were returned to Step 3 to allow governments an opportunity to consider the toxicity data to be published in the 1982 Evaluations.

CHINOMETHIONAT (080)

Tomatoes
124. The delegation of The Netherlands proposed that an MRL should be established for tomatoes on the basis of data already presented in the 1981 Evaluations (page 34). It was decided to ask the JMPR to consider this matter.

CHLOROTHALONIL (081)
125. The delegation of the Federal Republic of Germany reserved its position because the toxicity of the compound was under review in its country. The contamination of the compound by HCB should also be taken into account.

 $\frac{\text{Grapes}}{126.} \qquad \text{As the proposal had been omitted from document CX/PR 83/2, the Committee } \frac{\text{decided}}{\text{decided}} \text{ to return the proposal to Step 6 to give governments} \\ \text{an opportunity to consider the proposal.}$

DICHLOFLUANID (082)

Cereal grains

127. The Committee noted that the Commission had regarded the proposal to replace separate Codex MRLs for barley, oats, rye and wheat as substantial. It will be considered by the next Session of the CCPR.

SEC-BUTYLAMINE (089)

Citrus molasses, Dried citrus pulp

The delegation of the Federal Republic of Germany enquired whether residues at the rather high levels of the MRLs set for these animal feeds could result in residues in animal products in excess of the proposed MRLs. The delegation of Australia confirmed that feeds containing residues at these levels had been taken into consideration. The delegation of the United States of America was of the opinion that an MRL of 90 mg/kg would be more appropriate for citrus molasses, on the basis of the data which had been available to the JMPR. The Committee requested the JMPR to reconsider the temporary MRL of 50 mg/kg in citrus molasses and agreed to hold both MRLs at Step 7 pending reconsideration of the temporary ADI by the JMPR.

Milk

The delegation of France indicated that levels below 1 mq/kg were being found in that country. The Committee noted that this MRL (held at Step 8) was needed to take into account sec-butylamine naturally present in milk.

DEMETON (092)

- 130. The Committee questioned whether this pesticide was still in use and noted that it was still used in Canada and the United States of America. The product was still manufactured by the same company. The delegation of Canada indicated concern in that country over the extent of use in relation to the ADI. The toxicological data were old and in the opinion of the delegation would no longer support an ADI.
- 131. The Committee $\frac{\text{decided}}{\text{decided}}$ to refer this information to the JMPR noting that demeton and related compounds were on the agenda of the 1983 JMPR. It was agreed to defer consideration of this pesticide until after the 1983 JMPR.

ACEPHATE (095)

132. The Committee noted that the 1982 JMPR had changed the full ADI to a temporary ADI valid until 1984, and that acephate would shortly be reviewed by the JMPR on the basis of new data that would be available. The Committee suggested that since methamidophos was related to acephate, it might be wise to review these compounds together. The delegation of the United States of America informed the Committee that the repeat toxicology studies for acephate were complete and could be considered by the 1984 JMPR. The delegation of the Federal Republic of Germany had a general reservation against the wide use pattern of acephate in view of its low ADI.

Potatoes

133. The Committee noted that acephate was still used in certain countries for aphid control in potatoes.

The Committee held the MRL of 0.5 mg/kg for potatoes at Step 7.

DIALIFOS (098)

134. The Committee was informed by the delegation of the United States of America that no new toxicological data could be expected from the manufacturer. Consequently it was recommended to the Commission to change the proposed MRLs to Guideline Levels.

EDIFENPHOS (099)

Cattle meat by-products, Carcase meat of cattle, Eggs, Poultry by-products, Poultry meat, Milk and Rice bran

As there were no comments on these proposals the Committee decided to advance them to Step 5 of the Procedure with the recommendation to the Commission that Steps 6 and 7 be omitted.

METHAMIDOPHOS (100)

The Committee noted that the 1982 JMPR had changed the full ADI for this pesticide to a temporary ADI valid until 1985. The delegation of the United States of America informed the Committee that toxicological studies on methamidophos, presently in progress in their country, would be completed by 1984.

Broccoli, Lettuce The delegation of the Federal Republic of Germany reserved its position because of the relatively high limits in relation to the low temporary ADI.

Eggplants The delegation of the United States of America informed the Committee that it had new data to support an MRL of 1 mq/kq for eggplants which it would transmit to the JMPR.

PIRIMICARB (101)

The delegation of the Federal Republic of Germany had a general reservation because of the toxicity data especially with regard to carcinogenicity. The question of the representative of WHO as to whether these data had been available to the JMPR was answered affirmatively by the delegation of the United Kingdom.

Oranges The delegation of Spain informed the Committee that new 140.

residue data on oranges were expected. The delegation of Israel would have preferred a group tolerance for citrus fruit but it was explained that the JMPR had not been able to establish such an MRL as the available residue data were only on oranges. Governments were requested to send data on citrus fruit to the JMPR for evaluation. The proposal was advanced to Step 5.

Cottonseed, Pecans, Sweet corn As these proposals were at the limit of determination they were advanced to Step 5 with the recommendation that Steps 6 and 7 be omitted.

Watercress

The question was raised whether this commodity was an important item in international trade. The delegations of The Netherlands and the United Kingdom stated that the commodity moved in international trade, although not on a large scale. The proposal was advanced to Step 5.

MALEIC HYDRAZIDE (102)

Specification for maleic hydrazide The Committee discussed the written comment of Sweden that the ADI and MRLs should specify the hydrazine content. It was pointed out

that it would be more practical to include a limit for hydrazine in the specifications of the pesticide. The delegation of the United States of America informed the Committee that in a review in the U.S.A. agreement had been reached by registrants on a maximum level of 15 mg/kg in technical maleic hydrazide, which was not used in agriculture, and 1 mg/kg in the potassium salt. It was noted that the ADI applied only to the sodium or potassium salt (not the diethanolamine salt) containing less than 1.5 mg/kg of free hydrazine (the 1980 Evaluations referer one ously to 15 mg/kg on p. 258, as a result of typing error). The delegation of France was of the opinion that a limit of 2 mg/kg for hydrazine in the potassium salt would be more suitable, partly because of analytical difficulties.

The Committee <u>agreed</u> to refer this question to the FAO Panel of Experts on Pesticide specifications.

Onions

The Committee considered a proposal by the Federal Republic of Germany to reduce the MRL of 15 mg/kg to 10 mg/kg. The delegation of France expressed reservations on both of these proposed MRLs. The delegation of The Netherlands indicated that improved analytical methods had shown that the limit of 10 mg/kg was appropriate. The delegation of the United states of America supported a limit of 15 mg/kg. The Committee decided that there was no reason to refer the MRL back to the JMPR and it was advanced to Step 5.

Potatoes

The delegation of the Federal Republic of Germany considered that the MRL of 50 mg/kg was too high. The delegation of France expressed reservations on the proposed MRL. The delegation of The Netherlands also had reservations about the MRL, noting however that this pesticide was one of the best available. The delegations of the United States of America and Australia supported the MRL of 50 mg/kg and indicated that a high level of residue was needed to preserve the potatoes during prolonged storage. The Committee decided that there was no reason to refer the MRL back to the JMPR and it was advanced to Step 5.

PHOSMET (103)

Apples, Apricots, Cranberries, Grapes, Nectarines, Peaches, Pears
146. The delegation of the Federal Republic of Germany queried the need for such a short (0-1 day) pre-harvest interval, requiring an MRL of 10 mg/kg for apples, peaches and pears. Other delegations expressed a similar reservation. It was noted that the original data had come from Canada and the U.S.A. It was agreed to keep these MRLs at Step 7 pending clarification by the JMPR of the short pre-harvest intervals.

Milk

147. The Committee noted that the MRL for milk was based on the limit of determination and had not been derived by recalculation of a previous MRL expressed on a fat basis. The Working Group on Methods of Analysis confirmed that 0.02 mg/kg was the practical limit of determination. The MRL was advanced to Step 8.

Forage crops (dry)

148. The delegation of the United States of America undertook to provide residue data to the JMPR so that this MRL, which had been

returned to the Committee by the 15th Session of the Codex Alimentarius Commission, could be reviewed. The MRL was <u>held</u> at Step 7.

DITHIOCARBAMATES (105)

149. The Committee noted that all the proposals for MRLs were at Step 7 and that the pesticides were included in the agenda for the 1983 Joint Meeting.

The delegation of France was informed that the new pesticide residue data that their government had provided on lettuce would be discussed by the 1983 meeting. Finland informed the Committee of the availability of a joint Scandinavian toxicity study carried out by the pesticides registration authorities of Denmark, Finland, Iceland, Norway, and Sweden which would be made available to the JMPR.

- 150. The representative of WHO reminded the Committee that the assessment of data in the Joint Meeting was made by experts acting in their individual capacity and that their conclusions would not be influenced by countries' decisions. If the countries wanted to contribute to the meeting, they should submit raw data that had not previously been available to the JMPR. The countries should submit such data to WHO and FAO soon after the announcement of the agenda for the meeting. The Chairman said that he anticipated that studies such as the Scandinavian one would be considered by the JMPR. The delegation of the Federal Republic of Germany was of the opinion that the Committee should consider the inclusion of propylenethiourea in the residue definition. (see also para 226).
- 151. All the MRLs were <u>retained</u> at Step 7 and will be considered at the next Session of the Committee in the light of the re-evaluation of the pesticide residue data by the 1983 Joint Meeting. It was noted that the re-evaluation of the ADI was not on the agenda of that JMPR.

ETHIOFENCARB (107)

Beans (with pod), Beans (without pod)
152. The Committee noted that the descriptions beans (with pod) and beans (without pod) referred to two different commodities. The delegations of The Netherlands and the Federal Republic of Germany were of the opinion that according to the data in the Evaluations of the 1977 JMPR an MRL of 2 mg/kg for beans (with pod) would be more appropriate. In the opinion of the delegation of the Federal Republic of Germany, the 1977 data showed that beans (without pod) required an MRL of 0.5 mg/kg. The Committee decided to keep the proposals at Step 7 and ask the JMPR to reconsider the data quoted in the 1977 Evaluations.

Beets, fodder: fodder beets tops
153. To prevent confusion it was decided to change the entry
"beets, fodder" in the Guide to "fodder beets."
The delegation of France questioned whether fodder beet tops could be
regarded as being an item in international trade. It was stated that the
MRL was probably established to control residues in products of animal
origin. Data were presented in the 1978 Evaluations (p. 124) but the
word "tops" was omitted from the table. It was decided to delete the
proposal for "fodder beets, tops" and to advance the proposal for fodder
beets to Step 8.

IPRODIONE (111)

The delegation of the United States of America was of the opinion that, as the metabolite 1-(3,5-dichlorophenylcarbamoy1)-3isopropylhydantoin could account for up to 30% of the residue, it should be included in the residue definition. The delegation of Australia, supported by the delegations of the Federal Republic of Germany and the United Kingdom, explained that the JMPR was of the opinion that metabolites of minor toxicological importance should not be included in the definition of the residue, as inclusion would only give rise to analytical problems. The delegation of the Federal Republic could not agree with the ADI because it did not believe that a no-effect level had been demonstrated. It was decided to retain the existing definition of the residue.

PHORATE (112)

155. A temporary ADI had been established by the 1982 JMPR and the guideline levels had therefore been converted to TMRLs. The delegation of The Netherlands, supported by the delegations of the Federal Republic of Germany and France preferred that, because of the toxicity of the compound, all proposals except those for animal feedstuffs should be at or about the limit of determination. Which figure should be regarded as the limit of determination was not clear, but using the compound would give rise to residues above the limit. The Committee decided to ask the Working Group on Methods of Analysis to consider what limits of determination would be appropriate for food of animal origin and for crops. All the proposals were returned to Step 3.

PROPARGITE (113)

Tea (dried, manufactured)

156. The footnote 185 in the Guide should read 187 and that the proposal was at Step 7. It was decided to return the proposal to Step 6 to enable governments to comment on it.

Raisins

157. The delegation of the United States of America informed the Committee that it would make data available to the JMPR to justify an MRL for raisins of 25 mg/kg although it was aware that the 1981 JMPR had changed the MRL from 25 to 10 mg/kg.

TECNAZENE (115)

Potatoes

158. The delegation of Sweden preferred an MRL of 0.5 mg/kg and proposed deletion of the qualification "washed before analysis". The latter point had been discussed at length at the previous Session (ALINORM 83/24 A para 160). The delegation of the United States of America supported an MRL of 25 mg/kg, did not concur that potatoes should be washed before analysis and expressed concern that washing the potato before analysis did not protect the health of the consumer. The delegation of the United Kingdom reminded the Committee that the variation in residues on unwashed potatoes was such that the data could not be interpreted. Thorough washing reduced the variation to acceptable limits. A proposal to insert "thoroughly" before "washed" was discussed but rejected. It was decided to retain the present wording. It was noted that data available to the 1981 JMPR gave some indication that an MRL of 1 mg/kg was too low, but were too limited to support an

increase. Governments were <u>requested</u> to make data available to the JMPR. The proposal was returned to Step 6.

Tomatoes

The delegation of the Federal Republic of Germany drew the attention of the Committee to the fact that the TMRL for tomatoes could be deleted as it was included in the group tolerance for vegetables at the same level. The Committee agreed to delete the TMRL.

ALDICARB (117)

Citrus fruit

The proposed MRL of 0.2 mg/kg had been confirmed by the 1982 JMPR. Several delegations were, however, still of the opinion that an MRL of 0.5 mg/kg would be more appropriate. The delegation of the United States of America informed the Committee that the manufacturer was developing more residue data which would be made available to the JMPR. It was decided to keep the proposal at Step 7 pending reconsideration by the JMPR.

- Maize fodder, Maize forage
 161. The delegation of France questioned whether these were two different commodities. It was pointed out that "forage" applied to the entire green plant and that "fodder" applied to the mature stalk after removal of the ear. Discussion of the MRLs was postponed to the next Session because they had been proposed by the 1982 JMPR.
- All the other proposals at Steps 3 and 6 will be discussed at the next Session.

CYPERMETHRIN (118)

- The delegation of the Federal Republic of Germany reserved its position on all of the proposals as the compound was currently under review in its country.
- The Committee noted that the phrase "fat-soluble residue" should be added after the definition of the residue.

Alfalfa, Maize fodder, Sorghum fodder

The delegation of The Netherlands was of the opinion that the data presented in the 1981 Evaluations justified an MRL of 2 mg/kg instead of 5 mg/kg. The JMPR was requested to reconsider the proposal in the light of the available data.

The MRLs for these commodities referred to the products on a dry weight basis. The Guide would be revised accordingly. The proposals were advanced to Step 5.

Carcase meat, Meat by-products

The delegation of Australia undertook to provide data to the JMPR justifying an increase of the proposed MRL to 0.5 mg/kg. These residue data were based on direct application of the compound to livestock.

It was indicated that the description "meat by-products" might need to be amended in the light of the new classification, and also in relation to its definition in other Codex standards. The proposals were advanced to Step 5.

Coffee beans

167. It was agreed to advance the proposal to Step 5 with the recommendation that Steps 6 and 7 be omitted.

Nectarines, Peaches

The delegation of France was of the opinion that their data and those recorded in the 1981 Evaluations did not justify an MRL of more than 1 mg/kg. The proposal was advanced to Step 5. The proposal for peaches will be before the next CCPR at Step 6.

FENVALERATE (119)

The delegation of the Federal Republic of Germany reserved its position on all proposals, as the compound was currently under review in its country. The delegation of Finland reserved its position for toxicological reasons. The delegation of Canada informed the Committee that a dog study with the compound had been carried out, but that a final report of this study had not yet been written. It was hoped that, in addition to the 6 months dog study which had already been evaluated, the manufacturer would repeat a 1 year dog study.

170. The delegation of France indicated that it was planned to review the group of pyrethroid compounds in the near future with respect to their toxicity, application rates and pre-harvest intervals. The results of this review would be submitted to the JMPR.

Brassica leafy vegetables

The delegation of the United States of America, while supporting the principle of group tolerances, believed that the data provided for brassica leafy vegetables were not sufficiently representative to support a group limit. Moreover, GAP for cabbage required a higher limit than 2 mg/kg. They undertook to provide additional data to the JMPR.

Melons

172. It was <u>decided</u> to delete the restriction to honeydew melons, so that the proposal would apply to all melons (it was noted that watermelons were not included in the commodity "melons"). The proposal was advanced to Step 5.

Peppers

173. Pending completion of the new classification, it was agreed to change the commodity description to "bell peppers", as in the 1981 JMPR Evaluations.

PERMETHRIN (120)

The delegation of the Federal Republic of Germany reserved its position as the toxicity of the compound was currently under review in its country. The delegation of Finland entered a general reservation against the compound for toxicological reasons.

- 175. The Committee agreed that the phrase "fat-soluble residue" should be added after the description of the residue.
- 176. The delegation of the United States of America informed the Committee that the definition of the residue in its country was different from that of the Committee. They undertook however to reconsider this matter.

177. The delegation of France drew attention to the differences in the MRLs recommended for cypermethrin, fenvalerate and permethrin, which seemed anomalous in view of their relative application rates. The Committee agreed to seek clarification from the JMPR.

Cereal grains, Wheat bran, Wheat flour (white), Wheat flour (wholemeal)

The delegation of The Netherlands questioned whether an MRL of 2 mg/kg for wheat flour (wholemeal) was justified, since an application rate of 1 mg/kg on grain was currently considered to be good agricultural practice. It was pointed out that 2 mg/kg for cereal grains was required to accomodate the inhomogeneous distribution of the residue. For milled products however, the residue would be distributed more evenly and in the opinion of the delegation of The Netherlands an MRL for wholemeal flour of 1 mg/kg would be adequate. It was indicated that the data on flour were not entirely reliable, as they had been derived using small-scale milling equipment. When using large-scale commercial equipment it might well be that the proposal would have to be amended. Moreover, GAP might require higher application rates in future. It was for these reasons that the Committee decided to consider the MRLs for wheat bran, wheat flour (white) and wheat flour (whole meal) as being temporary, irrespective of the status of the ADI.

The delegation of the Federal Republic of Germany asked why for permethrin the residue in poultry meat was expressed on a fat basis, whereas for the related compound cypermethrin it was expressed on a whole product basis. The Committee was informed that the 1982 JMPR had set the MRL for cypermethrin for the whole product on the basis of available data. The proposal was advanced to Step 5.

 $\frac{2,4,5-7}{180}$. The Commission, at its 15th Session, had not accepted the recommendation of the Committee to omit Steps 6 and 7 for this compound. The proposals would therefore come before the next Session of the Committee at Step 6.

AMITRAZ (122)

The delegation of the Federal Republic of Germany reserved its position as the compound was currently under review in its country, especially with regard to possible carcinogenicity. The delegation of Brazil informed the Committee that in its country amitraz was permitted only for veterinary use, and not for agricultural uses.

The delegation of France reserved its position, both for toxicological reasons and because the proposed MRLs, especially for fruits, were considered too high.

The delegation of the United States of America stated that, according to the registrant, the mouse study requested by the 1980 JMPR would be available in 1984.

Carcase meat of sheep 182. The delegation of The Netherlands was of the opinion that the data in the 1980 Evaluations supported an MRL of 0.1 mg/kg rather than of 0.2 mg/kg. Because of the low ADI of the compound, the lower figure

was preferred. The JMPR was $\frac{\text{requested}}{\text{to reconsider}}$ to reconsider the proposal, which was advanced to Step 5.

Cattle meat by-products

183. It was indicated that the MRL for this commodity was higher than that for cattle meat because the residue occurred mainly in the fat and in organs such as liver and kidney. The proposal was advanced to Step 5.

Cottonseed oil

184. The delegation of The Netherlands questioned whether the proposed MRL referred to crude or refined oil. Reference to the Evaluations indicated that crude oil was intended. The proposal was advanced to Step 5.

Cucumber

185. The delegation of The Netherlands indicated that on the basis of the data in the 1980 Evaluations, and taking into account a pre-harvest interval of 3 days, an MRL of 0.2 mg/kg would be appropriate. The JMPR was requested to reconsider the proposal, which was advanced to Step 5.

ETRIMFOS (123)

Barley, Maize, Wheat, Wheat bran (unprocessed), Wheat flour (white), Wheat flour (wholemeal).

186. The delegations of the Federal Republic of Germany, France, Italy and The Netherlands expressed strong reservations against these proposals in view of the very low ADI, the high consumption of cereal products in their countries and the persistence of the residues when preparing cooked or baked foodstuffs. The proposals were advanced to Step 5.

MECARBAM (124)

Oranges

187. The delegation of the Federal Republic of Germany indicated that in its opinion the metabolites 0,0-diethyl S-methylcarbamoylmethyl phosphorodithicate ("diethoate") and diethoate-oxon had not been studied sufficiently. It pointed to an analogous situation with dimethoate, where the metabolite omethoate was much more toxic than the parent compound. Moreover, diethoate was also a pesticide in its own right. It was indicated that data in the 1980 Evaluations showed that the parent compound remained the predominant residue in the peel.

188. The delegation of Finland was of the opinion that, on the basis of extensive monitoring of imported oranges, an MRL of 1 mg/kg was adequate and was preferred because of the low ADI. It was indicated that the basis for setting MRLs was the residue at the farm gate, not at the time of arrival at an importing country.

METHACRIFOS (125)

The delegations of The Netherlands, Finland, the Federal Republic of Germany, Italy and France were of the opinion that, as the ADI was very low, it was difficult to accept the MRLs for commodities such as cereals, pulses, peanuts, cocoa beans etc. The delegation of Australia pointed out that methacrifos was unstable and was totally destroyed on cooking. It was therefore an ideal grain protectant with a wide spectrum of activity.

190. The Committee, in advancing the MRLs to Step 5, noted that it would have an opportunity to reconsider the above question at a future Session in the light of further information.

OXAMYL (126)

Definition of Residue

191. The delegation of Canada pointed out that N,N-dimethyl-1-cyanoformamide (DMCF), which is present frequently as a plant metabolite, was apparently not a significant animal metabolite. Data on its toxicity were therefore needed. The Committee agreed that this matter should be referred to the JMPR. The Committee noted that the residue definition included oxamyl oxime and that this correction should be made in the Codex document.

Temporary MRLs and general comments

192. It was noted that some of the MRLs were temporary owing to the lack of certain residue data. The delegation of the United States of America indicated that the required information had been sent to the JMPR Secretariat. The delegation of the Federal Republic of Germany had reservations on a number of the MRLs.

Lima beans, Celery, Citrus fruit

The delegation of Australia indicated that higher limits were needed for these commodities. It was agreed to request the JMPR to reconsider these MRLs in the light of data to be supplied by Australia. The delegation of The Netherlands had reservations about the excessive application rates studied in celery and citrus fruit. It was agreed that countries where shorter pre-harvest intervals were required, leading to higher MRLs, should provide information on the need for such agricultural practices.

Cucumbers, Peppers

The delegation of The Netherlands was of the opinion that 1 mg/kg in cucumbers was sufficient to cover the recommended application rate. Information was needed on current GAP. For similar reasons an MRL of 2 mg/kg was thought to be sufficient for peppers.

Additional MRL for onions

195. The delegation of The Netherlands indicated that it would try to submit residue data to the JMPR to enable it to recommend an MRL for onions.

Conclusion

The Committee noted that the JMPR intended to review the MRLs for oxamyl. The MRLs were advanced to Step 5.

PHENOTHRIN (127)

197. The Committee was informed that appropriate toxicological studies had been commissioned and it was expected that the results would be submitted to the 1984 JMPR.

198. The delegation of The Netherlands suggested that MRLs should be established for wholemeal flour and white flour. The Committee <u>agreed</u> to request the 1984 JMPR to examine the possibility of setting such MRLs. Governments were <u>requested</u> to supply data to the JMPR.

PHENTHOATE (128)

The delegation of the Federal Republic of Germany expressed reservations concerning this pesticide in view of the fact that the long-term toxicological studies were not yet available.

Rice (de-husked)

The Committee <u>decided</u> to change this description to "rice (hulled)" and advanced the proposal to Step 5.

AZOCYCLOTIN (129)

Definition of Residue

201. The Committee noted that the 1982 JMPR had adopted new definitions of the residues of azocyclotin and cyhexatin and that the Working Group on Analysis had agreed that these definitions should replace the present Codex definitions. The Committee concurred with the conclusions of the Working Group and also agreed that the identical MRLs for azocyclotin and cyhexatin in apples and strawberries referred to the total residues arising from the use of both pesticides. The Secretariat was requested to ensure that the MRLs for these commodities were presented in such a way as to make it clear that MRLs for cyhexatin and azocyclotin covered the total residue arising from the use of one or both of these pesticides in the three commodities concerned (see also para 114):

Grapes, Eggplants

- The delegation of Italy indicated that an MRL of 1 mg/kg in grapes would be more appropriate on the basis of information available in that country. The delegation of France indicated that with a pre-harvest interval of 30 days residues of 0.5 mg/kg were found in grapes. The delegation of Australia indicated that there were some anomalies in the recommendations which should be resolved (e.g., 0.1 mg/kg for azocyclotin in eggplants in relation to the MRLs for cyhexatin in bell peppers and tomatoes). The delegation of The Netherlands indicated that there was evidence in one country that the MRL of 0.1 mq/kq was too low.
- The Committee agreed to request the JMPR to re-evaluate the fruiting vegetables.
- It was decided that the MRLs should be kept at Step 4 pending the review of fruiting vegetables by the JMPR and the clarification by the Secretariat of the implications of the new residue definitions adopted for cyhexatin and azocyclotin.

DIFLUBENZURON (130)

Brussels sprouts, Mushrooms, Cabbage, Plums
205. The written comments of The Netherlands questioned the basis on which the MRL for e.g. Brussels sprouts had been established. The delegation of The Netherlands indicated that an MRL of 0.1 mg/kg for mushrooms would be more appropriate than the proposed 0.2 mg/kg. The delegation of France was of the opinion that there were insufficient data in the Evaluations to justify setting the MRLs for cabbage, Brussels sprouts and plums. The JMPR was $\frac{1}{1}$ requested to clarify the situation. All the proposals were advanced to Step 5.

ISOFENPHOS (131)

Potatoes

The delegation of The Netherlands indicated that it would be desirable to set an MRL for potatoes. Unfortunately, The Netherlands did not have any residue data to submit to the JMPR.

Definition of Residue

The delegation of the United States of America informed the Committee that it disagreed with the way the residue had been defined. The United States tolerances included two cholinesterase-inhibiting metabolites, the des N-isopropyl isofenphos (DNI) and des N-isopropyl isofenphos oxygen analogue (DNIOA). These two additional cholinesterase-inhibiting metabolites had been included in the United States residue definition since they occurred in commodities of concern and they had not been determined to be toxicologically insignificant. Crop rotation metabolism studies (apparently available to the 1981 JMPR) suggested that DNIOA might exceed residues of isofenphos or its oxygen analogue in some crops. Analytical methods were available for their determination.

METHIOCARB (132)

- The Committee noted that GAP had not yet been established for the use of the pesticide in certain crops. The pesticide was used mainly as a bird repellant or as a molluscicide against snails or slugs. While it was sprayed when used as a bird repellant, it was used in pellet form as a molluscicide. When sprayed the pesticide was uniformly distributed in the crop and did not offer any analytical problems, but when used in pellet form, it could result in very wide variation in the pesticide residue content of the portion of the crop analysed.
- 209. It was also noted that use of the pesticide on grapes and blueberries was current GAP in the United States of America, and while there were temporary tolerances for several other crops (apples, cherries, strawberries, broccoli, cabbage), these uses were not yet GAP.
- 210. The delegation of The Netherlands was uncertain as to whether the proposed MRLs reflected GAP and expressed strong reservations against the proposed MRLs for apples, cherries, grapes, peaches and plums.
- 211. The delegations of the Federal Republic of Germany, Italy and France expressed certain reservations against the MRLs, some being too low and some too high. Finland and Sweden expressed general reservations in view of the low ADI of the pesticide.
- 212. The delegation of the Federal Republic of Germany asked the Committee to consider 0.1 mg/kg as the limit of determination for the pesticide which could be achieved by analytical techniques used in normal regulatory practice, rather than 0.02 mg/kg as suggested by the JMPR.
- 213. The Committee noted that methiocarb was included in the agenda for the 1983 Joint Meeting, which was seeking more information on GAP for the use of the pesticide.

214. The Committee <u>agreed</u> to return all the MRLs to Step 3 of the procedure and to reconsider them when the Evaluations of the 1983 Joint Meeting are available.

TRIADIMEFON (133)

- The Committee noted that many of the MRLs for a number of crops, which are presently at Step 3 of the Procedure, were at the limit of determination.
- 216. The delegation of the Federal Republic of Germany informed the Committee that the residues observed in barley were usually higher than 0.1 mg/kg and might approach 1 mg/kg dependent on the climatic conditions. It also informed the Committee that higher MRLs of 3 mg/kg for barley straw and wheat straw would be acceptable. It was noted that a tolerance of 1 mg/kg for barley had been established according to GAP in the United States of America, but as yet there were no tolerances for a number of other crops for which the JMPR had recommended MRLs.
- 217. The delegation of the Netherlands informed the Committee that the MRL of 0.1 mg/kg for barley, oats and wheat was acceptable to it but that it preferred to retain these commodities in a restricted group rather than to extend the MRL to the whole group of cereal grains. The delegation was of the opinion that similar crops should have similar MRLs.
- 218. The Committee noted that the pesticide was included in the agenda for the 1983 Joint Meeting and agreed to return all the MRLs to Step 3 and to reconsider them when the Evaluations of the 1983 Joint Meeting are available. Both GIFAP and the delegation of the Federal Republic of Germany agreed to make some new data available to the JMPR.

DELTAMETHRIN (135)

- The delegation of the Federal Republic of Germany informed the Committee that the pesticide was registered in its country, which was presently reviewing the available toxicological data on the pesticide to make an independent evaluation. Higher MRLs for certain crops were suggested.
- 220. The Committee was of the opinion that new data on the use pattern and residue levels should be submitted to the Joint Meeting for a further evaluation. GIFAP and the delegation of the Federal Republic of Germany agreed to request the manufacturer to make any such data available to the JMPR.
- 221. The Committee agreed to retain all the MRLs at Step 4 and to await further developments.

CONSIDERATION OF THE REPORT OF THE AD HOC WORKING GROUP ON METHODS OF ANALYSIS

The Committee received the Report of the Ad Hoc Working Group on Methods of Analysis (see Appendix II to this report). It was introduced by the Chairman of the Working Group, Mr. P.A. Greve of The Netherlands.

He thanked GIFAP for publishing the results of the Working Group on Analysis as a special edition of their Technical Monographs (No. 8, 1983) under the title: "Guidelines on Good Analytical Practice in Residue Analysis and Recommendations for Methods of Analysis for Pesticide Residues".
The following subjects were discussed by the Committee.

Recommendations for methods of analysis

223. The Working Group up-dated and reviewed the recommendations of the previous Session. The new list of methods of analysis (to be published) included 138 compounds, as did the Guide to Codex Maximum Limits for Pesticide Residues.

Comments should be received by the Chairman before 1 February 1984.

Role of analytical variability in deciding whether a Codex MRL has been exceeded

At the request of the Chairman of the Committee the United Kingdom delegation clarified the expression "rounding off". It meant rounding up as well as rounding down. The Committee was informed that the role of analytical variation in decision making would be further discussed in the document on regulatory practices that the Working Group on Regulatory Principles was preparing for the next Session (see para 243).

Expression of residues relating to analytical practice 225. With the agreement of the delegation of the United States of America which had submitted a letter on this subject, discussion was deferred to the next Session, when the conclusions of the forthcoming JMPR would be available.

- 226. With regard to ethylenebisdithiocarbamates (EBDCs), the delegation of The Netherlands advocated an approach which consisted in the regulation of EBDCs through the GLs for ETU in those foodstuffs which were normally heated before consumption. The samples were analysed for their ETU content after a standard cooking procedure. After a further explanation of this approach the delegations of Denmark, France and Switzerland expressed reservations regarding it. Referring to the request of the delegation of the Federal Republic of Germany to have propylenethiourea (PTU) included in the JMPR review of EBDCs, Mr. Greve informed the meeting that PTU could also be determined by the same HPLC analytical procedure as was used for ETU.
- 227. According to the Secretariat several countries had problems in obtaining references to methods of analysis given in the Recommendations. Mr. Greve offered to supply reprints on special request.

Establishment of an Ad Hoc Working Group on Methods of Analysis 228. The Committee thanked the members and the Chairman of the Working Group for the work done prior to and during the Session. It was decided to set up a new Ad Hoc Working Group under the Chairmanship of Mr. P.A. Greve (The Netherlands) and with the same membership as before. If other countries or organizations wished to participate, they would be very welcome.

CONSIDERATION OF THE REPORT OF THE AD HOC WORKING GROUP ON SAMPLING
The Committee considered the report of the Ad Hoc Working
Group on Sampling (see Appendix III to this report) which was introduced
by Mr. J.A.R. Bates (United Kingdom), Chairman of the Working Group.

Guidelines on pesticide residue trials and sampling As three years had elapsed since these guidelines had been adopted, it was agreed that the Chairman of the Working Group would send a questionnaire to the participants at this Session of the Committee with the aim of obtaining a better insight into the acceptance these guidelines had received and an indication of any difficulties with their use. Delegates were requested to reply to this questionnaire at their earliest convenience.

Portion of Commodities to which Codex Maximum Residue Limits

apply and which is analyzed

231. The delegation of the Federal Republic of Germany drew attention to a written comment which had been sent to FAO in June 1983, but which apparently had not reached the Working Group. The Secretariat undertook to retrieve these comments and to pass them to Mr. Bates.

Appointment of an Ad Hoc Working Group on Sampling The Committee thanked the Working Group on Sampling and its Chairman for their contribution to this Session. A new Ad Hoc Working Group was appointed, under the Chairmanship of Mr. J.A.R. Bates (United Kingdom) and with the same membership as the outgoing group. It was suggested that a more appropriate name might be found for the new $\,$ Group. The delegation of The Netherlands indicated that they would also like to participate in this new group.

CONSIDERATION OF THE REPORT OF THE AD HOC WORKING GROUP ON PESTICIDE RESIDUE PROBLEMS IN DEVELOPING COUNTRIES

- The Committee had before it the Report of the Ad Hoc Working Group on Pesticide Residue Problems in Developing Countries (Appendix IV). The Report was introduced by Mr. A.F. Rahde (Brazil).
- In introducing the report of the Ad Hoc Working Group, the Chairman of the group drew the attention of the Committee to the statements made by the delegations of the Philippines, Thailand and Argentina highlighting the efforts made by these governments in promoting programmes on pesticides. The delegation of the Philippines mentioned the work of the UNDP/UNIDO Regional Network for production, marketing and control of pesticides in Asia and the Far East. The delegation of Thailand reported on the status of pesticide legislation and the delegation of Argentina drew attention to its food contaminants programme. The increased interest of the developing countries in pesticide problems could be gauged from the fact that two developing countries, Cuba and Argentina, had offered to host a Session of the CCPR.
- Both FAO and WHO were assisting developing countries in solving some of their pesticide problems. Examples of this assistance were: the pilot training course on residue analysis held in Hungary, a mission to Africa to study training requirements on the safe and efficient use of pesticides with special consideration of pesticide residue problems, and to offer advice on the functioning of some pesticide laboratories organized by FAO, and the Joint FAO/WHO Contamination Programmes being carried out under the auspices of FAD/WHO/UNEP. Certain developed countries such as the United States of America and the United Kingdom through some of their organizations such

as USAID and the Tropical Development and Research Institute, as well as pesticide manufacturers through GIFAP were also assisting developing countries to solve some of their pesticide problems.

- 236. The representatives of FAO, GIFAP and the Codex Secretariat agreed to issue a third (revised) questionnaire on manpower development and facilities for pesticide residue control in developing countries. The Committee noted that information resulting from the questionnaire could be used to identify the needs of developing countries for pesticide residue evaluation, training in analytical techniques and training in handling specialised equipment.
- 237. The Committee strongly endorsed the need for the Code of Conduct on the Distribution and use of Pesticides which was elaborated by FAO in collaboration with relevant agencies and organizations. The Committee noted that the 6th draft of the Code would shortly be sent to all governments and non-governmental institutions for comments, which would be taken into consideration by an expert consultation which would finalize the Code of Conduct. The Committee was of the opinion that the draft Code of Conduct should also be sent to all Codex Contact points.
- 238. The Committee endorsed the revision of the recommendations of the Working Group (Annex 3 to Appendix IV). The representative of FAO was of the opinion that developing countries should ensure the availability of adequate funds for the effective operation and maintenance of residue laboratories.
- 239. On the intervention of the delegation of the United Kingdom the Committee agreed to change recommendation 8(c)iii to read: "taking into account, where appropriate, the evaluations and reports of the Joint FAO/WHO Meetings on Pesticide Residues."
- 240. The Committee appreciated the work done by the members and the Chairman of the Working Group during the year. It decided to set up a new ad hoc Working Group under the Chairmanship of Mr. A.F. Rahde (Brazil) and with the same membership as before. Mr. Prayoon Deema of Thailand and Mr. E. Astolfi were appointed as Vice Chairman for the regions of Asia and Latin America respectively. It was agreed that the Vice Chairman for the region of Africa should be selected by the Coordinating Committee for Africa.

CONSIDERATION OF THE REPORT OF THE AD HOC WORKING GROUP ON REGULATORY PRINCIPLES

The Committee considered the Report of the Ad Hoc Working Group on Regulatory Principles (see Appendix V to this report) and document CX/PR 83/13.

The report was introduced by Mr. J.R. Wessel, United States of America, Chairman of the Working Group.

Questionnaire on National Pesticide Regulatory Systems
242. The Chairman informed the Committee that following a repeated request to respond to the questionnaire another 6 countries had replied in time for details to be included in the amendments circulated in March 1983. A further 4 countries has since replied and this new information would be incorporated in amendment sheets to be inssued early in 1984. Furthermore, the Committee accepted the proposal of the Working Group to send a questionnaire of a similar type to countries in the year before

the 18th Session, and also <u>agreed</u> that in the interim countries which had not yet replied to the <u>original</u> questionnaire or whose situation had changed, should send details to Mr. G.R.R. Jenkins, Environmental Pollution, Pesticides and Infestation Control Division, Branch A, Ministry of Agriculture, Fisheries and Food, Great Westminster House, Horseferry Road, London SW1P 2 AE (UK).

Acceptance of Codex MRLs - Problems and Practices
243. The Chairman of the Working Group informed the Committee that the Group had agreed to prepare a second draft of a document "Guidelines on Regulatory Practices to Facilitate Acceptance of Codex MRLs", taking into account the various comments made during the discussion in the Working Group.

The Committee agreed with the proposal that a final document on this matter should be available for discussion at the next Session.

Glossary of Terms

The Committee was informed by the Chairman of the Working Group of some minor changes in paper CX/PR 83/13. In discussing this paper the delegation of France pointed out that the definition of a "pesticide" (definition 2) included post-harvest treatment of agricultural crops. This would cause legislative problems in their country, where pesticides used post-harvest were regarded as food additives. The Committee made the following changes to the glossary:

in definition 5 (ADI), "For Man" was deleted from the term: in definition 7 (MRL) in the first line "for a residue" was changed to "of a pesticide residue", and

to definition 13 (Intake study) an Explanatory Note was added to refer to the "Guidelines for the Study of Dietary Intakes of Chemical Contaminants" (WHO-EFP/83.53//FAO-ESN/MISC/83/2). The Committee agreed to accept the Glossary of Terms as amended.

- Reacting to a remark of the delegation of Canada, the Chairman confirmed that the Glossary of Terms always had been and would continue to be considered as working definitions without any legal status (i.e. not subject to acceptance by governments).
- 246. The Committee thanked the Chairman and members of the $\frac{Ad}{D}$ Hoc Working Group. It was $\frac{decided}{d}$ to set up a new $\frac{Ad}{M}$ Hoc Group with the same membership and under the Chairmanship of $\frac{1}{M}$. J.R. Wessel (United States of America).
- REPORT OF THE AD HOC WORKING GROUP ON PRIORITIES

 247. The Committee had before it the report of the above Working Group and a proposal by The Netherlands for the addition of PCBs to the Codex Priority Lists (Room Document 9).
- 248. The report of the Working Group (see Appendix VI to this Report) was introduced by its Chairman, Mr. A.F.H. Besemer (The Netherlands). He indicated that the Working Group had assembled two lists, list I for 1984 and II for 1985 or later. List I might be too long to enable the JMPR to consider all the compounds at that Meeting. List II contained substances for which the availability of data was known, and those on which it was hoped to receive information.

The Group had also considered a proposal by The Netherlands concerning the re-evaluation of bromide arising from the use of organic bromine fumigants. The Group had also discussed in some detail a proposal by The Netherlands that the CCPR and the JMPR should consider PCBs in certain foods.

- 249. The Committee noted that prochloraz, not on any of Priority Lists I, II or III established at the 14th Session of the CCPR, was also on the agenda of the 1983 JMPR.
- 250. As regards list I established at the present Session, the JMPR Secretariat confirmed that it would not be possible to consider more than say 5 compounds at the 1984 JMPR Session because of commitments to re-evaluate a number of other compounds and because of the rather extensive data available on the new compounds. It was planned to finalize the agenda of the 1984 JMPR immediately after the 1983 JMPR and to bring it immediately to the attention of Governments and industry.
- 251. The question was raised as to whether it would be possible to arrange the compounds on lists I and II in an order of priority. The Chairman of the Working Group pointed out that such a priority setting would not be easy but could be attempted at the next Session of the Working Group. He then presented his views concerning what might be considered an order of priority as follows:
- List I : High priority: cyhalothrin, flucythrinate, propamocarb, dimethipin, carbosulfan
 Lower priority: oxycarboxin, methoprene
- List II: Compounds on which data will probably be available in 1985: prothiophos, fluvalinate
 Compounds on which it is hoped to receive data: vinclozolin, thiofanox, glyphosate.
- 252. The Committee accepted the recommendations of the Working Group and requested Governments and industry to supply the necessary information to the JMPR. The representative of FAO indicated that late residue information received prior to the 1983 JMPR could still be considered if sent without delay.
- 253. The Committee discussed a proposal of the delegation of The Netherlands that consideration be given to the problem of PCBs in food arising from environmental contamination. The presence of these contaminants in foods and human milk gave rise to serious health concern and caused difficulties in trade in foods. The delegation of The Netherlands referred to a recent OECD Seminar on PCBs held in The Hague. Amongst other subjects, the seminar discussed problems related to toxicity, and the results of monitoring studies. It had been shown that although the use of PCBs had been severely restricted, residues remained at about the same level. The question of PCBs and environmental contaminants should be studied, possibly with the assistance of a consultant.
- 254. The delegation of the United Kingdom, supported by other delegations, pointed out that The Netherlands proposal raised fundamental issues of procedures and approach to handling environmental contaminants in food within Codex. It was therefore necessary to proceed

cautiously and, as a first step, there was a need to appoint a consultant to examine the question in depth and produce a set of quiding principles in consultation with appropriate experts. For example it would be necessary to discuss the question of which bodies and resources would be used to provide expert advice to the CCPR. The consultant's paper would not necessarily provide all the answers. The delegation of Ireland pointed to the presence of other contaminants such as dioxins associated with PCBs and suggested that the consultant's paper should distil available information for submission to the JMPR and that the JMPR should discuss the scientific principles of handling environmental contaminants.

- The delegation of Switzerland pointed to the problems created by the fact that the methods of analysis of PCBs varied widely and that data from monitoring studies were, therefore, not fully comparable. The delegation of Denmark supported the proposal of The Netherlands and recalled that the CCPR had already decided to handle compounds such as HCB, PCP and PCBs. The Committee noted that the setting of maximum limits for such contaminants fell within its new terms of reference (para 8, ALINORM 83/24A). The Secretariat informed the Committee that a paper on the subject of environmental contaminants had been prepared by an FAO consultant and that this paper had been considered by the Codex Committee on Food Additives. The Secretariat had omitted to put that paper before the present Session of the CCPR, but would do so at the next Session. As regards the preparation of a new paper for the next Session of the CCPR, the Secretariat undertook to look into the matter of whether a consultant could be hired. In view of the short time before the next Session of the CCPR, the preparation by a consultant of a working paper for the next Session of the Committee would present technical difficulties.
- 256. The Secretariat was of the opinion that work on environmental contaminants such as PCBs in food should be seen in a much wider context than the harmonization of maximum limits in food. A number of UN agencies and programmes were involved and it was necessary to work out the procedures and principles to be followed. The setting of Codex limits should be followed with caution, bearing in mind the economic impact such limits would have on trade. A detailed case study involving PCBs might be a way of arriving at conclusions as to how to proceed.
- 257. The Committee noted the views expressed in the above paragraphs and <u>agreed</u> that the question of maximum levels for PCBs in food and the general problem of how consumer protection and facilitation of trade should be addressed, should be discussed at the next Session in the light of an appropriate paper to be supplied by the Secretariat.
- 258. As regards the recommendation from the Working Group on Priorities that information on GAP should be made available to the JMPR in addition to residue data, the Committee agreed that the Codex Secretariat and GIFAP should assist in obtaining such information.
- 259. The Committee thanked the Working Group and its Chairman, Mr. Besemer. It was $\frac{\text{decided}}{\text{decided}}$ to re-establish the $\frac{\text{Ad}}{\text{of}}$ Morking Group with the same membership as before. The delegation of Canada expressed its willingness to continue to provide Secretariat assistance as in the

past, and Mr. Besemer agreed to continue to act as Chairman of the Group.

OTHER BUSINESS

- Mr. J.T. Snelson of the Australian delegation informed the Committee that this was probably the last time that he would personally participate in a Session of the Committee. The Committee noted that Mr. Snelson had participated in all Sessions of the CCPR, except the first one and had been a member of many JMPRs. He thanked the Chairman and the members of the Committee for their willingness to give attention to the Australian views expressed during all the meetings.
- The representative of GIFAP stated that GIFAP noted with great regret Mr. Snelson's announcement that this might be his last participation in the CCPR. Mr. Snelson had always brought to every problem a wisdom and integrity which had contributed significantly to the work of this Committee as well as to the many other international activities in which he had been involved. GIFAP expressed the hope that a way might be found so that Mr. Snelson might yet return to contribute to future meetings as he had done in the past. If, however, that was not to be, than GIFAP wished him and his family good health and happiness now and for the future.

The Chairman and the Committee shared the sentiments and wishes expressed by GIFAP and thanked Mr. Snelson for his very valuable contributions both to the Committee and to the JMPR.

DATE AND PLACE OF NEXT SESSION

262. The Chairman of the Committee indicated that the next
(Sixteenth) Session of the Codex Committee on Pesticide Residues and its Groups would take place in The Hague from 28 May to 4 June 1984, and suggested the following time table:

Opening of the plenary Session 28 May 10.00 hrs. 28 May 14.00 hrs. Ad Hoc Working Group on Regulatory Principles 28 May 14.00 hrs. Ad Hoc Working Group on Sampling 28 May 15.00 hrs. Ad Hoc Working Group on Methods of Analysis 28 May 16.00 hrs. Ad Hoc Working Group on Priorities Ad Hoc Working Group on Pesticide Residue 29 May 09.00 hrs. Problems in Developing Countries

The Committee was informed that similar arrangements as at the present Session for simultaneous interpretation would be made available to the Ad Hoc Working Group on Pesticide Residue Problems in Developing Countries.

CLOSURE OF THE SESSION

- In his closing remarks, the Chairman noted that 39 countries had participated as compared with 46 attending the fourteenth Session. The loss of seven countries was the result of 11 countries not appearing at this Session, whereas 4 countries were present which had not attended in 1982. It was to be noted that four of the seven missing countries were from Europe.
- The Chairman noted the value of the new technical facilities available to the Secretariat which had contributed to the efficiency and quality of its work. It was from the interaction between advanced and experienced people in and outside the Secretariat that techniques

the Committee derived considerable benefit. It was for these reasons that he was reluctant to promote strongly a change in the venue of CCPR Session.

- The Chairman drew attention to another aspect. Although more than one third of the participants at the CCPR were from the developing countries their involvement in the discussions in the plenary meetings had been limited. One reason for this might lie in the routine that had developed in 15 meetings, the formal language and procedures of the CCPR which regular members were accustomed to, but which might be puzzling to relative newcomers. To overcome this barrier it might be useful to arrange a short seminar on the Committee and its activities, perhaps in combination with a regular meeting with a restricted agenda. For such a meeting, one of the offers of a meeting place elsewhere that the Commission had received could with advantage be accepted.
- 267. The Chairman mentioned the progress of the Committee's work on the "Guidelines on Regulatory Practices to Facilitate Acceptance of Codex MRLs". This document, which would probably be adopted at the next Session, would form an excellent basis for the clarification of the aims and working procedures of the CCPR in the context of the seminar mentioned above.
- 268. Finally, the Chairman touched on the potential extension of the work of the Committee to substances chemically related to pesticides, such as the PCBs. The difficulties of providing useful suggestions for the limitation of contaminants of this type offered a challenge to the Committee for the future.

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REPORT OF THE AD-HOC WORKING GROUP ON METHODS OF ANALYSIS

1. Membership The Ad-Hoc Working Group on Methods of Analysis consisted of the following persons: United Kingdom D.C. Abbott Hungary A. Ambrus Sweden A. Andersson J.A.R. Bates United Kingdom Federal Republic of Germany G. Becker Australia R.S. Belcher Federal Republic of Germany G. Bressau Egypt Dalal Abo El Nasr Belgium W. DeJonckheere Federal Republic of Germany D. Eichler H. Frehse IUPAC Norway H.O. Friestad Federal Republic of Germany S. Gorbach M. Green Lauridsen Denmark The Netherlands (Chairman) P.A. Greve France M. Hascoët R. Hemingway GIFAP F. Ives United States of America A. Kivirantá Finland Jápan T. Kagatsume GIFAP M. Laurent Ireland M. Lynch United Kingdom D.F. Lee Canada R.B. Maybury GIFAP H. Regenstein M. Sakano A. Schlossar T. Stijve S. Takei Japan Austria Switzerland G.M. Telling United Kingdom Federal Republic of Germany G. Timme The Netherlands L.G.M.Th. Tuinstra Thailand A. Vongbuddhapitak United States of America J. Wessel Finland K. Wickström

Agenda

The Working Group discussed the following points:

 recommendations for methods of analysis for pesticides for which Codex MRLs or Guideline Levels are under discussion;

Good Analytical Practice;

- role of analytical variability in deciding whether a Codex MRL has been exceeded;
- expression of residues;

- presentation of residue data;

 comments from Codex Committee on Methods of Analysis and Sampling (CCMAS) on the recommendations for methods of analysis given by the Group. 3. Recommendations for methods of analysis

The Working Group undertook the up-dating and reviewing of the recommendations given at the previous Session (see GIFAP Technical Monograph No. 8, 1983) The revised list was distributed to the participants to this Session of the Committee. It supersedes the lists given presiously and will be published by the Codex Secretariat. The Working Group also reviewed the criteria for the selection of methods. The criteria were still considered valid by the Group; it was decided however that, as an expansion of criterion A (i.e. that the method should haven been published in the open literature), written accounts on the applicability of methods to compounds not mentioned in the original publication can be considered as well.

4. Good Analytical Practice

The document on Good Analytical Practice presented last year by the Working Group was revised with regard to a number of mainly editorial points. The revised version will be published by the Codex Secretariat.

5. Role of analytical variability in deciding whether a Codex MRL has been exceeded

As agreed last year, the various systems which are in use or under discussion in different countries for reaching conclusions as to whether or not an MRL has been exceeded, were discussed again in the light of comments received by the Chairman.

The views expressed in the Group could be summarised as follows:

Technically, the decision whether an MRL has been exceeded or not is based on a comparison of a fixed value (the MRL) with an experimentally obtained figure which can only be an estimate of the true value. The MRL can be deemed to be exceeded if the experimental value is greater than the MRL by an amount that is significantly different from zero. The making of this decision is within the competence of a well-trained analyst.

The procedure outlined above means in practice that a "correction" (to be discussed below) is applied to the experimental value and that the corrected figure is compared with the MRL. It must be emphasised that the procedure does not mean that "a tolerance is put on top of the tolerance": the experimental value is the source of the

uncertainty, not the MRL.

Due to the possibly serious consequences of an infringement of an MRL, the analyst must in all cases use sound scientific judgement before reporting that an MRL has been exceeded. Even if certain generalisations, as discussed here, are possible, they must never lead to "automatic" decisions. One widely practised way of minimising the chance of wrong decisions is to confirm the initial determination by an independent second determination, carried out by another analyst and, if at all possible, by a different method. The Working Group agreed that the conclusion that an MRL had been exceeded should never be based on a single determination.

The "correction" on the experimental figure (in practice, the average of at least two experimental figures) which accounts for the intrinsic analytical uncertainty of the figures can be arrived at in different ways. Two main approaches have been distinguished: the "rounding-off" approach: the values obtained are rounded off

according to standard procedures to one significant figure and this rounded-off figure is compared with the MRL.

(ii) the "semi-mathematical" approach: a "latitude" is calculated, either from previous experiments (e.g. collaborative studies) or from especially designed new experiments (e.g. recovery studies), the latitude is subtracted from the experimental value and this corrected (lower) value is compared with the MRL. One difference between the two approaches is that the corrections used in the rounding-off procedure follow a discontinuous function ("zig-zag line") whereas the other approach uses continuous functions. It was noted that, in spite of the apparent difference between the two approaches, no substantial difficulties should be encountered on a national level when either of the two systems is used.

It was understood that this matter will be given consideration by the Working Group on Regulatory Principles during the next Session of ${\tt CCPR.}$

6. Expression of residues

- 6.1. Expression of residues relating to analytical practice
 This subject was deferred to next year, pending the discussion in the forthcoming JMPR.
- 6.2. Cyhexatin/azocyclotin

 It was noted that the metabolite dicyclohexyltin oxide was considered of sufficient importance by the 1982 JMPR to be included in the residue, and the Working Group accepted their revised expressions. As the Moellhoff procedure recommended by the Working Group also describes the (separate) determination of the metabolite, no changes were needed in the list of references.
- 6.3. Ethylene bis-dithiocarbamates (EBDCs)

 Separate MRLs for EBDCs, supplementary to the existing MRLs for the dithiocarbamates as a whole, were under consideration in a number of countries. Determination of the EBDCs as the pentafluorobenzoyl-derivative was being studied by several investigators in order to broaden the scope of the method. The approach, advocated in the Netherlands, to regulate the level of EBDCs in food-stuffs after heating through the MRL for ETU (determined after a standard cooking procedure) did not meet with approval from other countries.
- 6.4. Phosmet
 Answering a question from the Plenary Session (ALINORM 83/24A, par. 147), the Working Group stated that the practical limit of determination for phosmet in milk should be 0.02 mg/kg.
- 7. Presentation of residue data
 The presentation of residue data for consideration by JMPR was discussed at the request of several members from the Federal Republic of Germany. As a result of the discussion it was restated by the Group that the format given previous year (cf par. 5, App. III, ALINORM 83/24A), in which entries on recovery and blank values are provided for, was the preferred one. Tables giving values proposed by the analyst after correction for blank values and/or recovery could give valuable additional information. Suggestions for amendments to the format mentioned would be discussed at the next meeting.

8. Comments from CCMAS on the recommendations for methods of analysis given by the Group (Room Document CX/PR 83/3, dated September 1983, and Agenda Item 3 (a)-(b))
In the report of the 13th Session of the Codex Committee on Methods of

In the report of the 13th Session of the Codex Committee on Methods of Analysis and Sampling (ALINORM 83/23, par, 30-37) mention is made of the recommendations for methods of analysis given by the Working Group. The Group restated the opinion that its procedures for making recommendations for methods of analysis, including confirmatory tests, had served the needs of CCPR and member countries. Therefore the Group concluded that the procedures as outlined previously should continue to be used.

REPORT OF THE AD HOC WORKING GROUP ON SAMPLING

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Guidelines on pesticide residue trials and sampling; definitions of commodity portions to be analyzed

It was reported to the Group that a number of member governments and some companies had already adopted, or were in the process of considering the adoption of, the CCPR guidelines on pesticide residue trials and sampling, and the definitions of the portions of the commodity to be analyzed. The Group agreed that it would be valuable to obtain a more positive indication of progress towards the use of these guidelines and asked the Chairman to circulate an appropriate questionnaire to participants and to consolidate replies for the next CCPR meeting.

Comments from participants should include any difficulties encountered so that the Group can consider these and decide if revisions are needed.

<u>Guidelines</u> on trials in which treated crops are fed to animals or the pesticide is applied directly to the animal

The Group did not have a draft to consider at the present meeting but agreed to study the guidelines in use in the United States with a view to producing a draft for the next CCPR meeting.

Codex MRLs expressed on the whole product and in the edible portion for the same food commodity

The Group considered the document CX/PR 83/7 proposed by the Secretariat for discussion under Item 7(a) of the Agenda. It again reaffirmed the view that MRLs should apply to commodities known to be moving in international trade, drew attention to CCPR classification of commodities and its recommendations on the portion of the commodity to which the MRL applies and made recommendations concerning several of the definitions which appear in revised document CX/PR 83/7.

REPORT OF THE AD HOC WORKING GROUP ON PESTICIDE RESIDUE PROBLEMS IN DEVELOPING COUNTRIES

1. The above Working Group held its session on 3 October 1983. In the absence of the Chairman of the Working Group, Dr. A.F. Rahde (Brazil), Vice Chairman of the Working Group, acted as Chairman. The list of participants attending the session of the Working Group is given in Annex I.

Appointment of rapporteurs

2. Mr. J. Snelson (Australia) was appointed to act as rapporteur of the session of the Working Group.

Adoption of the Provisional Agenda

3. The Working Group adopted the provisional agenda (WG 3/PR 83/1) without change.

Matters of interest to the Working Group

4. The Group had before it document WG3/PR R3/2 indicating matters of interest to the Working Group.

It was noted that the Commission, at its 15th Session, had considered and endorsed a summary of the recommendations of the Group (ALINORM 83/24A-Add 3) prepared by the Secretariat. The Group agreed to reconsider the recommendations before their submission to the appropriate bodies for action, under another item of the agenda.

- As regards hosting of Codex Sessions in developing countries, the Group noted the offer of Argentina to host a session of the CCPR and the offer of Cuba to host a Session of any Codex Committee. The Secretariat pointed out that the question of hosting Codex Sessions in countries other than the existing host countries was a matter of agreement between the countries involved and the Secretariat. It was also noted that Cuba would host the next session of the Coordinating Committee for Latin America.
- 6. The Group noted that the Coordinating Committee for Asia had agreed that it is important for countries in the region of Asia to generate pesticide residue data from supervised trials and to make this available to the CCPR.
- 7. The representative of FAO drew attention to a pilot training course in residue analysis held in Hungary. A project for six training courses in the safe and efficient use of pesticides, two each in Africa, South East Asia and Latin America of two weeks duration each is in the process of approval. A mission in Africa during 1983 had revealed that laboratories suffered shortage in local funds and in foreign exchange to enable them to purchase spare parts, analytical gases and chemicals to remain operational. He suggested that governments provide such funds to ensure the proper functioning of the laboratories.
- 8. The representative of WHO informed the Group of activities of interest within WHO. Technical cooperation with developing countries is being carried out under the Joint FAO/WHO Food Contamination Monitoring Programme. Main activities include (i) training (ii) analytical quality assurance studies and (iii) information exchange.

Training has included assignent of scientists from a developing country institute to a Collaborating Centre having the requisit expertise facilities, for training in the analysis of contaminants in food. Alternatively, expert analysts have been assigned to developing countries to carry out on-the-spot training.

Inter-laboratory analytical quality assurance studies have been carried out using samples of known concentrations of chlorinated pesticides, PCBs, lead, cadmium or aflatoxins in various food matrices. The results have been evaluated and training provided to various laboratories where required.

- 9. In terms of information exchange, monitoring data collected from the 22 Collaborating Centres for Food Contamination Monitoring have been summarized, evaluated and the results disseminated. FAO manuals on food control have been distributed to the Collaborating Centres; these manuals include information on methods for the determination of microbiological and chemical contaminants in food, on control of mycotoxins, food inspection and food control laboratories. WHO Environmental Health Criteria documents issued by the International Programme on Chemical Safety and dealing with contaminants relevant to food such as mercury, lead, polychlorinated biphenyls and terphenyls, mycotoxins, arsenic, etc. have been distributed to the Collaborating Centres. Similarly, the International Agency for Research on Cancer publications dealing with the analysis of environmental carcinogens (e.g. mycotoxins) have been made available to the Collaborating Centres. Publications issued under the Monitoring Programme itself such as the "Guidelines for Establishing or Strengthening National Food Contamination Monitoring Programmes "and the" Guidelines for the Study of Dietary Intakes of Chemical Contaminants" have been distributed to the Collaborating Centres as well as to the relevant Codex Committees.
- 10. The delegation of the USA, speaking on behalf of USAID, outlined the work of that organization of interest to the Working Group. The work of USAID is given in Annex 2.
- 11. The delegation of the Philippines outlined work undertaken under a UNIDO/FAO/ESCAP sponsored programme. An outline of this work is given in Annex 2.
- 12. The delegation of the UK outlined the work of the Tropical Development and Research Institute (TDRI) in promoting the safe and effective use of pesticides in developing countries (see Annex 2).
- 13. The delegation of Thailand gave a report of activities in that country in relation to the control of pesticides and their residues (see Annex 2).
- 14. The delegation of Argentina informed the Group that Argentina has submitted a technical assistance project to the FAO concerning the determination of contaminants in food, including meat products, milk and its derivatives, flours and oils. This programme will determine: pesticide residues, heavy metals, mycotoxins, antimicrobials and bacterial contaminants in the above foods.
- 15. The representative of GIFAP gave an outline of work involving questions on the labelling of pesticides, proprietary rights, confidentiality of data etc. (see Annex 2).

Revision of the Recommendations of the Working Group
16. The Group had before it document ALINORM 83/24A-Add. 3
containing all recommendations previously made by the Group. It was
noted that the Commission, at its 15th Session, had adopted the
recommendations and had agreed that they be submitted to the interested
bodies for action. The Group agreed to reexamine the recommendations in
order to ensure that they were still up-to-date and correctly
represented the views of the Working Group.

- 17. As regards recommendation 1(a) for a simplified stepwise registration of pesticides the Group was informed that the FAO Model Scheme provided the elements required for a simplified approach to controlling the sale and use of pesticides. However, the representative of FAO was requested to investigate whether the available FAO recommendations covered the needs of developing countries. The Group was also informed that the document dealing with the essential components of an ideal pesticide laboratory was not yet available, but that its preparation was under consideration.
- 18. Recommendation 2. was amended following detailed discussions to make it clear that available information on pesticides should be made available to developing countries on request.
- 19. The Group agreed that recommendation 7 in ALINORM 83/24 A Add. 3. was more appropriately addressed to developing countries rather than to FAO/WHO. The delegation of the Federal Republic of Germany pointed out that additional funds should be made available to the FAO/WHO in order to give effect to such recommendations as those included in paras 2. and 7.
- 20. Noting that it would not be practical to observe a time target for the implementation of the recommendations of the Group, it was decided to amend recommendation 12 as shown in Appendix 3.
- 21. The representative of FAO noted that in a number of developing countries, laboratories for pesticide formulation control and residue analysis were not able to function properly for lack of adequate funds and foreign exchange. The Group agreed to recommend to developing countries that such funds should be made available in order to ensure that the laboratories remain operational.

Third Questionnaire on Pesticide Residue Control and Man-Power Development

- The Group was informed that Dr. Roger Blinn, who had represented GIFAP during many sessions of the CCPR, had passed away. The Group recalled the work Dr. Blinn had done on behalf of the Group and of developing countries and observed a minute's silence in his memory.
- 23. As regards the issue of a third questionnaire on the above subject the Group agreed that it should be issued so that a report can be prepared for the 1985 meeting. Mr. Kopisch-Obuch (FAO), GIFAP and the Codex Secretariat were requested to revise and issue the questionnaire.

Code of Conduct on Distribution and Use of Pesticides

The Secretariat pointed out that the interest of Codex in the above Code of Conduct derived from the fact that the safe and proper use of pesticides was a prerequisite for consumer protection and the prevention of rejection by importing countries of produce exported from developing countries.

The Group was informed that a sixth version of the Code of Conduct prepared following an interagency meeting would be distributed for comment around the end of 1983. A final version would be prepared on the basis of comments for consideration by a consultation to be held in 1984.

25. The Group expressed its appreciation and considered that it would be desirable if Codex Contact Points were included in the distribution of the Code of Conduct for comment.

Nomination of Chairman and vice-Chairmen of the Working Group 26. The delegation of Mexico conveyed Dr. Martinez' good wishes to the Group and his regret for not being able to be present at the session. For personal reasons Dr. Martinez would not be able to continue to act as Chairman of the Group.

- 27. The Group expressed its appreciation to Dr. Martinez for his work as Chairman and his support of the work of the Working Group.
- 28. The Group elected the following officers from among the delegates:

Chairman : Dr. A.F. Rahde (Brazil)

Vice-Chairman (Latin America): Prof. E. Astolfi (Argentina)

Vice-Chairman (Asia) : Dr. P. Deema (Thailand)

Vice-Chairman (Africa) : To be selected by the Coordinating

Committee for Africa

Other business

29. There was no other business to discuss.

LIST OF PARTICIPANTS

Argentina

Australia Belgium Brazil

Canada

Cuba
Denmark
Egypt
France
Germany, Fed. Rep. of
Israel
Kuwait
Mexico
The Netherlands

New Zealand Philippines Spain Sweden Thailand

United Kingdom

United States of America

FAO

WHO

GIFAP

Sergio R. Bocanegra Emilio Astolfi J.T. Snelson (Rapporteur) R. van Havere M. da Costa Ferreira Alberto Furtado Rahde (Chairman) José Vicente da Silva Lessa J. Stalker R.B. Maybury A. Castro Knud Voldum-Clausen Dalal Abo El Naser M. de Cacqueray G. Bressau P. Vernes Rafaat Zaki Hassan Rubén Amaya Protection L. Brader H.M. Nollen B.B. Watts Cecilia P. Gaston E. Celma G. Ekstöm Sompool Kritalugsana Oratai Silapanapaporn G.R.R. Jenkins D. Halliday R.C. Ticknell G.A. Willis C. Collier S.N. Fertiq E. Johnson D.D. McCollister R.M. Parry, Jr. F.-W. Kopisch-Obuch L.G. Ladomery (Secretary) N. Rao Maturu H. Gorchev G. Vettorazzi R.A. Conkin D. Dye G.A. Gardiner H.S. Gold W. Graham B. Julin R.J. Lacoste D.S. Lahoda M.L. Leng R. Meck F.J. Raveney R. Rowe S.F. Rickard Y. Sato G.M. Stone

S. Takei B. Thomas

STATEMENTS BY DELEGATIONS

Thailand

The Poisonous Article Act is in the progress of modifying to be more effective in controlling pesticide use in the country. The government is concentrating on Good Agricultural Practice Research to get more data on pesticide residues in agricultural products. The government plan to set up two more Regional Pesticide Research Laboratories in the North East and in the Southern part of Thailand: all together Thailand will have four regional pesticide research laboratories which will handle all the problems of pesticides in Thailand.

The Toxicological Centre is going to be set up in the near future. This centre is responsible to collect all toxicological data including pesticides.

The First Session of the Group of Developing Countries in Asia concerning Pesticide Residues Problems will be held in Thailand during February 24th-27th, 1984. The government of Thailand would like to invite all member countries and representatives from all international organizations such as FAO, WHO, GIFAP, etc. to attend the session.

United Kingdom

The delegation of the United Kingdom outlined work at the Tropical Development and Research Institute (TDRI) in promoting the safe and effective use of pesticides in developing countries. TDRI undertakes research on the use of pesticides (including insect pheromones) in developing countries and is also able to provide training and advice in this area. Particular aspects in which training can be provided include pesticide management and useage and pesticide analysis. In the latter connection TDRI is now able to provide training for up to six analysts per annum at its laboratories. Each course lasts 3-4-months and trains experienced chemical analysts so that they can eventually become supervisors of pesticide analytical laboratories.

TDRI was recently formed by the amalgamations of the Tropical Products Institute with the Centre for Overseas Pests Research.

United States of America

The U.S. Agency for International Development (AID) has a special interest in working with the Ad Hoc Working Group on Pesticide Residue Problems in Developing countries. As part of its foreign assistance efforts it is providing funding for agricultural production/research/extension projects in more than 40 developing countries. In many of the country projects, pesticides will play a key role in achieving the needed degree of crop protection against plant pests.

AID under its environmental regulation (AID Regulation 16) is required in all cases where pesticides are provided in a project to consider the impact of the pesticide use on man and his environment. In considering this impact within typical developing country agricultural projects it has concluded that the use of more highly toxic pesticide formulations by small farmers, is appropriate only where special provisions are made in terms of training, access to needed storage facilities and the provision of adequate safety equipment to prevent excessive exposure.

In most AID funded projects one or most of these special provisions cannot be met and therefore pesticides recommended and/or purchased for the projects are from those chemical formulations having low to moderate toxicity hazard.

In cases of pesticides which have not been reviewed or registered by the USEPA, a heavy reliance is placed on the ADIs and MRLs recommended by the JMPR to Codex and on the technical data as supplied in the annual

monographs of the JMPR.

To prevent or reduce the misuse of pesticides in the developing world AID has sponsored the development of two train-the-trainer programs on pesticide safety. One of these related to "An Agromedical Approach to Pest Management" has been developed by Dr. John Davies and staff at the University of Miami. This course has been given in Trinidad, St. Lucia and Jamaica and in the case of the latter countries led to the formation of the Jamaican Agromedical Association which has membership from both the health and agricultural communities and in actively promoting pesticide safety within the country. Two of these training efforts were in collaboration with the Pan American Health Organization.

Another train-the-trainer course aimed at the developing country small farmer has been developed for AID by Texas A&M University. This course has been field tested in Paraguay with both midlevel agricultural officials as well as Peace Corps Volunteers.

The development and refinement of training techniques is still a subject of active interest and improvement of existing courses as well as the development of new training materials will be encouraged.

At a recent AID/State Department/Industry conference on Pesticide Training in Developing Countries (June 1983) it was found that there is an active interest in training by many diverse groups including state and federal regulatory agencies, the pesticide manufacturer, the environmental community and public service groups. At this meeting the use of pictographic techniques for communicating with farmers received a great deal of attention. AID has an ongoing project to develop pictographic labelling and to evaluate them within a developing country context.

Another effort aimed at developing better communications in the developing world is the sponsorship of regional pest and pesticide management seminar/workshops.

One such workshop held in the Caribbean in 1982 has been directly instrumental in speeding up the development and adoption of pesticide legislation and interest in monitoring surveillance in several countries. Current plans call for a similar workshop in East Africa in 1984 and one in Asia in late 1984 or early 1985. Copies of the 1982 proceedings of the Caribbean seminar/workshop are available on reguest from: AIDPEST, Room 1404, National Agricultural Laboratory, Beltsville, MD. 20705, USA.

In addition, AID, through the Consortium for <u>International</u> Crop Protection, conducts 6 week courses in pesticide residue analysis training at the University of Miami as well as at specific developing coutries sites.

As an adjoint to the training program it conducts an international quality control program with over 40 participating laboratories and maintains a residue analysis capability to assist in special developing country problems.

Another area of interest is that related to monitoring of pesticide exposure in situations where it cannot be determined beforehand as to the degree and significance of a pesticides possible misuse. An example of such an effort is an ongoing collaborative study involving AID, the Government of Sudan and Union Carbide Corporation where the health and environmental aspects, including residues, of the application of $\mathsf{TEMIC}^{(R)}$ (aldicarb) for control of whitefly on cotton are being studied by a multidisciplinary team.

Since a number of proposed AID projects may result in export of fruit and vegetable products, between countries, especially to developed countries, the need for endorsement of Codex maximum limits in obvious. To the extent practical, AID will encourage and help stimulate attendance of developing country participants to the CCPR. AID is willing to share its experiences on pesticides in the developing country context and to the extent practical wishes to collaborate with other bi- and multilateral agencies in efforts related to furthering the safe use of pesticides.

GIFAP

A series of meetings, starting in 1982 at Contadora, Panama and culminating in August 1983 in Santiago, Chile, have led to harmonization of labelling, toxicological classifications including uniform colour banding of labels, and certain aspects of proprietary rights as regards the confidentiality and use of the data submitted for registration. Agreements were also reached on training programmes and other cooperative activities for the safe and efficient use of pesticides.

Philippines

UNDP/UNIDO Regional Network for Production, Marketing and Control of Pesticides in Asia and the Far East. (Executed by UNIDO in association with FAO and ESCAP).

The project which started in November 1982 is composed of nine member countries - Afghanistan, Bangladesh, India, Indonesia, Korea, Pakistan, Philippines, Sri-Lanka and Thailand. The Philippines was designated as the Regional Coordinator. The following are the priority activites:

- a) Data collection and Information Exchange
- b) Standardization of Quality Control and Methods of Analysis
- c) Harmonization of Pesticide Registration Requirements
- d) Formulation and Marketing
- e) Trade and Tariff
- f) Toxicology

The Regional Network on Pesticides in a TCDC project where technical assistance is provided through consultancy records, fellowships/ study tours and group training activities/workshops/conferences. Supply and production data from the member countries have been collected for 1980 - 1982 and the consolidated report will be available by November.

A Regional Consultation on Harmonization of Pesticide Registration Requirements willbe held at Baguin City, Philippines from October 24 - 29, 1983.
All ESCAP*-member countries have been invited and are expected to attend. It is hoped that the Regional Network on Pesticides can coordinate its activities with those of the Working Group's Sub-Committeeon Asia and the Pacific in order to support each other in

* ESCAP - Economic and Social Commission for Asia and the Pacific

the attainment our mutual objectives.

Recommendations

The Committee, on the advice of the Working Group:

Noting that most of the countries, in spite of having food laws and regulations for the prevention of food adulteration, do not have adequate laws/regulations for the registration of pesticides;

Noting that facilities for pre-registration trials on pesticides and their formulation, toxicity tests, determination of residues on crops, stored food commodities, animal foods, processed foods, etc., generation of appropriate data on intake and on the impact of pesticides on the environment are inadequate or even non-existant in many countries;

Noting that, wherever laboratory facilities exist, the available equipment and funds, including foreign exchange, for the continued operation of the laboratory are insufficient, and that the number of laboratories is inadequate;

Agreeing that the training of appropriate personnel in the above fields deserves immediate attention;

- Requests that, in order to overcome the above drawbacks, FAO and WHO should:
 - (a) prepare and supply to developing countries, at the earliest, guidelines for a simplified stepwise registration of pesticides with an ultimate aim of preparing a model pesticides law/regulations for appropriate action by the governments of developing countries, and (b) prepare for circulation to developing countries the essential components of an ideal pesticide laboratory, covering different food commodities, specifications and availability of the required equipment.
- 2. Recommends that FAO/WHO and other International Bodies should be prepared to supply, on request, information on toxicological data (including toxic hazards and precautions to be taken) and efficacy of pesticides and formulations to developing countries.
- 3. Requests that FAO and WHO and International Organizations such as UNDP, UNEP, IAEA, IUPAC and GIFAP as well as Governments should intensify their assistance to developing countries for establishing suitable laboratory facilities for pesticide analysis and training.
- 4. Recommends that, with respect to the WHO "International Programme on Chemical Safety", the implications especially concerning the use and control of pesticides in developing countries should be examined.
- control of pesticides in developing countries should be examined.

 5. Recommends that, in order to accelerate the development of pesticide control, consultations among the developing countries be arranged in the various regions in order to study the needs and means so that action programmes on pesticide residues could be drawn up on the basis of priorities decided in these consultations, through an approach involving "Technical Cooperation among Developing Countries (TCDC)".
- 6. Recommends that, as a collaborative effort among countries, Regional Committees on Pesticides should be established to discuss problems related to pesticides in the Region and that seminars and conferences for exchange of technical information and experiences quined in this field be held frequently.
- 7. Requests that the Codex Committee on Pesticide Residues and Codex Regional Coordinating Committees should include on their agenda subjects of interest to developing countries in the field of pesticides including those proposed by the Working Group.

- 8. Recommends that developing countries should:
 - (a) Establish national inter-departmental committees to deal with matters related to pesticide residues and to act as a National Codex Committee and as the Codex Contact Point in this field.
 - (b) Ensure control of import, sale and use of pesticides and their residues in food.
 - (c) Take steps to ensure that pesticides are registered on the basis of:
 - appropriate data such as those recommended by FAO/WHO; (i)
 - local agricultural information; and taking into account, (ii) where appropriate
 - the Evaluations and Reports of the Joint FAO/WHO Meetings on (iii) Pesticide Residues.
 - (d) Prepare a document indicating the presently available facilities and expertise in developing countries for pre-registration trials, toxicological evaluation, residue analysis, generation of appropriate data on intake of pesticide residues, and impact on the environment:
 - (e) To carry out regular monitoring where facilities exist or are developed subsequently and, pending the availability of such facilities, to cooperate/collaborate in residue analysis of food items of national/international importance.
 - 9. Agrees that there is increasing need for governments to identify clearly the department(s) in charge of national programmes of pesticide residues, to whom policy matters and documents should be referred;
- 10. Recommends that all Governments should prepare or update without delay the mailing list of personnel connected with pesticide residues for ensuring timely supply of FAO/WHO documents on the
- 11. Agrees that there is a need for further questionnaires to be sent to all Governments to elicit information on:
 - (a) available technical facilities;(b) infrastructures;

 - (c) instrumental analysis, control and toxicological aspects of pesticides; and
 - (d) availability of expert manpower in the area.
- 12. Observes that there is an increasing interest and need felt to promote regional meetings on pesticide residues, at least three months prior to the regular sessions of the Codex Committee on Pesticide Residues, aiming at technical cooperation and the evaluation of common problems in the area relating to:
 - registration (i)
 - analytical methods (ii)
 - (iii) good agricultural practice; and
 - (iv) acceptances of Codex maximum residue limits; and agrees that assistance from FAO and WHO in such meetings would be most welcome.
- 13. Recommends that developing countries take steps to ensure the continued availability of funds and foreign exchange so that laboratories including those established under UN technical assistence arrangements remain fully operational.
- 14. Recommends that the Governments UN Bodies and International organisations to whom the above recommendations are directed take follow-up action as early as possible and that appropriate funds be earmarked so that the recommendations be given effect.

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REPORT OF THE AD HOC WORKING GROUP ON REGULATORY PRINCIPLES

Membership

The following persons took part in the discussions of the ad hoc Working Group on Regulatory Principles: D.C. Abbott United Kingdom Mexico R. Amaya A. Andersson Sweden J.A.R. Bates United Kingdom P. Bennett Canada J. Benstead Australia R.S. Belcher Australia A.F.H. Besemer The Netherlands G. Bressau Federal Republic of Germany G. de Cacqueray France E. Campbell United States of America R. Conkin GIFAP G. Ekström Sweden S. Fertiq United States of America H.S. Gold S. Govleach F. Ives Federal Republic of Germany . United States of America G.R.R. Jenkins United Kingdom B. Juzin GIFAP J. v.d. Kolk The Netherlands F.W. Kopisch-Obuch FAO S. Kritaluqsana Thailand FAO , L.G. Ladomery (secretary) D. Lahoda GIFAP M. Laurent GIFAP D.F. Lee United Kinadom D.G. Lindsay United Kingdom M. Lynch N. Rao Maturu R. Meck Ireland GIFAP H.M. Nollen The Netherlands R. Parry United States of America A. Rahde Brazil GIFAP GIFAP H. Regenstein S. Rickard O. Silapanapaporn Thailand T.H. Smith Norway J. Stalker Canada J. Snelson Australia R.C. Ticknell United Kingdom V. Tuomaala P. Vermes A. Vongbuddhapitar Finland Israël Thailand M. Walsh European Economic Community B. Watts New Zealand J. Wessel (Chairman) United States of America

Questionnaire on National Pesticide Regulatory Systems

- 2. At the 14th Session of the CCPR, the Working Group presented two documents on the questionnaire on national pesticide regulatory practice (paras. 205-206, ALINORM 83/24A). The first document described the results of the Working Group's analysis of the replies received from 48 countries (CX/PR 82/15). The second document, which was prepared by the United Kingdom, provided a tabular summary of each country's reply to the questionnaire.
- As requested by the Committee at the 14th Session, a circular letter was sent by the Working Group chairman requesting the 75 countries that had not responded to the questionnaire to do so. Completed questionnaires were received from the following additional countries: Barbados, Czechoslovakia, Equador, Mauritius, Qatar, and Italy. Their replies were incorporated into amendment sheets for the tabular summary document, which the United Kingdom circulated to Codex Contact Points in March 1983. The Working Group noted that completed questionnaires which were received later from Guyana, Spain, Turkey, and Zambia will form part of a further set of amendment sheets to be issued in early 1984.
- 4. The Working Group agreed that it should circulate a similar type of questionnaire to member countries in the year prior to the 18th session of the CCPR. The Working Group recommended that, in the interim, countries that have not yet replied to the original questionnaire and those countries that want to make changes in their previous submission should send the information to the United Kingdom.

Acceptance of Codex MRL's - Problems and Practices

- The Working Group informed the Committee at the 14th Session that the review of the completed questionnaires identified a number of problems that could serve as obstacles to acceptance of Codex MRLs by governments (see CX/PR 82/15). The Committee agreed with the recommendation that the Working Group undertake the development of guidelines on regulatory practices to assist countries in overcoming these obstacles (para. 206 and Appendix VI, ALINORM 83/24A).
- The information from the completed questionnaires provided the framework for the preparation of draft guidelines for discussion by the Working Group at this Session's meeting. The draft entitled "Guidelines on Regulatory Practices to Facilitate Acceptance of Codex MRL's "is intended to provide a source of information and advice for national governments to harmonize their policies and practices in relation to the objectives of the CCPR. The draft guidelines describe the benefits that countries can derive from achieving international agreement on legal limits for pesticide residues in food; the JMPR and Codex systems for developing and elaborating such limits; the problems that confront countries in accepting these limits; and the rationale and recommendations for governments to deal with these problems.

The Working Group agreed with the overall format and content of the draft document and noted that although several sections remain to be drafted, the document deals with almost every aspect of governments acceptance and application of Codex limits for pesticide residues in food in international trade. It was further agreed that referring to the document as "guidelines" may not be appropriate and that a more descriptive title is needed. The Working Group also decided that a series of recommendations on national regulatory policies and practices in the context of the CCPR should be developed as a preamble to and as part of the document.

The Working Group suggested a number of changes and additions in the text of the document. It was agreed that a second draft should be prepared as quickly as possible for review and comment by Working Group members and that a final document be circulated to governments for discussion by the Committee at the next session.

Glossary of Terms

- 8. The Working Group reviewed the proposed glossary of terms that is contained in the paper CX/PR 83/13. It was noted that the glossary was a major revision of the previous version the Working Group presented to the Committee at the 14th Session. The revision takes into account comments made by the Committee at that session and by members of the Working Group, who have had several opportunities during the past year to offer comments on the glossary.
- At this session's meeting, the Working Group made several relatively minor changes in some of the definitions as shown in Annex I to this Appendix. With these changes the Working Group agreed that the glossary will serve its intended purpose of updating and clarifying the definition of key terms frequently used by the CCPR and assuring their consistency with the definitions used by the JMPR. The Working Group recommended that the Committee adopt the glossary of terms for use by the CCPR.

GLOSSARY

(Definition of Terms Used by the Codex Committee on Pesticide Residues)

- 1. Animal Feed means harvested fodder crops, by-products of agricultural crops and other products of plant or animal origin which are used for animal feeding and which are not intended for human consumption.
- 2. Pesticide means any substance intended for preventing, destroying, attracting, repelling, or controlling any pest including unwanted species of plants or animals during the production, storage, transport, distribution, and processing of food, agricultural commodities, or animal feeds or which may be administered to animals for the control of ectoparasites. The term includes substances intended for use as a plant-growth regulator, defoliant, dessicant, fruit thinning agent, or sprouting inhibitor and substances applied to crops either before or after harvest to protect the commodity from deterioration during storage and transport. The term normally excludes fertilizers, plant and animal nutrients, food additives, and animal drugs.

<u>Explanatory Note.</u> "Agricultural commodities" refers to commodities such as raw cereals, sugar beet, and cottonseed which might not, in the general sense, be considered a food.

3. Pesticide Residue means any specified substance in food, agricultural commodities, or animal feed resulting from the use of a pesticide. The term includes any derivatives of a pesticide, such as conversion products, metabolites, reaction products, and impurities considered to be of toxicological significance.

Explanatory Note. The term "pesticide residue" includes residues from unknown or unavoidable sources (e.g., environmental), as well as known uses of the chemical.

4. Good Agricultural Practice in the Use of Pesticides (GAP) is the officially recommended or authorized usage of pesticides under practical conditions at any stage of production, storage, transport, distribution and processing of food, agricultural commodities, and animal feed bearing in mind the variations in requirements within and between regions, which takes into account the minimum quantities necessary to achieve adequate control, applied in a manner so as to leave a residue which is the smallest amount practicable and which is toxicologically acceptable.

<u>Explanatory Note</u>. The "officially recommended or authorized usage of pesticides" is that which complies with the procedures, including formulation, dosage rates, frequency of application and pre-harvest intervals, approved by the national authorities.

5. Acceptable Daily Intake (ADI) of a chemical is the daily intake which, during an entire lifetime, appears to be without appreciable risk to the health of the consumer on the basis of all the known facts at the time of the evaluation of the chemical by the Joint FAO/WHO Meeting on Pesticide Residues. It is expressed in milligrams of the chemical per kilogram of body weight.

Explanatory Note. For additional information on ADI's relative to pesticide residues refer to the Report of the 1975 Joint FAO/WHO Meeting on Pesticide Residues, FAO Plant Production and Protection Series No. 1 or WHO Technical Report Series No. 592.

6. <u>Temporary Acceptable Daily Intake (TADI)</u> is an acceptable daily intake established for a specified, limited period to enable additional biochemical, toxicological or other data to be obtained as may be required for estimating an acceptable daily intake.

Explanatory Note. A TADI estimated by the Joint FAO/WHO Meeting on Pesticide Residues normally involves the application of a safety factor larger than that used in estimating an ADI.

7. <u>Maximum Residue Limit (MRL)</u> is the maximum concentration for a pesticide residue resulting from the use of a pesticide according to good agricultural practice that is recommended by the Codex Alimentarius Commission to be legally permitted or recognized as acceptable in or on a food, agricultural commodity, or animal feed. The concentration is expressed in milligrams of pesticide residue per kilogram of the commodity.

Explanatory Note. The "recognized as acceptable" is intended to accommodate Member Countries which, under national legislation, do not use MRLs as legal limits. An MRL is principally based on supervised trials carried out under varying conditions of climate and pest control needs.

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

Explanatory Note. The term "practical residue limit" has been used for residues in food from unavoidable sources and in food of animal origin arising from residues in animal feed. This term, which had led to much confusion, was abandoned. Residues in food of animal origin that are controllable by farming practices are now covered by MRLs. Residues from unavoidable sources are covered by ERLs which are usually based on residue data from food monitoring programmes.

- 9. <u>Temporary MRL (TMRL) or Temporary ERL (TERL)</u> is an MRL or ERL established for a specified, limited period and is recommended under either of the following conditions:
 - (a) where a temporary acceptable daily intake has been estimated by the Joint FAO/WHO Meeting on Pesticide Residues for the pesticide or contaminant of concern; or

(b) where, although an acceptable daily intake has been estimated, the good agricultural practice is not sufficiently known or residue data are inadequate for proposing an MRL or ERL by the Joint FAO/WHO Meeting on Pesticide Residues.

Explanatory Note. TMRLs and TERLs are not to be advanced further than Step 7 of the Codex Procedure.

10. <u>Guideline Level</u> is used to assist authorities in determining the maximum concentration of a pesticide residue resulting from a use reflecting good agricultural practice but an acceptable daily intake or temporary acceptable daily intake for the pesticide has not been estimated or has been withdrawn by the Joint FAO/WHO Meeting on Pesticide Residues. The concentration is expressed in milligrams of pesticide residue per kilogram of the commodity.

Explanatory Note. Guideline Levels are not to be advanced further than Step 4 in the Codex Procedure and are to be listed separate from MRLs and TMRLs in Codex documents.

- 11. Limit of Determination is the lowest concentration of a pesticide residue or contaminant that can be identified and quantitatively measured in a specified food, agricultural commodity, or animal feed with an acceptable degree of certainty by a regulatory method of analysis.
- 12. Regulatory Method of Analysis is a method that has been validated and can be applied using normal laboratory equipment and instrumentation to detect and determine the concentration of a pesticide residue or contaminant in a food, agricultural commodity or animal feed for purposes of determining compliance with a maximum residue limit or extraneous residue limit.

Explanatory Note. For more information on regulatory methods of analysis and their application, refer to Recommendations for Methods of Analysis for Pesticide Residues and Codex Guidelines on Good Analytical Practice (ref., to be published).

13. <u>Intake Study</u> is a study designed to measure or estimate actual dietary exposures of consumers to pesticide residues or contaminants in order to compare such exposures to the acceptable daily intakes for pesticides or contaminants.

Explanatory Note. For more information on intake studies, refer to Guidelines for the Study of Dietary Intakes of Chemical Contaminants prepared by the Joint FAO/WHO Food Contamination Monitoring Programme (WHO-EFP/83.53, FAO-ESN/MISC/83/2).

REPORT OF THE AD HOC WORKING GROUP ON PRIORITIES

Membership:

•	
A. Anderson	Sweden
J.A.R. Bates	United Kingdom
R. Belcher	Australia
J. Benstead	Australia
A.F.H. Besemer	The Netherlands (Chairman)
G. Bressau	Federal Republic of Germany
C. Collier	United States of America
G. Dupuis	Switzerland
G. Ekstrom	Sweden
S. Fertiq	United States of America
S. Gorbach	Federal Republic of Germany
M. L'Hôtellier	France
N.F. Ives	United States of America
G.R.R. Jenkins	United Kingdom
J. van der Kolk	Netherlands
F.W. Kopisch-Obuch	FAO
L.G. Ladomery	FAO .
M. Laurent	GIFAP
M.R. Lynch	Ireland
N. Rao Maturu	FAO
R.M. Parry	United States of America (Rapporteur)
H. Regenstein	GIFAP
J.T. Snelson	Australia
J. Stalker	Canada
V. Tuomaala	Finland
R. Tincknell	United Kingdom
P. Vermes	Israel
M. Walsh	- · · - -
B. Watts	Commission of European Communities New Zealand
G. Willis	
u. #11113	United Kingdom

1. The Working Group reviewed priority lists I, II and III as assigned at the 14th CCPR session (ALINORM 83/24A Appendix VII) The Working Group noted that the following compounds were on the agenda for the 1983 JMPR agenda:

Priorities Group Number	. 3	Country Submitting	Manufacturer
81-08 81-02 81-05 82-03	butocarboxin bitertanol	Greece Federal Republic of Germany Federal Republic of Germany Australia	Rohm & Haas Wacker Bayer Cyanamid Rhône-Poulenc FBC

It was confirmed that the remaining compounds continued to meet the criteria for priority and assigned them to new lists I and II on the basis of availability of technical and scientific data.

2. Number	The Group reviews ISO Common Name	chemical Name, Submitting Country, Trade Names and Basic Producer	
83-01	flucythrinate	(RS)-α-cyano-3-phenoxybenzyl (S)-2-(4-difluoro-methoxyphenyl)-3-methyl- butyrate. New Zealand /PAY-OFF, CYBOLT/ American Cyanamid.	
83-02	methoprene	isopropyl $(\underline{E},\underline{E})$ -11-methoxy-3,7,11-trimethyl 1-2,4 dodecadienoate. United States of America/ALTOSID, APEX, DIACON, DIANEX, KABAT, MANTA, MINEX, PHARORID, PRECOR, SPAWNMATE/Zoecon	
83-03	fluvalinate	(RS)-alpha-cyano-3-phenoxybenzyl(R)-2- 2-chloro-4-(trifluormethyl)-anilino-3- methylbutanoate. United States of America/MAVRIK, MAVRIK AQUAFLOW/Zoecon	
83-04	dimethipin	2,3-dihydro-5,6-dimethyl-1,4-dithiin 1,1,4,4-tetraoxide. United States of America/HARVADE/Uniroyal	
83-05	propamocarb	<pre>propyl-3-(dimethylamino)propyl-carbamate. Federal Republic of Germany/PREVICUR N, PREVEX, FILEX/Schering</pre>	
83-06	carbosulfan	2,3-dihydro-2,2-dimethyl-1-benzofuranyl [(dibutylamino)thio]methylcarbamate. Israel/MARSHAL/FMC.	

3. The group established 1983 priority lists as follows: A. List I: This list gives compounds judged to meet selection criteria and can be considered for evaluation by the 1984 JMPR.

Number	ISO Common Name	Submitting Country	<u>Manufacturer</u>
81-01	oxycarboxin	United States of America	Uniroyal
82-04	cyhalothrin	United Kingdom	ICI
83-01	flucythrinate	New Zealand	Cyanamid
83-02	methoprene	United States of America	Zoecon
83-04	dimethipin	United States of America	Uniroyal
83-05	propamocarb	Federal Republic of Germany	Schering
83-06	carbosulfan	Israel	FMC

B. List II: This list gives compounds judged to meet selection criteria and can be considered for evaluation by the 1985 or later ${\sf JMPR.}$

Number	ISO Common Name	Submitting Country	Manufacturer
77-	vinclozolin	New Zealand	BASF
77-	thiofanox	United States of America	Diamond Shamrock
81-11	qlyphosate	Sweden	Monsanto
82-02	prothiophos	Australia	Bayer
83-03	fluvalinate	United States of America	Zoecon

- The Australian delegate withdrew promacyl from the priority list.

 The Netherlands delegate noted that new toxicological data on inorganic bromides may be available in early 1984 which may affect the ADI. The Committee recommended that the JMPR consider this new data at their 1984 meeting, together with residue data, especially on products of animal origin. The Secretariat informed the Working Group that isoprocarb was not to be considered by the JMPR.
- The delegation of The Netherlands submitted a proposal that environmental contaminants of the polychlorinated biphenyl (PCB) group be added to the priority lists for consideration. The Working Group recognized that these compounds bear certain similarities to the organochlorine pesticides, that residues occur in food of animal origin, that residues constitute a barrier to international trade, and present health concerns. It was noted that CCFA has established a Working Group on Contaminants to advise that Committee on a definition of "guideline levels of contaminants" and other terms of reference (16th CCFA Report ALINORM 83/12A para. 256).

The Working Group also noted that there is a Joint ${\sf FAO/WHO}$ program monitoring residues of PCB's.

The terms of reference in use by the Priorities Group, include information on good agricultural practices which is not appropriate for environmental contaminants such as PCB's. A new term might have to be devised. Estimated Residue Limits (ERL) would not be a suitable term since these are only proposed for compounds for which a (temporary) ADI has been estimated and data were not expected enabling the estimation of an ADI in the forseeable future. Similarly Guideline level would not be a suitable term, since these reflected good agricultural practice. The Chairman referred the issue to the Committee for additional guidance.

6. The U.S. delegate noted the importance of submitting complete information on good agricultural practice in addition to the residue data when compounds were to be evaluated by the Joint Meeting on Pesticide Residues. Manufacturers and/or governments were encouraged to follow guidelines presented in Section 2.3 of the 1982 Joint Meeting Report.

The Chairman noted that it may be necessary for the Codex Alimentarius to assist in collecting information about Good Agricultural Practice where gaps exist in some submissions.