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Both the FAO Panel and the WHO Core Assessment Group have applied consistent scientific principles and data requirements in their respective areas over the years, although elements of these have gradually been revised to higher standards, as has also occurred at the national level. The formats of the evaluations (monographs) have also been gradually revised.

The aims of the FAO Manual are to

- clarify, update and consolidate the procedures used by the FAO Panel for the evaluation of experimental data and related information,
- improve transparency of the work of the FAO Panel,
- define and provide guidance on the type, amount, quality and format of data submissions required for the estimation of maximum residue levels on which the Codex MRLs are based,
- facilitate the acceptance of Codex MRLs by the governments and their use within the WTO Agreement on the Application of Sanitary and Phytosanitary Measures,
- serve as a source of information and instruction for all those directly involved in the activities of the FAO Panel of the JMPR, including data submitters and FAO Panel data reviewers, and
- assist member countries in evaluating residue data for the registration of pesticides and in developing their national evaluation systems.

The present FAO Manual incorporates all relevant information and principles which are currently used by the JMPR to estimate maximum residue levels and supervised trials median residue levels. Because guidelines by their very nature are subject to revision with time in order to accommodate new scientific developments and standards, users of these guidelines are advised to keep abreast of these changes by reading future JMPR reports where such updates are recorded. The FAO Manual will be updated in the future in the light of experience gained and further developments in residue data evaluation.

The FAO Manual is referred to in the text as “the Manual”

ACKNOWLEDGEMENT

This revised edition of the Manual has been updated with recommendations of the JMPR since 1997

Mr Denis Hamilton, an FAO Panel member, prepared the technical and scientific content. Input is greatly appreciated from the other members of the 2001 FAO Panel and invited experts: Dr Árpád Ambrus, Dr Ursula Banasiak, Prof Eloisa Dutra Caldas, Dr Steve Funk, Mrs Caroline Harris, Dr Dugald MacLachlan, Dr Bernadette Ossendorp and Dr Yukiko Yamada. Comments and suggestions from Mr Tony Machin are also gratefully acknowledged.

Dr Amelia Tejada, the FAO Joint Secretary, was responsible for organizing the project.

Ms Jacinta Norton assisted with the grammatical editing of the text and with the style of the Manual layout.

Acknowledgement from the first edition (1997)

The preparation of this Manual was initiated by the FAO Secretary to the JMPR and work was started by Dr A. J. Pieters and Prof A. F. H. Besemer, and then continued by Dr K. Voldum-Clausen.

Based on the recommendations of the members of the FAO Panel of the 1996 JMPR, the previous text of the manual was revised by Dr Árpád Ambrus in close co-operation with the members of the Panel and invited experts, namely Dr Angie V. Adam, Dr Ursula Banasiak, Mr Stephen Crossley, Dr Eloisa Dutra Caldas, Mr Denis Hamilton, Mr Fred Ives, Ms Elena Masoller, Dr Tsuyoshi Sakamoto and Dr Yukiko Yamada.

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PREFACE

The preface to the first edition of this manual in 1997 accurately describes the Joint Meeting on Pesticide Residues (JMPR) and the aims of the FAO Manual

The second edition (2002) incorporates information from the JMPR Reports of 1997-2001. The reports are revisions of previous guidelines or additions because of recent developments in residue assessment

The last five years have seen many changes in residue evaluations. In particular, long-term dietary risk assessment was placed on a more formal basis in 1998 when JMPR first published detailed intake estimates for the compounds evaluated that year. The methods for short-term risk assessment were developed to a stage where, in 1999, the JMPR was able to publish detailed assessments for many of the compound-commodity combinations being evaluated

Other areas where there have been substantial changes since the first edition are

- residue evaluation for commodities of animal origin,
- residues in genetically modified crops, and
- effects of food processing on residues

Guidelines should be understood in the context of their origins. In JMPR this is usually a new situation where the current guidelines are silent or clearly do not make sense. A Panel member documents the approach taken in dealing with the new situation and, after agreement by the JMPR, the published report becomes the new or revised guideline. Guidelines should not be extrapolated too far, there is no reason to expect them to apply more widely than in the situations envisaged at the time they were formulated

Guidelines will continue to be revised as new developments occur

A further aim of this Manual, although implicit in the others, should be explicitly stated as

- to communicate with the CCPR, its member countries and other CCPR participants and to explain the procedures currently adopted by the FAO Panel

As stated in the preface to the first edition "The FAO Manual will be updated in the future in the light of experience gained and further developments in residue data evaluation "

Preface to the first edition 1997

The "Joint Meeting on Pesticide Residues" (JMPR) is an expert *ad hoc* body administered jointly by FAO and WHO. The JMPR evaluates pesticide residue and toxicology data for estimation of maximum residue levels and Acceptable Daily Intakes (ADIs). It is composed of two groups, the FAO Panel on Pesticide Residues in Food and the Environment which estimates maximum residue levels and the WHO Core Assessment Group (formerly WHO Expert Group on Pesticide Residues) which estimates ADIs and identifies risks to organisms in the environment

The JMPR has evaluated pesticides over the last 30 years with the aim of estimating the maximum residue levels in food and feed which are likely to result from legally permitted

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INTRODUCTION

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- Historical background
- The object of the work of the JMPR
- The JMPR assessment process

SCOPE OF THIS MANUAL

The Manual gives the historical background of the operation of the JMPR and describes the object of the work, the procedures involved in selection of compounds, the data requirements for estimating maximum residue levels and the principles followed in the evaluation of experimental results and information provided

Definitions of terms used in this Manual are given in Appendix II. The documents which were used for the preparation of the Manual are listed in Chapter 9, "References"

HISTORICAL BACKGROUND

The rapidly growing use of pesticides in agriculture after World War II gave rise to regulation by governments of the sale and use of pesticides to prevent chemicals with unacceptable properties being introduced onto the market. The use of chemicals was regulated in order to protect the users of pesticides, the consumers of treated foodstuffs, domestic animals and, at a later stage, the environment.

For this purpose governments requested manufacturers and other data submitters to submit information on the properties of their products and on their intended uses. As differences arose among countries on the extent and scope of data to be supplied, international organizations initiated attempts to harmonize requirements.

In April 1959, the Director-General of FAO convened a Panel of Experts on the Use of Pesticides in Agriculture in Rome. This panel considered various problems connected with the use of pesticides. With regard to pesticide residues the panel concluded that governments should be urged to include, in addition to public health authorities, bodies involved in agricultural pesticide and plant and animal protection which advise on regulations to control pesticide residue levels. Studies should be intensified on problems involving the analysis of pesticide residues in or on foodstuffs. Furthermore, the panel recommended studies to be undertaken jointly by FAO and WHO on the hazards arising from pesticide residues in and on food and feedstuffs, on the establishment of principles governing the setting up of pesticide tolerances and on the feasibility of preparing an International Code for toxicological data and residue data required to achieve the safe use of a pesticide.

A joint meeting of the FAO Panel of Experts and the WHO Expert Committee on Pesticide Residues was held in Rome in October 1961 to implement this recommendation. In their letter to the members of this meeting, the Directors-General of FAO and WHO stated that the meeting should consider, among other matters, principles for establishing tolerances for pesticide residues in food. The meeting developed definitions for a number of terms, which laid the foundation for the current "Glossary of Terms" used by the JMPR. Although the meeting developed the concept of a "permissible level", calculated from the Acceptable Daily Intake (ADI), the food factor and the average weight of the consumer, it accepted at the same time that the "tolerance", which is comparable with the present MRL, be estimated "taking into account the range of residues actually remaining when the food is first offered for consumption (following Good Agricultural Practice)". The meeting recommended to the Directors-General of FAO and WHO the promotion of studies on methods for carrying out toxicity studies and their evaluation, leading to ADIs and promotion of collaborative studies, leading to internationally acceptable analytical methods for pesticide residues. No conclusion was drawn with regard to the estimation of internationally acceptable tolerances. This might be ascribed to the meeting's opinion that different countries may establish different tolerances for the same pesticide on the same food, but that this would not impede the free movement of that food in international trade as long as the permissible level was not exceeded.

In November 1962, an FAO Conference on Pesticides in Agriculture was held in Rome. The Conference expressed its concern that differences in residue tolerances existed not only among countries of different regions but also among those of the same region. FAO was strongly urged to investigate the reasons for these differences and, if possible, find ways to harmonize them. Consequently, the Conference recommended that the proposed Working Party on Pesticide Residues should pay particular attention to (a) the toxicity of pesticides and test methods, (b) the possible unification of tolerances, (c) coordination of methods of analysis, (d) surveys for collecting residue data, and (e) the establishment of a list of pesticides to which interested governments should give research priority. The Conference supported the principle that the amount of pesticide residue in food should not exceed that resulting from "Good Agricultural Practices" but recommended that governments should not adopt residue tolerances before international agreement on this subject had been achieved.

In a Joint Meeting of the FAO Committee on Pesticides in Agriculture and the WHO Expert Committee on Pesticide Residues held in Geneva from 30 September to 7 October 1963, the toxicological properties of a number of pesticides were studied for the first time and a few ADIs established. No developments took place in the area of residues.

The first meeting of the FAO Working Party on Pesticide Residues, recommended by the 1962 FAO Conference, took place in December 1963. The Working Party studied ways and means to arrive at recommendations for levels of residue tolerances. The following were considered essential:

- (1) residue levels resulting from Good Agricultural Practice (GAP) should be obtained by FAO from governments and pesticide manufacturers. These data should be considered by the FAO Working Party on Pesticide Residues. After consideration of the ADI and of the national nutritional patterns as stated in the FAO Food Balance Sheets, the Working Party would propose tolerances for residues on individual crops for consideration by governments and by the Expert Committee on Pesticide Residues of the Codex Alimentarius Commission,

- (ii) residues found in surveys of marketed commodities,
- (iii) ADIs to be estimated by joint meetings of the WHO Committee on Pesticide Residues and the FAO Committee on Pesticides in Agriculture,
- (iv) national nutritional patterns, and
- (v) acceptable analytical methods for residues. These methods should also be adopted by the Pesticide Committee of the Codex Alimentarius

For pesticides where an ADI had still to be estimated the Working Party would propose provisional tolerances. It was stated that the Expert Committee on Pesticide Residues of the Codex Alimentarius Commission (the predecessor of CCPR) should meet only after the FAO Working Party had collected and evaluated the required data and made its proposals for tolerances. This procedure would enable the Codex Committee, composed of government representatives, to act on the basis of technical information developed by specialists acting in their individual capacities.

THE OBJECT OF THE WORK OF THE JMPR

The current JMPR comprises the WHO Core Assessment Group and the FAO Panel of Experts on Pesticide Residues in Food and the Environment. The WHO Core Assessment Group is responsible for reviewing pesticide toxicological and related data and estimating no-observed-adverse-effect-levels (NOAELs) of pesticides and Acceptable Daily Intakes (ADI) of their residues in food for humans. In addition, as data and circumstances dictate, the Group estimates acute reference doses (acute RfDs) and characterizes other toxicological criteria such as non-dietary exposures.

The FAO Panel is responsible for reviewing pesticide use patterns (GAPs), data on the chemistry and composition of pesticides, environmental fate, metabolism in farm animals and crops, methods of analysis for pesticide residues and processing studies and for estimating maximum residue levels, supervised trials median residue values (STMRs) and highest residues (HRs) in food and feed commodities. The toxicity of the active ingredient and its metabolites, evaluated by the WHO Core Assessment Group, is taken into consideration in deciding if residues may or may not give rise to problems of public health. The maximum residue levels are recommended to the Codex Committee on Pesticide Residues (CCPR) as suitable for consideration as Codex Maximum Residue Limits (Codex MRLs) to be adopted by the Codex Alimentarius Commission (CAC).

The monographs prepared by the FAO Panel contain all the information which was used to estimate maximum residue levels. In addition, they give supporting information such as the physical and chemical characteristics of the pesticides, distribution of residues in various tissues, storage stability of residues, effect of processing on residue levels and fate in the environment.

THE JMPR ASSESSMENT PROCESS

This Manual is limited to the procedure followed by the FAO Panel of Experts

The evaluations carried out by the JMPR comprise three main categories

- review of new compounds (compounds evaluated by the JMPR for the first time),
- review of compounds under the periodic review programme,
- re-evaluation of new information relating to compounds other than new or periodic review chemicals

The principles of evaluation of new compounds and compounds under the periodic review programme are very similar and follow the order of subjects described under Data Requirements (Chapter 3) Re-evaluation of a compound is carried out when new information related to its use and residue levels becomes available (e.g. change in or new use patterns, data on metabolism, residue behaviour, etc.) The re-evaluation often deals with and clarifies a single question raised by the Codex Committee on Pesticide Residues. The scope and depth of periodic review and re-evaluations are substantially different, and they are explained in Chapter 5. To make a clear distinction between the periodic review and re-evaluation of compounds, the latter is referred to by the FAO Panel as normal re-evaluation.

The agenda of the meetings are decided by the FAO and WHO Joint Secretaries, based on the priority list proposed by the Codex Committee on Pesticide Residues and approved by CAC, and on the information on availability of sufficient data for evaluation.

Member countries, industry and other data submitters are requested to supply the FAO Panel with all relevant information on identity, metabolism and environmental fate, methods of residue analysis, use patterns (registered and officially authorized uses), supervised residue trials, and farm animal feeding studies, fate of residues in storage and processing, residues in food in commerce or at consumption, and national maximum residue limits.

The FAO Joint Secretary of JMPR assigns the compounds for review to the members of the FAO Panel and informs data submitters accordingly. The companies submit the required information to the Panel member, who performs the evaluation of the company's data together with the information received from the member countries through the FAO Joint Secretary before the meeting, and prepares (i) the draft Evaluation containing the summarized experimental data and relevant information and (ii) the draft Appraisal containing an assessment of the results and draft recommendations.

During the Joint Meeting the FAO Panel discusses the draft evaluations and appraisals and agrees on the recommendations. The FAO and WHO Expert Groups coordinate their activities and, as needed, discuss chemical and toxicological aspects (e.g. metabolism patterns, level and toxicological significance of metabolites), clarify or resolve problematic issues, and finally, issue a joint Report containing the conclusions and recommendations of the Meeting.

A short introduction to the assessment process carried out by the FAO Panel is described below. A more detailed account of each stage of the process is given in succeeding sections.

In the process of evaluation of a new compound (or periodic review compound), a wide range of information and experimental data are reviewed.

The physical and chemical properties of the active ingredient and the metabolism and degradation of the compound in animals, plants, soil and water are studied to determine the composition and distribution of residues. Based on this information, and taking into account the available analytical methodology as well as the toxicological significance of metabolites and degradation products, the Panel recommends the definitions of residues for enforcement purposes and for dietary intake calculations.

The fate of residues in the environment is evaluated to assess the possibility of uptake of residue by the crop (e.g. from a soil treatment) and by following crops, and the contamination of the environment by persistent residues.

The analytical methods with accompanying chromatograms and information on stability of residues during sample storage are evaluated to assess the reliability of trial data and to estimate limits of quantification of residues which can be realistically achieved in regulatory laboratories.

It is emphasized that residues deriving from supervised field trials can only be used for estimating maximum residue levels if the trial conditions can be matched with relevant national GAPs. The maximum residue level estimates are based on already approved national uses (national GAP), which lead to the highest residue populations in the portion of commodities to which Codex MRLs apply (Appendix VI). The JMPR does not approve uses

The fate of residues during processing and cooking, as well as residues in the edible portion, are taken into consideration in the estimation of dietary intake.

The maximum residue levels for residues in commodities of animal origin are mainly estimated taking into consideration the results of farm animal feeding studies and residues occurring in feed items and, to a lesser extent, the information obtained from animal metabolism studies. MRLs for animal commodities may also relate to the residues arising from direct animal treatments.

The results of national monitoring programmes and total diet studies provide useful information, especially for dietary intakes, on residues occurring under practical use conditions. Furthermore, the estimation of extraneous residue levels is based on monitoring data (see Chapter 5 section, "Estimation of extraneous maximum residue levels").

CHAPTER 2

SELECTION OF COMPOUNDS FOR EVALUATION

CONTENTS

- Selection of new compounds
- Periodic review of old compounds
- Re-evaluation of compounds

SELECTION OF NEW COMPOUNDS

The Secretariat of the Joint FAO/WHO Food Standards Programme regularly invites member countries of CAC to propose pesticides to be added to the Codex Priority List of Pesticides for subsequent recommendation to the JMPR for evaluation. The proposals are considered by CCPR at the successive meeting. Based on the information received, CCPR prepares the priority list of pesticides and the tentative lists of compounds to be considered by the JMPR at its subsequent meetings.

Procedure for proposing pesticides for Codex Priority List

The procedure is described in the Circular of Codex Secretariat, CL 1996/35-PR. The procedure to be followed when proposing pesticides for inclusion in the Codex Priority List is given below. The form in which information is to be provided is given in Appendix VIII.

Criteria for inclusion of compounds in the Priority List

Before a pesticide can be considered for the Priority List it

- (a) must be available for use as a commercial product, and
- (b) must not have been already accepted for consideration

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

Criteria for selecting food commodities for which Codex MRLs or EMRLs should be established

The commodity for which the establishment of a Codex MRL or EMRL is sought should

- (a) form a component of international trade,
- (b) represent a significant proportion of the diet, and
- (c) contain pesticide residues as evidenced in monitoring programmes

Procedures to be followed for commodity-pesticide combinations which meet the selection criteria

Governments are recommended to check if the pesticide is already in the Codex system

NOTE Pesticide-commodity combinations which are already included in the Codex system or under consideration are found in a working document prepared for and used as a basis of discussion by each Session of the Codex Committee on Pesticide Residues. Consult the most current revision of the document to see whether or not a given pesticide has already been considered

If “YES”, proceed to section (b) below,

If “NO”, proceed as follows in (a)

(a)

(i) consult the manufacturer(s) regarding the existence of sufficient toxicological, residue and critical supporting data and confirm that the manufacturer(s) would be willing to submit data to the JMPR, and in which year, and

(ii) submit the information to the person designated by the CCPR using the form given in Appendix VIII

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

(i) interest exists in proposing MRLs for a new commodity. Consult the most recent working document containing all MRLs to ensure that MRLs have not already been established or considered for the commodity-pesticide combination. Where interest exists in developing data for a new commodity, governments are urged to discuss with industry the possibility of collaborative programmes, e.g., manufacturers may be willing to analyse samples from supervised residue trials conducted in accordance with *FAO Guidelines on Pesticide Residue Trials to Provide Data for the Registration of Pesticides and for the Establishment of Maximum Residue Limits*. Proposals for new commodity-pesticide combinations and new residue data may be submitted directly to the FAO Joint Secretary of the JMPR without the need for submissions according to Appendix VIII, as described in (a) above

(ii) in those cases where additional toxicological data have become available, governments may wish to propose a pesticide for re-evaluation. The form given in Appendix VIII should be used for this purpose. Where a serious public health concern exists in relation to a particular pesticide, governments should notify the WHO Joint Secretary of the JMPR promptly and provide appropriate data

Copies of correspondence

All communications to the various persons mentioned above should be copied to the Chairman of the CCPR. Communications on 3(a) and 3(b) above should also be copied to the designated person without enclosing the detailed toxicological or residue data

Data deadline

The above procedures relate mainly to the establishment of Codex Priority Lists. Once the agenda of the JMPR have been agreed, the Secretariat of the JMPR requests that detailed residue and toxicological data be submitted by a stated deadline. Normally directories or lists of studies to be submitted to the FAO Panel are required by 30 November of the year before the scheduled review. The actual data submissions and working paper are expected no later than 28 February of the year of the scheduled FAO Panel review. Less substantial submissions to support FAO Panel consideration of questions from a CCPR meeting may normally be accepted by 31 May of the year in which the issue will be considered. The agreed Priority Lists indicating the pesticides scheduled to be evaluated by the JMPR are attached to the Reports of the Sessions of the CCPR and distributed to Member Countries.

Industry contact points

Further information about industry contact points on specific chemicals is available from the Technical Director of CropLife International, Avenue Louise 143 B-1050 Brussels, Belgium, info@croplife.org, www.croplife.org

PERIODIC REVIEW OF OLD COMPOUNDS

Since the use conditions of the compounds may change with time, the Codex MRLs established several years ago may not reflect current use patterns. Furthermore, some of the old toxicological studies and residue trials may not meet the current standards. Within the CCPR, and also within the JMPR, there has been concern with respect to maintaining official Codex MRLs (CXLs) that may no longer reflect the current information. Consequently, old compounds are re-evaluated under the CCPR Periodic Review Programme (Appendix IV).

Periodic review of compounds currently being re-registered nationally

See also Chapter 3 section, "Periodic review of compounds currently being re-registered nationally"

The following information should be provided to the FAO Joint Secretary for compounds notified for periodic review while undergoing re-registration by national authorities

- current registered uses
- current registered uses that will be supported
- envisaged new or amended uses
- the status of the registration and an estimate of the date on which new or amended uses will become GAP
- an estimate of the date on which old registered uses will be revoked
- a clear description of the uses (new, amended or current but not to be supported) to which the data from supervised trials of residues relate

RE-EVALUATION OF COMPOUNDS

After a compound has been evaluated by the JMPR, changes in the authorized uses may occur or new information on the properties of the pesticide may become available which affect the recommended MRLs or require the estimation of new maximum residue levels for the

additional commodities See also Chapter 3 section, “Reconsideration of previous recommendations”

Furthermore, the CCPR may refer certain recommendations back to the JMPR for clarification or reconsideration in the light of the comments received from member countries

In both cases the compound is re-evaluated by the JMPR at subsequent meetings