

Submission and evaluation of pesticide residues data for the estimation of maximum residue levels in food and feed

PESTICIDE RESIDUES



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PREFACE

The revised first version of the FAO Manual published in 2002 incorporated additional information from the JMPR Reports of 1997–2001. Since its publication the JMPR has elaborated some new, as well as revised many existing principles used for the evaluation of pesticide residues which have been reproduced in the Reports of its meetings. The OECD Working Group on Pesticide Residues has also elaborated several Guidelines (GLs) and Guidance Documents which are directly related to the design of supporting studies used in the evaluation of pesticide residues. The activities of the JMPR FAO Panel and the OECD WG were complementary, as several experts contributed to both activities. The OECD WG considered the principles applied by the JMPR, and the JMPR incorporated a number of the OECD GLs in its evaluations.

The second edition describes the basic principles currently applied by the FAO Panel in the evaluation of pesticide residues for recommending maximum residue levels. These recommendations are for the consideration by the Codex Committee on Pesticide Residues (CCPR) for possible advancement as Codex Maximum Residue Limits (Codex MRLs) to be adopted by the Codex Alimentarius Commission (CAC). Some elements of the OECD documents have been incorporated in the Manual without specific attribution. These GLs and Guidance documents have been listed under references. In cases where more detailed information relating to a specific subject was considered to be particularly useful for the reader the reference to the relevant GLs is given.

In addition to the general updating of the text, the second edition contains new information on

- metabolism studies,
- data requirement on environmental fate,
- performance characteristics of analytical methods,
- planning and implementing supervised trials,
- use of monitoring data for estimation of maximum residue levels for spices,
- statistical evaluation of residue data,
- calculation of animal burden based on expanded feed consumption tables,
- estimation of dietary intake of residues.

In order to facilitate location of various subjects in the Manual, the sections are numbered. The chapter number is indicated with bold-faced number, the appendices are referenced with Roman numbers.

Preface to the first edition 2002

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

The first 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
- 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
- to explain the procedures currently adopted by the FAO Panel.

As stated in the preface to the first version: “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 version 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 uses of pesticides. These estimates are the basis for establishing international Maximum Residue Limits (MRLs) in food and feed commodities moving in international trade.

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
- 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

The first edition of the Manual has been updated with the new principles applied by the JMPR since 2002.

Professor Árpád Ambrus, a FAO temporary advisor, prepared the manuscript for the second edition.

Dr. Ursula Banasiak, Prof. Eloisa Dutra Caldas, Mr. Steve Funk, Mr. Denis Hamilton, Mr. David Lunn, Dr. Dugald MacLachlan, Dr. Katerina Mastovska, Dr. Bernadette Ossendorp, and Mr. Christian Sieke, members of the FAO Panel, and Dr. Yong Zhen Yang, FAO Joint Secretary, contributed with useful comments and suggestions to the preparation of the manuscript. Their contribution and assistance are sincerely appreciated.

Mr. Kevin Bodnaruk, FAO Editor, assisted with the editing of the text and with the style of the Manual layout.

Acknowledgement from the first edition (2002)

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

Mr. Denis Hamilton, a 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 version (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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