

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

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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.

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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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CHAPTER 1

INTRODUCTION

CONTENTS

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

1. 1 SCOPE OF THIS MANUAL

The Manual gives the historical background of the operation of the JMPR and describes the purpose 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.

The definition of terms used in this Manual is given in Appendix II. The documents which were used in the preparation of the Manual are listed under “References.”

1.2 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, 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 analyses; (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:

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

residues found in surveys of marketed commodities

ADIs to be estimated by joint meetings of the WHO Committee on Pesticide Residues and the FAO Committee on Pesticides in Agriculture

national nutritional patterns

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.

1.3 THE OBJECT OF THE WORK OF JMPR

The current JMPR comprises the WHO Core Assessment Group and the FAO Panel of Experts on Pesticide Residues in Food and the Environment. It is an independent scientific expert body convened by both Directors General of FAO and WHO according to the rules of both organizations, charged with the task to provide scientific advice on pesticide residues.

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 establishes Acceptable Daily Intakes (ADI) of their residues in food for humans. In addition, as data and circumstances dictate, the Group estimates acute reference doses (ARfDs) 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 (as it impacts on residues in food or feed commodities), metabolism in farm animals and crops, methods of analysis for pesticide residues and for estimating maximum residue levels and supervised trial median residue values (STMRs) of pesticides 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) for consideration as Codex Maximum Residue Limits (Codex MRLs) to be adopted by the Codex Alimentarius Commission (CAC). The CCPR relies on the scientific advice provided by the JMPR when recommending international food standards for pesticide residues. It is essential that the Meeting provides state-of-knowledge evaluations. This requires independent assessment of all available data.

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 and cooking on residue levels and fate in the environment.

1.4 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 and Information 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 or residue behaviour. 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 often referred to by the FAO Panel as normal re-evaluation.

The agenda of the meetings is decided by the Joint Secretaries of FAO and WHO, 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. When a new compound or one undergoing periodic review is evaluated, it is generally preferable to conduct the toxicological and residue reviews in the same year. Practical problems may, however, arise, e.g., when the residue definition is uncertain the residue evaluation cannot proceed satisfactorily or efficiently. In such cases, it is preferable that the toxicological evaluation precede the residue 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, farm animal feeding studies), fate of residues in storage and processing, and in special cases information on residues occurring in food in commerce or at consumption, and national residue definitions.

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 companies' data together with the information received from the member countries through the FAO Joint Secretary before the meeting, and prepares the draft Monograph containing the summarized experimental data and relevant information, and the draft Appraisal containing an assessment of the results and draft recommendations.

During the Joint Meeting the FAO Panel discusses the draft monographs and appraisals and agrees on the recommendations. The JMPR recommendations are based only on the results of the scientific assessment of the data supplied. In the absence of sufficient toxicological and residue data the Meeting cannot make recommendations for maximum residue levels. 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 the groups issue a joint Report containing the conclusions and recommendations of the Meeting.

It is the prerogative of the CCPR to accept or reject those recommendations, including recommendations to withdraw previous maximum residue levels suitable for use as Codex MRLs. The CCPR has the option to consider other factors that it deems appropriate in retaining MRLs.

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, 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 JMPR does not approve uses. It is emphasised that residues derived 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 maximum national uses (critical or maximum GAP), which normally lead to the highest residue populations in the portion of commodities to which Codex MRLs apply (Appendix VI). An exception is where the highest residue may raise acute intake concerns. Under such circumstances, if suitable residue data are available, the JMPR identifies an alternative GAP that would lead to residues of an acceptable magnitude.

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 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.

The fates 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 results of national monitoring programmes provide useful information, on residues occurring under practical use conditions, which are used for the estimation of extraneous residue levels (EMRLs) and as a special case maximum residue levels in spices (Chapter 6, Section 11.1).

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 follow-up crops, and the contamination of the environment by persistent residues likely to lead to residues in food or feed commodities.

CHAPTER 2

SELECTION OF COMPOUNDS FOR EVALUATION

CONTENTS

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

2.1 SELECTION OF NEW COMPOUNDS

The Secretariat of the Joint FAO/WHO Food Standard 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.

When prioritizing new chemicals for evaluation by the JMPR, the Committee follows the criteria described in the Codex Alimentarius Procedural Manual¹.

2.1.1 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 registered for use in a member country
- b. must be available for use as a commercial product
- c. must not have been already accepted for consideration
- d. must give rise to residues in or on a food or feed commodity moving in international trade, the presence of which is (or may be) a matter of public health concern and thus 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

¹ Codex Alimentarius Commission Procedural Manual –Eighteenth edition, 2008, www.codexalimentarius.net

- c. contain pesticide residues as evidenced in monitoring programmes (for EMRL).

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 GLs 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 the basic requirements described in Chapter 3. Proposals for new commodity-pesticide combinations and new residue data may be submitted directly to the FAO Joint Secretary of the JMPR, who may decide on scheduling the new proposal for evaluation, 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 Chairperson of the CCPR and 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. The 2009 Session of CCPR confirmed² that proposals for evaluation by the JMPR would be finalized by the Committee for adoption by the CAC in the same year and no further changes to the current year's schedule would be possible. Once the agenda of the JMPR has been agreed, the Secretariat of the JMPR requests that detailed residue and toxicological data be submitted by a stated deadline.

Starting in 2010, the data directory should be submitted to the joint FAO Secretary by 1 September and the full residue data submissions are required by 30 November of the year before the scheduled review. Less substantial submissions to support FAO Panel consideration of questions from a CCPR meeting, (usually raised by way of a 'CCPR Concerns Form') 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.

2.2 PERIODIC REVIEW OF OLD COMPOUNDS

Since the use conditions of the compounds may change with time, older existing Codex MRLs may not reflect current use patterns. Furthermore, some of the old toxicological studies and residue trials may not meet the contemporary 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).

When prioritizing chemicals for periodic re-evaluation by the JMPR, the CCPR will consider the following criteria:

- a. if the intake and/or toxicity profile indicate some level of public health concern
- b. chemicals that have not been reviewed toxicologically for more than 15 years and/or not having a significant review of maximum residue limits for 15 years
- c. the year the chemical is listed in the list for Candidate Chemicals for Periodic Re-evaluation – Not Yet Scheduled

² Report of the forty-first session of the codex committee on pesticide residues, para 187, Beijing, China, 20 – 25 April 2009

- d. the date that data will be submitted
- e. whether the CCPR has been advised by a national government that the chemical has been responsible for trade disruption
- f. if there is a closely related chemical that is a candidate for periodic re-evaluation that can be evaluated concurrently
- g. the availability of current labels arising from recent national re-evaluations.

2.2.1 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.

See also section 3.4.1 “*Periodic review of compounds undergoing re-registration by national authorities*”.

2.3 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 may affect the recommended MRLs or require the estimation of new maximum residue levels for the additional commodities.

Where a pesticide has already been evaluated by the JMPR, new evaluations may be initiated if one or more of the following situations arise:

- a. New toxicological data becomes available to indicate a significant change in the ADI or ARfD.
- b. The JMPR may note a data deficiency in a Periodic Re-evaluation or New Chemical evaluation. In response, national governments or other interested parties may pledge to supply the information to the appropriate Joint Secretary of the JMPR with a copy for consideration by the CCPR. Following scheduling in the JMPR tentative schedule, the data should be submitted subsequently to the appropriate Joint Secretary of the JMPR.
- c. The CCPR may place a chemical under the four-year rule, in which case the government or industry should indicate support for the specific MRLs to the FAO Joint Secretary of the JMPR. Following scheduling in the JMPR tentative schedule,

any data in support of maintenance of the MRL(s) would be submitted to the FAO Joint Secretary of the JMPR.

- d. A government member may seek to expand the use of an existing Codex chemical: that is, obtain MRLs for one or more new commodities where some MRLs already exist for other commodities. Such requests should be directed to the FAO Joint Secretary of the JMPR and submitted for consideration by the CCPR. Following scheduling in the JMPR tentative schedule, the data would be submitted to the FAO Joint Secretary of the JMPR.
- e. A government member may seek to review a MRL due to a change in GAP. For example a new GAP may necessitate a larger MRL. In this case the request should be made to the FAO Joint Secretary and submitted for consideration by the CCPR. Following scheduling in the JMPR tentative schedule, the data would be submitted to the FAO Joint Secretary of the JMPR.
- f. The CCPR may request a clarification or reconsideration of a recommendation from the JMPR. In such cases the relevant Joint Secretary will schedule the request for the next JMPR.

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

CHAPTER 3

DATA AND INFORMATION REQUIRED FOR JMPR EVALUATIONS

CONTENTS

Introduction
New and periodic review compounds
Sampling and residue analysis
Use pattern
Residues resulting from supervised trials on crops
Submission of information for estimation of MRLs of pesticide residues in/on spices
Fate of residues in storage and processing
Information and data from farm animal feeding and external animal treatment studies
Residues in food in commerce and at consumption
National residue definitions
Reconsideration of previous recommendations
Data requirements for EMRL estimation

3.1 INTRODUCTION

The JMPR is not a regulatory body and therefore cannot “require” (in the strict sense of the word) submission of data. However, it can and does refrain from estimating maximum residue levels when data are inadequate. In such cases, the data inadequacies are identified in the Report. For residue evaluations, the Meeting considers all aspects of the use and the fate of a pesticide and its residues, which implies that all studies that provide such information are necessary. It is solely for the JMPR to decide which data are relevant and which are not. The JMPR publishes lists of those data which it considers “desirable” when these are found to be lacking or if areas are insufficiently addressed in data submissions.

Data submitters are advised to follow the guidelines in this chapter when compiling their data package.

3.2 NEW AND PERIODIC REVIEW COMPOUNDS

The data and information needed for the evaluation of pesticide residues of new compounds and compounds evaluated within the periodic review programme are outlined in this section.

An objective of the periodic review is to make the best use of the existing database, regardless of the age of the studies. Consequently, countries and industry are requested to provide all relevant information irrespective of whether it had been previously supplied. However, experience has shown that some periodic review submissions contain data that are of limited use for estimating maximum residue levels. For example:

- Residue data that do not relate to current good agricultural practice (GAP) and are not accompanied by adequate details of the conduct of the field trial, the handling of the samples or details of the analysis (including associated recovery data).
- Residue data developed with non-selective analytical methods, e.g., colorimetric analysis or bioassay.

- Lack of information on specifics and conditions of sampling, sample transportation, sample storage and intervals from sampling until storage and storage until analysis.
- Omission of critical supporting studies, such as metabolism, farm animal feeding, processing, analytical methods and freezer storage stability studies.

Residue data or studies with obvious deficiencies submitted even as supplementary data can be judged only on a case-by-case basis when considered in the context of the available database.

In preparing product monographs (working papers) the data submitters should consider the relevance of residue data in the light of current use practices, residue definitions, analytical methods etc., and that only data pertinent to commodities with current or proposed uses should be provided. If critical supporting studies are not provided, the submission must include an explanation of why specific critical supporting studies, e.g., processing information, were not provided. Studies which fulfil the requirements of modern national registration systems will generally meet the needs of the JMPR.

The content and format of a submission (data package) should follow the format of the JMPR evaluations.

3.2.1 Identity

ISO common name

Chemical name

(IUPAC)

(Chemical Abstract)

CAS Registry. No.

CIPAC No.

Synonyms

Structural formula

Molecular formula

Molecular weight

3.2.2 Physical and chemical properties

Provide a detailed physical and chemical characterization for new and periodic review compounds as guidance for the interpretation of available test data.

Pure active ingredient

Appearance

Vapour pressure (in mPa at stated temperature)

Melting point

Octanol-water partition coefficient (at stated pH and temperature)

Solubility (Water and organic solvents at stated temperatures)

Specific gravity (... g/cm³ at ...stated temperature)

Hydrolysis (at stated pH and temperature)

Photolysis

Dissociation constant

Thermal stability

Technical material

Minimum purity (in %)

Main impurities (range of amounts; confidential information will not be presented as such in the JMPR monographs)

Melting range

Stability

Reference to FAO specifications for TC or TK (TC, technical material; TK, technical concentrate).

Formulations

Provide a list of commercially available formulations.

Reference to FAO specifications for formulations

3.2.3 Metabolism and environmental fate

Information is required on:

- Animal metabolism
- Plant metabolism
- Environmental fate in soil
- Environmental fate in water-sediment systems.

In addition, *in vitro* data are useful to show if the pesticide is likely to undergo hydrolysis (acid, base, or enzymatic), oxidation or reduction, photolysis, or other changes.

The dose level and criteria for identification and characterization of residue components, including non-extracted residues, are similar to those described in guidelines of registration authorities. In order to guide data submitters and assist the evaluation of experimental results, the most important principles are summarised below.

Metabolism studies are conducted to determine the qualitative metabolic fate of the active ingredient and elucidate its metabolic pathway. Many pesticides undergo change during and after application to plants, soil, water and livestock. The composition of the terminal residue must, therefore, be determined before the residue analytical methodology can be developed and residues quantified.

Radiolabelled active ingredients are required to allow quantification of the total, extractable and unextracted radiolabel residues. The active ingredient should be labelled so that the degradation pathway can be traced as far as possible. The radiolabel should be positioned in the molecule so that all significant moieties or degradation products can be tracked. If multiple ring structures or significant side chains are present, separate studies reflecting labelling of each ring or side chain will normally be required if it is anticipated that cleavage between these moieties may occur. A scientifically based rationale may be submitted in lieu of conducting studies with multiple radiolabels if no cleavage is anticipated.

In choosing the position to be labelled, assurance is needed that a stable position is selected. The preferred isotope is ^{14}C , although ^{32}P , ^{35}S , or other radioisotopes may be more appropriate if no carbon or only labile carbon side chains exist in the molecule. The use of tritium (^3H) as a label is strongly discouraged due to the possibility of hydrogen exchange with endogenous materials. If a potentially labile side chain or tritium labelling is chosen, a metabolism study will be considered adequate if all significant radioactivity in the crop is identified and found to be associated with the active ingredient, and not related to loss of the label from the basic structure of the active ingredient molecule.

The specific activity of the radiolabelled active ingredient should be adequate to meet the general data requirements of the metabolism study (quantification of 0.01 mg/kg total radioactive residue (TRR) in edible tissues, milk, eggs or crop matrices). Studies with 1× application rates are generally necessary for the decision of exceeding or not exceeding the threshold levels. However, dosing with an exaggerated rate, e.g., 5×, is recommended when low residue levels are anticipated, which in turn may result in a lack of data to define the metabolic pathways from the 1× treatment.

The desired goal of a metabolism study is the identification and characterization of at least 90% of the TRR in edible tissues, milk, eggs and in each raw agricultural commodity (RAC) of the treated crop. In many cases it may not be possible to identify significant portions of the TRRs especially when low total amounts of residue are present, when incorporated into biomolecules, or when the active ingredient is extensively metabolised to numerous low level components. In the latter case it is important for the applicants to demonstrate clearly the presence and levels of the components, and if possible, attempt to characterise them. Studies should utilize state-of-the-art techniques and include citations of such techniques when used. Table 3.1 provides guidance on strategy for identification and characterization of extractable residues.

Table 3.1 Strategy for Identification and Characterization of Extractable Residues from Metabolism in Crops

Relative amount (%)	Concentration (mg/kg)	Required Action
< 10	< 0.01	No action if no toxicological concern
< 10	0.01 – 0.05	Characterize. Only attempt to confirm identity if straightforward, e.g., a reference compound is available or the identification is known from a previous study.
< 10	> 0.05	Characterization/identification needs to be decided on a case-by-case basis taking into account how much has been identified.
> 10	< 0.01	Characterize. Only attempt to confirm identity if straightforward, e.g., a reference compound is available or the identification is known from a previous study.
> 10	0.01 – 0.05	Significant attempts to identify should be made especially if needed to establish a pathway, ultimately characterization might be accepted.
> 10	> 0.05	Identify using all possible means.
> 10	> 0.05 unextracted radiolabel	See notes

Notes: The extracted solid material should be assayed and, if radioactivity is present in the unextracted radiolabel fraction down to the trigger values of 0.05 mg/kg or 10% of the TRR, whichever is greater, release of the radioactivity should be attempted for further identification.

Treatments of extracted solids materials may be performed sequentially or in parallel. Types of treatments suggested include addition of dilute acid and alkaline at 37 °C, use of surfactants, enzymes, and 6N acid and/or 10N alkali with reflux. It should be kept in mind that the milder procedures provide more accurate assignments of metabolite structures released. Exhaustive extraction such as acid/alkaline reflux would probably release moieties as their final hydrolysis products, which may have little structural relationship to the original unextracted radiolabel. Further details on the recommended procedures for performing metabolism studies (test site and conditions, sampling, analysis, identification and characterization of residues, etc.) are given in the OECD Guidelines for the Testing of Chemicals, Test No. 501: Metabolism in Crops, and Test No. 503: Metabolism in Livestock³.

³ OECD Guidelines for the Testing of Chemicals, Test No. 501: Metabolism in Crops; Test No. 503: Metabolism in Livestock

<http://puck.sourceoecd.org/vl=3615016/cl=46/nw=1/rpsv/cw/vhosts/oecdjournals/1607310x/v1n7/contp1-1.htm>

During the conduct of the metabolism studies, it may be helpful to retain radiolabelled samples for future analyses by the subsequently developed analytical methods (for enforcement, data collection or dietary risk assessment) in order to assess the extraction efficiency of these methods (sometimes referred to as "radiovalidation" of methods). Samples retained should include representative portions of crops, muscle, liver milk and eggs. If specific metabolites accumulate in specific organs, samples of these organs should also be retained. However, if the analytical methods mirror those used in the radiolabelled studies, such data would generally not be necessary. The radiovalidation of the extraction process of analytical methods should be submitted as part of the report on the analytical method, or it may stand by itself as a report, or in the metabolism report itself. The cover letter or summary of the full data package should indicate where it has been placed.

The information provided for evaluation should include documentation on the proposed metabolic pathway, including a table with associated chemical structures and names (Chemical Abstract Service (CAS) and International Union of Pure and Applied Chemistry (IUPAC) as available), the quantities of the metabolites in the different parts of the plants (surface, leaves, stems and edible root), in different animal tissues (fat, muscles, kidneys, liver, eggs and milk) and in different soil types. Any postulated intermediates/metabolites should also be indicated in the pathway. The rate of the formation and disappearance of metabolites in plants, animals and soil must also be investigated. Where the structure of a metabolite or alteration product is identical to that of another registered pesticide and the information is in the public domain, the data submission should state this fact.

The capability of the analytical methods utilized in the metabolism study to determine the components of the residue, whether free, conjugated, or unextracted, should be clearly specified.

It is emphasised that all data on animal metabolism have to be provided to both the WHO Core Assessment Group and the FAO Panel of Experts. Normally the WHO Group will include detailed discussion on the metabolism of small experimental laboratory animals, e.g., rats, mice, guinea pigs, rabbits and dogs, in their monographs and the FAO Panel will include detailed discussion of the metabolism of farm animals, e.g., cattle, goats, sheep, pigs and chickens, in their monographs. The required data on plant metabolism should be submitted to the FAO Panel, while the WHO Group wishes to receive only schemes of plant metabolism.

The metabolism studies on farm animals and crops should provide the basic evidence to support proposed residue definition(s) for food commodities, and provide evidence as to whether or not a residue should be classified as fat soluble.

3.2.3.1 Farm animal metabolism

These studies are required whenever a pesticide is applied directly to livestock, to animal premises or housing, or where significant residues remain in crops or commodities used in animal feed, in forage crops, or in any plant parts that could be used in animal feeds.

Separate animal feeding studies (farm animal feeding studies) are required for ruminants and poultry. Except in special cases, it is not necessary to carry out metabolism studies with pigs since information on metabolism in a monogastric animal is available from studies with rats. If metabolism in the rat is different from that in the cow, goat and chicken, pig metabolism studies may be necessary. Such differences may include (but are not limited to) the following:

- differences in the extent of the metabolism

- differences in the nature of the observed residue
- the appearance of metabolites with sub-structures, which are of known potential toxicological concern.

Usually the most important metabolism studies are those involving ruminants and poultry. Lactating goats or cows and in the case of poultry, chickens are the preferred animals.

For each set of experimental conditions for pesticides (dermal *vs.* oral application or for each radiolabelled position), the following number of animals should be used. A ruminant metabolism study can be carried out on a single animal. For poultry, the use of ten birds per experiments (or dose) is recommended. Additional animals may be included if it is scientifically required. It is not necessary to include control animals in livestock metabolism studies. The minimum dosage used in livestock oral metabolism studies should approximate the level of exposure expected from the feeding of treated crops with the highest observed residues. However, for oral studies, livestock should be dosed at least at a level of 10 mg/kg in the diet. In the case of dermal application the minimum dose should be the maximum concentration from the label. Exaggerated dosages are usually needed to obtain sufficient residue in the tissues for characterization and/or identification. Ruminants and swine should be dosed daily for at least five days, and poultry for at least seven days.

If the metabolism study is intended to be used in place of a separate livestock feeding study with unlabelled compound, inclusion of a second animal (or group of animals in the case of poultry) treated with a realistic dose and extended dosing period is strongly recommended, if it is suspected that a plateau is not likely to be reached. Such a study may allow JMPR to propose maximum residue levels for animal tissues in the absence of livestock feeding studies. Use of a metabolism study in place of a feeding study would require fully adequate scientific reasoning, especially if a plateau has not been reached in milk or eggs in the metabolism study.

All estimates of relative dose used in animal metabolism studies should be based on a feed dry weight basis. It should be noted that the use of percent crop treated information and median residue values are not acceptable to determine the dose level in these experiments.

3.2.3.2 Plant metabolism

Plant metabolism studies should be designed in such a way as to represent the composition of the residues when the pesticide use matches maximum GAP conditions. When low residue levels in crops are expected from the maximum application rate, experiments at exaggerated rates may be needed to aid metabolite identification. The crop should be treated with radiolabelled active ingredient, preferably containing formulation ingredients typical of an end-use product as applied in the field.

A metabolism study should be submitted for each type of crop group for which use is proposed. Crops can be considered to belong to one of five categories for crop metabolism studies:

- root crops (root and tuber vegetables, bulb vegetables)
- leafy crops (Brassica vegetables, leafy vegetables, stem vegetables, hops)
- fruits (citrus fruit, pome fruit, stone fruit small fruits, berries, grapes, banana, tree nuts, fruiting vegetables, persimmon)
- pulses and oilseeds (legume vegetables, pulses, oilseeds, peanuts, legume fodder crops, cacao beans, coffee beans)

- cereals (cereals, grass and forage crops).

One crop from a group will cover the entire group for purposes of metabolism in those crops within the group. In order to extrapolate metabolism of a pesticide to all crop groupings, metabolism studies on a minimum of three representative crops (from the five different crop categories) should be conducted. If the results of these three studies indicate a comparable metabolic route, then additional studies will not be needed on crops in the other two groups.

The studies should reflect the intended use pattern of the active ingredient such as foliar, soil/seed, or post-harvest treatments. If, for instance, three studies have been conducted using foliar application and at a later date the authorised uses also include soil application, e.g., seed treatment, granular, or soil drench, then an additional study reflecting soil application should be carried out.

On the other hand, if different metabolic routes are observed among the representative crops from studies conducted in a similar manner, e.g., foliar spray with similar pre-harvest interval (PHI) and growth stages, further studies should be conducted for uses on crops in the remaining categories for which MRLs are being requested. Differences in the quantities of metabolites belonging to the same pathway will not trigger the need for additional studies.

There are situations where an *authorised use is unique*, in terms of the crop and/or its growing conditions, for which a metabolism study would be necessary, in addition to the three representative crops. For example, if a use exists on paddy rice, a metabolism study should be submitted for paddy rice, regardless of other available metabolism studies.

Metabolism in rotational crops studies are conducted to determine the nature and amount of pesticide residue uptake in rotational crops that are used as human food or as livestock feed. Such studies are generally not required for uses of pesticides on permanent or semi-permanent crops including, but not limited to, the following commodities or crop groups: asparagus, avocado, banana, berries crop group, citrus fruit crop group, coconut, cranberry, dates, fig, ginseng, globe artichoke, grapes, guava, kiwi fruit, mango, mushrooms, olives, papaya, passion fruit, pineapple, plantain, the pome fruits crop group, rhubarb, the stone fruits crop group, and the tree nuts crop group⁴.

Specifically the studies fulfil these purposes:

- Provide an estimate of total radioactive residues (TRRs) in the various raw agricultural commodities (RACs) via soil uptake.
- Identify the major components of the terminal residue in the various RACs, thus indicating the components to be analysed for in residue quantification studies, i.e., the residue definition(s) for both risk assessment and enforcement.
- Elucidate the degradation pathway of the active ingredient in rotated crops.
- Provide data to determine rotational crop restrictions based on residue uptake levels. This information is mainly used by national regulators.)
- Provide information for determining if limited field trials for rotational crops (see section 3.5.2) should be submitted.

The study should normally be performed using a sandy loam soil that has been treated with the radiolabelled test substance applied at a rate equivalent to the maximum seasonal rate

⁴ OECD Guidelines for the Testing of Chemicals, Test No. 502: Metabolism in Rotational Crops

(1×), unless the label limits its use to one soil type other than sandy loam. In either case, the soil should not be sterilized. Where the label allows nine applications at weekly intervals of 1 kg active ingredient *per* hectare, the maximum seasonal application rate may be obtained, for instance, with one application of 9 kg active ingredient *per* hectare or three applications of 3 kg active ingredient *per* hectare or other application scheme as long as the maximum seasonal rate was met. In all such cases, the aging period for the soil will be considered to start at the last application. The soil should be treated with radiolabelled pesticide active ingredient, preferably containing formulation ingredients typical of an end use product as applied in the field. Following application to the soil, the pesticide may be incorporated into the soil if this represents typical agricultural practice.

Rotational crops should be representative of each of the following crop groupings:

- root and tuber vegetable, e.g., radish, beets or carrots
- small grain, e.g., wheat, barley, oats or rye
- leafy vegetable, e.g., spinach or lettuce.

Where possible, crops should include those expected in the rotational schedule on the label, if known.

Representative rotational crops should be planted at three appropriate rotational intervals, e.g., 7–30 days for assessing circumstances of crop failure or closely rotated crops, 60–270 days to reflect a typical rotation after harvest of the primary crop and 270–365 days for crops rotated the following year. The rotational intervals selected should be based on the expected agricultural use for the pesticide and typical rotational practices. In cases where the pesticide applied, e.g., certain herbicides, results in excessive phytotoxicity to rotational crops at 7–30 days, an alternative timing for the first rotational interval should be studied. Information regarding planting restrictions due to phytotoxicity should be provided.

The study may be performed either in a greenhouse or in an outdoor plot or container or a combination of the two, e.g., rotated crops can be grown under greenhouse conditions in soils that were treated and aged under outdoor or field conditions.

Post-harvest uses require at least one study if no other appropriate foliar metabolism study is available. A foliar study can substitute for a post-harvest study if the mature commodity was present and exposed at application. If there are post-harvest uses on a number of commodities from different crop groupings, then up to three additional studies should be submitted.

These studies provide information on the approximate level of total residues, identify the major components of the total terminal residue, indicate the route of distribution of residues and its mobility (uptake from soil, absorption by plants or surface residue) and show the efficiency of extraction procedures for various components of the residue.

Transgenic and non-transgenic crops may metabolize the pesticide differently. Full and detailed information will be required for a transgenic crop with metabolism differences from the non-transgenic crop. For genetically modified crops that do not involve the insertion of a gene conveying resistance by means of metabolism, no additional metabolism studies are needed. However, the rationale for concluding that the gene does not alter metabolism should be detailed. When a gene is inserted that conveys active ingredient resistance due to pesticide metabolism, then a crop metabolism study should be conducted for each crop grouping to which the genetically modified crops belong. If one such study shows a similar metabolism to conventional crops, however, no additional studies would be needed. If a different metabolic route is observed, then two additional studies should be submitted.

3.2.3.3 Environmental fate in soil, water and water-sediment systems

The FAO Panel does not evaluate data on environmental toxicology, but does require studies on environmental fate relevant to the potential for uptake of residues by food and feed crops.

These studies are normally required for all pesticides except those with a specific restricted use, e.g., seed treatment, post-harvest application in storage. The availability of relevant studies is essential for the assessment of the potential for residues in food and feeds.

The FAO Panel reviewed the various types of environmental fate studies as related to the process of estimating residues in commodities and concluded that some of the studies included in previous evaluations do not assist significantly in defining the residue of concern or estimating residue levels. It should be noted that the studies required are in some cases dependent upon the use pattern (soil, foliar, seed treatment) and that paddy rice presents a unique situation. The data requirements on environmental fate are summarized in Table 3.2.

Table 3.2: Requirements for submission of data on environmental fate for the JMPR

Type of study	Type of use and requirement (yes/no/conditional)						Comments
	Foliar	Soil	Plants of root, tuber, bulb, or peanut (at/after pegging)	Seed dressing (including seed potato)	Herbicide (for weeds in crop)	Paddy rice	
Physical and chemical properties	Conditional	Conditional	Conditional	Conditional	Conditional	Conditional	Only to the extent not provided for the technical material, e.g., hydrolysis and photolysis.
Degradation in soil (aerobic)	No	Yes	Yes	Yes	Yes	No	May be part of confined rotational crop.
Soil photolysis	No	Yes	Yes	Yes	Yes	No	
Degradation in soil (anaerobic)	No	No	No	No	No	No	
Persistence in soil	No	No	No	No	No	No	
Mobility/leaching in soil	No	No	No	No	No	No	
Adsorption by soil types	No	No	No	No	No	No	
Hydrolysis rate and products	Yes	Yes	Yes	Yes	Yes	Yes	Hydrolysis in sterile aqueous buffers. Abiotic epimerization should be provided as appropriate (e.g., pyrethroids)
Photolysis-plant surface	Conditional	No	See foliar	No	No	See foliar	Plant metabolism may suffice. Needed for special cases (e.g., abamectin)
Photolysis-natural pond water	No	No	No	No	No	Conditional	Plant metabolism may be adequate for rice. Useful for GAP involving application to water surface.
Crop uptake and bioavailability (see rotational crops)	No	No	No	No	No	No	

Type of study	Type of use and requirement (yes/no/conditional)						Comments
	Foliar	Soil	Plants of root, tuber, bulb, or peanut (at/after pegging)	Seed dressing (including seed potato)	Herbicide (for weeds in crop)	Paddy rice	
Rotational crops-confined	Yes	Yes	Yes	Yes	Yes	No	Not required where no crop rotation (e.g., orchard crops). Soil and crop should be analysed for radiolabelled residues.
Rotational crops-field	Conditional	Conditional	Conditional	Conditional	Conditional	No	Requirement conditional on results of confined rotational crop study.
Field dissipation studies	Conditional	Conditional	Conditional	Conditional	Conditional	No	Requirement conditional on results of confined rotational crop study.
Residue degradation (biodegradability) in water-sediment systems	No	No	No	No	No	Conditional	Metabolism study for paddy rice may be adequate. In other cases, metabolism/degradation needed, e.g., application to pond water.

3.3 SAMPLING AND RESIDUE ANALYSIS

3.3.1 Sampling

Reliable results can only be obtained from samples taken according to the objectives of the study. Utmost attention should be given to the selection of sampling methods, handling (packing, labelling, shipping and storage) of samples. The study should be designed to assure the integrity of the whole chain of activities. The sampling method and the selection of the objects of sampling depend on the purpose of the study.

In crop metabolism studies, samples of all raw agricultural commodities should be obtained for characterization and/or identification of residues. In commodities with inedible peel such as oranges, melons, and bananas, the distribution of the residue between peel and pulp should be determined. For crops that are sometimes consumed at an immature stage, such as baby corn or leafy salads, samples should also be taken of such commodities for analysis. Where mature inedible crop parts, e.g., apple leaves, potato foliage, are used to help identify residues, the edible parts must also be sampled and analysed to demonstrate the similarity of metabolic profiles. If more than one use pattern is involved, extra samples need to be taken to reflect, for example, the different PHIs.

In rotational crop studies the selected representative rotated crops should be harvested and the appropriate plant parts of raw agricultural commodities (RAC) for human and livestock feed sampled. Samples should also be collected on selected crops at multiple intervals if both immature and mature crops are normally harvested as part of normal agricultural practices. Harvested samples should include forage, hay, straw and grain for cereal crops; an immature and mature leafy vegetable sample and both the root or tuber and the leafy (aerial) portion of the root crop, even if the leafy portion is not a RAC of the actual root crop planted. Data from the leafy portion of the root crop and the immature leafy vegetable are needed as these crops can be used as models to extrapolate to wider ranges of food crops. In addition, due to the increase in the culinary use of immature greens, an immature leafy vegetable sample is

needed. Immature leafy vegetables are defined as the crop stage representing approximately 50% of the normal time period for the plant to reach full maturity. Sampling of the soil is not required, but may be performed depending on the specific objectives of the study.

In livestock metabolism studies excreta, milk and eggs should be collected twice daily (if applicable). Tissues to be collected should include at least muscle (loin and flank muscles in ruminant and leg and breast muscle in poultry), liver (whole organ for the goat and poultry and representative parts of the different lobes of the liver if cattle or swine are used), kidney (ruminants only), and fat (renal, omental and subcutaneous). The TRR should be quantified for all tissues, excreta, milk, and eggs. For milk the fat fraction should be separated from the aqueous portion by physical means and the TRR in each fraction quantified⁵.

In supervised field trials the whole RAC should be sampled as it moves in commerce. For some crops, there may be more than one RAC. For example, the RACs for field corn include the grain (seed), fodder (stover), and forage. One sample from each RAC should normally be taken from treated plots at each sampling interval.

Some crops may be shipped without having been stripped, trimmed or washed; therefore these procedures should only be used on residue samples to the extent that these are commercial practices prior to shipment. Of course, data on trimmed or washed samples may be generated optionally for use in risk assessments. The recommended sampling method for supervised trials is described in Appendix V.

In selective field surveys and monitoring programmes the Codex standard method of sampling for the determination of pesticide residues for compliance with MRLs⁶ should be used. The method of sampling, handling and storage condition of samples should be described in detail in all studies. In the case of supervised trials, field surveys and monitoring programmes the information provided should also include the method for selecting the timing of primary samples (sample increments), the number of primary samples in the composite sample and the total weight of the composite sample.

3.3.2 Sample preparation and processing

To provide residue data for estimation of the MRLs, samples of commodities should be prepared according to the Codex standard to obtain the portion of commodity to which the Codex MRLs apply⁷. The guidance for sample preparation is given in Appendix VI.

Edible portion residue data are required for dietary intake estimation. For commodities where the RAC differs from the edible portion, e.g., bananas, samples should be further prepared to separate the edible and inedible portions for separate analysis.

3.3.3 Analytical methods

Analytical methods are used to generate the data for estimating dietary exposure, to establish Maximum Residue Limits (MRLs), and to determine processing factors. Analytical methods are also used in enforcement of any MRLs that may be established. It is important to note that the methods should be able to determine all analytes included in the residue definition for the particular pesticide. The residue definition used for dietary risk assessment purposes may

⁵ OECD Guidelines for the Testing of Chemicals Test No. 503: Metabolism in Livestock

⁶ Codex Alimentarius Commission, Recommended method of sampling for the determination of pesticide residues for compliance with MRLs, ftp://ftp.fao.org/codex/standard/en/cxg_033e.pdf

⁷ FAO, Portion of Commodities to which Codex Maximum Residue Limits Apply and which is Analyzed. In Joint FAO/WHO Food Standards Programme Codex Alimentarius Vol. 2A, Part I. Section 2. Analysis of Pesticide Residues, FAO, Rome, 2000, 27-36. www.codexalimentarius.net/download/standards/43/CXG_041e.pdf

differ from that used for MRL enforcement purposes, thereby requiring different analytical methods. In the event one analytical method cannot cover all compounds included in a particular residue definition, more than one method may be necessary.

The major residue components should be determined individually as far as technically possible. The use of non-specific methods is generally discouraged. For some analytes, specific residue analytical methods might be unavailable or difficult to perform. In these cases, conversion to a common moiety is valid when all components containing that moiety are considered toxicologically important and when no single component is an adequate marker of residue concentration. Under these circumstances, a "common moiety method" may be used.

For enforcement methods surveillance laboratories prefer multi-residue methods, which could include a large number of analytes, as the laboratories generally do not have sufficient capacity to apply individual methods for all compounds possibly present. Despite potentially lower recovery rates associated with multi-residue methods. This fact is clearly demonstrated by the published results of national monitoring studies which indicate that compounds recoverable with multi-residue procedures are much more frequently analysed than those requiring individual methods. When the analyte is not amenable to the multi-residue method techniques, a single residue method may be provided.

In practice, data may have to be generated in such a way as to provide the flexibility to establish two separate residue definitions where appropriate, one for risk assessment and a second for MRL compliance monitoring. In such cases, where possible, applicants should either separately analyse for the individual components of the residue definition, rather than carrying out a common moiety method; or carry out first analyses according to a common moiety approach and a second series of analyses of the field trial samples for a suitable indicator molecule in parallel, if the common moiety methodology is unsuitable for practical routine monitoring and enforcement of the MRL at reasonable cost. The availability of appropriate methods for monitoring purposes should be considered.

The method(s) should:

- have the ability to determine all of the likely analytes that may be included in the residue definition (both for risk assessment and enforcement) in the presence of the sample matrix
- distinguish between individual isomers/analogues when necessary for the conduct of dietary risk assessments
- be sufficiently selective so that interfering substances never exceed 30% of the limit of analytical quantification (LOQ)
- demonstrate acceptable recovery and repeatability
- cover all crops, animals, and feed items being treated. If significant residues occur, cover processing fractions and drinking water
- cover all edible animal commodities if animals are likely to consume treated crops.

Enforcement methods should be suitable, where technically possible, to quantify residues at or below 0.01 mg/kg.

The methods used in various studies should be validated to demonstrate that they are fit for the purpose of the study. During the analyses of the samples the performance of the methods should be verified with appropriate quality control tests. Details of method validation

procedures, including testing the efficiency of extraction and confirmation, the criteria for acceptable performance parameters and format for reporting the method are given for pre- and post-registration studies in the OECD Guidance document on analytical methods⁸ and in the Good Laboratory Practice elaborated by the CCPR⁹.

Analytical methods provided should include:

- specialised methods used in the supervised trials and environmental fate studies which were submitted for evaluation, and
- enforcement methods.

The methods should be summarised including a clear outline of the compounds determined and the commodities for which the method is recommended. In addition, the specificity, repeatability of the method, the limit of quantification and the range of residue levels for which the method has been validated, the mean recovery and the relative standard deviation of recoveries at each fortification level, including the limit of quantification, etc should be given.

Information should be submitted to the JMPR not only on the principles of analytical methods used in the supervised trials and experiments but also the whole analytical procedure in detail including a precise description of the portion of sample analysed, stability of residues during sample processing, tests to prove the efficiency of extraction, recoveries at various levels, limits of quantification, limits of detection, chromatograms of samples and controls and a description of how the limit of quantification and detection were derived.

In addition to the methods developed by the manufacturers, published methods suitable for use by regulatory authorities should also be provided. The CCPR may not proceed with an MRL if no published regulatory method is available.

3.3.3.1 Extraction efficiency of residue analytical methods

Extraction efficiency is regarded as key for the development of methods, and data should be provided for the solvents and conditions (temperature, pH, time) typically used. Extraction efficiency may significantly influence the accuracy of the analytical results as poor extraction efficiency can be a major source of bias in a method. However, it cannot be checked by traditional recovery studies carried out with samples fortified shortly before analysis. The rigorous validation of the efficient extraction of all residues included in the residue definition can only be performed with samples that have incurred the analyte(s) through the route by which they would normally reach the sample. This is generally the case in metabolism studies, where the efficiency of extraction can be determined by means of radiolabelled analytes.

An IUPAC report¹⁰ on bound xenobiotic residues in food commodities of plant and animal origin has recommended that “the extraction procedures used in residue analytical methods should be validated using samples from radiolabelled studies where the chemical has been applied in a manner consistent with the label and Good Agricultural Practices”.

Ideally, the commodities of interest from the metabolism and rotational crop studies should be retained for determining the extraction efficiency of the regulatory methods and methods used in supervised field trials and rotational crop studies. Justification for the commodities selected

⁸ OECD Guidance Document on Pesticide Residue Analytical Methods, Series on Pesticides Number 39, Series on Testing And Assessment Number 72, 2007

⁹ Codex Secretariat (2003) Revised Guidelines on Good Laboratory Practice in Residue Analysis CAC/GL 40 1993, Rev.1-2003, http://www.codexalimentarius.net/download/standards/378/cxg_040e.pdf

¹⁰ Skidmore, M.W., Paulson, G.D., Kuiper, H.A., Ohlin, B. and Reynolds, S. 1998. Bound xenobiotic residues in food commodities of plant and animal origin. *Pure & Applied Chemistry*, 70, 1423–1447.

should be included in the study report. The retained commodities should be subjected to the extraction procedures from the analytical methods of interest so the extraction efficiency can be readily determined using radiochemical procedures (combustion analysis, liquid scintillation counting and chromatographic analyses using a radio detector). The efficiency can be compared to the relative amount extracted from the metabolism study, wherein the commodities are subjected to rigorous extraction procedures designed to remove most, if not all, of the potential analytes of interest. This comparison is known as radio-validation and should be conducted for the extraction schemes from all methods, if possible.

Alternatively, comparative extraction efficiency studies including the frequently used extraction solvents, such as acetone + water, ethyl acetate, and acetonitrile, can be conducted on samples from metabolism studies for compounds expected to be included in the residue definition(s). Information should be provided on the efficiency of extraction with the solvents used in relevant regulatory methods.

In cases where samples from metabolism studies are no longer available for development of a new analytical method, it is possible to "bridge" between two solvent systems. Incurred residues obtained, e.g., during supervised field trials, might be extracted using as a first step the solvent system under the conditions applied during the metabolism studies and then, in a second step, by using the solvent under consideration. Information on extractability can be obtained by direct comparison of the analytical results.

The testing of extraction efficiency can be either part of the metabolism study or the method development study. In any case, the results of the investigations should be cited in the relevant method validation studies since they are essential for the development of both types of methods (pre-registration and post-registration).

3.3.4 Stability of residues during storage and sample processing

Ideally samples for metabolism studies and residue analysis should be stored at/or below – 18 °C. Storage under any other conditions needs to be recorded and justified. Storage stability studies are required because many routes of degradation and dissipation can occur, even under cold storage conditions.

In most residue studies, samples are stored for a period of time prior to analysis. During this storage period residues of the pesticide and/or its metabolites included in the residue definitions may decline due to processes such as volatilization or enzymatic degradation. Therefore, in order to be certain that the level of residues that were present in samples at the time of their collection are the same at the time of analysis, controlled studies are needed to assess the effect of storage on residue levels. Storage stability studies are performed to demonstrate that pesticide residues are stable during frozen storage of the samples to be analysed or show the degree to which residues decline in that period of time.

Storage stability studies should be designed in such a way that the stability of residues in the stored samples can be definitely determined. When the analytical method determines a "total residue", storage stability studies should include not only the total residue, but also separate analyses of all compounds which may be included in the residue definitions.

Normally, samples should be frozen within 24 hours of sampling or harvest. However, where this is not the case, the period of ambient or cooled storage should be considered in the planning of the freezer storage stability study.

It is preferred that the form of the commodity e.g., homogenate, coarse chop, whole commodity, extract, in a freezer storage stability study should be, as far as possible, the same

as that in the corresponding residue studies. In some cases the freezer storage stability study may need to reflect storage of more than one of the above forms. For example, if the trial samples are stored as homogenates for several months, extracted, and then these extracts stored for several weeks prior to final analysis, the freezer storage stability commodities should be handled in the same manner.

Where residues are considered to be stable, typical sampling intervals of 0, 1, 3, 6 and 12 months could be employed, which can be extended if the samples are stored for longer periods e.g., up to 2 years. In contrast, if relatively rapid decline of residues is suspected, sampling intervals such as 0, 2, 4, 8 and 16 weeks could be chosen. If there is no prior knowledge then the choice of intervals could be a combination of the above¹¹.

Duplicate samples of every commodity at each time point for all components of the residue definitions need to be analysed. However, if a significant difference (greater than 20%) exists between the results for the duplicate samples from the same time point, judgement should be applied and consideration given to analysing additional samples of the commodity from that time point.

If the freezer storage stability study uses incurred residues, then it should be established that all components of the residue definitions are present in the samples and at sufficient levels to allow any decline to be observed. In this case it is important that the sample is analysed fresh, i.e., immediately after sampling, and at appropriate storage periods thereafter. An old, i.e., frozen, sample with incurred residues may already have degraded to a stable level and when storage stability studies are conducted on an old sample, this may not reflect storage stability behaviour on fresh samples.

If test substances are added to untreated commodities in the laboratory, it is usually the active substance and/or relevant identified metabolites that are added. Where the residue definitions contain more than one component studies need to be designed to demonstrate stability of each component. Consequently, the use of mixed spiking solutions is not recommended as it could mask potential transformations from one compound to another. Therefore, the freezer storage stability study should be conducted with separate samples of each commodity under investigation spiked with the individual components of the residue definitions.

Samples should be spiked at 10×LOQ, the limit of quantification of the method for each analyte in order to adequately determine the stability of the residues under storage conditions. This will make it less likely that highly variable recoveries would prevent the determination of the stability of the residues. Spiking procedures should be undertaken in the same way as the spiking of the samples in the validation of the analytical methods e.g., for the recovery data. Where this is not possible, then a full rationale/ justification for the applicability of the data should be provided. In instances where no detectable residues are found in field treated commodities, or residue levels are close to the analytical method's LOQ, spiked control commodities should be employed in the freezer storage stability studies rather than incurred residues.

Residue storage stability studies in animal tissues, milk and eggs should be provided in the event animal commodity MRLs are needed.

In the case of studies involving crop commodities, the principles of extrapolation between commodities within specific commodity categories is supported. The commodity categories are as follows:

¹¹ OECD Guidelines for the Testing of Chemicals, Test No 506: Stability of Pesticide Residues in Stored Commodities

- commodities with high water content
- commodities with high acid content
- commodities with high oil content
- commodities with high protein content
- commodities with high starch content.

If residues are shown to be stable in all commodities studied, a study on one commodity from each of the five commodity categories is acceptable. In such cases, residues in all other commodities would be assumed to be stable for the same duration of time under the same storage conditions.

If MRLs are sought in just one of the five commodity categories, the stability of the test substance in 2–3 diverse commodities within the desired category should be tested. If the stability of analytes is confirmed, further studies with other crops in that category are not required.

If there is no observed decline of residues across the range of the five different commodity categories then specific freezer storage stability data for processed foods will not be needed. However, if instability is shown after a certain length of storage, any commodities (RAC or processed commodity) should be analysed within the demonstrated time period for stable storage.

Determinations as to whether sample integrity was maintained during collection, sample preparation, and storage should be made. The study conditions should reflect those to which the samples from the residue trials have been subjected. Where sample extracts have been stored for more than 24 hours prior to analysis, the stability of residues should be demonstrated with recovery studies performed under similar conditions.

In case of metabolism studies, the tests should show that the basic profile of radiolabelled residues has not changed throughout the duration of the study. It is impossible to spike samples before the identity of the residue and the length of time needed for metabolism studies are known. Storage stability data are not normally necessary for samples analysed within six months of collection, provided evidence is given that attempts were made to limit degradation of residues by appropriate storage of matrices and extracts during the analytical portion of the study.

If instability of the active ingredient is suspected or observed, based on other information, steps should be taken to safeguard the integrity of the study. In those cases where a metabolism study cannot be completed within six months of sample collection, evidence should be provided that the identity of residues did not change during the period between collection and final analysis. This can be done by analyses of representative substrates early in the study and at its completion. The substrate should be the item stored, i.e., if the matrix extract is used throughout the study and the matrix is not extracted later in the study, the stability of the extract should be shown.

If changes are observed, e.g., disappearance of a particular HPLC peak or TLC spot, additional analyses or another metabolism study with a shorter collection to analysis interval may be necessary

The residue concentration present in the intact sample material may also significantly change during the sample homogenization process (mincing, chopping grinding). The decomposition, evaporation of residues cannot always be observed with the usual recovery studies performed

by adding known amount of analytical standards to the homogenised test portion shortly before extraction. Acceptable recoveries may be obtained even if substantial portion of the test material ‘disappeared’ during homogenization. Systematic studies, performed with fruits and vegetables applying test substance mixtures containing a stable and several other compounds with unknown stability, revealed that the decomposition of residues can be substantially reduced or eliminated under cryogenic processing of deep-frozen sample materials^{12,13}.

Detailed reports should be submitted on stability of residues during storage and sample processing.

If trial supervised trial samples are always analysed within 30 days of their storage in frozen conditions, applicants can omit conducting a freezer storage stability study provided justification is given e.g., basic physical chemical properties data show residues are not volatile or labile.

3.4 USE PATTERN

Current GAP information on pesticides under consideration must be made available to the JMPR. The essential GAP is the set of current registered uses involving the highest rates and shortest PHIs for the same pesticide on the same crop in the same country and the use patterns in the supervised field trials should reflect this essential (often referred to as critical) GAP. The GAP information should be presented in a systematic manner according to the standardized format(s) given in this Manual. Formats are available for applications on agricultural and horticultural crops, post-harvest uses and direct animal treatments; other formats may be necessary for other types of use. The information should be presented in such a way as to facilitate comparison with supervised trial conditions.

GAP summaries are intended as an aid to the evaluation of submitted data and are to be provided in addition to certified labels. It is emphasised that copies of original labels have to be provided by the manufacturer(s) (or other data submitters) in addition to the summary information. Furthermore, the original label should be accompanied by an English translation of the relevant sections, e.g., dosage specifying if the concentration of spray or the kg/ha rate is primarily defined, application methods, growth stage of plants at the time of application of the pesticide, use conditions, and any restriction of use, if it is printed in a language other than English.

The summary should not include any use information which is not specifically given on the label, e.g., not kg ai/hL if only kg ai/ha is specified; not calculated PHI if application at a specific growth stage is authorized, not number of applications calculated from specified intervals and PHI. Crops included in groups, e.g., leafy vegetables, or fruits, should be individually named, unless they correspond with the commodities of the commodity groups in

¹² Fussell R.J., Jackson-Addie K., Reynolds S.L. and Wilson M.F., (2002): Assessment of the stability of pesticides during cryogenic sample processing, *J. Agric. Food Chem.*, 50, 441.

¹³ Fussell, R.J., Hetmanski, M.T., Macarthur, R., Findlay, D. Smith, F., Ambrus Á. and Brodesser J.P. (2007): Measurement Uncertainty Associated with Sample Processing of Oranges and Tomatoes for Pesticide Residue Analysis. *J. Agric. Food Chem.*, 55, 1062-1070.

the actual Codex Commodity Classification¹⁴. The specific uses of a compound will not be evaluated if the relevant labels have not been provided.

Labels reflecting current GAP should be clearly distinguished from “proposed” labels. Furthermore, indexing of labels in such a manner to allow easy cross-reference to GAP summaries and supervised field trials would facilitate the evaluation. The specific uses of a compound will not be evaluated if the relevant labels have not been provided.

If GAP information is provided by responsible national regulatory authorities the above detailed information is required and the submission of the label is desirable. The submission of GAP information by national authorities is especially important in case of a generic pesticide produced by several manufacturers. In the latter case information on the chemical composition of technical products and their formulations used in the reporting country would also be desirable.

The use patterns should be summarised by the data submitters from two aspects, (1) biological efficacy and (2) formulation and application. The biological efficacy may be described by listing the major pests or diseases controlled, or it can be given in tabular form. In the latter case, the table should contain the commodities, pests controlled and the growth stage of crop when the application(s) is (are) likely to be required (see an example in Table 3.3).

Table 3.3 Information on pests and diseases controlled by terbufos (JMPR 1989)

Crop	Pests/diseases controlled	Timing of application(s)
Banana	Aphids, corm borer, corm weevil, nematodes	2-4 times per year
Cotton	Soil pests, wireworms	Furrow treatment at planting
Potato	Black maize beetle, wireworm	Furrow treatment at planting
Sugar cane	Nematodes, pink spittlebug, sugarcane froghopper, West Indian canefly, white grubs, wireworm	Furrow treatment, at planting or side dressing, 4 months PHI

Information on formulations, application methods and active ingredient dosage rates should be summarised in tabular form (see Tables 3.4–3.6). Specific information relevant to the use according to GAP (such as dosage depending on the pest; specified minimum intervals between repeated applications; total amount of active ingredient which may be applied during the growing season; restrictions on irrigation or aerial application) should be added as a comment or footnote(s).

Table 3.4 Registered uses of folpet on vegetables and cereals.

Crop	Country	Formulation	Application ^a		Spray			PHI, days
			Method	Rate kg ai/ha	Conc., kg ai/hL	Number	Interval ^b	
Barley	France			1.5				21
Beans	Greece	WP 800 g/kg	foliar	0.6–1.5	0.1-0.25	3–4		7
Beans	Portugal	WP 800 g/kg	foliar		0.13	1–2		7
Beans, green	Spain	WP 800 g/kg	foliar	1.6	0.16			21
Brassica vegetables	Italy	WP 800 g/kg	foliar	0.35–0.40				10

¹⁴ FAO/WHO. 1993. Codex Classification of Foods and Animal Feeds in Codex Alimentarius, 2nd ed., Volume 2. Pesticide Residues, Section 2. Joint FAO/WHO Food Standard Programme. FAO, Rome. Note: the CCPR currently is working on the revision of classification of commodities. The reader is advised to check which groups have been finalised and enforced BY the Committee/CAC

Crop	Country	Formulation	Application ^a		Spray			PHI, days
			Method	Rate kg ai/ha	Conc., kg ai/hL	Number	Interval ^b	
Lettuce	France	WP 800 g/kg	foliar	0.64				21-41 ^a
Lettuce	Israel ³	WP 800 g/kg	foliar	2.0		weekly		11

^a summer PHI 21 days, winter PHI 41 days

^b in days or weeks

Table 3.5 Post-harvest GAP uses of on fruit.

Crop	Country	Formulation	Application			Notes ^d
			Method ^a	Conc. kg ai/hL ^b	Contact time ^c	
Apples	Australia	EC 310 g/l	dip	0.05-0.36	minimum 10-30 secs	
Apples	France		dip	0.04-0.20	30 secs	
Apples	France		drench	0.04-0.20	30 secs to 2 mins	
Pears	Turkey		dip, drench or fog	0.075	max 2 mins	

^a Examples of method: dip, drench, spray, fog

^b Concentration of dip, drench, spray, etc

^c Contact time or other requirement, as specified on the label

^d Explain if treatment is variety dependent, if commodity is not to be consumed or sold for an interval after treatment, etc, as specified on the label.

Table 3.6 Registered uses of for direct external animal treatment.

Animal ^a	Country	Formulation	Application			WHP slaughter ^e days	WHP milk ^f days
			Method ^b	Rate ^c	Conc. ^d		
Beef cattle	USA	SC 25	pour-on	2 mg ai/kg bw	25 g/L		
Dairy cattle, non-lactating	USA	SC 25	pour-on	2 mg ai/kg bw	25 g/L		
Dairy cattle, lactating	USA	SC 25	pour-on	2 mg ai/kg bw	25 g/L		
Sheep	Australia	25	jetting	0.5 L fluid per month of wool growth	25 mg/L	0	

^a Farm animal as stated on the label.

^b Methods include pour-on, dip, ear-tag, jetting, spraying.

^c The rate or dose may be expressed per animal or per kg bodyweight. State explicitly if the dose is expressed on active ingredient, formulation or spray solution.

^d The concentration of the spray or dip, etc., applied to the animal. The application concentration for a pour-on is the same as the formulation concentration.

^e With-holding period. Label instruction on interval between animal treatment and slaughter for human consumption.

^f Label instruction on interval between animal treatment and milking.

When different formats are used to report GAP data on special uses, e.g., seed dressings, they should always include details on the following aspects of the use pattern:

- Responsible reporting body
- Pesticide names
- ISO-E common name. For other international code names, indicate the Standards organisation between brackets-, e.g., (British Standards Institute: BSI), (American National Standards Institute: ANSI), (Japanese Ministry for Agriculture, Forestry

and Fisheries: JMAF). Proprietary name(s) or trade name(s) can also be given if relevant.

- CCPR number of pesticide, if available
- Information on the use pattern as described on the approved label. Use rates and concentrations must be explicitly expressed in terms of active ingredient.

If GAP information is provided by responsible national regulatory authorities the above detailed information is required and the submission of the label is desirable. The submission of GAP information by national authorities is especially important in case of a generic pesticide produced by several manufacturers. In the latter case, information on the chemical composition of technical products and their formulations used in the reporting country would also be desirable. Governments or responsible national organisations are requested to summarise the GAP information, as shown in Table XI.2 (Appendix XI). The entry required under “Country” is the name of the country whose GAP is listed in the table, which is not necessarily the same as that of the country submitting the information. The table should strictly reflect the information contained on the label. In the case of extensions of use that do not appear on the product label, i.e., off-label approvals, a copy of the ‘regulatory approval’ document or its English translation should be provided.

The following GAP information requirements are re-emphasised:

- The summary should not include any information on use that is not given on the label.
- Valid copies of current labels must be provided, together with English translations of the relevant sections.
- Crops included in crop groups should be named individually unless they correspond with the actual Codex Commodity Classification of Food and Animal Feed¹⁵.
- Individual commodities should preferably be referenced to the Codex Classification of Food and Animal Feed.
- Labels reflecting current GAP should be clearly distinguished from ‘proposed’ labels.
- Summary information on GAP relevant to the submitted supervised trials and current GAP with higher rates or smaller PHIs, etc for the same pesticide on the same crop in the same country should be submitted. However, to avoid unnecessary costs for the translation of labels by industry and to avoid unnecessary extra work on uses that are inadequately supported by residue data, copies of the original labels (and if necessary the translations) need be provided only for those uses that are adequately supported by residue data according to FAO requirements.

3.4.1 Periodic review compounds undergoing re-registration by national authorities

In national review programmes, current uses are frequently revised to meet new requirements for the safety of human health and the environment. The data submitted to JMPR therefore often include both current registered uses and labels awaiting approval by national authorities. Data from field trials, however, usually relate to new uses. In such cases, the JMPR cannot amend or recommend maintenance of existing MRLs.

¹⁵ FAO/WHO. 1993. Codex Classification of Foods and Animal Feeds in Codex Alimentarius, 2nd ed., Volume 2. Pesticide Residues, Section 2. Joint FAO/WHO Food Standard Programme. FAO, Rome.

Furthermore, for some compounds, both old labels and revised labels stipulating lower rates exist simultaneously, and MRLs reflecting the adjusted uses cannot be established.

In order to ensure the best review of data on residues, the following information on periodic review compounds undergoing national re-registration should be submitted to the FAO Joint Secretary to the JMPR:

- 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.

Reviews of such compounds should focus on new or amended uses or current uses that will be supported, giving full details of the evaluation. MRLs will be recommended only for current uses.

MRLs will be recommended for new and amended uses only when those uses have become GAP.

3.4.2 Presentation of GAP information

All information should be presented in English and must come directly from approved labels.

Crops and situations should be described exactly as on the approved label. If the approved label is for use on crop groups, e.g., “citrus” or “orchard trees”, this should be the entry in the GAP table. Individual crops included in national grouping should be identified by their English names (local varieties in brackets) in Table endnotes, preferably using crops associated with the commodity descriptions given in the Codex Classification of Foods and Animal Feeds.

Pest information can be given in the form of the English name of a specific pest or in the form of a “broader” group of related pest species, e.g., powdery mildews, spider mites, lepidopterous insects, yeasts, etc. The use of a Latin name (between brackets) may often provide clarification. Avoid the use of very broad classes of pest organisms, such as fungus diseases, insect pests or similar indications, as this generally provides insufficient information.

Present the formulation of the pesticide product using the two-letter coding system developed by GIFAP and adopted by FAO and CIPAC. The codes are given in Appendix III. The definition of the terms can be found in the FAO Manual on the Development and Use of FAO Specifications for Plant Protection Products (2006)¹⁶.

The concentration of active ingredient in the formulated product has to be presented for liquid formulations in g/L, such as EC (emulsifiable concentrate) or SC (suspension concentrate, also called flowable concentrate) provided that the label instructions give the dosage rate in litres of the formulated product per ha or per 100 litres spray liquid (or in similar measures).

¹⁶ FAO. 2006. Manual on the development and use of FAO specifications for pesticides. 1st edition.. <http://www.fao.org/agriculture/crops/core-themes/theme/pests/pm/jmps/manual/en/>

The concentration of active ingredient in solid formulations is expressed on a w/w basis as g/kg or % of active ingredient in the solid product.

The type of treatment must be given in sufficient detail, e.g., the type of apparatus used and its output, such as ULV, high volume sprayer, etc. There is often a link between the type of treatment and specific formulations developed for such applications. It has to be recognised that the residue deposit from different types of treatment may differ considerably, e.g., a ULV application may give rise to a larger residue deposit than a high volume application, both with the same amount of active ingredient per hectare.

The greater part of the residue at harvest consists of the residue deposit applied at the last application. Since the persistence of the pesticide residue may be different in different times of the season, the growing stage at the last application should be recorded. For example, in moderate climate zones the residue decrease of several pesticides in autumn is in general less than in high summer, due to the higher light intensity (UV) and the higher temperature in the latter period. Code numbers (preferably BBCH) used to describe growth stages should be fully explained.

State the number of treatments per season only if specified on the label. Since the treatment intervals, and thus the number of treatments, are often linked to dosage rates, the recommended alternative situations should be clearly indicated, e.g., for scab control on apples dosage A is applied for preventive treatments at 7–8 days intervals or a higher dosage B (approximately $1.5 \times A$) with an interval of 10–14 days. The interval between successive applications may have a considerable impact on the amount of residue deposit at a certain time since residues from earlier applications of the pesticides may still be present at the time of a successive treatment. Some labels specify the maximum total application rate per season. This information should be included preferably as a footnote.

The application rate should always be expressed in metric units. See Appendix X, section “General” for non-metric to metric unit conversion factors. The dosage rates should also be expressed as amounts of active ingredient in g or kg/ha. When indicated on the label, the maximum amount of active ingredient which can be applied within a growing season should also be provided as such, and not calculated as a maximum number of applications.

In cases where the indications on the label are given in g/hL or kg/hL (spray concentration), state this spray concentration but do not calculate the kg ai/ha equivalent with the average amount of spray liquid used per hectare. If prior compilations included calculated kg ai/ha values, this fact should be clearly distinguished from label instructions.

The pre-harvest interval (PHI) in days prescribed or recommended and stated on the label should be presented for the commodities concerned. If different PHIs are recommended for the same or similar commodity, e.g., for glasshouse or outdoor grown crops, or in the case of higher dosage rates, the particular circumstances should be clearly indicated. Sometimes the timing is indicated in terms of crop growth stage, e.g., when the pesticide is recommended for use at a very early stage of the crop development, such as bud burst in apple and pears, pre- and post-emergence applications for weed control, etc. In such cases the reference to the growth stage of last application can be extremely helpful to clarify GAP. PHIs included in the GAP table should only be taken from explicit PHI statements on approved labels.

In the case of direct treatment of animals, the withdrawal or withholding period between treatment and slaughter for human consumption or treatment and collection of milk or eggs should be stated. For application of pesticide to forage and fodder crops, the subsequent grazing restrictions for food-producing animals should also be indicated.

3.5 RESIDUES RESULTING FROM SUPERVISED TRIALS ON CROPS

Supervised field trials (crop field trials) are conducted to determine pesticide residue levels in or on raw agricultural commodities, including feed items, and should be designed to reflect pesticide use patterns that lead to the highest possible residues. Objectives of crop field trials are to:

- quantify the expected range of residue(s) in crop commodities following treatment according to the proposed or established good agricultural practice (GAP)
- determine, when appropriate, the rate of decline of the residue(s) of plant protection product(s) on commodities of interest
- determine residue values such as the Supervised Trial Median Residue (STMR) and Highest Residue (HR) for conducting dietary risk assessment
- derive maximum residue limits (MRLs).

Crop field trials may also be useful for selecting residue definitions by providing information on the relative and absolute amounts of parent pesticide and metabolites.

The term “supervised trials” covers the application of a pesticide approximating targeted or authorised use including studies for residues in crops grown in fields, e.g., outdoor, in greenhouses (glass or plastic covering) and in crops treated after harvest, e.g., stored grains, wax or dip treatment of fruits, and involves careful management of the trial procedure and reliable experimental design and sampling. Residue trials performed along the lines described in the OECD Test Guideline^{17,18} are considered by the JMPR as supervised trials. New supervised trials should be planned, implemented, documented and reported according to the OECD (or comparable) GLP principles (OECD, 1995–2002) or in compliance with national regulations which ensure the quality of residue data.

Maximum Residue Limits are largely derived from residue data obtained from supervised trials designed to determine the nature and level of residues resulting from the registered or approved use of the pesticide. Since this work will usually have been done before registration is obtained, in many cases the trials should be based on the intended registered use. Since the compounds are evaluated by the JMPR after they have been registered by national authorities (see Chapter 2 “*Selection of compounds for evaluation*”) some of the trial data may not be relevant for JMPR evaluations. Therefore normally only supervised trial data reflecting the current GAPs should be submitted. Note however, that in cases with a limited number of trials at GAP, results from other supervised trials can provide supporting information, such as residue decline study to indicate rate of concentration decrease or trials with higher rates leading to residues below LOQ. Residue data should be presented primarily for mature crops at normal harvest. However, where a significant part of the consumable crop is present at the time of application, some residue dissipation studies are required to complement the residue data obtained at normal harvest.

Residue decline data are necessary for uses where the pesticide is applied when the edible portion (human food or animal feed) of the crop has formed or it is expected that residues may occur on the food or feed commodities at, or close to, the earliest harvest time. Residue decline data are used in residue evaluation for purposes such as:

¹⁷ OECD Draft Test Guideline: Crop Field Trial 19-Feb-2009

¹⁸ Draft Revised Guidance Document on Overview of Residue Chemistry Studies, (Series on Testing And Assessment No.64) 18-Feb-2009

- determining if residues are higher at longer PHIs than requested;
- estimating the half-life of the residues
- determining whether alteration of the PHI to levels represented in the decline trials around the GAP PHI affects the residue levels
- allowing for a degree of interpolation to support use patterns, including PHIs, not directly equivalent to those used in the trials on a case-by-case basis
- determining the profile of the residue over time to add to the understanding of metabolism of the pesticide under conditions more applicable to GAP and to assist in appropriate selection of residue definitions
- determining the time interval to reach maximum residues for a systemic compound applied to crops such as potatoes or peanuts.

For estimating maximum residue levels of pesticide residues in commodities moving in international trade, results of supervised trials representing the typical agriculture practices, growing and climatic conditions prevailing in all exporting countries should ideally be considered. Therefore, it is in the interests of national governments and the responsibility of data submitters to provide all relevant valid supervised trial data and supplementary information to the FAO Panel in order to ensure that the recommended limits cover the maximum residues arising from the authorised use of a pesticide and a realistic estimate can be made for the long- and short-term dietary intake of residues.

It is emphasised, however, that the JMPR performs the evaluation of the submitted information and estimates maximum residue levels if the database is considered sufficient, regardless of whether it represents worldwide use or is limited to a region. The number of trials (generally minimum 6–10) and samples is dependent on the variability of use conditions, the consequent scatter of the residue data, and the importance of the commodity in terms of production, trade and dietary consumption. Residue data should be available from trials, preferably carried out in at least two separate years or at least representative of different weather conditions in accordance, or approximately in accordance, with Good Agricultural Practice. If uses are authorised in regions with substantially different climatic conditions, trials should also be carried out in each region. Residue data from only one season may be considered sufficient provided that crop field trials are located in a wide range of crop production areas such that a variety of climatic conditions and crop production systems are taken into account.

3.5.1 Planning and implementation of supervised trials

The general principles which should be considered in planning, conducting and reporting supervised trials are briefly described hereunder. Detailed guidance can be found in the referred documents.

Field trials should be conducted in regions where the crops are predominantly grown commercially and should reflect the main types of crop maintenance and agricultural practice, especially those which can significantly impact residues, e.g., bagged and unbagged bananas, furrow and overhead irrigation, pruning of grape leaves. Soil type, e.g., sand, loam, sandy loam, should be identified and reported for all crop field trial sites. If the product is directly applied to soil, the field trials should include field sites with different soil types.

Post-harvest treatments on stored products such as potatoes, grains and seeds are often carried out in a number of storage locations with variable conditions in regard to temperature,

humidity, aeration, etc. Information should be available on the use practice and all the conditions under which the treated commodities are kept. How commodities are stored during application can vary from commodities stacked in sacks, box stores and heaps to automated systems in large-scale silos or automated systems for fruit treatment.

Crop variety may influence the uptake of the active ingredient and the metabolism capability. Residue trial reports should identify which crop varieties were utilized. In a set of residue trials, a selection of commercially important varieties of a crop, e.g., table and wine grapes, seasonal variations, e.g., winter wheat vs. spring wheat, vegetation period of different varieties, different maturation periods, e.g., early and late maturing fruit varieties, and morphologic variability, e.g., cherry tomatoes, should be considered. This will provide a range of conditions of use that are representative of actual agricultural situations.

Plot size may vary from crop to crop. However, plots should be large enough to allow application of the test substance in a manner which reflects or simulates routine use and such that sufficient representative sample(s) can be obtained without bias, generally at least 10 m² for row crops and typically four trees or eight vines for orchard and vineyard crops. Plots should also be large enough to avoid contamination during mechanical sampling or harvesting if applicable. Control (untreated) plots should be located in the immediate vicinity of the treated plot(s) so that cultivation and cropping take place under similar/identical conditions. It is also important to ensure that plots are adequately buffered or separated to avoid cross contamination.

Application of the test substance may be made with hand-held or commercial equipment as long as the equipment can be calibrated. Hand-held equipment used to make test substance applications in crop field trials should do so in a manner that simulates commercial practice. Where water is used for preparing the spray solution for aerial application and the label rate specifies spray volumes ≥ 18.7 litre/ha (2 gallons/acre) for row crops and ≥ 93.5 litre/ha (10 gallons/acre) for tree and orchard crops, the field trials can be performed with ground equipment instead of aerial application.

The *maximum label rate* of the active ingredient with maximum number of applications and minimum re-treatment interval (according to the critical GAP, cGAP) should be used when applying the test substance for crop trials.

Application timing is governed by requirements to control pest and plant growth stage, e.g., pre-bloom or 50% head emergence, and/or as number of days prior to harvest. Any time that a specific PHI is indicated on the label, e.g., “Do not apply this product less than 14 days prior to harvest.”, that specific PHI must be used in the crop field trials as a component of the cGAP, whereas the growth stage at application is of minor importance. Inversely, there are cases where the growth stage is a critical component of the GAP, e.g., pre-emergence, at planting, pre-bloom, flag leaf or head emergence, while the PHI is of secondary importance. In these cases it is important to include as many varieties of the crop as possible in order to evaluate an appropriate range of PHIs, e.g., shorter and longer intervals from planting to maturity in the case of pre-emergence application to an annual crop. Basically in all trials both the growth stage at application (preferably as BBCH code) and PHI should be recorded.

For all *pre-harvest applications*, the *application rate* should be expressed in terms of amount of product and/or active ingredient per unit area, e.g., kg ai per hectare, and where appropriate, the concentration, e.g., kg ai/100 litres, at which it is applied.

Row crops (potatoes, wheat, soya beans, etc.) are typically treated with broadcast sprays for which plot area (length \times width) is a key consideration. In contrast, for some crops such as tree nuts, tree fruits, trellised vegetables and vines, the crop height, crown height or tree

height, i.e., treated foliage height, should be recorded in order to allow crop row volume or tree row volume estimations or rate per unit area calculation as needed. Special consideration may be needed for foliar applications to ‘*tall*’ crops, e.g., orchard and vine crops, hops, greenhouse tomatoes, where flat boom spraying is not common practice and (air assisted) mist blowing equipment is often used. It is important to consider and report both the spray concentration, e.g., kg ai/100 litres, and spray volumes, e.g., litres spray mixture/ha, at the various crop growth stages when planning and conducting crop field trials in these crops.

Application rates for *seed treatments* are normally expressed as amount of active ingredient per unit of seed weight, e.g., g ai/1000 kg seed, and seeding rate, e.g., kg seed/hectare.

In case of post-harvest dip or drench treatment of fruit, concentration of the active ingredient in spray liquid should be recorded, e.g., kg ai/100 litres or hL, as well as the amount of fruit treated per volume and contact time in seconds. Where dips are replenished to maintain the active ingredient concentration during treatment, i.e., where residue stripping occurs, the additional ‘top-up’ treatments should also be recorded. For powdering, fogging or spraying of stored goods, e.g., potatoes or grains, the application rate should be recorded, e.g., kg ai/ton or 1000 kg. The application rate for gases and aerosols used in *fumigation* should be expressed as amount per unit volume of treated bulk good, e.g., g ai/m³.

The design of *residue decline studies* should include 3 to 5 sampling intervals in addition to the target PHI (if practical, include 0 day sampling). These sampling intervals should be spaced somewhat equally and, where possible, sampling should occur at shorter and longer time points relative to the target PHI, when such is permitted by the window of commercial maturity. When multiple applications are involved, a sampling point immediately prior to the final application is desirable to determine the contribution of earlier applications and the effect on residual half-life.

Another acceptable residue decline study design option, referred to as “reverse decline,” involves applications being made to separate plots at different time intervals from the targeted commercial harvest date. All plots are then harvested on the same day, the commercial harvest date, resulting in different intervals from last application to harvest. Such a design may be appropriate for situations where the commodity is likely to be harvested within a narrow time window. For example, such a study could examine the use of a pre-harvest desiccant close to maturity where harvest must occur within a short time frame after application.

When residue decline studies are conducted, sampling of more than one commodity or matrix per crop may be needed. This will be the case whenever different commodities are used as food or feed at different growth stages of the crop, e.g., cereal forage, cereal fodder, cereal grain and straw. This will result in two or more sets of sampling dates within one residue decline trial.

The *formulation tested* in crop field trials should be as close as possible to the commercially available end-use product for the crop or commodity.

Adjuvants such as wetting agents, spreader-stickers, non-ionic surfactants, and crop oil concentrates may result in better deposition, penetration, or persistence of pesticide residues in or on the plant. Therefore, for a test substance which has a label allowance for the use of an unspecified adjuvant, crop field trials must include an adjuvant (any locally-available adjuvant), applied according to the label recommendation of the adjuvant. For a test substance which has a label recommendation for the use of a specific adjuvant, crop field trials must include the adjuvant, or another adjuvant with similar properties, applied according to the label recommendation of the adjuvant.

Additional plant protection measures, which are not the subject of crop field trials, are often required for crop management during the course of a study to control weeds, disease or other pests (could also include fertilizers, plant tonics or plant growth regulators). These crop and plot maintenance products should be chosen from among those products which do not affect, i.e., interfere with, residue analyses for the components of the relevant residue definition. Additionally, these maintenance products should be applied to both the control and treated plots in the same manner, i.e., rate and timing.

In many cases, active ingredients may be applied in combination, i.e., tank mix, pre-mix or sequential, in crop field trials to a single treated plot as long as there is clear analytical separation, i.e., no analytical interference, of active ingredients and any relevant metabolites. A single sample may then be collected from the treated plot and prepared for residue analysis for two or more active ingredients. The exception to the combination of active ingredients in this manner would be those that are known to be synergistic, but will not be formulated together in registered products.

3.5.1.1 Number of trials

Currently there is no international agreement on the minimum number of trials to be provided for the estimation of STMR, HR and MRL. Different countries have determined the minimum number of crop field trials required for registration of a use on a crop and establishment of a suitable MRL. Geographic distribution of field trials within a country or region serves to ensure that data will be available for trials in key crop production areas, and a sufficient variety of horticultural practices may be represented in a crop field trial data set.

The JMPR has not specified the minimum number of trials required for estimation of maximum residue levels, high (HR) and supervised trial median residues (STMR). The evaluation of the experience gained with the application of statistical methods for supporting the estimation of maximum residue levels (see section 6.10) indicated, however, that a minimum of 15 valid residue data would be required to obtain a realistic estimate for maximum residue level using the statistical method.

The OECD Working Group on Pesticides elaborated guidance on the minimum number of trials¹⁹ which should be generated for registration of a pesticide in all OECD countries where the target GAP is uniform, i.e., maximum 25% deviation in one of the key parameters. The number of supervised trials required in various OECD countries and the number of trials recommended for a comprehensive submission is described in Appendix XII. Though, the JMPR does not require specified number of trials, adherence to the OECD guidance may be a safe way to decide on the minimum number of outdoor field trials to be submitted for evaluation.

3.5.1.2 Consideration of various types of formulations and derivatives of active ingredient

Data needed to cover *additional formulation types* or classes shall be addressed on a case-by-case basis.

Controlled release formulations, e.g., certain microencapsulated products, normally require a complete data set tailored to that particular use. Since these formulations are designed to control the release rate of the active ingredient, increased residues are possible compared to other formulation types.

¹⁹ Draft Revised Guidance Document on Overview of Residue Chemistry Studies (Series on Testing And Assessment No.64)
18 Feb 2009

Granular formulations applied intact will generally require a complete data set regardless of what data are already available for other formulation types. No residue data will be required for dusts if data are available at the *c*GAP for a formulation of the active ingredient applied as a wetting spray, e.g., emulsifiable concentrates (EC), wettable powders (WP).

The most common formulation types which are diluted in water prior to application include EC, WP, water dispersible granules (WG), suspension concentrates (SC) (also called flowable concentrates), and soluble concentrates (SL). Residue data may be translated among these formulation types for applications that are made to seeds, prior to crop emergence, i.e., pre-plant, at-planting, and pre-emergence applications, just after crop emergence or directed to the soil, such as row middle or post-directed applications (as opposed to foliar treatments).

Some active ingredients, e.g., phenoxy herbicides, can be applied as one or more salts and/or esters. Different salts of an active ingredient may be considered equivalent for residue purposes in most cases regardless of the timing of the application. However, examples for which additional data may be needed for a new salt include the presence of counter ions that impart surfactant properties, significantly change the degree of dissociation, or chelate with the active ingredient ion. If the PHI is less than or equal to 7 days, the different esters are considered as new formulations of that active ingredient for the purposes of determining data needs, and bridging studies would be required as for different formulations.

In the case of up to 25% increases or decreases of the nominal active ingredient application rate, the number of applications, or the PHI, under otherwise identical conditions, the residue results can be assumed to be comparable. Tolerances on the parameters should be those that would result in $\pm 25\%$ change in the residue concentration, not $\pm 25\%$ changes in the parameters themselves. It is $\pm 25\%$ for application rate because application rate is directly proportional to residue concentration (see also section 6.2). When combining field trials for a complete data set for a crop use, this “25% rule” may be applied to any one of the critical GAP components; however it is not acceptable to apply the rule to more than one *c*GAP component listed here at a time. The same principle may be applied for judging the equivalency of residue data where a specific formulation type with different active ingredient content was used in the trials, provided that the *c*GAP is not changed significantly as a result, e.g., no more than 25% increase in amount of active ingredient per unit area.

Bridging studies (see also 6.2 Formulations) are an essential extrapolation tool to make the best use of existing data to support minor changes or variations to existing uses. A bridging study normally involves a comparison of different formulations or application methods for the purpose of data extrapolation, but may or may not involve side-by-side comparisons. If bridging trials are deemed necessary and a pesticide is used on a wide range of crops, data should be generated for at least three major crop groups (one crop per crop group), e.g., a leafy crop, a root crop, a tree fruit, a cereal grain, an oilseed with a minimum of four trials per crop. The trials should be carried out on crops that would be expected to show high levels of residue (often those with applications at or near harvest). If a bridging study is conducted and residues are significantly higher with a new formulation or different application method, or the combined residue data set obtained with different formulations would lead to a higher MRL, generation of a complete new data set may be necessary.

3.5.2 Rotational crop studies (limited field study)

Metabolism and residue studies conducted in rotational crops (sometimes referred to as follow up, following, succeeding crops) are typically required for uses of pesticides where it is reasonable that a food or livestock feed crop may be planted after the harvest of a pesticide treated crop (or in some cases replanting of crops after failure of the pesticide treated crop).

Residues in rotational crops are determined to verify if and at what levels residues detected in the rotational crop metabolism study (see section 3.2.3.2) may be found under field conditions. The data generated are used to determine if MRLs in rotational crops will be required or to establish appropriate rotational restrictions at the national level, i.e., the time from application to a time when rotation crops can be planted where there will be no residues of toxicological significance in rotational crops.

The residues in rotational crops are usually composed of various metabolites in low concentrations and the compounds included in the residue definition are generally below the LOQ and do not require any further action. Rotational crop studies are normally not required for pesticide uses in permanent crops, e.g., various tree and vine crops, or semi-permanent crops, such as asparagus, where rotations are not part of the normal agricultural practices.

In cases where the TRRs exceed the trigger value (0.01 mg/kg) in a RAC from crops in the confined rotational crop metabolism studies, then the nature of the residues in those test crops having a TRR greater than 0.01 mg/kg will normally need to be determined and submitted.

If the relative toxicity of the components found in the rotational crop metabolism study is considered to be less than that for the primary crops residue definition, then rotational crop studies may not be needed, even if residues above 0.01 mg/kg could be expected. In such cases, a reasoned argument should be provided to support the decision.

If there are particular toxicological concerns, it may be necessary to require residues in rotational crops (limited field) study in circumstances where residues could be expected below 0.01 mg/kg.

Field rotational crop studies are conducted with a non-radiolabelled pesticide applied under the agronomic use practices at the maximum seasonal application rates in at least two diverse agricultural regions representative of the use. The study design should seek to address situations where the potential uptake of pesticide soil residues in rotational crops is the highest, either due to mode of application, soil type and soil temperatures, pesticide persistence or other environmental or cultural practices.

Studies involving a root/tuber crop, a small grain crop, and a leafy vegetable crop are normally sufficient to represent all possible rotational crops. If there is no uptake of significant residues in one or two of the representative crops in the metabolism in rotational crop study, a limited field study is still required for three different representative crops²⁰. If the pesticide is to be applied primarily to paddy rice, an alternative study design, such as aging the pesticide under flood conditions prior to rotation to field crops, may be required.

3.5.3 Sampling and analytical methods

The basic requirements concerning sampling and analysis are described in section 3.3 of this chapter. The sampling methods are given in Appendix V.

Analysis should include all residues significant for both residue definitions (MRL compliance and dietary intake assessment). The concentration of residue components should be determined individually as far as technically possible.

²⁰ OECD Guidelines for the Testing of Chemicals, Test No. 504: Residues in Rotational Crops (Limited Field Studies)

3.5.4 Reporting the results of trials

To ensure the availability of all detailed information necessary for evaluation, copies of the complete original reports on the supervised trials have to be submitted, preferably in English or with sufficient keys or translation to facilitate review. In addition, the results of supervised trials should be summarised in the form given in Table XI.3 (Appendix XI). The explanations for the entries in the table are the same as those given under section 3.4 “*Use pattern*” in this chapter. The location of trials should be given by country and region within that country. Names of countries should preferably be recorded in English. An acceptable, but less preferred, alternative is to use the ISO alpha 3 code made up of 3 capital letters (ISO, 1993).

If more than one analyte is measured, the concentrations of individual residues should be reported separately. The total residue may be calculated additionally. In the latter case the conversion factors used for the calculation should also be reported.

The residue values should be reported taking into account the uncertainty of analytical measurement. In view of the performance of current analytical techniques, that would correspond to two significant figures. E.g. 0.0012; 0.012; 0.12; 1.2; 12 up to 99 mg/kg. For convenience residues ≥ 100 may be expressed with three figures.

The recovery values obtained at different concentration levels should be reported, but the residues measured should not be corrected for recovery. If the correction was done by the laboratory, this fact should be specifically mentioned together with the reasons for the correction and the method used for correction.

The analytical replicates (obtained by analysing replicate portions of the same laboratory sample) should be distinguished from results of replicate samples. The average value of the analytical replicates should be included in the summary table (Table XI.3, Appendix XI).

- Samples taken from replicate plots (in close vicinity and treated on the same day with the same equipment using the same formulation at the same nominal rate) and replicate samples taken from a single plot should be clearly distinguished. For each trial, result from each replicate plot should be listed separately.

When primary samples are analysed, the weight of the primary samples should be included in the report.

The method of expression of residues should be clearly indicated including, for instance, conversion factors applied, correction for blank or control samples, or recoveries. Uncorrected (or unadjusted) residue data should always be included in the report.

The residues in animal feed should be reported on a dry weight basis (see also 6.13 Expression of Maximum Residue Limits). If it is not expressed on a dry weight basis this should be clearly stated, together with any information on the moisture content.

Based on the experience of the FAO Panel, the presentation of the following information in the summary of supervised trials is often insufficient or ambiguous, and needs special attention. The supplementary information and explanation of trial conditions can be given as remarks or footnotes.

- Description of crop – other names (varieties or cultivars) can be given in brackets.
- Dates of application in relation to growth stage and intervals between applications and between last application and sampling. Clear indication of the related dates of multiple applications and sequential sampling is of special importance. Especially important is information on the intervals of handling and storage conditions from

sampling to sample storage, and intervals and conditions of sample storage prior to analysis.

- Method of application in relation to GAP. Application rate in metric units.
- Sampling method should be described in detail, including the number of primary samples in the composite sample and the total weight of composite sample, and the method of preparation of subsamples from a bulk sample. In the case of new trials, the sample sizes given in the FAO Guidelines on Producing Pesticide Residues Data from Supervised Trials should be followed as far as possible (Appendix V).
- Sample preparation should be carried out according to the Codex Guide on “Portion of Commodities to which Codex MRLs Apply” (Appendix VI). The portion of the commodity which is analysed should be unambiguously described.

When the residues in edible and inedible portions are analysed separately the mass ratios of the two portions should be reported for each sample, for example, residue data measured in citrus pulp alone are useful for estimating dietary intake but cannot be used for estimating a maximum residue level.

The JMPR must be able to clearly identify the portion of commodity in which the residues were determined.

In the case of cereal grains, some grains and seeds are still in the husks, and for rice results are often reported on polished rice. (The residue levels are usually considerably different for those sorts of commodities. Furthermore, the rice commodities analysed should be in the form in which they may enter international trade.)

Stone fruit data should clearly indicate whether the residue is expressed on the whole commodity without stem or with stone and stem removed. In the latter case the proportion of stone in whole fruit (% w/w) should be given at each sampling interval.

In animal products, for fat-soluble pesticides, the data for meat should indicate whether it is expressed on the whole trimmable fat basis or on extracted or rendered fat and the types of fat involved.

The requirements described in this chapter should be applied for all trials, including those performed by government institutions, irrespective of their sponsor

3.6 SUBMISSION OF INFORMATION FOR ESTIMATION OF MRLs OF PESTICIDE RESIDUES IN/ON SPICES

The 35th Session of the CCPR decided to elaborate MRLs based on monitoring data. Monitoring data had previously been used by the JMPR for estimating EMRLs; however, more detailed information is required for estimating MRLs for pesticides which may be used according to the current agricultural practice.

Registered or permitted uses of pesticides on specific spices may not be generally available, and farmers may use a range of available pesticides to protect their spice crops from pests and diseases that have been found to be effective against pests and diseases on vegetables. In addition, the spices may be indirectly exposed to pesticides applied to the primary crops within which spice-producing plants are also grown, i.e., as an inter-crop. Therefore, supervised residue trial data on spices may not be readily available. Residue monitoring data can be a source of information in the estimation of MRLs for these commodities.

Post-harvest treatment is usually made on a spice that has been aggregated from several different cropping areas. The original crops may have been exposed to different pesticides, which may increase the number of pesticide residues for which analysis should be undertaken when spice samples are investigated.

3.6.1 Submission of monitoring data

Spices are usually difficult substrates for the determination of trace organic contaminants. Reliable identification and quantitative determination of pesticide residues in spice samples of unknown origin can be a very laborious and complicated task, especially where access to GC-MS and LC-MS-MS techniques is limited. More commonly multi-residue methods are used for analysis of samples in such situations. However, MRLs may only be estimated for pesticides for which analysis was specifically targeted and positive results were confirmed with an appropriate method.

As the spice commodity is usually aggregated from several sources (fields) and not blended, it cannot be considered a single lot, as with samples from supervised trials. Consequently, the sampling procedure involved in the provision of residue data for the estimation of MRLs should be performed with utmost care. Primary samples should be taken from as many randomly selected positions as technically possible (preferably > 25) and the mass of laboratory sample should be ≥ 1 kg. Where a large amount of material (> 5 tons) is involved it is preferable that more than one independent sample be taken to obtain information on the residue distribution.

The evaluation of monitoring data submitted to the JMPR indicated that the distributions of residues were scattered or skewed upwards, and no distribution fitting appeared to be appropriate. The 2004 JMPR concluded that the analyses of at least 58 samples are required for a given pesticide commodity combination to estimate a maximum residue level based on monitoring data alone.

The submission for supporting the estimation of a MRL in a spice commodity should contain:

- a. the scientific and English name of the spice producing plant and its Codex Classification (Para 199, ALINORM 03/24A, 2003) if available.
- b. description of the agricultural practice for growing the spice producing plant including:
 - cultivation as a main crop or as an inter-crop;
 - pesticides authorised on the main crop and their likely use in relation to the harvest of the spice-crop (if relevant);
 - likely direct pesticide applications to the spice-crop and their timing in relation to harvest;
 - frequency of harvest and harvesting method;
 - information on the processing of the spice-crop to obtain the spice commodity; and
 - storage conditions and need for post-harvest protection.
- c. a detailed description of sampling and sample processing methods
- d. a description of the analytical method, or reference to a well established procedure, used for quantitative determination and confirmation together with its validation data and performance characteristics [Residue components included in the reported result (residue definition); LOQ, mean recovery and its CV at various fortification

levels (if reported results were adjusted for recovery, the method of adjustment)] for individual pesticide residues recovered by the method. The actual LOQ values should be reported which were verified during the analyses of the samples. For further details on basic requirements for analytical methods see sections 3.3.

- e. The summary table of results presented for individual spice×pesticide residue combinations as shown in section 3.13. “Data requirements for EMRL estimation”.
- f. Any other information considered relevant for the evaluation of residue data.

3.6.2 Designing of selective field surveys and reporting data for obtaining residue data in/on spices

Selective field surveys are an alternative approach to generate residue data to support the elaboration of MRLs for spices, as monitoring results have limited use in estimating maximum residue levels mainly because of the lack of information on the pesticide treatment history of the sampled commodity. In such situations pesticide residues present in the samples may not be detected precluding the estimation of suitable MRLs, which could lead to trade problems. The analysts should, therefore, have as much information as possible on the actual or possible use of pesticides on the spices to be analysed.

In a selective field survey samples are taken from fields where the crop is grown, treated directly or indirectly with pesticides, and harvested according to the local agricultural practice. The essential feature of the selective field survey is that all pesticide applications, the growth stage of the crop and post-harvest treatment of spices are recorded and are attached to the sampling report. This allows the laboratory to identify for analysis all pesticides applied, in addition to environmental contaminants such as organochlorine pesticides, which may be taken up from soil.

For MRL estimation the selective field survey is a better data source as the pesticides used are known rather than pesticide monitoring data involving the testing for pesticide residues in samples of unknown origin.

The following aspects should be considered in planning and conducting selective field surveys:

- A successful survey requires the full co-operation of the growers who should understand that it is being undertaken to help facilitate their production and that the correct information is essential for success.
- Sites for surveys should be selected to represent typical growing conditions of the particular spice. The more information and residue data provided the more accurate the maximum residue level that can be estimated.
- The minimum number of fields surveyed and samples collected depends on the diversity of the growing conditions. As an initial step, a minimum of 10 reliable residue results representing the typical growing or processing conditions with supplementary information are required for each spice×pesticide combination. Field samples are taken with 12 primary samples sufficient for preparing one laboratory sample.
- In the case of post-harvest application a minimum of 10 lots, treated independently, should be sampled, preferably from different processing or storage facilities. The laboratory samples should consist of a minimum of 25 primary samples.

The following details should be reported in addition to those listed in section 3.7.1.

- Person and organization responsible for organizing, supervising and reporting on the selective field survey.
- Typical agricultural practice (see details under section 3.7.1)
- Description of growing conditions of the plant producing the spice, e.g., main or intermediate crop, the growth stage at harvest, date of harvest and harvested part of the plant.
- Where the plant is grown as an intercrop between rows of a major crop, the registered or permitted uses of pesticides on the major crop.
- The date and method of application, and dosage of pesticides actually applied on the main crop and intercrop, for treatments carried out on the fields where the samples are taken directly from the fields
- Details of post-harvest application together with information on pre-harvest treatments where available.
- Description of any processing of the spice and its storage conditions.
- Storage conditions of samples until analysis.
- Portion of sample analysed
- Residues of ai and metabolites (mg/kg) found in the samples. The results should be tabulated as shown in Table 3.7.

Table 3.7 Summary of selective field survey results

Commodity name with Codex Number (if available)

Pesticide application			Date of		Analysis			
ai ^a	kg ai/ha kg ai/hL	Date(s)	Harvest	Sampling	Date	Residues mg/kg		Method

^a indicate whether the application was direct or indirect.

3.7 FATE OF RESIDUES IN STORAGE AND FOOD PROCESSING

Once the residue has been identified, information on its fate during storage and processing should be included.

Processing studies are among the critical supporting studies required for the evaluation of a new or periodic review compound. The effects of industrial processing and household preparation on residues have to be studied to estimate residue levels in processed products.

Objectives of processing studies

Processing studies have the following objectives.

- To obtain information about breakdown or reaction products which require a separate risk assessment.

- To determine the quantitative distribution of residues in the various processed products, allowing the estimation of processing factors for products which may be consumed.
- To allow more realistic estimates to be made of the chronic or acute dietary intake of pesticide residues.

Need for processing studies

Studies are not normally required if:

- the plant or plant product is normally only eaten raw, e.g., head lettuce
- only simple physical operations such as washing and cleaning are involved
- no residues above the limit of quantification occur.

Studies are necessary if significant residues occur in plants or plant products which are processed. “Significant residues” normally means residues above 0.1 mg/kg in RAC. If the pesticide concerned has a low ARfD or ADI consideration has to be given to conducting processing studies with analyses for residues below 0.1 mg/kg. In the case of hops this level should be 5 mg/kg (residues in beer are then < 0.01 mg/kg because of the dilution factor). For residues of a fat-soluble pesticide in oilseeds, the possibility of concentration in the oil has to be taken into account.

Determinations of the nature of pesticide residues in processed products are basic to processing studies. They make it possible to confirm the definition of the residue for processed products or to define extra breakdown products to be determined in further studies.

3.7.1 Guidelines for the conduct of processing studies on the nature of the residues

The objective of studies of the nature of residues is to establish whether or not breakdown or reaction products of residues in the raw commodities are formed during processing which may require a separate risk assessment.

On examining the effects of processing on pesticide residues one will find that the main procedures, e.g., preparation of fruit juices, preserves, wine, will be mainly hydrolytic, because processes involving heating would generally inactivate enzymes present in the commodity. Studies of hydrolysis are therefore chosen as the model for degradation in processing. Since the substrate itself is not likely to have a major effect, the presence of the commodity during such studies is not required. Studies of hydrolysis are not required if the water solubility of the substance is ≤ 0.01 mg/L.

Hydrolysis data (required as part of the physical-chemical properties of an active ingredient) are normally generated at temperatures between 0 °C and 40 °C for a time chosen to allow observance of degradation up to at least 70% at pH 4, 7 and 9. The objective of these studies is primarily related to environmental conditions. Therefore, they are not interchangeable with the required data needed to assess residue behaviour during processing, where higher temperatures but normally much shorter periods and, in some cases, at more extreme pH values are typically involved. Reactions are therefore faster and may lead to the formation of different degradation products.

Table 3.8 summarises typical conditions (temperature, time and pH) which prevail for each of the processing operations²¹.

Table 3.8 Typical parameters during processing operations

Type of process	Critical operation	Temperature (°C)	Time (min)	pH
Cooking vegetables, cereals	Boiling	100 ^a	15–50 ^b	4.5–7
Fruit preserves	Pasteurisation	90–95 ^c	1–20 ^d	3–4.5
Vegetable preserves	Sterilisation	118–125 ^e	5–20 ^f	4.5–7
Fruit Juice	Pasteurisation	82–90 ^g	1–2 ^h	3–4.5
Oil	Raffination	190–270 ⁱ	20–360 ^j	6–7
Beer	Brewing	100	60–120	4.1–4.7
Red wine ^k	Heating of grape mash	60	2 ^l	2.8–3.8
Bread	Baking	100–120 ^m	20–40 ⁿ	4–6
Instant noodle	Steam and dehydration (by frying or hot air)	100 140–150 (frying) • 80 (air)	1–2 1–2(frying) 120(air)	9 ^o

^a Temperature of the vegetables during cooking

^b Time the vegetables or cereals are kept at 100 °C

^c Temperature within the fruit preserves during pasteurisation

^d Time the fruit preserves are kept at 90–95 °C

^e Temperature within the vegetable preserves during sterilisation

^f Time the preserves are kept at 118–125 °C

^g Temperature of the fruit juice during pasteurisation

^h Time the fruit juice is kept at 82–90 °C

ⁱ Temperature of the deodorization during raffination

^j Time of the deodorization

^k White wine is not heated

^l Subsequently either chilled quickly or allowed to cool slowly (overnight)

^m Temperature within the loaf and on the surface during 20–40 minutes

ⁿ Time the loaf and the surface is kept at 100–120 °C

^o Wheat flour is kneaded with 0.1–0.6% *Kansui* (alkaline water containing 20% K₂CO₃ and 3.3% Na₂CO₃)

Based on the details given in Table 3.8 three representative sets of hydrolytic conditions can be considered appropriate to investigate the effects of hydrolysis for the relevant processing operations. These are defined in Table 3.9.

Table 3.9: The hydrolysis conditions listed below are selected to cover most processing procedures.

Temperature, °C	Time, min	pH	Processes represented
90	20	4	Pasteurisation
100	60	5	Baking, brewing, boiling
120 ^a	20	6	Sterilization

^a Closed system under pressure (e.g. Autoclave or similar)

For other processing practices involving more extreme conditions (deodorization during raffination, high pH of instant noodles (Table 3.8), the temperature and time for preparation of meat and fish) specific studies should be considered on a case-by-case basis.

²¹ OECD Guidelines for the Testing of Chemicals, Test No. 507: Nature of the Pesticide Residues in Processed Commodities - High Temperature Hydrolysis

The effects of processes other than hydrolysis, e.g., oxidation, reduction, enzymic or thermal degradation, may also have to be investigated if the properties of the pesticide or its metabolites indicate that such processes may produce toxicologically significant degradation products.

Depending upon the potential range of pesticide uses, one or more of the representative hydrolysis situations should be investigated. The studies are normally conducted with a radiolabelled form of the active substance or the residue in question. The desired goal of such a study is the identification and characterization of at least 90% of the remaining TRR. The principles for selecting position for labelling, identification and or characterization of residue components and basic requirements for performing and reporting the studies are the same as or very similar to those described under metabolism studies (Section 3.2.3).

The JMPR will take into account the nature of the major products in the hydrolysis study, dilution or concentration factors during processing, and the initial residue levels in the raw agricultural commodity when evaluating the results of the studies.

3.7.2 Guidelines for the conduct of processing studies on effects on residue levels

Processed products can be classified according to certain types of process. The studies have to take into account the importance of the processed product in human or animal diets. Degradation products of toxicological significance occurring in the hydrolysis studies have to be taken into consideration as well as residues of concern found in plant metabolism studies.

For a core set of data on an active ingredient the processing studies should be conducted on representative commodities such as citrus fruits, apples, grapes, tomatoes, potatoes, cereals and oilseeds. By using core processing procedures and selected crops it should be possible to extrapolate to other crops processed by the same procedure. Only in cases where it is not possible to derive consistent processing factors or where a very low ADI is established would it be necessary to conduct processing studies on every crop²².

In some cases further trials may be necessary to cover particular circumstances. Examples are the determination of residues in oil produced from oilseeds with no significant residues where the active substance has a log P_{ow} above 4, and extended studies on active substances with a very low ADI.

3.7.2.1. Test conditions for processing procedures

The procedures to be used in processing studies should always correspond as closely as possible to those that normally occur in practice. Thus products of household preparation, e.g., cooked vegetables, should be produced using the equipment and preparation techniques normally used in households, whereas industrial items such as cereal products, preserves, fruit juices or sugar should be produced by procedures representative of commercial food technology.

In some cases more than one commercial process may be routinely used, e.g., the different UK and US commercial practices in the production of potato chips; see the 1998 JMPR evaluation of maleic hydrazide. Reasons should be provided for the chosen process.

²² OECD Guidelines for the Testing of Chemicals, Test No. 508: Magnitude of the Pesticide Residues in Processed Commodities

Importance should be attached to carrying out processing studies for commodities included in GEMS/Food diets and for animal feedstuffs derived from crops, e.g., products of cereals, oilseeds, apples, citrus and tomatoes.

3.7.2.2 Nature of the processing studies

The studies should be designed so that processing factors can be derived and MRLs recommended for processed foods and feed important in international trade. For consistent processing factors the results of more than one study are necessary.

Processing studies should simulate commercial or household practices as closely as possible. The RAC used in the studies should be a field-treated commodity containing quantifiable residues, so that processing factors for the processed products can be determined. This may require field treatment at an exaggerated application rate to obtain sufficiently high residue levels. Processing studies with spiked samples are not acceptable unless it can be demonstrated that the residue in the RAC is entirely on the surface.

3.8 INFORMATION AND DATA FROM TRIALS ON STORED PRODUCTS

When residue data are submitted to the JMPR from treatment of stored products such as grains and seeds, the treatments are often carried out in a number of stores with variable conditions with regard to temperature, humidity, aeration, etc. Information should be available on the use practice and all the conditions under which the products are kept.

Treatments of grain and other products in store give rise to particular difficulties. Pesticides used for storage vary considerably in stability. The rate of disappearance can be influenced by variations in ambient temperatures, e.g., tropical compared to temperate, moisture content and aeration. Application of pesticides can vary from commodities stacked in sacks to automated systems in large-scale silos. In addition, the variability of residues within a store, i.e., intra-store variability, can be particularly high, for instance in situations such as fogged potatoes in box stores. For this reason sampling procedures must be designed to obtain a sample, representative of the lot.

3.9 INFORMATION AND DATA FROM FARM ANIMAL FEEDING AND EXTERNAL ANIMAL TREATMENT STUDIES

The results of livestock feeding studies are used for estimating MRLs in food of animal origin and to assess the dietary exposure of pesticides due to consumption of such foods.

Feeding studies are generally required where significant residues occur in crops or commodities fed to animals and metabolism studies indicate that significant residues (> 0.01 mg/kg) may occur in edible tissues or that the potential for bioaccumulation exists.

Residues in livestock studies are typically conducted in ruminants (dairy cattle) and poultry (laying hen). In general, the results of cattle feeding studies may be extrapolated to other domestic animals (ruminants, horses, pigs, rabbits and others) and laying hen feeding studies to other types of poultry (turkey, goose, duck and others).

Except in special cases, it is not necessary to carry out metabolism studies with pigs since information on metabolism in a monogastric animal is available from studies with rats. If metabolism in the rat is different from that in the cow, goat and chicken, pig metabolism studies may be necessary. In such circumstances, if the metabolic pathways in the pig study

are different from those in the ruminant study, a pig feeding study should be conducted unless the expected intake by pigs is not significant²³.

Farm animal feeding studies are not necessary when residues levels are below the limit of quantification in feed items from crop field trials that reflect the proposed critical GAP of the pesticide, i.e., maximum rate, maximum number of applications, minimum pre-harvest interval), unless the livestock metabolism study shows a potential for significant bioaccumulation of the pesticide in animal commodities. However, when quantifiable residues are present in the feed items, it will be necessary to consider the anticipated dietary burden and the results of the livestock metabolism study.

In cases where a metabolism study with dosing at the equivalent of 10×, where 1× is the anticipated dietary burden, results in levels of the residues of concern below the limit of quantification (LOQ) (typically 0.01 mg/kg) in all edible commodities, then no quantifiable residues would be anticipated in livestock commodities as a result of the proposed use. In such situations, the metabolism study can also serve as a feeding study.

3.9.1 Animal feeding study

Farm animal feeding studies use unlabelled compounds to establish the relationship between levels in feed and likely residues in tissues, milk and eggs.

Animal feeding studies should be designed to provide clear information on the fat solubility of the residues. Therefore, the likely fat solubility of residues with $\log P_{ow} > 3$ should be taken into account in preparing the study plan including sampling.

The test substance used in the study should be representative of the residue in the crop or feed. Livestock are dosed with the representative component(s) of the residue as defined in the feed, which is derived from crop metabolism, confined rotational crop and processing studies. The residue definition of a pesticide might consist of parent compound plus one or more metabolites, or a single or several metabolites or degradation products. If the parent compound is the major residue in feeds/plants, and when it is metabolised by livestock similarly as in plants, it is appropriate to dose the animals with the parent compound only. If a unique plant metabolite is the predominant residue in the feeds and plants, then it may be appropriate to dose with the metabolite only. Generally the feeding of mixtures is not recommended and needs a specific rationale. In some cases the use of field aged residues is preferable.

The test substance(s) should be applied in a suitable form, preferably by capsule to simulate the residue concentrations in feed and to ensure consistent exposure over the duration of the study. If the substance is applied to the feed, it must be thoroughly mixed with the feed and regular analytical checks must be made to ensure the consistency and stability of the chemical in the feed over the study duration.

Once acclimatized, which is indicated, for example, by normal feed consumption, body weight stability, or the production of average quantities of milk or eggs, the animals should be dosed daily for a minimum of 28 days or until residues plateau in milk or eggs, if they have not done so in 28 days.

It is important that the study period is long enough to reach plateau levels for residues in meat, milk and eggs and to observe the rates of decline of the residue levels when the intake

²³ OECD Guidelines for the Testing of Chemicals, Test No. 505: Residues in Livestock

of feed with pesticides has ceased and quantifiable residues are present in milk, meat, fat or eggs after the terminal dose at the nominal 1× dose level. A depuration phase conducted with the highest dose group is sufficient to cover all feeding levels associated with GAP, as the objective of the depuration phase is to provide information on the decline rate. At least three time points following cessation of dosing at the highest dose level should be included, i.e., practical zero withdrawal and three other time points, with at least one ruminant and three hens to be slaughtered per time point. An adequate number of time points should be chosen to be able to estimate a half-life of depuration in meat/fat, milk or eggs. In some circumstances, such as the cases of compounds that preferentially accumulate in fat as opposed to milk, registrants may consider conducting a separate depuration study using beef rather than lactating cattle, as the rates of depuration may be different where milk becomes an additional route of elimination for the chemical. Typically, three animals should be included at each depuration time point. Livestock are typically fed at 1×, 3× (or 5×), and 10×, where 1× is a level based on the lowest expected regional dietary burden, as estimated from the highest residue levels in individual feedstuffs (median residues in processed feedstuffs) and the percentage of each feedstuff in the regional livestock diets. Additional dose levels may be added as necessary, for example, to refine dietary risk assessments. As the basic assumption is that all feedstuff that make up the total livestock diet will be pesticide treated, the dietary burden reflects the reasonable worst case that may occur in practice.

The 10X dose will allow an estimate of what will happen if the normal level is exceeded, will indicate whether residues are proportionate to the intake and will provide additional data if new uses of the product are introduced.

For studies with ruminants and monogastrics one untreated (control) animal per study and three (3) animals per dose groups are required. In the case of bioaccumulating substances, the highest dose group will comprise a minimum of 3 additional animals. For studies with poultry one untreated (control) animal per dose level (3 to 4 per study) and 9–10 animals per dose group are normally used. In the case of bioaccumulating substances, the highest dose group will comprise a minimum of nine (9) additional animals. Cows should be in mid-lactation producing an average milk yield, and chickens should be in full egg production before dosing is started. The condition of the animals, both during the acclimatisation and dosing phases should be recorded throughout the study period, together with information on the age and individual bodyweights, daily feed consumption (individual or mean group basis), milk production or egg production. The physical condition of the animals can provide important information on rates of absorption and depuration of the administered chemical. Any health problems, abnormal behaviour, low feed consumption or unusual treatment of the animals should be reported and the effect of these on the study results should be discussed where relevant.

3.9.2 Direct treatment of animals or premises

For pesticides that are directly applied to livestock or are used in agricultural premises and label restrictions cannot preclude the possibility of residues in meat, milk or eggs, residue studies to determine residues levels in edible livestock commodities should be provided. The studies should reflect the maximum exposure conditions and all possible residue transfer routes such as direct absorption, direct consumption or direct contamination, e.g., contamination of milk from milking equipment.

Separate studies are required for each application type, e.g., ruminants (cattle), non-ruminants (swine) and poultry (chicken). Extrapolation based on direct animal treatment is generally not justified. Dermal treatments on cattle cannot be extrapolated to dermal treatment of sheep.

MRLs are set only for sheep if application is on sheep. For direct treatments, the formulation might also be important and therefore separate studies might be required for different formulation types.

Each study should include a treatment at the highest exposure (treatment) rate, and at 1.5 to 2 times that rate, using the proposed methods as indicated on the label in two separate premises, or in two isolated areas of the same premises. In a third separate area animals should be kept as control animals. The animals in all three areas should be of the same breed and sex and of the same general age, weight and body condition. In the study, adequate details of the nature of the housing and application of the treatment should be reported. Where multiple treatments are proposed, the trials should be carried out accordingly and the animals slaughtered or eggs/milk collected after all treatments are completed.

There may be specific situations where data are needed to simulate exposure from direct application of a product to livestock in addition to exposure through feeding of treated crops. In such cases, the residue study should reflect the level of residues to be expected from the combined exposure scenarios. If separate feeding and direct treatment studies have been conducted, it is normally acceptable to add the residues from these studies to determine the appropriate maximum residue levels. However, this may result in higher than necessary MRLs for animal commodities.

3.9.3 Documentation of animal feeding studies

Information should be provided on:

- number of animals per feeding group
- weight of each animal
- nature of the residue or compound being dosed (pure compound, aged residue, mixture of parent and metabolite)
- dose rates per day (mg compound/kg bw/day or mg compound/animal/day)
- equivalent feeding levels (ppm in feed on a dry weight basis)
- feed intake (dry weight basis)
- description of the feed
- milk or egg production
- duration of dosing and withdrawal, times for milk or egg collection and animal slaughter
- residue levels in tissues and milk (and milk fat for fat soluble pesticides) or eggs.

Tissues to be analysed should include, as a minimum, skeletal muscle, perirenal fat, subcutaneous fat or backfat, liver and kidney. Special care should be taken to ensure that residues on the skin or wool do not contaminate the tissue samples during sample collection. Individual animal residue data should be reported. In the case of fat-soluble chemicals fat depots should not be pooled, but analysed separately. However, if there is insufficient backfat for analysis, the backfat should be supplemented with other subcutaneous fats, preferably brisket fat, and its source reported in the study.

3.9.3.1 Nature of fat samples in studies on fat-soluble compounds

The information obtained from feeding and direct treatment studies must allow an MRL to be recommended to cover residues in the various types of fat which may be subsequently sampled by regulatory authorities. It is sometimes assumed that the levels of residues are approximately the same in the different fat depots within an animal (except at the site of a direct treatment), but this is not necessarily the case.

Farm animal feeding and external animal treatment studies for fat-soluble compounds should provide information on the highest residue levels likely to occur in any fat depot when directions for registered uses of the pesticide are followed. The highest levels would be the basis for an MRL recommendation. In such studies fat samples from the various fat depots need to be analysed separately.

The description of “fat” in some studies has not always been totally clear. It could be taken to mean “trimmable fat” containing moisture and possibly some other tissue or it could mean the lipid portion. Residue levels of fat-soluble pesticides should be expressed on the lipid portion.

For fat-soluble pesticides in both feeding and direct animal treatment trials, the fat samples analysed should be fully described because residue levels may vary in fat from several fat depots within the body of the same animal. The fat description should include:

- the nature of the fat, e.g., peri-renal, mesenteric, subcutaneous,
- location in the animal body (if more than one possibility)
- lipid content (rendered or extracted fat may be assumed as 100% lipid).

In external animal treatment studies a sample of the fat at the treatment site, e.g., the site of a pour-on treatment, should also be taken for analysis.

Residue levels of fat-soluble pesticides may depend on the condition of the animal, which should also be recorded.

3.9.4 Information on direct treatment of animals and animal housing

When a compound is used both as a pesticide on crops and for direct animal or animal housing treatments full information on approved uses for both purposes and data from residue trials according to the approved uses, together with metabolism data in animals, should be included in the submission to the FAO Panel.

In the case of the first evaluation of a compound or re-evaluation within the periodic review, veterinary uses will be treated in the same way as all other uses. If information is not supplied, the FAO Panel will not recommend MRLs covering direct animal or animal housing treatments for new compounds and will recommend withdrawal of the old MRLs which were based on such uses.

3.10 RESIDUES IN FOOD IN COMMERCE AND AT CONSUMPTION

Monitoring data are the basis for establishing EMRLs for pesticides which have become environmental contaminants (see Chapter 5, Estimating extraneous maximum residue levels), and in the case of spices. The spice monitoring data shall be provided in the formats specified in section 3.6.1).

3.11 NATIONAL RESIDUE DEFINITIONS

Information on national residue definitions is needed for new and periodic review compounds. This background information assists decision making on residue definitions.

3.12 RECONSIDERATION OF PREVIOUS RECOMMENDATIONS

In the light of new uses of a compound or additional information on its residues the compound may have to be re-evaluated, in which case all new information, additions or corrections must be presented.

The new information and data will mainly be related to additional GAP and new data from supervised trials, which enable the JMPR to estimate maximum residue levels and eventually propose MRLs for additional commodities, change of established MRLs or confirm existing MRLs. Other types of information may also be submitted, such as reports about additional metabolites which were unknown at the time when the pesticide was first evaluated; ratio and magnitude of the parent compound and the metabolites in additional matrices; new reports about animal feeding studies; improved analytical methods with lower limits of quantification and improved ability to differentiate between parent compound and metabolites.

When transgenic crops are developed, additional information on metabolism and analytical methods will be needed as well as the usual data requirements for new uses.

It is emphasised that recommendations of the FAO Panel can only be based on information available to the JMPR, and requests or suggestions from the CCPR for changes of recommendations should always be accompanied by a clear statement of the reason for the referral, and must be supported by the data necessary for the JMPR to (re)consider the issue.

The experience of the meeting shows that often the information available to national governments has not been provided to the JMPR. The full documentation available to governments should be provided to resolve any questions referred to the JMPR.

It is only possible to obtain STMR and HR values when all the relevant data for a particular compound are available. A complete dossier of information is available for new and periodic review compounds. For other evaluations related to new uses of a compound or additional information on its residues, estimation of a revised maximum residue level may be possible, but calculating the revised international estimated daily intake, IEDI, value may not, as it would require consideration of all residue data evaluated previously.

3.13 DATA REQUIREMENTS FOR EMRL ESTIMATION

The Extraneous Maximum Residue Limit (EMRL), for JMPR purposes, refers to a pesticide residue arising from environmental sources (including former agricultural uses) other than the use of a pesticide directly or indirectly on the commodity (See Appendix II, Glossary of Terms). EMRLs are estimated from residue data generated in food monitoring programmes.

In any proposal for EMRLs a clear statement that the pesticide (or any precursor) has no permitted uses on the crop, the animal or animal feeds is required. If former uses have been discontinued, provide the date of the withdrawal of the compound from the market.

Include the following monitoring data and supporting information for evaluation:

- Country
- Year or years

- Commodity description (Codex Classification of Foods and Animal Feeds) and portion analysed
- Pesticide, and residue definition
- Sample classification as import, export or domestic production and consumption
- Statement whether the samples derive from random monitoring or are aimed at a particular problem or situation.
- Analytical method used together with its performance characteristics (see basic requirements for reporting methods in section 3.5.4). In addition, indicate each LOQ level reported by the laboratories, e.g., LOQ: 0.05 mg/kg, 0.02 mg/kg or 0.01 mg/kg.
- The detectable residues should be reported individually in order to facilitate the application of statistical methods for estimation of maximum residue level.

The detailed residue data should be presented in an Excel workbook in tabular form shown hereunder.

Standard format for reporting pesticide residues monitoring data

Country:

Pesticide:

Residue components measured by the method:

Commodity:

National MRL:

LOQ or limit of reporting (mg/kg):

LOQ or limit of reporting [mg/kg]	Commodity ^{a,b}	No of samples ^c	Year
0.01	GC0640 Barley grain	52	2000-2006
0.02	MM0812 Cattle meat	23	2000-2003
0.01	MM0812 Cattle meat	34	2004-2006

^a Describe the commodity according to Codex Commodity Classification together with the portion of commodity analysed.

^b List different commodities under each other

^c The table contains example for reporting LOQ values

Detected residues ^a [mg/kg]:

Year	Commodities ^{b,c}		
	Barley grain	Cattle meat	
2000	0.012	0.02	
	0.012	0.021	
	0.013	0.021	

^a Replicate samples taken from the same stored commodity should be marked

^b Describe the commodity according to Codex Commodity Classification together with the portion of commodity analysed.

^c Insert additional columns to the table as needed.

CHAPTER 4

PREPARATION OF DATA DOSSIERS FOR THE CONSIDERATION OF THE FAO PANEL OF JMPR

CONTENTS

Organization of the dossier
Data directory
Working paper or monograph

4.1 ORGANIZATION OF THE DOSSIER

Before a pesticide can be considered for JMPR evaluation it must already be available for use as a commercial product, which means that scientific studies have been prepared and then evaluated in national registration systems. Such studies are generally adequate for JMPR purposes and dossiers of reports prepared for modern registration systems are generally suitable for JMPR. However, JMPR does not review some topics, e.g., efficacy, some environmental fate aspects and ecotoxicology, and they need not be included in the dossier submitted to JMPR. If submitted, these studies will not be referenced or summarised in the Monograph.

The dossier to be submitted to the FAO Panel of JMPR should be arranged within the following topics. It comprises the technical reports provided in support of the working paper or submission summary (see below).

0. Data directory (see below, also Appendix VII)
1. Background information
2. Metabolism and environmental fate
3. Residue analysis
4. Use patterns
5. Residues resulting from supervised trials on crops
6. Fate of residues in storage and processing
7. Residues in animal commodities
8. Residues in food in commerce
9. National residue definitions
10. References, for all studies submitted

A table of contents should be included at the beginning of each volume. Each volume should be clearly labelled as per the example below:

Company name
Date
Common name of the active ingredient
Number of the volume and total number of volumes in the submission
Title of the section

A list of commodities dealt with in that volume (for residue trials, farm animal feeding, processing and storage stability) and a list of animals, crops, soil and water (for metabolism).

Example:

Bayer AG
November 1992
Fenthion

Volume 15 of 18
Section 5 Residues resulting from supervised trials

Citrus fruits
lemons, oranges, tangelos

Pome fruits
apples, pears

4.1.1 Data submission

A hard copy and or electronic copy, based on the reviewer's preference, of the data is to be submitted directly to the reviewer, with an electronic copy provided to the FAO Joint Secretary. If the original data are not available in electronic files, the reports shall first be scanned in pdf formats.

Working papers, summaries of GAP and residue data should be provided in Word format and diagrams of metabolism pathways prepared using a commercial chemical structure drawing program suitable for inclusion as a graphic in the document.

4.2 DATA DIRECTORY

See also Appendix VII, "Standardized format for organizing the data directory (index) of information to be submitted for evaluation."

Manufacturers are required to supply to the FAO Joint Secretary a detailed index or directory of the information to be provided for the residue evaluation by 1 September of the year preceding the scheduled review.

The directory provides an opportunity for data submitters to conduct a brief overview of the data package and identify gaps or omit studies which are not up to current standards and it ensures that an acceptable data package will be available for the consideration of the FAO Panel.

A review of the directory prior to submission of the actual data facilitates planning for the JMPR and helps ensure an equitable distribution of work among the Panel members. A comprehensive data directory simplifies the process of finding relevant sections or studies during the evaluation, particularly in a large submission. In addition, these directories provide a permanent record of the data submitted.

It is not possible for the FAO Joint Secretary to determine from the directory the acceptability of residue data in relation to the use pattern, the availability of critical supporting studies or the monograph. This initially remains the responsibility of the data submitter and ultimately the task of the FAO Panel.

The detailed reports submitted to the FAO Panel in support of the monograph must be organised according to the standardised format of the directory (Appendix VII). Reports or submissions developed for national regulatory authorities may still be collated according to this format.

An electronic copy of the data directory should be supplied in Word format to allow document searches and for incorporation of the references into the Evaluation.

The JMPR manual for FAO Panel members (Appendix X) may also be useful to those preparing data submissions for review.

4.3 WORKING PAPER OR MONOGRAPH

Manufacturers are required to submit a working paper or monograph in MS Word format summarising the results of the trials and the conclusions drawn from them, together with copies of original reports, by 30 November of the year before the scheduled review.

The working paper should, where appropriate, relate the residue data to the residue definition, analytical methods, GAP information, dose levels in animal studies etc., and clearly demonstrate the basis for a proposed MRL. The sub-sections describing supervised trials should follow the sequence of the Codex Commodity Classification and conclude with an evaluation of the information provided.

In the case of submissions provided in support of a new or revised MRL, the evaluation may be limited to a brief discussion of the available residue data and GAP information. In the latter case, new critical supporting studies are valuable information and should be submitted. The re-submission of previously evaluated studies is not necessary, but the relevant studies should be referenced.

The preparation of a draft working paper is expected to facilitate the evaluation of the data by the reviewer and the overall operation of the Panel. It is not intended as a substitute for the FAO Panel review of the individual study reports.

Reports (in English) prepared for submission to authorities, for example in USA and Europe, are likely to be considered generally acceptable. Where such reports are not in the format specified below, a directory must be provided which permits the reviewer ready access to the individual technical reports. There may also be the need for additions to such submissions, for example:

- commodity descriptions in Codex terms,
- summaries of good agricultural practices,
- summaries of residue data from supervised trials,
- summary of residue definitions.

The data and information required for JMPR evaluation and the formats recommended for preparing the summary information are described in detail in Chapter 3 “*Data and information required for JMPR evaluations*”. The information from the individual studies should be organised according to the suggested subheadings in the directory with an evaluation of the available data in each subsection. Under the various subheadings, explain any trial details relevant to the assessment of the data that might be considered to influence the residues or the validity of the trials.

Include schematic diagrams of metabolism pathways in electronic form.

Processing studies should be grouped according to the commodity or substrate of interest. Summarise the data in tabular format. Such tables should be set out carefully so that it is absolutely clear which sample is derived from which product in the processing phase. The scale of the processing by the weight of commodity processed should be indicated. The review of each study should describe the field treatments and state the application rate in the study.

Include flow diagrams to explain any complex commercial processes.

4.3.1 Utilisation of national evaluations

The evaluations conducted by national and regional authorities are useful to JMPR in the preparation of compound evaluations.

With the dossier submitted to the JMPR, submitters should include copies of available evaluations performed by regional or national authorities. This recommendation in no manner negates the requirement for the manufacturer(s) to provide *all* relevant original studies, as these will continue to be the primary source.

CHAPTER 5

JMPR PRACTICES IN EVALUATION OF PESTICIDE RESIDUE DATA

CONTENTS

Introduction
Physical and chemical properties
Metabolism and degradation of pesticides after application to animals, plants and soil
Analytical methods
Stability of pesticide residues in stored analytical samples
Information on good agricultural practices (GAP)
Results of supervised trials
Processing studies
Results of national monitoring programmes
Re-evaluation of additional information
Re-evaluation of compounds in the CCPR periodic review programme
Definition of residues

5.1 INTRODUCTION

The Joint Meeting carries out a scientific evaluation and takes into account all information to which it has access. Better evaluations result from an understanding of the processes of residue behaviour rather than from only an empirical treatment of data. In addition, the available information varies to a great extent. Therefore, the JMPR does not follow rigid rules in its evaluations but considers the submitted information on a case-by-case basis. The basic principles outlined below are followed as far as practical and possible.

As part of the evaluation process the members of the FAO Panel prepare the monographs, including all relevant information concerning the pesticide, and the appraisal summarising the findings, conclusions and recommendations, and giving full explanation and reasoning for them. The monographs and appraisals are prepared in a uniform format, described in the FAO Panel Manual attached as Appendix X, to facilitate access to the required information by the reader. The monographs and appraisals are published by FAO in the series *Pesticide Residues in Food - Evaluations Part I. Residues*. In addition, a short summary of information evaluated and the recommendations for each compound are included in the Report of the JMPR.

The JMPR has recognized the need to explain the basis for its recommendations in full. Information on GAP and data on supervised residue trials are summarized in detail in the monograph and the reasoning behind the conclusions and recommendations is explained, i.e., data are provided in sufficient detail for the reader to understand the basis for the recommendations. The increased volume of the monographs since the early to mid 90s is largely due to the inclusion of more detailed explanations and reflects the increased resources required for the work.

5.2 PHYSICAL AND CHEMICAL PROPERTIES

Data submitted on physical and chemical properties of pure active ingredient are evaluated in order to recognize the influence of these properties on the behaviour of the pesticide during

and after its application on crops or animals. Data on physical and chemical properties are also needed for an understanding of analytical methods.

The volatility of the compound and its stability in water and after radiation from ultraviolet light may considerably affect the disappearance after application.

The solubility of the pesticide is especially of great interest, as the ability of the compound to penetrate plant and animal tissues is dependent on its solubility in water and organic materials, as is its behaviour during processing.

The designation of a residue as either ‘fat-soluble’ or non-fat soluble is important for MRL-setting purposes and for compliance with relevant standards. The ‘fat-soluble’ status determines the nature of a sample that should be taken for enforcement analysis.

The distribution of the residue between muscle and fat obtained from livestock metabolism and feeding studies should be the prime indicator of fat-solubility. In some cases the information available on distribution of the residue (parent compound and/or metabolites) from metabolism or feeding studies does not allow an assessment of fat solubility to be made. In the absence of other useful information, the physical property chosen by the JMPR to provide an indication of solubility in fat is the octanol-water partition coefficient, usually reported as $\log P_{ow}$.

It should be noted that there are errors in estimates of $\log P_{ow}$ with differences of one unit for the same compound being reported. Different approaches to the development of these data often give different results. Interpretations must recognize these differences.

The partitioning of residues between fat and muscle as a function of P_{ow} can be predicted²⁴. The fat tissue/blood partition coefficient refers to the ratio of chemical concentration or solubility in adipose tissue and blood. The solubility of a chemical in adipose tissue or whole blood is equal to the sum total of its solubility in lipid and water fractions of these matrices. The partition constant k for fat and muscle can be calculated assuming P_{ow} (octanol:water) has the same value as P_{lw} , the partition constant for lipid and water. Further, if it is assumed that muscle contains 5% lipid with the remainder water and that fat is 80% lipid then:

$$P_{lw} = [\text{lipid}]/[\text{water}] \approx P_{ow};$$

$k = [\text{partition coefficient residues in fat:blood}]/[\text{partition coefficient of residues in muscle:blood}];$

$$k = \frac{P_{ow} [\text{fraction lipid}]_{\text{fat}} + [\text{fraction water}]_{\text{fat}}}{P_{ow} [\text{fraction lipid}]_{\text{muscle}} + [\text{fraction water}]_{\text{muscle}}}$$

$$k = \frac{(P_{ow} \times 0.8) + 0.2}{(P_{ow} \times 0.1) + 0.9}$$

A plot of $\log P_{ow}$ versus predicted partitioning between fat and muscle (Figure 5.1) reveals that partitioning is essentially independent of $\log P_{ow}$ for compounds with values greater than 3.

The 2005 JMPR decided to revise the empirical limits recommended by the 1991 JMPR when considering $\log P_{ow}$ so that when no evidence is available to the contrary and $\log P_{ow}$ exceeds 3, the compound would be designated fat-soluble and when $\log P_{ow}$ is less than 3 it would not²⁵.

²⁴ Haddad S, Poulin P, Krishnan K. 2000. Relative lipid content as the sole mechanistic determinant of the adipose tissue:blood partition coefficients of highly lipophilic organic chemicals. *Chemosphere* 40:839-843.

²⁵ 2005 JMPR Report p. 28

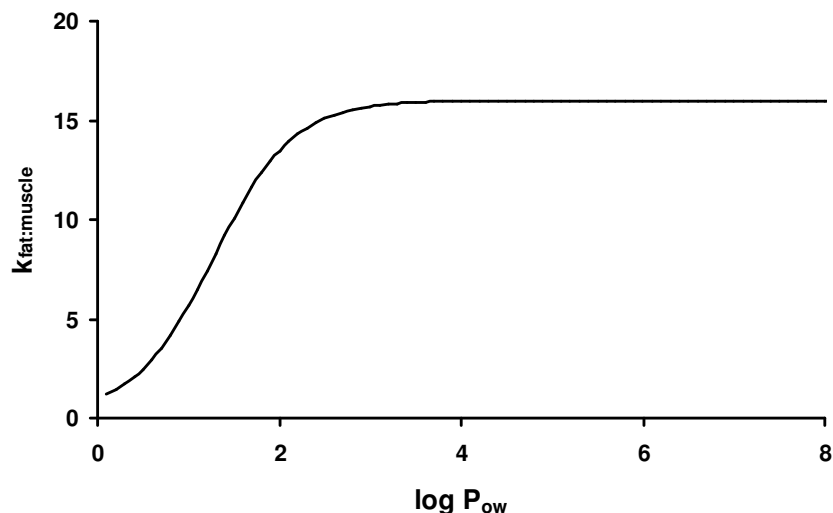


Figure 5.1 Plot of predicted partition of residue between meat and fat based on $\log P_{ow}$
 k = concentration ratio of residues in fat/muscle

The variable composition of some residues, e.g., where the residue is defined as a mixture of parent and metabolites, presents a problem since the fat-solubilities of the metabolites may be different from those of the parent compound. In this case, information on the $\log P_{ow}$ of each individual metabolite should be considered if available. The relative concentrations within the mixture are also subject to change and, as a result, the tendency of the mixture to partition into fat will also change. The JMPR recognized that many compounds which are neither clearly fat-soluble nor clearly water-soluble required special consideration.

Residue concentrations for the residue definition in both muscle and fat may be determined in the goat metabolism study, where the data allow. These values are compared to the residue concentrations found in the muscle and fat in the corresponding cattle feeding study. Data for milk and milk fat may also be considered as an additional factor regarding the fat solubility of a pesticide, although in some instances the residue may be designated fat soluble in meat but not in milk due to differences in partitioning of the individual components included in the residue definition.

Some worked examples are provided for recently reviewed compounds with $\log P_{ow} > 3$ to illustrate different situations and the determinants that may be used to define a residue as being fat-soluble or not fat-soluble for the purposes of JMPR and the estimation of maximum residue levels for meat.

Cyprodinil has a $\log P_{ow} = 4$, the residue is defined as parent compound. The residue in goat fat is 75× higher than the residue in muscle in the metabolism study, indicating greater solubility of the residue in fat versus muscle (2003 JMPR). On the basis of the data from the metabolism study, the residue is designated as being fat-soluble.

Flutolanil has a $\log P_{ow} = 3.17$ and the residue is defined as the sum of flutolanil and trifluoromethyl benzoic acid for animal commodities. The cattle feeding study indicates that the residues in muscle and fat are comparable (2002 JMPR). On the basis of the data provided, the residue as defined for flutolanil is designated as not being fat-soluble.

Haloxifop-R-methyl ester (active form) has $\log P_{ow} = 4$; haloxifop methyl (racemate) $\log P_{ow} = 3.52$; haloxifop acid $\log P_{ow} = 1.32$; the residue of haloxifop is defined as haloxifop esters, haloxifop and its conjugates expressed as haloxifop. Results from two cattle feeding studies

have been reported by the JMPR (1996, 2001); the first by the 1996 JMPR showed residues in fat are higher than in muscle while the second reported by the 2001 JMPR showed residues in fat and muscle were comparable. The results can be explained by the analytical methods utilised in the two studies. Metabolism studies showed haloxyfop was present in fat as a non-polar conjugate that is easily hydrolysed under alkaline conditions to yield haloxyfop; in milk fat the conjugates were identified as conjugates of triacylglycerols. The cattle feeding study reported in the 1996 JMPR utilised an alkaline hydrolysis step to extract residues from all tissues while the later study utilised base extraction for muscle, kidney and liver but not fat. An alkaline extraction is an integral part of the analytical method for both plant and animal matrices and it is clear that the later study reported by the 2001 JMPR should be discounted. On the basis of the cattle feeding study where both fat and muscle samples were analysed using an appropriate residue method, the residue should be designated as fat-soluble.

Fipronil has a complex residue definition and the log P_{ow} for fipronil is 3.5 and log P_{ow} for a primary metabolite (MB 46136) is 3.8. The residue concentrations (parent + MB 46136) are 20 to 30× higher in goat fat compared to muscle in the metabolism study (2001 JMPR). In the cattle feeding study, residues (fipronil and MB 46136) were not detected in muscle (< 0.01 mg/kg) following dosing at the equivalent of 0.43 ppm. The individual components of the residue in fat were 3 to 4× higher for fipronil and were 40 to 50× higher for MB 46136 than those in muscle (< 0.01 mg/kg). Following combined dermal and oral administration to cattle, levels of fipronil and MB 46136 were < 0.01 mg/kg in muscle, however fipronil levels in fat were 4 to 6 × higher than the muscle LOQ and levels of MB 46136 ranged from 7 to 77× higher than the muscle LOQ over three fat depots sampled. The data clearly show that the residue as defined (fipronil and MB 46136) is fat-soluble. As is often the case, there are significant differences in residue levels in renal fat compared to abdominal fat illustrating the need for individual fat depots to be analysed in cattle feeding studies.

The above examples demonstrate that log P_{ow} of an individual component of a residue is an initial indicator, however it is not the only factor used to assess fat-solubility.

In order to apply these principles consistently, all residue definitions are re-examined during the periodic review of the compounds.

5.3 METABOLISM AND DEGRADATION OF PESTICIDES AFTER APPLICATION TO PLANTS, ANIMALS AND SOIL

Chemical degradation and metabolism are major mechanisms of disappearance of pesticides after application to plants, animals or soil. The rates of degradation and metabolism are dependent on the chemistry of the compounds and factors such as temperature, humidity, light, surface of the crops, pH of crop liquid and composition of soils. Metabolism studies provide fundamental information on the fate of the compound. Metabolites provide a qualitative or semi-quantitative picture of the composition of the residues, suggest probable residue behaviour, and indicate the distribution of residues within various tissues. The site and level of residues may also depend on whether the compound is absorbed by the leaves or roots of crops, whether it is mobile in the plant, and its persistence and mobility in soil.

Data on metabolism are used in evaluating both the toxicological and residue profiles of pesticides. The FAO Panel examines the metabolism in experimental animals and compares it with both that in food-producing farm animals and in plant species on which the pesticide is used. This is required to decide upon the relevance of the toxicological studies to humans, and to define the residues in plants and farm animal products. The ADI and ARfD estimate, based on toxicological studies in experimental mammalian animals, are valid for foodstuffs only if

the metabolite pattern is qualitatively and semi-quantitatively similar. If there are plant or farm animal metabolites which have not been identified as mammalian metabolites in experimental animals, these toxicological end points do not encompass those metabolites. Separate studies dosing with these metabolites may be necessary for assessment of their toxicological properties if significant residues occur in food items.

The information on the composition of the terminal residue is used to assess the suitability of the residue analytical methods for the development of residue data from supervised trials and to decide on the definition of residues.

5.4 ANALYTICAL METHODS

As part of the evaluation process the JMPR regularly assesses the validity of the analytical methods used in the supervised trials, food processing studies and farm animal feeding studies.

Each method is examined, based on its validation data and performance characteristics, for its overall suitability for the purpose intended, the compounds determined by the method and the substrates that may be analysed. Particularly important are the data for analytical recoveries. Method validation is needed on matrices representative of those in the trials and studies. The JMPR estimates the LOQ for the method as the lowest residue concentration where reliable recoveries (usually 70–120%) were achieved. The limit of detection provides an indication of presence of low level residues in various matrices, but as they do not provide quantitative data, they are not taken into account in estimation of residue levels. The JMPR, however, recognises that over time the LOQ may vary or change compared to the value estimated during method validation.

Where data are available the efficiency of the sample extraction steps used in the analytical methods are compared with radiolabel measurements on residue components in samples from the metabolism studies.

5.5 STABILITY OF PESTICIDE RESIDUES IN STORED ANALYTICAL SAMPLES

Residue samples from supervised trials, food processing studies and farm animal feeding studies are routinely stored under frozen conditions for a year or more before laboratory analysis. In such situations freezer storage stability studies are needed to provide assurance that the residues in the stored sample are essentially the same as in the fresh sample. If more than 30% of the residue is lost during storage before analysis, residues from studies involving similar storage periods may not be valid.

The results and conditions of the frozen stored sample testing should be compared with the duration and storage conditions of the analytical samples from the trials to help deciding on the validity of the trial residue data.

The following points are to be noted during evaluation of a freezer storage study (See also section 3.3.4 “*Stability of residues during storage and sample processing*”):

- design of the study - (intended sampling intervals, replication, number of procedural recovery tests)
- storage vessels (size, material, sealed)
- nature of the samples being tested (commodity, unchopped, chopped or homogenised)

- nature of the residue (single compound or mixed)
- incurred or spiked residue (spiking levels)
- procedural recoveries and variability of procedural recoveries
- temperatures of storage (intended and actual record of temperature).

Procedural recoveries (samples spiked and analysed at the time a stored sample is analysed) should be used to decide on the validity of the batch of analyses. The analytical results for the stored sample should not be adjusted for the procedural recoveries.

In some storage stability study reports the term “% recovery” is used for “% analytical or procedural recovery” and also for “% remaining after storage.” To avoid confusion, JMPR evaluations will report the concentration remaining or % remaining after storage for the stored samples and % procedural recovery for the analytical recovery tests.

In many cases simple inspection of the residue data can indicate whether the residues were stable for the intervals tested. Where the result is not so clear because of data scatter or because of marginal stability, further analysis of the data is warranted.

If a first-order decay is assumed, a plot of $\ln(\text{conc})$ vs time will provide the disappearance half-life. $\text{Half-life} = \ln(0.5) \div \text{slope}$.

Storage time for 30% loss of residue = $0.51 \times \text{half-life}$ = approx $0.5 \times \text{half-life}$.

The validity of residue samples stored for intervals exceeding this time should be questioned.

5.6 INFORMATION ON GOOD AGRICULTURAL PRACTICES (GAP)

An essential element to enable the JMPR to estimate maximum residue levels of pesticides is information on Good Agricultural Practices. The FAO Panel relies on current registered labels for reliable GAP information. The FAO Panel uses the information on national GAPs to identify the likely scenarios which may lead to the highest residues in food or feed (often referred to as the ‘critical GAP’ or ‘maximum GAP’), and relates these uses to the conditions prevailing in the execution of supervised trials. Therefore information on national GAP from those countries in which the supervised trials have been carried out, or from countries in close proximity with similar climatic conditions and agricultural practice is of the utmost importance.

With regard to the required presentation of adequate information on Good Agricultural Practice in the use of a pesticide in a country, the FAO Panel recognized that several countries may apply different pesticide use authorization systems. Some use a rigorous formal product-based registration scheme, while others use less formal authorization approaches. The “authorized safe use” or “approved uses” from the latter countries may still be included in the GAP table provided that the country involved supplies the information on nationally approved uses or authorized safe use. The terms “approved” and “authorized” are understood as GAP information from countries which do not have a full registration scheme, but where there is a form of authorization of use. This distinction recognizes the different terminologies and approaches to GAP authorizations at the national levels and does not imply that one national system is preferred over another.

Registered and approved use of a pesticide may vary considerably from country to country and the use patterns are often very different, especially in regions with great differences in climate. Growing conditions and, naturally, types of crops may also cause differences in the use pattern. According to the definition of Good Agricultural Practice, a pesticide should be

applied in such a way as to leave a residue which is the smallest amount practicable. Residue levels exceeding the smallest amount practicable, due to unnecessarily high application rates (“overdose”) or unnecessarily short pre-harvest intervals (PHIs), are contrary to the concept of GAP.

5.7 RESULTS OF SUPERVISED TRIALS

Estimation of maximum residue levels is mainly based on reliable residue data from supervised trials carried out in such a way that treatments in the trials are equivalent to the uses which normally reflect the corresponding critical Good Agricultural Practice.

Where residues derived from the most critical GAP lead to acute intake concern, trials reflecting a less critical alternative GAP are considered for estimation of maximum residue levels.

The importance of reliable data has already been emphasized in the requirements for information and data from trials described in section 3.5 ‘*Residues resulting from supervised trials on crops*’.

The principles followed in evaluating supervised trial data are described in detail in the section in Chapter, 6 ‘*JMPR Practices in estimation of maximum residue levels*’.

5.8 PROCESSING STUDIES

“Processed food” in connection with Codex MRLs for pesticides refers to products resulting from the application of physical, chemical or biological processes to a “primary food commodity” whereas primary food commodities treated with ionising radiation, washed or submitted to similar treatments are not considered to be processed food in this context. The term “raw agricultural commodity (RAC)” is the same as “primary food commodity.”

Originally the main interest for processed foods was on those important in international trade, such as milled cereal grains and other grain products, oil from oilseeds, juices and dried fruit. MRLs were established on these commodities. More recently interest has increased in obtaining better information about the residue levels in other types of processed food, e.g., primary food commodities which are peeled, cooked or baked. Some of those commodities are usually not moving in international trade, but information on the residue levels is essential to allow more refined dietary intake estimates to be conducted. As in the case of residue distributions between edible and non-edible parts of a food commodity, this may have the consequence that higher MRLs are acceptable when it is demonstrated that residues found in the whole commodity are destroyed or depleted through food processing. Experience has shown that residue levels usually decrease during processing, such as peeling, cooking and juicing. However, in other cases the residue level may increase during processing as in the case of oil from oilseeds and olives. Further, in some cases the active ingredient can be transformed during processing into metabolites that are more toxic than the parent compound.

The JMPR is aware that there is a considerable trade in manufactured foods based, for example, on fruits, vegetables, cereals and meat. However, the variety of forms under which the products are offered makes it impossible to recommend MRLs for all possible processed foods. For this reason the JMPR has agreed that in the case of processed foods where residues do not concentrate, MRLs will not be recommended, but for dietary intake purposes, residues present in the processed food are taken into account where possible.

The JMPR frequently estimates maximum residue levels for important processed foods and feeds moving in international trade when residues concentrate in these products at levels higher than in the RAC from which they are derived, e.g., oil, bran and peel. Even when the estimates are not recommended for use as maximum residue limits or when residues do not concentrate in the processed product, the JMPR will continue to record in its monographs the effect of processing on the level and fate of residues in food in order to allow better estimates of the dietary intake of pesticides.

Processing studies are among the critical supporting studies required for the evaluation of a new and periodic review compound. See Chapter 3 section 7, “*Fate of residues in storage and processing*”, for the objectives and data requirements.

All the residues (parent and relevant metabolites) determined in the RAC also have to be determined in the processed products. In addition, any degradation products found in metabolism studies which require a separate dietary risk assessment also have to be considered. The residue has to be calculated according to the definition relevant for compliance with MRLs and the estimations of dietary intake.

As a result of the processing studies, it is possible to recognize residue reductions and concentrations and to calculate processing factors for important products.

The processing factor, *Pf*, is defined as the ratio of the residue found in the processed commodity to the residue in the raw commodity before processing.

$$Pf = \frac{\text{residue level [mg/kg] in processed product}}{\text{residue level [mg/kg] in RAC}}$$

Processing factors are very much affected and depend on the processing yield. The characteristics of pesticide residues such as water or fat solubility, the distribution of the pesticide on the commodity, e.g., surface or systemic, or its application in pre or post-harvest treatments are also relevant. Therefore, the processing factor should be considered as a combination of the process and the commodity.

Whenever more than two processing studies have been conducted for a particular pesticide in the same RAC, the median *Pf* would generally provide the best estimate for the processing factor, especially where studies may result in processing factors including both "less than" and real values, or some high unexplainable processing factors.

If the processing factors from two trials are irreconcilable, e.g., 10-fold different, the mean is inappropriate as it would represent neither process. In this case it is preferable to choose one of the values as being representative. The highest processing factor should be chosen as the default (conservative) value if there is no other reason to choose the alternative.

Processing factors may be determined from the RAC at various days after the last application. In this case the results from the shortest PHI, which closely reflects the critical GAP, onward should be taken into account. However, where the processing factors are not different all data can be considered as shown with the example of processing of grape treated with fenhexamid:

PHI (days)	14	21	28–35
Average PF	0.343	0.298	0.366
Median	0.355	0.32	0.36

When residues in the processed commodity are undetectable or $< \text{LOQ}$ the calculated processing factor (residue level in RAC \div LOQ) should be reported with a “less than” ($<$) symbol. If residues in the processed commodity are undetectable or $< \text{LOQ}$ in several processing studies it may mean that residues in the processed commodity are very low or essentially zero and the calculated processing factors are merely a reflection of the starting residue levels in the RAC. In this case the best estimate of the processing factor is the lowest “less than” value rather than the median of “less than” values.

When residues in the in the RAC are $< \text{LOQ}$ but they are concentrated in the processed commodity (level $> \text{LOQ}$), the calculated processing factor (level in processed commodity/LOQ in RAC) should be reported with a “higher than” ($>$) symbol.

When residues in the processed commodity and in the RAC are both $< \text{LOQ}$ (unquantifiable) the study is of no value for deriving a processing factor.

If several studies are available and a step that is routinely used in the processing of that RAC, e.g., cleaning or washing, is omitted in a study, it may be inappropriate to include that study in the calculation of the average processing factor.

5.9 RESULTS OF NATIONAL MONITORING PROGRAMMES

Data from national monitoring programmes are essential for estimation of EMRLs and maximum residue limits for spices. See also sections 6.11.1 and 6.11.2 in Chapter 6 on ‘Estimation of maximum residue levels, HR and STMR values in spices’ and ‘Estimation of extraneous maximum residue levels’.

5.10 EVALUATION OF ADDITIONAL INFORMATION

Usually new information on GAP and related data from trials do not cause difficulties if the data received are of the same type and in agreement with data from earlier evaluations. However, information about new developments in the area of metabolism of the compound may be more problematic. Such information may require that the original residue definition be changed, which means that evaluation of old and new data together may be very complicated. Other than in exceptional circumstances, the evaluation of the results of additional metabolism studies, and of supervised trials revealing information on the proportions of the parent compound and significant metabolites can only be carried out at the time of a periodic review when all relevant information is available and taken into consideration in deciding on the definition of the residue.

In a similar way, problems may arise when a residue definition originally included two pesticides of which one of the compounds is also a metabolite of the other, and for toxicological or other reasons the decision is taken that the pesticides must subsequently be determined separately. In such a case old residue data are often inapplicable.

Improvements of analytical procedures may also cause difficulties. If the LOQ is lowered, the old residue data below the original LOQ are difficult to interpret and may be inapplicable and unavailable for later evaluations. In this context, as for new information on the metabolic profile of the compounds, the whole set of data on the compound has to be taken into consideration and decisions have to be taken by the JMPR on a case-by-case basis.

In most of such cases, however, all of the information required for the scientific re-evaluation is not available to the JMPR. Therefore, such complex problems are best and most efficiently handled during the periodic review of the compound for which all relevant original reports are required to be resubmitted and can be taken into consideration.

5.11 RE-EVALUATION OF COMPOUNDS IN THE CCPR PERIODIC REVIEW PROGRAMME

The periodic review programme requires different actions from those for the re-evaluation of additional information, called hereunder normal situation, and those compounds to be evaluated within the periodic review programme must be clearly identified in advance. See also Chapter 3 section 2 “*New and periodic review compounds*”.

As discussed in detail in Chapter 3, data submitters should supply all relevant valid information at the time of the periodic review irrespective of whether it has been supplied previously.

The JMPR evaluates all relevant information on periodic review compounds in terms of identity, metabolism and environmental fate (methods of residue analysis, current use patterns (registered and officially authorized uses), supervised residue trials, farm animal feeding studies, and fate of residues in storage and processing, as in the case of a new compound. However, the conclusions and recommendations are somewhat different in periodic reviews and normal reviews.

A periodic review compound, unlike a new compound, already has existing MRL recommendations. Existing MRL recommendations are dealt with differently in a normal review and a periodic review.

Comparison of the data evaluation of a periodic review compound with normal re-evaluation (re-evaluation of some particular information made available to the JMPR) clarifies the major differences.

5.11.1 New and existing MRLs

If no MRL exists for the individual commodity or for the relevant commodity group, there is little difference in the treatment of information supplied for a normal evaluation or for a periodic review.

For an individual commodity subject to an evaluation, if new data are supplied where an MRL already exists the data are evaluated and the MRL may or may not require revision.

In a periodic review, where adequate information is supplied on an individual commodity, the MRL is either revised or confirmed to be relevant to modern GAP.

In a normal evaluation, when information on a single commodity included in a group commodity MRL is received, evaluation would either show that the group MRL could remain or that an individual MRL and a group (with specified exceptions) MRL could be recommended.

In a periodic review when information on only a single commodity included in a group commodity MRL is received it may be necessary to withdraw the group MRL and estimate a single-commodity MRL.

5.11.2 GAP information.

Under normal circumstances if no new GAP information is supplied the MRL would remain. New GAP information may allow previously recorded residue data to be reinterpreted to permit estimation of a new maximum residue level.

In the normal situation where new residue data are to be evaluated, judgement is required on a case-by-case basis to decide whether previously recorded GAP is still valid. GAP information recorded many years ago for some compounds may still be acceptable.

Under the periodic review programme the absence of GAP and residue information becomes significant. For example, if no GAP information is supplied for a particular commodity the JMPR reviewer can assume that there is no GAP for that commodity. Only GAP supplied for the purposes of re-evaluation is considered valid. If no GAP information is supplied, withdrawal of the MRL will be recommended. Similarly, if GAP information is available but insufficient supporting residue data are provided, the MRL may be recommended for withdrawal.

5.11.3 Supporting studies.

Critical supporting studies (metabolism, farm animal feeding, processing, analytical methods and storage stability of analytical samples) are evaluated to assist with the interpretation of data from supervised residue trials, to revise or confirm the residue definition, to validate residue and other trials and provide further information on residues in food as consumed. The FAO Panel may not recommend MRLs for new or periodic review compounds in the absence of critical supporting studies if their omission is not adequately justified.

5.12 DEFINITION OF RESIDUES

5.12.1 General principles

Residue definitions are required to clearly establish the compound or compounds of interest when estimating dietary intake risks associated with the presence of residues in food or feed commodities and also to provide the basis for monitoring of MRL compliance.

A pesticide residue is the combination of the pesticide and its metabolites, degradates, and other transformation products. Although metabolites, degradation products and impurities are included in the definition of pesticide residues, this does not necessarily mean that metabolites or degradation products should always be included in the residue definition for enforcement (MRLs) purposes or for estimation of dietary intake (STMR, HR).

The WHO Panel considers and indicates in its evaluations which metabolites are of toxicological significance and should be included in the dietary risk assessment.

FAO Panel reviewers and the respective reviewers on the Toxicological and Environmental Groups should communicate closely prior to the JMPR meeting on questions such as which metabolites are of toxicological significance.

In tabulating the residue trials data the FAO Panel reviewer should indicate the levels of relevant metabolites separately from those of the parent compound, but in a way which allows subsequent combination, in order to ensure that changes in the residue definition can be accommodated at the Joint Meeting.

If it is recommended that the residue definition for the risk assessment be different from that for enforcement this must be clearly stated in the appraisal.

These two requirements (intake risk assessment and MRL compliance) are sometimes not compatible and residue definitions that are the result of compromise between these competing requirements may sometimes appear arbitrary. For this reason, and because of the various purposes for which they are used, definitions of residues established by national governments often do not agree.

The basic requirements for the definition of residues are:

- The residue definition for MRL purposes should be
 - based on a single compound whenever possible
 - most suitable for *monitoring compliance* with GAP
 - the same for all commodities if possible
- Common moiety residues for MRL purposes should be avoided
- The residue definition for *dietary intake estimations and risk assessment* should include compounds of toxicological interest.

The requirements for the two residue definitions are sometimes not compatible and, as a compromise, various definitions of residues are possible. For some compounds it may be necessary to establish separate residue definitions for MRL enforcement and dietary intake estimation purposes. The residue definition for dietary intake purposes should include metabolites and degradation products of toxicological concern irrespective of their source, whereas the residue definition for compliance with MRLs needs to be a simple residue definition, i.e., indicator molecule, suitable for practical routine monitoring and enforcement of the MRL at a reasonable cost.

Although metabolites, degradation products and impurities are included in the definition of pesticide residues, this does not necessarily mean that metabolites or degradation products should always be included in the residue definition for enforcement (MRLs) purposes or for estimation of dietary intake (STMR). Inclusion of transformation products (metabolites and degradation products) in the residue definition depends on a number of factors, and the decision on whether they should be included is very complex and decisions have to be made on a case-by-case basis.

The metabolites and other transformation products have generally been identified and quantified in metabolism experiments with methods based on the use of labelled compounds. In some cases the methods used for supervised trials are complicated and or require specific extraction and cleanup procedures, sophisticated instrumentation, and consequently do not fit in multi-residue procedures, which increase the cost and limit their application for regulatory analytical work.

Furthermore, residue methods for incurred conjugated metabolites cannot be validated without labelled compound and having access to specialised laboratories, and some countries may experience extreme difficulty obtaining even 'cold' metabolites for use as standards in the analytical work. Therefore, inclusion of metabolites in the residue definition, particularly polar metabolites, is not practical for monitoring compliance with GAP. Complicated residue definitions typically require single-residue methods, thus lead to lower number of monitoring and/or enforcement analyses (*vs.* residues that can be analysed using multi-residue methods), as clearly indicated by the results of EU or US monitoring programmes.

It should be stressed that in choosing the appropriate analytes and the analytical method for the testing of the residue trials samples, the manufacturer or sponsor must consider the needs

of both risk assessment and compliance. In practice this will mean generating the data in such a way as to give the flexibility to establish two separate residue definitions where appropriate. In cases where it is likely that a multi-component residue definition will be required for risk assessment purposes, the manufacturer or sponsor should, in testing field trial samples, either:

- a. analyse separately for the individual components of the residue, where analytical methods allow, rather than carrying out a total residue analysis,

or

- b. if total residue methodology is used to produce data for risk assessment, and the suitable “indicator molecule” can be analysed with a multi-residue procedure, a second series of analyses of the field trial samples should be carried out for the indicator molecule, e.g., parent compound.

This approach allows the risk assessment to be carried out on the toxicologically significant residue components whilst ensuring that data are available to allow a different simple residue definition to be established, where appropriate, for compliance with the MRLs.

In cases where the manufacturer or sponsor has submitted residue trials data in which an analytical method for total residues has been used and it is not possible to identify a suitable simple residue definition for practical routine monitoring and enforcement of the MRL at reasonable cost, the FAO Panel may be unable to estimate MRLs for the compound.

The following examples further illustrate the complexity of the situation.

Several pesticides are metabolized to a compound, which itself is used as a pesticide (example: benomyl → carbendazim), and in some cases, the toxicology is substantially different for the pesticide and the metabolite (example: dimethoate → omethoate). Whenever possible, the parent pesticide and its metabolite(s) used as pesticides should be subject to separate MRLs. Analysing food commodities in trade for the metabolite may provide no information on which compound was used.

Where it is not possible to set separate MRLs because the parent pesticide is degraded rapidly or an analytical method is not available for measuring and distinguishing the parent compounds (examples: ethylene-bis-dithiocarbamates, benomyl → carbendazim, thiophanate-methyl → carbendazim), the MRLs applying to the pesticides concerned can only be determined in terms of the metabolite(s) or conversion products.

Another problem occurs when the metabolite from a pesticide may also originate from sources other than use of the pesticide. In this case, a residue of the metabolite present in a sample is of no use in determining GAP compliance, and the metabolite should not be included in the residue definition for MRL (example; cyromazine → melamine, also prometryn → melamine). Common metabolites for a certain group of pesticides, e.g., triazoles, should also be excluded from residue definitions of individual pesticides.

The JMPR considers the following factors when proposing or revising a residue definition:

- The composition of the residues found in animal and plant metabolism studies.
- The toxicological properties of metabolites and degradation products (for risk assessment).
- The nature of the residues determined in supervised residue trials.
- The fat-solubility.

- The practicality of regulatory analytical methods.
- Whether metabolites or analytes common to other pesticides are formed.
- Whether a metabolite of one pesticide is registered for use as another pesticide
- The definitions of residues already established by national governments and long-established and customarily accepted definitions.
- JECFA marker residue definitions already established for compounds that may leave pesticide residues in animal commodities.

Transgenic and non-transgenic crops may metabolize the pesticide differently. The principles for deciding residue definition do not change and depend strongly on metabolism and analytical methods. When a commodity produced by a non-transgenic crop cannot be readily distinguished from the transgenic crop commodity, the residue definition should be the same for both. No single approach is applicable to all situations and a case-by-case approach is needed at present.

Fat-solubility is a property of the residue and is primarily assessed from the partition of the residue between muscle and fat observed in metabolism and farm animal feeding studies. Should this information be insufficient, section 2 in this chapter, “*Physical and chemical properties*” provides guidelines for deciding whether a pesticide is fat-soluble based on the octanol-water partition coefficient. Sampling protocols for animal commodities depend on whether a residue is fat-soluble or not.

The JMPR has for many years included the qualification ‘fat-soluble’ in the definition of the residues of fat-soluble pesticides, using the expression:

“Definition of the residue: [pesticide] (fat-soluble)”

The 1996 JMPR recommended that ‘fat-soluble’ should no longer be included in the definition of the residue because ‘fat-soluble’ is a qualification of sampling instructions and is not relevant to the dietary intake residue definition. In order to avoid confusion while conveying the information that a residue is fat-soluble, the JMPR agreed that a separate sentence should indicate that the residue is fat-soluble.

JMPR policies on residue definitions have evolved over recent years and, therefore, all residue definitions are re-examined during the periodic review of the compounds.

An explanation of the residue definition for each compound is located in the monographs under the section, Residue Analysis. The residue definition should explicitly state if it applies to plant commodities or animal commodities or both.

5.12.2 Principles followed in defining residues for MRLs

The definition of residues for enforcement purposes should be as practical as possible and preferably based on a single residue component as an indicator of the total significant residue - the parent compound, a metabolite or a derivative produced in an analytical procedure. A residue definition for prothioconazole (JMPR 2008) may serve as a good example of a practical residue definition for MRL compliance, in which case the major metabolite, desthio-prothioconazole, (which can be recovered with several multi-residue procedures), was selected as a marker residue from a very complex residue composition. The selected residue component should reflect the application condition of the pesticide (dosage rate, pre-harvest interval) and it should be determined with a multi-residue procedure whenever possible. Monitoring for additional residue components only adds to the cost of analyses.

The advantage of this approach is appreciable as overall costs can be reduced and many more samples may be analysed by the regulatory laboratories. In addition, more laboratories can participate in regulatory monitoring of residues, since a relatively simple and rapid analytical procedure may not require the expensive equipment and time necessary for an extensive determination of all components of a residue. Nevertheless, the expression of residues with a single compound does not reduce the data requirement. Complete information on the total residue composition and the relative ratio of residue components is needed to determine whether a single compound can be used and is often needed for risk assessment purposes.

As far as possible the same definition of the residue should apply to all commodities, although there are exceptions. For example, if the major residue in animal commodities is a specific animal metabolite, a definition which includes that metabolite is needed for regulatory monitoring. However, the animal metabolite is not required in the residue definition for crop commodities if it is not found in the crops. Separate definitions would then be proposed for commodities of plant and animal origin.

Example: residue definition of thiabendazole:

thiabendazole or, in the case of animal products, sum of thiabendazole and 5-hydroxythiabendazole.

It is generally preferable to express a residue in terms of the parent compound. Even if the residue consists mainly of a metabolite, the residue should be expressed in terms of the parent pesticide after molecular weight adjustment. Some examples are given to illustrate the practical application of the principle:

If the parent compound can exist as an acid or its salts, the residue is preferably expressed as the free acid.

Example: residue definition of 2,4-D:

2,4-D.

If metabolites are known to be present in significant amounts but the analytical method measures the total residue as a single compound, the residue is expressed as the parent compound. The metabolites included in the residue should be listed.

Example: residue definition of fenthion:

sum of fenthion, its oxygen analogue and their sulphoxides and sulphones, expressed as fenthion.

Fenthion, its oxygen analogue and their sulphoxides and sulphones are all oxidised to a single compound (fenthion oxygen analogue sulphone) for measurement, but the residue is expressed as the parent fenthion.

There are exceptions:

Example: residue definition of amitraz:

sum of amitraz and N-(2,4-dimethylphenyl)-N'-methylformamidine calculated as N-(2,4-dimethylphenyl)-N'-methylformamidine.

Ideally it should be possible to measure the residue as defined, with an LOQ adequate for proposed MRLs, with a high degree of specificity by a multi-residue regulatory analytical method. Although circumstances may warrant exceptions, the definition of a residue should not normally depend on a particular method of analysis, which means that the definition should not contain the words “determined as”. However, in the case of dithiocarbamates it is

necessary to describe the residue as “... determined and expressed as ...” to produce a practical definition for residues.

Example: residue definition of thiram for compliance with MRLs:

total dithiocarbamates, determined as CS₂ evolved during acid digestion and expressed as mg CS₂/kg.

Where the residue is defined as the sum of the parent compound and metabolites expressed as the parent, the concentrations of the metabolites should be adjusted according to their molecular weight before being added to produce the total residue. The words “expressed as” in the residue definition signify adjustment for molecular weight.

Example: residue definition of methiocarb:

sum of methiocarb, its sulfoxide and its sulphone, expressed as methiocarb.

No allowance was made for molecular weights in the definitions of residues of some older compounds. Because such definitions are widely accepted the need for change should be carefully considered. The best time for the reconsideration of an existing residue definition is during a periodic review.

Examples: (no recalculation for molecular weight)

residue definition of DDT:

sum of p,p'-DDT, o,p'-DDT, p,p'-DDE and p,p' TDE (DDD).

residue definition of heptachlor:

sum of heptachlor and heptachlor epoxide

Metabolites arising from different sources should generally be excluded from definitions of residues for enforcement purposes unless the definition is a combined one covering the various sources. For example, p-nitrophenol arises from both parathion and parathion-methyl. It is often a major component of aged residues but is not included in the definitions of the residues.

Where a metabolite of one pesticide is registered for use as a second pesticide, separate MRLs would normally be established if the analytes of the two compounds were different. Preferably no compound, metabolite or analyte should appear in more than one residue definition.

Example: Triadimenol is a registered pesticide and a metabolite of triadimefon. The MRLs for triadimefon are for triadimefon only. The MRLs for triadimenol are for triadimenol only, but cover triadimenol residues arising from the use of either triadimefon or triadimenol.

There are cases of pesticides, however, where the chemical instability of the parent compound or the limitations of analytical methodology do not allow the application of the above principle. In such cases the residue definition has to be based on the stable common moiety. Benomyl and thiophanate-methyl both degrade to carbendazim.

Examples: residue definition of benomyl,; thiophanate-methyl and carbendazim.

residue definition of benomyl:

sum of benomyl and carbendazim, expressed as carbendazim.

residue definition of carbendazim:

carbendazim.

residue definition of thiophanate-methyl:

sum of thiophanate-methyl and carbendazim, expressed as carbendazim

Notes: *Benomyl*: Residues arising from the use of benomyl are covered by the MRLs for carbendazim.

Carbendazim: MRLs cover carbendazim residues occurring as a metabolic product of benomyl or thiophanate-methyl, or from direct use of carbendazim.

Thiophanate-methyl: Residues arising from the use of thiophanate-methyl are covered by the MRLs for carbendazim.

A major part of the residue of some pesticides is bound or conjugated, with the free residue disappearing very quickly. The bound or conjugated residue is therefore a better indicator for monitoring compliance with GAP. If the residue is defined as bound or conjugated there must be a clear instruction for the regulatory analyst as to how to measure it. The instruction could, for example, be to extract samples with a particular solvent under specified conditions, or perhaps to begin with a hydrolysis step. This option should be avoided as far as possible, as such a method cannot be validated without the use of incurred labelled residue in various sample matrices, and neither the labelled incurred residue nor facilities for detecting ¹⁴C residues are available in all regulatory laboratories.

Example: residue definition of bendiocarb:

plant products: unconjugated bendiocarb;

animal products: sum of conjugated/unconjugated bendiocarb, 2,2 dimethyl-1,3-benzodioxol-4-ol/N-hydroxymethyl-bendiocarb, expressed as bendiocarb.

CHAPTER 6

JMPR PRACTICES IN ESTIMATION OF MAXIMUM RESIDUE LEVELS, AND RESIDUES LEVELS FOR CALCULATION OF DIETARY INTAKE OF PESTICIDE RESIDUES

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6.1 INTRODUCTION

The JMPR evaluates the possible risks to consumers from pesticide residues in foods by assessing available residue data and then using this information to estimate the short-term and long-term dietary intakes of residues. This chapter deals with the residue data assessment and the following chapter will deal with estimating dietary intakes.

The following guidelines are provided for selecting data for estimation of maximum residue levels for establishing MRLs, and supervised trials median residue (STMR) levels as well as the highest residue in edible portion of composite sample (HR) where an acute reference dose (ARfD) had been established by the JMPR.

Maximum residue levels are estimated for residues in or on the portion of the commodities to which Codex MRLs apply. For dietary intake purposes the residue levels are estimated on the edible portion of the commodity. In some cases, however, sufficient data on the edible portion is not available. In this case, STMR and HR are also estimated on the commodities to which Codex MRLs apply.

In addition to residues in or on the whole commodity, the JMPR is also interested in residues in the edible part of the crop. Residues of systemic pesticides may be expected to be present in all parts of the crop, while residues of non-systemic pesticides are not always present or may be present in minor quantities in the edible part of a crop. For each pesticide, information on the distribution between edible and non-edible parts should be available to the JMPR from

supervised trials or specific experiments. This information is also essential for deciding on the toxicological acceptability of the dietary intake of residues on or in food commodities. For example, MRLs are established for whole bananas including the inedible peel. Some MRLs may appear to be unacceptably high, based on residues on the whole commodity. However, information that residues in the edible portion are practically non-detectable often alleviates that concern. Another example is oranges where usually most residues are found in the peel, especially for non-systemic pesticides.

Besides primary and some processed food commodities, when the available information permits, JMPR also recommends MRLs for animal feeds and food processing by-products, e.g., apple pomace and grape pomace, which can be used as animal feed and are traded internationally. With the exception of fresh forage commodities, animal feeds are commodities of trade and therefore require Codex MRLs if pesticide use results in detectable residues in the feed. While JMPR no longer recommends maximum residue levels for fresh forage commodities, residues in these animal feeds are taken into account when estimating livestock dietary burdens. Residues in feed may also lead to detectable residues in animal tissues, milk and eggs, necessitating MRLs for those commodities. Some food commodities themselves, e.g., cereal grains, may be used as feedstuffs for food-producing animals.

6.2 COMPARABILITY OF SUPERVISED TRIAL CONDITIONS TO GAP

General principles

When estimating maximum residue levels, the FAO Panel examines all residue data arising from supervised trials supporting or reflecting the reported GAPs. As a general precondition, for reliable estimation of maximum residue levels an adequate number of independent trials are required reflecting the highest of national maximum GAPs and conducted according to well designed protocols that consider geographical distribution and the inclusion of a number of different growing and management practices, and growing seasons.

Firstly, the uniformity or continuity of residue population reflecting GAPs is considered. When there is a large gap in residue values, indicated by a high coefficient of variation of residues in composite samples or other appropriate statistical methods, the presence of different populations may be suspected. In such cases the residue data and trial conditions need more stringent analysis before residue levels for MRL, STMR or HR can be estimated.

The decline rate of a pesticide may vary between different geographical locations due to such factors as the weather, cultivation practices and soil conditions. Under practical conditions the number of trials which can be performed for a given commodity is limited. Nevertheless, a larger data set *representing a statistically, not different residue population* provides a more accurate estimation of the selected percentile than a small data set derived from trials representing only one critical GAP. Consequently, where only limited number of trial data is available from a GAP, assumed to lead to the highest magnitude of residues, one approach is to consider those GAPs which may possibly lead to a similar magnitude of residues, and this assumption can be confirmed based on prior experience and with suitable statistical methods. However, caution must be exercised in combining residue data populations of statistically different magnitude, as it may lead to erroneous estimation of maximum residues, when based on statistical methods (described in the following section), and an underestimation of the dietary intake.

The JMPR takes into account the following general principles in selecting the residue data population(s) for the estimation of maximum residue levels, STMR and HR values.

Only the results of “supervised trials conducted at the highest nationally recommended, authorized or registered uses”, i.e., maximum application rate, maximum number of treatments, minimum pre-harvest interval (PHI), are considered in estimation of maximum residue levels, i.e., maximum GAP per country.

If a sufficient number of trials are available, reflecting the maximum GAP of one country or geographical region, the MRL estimates should be based on those residue data alone.

Where prior experience indicate that the agricultural practice and climatic conditions lead to similar residues, the critical GAP of one country can be applied for the evaluation of supervised trials matching this critical GAP but carried out in another country.

The Meeting does not consider it appropriate to combine residue data sets deriving from different GAPs without sufficient justification. This method could include residue data with different median (mean) values, which would result in lower estimated daily intake and also lower MRLs if the latter would be calculated based on statistical methods, e.g., using the NAFTA statistical calculator.

When considering combining different residue data, the distribution of residue data is carefully examined and only those datasets combined which may be expected to arise from the same parent populations, based on comparable GAP. In such cases expert judgement can be assisted with appropriate statistical tests, e.g., Mann-Whitney U-test or Kruskal-Wallis H-test.

In establishing comparability of residue trials data in which more than one parameter, i.e., application rate, number of treatments or PHI, deviate from the maximum registered use, consideration should be given to the combination effect on the residue value which may lead to an underestimation or overestimation of the STMR. Generally, trials should not be used where two critical parameters of GAP deviate. For example, a trial result should not normally be selected for the estimation of the STMR if both the application rate is lower (perhaps 0.75 kg/ha in the trial; 1 kg ai/ha GAP) than the maximum rate registered and the PHI is longer (perhaps 18 days in the trial, 14 days GAP) than the minimum registered PHI, as these parameters could combine to underestimate the residue. When results are selected for the estimation of STMRs and HR values, despite combination effects, the reasoning should be outlined in the appraisal.

If a residue value is lower than another residue value from the same trial which is within GAP, then the higher residue value should be selected in identifying the STMR and HR values. For example, if the GAP specified a minimum PHI of 21 days and the residue levels in a trial reflecting GAP were 0.7, 0.6 and 0.9 mg/kg at 21, 28 and 35 days respectively, then the residue value of 0.9 mg/kg would be selected.

Application rate

The actual application rates in the trials should generally deviate no more than $\pm 25\%$ of the maximum application rate. Deviations from this should be explained in the appraisal.

Pre-harvest interval

The latitude of acceptable intervals around the PHI depends on the rate of decline of residues of the compound under evaluation. The allowable latitude should relate to a $\pm 25\%$ change in residue level and may be estimated from residue decline studies. As the rate of decline is gradually decreasing, the deviation corresponding to the +25% concentration is shorter than that reflecting the -25% concentration. The ranges around the label PHI for accepting supervised trials data are wider for a slowly declining residue than a rapidly declining residue.

The situation for 1st order decline is illustrated²⁶ in Figure 6.1. Where the information available does not enable applying this principle, the ±25% permissible deviation recommended by the OECD Guidelines may be applied, but it should be based on a case by case assessment, as in case of -25% PHI and rapidly declining residues it may lead to acceptance of larger residues than + 25%.

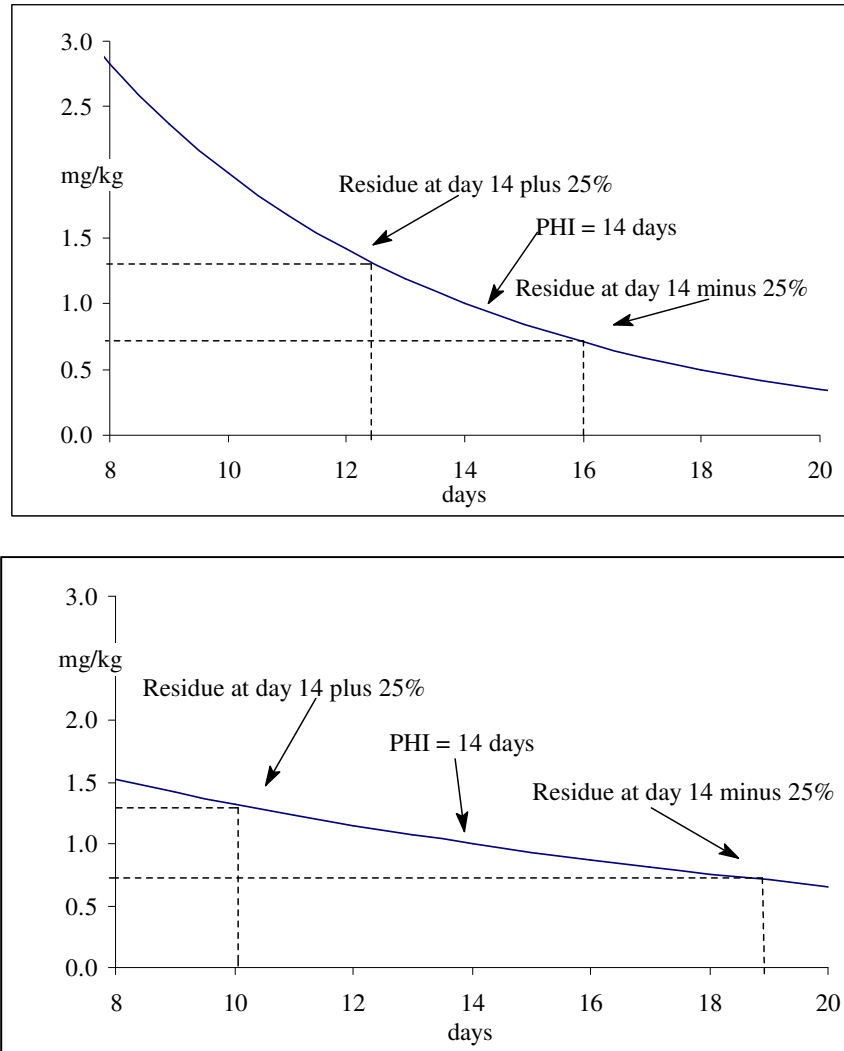


Figure 6.1 Illustration of latitude of permissible ± deviation from the PHI indicated on the label

For first order decay

$$C = C_0 \times e^{-kt} \dots\dots\dots 1$$

At time t_1 , $C_1 = C_0 \times e^{-kt_1}$

At time t_2 , $C_2 = C_0 \times e^{-kt_2}$

$$\frac{C_1}{C_2} = e^{-k(t_1 - t_2)}$$

$$-k(t_1 - t_2) = \ln\left(\frac{C_1}{C_2}\right) \dots\dots\dots 2$$

²⁶ Hamilton, D., Personal communication, 2009

Relation between k and $t_{1/2}$ (half-life)

$$\frac{C}{C_0} = 0.5 = e^{-kt_{1/2}}$$

$$\text{i.e., } -k = \frac{\ln(0.5)}{t_{1/2}} \dots\dots\dots 3$$

From 2 and 3

$$\frac{\ln(0.5)}{t_{1/2}} \times (t_1 - t_2) = \ln\left(\frac{C_1}{C_2}\right)$$

$$\text{i.e., } t_1 - t_2 = \ln\left(\frac{C_1}{C_2}\right) \times \frac{t_{1/2}}{\ln(0.5)} \dots\dots\dots 4$$

If t_1 is the PHI and C_1 is the residue concentration at the PHI, we can calculate the time intervals where the concentration is within \pm a chosen percentage.

$$C_2 = 125\% \text{ of } C_1 \qquad t_1 - t_2 = 0.32 \times t_{1/2}$$

$$C_2 = 75\% \text{ of } C_1 \qquad t_2 - t_1 = 0.42 \times t_{1/2}$$

When the PHI is more than a few days, the estimation of half-life should exclude the data from day 0 (day of application) because the initial decline of residues is generally much faster than the later decline. As the 1st order decline provided the best fit for about 35% of cases²⁷ of large number of trials, the calculation described with equations 1–4 may not always provide reliable estimates. However, the graphical method shown in Figure 6.1 can be used for any situation.

Number of treatments

Consideration of whether the number of applications reported in trials is comparable to the registered maximum number will depend on the persistence of the compound and the interval between applications. Nevertheless, when a large number of applications are made in trials (more than 5 or 6) earlier treatments should not be considered to contribute greatly to the final residue unless the compound is persistent or the treatments are made with unusually short intervals. Residue data are sometimes provided from just prior to the final treatment as well as after it, which is direct evidence of residue contributions from previous applications to the final residue. Also, treatments from more than about 3 half-lives (obtained from residue decline trials) prior to the final treatment should not make a significant contribution to the final residue.

Formulation

In many situations different formulations would cause no more variation than other factors, and data derived with different formulations would be considered comparable. The most common formulation types which are diluted in water prior to application include EC, WP, water dispersible granules (WG), suspension concentrates (SC) (also called flowable concentrates), and soluble concentrates (SL). Experience from trials demonstrates that these formulations lead to similar residues. Residue data may be translated among these formulation types for applications that are made to seeds, prior to crop emergence, i.e., pre-plant, at-plant, and pre-emergence applications, just after crop emergence or directed to the soil, such as row middle or post-directed applications (as opposed to foliar treatments).

²⁷ Timme, G.; Frehse, H., Laska, V. Statistical interpretation and graphic representation of the degradation behaviour of pesticide residues II. Pflanzenschutz-Nachrichten Bayer 33. 47-, Pflanzenschutz-Nachrichten Bayer, 1986, 39, 187-203.

For late season foliar applications of formulations diluted in water, the decision on the need for additional data depends upon two factors: (1) the presence of organic solvents or oils in the product and (2) the pre-harvest interval. Provided the pre-harvest interval is longer than 7 days, formulations without organic solvents or oils will be considered equivalent for residue purposes. With the exception of water dispersible granular formulations, when the PHI is less than or equal to 7 days, bridging data will normally be needed to show residues are equivalent from these formulations.

For mid- to late-season uses of formulations containing organic solvents or oils, e.g., EC, or water in oil emulsions (EO), bridging studies should be provided to establish whether the residues resulted from their application are comparable to those obtained with another formulation.

6.2.1 Interpretation tables for supervised trials data

When residue data are available from several countries the results may be tabulated to show the comparison of trial conditions with GAP to assist with interpretation. In the example in Table XI.1 residue data on tomatoes from six countries are compared with GAP. Note that some countries specify application rate (kg ai/ha) while others specify spray concentration (kg ai/hL) in their GAP. Italian trials may be evaluated against the conditions of Spanish GAP.

This concept may also be used for tabulation of trial data used for evaluations of alternative GAP.

The interpretation table provides the set of residues that match maximum GAP from the various countries. The next step is to decide if the residues constitute a single population or different populations.

6.3 DEFINITION OF INDEPENDENT SUPERVISED RESIDUE TRIALS

The estimation of maximum residue level, STMR and HR values relies on the selection of residue data from trials within GAP. One data point (residue value) is selected from each relevant and independent trial. A sufficient number of trials are needed to represent field and cultural practice variability.

Judgements are needed on whether trials should be considered sufficiently independent to be treated separately.

The following trial conditions are usually recorded and are taken into consideration:

- geographical location and site – trials at different geographic locations are considered independent
- dates of planting (annual crops) and treatments - trials involving different planting dates or treatment dates are considered independent
- crop varieties – some varieties may be sufficiently different to influence the residue
- formulations – comparability or independence of trials with different formulations should to be assessed taking into account the principles described in sections 6.2 and 6.5
- application rates and spray concentrations – trials at significantly different application rates and spray concentrations are counted as separate trials;

- types of treatment, e.g., foliar, seed treatment, directed application – different types of treatment on different plots at the same site are considered as separate trials
- treatment operations – trials at the same site treated in the same spray operation are not counted as separate trials
- application equipment – trials at the same site treated by different equipment, other things being equal, are not counted as separate trials
- addition of surfactants – a trial with the addition of surfactant may constitute sufficient difference to be treated as independent.

As weather (not climate) is usually a major factor in determining the resultant residues for such trials, only one field trial would normally be selected per trial site if multiple plots/trials are conducted in parallel. For trials at the same location there should be convincing evidence that additional trials are providing further independent information on the influence of the range of farming practices on residue levels.

Various situations may apply when several residue values are described as “replicates” such as when there are:

- a. replicate analysis samples from one laboratory sample (duplicate analysis)
- b. replicate laboratory samples obtained with sub-division from one field sample
- c. replicate field samples analysed separately (each sample is taken randomly through a whole sprayed plot)
- d. replicate plots or sub or split-plot field samples are analysed separately (the whole trial is subject to the same spraying operation, but it is divided into 2 or more areas that are sampled separately)
- e. replicate trial samples are analysed separately (trials from the same site that are not independent may be considered as replicate trials).

The reviewer should therefore specify the type of replicate when preparing the monograph.

The highest value of the residues from replicate field samples (c, d, e) should be taken as the single value for the trial, while the mean value of residues obtained from replicate test portions (a) withdrawn from one laboratory sample or from replicate laboratory samples (b) shall be used for the purpose of identifying the STMR or HR value or estimating the maximum residue level.

6.3.1 Treatment of apparent outliers

Residue values above the majority of the population have to be treated individually and should only be disregarded if there is adequate information, experimental evidence to justify their exclusion. At the time of evaluating the results, utmost care is required to decide that a result is invalid. The exclusion of an apparent outlier must be justified by agricultural practice or other evidence deriving from the experimental set up or analytical conditions.

6.3.2 Residues below LOQ

As a general rule, where all residue trials data are < LOQ, the STMR value would be assumed to be at the LOQ, unless there is scientific evidence that residues are “essentially zero”. Such supporting evidence would include residues from related trials at shorter PHIs, exaggerated,

but related application rates or a greater number of applications, expectations from metabolism studies or data from related commodities.

Where there are two or more sets of trials with different LOQs, and no residues exceeding LOQ have been reported in the trials, the lowest LOQ should normally be used for the purpose of selection of the STMR value (unless the residues can be assumed to be essentially zero as given above). The size of the trials database supporting the lowest LOQ value should be taken into account in the decision.

The HR value should also be assigned a level of 0 when there is evidence that the residues are “essentially zero”.

6.3.3 Rounding of residue values

In identifying the STMR or HR value from a residue trial, the actual residue value reported should be used in the estimation of dietary intake without rounding up or down. This would even be the case where the actual results were below the practical LOQ considered appropriate for enforcement purposes. Rounding of residue values is inappropriate since the STMR and HR value are used at an intermediate stage in the dietary intake calculation.

6.4 COMBINING OF DATA POPULATIONS

As a general precondition, for reliable estimation of residue levels an adequate number of independent trials are required which reflect the national maximum GAP and conducted according to well designed protocols that consider geographical distribution and the inclusion of a number of different growing and management practices, and growing seasons.

Under practical conditions the number of trials which can be performed for a given commodity is limited. On the other hand, a larger data set *representing statistically not different residue population* provides more accurate estimation of the selected percentile of residue population than a small data set derived from trials representing the critical ‘one’ GAP.

In estimating an STMR, the JMPR evaluates whether data sets for a given commodity or commodity group should be combined and whether residue data reflecting different countries’ GAPs should be combined, provided that the GAP-s are similar.

The inevitable sampling variation may lead to an inaccurate estimation of the true residue population resulted from the use of a pesticide according to maximum GAP. In deciding whether the results of trials reflecting different countries’ GAPs give rise to different populations of residues data, the size of the database reflecting the different countries’ GAPs should be taken into account. Statistical tools are available that can be used to ascertain if data sets come from populations characterized by similar median/mean and variance.

In view of the skewed distribution of residues and the difficulties of describing the residue distribution with parametric methods, distribution free statistical methods should be applied for testing the similarity of sample populations.

Statistical tests are useful tools in the evaluation of pesticide residue trial data. However, due to the complexity of the task, which includes the consideration of several factors such as metabolism and rate of disappearance, such tests are not definitive and can only support expert judgement.

The field to field variation of residues skewed towards the high values do not follow normal distribution, even if this might be indicated by statistical tests based on small data sets.

Consequently, distribution free statistics should be used for comparing two or more residue data sets.

The JMPR routinely use the Mann-Whitney U-test in comparing two data sets to assess whether they can be combined. For cases where more than two data sets are to be compared the U-test is not applicable, in which case the Kruskal-Wallis H-test may be used. Their principles are explained in the next sections, and the calculation can be performed automatically with the Excel template which can be downloaded from <http://udel.edu/~mcdonald/statkruskalwallis.html>. As usual if the calculated probability is larger than 0.05 the null hypothesis is accepted and the data sets can be combined.

6.4.1 The Mann-Whitney U-test

Test statistics (U_1 and U_2) are calculated using the individual results from both residue populations and then the smaller test statistic is compared to a tabulated critical value ($\alpha_2=5\%$). Where the test statistic is less than or equal to the tabulated value, the two median values are considered to be similar.

The JMPR has agreed to combine residue populations where GAPs were similar and where the U-test suggested their medians are similar and to use the combined population for the estimation of maximum residue levels and STMR values. Where the populations are different, only the population which contained the highest valid residue value for both estimates is used.

Example: tebufenozide

Residue populations of mandarin and orange flesh from Italy and Spain were compared using the Mann-Whitney U-test to determine whether the populations were similar or different.

Residues in mandarin flesh: 0.069, 0.076, 0.082, 0.092, 0.14, 0.18 mg/kg

Residues in orange flesh: 0.021, 0.03, 0.04, 0.04, 0.05, 0.053, 0.11, 0.13, 0.13, 0.15 mg/kg

The test statistics, U_1 and U_2 values, are calculated as:

$$U_1 = n_1n_2 + [n_1(n_1+1)]/2 - \Sigma R_1$$

$$U_2 = n_1n_2 + [n_2(n_2+1)]/2 - \Sigma R_2$$

Where:

- n_1 and n_2 are the number of data points in populations 1 and 2 respectively (n_1 and ΣR_1 are assigned to the smaller when the sample sizes are different)
- ΣR is the sum of ranks of the corresponding values

The calculation for Mann-Whitney U-test is shown in Table 6.1

1. In a table, list all the measurements from lowest to highest. Use bold or coloured fonts to distinguish between the two data sets.

Table 6.1 Illustration of the calculations for the U-test

Residues (mg/kg)	Ranks for mandarins	Ranks for oranges
0.021		1
0.03		2
0.04		3.5
0.04		3.5
0.05		5
0.053		6
0.069	7	

Residues (mg/kg)	Ranks for mandarins	Ranks for oranges
0.076	8	
0.082	9	
0.092	10	
0.11		11
0.13		12.5
0.13		12.5
0.14	14	
0.15		15
0.18	16	
Σ Rank	64	72
U values	$U_1 = 17$	$U_2 = 43$
Critical Value ($n_1 = 6, n_2 = 10, \alpha_2 = 5\%$)		11
$U_1 > 11$	Populations similar	

- In a column for each population, place the corresponding ranks next to each measurement. For ties assign the average of the ranks, e.g., for 0.04, 0.04 the ranks are 3.5 and 3.5 instead of 3 and 4.
- Calculate the sum of the ranks for each population.
- Calculate the U values using the above equations ($U_1 = 17; U_2 = 43$).
- Check the correctness of the calculation ($U_1 + U_2 = n_1 n_2$).
- Compare the lower U value with the tabulated critical value (Appendix XIII). The critical value is 11 ($n_1 = 6, n_2 = 10$). Since U_1 is greater than 11, it is concluded that the samples probably came from populations with the same median.

As the lower of U_1 and U_2 is greater than the critical value of 11 it can be concluded that the populations have similar distributions and can be combined for the purposes of estimating an STMR value. This conclusion has an effect on the calculation of the long-term intake of the residues, as the median values for the individual populations were 0.087 mg/kg for mandarin flesh and 0.0515 mg/kg for orange flesh instead of 0.079 mg/kg for the combined population.

6.4.2 Kruskal-Wallis H-test

Kruskal-Wallis H-test assumes that the samples are taken from continuous populations of similar shape, the errors in individual residue values are independent. It is applicable for k independent samples, provided that the data sets are not too small (≥ 4). For the purpose of the test, samples are independent if the supervised trials have been carried out at different sites.

The null hypothesis, H_0 , is that the k independent sets of samples were taken from the same parent population. The alternative hypothesis is that the samples come from different populations. However, if the null hypothesis is rejected we do not know whether the median values, the shape or the variance of the tested populations are different.

The calculation is illustrated in Table 6.2 with the example of deltamethrin residues in leafy vegetables (2002 JMPR) and performed as follows:

The residue values belonging to the k data sets consisting of N_i residue values are marked with different colours and or letters to differentiate the data sets from each other.

Table 6.2 Illustration of the calculations for Kruskal-Wallis test for comparison of multiple independent samples

	Independent residue data sets			All residues	Corrected ranks	Corrected rank numbers for sample sets			Ties	T _j
	Curly kale	Lettuce	Spinach			Curly kale	Lettuce	Spinach		
No of data	8	10	16	34	34	8	10	16		
Sum of ranks, R _i					595	160	215.5	219.5	17	156
R _i ² /N _i						3200	4644.02	3011.27		
	0.07	0.07	0.03	0.03	1.5			1.5	2	6
	0.08	0.12	0.03	0.03	1.5			1.5		
	0.1	0.13	0.04	0.04	3			3		
	0.11	0.15	0.06	0.06	4			4		
	0.32	0.18	0.08	0.07	5.5	5.5			2	6
	0.32	0.18	0.09	0.07	5.5		5.5			
	0.34	0.25	0.09	0.08	7.5	7.5			2	6
	0.39	0.26	0.1	0.08	7.5			7.5		
		0.29	0.1	0.09	9.5			9.5	2	6
		0.41	0.1	0.09	9.5			9.5		
			0.1	0.1	13	13			5	120
			0.14	0.1	13			13		
			0.17	0.1	13			13		
			0.2	0.1	13			13		
			0.5	0.1	13			13		
			1	0.11	16	16				
				0.12	17		17			
				0.13	18		18			
				0.14	19			19		
				0.15	20		20			
				0.17	21			21		
				0.18	22.5		22.5		2	6
				0.18	22.5		22.5			
				0.2	24			24		
				0.25	25		25			
				0.26	26		26			
				0.29	27		27			
				0.32	28.5	28.5			2	6
				0.32	28.5	28.5				
				0.34	30	30				
				0.39	31	31				
				0.41	32		32			
				0.5	33			33		
				1.0	34			34		

Combine the residues from the k data sets in one data set consisting of $N = \sum N_i$ residue data, and arrange the residues in ascending order.

Determine the rank number of individual residues (r_i) giving the same rank for the same residue values (ties) and calculate the sum of the ranks (R_i) for each data set.

Calculate the H statistics and the correction factor (C_f) for the ties.

$$H = \frac{12}{N(N+1)} \sum_{i=1}^k \left(\frac{R_i^2}{N_i} \right) - 3(N+1)$$

The calculated H value is 4.465

$$C_f = 1 - \frac{\sum_j T_j}{N^3 - N}$$

Where $T_j = t^3 - t$, and t is the number of ties. For instance the residue values of 0.03 occur twice, so $t = 2$ and $T_j = 2^3 - 2 = 6$. The value of 0.1 occurs 5 times, so $t = 5$ and $T_j = 5^3 - 5 = 120$.

Calculate the corrected H_c value:

$$H_c = \frac{H}{C_f}$$

The calculated C_f and H_c values are 0.9960 and 4.4829, respectively

The H_c value follows χ^2 (chi square) distribution with $\mathbf{v} = \mathbf{k}-1$ degrees of freedom. If $H_c \leq \chi_{0.05, v}^2$ the null hypothesis is retained, this indicates that the tested residue populations are not significantly different and can be combined for the estimation of maximum residue levels and STMR values.

The critical $\chi_{0.05}^2$ values are:

v	2	3	4	5	6
$\chi_{0.05}^2$	5.9915	7.8147	9.4877	11.0705	12.5916

In our example $v = 3-1=2$, the corresponding critical value is 5.99, consequently we can conclude that the three populations tested are not significantly different from each other and can be combined.

The performance of the Kruskal-Wallis test is facilitated by an Excel template, which performs the calculations for 7 data sets after inserting the residues composing of the data sets and arranging the ranks corrected for ties for each sample set.

The ranks are corrected for ties accurately if the sum of corrected ranks is equal to the total number of samples.

6.5 ESTIMATION OF MAXIMUM RESIDUE LEVELS

The JMPR examines the possibility of estimating maximum residue levels based on the residue values selected from submitted information and trial data, and subsequently proposes Maximum Residue Limits in commodities for pesticides used according to Good Agricultural Practice.

In estimating maximum residue levels, the FAO Panel takes into account all relevant information and especially the residues arising from supervised trials (see Chapter 3, Section 5 '*Residues resulting from supervised trials on crops*') and the congruence of the trial conditions and the established GAP. (See Chapter 3, Section 4 '*Use Patterns*' and Chapter 5, Section 6 '*Information on good agriculture practice*'.) The procedure for estimating and recommending Codex MRLs may be somewhat different from that applicable at national level as Codex MRLs cover residues derived from authorized uses worldwide and therefore reflect

a variety of agricultural practices and environmental conditions while at the national level MRLs are more related to the national GAP.

Although supervised residue trials are conducted according to the GAP prevailing at the time, GAP can often be modified by changes in the rate of application, the type of formulation, the method of application, the number of applications and PHI. Judgement is then required in order to determine whether the trial conditions are still close enough to GAP to be relevant.

6.5.1 Information considered in estimating maximum residue levels

The nominal rate of application in a trial would normally be considered still consistent with GAP when it is within approximately $\pm 25\%$ of the GAP rate, which includes the probable variation in commercial practice. When little or no residue is present, data from higher application rates may be important.

Formulations

See sections 3.5.1.2, 5.3 and 6.2

Application method and number

The method of application can be quite influential on residue levels. For example, directed application is not comparable to cover spray, and aerial application may not be comparable to ground application.

For a non-persistent pesticide the number of applications is unlikely to influence residue levels. For a persistent pesticide the number of applications would be expected to influence residue levels. The nature of the crop should also be considered. For example, summer squash may be harvested only a few days after flowering; hence residues of a non-systemic pesticide applied before flowering would be expected to be low and the number of applications should have little influence on the residue level.

Pre-harvest interval

The pre-harvest interval usually, but not always, influences the level of residues found. (See section 6.2. “*Comparability of supervised trial conditions to GAP*”).

Non-detectable residues

Some pesticide uses, such as seed treatments and pre-emergence herbicide treatments, usually lead to non-detectable residues in the final harvested commodity; but when many results are provided residues may be detected in occasional samples. While residues resulting from use according to GAP are most likely to be undetectable, the occasional detectable residues should not be ignored when a maximum residue level is estimated. Phorate on potatoes and residues arising from the pre-planting application of glyphosate are two examples.

Climate

Greater certainty that the climatic conditions are properly reflected in the supervised trials is afforded when the trials are carried out in a country with established GAP and reflect the range of climatic conditions and crop management practices within that country. Trials conducted in other countries with similar climatic conditions and crop management practices may be acceptable on a case-by-case basis. An assessment of those conditions is difficult, and a critical evaluation is needed as only some difference in conditions, such as temperature or intensity of sunlight, may be of great importance for the persistence of many pesticides and consequently for the residue level.

Crop description

The CCPR establishes MRLs on commodities as they move in trade to enable the control of compliance with and enforcement of GAP. Consequently, the maximum residue levels are estimated on a whole commodity basis (see Appendix VI) as far as practical.

The trials should be carried out with the same crops as those specified in the national GAPs. The proper description of the crops used in the supervised trials is important for deciding if crops referred to in GAP are in accordance with those for which trials have been carried out. Codex Classifications should be used for describing harvested commodities. A crop description such as “beans” is difficult to interpret because of the wide variety of beans grown. A more specific description is needed. Foliar application to head lettuce and leaf lettuce may produce different residue levels, so it may not be possible to use trials for a crop simply described as “lettuce”.

Crop groups such as leafy vegetables, cole crops and grain legumes on national labels may not have the same meaning as the Codex commodity groups. It is necessary to check the crops included in a national label crop grouping.

Variability of residues

An awareness of the expected variability of residues is necessary. If the data truly reflect the range of conditions, application methods, seasons and cultural practices likely to be encountered commercially, then considerable variation in the resulting residue levels is expected. Analysis of supervised trials evaluated by the JMPR between 1997 and 2007 revealed that the coefficient of variation of residues between fields can sometimes be over 110%. Where copious data are available, consideration of the spread and variability of the residues helps to avoid misleading interpretations of small differences in estimates of the maximum level. Where only limited data are available, which is the case for the majority of supervised data sets (most frequently 8–9)²⁸ actual variability may be underestimated and judgement is required to arrive at an estimate that is realistic, practical and consistent. It is not a criticism to say that the data are widely spread and variable. If results have been obtained at a number of places over some years they are likely to be a better approximation to commercial practice and will be widely spread. In addition to the variability of residues within a confined area which can be considered uniform regarding climate, agricultural practices, pest situation and use recommendations, there may be an even greater variation of residues among areas of widely differing conditions, e.g., countries being in temperate, Mediterranean and tropical zones. The differences in use conditions can be so large that they result in different residue populations (see section 6.4 “*Combining of data populations*”).

Frequently the situation is complex even when much data and information is available. There can be alternative interpretations, and judgement is required to arrive at an estimate that is realistic, practical and consistent.

6.5.2 Principles of selection of residue data for estimation of MRLs

When estimating maximum residue levels, the FAO Panel examines all residue data arising from supervised trials supporting or reflecting the reported GAPs.

In the case of suspected multiple residue populations, limited data indicating the high population may not be sufficient to estimate a maximum residue level reflecting that population (and use pattern), and the FAO Panel may estimate a maximum residue level reflecting only those uses for which sufficient residue data are available. On the other hand, it

²⁸ FAO Pesticide Residues in Food 2008- Report. FAO Plant Production and Protection Paper No. 193 FAO, Rome.

is not possible to reconsider and reduce a previous estimate based on a new small trial data set indicating lower residues, unless the GAP on which the old recommendation was based has been changed or the original trials on which the MRL were estimated are now considered inadequate.

In accordance with the Codex definitions and general practice of the JMPR, the maximum residue levels are primarily estimated based on the GAP that leads to the highest residue (ONE GAP, the critical or maximum GAP), i.e., the trials represent the maximum residue anticipated when a pesticide is applied according to the one GAP (label directions, usually maximum permitted application rate, shortest PHI). Application should be made using equipment and spray volumes likely to give rise to the highest residues. The Codex Alimentarius definition (JMPR practice) implies that only the results of “supervised trials conducted at the highest nationally recommended, authorized or registered use” are included in MRL estimation, i.e., one maximum GAP per country, and one of these is used to select data for MRL estimation. To ensure the residue values selected for estimating maximum residue levels are independent, only one field trial would normally be selected per trial site if multiple plots/trials are conducted in parallel. See also section 6.2.

The focus on the maximum GAP allows for alternative GAP to be assessed if there is an identified dietary intake problem. In such cases, where residue data permits, an alternative national GAP is considered and the supporting residue data sets are used for estimation of MRLs which do not raise acute intake concern.

Maximum residue level estimates may be based on an accepted/recognized extrapolation of trial data to cover commodities within a group which had shown a similar residue pattern. Principles used for the evaluation of data sets for one pesticide×commodity combination may be applied for evaluation of residues within one commodity group, e.g., application of ‘one GAP’ principle for estimating MRL for a group based on the highest residues data set obtained in one commodity.

There may be some situations which are not covered by the general principles outlined in this section. Such cases require a case-by-case consideration and expert judgement based on all available information and prior experience.

In cases, where only small number of residue data is available, MRL estimates should take into account:

- the highest values, median value and approximate 75th percentile value in the available data set of supervised residue trials
- residue levels resulting from application rates other than the label rate (for instance, using residues below LOQ in samples derived from double rate treatments to support no detectable residues following the application at maximum label rate, using highest residues from samples taken at longer intervals than PHI)
- experience of typical distributions of residue data from supervised trials
- knowledge of residue behaviour from the metabolism studies, e.g., is it a surface residue, does it translocate from foliage to seeds or roots
- knowledge of residue trials on comparable crops.

6.6 SPECIFIC CONSIDERATIONS IN ESTIMATING MAXIMUM RESIDUE LEVELS FOR INDIVIDUAL COMMODITIES

6.6.1 Fruits and vegetables

All the previously described general considerations apply for estimating maximum residue levels in fruits and vegetables. Applications on fruit and vegetables may take place at any stage of the developments of the plants and in the soil before and after sowing, and the residue levels are highly dependent on the treatment.

The pre-harvest interval (PHI) is usually an important component of GAP that has a strong influence on the resulting residues. It is especially important for fruit and vegetables for foliar application close to harvest. See Chapter 6 section 2 “*Comparability of supervised trial conditions to GAP*” for the latitude of acceptable intervals around the PHI.

The whole fruit residue level may sometimes be derived from residue data obtained separately for peel and pulp if the weights of peel and pulp are available.

6.6.2 Grains and seeds

Maximum Residue Limits for seeds or grains apply to the whole commodity. It is important for the JMPR to be able to distinguish between the forms in which the commodities are present and to describe the raw and processed commodities according to the Codex Commodity Classification, as some grains and seeds are still in the husks and others are without husk. Sometimes residues are reported in polished rice. The residue levels are usually considerably different for those sorts of commodities. The estimation of the maximum residue levels should be based on residues in commodities which may move in international trade.

When grains and seeds are milled, the commodities belong to the processed commodities.

6.6.3 Forage and fodder

Pesticides are needed in the production of animal forage and fodder crops, so residues in the resulting forage and fodder may be expected.

The succulent or high-moisture stages of the crop are known as forage and mostly are grazed directly or are cut and fed to livestock without delay. Examples are: maize forage, alfalfa forage and pea vines. The dry or low-moisture stages of the crop are known as hay, straw or fodder, which may be readily stored and transported as commodities of trade.

In the past, JMPR has recommended MRLs for forage crops and has used information on their residue status in estimating farm animal dietary burden. The 2002 JMPR decided that forage was not an item of international trade requiring Codex MRLs and would no longer recommend MRLs for forage commodities. Forage residue data would continue to be evaluated and used in the estimation of farm animal dietary burden.

MRLs are recommended for fodder which is an item in international trade.

6.6.4 Animal products

When residues occur in crops and animal feeds there is the potential for residues to be transferred to animals. The results of farm animal feeding studies and residues in animal feed and processing by-products of food serve as a primary source of information for estimating animal commodity maximum residue levels (See also Chapter 3 section 9 “*Information and data from farm animal feeding and external animal treatment studies*” and Chapter 6 section

12 “*Estimation of maximum residue levels and STMR values for commodities of animal origin*”). In addition, animal metabolism studies may also provide useful information.

Uptake of pesticides by animals can lead to residues in animal products following either direct application of the pesticide to the animal or its housing, or ingestion of feed containing pesticide residues.

Animal feeds with residues of pesticides may derive from:

- crops produced mainly for animal feed, e.g., pasture, straw, forage,
- crops produced mainly for human food which are fed to animals, e.g., cereal grains,
- waste from crops grown primarily for human food, e.g., skins, pulp, stems, stubble or trash,
- animal feeds that have not themselves been treated, but in which environmental contaminants occur, for example, from crops or pastures grown in DDT contaminated soil.

When animals are fed, the potential for dilution of feed residues is considerable. Not all producers of the primary crop are likely to have used the same pesticide simultaneously, and the pesticides used are not always used at their highest permitted use rates or at the nearest time to harvest. However, the animals could be exposed for extended periods to certain commodities such as fodder, grain and feeds treated post-harvest which contain residues at the highest level²⁹. For example, on a farm on which 20 ha of an animal feed (forage, fodder or grain) were grown per year with a yield of 10 t/ha on a dry weight basis, enough would be produced to feed 333 head of cattle for 1 month. If the feed constituted less than 100% of the diet, more head of cattle could be fed for 1 month, or the duration of feeding might be longer. On the other hand, it is unlikely that the individual ingredients of mixed feeds produced from commercially available ingredients would all contain residues at the theoretical maximum level. Consequently, the highest residues in individual feed items are used for estimating the maximum residue levels in animal commodities, and the STMR or STMR_P should be applied to each of the components of mixed commodities.

The 2002 JMPR³⁰ recognized that the practice followed in species selection for the recommendation of maximum residue levels for animal tissues, milk and eggs has not always been consistent. Following an evaluation of the results of animal transfer studies and taking into account current practices in many countries, the Meeting decided that when residues in animal products arise from residues in feeds, in general, the results of cattle feeding studies may be extrapolated to other domestic animals (ruminants, horses, pigs, rabbits and others) and laying hen feeding studies to other types of poultry (turkey, goose, duck and others). The suite of maximum residue levels recommended should be selected from: MM 0095 Meat (from mammals other than marine mammals)³¹, MO 0098 Kidney of cattle, goats, pigs and sheep, MO 0099 Liver of cattle, goats, pigs and sheep and ML 0106 Milks. Where residues in liver and kidney are essentially the same or nil, an option is to recommend a MRL for MO 0105 Edible offal (Mammalian). Maximum residue levels should be recommended for

²⁹ FAO, Pesticide residues in food, Report 2004, FAO Plant Production and Protection Paper No. 178 FAO, Rome p. 26

³⁰ FAO, Pesticide residues in food, Report 2002, FAO Plant Production and Protection Paper No. 172 FAO, Rome p. 22

³¹ muscular tissues with trimmable fat removed. For fat-soluble pesticides a portion of adhering fat is analysed and MRLs apply to the fat.

poultry and selected from: PM 0110 Poultry meat³², PO 0111 Poultry, Edible offal of³³ and PE 0112 Eggs.

The 2002 JMPR also noted that extrapolation based on direct animal treatment is generally not justified as there are significant species differences in residue transport through skin and in animal behaviour, e.g., grooming in cattle but not in sheep, that have implications for possible residues in tissues. Therefore, when residues arise from direct application to animals the resulting MRLs should relate to the species stated on the registered label and the animal studies provided, i.e., if the label use specifically applies to sheep MRLs should only apply to sheep commodities (meat, offal). The JMPR agreed that extrapolation to a second species would be considered where the uses were similar and where past experience suggests sufficient comparability between species.

The information from the animal metabolism and feeding studies and the likely levels of residues should support the decision to extrapolate. Extrapolation is encouraged to the group when there is no reason to expect higher residues than in cattle.

Some compounds are very readily metabolised or are quickly broken down in the presence of animal tissues, eggs or milk. In such cases the parent compound and sometimes their primary metabolites are not found in animal tissues, eggs or milk following exposure of animals to residues in their feed, irrespective of the feeding levels. Consequently, monitoring programs are unlikely to detect residues of such compounds in animal commodities.

When suitable farm animal metabolism and feeding studies and analytical methods are available for such compounds JMPR recommends MRLs at or about the LOQ for animal commodities. These recommended MRLs indicate that the situation has been fully evaluated and that, for the commodities moving in trade, residues should not occur above the stated LOQ. In such cases, a footnote is inserted under the recommended MRLs stating that '*no residues are expected from consumption of feed commodities with [xxx pesticide] residues as evaluated by JMPR*'.

Meat

For pesticides which are not fat-soluble, maximum residue levels are estimated for muscle tissue and recommended for use as MRLs for meat.

For fat-soluble pesticides, maximum residue levels are estimated based on residues in trimmable fat expressed on the lipid content. For those commodities, e.g., rabbit meat, where the adhering fat is insufficient to provide a suitable sample, the whole meat commodity (without bone) is analysed and the maximum residue level is estimated on the whole commodity basis.

Edible offal

The maximum residue levels are estimated on a whole commodity basis.

Milk and milk products

For milk it is known that the fat content varies widely among different breeds of dairy cattle. In addition, as there are a large number of milk products, with varying fat content, it would be impractical to propose separate MRLs for each product. It was therefore originally decided to

³² muscular tissues including adhering fat and skin from poultry carcasses as prepared for wholesale or retail distribution. For fat-soluble pesticides a portion of adhering fat is analysed and MRLs apply to the poultry fat.

³³ such edible tissues and organs, other than poultry meat and poultry fat, from slaughtered poultry as have been passed fit for human consumption. Examples: liver, gizzard, heart, skin.

estimate MRLs for fat-soluble compounds for milk and milk products on a fat basis, i.e., the residue levels expressed as if wholly contained in the extracted fat.

The JMPR had followed the CCPR convention³⁴, until 2007, of expressing the MRL for fat-soluble compounds in milk on a calculated whole product basis, assuming all milks contained 4% fat. (The residue is calculated for the whole product based on the residue measured in the fat.) For compounds which are not fat-soluble, the analytical portion for enforcement purposes is whole milk and MRLs are expressed on a whole milk basis. Many pesticides, however, have intermediate solubility in fat; even if they are regarded as fat-soluble, they can be distributed equally between the fat and non-fat portions of milk.

The 2007 JMPR decided that, for fat-soluble pesticides, two maximum residue levels would be estimated, if the data permitted. One MRL for whole milk and one for milk fat. For enforcement purposes, a comparison can be made between either the residues in milk fat with the MRL for milk (fat), or the residue in whole milk with the MRL for milk. When needed, maximum residue levels for milk products can then be calculated from the two values, by taking into account the fat content of the milk product and the contribution from the non-fat fraction. The 2008 CCPR agreed³⁵ that for regulation and monitoring of residues of fat-soluble pesticides in milk, where MRLs have been established for both whole milk and milk fat, whole milk should be analysed and the result should be compared with the Codex MRL for whole milk. The Committee asked the JMPR to insert a footnote to this effect for MRLs for whole milk in all cases where the MRLs have been established for both milk fat and whole milk.

Details of expressing residues in milk and milk products are given in this chapter in section 13 “*Expression of maximum residue limits.*”

Eggs

For eggs, the maximum residue level is estimated on the whole commodity after removal of the shell.

6.7 ESTIMATION OF GROUP MAXIMUM RESIDUE LEVELS STMR AND HR VALUES FOR PLANT COMMODITIES

The establishment of commodity group MRLs as opposed to MRLs for individual commodities has long been considered an acceptable procedure at both the national and international levels. The use of the approach recognises that economics may not justify residue trials on all of the individual crops in a group. It also follows logically national registration systems where the registered use may be on a crop group, such as citrus. In principle the approach recognizes that adequate data for the major crops of a group may be sufficient to estimate maximum residue levels for the whole group.

Some pesticides may behave differently in different circumstances. Consequently, it is not possible to define precisely those commodities on which trials will always provide data that can lead to a group MRL. If the “highest residue” situation can be identified, however, the relevant data can be extrapolated to other crops with confidence, although it is recognised that this approach may result in an over-estimate of residues in some commodities. An acceptable

³⁴ FAO/WHO 2000: Codex Alimentarius Volume 2B, Pesticide Residues in Food – Maximum residue limits. Joint FAO/WHO Food Standards Programme, page 4. Rome, 2000.

³⁵ Report of the fortieth session of the Codex committee on pesticide residues 2008, Alinorm 08/31/24, para 125 and 161, http://www.codexalimentarius.net/web/standard_list.do?lang=en

example is extrapolation of residue data from gherkins to cucumber; however, the converse is not possible due to the higher residues that can be expected in gherkins as a consequence of the difference in surface/weight ratio.

Extrapolation requires a detailed knowledge of local agricultural practices and growth patterns. For example, wheat is generally grown under similar practices around the world, but grapes may be grown utilising widely varying practices. For the latter, care must be taken to ascertain if the relevant GAPs are comparable. In view of the large differences in commodity surface texture, shape, plant growth habits, rate of growth and seasonal cultivation and the significant role played by the surface/weight ratio, the JMPR has emphasized that decisions to extrapolate should be made on a case-by-case basis when adequate relevant information is available.

As many factors can influence a decision to propose a group MRL the JMPR approaches the issue of setting group or individual MRLs on a case-by-case basis. The potential complexity of the process is highlighted by the current lack of international consensus on suitable criteria. These considerations have prevented the JMPR from developing specific guidance for group MRL estimation that might be applied at the international level.

Although no specific guidance is available, the following general principles and observations reflect the current views of the JMPR on estimating group MRLs.

- a. The use pattern (rate, application method, timing, PHI) should be the same and applicable for the whole crop group. Crops within a crop group should have similar physical nature, growth pattern and production characteristics, similar cultural practices and similar pests that require the same pesticide treatment.
- b. The nature of residues: systemic or non-systemic, degradation/disappearance rate.
- c. Relevant and adequate residue data should be available for at least one major commodity of the group. (However, all relevant data for the commodities of the group should be taken into account including Residue levels measured across several crop or commodity types.)
- d. The JMPR continues to rely on the Codex Classification of Foods and Feeds as the primary basis for recommending MRLs for individual or grouped commodities. The distinction between the crop group and the commodity group should be noted. The distinction is not always clear because the same words are used to describe the crop and the commodity, e.g., in one context, "pineapples" can mean the crop in the field and in another context "pineapples" can mean the fruit itself. For field uses, pesticides are applied to the crop, so it is the crop or crop group that should appear on pesticide product labels. MRLs and residues are expressed on commodities, so commodities and commodity groups appear in MRL tables.
- e. Generally the JMPR now refrains from estimating maximum residue levels for large Codex 'classes' of foods or feeds such as fruits, vegetables, grasses, nuts and seeds, herbs and spices, or mammalian products. Residue data and approved uses are usually more likely to refer to smaller Codex 'groups' such as pome fruits, citrus fruits, root and tuber vegetables, pulses, cereal grains, cucurbit fruiting vegetables, milks, meat of cattle, pigs and sheep. As well as being more likely to be supported by the available residue data and information on GAP, this approach is considered to be more in line with current national approaches and affords a more accurate estimation of dietary intake.

- f. In some cases the JMPR may, in the absence of sufficient data for one commodity, use data from a similar crop for which GAP is similar to support estimates of maximum residue levels, e.g., pears and apples or broccoli and cauliflower.
- g. After dietary intake assessment, commodity group MRLs may be proposed on the following minimum conditions³⁶:
 - The pesticide is registered or authorized for use on the crop group;
 - Relevant and adequate residue data are available for at least one major commodity of the group. (However, all relevant data for the commodities of the group should be taken into account.) If the recommended group MRL is subsequently found to be inadequate for some commodities and their registered uses, there would be no impediment to submission of further data to amend the group MRL or to propose specific commodity MRLs.
 - In line with the alternative GAP proposal, if the IESTI calculations suggested that short-term intake would exceed the ARfD of the compound for one or more commodities in the group, the JMPR would examine and recommend alternative proposals including alternative GAP and single commodity MRLs.
- h. If other considerations permit, data on residues in one or more of the major commodities with the potential for high residues within a group may allow estimates of maximum residue levels to be extrapolated to minor crops in the group. An example of where other considerations do not permit such extrapolation is where the variability of the residue levels is too great, despite there being data available on the major crop within the group. In such circumstance a group limit cannot then be estimated.
- i. When residue levels in a number of commodities in a group vary widely, separate recommendations should be made for each commodity. A limit for a group 'except one or more commodities' which are known to deviate from the norm may be justified, e.g., citrus fruits, except mandarins; in such cases separate MRLs should be estimated for the exceptional commodities.
- j. Residue data for a crop growing quickly in summer cannot be extrapolated to the same or related crops growing slowly under less favourable conditions, e.g., from summer to winter squash.
- k. In establishing group MRLs, detailed knowledge of the metabolism or mechanism of disappearance of a pesticide in one or more crops must be taken into account.
- l. Group MRLs recommended by the JMPR that generally appear to be acceptable include those listed in Table 6.1
- m. All else being equal, data may sometimes be extrapolated from a crop picked when immature but which grows quickly to maturity, to a closely related species with a lower surface area/weight ratio. Thus, because of dilution by crop growth, estimated maximum residue levels can be extrapolated from gherkins to cucumbers, but not vice versa.

³⁶ Report of the 39th Session of the CCPR (2007) para 34

- n. Individual MRLs can be extrapolated more readily to groups when there is no expectation that terminal residues will occur and when this is supported by studies of metabolism. Examples are early treatments, seed treatments and herbicide treatments in orchard crops.

While the JMPR generally follows these principles on a case-by-case basis, it recognizes certain difficulties or limitations in the acceptance of group limits at the international level. A primary weakness is the lack of formal criteria or an agreed mechanism to determine the members of a group for which data are needed before a group MRL can be established. One approach, as occasionally used at the national level, is to identify commodities of a group (often botanical) that represent both major crops within the group and those most likely to contain the highest residues. The factors used to determine whether a crop is a major or representative member of the group include its dietary significance as a food or feed.

Table 6.1 Examples for commodity groups and mutual support for estimation of maximum residue levels

Compound	Commodities with data supporting MRL	Group or commodities with MRL recommendation	Code
Pirimicarb	mandarin, orange	citrus fruits	FC
Thiabendazole	mandarin, orange	citrus fruits	FC
Bifenazate	apple, pear	pome fruits	FP
Fludioxonil	apple, pear	pome fruits	FP
Pirimicarb	apple	pome fruits	FP
Thiacloprid	apple, pear	pome fruits	FP
Bifenazate	apricot, cherry, peach	stone fruits	FS
Pirimicarb	cherry, nectarine, peach, plum	stone fruits	FS
Pyraclostrobin	cherry, peach, plum	stone fruits	FS
Thiacloprid	peach, sweet cherry	stone fruits	FS
Pirimicarb	currant, gooseberry, raspberry	berries and other small fruits (except grapes and strawberries)	FB
Thiacloprid	currant, raspberry, strawberry	berries and other small fruits (except grapes)	FB
Endosulfan	avocado, custard apple, mango, papaya	mutual support: avocado, custard apple, mango, papaya	FI
Endosulfan	litchi, persimmon	mutual support: litchi, persimmon	FI
Pirimicarb	broccoli, Brussels sprouts, cauliflower, cabbage	Brassica vegetables	VB
Bifenazate	cantaloupe, cucumber, summer squash	cucurbit fruiting vegetables	VC
Propamocarb	cucumber, melon, summer squash	cucurbit fruiting vegetables	VC
Pirimicarb	cucumber, summer squash	cucurbit fruiting vegetables (except melons and watermelons)	VC
Thiacloprid	melon, watermelon	mutual support: melon, watermelon	VC
Pirimicarb	sweet peppers, tomato	fruiting vegetables other than cucurbits (except mushrooms, fungi, sweet corn)	VO
Pirimicarb	beans, peas	legume vegetables (except soybeans)	VP
Propargite	dry beans, dry broad-bean, dry chick-pea, dry lupin	mutual support: dry beans, dry broad-bean, dry chick-pea, dry lupin	VD
Pirimicarb	dry beans, dry peas	pulses (except soybeans)	VD
Endosulfan	potato, sweet potato	mutual support: potato, sweet potato	VR
Pirimicarb	carrot, potato, sugar beet	root and tuber vegetables	VR
Endosulfan	hazel nuts, Macadamia nuts	mutual support: hazel nuts, Macadamia nuts	TN
Bifenazate	almond, pecan	tree nuts	TN
Thiacloprid	almond, pecan, walnut	tree nuts	TN
Aminopyralid	barley, oats, wheat	barley, oats, wheat, triticale	GC

Compound	Commodities with data supporting MRL	Group or commodities with MRL recommendation	Code
Pirimicarb	barley, maize, wheat	cereal grains (except rice)	GC
Pirimicarb	barley straw, maize fodder, wheat straw	straw and fodder of cereal grains except rice	AS
Aminopyralid	barley straw, oats straw, wheat straw	straw of barley, oats, wheat and triticales	AS

The premise of this approach is that if data are available for representative crops, and if GAP and cultural practices among the individual members are similar, the residue levels should not vary widely then a maximum residue level can be estimated that will suffice for those members of the group for which no data are available. This approach is necessitated by the economics of data generation and evaluation requires the use of common sense and expert judgment.

While the JMPR acknowledges advantages in this approach, there is unfortunately no consensus at the international level on the selection of representative commodities for estimating maximum residue levels for groups. Similarly, while the JMPR bases its recommendations on the Codex Classification of Foods and Feeds, this classification has not been uniformly adopted at the national level.

Until agreement is reached at the international level, the JMPR will continue to make judgements on a case-by-case basis, using the general policy summarized above or as it may be subsequently amended.

6.7.1 Estimation of HR and STMR values

Where there are adequate trials data the STMR values should, in principle, be identified for the individual commodities and these values used for the intake assessment. However, where the MRL has been recommended for a group of commodities, e.g., pome fruit, a single STMR value should be calculated for the group of commodities.

Large portion size and unit weights are available for single commodities, not for commodity groups. Consequently, when an HR value is identified for a commodity group it can be used only on single commodities for IESTI calculation. The IESTI calculations for a group HR should be applied to the key commodities of the group for which large portion size and unit weight data are available, especially to those commodities with data supporting a MRL estimation.

6.8 EXTRAPOLATION OF RESIDUE DATA TO MINOR CROPS

Section 6.7 outlined the process involved in the estimation of group maximum residue levels, provided examples and discussed limitations. Data considered adequate for the estimation of an MRL of a major crop, of a group, are considered generally sufficient to estimate maximum residue levels for the whole group, including the minor crops of that group.

However, decisions to extrapolate from one or more major crops to minor crops are taken by JMPR are on a case-by-case basis when adequate information is available. Adequate information includes information on GAP for the relevant crops, a reference to the residue data used to support the original MRL, and an explanation of the logic for the extrapolation.

The data submitted to support extrapolation to a minor crop must include the following information.

- Background information on the reasons for describing the crop as minor, the importance of the use of the pesticide in terms of pests controlled, the extent of its use on the minor crop, and the nature of the problems or potential problems for international trade
- A description of the cultural practices for the production of the major crop and the approved or registered uses of the pesticide on the major crop from which extrapolation is proposed
- A description of the cultural practices for the production of the minor crop, the approved or registered uses of the pesticide on the minor crop, and the reasons for expecting similar residue levels on the minor crop to those of the major crop
- Supervised residue trials on the major crop supporting the MRL or reference to the JMPR Evaluations, if trials data have previously been reviewed by the JMPR.

The data submission should also include the following supporting information where available.

- Data on supervised trials with approved or registered uses on the minor crop
- A copy of the label describing the registered or approved uses and an English translation of the instructions for use
- Monitoring data from selective surveys on the minor crop produced under typical commercial conditions where the pesticide is known to have been used.

6.9 PROCESSED COMMODITIES

6.9.1 General principles

The use of data on the effects of processing or cooking practices on residue levels in RAC for estimation of processing factors is described in Chapter 5, Section 8 “*Processing studies*”

The best estimate of the processing factor should be applied for the estimation of maximum residue level, HR-P and STMR-P in processed commodities.

To estimate a maximum residue level for a processed product the MRL or maximum residue level of the RAC is multiplied by the processing factor. For the purpose of IEDI estimation, the STMR of the RAC is multiplied by the processing factor to give the median residue in the processed commodity. The HR, STMR value estimated in this way for the processed commodity should be referred to as the HR-P and STMR-P of the processed product.

Maximum residue level for the processed commodity will only be recommended if the resulting residue value is higher than the maximum residue level proposed for the corresponding RAC.

HR-Ps and/or STMR-Ps for commodities for human consumption are estimated regardless of the availability of consumption data.

If data are available for the residues in the edible portion of the commodity, e.g., in banana pulp, the HR and STMR should be estimated directly from the residues in the edible portion found in supervised trials at the maximum registered use rate (as opposed to using pesticide residue values for the whole commodity).

If these data are not available for the edible portion, the whole commodity residue values are used in the dietary intake estimations, even though this may result in a gross over-estimate of the actual residues likely to be consumed.

6.9.2 Special considerations for dried chili peppers

As a special case the CCPR agreed for dried chili peppers, a very minor crop, that a generic factor can be used for conversion of residues from fresh peppers to dried chili peppers. The JMPR evaluated the available information and used the concentration factor of:

- 10 for the estimation of residue levels of pesticides in dried chili peppers from the HR values estimated for residues in or on sweet peppers;
- 7 for the estimation of residue levels in dried chili peppers from maximum residue levels in or on fresh chili peppers.

The 2007 JMPR recommended that:

- where representative processing studies on residues in or on chili peppers are available, the residue levels for dried chili peppers should be estimated based on the actual experimental data
- the relevant concentration factor should be applied to multiply the actual measured residue values in fresh chili peppers, and estimate the maximum residue and median residue levels from the converted data set.

6.10 STATISTICAL METHODS FOR ESTIMATION OF MRLS FOR PLANT COMMODITIES BASED ON SUPERVISED TRIAL DATA

Some regulatory agencies use statistically based calculation methods to facilitate harmonised estimation of maximum residue levels, i.e., aimed at obtaining the same MRL estimates by different evaluators from the same residue data set. It has also been suggested that application of appropriate, validated statistical methods would also improve the transparency of Codex maximum residue level estimation and, consequently, might lead to their wider acceptance at the international level.

The FAO Panel currently applies statistical methods to assist in the selection of similar data populations, and, where the data package is suitable, takes into account statistical considerations, e.g., evaluations of aldicarb residues in potato (1996), EMRL recommendations for DDT residues in meat (2000), and estimation of MRLs for spices (2004).

The FAO Panel has therefore welcomed the development and availability of the NAFTA statistical calculation method, described in the NAFTA paper Statistical Basis of the NAFTA Method for Calculating Pesticide maximum Residue Limits from Field Trial Data³⁷. The NAFTA spreadsheet³⁸ is a decision-tree logic (Figure 6.2 Chapter 6, Section 10) that utilizes statistical calculations to arrive at maximum residue level that should be acceptable to different parties considering the same data set. The spreadsheet looks only at numbers and not at the basis of those numbers. It is designed to give a consistent decision, independent of the prejudice of the reviewer(s). Detailed instruction for its use can be downloaded from

³⁷ Statistical Basis of the NAFTA Method for Calculating Pesticide maximum Residue Limits from Field Trial Data US EPA and Canada PMRA, May, 2007: EPA-HQ-OPP-2007-0632-0002

<http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=EPA-HQ-OPP-2007-0632>

³⁸ http://www.pmra-arla.gc.ca/english/pdf/mrl/method_calc_v2.xls

<http://www.pmra-arla.gc.ca/english/pdf/pro/pro2005-04-e.pdf>. Where more than 10% of the residue data are below the LOQ, the maximum likelihood estimation (MLE) spreadsheet, assuming lognormal distribution of residue data, should be used to convert the < LOQ values to real numbers. Based on the MLE parameters, fill-in values consistent with the associated lognormal distribution are calculated for the censored data points. These fill-in values are generally considered more appropriate than standard imputed values such as ½ LOQ when calculating summary statistics and statistical intervals for lognormal distributions, such as those calculated using the NAFTA tolerance spreadsheet. The effect of the converting the residue data to the postulated lognormal distribution is illustrated in Figure 6.3 (Chapter 6, Section 10). It should be noted that the MLE assumes that the data set follows a lognormal distribution which is the case in about 70% of residue data sets. If the residue data does not follow lognormal distribution, the use of MLE methods will produce a biased estimate.

The spreadsheets for the calculations can be downloaded from the NAFTA website or can also be obtained from the joint FAO Secretary of the JMPR.

The output of the calculations is shown in Table 6.2 (Chapter 6, Section 10). The spreadsheet automatically selects the best estimate for the MRL and indicates it with highlighted cell.

The NAFTA spreadsheet suggests the use of the 95/99 Rule where the residue data set contains more than 15 data points. The White Paper³⁹ states that MRL spreadsheet provides reasonable estimates with a relatively small range of calculated MRLs for sample sizes as small as 10. If the data set has less than 10 data points, the MRL calculations from the NAFTA spreadsheet have large probability of underestimating the true 95th percentile value and are not very precise.

The outcome of NAFTA simulations, using lognormal data populations, indicate that the failure rate is practically independent from the spread of residue data (CV) within the parent population, which enables the drawing of general conclusions from the simulated data. However, where the NAFTA procedure would be used alone for estimation of maximum residue levels based on 6 to 10 data points, which occurs frequently in the deliberations of the JMPR (Figure 6.4), the recommended MRL would be underestimated, i.e., it would be below the targeted 95th percentile of the residue data populations, in 27% and 20% of cases.

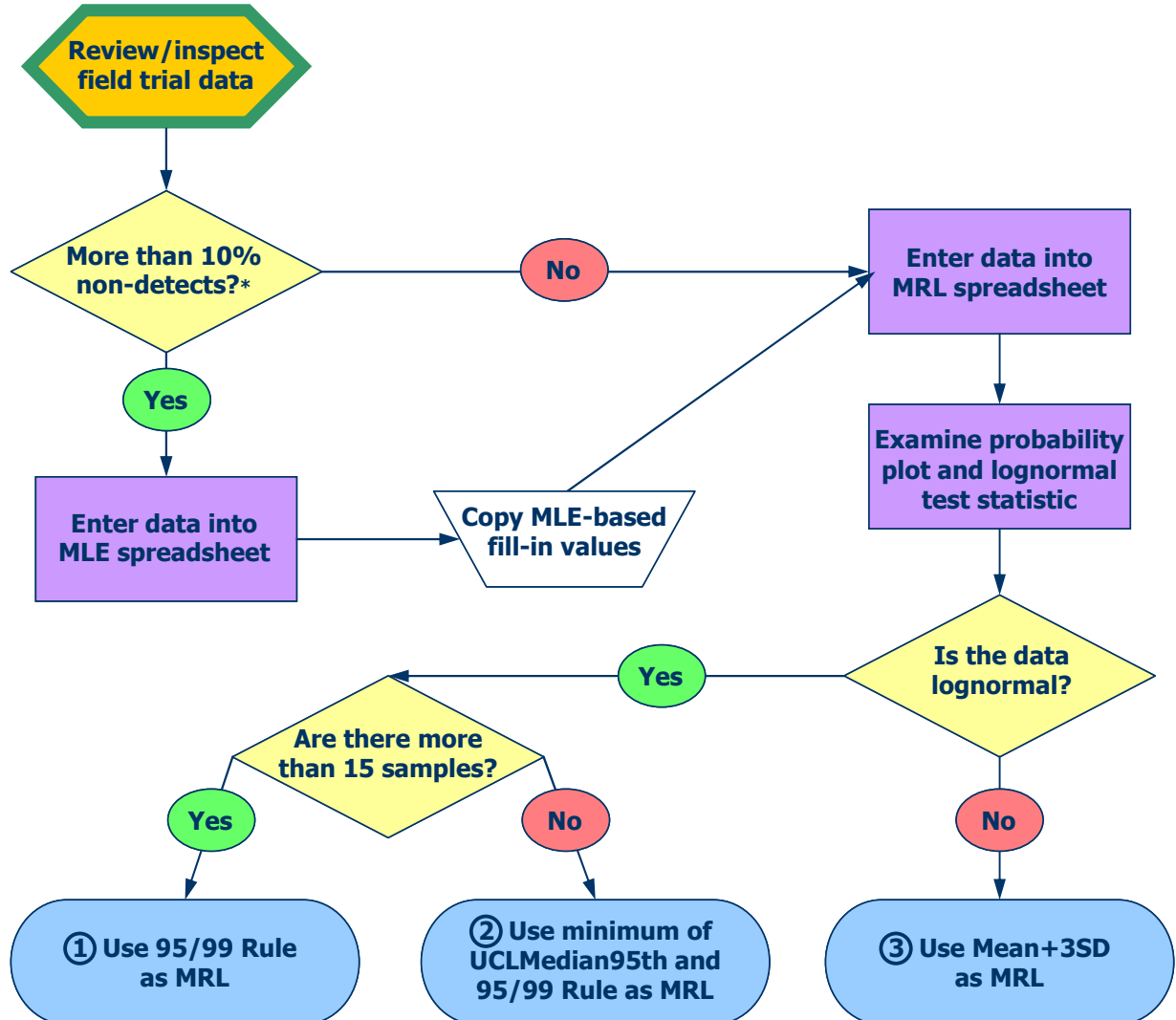
The FAO Panel have utilised the NAFTA procedure on various data sets in the estimation of MRLs since 2005, and concluded that the statistical spreadsheet can be used as a tool to assist evaluators in the estimation of maximum residue levels, but that the output could not be automatically applied. It is emphasised that expert judgement in the proper selection of residue data set is the key component in obtaining a reliable estimate for a MRL.

The 2008 JMPR concluded that statistical calculations, as part of the maximum residue level estimation process, should only be used where the data are suitable to yield valid conclusions. Considerations should include:

- data from a single population or the equivalent of a single population
- the data should be from a random sample or stratified random sample from the population
- sufficient data (≥ 15) should be available to minimize the errors of extrapolation to the required high percentile values

³⁹ Statistical Basis of the NAFTA Method for Calculating Pesticide Maximum Residue Limits from Field Trial Data
<http://www.regulations.gov/search/Regs/home.html#documentDetail?R=090000648026e8d0>

- the number of residue values below the LOQ and the residue distribution around LOQ
- no statistical test should be applied for excluding potential outliers; residue data should only be excluded if experimental evidence indicates that the data is invalid.



*If more than 60% of the data are non-detects, the fill-in values from the MLE spreadsheet should be used with caution.

Figure 6.2 Decision tree for applying the NAFTA spreadsheet for obtaining the estimated maximum residue value

In cases, where only small number of residue data is available, MRL estimates should take into account:

- the highest values, median value and approximate 75th percentile value in the available data set of supervised residue trials
- residue levels resulting from application rates other than GAP (for instance, using residues below LOQ in samples derived from double rate treatments to support no detectable residues following the application at maximum application rate, using highest residues from samples taken at longer intervals than PHI)
- experience of typical distributions of residue data from supervised trials

- knowledge of residue behaviour from the metabolism studies, e.g., is it a surface residue, does it translocate from foliage to seeds or roots
- knowledge of residue trials on comparable crops.

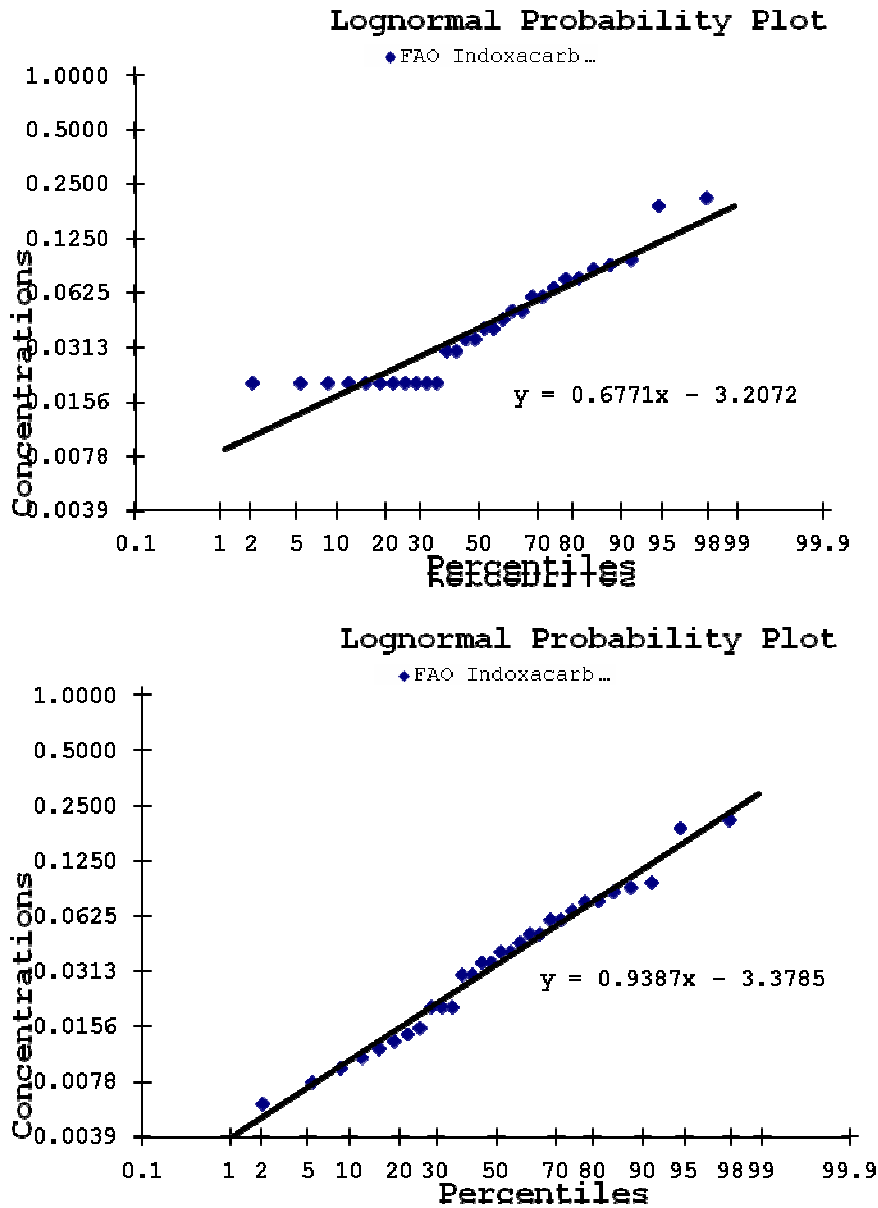


Figure 6.3 The lognormal probability plots based on original data (upper chart) and after fitting the residues reported as < LOQ to the most likely lognormal distribution (lower chart)

The use of the statistical spreadsheets provides information on the 95th and 99th/99.5th percentile of residue distributions. It was previously judged necessary to “round up” considerably on the value selected for the maximum residue level. This is no longer the situation where the statistical estimation tools are utilized. In order to more fully reflect the impact of this new tool, the Meeting concluded that the scaling steps last presented in the 2001 JMPR Report would be replaced by a refined scale (see Section 6.13 “*Expression of Maximum residue limits*”)

Table 6.2 Output of NAFTA calculation

	Regulator: EPA Chemical: Pymetrozine Crop: Leaf Lettuce PHI: 0-1 Day App. Rate: Submitter:		
	n: 14 min: 0.14 max: 1.94 median: 0.77 average: 0.83		
	95 th Percentile	99 th Percentile	99.9 th Percentile
EU Method I Normal	1.7 (2.5) ^b	2.0 (3.0)	2.5 (-)
95/99 Rule	2.5 (4.5) ^d	3.5 ^c (9.0)	6.0 (-)
EU Method II Distribution-Free	2.5 ^e		
Mean+3SD	2.5 ^f		
UCLMedian95 th	5.0 ^g		
Approximate Shapiro-Francia Normality Test Statistic	0.9503p-value > 0.05 : Do not reject lognormality assumption		

^a Tabled values in parentheses indicate 95% upper confidence bounds on the point estimates of the 95th or 99th percentiles. No upper confidence bounds on the 99.9th percentile are provided and these are represented by "(-)". Tabled values that are shown directly without parentheses represent point estimates of the indicated percentile (e.g., 95, 99, or 99.9)

^b This is the MRL estimate that would be produced by EU Method I. It is the 95% upper confidence limit on the 95th percentile, but assumes that the residues are distributed normally.

^c This is the estimated 99th percentile value assuming a lognormal distribution with the given mean and standard deviation.

^d Lognormal distribution with the given mean, standard deviation, and sample size. If the residues are distributed lognormally, one can be 95% confident that 95% of the values in the parent distribution lie below this estimate.

^e EU Method II. This method makes no assumption regarding the form of the distribution (e.g. normal, lognormal, etc.). It is calculated by doubling the 75th percentile of the residue values.

^f This estimate is produced by adding 3 standard deviations to the mean. By Chebychev's Rule, at least 8/9 or 89% of measurements will fall within 3 standard deviations of the mean. This is true regardless of the shape of the frequency distribution.

^g This value is calculated by estimating the 95th percentile from the upper confidence limit of the median value (50th percentile). It assumes a coefficient of variation of 1 and a lognormal distribution. In a lognormal distribution, the 95th percentile is 3.9 times the median. The value represented in this cell is 3.9 times the upper confidence limit on the median.

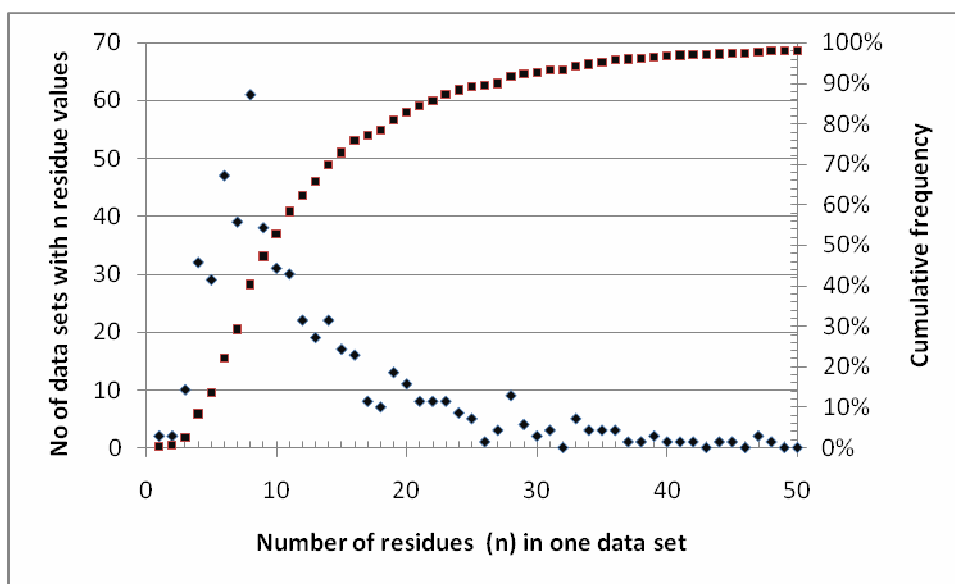


Figure 6.4: Frequency of occurrence of data sets consisting of n residue values used by JMPR between 2002 and 2007

The JMPR is aware of the need for harmonised approach in estimation of MRLs which would also facilitate work sharing, and looks forward to the further developments in statistical methods for estimation of MRLs such as being developed by the OECD Working Group on Pesticide Residues. The FAO Panel will apply the most reliable method available in combination with the general principles described in this and the previous sections.

6.11 ESTIMATION OF MAXIMUM RESIDUE LEVELS BASED ON MONITORING DATA

6.11.1 Estimation of maximum residue levels, HR and STMR values in spices

The 2004 CCPR accepted the definition of spices irrespective of whether they were classified as spices in the Codex Classification, and agreed to the setting of MRLs for spices on the basis of monitoring data⁴⁰. It was further clarified that chili peppers, herbs⁴¹ and tea are excluded from the definition of spices, and GAP and corresponding supervised trial data should be used for estimation of maximum residue levels for these commodities.

The principal differences between the residue data derived from monitoring programmes and supervised field trials are as follows:

- The origin and treatment of the commodities sampled are not known.
- The sampled commodity might be aggregated from the produce of several small fields.
- The residues in spice samples are determined by multi-residue procedures with relatively high LOQs.
- When residue values are reported as being below the LOQ, it is not known whether the sampled commodity was or was not treated with or exposed to the pesticide.

⁴⁰ Report of the thirty-sixth session of the Codex Committee on Pesticide Residues, Alinorm 04/27/24, (paras 235 – 247) 2004, www.codexalimentarius.net

⁴¹ Report of the thirty-seventh session of the Codex Committee on Pesticide Residues, Alinorm 05/28/24, (para 182) 2005, www.codexalimentarius.net

Consequently, estimation of maximum residue levels for pesticides on the basis of monitoring results requires a different approach to that used in evaluating the results of supervised residue trials.

The Meeting assumes that the Member States report only valid results. Therefore, all residue data are taken into account as there are no scientific grounds to exclude any value as an outlier.

The distributions of residues are scattered or skewed upwards, and no distribution fitting appeared to be appropriate. Consequently, distribution-free statistics should be used in estimating the maximum residue level, covering the 95th percentile of the population at the 95% confidence level. Thus, the estimated maximum residue level encompasses at least 95% of the residues with 95% probability (in 95% of cases). To satisfy this requirement, a minimum of 58–59 samples are required. The minimum sample size of 58 provides 95% assurance of finding at least one residue value above the 95th percentile of the residue population in the sampled object. It is not known, however, how many of the measured values are above the 95th percentile and what percentile (95.1th, 99th or 99.9th) the highest residue represents.

The procedure used for estimating maximum residue levels depends on the number of samples containing detectable residues.

- When no sample contains detectable residues, the highest reported LOQ value is used as the maximum residue level and the high residue value. The median residue value is calculated from the reported LOQ values.
- When large numbers of residue data is available, the highest residues may be above the upper confidence limit of the 95th percentile of the residues and they need not be considered in estimating maximum residue levels.
- Where the number of samples containing detectable residues does not allow the calculation of the upper 95th confidence limit for the 95th percentile, sufficient allowance should be given when the maximum residue level is estimated to be above the highest residue value observed. Note that the samples with residues reported below the LOQ cannot be taken into consideration as they were not necessarily treated with or exposed to the pesticide.

The 2004 JMPR recommended that monitoring results should not be used for estimating maximum residue levels that reflect post-harvest use, which results in much higher residue values than foliar application or spray drift exposure.

STMR and the highest residue values can be calculated only from supervised trials. The corresponding values from the monitoring data are indicated as median and high residue values, and these can be used like the STMR and highest residue values for estimating short-term and long-term dietary intake of residues (see Chapter 7).

6.11.2 Estimation of extraneous maximum residue levels

Chemicals for which EMRLs (extraneous maximum residue limits) are most likely to be needed are those which have been widely used as pesticides, are persistent in the environment for relatively long periods after use has been discontinued and are expected to occur in foods or feeds at levels of sufficient concern to warrant monitoring.

Predictions of persistence in the environment (and the potential for uptake by food or feed crops) can often be based on a combination of data sources normally available for chemicals

previously approved as pesticides. These may include information on their physical and chemical properties, metabolism studies, data on supervised field trials, data on environmental fate, rotational crop data, the known persistence of similar chemicals, and especially from monitoring data.

All relevant and geographically representative monitoring data (including nil residue results) are required to make reasonable estimates to cover international trade. Better extraneous maximum residue level estimates, taking into account trade concerns, can be made when more extensive data are available. However, typically data are available from only three or four (usually developed) countries at the most. By the nature of national monitoring, data are usually received primarily on those commodities in which residues have been found at the national level and which have the potential to create trade difficulties.

In estimating an extraneous maximum residue level the JMPR attempts to take into account a number of factors. These include the amount of data, the relative importance of the commodity in international trade, the potential for trade difficulties or accounts thereof, the frequency of positive results, a knowledge of the propensity of a particular crop to take up residues, e.g., the uptake of DDT by carrots, historical monitoring data, e.g., previous monographs, and the level and frequency of residues in similar crops, especially those in the same crop group. In some cases the estimate has turned out to be the highest level reported, especially if a relatively good database is available and the spread of results is reasonably narrow.

In recent years there have been cases where the extraneous maximum residue level was estimated below the highest residue found, especially if the higher values occur infrequently. For example, the 1993 JMPR recommended an EMRL of 0.2 mg/kg for DDT in carrots, although 2 of 4 imported samples reported from one country were 0.4 and 0.5 mg/kg. The JMPR took into account that only 2 of over 800 imported samples exceeded 0.2 mg/kg. This limit covers > 99% of the residue population with 99% confidence. A similar approach was taken for DDT in the fat of meat by the 1996 JMPR. This approach also recognizes that residues gradually decline and that monitoring data can be outdated by the time they are received by the JMPR. It is more likely to be used when the higher residues occur infrequently.

In the context of EMRLs, the JMPR does not consider extreme values to be outliers in a statistical sense, because high residue levels are usually not true statistical outliers but values on one tail of a large distribution. The challenge is to decide when it is reasonable to discard those values in order to reflect the expected gradual decline in the levels of chemicals that are typically subject to EMRL recommendations, while not creating unnecessary barriers to trade.

Generally, the JMPR considers that the databases needed for estimating extraneous maximum residue levels should be substantial because the EMRL data are based on analysis of samples of unknown origin and very far from a normal distribution. (Note that it is difficult to compare the database required for EMRLs and MRLs because the nature of the data is quite different – supervised trials for MRLs and monitoring data for EMRLs). For example, samples from 598 randomly selected animals are needed to ensure that the estimated EMRLs cover 99.5% of a population, allowing a 0.5% violation rate with 95% confidence (Codex Alimentarius, Vol. II, 2nd Ed., p. 372). On the other hand, if a country had only 100 random samples analysed with a 10% violation rate this is quite significant, despite the small number of samples.

As EMRL databases are derived from the random monitoring of different populations, the JMPR does not normally consider a ‘world’ population of data, but gives independent consideration to different populations, e.g., of different geographical regions or of different

animals, before deciding which data populations might be combined. Therefore, all relevant monitoring data should be submitted regardless of the number of samples analysed.

The JMPR compares data distribution in terms of the likely percentages of violations that might occur if a given EMRL is proposed. Since there is no internationally agreed level of acceptable violation rate, the JMPR recommends EMRLs based on the available data. However, violation rates of 0.5 to 1% or greater are generally considered unacceptable.

The 2000 JMPR, in the evaluation of DDT in meat, estimated the residue levels in fat that related to violation rates of 0.1, 0.2 and 0.5%. The compromise among an acceptable violation rate, recommended EMRL and the potential for trade disruption are not scientific matters to be decided by JMPR. They are the province of risk manager decision making.

It is to be expected that there will be a gradual reduction or elimination of residues of the chemicals for which EMRLs have been proposed. The rate will depend on a number of factors, including the nature of the chemical, the crop, the location and environmental conditions.

Because residues gradually decrease, the JMPR recommends reassessment of EMRLs about every 5 years. Eventually, the data may indicate that there is no longer a need to monitor for the chemical. This view would be based on the conclusion that there is no longer a potential for significant disruption of trade and that the incidence or level of residues is no longer a significant health concern.

Although the JMPR does not use targeted monitoring data for estimating extraneous maximum residue levels, it agrees that follow-up studies are important when high residues are found in random monitoring to give a clearer view of the significance of the high levels. If properly conducted, such studies may indicate whether or not the higher residues resulted from intentional unauthorized uses and may allow the identification of areas in which production should be limited or where residue reduction strategies should be implemented.

6.12 ESTIMATION OF MAXIMUM RESIDUE LEVELS AND STMR VALUES FOR COMMODITIES OF ANIMAL ORIGIN

Residue levels in animal commodities, e.g. meat, milk and eggs, may arise from consumption of feed items containing residues or from direct application to a farm animal of a pesticide to control pests such as ectoparasites. Methods of estimating maximum residue levels in animal commodities have been developed in recent years and their detailed explanations were given in the JMPR reports.

The current procedures applied by the Meeting are described below.

6.12.1 Residues arising from consumption of feed items

Animals can be exposed, for extended periods, to certain commodities such as fodder, grain and feeds treated post-harvest containing residues at the highest level. In addition, in the experience of the Meeting, the residue levels of many pesticides on animal feed commodities show only a limited decrease during storage. Alternatively, it is unlikely that the individual ingredients of mixed feeds produced from commercially available ingredients would all contain residues at the theoretical maximum level.

Consequently, the highest residues in individual feed items are used for estimating the maximum residue levels in animal commodities, and the STMR or STMR-P should be applied to each of the components of mixed commodities. The STMR-P is also used for individual

feed items that are processed commodities, e.g., apple pomace. The estimation of residues that will arise in animal commodities is a two-step process involving farm animal feeding studies and dietary burden calculations. These two independent sets of information are compiled (Figure 6.5), then combined in order to estimate animal commodity residues that may arise.

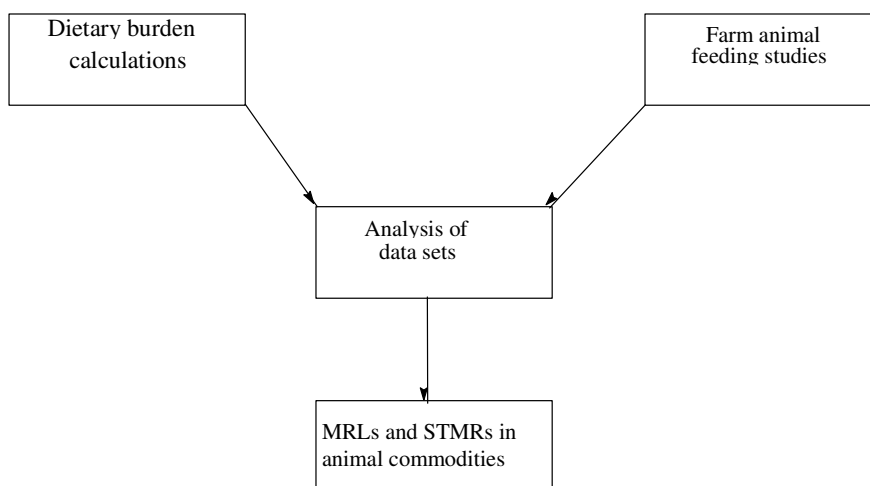


Figure 6.5 Estimation of residues in animal commodities

The following decision matrix is recommended for use in estimating maximum residue levels and STMR values:

Maximum residue level	STMR
Choose: feed commodity, highest residue or STMR-P (for dietary burden calculation)	Choose: feed commodity STMR or STMR-P (for dietary burden calculation)
highest residue level ^a (from feeding study in farm animals)	mean residue level ¹ (from feeding study in farm animals)

STMR-P: supervised trials median residue in a processed commodity calculated by multiplying the STMR of the raw commodity by the corresponding processing factor

^a Residue levels in tissues and eggs of the relevant group of animals in the feeding study. For milk, choose the mean residue in milk from the relevant group of animals in all cases.

The JMPR is currently utilising the livestock diets listed in the tables included in Appendix IX to estimate livestock dietary burdens from available residue data. To assist their use, Table IX.1 lists the Codex commodities with their code numbers corresponding to the feedstuffs. The tables IX.2-IX.4 include the Codex commodity group codes for all feedstuffs to facilitate the selection of commodities for calculation of the appropriate animal burden. The Excel spreadsheet which can be used for the calculations can be downloaded from the FAO/AGP Website (<http://www.fao.org/ag/agp/agpp/pesticid/JMPR/>).

The livestock diet tables were developed by the OECD Working Group on Pesticides⁴². They include data for beef cattle, dairy cattle, sheep, lambs, swine, broilers, layers and turkeys. Data are available from different geographic regions: Australia, Japan, EU, and US-Canada. Feedstuff categories in the OECD tables were chosen to ensure that the highest residue levels are estimated and a realistic although not nutritionally optimal livestock diet is composed. The

⁴² http://www.oecd.org/document/52/0,2340,en_2649_34383_1897652_1_1_1_1,00.html

primary purpose of the tables was to estimate a highest livestock dietary burden from the geographic regions which could then be used to set an appropriate dosing regime for a livestock feeding study.

For simplicity and ease of use, the tables include information on percentage dry matter (DM) for each feed item as well as whether the STMR or highest residue (HR) should be used in the maximum dietary burden calculations. If the residues are already expressed on dry matter basis then the corresponding percentage of dry matter (DM%) should be replaced with 100%.

Feeding studies are normally available for lactating dairy cattle and laying hens. In such situations, livestock dietary burdens will be calculated for beef and dairy cattle, broiler and laying hens.

Maximum residue levels in animal commodities are derived from the highest residue values in feed commodities, and STMRs for animal commodities are derived from the STMRs for feed commodities. Separate tables are made for each MRL and STMR estimate, in which all feed items, their Codex commodity group and the residue levels found in crop residue trials are listed. The basis for the residue level is provided; i.e., the basis of the maximum residue level estimate is the highest level for raw agricultural commodities and the STMR-P for processed commodities.

The steps involved in the calculation are explained below with an example, see Table 6.3. For simplifying the example the Japanese feed consumption figures are not included, but should be considered in the evaluations.

- a. The highest residue or the STMR /STMR-P values are entered into the Excel spreadsheet containing the corresponding livestock diet (Appendix IX), and the residues are expressed on dry weight basis;
- b. The dietary burdens are calculated from commodity percent of diet;
- c. Feed items having no residue value are deleted from the spreadsheet, and the remaining entries are sorted on Crop/Commodity group (ascending) and Residue DW (descending).

Table 6.3: Maximum dietary burden of beef cattle

Commodity/crop	Commod group	Residue mg/kg	Basis	% Dry matter	Residue dw mg/kg	Diet content (%)			Residue contribution (ppm)		
						US-CAN	EU	AU	US-CAN	EU	AU
Grape pomace, dry	AB	0.038	STMR-P	100	0.038			20			0.01
Bean forage (green)	AL	2.1	high residue	35	6.000	30		60	1.80		3.60
Alfalfa fodder	AL	4	high residue	89	4.494	60		80	2.70		3.60
Pea vines (green)	AL	0.86	high residue	25	3.440	20	20	60	0.69	0.69	2.06
Maize fodder	AS AF	4.3	high residue	83	5.181	25	25	40	1.30	1.30	2.07
Wheat straw and fodder, Dry	AS AF	4.3	high residue	88	4.886	10	20	80	0.49	0.98	3.91
Barley forage	AS AF	1.4	high residue	30	4.667	30	30	50	1.40	1.40	2.33
Wheat milled (bran)	CM	0.084	STMR-P	88	0.095	40	30	40	0.04	0.03	0.04
Rice	GC	0.57	STMR	88	0.648	20		40	0.13		0.26
Wheat	GC	0.035	STMR	89	0.039	20	40	80	0.01	0.02	0.03
Total						255	165	550	8.54	4.40	17.91

- d. Selection of commodities from each group

Starting with the feed item with the highest residue level, the percentage of each feed in the livestock diet is allocated. Usually, only one feed commodity from each Codex commodity group is used; if more than one is used, it is only up to the full percentage

feed allocation for that group. Note that some groups have two codes (e.g. AS and AF; AM and AV). Feeds are allocated a percentage of the diet for each animal until no more than 100% of the diet is used. The assignment of feed commodities to Codex groups is illustrated in Figure 6.6

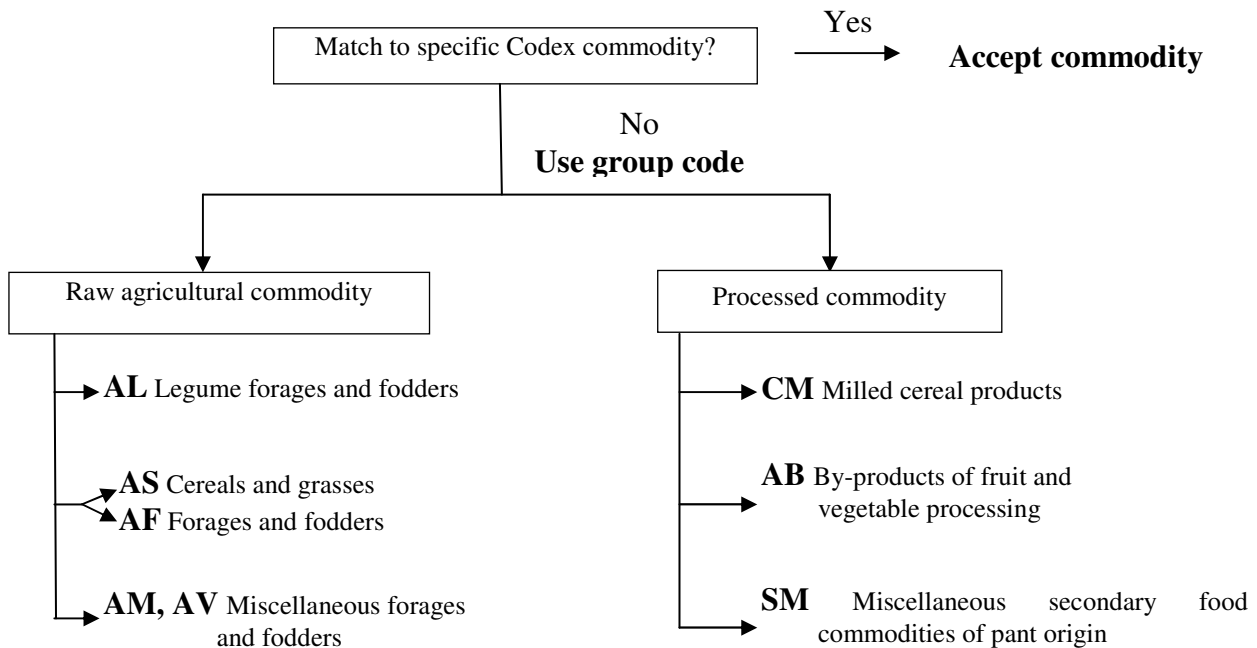


Figure 6.6 Grouping feed items for calculation of dietary burden of livestock

The first commodity group in Table 6.3 is AB, but with only one commodity, no change.

For AL (legume feeds) the animal diet content in US-Canada, Bean forage is first with 30%, no change. Alfalfa fodder is next with 60%, but bean forage has used 30% for the group, so alfalfa fodder becomes 30% (=60–30). As pea vines, at 20%, are less than the previous total for the group, the 20% is deleted.

For the animal diet content in EU, the only commodity is Pea vines with 20%, no change.

For the animal diet content in Australia, Bean forage is first with 60%, no change. Alfalfa fodder is next with 80%, but bean forage has used 60% for the group, so alfalfa fodder becomes 20% (=80–60). As pea vines, at 60%, are less than the previous total for the group, the 60% is deleted.

After selection of commodities within each group the following commodities remain (Table 6.4)

Table 6.4 Commodities selected to contribute to the maximum burden of beef cattle

Commodity/crop	Commod group	Residue mg/kg	Basis	% Dry matter	Residue dw mg/kg	Diet content (%)			Residue contribution (ppm)		
						US-CAN	EU	AU	US-CAN	EU	AU
Grape pomace, dry	AB	0.038	STMR-P	100	0.038			20			0.01
Bean forage (green)	AL	2.1	high residue	35	6.000	30		60	1.80		3.60
Alfalfa fodder	AL	4	high residue	89	4.494	30		20	1.35		0.90
Pea vines (green)	AL	0.86	high residue	25	3.440		20			0.69	
Maize fodder	AS AF	4.3	high residue	83	5.181	25	25	40	1.30	1.30	2.07
Wheat straw and fodder, Dry	AS AF	4.3	high residue	88	4.886			40			1.95
Barley forage	AS AF	1.4	high residue	30	4.667	5	5		0.23	0.23	
Wheat milled (bran)	CM	0.084	STMR-P	88	0.095	40	30	40	0.04	0.03	0.04
Rice	GC	0.57	STMR	88	0.648	20		40	0.13		0.26
Wheat	GC	0.035	STMR	89	0.039		40	40		0.02	0.02
Total						150	120	300	4.84	2.26	8.85

- e. If the total diet contributions exceed 100 % reduce diet contributions to 100 % in such a way as to retain the highest possible dietary burden. Delete (or reduce) the contributions from those commodities with lowest residue dw until the 100 % is achieved.

Sort on Residue dw (descending), and delete the diet content values from the lower rows first, to achieve a 100% diet.

For the US-Canadian list, delete the 40% for wheat bran, and reduce the rice to 10%. For the EU list, reduce the 40% wheat to 20% wheat. For the Australian list, retain only the first two entries to achieve 100% of diet (Table 6.5)

- f. Where the selected feed items with residues from the use of the pesticide do not add up to 100% it is assumed that the animals are fed with other feed items which do not contain residue.

The STMR dietary burden is calculated from the STMR or STMR-P residue values estimated for the animal feed items following the same procedure as for the maximum burden.

Table 6.5 Selection of commodities to obtain 100% diet with maximum residue burden

Commodity/crop	Commod group	Residue mg/kg	Basis	% Dry matter	Residue dw mg/kg	Diet content (%)			Residue contribution (ppm)		
						US-CAN	EU	AU	US-CAN	EU	AU
Bean forage (green)	AL	2.1	high residue	35	6.000	30		60	1.80		3.60
Maize fodder	AS AF	4.3	high residue	83	5.181	25	25	40	1.30	1.30	2.07
Wheat straw and fodder, Dry	AS AF	4.3	high residue	88	4.886			40			
Barley forage	AS AF	1.4	high residue	30	4.667	5	5		0.23	0.23	0.00
Alfalfa fodder	AL	4	high residue	89	4.494	30		20	1.35		
Pea vines (green)	AL	0.86	high residue	25	3.440		20			0.69	
Rice	GC	0.57	STMR	88	0.648	10		40	0.06		
Wheat milled (bran)	CM	0.084	STMR-P	88	0.095	40	30	40		0.03	
Wheat	GC	0.035	STMR	89	0.039		20	40		0.01	
Grape pomace, dry	AB	0.038	STMR-P	100	0.038			20			
Total						100	100	100	4.7416	2.2529	5.6724

The calculation for dairy cattle and poultry are the same as for beef.

The final results of the calculated dietary burden as shown in Table 6.6 for beef-cattle, together with the dairy-cattle as well as broiler- and layer-poultry, are included as appendix of the Report of the JMPR.

Table 6.6: Final table with 100% diet calculation for maximum residue burden for beef cattle.

Commodity/crop	Commod group	Residue mg/kg	Basis	% Dry matter	Residue dw mg/kg	Diet content (%)			Residue contribution (ppm)		
						US-CAN	EU	AU	US-CAN	EU	AU
Bean forage (green)	AL	2.1	high residue	35	6.000	30		60	1.80		3.60
Maize fodder	AS AF	4.3	high residue	83	5.181	25	25	40	1.30	1.30	2.07
Barley forage	AS AF	1.4	high residue	30	4.667	5	5		0.23	0.23	
Alfalfa fodder	AL	4	high residue	89	4.494	30			1.35		
Pea vines (green)	AL	0.86	high residue	25	3.440		20			0.69	
Rice	GC	0.57	STMR	88	0.648	10			0.06		
Wheat milled (bran)	CM	0.084	STMR-P	88	0.095		30			0.028	
Wheat	GC	0.035	STMR	89	0.039		20			0.008	
Total						100	100	100	4.74	2.25	5.67

The maximum and STMR dietary burdens used for the estimation of maximum and STMR residues are reported in the appraisal of the evaluation of residues (Table 6.7).

Table 6.7: Example for summarising the maximum and STMR livestock dietary burdens

	Livestock dietary burden, [xxxx compound], ppm of dry matter diet					
	US-Canada		EU		Australia	
	max.	mean	max.	mean	max.	mean
Beef cattle	4.74	2.83	2.25	2.03	5.67	4.05
Dairy cattle	4.55	3.1	4.79	3.27	6.12 ^a	4.07 ^b

^a Highest maximum beef or dairy cattle dietary burden suitable for MRL estimates for mammalian tissues and milk

^b Highest mean beef or dairy cattle dietary burden suitable for STMR estimates for mammalian tissues and milk.

Note: if the maximum or mean burden for beef is higher than that of dairy cattle then those values shall be used for estimation of residue levels for mammalian tissues.

6.12.1.1 Use of the calculated dietary burdens to estimate maximum residue levels and STMR values for commodities of animal origin

The calculations of dietary burden are compared with the feeding levels in studies of farm animals to estimate maximum residue levels and STMR values on the basis of the following guidelines.

- When a feeding level in a feeding study matches the dietary burden, the residue levels reported in the study can be used directly as estimates of residue levels in tissues, milk and eggs resulting from the dietary burden.
- When a feeding levels in a feeding study differs from the dietary burden, the resulting residues in tissues, milk and eggs can be estimated either by interpolation between the closest feeding levels or calculation from the linear regression equation if good fit is observed as shown in Figure 6.7.
- When the dietary burden is below the lowest feeding level in the study, the resulting residues in tissues, milk and eggs can be estimated by applying the transfer factor (residue level in milk or tissue ÷ residue level in diet) at the lowest feeding level to the dietary burden.
- When the dietary burdens of beef and dairy cattle are different, the higher value should be used for calculating the residues in muscle, fat, liver and kidney, as in the case shown in Table 6.7.

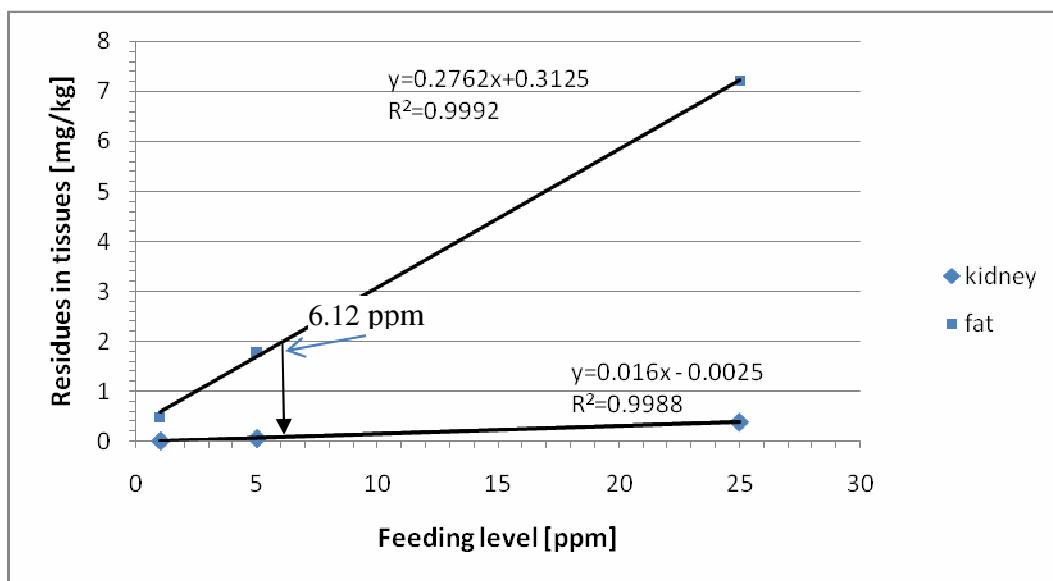


Figure 6.7 Interpolation between closest feeding levels

- For estimating maximum and highest residue levels in meat, fat, liver, kidney and eggs, the highest residue level found in an animal in the relevant feeding group of the study should be used.
- For estimating STMR values in meat, fat, liver, kidney and eggs, the mean residue levels in animals in the relevant feeding group of the study are used.
- For estimating maximum residue levels and STMRs in milk, the mean residue levels in the animals in the relevant feeding group of the study are used.
- No more than about 30% above the highest feeding level can be extrapolated to a dietary burden.

The estimated maximum and mean animal dietary burdens (listed in Table 6.7) are compared with the residues obtained from animal transfer studies for estimating maximum residue levels and STMR for animal commodities.

For MRL estimation, the high residues in the tissues are calculated by interpolating the maximum dietary burden (6.12 ppm) between the relevant feeding levels (5 and 25 ppm) from the dairy cow feeding study and using the highest tissue concentrations from individual animals within those feeding groups.

The STMR values for the tissues were calculated by interpolating the mean dietary burden (4.07 ppm) between the relevant feeding levels (1 and 5 ppm) and using the mean tissue concentration from each feeding group.

In Table 6.8 below, dietary burdens are shown in round brackets (), feeding levels and residue concentrations from the feeding studies are shown in square brackets [] and estimated concentrations related to the dietary burden are shown without brackets.

The data from the dairy cattle feeding study are used to support mammalian meat and milk MRLs, as the dietary burden for dairy cattle is higher than that of beef-cattle.

The mean and highest residues corresponding to the calculated maximum and mean dietary burden are used for estimation of maximum residue levels and STMR values for the relevant animal commodities taking into account the fat solubility of the residues.

Table 6.8 Summary of residues corresponding to the estimated dietary burden

Dietary burden (ppm) Feeding level [ppm]	Milk	Muscle	Liver	Kidney	Fat
MRL					
	mean	highest	highest	highest	highest
MRL beef or dairy cattle (6.12) [5, 25]	0.12 [0.1, 0.57]	0.1 [0.07, 0.4]	0.02 [0.01, 0.08]	0.09 [0.07, 0.4]	2.2 [1.8, 7.2]
STMR					
	mean	mean	mean	mean	mean
STMR beef or dairy cattle (4.07) [1, 5]	0.08 [0.03, 0.1]	0.04 [0.01, 0.05]	0.008 [0.03, 0.01]	0.03 [0.01, 0.04]	1.0 [0.25, 1.3]

Where the pesticide also has veterinary uses and JECFA has recommended maximum residue limits for animal commodities the higher residues deriving from the two kinds of use will form the basis for recommending maximum residue levels for Codex purposes.

6.12.2 Residues arising from direct application to farm animals

Pesticides may be applied directly to farm animals for control of lice, flies, mites and ticks. Application methods include dips, sprays, pour-ons and jetting. Residue trials using the required method of application, dosage and withdrawal times are needed if residues may occur in animal commodities.

The number of supervised trials on animals is, of necessity, far less than for crops. (See also Chapter 3 Section 9 “*Information and data from farm animal feeding and external animal treatment studies*”).

The conditions of a supervised residue trial on farm animals should match the maximum conditions described on the label. If more than one application method is permitted, e.g., dip or pour-on treatments, residue data should be available for each method. The evaluation should record the highest residue occurring in individual animal tissues resulting from the approved method and dose. The highest residues will support the MRL recommendations. The evaluation should record the average milk residues each day across the treatment group and the MRL recommendation will depend on the highest of these average milk residues on a day achieved within the conditions described on the label.

The STMR concept is designed for supervised field trials on crops to obtain the typical residue value when a pesticide is used at maximum GAP. The STMR methodology is not directly applicable to a single direct-animal treatment trial. However, the idea of a typical residue value when a pesticide is used directly on animals (at maximum label conditions) is useful in long-term dietary intake estimations. For this purpose the median of the residues in the tissues of animals slaughtered at the shortest interval after treatment (or later if residues were higher later) is taken to represent that typical value.

6.12.3 Reconciliation of MRL recommendations resulting from direct treatment and from residues in animal feed

Where the maximum residue level recommendations from the two sources of residues do not agree, the higher recommendation will prevail. Similarly, the estimates for typical residues

from direct use at maximum label conditions or STMR values derived from the farm animal dietary burden and animal feeding studies, whichever is the higher, should be adopted for long-term intake estimation.

6.13 EXPRESSION OF MAXIMUM RESIDUE LIMITS (MRLs)

The estimated maximum residue levels and recommended residue limits are expressed in mg residue (as defined)/kg commodity. The portion of commodity to which Codex MRLs apply is given in Codex Alimentarius Vol. 2 (extracted in Appendix VI).

The residues are expressed on fresh-weight basis or as they enter international trade (as received by the laboratory) in most commodities, with the exception of animal feeds. Because of the great variation of their moisture content, MRLs for animal feeds are recommended on a dry-weight basis. This implies that the commodity is analysed for pesticide residues as received, that the moisture content of the sample is determined (preferably) by a standard method recommended for use on that commodity, and that the residue content is then calculated as if it were wholly contained in the dry matter.

If it is not clear in animal feed residue data submissions whether residues are expressed on a dry weight basis, or the moisture content of the feed is not reported, either a ‘worst case’ assumption could be made that the residues are expressed on a fresh weight basis or the data may not be suitable for estimating maximum residue levels.

For animal products there are certain special cases which need to be mentioned:

For meat and fat-soluble pesticides (see also Chapter 5 section 2 “*Physical and chemical properties*” and Chapter 3 section 9.3.1 “*Nature of fat samples in studies on fat-soluble compounds*”) the residue limits for meat are expressed on the fat (the residue content in trimmable fat or fat tissue expressed on the lipid content) which is indicated in brackets (fat) after the residue value. For those commodities where the adhering fat is insufficient to provide a suitable sample, the whole meat commodity (without bone) is analysed and the MRL applies to the whole commodity.

For all other pesticides the MRLs apply to the whole commodity as it moves in trade.

During the past years, the MRLs and EMRLs for fat-soluble pesticide residues in milk and milk products had been expressed on a calculated whole product basis assuming all milks to contain 4% fat. Milk products with a fat content of 2% or more had been expressed on a fat basis. The MRL would be 25 times the MRL for milk, i.e., the same value as if expressed on the fat of milk. The MRL for milk products, with a fat content lower than 2%, were considered to be half the value for milk and are expressed on a whole product basis.

The 2004 JMPR decided that two maximum residue levels would be estimated, if the data permit: one for whole milk and one for milk fat. For enforcement purposes, a comparison can be made either of the residue in milk fat with the MRL for milk (fat) or of the residue in whole milk with the MRL for milk. When needed, maximum residue levels for milk products can then be calculated from the two values, by taking into account the fat content of the milk product and the contribution from the non-fat fraction.

Milk MRLs for fat-soluble pesticides were indicated by the letter “F”.

Examples for recommended MRLs (mg/kg) for diazinon –

MO 0098	Kidney of cattle, pigs and sheep:	0.03
MM 0097	Meat of cattle, pigs and sheep:	2 (fat)
ML 0106	Milks	0.02 F

Based on the decision of the 2008 CCPR, a footnote will be inserted to indicate where MRLs are established for both milk fat and whole milk: “for monitoring and regulatory purposes, whole milk is to be analysed and the result compared to the MRL for whole milk”.

For compounds that are not fat-soluble, MRLs are expressed on the whole milk.

MRLs based on direct animal treatment are footnoted “the MRL accommodates external animal treatment”.

MRLs reflecting special uses or conditions are also distinguished by letters after the limit: Currently the following cases are distinguished by the letters indicated below:

E	The MRL is based on extraneous residues
Po	The MRL accommodates post-harvest treatment of the commodity
PoP	The MRL for the processed commodity accommodates post-harvest treatment of the primary commodity

In order to more fully reflect the impact of the statistical calculation methods, the JMPR concluded that the scaling steps last presented in the 2001 JMPR Report (0.01, 0.02, 0.03, 0.05, 0.07, 0.1, 0.2, 0.3, 0.5, 0.7, 1, 2, 3, 5, 7, 10, 15, 20, 25, 30, 40, and 50 mg/kg would be replaced with a more detailed scale where the statistical tools are successfully used. The Meeting continues using one significant figure for residues below 10 mg/kg and 2 significant figures up to 99 mg/kg. Residues from 100 would be expressed as multiple of 10, e.g., 110, 120. Applying more digits in expressing the MRLs would provide a false impression on the precision (uncertainty) of the estimation process including also the uncertainty of sampling, sample preparation and analysis. Nevertheless, the option to use other values as necessary is maintained.

6.13.1 Expression of MRLs at or about the LOQ

The LOQ is the lowest concentration of a compound that can be determined in a commodity with an acceptable degree of certainty. See Appendix II “Glossary of terms”.

The JMPR recognizes the difficulties that may arise in regulatory laboratories analysing low levels of residues in samples of unknown origin, and so usually estimates an LOQ which is achievable under those conditions. It is this figure that is proposed as a maximum residue limit “at or about the LOQ”. These limits are indicated with an asterisk (*) after the numerical value, e.g., 0.02*. This limit is often referred to as a “practical LOQ” to distinguish it from the LOQs reported in supervised trials.

An MRL so identified does not always necessarily imply that residues of the pesticides do not occur in that commodity. The application of a more sensitive or specific method may reveal detectable residues in some commodities as shown, e.g., in Tables 14 and 26 of the 1995 monograph on quintozene⁴³.

In many instances the use of a pesticide according to GAP results in a residue level in crops or commodities that is too low to be measurable by available analytical methods. Setting and enforcing MRLs for residues occurring at or about the LOQ of analytical procedures may require different approaches depending on the composition and definition of the residues. It is emphasized that all available relevant information should be carefully considered ensuring

⁴³ Pesticide residues in food—1995 evaluations. Part I. Residues. FAO Plant Production and Protection Paper 137, 1996.

that an MRL established at a level equivalent to a practical LOQ of the individual residue components will fully accommodate the levels of these components which could occur in commodities following treatment according to GAP.

As in cases of detectable residues, the definition of residues at or about the LOQ may also include a single residue component, e.g., fenpropimorph in sugar beet, or several residues components, e.g., aldicarb, its sulphoxide and its sulphone expressed as aldicarb in peanut oil, bentazone, 6-hydroxy bentazone and 8-hydroxy bentazone expressed as bentazone in soya bean; and fenthion, its oxygen analogue and their sulphoxides and sulphones expressed as fenthion in potato.

In cases where several metabolites are included in the definition of the residue two basic situations can be distinguished.

- a. The residue components are, or may be converted to, a single compound or analyte by the analytical method, e.g., fenthion. The total residue is measured as a single compound and expressed as the parent compound, i.e., fenthion oxygen analogue sulphone is measured and expressed as fenthion. The MRL is set and enforced on the basis of the total measured residue. After the conversion of all the residue components a single compound is determined, the MRL can be simply enforced either at or above the LOQ. This situation is similar to other cases where the residue is defined as a single compound.
- b. The residue components are determined separately by the method. The concentrations of measurable residues are adjusted for molecular weight and summed, and their sum is used for estimating the maximum residue level.

The problem is best illustrated with an example. The residues of bentazone in plant commodities are defined as the sum of bentazone, 6-hydroxybentazone and 8-hydroxybentazone, expressed as bentazone. The LOQs reported in supervised trials for each of the three components were generally 0.02 mg/kg, but the practical LOQs were regarded as 0.05 mg/kg for regulatory purposes. If an MRL for bentazone was set as the sum of the practical LOQs of the three components of the residue, it would have to be established at 0.2 mg/kg (3 times the practical limit of determination to incorporate all three residue components and round it to the next whole number). In this case, any one of the residue components could be present at 0.2 mg/kg, or all of the three at 0.06 mg/kg, without exceeding the MRL. Consequently, individual residue components could be respectively 10 and 3 times those which should arise from the recommended use of the compound but would be within the MRL. Similarly, if the sum of the LOQs achieved in the supervised trials was considered, an MRL of 0.1 mg/kg would be needed, which would still allow 5 times the residue that would arise from treatments complying with GAP.

The 1995 JMPR concluded that when residues are undetectable in a commodity an MRL based on the sum of the LOQs of the individual residue components may not be appropriate for enforcement purposes. The best option should be selected on a case-by case basis taking into account the relative ratio of metabolites.

From the regulatory laboratory perspective the best option is to choose a simple enforcement residue definition, i.e., a single component if possible. Standards of the single component should be readily available and not excessively expensive.

6.14 RECOMMENDATIONS FOR MAXIMUM RESIDUE LIMITS

The JMPR recommends to the CCPR that the estimated maximum residue levels be used as MRLs if the risk assessment process demonstrates that consumption of the relevant foods does not result in dietary intakes of residues exceeding the ADI or ARfD (Chapter 7, “*Estimating dietary intake of pesticide residues*”).

In those cases where a full ADI could not be estimated or the previously estimated ADI has to be withdrawn, the JMPR does not recommend MRLs or withdraws its previous recommendation

6.14.1 Recommendation of temporary MRLs

A temporary maximum residue limit is a maximum residue limit for a specified limited period, which is clearly related to required information.

As a general JMPR policy, TMRLs will not be introduced for a new compound, a compound in the periodic review programme or when there is no established GAP.

In the past the JMPR recommended a TMRL in some special circumstances on a case-by-case basis, for example:

- The JMPR was informed that experiments were in progress and data from residue or processing trials would be available for a specified meeting in the future.
- Immediate withdrawal of an MRL might be too disruptive if insufficient opportunity had been given for comment and data submission.
- TMRLs for specific commodities were recommended to replace group commodity MRLs or “fruit” and “vegetable” MRLs where residue trials on those specific commodities were known to be in progress

6.14.2 Guideline Levels

A Guideline Level is the maximum concentration of a pesticide residue occurring after use of the pesticide according to Good Agricultural Practice, but for which no Acceptable Daily Intake has been established or it has been withdrawn by the JMPR. There may still be a need to inform regulatory authorities about the residue levels to be expected in food items when these pesticides are used in accordance with Good Agricultural Practice.

Over a number of years the Codex Committee established a list of Guideline Levels for pesticides. These Guideline Levels had not been submitted to the Commission for adoption, but were used for the internal reference of the Committee. In 1993 the Codex Alimentarius Commission decided that Guideline Levels would no longer be established. The existing Guideline Levels had been submitted to a review programme in order to delete compounds from the list. Currently, Guideline Levels exist for methyl bromide and guazatine.

CHAPTER 7

ESTIMATING DIETARY INTAKE OF PESTICIDE RESIDUES

CONTENTS

Background

Long-term dietary intake

Short-term dietary intake

Handling of cases where JMPR estimates of dietary intake exceed the ADI or ARfD

7.1 BACKGROUND

To assess whether the maximum residue level proposed to CCPR, for use as a MRL, provides sufficient consumer safety, available residue data are combined with cultural dietary information to estimate potential residue intake by consumers. The consumer is considered to be adequately protected when estimated dietary intake of pesticide residues does not exceed the acceptable daily intake (ADI) or the acute reference dose (ARfD).

The JMPR has, from the outset, tried to estimate potential pesticide residue intake by utilising available data. In using the MRL as the residue level and the dietary patterns for the quantity of food consumed, then summing all intakes, the JMPR arrived at the Theoretical Maximum Daily Intake or TMDI. Nonetheless the JMPR was aware that TMDI calculations can result in a gross overestimation of intake. Conversely, existing uses of a pesticide, not brought to the attention of the JMPR, could result in an underestimation of the residue intake.

Until 1997 the TMDI dietary intake calculations had been carried out according to the Guidelines for predicting dietary intake of pesticide residues⁴⁴ published by the WHO in 1989. The dietary intake of any particular pesticide residue was obtained by multiplying the residue level in the food by the amount of commodity consumed from a “global” and five “cultural” diets, also known as “regional” diets. Total intake of the pesticide residue in each of the diet groups was then obtained by summing the intakes from all commodities containing the residue concerned. Intake estimation could be refined by allowing for the residue level in the edible portion of the commodity, the reduction or increase of residue levels on commercial processing such as canning and milling, and the reduction or increase in the level of residue on preparation or cooking of the food.

Based on the request of the CCPR a Joint FAO/WHO Consultation on Guidelines for predicting the Dietary Intake of Pesticide Residues⁴⁵ in 1995 reviewed the existing guidelines and recommended feasible approaches for improving the reliability and accuracy of methods for predicting the dietary intake of pesticide residues. The aim was to promote a greater acceptance of Codex MRLs by governments and, more importantly, by consumers. The report of the consultation contained recommendations for improving estimates of dietary intake, most notably the use of supervised trials median residue (STMR) levels in lieu of MRLs in the calculation of International Estimated Daily Intakes (IEDIs) and National Estimated Daily Intakes (NEDIs).

⁴⁴ WHO. 1989. Guidelines for predicting dietary intake of pesticide residues. GEMS/Food WHO, Geneva.

⁴⁵ WHO. 1995. Recommendations for the revision of the guidelines for predicting dietary intake of pesticide residues. Report of the FAO/WHO Consultation, (WHO/FNU/FOS/95.11) Geneva.

The IEDI incorporates those factors which can be applied at the international level and which comprise a subset of factors that might be considered at national level. The factors to be considered for IEDI calculations are:

- median residue data from supervised trials (STMR)
- residue definitions, which include all metabolites and degradation products of toxicological concern
- for residues at or below the limit of quantification (indicated with *), the median residue should be estimated to be the LOQ except when evidence from trials and supporting studies suggests that that residues are essentially zero
- the edible portion
- effects on residue levels due to storage, processing or cooking practices
- other known uses of the pesticide.

The National Estimated Daily Intake (NEDI) should be based on the same factors as for the IEDI, but the following additional factors based on national use pattern of the pesticides and food consumption data should also be taken into consideration, which would allow a refinement of the NEDI:

- proportion of crop or food commodity treated
- proportion of crop domestically produced and imported
- compliance monitoring and surveillance data
- total diet (market basket) studies
- food consumption data, including that of subgroups of the population.

The revised guidelines also contained sections on the risk assessment of acute hazards posed by pesticide residues and predicting dietary intake of acutely toxic pesticide residues. The guidelines have been further refined into operating procedures. See this chapter, Section 3 “*Short-term dietary intake*”.

The revised guidelines⁴⁶ were issued in 1997.

7.2 LONG-TERM DIETARY INTAKE

Long-term dietary intakes are calculated by multiplying the residue concentrations (STMRs, STMR-Ps or, where these are not available, recommended MRLs) by the ‘average’ daily per capita consumption estimated for each commodity, on the basis of the GEMS/Food diets⁴⁷, and summing the intakes for each food.

GEMS/Food Regional Diets, also referred to as cultural diets, are based on FAO food balance sheets from selected countries and expert knowledge. Consumption data derived from Food Balance Sheets reflect what is grown in a country plus what is imported, minus what is exported, and then divided by the number of inhabitants. GEMS/Food regional diets based on

⁴⁶ WHO. 1997. Guidelines for predicting dietary intake of pesticide residues, 2nd revised edition Unpublished document (WHO/FSF/FOS/97.7). <http://www.who.int/foodsafety/publications/chem/pesticides/en/>

⁴⁷ WHO. 1998. GEMS/Food Regional Diets. Regional per capita consumption of raw and semi-processed agricultural commodities. Food Safety Unit. WHO/FSF/FOS/98.3, Geneva. <http://www.who.int/foodsafety/chem/gems/en/index1.html>

food balance sheets include commodities that contain inedible or non-eaten portions. The consumption of the edible portion of food commodities should be used in estimating intakes rather than that of entire commodities. Corrections for wastage and home production can also improve this data. Because food balance sheets are thought to overestimate consumption of most commodities, the use of the per capita food consumption based on these sheets is generally thought to accommodate high percentile consumers (WHO 1997).

Until 2005 the JMPR used 5 regional diets. In 1997 Joint FAO/WHO Consultation on Food Consumption and Exposure Assessment of Chemicals recommended that new diets be developed based on a cluster analysis approach using major food groups. This recommendation was reconfirmed at a Joint FAO/WHO Expert Consultation on Exposure Assessment held in May 2005 in Annapolis, Maryland USA. This meeting agreed that the new diets would more accurately reflect the diversity of global food consumption patterns than the original five GEMS/Food Regional Diets⁴⁸. Accordingly, 13 GEMS/Food Consumption Cluster Diets were developed based on FAO Food Balance Sheets. Data are currently available for 13 cluster diets with the number of countries given in brackets: A: Africa (22), B: Africa/Europe/Middle East (9), C: Africa/Middle East (10), D: Europe/Middle East (19), E: Europe (17), F: Europe (7), G: Far East (15), H: Latin America (12), I: Africa (15), J: Africa (11), K: Latin America (20), L: Far East (10) and M: Europe/Latin America (7). These Consumption Cluster Diets have been incorporated by the Dutch National Institute for Public Health and the Environment (RIVM), in cooperation with WHO/GEMS/Food, into an automated spreadsheet⁴⁹ to ensure consistency in IEDI calculations.

To use the spreadsheets, estimates made by JMPR (ADI, STMR (-P), HR (-P), and when necessary MRL values) are entered according to the manual attached to the templates. The calculations and generation of a final table are performed automatically. Great care is needed in data entry to ensure the food items are correctly matched with the corresponding residue value, taking into account, such factors as the processed proportion of a raw agriculture commodity where STMR-P values are available for the processed food, or the edible portion of the commodity if residues are available for the edible portion. To calculate processing factors, the principles described in Section 8 of Chapter 5 should be followed.

On some occasions STMR values may not be available for certain residue×commodity combinations. In such cases the MRL values may be entered in the spreadsheet to provide an intermediate estimate between the TMDI and the IEDI. Such situations should be fully explained in the report.

Notes for intake spreadsheets:

- diets are expressed in g/person/day
- daily intakes are expressed in µg/person
- the MRL is not entered unless it is used in the calculation
- data entry for meat and fat is based on 20/80% fat/muscle values for cattle and other mammalian animals and 10/90% fat/muscle values for poultry.

The procedure followed is illustrated in the example below.

⁴⁸ WHO 2008a. Dietary exposure assessment of chemicals in food Report of a Joint FAO/WHO Consultation Annapolis, Maryland, USA 2–6 May 2005, http://whqlibdoc.who.int/publications/2008/9789241597470_eng.pdf

⁴⁹ http://www.who.int/foodsafety/chem/acute_data/en/index.html

For deltamethrin, the cattle fat residue values from *dietary* exposure were a HR of 0.19 mg/kg and a STMR of 0.16 mg/kg. The cattle muscle residue values were a HR of 0.027 mg/kg and a STMR of 0.01 mg/kg. The poultry fat residue values were a HR of 0.09 mg/kg and a STMR of 0.038 mg/kg. The poultry muscle residue values were a HR of 0.02 mg/kg and a STMR of 0.02 mg/kg. The following tables illustrate the new calculation procedure for meat.

The automated excel template has the entries for 20/80% fat/muscle values for mammals and the 10/90% fat/muscle values for poultry, and performs the calculation correctly.

DELTAMETHRIN (135): International Estimate of Daily Intake ADI=0.01 mg/kg bw or 600 µg/person; 550 µg/person for Far East									
		MRL	STMR or STMR- P	Diets: g/person/day. Intake = daily intake: µg/person					
				A		E		M	
Code	Commodity	mg/kg	mg/kg	diet	intake	diet	intake	diet	Intake
MM 95	Meat (mammals other than marine)			27.7		90.2		158.3	
	<i>Muscle (meat consumption×80%)</i>		0.01	22.16	0.222	72.16	0.722	126.64	1.266
	<i>Fat (meat consumption×20%)</i>		0.16	5.54	0.886	18.04	2.887	31.66	5.066
PM110	Poultry meat			7.1		61		115.1	
	<i>Muscle (meat consumption×90%)</i>		0.02	5.68	0.114	48.8	0.976	103.59	2.072
	<i>Fat (meat consumption ×10%)</i>		0.04	1.42	0.057	12.2	0.488	11.51	0.460
		TOTAL =			1.278		5.072		8.864
		% ADI =			0%		1%		2%

The format of a spreadsheet for calculating long-term intake is provided in Tables XI.4 and XI.5 (Appendix XI). The tables are completed for an IEDI estimation for parathion-methyl and for a mixed TMDI-IEDI calculation for myclobutanil.

International estimated daily intakes (IEDIs) are derived only where STMRs or STMR-Ps are used in the calculation. Theoretical maximum daily intakes (TMDIs) use MRLs in the calculation.

$$\text{IEDI} = \sum (\text{STMR}_i \times F_i)$$

$$\text{TMDI} = \sum (\text{MRL}_i \times F_i)$$

where

STMR_i (or STMR-P_i) is STMR (or STMR-P) for food commodity i

MRL_i is MRL for food commodity i

F_i is GEMS/Food regional consumption of food commodity i

JMPR intake estimates take into account JMPR recommendations. They may not always agree with a calculation that includes all current Codex MRLs because Codex MRLs whose withdrawal has been recommended by the JMPR are not included in the estimate.

Long-term dietary intakes are expressed as percentage of the ADI for a 60 kg person with the exception of the intake calculated for the diets G and L, in which a body weight of 55 kg is used⁵⁰. The percentages are rounded up to one whole number up to nine and to the nearest 10 above that. When the percentage is higher than 100 for the compounds for which IEDIs are calculated, the information provided to the JMPR does not allow an estimate that the dietary intake would be below the ADI and a note to this effect is included in the Report. However, percentages above 100 should not necessarily be interpreted as giving rise to a health concern due to the conservative assumptions upon which the assessments are based⁵¹. In cases where the ADI is exceeded, JMPR indicates in its report which part of the risk assessment leaves most room for refinement (see Chapter 7. Section 6).

At the National level, further refinements of the dietary intake calculations are possible, taking into account more detailed information on food consumption, monitoring and surveillance data, total diet or reliable data on the percentage of crop treated and percentage of crop imported.

7.3 SHORT-TERM DIETARY INTAKE

In 1994 the JMPR considered the assessment of acute dietary risk in response to the CCPR's reservations about MRLs proposed for acutely toxic pesticides. The CCPR had suggested that the traditional ADI may not be appropriate for assessing risks reflecting short-term exposure to residues. Revised guidelines⁵² were published in 1997 by the WHO and contained chapters on risk assessment of acute hazards and predicting dietary intake of acutely toxic pesticide residues. Procedures and practical guidelines were subsequently developed and the 1999 JMPR commenced formal routine assessment of acute dietary risk for pesticide residues in food.

High intake of a residue would occur when a large portion of a food with a high residue was consumed. The large portion size was agreed as the 97.5th percentile daily consumption for eaters of that food. Research in the UK and other countries had shown that the residue level in a unit of fruit or vegetable, e.g., a single apple or a single carrot, may be substantially higher than the residue in a composite sample representing the typical residue in the lot. This issue was accounted for through the introduction of a variability factor into the risk assessment. This concept provided the basis for the assessment of short-term dietary intake of pesticide residues.

The highest residue from the supervised residue trials at maximum GAP was generally seen as the better option than the MRL for short-term dietary intake calculations. The MRL is expressed on commodity moving in trade rather than the edible portion and the residue definition for enforcement does not necessarily match the residue definition for dietary intake estimation. The estimation of an MRL usually involves 'rounding up' to an accepted value, and rounding of values at an intermediate stage of a calculation is undesirable. Furthermore, the use of the MRL in an intake calculation may give the impression that adjusting the MRL

⁵⁰ FAO. 2003. Pesticide Residues in Food 2003- Report. FAO Plant Production and Protection Paper No. 176 FAO, Rome. Chapter 3.

⁵¹ FAO. 2008. Pesticide Residues in Food 2008- Report. FAO Plant Production and Protection Paper No. 193 FAO, Rome. P 51.

⁵² WHO. 1997. Guidelines for predicting dietary intake of pesticide residues, 2nd revised edition Unpublished document (WHO/FSF/FOS/97.7). <http://www.who.int/foodsafety/publications/chem/pesticides/en/>

will change the intake, but there will be no real change of dietary intake if the MRL is changed but GAP and other factors remain the same.

The highest residue in the composite sample of the edible portion from the trials used for estimating the maximum residue level is defined as the HR, expressed in mg/kg. In those cases where information is available only on the whole commodity and not on the edible portion, the HR expressed on the whole commodity may be used in the dietary intake calculations, though this is the least preferred option.

A 'high residue' is needed in the intake calculation for those processed commodities where bulking and blending are not likely to influence residues in the commodity as consumed, e.g., dried fruit or canned pineapple. In such cases the processing factor is applied to the highest residue from the supervised residue trials at maximum GAP rather than to the MRL. Similar arguments regarding rounding and residue definition apply as for the HR. The high residue in a processed commodity is referred to as the HR-P (highest residue - processed commodity).

The HR-P is the residue in a processed commodity calculated from the highest residue of the raw agricultural commodity and the corresponding processing factor.

The values provided by WHO GEMS/Food for the highest large-portion diet with the associated body weight and country for children and general population are used in the IESTI calculations.

Data on unit weights and large portion consumption (97.5th percentile diets) and the mean body weights for the populations associated with the food consumption data are provided on the WHO Web site⁵³.

Calculations of intake recognize four different cases (1, 2a, 2b and 3). Case 1 is the simple case where the residue in a composite sample reflects the residue level in a meal-sized portion of the commodity. Case 2 is the situation where the meal-sized portion as a single fruit or vegetable unit might have a higher residue than the composite. Case 2 is further divided into case 2a and case 2b where the unit size is less than or greater than the large portion size respectively. Case 3 allows for the likely bulking and blending of processed commodities such as flour, vegetable oils and fruit juices.

LP:	Highest large portion reported (97.5 th percentile of eaters), in kg food per day
HR:	Highest residue in composite sample of edible portion found in the supervised trials used for estimating the maximum residue level, in mg/kg
HR-P:	Highest residue in a processed commodity, in mg/kg, calculated by multiplying the highest residue in the raw commodity by the processing factor
U	Unit weight of the whole commodity (as defined for MRL setting, including inedible parts)
U _e :	Unit weight of the edible portion, in kg, median value provided by the country where the trials which gave the highest residue were carried out
v:	Variability factor - the factor applied to the composite residue to estimate the residue level in a high-residue unit; defined as the residue level in the 97.5 th percentile unit divided by the mean residue level for the lot.
STMR:	Supervised trials median residue, in mg/kg
STMR-P:	Supervised trials median residue in processed commodity, in mg/kg

See Appendix II, Glossary of Terms, for definitions of ARfD, HR, HR-P, STMR and STMR-P, and processing factor.

⁵³ http://www.who.int/fsf/Chemicalcontaminants/Acute_Haz_Exp_Ass.htm,

It should be noted that:

- The LP should be matched to the Codex commodity to which the HR or STMR values relate. In the case of commodities that are predominantly eaten as the fresh fruit or vegetable, the LP should relate to the raw agricultural commodity. However, when major portions of the commodity are eaten in a processed way, e.g., grains, and when information on the residue in the processed commodity is available, the LP should relate to the processed commodity, e.g., flour or bread.
- Although it was decided at the International Conference on Pesticide Residues Variability and Acute Dietary Risk Assessment in 1998⁵⁴ that the median unit weight (U_e) should be used in the IESTI equation, this value is not always available. Countries frequently use other values, such as the mean or an approximate value. JMPR uses the values that were submitted by Codex Member States to WHO GEMS/Food, on the assumption that these values represent median unit weights.

Case 1

The residue in a composite sample (raw or processed) reflects the residue level in a meal-sized portion of the commodity (unit weight, U , is below 0.025 kg). Case 1 also applies to meat, liver, kidney, edible offal, and eggs, and for grains, oil seed, and pulse commodities when the estimates are based on post-harvest use of the pesticide.

$$\text{IESTI} = \frac{\text{LP} \times (\text{HR or HR-P})}{\text{bw}}$$

Case 2

The meal-sized portion, such as a single fruit or vegetable unit might have a higher residue than the composite (whole fruit or vegetable unit weight, U , is above 0.025 kg).

Case 2a

Unit edible weight of raw commodity (U_e) is less than large portion weight.

$$\text{IESTI} = \frac{U_e \times (\text{HR or HR-P}) \times v + (\text{LP} - U_e) \times (\text{HR or HR-P})}{\text{bw}}$$

The Case 2a formula is based on the assumption that the first unit contains residues at the $[\text{HR} \times v]$ level and the next ones contain residues at the HR level, which represents the residue in the composite from the same lot as the first one.

Case 2b

Unit edible weight of raw commodity, U_e , exceeds large portion weight.

$$\text{IESTI} = \frac{\text{LP} \times (\text{HR or HR-P}) \times v}{\text{bw}}$$

The Case 2b formula is based on the assumption that there is only one consumed unit and it contains residues at the $[\text{HR} \times v]$ level.

⁵⁴ PSD Report of the International Conference on Pesticide Residues Variability and Acute Dietary Risk Assessment. York UK. Feb 1999. http://www.pesticides.gov.uk/uploadedfiles/web_assets/prc/WPPR_final_report.pdf

Case 3

Case 3 is for those processed commodities where due to bulking or blending the STMR-P represents the likely highest residue. Case 3 also applies to milk, grains, oil seeds, and pulses for which estimates are based on the pre-harvest use of the pesticide.

$$\text{IESTI} = \frac{\text{LP} \times \text{STMR-P}}{\text{bw}}$$

7.4 ACUTE REFERENCE DOSE

The acute reference dose (ARfD) of a chemical is the estimate of the amount of a substance in food or drinking-water, expressed on a body weight basis, that can be ingested over a short period of time, usually during one meal or one day, without appreciable health risk to the consumer on the basis of all the known facts at the time of the evaluation. ARfDs are derived from toxicological data obtained from feeding studies on laboratory animals. The estimated short-term dietary intake of a residue is compared with its ARfD in the risk assessment.

The JMPR WHO Core Assessment Group has already assessed many compounds and either assigned an ARfD or decided that an ARfD is unnecessary. The JMPR decided that it was inappropriate to use the ADI for a compound that has not yet been assessed for an ARfD.

In the short-term risk assessment of a compound, there are three situations with respect to the ARfD:

- 1) an ARfD is available
- 2) an ARfD is unnecessary
- 3) the compound has not yet been evaluated for an ARfD.

When an ARfD is available the calculated IESTI values may be expressed as % of ARfD.

When an ARfD is deemed unnecessary, IESTI calculations are not necessary. In this case in the residue evaluations it is not necessary to estimate HR and HR-P values because they are not required.

When the compound has not yet been evaluated for an ARfD, HR and HR-P values should be estimated and IESTI values calculated. The ARfD section in the table heading should state: “may be necessary but has not yet been established.” The final column in the IESTI tables cannot be completed (% ARfD) and entries should be indicated by a dash “–”.

7.5 IESTI TABLES

For commodities where large portion diet information is available and for compounds for which ARfDs have been established, an acute risk assessment is carried out for each commodity×compound combination by assessing the IESTI as a percentage of the ARfD of the compound. If the percentage is higher than 100, the information provided to the JMPR does not allow an estimate that the acute dietary intake of the residue in that commodity would be below the acute reference dose and a note to this effect is included in the Report. See Appendix X, section “Dietary risk assessment” for standard statements depending on the results of the IESTI calculations.

An automated Excel template, similar to that described under long-term intake calculation, had been developed by Dutch National Institute for Public Health and the Environment (RIVM), in cooperation with WHO/GEMS/Food⁵⁵.

Tables XI.6 and XI.7 (Appendix XI) provide examples of the format used in the IESTI calculation spreadsheets; the examples used are for parathion-methyl. For each compound, two tables are required, one for the general population and one for children between the ages of 2 and 6 years.

The table heading should show the compound, IESTI, general population or children and the ARfD.

The commodities and the STMR, STMR-P, HR and HR-P values are taken from the recommendation tables. Only those values needed in the calculations should be entered in the IESTI tables. Note that STMR values are generally not used in IESTI calculations and should not be entered into the tables (exceptions: STMR values are used for milk, STMR values for commodities like wheat are precursors to the STMR-P values for the processed commodities).

The percentages of the ARfD are rounded to one significant figure for values up to and including 100% and to two significant figures for values above 100%.

The IESTI values in the table are expressed as $\mu\text{g}/\text{kg}$ bw in preference to the traditional mg/kg bw for more convenient reading; the % ARfD is unchanged by the choice of units.

Body weights

In selecting the appropriate body weight, an ad hoc meeting (1999) recommended the use of 15 kg for children aged 6 and under and 60 kg for the general population. Since it is necessary to express the IESTI as per kg bodyweight for comparison with the ARfD, the JMPR recommended that body weights provided by the appropriate national Governments should be used in the calculation. The JMPR agreed that where these were not available, default values of 15 or 60 kg should be used.

Food unit weights and % edible portion

Food unit weights are quite influential on Case 2 IESTI calculations. Data on unit weights for a particular food provided to WHO GEMS/Food may cover a range.

The JMPR decided to use the unit weight appropriate to the region where GAP had been used to recommend the MRL. The JMPR agreed that in cases where no data had been supplied the calculation would not be carried out unless it could be concluded that a typical unit size was generally similar from region to region.

National governments that supplied unit weight data (U) also supplied information on the percentage edible portion size. The unit weight in Case 2 calculations is the edible portion unit weight (U_e). For example, the avocado unit weight (U) is 0.3 kg with 60% of its weight edible, resulting in a unit weight edible portion (U_e) of 0.18 kg.

Variability factors

Since its introduction by the 1997 Expert consultation⁵⁶, the variability factor has been gradually refined based on the increased data base and information on the nature of the distribution of residues in crop units.

⁵⁵ http://www.who.int/foodsafety/publication/chem/regional_diets

⁵⁶ FAO/WHO. 1997. Geneva consultation acute dietary intake methodology. Geneva, Switzerland. 10-14 February 1997. WHO/FSF/FOS/97.5

The 2003 JMPR⁵⁷ evaluated the available information on the relation of maximum residues in crop units and the average residue in the corresponding composite samples⁵⁸. The Meeting agreed to adopt a default variability factor of 3 for the estimation of residue levels in high-residue units in the IESTI calculations where unit weights, U, exceed 25 g (0.025 kg). The default variability factors of 5, 7 and 10 were replaced by a common default factor of 3 (JMPR report 2003). The applicability of the default variability factor of 3, which is the rounded mean (2.8) of variability factors, was confirmed by the 2005 JMPR⁵⁹ based on the evaluation of an extensive data base of residues in crop units⁶⁰. The FAO Panel agreed to continue the current practice of using specific unit variability factors in preference to the default value where the supporting data are available, valid and sufficient.

The 2007 JMPR⁶¹ noted that the parameters to be used in the IESTI equation are under debate, especially within the EU. The reason for this is the different views on which level of conservatism in the calculations is appropriate. CCPR concurs with the level of conservatism that JMPR currently applies.

Summary of choice of values in IESTI calculation spreadsheets

1. Commodity, STMR, STMR-P, HR and HR-P: use the relevant values directly from the recommendations table.
2. Large portion diet: use the values provided by WHO GEMS/Food for the highest large-portion diet, body weight and country for children and general population.
3. Unit weight: choose the country, unit weight and edible portion weight from the values provided by WHO GEMS/Food. The country should be associated with the region where GAP had been used to recommend the MRL.
4. Case: decide the case from the unit weight, U, unit weight edible portion, U_e, and large portion size.

7.5.1 Animal commodities IESTI calculations

See also Chapter 6, section 12 “*Estimation of maximum residue levels and STMR values for commodities of animal origin*”.

According to the recommended sampling principles (References—Pesticide Residues in Food, CODEX ALIMENTARIUS, 1993), “a lot would comply with the MRL” if:

- a. the final sample (consisting of combined primary samples) of commodities other than meat and poultry products did not contain a residue above the MRL, or
- b. none of the primary samples of meat and poultry products analysed contained a residue above the MRL”.

This implies that a variability factor should not be used in the IESTI calculation for animal commodities.

⁵⁷ Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group. [FAO Plant Production and Protection Paper](#), 176, 2004

⁵⁸ Hamilton DJ, Ambrus Á, Dieterle RM, Felsot A, Harris C, Petersen B, Racke K, Wong S-S, Gonzalez R, Tanaka K, Earl M, Roberts G and Bhula R. Pesticide residues in food – Acute dietary Intake. *Pest Manag Sci* 60:311-339 (2004).

⁵⁹ Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group. [FAO Plant Production and Protection Paper](#), 183, 2005

⁶⁰ Ambrus Á., Variability of pesticide residues in crop units, *Pest Manag Sci*. 62: 693-714, 2006.

⁶¹ FAO. 2007. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group.. *FAO Plant Production and Protection Paper No. 191* 2007. FAO, Rome.

The estimation of acute intake from the consumption of animal commodities, except milk, should be performed using the Case 1 defined by the methodology. The mixed 20/80% fat/muscle values for cattle and other mammalian animals and the mixed 10/90% fat/muscle values for poultry should be used.

For milk, Case 3 should be applied (bulking or blending large portion at the STMR level).

7.6 HANDLING OF CASES WHERE JMPR ESTIMATES OF DIETARY INTAKE EXCEED THE ADI OR ARfD

Where the procedures described in this chapter have been applied to pesticides evaluated as new compounds or under the periodic review program the results are the best estimates of dietary intake of those pesticides according to the available data and methods applicable at the international level. The JMPR, by the use of footnotes, draws attention to those cases when intake estimates exceed the ADI or the ARfD.

If the JMPR estimate of long-term intake for a new or periodic review compound still exceeds the ADI for one or more of the GEMS/Food regional diets a footnote will be attached to the compound in the recommendations table:

“The information provided to the JMPR precludes an estimate that the dietary intake would be below the ADI – JMPR [year].”

If the JMPR estimate of short-term intake of a new or periodic review compound still exceeds the ARfD for one or more food commodities a footnote will be attached to those commodities in the recommendations table:

“The information provided to the JMPR precludes an estimate that the dietary intake would be below the ARfD – JMPR [year].”

There is a public perception that small differences in estimated intake are real differences in terms of food safety, e.g., 120% ARfD is unacceptable whereas 80% ARfD is acceptable. However, there is conservatism in the derivation of the ARfD and in the estimation of intake. For example, a safety factor for inter-individual variation is included when the ARfD is established, and as such the ARfD is designed to protect those individuals at the upper-end of human susceptibility. There is likely to be very limited overlap between the population with the greatest sensitivity to a particular pesticide and the population with estimated intake of residues greater than the ARfD. Therefore, in cases where the ARfD is exceeded, additional considerations should be taken into account, e.g., the amount by which the ARfD is exceeded, the basis on which the ARfD has been established, and the uncertainties in the estimate of intake⁶². In cases where the ADI and/or ARfD are exceeded, the JMPR indicates in its Report which part of the risk assessment leaves most room for refinement. If no more refinements are possible, the estimated maximum residue level will not be adopted as an MRL by CCPR.

⁶² FAO. 2007. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group.. FAO Plant Production and Protection Paper No. 191 2007. FAO, Rome.

CHAPTER 8

USE OF JMPR RECOMMENDATIONS BY REGULATORY AUTHORITIES

CONTENTS

Introduction

Safety assessment of pesticides

Residue studies and recommended MRLs

Interpretation of residue analytical results in comparison with MRLs

8.1 INTRODUCTION

The evaluations and appraisals of the compounds are, in most cases, based on unpublished proprietary data submitted for the purpose of the JMPR assessment. In this context the JMPR documents are a unique source of information. Regulatory authorities and other interested specialists are encouraged to make use of the critical evaluations of the JMPR.

8.2 SAFETY ASSESSMENT OF PESTICIDES

The JMPR monographs and reports should be of help to FAO and WHO Member States in the safety assessment of pesticides and their residues. However, two major problems can be encountered when a Member State attempts to use these assessments: (1) the JMPR assesses the toxicology of active ingredients and not formulations, which are controlled at the national level, and (2) relationships between the purity and specifications of the active ingredients involved in the tests evaluated by the JMPR and the technical materials of commerce are often unknown.

The purity of technical active ingredient depends on, among others, the route and conditions of synthesis, the purity of raw materials used for the manufacture, and the packing and storage conditions. The toxicity of certain impurities can be several magnitudes higher than that of the active ingredient, and therefore their presence even in very small concentrations may substantially affect the toxicity of the pesticide product.

The Joint Meeting evaluates toxicological studies on test materials that in most cases correspond to active ingredients that are sold by the companies which provided the data. The purity and specifications of active ingredients that national regulatory authorities are asked to approve may or may not correspond to those that were tested and summarized in the JMPR monographs. For this reason, national registration authorities should carefully consider the extent of similarity between any active ingredient being considered for registration and the technical material assessed by the Joint Meeting. To be able to make this determination, registration authorities should seek information on manufacturing impurities in pesticide products, as emphasised in the *FAO International Code of Conduct on the Distribution and Use of Pesticides* (Sections 6.2.2 and 6.2.3)⁶³. The safety of other components of formulations should also be considered when registering pesticides. For these reasons the JMPR does not

⁶³ FAO International Code of Conduct on the Distribution and Use of Pesticides <http://www.fao.org/agriculture/crops/core-themes/theme/pests/pm/code/en/>

recommend use of JMPR Evaluations as the sole basis for safety assessment for national registrations.

If the evaluations are used for registration purposes, authorities should use documentation provided by manufacturers in accordance with national laws relating to the submission and use of unpublished proprietary data to ensure that the JMPR evaluations are of pesticides manufactured by the same routes, of comparable purity and with similar impurities to the pesticides that are being registered.

8.2.1 Relevance of pesticide specifications for JMPR evaluations

The 2006 edition of the FAO Manual on the development and use of FAO specifications for plant protection products⁶⁴ provide an outline of the current procedure for data evaluation. Under this new procedure the data requirements were expanded dramatically. FAO in co-operation with WHO now evaluates, in confidence, the physico-chemical properties, the impurity, toxicological and ecotoxicological profiles of technical materials. The evaluations ensure that specifications include all relevant impurities. These impurities, following the definition in the FAO-Manual on specifications, are those by-products of the manufacture or storage of a pesticide which, compared with the active ingredient, are toxicologically significant to health or the environment, are phytotoxic to treated plants, cause taint in food crops, affect the stability of the pesticide, or cause any other adverse effect. Besides the assessment of the toxicological, ecotoxicological and impurity profile data by WHO, the FAO also seeks access to registration data from competent authorities to assess whether:

- (i) the technical material, for which an FAO specification is proposed, is equivalent to that registered by the authority, as assessed by a comparison between the data submitted to FAO and those submitted for registration; or
- (ii) their decision that technical materials from different manufacturers are equivalent was based on data similar to those provided to FAO.

FAO specifications apply now only to products for which the technical materials produced by each manufacturer have been evaluated by these organisations. This is a radical change because, under the previous procedure, the FAO specification could be taken to apply to any notionally similar product. To take account of this change, the new procedure also defines the process for the determination of equivalence (similarity) of technical pesticides, so that an FAO specification can be extended to truly equivalent products.

The new procedure, including the definition of equivalence, was developed to enhance product quality, to improve pesticide user and consumer protection as well as to reduce unwanted effects on the environment. This procedure is now widely accepted by both research companies and manufacturers of generic compounds.

The data submissions to the Joint FAO/WHO Meeting on Pesticide Specifications (JMPS) are coordinated with JMPR evaluations, however it should be noted that JMPS itself does not serve Codex directly.

⁶⁴ Manual on development and use of FAO and WHO specifications for pesticides. February 2006 Revision of First Edition. FAO Plant Production and Protection Paper. Revised. www.fao.org/ag/AGP/AGPP/Pesticid/Default.htm

8.3 RESIDUE STUDIES AND RECOMMENDED MRLs

The information relating to pesticide residues, e.g., results of supervised trials, metabolism, animal transfer and processing studies, can be used more generally than the safety assessments of pesticides.

The comparability of the trial conditions discussed in detail in Chapters 5 and 6 should be assessed for deciding on the applicability of JMPR conclusions and recommendations for the particular national use conditions.

Codex MRLs are intended to be used primarily to enforce and control compliance with nationally authorized uses of pesticides on commodities moving in international trade. The applicability of Codex MRLs for national use, depends on the relation of GAP on which the maximum residue level estimates were based to the national GAP. In making decisions on comparability of national use conditions to the trial conditions described in the monographs, the results of a few supervised trials carried out under typical growing conditions of the country can be of great value.

In accordance with the principles of *FAO International Code of Conduct on the Distribution and Use of Pesticides*, governments “should promote the use of safe, efficient and cost effective application methods” in order to reduce the exposure of consumers and the environment resulting from the use of pesticides. When the national use conditions lead to substantially lower residues than the Codex MRL, the establishment of lower national MRLs may be considered for enforcing domestic uses since higher MRLs would encourage unauthorized use of the pesticide, which is against the principle of GAP. However, for imported commodities the national authorities have an obligation to accept higher Codex MRLs which afford an acceptable level of consumer protection, in accordance with the provisions laid down in the Sanitary and Phytosanitary (SPS) agreement of the Uruguay Round of GATT (General Agreements on Tariffs and Trade).

8.4 INTERPRETATION OF RESIDUE ANALYTICAL RESULTS IN COMPARISON WITH MRLs

A question frequently asked is whether the Codex MRLs, which are based on the limits recommended by the JMPR, should be considered either as strict limits or with the allowance of a further margin when considering the analysis of samples for enforcement purposes.

By definition an MRL is a limit not to be exceeded. The burden of proof is on the monitoring authority to establish, with a high degree of assurance, whether the residue in the lot being examined exceeds the MRL, in order to take any regulatory actions.

The uncertainty of the analytical results (S_R) deriving from the random variation of the consecutive procedures comprises the uncertainties of sampling (S_S), sample preparation (S_{Sp}) and analysis (S_A).

$$(S_R) = \sqrt{[(S_S)^2 + (S_{Sp})^2 + (S_A)^2]}$$

Since the average residue is the same the equation can be written as:

$$(CV_R) = \sqrt{[(CV_S)^2 + (CV_{Sp})^2 + (CV_A)^2]}$$

The uncertainty of the final analytical result (CV_R) cannot be smaller than that of any step of its measurement.

Based on the evaluation of large number of residue data, the average sampling uncertainty following the Codex sampling procedure was estimated⁶⁵ to be:

- small and medium size crops (unit mass \leq 250g, minimum sample size =10): 25%
- large crops (unit mass $>$ 250 g, minimum sample size = 5): 33%
- Brassica leafy vegetables (unit mass $>$ 250 g, minimum sample size = 5): 20%.

The Codex Committee on Pesticide Residues⁶⁶ is currently working on a revision of the Guidelines on the estimation of uncertainty of results for the determination of pesticide residues (CAC/GL 59-2006), taking into account the general Codex criteria for acceptable precision and trueness of the residue data. Both parameters should be considered when the measurement results are interpreted.

International collaborative studies revealed that, in the comparison of an analytical result with the MRL, trueness (influenced by mainly systematic errors) is more important than precision, i.e., random errors.

In order to obtain reliable results, the laboratories performing regulatory enforcement analysis are encouraged to:

- establish internal quality control measures which enable them to assess the within laboratory variation of results
- participate in international sample check programmes to assess the accuracy of their analysis
- pay attention to information on storage stability of residues and the definition of residues
- strictly adhere to Codex guidelines for preparing the portion of commodity for analysis
- validate the sampling procedures used for obtaining samples, and ensure proper training of sampling officers.

The same precautions should be applied in performing supervised trials or selective surveys to provide data for estimating maximum residue levels.

⁶⁵ Ambrus, A. & Soboleva, E. (2004) *JAOAC International*. 87, 1368-1379

⁶⁶ Report of the Forty-first Session of the Codex Committee on Pesticide Residues, *Beijing, China, 20 – 25 April 2009*, <http://www.codexalimentarius.net/download/standards>

CHAPTER 9

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FAO, Portion of Commodities to which Codex Maximum Residue Limits Apply and which is Analysed. In Joint FAO/WHO Food Standards Programme Codex Alimentarius Vol. 2A, Part I. Section 2. Analysis of Pesticide Residues, FAO, Rome, 2000, 27-36.

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Appendix I

ABBREVIATIONS USED IN THE TEXT

ADI	acceptable daily intake
ai	active ingredient
ARfD	acute reference dose
bw	body weight
CAS	Chemical Abstracts Service
CAC	Codex Alimentarius Commission
CCN	Codex Classification Number (this may refer to classification number for compounds or commodities)
CCPR	Codex Committee on Pesticide Residues
CIPAC	Collaborative International Pesticides Analytical Council
CLI	Crop Life International (formerly GCPF)
cv	coefficient of variation
CXL	Codex Maximum Residue Limit (Codex MRL). See MRL.
EMDI	estimated maximum daily intake
EMRL	extraneous maximum residue limit
FAO	Food and Agriculture Organization of the United Nations
GAP	good agricultural practice(s)
GCPF	Global Crop Protection Federation (replaced by CLI)
GEMS/Food	Global Environment Monitoring System – Food Contamination Monitoring and Assessment Programme
GIFAP	Groupement International des Associations Nationales de Fabricants de Produits Agrochimiques (International Group of National Associations of Manufacturers of Agrochemical Products) (replaced by GCPF)
GLP	good laboratory practice
HPLC-MS-MS	high performance liquid chromatography with tandem mass spectrometric detection
HR	highest residue in the edible portion of the commodity found in the trials used to estimate a maximum residue level in the commodity
HR-P	residue in a processed commodity calculated by multiplying the HR of the raw agricultural commodity by the corresponding processing factor
IEDI	International estimated daily intake
IESTI	International estimate of short term intake
IUPAC	International Union of Pure and Applied Chemistry

ISO	International Standard Organization
ISO-E	International Standard Organization – English common name
JMPR	Joint FAO/WHO Meeting on Pesticide Residues (Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group)
LOQ	limit of quantification, limit of quantification (synonymous with LOD, limit of determination)
LP	large portion consumed (kg food/day) for IESTI calculations
MRL	Maximum Residue Limit
NEDI	national estimated daily intake
NOAEL	no-observed-adverse-effect level
OECD	Organization for Economic Cooperation and Development
PHI	pre-harvest interval
RAC	raw agricultural commodity
SPS	WTO Agreement on the Application of Sanitary and Phytosanitary Measures
STMR	supervised trials median residue
STMR-P	supervised trials median residue – processed commodity
TAR	total applied radioactivity (crops) or total administered radioactivity (livestock)
TMDI	theoretical maximum daily intake
TMRL	Temporary Maximum Residue Limit
TRR	Total radioactive residue (Note: the same abbreviation is sometimes used for :total recovered radioactivity in specified plant part or animal part)
U	Unit weight of the whole agricultural commodity, i.e., as defined for MRL compliance including inedible parts
U _e	Unit weight of the edible portion (kg) for IESTI calculations
USEPA	United States Environmental Protection Agency
UV	ultraviolet
v	variability factor for IESTI calculations
WHO	World Health Organization of the United Nations
WTO	World Trade Organization

Appendix II

GLOSSARY OF TERMS

At the very early meetings some definitions were adopted by JMPR. A glossary of definitions accepted by successive JMPR Meetings was added as Appendix IV to the report of the 1969 Meeting (FAO/WHO Report, 1970a). Additions and amendments to the definitions have since been made at subsequent meetings. Below are the present definitions used by the JMPR and CAC with the explanatory notes added to the definitions. The reader is referred to the IUPAC recommended Glossary of Terms relating to Pesticides (Stephenson 2006⁶⁷) for the definition of relevant terms not given in these Guidelines.

Acceptable daily intake (ADI)

The 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. (Codex Alimentarius, Vol. 2A)

Note. For additional information on ADIs 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.

Acute reference dose (ARfD)

ARfD of a chemical is an estimate of the amount of a substance in food and/or drinking-water, normally expressed on a body-weight basis, which can be ingested in a period of 24 hours or less without appreciable health risk to the consumer on the basis of all known facts at the time of the evaluation. (JMPR 2002)

Note: This definition differs from that used previously with respect to the duration of intake. This change was made because consumption data are available on a daily basis and cannot be further divided into individual meals.

Accuracy (of measurement)

Closeness of agreement between the result of a measurement and the (conventional) true value of the measure⁶⁷.

Note 1: Use of the term *precision* for *accuracy* should be avoided.

Note 2: True value is an ideal concept and, in general, cannot be known exactly.

Application rate

Mass of *pesticide active ingredient* applied over a specific area or per unit volume of an environmental component (air, water, soil)⁶⁷.

Critical supporting studies

Critical supporting studies are metabolism, farm animal feeding, processing, analytical methods and freezer storage stability studies.

⁶⁷ Stephenson G.S., Ferris, I.G., Holland, P.T., and Nordberg, M., 2006, Glossary of terms related to pesticides (IUPAC Recommendations 2006), Pure & Appl. Chem. 78. 2075-2154.

Definition of residues (for compliance with MRLs)

The definition of a residue (for compliance with MRLs) is that combination of the pesticide and its metabolites, derivatives and related compounds to which the MRL applies. (JMPR Report 1995, 2.8.1.)

Explanatory note: The residue definition for compliance with MRLs depends on the results of metabolism and toxicology studies, supervised residue trials, analytical methods and its general suitability for monitoring compliance with GAP.

Definition of residues (for estimation of dietary intake)

The definition of a residue (for estimation of dietary intake) is that combination of the pesticide and its metabolites, impurities and degradation products to which the STMR applies.

Explanatory note: The residue definition for estimation of dietary intake depends on the results of metabolism and toxicology studies and its general suitability for estimating dietary intake of the residue for comparison with the ADI.

Derived edible products

For the purposes of Codex Alimentarius, the term “derived edible products” means food or edible substances isolated from primary food commodities or raw agricultural commodities not intended for human consumption as such, using physical, biological or chemical processes”. (JMPR Report 1979, Annex 3)

Desirable information

Information desired for the continued evaluation of the compound. (JMPR Report 1986, 2.5)

Extraneous Maximum Residue Limit (EMRL)

The EMRL refers to a pesticide residue or a contaminant arising from environmental sources (including former agricultural uses) other than the use of the pesticide or contaminant substance directly or indirectly on the commodity. It is the maximum concentration of a pesticide residue 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 (Codex Alimentarius Vol. 2A).

Explanatory notes:

The term EMRL is synonymous with “Extraneous Residue Limit” (ERL) previously used by the JMPR.

Residues in food of animal origin arising from residues in animal feed derived from activities that are controllable by farming practices are covered by “maximum residue limits”. The term “practical residue limit”, which has led to much confusion, has been abandoned.

The definition of EMRL replaced the expressions “practical residue limit” and “unintentional residue”, in existence since the 1967 JMPR.

Good Agricultural Practice

Good agricultural practice in the use of pesticides (GAP) includes the nationally authorized safe uses of pesticides under actual conditions necessary for effective pest control. It encompasses a range of levels of pesticide applications up to the highest authorized use, applied in a manner which leaves a residue which is the smallest amount practicable.

Authorized safe uses are determined at the national level and include nationally registered or recommended uses, which take into account public and occupational health and environmental safety considerations.

Actual conditions include any stage in the production, storage, transport, distribution of food commodities and animal feed. (CAC, 1995)

Guideline level

A Guideline Level is the maximum concentration of a pesticide residue that might occur after the official recommended or authorized use of a pesticide for which no acceptable daily intake or temporary acceptable daily intake is established and that need not be exceeded if good practices are followed. It is expressed in milligrams of the residue per kilogram of the food. (JMPR Report 1975, Annex 3)

Highest residue (HR)

The HR is the highest residue level (expressed as mg/kg) in a composite sample of the edible portion of a food commodity when a pesticide has been used according to maximum GAP conditions. The HR is estimated as the highest of the residue values (one from each trial) from supervised trials conducted according to maximum GAP conditions, and includes residue components defined by the JMPR for estimation of dietary intake.

Highest residue – processed (HR-P)

The HR-P is the highest residue in a processed commodity calculated by multiplying the HR of the raw agricultural commodity by the corresponding processing factor.

International estimated daily intake (IEDI)

The IEDI is a prediction of the long-term daily intake of a pesticide residue on the basis of the assumptions of average daily food consumption per person and median residues from supervised trials, allowing for residues in the edible portion of a commodity and including residue components defined by the JMPR for estimation of dietary intake. Changes in residue levels resulting from preparation, cooking, or commercial processing are included. When information is available, dietary intake of residues resulting from other sources should be included. The IEDI is expressed in milligrams of residue per person.

Reference: WHO. 1997. Guidelines for predicting dietary intake of pesticide residues (revised). Prepared by the Global Environment Monitoring System – Food Contamination Monitoring and Assessment Programme (GEMS/Food) in collaboration with Codex Committee on Pesticide Residues (WHO/FSF/FOS/97.7).

International estimated short-term intake (IESTI)

The IESTI is a prediction of the short-term intake of a pesticide residue on the basis of the assumptions of high daily food consumption per person and highest residues from supervised trials, allowing for residues in the edible portion of a commodity and including residue components defined by the JMPR for estimation of dietary intake. The IESTI is expressed in milligrams of residue per kg body weight.

Note: IESTI has been used as an acronym for “international estimated short-term intake” and “international estimate of short-term intake”. Both are intended to have the same meaning.

Limit of determination (LOD)

The LOD 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. (Codex Alimentarius, Vol. 2A)

Explanatory note: LOD has also been used as an abbreviation for “limit of detection,” which may be confusing. JMPR has now adopted LOQ – see the following definition

Limit of quantification (LOQ)

The LOQ is the smallest concentration of the analyte that can be quantified. It is commonly defined as the minimum concentration of analyte in the test sample that can be determined with acceptable precision (repeatability) and accuracy under the stated conditions of the test.

Reference: Joint FAO/IAEA Expert Consultation on ‘Practical Procedures to Validate Method Performance of Analysis of Pesticide and Veterinary Drug Residues, and Trace Organic Contaminants in Food’ (Hungary, 8-11 Nov, 1999). Annex 5, Glossary of Terms. www.iaea.org/trc/pest-qa_val3.htm.

Explanatory note: ‘Limit of quantification’ and ‘limit of quantitation’ are used synonymously and are abbreviated to LOQ. The FAO Panel estimates the LOQ of an analytical method for residues in specified substrates as being the lowest level where satisfactory recoveries were achieved. JMPR has used LOD (limit of determination) in the past with the same meaning as LOQ.

Maximum residue level

The maximum residue level is estimated by the JMPR as the maximum concentration of residues (expressed as mg/kg) which may occur in a food or feed commodity following Good Agricultural Practices. The estimated maximum residue level is considered by the JMPR to be suitable for establishing Codex MRLs.

Maximum Residue Limit (MRL)

The MRL is the maximum concentration of a pesticide residue (expressed as mg/kg), recommended by the Codex Alimentarius Commission to be legally permitted in or on food commodities and animal feeds. MRLs are based on GAP data and foods derived from commodities that comply with the respective MRLs are intended to be toxicologically acceptable. (Codex Alimentarius Vol. 2A)

Codex MRLs, which are primarily intended to apply in international trade, are derived from estimations made by the JMPR following:

- a) a toxicological assessment of the pesticide and its residue; and
- b) a review of residue data from supervised trials and supervised uses including those reflecting national good agricultural practices. Data from supervised trials conducted at the highest nationally recommended, authorized or registered uses are included in the review. In order to accommodate variations in national pest control requirements, Codex MRLs take into account the higher levels shown to arise in such supervised trials, which are considered to represent effective pest control practices.

Consideration of the various dietary residue estimates and determinations both at the national and international level in comparison with the ADI, should indicate that foods complying with Codex MRLs are safe for human consumption.

Explanatory note: The MRL applies to the product when first offered in commerce, unless otherwise indicated. For commodities entering international trade the MRL is applicable at the point of entry into a country or as soon as practicable thereafter and, in any event, before processing.

Multi-ingredient manufactured food

For the purposes of Codex Alimentarius, the term “multi-ingredient manufactured food” means a “processed food” consisting of more than one major ingredient. (JMPR Report 1979, Annex 3)

Pesticide

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, desiccant, 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. (CAC, 1995)

Pesticide residue

A pesticide residue is 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 (Codex Procedural Manual 18th.ed).

Explanatory note: The term “pesticide residue” includes residues from unknown sources, i.e., background residues, as well as those from known uses of the chemical in question.

Adjuvants are not included in the definition of residues.

Primary feed commodity

For the purpose of the Codex Alimentarius the term “primary feed commodity” means the product in or nearly in its natural state intended for sale to:

- a) the stock farmer as feed which is used without further processing for livestock animals or after silaging or similar farm processes;
- b) the animal feed industry as a raw material for preparing compounded feeds.

Reference: FAO/WHO. 1993. Codex Classification of Foods and Animal Feeds in Codex Alimentarius, 2nd ed., Volume 2. Pesticide Residues, Section 2. Joint FAO/WHO Food Standard Programme. FAO, Rome.

Primary food commodity

For the purposes of the Codex Alimentarius, the term “primary food commodity” means the product in or nearly in its natural state intended for processing into food for sale to the consumer or as a food without further processing. It includes irradiated primary food commodities and products after removal of certain parts of the plant or parts of animal tissue.” (JMPR Report 1979, Annex 3)

Processing factor

The processing factor for a specified pesticide residue, commodity and food process is the residue level in the processed product divided by the residue level in the starting commodity, usually a raw agricultural commodity.

$$\text{Processing factor} = \frac{\text{residue level [mg/kg] in processed product}}{\text{residue level [mg/kg] in RAC}}$$

Explanatory note: Alternative terms sometimes used for processing factor are; “concentration factor” when residue levels increase, and “reduction factor” (inverse of processing factor) when residue levels decrease.

Processed food - general definition

For the purposes of the Codex Alimentarius, the term “processed food” means the product, resulting from the application of physical, chemical or biological processes to a “primary food commodity” intended for direct sale to the consumer, for direct use as an ingredient in the manufacture of food or for further processing. “Primary food commodities” treated with ionizing radiation, washed, sorted or submitted to similar treatment are not considered to be “processed foods” (JMPR Report 1979, Annex 3)

Provisional tolerable daily intake

A value based on toxicological data. It represents tolerable human intake of a former agricultural pesticide that may occur as a contaminant in food, drinking water and the environment. (JMPR Report 1994, 2.3)

Explanatory note: The term “tolerable” rather than “acceptable” is used to signify permissibility rather than acceptability of the intake of environmental contaminants unavoidably associated with the consumption of otherwise wholesome food. Use of the term “provisional” expresses the fact that reliable data on the consequences of human exposure to these pesticides are lacking and that the submission from any source of relevant safety data is encouraged.

Regulatory method of analysis

A regulatory method of analysis is a method suitable for the determination of a pesticide residue in connexion with the enforcement of legislation” (JMPR Report 1975, Annex 3).

Explanatory note: For this purpose, it is often necessary to identify the nature of the residue as well as to determine its concentration. Subject to any expression of requirements in the particular legislation, the accuracy, the precision and limit of determination of a regulatory method need to be sufficient only to demonstrate clearly whether or not a Maximum Residue Limit has been exceeded. Usually regulatory methods are not specified in pesticide residues legislation, and at any given time there may be a number of methods suitable for a particular purpose.

Required information

Information required to estimate maximum residue levels or confirm temporary estimates. (JMPR Report 1986, 2.5)

Explanatory note: Results of further work required should be made available not later than the specified date, after which the compound will be re-evaluated. The re-evaluation may be carried out at an earlier Meeting if relevant information should become available. Each recommended TMRL will be directly related to an item of required information (JMPR Report 1992, 2.8).

Secondary food commodity

For the purposes of Codex Alimentarius, the term “secondary food commodity” means a “primary food commodity” which has undergone simple processing, such as removal of certain portions, drying, husking and comminution, which do not basically alter the

composition or identity of the product. Secondary food commodities may be processed further or may be used as ingredients in the manufacture of food or may be sold directly to the consumer. (JMPR Report 1979, Annex 3)

Single-ingredient manufactured food (JMPR Report 1979, Annex 3)

For the purposes of Codex Alimentarius, the term “single-ingredient manufactured food” means a “processed food” which consists of one identifiable food ingredient with or without packing medium or with or without minor ingredients, such as flavouring agents, spices and condiments, and which is normally pre-packaged and ready for consumption with or without cooking.

Supervised trials (for estimating maximum residue levels)

Supervised trials for estimating maximum residue levels are scientific studies in which pesticides are applied to crops or animals according to specified conditions intended to reflect commercial practice after which harvested crops or tissues of slaughtered animals are analysed for pesticide residues. Usually specified conditions are those which approximate existing or proposed GAP.

Supervised trials median residue (STMR)

The STMR is the expected residue level (expressed as mg/kg) in the edible portion of a food commodity when a pesticide has been used according to maximum GAP conditions. The STMR is estimated as the median of the residue values (one from each trial) from supervised trials conducted according to maximum GAP conditions.

Supervised trials median residue – processed (STMR-P) (new definition)

The STMR-P is the expected residue in a processed commodity calculated by multiplying the STMR of the raw agricultural commodity by the corresponding processing factor.

Temporary MRL (TMRL) or Temporary EMRL (TEMRL) (Codex Alimentarius Vol. 2A)

A TMRL or a TEMRL is an MRL or EMRL established for a specified, limited period and is recommended under either of the following conditions:

1. 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
2. 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.

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

The 1992 JMPR gave the following definition (Report, section 2.8):

A temporary maximum residue limit is a maximum residue limit for a specified, limited period, which is clearly related to required information.

Comments

The “temporary maximum residue limit” is a successor of the “temporary tolerance” introduced by the 1966 JMPR, which was changed to “temporary maximum residue limit” in 1975.

At the 1988 JMPR the decision was taken not to establish Temporary Acceptable Daily Intakes any longer for new and periodic review compounds.

According to the Report of 1992 JMPR, there is still a possibility that TMRLs may be recommended when the information lacking on some residue aspects is unlikely to affect the validity of an estimated maximum residue level and would be available shortly. Each recommended TMRL will be directly related to an item of required information.

See also Chapter 6 section 14.1, “Recommendation of temporary MRLs.”

Appendix III

CIPAC CODES FOR PESTICIDE FORMULATIONS

AB	Grain bait	KP	Combi-pack solid/solid
AE	Aerosol dispenser	LA	Lacquer
AL	Other liquids to be applied undiluted	LN	Long-lasting insecticidal net
AP	Other powders to be applied undiluted	LS	Solution for seed treatment
BB	Block bait	LV	Liquid vapouriser
BR	Briquette	MC	Mosquito coil
CB	Bait concentrate	ME	Micro-emulsion
CF	Capsule Suspension for Seed Treatment	MG	Microgranule
CG	Encapsulated granule	MV	Vapourizing mats
CL	Contact liquid or gel	OD	Oil dispersion
CP	Contact powder	OF	Oil miscible flowable concentrate (oil miscible suspension)
CS	Capsule suspension	OL	Oil miscible liquid
DC	Dispersible concentrate	OP	Oil dispersible powder
DP	Dustable powder	PA	Paste
DS	Powder for dry seed treatment	PB	Plate bait
DT	Tablet for direct application	PC	Gel concentrate or paste concentrate
EC	Emulsifiable concentrate	PO	Pour-on
ED	Electrochargeable liquid	PR	Plant rodlet
EG	Emulsifiable Granule	PS	Seed coated with a pesticide
EO	Emulsion, water in oil	RB	Bait (ready to use)
EP	Emulsifiable powder	SA	Spot-on
ES	Emulsion for seed treatment	SB	Scrap bait
EW	Emulsion, oil in water	SC	Suspension concentrate (= flowable concentrate)
FD	Smoke tin	SD	Suspension concentrate for direct application
FG	Fine granule	SE	Suspo-emulsion
FK	Smoke candle	SG	Water soluble granule
FP	Smoke cartridge	SL	Soluble concentrate
FR	Smoke rodlet	SO	Spreading oil
FS	Flowable concentrate for seed treatment	SP	Water soluble powder
FT	Smoke tablet	SS	Water soluble powder for seed treatment
FU	Smoke generator	ST	Water soluble tablet
FW	Smoke pellet	SU	Ultra-low volume (ULV) suspension
GA	Gas	TB	Tablet
GB	Granular bait	TC	Technical material
GE	Gas generating product	TK	Technical concentrate
GF	Gel for Seed Treatment	TP	Tracking powder
GG	Macrogranule	UL	Ultra-low volume (ULV) liquid
GL	Emulsifiable gel	VP	Vapour releasing product
GP	Flo-dust	WG	Water dispersible granule
GR	Granule	WP	Wettable powder
GS	Grease	WS	Water dispersible powder for slurry seed treatment
GW	Water soluble gel	WT	Water dispersible tablet
HN	Hot fogging concentrate	XX	Others
KK	Combi-pack solid/liquid	ZC	Mixed formulation of CS and SC

KL Combi-pack liquid/liquid
KN Cold fogging concentrate

ZE Mixed formulation of CS and SE
ZW Mixed formulation of CS and EW

Appendix IV

MRL PERIODIC REVIEW PROCEDURE BY CCPR
(ALINORM 97/24 APPENDIX III)**CODEX COMMITTEE ON PESTICIDE RESIDUES
MRL PERIODIC REVIEW PROCEDURE**

Periodic review may also be referred to as periodic re-evaluation. The two terms are synonymous. “Periodic review programme” and “periodic review procedure” also mean the same thing.

The periodic review programme was initiated to ensure that the data supporting Codex MRLs met contemporary standards. A complete data submission is requested for old compounds. Recommendations to confirm, amend or delete existing MRLs or to introduce new MRLs arise from the new data. The periodic review procedure consists of two distinct phases as described below:

1. PHASE I*IDENTIFY PERIODIC REVIEW CHEMICALS AND SOLICIT DATA COMMITMENTS***Identify candidate chemicals for re-evaluation**

CCPR will submit a proposal to the CAC each year, as ongoing work, to re-establish the Electronic Working Group (EWG) on Priorities. The EWG on Priorities is tasked with preparing a draft ‘Codex Priority List of Pesticides for JMPR evaluation’ for the consideration of CCPR, i.e., proposals for evaluation by JMPR are finalized by the Committee for adoption by the CAC in the same year.

When prioritizing chemicals for periodic re-evaluation by the JMPR, the Committee will consider the following criteria:

- If the intake and/or toxicity profile indicates, through scientific and/or technical data, some level of public health concern;
- Chemicals that have not been reviewed toxicologically for more than 15 years and/or not having a significant review of maximum residue limits for 15 years;
- The year the chemical is listed in the list for Candidate Chemicals for Periodic Re-evaluation – Not Yet Scheduled;
- The date that data will be submitted;
- Whether the CCPR has been advised by a national government that the chemical has been responsible for trade disruption;
- If there is a closely related chemical that is a candidate for periodic re-evaluation that can be evaluated concurrently;
- The availability of current labels arising from recent national re-evaluations.
- The nature of the data to be submitted, and the reason for its submission; for example, a request from CCPR.

Notify data owners or other parties of candidate list

Within two months of the CAC meeting, the Chair of the EWG will issue a broadcast email to all CCPR member countries and observers proposing additions to the previously prepared periodic re-evaluation schedule (noting the 15 year rule).

Each CCPR meeting will have finalised the Priority Lists of Pesticides for the following year's JMPR evaluations. Therefore, nominations and comments on the Codex Priority Lists of Pesticides will apply to subsequent years to the forthcoming CCPR meeting.

The due date for nominations and comments on the draft priority list of compounds will be 30 November. The Chair of the EWG on Priorities then prepares a draft CCPR agenda paper 'Establishment of Codex Priority Lists of Pesticides' by 21 December of that year.

The draft agenda paper will then be submitted to the Codex Secretariat for circulation to all member countries and observers as a circular letter on 1 January with comments due on 1 March.

The Chair of the EWG on Priorities will finalise the CCPR agenda paper which includes the Codex Priority Lists of Pesticides and submit to Codex Secretariat. The Codex Priority Lists of Pesticides will comprise four appendices: Appendix 1 – Codex Priority List of Pesticides, Appendix 2 - Periodic Re-evaluations, Appendix 3: Chemical-commodity combinations for which specific GAP is no longer supported and Appendix 4: Chemicals with extraneous MRLs and recent deletions.

Invite commitment to support continued (or new) codex maximum residue limits (CXLs)

Following nomination the data owners (or other interested parties) of the chemicals for periodic review, governments and international organizations inquire of data owners their willingness to provide data for that review and also to advise them of the implications should support not be forthcoming.

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

- Chairman, CCPR
- Chairman, Electronic Working Group on Priorities
- JMPR Secretariats
- the requester (government or international organization representative). Names, titles and addresses will be provided.

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

- A list of all commodities for which interested parties are willing to support CXLs
- A brief summary of all current Good Agricultural Practice (GAP) which they are willing to provide and which is pertinent to the residue data they are willing to provide, e.g., commodities and countries for which detailed GAP summaries and representative labels can be provided,
- A list of all chemistry (residue, metabolism, animal transfer, processing, analytical sample storage stability and analytical methods) and toxicology studies and other data that they are willing to provide (regardless of whether previously provided)

and the complete data package submissions to the JMPR. Comments on the status of registrations for the chemicals at the national level are encouraged. Data for which a submission is committed should be identified in the response by study or report title and number, author and date.

Note: Data should be submitted in both paper and electronic form.

Repeat the notification and invitation

By means of a Codex Circular Letter to accompany the report of the Meeting the Secretariat will repeat the notification and request. On receipt of the request by the Circular Letter, governments and international organizations will immediately repeat their notification and invitation to identified interested parties who may not have been represented at the CCPR (they would not have received the report of the Meeting or the accompanying Circular Letter). Interested parties need only respond to one of the requests, but should copy addressees listed under “Invite commitment to support continued (or new) codex maximum residue limits”.

2. PHASE II

STATUS REPORT ON DATA COMMITMENTS AND CCPR FOLLOW-UP

Status report on data commitments

The Electronic Working Group on Priorities provides a report to the CCPR on the status of commitments received to provide data for each compound previously identified. This information will be used to schedule JMPR reviews or to make other recommendations such as withdrawal of CXLs.

Response to data commitments

If there is no commitment to provide and identify or develop data to support current CXLs, the CXL(s) will be recommended by the CCPR for withdrawal by the next session of the Codex Commission.

If a commitment is made to provide and identify or develop data to support current CXLs, the MRL(s) are scheduled for JMPR review. The JMPR review will result in one of the following scenarios:

- (i) Sufficient data are submitted to confirm the CXL and it remains in place.
- (ii) Sufficient data are submitted to support a new proposed MRL, it enters the process at Step 3 and the existing CXL is deleted automatically after no more than 4 years.

If insufficient data have been submitted to support a new MRL or to confirm the existing CXL, data submitters are so advised by written notification from the FAO Joint Secretary or by issuance of the JMPR Report.

On being advised of the data inadequacy, data submitters may by the next CCPR Meeting, provide to the FAO and CCPR Secretaries a written commitment to generate and submit a complete dossier of required data for review within 4 years. The CXL is maintained for no more than 4 years following advice of data inadequacy (by direct notification or by issuance of the JMPR Report). The 4-year period may be extended by the CCPR only to the extent necessary for the JMPR to schedule and complete review of the available new data.

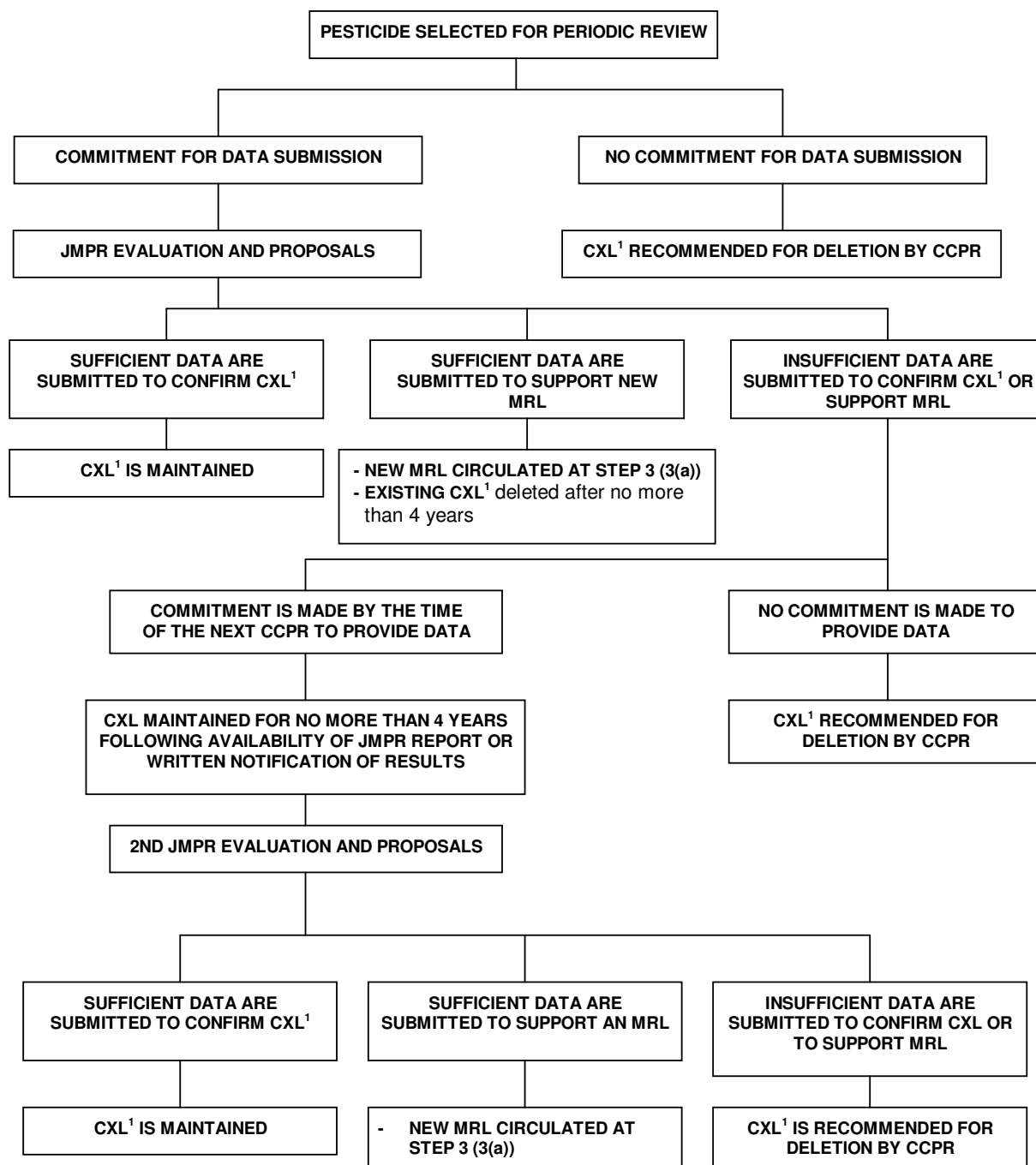
The new data are scheduled for the second JMPR review and the first part of the PHASE II “if a commitment is made” procedure is repeated:

Sufficient data are submitted to confirm the CXL and it remains in place.

Sufficient data are submitted to support a new proposed MRL and it enters the process at Step 3. The CXL is automatically deleted no more than 4 years after the new proposal enters the process.

- (iii) Insufficient data are submitted to confirm the CXL or support a proposed MRL and the CCPR recommends deletion of the CXL.
- (iv) If the committed data are not submitted, or if the data submitted for the initial periodic review are insufficient and no commitment is made by the next CCPR Meeting to generate new data, the CCPR recommends deletion of the CXL.

SUMMARY OF PERIODIC REVIEW PROCEDURE FOR CODEX MRLs



¹Codex MRL adopted by the Codex Alimentarius Commission. The Codex Alimentarius Commission may decide to delete certain Codex MRLs based on the recommendations made to it by the Codex Committee on Pesticide Residues.

Appendix V

RECOMMENDED SAMPLING METHODS FOR SUPERVISED FIELD TRIALS

CONTENTS

- General recommendations
- Contamination
- Control samples
- Sampling in decline studies and at normal harvest time
- Sampling processed commodities
- Sampling stored commodities
- Sample size reduction
- Sample packing and storage

1. GENERAL RECOMMENDATIONS

The best information about the residue behaviour of the pesticide under study would be obtained by the analysis of the entire yield of a plot. Since this is not practicable, representative samples have to be taken. Careful attention to the details of sampling is essential if worthwhile samples are to be obtained. Valid analytical results can only be obtained if the samples have been properly taken, despatched and stored before analysis.

In selecting sampling points and the sampling methods, all factors that control the residue distributions over the entire experimental plot must be considered. The best approach for any given plot can only be determined by a sufficiently trained person who is capable of recognising the importance and usefulness of the residue data sought, and who can interpret the results.

The samples must be representative to enable the analytical result to be applied to the entire experimental unit. The greater the number of plants sampled in a field plot, the more representative the sample will be. However, economics and the practical problems involved in handling large samples affect the magnitude of the sampling programme. The sample size suggested is the minimum that experience has shown is needed to give a representative, valid sample. The sizes are not usually dictated by the analytical method, which can often determine minute amounts of pesticides in small sample amounts.

Method of sampling

Generally, the selection of the portions that make up the field sample should be made depending on the circumstances:

- randomly, e.g., by the use of random numbers
- systematically, .e.g., in the case of field crops on a diagonal (“X” or an “S” course)
- stratified random sampling from predetermined sampling-positions, e.g., in the case of tree fruits inner part and outer part of the canopy, i.e., fruits , directly exposed to spray and those covered by foliage, proportionally to the abundance of fruits in each strata; within one strata each fruit has an equal chance of being taken.

Points to be considered are:

- Avoid taking samples at the beginning or at the extreme ends of plots (start and finish of spraying).
- Take and bag the required weight or number of samples in the field and do not subsample until the samples are in a clean field laboratory or in the analytical laboratory.
- Sample all parts of the crop that can be consumed by humans or livestock.
- Sample the parts of the crop that normally constitute the commercial commodity as described in Appendix V.
- Where appropriate, consider commercial harvesting practice which reflects normal “Good Agricultural Practice” (see also this appendix section “Contamination”).

Replication

Under normal circumstances one sample per plot is sufficient. Additional samples may be taken and held for security reasons, i.e., to guard against the possibility that a sample is lost or destroyed during transport, to ensure the investment in the trial is not wasted.

Sample integrity should be maintained throughout the procedure.

Sample handling

- Take care not to remove surface residues during handling, packing or preparation.
- Avoid any damage to or deterioration of the sample which might affect residue levels.
- To provide a representative sample of the raw commodity, adhering soil may have to be removed from some crops, such as root crops. This may be done by brushing and, if necessary, gentle rinsing with cold running water (see also this Appendix V, section “Bulb vegetables, root vegetables, tuber vegetables”).
- Sample control plots before treated plots (see also this appendix sections “Contamination” and “Control samples”).

2. CONTAMINATION

It is vital to avoid any contamination with the pesticide under study or with other chemicals during sampling, transportation or subsequent operations. Special attention should, therefore, be paid to the following:

- Ensure that sampling tools and bags are clean. To avoid contamination use new bags and containers of suitable size and adequate strength. The bags or containers should be made of materials which will not interfere with the analysis.
- Avoid contamination of the sample by hands and clothes which may have been in contact with pesticides.
- Do not allow the samples to come into contact with containers or equipment (including vehicles) that have been used for transporting or storing pesticides.
- Avoid sampling at the plot borders because the residue deposit may not be representative.

- Take special care to avoid contamination when commercial mechanical harvesting practices are used (see also this appendix sections “Cereals”, “Seeds” and “Herbs and Spices: tea leaves: hops; beer”).
- Avoid cross-contamination of crop and soil samples.
- Sampling should proceed from the control to the lowest treatment and so on to the highest treatment.

3. CONTROL SAMPLES

Control samples are in every way as important as samples from test plots. The quality of control samples should be similar to that of the test samples, e.g., maturity of fruit, type of foliage, etc.

Always take control samples. In decline studies of up to 14 days’ duration, control samples from the start and from the end of the study may suffice (see also this appendix section “Sampling in decline studies.”).

4. SAMPLING IN DECLINE STUDIES AND AT NORMAL HARVEST TIME

Representative and valid sampling protocols might be different for decline studies and residue trials at normal harvest time.

Sampling in decline studies

The first sampling may take place on the day of application. These samples have to be taken immediately after application, or in the case of spray application, immediately after the spray has dried (approximately two hours).

- Take great care to avoid contamination.
- Take samples so as to be representative of the average size or weight of crop on the plot.

Sampling at normal harvest time

- Take samples so as to be representative of typical harvesting practice.
- Avoid taking diseased or undersized crop parts or commodities at a stage when they would not normally be harvested.

Detailed sampling procedures

The following recommendations refer to the sampling of mature crops at normal harvest time, unless otherwise stated. The classification of the crops is contained in Section 2 of Codex Alimentarius Volume 2A⁶⁸.

Fruits and tree nuts

- Circle each tree or bush and select fruit from all segments of the tree or plant, high and low, exposed and protected by foliage. For small fruits grown in a row, select fruit from both sides, but not within 1 metre of the end of the row.

⁶⁸ FAO/WHO. 1993. Codex Classification of Foods and Animal Feeds in Codex Alimentarius, 2nd ed., Volume 2. Pesticide Residues, Section 2. Joint FAO/WHO Food Standards Programme. FAO, Rome.

- Select the quantity of the fruit according to its density on the tree or plant, i.e., take more from the heavily-laden parts.
- Take both large and small fruits where appropriate, but not so small or damaged that they could not be sold (except when taking immature samples for a residue decline study).
- Take samples of fruit juices, cider and wine in a manner reflecting common practice.

Table V.1 Sampling of fruits

Commodity	Codex Code No.	Quantity, method of collection
Citrus fruits e.g., orange, lemon, mandarin, pomelo, grapefruit, clementine, tangelo, tangerine	Group 001	12 fruits from several places on 4 individual trees. (If this produces a sample weight of less than 2 kg, more fruit should be taken to yield a 2 kg sample)
Pome fruits e.g., apples, pears, quinces, medlars	Group 002	
Large stone fruit e.g., apricots, nectarines, peaches, plums	Group 003	
Miscellaneous fruit e.g., avocados, guavas, mangoes, papayas, pomegranates, persimmons, kiwifruit, litchi	Group 006	
Small stone fruit e.g., cherries	Group 003	1 kg from several places on 4 trees
Grapes	FB 0269	12 bunches, or parts of 12 bunches, from separate vines to give at least 1 kg
Currants, raspberries and other small berries	Group 004	1 kg from 12 separate areas or bushes
Strawberries, Gooseberries	FB 0275, FB 0276 FB 0268	1 kg from 12 separate areas or bushes
Miscellaneous small fruits e.g., olives, dates, figs	Group 005	1 kg from several places on 4 trees
Pineapples	FI 0353	12 fruits
Bananas	FI 0327	24 fruits. Take two fingers each from top, middle and lowest hand of four harvestable bunches
Tree nuts e.g., walnuts, chestnuts, almonds	Group 022	1 kg
Coconut	TN 0655	12 nuts
Fruit juices , wine, cider	Group 070	1 litre

Vegetables

Bulb vegetables, root vegetables, tuber vegetables:

- Take samples from all over the plot, excluding 1 metre at the edges of the plot and the ends of the rows. The number of sampling points depends on the sample size of the crop (see below).
- To provide a representative sample of the raw commodity, adhering soil may have to be removed. This may be done by brushing and, if necessary, gentle rinsing with cold running water.
- Trim off tops according to local agricultural practice. Details of any trimming should be recorded. Where the tops are not used as animal feed (carrots, potatoes) they should be discarded; otherwise, e.g., turnips, beets, they should be bagged separately.

Table V.2 Sampling of bulb, root and tuber vegetables

Commodity	Codex Code No.	Quantity, method of collection
Fodder beets, Sugar beets	AM 1051 VR 0596	12 plants
Potatoes	VR 0589	12 tubers (the sample should weigh at least 2 kg - where necessary, take a larger number to produce a 2 kg sample)
Other root crops e.g., carrots, red beet, Jerusalem artichoke, sweet potato, celeriac, turnip, swede, parsnip, horseradish, salsify, chicory, radish, scorzonera	Group 016	12 roots (the sample should weigh at least 2 kg - where necessary, take a larger number to produce a 2 kg sample)
Leeks, Bulb onions	VA 0384 VA 0385	12 plants
Spring onions	VA 0389	24 plants (the sample should weigh at least 2 kg - where necessary, take a larger number to produce a 2 kg sample)
Garlic, Shallots	VA 0381 VA 0388	12 bulbs from 12 plants.(the sample should weigh at least 2 kg - where necessary, take a larger number to produce a 2 kg sample)

Brassica vegetables, leafy vegetables, stalk and stem vegetables, legume vegetables and fruiting vegetables:

- Take the sample from all parts of the plot, leaving 1 metre at the edges and ends of rows. The number of sampling points depends on the sample size of the crop (see below).
- Sample items of crops such as peas or beans protected from the spray by foliage and also from parts exposed to the spray.
- To provide a representative sample of the raw commodity, adhering soil may have to be removed. This may be done by brushing and, if necessary, gentle rinsing with cold running water.
- Do not trim except for the removal of obviously decomposed or withered leaves. Details of any trimming should be recorded.

The quantities to be taken are shown in Table V.3.

Cereals:

- If the plot is small, cut the whole yield.
- If the plot is large but mechanical harvesting is not carried out, cut not less than twelve short lengths of row chosen from all over the plot. Cut stalks 15 cm above the ground and remove the grain from the straw.
- Care should be taken to avoid contamination when mechanical methods are used to separate the parts of the crop. The operation is best carried out in the laboratory.
- If the plots are harvested mechanically, take not less than twelve grab samples of grain and straw from the harvester at uniform intervals over the plot.
- Do not sample within 1 metre of the edges of the plot.

The quantities to be taken are shown in Table V.4.

Grasses, forage and animal feed:

- Cut with shears at normal harvest height (usually 5 cm above the ground) the vegetation from not less than twelve areas uniformly spaced over the entire plot, leaving 1 metre at the edges of the plot.
- Record height of cutting and avoid soil contamination.
- Crops which are harvested mechanically can be sampled from the harvester as it proceeds through the crop.

The quantities to be taken are shown in Table V.5.

Sugar cane (GS 0659)

Select whole canes from 12 areas of the plot and take short, e.g., 20 cm, sections from all parts of the length of the canes. Care is necessary owing to the rapid changes which normally occur in cane juices. If required, 1 litre samples of juice should be taken and frozen immediately and then shipped in cans.

Table V.3 Sampling of other vegetables

Commodity	Codex Code No.	Quantity, method of collection
Large Brassica crops e.g., cabbage, cauliflower, kohlrabi	Group 010	12 plants
Broccoli	VB 0400	1 kg from 12 plants
Brussels sprouts	VB 0402	1 kg from 12 plants. Buttons to be taken from at least two levels on each plant.
Cucumbers	VC 0424	12 fruits from 12 separate plants
Gherkins, courgettes, squash	Group p 011	12 fruits from 12 plants (the sample should weigh at least 2 kg - where necessary take a larger number of fruit to produce a 2 kg sample)
Melons, gourds, pumpkins, watermelons	Group 011	12 fruits from 12 separate plants
Egg plants (aubergines)	VO 0440	12 fruits from 12 separate plants
Sweet corn	VO 0447	12 ears (the sample should weigh at least 2 kg - where necessary take a larger number of items to produce a 2 kg sample.)
Mushrooms	VO 0450	12 items (the sample should weigh at least 0.5 kg - where necessary take a larger number of items to produce a 0.5 kg sample)
Tomatoes, Peppers	VO 0448 VO 0051	24 fruits from small-fruited varieties, 12 from large fruited varieties. From 12 plants in all cases. (The sample should weigh a minimum of 2 kg - where necessary take a larger number of items to produce a 2 kg sample.)
Endive ^a	VL 0476	12 plants
Lettuce ^a	VL 0482, VL 0483	12 plants
Spinach ^a , Chicory leaves ^a	VL 0502 VL 0469	1 kg from 12 plants
Kale	VL 0480	2 kg from 12 plants sampled from two levels on the plant
Small-leaf salad crops e.g., cress, dandelion, corn salad	Group 013	0.5 kg from 12 plants (or sites in plot)
Peas, Phaseolus beans e.g., French, kidney, runner	Group 014	1 kg (fresh green or dry seed as appropriate)
Pulses e.g., dried broad beans, field beans, lentils, soya beans	Group 015	1 kg

Commodity	Codex Code No.	Quantity, method of collection
Celery	VS 0624	12 plants
Asparagus, Rhubarb	VS 0621 VS 0627	12 sticks from 12 separate plants.(the sample should weigh a minimum of 2 kg where necessary take a larger number of sticks to produce a 2 kg sample)
Globe artichoke	VS 0620	12 heads
Fodder crops	Groups 050, 051, 052	2 kg from 12 separate areas of plot. (Crops harvested mechanically can be sampled from the harvester as it proceeds through the crop.)
Oilseed e.g., rape seed, mustard seed, poppy seed	Group 023	

Note: (a) also at immature stages during decline studies

Table V.4 Sampling of cereals

Commodity	Codex Code No.	Quantity, method of collection
Cereal grains e.g., wheat, barley, oats, rye, triticale and other small grain cereals; maize (off the cob), rice, sorghum	Group 020	1 kg
Straw of the above crops	Group 051	0.5 kg
Maize straw, fodder and forage (mature plants excluding cobs)	AF 0645 (forage) AS 0645 (fodder)	12 plants. (Cut each stem into three equal lengths (with leaves attached). Take top portion from stems 1 to 4, middle portion from stems 5 to 8 and bottom portion from stems 9 to 12, thus ensuring that parts of all 12 stems are included in the sample.)
Green or silage maize	Group 051	12 plants. (Cut each stem and subsample as in previous item, retaining any cobs present on the appropriate portions of stem.)
Maize cobs	Group 051	12 ears. (The sample should weigh at least 2 kg - where necessary, take a larger number of ears to produce a 2 kg sample.)

Table V.5 Sampling of forage crops and animal feed

Commodity	Codex Code No.	Quantity, method of collection
Green forage or silage crops of alfalfa, clover, pea and bean forage, vetch, sainfoin, lotus, soya bean fodder and forage, rye forage, fodder cereals, sorghum forage	Group 050, 051	1 kg
Dry hay of the above crops	Group 050, 051	0.5 kg

Seeds

Use essentially the same technique as for cereals, taking samples of mature seed from at least twelve parts of the plot. Where the sample is harvested by hand, seed should normally be sent to the laboratory in the pod. Where mechanical harvesting is used, only the seed should be supplied.

Cotton seed (Codex Code No. SO 0691):

- Pick the cotton at the normal stage of harvesting. Take 1 kg, with or without fibre.

Peanuts (Codex Code No. SO 0697):

- Collect at the normal stage of harvesting. Take 1 kg.

Sesame seed, rape seed (Codex Code Nos. SO 0700, SO 0495):

- Collect the pods when they have reached the stage of maturity at which they are normally harvested. Take 1 kg.

Sunflower seed, safflower seed (Codex Code Nos. SO 0702, 0699):

- Where the sampling is done by hand select ripe heads. Where it is done mechanically submit the seed to the laboratory. Take 12 heads or 1 kg of seed .

Coffee and cacao beans (Codex Code Nos. SB 0716, 0715):

- Take samples in a manner reflecting common practice, quantity 1 kg. - The freshly harvested produce is not normally required.

Herbs and spices; tea leaves; hops; beer

- Take samples in a manner reflecting common practice.
- The freshly harvested produce is not normally required for tea although herbs, such as parsley and chives, should be sampled fresh. In the case of hops, both fresh and dried cones should be supplied.

Table V.6. Sampling of herbs, spices; tea leaves; hops and beer

Commodity	Codex Code No.	Quantity, method of collection
Garden herbs and medicinal plants e.g., parsley, thyme	Group 027 Group 028 Group 057	0.5 kg fresh 0.2 kg dry
Teas (dry leaves)	Group 066	0.2 kg
Hops (dry cones)	DH 1100	0.5 kg
Beer		1 litre

5. SAMPLING ANIMAL TISSUES, MILK AND EGGS

Farm animal feeding and external animal treatment studies are conducted in order to quantify levels of residues in meat, milk, eggs and edible meat by-products, such as fat, liver, kidney following the use of a pesticide product.

The sampling protocol shall be designed taking into account the specific objectives of the studies. The minimum mass of samples to be collected (taken from OECD Guidelines for the Testing of Chemicals, Test No. 505: Residues in Livestock) is shown in the following tables.

Table V.7. Sampling ruminants

Sample Material	Sampling Method	Analytical Sample Preparation	Weight/unit (homogenised) Laboratory Sample
Meat	Collect approx. equal pieces of loin, flank or hind-leg (round piece) muscle	After coarse pre-chopping, macerate in a mincer and then mix carefully.	0.5 kg

Sample Material	Sampling Method	Analytical Sample Preparation	Weight/unit (homogenised) Laboratory Sample
Fat	Collect approx. equal quantities of subcutaneous, mesenterial and perirenal fat	After coarse pre-chopping, macerate in a mincer and then mix carefully ^a	0.5 kg
Liver	Collect the entire organ or representative parts thereof, e.g., a cross-section of the lobes	After coarse pre-chopping, macerate in a mincer and then mix carefully.	0.4 kg
Kidney	Sub-sample from both kidneys	Macerate tissue in a mincer and then mix carefully.	0.2 kg
Raw Milk ^b	Collect milk from each animal separately		0.5 l

^a For fat-soluble compounds, samples of perirenal, mesenterial and subcutaneous fat from ruminants should be analysed individually, not as a composite

^b For fat-soluble compounds, residues in the milk fat need to be determined at the end of dosing in addition to the plateau level. The fat should preferably be separated from the milk by physical means, not by chemical solvent extraction, because in solvent extraction residues are extracted from both the aqueous and the lipid phase. As in this way, cream (containing 40–60% fat) and not 100% milk fat is obtained; the lipid content of the cream should also be reported. Where a depuration phase is included after the dosing period, samples taken at a minimum of four time-points after the last day of treatment is recommended

Tissues from different animals should not be combined or pooled at sampling.

Table V.8. Poultry

Sample Material ^a	Sampling Method	Analytical Sample Preparation	Weight/unit (homogenised) Laboratory Sample
Meat	Collect approx. equal pieces of leg and breast	Macerate pieces of meat from 3 hens ^b in a mincer and then mix carefully.	0.5 kg
Skin with fat	Collect all the abdominal fat from at least 3 hens	Chop the fat of 3 hens ^b	0.05 kg
Liver	Collect the entire organ	Chop the livers of 3 hens ^b	0.05 kg
Eggs		Clean shells, break eggs from 3 hens, combine the whites/yolks, discard the shells ^c Limited analysis of yolk and white separately for some chemicals ^{c,d}	3 units

^a For dermal uses on poultry, skin should also be analysed.

^b The prerequisite for combining of sample material is that at least 3 samples per dose group are available (i.e., at least 9 animals are involved).

^c Samples can be prepared either before or after transport to the analytical laboratory. The eggs are homogenised by addition of solvent on commencement of analysis.

^d Analyses of eggs should be conducted on the egg yolk and white combined in one sample, For fat-soluble residues some analysis of the deposition of residues into yolk and white fractions may be conducted to determine how the residue partitions between the egg fractions. The residue levels in yolk and whites may be analysed separately provided the weights of each are known, so that the residue can be calculated on a whole egg basis for the purpose of MRL setting. Yolk and white would require separation prior to storage of the samples.

Table V.9. Pig/Swine

Sample Material ^a	Sampling Method	Analytical Sample Preparation	Weight/unit (homogenised) Laboratory Sample
Meat	Collect approx. equal pieces of loin, flank or hind-leg (round	After coarse pre-chopping, macerate in a mincer and then mix carefully.	0.5 kg

	piece) muscle		
Fat	Collect approx. equal quantities of subcutaneous, mesenterial and perirenal fat	After coarse pre-chopping, macerate in a mincer and then mix carefully ^b .	0.5 kg
Liver	Collect the entire organ or representative parts thereof	After coarse pre-chopping, macerate in a mincer and then mix carefully.	0.4 kg
Kidney	Sub-sample from both kidneys	Macerate tissue in a mincer and then mix carefully.	0.2 kg
Skin	Collect approx. equal pieces of back, flank and belly	After coarse pre-chopping, macerate in a mincer and then mix carefully	0.5 kg

^a For dermal uses on swine, skin should also be analysed.

^b For fat-soluble compounds, samples of perirenal, mesenterial and subcutaneous fat from ruminants should be analysed individually, not as a composite.

6. SAMPLING PROCESSED COMMODITIES

Where a commodity is normally processed between harvest and marketing, for example by milling, pressing, fermentation, drying or extraction, data may be required on the processed crop or its products. Details of the processing method should be supplied with the samples together with storage and handling histories. In such cases, the trials should be designed to provide samples with appropriate residue levels so that the fate of residues can be studied during the processing. Sample separately any cleanings, husks or by-products which could be used for animal feed. The minimum mass of samples as described in the Codex recommended method of sampling should be observed as far as practical.

7. SAMPLING STORED COMMODITIES

Supervised trials of post-harvest treatments of stored products should be carried out over a wide range of storage facilities, and the sampling technique must be carefully chosen if valid samples are to be obtained. Procedures for taking valid samples from most commodities in storage units are well established. Such procedures are acceptable in sampling for pesticide residue analysis and may be used if adequate references are given.

The sampling procedures are usually designed for three kinds of storage conditions.

Sampling from bulk

Obtaining a representative sample from a (large) bulk container, e.g., of cereal grains, is difficult; if possible, samples should be taken at frequent intervals from the stream during transfer into another container. A probe sample is not representative but may be acceptable if:

- it is possible to reach every part of the storage container
- a larger number of individual samples are taken before mixing and reducing to produce a final sample.

Pesticide residues are normally higher in the dust fraction and this should be recognised in the sampling procedure.

Sampling bagged commodities

Sampling of the commodity within a bag must be random. A representative sample from a large stack of bags can be obtained only if every bag is accessible. This is not always possible

in practice and the alternative is to obtain a sample from a number of randomly chosen bags by probing. Since pesticide treatments are often directed to the surface of the bag, selective sampling to show the effect of the position of the bag in the stack and the penetration of the pesticide into the bag may be necessary.

Sampling fruit and vegetables in packing houses

Where post-harvest treatments are applied to fruit and vegetables in packing houses, an adequate number of samples must be taken to determine the range of residue levels resulting from variations in the treatment process. The effects on residue levels of concentration, temperature, duration of treatment, drying (after dip treatments) and subsequent handling may need to be considered.

Post-harvest treated fruit and vegetables should be kept in, or packed in, commercial containers or punnets and stored at ambient or cool-room temperature according to normal commercial practice. Samples should then be drawn for analysis from the commercial containers at suitable intervals representing the time expected between treatment and subsequent marketing. The rate of disappearance or degradation of some residues depends on whether the commodity is held in a sealed or partly sealed container or is open to the air.

The sizes of samples to be taken are the identical as suggested in Tables V.1–V.3.

8. SAMPLE SIZE REDUCTION

Large samples cannot be handled economically, especially if freezing and long transport are involved. Take only that amount prescribed in the Study Plan noting the minimum sample size requirements indicated in Tables V.1–V.9.

Except cereal grains sampled on a conveyor belt or from the stream of material transferred from one large container to another, mixing of samples and sample size reduction at the field site is not recommended and should be avoided.

9. SAMPLE PACKING AND STORAGE

Once packed and labelled, samples may be stored or immediately sent to the residue laboratory according to the nature of the sample. The mode of shipping (e.g. deep-frozen or at ambient temperature) shall be selected taking into account the stability of the residue and the kind of study undertaken.

It is important that packing and shipment are carried out in such a way that the samples arrive as soon as possible (normally within 24–36 hours) after being taken and without change of any kind, e.g., deterioration, physical damage, contamination, loss of residue, or change in moisture content.

Storage and shipping should always be under deep-frozen conditions.

Packing

Containers

Individual samples should be placed in suitable containers, e.g., heavy polyethylene bags, and then put inside additional heavy paper bags and, where necessary, frozen or refrigerated as soon as possible after sampling according to the nature of the chemical involved. Polyethylene

bags alone may become brittle in contact with dry ice and therefore there is a risk of breakage and subsequent loss of the sample.

Avoid other plastic containers or plastic-lined caps, unless made of “Teflon” or other inert plastic which does not interfere with the analytical method (laboratories have frequently experienced such interference), and PVC bags should be avoided. If cans are used, they should first be checked to demonstrate the absence of materials such as oil films, lacquers or resin from soldered joints that could interfere with analyses.

Glass containers should be used for liquid samples and should be thoroughly cleaned and rinsed with one or more suitable pesticide-free solvent such as acetone, isopropyl alcohol or hexane, and dried before use. Pesticides can migrate to the walls of a container and be adsorbed; hence even a glass container, after the sample is poured out, should be rinsed with solvent if the extraction is not made in the container itself.

In summary, any type of container or wrapping material should be checked before use for possible interference with the analytical method and at the limit of determination of the analysis.

Fasten boxes securely with strong twine, rope or tape.

Shipment of samples

Non-perishable commodities containing residues that are known to be stable over the period required to reach the laboratory can be shipped in a non-frozen state, but samples should be protected against any effects which might cause degradation or contamination.

Where samples need to be frozen, use shipping containers of polystyrene foam, if available, as they are excellent for this purpose. If not available, use two cardboard boxes of slightly different size with insulation between. Proper insulation is essential to ensure samples arrive at the residue laboratory still frozen. Sufficient dry ice must be used for some to remain when samples are received at the residue laboratory. This usually requires a minimum of one kg of dry ice per kg of sample. For journeys lasting more than two days, two kg of dry ice or more per kg of sample may be required. Poorly insulated containers require more dry ice. Use caution in handling dry ice (gloves and ventilated work area). Packages must of course comply with transport regulations.

Frozen samples must never be allowed to thaw, either before or during shipment. They must be shipped under conditions that permit their arrival at the residue laboratory still solidly frozen.

The consignee should be advised by FAX or email of the full details of shipment of samples, including shipping document numbers and flight numbers, so that delay in delivery to the laboratory is avoided.

When samples have to be shipped across national boundaries, quarantine regulations must be observed and appropriate permits obtained well in advance of dispatching samples.

Labels and records

Label each sample with the appropriate sample identification. The label and ink should be such that the writing will not be illegible if the label becomes wet. Attach the label securely so that it cannot come loose during shipment, and place the label so that it will not become wet from condensation.

Complete the Sampling Report (residue data sheets) clearly and accurately with all the requested trial details. Failure to do so may mean that data will not be acceptable. The

completed sheets should be protected by enclosing them in protective polythene bags which should be sent with the sample. Duplicate sheets should be kept by the sender.

Use a label on the outside of the shipping container stating the following: “Perishable Goods: Deliver immediately upon arrival” and “This material is not fit for human consumption”.

Sample reception and handling

Immediately upon arrival of the samples, the residue laboratory personnel should:

- Verify that the copy of the Sampling Report is included with the samples.
- Check and report on the condition of the samples.
- Check to see that the samples match the details of the Sampling Report.
- Check the Sampling Report for accuracy (especially the rate and interval data) and verify that the information is complete.
- Check the Sampling Report to determine whether any special treatment or testing is indicated.

If there are any deviations of any consequence, or the Sampling Report is not received or is incomplete (in such a way that a proper comparison is not possible), the samples should be stored in the simplest form that will preserve the residue and the crop. The trial organiser should then be contacted immediately to determine how to proceed.

Note: it is dangerous to put packages containing dry ice into deep freeze.

Storage

Samples should be analysed as quickly as possible after collection before physical and chemical changes occur. If prolonged storage is unavoidable, it is usually preferable to store the samples at a low temperature, preferably at or below $-20\text{ }^{\circ}\text{C}$. This removes the residue from contact with enzymes which might degrade the pesticide and also prevents further possibility of residues being “bound” in the tissue. Do not store samples (whole or homogenised) for analysis unless an adequate check has been made on the stability of the residue. Fumigant residue samples need special attention and ideally should be analysed immediately on receipt at the laboratory. Storage at $-20\text{ }^{\circ}\text{C}$ is likely to be inadequate to prevent loss of fumigant residues.

Studies of the stability of residues in samples, over the time and at the temperature of storage, should be carried out with representative pesticides and substrates. When there is doubt about the stability of residues in storage, spiked control samples should be held under the same conditions as the samples or extracts.

Light degrades many pesticides; it is therefore advisable to protect the sample and any solutions or extracts from needless exposure. Samples other than water should ordinarily be stored in a freezer, preferably at $-20\text{ }^{\circ}\text{C}$ or below. Even then, physical and chemical changes may occur either in the sample or in the residues sought. Extended storage in freezers can cause moisture to migrate to the surface of the sample then to the freezer coils, slowly desiccating the sample. This effect may be of importance if water content affects the subsequent analysis and can affect the calculated residue concentration. Water samples should be stored slightly above freezing to avoid rupture of the container as a result of freezing.

Appendix VI

PORTION OF COMMODITIES TO WHICH CODEX MAXIMUM RESIDUE LIMITS APPLY AND WHICH IS ANALYSED

INTRODUCTION

Codex Maximum Residue Limits are in most cases stated in terms of a specific whole raw agricultural commodity as it moves in international trade. In some instances, a qualification is included that describes the part of the raw agricultural commodity to which the maximum residue limit applies, for example, almonds on a shell-free basis and beans without pods. In other instances, such qualifications are not provided. Therefore, unless otherwise specified, the portion of the raw agricultural commodity to which the MRL applies and which is to be prepared as the analytical sample for the determination of pesticide residues is as described in the following table.

Classification of Commodities	Portion of Commodity to Which the Codex MRL Applies (and Which Is Analysed)
Group 1 - ROOT AND TUBER VEGETABLES (Codex Classification ⁶⁹ Group 016: Root and tuber vegetables)	
Root and tuber vegetables are starchy foods derived from the enlarged solid roots, tubers, corms or rhizomes, mostly subterranean, of various species of plants. The entire vegetable may be consumed.	
<u>Root and tuber vegetables:</u> beets, carrots, celeriac, parsnips, potatoes, radishes, rutabagas, sugar beet, sweet potatoes, turnips, yams	Whole commodity after removing tops. Wash the roots or tubers in cold running water, brushing gently with a soft brush to remove loose soil and debris, if necessary, and then dab lightly with clean tissue paper to dry. For carrots, after drying the tops are carefully cut off with a knife by cutting through the bottom of the stem at the lowest point of attachment of the outer petioles. If an annulus of root tissue is thereby severed from hollow-crown roots, the material should be re-combined with the roots.
Group 2 - BULB VEGETABLES (Codex Classification Group: 009 Bulb vegetables)	
Bulb vegetables are pungent, flavourful foods derived from the fleshy scale bulbs or growth buds of alliums of the lily family (<i>Liliaceae</i>). The entire bulb may be consumed following removal of the parchment-like skin.	Remove adhering soil (e.g., by rinsing in running water or by gentle brushing of the dry commodity)
<u>Bulb vegetables:</u> garlic, leeks, onions, spring onions	Bulb, dry onions and garlic: Whole commodity after removal of roots and whatever parchment skin is easily detached. Leeks and spring onions: Whole vegetable after removal of roots and adhering soil.

⁶⁹ The number and categories of groups for portion of commodities do not always correspond to the grouping used by the current Codex Classification of Foods and Animal Feeds. The corresponding groups are given in brackets.

Group 3 - LEAFY VEGETABLES (EXCEPT BRASSICA VEGETABLES) (Does not correspond to Codex Classification Group 013: Leafy vegetables (including Brassica leafy vegetables))	
Leafy vegetables (except Group 4 vegetables) are foods derived from the leaves of a wide variety of edible plants including leafy parts of Group 1 vegetables. The entire leaf may be consumed. Leafy vegetables of the brassica family are grouped separately.	
<u>Leafy vegetables:</u> beet leaves, corn salad, endive, lettuce, radish leaves, spinach, sugar beet leaves, Swiss chard	Whole commodity after removal of obviously decomposed or withered leaves.
Group 4 - BRASSICA (COLE) LEAFY VEGETABLES (Does not correspond to Codex Classification Group 010: Brassica vegetables)	
Brassica (cole) leafy vegetables are foods derived from the leafy parts, stems and immature inflorescences of plants commonly known and botanically classified as brassicas and also known as cole vegetables. The entire vegetable may be consumed.	
<u>Brassica leafy vegetables:</u> broccoli, Brussels sprouts, cabbage, Chinese, cabbage, red, cabbage, Savoy, cauliflower, collards, kales, kohlrabi, mustard greens	Whole commodity after removal of obviously decomposed or withered leaves. For cauliflower and headed broccoli analyse flower head and stems, discarding leaves; for Brussels sprouts analyse “buttons” only.
Group 5 - STEM VEGETABLES (Codex Classification Group 017: Stalk and stem vegetables)	
Stem vegetables are foods derived from the edible stems or shoots of a variety of plants.	
<u>Stem vegetables:</u> artichoke, celery, chicory (witloof), rhubarb	Whole commodity after removal of obviously decomposed or withered leaves. Rhubarb and asparagus: stems only. Celery and asparagus: remove adhering soil (e.g., by rinsing in running water or by gentle brushing of the dry commodity).
Group 6 - LEGUME VEGETABLES (Codex Classification Group 014: Legume vegetables Group 015: Pulses)	
Legume vegetables are derived from the dried or succulent seeds and immature pods or leguminous plants commonly known as beans and peas. Succulent forms may be consumed as whole pods or as the shelled product. Legume fodder is in Group 18.	
<u>Legume vegetables:</u> beans, broad beans, cow peas, dwarf beans, French beans, green beans, kidney beans, Lima beans, navy beans, runner beans, snap beans, soybeans, peas, sugar peas	Whole commodity.
Group 7 - FRUITING VEGETABLES - EDIBLE PEEL (Combination of Codex Classification Groups 011: Fruiting vegetables, Cucurbits; 012 Fruiting vegetables other than Cucurbits)	
Fruiting vegetables - edible peel are derived from the immature or mature fruits of various plants, usually annual vines or bushes. The entire fruiting vegetables may be consumed.	
<u>Fruiting vegetables - edible peel:</u> cucumber, egg plant, gherkin, okra, pepper, summer squash, tomato, mushroom ⁷⁰	Whole commodity after removal of stems.

⁷⁰ Mushroom is not included in the commodities listed in the original document

Group 8 - FRUITING VEGETABLES - INEDIBLE PEEL (Codex Classification Group 011 Fruiting vegetables, Cucurbits)	
Fruiting vegetables inedible peel are derived from the immature or mature fruits of various plants, usually annual vines or bushes. Edible portion is protected by skin, peel or husk which is removed or discarded before consumption.	
<u>Fruiting vegetables - inedible peel:</u> cantaloupe, melon, pumpkin, squash, watermelon, winter squash	Whole commodity after removal of stems.
Group 9 - CITRUS FRUITS (Codex Classification Group 001 Citrus fruits)	
Citrus fruits are produced by trees of the <i>Rutaceae</i> family and are characterized by aromatic oily peel, globular form and interior segments of juice-filled vesicles. The fruit is fully exposed to pesticides during the growing season. The fruit pulp may be consumed in succulent form and as a beverage. The entire fruit may be used for preserving.	
<u>Citrus fruits:</u> Orange, lemon, mandarin	Whole commodity.
Group 10 - POME FRUITS (Codex Classification Group 002 Pome fruits)	
Pome fruits are produced by trees related to the genus <i>Pyrus</i> of the rose family (<i>Rosaceae</i>). They are characterized by fleshy tissue surrounding a core consisting of parchment-like carpels enclosing the seed. The entire fruit, except the core, may be consumed in the succulent form or after processing.	
<u>Pome fruits:</u> apple, pear, quince	Whole commodity after removal of stems.
Group 11 - STONE FRUITS (Codex Classification Group 003 Stone fruits)	
Stone fruits are produced by trees related to the genus <i>Prunus</i> of the rose family (<i>Rosaceae</i>) characterized by fleshy tissue surrounding a single hard-shelled seed. The entire fruit, except seed, may be consumed in a succulent or processed form.	
<u>Stone fruits:</u> apricots, cherries, sour cherries, sweet cherries, nectarines, peaches, plums	Whole commodity after removal of stems and stones but the residue calculated and expressed on the whole commodity without stem.
Group 12 - SMALL FRUITS AND BERRIES (Codex Classification Group 004: Berries and other small fruits)	
Small fruits and berries are derived from a variety of plants whose fruit is characterized by a high surface-weight ratio. The entire fruit, often including seed, may be consumed in a succulent or processed form.	
<u>Small fruits and berries:</u> blackberries, blueberries, boysenberries, cranberries, currants, dewberries, gooseberries, grapes, loganberries, raspberries, strawberries	Whole commodity after removal of caps and stems. Currants: fruit with stems.
Group 13 - ASSORTED FRUITS - EDIBLE PEEL (Codex Classification Group 005: Assorted tropical and sub-tropical fruit - edible peel)	
Assorted fruits - edible peel are derived from the immature or mature fruits of a variety of plants, usually shrubs or trees from tropical or subtropical regions. The whole fruit may be consumed in a succulent or processed form.	
<u>Assorted fruits - edible peel:</u> dates, figs, olives	Dates and olives: whole commodity after removal of stems and stones but residue calculated and expressed on the whole fruit. Figs: Whole commodity.

Group 14 - ASSORTED FRUITS - INEDIBLE PEEL (Codex Classification Group 006: Assorted tropical and sub-tropical fruit - inedible peel)	
Assorted fruits - inedible peel are derived from the immature or mature fruits of different kinds of plants, usually shrubs or trees from tropical or subtropical regions. Edible portion is protected by skin, peel or husk. Fruit may be consumed in a fresh or processed form.	
<u>Assorted fruits - inedible peel:</u> avocados, bananas, guavas, kiwi fruit, mangoes, papayas, passion fruits, pineapples	Whole commodity unless qualified. Pineapples: after removal of crown. Avocado and mangoes: whole commodity after removal of stone but calculated on whole fruit. Bananas: after removal of crown tissue and stalks.
Group 15 - CEREAL GRAINS (Codex Classification Group 020: Cereal grains)	
Cereal grains are derived from the clusters of starchy seeds produced by a variety of plants primarily of the grass family (<i>Gramineae</i>). Husks are removed before consumption.	
<u>Cereal grains:</u> barley, maize, oats, rice, rye, sorghum, sweet corn, wheat	Whole commodity. Fresh corn and sweet corn: kernels plus cob without husk.
Group 16 - STALK AND STEM CROPS (Codex Classification Group 051: Straw, fodder and forage of cereal grains and grasses)	
Stalk and stem crops are various kinds of plants, mostly of the grass family (<i>Gramineae</i>) cultivated extensively as animal feed and for the production of sugar. Stems and stalks used for animal feeds are consumed as succulent forage, silage, or as dried fodder or hay. Sugar crops are processed.	
<u>Stalk and stem crops:</u> barley fodder and straw, grass fodders, maize fodder, sorghum fodder	Whole commodity.
Group 17 - LEGUME OILSEEDS (Part of Codex Classification Group 023: Nuts and seeds)	
Legume oilseeds are mature seeds from legumes cultivated for processing into edible vegetable oil or for direct use as human food.	
<u>Legume oilseeds:</u> peanuts	Whole kernel after removal of shell.
Group 18 - LEGUME ANIMAL FEEDS (Codex Classification Group 050: Legume animal feeds)	
Legume animal feeds are various species of legumes used for animal forage, grazing, fodder, hay or silage with or without seed. Legume animal feeds are consumed as succulent forage or as dried fodder or hay.	
<u>Legume animal feeds:</u> alfalfa fodder, bean fodder, clover fodder, peanut fodder, pea fodder, soybean fodder	Whole commodity.
Group 19 - TREE NUTS (Codex Classification Group 022: Tree nuts)	
Tree nuts are the seeds of a variety of trees and shrubs which are characterized by a hard, inedible shell enclosing an oil seed. The edible portion of the nut is consumed in succulent, dried or processed form.	
<u>Tree nuts:</u> almonds, chestnuts, filberts, macadamia nuts, pecans, walnuts	Whole commodity after removal of shell. Chestnuts: whole in skin.

Group 20 - OILSEEDS (Codex Classification Group 23: Nuts and seeds)	
Oilseed consists of the seed from a variety of plants used in the production of edible vegetable oils. Some important vegetable oilseeds are by-products of fibre or fruit crops.	
<u>Oilseed:</u> cotton seed, linseed, rapeseed, safflower seed, sunflower seed	Whole commodity.
Group 21 - TROPICAL SEEDS (Codex Classification Group 024: Seed for beverages and sweets)	
Tropical seeds consist of the seeds from several tropical and semitropical trees and shrubs mostly used in the production of beverages and confections. Tropical seeds are consumed after processing.	
<u>Tropical seeds:</u> cacao beans, coffee beans	Whole commodity.
Group 22 - HERBS (Codex Classification Group 027: Herbs)	
Herbs consist of leaves, stems and roots from a variety of herbaceous plants used in relatively small amounts to flavour other foods. They are consumed in succulent or dried form as components of other foods.	
<u>Herbs:</u>	Whole commodity.
Group 23 - SPICES (Codex Classification Group 028: Spices)	
Spices consist of aromatic seeds, roots, fruits and berries from a variety of plants used in relatively small amounts to flavour other foods. They are consumed primarily in the dried form as components of other foods.	
<u>Spices:</u>	Whole commodity.
Group 24 - TEAS (Codex Classification Group 066: Teas)	
Teas are derived from the leaves of several plants, but principally <i>Camellia sinensis</i> . They are used in the preparation of infusions for consumption as stimulating beverages. They are consumed as extracts of the dried or processed product.	
<u>Teas:</u>	Whole commodity.
Group 25 - MEATS (Codex Classification Group 030: Meat)	
Meats are the muscular tissue, including adhering fatty tissue, from animal carcasses prepared for wholesale distribution. The entire product may be consumed.	
<u>Meats:</u> carcass meat (and carcass fat), carcass meat of cattle, carcass meat of goats, carcass meat of horses, carcass meat of pigs, carcass meat of sheep	Whole commodity. (For fat soluble pesticides a portion of carcass fat is analysed and MRLs apply to carcass fat.)
Group 26 - ANIMAL FATS (Codex Classification Group 031: Mammalian fats)	
Animal fats are the rendered or extracted fat from the fatty tissue of animals. The entire product may be consumed.	
<u>Animal fats:</u> cattle fat, pig fat, sheep fat	Whole commodity.
Group 27 - MEAT BYPRODUCTS (Codex Classification Group 0032: Edible offal (mammalian))	
Meat byproducts are edible tissues and organs, other than meat and animal fat, from slaughtered animals as prepared for wholesale distribution. Examples: liver, kidney, tongue, heart. The entire product may be consumed.	

<u>Meat byproducts (such as liver, kidney, etc.):</u> cattle meat byproducts, goat meat byproducts, pig meat byproducts, sheep meat byproducts	Whole commodity.
Group 28 - MILKS (Codex Classification Group 033: Milks)	
Milks are the mammary secretions of various species of lactating herbivorous ruminant animals, usually domesticated. The entire product may be consumed.	
<u>Milks:</u>	Whole commodity ⁷¹ .
Group 29 - MILK FATS (Codex Classification Group 086: Milk fats)	
Milk fats are the fats rendered or extracted from milk.	
<u>Milk fats:</u>	Whole commodity.
Group 30 - POULTRY MEATS (Codex Classification Group 036: Poultry meat)	
Poultry meats are the muscular tissues, including adhering fat and skin, from poultry carcasses as prepared for wholesale distribution. The entire product may be consumed.	
<u>Poultry Meats:</u>	Whole commodity. (For fat soluble pesticides a portion of carcass fat is analysed and MRLs apply to carcass fat.)
Group 31 - POULTRY FATS (Codex Classification Group 037: Poultry fat)	
Poultry fats are the rendered or extracted fats from fatty tissues of poultry. The entire product may be consumed.	
<u>Poultry fats:</u>	Whole commodity.
Group 32 - POULTRY BYPRODUCTS (Codex Classification Group 038: Poultry, edible offal of)	
Poultry byproducts are edible tissue and organs, other than poultry meat and poultry fat, from slaughtered poultry.	
<u>Poultry byproducts:</u>	Whole commodity.
Group 33 - EGGS (Codex Classification Group 039: Eggs)	
Eggs are the fresh edible portion of the reproductive body of several avian species. The edible portion includes egg white and egg yolk after removal of the shell.	
<u>Eggs:</u>	Whole egg whites and yolks combined after removal of shells.

⁷¹ Deviation from the Codex Guideline based on the decision of CCPR

Appendix VII

STANDARDIZED FORMAT FOR ORGANIZING THE DATA DIRECTORY (INDEX) OF INFORMATION TO BE SUBMITTED FOR EVALUATION

The purpose of the data directory is to assist the reader (reviewer) to find the studies related to the standard headings of a residue evaluation; or to be quite certain that no studies are available for particular sections. Initially the data directory will also assist the FAO Secretary to decide on the size of the review and how much work is required. See also Chapter 4, “Preparation of data submissions for the consideration of the FAO Panel of the JMPR.”

The relevant sections required for the data directory are provided below and examples of subheadings are included. OECD data point numbers indicate the studies classified in the OECD Guidance Documents for Pesticide Registration⁷².

In each section the references should be in systematic order. The year is the year of publication of the study, project or experiment in the residue evaluations. The study, project or experiment number should correspond with the company name, i.e., if the study number quoted is that of the contracted laboratory, the contracted laboratory’s name should be given in the reference. Where a laboratory name and study number and a company name and study number are provided, both sets of information may be included. Where a study consists of a number of individual trials, include all trial numbers in the reference. Refer to the following examples.

- Boner, P. L. 1998. Metabolism of [¹⁴C] methyl parathion in lettuce. Xenobiotic Laboratories, Inc., Project XBL97072, PSI 97.438. Unpublished.
- van Zyl, P. 1997. Determination of the magnitude of residues of pyriproxyfen in citrus. South-Africa, 1996 trials. Study 96/194. Report 311/88176/N194. South African Bureau of Standards. Report NNR-0048. Sumitomo, Japan. Unpublished.
- Cañez, V.M. 1989. The magnitude of methyl parathion residues on sunflower. Huntingdon Analytical Services, Project PAL-MP-SS, includes MP-SS-7128, MP-SS-7129. Unpublished.

If a section has no study, include the heading and the statement “No study submitted”.

The data directory should include the volume numbers in the dossier showing where each study is located. For very large dossiers (five boxes or more), a summary of the allocations of volumes to boxes should also be provided. In situations where the volume number is not known at the time the directory is first submitted, an amended directory (including the volume number) should be included with the final data submission.

Provide an electronic copy of the data directory in Word format.

DATA DIRECTORY FORMAT

1. BACKGROUND INFORMATION

Identity

(OECD data point numbers IIA 2.1, 2.2, 2.3, 2.4, 2.6, 2.7, 2.7, 2.9)

⁷² OECD. 2001. Dossier Guidance —OECD guidance for industry data submissions on plant protection products and their active substances. <http://www1.oecd.org/ehs/PestGD03.htm>

Physical and chemical properties

Vapour pressure

Relevant study references. Volume in data dossier.

Octanol-water partition coefficient

Relevant study references. Volume in data dossier.

.....etc

2. METABOLISM AND ENVIRONMENTAL FATE

Proposed subdivisions are indicated under those headings where generally a number of reports for a range of commodities are provided. Rotational crop studies should appear under environmental fate in soil.

Animal metabolism

(OECD data point numbers IIA 6.2.2, 6.2.3)

Subdivided according to laboratory animal, livestock, poultry

Relevant study references. Volume in data dossier.

Plant metabolism

(OECD data point number IIA 6.2.1)

Subdivided, where necessary, according to crop

Relevant study references. Volume in data dossier.

Environmental fate in soil

(OECD data point numbers IIA 6.6, 7.1, 7.2.1, 7.2.4, 7.3.1, 7.4.1, 7.4.2, 7.4.3, 7.4.4, 7.4.5)

Relevant study references. Volume in data dossier.

Environmental fate in water-sediment systems

(OECD data point numbers IIA 7.5, 7.6, 7.8.3)

Relevant study references. Volume in data dossier.

3. RESIDUE ANALYSIS

Analytical methods

- Methods used in the supervised trials and processing studies
- Enforcement methods (OECD data point number IIA 4.3)
- Specialized methods
- Subheadings by substrate, e.g., commodity or soil, may be of use.

Relevant study references. Volume in data dossier.

Stability of residues in stored analytical samples

(OECD data point number IIA 6.1)

Subdivided, where necessary, according to commodity
Relevant study references. Volume in data dossier.

4. USE PATTERNS

List of crops for which Good Agricultural Practice (GAP) information is available, the relevant country(ies) (listed alphabetically), and whether labels will be available.

List of labels.

5. RESIDUES RESULTING FROM SUPERVISED TRIALS ON CROPS

(OECD data point number IIA 6.3)

Subheadings by commodity organized according to the Codex Classification

Citrus fruits

lemons
oranges
tangelos

Relevant study references. Volume in data dossier.

Pome fruits

apples
pears

Relevant study references. Volume in data dossier.

Stone fruits

Relevant study references. Volume in data dossier.....etc.

Relevant study references. Volume in data dossier etc.

6. FATE OF RESIDUES IN STORAGE AND PROCESSING

In storage

Subdivided, where necessary, according to commodity.
Relevant study references. Volume in data dossier.

In processing

(OECD data point number IIA 6.5)

Subdivided, where necessary, according to commodity.
Relevant study references. Volume in data dossier.

7. RESIDUES IN ANIMAL COMMODITIES

Farm animal feeding studies
(OECD data point number IIA 6.4)

Relevant study references. Volume in data dossier.

Direct animal treatments
Relevant study references. Volume in data dossier.

8. RESIDUES IN FOOD IN COMMERCE OR AT CONSUMPTION

Relevant study references. Volume in data dossier.

9. NATIONAL RESIDUE DEFINITIONS

A list of the countries for which this information is available should be included.

State the source of the information and its date.

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Appendix VIII

PESTICIDE INFORMATION FOR CCPR WORKING GROUP ON PRIORITIES⁷³

for evaluation _____

for re-evaluation _____

1. NAME:
2. STRUCTURAL FORMULA:
3. CHEMICAL NAME:
4. TRADE NAME:
5. NAMES AND ADDRESSES OF BASIC PRODUCERS:
6. JUSTIFICATION FOR USE:
7. USES: MAJOR
 MINOR
8. COMMODITIES MOVING IN INTERNATIONAL TRADE AND LEVELS OF RESIDUES:
9. COUNTRIES WHERE PESTICIDE IS REGISTERED:
10. NATIONAL MAXIMUM RESIDUE LIMITS:
11. COMMODITIES FOR WHICH THE NEED FOR ESTABLISHING CODEX MRLs ARE RECOGNIZED:
12. MAJOR INTERNATIONAL USE PATTERN:
13. LIST OF DATA (TOXICOLOGY, METABOLISM, RESIDUE) AVAILABLE:
14. DATE DATA COULD BE SUBMITTED TO THE JMPR:
15. PROPOSAL FOR INCLUSION SUBMITTED BY (COUNTRY):

⁷³ This information is to be provided by Codex member countries for inclusion of a pesticide in the Codex Priority List.

Appendix IX

MAXIMUM PROPORTION OF AGRICULTURAL COMMODITIES IN ANIMAL FEED

The livestock feed tables were developed by the OECD Pesticide Residue Chemistry Group and published in Draft Revised Guidance Document on Overview of Residue Chemistry Studies (Series on Testing And Assessment No.64) 18Feb 2009.

The tables should be used based on the procedure described in section 6.12.1 of the Manual. To assist their use, Table IX.1 provides matching Codex commodities with the feedstuffs listed in the tables together with the Codex commodity code numbers.

The tables IX.2-IX.4 include the Codex commodity group codes as well to facilitate the selection of commodities for calculation of the appropriate animal burden.

If the residues are already expressed on dry weight basis then the dry matter content given in the tables should be replaced with 100%.

Table IX.1 Description of feedstuffs and the corresponding Codex commodity description

Codex		OECD		Name of group
Code	Commodity	Crop	Feedstuff	
AL1020	Alfalfa forage (green)	Alfalfa	forage	legumes, forage and fodder
AL1021	Alfalfa fodder	Alfalfa	hay	legumes, forage and fodder
AF		Alfalfa	meal	legumes, forage and fodder
AF		Alfalfa	silage	legumes, forage and fodder
AF		Barley	forage	legumes, forage and fodder
AS0640	Barley straw and fodder, dry	Barley	hay	pulp, processed
VB0041	Cabbages, head	Cabbage	heads, leaves	cereal, processed
AS0641	Barley straw and fodder, dry	Barley	straw	grasses, forage
VR0596	Sugar beet	Beet, sugar	tops	cereal grain
AF		Barley	silage	grasses, fodder
AV0569	Sugar beet leaves or tops	Beet, mangel	fodder	grasses, forage
AL1030	Bean forage (green)	Bean	vines	grasses, fodder
AL1031	Clover hay and fodder	Clover	hay	pulses
AL1023	Clover	Clover	forage	legumes, forage and fodder
AF		Clover	silage	misc, forage and fodder
AS0645	Maize fodder	Corn, field	stover	pulp, processed
AF		Corn, pop	stover	pulp, processed
AF		Corn, sweet	forage	misc. edible products of plant origin
AF0645	Maize forage	Corn, field	forage/silage	miscellaneous, fodder and forage
AF		Corn, sweet	stover	pulp, processed
AF		Cowpea	forage	Brassica leafy vegetables
AF		Cowpea	hay	miscellaneous, processed
AF		Crown vetch	forage	root vegetables

Appendix IX – Maximum proportion of agricultural commodities in animal feed

Codex		OECD		Name of group
Code	Commodity	Crop	Feedstuff	
AF		Crown vetch	hay	root vegetables
AF		Grass	forage (fresh)	
AF		Grass	hay	pulp, processed
AF		Grass	silage	legumes, forage and fodder
AV480	Kale forage	Kale	leaves	legumes, forage and fodder
AL1025	Lespedeza	Lespedeza	forage	legumes, forage and fodder
AF	Lespedeza	Lespedeza	hay	miscellaneous, processed
AF		Millet	forage	cereal, processed
AF		Millet	hay	cereal, processed
AF		Oat	straw	cereal, processed
AS0646	Millet fodder, dry	Millet	straw	grasses, forage
AS0647	Oat straw and fodder, dry	Oat	hay	cereal grain
AL0528	Pea vines (green)	Pea	vines	cereal, processed
AF		Oat	silage	cereal, processed
AF0647	Oat forage	Oat	forage	grasses, fodder
AF		Pea	silage	cereal grain
AL0072	Pea hay or fodder	Pea	hay	grasses, fodder
AS0649	Rice straw and fodder, dry	Rice	straw	pulp, processed
AL0697	Peanut fodder	Peanut	hay	grasses, forage
VL0495	Rape greens	Rape	forage	grasses, fodder
AF		Rye	silage	miscellaneous, processed
AS0650	Rye straw and fodder, dry	Rye	straw	miscellaneous, processed
AF		Rice	whole crop silage	miscellaneous, processed
AF0650	Rye forage (green)	Rye	forage	oilseed
AF0651	Sorghum forage (green)	Sorghum, forage	see Grasses	legumes, forage and fodder
		Sorghum, grain	forage	legumes, forage and fodder
AS	Sorghum straw and fodder, dry	Sorghum, grain	stover	pulses
AF		Sorghum, grain	silage	legumes, forage and fodder
AL1265	Soya bean forage (green)	Soybean	forage	legumes, forage and fodder
AL0541	Soya bean fodder	Soybean	hay	pulp, processed
AF		Soybean	silage	miscellaneous, processed
AF		Sugarcane	tops	pulp, processed
AL		Trefoil	forage	grasses, forage
AF		Trefoil	hay	grasses, fodder
AF		Triticale	forage	grasses, forage
AF		Triticale	hay	misc, forage and fodder
AF		Triticale	straw	legumes, forage and fodder
AF		Triticale	silage	legumes, forage and fodder
AV0506	Turnip leaves or tops	Turnip	tops (leaves)	pulses
AF		Vetch	forage	miscellaneous, processed
AF		Vetch	hay	grasses, forage
AS0654	Wheat straw and fodder, dry	Wheat	hay	cereal grain
AF		Vetch	silage	grasses, fodder
AF		Wheat	forage	grasses, fodder
AS0654	Wheat straw and fodder, dry	Wheat	straw	grasses, forage
VR0463	Cassava	Cassava/tapioca	roots	cereal grain
AF		Wheat	silage	grasses, fodder
VR0577	Carrot	Carrot	culls	grasses, forage
VR0589	Potato culls	Potato	culls	miscellaneous, processed

Appendix IX – Maximum proportion of agricultural commodities in animal feed

Codex		OECD		Name of group
Code	Commodity	Crop	Feedstuff	
VR506	Turnip, Garden	Turnip	roots	legumes, forage and fodder
GC0640	Barley	Barley	grain	pulses
VR0497	Swede	Swede	roots	legumes, forage and fodder
VD0071	Beans, dry	Bean	seed	legumes, forage and fodder
GC0645	Maize	Corn, field	grain	miscellaneous, processed
GC0656	Popcorn	Corn, pop	grain	pulp, processed
VG0527	Cowpea	Cowpea	seed	root vegetables
GC0646	Millet	Millet	grain	pulp, processed
VD0545	Lupin	Lupin	seed	pulp, processed
GC0647	Oats	Oat	grain	misc, forage and fodder
VD0561	Field pea, (dry)	Pea	seed	miscellaneous, processed
GC0653	Triticale	Triticale	grain	cereal, processed
GC0651	Sorghum	Sorghum, grain	grain	cereal grain
SO4724 VD4521	Soya bean, dry	Soybean	seed	cereal, processed
GC0649	Rice	Rice	grain	grasses, fodder
GC0650	Rye	Rye	grain	grasses, forage
AL1029	Vetch	Vetch	seed	
GC0654	Wheat	Wheat	grain	grasses, forage
AB		Barley	bran fractions	cereal grain
AB9226	Apple pomace, dry	Apple	pomace, wet	grasses, forage
AB		Almond	hulls	grasses, fodder
AB0596	Sugar beet pulp, dry	Beet, sugar	dried pulp	miscellaneous, processed
AB		Beet, sugar	ensiled pulp	miscellaneous, processed
SM		Coconut	meal	cereal, processed
DM0596	Sugar beet molasses	Beet, sugar	molasses	grasses, forage
AB001	Citrus pulp, dry	Citrus	dried pulp	cereal grain
AB	Rape seed meal	Canola	meal	grasses, forage
AB		Brewer's grain	dried	grasses, fodder
AB	Maize aspirated grain fraction	Corn, field	asp gr fn	grasses, forage
AB	Maize gluten meal	Corn gluten	meal	miscellaneous, processed
AB	Maize milled byproducts	Corn, field	milled bypds	legumes, forage and fodder
AB		Corn, field	hominy meal	legumes, forage and fodder
AB		Cotton	undelinted seed	miscellaneous, processed
AB		Cotton	meal	miscellaneous, processed
AB		Cotton	hulls	miscellaneous, processed
AB		Cotton	gin byproducts	miscellaneous, processed
AB		Corn gluten	feed	pulses
AB		Corn, sweet	cannery waste	legumes, forage and fodder
AB0269	Grape pomce, dry	Grape	pomace, wet	miscellaneous, processed
SO0693	Linseed	Flaxseed/linseed	meal	
AB		Distiller's grain	dried	misc, forage and fodder
AB		Lupin seed	meal	miscellaneous, processed
VS0626	Palm hearts	Palm	kernel meal	root vegetables
SO0697	Peanut	Peanut	meal	pulp, processed
AB		Pineapple	process waste	legumes, forage and fodder
		Potato	process waste	grasses, fodder
AB		Potato	dried pulp	grasses, fodder
AB		Rice	hulls	grasses, forage
AB		Rape	meal	grasses, fodder
CM		Rice	bran/pollard	grasses, forage
		Sesame seed	meal	cereal grain
AB		Sorghum, grain	asp gr. Fn,	root vegetables

Codex		OECD		Name of group
Code	Commodity	Crop	Feedstuff	
		Safflower	meal	misc, forage and fodder
AB		Soybean	asp gr fn	grasses, forage
AB		Soybean	meal	grasses, fodder
AB		Soybean	okara	
AB		Soybean	hulls	grasses, forage
AB		Wheat	asp gr fn	cereal, processed
AB		Soybean	pollard	grasses, forage
AB		Tomato	pomace, wet	cereal grain
AB		Sugarcane	molasses	grasses, fodder
AB		Wheat gluten	meal	cereal, processed
AB		Sunflower	meal	grasses, forage
AB		Sugarcane	bagasse	grasses, fodder
AB		Wheat	milled bypds	cereal, processed

Table IX.2 Beef and dairy cattle

Codex Code	CROP	Feedstuff	IFN Code	Residue Level	DM (%)	BEEF Cattle				DAIRY Cattle			
						US CAN	EU	AU	JP	US CAN	EU	AU	JP
	Body weight (kg)					500	500	500	730	600	650	500	600
	Daily intake (DM in kg)					9.1	12	20	14	24	25	20	17
	Forages												
AL1020	Alfalfa	forage	2-00-196	HR	35	*	70	100	*	20	40	60	*
AL1021	Alfalfa	hay	1-00-054	HR	89	15	*	80	10	20	40	60	25
AF	Alfalfa	meal	1-00-023	HR	89	*	*	40	10	10	40	40	25
AF	Alfalfa	silage	3-08-150	HR	40	*	25	100	*	20	40	40	20
AF	Barley	forage	2-00-511	HR	30	*	30	50	*	*	30	50	*
AS0640	Barley	hay	1-00-495	HR	88	15	*	100	*	20	*	50	*
AS0641	Barley	straw	1-00-498	HR	89	10	30	100	*	10	30	20	*
AF	Barley	silage	NA	HR	40	*	30	100	*	*	30	50	*
AL1030	Bean	vines	2-14-388	HR	35	*	*	60	*	*	20	70	*
AV0569	Beet, mangel	fodder	2-00-632	HR	15	*	30	*	*	*	25	*	*
VR0596	Beet, sugar	tops	2-00-649	HR	23	*	20	*	*	*	30	*	*
VB0041	Cabbage	heads, leaves	2-01-046	HR	15	*	20	*	*	*	20	*	*
AL1023	Clover	forage	2-01-434	HR	30	*	30	100	*	20	40	60	*
AL1031	Clover	hay	1-01-415	HR	89	15	30	100	*	20	40	60	*
AF	Clover	silage	3-01-441	HR	30	*	25	100	*	20	40	60	*
AF0645	Corn, field	forage/silage	3-28-345	HR	40	15	80	80	*	45	60	80	20/50
AS0645	Corn, field	stover	3-28-251	HR	83	15	25	40	*	15	20	40	*
AF	Corn, pop	stover	2-02-963	HR	85	15	25	20	*	*	20	20	*
AF	Corn, sweet	forage	1-08-407	HR	48	*	*	80	*	45	*	40	*
AF	Corn, sweet	stover	NA	HR	83	*	*	40	*	15	*	20	*
AF	Cowpea	forage	2-01-655	HR	30	*	35	100	*	20	35	60	*
AF	Cowpea	hay	1-01-645	HR	86	*	35	100	*	20	35	60	*
AF	Crown vetch	forage	2-19-834	HR	30	*	*	100	*	10	*	100	*
AF	Crown vetch	hay	1-20-803	HR	90	*	*	100	*	*	*	100	*
AF	Grass	forage (fresh)	2-02-260	HR	25	*	50	100	5	45	60	100	10
AF	Grass	hay	1-02-250	HR	88	15	50	100	40	45	60	60	70
AF	Grass	silage	3-02-222	HR	40	*	50	100	5	45	60	60	80
AV480	Kale	leaves	2-02-446	HR	15	*	20	*	*	*	20	40	*
AL1025	Lespedeza	forage	2-07-058	HR	22	*	*	20	*	40	*	60	*
AF	Lespedeza	hay	1-02-522	HR	88	15	*	20	*	40	*	60	*
AF	Millet	forage	2-03-801	HR	30	*	*	100	*	20	30	50	*
AF	Millet	hay	1-03-119	HR	85	10	*	100	*	20	*	50	*
AS0646	Millet	straw	1-23-802	HR	90	10	10	80	*	10	*	50	*
AF0647	Oat	forage	2-03-292	HR	30	*	20	100	*	30	20	90	5
AS0647	Oat	hay	1-03-280	HR	90	15	20	100	*	30	20	90	5
AF	Oat	straw	1-03-283	HR	90	10	20	80	*	10	20	60	5
AF	Oat	silage	3-03-298	HR	35	*	*	100	*	*	*	40	5
AL0528	Pea	vines	3-03-596	HR	25	*	20	60	*	10	20	40	*
AL0072	Pea	hay	1-03-572	HR	88	*	25	100	*	10	30	70	*
AF	Pea	silage	3-03-590	HR	40	*	25	100	*	10	30	40	*
AL0697	Peanut	hay	1-03-619	HR	85	*	*	60	*	15	*	60	*
VL0495	Rape	forage	2-03-867	HR	30	*	10	100	*	10	10	40	*
AS0649	Rice	straw	1-03-925	HR	90	*	10	60	55	*	5	20	25
AF	Rice	whole crop silage		HR	40				5				55
AF0650	Rye	forage	2-04-018	HR	30	*	20	100	*	20	20	20	*
AS0650	Rye	straw	1-04-007	HR	88	10	20	20	*	10	20	20	5
AF	Rye	silage		HR	28				*				5
AF0651	Sorghum, forage	see Grasses											
	Sorghum, grain	forage	2-04-317	HR	35	15	20	70	*	40	20	70	40
AS	Sorghum, grain	stover	1-07-960	HR	88	15	15	70	*	15	15	70	5
AF	Sorghum, grain	silage		HR	21				*				10
AL1265	Soybean	forage	2-04-574	HR	56	*	*	100	*	20	*	40	*
AL0541	Soybean	hay	1-04-558	HR	85	*	*	80	*	20	*	40	*

Appendix IX – Maximum proportion of agricultural commodities in animal feed

Codex Code	CROP	Feedstuff	IFN Code	Residue Level	DM (%)	BEEF Cattle				DAIRY Cattle			
						US CAN	EU	AU	JP	US CAN	EU	AU	JP
	Body weight (kg)					500	500	500	730	600	650	500	600
	Daily intake (DM in kg)					9.1	12	20	14	24	25	20	17
AF	Soybean	silage	3-04-581	HR	30	*	*	80	*	20	*	40	*
AF	Sugarcane	tops	2-04-692	HR	25	*	*	50	*	*	*	25	*
AL	Trefoil	forage	2-20-786	HR	30	*	20	100	*	40	40	40	*
AF	Trefoil	hay	1-05-044	HR	85	15	20	90	*	40	40	40	*
AF	Triticale	forage	2-02-647	HR	30	*	20	100	*	20	20	70	*
AF	Triticale	hay	NA	HR	88	15	20	100	*	20	20	70	*
AF	Triticale	straw	NA	HR	90	10	20	50	*	10	20	70	*
AF	Triticale	silage	3-26-208	HR	35	*	*	90	*	*	*	50	*
AV0506	Turnip	tops (leaves)	2-05-063	HR	30	*	40	80	*	30	20	*	*
AF	Vetch	forage	2-05-112	HR	30	*	25	90	*	20	25	35	*
AF	Vetch	hay	1-05-122	HR	85	15	25	90	65	20	25	35	25
AF	Vetch	silage	3-26-357	HR	30	*	*	90	*	*	*	50	60
AF	Wheat	forage	2-08-078	HR	25	*	20	100	*	20	20	60	*
AS0654	Wheat	hay	1-05-172	HR	88	15	20	100	*	20	20	20	*
AS0654	Wheat	straw	1-05-175	HR	88	10	20	80	*	10	20	20	*
AF	Wheat	silage	3-05-186	HR	30	*	*	90	*	*	*	50	*
	Roots & Tubers												
VR0577	Carrot	culls	2-01-146	HR	12	*	15	5	*	10	15	5	*
VR0463	Cassava/tapioca	roots	2-01-156	HR	37	*	20	*	*	*	15	*	*
VR0589	Potato	culls	4-03-787	HR	20	30	30	10	*	10	30	10	*
VR0497	Swede	roots	4-04-001	HR	10	*	40	10	*	*	20	10	*
VR506	Turnip	roots	4-05-067	HR	15	*	20	10	*	10	20	10	*
	Cereal Grains/Crops Seeds												
GC0640	Barley	grain	4-00-549	HR	88	50	70	80	70	45	40	40	40
VD0071	Bean	seed	4-00-515	HR	88	*	20	50	*	*	20	15	*
GC0645	Corn, field	grain	4-20-698	HR	88	80	80	80	75	45	30	20	80
GC0656	Corn, pop	grain	4-02-964	HR	88	80	*	80	75	45	30	20	80
VG0527	Cowpea	seed	5-01-661	HR	88	*	20	20	*	*	20	20	*
VD0545	Lupin	seed	5-02-707	HR	88	*	20	40	*	*	20	20	*
GC0646	Millet	grain	4-03-120	HR	88	50	40	50	*	20	40	50	*
GC0647	Oat	grain	4-03-309	HR	89	*	40	80	55	20	40	10	5
VD0561	Pea	seed	5-03-600	HR	90	*	20	40	*	*	20	20	*
GC0649	Rice	grain	4-03-939	HR	88	20	*	40	*	20	*	20	*
GC0650	Rye	grain	4-04-047	HR	88	20	40	80	35	20	40	*	15
GC0651	Sorghum, grain	grain	4-04-383	HR	86	40	40	80	35	45	40	50	30
SO4724													
VD4521	Soybean	seed	5-64-610	HR	89	5	10	20	15	10	10	20	10
GC0653	Triticale	grain	4-20-362	HR	89	20	40	80	*	20	40	30	*
AL1029	Vetch	seed	5-26-351	HR	89	*	*	20	*	*	*	20	*
GC0654	Wheat	grain	4-05-211	HR	89	20	40	80	25	20	40	20	10
	By-products												
AM 0660	Almond	hulls	4-00-359	STMR	90	*	*	10	*	10	*	10	*
AB9226	Apple	pomace, wet	4-00-419	STMR	40	*	20	20	*	10	10	10	*
AB	Barley	bran fractions		STMR	90				10				*
AB0596	Beet, sugar	dried pulp	4-29-307	STMR	88	15	20	*	5	15	20	*	40
AB	Beet, sugar	ensiled pulp	4-00-662	STMR	15	*	25	*	*	*	40	*	*
DM0596	Beet, sugar	molasses	4-30-289	STMR	75	10	10	*	*	10	10	*	*
AB	Brewer's grain	dried	5-00-516	STMR	92	50	10	50	45	30	15	20	40
AB	Canola	meal	5-08-136	STMR	88	5	*	20	*	10	10	15	*
AB001	Citrus	dried pulp	4-01-237	STMR	91	10	5	30	*	10	20	30	*
SM	Coconut	meal	5-01-572	STMR	91	*	20	30	*	*	10	*	*
AB	Corn, field	asp gr. fn.	4-02-880	STMR	85	5	*	*	*	*	*	*	*
AB	Corn, field	milled bypds	5-28-235	STMR	85	50	30	15	5	25	30	15	*
AB	Corn, field	hominy meal	4-03-010	STMR	88	50	*	40	35	25	*	40	*
AB	Corn, sweet	cannery waste	2-02-875	STMR	30	*	*	30	*	10	*	10	*

Appendix IX – Maximum proportion of agricultural commodities in animal feed

Codex Code	CROP	Feedstuff	IFN Code	Residue Level	DM (%)	BEEF Cattle				DAIRY Cattle			
						US CAN	EU	AU	JP	US CAN	EU	AU	JP
	Body weight (kg)					500	500	500	730	600	650	500	600
	Daily intake (DM in kg)					9.1	12	20	14	24	25	20	17
AB	Corn gluten	feed	5-28-243	STMR	40	75	30	20	25	25	30	*	20
AB	Corn gluten	meal	5-28-242	STMR	40	75	15	20	*	25	20	*	15
AB	Cotton	meal	5-01-617	STMR	89	5	5	30	*	10	5	15	*
AB	Cotton	undelinted seed	5-01-614	STMR	88	*	*	30	*	10	10	20	*
AB	Cotton	hulls	1-01-599	STMR	90	10	*	20	*	*	*	10	*
AB	Cotton	gin by-products	1-08-413	STMR	90	5	*	*	*	*	*	*	*
AB	Distiller's grain	dried	5-00-518	STMR	92	50	10	50	10	25	10	*	15
SO0693	Flaxseed/linseed	meal	5-02-043	STMR	88	5	10	10	*	10	15	10	*
AB0269	Grape	pomace, wet	2-02-206	STMR	15	*	*	20	*	*	*	20	*
AB	Lupin seed	meal	NA	STMR	85	*	20	15	*	*	20	15	*
VS0626	Palm	kernel meal	5-03-486	STMR	90	*	*	20	5	*	25	10	5
SO0697	Peanut	meal	5-03-649	STMR	85	*	20	10	*	10	10	15	*
AB	Pineapple	process waste	NA	STMR	25	10	*	60	*	10	*	30	*
AB	Potato	process waste	4-03-777	STMR	12	30	40	5	*	10	30	*	*
AB	Potato	dried pulp	4-03-775	STMR	88	*	10	5	*	*	10	5	*
AB	Rape	meal	5-26-093	STMR	88	*	20	15	15	*	10	15	25
AB	Rice	hulls	1-08-075	STMR	90	*	*	5	*	*	*	10	*
CM	Rice	bran/pollard	4-03-928	STMR	90	15	*	40	20	15	20	40	10
SN	Sesame seed	meal	NA	STMR	90								
SM	Safflower	meal	5-26-095	STMR	91	5	20	20	*	10	10	15	*
AB	Sorghum, grain	asp gr fn	NA	STMR	85	5	*	20	*	*	*	*	*
AB	Soybean	asp gr fn	NA	STMR	85	5	*	*	*	*	*	*	*
AB	Soybean	meal	5-20-638	STMR	92	5	20	10	65	10	25	15	60
AB	Soybean	hulls	1-04-560	STMR	90	15	10	*	*	*	10	*	*
AB	Soybean	okara	NA	STMR	20	*	*	*	40				20
AB	Soybean	pollard	NA	STMR	?	*	*	15	*	*	*	*	*
AB	Sugarcane	molasses	4-13-251	STMR	75	10	10	30	*	10	10	25	*
AB	Sugarcane	bagasse	1-04-686	STMR	32	*	*	20	*	*	*	25	*
AB	Sunflower	meal	5-26-098	STMR	92	5	20	30	*	10	10	15	*
AB	Tomato	pomace, wet	NA	STMR	20			10	*			10	*
AB	Wheat	asp gr fn	NA	STMR	85	5	*	*	*	*	*	*	*
AB	Wheat gluten	meal	5-05-221	STMR	40	10	15	*	*	10	20	*	*
AB	Wheat	milled bypds.	4-06-749	STMR	88	40	30	40	55	30	30	40	45

Table IX. 3 Percent of poultry diet

Codex code	CROP	Feedstuff	IFN Code	Residue Level	DM (%)	POULTRY, BROILER				POULTRY, LAYER				TURKEY		
						US CAN	EU	AU	JP	US CAN	EU	AU	JP	US CAN	EU	AU
	Body weight (kg)					2	1.7	2	3	1.9	1.9	2	2	8	7	2
	Daily intake (DM in kg)					0.16	0.12	0.15	N/A	0.12	0.13	0.15	0.10	0.50	0.50	0.15
	Forages															
AL1020	Alfalfa	forage	2-00-196	HR	35	*	*	*	5	*	*	*	*	*	*	*
AL1021	Alfalfa	hay	1-00-054	HR	89	*	*	*	*	*	*	*	*	*	*	*
AF	Alfalfa	meal	1-00-023	HR	89	5	5	10	*	5	10	10	10	5	5	10
AF	Alfalfa	silage	3-08-150	HR	40	*	*	*	*	*	*	*	*	*	*	*
AF	Barley	forage	2-00-511	HR	30	*	*	*	*	*	*	*	*	*	*	*
AS0640	Barley	hay	1-00-495	HR	88	*	*	*	*	*	*	*	*	*	*	*
AS0641	Barley	straw	1-00-498	HR	89	*	*	*	*	*	5	*	*	*	*	*
AF	Barley	silage	NA	HR	40	*	*	*	*	*	*	*	*	*	*	*
AL1030	Bean	vines	2-14-388	HR	35	*	*	*	*	*	*	*	*	*	*	*
AV0569	Beet, mangel	fodder	2-00-632	HR	15	*	*	*	*	*	*	*	*	*	*	*
VR0596	Beet, sugar	tops	2-00-649	HR	23	*	*	*	*	*	5	*	*	*	*	*
VB0041	Cabbage	heads, leaves	2-01-046	HR	15	*	*	*	*	*	5	*	*	*	*	*
AL1023	Clover	forage	2-01-434	HR	30	*	*	*	*	*	10	*	*	*	*	*
AL1031	Clover	hay	1-01-415	HR	89	*	*	*	*	*	10	*	*	*	*	*
AF	Clover	silage	3-01-441	HR	30	*	*	*	*	*	10	*	*	*	*	*
AF0645	Corn, field	forage/ silage	3-28-345	HR	40	*	*	*	*	*	10	*	*	*	*	*
AS0645	Corn, field	stover	3-28-251	HR	83	*	*	*	*	*	10	*	*	*	*	*
AF	Corn, pop	stover	2-02-963	HR	85	*	*	*	*	*	10	*	*	*	*	*
AF	Corn, sweet	forage	1-08-407	HR	48	*	*	*	*	*	*	*	*	*	*	*
AF	Corn, sweet	stover	NA	HR	83	*	*	*	*	*	*	*	*	*	*	*
AF	Cowpea	forage	2-01-655	HR	30	*	*	*	*	*	10	*	*	*	*	*
AF	Cowpea	hay	1-01-645	HR	86	*	*	*	*	*	10	*	*	*	*	*
AF	Crown vetch	forage	2-19-834	HR	30	*	*	*	*	*	10	*	*	*	*	*
AF	Crown vetch	hay	1-20-803	HR	90	*	*	*	*	*	10	*	*	*	*	*
AF	Grass	forage (fresh)	2-02-260	HR	25	*	*	*	*	*	10	*	*	*	*	*
AF	Grass	hay	1-02-250	HR	88	*	*	*	*	*	10	*	*	*	*	*
AF	Grass	silage	3-02-222	HR	40	*	*	*	*	*	10	*	*	*	*	*
AV480	Kale	leaves	2-02-446	HR	15	*	*	*	*	*	5	*	*	*	*	*
AL1025	Lespedeza	forage	2-07-058	HR	22	*	*	*	*	*	10	*	*	*	*	*
AF	Lespedeza	hay	1-02-522	HR	88	*	*	*	*	*	10	*	*	*	*	*
AF	Millet	forage	2-03-801	HR	30	*	*	*	*	*	10	*	*	*	*	*

Codex code	CROP	Feedstuff	IFN Code	Residue Level	DM (%)	POULTRY, BROILER				POULTRY, LAYER				TURKEY		
						US CAN	EU	AU	JP	US CAN	EU	AU	JP	US CAN	EU	AU
	Body weight (kg)					2	1.7	2	3	1.9	1.9	2	2	8	7	2
	Daily intake (DM in kg)					0.16	0.12	0.15	N/A	0.12	0.13	0.15	0.10	0.50	0.50	0.15
AF	Millet	hay	1-03-119	HR	85	*	*	*	*	*	10	*	*	*	*	*
AS0646	Millet	straw	1-23-802	HR	90	*	*	*	*	*	*	*	*	*	*	*
AF0647	Oat	forage	2-03-292	HR	30	*	*	*	*	*	10	*	*	*	*	*
AS0647	Oat	hay	1-03-280	HR	90	*	*	*	*	*	10	*	*	*	*	*
AF	Oat	straw	1-03-283	HR	90	*	*	*	*	*	*	*	*	*	*	*
AF	Oat	silage	3-03-298	HR	35	*	*	*	*	*	*	*	*	*	*	*
AL0528	Pea	vines	3-03-596	HR	25	*	*	*	*	*	10	*	*	*	*	*
AL0072	Pea	hay	1-03-572	HR	88	*	*	*	*	*	10	*	*	*	*	*
AF	Pea	silage	3-03-590	HR	40	*	*	*	*	*	10	*	*	*	*	*
AL0697	Peanut	hay	1-03-619	HR	85	*	*	*	*	*	*	*	*	*	*	*
VL0495	Rape	forage	2-03-867	HR	30	*	*	*	*	*	10	*	*	*	*	*
AS0649	Rice	straw	1-03-925	HR	90	*	*	*	*	*	*	*	*	*	*	*
AF	Rice	whole crop silage		HR	40											
AF0650	Rye	forage	2-04-018	HR	30	*	*	*	*	*	10	*	*	*	*	*
AS0650	Rye	straw	1-04-007	HR	88	*	*	*	*	*	*	*	*	*	*	*
AF	Rye	silage		HR	28											
AF0651	Sorghum, forage	see Grasses														
	Sorghum, grain	forage	2-04-317	HR	35	*	*	*	*	*	10	*	*	*	*	*
AS	Sorghum, grain	stover	1-07-960	HR	88	*	*	*	*	*	10	*	*	*	*	*
AF	Sorghum, grain	silage		HR	21											
AL1265	Soybean	forage	2-04-574	HR	56	*	*	*	*	*	10	*	*	*	*	*
AL0541	Soybean	hay	1-04-558	HR	85	*	*	*	*	*	10	*	*	*	*	*
AF	Soybean	silage	3-04-581	HR	30	*	*	*	*	*	10	*	*	*	*	*
AF	Sugarcane	tops	2-04-692	HR	25	*	*	*	*	*	*	*	*	*	*	*
AL	Trefoil	forage	2-20-786	HR	30	*	*	*	*	*	10	*	*	*	*	*
AF	Trefoil	hay	1-05-044	HR	85	*	*	*	*	*	10	*	*	*	*	*
AF	Triticale	forage	2-02-647	HR	30	*	*	*	*	*	*	*	*	*	*	*
AF	Triticale	hay	NA	HR	88	*	*	*	*	*	*	*	*	*	*	*
AF	Triticale	straw	NA	HR	90	*	*	*	*	*	*	*	*	*	*	*
AF	Triticale	silage	3-26-208	HR	35	*	*	*	*	*	*	*	*	*	*	*
AV0506	Turnip	tops (leaves)	2-05-063	HR	30	*	*	*	*	*	*	*	*	*	*	*
AF	Vetch	forage	2-05-112	HR	30	*	*	*	*	*	10	*	*	*	*	*
AF	Vetch	hay	1-05-122	HR	85	*	*	*	*	*	10	*	*	*	*	*
AF	Vetch	silage	3-26-357	HR	30	*	*	*	*	*	*	*	*	*	*	*
AF	Wheat	forage	2-08-078	HR	25	*	*	*	*	*	10	*	*	*	*	*
AS0654	Wheat	hay	1-05-172	HR	88	*	*	*	*	*	10	*	*	*	*	*
AS0654	Wheat	straw	1-05-175	HR	88	*	*	*	*	*	10	*	*	*	*	*
AF	Wheat	silage	3-05-186	HR	30	*	*	*	*	*	*	*	*	*	*	*

Codex code	CROP	Feedstuff	IFN Code	Residue Level	DM (%)	POULTRY, BROILER				POULTRY, LAYER				TURKEY		
						US CAN	EU	AU	JP	US CAN	EU	AU	JP	US CAN	EU	AU
	Body weight (kg)					2	1.7	2	3	1.9	1.9	2	2	8	7	2
	Daily intake (DM in kg)					0.16	0.12	0.15	N/A	0.12	0.13	0.15	0.10	0.50	0.50	0.15
	Roots & Tubers															
VR0577	Carrot	culls	2-01-146	HR	12	*	10	*	*	*	10	*	*	*	10	*
VR0463	Cassava/tapioca	roots	2-01-156	HR	37	*	20	*	*	*	15	*	*	*	5	*
VR0589	Potato	culls	4-03-787	HR	20	*	10	*	*	*	10	*	*	*	20	*
VR0497	Swede	roots	4-04-001	HR	10	*	10	*	*	*	10	*	*	*	10	*
VR506	Turnip	roots	4-05-067	HR	15	*	10	*	*	*	10	*	*	*	10	*
	Cereal Grains/Crops Seeds															
GC0640	Barley	grain	4-00-549	HR	88	75	70	15	10	75	100	15	*	75	50	15
VD0071	Bean	seed	4-00-515	HR	88	*	20	70	*	*	20	70	*	*	20	70
GC0645	Corn, field	grain	4-20-698	HR	88	75	70	*	70	75	70	*	80	75	50	*
GC0656	Corn, pop	grain	4-02-964	HR	88	75	*	*	70	75	*	*	80	*	*	*
VG0527	Cowpea	seed	5-01-661	HR	88	10	5	5	*	10	10	5	*	10	5	10
VD0545	Lupin	seed	5-02-707	HR	88	10	15	15	*	10	10	10	*	10	10	50
GC0646	Millet	grain	4-03-120	HR	88	60	70	70	*	60	70	60	*	60	50	15
GC0647	Oat	grain	4-03-309	HR	89	75	70	15	*	75	70	15	*	75	50	5
VD0561	Pea	seed	5-03-600	HR	90	20	20	5	*	20	20	5	*	20	20	40
GC0649	Rice	grain	4-03-939	HR	88	20	*	50	*	20	*	50	*	20	*	60
GC0650	Rye	grain	4-04-047	HR	88	35	70	50	*	35	35	35	*	35	60	60
GC0651	Sorghum, grain	grain	4-04-383	HR	86	75	70	70	65	75	70	70	55	75	50	15
SO4724 VD4521	Soybean	seed	5-64-610	HR	89	20	20	15	*	20	15	15	*	20	15	15
GC0653	Triticale	grain	4-20-362	HR	89	75	15	*	*	75	15	*	*	75	15	60
AL1029	Vetch	seed	5-26-351	HR	89	*	*	*	*	*	*	*	*	*	*	*
GC0654	Wheat	grain	4-05-211	HR	89	75	70	70	10	75	70	55	*	75	50	*
	By-products															
AM 0660	Almond	hulls	4-00-359	STMR	90	*	*	*	*	*	*	*		*	*	*
AB9226	Apple	pomace, wet	4-00-419	STMR	40	*	*	*	*	*	*	*		*	*	*
AB	Barley	bran fractions		STMR	90				*							
AB0596	Beet, sugar	dried pulp	4-29-307	STMR	88	*	*	*	*	*	*	*		*	*	*
AB	Beet, sugar	ensiled pulp	4-00-662	STMR	15	*	*	*	*	*	*	*		*	*	*
DM0596	Beet, sugar	molasses	4-30-289	STMR	75	*	*	*	*	*	*	*		*	*	*
AB	Brewer's grain	dried	5-00-516	STMR	92	*	10	*	*	*	10	*		*	10	5
AB	Canola	meal	5-08-136	STMR	88	15	18	5	*	15	10	5		15	20	*
AB001	Citrus	dried pulp	4-01-237	STMR	91	*	*	*	*	*	*	*		*	*	*
SM	Coconut	meal	5-01-572	STMR	91	*	*	*	*	*	*	*		*	*	*
AB	Corn, field	asp gr fn	4-02-880	STMR	85	*	*	*	*	*	*	*		*	*	*

Appendix IX – Maximum proportion of agricultural commodities in animal feed

Codex code	CROP	Feedstuff	IFN Code	Residue Level	DM (%)	POULTRY, BROILER				POULTRY, LAYER				TURKEY		
						US CAN	EU	AU	JP	US CAN	EU	AU	JP	US CAN	EU	AU
	Body weight (kg)					2	1.7	2	3	1.9	1.9	2	2	8	7	2
	Daily intake (DM in kg)					0.16	0.12	0.15	N/A	0.12	0.13	0.15	0.10	0.50	0.50	0.15
AB	Corn, field	milled bypds	5-28-235	STMR	85	50	60	*	*	50	50	*		50	50	20
AB	Corn, field	hominy meal	4-03-010	STMR	88	20	*	20	*	20	20	20		20	20	*
AB	Corn, sweet	cannery waste	2-02-875	STMR	30	*	*	*	*	*	*	*		*	*	*
AB	Corn gluten	feed	5-28-243	STMR	40	*	10	*	*	*	*	*		*	*	*
AB	Corn gluten	meal	5-28-242	STMR	40	*	10	*	*	*	10	*		*	10	10
AB	Cotton	meal	5-01-617	STMR	89	20	5	10	*	20	5	10		20	10	*
AB	Cotton	undelinted seed	5-01-614	STMR	88	*	*	*	*	*	*	*		*	*	*
AB	Cotton	hulls	1-01-599	STMR	90	*	*	*	*	*	*	*		*	*	*
AB	Cotton	gin by-products	1-08-413	STMR	90	*	*	*	*	*	*	*		*	*	*
AB	Distiller's grain	dried	5-00-518	STMR	92	*	10	*	5	*	10	*		*	10	*
SO0693	Flaxseed/linseed	meal	5-02-043	STMR	88	20	10	*	*	20	10	*		20	10	*
AB0269	Grape	pomace, wet	2-02-206	STMR	15	*	*	*	*	*	*	*		*	*	20
AB	Lupin seed	meal	NA	STMR	85	*	10	20	*	*	10	20		*	10	*
VS0626	Palm	kernel meal	5-03-486	STMR	90	*	*	*	*	*	*	*		*	5	10
SO0697	Peanut	meal	5-03-649	STMR	85	25	10	10	*	25	10	10		25	10	*
AB	Pineapple	process waste	NA	STMR	25	*	*	*	*	*	*	*		*	*	*
AB	Potato	process waste	4-03-777	STMR	12	*	*	*	*	*	*	*		*	*	*
AB	Potato	dried pulp	4-03-775	STMR	88	*	20	*	*	*	15	*		*	*	5
AB	Rape	meal	5-26-093	STMR	88	*	*	5	5	*	10	5		*	20	*
AB	Rice	hulls	1-08-075	STMR	90	*	*	*	*	*	*	*	*	*	*	20
CM	Rice	bran/pollard	4-03-928	STMR	90	10	10	20	5	10	5	20	20	10	*	15
SN	Sesame seed	meal	NA	STMR	90							5				
SM	Safflower	meal	5-26-095	STMR	91	25	10	15	*	25	5	15	*	25	5	*
AB	Sorghum, grain	asp gr fn	NA	STMR	85	*	*	*	*	*	*	*	*	*	*	*
AB	Soybean	asp gr fn	NA	STMR	85	*	*	*	*	*	*	*	*	*	*	25
AB	Soybean	meal	5-20-638	STMR	92	25	40	25	35	25	25	25	30	25	45	*
AB	Soybean	hulls	1-04-560	STMR	90	*	10	5	*	*	5	5	*	*	*	*
AB	Soybean	okara	NA	STMR	20											
AB	Soybean	pollard	NA	STMR	?	*	*	*	*	*	*	*	*	*	*	*
AB	Sugarcane	molasses	4-13-251	STMR	75	*	*	*	*	*	*	*	*	*	*	*
AB	Sugarcane	bagasse	1-04-686	STMR	32	*	*	*	*	*	*	*	*	*	*	15

Appendix IX – Maximum proportion of agricultural commodities in animal feed

Codex code	CROP	Feedstuff	IFN Code	Residue Level	DM (%)	POULTRY, BROILER				POULTRY, LAYER				TURKEY		
						US CAN	EU	AU	JP	US CAN	EU	AU	JP	US CAN	EU	AU
	Body weight (kg)					2	1.7	2	3	1.9	1.9	2	2	8	7	2
	Daily intake (DM in kg)					0.16	0.12	0.15	N/A	0.12	0.13	0.15	0.10	0.50	0.50	0.15
AB	Sunflower	meal	5-26-098	STMR	92	25	10	15	*	25	10	15	*	25	10	*
AB	Tomato	pomace, wet	NA	STMR	20											
AB	Wheat	asp gr fn	NA	STMR	85	*	*	*	*	*	*	*	*	*	*	20
AB	Wheat gluten	meal	5-05-221	STMR	40	*	10	*	*	*	10	*	*	*	10	10
AB	Wheat	milled bypdt	4-06-749	STMR	88	50	20	20	5	50	20	20	30	50	20	20

Table IX. 4 Percent of sheep diet

	CROP	Feedstuff	IFN Code	Residue Level	DM (%)	RAM/EWE			LAMB			SWINE, breeding			SWINE, finishing			
						US CAN	EU	AU	US CAN	EU	AU	US CAN	EU	AU	US CAN	EU	AU	JP
	Body weight (kg)					85	75	60	40	40	60	270	260	60	100	100	60	110
	Daily intake (DM in kg)					2	2.5	2.5	1.5	1.7	2.5	2	6	2.5	3.1	3	2.50	1.00
	Forages																	
AL1020	Alfalfa	forage	2-00-196	HR	35	90	40	100	90	40	90	*	*	*	*	*	*	*
AL1021	Alfalfa	hay	1-00-054	HR	89	70	40	70	70	40	35	*	*	10	*	*	10	*
AF	Alfalfa	meal	1-00-023	HR	89	20	20	*	20	20	*	5	10	10	5	10	10	5
AF	Alfalfa	silage	3-08-150	HR	40	75	40	75	75	40	75	*	*	*	*	*	*	*
AF	Barley	forage	2-00-511	HR	30	70	50	100	30	50	100	*	*	*	*	*	*	*
AS0640	Barley	hay	1-00-495	HR	88	65	*	70	65	*	25	*	*	10	*	*	5	*
AS0641	Barley	straw	1-00-498	HR	89	25	60	30	25	60	30	*	*	10	*	*	10	*
AF	Barley	silage	NA	HR	40	*	50	*	*	50	*	*	*	*	*	*	*	*
AL1030	Bean	vines	2-14-388	HR	35	30	30	*	30	30	*	*	*	*	*	*	*	*
AV0569	Beet, mangel	fodder	2-00-632	HR	15	*	10	*	*	10	*	*	15	*	*	*	*	*
VR0596	Beet, sugar	tops	2-00-649	HR	23	15	20	*	20	20	*	*	10	*	*	*	*	*
VB0041	Cabbage	heads, leaves	2-01-046	HR	15	*	10	*	*	10	*	*	10	*	*	*	*	*
AL1023	Clover	forage	2-01-434	HR	30	85	85	100	30	30	100	*	20	*	*	*	*	*
AL1031	Clover	hay	1-01-415	HR	89	80	80	75	20	20	35	*	20	10	*	*	10	*
AF	Clover	silage	3-01-441	HR	30	85	85	75	30	30	75	*	20	*	*	*	*	*
AF0645	Corn, field	forage/ silage	3-28-345	HR	40	70	*	80	30	30	60	*	20	*	*	*	*	*
AS0645	Corn, field	stover	3-28-251	HR	83	50	*	*	25	*	*	*	20	*	*	*	*	*
AF	Corn, pop	stover	2-02-963	HR	85	25	*	*	25	*	*	*	20	*	*	*	*	*
AF	Corn, sweet	forage	1-08-407	HR	48	75	*	25	25	*	*	*	*	*	*	*	*	*
AF	Corn, sweet	stover	NA	HR	83	70	*	30	30	*	*	*	*	*	*	*	*	*
AF	Cowpea	forage	2-01-655	HR	30	75	35	100	30	35	100	*	20	*	*	*	*	*
AF	Cowpea	hay	1-01-645	HR	86	50	35	65	20	35	35	*	20	10	*	*	10	*
AF	Crown vetch	forage	2-19-834	HR	30	80	*	95	30	*	95	*	*	*	*	*	*	*
AF	Crown vetch	hay	1-20-803	HR	90	65	*	70	20	*	35	*	*	*	*	*	*	*
AF	Grass	forage (fresh)	2-02-260	HR	25	95	95	100	25	50	100	*	20	*	*	*	*	*
AF	Grass	hay	1-02-250	HR	88	90	90	70	15	30	25	*	20	10	*	*	10	*
AF	Grass	silage	3-02-222	HR	40	90	90	75	20	50	50	*	20	*	*	*	*	*
AV480	Kale	leaves	2-02-446	HR	15	*	10	*	*	10	*	*	10	*	*	*	*	*
AL1025	Lespedeza	forage	2-07-058	HR	22	80	*	*	30	*	*	*	*	*	10	*	*	
AF	Lespedeza	hay	1-02-522	HR	88	70	*	20	20	*	*	*	*	*	10	*	*	

Appendix IX – Maximum proportion of agricultural commodities in animal feed

	CROP	Feedstuff	IFN Code	Residue Level	DM (%)	RAM/EWE			LAMB			SWINE, breeding			SWINE, finishing			
						US CAN	EU	AU	US CAN	EU	AU	US CAN	EU	AU	US CAN	EU	AU	JP
	Body weight (kg)					85	75	60	40	40	60	270	260	60	100	100	60	110
	Daily intake (DM in kg)					2	2.5	2.5	1.5	1.7	2.5	2	6	2.5	3.1	3	2.50	1.00
AF	Millet	forage	2-03-801	HR	30	80	*	100	35	*	60	*	*	*	*	*	*	*
AF	Millet	hay	1-03-119	HR	85	75	*	65	20	*	20	*	*	10	*	*	10	*
AS0646	Millet	straw	1-23-802	HR	90	50	*	35	15	*	15	*	*	10	*	*	10	*
AF0647	Oat	forage	2-03-292	HR	30	25	40	100	35	40	100	*	20	*	*	*	*	*
AS0647	Oat	hay	1-03-280	HR	90	80	40	65	20	40	20	*	20	10	*	*	10	*
AF	Oat	straw	1-03-283	HR	90	10	40	35	20	40	15	*	*	10	*	*	10	*
AF	Oat	silage	3-03-298	HR	35	*	*	*	*	*	*	*	*	*	*	*	*	*
AL0528	Pea	vines	3-03-596	HR	25	75	20	90	35	20	90	*	20	*	*	*	*	*
AL0072	Pea	hay	1-03-572	HR	88	75	20	70	25	20	30	*	20	15	*	*	10	*
AF	Pea	silage	3-03-590	HR	40	73	20	75	35	20	70	*	20	*	*	*	*	*
AL0697	Peanut	hay	1-03-619	HR	85	79	*	25	25	*	*	*	*	*	*	*	*	*
VL0495	Rape	forage	2-03-867	HR	30	50	40	90	30	40	90	*	20	*	*	*	*	*
AS0649	Rice	straw	1-03-925	HR	90	10	10	20	10	10	15	*	*	10	*	*	10	*
AF	Rice	whole crop silage		HR	40													
AF0650	Rye	forage	2-04-018	HR	30	75	40	100	30	40	100	*	20	*	*	*	*	*
AS0650	Rye	straw	1-04-007	HR	88	25	40	20	10	40	20	*	*	*	*	*	*	*
AF	Rye	silage		HR	28													
AF0651	Sorghum,forage	see Grasses																
	Sorghum, grain	forage	2-04-317	HR	35	30	20	100	30	20	65	*	20	10	*	*	*	*
AS	Sorghum, grain	stover	1-07-960	HR	88	30	20	*	20	20	*	*	20	*	*	*	*	*
AF	Sorghum, grain	silage		HR	21													
AL1265	Soybean	forage	2-04-574	HR	56	80	*	90	35	*	80	*	*	*	*	*	*	*
AL0541	Soybean	hay	1-04-558	HR	85	65	*	70	20	*	25	*	*	*	*	*	*	*
AF	Soybean	silage	3-04-581	HR	30	70	*	75	40	*	65	*	*	*	*	*	*	*
AF	Sugarcane	tops	2-04-692	HR	25	*	*	*	*	*	*	*	*	*	*	*	*	*
AL	Trefoil	forage	2-20-786	HR	30	75	40	90	35	20	90	*	20	*	*	*	*	*
AF	Trefoil	hay	1-05-044	HR	85	60	40	70	25	20	70	*	20	15	*	*	10	*
AF	Triticale	forage	2-02-647	HR	30	60	40	100	30	30	100	*	20	*	*	*	*	*
AF	Triticale	hay	NA	HR	88	80	40	70	20	20	25	*	20	10	*	*	10	*
AF	Triticale	straw	NA	HR	90	10	40	20	10	10	15	*	*	10	*	*	10	*
AF	Triticale	silage	3-26-208	HR	35	30	*	*	25	*	*	*	*	*	*	*	*	*
AV0506	Turnip	tops (leaves)	2-05-063	HR	30	65	30	75	20	30	75	*	*	*	*	*	*	*
AF	Vetch	forage	2-05-112	HR	30	80	30	100	30	20	100	*	*	10	*	*	*	*
AF	Vetch	hay	1-05-122	HR	85	75	30	75	20	20	30	*	*	10	*	*	10	*
AF	Vetch	silage	3-26-357	HR	30	80	*	*	30	*	*	*	*	*	*	*	*	*
AF	Wheat	forage	2-08-078	HR	25	75	40	100	30	30	100	*	20	10	*	*	*	*
AS0654	Wheat	hay	1-05-172	HR	88	80	40	65	20	20	25	*	20	10	*	*	10	*

Appendix IX – Maximum proportion of agricultural commodities in animal feed

	CROP	Feedstuff	IFN Code	Residue Level	DM (%)	RAM/EWE			LAMB			SWINE, breeding			SWINE, finishing			
						US CAN	EU	AU	US CAN	EU	AU	US CAN	EU	AU	US CAN	EU	AU	JP
	Body weight (kg)					85	75	60	40	40	60	270	260	60	100	100	60	110
	Daily intake (DM in kg)					2	2.5	2.5	1.5	1.7	2.5	2	6	2.5	3.1	3	2.50	1.00
AS0654	Wheat	straw	1-05-175	HR	88	25	40	20	10	40	15	*	*	10	*	*	10	*
AF	Wheat	silage	3-05-186	HR	30	30	*	*	25	*	*	*	*	*	*	*	*	*
	Roots & Tubers																	
VR0577	Carrot	culls	2-01-146	HR	12	20	20	*	40	20	*	*	25	10	*	25	5	*
VR0463	Cassava/tapioca	roots	2-01-156	HR	37	*	20	*	*	20	*	*	40	*	*	40	*	*
VR0589	Potato	culls	4-03-787	HR	20	50	30	*	40	20	*	*	50	10	*	50	*	*
VR0497	Swede	roots	4-04-001	HR	10	*	30	80	*	30	80	*	40	5	*	40	*	*
VR506	Turnip	roots	4-05-067	HR	15	75	30	80	75	30	80	*	40	5	*	40	5	*
	Cereal Grains/Crops Seeds																	
GC0640	Barley	grain	4-00-549	HR	88	40	40	85	40	60	85	20	80	85	20	80	80	30
VD0071	Bean	seed	4-00-515	HR	88	20	20	85	20	20	85	*	20	20	*	20	20	*
GC0645	Corn, field	grain	4-20-698	HR	88	50	30	85	50	30	85	85	70	80	85	70	80	85
GC0656	Corn, pop	grain	4-02-964	HR	88	50	30	85	50	30	85	*	*	*	*	*	*	*
VG0527	Cowpea	seed	5-01-661	HR	88	*	20	75	*	20	75	10	10	10	10	20	10	*
VD0545	Lupin	seed	5-02-707	HR	88	*	10	100	*	10	100	*	15	25	*	20	25	*
GC0646	Millet	grain	4-03-120	HR	88	40	30	*	40	30	*	20	70	70	20	70	70	*
GC0647	Oat	grain	4-03-309	HR	89	*	40	90	*	60	90	*	70	80	*	70	80	*
VD0561	Pea	seed	5-03-600	HR	90	20	20	*	20	20	*	15	20	40	15	20	40	*
GC0649	Rice	grain	4-03-939	HR	88	20	*	*	20	*	*	20	*	60	20	*	65	*
GC0650	Rye	grain	4-04-047	HR	88	20	40	*	20	45	*	*	70	80	*	70	70	35
GC0651	Sorghum, grain	grain	4-04-383	HR	86	40	40	80	50	40	80	80	70	80	80	70	80	55
SO4724 VD4521	Soybean	seed	5-64-610	HR	89	25	10	40	15	20	40	15	10	10	15	20	10	*
GC0653	Triticale	grain	4-20-362	HR	89	20	30	85	20	40	85	*	60	80	*	60	80	*
AL1029	Vetch	seed	5-26-351	HR	89	*	*	*	*	*	*	*	*	10	*	*	10	*
GC0654	Wheat	grain	4-05-211	HR	89	20	40	80	20	60	80	*	70	80	*	70	80	35
	By-products																	
AM 0660	Almond	hulls	4-00-359	STMR	90	*	*	*	*	*	*	*	*	*	*	*	*	*
AB9226	Apple	pomace, wet	4-00-419	STMR	40	10	10	*	10	10	*	*	*	*	*	*	*	*
AB	Barley	bran fractions		STMR	90													
AB0596	Beet, sugar	dried pulp	4-29-307	STMR	88	15	40	*	20	40	*	*	20	*	*	20	*	*
AB	Beet, sugar	ensiled pulp	4-00-662	STMR	15	*	*	*	*	*	*	*	*	*	*	*	*	*
DM0596	Beet, sugar	molasses	4-30-289	STMR	75	15	5	*	10	5	*	*	5	*	*	5	*	*
AB	Brewer's grain	dried	5-00-516	STMR	92	70	30	*	40	10	*	*	10	10	*	10	10	*
AB	Canola	meal	5-08-136	STMR	88	15	*	35	15	*	35	15	20	20	15	20	20	*
AB001	Citrus	dried pulp	4-01-237	STMR	91	20	*	*	15	*	*	*	15	10	*	*	10	*

Appendix IX – Maximum proportion of agricultural commodities in animal feed

	CROP	Feedstuff	IFN Code	Residue Level	DM (%)	RAM/EWE			LAMB			SWINE, breeding			SWINE, finishing			
						US CAN	EU	AU	US CAN	EU	AU	US CAN	EU	AU	US CAN	EU	AU	JP
	Body weight (kg)					85	75	60	40	40	60	270	260	60	100	100	60	110
	Daily intake (DM in kg)					2	2.5	2.5	1.5	1.7	2.5	2	6	2.5	3.1	3	2.50	1.00
SM	Coconut	meal	5-01-572	STMR	91	*	20	35	*	20	35	*	*	10	*	*	10	*
AB	Corn, field	asp gr fn	4-02-880	STMR	85	*	*	*	*	*	*	*	*	*	*	*	*	*
AB	Corn, field	milled bypds	5-28-235	STMR	85	35	30	*	50	30	*	60	75	70	60	75	70	*
AB	Corn, field	hominy meal	4-03-010	STMR	88	50	*	*	50	*	*	20	*	40	20	*	40	*
AB	Corn, sweet	cannery waste	2-02-875	STMR	30	30	*	*	20	*	*	*	*	*	*	*	*	*
AB	Corn gluten	feed	5-28-243	STMR	40	35	30	80	50	30	80	20	20	20	20	20	20	10
AB	Corn gluten	meal	5-28-242	STMR	40	35	30	*	50	30	*	20	10	25	20	10	25	5
AB	Cotton	meal	5-01-617	STMR	89	15	15	45	10	10	45	15	10	10	15	5	10	*
AB	Cotton	undelinted seed	5-01-614	STMR	88	25	*	25	25	*	25	*	*	*	*	*	*	*
AB	Cotton	hulls	1-01-599	STMR	90	15	*	20	20	*	20	*	*	*	*	*	*	*
AB	Cotton	gin by-products	1-08-413	STMR	90	*	*	*	*	*	*	*	*	*	*	*	*	*
AB	Distiller's grain	dried	5-00-518	STMR	92	35	10	*	25	10	*	*	20	20	*	20	20	*
SO0693	Flaxseed/linseed	meal	5-02-043	STMR	88	15	20	*	20	10	*	10	20	10	10	20	10	*
AB0269	Grape	pomace, wet	2-02-206	STMR	15	*	*	*	*	*	*	*	*	10	*	*	10	*
AB	Lupin seed	meal	NA	STMR	85	*	25	*	*	20	*	*	10	25	*	10	25	*
VS0626	Palm	kernel meal	5-03-486	STMR	90	*	*	*	*	*	*	*	10	10	*	10	10	15
SO0697	Peanut	meal	5-03-649	STMR	85	20	20	*	15	20	*	15	20	10	15	20	10	*
AB	Pineapple	process waste	NA	STMR	25	*	*	*	*	*	*	*	*	*	*	*	*	*
AB	Potato	process waste	4-03-777	STMR	12	50	40	*	25	20	*	*	20	*	*	*	*	*
AB	Potato	dried pulp	4-03-775	STMR	88	*	40	*	*	20	*	*	10	*	*	20	*	*
AB	Rape	meal	5-26-093	STMR	88	15	15	*	15	15	*	*	10	15	*	20	15	20
AB	Rice	hulls	1-08-075	STMR	90	20	*	20	10	*	15	*	*	10	*	0	10	*
CM	Rice	bran/pollard	4-03-928	STMR	90	*	30	*	*	30	*	10	10	30	10	0	20	10
SN	Sesame seed	meal	NA	STMR	90													
SM	Safflower	meal	5-26-095	STMR	91	15	*	*	15	*	*	15	*	20	15	*	20	*
AB	Sorghum, grain	asp gr fn	NA	STMR	85	*	*	*	*	*	*	*	*	*	*	*	*	*
AB	Soybean	asp gr fn	NA	STMR	85	*	*	*	*	*	*	*	*	*	*	*	*	*
AB	Soybean	meal	5-20-638	STMR	92	25	25	35	15	25	35	15	30	30	15	30	30	*
AB	Soybean	hulls	1-04-560	STMR	90	50	*	20	20	*	20	*	*	10	*	*	10	*
AB	Soybean	okara	NA	STMR	20													

	CROP	Feedstuff	IFN Code	Residue Level	DM (%)	RAM/EWE			LAMB			SWINE, breeding			SWINE, finishing			
						US CAN	EU	AU	US CAN	EU	AU	US CAN	EU	AU	US CAN	EU	AU	JP
	Body weight (kg)					85	75	60	40	40	60	270	260	60	100	100	60	110
	Daily intake (DM in kg)					2	2.5	2.5	1.5	1.7	2.5	2	6	2.5	3.1	3	2.50	1.00
AB	Soybean	pollard	NA	STMR	?	*	*	*	*	*	*	*	*	*	*	*	*	*
AB	Sugarcane	molasses	4-13-251	STMR	75	10	5	10	10	5	10	*	*	*	*	*	*	*
AB	Sugarcane	bagasse	1-04-686	STMR	32	*	*	10	*	*	*	*	*	*	*	*	*	*
AB	Sunflower	meal	5-26-098	STMR	92	20	20	40	20	20	40	15	10	30	15	10	30	*
AB	Tomato	pomace, wet	NA	STMR	20													
AB	Wheat	asp gr fn	NA	STMR	85	*	*	*	*	*	*	*	*	*	*	*	*	*
AB	Wheat gluten	meal	5-05-221	STMR	40	10	30	*	10	30	*	10	10	25	10	10	25	*
AB	Wheat	milled bypds	4-06-749	STMR	88	40	40	*	50	50	*	50	50	40	50	50	40	15

Notes:

Percent DM. (Percent dry matter) for beef, dairy, and sheep feedstuffs, the percent moisture should be reported for representative samples of raw agricultural and processed commodities.

Classification of Feedstuff. **R:** roughage; **CC:** carbohydrate concentrate; **PC:** protein concentrate.

Residue Level. **HR:** Highest Residue (or HAFT); **STMR:** Supervised Trial Median Residue.

Percent DM. Percent dry matter. For beef, dairy, and sheep feedstuffs, the percent moisture should be reported for representative samples of raw agricultural and processed commodities.

* Indicates that item is not used or is a minor feedstuff (less than 5 percent of livestock diet).

Percent of Livestock Diet. Percentages of feedstuffs in livestock daily rations for mature and marketable animals are best estimates based upon production data of livestock meat, milk, and eggs for human consumption. Percent of diet is based on a dry weight basis for beef and dairy cattle, sheep, and on an as-fed basis for poultry and swine. The reference animals used for the table values are based on the listed body weights and daily dry matter intake. The following reference animals were used:

United States/Canada

Beef: Finishing, body weight of 500 kg, consuming 9.1 kg of daily dry matter feed. **Dairy:** mature cows, body weight of 600 kg, producing 23 kg of milk a day, consuming 18.2 kg of daily dry matter feed.

Ram/Ewe: breeding, body weight of 85 kg, consuming 2.0 kg of daily dry matter feed. *Fattened Lamb*, finishing, body weight of 40 kg, consuming 1.5 kg of daily dry matter feed.

Boar/Sow, breeding, body weight of 270 kg, consuming 2.0 kg of daily dry matter feed. *Finishing Hog*, body weight of 100 kg, consuming 3.1 kg of daily dry matter feed.

Broiler, body weight of 2.5 kg, consuming 0.16 kg of daily dry matter feed. *Layer*: body weight of 3.2 kg, consuming 0.12 kg of daily dry matter feed.

Turkey: body weight of 12 kg, consuming 0.5 kg of daily dry matter feed.

European Union

Beef: Finishing, body weight of 500 kg, consuming 10 kg of daily dry matter feed. *Dairy*: mature cows, body weight of 650 kg, producing 40 kg of milk a day, consuming 25 kg of daily dry matter feed.

Ram/Ewe: breeding, body weight of 75 kg, consuming 2.5 kg of daily dry matter feed. *Fattened Lamb*, finishing, body weight of 40 kg, consuming 1.7 kg of daily dry matter feed.

Boar/Sow, breeding, body weight of 260 kg, consuming 2.0 kg of daily dry matter feed. *Finishing Hog*, body weight of 100 kg, consuming 3 kg of daily dry matter feed.

Broiler, body weight of 1.7 kg, consuming 0.12 kg of daily dry matter feed. *Layer*: body weight of 1.9 kg, consuming 0.13 kg of daily dry matter feed.

Turkey: body weight of 20 kg, consuming 0.7 kg of daily dry matter feed.

Australia

Beef: Finishing, body weight of 400 kg, consuming 9.1 kg of daily dry matter feed. *Dairy*: mature cows, body weight of 600 kg, producing 23 kg of milk a day, consuming 18.2 kg of daily dry matter feed.

Ram/Ewe: breeding, body weight of 85 kg, consuming 2.0 kg of daily dry matter feed. *Fattened Lamb*, finishing, body weight of 40 kg, consuming 1.5 kg of daily dry matter feed.

Boar/Sow, breeding, body weight of 270 kg, consuming 2.0 kg of daily dry matter feed. *Finishing Hog*, body weight of 100 kg, consuming 3.1 kg of daily dry matter feed.

Broiler, body weight of 2.5 kg, consuming 0.16 kg of daily dry matter feed. *Layer*: body weight of 3.2 kg, consuming 0.12 kg of daily dry matter feed.

Turkey: body weight of 12 kg, consuming 0.5 kg of daily dry matter feed.

FORAGES

Alfalfa. Residue data are needed from a minimum of three cuttings, unless climatic conditions restrict the number of cuttings. Cut sample at late bud to early bloom stage (first cut), and/or at early (one-tenth) bloom stage (later cuts). **Alfalfa meal (17% protein).** Residue data are not needed for meal; however, the meal should be included in the livestock diet, using the hay MRL. **Alfalfa hay** should be field-dried to a moisture content of 10 to 20%. **Alfalfa silage.** Residue data on silage are optional, but are desirable for assessment of dietary exposure. Cut at late bud to one-tenth bloom stage for alfalfa, allow to wilt to approximately 60% moisture, then chop fine, pack tight, and allow to ferment for three weeks maximum in an air-tight environment until it reaches pH 4. This applies to both silage and haylage. In the absence of silage data, residues in forage will be used for silage, with correction for dry matter.

Barley hay. Cut when the grain is in the milk to soft dough stage. Hay should be field-dried to a moisture content of 10 to 20%.

Barley straw. Plant residue (dried stalks or stems with leaves) left after the grain has been harvested (threshed).

Barley silage. Residue data on silage are optional, but are desirable for assessment of dietary exposure. Cut sample at boot to early head stage, allow to wilt to 55 to 65% moisture, then chop fine, pack tight, and allow to ferment for three weeks maximum in an air-tight environment until it reaches pH 4. In the absence of silage data, residues in forage will be used for silage, with correction for dry matter.

Beet, sugar, tops. Based on current US agricultural practices, tops are fed only to grazing beef cattle and sheep. Other countries may feed differently.

Cabbage. Heads, fresh.

Clover forage. Cut sample at the 10-20 cm (4-8 inch) to pre-bloom stage, at approximately 30% DM.

Clover hay. Cut at early to full bloom stage. Hay should be field-dried to a moisture content of 10 to 20%. Residue data for clover seeds are not needed.

Clover silage. Residue data on silage are optional, but are desirable for assessment of dietary exposure. Cut sample at early to one-fourth bloom stage for clover, allow to wilt to approximately 60% moisture, then chop fine, pack tight, and allow to ferment for three weeks maximum in an air-tight environment until it reaches pH 4. This applies to both silage and haylage. In the absence of silage data, residues in forage will be used for silage, with correction for dry matter. IFN codes are given for most commonly used red clover.

Corn forage (field and pop). Cut sample (whole aerial portion of the plant) at late dough/early dent stage (black ring/layer stage for corn only).

Corn stover (field and pop). Mature dried stalks from which the grain or whole ear (cob + grain) have been removed; contains 80 to 85% DM.

Corn silage (field and pop). Freshly cut samples may be analysed or ensiled samples after ensiling for three weeks maximum, and reaching pH 5 or less, with correction for percent dry matter.

Corn forage (sweet). Samples should be taken when sweet corn is normally harvested for fresh market, and may or may not include the ears. Freshly cut samples may be analysed or ensiled samples after ensiling for three weeks maximum, and reaching pH 5 or less, with correction for percent dry matter.

Cowpea forage. Cut sample at 15 cm (6 inch) to pre-bloom stage, at approximately 30% DM.

Cowpea hay. Cut when pods are one-half to fully mature. Hay should be field-dried to a moisture content of 10 to 20%.

Crownvetch forage. Cut sample at 15 cm (6 inch) to pre-bloom stage, at approximately 30% DM.

Crownvetch hay. Cut at full bloom stage. Hay should be field-dried to a moisture content of 10 to 20 percent.

Grass. Zero day crop field residue data for grasses cut for forage should be provided unless it is not feasible, e.g., pre-plant/pre-emergent pesticide uses. A reasonable interval before cutting for hay is allowed. Grasses include barnyard grass, bent grass, Bermuda grass, Kentucky bluegrass, big bluestem, smooth brome grass, buffalo grass, reed canary grass, crabgrass, cup grass, dallies grass, sand dropseed, meadow foxtail, eastern grama grass, side-oats grama, guinea grass, Indian grass, Johnson grass, love grass, napier grass, oat grass, orchard grass, pangola grass, redtop, Italian ryegrass, sprangletop, squirreltail grass, stargrass, switch grass, timothy, crested wheatgrass, and wild ryegrass. Also included are Sudan grass and sorghum forages and their hybrids.

Grass forage. Cut sample at 15-20 cm (6-8 inch) to boot stage, at approximately 25% DM.

Grass hay. Cut in boot to early head stage. Hay should be field-dried to a moisture content of 10 to 20%. Included are Sudan grass and sorghum forages and their hybrids. For grass grown for seed only, PGIs (pre-grazing interval) and PHIs (pre-harvest interval) are acceptable. Residue data may be harvesting the seed.

Grass silage. Residue data on silage are optional, but are desirable for assessment of dietary exposure. Cut sample at boot to early head stage, allow to wilt to 55 to 65% moisture, then chop fine, pack tight, and allow to ferment for three weeks maximum in an air-tight environment until it reaches pH 4. In the absence of silage data, residues in forage will be used for silage, with correction for dry matter. For the three grass feed types in Japan, the listed values are the highest of percentages of Italian rye grass, orchard grass and timothy in diet for beef cattle and dairy cattle..

Kale Leaves, fresh

Lespedeza forage. Cut sample at 10-15 cm (4-6 inch) to pre-bloom stage, at 20 to 25% DM.

Lespedeza hay. Annual/Korean. Cut at early blossom to full bloom stage. Sericea. Cut when 30-37.5 cm (12-15 inches) tall. Hay should be field-dried to a moisture content of 10 to 20%.

Millet forage. Cut sample at 10 inch to early boot stage, at approximately 30% DM.

Millet hay. Cut at early boot stage or approximately 1 m (40 inches) tall, whichever is reached first. Hay should be field-dried to a moisture content of 10 to 20%. Millet includes pearl millet.

Millet straw. Data are required for proso millet only:

Proso millet straw. Plant residue (dried stalks or stems with leaves) left after the grain has been harvested.

Oats forage. Cut sample between tillering to stem elongation (jointing) stage.

Oats hay. Cut sample from early lower to soft dough stage. Hay should be field-dried to a moisture content of 10 to 20%.

Oats straw. Cut plant residue (dried stalks or stems with leaves) left after the grain has been harvested (threshed).

Pea, field. Does not include the canning field pea cultivars used for human food. It includes cultivars grown for livestock feeding only such as 'Austrian winter pea'.

Field pea vines. Cut sample anytime after pods begin to form, at approximately 25% DM.

Field pea hay. Succulent plant cut from full bloom thru pod formation. Hay should be field-dried to a moisture content of 10 to 20%.

Pea, field, silage. Use field pea vine residue data for field pea silage, with correction for dry matter.

Peanut hay. Peanut hay consists of the dried vines and leaves left after the mechanical harvesting of peanuts from vines that have been sun-dried to a moisture content of 10 to 20%.

Rice straw. Stubble (basal portion of the stems) left standing after harvesting the grain. In Japan, the maximum fed to cattle destined for human consumption is limited to 20% on a wet weight basis by a regulation, and the maximum fed to lactating cows is limited to 20% on a wet basis by a regulation.

Rye forage. Cut sample at 15-20 cm (6-8 inch) stage to stem elongation (jointing) stage, at approximately 30% DM.

Rye straw. Cut plant residue (dried stalks or stems with leaves) left after the grain has been harvested (threshed).

Sorghum forage. Cut sample (whole aerial portion of the plant) at soft dough to hard dough stage. Forage samples should be analysed as is, or may be analysed after ensiling for three weeks maximum, and reaching pH 5 or less, with correction for dry matter.

Sorghum stover. Mature dried stalks from which the grain have been removed; contains approximately 85% DM.

Soybean forage. Cut samples at 15-20 cm (6-8 inches) tall (sixth node) to beginning pod formation, at approximately 35% DM.

Soybean hay. Cut samples at mid-to-full bloom and before bottom leaves begin to fall or when pods are approximately 50% developed. Hay should be field-dried to a moisture content of 10 to 20%.

Soybean silage. Residue data on silage are optional. Harvest sample when pods are one-half to fully mature (full pod stage). In the absence of silage data, residues in forage will be used for silage, with correction for dry matter.

Trefoil forage. Cut sample at 12.5-25 cm (5-10 inch) or early bloom stage, at approximately 30% DM.

Trefoil hay. Cut at first flower to full bloom. Hay should be field-dried to a moisture content of 10 to 20%.

Triticale. See wheat.

Vetch forage. Cut sample at 15 cm (6 inch) to pre-bloom stage, at approximately 30% DM.

Vetch hay. Cut at early bloom stage to when seeds in the lower half of the plant are approximately 50% developed. Hay should be field-dried to a moisture content of 10 to 20%. Vetch does not include crown vetch.

Wheat. Includes emmer wheat and triticale. No processing study is needed for a specific MRL on emmer wheat.

Wheat forage. Cut sample at 15-20 cm (6-8 inch) stage to stem elongation (jointing) stage, at approximately 25% DM.

Wheat hay. Cut samples at early flower (boot) to soft dough stage. Hay should be field-dried to a moisture content of 10 to 20%.

Wheat straw. Cut plant residue (dried stalks or stems with leaves) left after the grain has been harvested (threshed).

ROOTS & TUBERS

Carrot culls. Residue data for the raw agricultural commodity will cover residues on culls.

Cassava/tapioca roots. The whole root chipped mechanically into small pieces, then dried, and the dried chips pelted.

Potato culls. Whole unpeeled potato not suited for fresh market or processing.

CEREAL GRAINS/CROP SEEDS

Barley or oat grain. Residue data are needed for kernel (caryopsis) with hull (lemma and palea).

Bean, cowpea, lupin, pea, soybean, vetch seed. Residue data are needed for mature, dried seed.

Corn grain (field and pop). Residue data are needed for mature kernel (caryopsis) with cob removed.

Millet grain. Residue data are needed for kernel plus hull (lemma and palea).

Pearl millet grain. Residue data are needed for kernel with hull (lemma and palea) removed

Rice grain. Residue data are needed for kernel (caryopsis) either with hull or without hull. Registrant should contact appropriate regulatory agency for their specific data needs for rice grain.

Rye, triticale, sorghum (grain), or wheat grain. Residue data are needed for kernel (caryopsis) with hull (lemma and palea) removed.

BY-PRODUCTS

General. In the US, no more than one by-product (almond hulls, apple pomace, aspirated grain fractions, carrot culls, citrus pulp, sweet corn cannery waste, cotton gin byproducts, pineapple process waste, potato culls and potato processing waste) would be included in a diet.

Almond hulls. Dried pericarp which surrounds the nut.

Apple pomace, wet. By-product of the apple processing industry which remains after cider has been expressed from small whole apples, and the stems, cores, and peelings remaining after preparation of apple juice and sauce for human consumption.

Aspirated grain fractions ("grain dust"). Dust collected at grain elevators during the moving/handling of grains/oilseeds for environmental and safety reasons.

Residue data should be provided for any postharvest use on corn, sorghum, soybeans or wheat. For a pre-harvest use after the reproduction stage begins and seed heads are formed, data are needed unless residues in the grain are less than the limit of quantification of the analytical method. For a pre-harvest use during the vegetative stage (before the reproduction stage begins), data will not normally be needed unless the plant metabolism or processing study shows a concentration of residues of regulatory concern in an outer seed coat, e.g., wheat bran, soya bean hulls. If a MRL is needed, then it should be set at the higher of the residues found in the aspirated grain fraction of corn, sorghum, soybean, or wheat.

Beet, sugar, dried pulp. Dried material remaining from sugar beets which have been cleaned and freed from crowns, leaves, and sand and to which has been extracted in the process of manufacturing sugar. Moisture content should be defined.

Beet, sugar, molasses. The by-product of the manufacture of sucrose from sugar beets, and contains not less than 48% total sugars expresses as invert and its density determined by double dilution must not be less than 79.5 Brix.

Brewer's grains. Dried extracted residue of barley malt alone or in a mixture with other cereal grain or cereal products resulting from the manufacture of wort or beer and may contain pulverized dried spent hops in an amount not to exceed 3%, evenly distributed. Moisture content should be defined.

Canola meal. Meal obtained after the removal of most of the oil by direct solvent or prepress solvent extraction process.

Citrus, dried pulp. It is the ground peel, residue of the inside portions, and occasional fruits of the citrus family which have been dried, producing a coarse, flaky product. It may contain dried citrus meal or pellets and whole citrus seeds.

Coconut meal. It is the ground residue which remains after removal of most of the oil from dried meat of coconut by a mechanical or solvent extraction process.

Corn (field) milled byproducts. (Dry milled: grits, meal, flour and refined oil). If a MRL is needed for dry-milled processed commodities, then it should be set at the highest concentration for grits, meal, and flour.

Corn (field). Hominy meal. A mixture of corn bran, germ, and part of starchy portion of corn kernels as produced in making of pearl hominy, hominy grits, or table meal (< 4% fat).

Corn gluten feed. Part of the commercial shelled corn that remains after the extraction of the larger portion of the starch, gluten, and germ by the processes employed in wet milling of field corn.

Corn gluten meal. It is the dried residue from corn after the removal of the larger portion of the starch and germ, and the separation of the bran by the process employed in wet milling of field corn.

Corn, sweet. Residue data on early sampled field corn should suffice to provide residue data on sweet corn, provided the residue data are generated at the milk stage on kernel plus cob with husk removed and there are adequate numbers of trials and geographical representation from the sweet corn growing regions.

Corn (sweet) cannery waste. It includes husks, leaves, cobs, and kernels. Residue data for forage will be used for sweet corn cannery waste.

Cotton meal. Material obtained by finely grinding the cake which remains after removal of most of the oil from the cottonseed either by a mechanical or solvent extraction process.

Cotton undelinted seed. Whole seed removed in the ginning process and still has fine cotton fibres attached.

Cotton hulls. It consists primarily of the outer covering of the harvested cottonseed.

Cotton gin byproducts (commonly called gin trash). Include the plant residues from ginning cotton, and consist of burrs, leaves, stems, lint, immature seeds, and sand and/or dirt. Cotton must be harvested by commercial equipment to provide an adequate representation of plant residue for the ginning process. Two field trials for harvesting of stripper cotton are needed. No data are needed for picker cotton.

Distiller's grains. The material obtained after distillation of ethyl alcohol from grain or grain mixture which has undergone yeast fermentation. Moisture content should be defined.

Flaxseed/linseed meal. The ground residue which remains after removal of most of the oil from the whole flaxseed by a mechanical or solvent extraction process.

Grape pomace, wet. Wet debris left behind after fruit have been pressed for juice, also called "marc". Moisture content should be defined.

Lupin seed meal The ground residue which remains after removal of most of the oil from the whole lupin seed by a mechanical or solvent extraction process.

Palm kernel meal. It is the ground residue which remains after removal of most of the oil from the whole palm kernel by a mechanical or solvent extraction process.

Peanut meal, It is the ground residue which remains after removal of most of the oil from the shelled nut by a mechanical or solvent extraction process.

Pineapple process residue (also known as wet bran). A wet waste by-product from the fresh-cut product line that includes pineapple tops (minus crown), bottoms, peels, any trimmings with peel cut up, and the pulp (left after squeezing for juice); it can include culls.

Potato dried pulp. Dried processed potato waste. See processed potato waste.

Processed potato waste. (including wet and dry peel, raw chip, French fries, and cooked potatoes). MRLs for wet peel should be used for dietary burden calculations. Residue data may be provided from actual processed potato waste generated using a pilot or commercial scale process that gives the highest percentage of wet peel in the waste.

Rapeseed meal. Residue data are not needed for rapeseed oil since it is produced for industrial uses and is not an edible oil. The edible oil is only produced from canola. (See canola).

Rice hulls. Consist primarily of the outer covering of the rice grain (with bran).

Safflower meal. It is the ground residue which remains after removal of most of the oil from the whole safflower seed by a mechanical or solvent extraction process.

Soya bean okara. Okara or soy pulp is a white or yellowish pulp consisting of insoluble parts of the soybean which remain in the filter sack when pureed soybeans are filtered in the production of soy milk. As a significant byproduct of soy milk and tofu manufacturing, okara is used as animal feed.

Soya bean meal. Material obtained by grinding the cake or chips which remain after the removal of most of the oil by solvent extraction process.

Sugarcane molasses. Residue data are needed for blackstrap molasses.

Sugarcane bagasse. US data indicates that sugarcane bagasse is mainly used for fuel. Other countries may use differently.

Sunflower meal. The ground residue which remains after removal of most of the oil from the whole sunflower seed by a mechanical or solvent extraction process.

Tomato pomace, wet. By-product of tomato paste production consisting mainly of skins and seeds.

Wheat milled byproducts. If a MRL is needed, then it should be set at the highest value for wheat middlings, bran and shorts.

Appendix X

JMPR MANUAL FOR FAO PANEL MEMBERS

CONTENTS

Introduction
General
Format
JMPR reports
Duties of the FAO panel chairman and rapporteur
Actions before the meeting
A residue evaluation (draft monograph)
Draft appraisal

1. INTRODUCTION

The purpose of this manual is to assist members of the FAO Panel to prepare draft documents for the Meeting in a consistent format. It may also be useful to people preparing submissions for review by the FAO Panel. The manual is not intended to deal with the evaluation process or to provide guidance on the estimation of maximum residue levels. Documents prepared in the correct format assist JMPR members to digest information quickly, and after the Meeting make it easier for the editor to produce final copy for publication.

2. GENERAL

Produce documents on a word-processor using Word version Office 2003 or later.

Introduce continuous line numbering into all documents for discussion. Line numbers assist readers to find parts of the document to be discussed.

Spell-check documents, if possible, with English (UK).

Use metric units and convert non-metric units to metric.

Fahrenheit °F	°C= (°F-32)×5/9
feet ²	0.0929 m ²
1 lb =	0.4536 kg
1 gal (US) =	3.7854 litres
1 fl oz =	0.02957 litres
1 acre (A) =	0.404687 ha
fl oz/A	0.073069 L/ha
g/acre	2.470058 g/ha
100 sq ft =	9.290 sq m
1 lb/100 gal (US) =	0.1198 kg/hL
1 gpa =	9.353 L/ha (gpa is gallon per acre)
1 lb/acre =	1.1208 kg/ha
1 oz/1000 cu ft =	1.0012 g/m ³ (space fumigation)
1 quarts, US Liquid	0.946325 litre

Convert lb ai/acre to kg ai/ha, formulation concentration % to g/kg or g/L, residue concentration ppm to mg/kg, but express feed concentrations of active ingredients in feeding

trials as ppm. This convention is used to avoid confusion between mg/kg feed and mg/kg body weight.

3. FORMAT

Use Times New Roman font size 11 for text and at least size 9 for tables.

Left and right margins should be 1 inch (25 mm) and top and bottom margins 0.5 inch (12.5 mm). Lines should be fully justified, with widow/orphan protection.

Tabs for general text should be set at half-inch (12.5 mm) intervals.

Paragraphs immediately following a heading should be left aligned. The first line of subsequent paragraphs should be indented half-inch (12.5 mm).

A page header should be introduced on the top left of each page of the draft document to show the title of the document, for example: PHORATE Evaluation, or PHORATE Appraisal, or RESIDUES IN FEEDS Report.

Position page numbers at “Top of page (header)”, and centred and use Times New Roman font size 12.

3.1 Tables

This section contains guidelines for creating tables. Examples of particular table layouts, e.g., residue data tables, are provided under the relevant headings in the section “A residue evaluation (draft monograph).”

Insert tables in their intended positions in the text or thereabouts, not at the end of the monograph.

Use the Table function in Word. Generally, separate items of information should be recorded in separate cells of tables. For example, the Codex Commodity Number and the Codex commodity description should be in separate cells of the row. In particular, ensure that separate lines of tables are in separate rows of cells.

Generally avoid the use of symbols and indicate endnotes to a table (at the end of the table rather than at the bottom of the page) by superscript letters.

Do not join cells vertically (as distinct from deleting lines separating them). This causes the same problems as cells that are several lines deep.

Use the portrait (vertical) rather than the landscape (horizontal) layout for tables as far as possible. Use the same page margins as stated above. Wide tables can be accommodated vertically by using font size 9.

Use the “Headings” function for multi-page tables to ensure that the table header appears at the top of each page. Do not include the table caption as a header within the table itself as the caption will appear on subsequent pages and thus make it difficult for the reader to find the beginning of a long table.

Do not construct a table covering several pages as a series of separate single-page tables. This usually produces a number of partly filled pages.

Avoid abbreviations if they make the table difficult to understand. If an abbreviation is unlikely to be familiar to readers and is not in the list of abbreviations at the beginning of the reports and evaluations, explain its meaning in a table endnote.

Common specialized abbreviations which do not need explanation are:

ARfD	acute reference dose
ADI	acceptable daily intake
CAC	Codex Alimentarius Commission
CAS	Chemical Abstracts Service
CCPR	Codex Committee on Pesticide Residues
CXL	Codex MRL
ECD	Electron capture detector
EMRL	extraneous maximum residue limit
FPD	Flame photometric detector
g ai/m	grams active ingredient per metre
g ai/m ³	grams active ingredient per cubic metre
g ai/t	grams active ingredient per tonne
GAP	good agricultural practice(s)
GC-MS(MS)	Gas chromatograph coupled with mass detector
HR	highest residue in the edible portion of the commodity found in the trials used to estimate a maximum residue level in the commodity
HR-P	residue in a processed commodity calculated by multiplying the HR of the raw agricultural commodity by the corresponding processing factor
IEDI	international estimated daily intake
IESTI	international estimate of short term intake
kg ai/ha	kilograms active ingredient per hectare
kg ai/hL	kilograms active ingredient per hectolitre
LC-MS/MS	Liquid chromatograph with mass detector
LOQ	limit of quantification (limit of quantification)
LP	large portion consumed (kg food/day) for IESTI calculations
mg/kg	milligrams per kilogram
MRL	Maximum Residue Limit
NTID	Nitrogen-phosphor selective detector
PHI	pre-harvest interval
RAC	raw agricultural commodity
STMTR	supervised trials median residue
STMTR-P	supervised trials median residue, processed commodity
TMDI	theoretical maximum daily intake

Note that the above abbreviations, and those of names of countries and organizations, are printed without stops (thus UK, USA, FAO, CCPR) but general abbreviations in common use have stops (c., e.g., etc., i.e., viz.). Consult the list at the beginning of recent JMPR Reports and Residue Evaluations for the correct form of abbreviations. Note the form of *et al.* (italics, with full stop after ‘al’).

Use Codex commodity descriptions⁷⁴ if possible and deal with commodities in the order of the “Types” in the Codex Classification of Foods and Feeds, i.e., Fruits, Vegetables,..., and then in the order of the groups within the types, e.g., Citrus fruits, Pome fruits, Stone fruits, etc.

Express residue concentrations as mg/kg and include references or study numbers in residue tables as it is important to identify the source of any reported data.

3.2 Diagrams

Use either electronic copies provided by manufacturers or draw diagrams using a commercial chemical structure drawing program, as shown below.

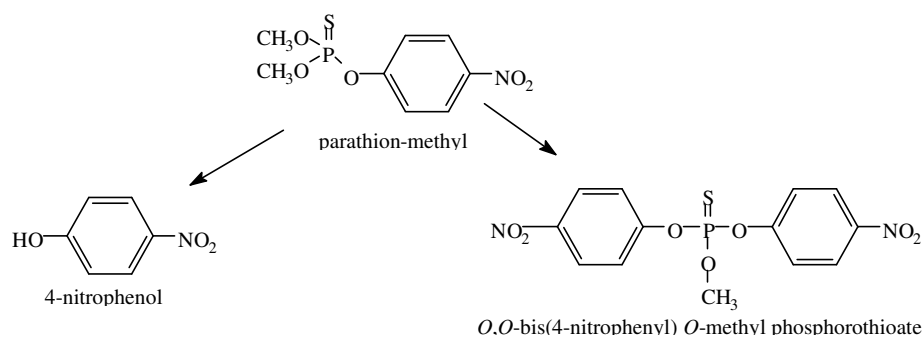


Figure X.1. Aerobic metabolism of parathion-methyl. (Evaluations 2000, Part 1 – Residues, p. 580).

4. JMPR REPORTS

Published JMPR Reports normally consist of 6 or 7 chapters and a number of annexes.

Some chapters and annexes are essentially compiled by the editor. The chapters and annexes of special interest to Panel members preparing for a Joint Meeting are the following.

Chapter 2. General considerations. Reports on any issue not specifically related to a compound are prepared for Chapter 2.

Chapter 3. Response to specific concerns raised by CCPR

Chapter 4. Dietary risk assessment for pesticide residues in food. The summarized results of the dietary risk assessments are reported in Chapter 4.

Chapter 5. Reports on individual compounds. The editor will convert Appraisal documents into reports for Chapter 4. Panel members, when writing Appraisals, should be aware that essentially the same words will appear as the JMPR report on the compound, which means that Appraisals should be complete in themselves and should not refer to specific Tables or Figures in the Evaluation.

⁷⁴ FAO/WHO. 1993. Codex Classification of Foods and Animal Feeds in Codex Alimentarius, 2nd ed., Volume 2. Pesticide Residues, Section 2. Joint FAO/WHO Food Standard Programme. FAO, Rome.

Annex 1. Detailed table of all MRL, STMR, HR, ADI, ARfD and residue definition recommendations from the meeting. Annex 1 is compiled from the recommendation tables of each compound.

Annex 3. Spreadsheet calculations of long-term intakes and comparison with ADIs.

Annex 4. International estimated short term intakes of pesticide residues

Annex 6. Livestock dietary burden

5. DUTIES OF THE FAO PANEL CHAIRPERSON AND RAPPORTEUR

The Chairperson maintains liaison with the WHO Group Chairperson on the progress of the Meeting, and together they arrange the schedule for joint sessions. The FAO Panel Chairperson serves as either Chairperson or Vice-Chairperson of the Joint Meeting.

The Chairperson ensures that all items are given reasonable discussion and tries to bring the Meeting to an agreement. Reasonable progress must be made, and the intention is to distribute advanced drafts of general report items to the WHO Group by the fourth last day of the Joint Meeting and final drafts of most report items by the third last day of the Joint Meeting.

The system has evolved where individual Panel members act as rapporteurs for discussion on any documents they have prepared. With the volume of work to be dealt with it would not be practical to channel all the work through one person.

The FAO Panel Rapporteur keeps in touch with the WHO Group Rapporteur, ensures that documents are exchanged, and keeps records of the exchanges.

The FAO Panel Rapporteur acts as the channel for copying, and ensures that documents are not delayed.

6. ACTIONS BEFORE THE MEETING

The FAO Joint Secretary to the JMPR will assign a “peer reviewer” for each compound on the FAO Panel agenda. The primary reviewer should send an essentially complete evaluation, an appraisal and dietary intake spreadsheets (electronic copies), to the peer reviewer approximately 4–6 weeks prior to the meeting. The peer reviewer should read the papers and send comments to the primary reviewer so that final drafts can be prepared for the meeting. In the last two or three weeks before the meeting, Panel members are usually very busy with final preparations and will not have time to devote full attention to the review of lengthy documents. For the pre-meeting peer review process to work properly documents must be distributed in adequate time.

Panel members should send an electronic copy of the table of recommendations for each compound to reach the FAO Joint Secretary two weeks before the commencement of the meeting. The purpose is to allow the FAO Joint Secretary or the editor to prepare much of Annex 1 before the meeting.

Panel members should send an electronic copy of the table of recommendations and of the section on processing studies and residues in the edible portion of food commodities for each compound to reach the WHO Joint Secretary two weeks before the commencement of the meeting. The purpose is to inform GEMS/Food about potential dietary intake situations for the compounds being evaluated.

Panel members should send final drafts of their papers to the FAO Joint Secretary in time for copies to be prepared for the meeting.

Authors should prepare a brief list of questions on each compound and points for discussion by Panel members. The list should be available on the first day of the Panel meeting and should aim to focus attention on any difficult questions that have arisen during the review.

7. A RESIDUE EVALUATION (DRAFT MONOGRAPH)

Prepare a draft evaluation for the Meeting using the following format. The use of uppercase, alignment of headings, bold and underlining should follow this format. In the top right-hand corner of the first page state the year, the draft number and the author's family name. A reference number will be assigned to the compound at the Meeting, e.g., FAO/2001/ref no. EV1 is added to the file name to show that it is draft 1 of the evaluation. The layout is shown below.

FAO/2001/
AUTHOR
COMPOUND_EV1.doc
DRAFT 1

COMPOUND (Codex number)

EXPLANATION

IDENTITY

METABOLISM AND ENVIRONMENTAL FATE

Animal metabolism

Plant metabolism

Environmental fate in soil

Environmental fate in water-sediment systems, if relevant

RESIDUE ANALYSIS

Analytical methods

Stability of pesticide residues in stored analytical samples

USE PATTERN

RESIDUES RESULTING FROM SUPERVISED TRIALS ON CROPS

FATE OF RESIDUES IN STORAGE AND PROCESSING

In storage

In processing

Residues in the edible portion of food commodities

RESIDUES IN ANIMAL COMMODITIES

Direct animal treatments

Farm animal feeding studies

RESIDUES IN FOOD IN COMMERCE OR AT CONSUMPTION

NATIONAL RESIDUE DEFINITIONS

REFERENCES

EXPLANATION

Provide a very brief history of the compound in the introductory sentence.

Parathion-methyl was first evaluated in 1965 and has been reviewed several times since, most recently in 1991, 1992, 1994 and 1995.

If a question was raised at the CCPR refer to the Session number and year.

At the 30th (1998) Session of the CCPR it was suggested (ALINORM 99/24, Appendix VII)...

If the compound is being reviewed in the CCPR periodic review programme, state this in the first paragraph.

Parathion-methyl was listed by the 1998 CCPR (30th Session, ALINORM 99/24, Appendix VII) for Periodic Re-evaluation for residues by the 2000 JMPR.

Mention briefly previous JMPR requests for further information if relevant to the topic. Summarize the information available to the Meeting. State that information was supplied by (list of countries) and the (basic) manufacturers. Do not include company names.

For new and periodic review compounds, state explicitly whether information was or was not provided on critical supporting studies (metabolism, farm animal feeding, processing, analytical methods, freezer storage stability).

For periodic review compounds, begin with the EXPLANATION section followed by the IDENTITY section. Omit the EXPLANATION section for new compounds.

IDENTITY

ISO common name:

Chemical name

IUPAC: [Indented 12.5 mm]

CAS:

CAS Registry No:

CIPAC No:

Synonyms and trade names:

Structural formula:

Molecular formula:

Molecular weight:

Physical and chemical properties

Pure active ingredient [Underlined, sentence case, left aligned]

Appearance:

Vapour pressure:

Melting point:

Octanol/water partition coefficient:

Solubility:

Specific gravity:

Hydrolysis:

Photolysis:

Dissociation constant:

Technical material [Underlined, sentence case, left aligned]

Appearance:

Density:

Purity:

Melting range:

Thermal Stability:

Stability:

Formulations

METABOLISM AND ENVIRONMENTAL FATE

Animal metabolism

For new and periodic review compounds animal metabolism studies should be available to both the FAO Panel and the WHO Group. Metabolism in laboratory animals, normally rats,

should be reviewed from the FAO Panel perspective. It should provide information which helps in the interpretation of farm animal metabolism and feeding studies. This information includes rates and pathways of excretion, identity and relative abundance of metabolites, and possible target organs for residues. Animal metabolism studies are sometimes supplied to the WHO Group only; the FAO Panel reviewer should specifically request these studies for a new compound or a periodic review compound if they have not been provided.

Introduce the section with a statement of the type of metabolism data received.

The Meeting received information on the fate of orally dosed spinosyns in lactating goats and laying hens and dermally applied spinosyns in lactating goats.

Each study can then be introduced with a paragraph which acts as a checklist of the information to be recorded.

Tissue, egg and excreta residues were measured in laying hens (groups of 5, each bird weighing 1.0–1.4 kg) dosed orally for 7 days by capsule with radiolabelled mancozeb ($[^{14}\text{C}]$ ethylenediamine) equivalent to 3, 14 or 36 ppm mancozeb in the feed (study reference). The feed intake was 88–96 g/bird/day. Eggs and excreta were collected throughout, and birds were slaughtered 24 hours after the final dose for tissue collection.

Examine the animal metabolism in terms of the requirements for farm animal feeding studies (see Chapter 3 section, “Information and data from farm animal feeding and external animal treatment studies”). Draw conclusions from the animal metabolism which will assist interpretation of the farm animal feeding studies. Make statements about bioaccumulation and possible target tissues for residues.

Include studies on bioaccumulation in fish in this section.

Include an animal metabolism diagram at the end of the section.

Plant metabolism

Introduce the section with a statement of the type of metabolism data received.

The Meeting received information on the fate of spinosyns after foliar application to apples, cabbage, tomatoes, turnips, grapes and cotton.

Again, the studies can then be introduced with a paragraph which acts as a checklist of the information to be recorded.

A tomato crop was treated with radiolabelled mancozeb ($[^{14}\text{C}]$ ethylenediamine) at 2.7 kg ai/ha, on nine occasions at approximately weekly intervals, and ripe tomatoes were harvested 5 days after the final treatment (study reference).

Draw conclusions from the plant metabolism studies which assist interpretation of the residue trials. State whether the residues are on the surface or within the plant tissues. Describe the mobility of the residues within the crop and say whether transfer from foliage to fruit, root or other edible portion is likely. Draw attention to any plant metabolite which is not also an animal metabolite.

Include a plant metabolism diagram at the end of the section.

Environmental fate in soil. Environmental fate in water-sediment systems

Follow the same format as described for the animal and plant metabolism sections, i.e., provide an introductory statement and then a paragraph describing the studies on each mode of environmental fate.

Include studies on residues in rotational crops in this section.

RESIDUE ANALYSIS

Analytical methods

The introductory sentence or paragraph should state the range of analytical methods received for evaluation and should mention the analytes (parent and degradation products) and the substrates tested.

Each analytical method should be briefly described in one or two paragraphs or in a summary table format. Include the extraction, cleanup and final method of determination, e.g., GLC-FPD. Draw attention to critical or difficult steps in the analysis and difficult substrates. Report the method validation analytical recoveries in terms of substrates tested, spiking levels, number of tests and range of recoveries. State the LOQ.

Include the results of testing the compound through standard enforcement and multiresidue analytical methods whether the compound is successfully analysed by the method or not.

Stability of pesticide residues in stored analytical samples

The introductory sentence should summarize the information provided to the JMPR.

The Meeting received data on the stability of residues in snap beans, kidney beans, cotton seed, strawberry, plum, apple, sunflower seed, almond kernel, spinach, green peppers, orange, clover, canola seed, canola crude oil, canola meal, canola processing waste, sorghum flour, maize and processed maize commodities stored frozen.

USE PATTERN

Introduce the section with a statement of the compound uses.

Parathion-methyl is registered in many countries for control of insect pests on fruit, vegetables, cereals, oilseeds and forage crops. The information available to the Meeting on registered uses is summarized in Table

Comparison of Good Agricultural Practice (GAP) with conditions in the supervised trials is a necessary part of the evaluation process and therefore the table of GAP should be prepared in such a way to allow easy comparison. An excerpt of the GAP table from the parathion-methyl evaluation (Evaluations 2000, Part 1–Residues, p. 617) is provided below for reference.

The first column in the table should list the crops, and all uses on each crop should be brought together. This facilitates evaluation of the residue data. Other columns in the table should list countries (in alphabetical order), the formulation type, application (method, rate, spray concentration, number) and PHI. Note that this is the general case and there is often a need for further information such as details of the use pattern, e.g., furrow treatment or seed treatment, crop growth stage, grazing withdrawal, etc.

Avoid trade names in the table; give the composition and formulation type, e.g., 100 g/kg WP, 200 g/L EC. Use CIPAC abbreviations for formulation types (see Appendix III).

Indicate where official labels have been provided. GAP summaries provided to JMPR have often included details that are not on labels, e.g., only one of application rate and spray concentration may be stated on the label but both have been included in GAP summaries provided to JMPR. The maximum number of applications is often not on the label. US labels may state the maximum amount of pesticide permitted in a season, which should be included in the table (preferably as a footnote) as maximum amount rather than calculated from the

application rate and maximum number of applications. Any information that is not on a label should be indicated by a table endnote if it is included in the table.

Indicate by an endnote to the table uses that are not yet official but are still proposed uses.

Table X.1. Registered parathion-methyl uses

Crop	Country	Form	Application Method	Rate, kg ai/ha	Spray conc. kg ai/hL	Number	PHI days
Agric and horti crops	Netherlands	EC	soil treatment	2.6		1	
Alfalfa	Hungary	CS 450 g/L	foliar	0.45			14
Alfalfa	Hungary	EC 480 g/L	foliar	0.24-0.34			14
Alfalfa	USA	EC 480 g/L	foliar	0.28-1.1			15
Apple	Australia	ME 240	foliar	-	0.03	note ^a	14

^a apples and pears—apply as determined by trap counts at minimum intervals of 2 weeks

Remarks can be added as table endnotes, e.g., aerial application, field and glasshouse use, glasshouse use only, growth stage restriction, interval between applications, post-harvest use, seed treatment, table grapes only, wine grapes only.

If there are many uses, split them into separate tables for fruits, vegetables, etc.

Use the following units for application rates and spray concentrations; note that abbreviations are without full stops:

field treatment	kg ai/ha
grain treatment, post-harvest	g ai/t
furrow treatment	g ai/m
space fumigation	g ai/m ³
spray concentration	kg/ai/hL

RESIDUES RESULTING FROM SUPERVISED TRIALS ON CROPS

Where there are many residue tables, insert a list of them at the beginning of the section, in numerical order. An excerpt from a list of parathion-methyl residue tables is provided below (Evaluations 2000, Part 1 – Residues, p. 594).

The Meeting received information on parathion-methyl supervised field trials for

Fruits	Apple, pear	Table 20.
	Peach	Table 21.
	Grapes	Table 22.
Vegetables	Onions	Table 23.
	Broccoli	Table 24.
	Cabbage	Table 25.

Describe in introductory paragraphs those points that apply to all the trials, e.g., expression of residues below LOQ, adjustment for recoveries, rounding and residues in control plots.

Residue levels and application rates were reported as chlormequat chloride, but the residues were generally recalculated as cation in the Appraisal. When residues were not detected they are shown as below the LOQ, e.g., < 0.1 mg/kg. Residues, application rates and spray concentrations have generally been rounded to two significant figures. HR and STMR values from the trials conducted according to maximum GAP have been used for the estimation of maximum residue levels. These results are underlined.

Laboratory reports included method validation including batch recoveries with spiking at residue levels similar to those occurring in samples from the supervised trials. Dates of analyses or duration of residue sample storage were also provided. Field reports provided data on the sprayers used and their calibration, plot size, residue sample size and sampling date. Although trials included control plots, no control data are recorded in the tables except where residues in control samples exceeded the LOQ. Residue data are recorded unadjusted for % recovery.

Discuss details which are not readily included in the tables but are still needed to assess the validity and relative importance of the results, for example the intervals between spray applications, the number of replicate plots, whether samples are replicates from the same or different plots or merely replicate analyses of the same sample, the size of plots, growing season, method of application, irrigation and, in animal trials and feed studies, animal weights and ages. The reviewer's judgement is required to decide which details could influence the residues or the validity of the trials.

Tables of residues resulting from supervised trials should be carefully prepared in such a way as to assist evaluations. An excerpt from the parathion-methyl evaluation (Evaluations 2000, Part 1–Residues, p. 602) is provided below for reference.

Deal with commodities in Codex commodity order, i.e., fruits before vegetables, citrus fruits, then pome fruits, stone fruits, etc. Where a crop produces more than one commodity, e.g., cereal crops produce grains and forage and fodder, prepare separate residue data tables for the grain and the forage and fodder.

The table caption should be clear and comprehensive. Include the compound and the crops or crop groups, and indicate that the residues were found in supervised trials.

The year in the first column of the table is the year of the trial rather than the year of the report. Where trials have been conducted in a large country, include the state or region in brackets after the country, e.g., USA (CA).

“Application” should include the formulation type, the rate of application (kg ai/ha), spray concentration (kg ai/hL), the water volume (L/ha) and the number of applications.

List the pre-harvest intervals (PHIs) vertically and report individual residues as far as possible. If there are a number of values at the same level they can be recorded as < 0.05 (7), where there are 7 values of < 0.05 mg/kg.

Underline those residues which are within GAP and have been selected for estimation of STMR, but wherever such underlining is used its meaning should be explained in the introductory paragraphs of the section, “Residues resulting from supervised trials on crops.” Underlining is very helpful for people assessing the results, particularly when the tables are extensive, and allows other Panel members to see where the reviewer has judged data to be within or outside GAP.

Round numbers in tables to a practical level. A formulation concentration should be reported as 250 g ai/kg, not 250.00 g ai/kg. Residues should be reported as 0.046, 0.36 and 4.5 mg/kg, not 0.0463, 0.363 and 4.47 mg/kg.

Table X.2. Parathion-methyl and paraoxon-methyl residues in wine grapes from supervised trials in France and Italy.

GRAPES country, year (variety)	Application					PHI days	Residues, mg/kg		Ref
	Form	kg ai/ha	kg ai/hL	water, L/ha	no.		parathion- methyl	paraoxon- methyl	
France, 1994 (Chenin Blanc)	CS	0.29	0.15	200	2	0	0.09	< 0.01	AP/2582/HR F1 951174
						3	0.05	< 0.01	
						7	0.11	< 0.01	
						14	0.06	< 0.01	
						21	0.05	< 0.01	
						35	0.07	< 0.01	
France, 1994 (Chenin blanc)	EC	0.30	0.15	200	2	0	0.05	< 0.01	Tours F1 951175
						3	0.04	< 0.01	
						7	0.01	< 0.01	
						14	< 0.01	< 0.01	
						21	< 0.01	< 0.01	
France, 1994 (Grenache)	CS	0.32	0.16	200	2	0	0.28	< 0.01	AP/2582/HR Site II 951174
						3	0.16	< 0.01	
						7	0.28	< 0.01	
						14	0.11	< 0.01	
						21	0.13	< 0.01	
						31	0.07	< 0.01	
Italy, 1994 (Sangiovese) - red	CS	0.30	0.060	500	2	0	0.30 0.12		407240
						7	0.14		
						14	0.16		
						21	0.18		

In tabulating the residue trials data the FAO Panel reviewer should indicate the levels of relevant metabolites separately from those of the parent compound, but in a way which allows subsequent combination, in order to ensure that changes in the residue definition can be accommodated at the Joint Meeting.

An example is taken from the 2008 JMPR evaluation of spinetoram which shows the proper presentation of residue levels of two metabolites obtained from replicate samples (Table X.3) together with the calculated total residue.

Where the residue definition for dietary intake assessment is different from enforcement the relevant residue data may be reported in separate table (X.4)

Table X.3. Residues of spinetoram from supervised trials on orange in the USA (for estimation of maximum residue level)

ORANGE Location, year (Variety)	Form	Application			Total/ season, g ai/ha	PHI, days	Residue, mg/kg			Report No.
		g ai/hL	g ai/ha	No			XDE- 175-J	XDE- 175-L	Total	
GAP, USA Citrus fruits	SC or WG		53-105	3	210	1				
Foliar application using low spray volume (~700 L/ha)										
Deleon Springs, FL, 2004 (Valencia)	SC	10	70-72	3	213	1	0.030 0.028	< 0.01 < 0.01	0.030 0.028	040063

ORANGE Location, year (Variety)	Form	Application			Total/ season, g ai/ha	PHI, days	Residue, mg/kg			Report No.
		g ai/hL	g ai/ha	No			XDE- 175-J	XDE- 175-L	Total	
Mount Dora, FL, 2004 (Valencia)	SC	11	71-72	3	214	1	0.011 0.022	ND < 0.01	0.011 <u>0.022</u>	040063

Table X.4. Residues of spinetoram and metabolites from supervised trials on orange in the USA (for estimation of STMR)

ORANGE Location, year (Variety)	Form	Application			Total/ season, g ai/ha	PHI, days	Residue, mg/kg					Report No.
		g ai/hL	g ai/ha	No			XDE- 175-J	XDE- 175-L	ND-J	NF-J	Total	
<i>GAP, USA Citrus fruits</i>	<i>SC or WG</i>		<i>53- 105</i>	<i>3</i>	<i>210</i>	<i>1</i>						
Foliar application using low spray volume (~700 L/ha)												
Deleon Springs, FL, 2004 (Valencia)	SC	10	70-72	3	213	1	0.030 0.028	< 0.01 < 0.01	0.011 0.014	0.016 0.024	0.057 <u>0.066</u>	040063
Mount Dora, FL, 2004 (Valencia)	SC	11	71-72	3	214	1	0.011 0.022	ND < 0.01	< 0.01 0.012	< 0.01 0.017	0.021 <u>0.051</u>	040063

FATE OF RESIDUES IN STORAGE AND PROCESSING

In storage

Include information on the fate of residues during commercial storage of food commodities, e.g., during cold storage of fruit or silo storage of cereal grains.

In processing

Introduce the section with a statement on the data provided on processed commodities.

The Meeting received information on the fate of incurred residues of parathion-methyl and paraoxon-methyl during the processing of apples, peaches, grapes, olives, snap beans, soya beans, potatoes, sugar beet, wheat, maize, rice, cotton seed, sunflower seed and canola. Information on the fate during drying of hops is included in the supervised residue trials.

Set out tables carefully so that it is absolutely clear which sample is derived from which in the processing. Indicate the scale of the process by the weight of commodity processed and whether the initial RAC residue is from the actual bulked sample or from a separate field sample from the same trial. Note any problems with sampling or analysis. Provide a brief description of the field treatments in the trial and state the application rate in the study with respect to the maximum label rate, e.g., 5×label rate.

Introduce each processed commodity with a paragraph summarizing the information provided, tabulate the residue data and include a flow diagram to explain complex commercial processes.

Soya beans. Parathion-methyl was applied twice to soybeans at 2.8 kg ai/ha (5×label rate) in two trials in USA in 1988 and the crops were harvested 15 days after the final treatment for processing (Figure X.2). In one trial (MP-SY-2102) the residue levels

were below LOQ for all commodities. In trial MP-SY-2101 parathion-methyl levels depleted in the meal and increased in the oils (Table X.5).

Table X.5 Parathion-methyl and paraoxon-methyl residues in soya beans and processed commodities

SOYA BEANS country, year (variety)	Application			PHI days	commodity	Residues, mg/kg		Ref	
	Form	kg ai/ha	kg water, ai/hL L/ha			no.	parathion- methyl		paraoxon- methyl
USA (IA), 1988 (Pioneer 9271)	EC	2.8	200	2	15	dry seed	0.15	< 0.05	MP-SY- 2101
						meal	< 0.05	< 0.05	
						hulls	0.12	< 0.05	
						crude oil	0.71	< 0.1	
						refined oil	0.57	< 0.1	

Excerpt from Table 59. (Evaluations 2000, Part 1–Residues, p. 654)

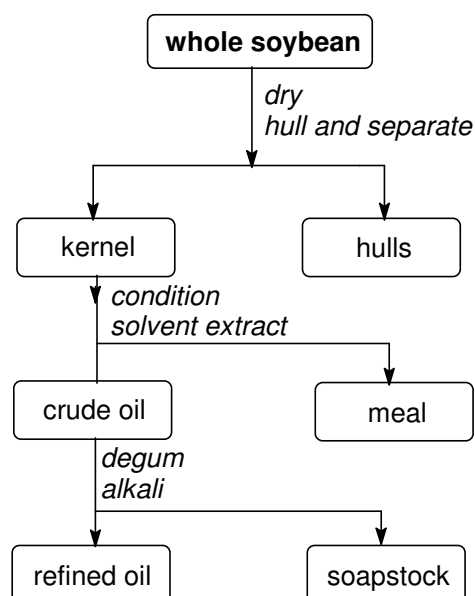


Figure X.2. Soybean processing (ref)

(Evaluations 2000, Part 1 – Residues, p. 655)

Processing factors (residue in processed commodity ÷ residue in raw commodity) may be included in the processing residue data table in simple cases. In more complex cases with different residue definitions for enforcement and dietary intake it is preferable to summarize processing factors in a separate table. Examples are given in tables X.6 and X.7.

Table X.6 Processing factors, HR-P and STMR-P values for various commodities

Raw agricultural commodity			Processed commodity			
Commodity	STMR (mg/kg)	HR (mg/kg)	Commodity	Processing factor	STMR-P (mg/kg)	HR-P (mg/kg)
Plum	0.80	3.6	Prunes (dried plums)	1.91	0.96	4.3
			Juice	0.10	0.080	

Raw agricultural commodity			Processed commodity			
Commodity	STMR (mg/kg)	HR (mg/kg)	Commodity	Processing factor	STMR-P (mg/kg)	HR-P (mg/kg)
			Preserves	0.50	0.40	
Xxx						

Table X.7 Example for presenting a complex case

Commodity	Processing factor _{propineb}	Propineb residues (mg/kg)		Processing factor _{PTU}	Propylenethiourea residues (mg/kg)		Adjusted values (mg/kg)	
		For STMR/ STMR-P	For HR/ HR-P		For STMR/ STMR-P	For HR/ HR-P	STMR ^a	HR ^b
Cherry		0.128	0.351		0.01	0.02		
Washed	0.63	0.0803	0.221	1	0.01	0.02	0.103	0.287
Juice	0.55	0.0701		0.68	0.0068		0.0858	
Preserves	0.15	0.0191		0.5	0.005		0.0306	
Jam	0.35	0.0446		0.78	0.0078		0.0626	
Tomato		1.0	2.93		0.03	0.16		
Washed	0.45	0.45	1.32	0.4	0.012	0.064	0.478	1.53
Juice	0.12	0.12		0.91	0.0273		0.183	
Preserves	0.15	0.15		0.75	0.0225		0.202	
Ketchup	0.12	0.12		0.54	0.0162		0.157	
Paste	1.1	1.1		11	0.33		1.86	

^a Adjusted STMR-P = STMR-P_{propineb} + 2.3 × STMR-P_{propylenethiourea}

^b adjusted HR-P = HR-P_{propineb} + 3.3 × HR-P_{propylenethiourea}

Residues in the edible portion of food commodities

Draw attention to those commodities where residue levels in the edible portion are different from those in the whole commodity, e.g., citrus, bananas, trimmed celery and cabbage with outer leaves discarded.

RESIDUES IN ANIMAL COMMODITIES

Direct animal treatments

Pesticides may be applied directly to farm animals for control of lice, flies, mites and ticks. Application may include dips, sprays, pour-ons and jetting. Residue trials using the required method of application, dosage and withdrawal times are needed if residues may occur in animal commodities. Where feasible, data from supervised residue trials on animals should be summarized in tables similar to those for crops.

Farm animal feeding studies

Farm animal feeding studies use unlabelled compounds to establish the relationship between the levels of the residues in the feed and likely residues in tissues, milk and eggs.

Farm animal feeding studies may be introduced by a paragraph that acts as a checklist of the information.

Groups of 10 laying hens (each bird weighing 1.0–1.3 kg) were fed aged mancozeb residues at nominal levels of 5, 15 and 50 ppm (1×, 3× and 10×) in the diet for 28 days (study reference). Eggs were collected each day for analysis. On day 29 six hens

from each group were slaughtered for tissue collection. The remaining hens from each group were placed on a residue-free diet and slaughtered on days 36 and 43. Birds consumed 130 g feed each per day.

RESIDUES IN FOOD IN COMMERCE OR AT CONSUMPTION

Introduce the section with a statement on the residue monitoring data provided. Tabulate the information and list the commodity, number of samples analysed and the residues detected according to Chapter 3, Section.10.

NATIONAL RESIDUE DEFINITION

It will usually be preferable to summarize the information in a table.

REFERENCES

References to unpublished reports, journals and books should be listed in tabular form as in the following example. References are sorted alphabetically according to study (or report) number, then author, then year.

Code	Author	Year	Title
	MacDougall D	1964	Guthion. In: Zweig, G., Analytical Methods for Pesticides, Plant Growth Regulators and Food Additives, Vol. II, Academic Press, New York, London.
	Meagher WR, Adams JM, Anderson CA and MacDougall D	1960	Colorimetric determination of Guthion residues in crops. <i>J. Agric. Food Chem.</i> 8, 282-6
B221/85	Gildemeister H, Bürkle WL and Sochor H	1985	Hoe 029664-14-C. Anaerobic soil metabolism study with the fungicide triphenyltin hydroxide (TPTH). Hoechst Analyt. Labor., Germany. Rep. B221/85. Unpublished.
OEK 83 001E	Fischer R and Schulze E-F	1983	The effect of Hoe 02782 OF AT202 (fentin acetate, active ingredient 96.4%) on <i>Salmo gairdneri</i> (Rainbow trout) in a static test. Hoechst Pfl. Fo. Biol., Germany. Rep. OEK 83 001E. Unpublished.
OEK 83/028E	Fischer R and Schulze E-F	1983	The effect of Hoe 29664 OF AT205 (fentin hydroxide, active ingredient 97.0%) on <i>Salmo gairdneri</i> (Rainbow trout) in a static test. Hoechst Pfl. Fo. Biol., Germany. Rep. OEK 83/028E. Unpublished.

Notes:

- Study references in tables require the study number (or report number).
- Citations in the text should be of the form: Author, year, study (or report) number.
- Citations in the text should name both of two authors, but only the first of three or more e.g., from the example above: Gildemeister *et al.* 1985, B221/85.

DRAFT APPRAISAL

Prepare a draft appraisal for the Meeting using the following format. The use of uppercase, alignment of headings, bold and underlining should follow this format. In the top right-hand corner of the first page state the year, the draft number and the author's family name. A reference number will be assigned to the compound at the Meeting, e.g., FAO/2001/ref no. AP1 is added to the file name to show that it is draft 1 of the appraisal. The layout is shown below.

FAO/2001/
AUTHOR
COMPOUND_AP1.doc
DRAFT 1

COMPOUND (Codex number)**APPRAISAL***Animal metabolism**Plant metabolism**Environmental fate in soil**Environmental fate in water-sediment systems**Methods of analysis**Stability of residues in stored analytical samples**Definition of the residue**Results of supervised trials on crops**Fates of residues during processing**Residues in animal commodities***RECOMMENDATIONS FURTHER WORK OR INFORMATION***Required (by [year])*

Desirable

DIETARY RISK ASSESSMENT*Long-term intake**Short-term intake*

Interpretation of the residue data should generally be in the APPRAISAL section of the evaluation rather than in RESIDUES RESULTING FROM SUPERVISED TRIALS ON CROPS.

The APPRAISAL section of the monograph, together with the FURTHER WORK OR INFORMATION, RECOMMENDATIONS and DIETARY RISK ASSESSMENT, is prepared as a separate document for intensive discussion at the meeting. It contains the logic and a full explanation for each recommendation.

Line numbering should be used in the draft Appraisal to assist discussion at the Meeting.

Briefly explain the reasons for the review and summarize the information available. The subject order in the appraisal should follow the order in the evaluation.

Do not include tables in the text of the appraisal, unless it makes the presentation clearer, i.e., abbreviations of metabolites used in the text, summary of detailed processing studies or corresponding processing factors, with the exception of the farm animal dietary burden calculation table and the animal commodity STMR and MRL calculation table.

If it is recommended that the residue definition for the risk assessment be different from that for enforcement, this must be clearly stated in the appraisal.

When the residue definition includes more than one component, the appraisal should include an explicit description of how the total residue is calculated from the components. The explanation should show necessary molecular weight adjustments and how “less-than LOQ” residues are dealt with.

Example: fipronil

When one component of the fipronil residue is above and the other below the LOQ, the combined residue is assumed to be close to the residue of the measurable component plus the LOQ of the other. To indicate that one of the residue results is a real measurement, express the sum of the values as a real figure, e.g., $< 0.002 + 0.004 \text{ mg/kg} = 0.006 \text{ mg/kg}$. The method for calculating the total residue for various situations is illustrated below.

Fipronil	Metabolite MB 46136 or MB 46513	Total
< 0.002	< 0.002	< 0.004
< 0.002	0.004	0.006
0.003	0.005	0.008

The residue concentrations for fipronil (437.2 g/mol) and the metabolites MB 46136 (453.1 g/mol, factor 0.965) and MB 46513 (389.02 g/mol, factor 1.1) are expressed in the evaluation tables as the individual compounds *per se*, but are calculated in the appraisal according to the respective residue definition (expressed as fipronil). The LOQs of the individual compounds are not adjusted by these factors.

Example: spinosad

The residue definition for spinosad requires the addition of spinosyns A and D residues. Spinosyn A constitutes approximately 85% of the residue initially and in practice constitutes the majority of the spinosyn residue. In this calculation where the residue of spinosyn D was < LOQ it was assumed to be zero except when both spinosyns A and D residues were < LOQ and in that case the total was taken as < LOQ. These are reasonable assumptions since the spinosyn D level is usually much less than the spinosyn A level. The method for calculating the total residue for various situations is illustrated below.

spinosyn A	spinosyn D	Sum of spinosyns A and D
0.59	0.082	0.67
0.03	< 0.01	0.03
< 0.01	< 0.01	< 0.01

Provide in full the interpretation used to estimate a maximum residue level. Explain extrapolations, comparability and any conditions of use, crop characteristics etc. which influence the interpretation. As an example the following paragraph states the relevant use pattern on the crop, the number of trials and country to match the use pattern and the residue data selected for estimating STMRs in rank order. The concluding paragraph on this

commodity states explicitly the recommended MRL and STMR and includes the residue expressions according to the relevant residue definitions.

The UK use pattern on strawberries allows thiram applications of 1.6 kg ai/ha beginning at white bud burst, with repeats at 7–10 day intervals and a PHI of 7 days. Seven strawberry trials in Belgium were evaluated against the use pattern of the UK. The highest thiram residues (median underlined) in each trial within range of the UK use pattern were: 1.4, 1.4, 2.1, 2.1, 2.4, 2.8 and 3.1 mg/kg. The highest residue, 3.1 mg/kg as thiram, is equivalent to 2.0 mg/kg dithiocarbamates as CS₂.

The Meeting estimated a maximum residue level of 5 mg/kg for dithiocarbamates (as CS₂) in strawberry arising from the use of thiram. The Meeting estimated an STMR value of 2.1 mg/kg for thiram (as thiram) on strawberry.

Examples of other concluding sentences are:

The Meeting agreed to withdraw the recommendations for cherries (1 mg/kg), peaches (3 mg/kg) and plums (1 mg/kg).

The Meeting estimated an STMR value of 0.05 mg/kg and a maximum residue level of 0.05 mg/kg for pecans. The HR was 0.05 mg/kg.*

The Meeting estimated an STMR value of 0.38 mg/kg and a maximum residue level of 2 mg/kg for sweet peppers. The latter replaces the previous recommendation (0.5 mg/kg). The HR was 1.4 mg/kg.

The Meeting agreed to withdraw the previous maximum residue level recommendation for citrus fruits (5 mg/kg), to be replaced by recommendations for oranges (1 mg/kg) and mandarins (2 mg/kg).

The Meeting agreed to maintain the current recommendation of 0.2 mg/kg for potatoes.

RECOMMENDATIONS

Use a standard introductory paragraph.

On the basis of the data from supervised trials the Meeting concluded that the residue levels listed below are suitable for establishing maximum residue limits and for IEDI and IESTI assessment.

State the residue definition—choose the appropriate statement. Additional statements will be required if the residue definitions are different for crops and animals.

For plants and animals: Definition of the residue for compliance with MRLs and estimation of dietary intake: [residue definition].

For plants and animals: Definition of the residue for compliance with MRLs: [residue definition 1]. For estimation of dietary intake: [residue definition 2].

If the residue is fat-soluble, insert the following sentence after the residue definition.

The residue is fat-soluble.

List all commodities with MRL, STMR and HR recommendations, alphabetically in the recommendations table. HR recommendations are not required for those compounds where an ARfD is unnecessary.

CCN	Commodity	MRL, mg/kg		STMR or STMR-P mg/kg	HR or HR-P mg/kg
	Name	New	current		

Include at the end of the table, HR-Ps and STMR-Ps for processed commodities with no recommended maximum residue levels if these residue values are used in the dietary intake estimates.

The recommendations table for periodic review compounds should include all current MRLs or, more correctly, current JMPR MRL recommendations. The table will then show whether each MRL is maintained, amended or withdrawn.

Any recommendations to withdraw MRLs should be entered in the table of Recommendations, which will be reproduced in Annex 1 to the report, and not merely mentioned as a recommendation in the text. A statement such as “the Meeting recommended the withdrawal of the MRL for pome fruits” could be easily missed when Annex 1 is being compiled.

Where no residue is expected in animal commodities, irrespective of feeding levels, the JMPR recommends MRLs at or about the LOQ for the animal commodities. These recommended MRLs alert users of Codex MRLs that the situation has been fully evaluated and that, for the commodities of trade, residues should not occur above the stated LOQ.

In such cases include a footnote under the recommendation table stating that ‘*No residues are expected from consumption of feed commodities with [xxx pesticide] residues as evaluated by JMPR*’.

FURTHER WORK OR INFORMATION

The items listed as required or desirable should be numbered if there is more than one.

Required

All items listed as required should have a year proposed as the due date. Choose 2 years from the current Meeting as the due date in the absence of other information, e.g., a definite commitment by a country or company to provide information by a nominated date.

Each item listed as required should be tied to a TMRL. If the required information is not supplied by the due date, the Meeting can then recommend withdrawal of the TMRL.

TMRLs are generally not introduced for new compounds or periodic review compounds. Their use should be kept to a minimum.

Desirable

Information requested as desirable is not vital to the continued existence of MRLs, but is requested because it may assist in an explanation, support an extrapolation or provide a more complete data base.

DIETARY RISK ASSESSMENT

Note that references to Annexes 3 are for text in the JMPR Reports. When converted to monographs for the Residue Evaluations, the references must be changed to “Annex [X] and [Y] of [year] JMPR Report.”

Long-term intake

Estimated intake within the ADI

Use the following standard statements for the long-term dietary risk assessment where the estimated intake is within the ADI.

Situation: The compound was subject to a toxicology evaluation but not a residue evaluation. MRLs, but not STMRs, are available. The TMDI for the 13 diets was less than the ADI.

Estimated Theoretical Maximum Daily Intakes for the GEMS/Food regional diets, based on recommended MRLs, were in the range of [...] to [...]% of the maximum [ADI] (Annex 3). The Meeting concluded that the long-term intake of residues of [pesticide] resulting from its uses that have been considered by the JMPR is unlikely to present a public health concern.

Situation: The compound was new or subject to a periodic review for residues. The IEDI for the 13diets was less than the ADI.

The International Estimated Daily Intakes of [pesticide], based on the STMRs estimated for [...] commodities, for the GEMS/Food regional diets were in the range of [...] to [...]% of the maximum ADI (Annex 3). The Meeting concluded that the long-term intake of residues of [pesticide] resulting from its uses that have been considered by JMPR is unlikely to present a public health concern.

Situation: The compound was subject to residue review, but not a periodic review, for a number of commodities. The estimated intakes for the 13 regional diets were less than the ADI.

In the current evaluation STMRs were estimated for [...] commodities. Where consumption data were available these STMRs were used in the estimates of dietary intake together with previous MRL recommendations for [...] other food commodities. The results are shown in Annex 3.

The estimated daily intake for the five GEMS/Food regional diets were in the range of [...] to [...]% of the maximum ADI (Annex 3). The Meeting concluded that the long-term intake of residues of [pesticide] resulting from its uses that have been considered by the JMPR is unlikely to present a public health concern.

Estimated intake exceeds the ADI

Use the following standard statements for the long-term dietary risk assessment where the estimated intake exceeds the ADI.

Situation: The compound was subject to a toxicology evaluation but not a residue evaluation. MRLs, but not STMRs, are available. The TMDI for at least one of the diets exceeded the ADI.

Estimated Theoretical Maximum Daily Intakes for the 13 GEMS/Food regional diets, based on recommended MRLs, were in the range of [...] to [...]% of the maximum ADI

(Annex 3). Further refinements of dietary intake estimates will be undertaken during the periodic review of residues scheduled for [year].

Situation: The compound was new or subject to a periodic review for residues. The IEDI for one of the diets exceeded the ADI.

The International Estimated Daily Intake of [pesticide], based on the STMRs estimated for [...] commodities, was [...]% of the maximum ADI for the GEMS/Food [list diet(s)] diet. International Estimated Daily Intakes for the other GEMS/Food regional diets were in the range of [...] to [...]% of the ADI (Annex 3).

The information provided to the JMPR precludes an estimate that the dietary intake would be below the maximum ADI.

Situation: The compound was subject to residue review, but not a periodic review, for a number of commodities. The estimated intake exceeded the ADI for the all regional diets.

In the current evaluation STMRs were estimated for [...] commodities. Where consumption data were available these STMRs were used in the estimates of dietary intake together with previous MRL recommendations for [...] other food commodities. The results are shown in Annex 3.

The estimated daily intake exceeds the ADI for the thirteen GEMS/Food regional diets: A [...]%, B and M [...]%.

The Meeting concluded that the long-term dietary intake of [pesticide] residues may exceed the ADI for all GEMS/Food regional diets. Further refinements of dietary intake estimates will be undertaken during the next periodic review of residues or when additional relevant data are provided.

Short-term intake

ARfD unnecessary

Situation: The JMPR toxicology assessment has concluded that an ARfD is unnecessary.

The [year] JMPR decided that an ARfD is unnecessary. The Meeting therefore concluded that the short-term intake of [pesticide] residues is unlikely to present a public health concern.

All IESTI values within ARfD

Situation: The compound was new or subject to periodic review for residues. The estimated short-term intakes for all commodities were within the ARfD.

The International Estimated Short term Intake (IESTI) for [pesticide] was calculated for [...] food commodities [(and their processed fractions)] for which maximum residue levels were estimated and for which consumption data were available. The results are shown in Annex 4.

The IESTI represented [...]% of the maximum ARfD for the general population and [...]% of the maximum ARfD for children. The Meeting concluded that the short-term intake of residues of [pesticide], when used in ways that have been considered by the JMPR, is unlikely to present a public health concern.

IESTI values exceed ARfD

Situation: The compound was new or subject to periodic review for residues. The estimated short-term intakes for some commodities exceeded the ARfD.

The International Estimated Short term Intake (IESTI) for [pesticide] was calculated for [...] food commodities [(and their processed fractions)] for which maximum residue levels were estimated and for which consumption data were available. The results are shown in Annex 4.

The IESTI represented [...] % of the maximum ARfD for the general population and [...] % of the maximum ARfD for children. The values [...], [...] and [...] % represent the estimated short-term intake for [commodity 1], [commodity 2] and [commodity 3] respectively for the total population. The values [...], [...] and [...] % represent the estimated short-term intake for [commodity 1], [commodity 2] and [commodity 3] respectively for children.

The Meeting concluded that the short term intake of residues of [pesticide] from uses, other than on these [...] commodities, that have been considered by the JMPR is unlikely to present a public health concern.

ARfD not available, but may be necessary

Situation: The compound was subject to residue review for a number of commodities. The compound has not been subject to a recent toxicological assessment, so there is no ARfD, but an ARfD may be necessary.

The International Estimated Short Term Intake (IESTI) for [pesticide] was calculated for [...] food commodities [(and their processed fractions)] for which maximum residue levels were estimated at the present meeting and for which consumption data were available. The results are shown in Annex 4. The Meeting concluded that an ARfD may be necessary, but as it has not yet been established, the acute risk assessment for [pesticide] was not finalized.

ARfD previously not available, but now established

Situation: The present JMPR has established an ARfD for a compound which had been subject to residue review for a number of commodities in a previous year and where the acute risk assessment was not then able to be finalized. The estimated short-term intakes for all commodities were within the ARfD.

The Meeting estimated an ARfD ([...] mg/kg bw) for [pesticide]. The [year] JMPR had calculated the International Estimated Short Term Intake (IESTI) for [pesticide] for [...] food commodities [(and their processed fractions)] for which maximum residue levels were estimated and for which consumption data were available, but was not able to finalize the risk assessment because an ARfD was not available.

The IESTI represented [...] % of the maximum ARfD for the general population and [...] % of the maximum ARfD for children. The Meeting concluded that the short term intake of residues of [pesticide], when used in ways that have been considered by the JMPR, is unlikely to present a public health concern.

Situation: The present JMPR has established an ARfD for a compound which had been subject to residue review for a number of commodities in a previous year and where the acute risk assessment was not then able to be finalized. The estimated short-term intakes for some commodities exceeded the ARfD.

The Meeting estimated an ARfD ([...] mg/kg bw) for [pesticide]. The [year] JMPR had calculated the International Estimated Short Term Intake (IESTI) for [pesticide] for [...] food commodities [(and their processed fractions)] for which maximum residue levels were estimated and for which consumption data were available, but was not able to finalize the risk assessment because an ARfD was not the available.

The IESTI represented [... - ...]% of the maximum ARfD for the total population and [... - ...]% of the maximum ARfD for children. The values [...], [...] and [...] represent the estimated short-term intake for [commodity 1], [commodity 2] and [commodity 3] respectively for the total population. The values [...], [...] and [...] represent the estimated short-term intake for [commodity 1], [commodity 2] and [commodity 3] respectively for children.

The Meeting concluded that the short term intake of residues of [pesticide] from uses, other than on these [...] commodities, that have been considered by the JMPR is unlikely to present a public health concern.

Appendix XI

TABLE AND SPREADSHEET EXAMPLES

CONTENTS

- Table XI.1. Residue interpretation table. See Chapter 6 section 2.1, "Interpretation tables for supervised trials data."
- Table XI.2. Summary of good agricultural practices for pesticide uses. See Chapter 3 section 4 "Use pattern."
- Table XI.3. Residues data summary from supervised trials. See Chapter 3 section 5. "Residues resulting from supervised trials on crops."
- Table XI.4. Table format for long-term dietary intake calculation (parathion-methyl). See Chapter 7 section 2 "Long-term dietary intake."
- Table XI.5. Table format for long-term dietary intake calculation (myclobutanil). See Chapter 7 section 2 "Long-term dietary intake."
- Table XI.6. Table format for IESTI calculation for general population (parathion-methyl). See Chapter 7 section 5 "IESTI tables."
- Table XI.7. Table format for IESTI calculation for children (parathion-methyl). See Chapter 7 section 5 "IESTI tables."

Table XI.1. Residue interpretation table for folpet residues on tomatoes. GAP and trial conditions are compared for treatments considered valid for MRL and STMR estimation. (JMPR 1998).

Crop	Country	Use pattern				Trial	folpet, mg/kg
		kg ai/ha	kg ai/hL	No of appl	PHI days		
Tomato	Chile GAP	1.7	0.15		7		
Tomato	Chile trial	1.7	1.5	7	7	[trial no.]	2.4
Tomato	Hungary GAP		0.13		14		
Tomato	Hungary trial	0.65	0.13	3	14		< 0.05
Tomato	Hungary trial	0.65	0.13	3	14		< 0.05
Tomato	Hungary trial	0.65	0.13	3	14		< 0.05
Tomato	Hungary trial	0.66	0.13	3	14		< 0.05
Tomato	Hungary trial	0.63	0.12	5	14		< 0.02
Tomato	Mexico GAP	2.0			no limit		
Tomato	Mexico trial	2.0	0.67	5	2		1.0
Tomato	Mexico trial	2.0	0.71	5	2		1.6
Tomato	Mexico trial	2.0	0.66	5	2		1.8
Tomato	Mexico trial	2.0	0.71	5	2		0.45
Tomato	Mexico trial	2.0	0.72	5	2		1.3
Tomato	Portugal GAP		0.13		7		
Tomato	Portugal trial	1.3	0.16	4	7		0.34
Tomato	Portugal trial	1.3	0.16	4	7		0.58
Tomato	Spain GAP		0.15		10		
Tomato	Italy trial	1.2	0.13	4	10		0.60
Tomato	Italy trial	1.3	0.13	4	10		0.70
Tomato	Italy trial	1.3	0.13	4	10 (14)	Note ^a	0.80
Tomato	Italy trial	1.2	0.13	4	10		0.43
Tomato	Spain trial	1.6	0.20	6	10		1.3
Tomato	Spain trial	2.5	0.16	6	10		1.2

^a The residue on day 14 (0.80 mg/kg) exceeded the residue on day 10 (0.62 mg/kg).

Table XI.2. Summary of good agricultural practices for pesticide uses.

(Application on agricultural and horticultural crops)

Responsible body for reporting (name, address):

Date:

Pesticide(s) (common name(s)):

Page:

CCPR No(s).:

Country:

Trade name(s):

Main uses, e.g., insecticide, fungicide:

Use Pattern

Crop and/or situation (a)	F or G (b)	Pest or group of pests controlled (c)	Formulation		Application			Application rate per treatment			PHI (days) (k)	Remarks (l)
			Type (d-f)	Conc. of ai (i)	method, kind (f-h)	growth stage (j)	number (range)	kg ai/hL	water L/ha	kg ai/ha		

Explanatory notes: (explanatory notes are needed only on page 1 of a multi-page GAP summary)

Include only the information provided on the label.

- | | |
|---|---|
| (a) In case of group of crops the Codex classification should be used | (g) Method, e.g., high volume spraying, low volume spraying, spreading, dusting, drench |
| (b) Outdoor or field use (F), or glasshouse application (G) | (h) Kind, e.g., overall, broadcast, aerial spraying, row, individual plant, between the plants |
| (c) e.g., biting and sucking insects, soil borne insects, foliar fungi | (i) g/kg or g/l |
| (d) e.g., wettable powder (WP), emulsifiable concentration (EC), granule (GR) | (j) Growth stage at last treatment |
| (e) Use CIPAC/FAO Codes where appropriate | (k) PHI = Pre-harvest interval |
| (f) All abbreviations used must be explained | (l) Remarks may include: Extent of use/economic importance/restrictions (e.g., feeding, grazing)/minimal intervals between applications |

Table XI.3. Residues data summary from supervised trials
(Application on agricultural and horticultural crops)

Active ingredient:

Responsible body for reporting (name, address):

Country:

Content of ai (g/kg or g/l):

Formulation (e.g., WP):

Commercial product (name):

Producer of commercial product

Crop/crop group:

Submission date:

Page:

Indoor/outdoor:

Other ai in formulation:

(Common name and content):

Residues calculated as:

Report-No.: Location incl. Postal code	Crop Variety	Date of (1) Sowing or planting; (2) Flowering or (3) Harvest (b)	Application rate per treatment			Dates of treatment(s) or no. of treatments and last date	Growth stage at last treatment or date	Commodity, Portion analysed (a)	Residues (mg/kg)	PHI days) (d)	Remarks (e)
			kg ai/ha	water L/ha	kg ai/hL						

Explanatory notes: (explanatory notes are needed only on page 1 of a multi-page residue data summary)

(a) According to Codex Classification/Guide

(b) Only if relevant

(c) Year must be indicated

(d) Days after last application (Label pre-harvest interval, PHI, underline)

(e) Remarks may include: Climatic conditions; Reference to analytical method and information on which metabolites are included

Note: All entries to be filled in as appropriate

Table XI.4. Table format for long-term dietary intake calculation (parathion-methyl example).**BUPROFEZIN (173)**

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.009 mg/kg bw

Codex Code	Commodity	STMTR or STMTR-P mg/kg	diet correction factor	Diets: g/person/day		Intake = daily intake: µg/person									
				A diet	intake	B diet	intake	C diet	intake	D diet	intake	E diet	intake	F diet	intake
FC 0001	Citrus fruit (excl lemon juice, excl mandarin juice, excl orange juice, excl grapefruit juice, excl NES juice)	0.04	0.7	15.7	0.4	86.5	2.4	52.6	1.5	24.2	0.7	16.2	0.5	12.0	0.3
-	Citrus juice NES	0.13	1	0.0	0.0	1.7	0.2	0.1	0.0	0.0	0.0	1.1	0.1	0.3	0.0
VC 0424	Cucumber	0.035	1	0.3	0.0	12.7	0.4	5.9	0.2	11.5	0.4	6.1	0.2	7.1	0.2
JF 0203	Grapefruit juice	0.13	1	0.0	0.0	0.2	0.0	0.1	0.0	0.1	0.0	1.1	0.1	0.2	0.0
-d	Lemon juice	0.13	1	0.0	0.0	0.9	0.1	0.1	0.0	0.0	0.0	0.2	0.0	0.4	0.1
-	Mandarin + mandarin-like hybrid juice	0.13	1	0.0	0.0	1.4	0.2	0.9	0.1	0.4	0.1	0.7	0.1	0.9	0.1
FI 0345	Mango (incl juice, incl pulp)	0.01	0.7	6.3	0.0	1.0	0.0	4.6	0.0	0.2	0.0	0.7	0.0	0.3	0.0
JF 0004	Orange juice	0.13	1	0.0	0.0	2.1	0.3	4.4	0.6	1.4	0.2	16.2	2.1	22.6	2.9
VO 0448	Tomato (excl juice, excl paste, excl peeled)	0.24	1	1.3	0.3	178.4	42.8	102.8	24.7	53.4	12.8	1.6	0.4	0.0	0.0
JF 0448	Tomato juice	0.053	1	5.2	0.3	0.5	0.0	0.4	0.0	2.1	0.1	6.9	0.4	15.2	0.8
-d	Tomato paste	0.22	1	0.5	0.1	1.3	0.3	3.5	0.8	1.0	0.2	3.8	0.8	4.5	1.0
-d	Tomato, peeled	0.041	1	0.1	0.0	0.4	0.0	0.5	0.0	0.4	0.0	4.9	0.2	3.2	0.1
Total intake (µg/person)=				1.2		46.8		27.9		14.5		5.0		5.7	
Body weight per region (kg bw) =				60		60		60		60		60		60	
ADI (µg/person)=				540		540		540		540		540		540	
%ADI=				0.2%		8.7%		5.2%		2.7%		0.9%		1.1%	
Rounded %ADI=				0%		9%		5%		3%		1%		1%	

Note: Only the first 6 regional diets are shown in the example table.

Table XI.5. Table format for long-term dietary intake calculation (myclobutanil example).

MYCLOBUTANIL (181): daily intake estimate (mixed TMDI-IEDI calculation). ADI = 0.03 mg/kg bw or 1800 µg/person

Code	Commodity	MRL mg/kg	STMR or STMR-P mg/kg
FI 0327	Banana		0.15
MM 0812	Cattle meat	0.01*	
ML 0812	Cattle milk	0.01*	
MO 0812	Cattle, Edible offal of	0.01*	
FB 0278	Currant, black		0.26
PE 0112	Eggs	0.01*	
FB 0269	Grapes	1	
DH 1100	Hops, dry		0
FS 0014	Plums (including prunes)	0.2	
FP 0009	Pome fruits	0.5	
PM 0110	Poultry meat	0.01*	
PO 0111	Poultry, edible offal of	0.01*	
DF 0014	Prunes	0.5	
FS 0012	Stone fruits ^a		0.62
FB 0275	Strawberry		0.19
VO 0448	Tomato		0.06
	Tomato juice		0.05
	Tomato paste		0.02

* at or about LOQ

^a except plums

As the diet table contains entries for (1) Stone fruit (excl dried plums, including dried apricots) and (2) Plum (excluding dried), the correct consumption figures for stone fruits can be obtained as: stone fruits excluding plums and prunes = (2) - (1). The values calculated for the 13 regional diets shall be inserted in the Excel spreadsheet. Attention: the new values shall be inserted in the appropriate cell one by one making sure that the formula in the intake columns are not affected.

The results of the calculation for the first 6 diets are shown below:

Myclobutanil ()

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.0300 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day Intake = daily intake: µg/person											
			A diet intake		B diet intake		C diet intake		D diet intake		E diet intake		F diet intake	
FI 0327	Banana	0.15	38.8	5.8	17.4	2.6	16.0	2.4	6.6	1.0	21.5	3.2	33.8	5.1
MM 0812	Cattle meat (incl calf meat)	0.01	13.4	0.1	49.4	0.5	13.6	0.1	35.8	0.4	42.4	0.4	53.9	0.5
ML 0812	Cattle milk (excl processed products)	0.01	34.5	0.3	178.5	1.8	52.0	0.5	284.2	2.8	178.6	1.8	237.1	2.4
MO 0812	Cattle, edible offal of	0.01	2.5	0.0	8.8	0.1	1.8	0.0	6.3	0.1	4.6	0.0	4.0	0.0
FB 0278	Currants, black	0.26	0.0	0.0	0.0	0.0	0.0	0.0	1.1	0.3	1.6	0.4	1.0	0.3
PE 0112	Eggs	0.01	2.5	0.0	29.7	0.3	25.1	0.3	24.5	0.2	37.8	0.4	27.4	0.3
FB 0269	Grape (incl dried, incl juice, incl wine)	1	3.7	3.7	128.5	128.5	27.1	27.1	33.1	33.1	107.5	107.5	44.0	44.0
DH 1100	Hops, dry	0	0.1	0.0	0.1	0.0	0.1	0.0	0.1	0.0	0.3	0.0	0.1	0.0
FS 0014	Plum (excl dried)	0.2	0.1	0.0	5.3	1.1	2.5	0.5	7.0	1.4	5.5	1.1	0.9	0.2
DF 0014	Plum, dried (prunes)	0.5	0.0	0.0	0.2	0.1	0.0	0.0	0.1	0.1	0.5	0.3	0.6	0.3
FP 0009	Pome fruit (incl apple juice)	0.5	0.5	0.3	84.1	42.1	21.9	11.0	45.2	22.6	61.7	30.9	46.2	23.1
PM 0110	Poultry meat	0.01	7.1	0.1	58.5	0.6	31.9	0.3	24.0	0.2	61.0	0.6	27.3	0.3
PO 0111	Poultry, edible offal of	0.01	0.4	0.0	0.4	0.0	1.7	0.0	0.1	0.0	0.6	0.0	0.2	0.0
FS 0012	Stone fruit (excl fresh and dried plums, excl dried apricots)	0.62	0.7	0.4	42.7	26.4	13.8	8.5	26.6	16.5	27.0	16.8	9.3	5.8
FB 0275	Strawberry	0.19	0.0	0.0	5.0	1.0	2.0	0.4	1.7	0.3	5.2	1.0	4.1	0.8
VO 0448	Tomato (excl juice, excl paste, excl peeled)	0.06	1.3	0.1	178.4	10.7	102.8	6.2	53.4	3.2	1.6	0.1	0.0	0.0
JF 0448	Tomato juice	0.05	5.2	0.3	0.5	0.0	0.4	0.0	2.1	0.1	6.9	0.3	15.2	0.8
-d	Tomato paste	0.02	0.5	0.0	1.3	0.0	3.5	0.1	1.0	0.0	3.8	0.1	4.5	0.1
Total intake (µg/person)=			11.2		215.7		57.4		82.3		164.8		83.8	
Bodyweight per region (kg bw) =			60		60		60		60		60		60	
ADI (µg/person)=			1800		1800		1800		1800		1800		1800	
%ADI=			0.6%		12.0%		3.2%		4.6%		9.2%		4.7%	
Rounded %ADI=			1%		10%		3%		5%		9%		5%	

Table XI.6. Table format for IESTI calculation for general population (parathion-methyl example).**PARATHION-METHYL (59):** international estimate of short-term intake (IESTI) for **GENERAL POPULATION**. ARfD = 0.03 mg/kg bw (30 ug/kg bw)

Code	Commodity	STMR or STMR-P, mg/kg	HR, mg/kg	Large portion diet		Unit weight			Variability factor	Case	IESTI, ug/kg bw	% ARfD, rounded	
				Country	Body weight, kg	Large portion, g	Unit weight g	Country					Unit wt, edible portion g
FP 0226	Apple		0.18	USA	65	1348	110	Fra	100	7	2a	5.4	20
	Apple juice	0.015			60						3		
VD 0071	Beans (dry)		0.05	Fra	62.3	255					1	0.2	1
VB 0041	Cabbages, Head		0.26	Fra	62.3	312	908	USA	717	5	2b	6.5	20
OR 0691	Cotton seed oil, edible	1.16		USA	65	9.1					3	0.2	1
DF 0269	Dried grapes (=Currants ...)		0.70	Fra	62.3	135.2					1	1.5	5
FB 0269	Grapes		0.41	Aus	67	513	125	Fra	118	7	2a	7.5	20
GC 0645	Maize	0.05	0.09	Fra	62.3	260				see maize flour			
CF 1255	Maize flour	0.021		Aus	67	90					3	0.03	0
OR 0645	Maize oil, edible	0.051		Nl	63	43					3	0.03	0
FS 0247	Peach		0.22	Jpn	52.6	626	110	Fra	99	7	2a	5.1	20
VD 0072	Peas (dry)		0.24	Fra	62.3	445					1	1.7	6
VR 0589	Potato		0	NL	63	687	122	USA	99	7	2a	0	0
OR 0495	Rape seed oil, edible	0.10		Aus	67	65					3	0.1	0
GC 0654	Wheat	0.29	4.1	USA	65	383				see wheat bran and flour			
CM 0654	Wheat bran, unprocessed	0.64		Aus	67	37					3	0.35	1
CF 1211	Wheat flour	0.11		USA	65	365					3	0.62	2
											MAX IESTI = 20		

Table XI.7. Table format for IESTI calculation for children up to 6 years (parathion-methyl example).**PARATHION-METHYL (59):** international estimate of short-term intake (IESTI) for **CHILDREN UP TO 6 YEARS** ARfD = 0.03 mg/kg bw (30 ug/kg bw)

Code	Commodity	STMR or STMR-P, mg/kg	HR, mg/kg	Large portion diet		Unit weight		Variability factor	Case	IESTI, ug/kg bw	% ARfD, rounded		
				Country	Body weight, kg	Large portion, g	Unit weight g					Country	Unit wt, edible portion g
FP 0226	Apple		0.18	USA	15	679	110	Fra	100	7	2a	15.4	50
	Apple juice	0.015			15						3		
VD 0071	Beans (dry)		0.05	Fra	17.8	209					1	0.59	2
VB 0041	Cabbages, Head		0.26	Jpn	15.9	142	908	USA	717	5	2b	11.6	40
OR 0691	Cotton seed oil, edible	1.16		USA	15	6					3	0.48	2
DF 0269	Dried grapes (=Currants ...)		0.70	USA	15	59					1	2.77	9
FB 0269	Grapes		0.41	Aus	19	342	125	Fra	118	7	2a	22.6	80
GC 0645	Maize	0.05	0.09	Fra	17.8	148				see maize flour			
CF 1255	Maize flour	0.021		Aus	19	60					3	0.07	0
OR 0645	Maize oil, edible	0.051		Fra	17.8	21					3	0.06	0
FS 0247	Peach		0.22	Aus	19	307	110	Fra	99	7	2a	10.4	30
VD 0072	Peas (dry)		0.24	Fra	17.8	107					1	1.44	5
VR 0589	Potato		0	UK	14.5	279	122	USA	99	7	2a	0	0
OR 0495	Rape seed oil, edible	0.10		Aus	19	18					3	0.1	0
GC 0654	Wheat	0.29	4.1	USA	15	151				see wheat bran and flour			
CM 0654	Wheat bran, unprocessed	0.64		Aus	19	13					3	0.43	1
CF 1211	Wheat flour	0.11		Aus	19	194					3	1.13	4
											MAX IESTI = 80		

Appendix XII.

NUMBER OF TRIALS REQUIRED BY OECD MEMBER COUNTRIES

The OECD Working Group on Pesticides elaborated guidance on the minimum number of trials which should be generated for registration of a pesticide in all OECD countries where the target GAP is uniform, i.e., maximum 25% deviation in one of the key parameters. The underlying principles of the proposed scheme are basically applicable for the purpose of the JMPR as well. The assumption is that the number of trials specified in each crop production region reflects the economic (acreage) importance and/or dietary significance of the crop within that production region. Therefore, there is no need to further consider acreage or dietary intake for a crop/commodity or to determine whether a crop is major or minor in terms of acreage, diet, or trade on a global basis for the purpose of determining a minimum number of crop field trials for a comprehensive submission.

The reduction in the total number of trials within any OECD country or crop production region is compensated for by the total number of crop field trials making up the comprehensive submission data set and the wider geographic distribution of these data.

To qualify for this comprehensive submission approach, all crop field trials must meet the following criteria:

- a. Field trials are conducted according to the *c*GAP (within +/- 25% of the application rate, number of applications or PHI). At least 50% of the trials must be conducted at or above (within 25%) the *c*GAP. For this purpose, trials whose intended application rates match the *c*GAP but actual rates fall up to 10% below the *c*GAP, e.g., due to the normal variability in preparing spray solutions, are considered acceptable. In addition, some of the trials need to be decline studies depending on national requirements.
- b. The trials span a range of representative crop production practices for each crop including those likely to lead to the highest residues, e.g., irrigated vs. non-irrigated, trellis vs. non-trellis production, fall-planted vs. spring-planted.

Any reduction in the number of crop field trials should be distributed proportionally among the crop production regions as shown in the example for a 40% reduction for barley below (Table XII.1). A table with trial numbers for crops grown throughout OECD countries is given in Table XII.2. In the event that the number of required trials changes in any given region, the total number and reduced number should be adjusted accordingly.

Table XII.1. Example for calculation of minimum number of trials depending on the crop production regions

Country/Region	USA/CAN	EU	JP	AUS	NZ	Total
Number required by legislation	24	16	2	8	4	54
Number with 40% reduction	14	10	2	5	2	33

In no case may the number of trials in a given crop production region be reduced below 2. Thus, in the example in Table 3.7 the 40% reduction does not apply in Japan and therefore the total number of trials is 33 rather than 32, which is the actual 40% reduction from 54.

The minimum total number of trials for any crop in a comprehensive submission is eight. In addition, the total number of trials to be conducted may not be less than the requirement for any given individual region.

The Table XII.2 addresses only outdoor crop field trials and not greenhouse (glasshouse) or post-harvest treatments. For a comprehensive submission with similar critical GAPs, a minimum of eight greenhouse trials is needed. For such greenhouse trials, geographic distribution typically is not an issue. However for active ingredients which are susceptible to photodegradation, consideration should be given to locations at different latitudes.

The number of post-harvest trials on a commodity should be at least four, taking into consideration the application techniques, storage facilities, and packaging materials used. At least three samples should be collected and analysed in studies on bulk and bagged commodities.

Table XII.2 Minimum number of Supervised Field Trials Required at cGAP for Field (or Outdoor) Uses

	Number of trials currently required by region						Number of Trials Required by Region with 40% Reduction					
	NAFTA	EU	JP	AUS	NZ	Total	NAFTA	EU	JP	AUS	NZ	Total
Acerola (Barbados cherry)	1	4	2			7	1	2	2			5
Alfalfa	18	12	2		4	36	11	7	2		2	22
Almond	5	4	2	6	2	19	3	2	2	4	2	13
Apple	20	16	2	8	6	52	12	10	2	5	4	33
Apple, Sugar	2	4	2			8	2	2	2			6
Apricot	7	12	2	6	2	29	4	7	2	4	2	19
Arracacha	2	4	2			8	2	2	2			6
Artichoke, Globe	3	4	2		2	11	2	2	2		2	8
Artichoke, Jerusalem	3	4	2		2	11	2	2	2		2	8
Asparagus	10	8	2	4	4	28	6	5	2	2	2	17
Atemoya	1	4	2		2	9	1	2	2		2	7
Avocado	5	4	2	8	2	21	3	2	2	5	2	14
Banana	5	4	2	8		19	3	2	2	5		12
Barley	24	16	2	8	4	54	14	10	2	5	2	33
Bean, Dried	12	16	2		2	32	7	10	2		2	21
Bean, Edible Podded	9	16	2		4	31	5	10	2		2	19
Bean, Lima, Dried	3	16	2		2	23	2	10	2		2	16
Bean, Lima, Green	8	8	2	8	2	28	5	5	2	5	2	19
Bean, Mung	3	16	2		2	23	2	10	2		2	16
Bean, Snap	8	16	2		2	28	5	10	2		2	19
Bean, Succulent Shelled	8	16	2		2	28	5	10	2		2	19
Beet, Garden	8	4	2		2	16	5	2	2		2	11
Blackberry	5	4	2		2	13	3	2	2		2	9
Blueberry	11	4	2	4	2	23	7	2	2	2	2	15
Bok choy	2	4	2		2	10	2	2	2		2	8
Boysenberry	2	8	2		2	14	2	5	2		2	11
Broccoli	12	8	2	8	4	34	7	5	2	5	2	21
Broccoli, Chinese (gal Ion)	2	8	2		2	14	2	5	2		2	11
Brussels Sprouts	5	12	2	4	2	25	3	7	2	2	2	16
Buckwheat	9	8	2		2	21	5	5	2		2	14
Cabbage	12	12	2	8	4	38	7	7	2		2	23
Cabbage, Chinese	5	8	2		2	17	3	5	2		2	12

	Number of trials currently required by region						Number of Trials Required by Region with 40% Reduction					
	NAFTA	EU	JP	AUS	NZ	Total	NAFTA	EU	JP	AUS	NZ	Total
Cacao Bean (cocoa)	3	8	2			13	2	5	2			9
Calabaza	2	4	2				2	2	2			6
Calamondin	1	4	2			7	1	2	2			5
Canary seed	5	4					3	2	2			7
Canola	22	12	2	8	2	46	13	7	2	5	2	29
Cantaloupe	8	12	2	8	2	32	5	7	2	5	2	21
Carambola	2	4	2		2	10	2	2	2		2	8
Caraway seed	2	4				6	2	2	2			6
Carob	3	4	2			9	2	2	2			6
Carrot	12	16	2	8	4	42	7	10	2	5	2	26
Cassava, bitter or sweet	2	4	2		2	10	2	2	2		2	8
Cauliflower	11	12	2	8	2	35	7	7	2	5	2	23
Celery	12	8	2	4	4	30	7	5		2	2	18
Cherry, Sweet	9	4	2	3	4	22	5	2	2	2	2	13
Cherry, Tart (Sour)	8	4	2	3	2	19	5	2	2	2	2	13
Chestnut	3	4	2	4	2	15	2	2	2	2	2	8
Chickpea (garbanzo bean)	3	16	2	4	2	27	2	10	2	2	2	18
Chicory	2	8	2		2	14	2	5	2		2	11
Clover	12	12	2		4	30	7	7	2		2	18
Coconut	5	4	2			11	3	2	2			7
Coffee	5	4	2	4		15	3	2	2	2		9
Collards	5	8	2		2	17	3	5	2		2	12
Corn, Field	20	16	2	2	4	44	12	10	2	2	2	28
Corn, Pop	3		2			5	2	0	2			4
Corn, Sweet	14	8	2	6	2	32	8	5	2	4	2	21
Cotton	12	8	2	8		30	7	5	2	5		19
Cowpea (dried shelled bean)	5	16	2		2	25	3	10	2		2	17
Cowpea (forage/hay)	3	12	2		2	19	2	7	2		2	13
Cowpea, (succulent, shelled bean)	3	8	2		2	15	2	5	2		2	11
Crabapple	3	8	2		2	15	2	5	2		2	11
Cranberry	6	4	2		2	14	4	2	2		2	10
Cress, Upland	1	4	2			7	1	2	2			5
Cucumber	11	16	2	4	4	37	7	10	2	2	2	23
Currant	2	8	2		2	14	2	5	2		2	11

	Number of trials currently required by region						Number of Trials Required by Region with 40% Reduction					
	NAFTA	EU	JP	AUS	NZ	Total	NAFTA	EU	JP	AUS	NZ	Total
Dandelion	1	8	2		2	13	1	5	2		2	10
Dasheen (taro)	2	4	2		2	10	2	2	2		2	8
Date	3	4	2			9	2	2	2			6
Dill (dill seed, dillweed)	2	8	2		2	14	2	5	2		2	11
Eggplant	3	8	2		2	15	2	5	2		2	11
Elderberry	3	4	2		2	11	2	2	2		2	8
Endive (escarole)	3	4	2		2	11	2	2	2		2	8
Fennel		8	2			10		5	2			7
Fig	3	4	2		2	11	2	2	2		2	8
Filbert (hazelnut)	5	4	2		2	13	3	2	2		2	9
Flax (= linseed)	10	8	2		2	22	6	5	2		2	15
Fodder beet	0	8	2		4	14	0	5	2		2	9
Garlic	3	8	2		2	15	2	5	2		2	11
Genip	1	4	2			7	1	2	2			5
Ginger	2	4	2			8	2	2	2			6
Ginseng	5	4	2			11	3	2	2			7
Gooseberry	3	4	2		2	11	2	2	2		2	8
Grape	16	16	2		6	40	10	10	2		4	26
Grape, table		12	2	8	4	26		7	2	5	2	16
Grapefruit	8	4	2	2	2	18	5	2	2	2	2	13
Grasses	12	16	2		4	34	7	10	2		2	21
Guar	3	4	2			9	2	2		2		6
Guava	2	4	2		2	10	2	2	2		2	8
Herbs		4	2			6		2	2			4
Hops	3	12	2		2	19	2	7	2		2	13
Horseradish	3	4	2		2	11	2	2	2		2	8
Huckleberry	3	4	2		2	11	2	2	2		2	8
Kale	3	12	2		2	19	2	7	2		2	13
Kiwi fruit	3	4	2		6	15	2	2	2		4	10
Kohlrabi	3	8	2		2	15	2	5	2		2	11
Kumquat	1	4	2		2	9	1	2	2		2	7
Leek	5	12	2	4	2	25	3	7	2	2	2	16
Lemon	5	8	2	6	2	23	3	5	2	4	2	16
Lentil	8	4	2		2	16	5	2	2		2	11
Lettuce, Head	13	8	2	8	3	34	8	5	2	5	2	22

	Number of trials currently required by region						Number of Trials Required by Region with 40% Reduction					
	NAFTA	EU	JP	AUS	NZ	Total	NAFTA	EU	JP	AUS	NZ	Total
Lettuce, Leaf	13	8	2	8	3	34	8	5	2	5	2	22
Lime	3	4	2		2	11	2	2	2		2	8
Loganberry	2	8	2		2	14	2	5	2		2	11
Longan	1	4	2			7	1	2	2			5
Lotus Root	1	4	2			7	1	2	2			5
Lychee	1	4	2	2		9	1	2	2	2		7
Macadamia Nut	3	4	2	6	2	17	2	2	2	4	2	12
Mamey Sapote	2	4	2			8	2	2	2			6
Mandarin (tangerine)	5	8	2	8	4	27	3	5	2	5	2	17
Mango	3	4	2	8		17	2	2	2	5		11
Melon	3	12	2		2	19	2	7	2		2	13
Melon, Casaba	3	12	2		2	19	2	7	2		2	13
Melon, Crenshaw	3	12	2		2	19	2	7	2		2	13
Melon, Honeydew	5	12	2		2	21	3	7	2		2	14
Millet, Proso	8	8	2		2	20	5	5	2		2	14
Mint	5	8	2		2	17	3	5	2		2	12
Mulberry	3	8	2			13	2	5	2			9
Mushrooms	3	8	2	6	2	21	2	5	2	4		13
Muskmelons	8	12	2		2	24	5	7	2		2	16
Mustard Greens	8	8	2		2	20	5	5	2		2	14
Mustard, Chinese	2	8	2		2	14	2	5	2		2	11
Mustard seed	5	8				13	3	5	2			10
Nectarine	10	12	2	8	2	34	6	7	2	5	2	22
Oat	26	16	2	6	2	52	16	10	2	4	2	34
Okra	5	4	2		2	13	3	2	2		2	9
Olive	3	8	2		2	15	2	5	2		2	11
Onion, Dry Bulb	12	16	2	8	4	42	7	10	2	5	2	26
Onion, Green	5	8	2	4	2	21	3	5	2	2	2	14
Orange, Sour and Sweet	16	8	2	8	4	38	10	5	2	5	2	24
Papaya	3	4	2			9	2	2	2			6
Parsley	3	4	2	2	2	13	2	2	2	1	2	9
Parsnip	6	8	2		2	18	4	5	2		2	13
Passion Fruit	2	4	2		2	10	1	2	2		2	7
Pawpaw	3	4	2			9	2	2	2			6
Pea, Chinese	1	8	2		2	13	1	5	2		2	10

	Number of trials currently required by region						Number of Trials Required by Region with 40% Reduction					
	NAFTA	EU	JP	AUS	NZ	Total	NAFTA	EU	JP	AUS	NZ	Total
Pea, Dried Shelled	13	16	2	8	2	41	8	10	2	5	2	27
Pea, Edible podded	8	12	2	6	2	30	5	7	2	4	2	20
Pea, Edible Podded	3	8	2		2	15	2	5	2		2	11
Pea, Field (Austrian Winter) (forage/hay)	3	12	2	8	2	27	2	7	2	5	2	18
Pea, Succulent Shelled (Pea, Garden, Succulent)	14	12	2		2	30	8	7	2		2	19
Peach	16	12	2	8	4	42	10	7	2	5	2	26
Peanut	12	4	2	8		26	7	2	2	5		16
Peanut, Perennial	3	4	2			9	2	2	2			6
Pear	11	16	2	8	4	41	7	10	2	5	2	26
Pecan	5	4	2	4	2	17	3	2	2	2	2	11
Pepper, (other than bell)	3	4	2		2	11	2	2	2		2	8
Pepper, Bell	12	12	2		2	28	7	7	2		2	18
Persimmon	3	4	2		4	13	2	2	2		2	8
Pimento	2	4	2		2	10	2	2	2		2	8
Pineapple	8	4	2			14	5	2	2			9
Pistachio	3	4	2			9	2	2	2			6
Plantain	3	4	2			9	2	2	2			6
Plum	11	12	2	8	2	35	7	7	2	5	2	23
Pomegranate	3	4	2			9	2	2	2			6
Potato	26	16	2	8	4	56	16	10	2	5	2	35
Pumpkin	8	8	2	4	2	24	5	5	2	2	2	16
Quince	3	4	2		2	11	2	2	2		2	8
Radish	7	8	2		2	19	4	5	2		2	13
Radish, Oriental (daikon)	2	4	2		2	10	2	2	2		2	8
Rapeseed	3	12	2		2	19	2	7	2		2	13
Raspberry, Black and Red	6	4	2		2	14	4	2	2		2	10
Rhubarb	5	4	2		2	13	3	2	2		2	9
Rice	16	8	2	6		32	10	5	2	4		21
Rice, Wild	5	8	2			15	3	5	2			10
Rutabaga	8	8	2		2	20	5	5	2		2	14
Rye	10	16	2		2	30	6	10	2		2	20
Safflower	6	8	2		2	18	4	5	2		2	13
Sainfoin	3	12	2		2	19	2	7	2		2	13

	Number of trials currently required by region						Number of Trials Required by Region with 40% Reduction					
	NAFTA	EU	JP	AUS	NZ	Total	NAFTA	EU	JP	AUS	NZ	Total
Salsify	3	8	2		2	15	2	5	2		2	11
Saskatoons	2	4				6	2	2	2			6
Sesame	3	4	2			9	2	2	2			6
Shallot	3	8	2		2	15	2	5	2		2	9
Sorghum, Grain	12	8	2	6	2	30	7	5	2	4	2	20
Soybean (dried)	20	12	2	8	4	46	12	7	2	5	2	28
Spices		4	2			6		2	2			4
Spinach	11	8	2		2	23	7	5	2		2	16
Squash, Summer	11	8	2		4	25	7	5	2		2	16
Squash, Winter	5	8	2		2	17	3	5	2		2	12
Strawberry	10	16	2	8	4	40	6	10	2	5	2	25
Sugar Beet	14	16	2	2		34	8	10	2	2		22
Sugarcane	8	4	2	8		22	5	2	2	5		14
Sunflower	10	12	2	8	2	34	6	7	2	5	2	22
Sweet Potato	8	4	2		2	16	5	2	2		2	11
Chard Swiss	3	4	2		2	11	2	2	2		2	8
Tangelo	3	4	2		2	11	2	2	2		2	8
Tanier (cocoyam)	2	4	2			8	2	2	2			6
Tea		4	2			6		2	2			4
Tobacco	8	4	2		2	16	5	2	2		2	11
Tomato	27	16	2	8	4	57	16	10	2	5	2	35
Triticale	5	16	2	4	2	29	3	10	2	2	2	19
Turnip, root	5	4	2		4	15	3	2	2		2	9
Turnip, tops (leaves)	5	4	2		2	13	3	2	2		2	9
Walnut, Black and English	3	8	2		2	15	2	5	2		2	11
Watercress	2	4	2		2	10	2	2	2		2	8
Watermelon	8	4	2	4	2	20	5	2	2	2	2	13
Wheat	33	16	2	12	4	67	20	10	2	7	2	41
Yam, True	3	4	2		2	11	2	2	2		2	8

Appendix XIII.

CRITICAL VALUES FOR MANN-WHITNEY U-TEST AT $\alpha=0.05$

n_1 and n_2 are the number of data points in residue data sets 1 and 2 respectively, where n_1 is the smaller when the sample sizes are different. If the calculated U_1 statistics is greater than the tabulated critical value, it indicates that the samples probably came from populations with the same median. (The two populations are not different.)

n_1	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25
n_2																							
4	-	0																					
5	0	1	2																				
6	1	2	3	5																			
7	1	3	5	6	8																		
8	2	4	6	8	10	13																	
9	2	4	7	10	12	15	17																
10	3	5	8	11	14	17	20	23															
11	3	6	9	13	16	19	23	26	30														
12	4	7	11	14	18	22	26	29	33	37													
13	4	8	12	16	20	24	28	33	37	41	45												
14	5	9	13	17	22	26	31	36	40	45	50	55											
15	5	10	14	19	24	29	34	39	44	49	54	59	64										
16	6	11	15	21	26	31	37	42	47	53	59	64	70	75									
17	6	11	17	22	28	34	39	45	51	57	63	69	75	81	87								
18	7	12	18	24	30	36	42	48	55	61	67	74	80	86	93	99							
19	7	13	19	25	32	38	45	52	58	65	72	78	85	92	99	106	113						
20	8	14	20	27	34	41	48	55	62	69	76	83	90	98	105	112	119	127					
21	8	15	22	29	36	43	50	58	65	73	80	88	96	103	111	119	126	134	142				
22	9	16	23	30	38	45	53	61	69	77	85	93	101	109	117	125	133	141	150	158			
23	9	17	24	32	40	48	56	64	73	81	89	98	106	115	123	132	140	149	157	166	175		
24	10	17	25	33	42	50	59	67	76	85	94	102	111	120	129	138	147	156	165	174	183	192	
25	10	18	27	35	44	53	62	71	80	89	98	107	117	126	135	145	154	163	173	182	192	201	211

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