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Food and Agriculture Organization
of the United Nations

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

Third edition

PESTICIDE RESIDUES

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FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS
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PREFACE

The basic principle of the work undertaken by members of the Joint FAO/WHO Meeting on Pesticide Residues (JMPR), is the continuous evaluation of new scientific developments and guidance documents. In considering such initiatives, the members draw on their own experience to elaborate and apply new principles and approaches in the assessment of data. The aim being to make best use of all available information when making recommendations to the Codex Committee on Pesticide Residues (CCPR) and Codex Members in order to ensure consumer safety and facilitate international trade.

The 3rd edition of the FAO Manual incorporates the current working principles applied by the FAO Panel for evaluation of pesticide residues to recommend maximum residue levels, STMR and HR values and to assess the dietary exposure of consumers.

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

- incorporation of the 'Risk analysis principles applied by the CCPR' in the working procedures of the JMPR;
- method validation and performance criteria of analytical methods applied in supervised trials, including sample preparation and processing, and considering residues below LOQ;
- risk assessment of metabolites and degradates of pesticides by applying the threshold toxicological concern, TTC, approach;
- principles of grouping crops for recommending residue levels for commodity groups;
- use of proportionality of residues for adjusting residue values to match cGAP;
- application of the concept of 'Global GAP';
- estimation of maximum residue levels based on the results obtained with the OECD MRL calculator;
- refined procedures for estimation EMRL and residue levels for spices;
- application of the GEMS/Food 17 cluster diet for estimation of long-term dietary intake of pesticide residues;

The reporting of supervised trials are assisted with the attached electronic versions of the Excel templates and spreadsheets to the Manual that can be downloaded from the FAO Homepage http://www.fao.org/agriculture/crops/thematic-sitemap/theme/pests/jmpr/jmpr-docs/en/

The JMPR will continue its activities with respect to considering and refining assessment methodologies to ensure the best use is made of all available information. Where modifications to current practices are deemed warranted, the basis for such changes will be elaborated in the annual JMPR Reports. The reader is advised to consult the Reports for information on any such new developments. (http://www.fao.org/agriculture/crops/core-themes/theme/pests/jmpr/jmpr-rep/en/).

ACKNOWLEDGEMENT

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

During past years the Members of the FAO Panels took active part in the elaboration of the working principles, which are included in this and the previous editions.

Mrs. Trijntje van der Velde-Koerts proposed substantial structural changes of the 3rd edition of the Manual to improve usability and facilitate the finding of relevant information. Professor Eloisa Dutra Caldas, Mr. Makato Irie, Dr. Dugald MacLachlan, Dr. Mi-Gyung Lee, Mr. David Lunn, Dr Samuel Margerison, Mr. Christian Sieke, Dr Anita Strömberg, Dr.Yukiko Yamada, and Dr Guibiao Ye provided additional suggestions for improving the clarity and relevance of the text. Dr Mi-Gyung Lee prepared Annex 2 of Appendix X. Mr. Christian Sieke provided the Excel template for calculation of animal burden

Dr Yong Zhen Yang, FAO Joint Secretary, contributed with useful comments and suggestions to the preparation of the manuscript. All contribution and assistance are sincerely appreciated.

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

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CHAPTER 1

INTRODUCTION

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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. The meeting was held 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:

a. 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

b. Residues found in surveys of marketed commodities

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

d. National nutritional patterns

e. 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 JMPR is primarily responsible for performing the dietary risk assessments and proposing maximum residue levels upon which the Codex Committee on Pesticide Residues (CCPR) and ultimately the Codex Alimentarius Commission (CAC), as well as other interested parties, base their dietary risk management decisions on Maximum Residue Limits (MRLs). JMPR proposes maximum residue levels based on residue data according to GAP/registered uses or in specific cases, such as Extraneous Maximum Residue Limit (EMRL) and MRL recommendations for spices, based on monitoring data.

The JMPR provides the CCPR and other interested parties with science-based risk assessments that include the four components of risk assessment as defined by CAC, namely hazard identification, hazard characterisation, dietary exposure assessment and dietary risk characterisation that can serve as the basis for CCPR's discussions.

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 Director Generals 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. Based on this information, the Panel propose residue definitions, estimates maximum residue levels, highest residues (HR) 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 MRLs as 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 JMPR, in its assessments, identifies and communicates to the CCPR any information on the applicability and any constraints of the risk assessment in regard to the general population and to particular subpopulations and shall, as far as possible, seek to identify potential risks to

populations of potentially enhanced vulnerability, e.g., children after conducting long- and short-term dietary exposure assessment.

The JMPR communicates to the CCPR possible sources of uncertainties in the dietary exposure assessment and/or in the hazard characterisation of the pesticide that, if resolved, would allow a refinement of the dietary risk assessment.

The monographs prepared by the FAO Panel summarise 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 assessments 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
- evaluation of new information relating to compounds other than new or periodic review chemicals.

The main aspects of the assessment process carried out by the FAO Panel[1] are described below.

- The Codex MRL-setting process begins with a member or observers nominating a pesticide for assessment by the JMPR. In considering the nomination, the CCPR, in consultation with the JMPR Joint Secretaries may then prioritise and schedule the pesticide for assessment.
- The WHO Core Assessment Group considers available data encompassing a wide range of toxicological endpoints with the aim of estimating an acceptable daily intake (ADI) and an acute reference dose (ARfD) where necessary and if sufficient data are available.
- The FAO Panel of Experts on Pesticide Residues in Food and the Environment considers data on registered use patterns, fate of residues, animal and plant metabolism, analytical methodology and residue data derived from supervised residue trials in order to propose residue definitions and maximum residues levels for the pesticide in food and feed.
- The JMPR risk assessment includes the estimation of both short-term (single day) and long-term (life time) dietary exposures and their comparison with the relevant health-based guidance values (toxicological benchmarks). Maximum residue level recommendations in or on food and animal feeds are based on Good Agricultural Practice (GAP) information, taking into account information on dietary intakes, and consumption of foods derived from commodities that comply with the respective MRLs and are intended to be toxicologically acceptable.

[1] Codex Alimentarius Commission Procedural Manual –Twenty third edition, 2015, www.codexalimentarius.net

- The CCPR considers the recommendations of the JMPR in the light of information provided in the relevant JMPR reports and monographs. Maximum residue level recommendations accepted by the CCPR are submitted to the CAC for adoption as Codex MRLs (CXLs). An active periodic review program complements this process.
- It is the prerogative of the CCPR to accept or reject those recommendations, including recommendations to withdraw previous proposed maximum residue levels. The CCPR has the option to consider other factors that it deems appropriate in retaining MRLs.

The principles of evaluation of new compounds and compounds under the periodic review programme are very similar. 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 and often deals with and clarifies a single question raised by the CPR. The scope and depth of periodic review and re-evaluations are substantially different.

The agenda of the meetings is decided by the Joint Secretaries of FAO and WHO, based on the priority list proposed by the CCPR 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. The data directory should be submitted to the joint FAO Secretary by 1 September.

Once the agenda of the JMPR has been agreed, The FAO Joint Secretary of JMPR assigns the compounds for review to the members of the FAO Panel and informs data submitters accordingly. 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.

Member countries, industry and other data submitters are requested to supply the FAO Joint Secretary of JMPR and the assigned Panel Member before the stated deadline 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 assigned Panel member performs the assessment 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.

1.5 Data and information required for JMPR evaluations

1.5.1 New and periodic reviews

The data and information needed for the evaluation of pesticide residues of new compounds and compounds evaluated within the periodic review programme are very similar and outlined in this section. Data submitters are advised to follow the guidelines in this chapter when compiling their data package.

In situations where the active ingredient is supported by a data owner, the JMPR would expect and require all relevant study reports, as described in this Manual, to be submitted for consideration and that these would be of an adequate quality. 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 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 and those data which it considers "desirable" are listed when these are found to be lacking or if areas are insufficiently addressed in data submissions.

An objective of the JMPR assessment is to make the best use of the submitted studies, regardless of the age of the studies. Consequently, countries and industry are requested to provide all relevant information, including original reports, irrespective of whether it has 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 are not accompanied by adequate details of the conduct of the field trial, the conditions of sample handling, transportation, storage conditions and pre-analysis storage intervals or details of the analysis (including associated recovery data).
- Residue data developed with non-selective analytical methods, e.g., colorimetric analysis or bioassay.
- 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.

The content and format of a submission (data package) should follow the format of the JMPR evaluations: identity, physical and chemical properties, plant metabolism, rotational crop studies, livestock metabolism, environmental fate, analytical methods, freezer storage stability, use pattern, residues from supervised trials, fate of residues in storage and processing, animal feeding studies, residues in food in commerce, national residue definitions, reference list.

Normally, plant protection products are supported by a commercial sponsor, i.e., a pesticide manufacturer, which would be expected to generate and provide the necessary data for consideration in the establishment of health-based guidance values and MRLs.

However, situations may occur for older pesticides in which is either no support from the company that generated the original data, or that the available data is either incomplete or does not meet contemporary standards, i.e., based on out-dated guidelines and or specifications, and as a result be of limited utility in a contemporary evaluation. Nevertheless, the JMPR may be asked by the CCPR, in the context of periodic re-evaluations, to consider such active ingredients for maximum residue level recommendations.

In formulating the problem to be addressed by the risk assessment, the following issues that will need to be resolved are[2]:

1. Is the compound supported by the data owner?
2. Is the compound or one of its isomers registered, reviewed or likely to be registered in a country or region?
3. Is there sufficient information available to enable a meaningful evaluation?
4. What is the specific concern (duration of exposure, population exposed, source of residue in food)?
5. What form of advice would be most helpful to the risk manager?
6. If such advice cannot be provided (e.g. because of data limitations), is there alternative advice that might be of value?

In situations where a pesticide is no longer sponsored or supported by a company (typically older active ingredients) a full data package may not be available. In these cases, in order to maintain consistency in the quality of its assessments, the JMPR would adhere to the following principles:

- The requesting country should be responsible for providing information on the intended uses, specification of the technical active substance used in the country and a justification for assessment by the JMPR.
- The information required would be such that it would allow the key questions relating to human health assessments to be addressed. Including the establishment of health based guidance values such as an acceptable daily intake (ADI) and/or acute reference dose (ARfD), when required, and the definition of residues for enforcement of MRLs and dietary risk assessment. Furthermore, data from a sufficient number of supervised trials in or on food and feed crops reflecting the current use patterns specified on the relevant labels would be required for the estimation of maximum residue levels and supervised trials median residue (STMR) and highest residue (HR) values. Trial data may be complemented by relevant selective survey residue data. A complete list of information required is described in Chapter 3.
- It is the responsibility of the requesting country to provide the available data and other relevant information, such as available assessments by supranational and national authorities and publications from a recently conducted literature search.
- If literature studies are to be relied upon, the JMPR will weigh such studies for their quality and design. As it is unlikely the raw data would be available, study reports need to include sufficient information on the methods and results to enable the findings to be reconstructed.

[2] . FAO/WHO, 2012. Pesticide Residues in Food, Joint FA/WHO Meeting on Pesticide Residues - Report 2012, FAO Plant Production and Protection Paper 2015, pp. 3-5.

- If critical data are missing, then the JMPR may still determine that an assessment is possible; in such cases, however, it is likely that conservative assumptions will be applied to address any information gaps.

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.

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. -

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.

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.

1.5.1.1 New and existing MRLs

A periodic review compound, unlike a new compound, already has existing MRL recommendations.

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.

Where adequate information is supplied on an individual commodity, the MRL is either revised or confirmed to be relevant to modern GAP.

When information is available on only a single commodity for which a group MRL exists it may be necessary to withdraw the group MRL and estimate a single-commodity MRL.

1.5.1.2 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 only assume that there is no GAP for that commodity. Only GAP supplied for the purposes of re-evaluation, corresponding to the targeted application conditions, is considered valid. If no GAP information is supplied, or GAP information is available but the supporting trial residue data provided is considered insufficient, the JMPR may withdraw its previous recommendation.

1.5.1.3 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:

- conclude on the definition of residues for new compounds, and
- revise or confirm the residue definition for periodic review compounds,
- 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.

1.5.2 Re-evaluations

In the light of new uses of a compound or additional information on its residues the compound may have to be re-assessed, 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 maximum residue levels for additional commodities, propose changes to 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 standard 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 on occasion 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 estimate STMR and HR values when all the relevant data for a particular compound are available, i.e., 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.

Usually new information on GAP and related data from trials do not cause difficulties provided the data received are of the same type and in agreement with data from earlier evaluations. However, information concerning new developments in the area of metabolism of a compound may be more problematic. Such information may require that the original residue definition be changed, complicating the evaluation of old and new data together. Other than in exceptional circumstances the evaluation of additional metabolism studies and of supervised trials providing 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 where one is also a metabolite of the other, and for toxicological or other reasons a decision is taken that each pesticide must subsequently be determined separately. In such cases old residue trial data can often be found to be unsuitable.

Improvements of analytical procedures may also cause difficulties. If the LOQ is lowered, the old residue data based on the original LOQ are difficult to interpret and may be inapplicable and unavailable for later evaluations. In this situation, as for new information on the metabolic profile of the compounds, the whole data set of 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 account.

CHAPTER 2

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

CONTENTS

2.1 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 or supranational 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 the JMPR. If submitted, these studies will not be referenced or summarised in the Monograph.

The dossier to be submitted to the FAO Panel of the 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. Identity and physical chemical properties
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 or at consumption
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).

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 an electronic format, the reports should first be scanned in pdf formats.

JMPR requests at least the electronic copies of the reports which can be submitted on a CD or DVD disk and/or secured file transfer systems. Electronic copies of the reports are preferably submitted in such a pdf format which enables copying the relevant parts (including figures of metabolic schemes). Some JMPR members may request paper copies of specific studies and word documents of the manufacturer's summary. Scanned documents should be provided only for old reports for which electronic copies are not available.

The structure of submission may follow the outline presented above. A good index prepared in MS Word giving the full title of the reports and the report number, preferably with a hyperlink to the report, is necessary to assist quick location of the relevant reports.

The working paper (monograph) should be prepared and submitted in MS Word. The summary of the relevant data of supervised trials should be prepared in the format needed for the FAO Evaluation (portrait, no merged cells) and preferably also in Excel file format, according to the example given in Appendix **VII.** Working papers, summaries of GAP and residue data should be provided in MS Word format and diagrams of metabolism pathways prepared using a commercial chemical structure drawing program suitable for inclusion as a graphic in the document.

2.2 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 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.

2.3 Working paper

Manufacturers are required to submit a working paper 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 "*JMPR evaluations requirements and practices*". 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.

2.3.1 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 3

JMPR EVALUATIONS – REQUIREMENTS AND PRACTICES

CONTENTS check if it reflecting the content

3.1 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 FAO Panel member prepares the Evaluation of all relevant information concerning the pesticide, and an Appraisal summarising the findings, conclusions and recommendations, and giving full explanation and reasoning for them. The Evaluations and Appraisals are prepared in a uniform format, described in Appendix X., to facilitate access to the required information by the reader. The Evaluations and Appraisals are published by FAO in the series *Pesticide Residues in Food - Evaluations Part I. Residues*. In addition, the recommendations for each compound and other issues discussed by the JMPR 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 Evaluation and Appraisal and includes the reasoning behind the conclusions and recommendations so that the reader can understand the basis for the recommendations. The increased volume of the Evaluations since the early to mid-1990s is largely due to the inclusion of more detailed explanations and reflects the increased resources required for the work.

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. 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 from multiple applications in successive years, by following crops, and the contamination of the environment by persistent residues likely to lead to residues in food or feed commodities. 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 analytical methods with accompanying chromatograms and information on stability of residues during sample storage are evaluated to assess the reliability of trial data and to estimate Limits of Quantification of residues which can be realistically achieved in regulatory laboratories.

It is outside of the responsibilities of JMPR to approve uses of pesticides. 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 supported by approved labels. The estimated maximum residue level is 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 estimated maximum residue levels for residues in commodities of animal origin are mainly based on 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 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 5, Section 11.1).

3.2 Identity and physical chemical properties

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)
Octanol-water partition coefficient (at stated pH and temperature)
Solubility (Water and organic solvents at stated temperatures)
Specific gravity (... g/cm^3 at ...stated temperature)
Hydrolysis in sterile water in the dark (at stated pH and temperature)
Photolysis in sterile water
Dissociation constant
Thermal stability

Technical material
Minimum purity (in %)
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

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 fate and behaviour of residues on treated crops after application.

The solubility of the pesticide is of particular 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.

3.3 Metabolism and environmental fate

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, 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. In addition to the chemical characteristics of the pesticide, the metabolism in animals depends on the species and the conditions of the dosing.

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

primarily on toxicological studies in experimental mammals, 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 obtained from metabolism studies 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.

Information is required on:

- Plant metabolism
- Rotational crop studies
- Animal metabolism
- Environmental fate in soil, and water-sediment systems

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, excretion in animals, soil degradation) and show the efficiency of extraction procedures for various components of the residue.

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; e.g. during processing of raw agricultural commodities.

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.

Radio-labelled 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 (^{3}H) 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 radio-labelled 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 targeted (1×) application rates are generally necessary to assess whether threshold levels are exceeded or not. However, dosing with an exaggerated rate, e.g., 5×, is recommended when it is anticipated that residue levels from 1× treatment will be too low to define the metabolic pathways.

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 Livestock[3].

[3] OECD Guidelines for the Testing of Chemicals, Test No. 501: Metabolism in Crops; Test No. 503: Metabolism in Livestock http://www.oecd-ilibrary.org/content/book/9789264061835-en

During the conduct of the metabolism studies, it may be helpful to retain radio-labelled 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 working document should indicate where this information can be found. Ideally the results of these studies should be presented as shown in Table 3.2.

Table 3.2 Summary of results of radiovalidation of analytical methods

Sample	Compound analysed	Results based on ^{14}C determination [mg/kg]	Reanalysis of samples	
			Residues found [mg/kg]	Method reference
Wheat grain		0.0152	0.0121	
Lettuce		0.2109	0.223	
Soya beans		0.342	0.296	
Goat liver		0.0553	0.0234	
Goat muscle		0.0662	0.0553	

The statement indicating that the chromatographic profile was similar provides only qualitative information

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.

In case of metabolism studies, the stability tests should show that the basic profile of radio-labelled residues has not changed throughout the duration 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.

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 consider in detail the metabolism of experimental laboratory animals, e.g., rats, mice, guinea pigs, rabbits and dogs, and the FAO Panel will assess the metabolism of farm animals, e.g., cattle, goats, sheep, pigs and chickens, in their Evaluations. 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.

3.3.1 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 radio-labelled 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).

Metabolism studies on one crop from a category 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 categories.

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.

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 through 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.

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.

3.3.2 Rotational crop studies

Metabolism and residue studies conducted in rotational crops (sometimes referred to as follow-up, following or succeeding crops) are typically required for uses of pesticides where it is reasonable to expect 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).

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 group[4].

Specifically the studies fulfil these purposes:

[4] OECD Guidelines for the Testing of Chemicals, Test No. 502: Metabolism in Rotational Crops http://www.oecd-ilibrary.org/content/book/9789264061859-en

- 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 radio-labelled test substance applied at a rate equivalent to the maximum seasonal rate (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 radio-labelled 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 expected in the rotational schedule should be included 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.

Residues in rotational crops are determined to verify if and at what levels residues detected in the rotational crop metabolism study 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 assessment.

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 crops[5]. 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.

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.

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

3.3.3 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 radio-labelled 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.

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 quantified[6].

3.3.4 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 3.3.

Table 3.3 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	Condi-tional	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)

[6] OECD Guidelines for the Testing of Chemicals Test No. 503: Metabolism in Livestock http://www.oecd-ilibrary.org/content/book/9789264061873-en

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	
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	
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	Condi-tional	Conditional	Conditional	Conditional	No	Requirement conditional on results of confined rotational crop study.
Field dissipation studies	Conditional	Condi-tional	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.

3.4 Residue analysis

3.4.1 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 (including efficiency of extraction), 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%) and relative standard deviation of replicate analyses (usually $\leq$ 20%) were achieved. The limit of detection provides an indication of presence of low level resides 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.

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 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, despite potentially lower recovery rates, 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. 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 dietary 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 expected 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 dietary 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, including those used as feed, animal tissues, milk and eggs as appropriate, and by-products used as feed;
- cover all edible animal commodities if animals are likely to consume treated crops;
- include processing fractions if detectable residues occur.

Enforcement methods should be suitable, where technically possible, to quantify residues at or below 0.01 mg/kg, or at least ≤0.3 × MRL, if the MRL ≤ 0.01 mg/kg. The exception is, in the latter case, when the residues are present in non-detectable concentration and the MRL is subsequently set at LOQ.

In general, residue analytical methods applied in various studies should be validated for all matrices to demonstrate that they fit for the purpose. The extent of validation depends on the information already available and reported. Full validation data should be provided only for new methods or when existing methods are significantly changed (e.g. change of solvent systems or quantitation techniques). Such changes may be required when adapting methods to different commodities.

In the case of studies involving plant material, the number of commodities to be tested is dependent on the use of the product. Validation data should be submitted for all sample matrices to be analysed and should be carried out for all components of the expected residue definition for enforcement and dietary risk assessment. Full validation experiments should be performed predominantly on one raw agricultural commodity (RAC) from each of the representative commodity categories given in Table 3.3.

If animals are likely to consume treated crops and if feeding studies are required/submitted, methods for determination of residues in products of animal origin should be validated in the following matrices: milk, eggs, and all edible tissues. The tissues normally include cattle muscle, fat, liver, and kidney as well as poultry muscle, fat, and liver. In most cases, the recovery data for cattle commodities are valid for products of goats, hogs, horses, sheep, and poultry.

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 in several internationally accepted guidance documents [7,8,9].

The minimum requirements of the full validation scheme are:

- five recovery experiments conducted on at least 2 levels (LOQ and 10× LOQ);
- analysis of two control samples;
- single point calibration at 5 or duplicate injections at 3 concentration levels covering the analytical range of the method

When an existing method, which has been previously fully validated, is adapted to other "comparable" commodities within a category usually reduced or limited validation sets are sufficient.

The minimum requirements of the reduced validation scheme are:

- three recovery experiments per level were conducted on at least 2 levels (LOQ and 10× LOQ);
- analysis of two control samples;

[7] 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

[8] OECD, Guidance Document on Pesticide Residue Analytical Methods, Series on Pesticides No. 39, ENV/JM/MONO(2007)17, 2007.

[9] European Commission, Guidance document on analytical quality control and validation procedures for pesticide residues analysis in food and feed. SANCO/12571/2013.

- single point calibration at 5 or duplicate injections at 3 concentration levels covering the analytical range of the method.

During the analyses of the samples the performance of the methods should be verified with appropriate quality control tests.

The minimum general performance criteria of the acceptable methods are:

- the concentration response relationship should be linear in the calibrated range (both pure solvents and/or matrix-matched calibration);
- the analyte concentration does not change during whole analysis procedure in the extracts and calibration solutions;
- the average recovery and its repeatability relative standard deviation is within the limits given in Table 3.6.

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.

It is useful to prepare a summary table giving the essential information about the methods used. With a brief description of the methods involved following the table.

Table 3.4 Example for summarised information on analytical methods used in various studies[10]

Matrix	Analyte	Method	Principle	LOQ (mg/kg)	Reference
Wheat forage Wheat straw Wheat grain Barley forage Barley straw Barley grain Barley products	Metrafenone CL 3000402 CL 434223 CL 376991	RLA 12619.02 RLA 12619.03V (993/0)	Methanol/water extraction Dichloromethane partition SPE clean-up LC-MS/MS analysis Metrafenone m/z 409 → m/z 209 / m/z 411 → m/z 209 CL 3000402 m/z 423 → m/z 241 / m/z 425 → m/z 243 CL 434223 m/z 395 → m/z 195 / m/z 397 → m/z 195 CL 376991 m/z 395 → m/z 209 / m/z 397 → m/z 209	0.01	2001/7001048, 2001/7001770, 2002/1004080
Grape Wine Barley grain	Metrafenone	DFG S19	Aqueous acetone extraction Acetone/ethyl acetate/cyclohexane partition GPC and silica gel column clean-up GC-ECD analysis	0.01	2000/7000136

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.

Table 3.5 Typical commodity groups[a] for validation of analytical methods[9]

Commodity groups	***Typical commodity categories***	***Typical representative commodities***
1. High water content	Pome fruit	Apples, pears
	Stone fruit	Apricots, cherries, peaches,
	Other fruit	Bananas
	Alliums	Onions, leeks
	Fruiting vegetables/cucurbits	Tomatoes, peppers, cucumber, melon
	Brassica vegetables	Cauliflower, Brussels-sprouts, cabbage, broccoli
	Leafy vegetables and fresh herbs	Lettuce, spinach, basil
	Stem and stalk vegetables	Celery, asparagus
	Forage/fodder crops	Fresh alfalfa, fodder vetch, fresh sugar beets
	Fresh legume vegetables	Fresh peas with pods, peas, mange tout, broad beans, runner beans, French beans
	Leaves of root and tuber vegetables	Sugar beet and fodder beet tops
	Fresh Fungi	Champignons, chanterelles
	Root and tuber vegetables or feed	Sugar beet and fodder beet roots, carrots, potatoes, sweet potatoes
2. High acid content and high water content	Citrus fruit	Lemons, mandarins, tangerines, oranges
	Small fruit and berries	Strawberry, blueberry, raspberry, black currant, red currant, white currant, grapes
	Other	Kiwifruit, pineapple, rhubarb
3. High sugar and low water	Honey, dried fruit	Honey, raisins, dried apricots, dried

[10] FAO/WHO. Pesticide Residues in Food, Joint FAO/WHO Meeting on Pesticide Residues – Report 2010, FAO Plant Production and Protection Paper 200, pp. 8-11

Commodity groups	***Typical commodity categories***	***Typical representative commodities***
content		plums, fruit jams
4a. High oil content and very low water content	Tree nuts	Walnuts, hazelnuts, chestnuts
	Oil seeds	Oilseed rape, sunflower, cotton-seed, soybeans, peanuts, sesame etc.
	Pastes of tree nuts and oil seeds	Peanut butter, tahini, hazelnut paste
4b. High oil content and intermediate water content	Oils from tree nuts, oil seeds and oily fruits	Olive oil, rapeseed oil, sunflower oil, pumpkin seed oil
	Oily fruits and products	Olives, avocados and pastes thereof
5. High starch and/or protein content and low water and fat content	Dry legume vegetables/pulses	Field bean, dried broad bean, dried haricot bean (yellow, white/navy, brown, speckled), lentils
	Cereal grain and products thereof	Wheat, rye, barley and oat grain; maize, rice Wholemeal bread, white bread, crackers, breakfast cereals, pasta
6. "Difficult or unique commodities"		Hops Cocoa beans and products thereof, coffee, tea Spices

[a]: The commodity groups and categories conform with the OECD Guidance document (ref. 8) but provides more detailed information.

Table 3.6 Method performance criteria for analysis of pesticides[7,9]

Concentration Level	Repeatability relative standard deviation [%]	Range of mean recovery [%]
≤ 1 µg/kg	35	50-120
> 1 µg/kg ≤ 0.01 mg/kg	30	60-120
> 0.01 mg/kg ≤ 0.1 mg/kg	20	70-120
> 0.1 mg/kg ≤ 1.0 mg/kg	15	70-110
➢1.0 mg/kg	10	70-110

3.4.2 Extraction efficiency of residue analytical methods

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.

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 report[11] 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 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).

3.4.3 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:

- design of the study - (intended sampling intervals, replication, number of procedural recovery tests);

[11] 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.

- 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(conc) vs time will provide the disappearance half-life. Half-life = $\ln(0.5) \div$ slope.

Storage time for 30% loss of residue = $0.51 \times$ half-life = approximately $0.5 \times$ half-life.

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

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 above[12].

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:

- commodities with high water content;

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

- 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.

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[9, 11,13].

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.

3.5 Use pattern

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

[13] 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.

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 the 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.

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

the actual Codex Commodity Classification[14]. 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 3.7).

Table 3.7 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 3.6–3.8). 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 3.8 Registered uses of ..... 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
Lettuce	France	WP 800 g/kg	foliar	0.64				21-41[c]
Lettuce	Israel[3]	WP 800 g/kg	foliar	2.0		weekly		11

[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 01 Fruits has been adopted by CAC (Annex 3 of Appendix X. The reader is advised to check which groups have been finalised and enforced by the Committee/CAC

[a] give growth stage if relevant for the application of the pesticide
[b] in days or weeks
[c] summer PHI 21 days, winter PHI 41 days

Table 3.9 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 3.10 Registered uses of .... for direct external animal treatment.

Animal [a]	Country	Formulation	Application			WHP slaughter [e]	WHP milk [f]
			Method [b]	Rate [c]	Conc. [d]	days	days
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. 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[15]:

- 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;
- The formulation of the pesticide product using the two-letter coding system used in FAO pesticide specifications and given in Appendix III;
- The concentration of active ingredient in the formulated product expressed in g/L for liquids and w/w basis as g/kg or % of active ingredient in the solid product;
- The type of treatment such as ULV or high volume spraying and the crop growth stage at the final application;
- Maximum application rate expressed as kg ai/ha or kg ai/hL, number of applications, interval between applications and pre-harvest interval corresponding to specified application rate, if relevant, and maximum total application rate per season where specified;
- Exact description of crops and use situations with English name and the commodity description as given in the Codex Classification of Foods and Animal Feeds;
- Crops included in crop groups should be named individually unless they correspond with the actual Codex Commodity Classification of Food and Animal Feed[16];
- 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

[15] FAO/WHO. Pesticide Residues in Food, Joint FA/WHO Meeting on Pesticide Residues - Report 2010, FAO Plant Production and Protection Paper 200, pp. 8-11.

[16] Report of the 47th session of the Codex committee on pesticide residues *2016, REP/15/PR Appendix XI*

(and if necessary the translations) need to be provided only for those uses that are adequately supported by residue data according to FAO requirements.

3.5.1 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.

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.

3.5.2 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, Lepidoptera, 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 (2010)[17].

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). 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 (approximately1.5×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

[17] FAO. 2006. Manual on the development and use of FAO specifications for pesticides. 2nd revision of 1st edition.. http://www.fao.org/fileadmin/templates/agphome/documents/Pests_Pesticides/PestSpecsManual.pdf

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.

3.6 Residues resulting from supervised trials on crops

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 principles followed in evaluating supervised trial data are described in detail in the sections in Chapter, 5 '*JMPR Practices in estimation of maximum residue levels*'.

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 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[18,19] are considered by the JMPR as supervised trials. New supervised trials should be planned, implemented, documented and reported according to the

[18] OECD Draft Guidance Document on Crop Field Trials September 2014. http://www.oecd.org/chemicalsafety/testing/OECD-draft-CFT-GD-for-review-12-Sept-2014.pdf

[19] OECD. Guidance Document on Overview of Residue Chemistry Studies (as Revised in 2009) Series on Testing and Assessment No. 64 ENV/JM/MONO(2009)31, http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2009)31&doclanguage=en

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. All available supervised trials corresponding to the crop commodities listed in the intended use table should be submitted. 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:

- 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.

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.

3.6.1 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.

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 m^2 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 , *c*GAP) 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 *c*GAP, whereas the growth stage at application is of minor importance. Inversely, there are cases where the growth stage is a critical component of the GAPe.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 (=kg ai/hL), at which it is applied.

Row crops (potatoes, wheat, soya beans, etc.) are typically treated with broadcast sprays for which plot area (length × 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.

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.

3.6.1.1 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 number of trials (generally minimum 6–8) 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. It is emphasised that the above number of trials reflect the absolute minimum of supervised field trials needed for estimating maximum residue levels and a higher number of trials (a minimum of eight and ideally at least 15 for major crops) is recommended for a robust estimate as maximum residue level estimates become increasingly unreliable as the number of residue values decrease.

For minor crops the 2015 JMPR[20] concurred with the recommendation of the 47th Session of the CCRP and decided[21] that from 2016 a minimum number of four independent supervised field trials reflecting the respective GAPs for Category 1 and 2 crops and five trials according to Category 3 crops will be used as basis for the recommendation of maximum residue levels. On a case by case basis, fewer trials may be acceptable when additional circumstances can be taken into account (e.g. undetected residues following treatment at exaggerated rates).

The OECD Working Group on Pesticides elaborated guidance on the minimum number of trials[19] 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

[20] FAO Pesticide Residues in Food 2015 Report. FAO Plant Production and Protection Paper No. XX FAO, Rome, http://www.fao.org/agriculture/crops/core-themes/theme/pests/jmpr/jmpr-rep/en/

[21] Report of the 47th session of the Codex committee on pesticide residues *2016, REP/15/PR Appendix XI* http://www.codexalimentarius.net/web/standard_list.do?lang=en

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.

3.6.1.2 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 type of formulations.

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 (i.e. 25% rule). A maximum change of +/-25% in the resulting residue concentration is considered acceptable. Tolerances on the parameters should be those that would result in ±25% change in the residue concentration, not ±25% changes in the parameters themselves 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 5.2.5 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.

3.6.2 Sampling and analytical methods

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 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.

The MRLs apply to the average residue in the laboratory sample complying with the minimum requirements of the number of primary samples and the mass of the laboratory samples[7]. To provide residue trial data for the estimation of maximum residue levels, samples of commodities should be prepared according to the Codex standard to obtain the portion of commodity to which the Codex MRLs will apply[22] 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.

Prior experience indicates that the interaction of surface residues with the internal part of plant materials may cause very rapid degradation of the residues[,23,24]. Classical examples are, for instance, benomyl, captan, chlorothalonil, dithiocarbamates, etoxazole and folpet. Fifty to 90% of the parent compounds may decompose within minutes during the chopping of various plant materials at room temperature. There are many other pesticides which may decompose to varying extents when the residues come into contact with plant enzymes and other liquids released from the plant cells during processing.

In order to avoid or minimize the degradation of residues as much as possible, the Codex Sampling Guidelines[25] states: "Where the bulk sample is larger than is required for a laboratory sample, it should be divided to provide a representative portion. A sampling

[22] Portion of Commodities to which Codex Maximum Residue Limits Apply and which is Analysed, CAC/GL 41-1993

[23] Hill, A. R. C.; Harris, C. A.; Warburton, A. G. Effects of sample processing on pesticide residues in fruits and vegetables. In *Principles and Practices of Method Validation*; Fajgelj, A.,Ambrus, AÄ ., Eds.; Royal Society of Chemistry: Cambridge, United Kingdom, 2000; pp 41-48.

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

[25] Codex Alimentarius Commission, Recommended method of sampling for the determination of pesticide residues for compliance with MRLs, CAC/GL 33-1999 http://www.codexalimentarius.org/standards/list-of-standards/

device, quartering, or other appropriate size reduction process may be used *but units of fresh plant products or whole eggs should not be cut or broken."*

The guidance for sample preparation is given in Appendix **VI**.

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.

3.6.3 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**.5 "*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 2 code made up of 2 capital letters (ISO, 1993) given in **Annex 1** of Appendix **X**.

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 **5**.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 Appendix V. should be considered as a minimum.
- 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.

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

3.7 Fate of residues in storage and processing

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

3.7.1 Information and data from trials on stored products

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.

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.

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.

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/m^3.

3.7.2 Fate of residues in food processing

"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.

A different approach is required for calculating processing factors for compounds not included in the residue definition as they may be created on processing, for example mancozeb and ETU which have separate health based guidance values.

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.

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

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, pesticide residue and the commodity.

When the definition of residues for enforcement purposes and for dietary risk assessment is different, two processing factors are needed. One, the Pf_{ENF}, is based on the residue definition for enforcement. This processing factor is used to recommend maximum residue levels for processed commodities in which the residue concentrates during processing, e.g. raisins. The other, the $Pf_{RISK,}$ is used for dietary risk assessment.

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 < LOQ the calculated processing factor (residue level in RAC ÷ LOQ) should be reported with a "less than" (<) symbol. If residues in the processed commodity are undetectable or < 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 always < LOQ following application with exaggerated rates, but they are concentrated in the processed commodity (level > LOQ), the study is of no value for deriving a processing factor. In such situations a sufficient number of processing studies should be carried out at maximum GAP to enable the estimation of residue levels based on their results.

When residues in the processed commodity and in the RAC are both < 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 to derive at the best estimate of the processing factor.

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 for 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.

3.7.2.1 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.

When 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 3.11 summarises typical conditions (temperature, time and pH) which prevail for each of the processing operations[26].

Table 3.11 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

[26] OECD Guidelines for the Testing of Chemicals, Test No. 507: Nature of the Pesticide Residues in Processed Commodities - High Temperature Hydrolysis, http://www.oecd-ilibrary.org/environment/test-no-507-nature-of-the-pesticide-residues-in-processed-commodities-high-temperature-hydrolysis_9789264067431-en

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 3.11 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 3.12.

Table 3.12: 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 3.11), the temperature and time for preparation of meat and fish) specific studies should be considered on a case-by-case basis.

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 radio-labelled 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.**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.

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 crop[27].

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.

3.7.2.2 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.

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.

The processing studies to determine residues in aqueous tea infusion are often carried out under an artificially "worst case" scenario, which cannot be used for the estimation of realistic processing factors. The standard test conditions for brewing and processing tea are included as Annex 3 of Appendix X.

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

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

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 Residues in animal commodities

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).

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 significant[28].

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.

3.8.1 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 and the results of metabolism studies 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

[28] OECD Guidelines for the Testing of Chemicals, Test No. 505: Residues in Livestock, http://www.oecd-ilibrary.org/environment/test-no-505-residues-in-livestock_9789264061903-en

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 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 10× 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 bio accumulating 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 bio accumulating 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.

3.8.2 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.

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.

3.8.2.1 Nature of fat samples in studies with 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, mesenterial, 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.

3.8.3 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 for sheep only 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.

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.

3.9 Residues in food in commerce and at consumption

Data from national monitoring programmes are essential for estimation of EMRLs and maximum residue limits for spices. See also sections 5**.**11.1 and 5.11.2 in Chapter 5 on 'Estimation of maximum residue levels, HR and STMR values in spices' and 'Estimation of extraneous maximum residue levels'.
In selective field surveys and monitoring programmes the Codex standard method of sampling for the determination of pesticide residues for compliance with MRLs should be used.[25] 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 primary samples (sample increments), the number of primary samples in the composite sample and the total weight of the composite sample.

3.9.1 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**.4.1). 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:

Example for reporting detected residues [mg/kg]:

Table 3.12 Residues detected in milk samples.

Commodity[a,b]	LOQ[c] [mg/kg]	No ≤ LOQ [d]	Expression of residues	Residue detected [mg/kg]
ML 0812 Cattle milk	0.00004		Whole product basis	0.00004, 0.00004, 0.00004, 0.00008
	0.00005		Whole product basis	
	0.0001		Whole product basis	0.0001
	0.0003		Fat basis	0.0006
ML 0814 Goat milk	0.0003		Whole product basis	0.0003
	0.0001		Whole product basis	0.0006
ML 0822 Sheep milk	0.001		Whole product basis	0.002

[a] Describe the commodity according to Codex Commodity Classification together with the portion of commodity analysed.
[b] Insert additional columns to the table as needed.
[c]: Report the results obtained with different LOQ values separately; The LOQ-s indicated are examples only.
[d] Number of samples containing residues below LOQ

3.9.2 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.

It is emphasised that maximum residue levels, and median and highest residues of pesticides used for post-harvest treatment will not be estimated based on monitoring data. Post-harvest treatment should be carried out under controlled conditions according to the authorised use of a given pesticide. The highest and median residues would be estimated based on the results of supervised trials which reflect the authorised use similarly to any other commodities

3.9.2.1 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 minimum ≥ 0.5 kg but preferably larger. 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 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.

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 59 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 section **3**.4**;**

e. The summary table of results presented for individual spice×pesticide residue combinations as shown in section **3**.9.1. "Data requirements for EMRL estimation".

f. Any other information considered relevant for the evaluation of residue data.

3.9.2.2 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 and include in the analysis of 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 facilitate their production and marketing their products, 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 estimated maximum residue level will be.
- 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**. 9.1.

- Person and organization responsible for organizing, supervising and reporting of the results of the selective field survey;
- Typical agricultural practice;
- 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 active ingredient and metabolites (mg/kg), included in the residue definition, found in the samples. The results should be tabulated as shown in Table 3.13.

Table 3.13 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.

3.10 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.

CHAPTER 4

DEFINITION OF RESIDUES

CONTENTS

4.1 Definition of residues

4.1.1 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 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 general 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 of the WHO Panel should communicate closely prior to the JMPR meeting on the metabolites of toxicological significance that should be considered in the dietary risk assessment.

In tabulating the residue trials data, the FAO Panel reviewer should present the levels of relevant metabolites separately from those of the parent compound to allow subsequent combination, if necessary 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 risk assessment* should include compounds of toxicological significance.

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.

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 clean-up 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 and carbendazim), and in some cases, the toxicology is substantially different for the pesticide and the metabolite (example: dimethoate and 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 and carbendazim, thiophanate-methyl and 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 and melamine, also prometryn and 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.

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.

4.1.2 Dietary risk assessment of metabolites and degradates of pesticides

Residues of the pesticides to which consumers are exposed often comprise not just (or even) the parent compound, but also metabolites produced in treated plants, environmental degradation products and possibly other pesticide-derived compounds (e.g., during food processing). Where such a compound is also produced at significant levels in test species, it is assumed that its hazard will have been addressed in assessment of the parent compound. When this is not the case, or where levels produced in test species are low, additional assessment of the compound is necessary. With improvements in analytical sensitivity and greater awareness of the potential for exposure to metabolites and degradates, the number of compounds identified of potential concern is increasing appreciably. It is not feasible or appropriate to insist on comprehensive toxicity testing of all such compounds, a fact recognized in a recent opinion[29] of the European Food Safety Authority (EFSA).

The EFSA Panel on Plant Protection Products and their Residues (PPR) identified the threshold of toxicological concern (TTC) concept as an appropriate screening tool. The TTC values for genotoxic and toxic compounds were found to be sufficiently conservative for chronic exposure, as a result of a validation study with a group of pesticides belonging to different chemical classes. Three critical steps were identified in the application of a TTC scheme: 1) the estimate of the level of the metabolite, 2) the evaluation of genotoxicity alerts and 3) the detection of neurotoxic metabolites. Tentative TTC values for acute exposure were established by the PPR Panel by analysis of the lowest 5th percentiles of No Observed Adverse Effect Levels (NOAELs) used to establish the Acute Reference Doses (ARfD) for the EFSA pesticide data set.

The PPR Panel recommended "acute exposure thresholds" for pesticide metabolites of 0.0025 µg/kg bw/d for metabolites with a structural alert for genotoxicity, of 0.3 µg/kg bw/d for substances having structures suggesting neurotoxicity (AChE inhibition) and of 5.0 µg/kg bw/d for all other metabolites (substances allocated in Cramer class II and III).

Since the chronic TTCs could be considered to be overly conservative for assessment of acute exposure it was concluded that if both chronic and acute exposure estimates for metabolites were relatively low, and below the chronic TTC thresholds, it could be proposed that no further toxicological assessment of the metabolites would be needed. In this way a 'screen' using the chronic TTC values would be adequate to propose an assessment scheme by comparing all intake values calculated for metabolites with the TTC values.

The 2014 JMPR agreed[30] with many of the principles outlined in the EFSA opinion. The Meeting agreed to produce guidance on this issue that will likely include the following:

- Where there is adequate exposure of test species to the compound of concern, hazard characterization will have been addressed by evaluation of the parent compound;

[29] EFSA Panel on Plant Protection Products and their Residues (PPR);Scientific Opinion on evaluation of the toxicological relevance of pesticide metabolites for dietary risk assessment. *EFSA Journal* 10(7):2799. [187 pp.] doi:10.2903/j.efsa.2012.2799. http://www.efsa.europa.eu/en/efsajournal/pub/2799

[30] FAO/WHO. Pesticide Residues in Food, Joint FA/WHO Meeting on Pesticide Residues - Report 2014, FAO Plant Production and Protection Paper 221, p. 6, 314 http://www.fao.org/agriculture/crops/core-themes/theme/pests/jmpr/jmpr-rep/en/

- Otherwise, a preliminary assessment of dietary exposure to the compound of concern should be undertaken;
- The tiered threshold of toxicological concern (TTC) approach, as recommended by EFSA[29], should be adopted;
- Where appropriate, read-across from the parent or other metabolites/degradates with relevant toxicological information should be undertaken;
- Where adequate data are available, and when necessary, relative toxic potencies will be determined, for use in calculating an appropriate exposure estimate for comparison with the respective reference value;
- The JMPR report will clearly indicate whether it was possible to assess significant metabolites or degradates for toxicological concern;
- Three possible outcomes will be identified:
    - Evaluation was possible, and there is no concern.;
    - Evaluation was possible, and there is concern;
    - No evaluation is possible. This does not necessarily mean that there is a concern, rather that it is not possible to reach such a conclusion on the basis of available data.

As an example, the 2014 JMPR (Report p.314) decided that a single-exposure TTC value of 0.2 µg/kg bw, would be applicable to potentially genotoxic metabolites of pesticides. This value was based on the approach of the European Medicines Agency (EMA), which set a TTC of 2 µg/kg bw (120 µg/person) for single exposures to genotoxic impurities in pharmaceuticals. The chronic TTC value used by EMA is 10-fold higher than that used by WHO for potentially genotoxic compounds. Therefore, the EMA single-exposure TTC value of 2 µg/kg bw (120 µg/person) was divided by 10 to give 0.2 µg/kg bw.

The 2014 JMPR applied the TTC concept for assessing the significance of the animal metabolites CGA245342, CGA294849, I_{A7} and I_{A17} of pymetrozine based on exposure levels related to the uses evaluated. Exposure to I_{A17} did not exceed the TTC value for chronic exposure of 0.0025 µg/kg bw per day (EMEA for genotoxic impurities) as well as the single-exposure TTC of 0.2 µg/kg bw. CGA245342 and I_{A7} gave estimated exposure levels below 1.5 µg/kg bw per day (Cramer Class III), respectively. Based on the assessed uses, these metabolites are not considered relevant for the dietary intake.

CGA294849 was also assessed with the TTC approach with the major part of the exposure resulting from plant commodities. CGA294849 has a structural alert for genotoxicity but has not been tested. Since the exposure assessment exceeded the applicable TTC values, no conclusion on the relevance of CGA294849 for dietary intake assessment can be made.

Besides parent pymetrozine, which is a major residue in plant commodities and should to be taken into account for dietary intake assessment, the relevance of the plant metabolites GS23199, CGA128632 and CGA294849 as well as of the degradation products formed during processing (CGA215525 & CGA300407) was assessed with the TTC approach.

Based on the exposure levels (IEDI and IESTI) estimated for the uses, including those foreseen in the future, evaluated, GS23199 (Cramer Class III) and CGA215525 (Cramer Class III) were not considered relevant for dietary intake.

For uses foreseen in future, the highest residue from a similar crop commodity for which trials were submitted can be taken as residue estimate. It needs to be clarified which exposures

where taken into account in deciding on inclusion or omission of certain metabolites in the residue definition.

CGA128632 has therapeutic uses as a vasodilator with a minimal therapeutic dose of 1 mg/kg bw. In view of the margin compared to the estimated exposure levels (>1000 to the IEDI and > 50 to the maximum IESTI), CGA128632 is not considered a relevant metabolite of pymetrozine for dietary intake.

CGA294849 was also assessed with the TTC approach with the major part of the exposure resulting from plant commodities. CGA294849 has a structural alert for genotoxicity but has not been tested. Since the exposure assessment exceeded the applicable TTC values, no conclusion on the relevance of CGA294849 for dietary intake assessment can be made.

The processing degradate CGA300407 does not have a structural alert for genotoxicity but the Meeting was made aware that positive genotoxicity results, in vitro and in vivo, exist for this compound. No conclusion on the relevance of CGA300407 can be made.

If future uses for pymetrozine result in changes of the dietary intake, reconsideration on the relevance of metabolites in plant and animal matrices and after processing may become necessary.

4.1.3 Principles followed in defining residues for enforcement

As it was already mentioned before, the definition of residues for testing compliance with MRL 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. 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.

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 analysed 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.

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 was necessary to describe the residue as “.... determined and expressed as ....” to produce a practical definition for residues. In the future when supervised trials will be carried out with compound specific methods, the definition of residue may be changed.

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. In some cases, separate residue definition may be required for a specific commodity (group) such as, for instance, transgenic crops.

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 thiram for compliance with MRLs:

> total dithiocarbamates, determined as CS_2 evolved during acid digestion and expressed as mg CS_2/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 sulphoxide 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 ^{14}C residues are available in all regulatory laboratories.

Example: residue definition of bendiocarb including conjugated form:

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.

Example: myclobutanil

Definition of the residue (for compliance with the MRL for plant and animal commodities and for estimation of dietary intake for and animal commodities): *myclobutanil.*
Definition of the residue (for estimation of dietary intake for plant commodities): *sum of myclobutanil, α-(4-chlorophenyl)-α-(3-hydroxybutyl)-1H-1,2,4-triazole- 1-propanenitrile (RH-9090) and its conjugates, expressed as myclobutanil*

The residue is not fat-soluble

Example: spirotetramat

Definition of the residue (for compliance with MRL) for plant commodities:

Spirotetramat and its enol metabolite, 3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]dec-3-en-2-one, expressed as spirotetramat.

Definition of the residue (for estimation of dietary intake) for plant commodities:

Spirotetramat, enol metabolite 3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]dec-3-en-2-one, ketohydroxy metabolite 3-(2,5-dimethylphenyl)-3-hydroxy-8-methoxy-1-azaspiro[4.5]decane-2,4-dione, monohydroxy metabolite cis-3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]decan -2-one, and enol glucoside metabolite glucoside of 3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]dec-3-en-2-one, expressed as spirotetramat.

Definition of the residue (for compliance with MRL and estimation of dietary intake) for animal commodities:

Spirotetramat enol metabolite, 3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]dec-3-en-2-one , expressed as spirotetramat.
Spirotetramat enol is not fat soluble.

The definition of residue includes the parent compound and four metabolites. In case of complex molecular structure, for avoiding any ambiguity, the chemical name of the residue components should be given.

Example: fenamidone

The toxicological relevance of two metabolites (RPA 412636 and its precursor RPA 412708), both detected as RPA 412636, were confirmed. *RPA 412636 was considered as 10 times more toxic than the parent.*

Definition of the residue (for estimation of dietary intake) for plant commodities: *Sum of fenamidone, (S)-5-methyl-5-phenyl-3-(phenylamino)- 2,4-imidazolidine-dione (RPA 410193), plus 10 x the sum of both (S)-5-methyl-5-phenyl-2,4-imidazolidine-dione (RPA 412636) and (5S)-5-methyl-2-(methylthio)-5-phenyl-3,5-dihydro- 4H-imidazol-4-one (RPA 412708), all calculated as fenamidone.*

Residue concentration $C_{total} = C_{fenamidone} + C_{RPA\ 410193} + 10\times\ (C_{RPA\ 412636} + C_{RPA\ 412708})$

Definition of the residue (for the estimation of dietary intake) for animal commodities: *Sum of fenamidone plus 10 × the sum of both (S)-5-methyl-5-phenyl-2,4-imidazolidine-dione (RPA*

412636) and (5S)-5-methyl-2-(methylthio)-5-phenyl-3,5-dihydro- 4H-imidazol-4-one (RPA 412708), all calculated as fenamidone.

Residue concentration $C_{total} = C_{fenamidone} + 10 \times (C_{RPA\ 412636} + C_{RPA\ 412708})$

The residue is fat soluble.

Example: residue definition of glyphosate accommodating GM tolerant crops

Because of the different proportions of residues in GM tolerant plants

Definition of the residue for compliance with MRL (for plant commodities): for soya bean, maize and rape: sum of glyphosate and N-acetyl-glyphosate, expressed as glyphosate

for other crops: glyphosate.

Definition of the residue for estimation of dietary intake (for plant and animal commodities): glyphosate, N-acetyl-glyphosate, AMPA and N-acetyl AMPA, expressed as glyphosate.

4.2 Fat solubility

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. 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.

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 predicted[31]. 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

[31] 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.

blood is equal to the total sum 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 = [partition coefficient residues in fat:blood]/[partition coefficient of residues in muscle:blood];

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

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

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 not[32].

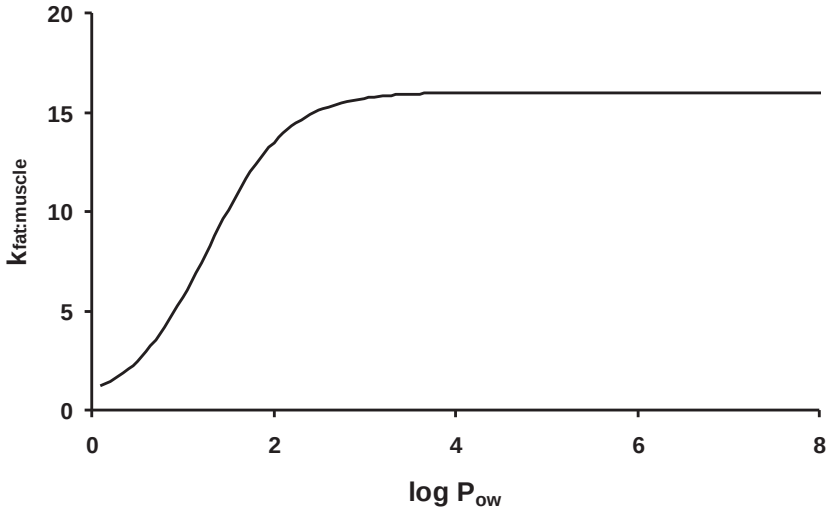


Figure 5.1 Plot of predicted partition of residue between meat and fat based on log P_{ow}
k = concentration ratio of residues in fat/muscle

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.

[32] FAO/WHO. Pesticide Residues in Food, Joint FA/WHO Meeting on Pesticide Residues - Report 2005, FAO Plant Production and Protection Paper 183, p 8. http://www.fao.org/agriculture/crops/core-themes/theme/pests/jmpr/jmpr-rep/en/

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.

Haloxyfop-R-methyl ester (active form) has log P_{ow} = 4; haloxyfop methyl (racemate) log P_{ow} = 3.52; haloxyfop acid log P_{ow} = 1.32; the residue of haloxyfop is defined as haloxyfop esters, haloxyfop and its conjugates expressed as haloxyfop. 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.

CHAPTER 5

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

CONTENTS

5.1 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 (HR) in edible portion of composite sample 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.[22] 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 primary commodities used as animal feeds, e.g., fodder and straw and grains, 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. For those commodities used only as feed, such as forage, fodder and straw, the terms "median residue" and "highest residue" must be used and they are estimated in the same manner as STMR and HR for food, for calculation of animal dietary burdens.

5.2 Comparability of supervised trial conditions to GAP

5.2.1 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 that can be performed for a given commodity is limited. Nevertheless, a larger data set *representing a statistically, not different residue population* provides the basis for a more accurate estimation of maximum residue level than a small data set derived from trials representing residues only from 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 .

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.

5.2.2 Application rate

The actual application rates in the trials should generally deviate by no more than ±25% of the maximum application rate.

When trial conditions permit the principle of proportionality is applied to adjust the residue data to the residue levels that would be expected if the pesticide was applied according to the critical GAP.[1]

1. Use of the concept for soil, seed and foliar treatments has been confirmed by analysis of residue data. Active substances confirmed included insecticides, fungicides, herbicides, and plant growth regulators, except desiccants.
2. The proportionality concept can be applied to data from field trials conducted within a rate range of between 0.3× and 4× the GAP rate. This is only valid when quantifiable

residues occur in the dataset. Where there are no quantifiable residues, i.e. values are less than the limit of quantitation; it is unacceptable to scale up in this situation.

3. The variation associated with residue values derived using this approach can be considered to be within±25% deviation of the actual residue concentrations.
4. Scaling is only acceptable if the application rate is the only deviation from critical GAP (*c*GAP). In agreement with JMPR practice, additional use of the ±25% rule for other parameters such as PHI is not acceptable. For additional uncertainties introduced, e.g., use of global residue data, these need to be considered on a case-by-case basis so that the overall uncertainty of the residue estimate is not increased.

   Note: The 2014 JMPR concluded that when decline studies indicate that the residues are nearly completely degraded within the PHI specified on the label, the additional treatments have no influence on the residue concentrations at harvest, allowing the use of the proportionality approach to adjust for the higher application rates involved.

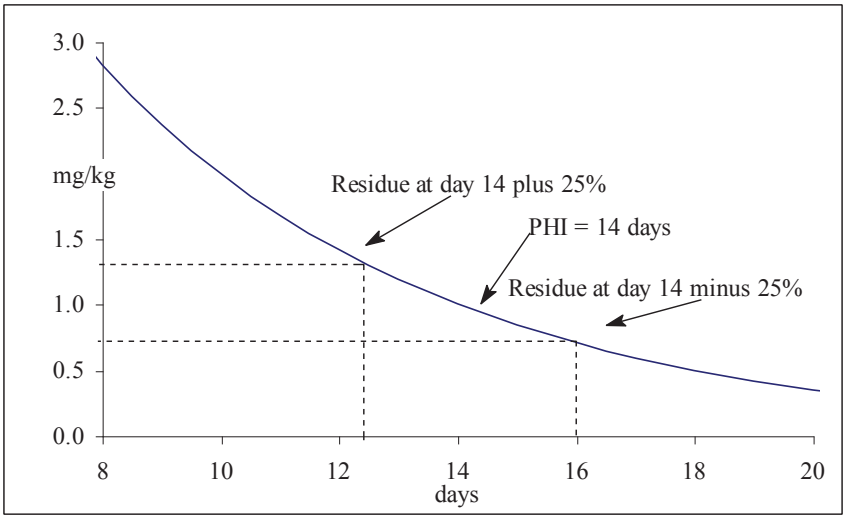
5. Proportionality cannot be used for post-harvest situations at this time. It is also recommended that the concept not be applied to hydroponic situations due to a lack of data.
6. Proportionality can be applied for both major and minor crops. The main difference between minor and major crops is the number of trials required by national/regional authorities, which has no direct relevance to the proportionality of residues. If scaling is applied on representative crops, there is no identified concern with extrapolation to other members of an entire crop group or subgroup.
7. Regarding processed commodities, it is assumed that the processing factor is constant within an application rate range and resulting residues in the commodity being processed. Therefore, existing processing factors can also be used for scaled datasets.
8. With respect to exposure assessments, no restrictions appear to be necessary. The approach may be used for distribution of residues in peel and pulp, provided the necessary information for scaling is available from each trial. Scaled datasets for feeds may also be used for livestock dietary burden calculations.
9. The approach may be used where the dataset is otherwise insufficient to make a maximum residue level recommendation. This is where the concept provides the greatest benefit. The concept has been used by JMPR and different national authorities on a case-by-case basis and in some cases MRLs may be estimated from trials where all of the data (100%) has been scaled.
10. Although the concept can be used on large datasets containing 100% scaled residue trials, at least 50% of trials at GAP may be requested on a case-by-case basis depending for example on the range of scaling factors.

In addition, some trials at GAP might be useful as confirmatory data to evaluate the outcome in cases where the uses result in residue levels leading to a significant dietary exposure.

5.2.3 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 ±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 PHI given on the label for accepting supervised trials data are wider for a slowly declining residue than a rapidly

declining residue. The situation for 1st order decline is illustrated[33] 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%.



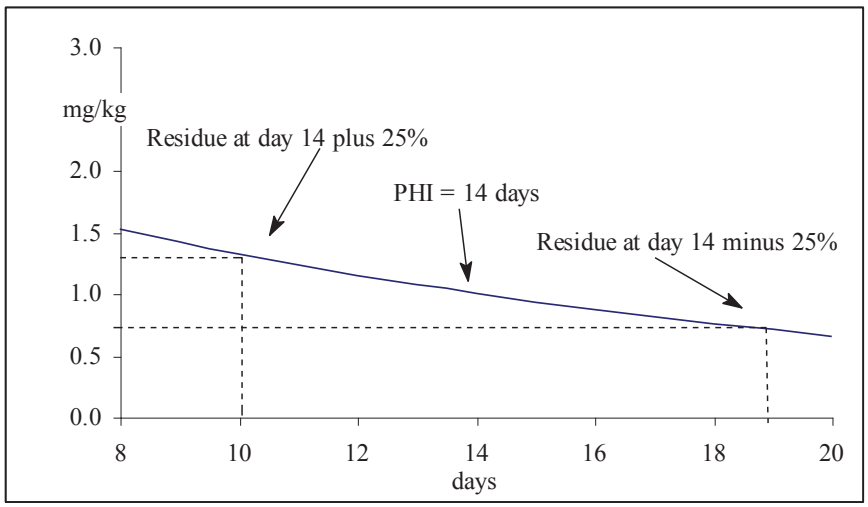


Figure 5.1 Illustration of latitude of permissible ± deviation from the PHI indicated on the label

For first order decay

$$C = C_0 \times e^{-kt} \quad \text{.....1}$$

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

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

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

$$-k(t_1 - t_2) = \ln(\frac{C_1}{C_2}) \quad \text{.....2}$$

[33] Hamilton, D., 2009. Personal communication.

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

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

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

From 2 and 3

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

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

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 ± a chosen percentage.

C_2 = 125% of C_1	t_1-t_2 = 0.32 × $t_{1/2}$
C_2 = 75% of C_1	t_2-t_1 = 0.42 × $t_{1/2}$

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 cases[34] 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.

5.2.4 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.

5.2.5 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,

[34] 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.

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).

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. Additional aspects of comparability of different formulations are described in section 3.6.1.2.

5.2.6 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, for instance, 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.

5.3 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 (> 30 days apart) are considered independent;
- formulations – comparability or independence of trials with different formulations should to be assessed taking into account the principles described in sections **5**.2.5;
- 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;

- addition of surfactants – a trial with the addition of surfactant may constitute sufficient difference to be treated as independent, provided the relevant label does not prescribe the use of adjuvant;
- application rates and spray concentrations – trials conducted at the same location with significantly different application rates and spray concentrations are not independent; the principle of proportionality may be applied to select that trial which leads to the highest residues;
- crop varieties – different varieties at a single site may not be 'independent'; some varieties may be sufficiently different (different morphology etc) to influence the residue;
- 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.

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. analyses of replicate test portions 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 test when preparing the monograph.

The average of the results obtained in cases (a) and (b) is considered as the best estimate of the residue content of one laboratory sample. The average residues in samples taken according to cases (c), (d), are used for estimation of maximum residue levels, high residues for calculation of animal burden and estimation of supervised trial median residues (STMR) for all cases. However, the highest residue of replicate samples is taken as HR for dietary intake calculation. The average residue values should be calculated from the unrounded measured residues in all cases.

In cases of non-independent trials, the plot in which the highest residue level is observed is selected for maximum residue level estimation and dietary intake assessment.

5.4 Selection and reporting of residue data

5.4.1Treatment 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.

5.4.2 Residues below LOQ

As a general rule, where all residues from relevant trials 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 at the level of 0 when there is evidence that the residues are "essentially zero".

5.4.3 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, and as a general rule rounding of calculated values should only be done at the last step of the calculations (before reporting the final results), taking into account the combined uncertainty of the process.

5.5 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.

Provided that the GAPs are similar, the JMPR evaluates whether data sets for a given commodity or commodity group grown in one country should be combined and whether residue data reflecting different countries' GAPs should be combined.

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.

The field to field variation of residues skewed towards the high values do not follow a normal distribution, even if this might be indicated by statistical tests based on small data sets. 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 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 this case the Kruskal-Wallis H-test may be used (http://www.biostathandbook.com/kruskalwallis.html). In both cases a minimum of 5 data points are required in each dataset to obtain meaningful results. Their principles are explained in Appendix XIII, and the calculation can be performed automatically with the Excel template which is attached *electronically* as Appendix XIV.1 As usual if the calculated probability is larger than 0.05 the null hypothesis is accepted and the data sets can be combined.

5.5.1 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 fruits. 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 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.

The revision of the Codex Classification has been taken up by the CCPR and was completed for the Type 01 Fruits groups with the final adoption by the CAC in 2014. The Revised classification includes suggested representative commodities for sub-groups (Annex 2 of Appendix X). The CCPR decided that the following principles should be used in the selection of representative commodities[35]:

- A representative commodity is most likely to contain the highest residues.
- A representative commodity is likely to be major in terms of production and/or consumption.
- A representative commodity is most likely similar in morphology, growth habit, pest problems and edible portion to the related commodities within a group or subgroup.

The application of the three principles is based on the assumption that all commodities of the respective group or subgroup are treated according to a similar use pattern or GAP. It was also agreed by the Committee that, to facilitate the global use of the commodity groups for MRLs, alternative representative commodities may be selected giving flexibility for use of residue research conducted in different countries or regions that may vary due to regional differences in dietary consumption and/or areas of production for certain commodities.

The 2014 JMPR noted however[30], that the principles applied by the CCPR are sometimes inconsistent and often not applicable simultaneously. For example, it is not always guaranteed that a commodity, which is representative in terms of morphology, also contains the upper residue level within the group. In addition, the selection of representative crops by the CCPR is mainly driven by production and/or consumption rather than likely residues.

The JMPR continues to rely on the Codex Classification of Foods and Feeds as the primary basis for recommending maximum residue levels for individual or grouped commodities on a case-by-case basis. If the data permit, recommendations will be made for the relevant sub-groups. 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.

In order to make the data assessment process transparent and facilitate its consistent application in various situations, the 2013 JMPR considered and evaluated past experience and decided on the following basic principles in estimation of residue levels for commodity groups[36].

- Group maximum residue levels are only estimated if the pesticide is registered for a group or sub-group of commodities, also allowing for the differences in Codex and national commodity group classifications.

[35] Report of the 44th session of the Codex Committee on Pesticide Residues, Alinorm 04/27/24, Appendix XI. 2012, www.codexalimentarius.net

[36] FAO Pesticide Residues in Food 2013 Report. FAO Plant Production and Protection Paper No. 219. FAO, Rome, Section 2.9. http://www.fao.org/agriculture/crops/core-themes/theme/pests/jmpr/jmpr-rep/en/

- Residue datasets reflecting *c*GAP will be compiled. Once the data sets have been established for individual commodities, the recommendations for residue levels for commodity groups would be considered according to the following principles.
    - The establishment of a commodity group residue level will generally be considered if the median residues of the commodities are within the 5 times range;
        - Where the residues in individual commodities in the commodity group are statistically not different (Mann-Whitney or Kruskal-Wallis tests) the residue data can be combined for the estimation of group residue levels;
        - Where the residue datasets in individual commodities are statistically different then the dataset leading to the highest maximum residue level would be used for the group, provided that sufficient residue data points are available;
        - If the dataset identified under (ii) does not contain sufficient data points (preferably $\geq$ 8) required to estimate a group maximum residue level, the commodity should be considered as an exception.
    - If the median of residues in an individual commodity dataset differs more than 5 times than those of other commodities, that commodity would not be included in the group and indicated as an exception.
    - If the medians of residues in more than one commodity of the group differ larger than five times, then recommending group residue levels may not be appropriate and would require decision based on all information available

In view of the large diversity of residue data dependant on the pesticide and other factors, the case-by-case evaluation of the available residue data is considered necessary. Where the Meeting deviates from the above principles, the rational for the divergence will be provided in the relevant JMPR Report.

For the case-by-case evaluation of the available information he following general principles and observations, based on prior experience of the JMPR, will be taken into account in estimating group MRLs.

a. In general, the use pattern should be similar and applicable for the whole crop group. If the use patterns are different for the individual crops but produce similar residues, a group maximum residue level might be recommended.

b. The nature of residues: systemic or non-systemic, degradation/disappearance rate.

c. 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.

d. Generally, the JMPR 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’ or sub-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.

e. 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.

f. For acute dietary intake purposes, the highest residue (HR) value of the commodity on which the maximum residue level is based, should be applied to the single commodities of the whole crop group. In cases when the ARfD is exceeded when using the group HR, a group maximum residue level cannot be recommended.

g. 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.

h. After dietary intake assessment, commodity group MRLs may be proposed on the following minimum conditions:

   - 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.

i. 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.

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.

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.

The JMPR generally follows these principles on a case-by-case basis, and tests the applicability of the representative commodities for recommending residue levels for the corresponding sub-groups. When sufficient and relevant residue data will be available for representative commodities the recommendations will be based on them.

Table 5.1 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
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
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 triticale	AS

5.5.2 Combining residue data from supervised trials conducted in different locations

At the 2003 JMPR, the Meeting considered the Zoning Report[37] and agreed with the conclusion that the impact of climatic zones on pesticide residues is small, and residue data derived from similar use patterns and growing conditions may be compared regardless of the geographical location of the trials.

The 2013 JMPR took into account the experience gained during previous years, and decided to build on the current practice and elaborated the principles for utilizing the globally available supervised trial residue data for estimation of residue levels, provided that the growing and processing practices to produce RAC are comparable.

Step1: Residues deriving from supervised trials reflecting the national or regional *c*GAP will be considered and the relevant residues selected.

- If sufficient numbers of residue data are available from the country or region representing the critical GAP, that dataset is used for estimating residue levels according to the current practice of the JMPR.
- 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.
- Where residue data from trials conducted in the country or region are not sufficient, then trials conducted with different application rates will be considered, and the residue values adjusted, based on the proportionality approach to obtain the largest possible residue dataset.

Step 2: Where sufficient residue data are not available from Step 1, then suitable residue data from the trials performed in other countries that meet *c*GAP, or can be adjusted using proportionality to the *c*GAP, the data can be considered with those from step 1.

The datasets obtained in Steps 1 and 2 can be combined if their median residues are within the 5 times range (see section 5.5.1). Where the spread of individual residues in the combined dataset exceeds the 7 times median range, the suitability of the dataset for estimation of residue levels would then need further careful examination, taking into account all relevant information. This criterion is based on the detailed analysis of 1950 residue data sets (25766 individual residue values) selected by the JMPR between 1997 and 2011, for estimation of maximum residue levels, which revealed that about 90% of the residues were within the seven times the median of the corresponding dataset, regardless whether the residue data was derived from a single country or countries in different regions[38].

	Percentage of data sets in the median (M) ranges					
	R<3M	3M≤R<4M	4M≤R<5M	5M≤R<6M	6M≤R<7M	7M≤R
All data	54.21	16.82	8.10	7.38	3.28	10.21
Average %	54.50	17.11	6.97	7.34	2.76	11.32
Cumulative %	**54.50**	**71.61**	**78.58**	**85.92**	**88.68**	**100.00**

The Meeting noted that there will be cases where regional differences in cultural practices will need to be considered.

[37] Report of the OECD/FAO Zoning Project Series on Pesticides, Number 19, ENV/JM/MONO(2003)4 16 May 2003 http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2003)4&doclanguage=en

[38] Ambrus, Á., Horváth, Zs., Farkas, Zs., Szabó, I., Dorogházi, E., Szeitzné-Szabó, M., Nature of the field-to-field distribution of pesticide residues. J. Environ. Sci and Health, 49, 4, 229-244 2014.

The JMPR will apply the above principles in further evaluations of the residue data and evaluate their applicability on a case by case basis. If the principles are considered not applicable the reason will be explained in the report. Upon gaining sufficient experience the JMPR would reconsider and further elaborate the principles if needed.

5.6 Estimation of maximum residue levels in plant commodities

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 6 '*Residues resulting from supervised trials on crops*') and the congruence of the trial conditions and the established GAP (See Chapter 3, Section 5 '*Use Patterns*'). 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 taking also consideration of applicability of the principles of proportionality in order to determine whether the trial conditions are still close enough to GAP to be relevant.

5.6.1 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 ±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. The principles of proportionality (6.2.2) are applied where the available data from the trials matching the cGAP are not sufficient to recommend a maximum residue level and it is possible to adjust the residue levels to the cGAP.

Formulations

*See sections **5**.3 and **5**.2.5*

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 **5**.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 occasionally detected 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 on the label 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 6-8)[38] 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 5.5 "*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.

5.6.2 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 population with high residues 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 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 (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 5.3.

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 and median 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, or 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.

5.7 Specific considerations in estimating maximum residue levels for individual commodities

5.7.1 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 section 5.2.3 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.

5.7.2 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.

5.7.3 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.

The JMPR does not recommend maximum residue levels for forage crops as they are not an item of international trade requiring Codex MRLs. Forage residue data are, however, evaluated and used in the estimation of farm animal dietary burden.

Where no recommendation is made for the major crop no recommendation will be made for animal feed and processed commodities

MRLs are recommended and expressed on a dry matter basis for dry feed items which are the items in international trade.

5.8 Extrapolation of residue data to minor crops

Section 5.5.1 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, including a copy of the label with English translation, 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;
- Monitoring data from selective surveys on the minor crop produced under typical commercial conditions where the pesticide is known to have been used.

5.9 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 has therefore welcomed the development and availability of the OECD MRL calculator[39]. The Meeting noted that the goals of the calculator are (1) to provide national regulators with a tool to estimate MRLs that reflect at least the 95th percentile of the underlying residue distribution and thus reduce the chance of non-compliance from pesticide use according to GAP and (2) to provide a mechanism for arriving at a harmonized MRL estimate when the same data are considered by different authorities and organizations.

For not fully censored datasets, the maximum of three calculated results is put forward as the MRL proposal by the calculator:

- • the highest residue value is used as a “floor” to guarantee that the MRL proposal is always greater than or equal to the highest residue;
- • the mean and the standard deviation values of the dataset are computed; the “mean + 4* standard deviation” value is evaluated as the base proposal (referred to as “Mean + 4*SD” method); and,
- • the “3*Mean*CF” method in which the CF correction factor assures that the relative standard deviation of the data set is at least 0.5 concording with the distribution of residues in data sets selected for estimation of maximum residue leveles.

When all residues are below the LOQ values, the highest LOQ value is used as an estimate for the MRL.

When duplicate samples are taken from one plot, the average residue should be imputed into the spreadsheet. If the calculated MRL is lower than the result of one of the measurements, the recommended maximum residue limit should be adjusted taking into account the distribution of residues in the dataset selected for estimation of maximum residue level.

If the dataset consists of 3-7 residue values, the message "High uncertainty of MRL estimate due to [small dataset]" is displayed to remind the user of the considerable level of uncertainty surrounding the calculation of any statistical quantity for such small datasets. For a dataset with 8 residue values, the estimated failure rate, (i.e. the probability that the MRL is below the 95th percentile of the residue distribution) reaches approximately 25 %. Ideally 15 - 20 valid data would be required to achieve the optimum of the under and overestimation of the 95th percentile of the residue population.

[39] OECD MRL Calculator: User Guide Series on Pesticides No 56, 2011.
http://search.oecd.org/officialdocuments/displaydocumentpdf/?cote=env/jm/mono(2011)2&doclanguage=en

The detailed description of the application of the calculator and the underlying statistical principles are given in the OECD MRL Calculator User Guide and OECD MRL Calculator Statistical White Paper[40].

Its electronic version is attached electronically as Appendix XIV.3

The FAO Panel currently applies other statistical methods as well 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), lindane residues in various commodities (2015) and estimation of MRLs for spices (2004, 2015).

5.10 Processed commodities

5.10.1 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 3**.** Section 7 "Fate of residues in storage and p*rocessing".*

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 derived from the residue definition for enforcement **(Pf_{ENF}).**

For the purpose of IEDI and IESTI estimation, the STMR and HR of the RAC is multiplied by the processing factor derived from the residue definition for dietary risk assessment (Pf_{RISK}) to give the median and highest 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).

The STMR estimates in the edible portion should be based on sufficient data. For instance, for sulfoxaflor, a systemic pesticide, the 2013 JMPR decided that three data points in edible portions were not sufficient to estimate STMR and HR values for citrus fruits. As a result the STMR and HR values were based on the whole fruit data.

[40] OECD MRL Calculator Statistical White Paper Series on Pesticides No. 57. http://www.oecd-ilibrary.org/docserver/download/9714381e.pdf?expires=1443880669&id=id&accname=guest&checksum=690A3054A68BA03D392355BF6119CFC0

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.

5.10.2 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.

5.11 Estimation of maximum residue levels based on monitoring data

5.11.1 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 data[41]. It was further clarified that chili peppers, herbs[42] 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.

[41] Report of the 36th session of the Codex Committee on Pesticide Residues, Alinorm 04/27/24, (paras 235 – 247) 2004, www.codexalimentarius.net

[42] Report of the 37th 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 principles applied in the evaluation of residue data detected in spices were elaborated by the 2004 JMPR[43] and further refined by the 2015 JMPR.[21] 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 59 samples are required. The minimum sample size of 59 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 measured represents.

The procedure used for estimating maximum residue levels depends on the number of samples containing detected residues.

- It is assumed that the laboratories reported only valid results. Therefore, all residue data are taken into account without excluding any value as an outlier.
- When residue values were reported as<LOQ, it does not necessarily mean that the sampled commodity was not treated with or exposed to the pesticide. While, it is unlikely that all the sampled commodities were treated with the pesticides looked for with the multi residue procedure it cannot be assumed to be a 'nil' residue situation.
- 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.
- When no sample contains detected residues, the highest reported LOQ value is used as the maximum residue level and the high residue value. "High residue" will not be calculated for seeds as it is assumed that they are mixed before placing them on the market. 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.
- When 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.
- 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.

[43] FAO Pesticide Residues in Food 2004 Report. FAO Plant Production and Protection Paper No. 178. FAO, Rome, Section 2.6. http://www.fao.org/agriculture/crops/core-themes/theme/pests/jmpr/jmpr-rep/en/

Maximum residue levels would only be estimated for those pesticide residues that were determined according to the definition of residues for enforcement purposes.

5.11.2 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, 598 randomly selected samples 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.

5.12 Estimation of maximum residue levels, STMR and HR 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.

5.12.1 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 (the average residue in replicate samples) 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 5.2), then combined in order to estimate animal commodity residues that may arise.

The following decision matrix is recommended for use in estimating maximum residue levels and STMR values:

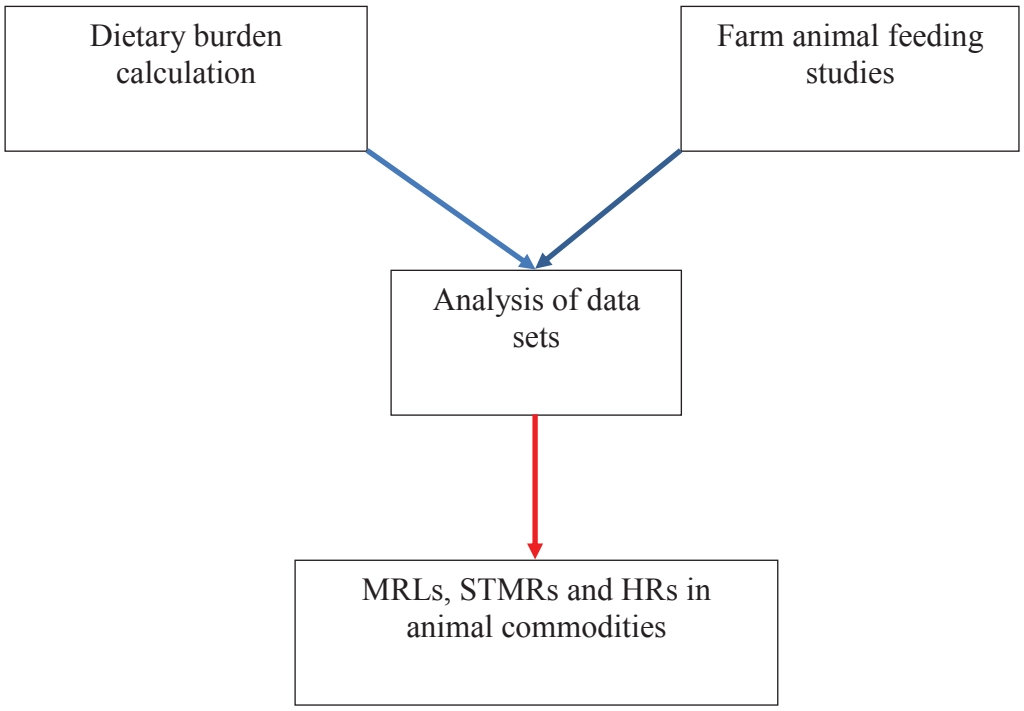


Figure 5.2 Estimation of residues in animal commodities

The following decision matrix is recommended for use in estimating maximum residue levels STMR and HR values:

Maximum residue level and HR	STMR
Choose:	Choose:
feed commodity, highest residue or STMR-P (for dietary burden calculation)	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 assists 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 MS Office Excel spreadsheet[44] which can be used for the calculations is attached as appendix XIV.2.

The livestock diet tables were developed by the OECD Working Group on Pesticides[26] 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 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.

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 5.2. 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;

[44] Sieke. C. Personal communication

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 5.2: Maximum dietary burden of beef cattle (example)[1]

Commodity/crop	Commod group	Residue mg/kg	Basis	% Dry matter	Residue dw mg/kg	*Diet content (%)* *US-CAN*	*EU*	*AU*	Residue contribution (ppm) 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

[1]: Japanese dietary burden is not shown

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 5.3.

The first commodity group in Table 5.3 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 5.4)

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 5.5).

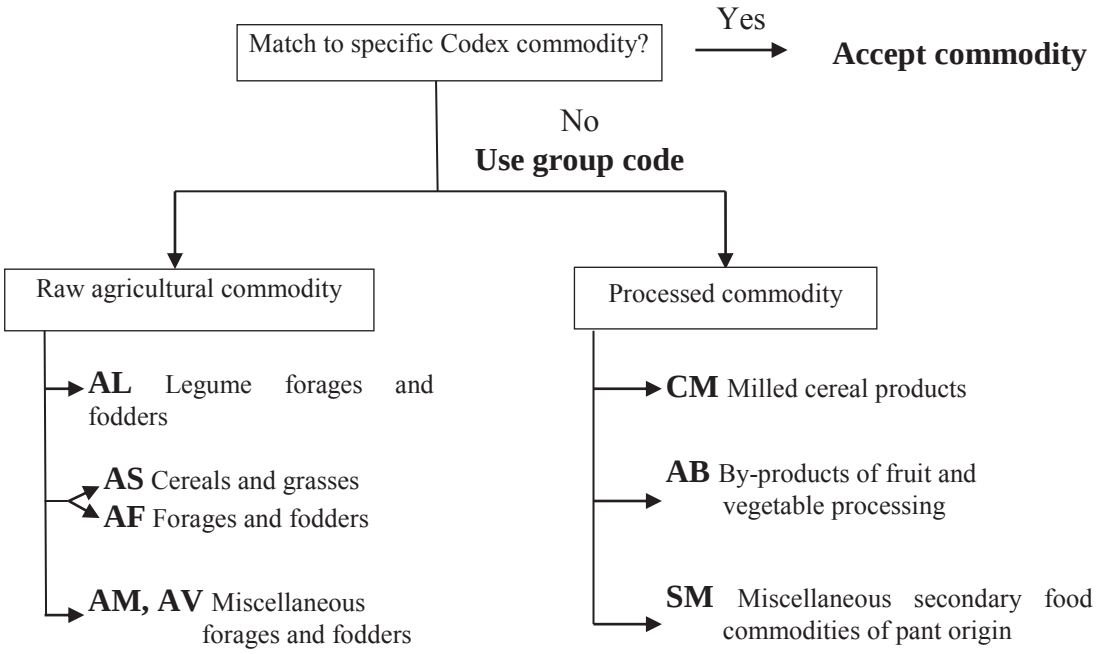


Figure 5.3 Grouping feed items for calculation of dietary burden of livestock

Table 5.3 Commodities selected to contribute to the maximum burden of beef cattle[1]

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

[1]: Japanese dietary burden is not shown

Table 5.4 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 5.5 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 5.5: 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*

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.

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 5.6).

Table 5.6: 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.

To facilitate the calculation an automated Excel spreadsheet was developed[44] which is attached electronically as Appendix XIV.2.

When replicate samples were taken from one plot, the average of the residues determined should be imputed in the Excel template. 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%.

5.12.1.1 Use of the calculated dietary burdens to estimate maximum residue levels, and STMR and HR 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 5.4.
- 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 5.7.

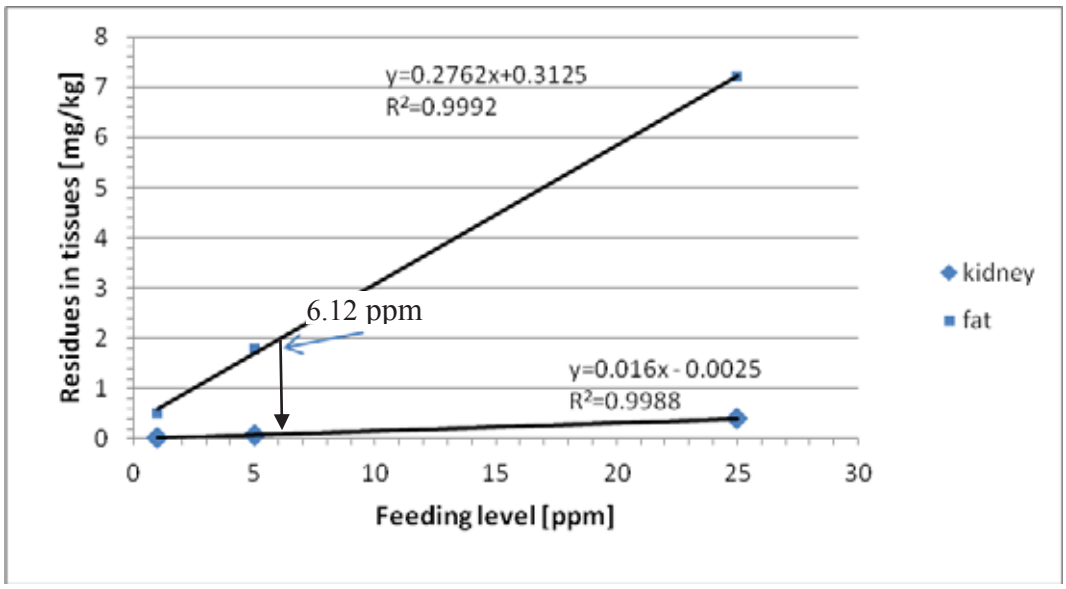


Figure 5.4 Interpolation between closest feeding levels

- 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 at plateau in the relevant feeding group of the study are used.

- Similarly, for estimating maximum residue levels and STMR values in eggs, the highest residue level and the mean residue level during the plateau 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.
- If the residue definition for animal commodity includes parent plus metabolite A, for which no specific transfer studies exist, and residues in animal feeds include metabolite A, then add metabolite A in the dietary burden calculations, assuming that residues of Metabolite A all go into tissues, milk etc. (worst case).

The estimated maximum and mean animal dietary burdens (listed in Table 5.6) are compared with the residues obtained from livestock feeding studies for estimating maximum residue levels, and STMR and HR values 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 numerical value of MRL is obtained by rounding up the estimated highest residue according to the scale described in section 5.13.

The STMR values for the tissues are 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 5.7 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 5.7 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.

5.12.2 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-on 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 8.3 "*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.

5.12.3 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.

5.12.4 Maximum Residues in 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 8.3). 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 level. 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 STMRor STMR-P should be applied to each of the components of mixed commodities.

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 food-producing 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)(Muscular tissues with trimmable fat removed. For fat-soluble pesticides a portion of adhering fat is analysed and MRLs apply to the fat) MO 0105 Edible offal (Mammalian), and ML 0106 Milks. Where residues in liver and kidney differ significantly, an option is to recommend a MRL for MO 0098 Kidney of cattle, goats, pigs and sheep or MO 0099 Liver of cattle, goats, pigs and sheep, whichever is higher and use MO 0105 Edible offal (Mammalian) for other edible offal.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 poultry and selected from: PM 0110 Poultry meat (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.), PO 0111 Poultry, Edible offal of (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) and PE 0112 Eggs.

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.

The JMPR had followed the CCPR convention, 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 agreed[45] 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 5.13 "*Expression of maximum residue limits.*"

Eggs

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

5.13 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 (copied to Appendix VI)[22].

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 expresses 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 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.

[45] Report of the 40th 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

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 would be replaced with a more detailed scale according to the recommendation of the OECD MRL Calculator User Guide.[39]

To facilitate the setting of harmonized MRLs in the global environment, maximum residue level proposals are rounded as a last step in the calculation. For numbers between 1 and 10, they are rounded to a single digit; for 10 to 100, they are rounded to multiples of 10; for 100 to 1000, they are rounded to multiples of 100 and so on. Intermediate values of 0.015, 0.15, 1.5, 15, etc, were introduced to avoid doubling of MRLs on rounding. So for example: 0.12 rounds up to 0.15, 0.16 rounds up to 0.2; and 12 rounds up to 15 instead of 20. The possibility for rounding down exists if a particular MRL level is surpassed by a specified amount. To be more precise, the rounding possibilities are (in mg/kg): 0.001, 0.0015, 0.002, 0.003, 0.004, 0.005, 0.006, 0.007, 0.008, 0.009, 0.01, 0.015, 0.02, 0.03, 0.04, 0.05, 0.06, 0.07, 0.08, 0.09, 0.1, 0.15, 0.2, 0.3, 0.4, 0.5, 0.6, 0.7, 0.8, 0.9, ,1 1.5, 2, 3, 4, 5, 6, 7, 8, 9, 10, 15, 20, 30, 40, 50, 60, 70, 80, 90, 100, 150, 200, 300, 400, 500, 600, 700, 800, 900, 1000 ...
The Excel template used for the MRL calculation provides both the rounded (recommended) and unrounded values. If residues are below 0.01 mg/kg the OECD calculator always rounds up to 0.01 mg/kg; if lower residues are needed, e.g., for compounds with a low maximum ADI and/or ARfD, the unrounded value may be needed.

5.13.1 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 quintozene[46].

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 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.

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.

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

[46] FAO/WHO Pesticide residues in food—1995 evaluations. Part I. Residues. FAO Plant Production and Protection Paper 137, 1996.

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 undetected 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.

Some examples for illustration of the possible approaches:[36, 43]

a. The residues of fenamidone and it metabolite RPA 410193 are found in the same order of magnitude as the parent in berries harvested 4 to 5 weeks after treatment. In plant commodities harvested at shorter periods (2 – 21 days), the level of the metabolite is much lower than the parent in most cases. The method for calculation of the total residues of the sum of fenamidone and RPA 410193 is illustrated as follows:

Plant commodities except grapes and strawberries

Fenamidone, mg/kg	RPA 410193, mg/kg	Total, mg/kg
< 0.02	< 0.02	< 0.02
0.05	< 0.02	0.05
0.42	0.08	0.51[a]

[a] 0.42 + (0.08 × 1.11) = 0.5088

b. For myclobutanil the definition of the residue for estimation of dietary intake for plant commodities is sum of myclobutanil, α-(4-chlorophenyl)-α-(3-hydroxybutyl)-1H-1,2,4-triazole- 1-propanenitrile (RH-9090) and its conjugates, expressed as myclobutanil. The similar molecular weight, suggest to sum up residues of myclobutanil and RH-9090 as total residue.

RH-9090 less than LOQ (0.01 mg/kg) and more than LOD (0.0025 mg/kg)

Myclobutanil, mg/kg	RH-9090, mg/kg	Total, mg/kg
< 0.01	< 0.01	< 0.02
0.08	< 0.01	0.09

(i)RH-9090 less LOD (0.0025 mg/kg)

Myclobutanil, mg/kg	RH-9090, mg/kg	Total, mg/kg
< 0.01	< 0.0025	< 0.01
0.08	< 0.0025	0.08

(ii)RH-9090 equal to or more than LOQ (0.01 mg/kg)

Myclobutanil, mg/kg	RH-9090, mg/kg	Total, mg/kg
0.21	0.03	0.24

c. For trifloxystrobin the residue definition for animal commodities and dietary intake assessment, the residue definition should be parent compound and CGA 321113 (expressed as trifloxystrobin equivalents). The sum of trifloxystrobin and CGA 321113 was calculated and expressed as trifloxystrobin on the basis of the relative molecular masses. A conversion factor of 1.036 is required to express CGA 321113 as trifloxystrobin. As CGA 321113 does not generally constitute a significant proportion of the residue in crops, when the levels of trifloxystrobin or CGA 321113 were below the LOQ, their sum was calculated as:

Trifloxystrobin (mg/kg)	CGA 321113 (mg/kg)	Total (expressed as trifloxystrobin) (mg/kg)
< 0.01	< 0.01	< 0.01
< 0.01	0.011	0.021
0.10	< 0.02	0.10
0.92	0.16	1.1

The above examples are not inclusive. The best method to express the residue levels most realistically may have to be decided on a case-by-case basis.

5.14 Recommendations for maximum residue limits

The JMPR recommends to the CCPR that the estimated maximum residue levels be used as MRLs. The JMPR indicates those cases where the maximum ADI or ARfD are likely to be exceeded (Chapter 6, "*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

5.14.1 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 in future evaluation of residues.

5.14.2 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. In 1993 the Codex Alimentarius Commission decided that Guideline Levels would no longer be established.

CHAPTER 6

ESTIMATING DIETARY INTAKE OF PESTICIDE RESIDUES

CONTENTS

6.1 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).

Until 1997 the Theoretical Maximum Daily Intake (TMDI) calculations had been carried out according to the Guidelines for predicting chronic dietary intake of pesticide residues[47] published by the WHO in 1989. The dietary intake of any particular pesticide residue was obtained by multiplying the MRL 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.

$$TMDI = \sum (MRL_i \times F_i)$$

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 Residues[47] 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).

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)

[47] WHO. 1989. Guidelines for predicting dietary intake of pesticide residues. GEMS/Food WHO, Geneva.

- 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 guidelines[48] were issued in 1997.

6.2 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 diets[49], and summing the intakes for each food.

In 1997, the WHO introduced the GEMS/Food cluster diets. The first cluster diets were based on the 1990–1994 FAO food Supply Utilisation Account (SUA) data. The method used cluster analysis and an iterative approach based on the use of 19 marker foods to define 13 diets representing 183 countries. The 13 cluster diets were later updated using food SUA data from 1997 to 2001. The updated 13 cluster diets were used by JMPR to predict pesticide residue exposures in the period of 2006–2013.

In 2012, WHO introduced a new methodology to cluster the FAO food SUA (available at: http://faostat3.fao.org) data into 17 diets based on statistical similarities between dietary patterns in 179 countries. The new cluster diets (available at:

[48] 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/pesticides/en/

[49] 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

http://www.who.int/foodsafety/databases/en/) were based on the more recent average 5-year FAO food supply utilisation account data from 2002–2007. These average data were weighted by the population size to get average kg/person/cluster over a 5 year period. In the 17 clusters the consumption of a food important to a certain country is now distributed together with countries where the same food is important. The main impact is that for that specific country there will be an increased intake of such a food when compared with the 13 cluster diets. Furthermore, because the 17 cluster diet data are based on more aggregated food commodities as collected in the FAO database, higher exposure levels may be estimated for certain commodities.

In 2014 WHO decided to split the aggregate consumption data in the GEMS/food database by use of split factors derived from national consumption databases, to facilitate the detailed consumption data needed for pesticide dietary risk assessments. These refined 17 Cluster Diets have been incorporated in the JMPR IEDI model by RIVM (Dutch National Institute for Public Health and the Environment) acting as WHO Collaborating Centre (http://www.who.int/foodsafety/areas_work/chemical-risks/gems-food/en/) and was used by the JMPR in 2014 for the first time. The JMPR IEDI model is an automated Excel spreadsheet for the calculation of chronic dietary intake of pesticide residues. To use the IEDI model, estimates made by JMPR (ADI, STMR (-P), and when necessary MRL values) are entered according to the manual attached to the model. Then calculations and generation of an overview table are performed automatically. The Meeting noted that the mean body weights used in the IEDI model are still 55 kg for cluster G09 and 60 kg for all others.

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 10 of Chapter 5 should be followed.

On some occasions STMRvalues 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.

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	STMRor STMR-P	Diets: g/person/day. Intake = daily intake: µg/person					
				G01		G02		G03	
Code	Commodity	mg/kg	mg/kg	diet	intake	diet	intake	diet	Intake
MM 95	Meat (mammals other than marine)			31.2		72.44		20.88	
	Muscle (meat consumption×80%)		0.01	24.96	0.25	57.95	0.58	16.70	0.17
	Fat (meat consumption×20%)		0.16	3.29	0.53	6.14	0.98	0.82	0.13
PM110	Poultry meat								
	Muscle (meat consumption×90%)		0.02	13.17	0.26	26.78	0.54	7.24	0.14
	Fat (meat consumption ×10%)		0.04	0.10	0.00	0.10	0.00	NC	-
		TOTAL =			1.0		2.1		0.4
		% ADI =			0%		0%		0%

The format of a spreadsheet for calculating long-term intake is provided in Tables XI.4 and XI.5 (Appendix XI).

International estimated daily intakes (IEDIs) are derived only where STMRs or STMR-Ps are used in the calculation. IEDI = $\sum (STMR_i \times F_i)$

where

$STMR_i$ (or $STMR\text{-}P_i$): STMR (or STMR-P) for food commodity i

F_i : 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.

When the pesticide is also used as veterinary drug and MRLs were established for animal commodities, the veterinary drug residues should also be taken into account in the IEDI calculation.

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 G09 (Asia) in which a body weight of 55 kg is used. 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 based[50]. In cases where

[50] FAO. Pesticide Residues in Food 2008- Report. FAO Plant Production and Protection Paper No. 193 FAO, Rome. P 51.

the ADI is exceeded, JMPR indicates in its report which part of the risk assessment leaves most room for refinement (see Chapter 6.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.

6.3 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 guidelines were published in 1997 by the WHO[48] 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 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.

Usually the trials conducted according to *c*GAP results in the highest residue in composite samples. However, when the highest residue is derived from a trial performed with less critical application conditions, then the HR should be selected from that trial.

When replicate samples are taken from one trial site and the MRL estimation is based on the average residues in the replicate samples, the HR should be selected from residues detected in single samples.

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 incorporated in the Excel template developed by RIVM.

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 (97.5th 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 97.5th 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.

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 1998, 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.

$$IESTI = \frac{LP \times (HR\ or\ HR - P)}{bw}$$

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.

$$IESTI = \frac{U_e \times (HR\ or\ HR - P) \times v + (LP - U_e) \times (HR\ or\ HR - P)}{bw}$$

The Case 2a formula is based on the assumption that the first unit contains residues at the [HR × 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.

$$IESTI = \frac{LP \times (HR\ or\ HR - P) \times v}{bw}$$

The Case 2b formula is based on the assumption that there is only one consumed unit and it contains residues at the [HR × v] level.

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.

$$\mathrm{IESTI} = \frac{\mathrm{LP} \times \mathrm{STMR} - \mathrm{P})}{\mathrm{bw}}$$

6.4 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.

In the short-term risk assessment of a compound, there are three situations with respect to the ARfD:

1) an ARfD is available, and as a special case the ARfD is established for women of child bearing age (14–50 yrs old)
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 are expressed as % of ARfD.

When an ARfD is deemed unnecessary, IESTI calculations are not necessary; estimation of HR and HR-P values are not required or used. However, for the estimation of animal dietary burden the "highest residue" values may still be necessary depending on the type of commodity.

6.5 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/Food[51].

Tables XI.6 and XI.7 (Appendix XI) provide examples of the format used in the IESTI calculation spreadsheets; 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: The automated IESTI model requires the STMR to be entered first, followed by the HR in the line indicated with a total for each commodity, for which an MRL has been proposed. Further instructions can be found in the manual within the automated IESTI model.
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 µg/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.

[51] Dutch National Institute for Public Health and the Environment (RIVM) and WHO/GEMS/Food http://www.who.int/foodsafety/areas_work/chemical-risks/gems-food/en/

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 consultation[52], 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.

The 2003 JMPR[53] evaluated the available information on the relation of maximum residues in crop units and the average residue in the corresponding composite samples[54]. 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 applicability of the default variability factor of 3, which is the rounded mean (2.8) of variability factors, was confirmed by the 2005 JMPR[32] based on the evaluation of an extensive data base of residues in crop units[55]. 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 JMPR[32] noted that the parameters to be used in the IESTI equation are under debate, especially within the European Union. 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 diets in the automated IESTI model are based on national consumption surveys, submitted to WHO. The highest submitted large portion value (on g/kg bw basis) was chosen for a particular group, whereby general population data are used to fill up missing data for women of childbearing age. Large portion data were only taken if the P97.5 percentile was based on at least 120 consumer days or if other data indicate that a large portion data based on less than 120 days is acceptable. If the highest large portion was not considered reliable, the next highest large portion data from another country were taken. 3. Unit weights. Large portion data in the automated IESTI model were combined with the unit weight and % edible portion data of the country in question. For those countries where no unit weights were available, large portion data were combined with unit weight data from any of the other countries resulting in the

[52] FAO/WHO. 1997. Geneva consultation acute dietary intake methodology. Geneva, Switzerland.10-14 February 1997. WHO/FSF/FOS/97.5

[53] FAO Pesticide Residues in Food 2003 Report. FAO Plant Production and Protection Paper No. 176. 2.10. FAO, Rome, http://www.fao.org/agriculture/crops/core-themes/theme/pests/jmpr/jmpr-rep/en/

[54] 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).

[55] Ambrus Á., Variability of pesticide residues in crop units, Pest Manag Sci. 62: 693-714, 2006.

highest Ue (unit weight of the edible portion).4. Case: decide the case from the unit weight, U, unit weight edible portion, U_e, and large portion size.

6.5.1 Animal commodities IESTI calculations

See also Chapter 5, 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.

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).

6.6 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 Cluster diets a footnote will be attached to the compound in the recommendations table and also in the Chapter 4 of the Report, which summarises the results of the risk assessments conducted by the Meeting.

"On the basis of information provided to the Meeting, it was concluded that the long-term dietary intake of [compound] residues may present a public health concern "

If the JMPR estimate of short-term intake of a compound exceeds the ARfD for one or more food commodities a footnote will be attached to those commodities in the recommendations table:

On the basis of information provided to the Meeting, it was concluded that the short-term intake of XX residues from the consumption of [commodity] may present a public health concern.
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 intake[56]. In cases where the maximum 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.

[56] FAO Pesticide Residues in Food 2007 Report. FAO Plant Production and Protection Paper No. 191. 2.1. FAO, Rome

CHAPTER 7

USE OF JMPR RECOMMENDATIONS BY REGULATORY AUTHORITIES

CONTENTS

7.1 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.

7.2 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. The safety of other components of formulations should also be considered when registering pesticides. For these reasons the JMPR does not 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.

7.2.1 Relevance of pesticide specifications for JMPR evaluations

The 2006 edition of the FAO Manual on the development and use of FAO/WHO specifications for Pesticides[57] 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.

7.3 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.

[57] Manual on development and use of FAO and WHO specifications for pesticides. February 2006. http://www.fao.org/agriculture/crops/thematic-sitemap/theme/pests/jmps/en/

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.

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).

7.4 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.

According to the relevant ISO[58] and Codex Guidelines[59] the expanded combined measurement uncertainty shall be taken into account in deciding on the compliance with legal limits (MRL, CXL).
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.

58 Joint Committee for Guides in Metrology (JCGM/WG 1). Evaluation of measurement data − guide to the expression of uncertainty in measurement; http://www.bipm.org/utils/common/documents/jcgm/JCGM_100_2008_E.pdf

59 Codex Alimentarius Commission. Guidelines on Measurement Uncertainty; CAC/GL 54-2004; Annex http://www.codexalimentarius.org/search-results/?cx=018170620143701104933%3Ai-zresgmxec&cof=FORID%3A11&q=GUIDELINES+ON+MEASUREMENT+UNCERTAINTY+CAC%2FGL+54&sa.x=17&sa.y=6&sa=search&siteurl=http%3A%2F%2Fwww.codexalimentarius.org%2F&siteurl=www.codexalimentarius.org%2F&ref=&ss=55j3025j2

For the determination of pesticide residues, only the contribution of sample preparation (homogenization of the laboratory sample with chopping, grinding etc. before the representative test portion is withdrawn) (S_{Sp}) and analysis (S_A) shall be taken into account.

When a marketed commodity is tested the combined uncertainty of the analysis of the residues in a laboratory sample complying with minimum size requirements of Codex Sampling Guideline[60] shall be taken into account. A default expanded combined uncertainty of 50% is used within the European Union[61], which is calculated from the results European proficiency tests. With this decision rule, the value of the measurand is above the MRL with at least 97.5% confidence. Thus, the MRL is exceeded if x-U > MRL. For example,, in a case where the MRL = 1 and x = 2.2, then x-U = 2.2 –1.1 = 1.1 which is > MRL (1.1= 50% of 2.2). As the default uncertainty is within the range of acceptable repeatability relative standard deviation of determination of 0.01–0.1 mg/kg pesticide residues at 1 µg–0.1 mg/kg concentrations (section 3.3.3 Table 3.5), it can be generally applied, provided the method validation results are lower than the default value.

When the product is tested before it is placed on the market, the combined uncertainty (CV_R) including sampling uncertainty shall be taken into account[62]. The sampled product would comply with the MRL if $x+ 2*CV_R*x \leq MRL$.

Based on the evaluation of large number of residue data, the average sampling uncertainty following the Codex sampling procedure was estimated[63] to be:

- small and medium size crops (unit mass ≤ 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%.

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:

- pay attention to the definition of residues for enforcement or dietary intake assessment purposes
- 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 strictly adhere to Codex guidelines for preparing the portion of commodity for analysis

[60] Codex Secretariat. 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

[61] European Commission. Guidance document on analytical quality control and validation procedures for pesticide residues analysis in food and feed. SANCO/12571/2013 http://www.eurl-pesticides.eu/docs/public/tmplt_article.asp?CntID=727

[62] Farkas, Zs., Slate, A., Whitaker, T.B. Suszter, G., and Ambrus Á. Use of Combined Uncertainty of Pesticide Residue Results for Testing Compliance with Maximum Residue Limits (MRLs) J. Agric. Food Chem. 2015, 63, 4418−4428.

[63] Ambrus, A. & Soboleva, E. (2004) JAOAC International. 87, 1368-1379

- 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.

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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.
DAT	Day after (last) application
EMDI	estimated maximum daily intake
EMRL	extraneous maximum residue limit
FAO	Food and Agriculture Organization of the United Nations
GAP	good agricultural practice(s)
GEMS/Food	Global Environment Monitoring System – Food Contamination Monitoring and Assessment Programme
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 short-term dietary exposure from the commodity
HR-P	highest 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 Organization for Standardization

ISO-E	International Organization for Standardization – 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; note that the term "LOD" may also be used to mean "limit of detection")
LP	large portion consumed (kg food/person/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 (median residue in the edible portion of the commodity found in the trials used to estimate long- and short-term dietary exposure)
STMR-P	supervised trials median residue – processed commodity (calculated by multiplying the STMR of the raw agricultural commodity by the corresponding processing factor)
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
US EPA	United States Environmental Protection Agency
UV	ultraviolet
υ	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 2006[64]) 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 measure[58]

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.

[64] 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.

$$\text{Processing factor} = \frac{\text{residue concentration [mg/kg] in processed product}}{\text{residue concentration [mg/kg] in RAC}}$$

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 **5** section 14.1, "Recommendation of temporary MRLs."

Appendix III

STANDARD TWO LETTERS CODE FOR PESTICIDE FORMULATIONS[65]

AB	Grain bait
AE	Aerosol dispenser
AL	Other liquids to be applied undiluted
AP	Other powders to be applied undiluted
(BB)	Block bait (see RB)
BR	Briquette
CB	Bait concentrate
CF	Capsule Suspension for Seed Treatment
CG	Encapsulated granule
CL	Contact liquid or gel
CP	Contact powder
CS	Capsule suspension
DC	Dispersible concentrate
DP	Dustable powder
DS	Powder for dry seed treatment
DT	Tablet for direct application
EC	Emulsifiable concentrate
(ED)	Electrochargeable liquid
EG	Emulsifiable Granule
EO	Emulsion, water in oil
EP	Emulsifiable powder
ES	Emulsion for seed treatment
EW	Emulsion, oil in water
(FD)	Smoke tin (see FU)
(FG)	Fine granule (see GR)
(FK)	Smoke candle (see FU)
(FP)	Smoke cartridge (see FU)
(FR)	Smoke rodlet (see FU)
FS	Flowable concentrate for seed treatment
(FT)	Smoke tablet (see FU)
FU	Smoke generator
(FW)	Smoke pellet (see FU)
GA	Gas
(GB)	Granular bait (see RB)
GE	Gas generating product
(GF)	Gel for Seed Treatment
(GG)	Macrogranule (see GR)
GL	Emulsifiable gel
(GP)	Flo-dust
GR	Granule
GS	Grease
KP	Combi-pack solid/solid
(LA)	Lacquer
LN	Long-lasting insecticidal net
LS	Solution for seed treatment
(LV)	Liquid vapouriser
MC	Mosquito coil
ME	Micro-emulsion
(MG)	Microgranule (see GR)
(MV)	Vapourizing mats
OD	Oil dispersion
OF	Oil miscible flowable concentrate (oil miscible suspension)
OL	Oil miscible liquid
OP	Oil dispersible powder
PA	Paste
(PB)	Plate bait (see RB)
PC	Gel concentrate or paste concentrate
PO	Pour-on
PR	Plant rodlet
PS	Seed coated with a pesticide
RB	Bait (ready to use)
(SA)	Spot-on
(SB)	Scrap bait (see RB)
SC	Suspension concentrate (= flowable concentrate)
SD	Suspension concentrate for direct application
SE	Suspo-emulsion
SG	Water soluble granule
SL	Soluble concentrate
SO	Spreading oil
SP	Water soluble powder
(SS)	Water soluble powder for seed treatment
ST	Water soluble tablet
SU	Ultra-low volume (ULV) suspension
TB	Tablet
TC	Technical material
TK	Technical concentrate
(TP)	Tracking powder
UL	Ultra-low volume (ULV) liquid
VP	Vapour releasing product
WG	Water dispersible granule
WP	Wettable powder
WS	Water dispersible powder for slurry seed

[65] Tomlin C.D.S. (ed). The Pesticide Manual 15th edition. British Crop Protection Council, 2009.

			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	ZE	Mixed formulation of CS and SE
KN	Cold fogging concentrate	ZW	Mixed formulation of CS and EW

Note: Codes in brackets are discontinued

Appendix IV

MRL PERIODIC REVIEW PROCEDURE BY CCPR
(PEP/14/PR APPENDIX XIII)

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:

SELECTION OF PESTICIDES FOR JMPR EVALUATION

Each year CCPR, in cooperation with the JMPR Secretariat, agrees on a schedule of JMPR evaluations in the following year and considers prioritisation of other pesticides for future scheduling.

Procedure for the preparation of the Schedules and Priority Lists

CCPR submits the Schedules and Priority Lists of Pesticides for JMPR Evaluation to the CAC for approval each year, as new work, and requests the re-establishment of the Electronic Working Group (EWG) on Priorities.

The EWG on Priorities is tasked with preparing a Schedule of Pesticides for JMPR (evaluations for the following year) for the consideration of CCPR and the maintenance of a Priority List of Pesticides for future scheduling by CCPR.

The Schedules and Priority Lists are provided in the following Tables:

a. Table 1 – CCPR Proposed Schedule and Priority Lists of Pesticides (new pesticides, new uses, and other evaluations);

b. Table 2A – Schedule and Priority Lists of Periodic Reviews;

c. Table 2B – Periodic Review List (Pesticides that have been last evaluated 15 years ago or more, but not yet scheduled or listed, 15 years-rule);

d. Table 3 – Record of Periodic Review;

e. Table 4 –Pesticide/Food combinations for which specific GAP is no longer supported.

Each year, the Codex Secretariat issues a letter, one month after the CAC, seeking application for membership of the EWG on Priorities.

In early September of each year, the EWG Chair will issue a broadcast e-mail to member/observers of the EWG requesting nominations for periodic reviews of pesticides for which there are concerns including public health.

The nomination form shall provide a clear indication of the availability of data and national evaluations, as well as, give an indication of the number of crops and residue trials to be evaluated. The request should also indicate the current status of national registrations for the pesticide.

Nominations for periodic reviews should be submitted, on concern forms Annex 1 of Appendix IV, with accompanying scientific data addressing the relevant concern. Information on the most recent evaluation, ADI and ARfD should be provided.

Nominations complying with the requirements are incorporated into a list, prioritised and scheduled according to the criteria specified below:

a. Those received by 30 November are incorporated into the draft agenda paper which is distributed as a circular letter in early January.

b. Members and observers are allowed two months from the date of distribution to provide comment to the EWG Chair and JMPR Joint Secretariat.

c. On the basis of comments received in response to the circular letter, the EWG Chair incorporates the new nominations into the Schedule and Priority Lists, and prepares an agenda paper for CCPR. The Schedule seeks to provide a balance of new pesticides, new uses, other evaluations and periodic reviews.

d. Following plenary discussions on MRL recommendations, the EWG Chair revises the Schedule and Priority List, which is then presented as Conference Room Document (CRD) for CCPR's consideration. To cover the possibility that a member/observer cannot meet the JMPR data call-in deadline CCPR will include reserve pesticides.

e. Following plenary discussion on CRD, the CCPR will agree on a JMPR Evaluation Schedule for the following year. The final Schedule will take into account available JMPR resources.

f. At this point, the Schedule will be closed for the inclusion of additional pesticides. However, with the agreement of the JMPR Secretariat, the inclusion of additional foods or feeds for scheduled pesticides may be accepted.

Nomination requirements and criteria for the prioritisation and scheduling pesticides for evaluation by JMPR

Pesticides that have not been reviewed toxicologically for more than 15 years and/or not having a significant review of CXL for 15 years will be listed in Table 2B of the Schedules and Priority Lists.

Pesticides listed in Table 2B should be considered for scheduling for periodic review when concerns, including public health concerns are identified and nominated for inclusion in Table 2A. The nominating member should submit the concern form in Annex 1 and accompanying relevant scientific information substantiating the concern for consideration by JMPR Secretariat /eWG on Priorities.

Pesticides listed in Table 2B may be nominated for inclusion in Table 2A and thus considered for scheduling for periodic review on the basis of the availability of data necessary for the review. The nominating member should submit an inventory and brief explanation of the relevant toxicological and residue data package for consideration by JMPR Secretariat/eWG on Priorities. The member should inform the eWG on Priorities whether all or some of the CXLs will be supported and should specify each supported and unsupported CXL.

Pesticides listed in Table 2B, for which no periodic review has been undertaken for 25 years, will be brought to the attention of CCPR with a view to transfer to Table 2A and subsequent scheduling.

Pesticides which have been the subject of a periodic review during the previous 15 years, and thus are not listed in Table 2B, may be considered for transferring to Table 2A where a concern form in Annex 1 and accompanying scientific information, upon review, demonstrates a public health concern.

Scheduling and Prioritisation Criteria for pesticides listed in Table 2A

The EWG on Priorities and CCPR will consider the following periodic review criteria:

a. If scientific data concerning the intake and/or toxicity profile of a pesticide indicates some level of public health concern;

b. If no ARfD has been established by Codex or if an established ADI or ARfD are of public health concern and information is available from members on national registrations and/or the conclusions from national/regional evaluations indicated a public health concern;

c. The availability of current labels (authorised GAP) arising from recent national reviews;

d. The CCPR has been advised by a member that the residues from a pesticide has been responsible for trade disruption;

e. The date the data will be submitted;

f. If there is a closely related pesticide that is a candidate for periodic review that can be evaluated concurrently.

g. The CCPR agrees to schedule the pesticide under the four-year rule.

In this case, the four-year rule is applied when insufficient data have been submitted to confirm or amend an existing CXL. The CXL is recommended for withdrawal. However, members/observers may provide a commitment to JMPR and CCPR to provide the necessary data for review within four years. The existing CXL is maintained for a period of no more

than four years pending the review of the additional data. A second period of four years is not granted.

Identify pesticides for Periodic Review and solicit data commitments

Pesticides are listed for periodic review according to the process and procedures described in section "Selection of pesticides for JMPR evaluation". The process provides members/observers a notice of a periodic review.

When a pesticide is listed for periodic review, members/observers are able to support it, regarding the two following possibilities:

a. Case A: The pesticide is supported by the original sponsor, who is committed to submit a complete data package to meet JMPR's data requirements.

If the original sponsor does not support some uses, members/observers may support them.

b. Case B: The pesticide is not supported by the original sponsor; in this case, interested members / observers may support the review of the pesticide.

Commitment to support pesticides or existing CXL or new proposed MRL

The commitment of members/observers to provide data for the periodic review should be addressed to the Chair of the EWG on Priorities and the JMPR Joint Secretariat according to Chapter 3 of FAO Manual1 and the considerations of the JMPR on pesticides no longer supported by the original sponsor.

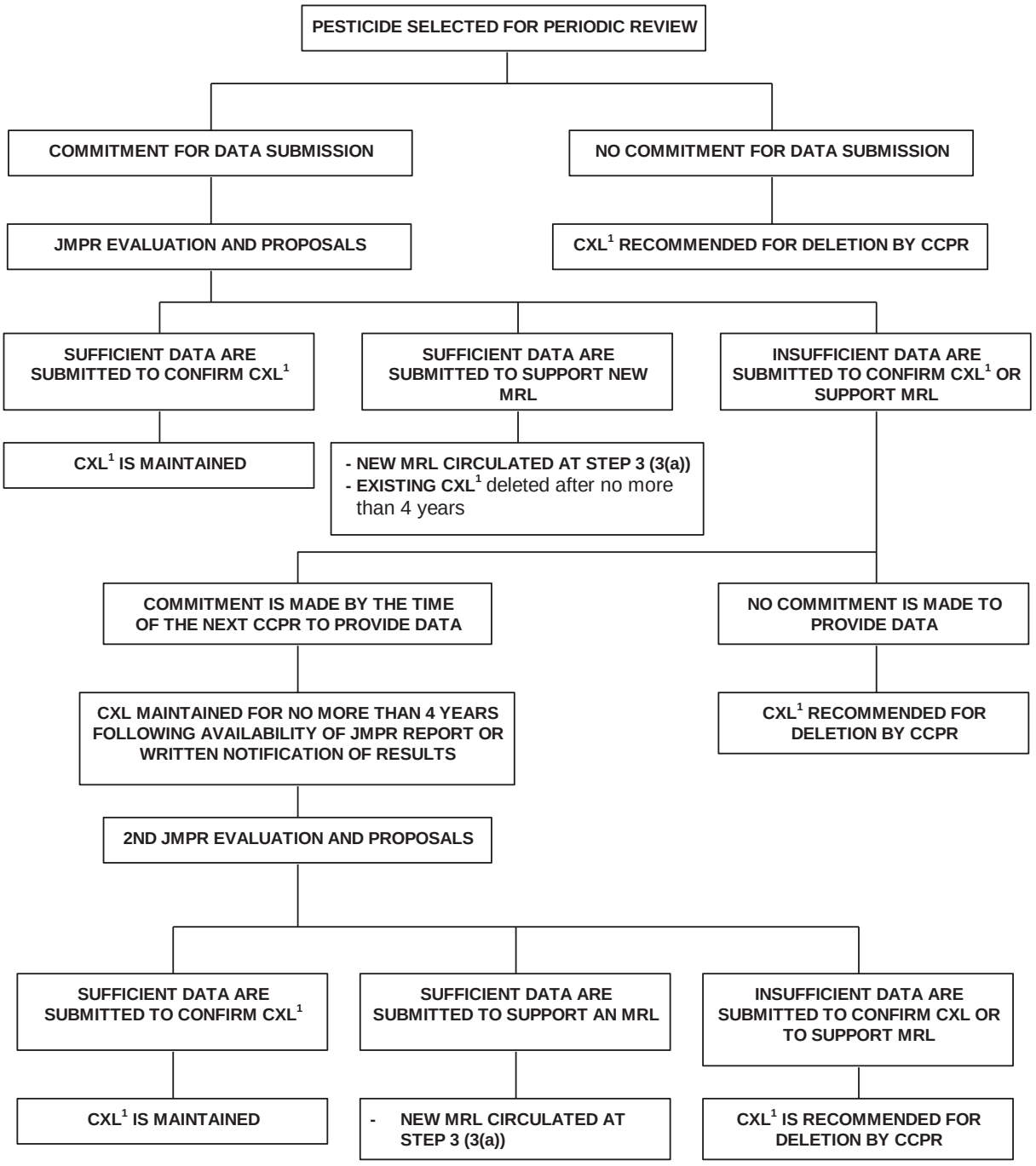
For Case A and Case B, data should be submitted in accordance with the guidance of the JMPR for the respective cases.

- In cases where some uses are not supported by the manufacturer, but are supported by members/observers:

- If the current GAP support the current CXL, justification for it as well as relevant labels are required;

- If GAP were modified, supervised residue trial studies conducted according to current GAP, and relevant studies to support new MRL in animal and processed foods are required.

SUMMARY OF PERIODIC REVIEW PROCEDURE FOR CODEX MRLs



[1]Codex 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.

Annex 1 of Appendix IV[a]

FORM FOR EXPRESING CONCERNS WITH PUBLIC HEALTH ON A PESTICIDE FOR PRIORITISATION OF PERIODIC REVIEW

Submitted by:		
Date:		
Pesticide/PesticideCodeNumber	***Food(s)/FoodCode Number(s)***	**CXL (mg/kg**
Is this a concern?		
The concern relates to which prioritisation criterion/criteria (Specific statement of concern)		
Is supporting data being provided?		
Data/Information (Description of each separate piece of data/information which is attached or will provided to the EWG Priorities and the appropriate JMPR Secretary within one month of the CCPR meeting)		
Is this a continuing concern?		
Outline ongoing concern and provide supporting data		

[a]: Annex B in CCPR Report

Appendix V

RECOMMENDED SAMPLING METHODS FOR SUPERVISED FIELD TRIALS

CONTENTS

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[66]

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

[66] OECD Test No. 509 Crop Field trial http://www.oecd-ilibrary.org/environment/test-no-509-crop-field-trial_9789264076457-en

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 Tables **V**.1-V.10
- 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 2A.[22]

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.

- 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, kumquat	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, pineapple	Group 006	
(Sub)tropical fruits with edible peels e.g. Date, olives, fig	Group 005	1 kg from several places on 4 trees
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 6 bushes
Strawberries, Gooseberries	FB 0275, FB 0276 FB 0268	1 kg from 12 separate plants or 6 bushes
Miscellaneous small fruits e.g., olives, dates, figs	Group 005	1 kg from several places on 4 trees
Pineapples	Fl 0353	12 fruits
Banana, Plantain	Fl 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
Potato, sweet potato, yam	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, tapioca, taro	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 (the sample should weigh at least 2 kg - where necessary, take a larger number to produce a 2 kg sample)
Spring onions (onion green)	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 Okra	VB 0400 VO4293	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-fruiting varieties, 12 from large fruiting 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], leaf, head Lettuce head endive/escarole/scarole	Group 013	12 plants
Spinach [a], Chicory leaves [a]	VL 0502 VL 0469	1 kg from 12 plants
Kale, Collards	VL 0480	2 kg from 12 plants sampled from two levels on the plant
Small-leaf salad crops, e.g., cress,	Group 013	0.5 kg from 12 plants (or sites

Commodity	Codex Code No.	Quantity, method of collection
dandelion, corn salad, lambs' salad, parsley, mint		in plot)
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
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
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.)
Hay		0.5 kg from 12 separate areas of plot
Fodder crops, straw	Groups 050, 051, 052	05-1 kg from 12 separate areas of plot
Forage		1 kg from 12 separate areas of plot

Note: (a) also at immature stages during decline studies

Oilseed e.g., rape seed, mustard seed, poppy seed	Group 023	2 kg from 12 separate areas of plot. (Crops harvested mechanically can be sampled from the harvester as it proceeds through the crop.)

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 (Crops harvested mechanically can be sampled from the harvester as it proceeds through the crop.)
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 from 12 separate areas of plot. (Crops harvested mechanically can be sampled from the harvester as it proceeds through the crop.)
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**	**Weight/unit (homogenised) Laboratory Sample**
Meat	Collect approx. equal pieces of loin, flank or hind-leg (round piece) muscle	0.5 kg
Fat	Collect approx. equal quantities of subcutaneous, mesenterial and perirenal fat [a]	0.5 kg
Liver	Collect the entire organ or representative parts thereof, e.g., a cross-section of the lobes	0.4 kg
Kidney	Sub-sample from both kidneys	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, breakeggs 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	Weight/unit (homogenised) Laboratory Sample
Meat	Collect approx. equal pieces of loin, flank or hind-leg (round piece) muscle	0.5 kg
Fat	Collect approx. equal quantities of subcutaneous, mesenterial and perirenal fat	0.5 kg
Liver	Collect the entire organ or representative parts thereof	0.4 kg
Kidney	Sub-sample from both kidneys	0.2 kg
Skin	Collect approx. equal pieces of back, flank and belly	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. See. Appendix VI. for procedures to avoid or limit change of residue concentration from the time of sampling to analysis in the laboratory.

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 °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 °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 °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[22]

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.

Prior experience indicated that the interaction of surface residues with the internal part of plant materials may cause very rapid degradation of the residues. Since the rate of such decomposition is a function of several factors including but not limited to: chemical properties of the residues, plant matrix, temperature, and duration of the contact; without specific information on the stability of the residue the only option provided in the guidelines is to not to permit the cutting individual commodity units prior to analysis.

The Codex Recommended Methods of Sampling for the Determination of Pesticide Residues for Compliance with MRLs, (CAC/GL 33-1999.) and the Codex Guidelines on Good Laboratory Practice in Residue Analysis, (CAC/GL 40-1993, Rev.1-2003) state that "A sampling device, quartering, or other appropriate size reduction process may be used but units of fresh plant products or whole eggs should not be cut or broken." Furthermore," if analyses are planned on matrices such as pulp and peel (e.g., for dietary risk assessment refinement), the whole commodity should be shipped to the analysis lab to avoid cross contamination of peel and pulp."

The 2013 JMPR recognized that cutting large bulky commodities or fruits with hard peel such as, for instance, jackfruit, watermelon, cabbage, pineapple and avocado in deep-frozen condition is very difficult. Furthermore, storing several samples of such fruits would require very large freezing capacity.

Keeping in mind the importance of assuring that the residue levels in the laboratory samples are the same or very similar to that at the time of sampling, the Meeting recommended:

- Locating trial sites at distances from which samples can be transported to the testing laboratory within 24 hours with coolant such as "blue ice". Allowing the large commodities to be immediately sub-sampled, appropriate representative sub-sample portions further homogenised and the test portions withdrawn and stored deep-frozen prior to extraction and analysis. This procedure concurs with the allowance given by both the Codex and OECD Guidelines[67] on transporting fresh plant materials without the need for deep-freezing; or
- Carry out a pre-test before conducting the supervised trials to verify the stability of residues in cut commodity. The test involves:

- surface treatment of the crops with a mixture of pesticides including two of known stability and those compounds which are the intended subject of the trials,
- performing the sub-sampling and homogenisation of the representative portions of sub-samples according to normal laboratory practice at room temperature, and analysing the residues remaining in the test portions.

If the ratio of the stable reference compounds and unknown stability residues remain the same (statistically not significantly different) taking into account the average procedural recoveries, the tested pesticides can be considered stable in the halved or quartered portions. In such cases cutting large crops is acceptable at the field site, provided that it can be done to avoid cross contamination. The applicability of the method has been extensively tested and described[67].

The selected sub-portions should be packed separately in suitable labelled bags for transportation to the analytical laboratory.

[67] Yolci Omeroglua*, A´ . Ambrus, D. Boyaciogluc and E. Solymosne Majzikd Uncertainty of the sample size reduction step in pesticide residue analysis of large-sized crops, Food Additives & Contaminants: Part *Part A* (30 (1): 116-126

Classification of Commodities	Portion of Commodity to Which the Codex MRL Applies (and Which Is Analysed)
Group 1 - ROOT AND TUBER VEGETABLES (Codex Classification† 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.	
Root and tuber vegetables: 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 *(Liliaceae)*. 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)
Bulb vegetables: 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.
Group 3 - LEAFY VEGETABLES (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: beet leaves, corn salad, endive, lettuce, radish leaves, spinach, sugar beet leaves, Swiss chard, collards, kales, mustard greens	Whole commodity after removal of obviously decomposed or withered leaves.
Group 4 - BRASSICA (COLE OR CABBAGE) VEGETABLES Codex Classification Group 010: Brassica **(cole or cabbage)** vegetables, Head cabbages, flowerhead brassicas)	
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.	
Brassica vegetables: broccoli, Brussels sprouts, cabbage, cabbage, Chinese, cabbage, red, cabbage, Savoy, cauliflower, kohlrabi	Whole commodity after removal of obviously decomposed or withered leaves. For cauliflower and broccoli analyse flower head and stems (immature inflorescence only), 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.	

Classification of Commodities	Portion of Commodity to Which the Codex MRL Applies (and Which Is Analysed)
Stem vegetables: 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. Dried forms (pulses) are consumed as seeds without the pods. Legume fodder is in Group 18.	
Legume vegetables: 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.	
Fruiting vegetables - edible peel: cucumber, egg plant, gherkin, okra, pepper, summer squash, tomato, mushroom♣	Whole commodity after removal of stems.
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.	
Fruiting vegetables - inedible peel: 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 *Rutaceae* 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.	
Citrus fruits: Orange, lemon, mandarin, pommelo	Whole commodity.
Group 10 - POME FRUITS (Codex Classification Group 002 Pome fruits)	
Pome fruits are produced by trees related to the genus *Pyrus* of the rose family (*Rosaceae*). 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.	

Classification of Commodities	Portion of Commodity to Which the Codex MRL Applies (and Which Is Analysed)
Pome fruits: 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 *Prunus* of the rose family (*Rosaceae*) characterized by fleshy tissue surrounding a single hard-shelled seed. The entire fruit, except seed, may be consumed in a succulent or processed form.	
Stone fruits: apricots, 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.	
Small fruits and berries: 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.	
Assorted fruits - edible peel: dates, figs, olives	Dates olives and similar fruits with hard seeds: 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.	
Assorted fruits - inedible peel: avocados, bananas, guavas, kiwi fruit, mangoes, papayas, passion fruits, pineapples	Whole commodity unless qualified. Pineapples: after removal of crown. Avocado, mangoes and similar fruits with hard seeds: 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 (*Gramineae*). Husks are removed before consumption.	
Cereal grains: barley, maize, oats, rice, rye, sorghum, sweet corn, wheat	Whole commodity. Fresh corn and sweet corn: kernels plus cob without husk.

Classification of Commodities	Portion of Commodity to Which the Codex MRL Applies (and Which Is Analysed)
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 (*Gramineae*) 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.	
Stalk and stem crops: 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.	
Legume oilseeds: 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.	
Legume animal feeds: alfalfa fodder, bean fodder, clover fodder, peanut fodder, pea fodder, soya bean 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.	
Tree nuts: 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.	
Oilseed: 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.	
Tropical seeds: 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.	

Classification of Commodities	Portion of Commodity to Which the Codex MRL Applies (and Which Is Analysed)
Herbs:	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.	
Spices:	Whole commodity.
Group 24 - TEAS (Codex Classification Group 066: Teas)	
Teas are derived from the leaves of several plants, but principally *Camellia sinensis*. They are used in the preparation of infusions for consumption as stimulating beverages. They are consumed as extracts of the dried or processed product.	
Teas:	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.	
Meats: 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.	
Animal fats: cattle fat, pig fat, sheep fat	Whole commodity.
Group 27 - MEAT BYPRODUCTS (Codex Classification Group 0032: Edible offal (mammalian))	
Meat by-products 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.	
Meat by-products (such as liver, kidney, etc.): cattle meat by-products, goat meat by-products, pig meat by-products, sheep meat by-products	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.	
Milks:	Whole commodity♦.
Group 29 - MILK FATS (Codex Classification Group 086: Milk fats)	
Milk fats are the fats rendered or extracted from milk.	
Milk fats:	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.	

Classification of Commodities	Portion of Commodity to Which the Codex MRL Applies (and Which Is Analysed)
Poultry Meats:	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.	
Poultry fats:	Whole commodity.
Group 32 - POULTRY BYPRODUCTS (Codex Classification Group 038: Poultry, edible offal of)	
Poultry by-products are edible tissue and organs, other than poultry meat and poultry fat, from slaughtered poultry.	
Poultry by-products:	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.	
Eggs:	Whole egg whites and yolks combined after removal of shells.

† 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.

♣ Mushroom is not included in the commodities listed in the original document

♦ Deviation form 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. The content of the information corresponds with the provisions of OECD Guidance for Industry Data Submissions on Plant Protection Products and their Active Substances[68].

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.

Doc. ID	Author(s)	Year	Title, Source, GLP status, Published or not
PAL-MP-SS	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.
2012/7004638	Gordon B.	2013 a	Freezer storage stability of Cyflumetofen (BAS 9210 I) and its relevant metabolites in plant samples, BASF Agricultural Research Center, Research Triangle Park NC, United States of America, GLP, Unpublished
	Nanita et al	2013	Analytical method and inter-laboratory study for the quantitation of aminocyclopyrachlor residues in vegetation by liquid chromatography/tandem mass spectrometry. *J AOAC Int.* 96:1473-1481.

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.

For details of information to be provided please consider Chapter 3.

[68] OECD. 2001. Dossier Guidance —OECD guidance for industry data submissions on plant protection products and their active substances Revision 2, 2005. http://www.oecd.org/chemicalsafety/pesticides-biocides/34870180.pdf

DATA DIRECTORY FORMAT

1. BACKGROUND INFORMATION

Identity

Physical and chemical properties

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

Subdivided according to laboratory animal, livestock, poultry

Relevant study references. Volume in data dossier.

Plant metabolism

Subdivided, where necessary, according to crop

Relevant study references. Volume in data dossier.

Rotational crop studies

Confined and field studies

Subdivided, where necessary, according to crop

Relevant study references. Volume in data dossier

Environmental fate in soil

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 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

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

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.

The summary of the details of the trials should be submitted in Excel spreadsheet (attached electronically as Annex 1) with the headings given in Appendix XI Table XI.3.

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

Subdivided, where necessary, according to commodity.
Relevant study references. Volume in data dossier.

7. RESIDUES IN ANIMAL COMMODITIES

Farm animal feeding studies
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 PRIORITIES[a]

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):

Note: 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[19] (Series on Testing and Assessment No.64) 18 Feb 2009.

The tables should be used based on the procedure described in section 5.12.1 of the Manual.

The tables IX.1-IX.3 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%.
The calculation of animal burden can be conveniently carried out with the automated Excel template attached in electronic form as Appendix XIV.2.

Table IX.1 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	*

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	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	*
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	*

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
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 bypdts	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	*
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 bypdts.	4-06-749	STMR	88	40	30	40	55	30	30	40	45

Table IX. 2 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	*	*	*	*	*
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	*	*	*	*	*

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
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	*	*	*	*	*	*	*	*	*	*	*
	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	*

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
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	*	*	*	*	*	*	*		*	*	*
AB	Corn, field	milled bypdts	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	*	*	*	*	*	*	*		*	*	*

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 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
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 bypdts	4-06-749	STMR	88	50	20	20	5	50	20	20	30	50	20	20

Table IX. 3 Percent of sheep diet

						RAM/EWE			LAMB			SWINE, breading			SWINE, finishing			
	CROP	Feedstuff	IFN Code	Residue Level	DM (%)	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	*	*
AF	Millet	forage	2-03-801	HR	30	80	*	100	35	*	60	*	*	*	*	*	*	*

						RAM/EWE			LAMB			SWINE, breading			SWINE, finishing			
	CROP	Feedstuff	IFN Code	Residue Level	DM (%)	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	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	*
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																	

						RAM/EWE			LAMB			SWINE, breading			SWINE, finishing			
	CROP	Feedstuff	IFN Code	Residue Level	DM (%)	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
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	*
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 bypdts	5-28-235	STMR	85	35	30	*	50	30	*	60	75	70	60	75	70	*

						RAM/EWE			LAMB			SWINE, breading			SWINE, finishing			
	CROP	Feedstuff	IFN Code	Residue Level	DM (%)	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	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													
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,	NA	STMR	20													

						RAM/EWE			LAMB			SWINE, breading			SWINE, finishing			
	CROP	Feedstuff	IFN Code	Residue Level	DM (%)	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
		wet																
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 bypdts	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 any time 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.

Soya bean forage. Cut samples at 15-20 cm (6-8 inches) tall (sixth node) to beginning pod formation, at approximately 35% DM.

Soya bean 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%.

Soya bean 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 by products, 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 by-products. (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 by-products (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 under gone 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 by-product 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 by-products. 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

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.

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. The most frequently used non-metric units and their metric equivalents are given in Tables X.1 and X.2

Table X.1 Conversion of areas, length, radioactivity, temperature, volumes and weights.

Measures of length	Measures of area	Measures of volume		
1 inch (in) = 2.54 cm 1 foot (ft) = 0.305 m 1 yard (yd) = 0.914 m 1 mile = 1.61 km 1 foot = 12 inch 1 yard = 3 feet	1 sq. inch = 6.45 cm^2 1 sq. foot (sqft) = 0.0929 m^2 1 sq. yard = 0.836 m^2 1 sq. mile = 2.59 km^2 1 acre (A) = 0.4047 ha 1 hectare (ha) = 10000 m^2 1 are (a) = 100 m^2		USA	UK
		1 fluid ounce (fl oz)	29.6 ml	28.35 ml
		1 gallon (gal)	3.785 l	4.546 l
		1 fluid quart (¼ gal)	0.946 l	1.137 l
		1 fluid pint (⅛ gal)	0.473 l	0.568 l
Measures of weight	Temperature	Combined measures		
1 grain = 64.80 mg 1 ounce (oz) = 28.35 g 1 pound (lb) = 0.4536 kg 1 metric tonne (t) = 1000 kg 1 mcg = 1 µg	°C = (°F-32)*5/9		USA	UK
		1 gal/acre (GPA)	9.346 L/ha	11.23 L/ha
		1 fl.oz/A	73.14 ml/ha	70.05ml/ha
		1 qt/A	2.338 L/ha	-
		1 pt/A	1.169 L/ha	-
		1 lb/gal	0.1198 kg/L	-
		1 gal/1000 sqft	407.4 L/ha	-
		1 fl.oz/1000 sqft	3.186 L/ha	-
		1 oz/1000 cu ft	1.0012 g/m^3	-
		1 oz/acre =0.07005 kg/ha 1 lb/acre =1.121 kg/ha 1 oz/lb = 62.5 kg/t		
Radioactivity		Others		
1 dpm = 0.0167 dps = 0.167 Bq 1 mCi = = 2.22 * 10^9 dpm= 3.7*10^7 Bq		1 % org. C = 1.724 % org. matter (om) 1 psi (pound per square inch) = 6.9 x 10^3 Pa		

Hundred weight (cwt)

Some seeds are expressed as hundred weights

In Imperial Units (UK and Ireland), 1 cwt = 112 lbs = 8 stones = 4 quarters = 50.80234544 kg.

In US customary units, 1 cwt = 100 lbs = 45.359 kg.

In both systems 20 cwt = 1 ton.

In Imperial Units this is the long ton of 2240 lbs = 1016 kg (approximately 1 metric tonne), hence the name long hundredweight.

In US Units this is the short ton of 2000 lbs = 907.2 kg, hence the name short hundredweight. (info http://encyclopedia.thefreedictionary.com/Hundred%20weight)

Thousand weight

Some seeds are expressed as thousand weights. This thousand seed weight depends on variety and should be given in the study report (e.g. thousand seed weight for Nantaise2 or Hilmar carrot seeds is equivalent to 1.86 g and Starca carrot seeds is equivalent to 1.74 g.

Bushels

Some seeds are expressed in bushels. For US such units can be converted to metric units using the following table.

Table X.2 Conversion of bushels of seeds to kg

Commodity	Bushel equivalent in kg USDA table[a]	Commodity	Bushel equivalent in kg USDA table
alfalfa seed	27.2 kg	oats	14.5
barley	21.8	rapeseed	22.7-27.2
buckwheat	21.8	rice (rough)	20.4
clover seed	27.2	rye	25.4
corn (shelled)	25.4	sorghum	25.4
cottonseed	14.5	soybean	27.2
cowpeas	27.2	timothy	20.4
flaxseed	25.4	wheat	27.2

Commodity	Bushel equivalent in kg USDA table[a]	Commodity	Bushel equivalent in kg USDA table
millet	21.8-22.7		

[a] 1 bushel of alfalfa seed is equivalent to 27.2 kg seed; only valid for USA

3. Format

Use Times New Roman font size 11 for text and at least size 9 for tables.

Left and right margins should preferably 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.

Do not insert two spaces between sentences

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. If necessary, narrow margin settings can be used to accommodate large tables. 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.

X.4 Common specialized abbreviations which do not need explanation are:

ADI	acceptable daily intake
ae	acid equivalent
ai	active ingredient
AR	applied radioactivity
ARfD	acute reference dose
BBCH	**B**iologischen Bundesanstalt, **B**undessortenamt und **CH**emische Industrie
bw	body weight
CAC	Codex Alimentarius Commission
CAS	Chemical Abstracts Service
CCN	Codex classification number (for compounds or commodities)
CCP	R Codex Committee on Pesticide Residues
*c*GAP	Critical GAP
CXL	Codex MRL
DAT	days after treatment
DM	dry matter
DNA	deoxyribonucleic acid
DT_{50}	time required for 50% dissipation of the initial concentration
ECD	electron capture detector
EFSA	European Food Safety Authority
EMRL	extraneous maximum residue limit
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
GAP	good agricultural practice
GC	gas chromatography
GC-ECD	gas chromatography with electron capture detection
GC/MS	gas chromatography/mass spectrometry
GC/MSD	gas chromatography/mass selective detector
GC-NPD	gas chromatography coupled with nitrogen-phosphorus detector
GEMS/Food	Global Environment Monitoring System – Food Contamination Monitoring and Assessment Programme
GLC	gas liquid chromatography
GLP	good laboratory practice
GPC	gel permeation chromatography
HPLC	high performance liquid chromatography
HR	highest residue in the edible portion of a commodity found in trials used to estimate a maximum residue level in the commodity
HR-P	highest residue in a processed commodity calculated by multiplying the HR of the raw commodity by the corresponding processing factor
IEDI	international estimated daily intake
IESTI	international estimate of short-term dietary intake
IPCS	International Programme on Chemical Safety
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
JECFA	Joint FAO/WHO Expert Committee on Food Additives

JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LC	liquid chromatography
LC_{50}	median lethal concentration
LD_{50}	median lethal dose
LOAEL	lowest-observed-adverse-effect level
LOD	limit of detection
log P_{ow}	octanol-water partition coefficient
LOQ	limit of quantification
MRL	maximum residue limit
MS	mass spectrometry
MS/MS	tandem mass spectrometry
m/z	mass to charge ratio
ND	non-detect - below limit of detection
NOAEL	no-observed-adverse-effect level
OECD	Organisation for Economic Co-operation and Development
PBI	plant back interval
Pf	processing factor
PHI	pre-harvest interval
ppm	parts per million
RAC	raw agricultural commodity
RSD	relative standard deviation
SPE	solid phase extraction
STMR	supervised trials median residue
STMR-P	supervised trials median residue in a processed commodity calculated by multiplying the STMR of the raw commodity by the corresponding processing factor
TAR	total administered radioactivity
TLC	thin-layer chromatography
TMDI	theoretical maximum daily intake
TRR	total radioactive residues
USEPA	United States Environmental Protection Agency
US-FDA	USA – Food and Drug Administration
WHO	World Health Organization

The ISO codes of countries are given in Annex 1 of Appendix X,

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 descriptions[17] 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. The CCPR is working on the revision of Codex Classification. The revised classification of fruits (REP/12/PR Appendix VIII) is attached as Annex 2 of Appendix X.

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.

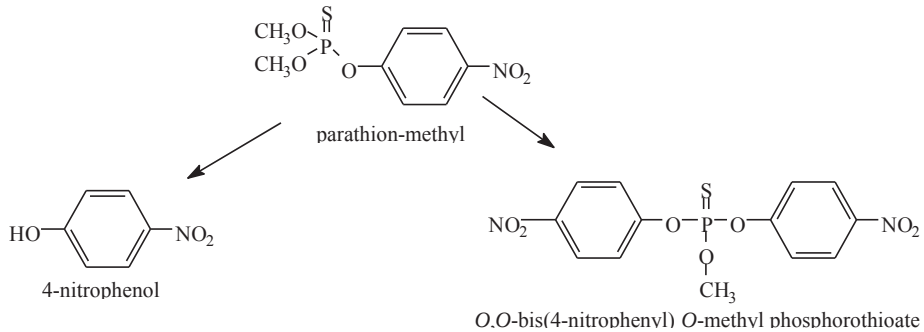
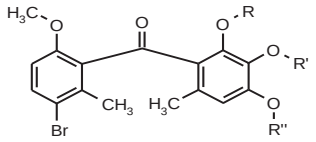


Figure X.1. Aerobic metabolism of parathion-methyl. (Evaluations 2000, Part 1 – Residues, p. 580).

The structural formula of ai and metabolites should depicted according to the standard format applied by for instance the Pesticide manual. It is ambiguous to indicate both hydrogen and methoxy group with a slash only.

Where either H or CH_3 can be present the following depiction is the recommended option:



R = H, R' and R'' = CH_3
or R' = H, R and R'' = CH_3
or R'' = H, R and R' = CH_3

4. JMPR reports

Published JMPR Reports normally consist of 8 chapters and a number of annexes.

Some chapters and annexes (Chapters 1, 6, 7, 8, Annexes 1, 2 and 5) are essentially compiled by the editor. The technical materials developed by the Panel members are included in Chapters 2, 3 4 and 5 and Annexes 3,4 and 6)..

Chapter 1 Introduction

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. *Evaluation of data for acceptable daily intake and acute reference dose for humans, maximum residue levels and supervised trials median residue values .*
The editor will convert Appraisal documents into reports for Chapter 5. 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.

Chapter 6. Recommendations

Chapter 7. Future Work

Chapter 8. Corrigenda Annex 1. Acceptable daily intakes, short-term dietary intakes, acute reference doses, recommended maximum residue limits and supervised trials median residue values recorded by the Meeting.

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 2. Index of reports and evaluations of pesticides by JMPR

Annex 3. International estimated daily intake of pesticide residues

Spreadsheet calculations of long-term intakes and comparison with ADIs.

Annex 4. International estimated short term intakes of pesticide residues

Spreadsheet calculations of long-term intakes and comparison with ADIs.

Annex 5. Reports and other documents resulting from previous Joint Meeting of FAO Panel of Experts on Pesticide residues in Food and the Environment and the WHO Core Assessment Group on Pesticide Residues

Annex 6. Livestock dietary burden

FAO Technical Papers

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 second 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. Do not separate sentences with two spaces. 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
Plant metabolism
Rotational crop studies (confined and field)
Animal 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.

Insert the last ADI and ARfD established and repeat the definition of residues for compounds evaluated under periodic review-

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.

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

The following brief explanation should be complemented with the detailed information provided in Chapters 3 – 7.

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}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.

Confined and field rotational crop studies

These studies should be evaluated for obtaining information on the nature and magnitude of residues (parent compound and its metabolites) taken up from soil by the rotational crops used as human food or as livestock feed. The information obtained will be considered for the definition of residues and estimation of maximum residue levels, if necessary, in follow crops which have not been directly treated or take into account the carried over residues in recommending residue levels for crops treated with the particular pesticide.

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}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.

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.

Draw conclusions briefly et the end of the section. For instance:

> In summary, metrafenone is stable to hydrolysis, rapidly degraded by photolysis, slowly degraded in soil under aerobic conditions (remaining mostly in the top 10 cm) and not found at significant levels in rotational crops. The Meeting concluded that residues are not expected in rotational crops following treatments according to the GAPs under consideration.

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, LC-MS/MS. 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.

Keep the summary of recovery results to the minimum

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.

Do not include proposed uses in the table. Under special circumstances they might be listed in a separate table, if justified. Table X.5. Registered uses of ..... on …..

Crop	Country	Formulation	Application [a]		Spray			PHI, days
			Method[a]	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
Lettuce	France	WP 800 g/kg	foliar	0.64				21-41[c]
Lettuce	Israel[3]	WP 800 g/kg	foliar	2.0		weekly		11

[a] give growth stage if relevant for the application of the pesticide
[b] in days or weeks
[c] summer PHI 21 days, winter PHI 41 days

Table X.6. Post-harvest GAP uses of .... on …...

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 X.7. Registered uses of .... for direct external animal treatment.

Animal [a]	Country	Formulation	Application			WHP slaughter [e]	WHP milk [f]
			Method [b]	Rate [c]	Conc. [d]	days	days
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.

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., trial conditions, expression of residues below LOQ, adjustment for recoveries, rounding and residues, residues in control plots, etc. The relevant parts of the examples below can be used in the evaluations

Trials were well documented with laboratory and field reports. The former included method validation including recoveries with spiking at residue levels similar to those occurring in samples from the supervised trials. Dates of analyses or duration of sample storage were also provided. Concurrent storage stability data was provided for the green onion trials, confirming sample stability over the trial storage period (24 months). Sufficient storage stability data for a range of crop matrices has also been evaluated by previous Meetings. Applications were generally made using backpack sprayers although occasionally tractor mounted sprayers were used. Samples were collected and stored frozen immediately or soon after sampling. Although trials included control plots, no control data are recorded in the Tables because, unless noted, no residues in control samples exceeded the LOQ. When residues were observed in the control samples they are shown as *c* followed by the residues observed in the control sample. Residues are unadjusted for recoveries. In some trials, samples were taken just before the final application and then again on the same day after the spray had dried. In the data tables the notation for these sampling times is '-0' and '0' respectively.

Residues from the trials conducted according to maximum GAP have been used for the estimation of maximum residue levels and dietary intake assessment. If a higher residue level was observed at a longer PHI than the GAP, the higher value has been used in MRL setting and dietary intake assessment. For replicate samples (from the same plot), the mean value (calculated from unrounded individual values) was used for maximum residue level estimation and dietary intake assessment with the individual results given in brackets. For two or more analyses of the same sample, the mean value was used for maximum residue level estimation and dietary intake assessment. For two or more analyses of the same sample, the mean value was used for maximum residue level estimation and dietary intake assessment, with the individual results given in brackets. For multiple trials on a crop from the same location, the result from the trial yielding the highest residue was utilised for maximum residue level estimation and dietary intake assessment. In this case the trials are separated by a dotted line.

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.

Detailed results of trials

List the commodities according to the group and sub-groups of Codex Commodity Classification; 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.

Before the summary tables 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. Some examples for table structures are. Provided below for reference X.8-X.11.

The table caption should be clear and comprehensive. Include the compound and the crops or crop groups, and other information which is the same for all trials. By this way one or more columns can be omitted from the tables which can assist to arrange the tables in the preferred portrait format.

The year in the first column of the table is the year of the trial rather than the year of the report. Include exact location of the trial, as it helps to decide the independence of the trial. "Application" should include the formulation type, the rate of application (kg ai/ha), spray concentration (kg ai/hL) or the water volume (L/ha) and the number of applications. In addition, the growth stage at the last treatment should be included, where relevant.

List the days after last treatment (DAT) vertically and report individual residues as far as possible.

Include the relevant GAP to which the trial conditions are compared in the first row of the table. This GAP is not necessarily the critical GAP on which the estimation of the maximum residue level is based, as the residue values may be adjusted applying proportionality.

Underline those residues which are within critical GAP and have been selected for estimation of MRL, 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 critical 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. However, the average residues should be calculated from all digits reported for individual samples.

Some examples are for table format are given in tables X.7-X.9.

Table X.8. Parathion-methyl and paraoxon-methyl residues in wine grapes from supervised trials in France and Italy.

GRAPES	Application				DAT	Residues, mg/kg		Ref
country, year Location (variety)	Form	kg ai/ha	kg ai/hL	no.		parathion-methyl	paraoxon-methyl	
GAP France[1]	CS,EC	0.3		2	21			

GRAPES country, year Location (variety)	Application Form	kg ai/ha	kg ai/hL	no.	DAT	Residues, mg/kg parathion-methyl	 paraoxon-methyl	Ref
France, 1994 (Chenin Blanc)	CS	0.29	0.15	2	0 3 7 14 21 35	0.09 0.05 0.11 0.06 0.05 0.07	< 0.01 < 0.01 < 0.01 < 0.01 < 0.01 < 0.01	AP/2582/HR F1 951174
France, 1994 (Chenin blanc)	EC	0.30	0.15	2	0 3 7 14 21	0.05 0.04 0.01 < 0.01 < 0.01	< 0.01 < 0.01 < 0.01 < 0.01 < 0.01	Tours F1 951175
France, 1994 (Grenache)	CS	0.32	0.16	2	0 3 7 14 21 31	0.28 0.16 0.28 0.11 0.13 0.07	< 0.01 < 0.01 < 0.01 < 0.01 < 0.01 < 0.01	AP/2582/HR Site II 951174
Italy, 1994 (Sangiovese) - red	CS	0.30	0.060	2	0 7 14 21	0.30 0.12 0.14 0.16 0.18		407240

[1]: Provide max GAP considered for the evaluation of the trials . List trials conducted in countries from the region which are evaluated against the max GAP of the indicated country.
Give different GAP above the corresponding trials.

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.

Table X.9.. Results of supervised residue trials on citrus fruits (whole fruits[1] of orange, grapefruit and lemon) conducted in Brazil and the USA.

CROP Country, Year Location variety Trial No.	Application Method	No.	Rate kg ai/ha	Spray volume L/ha	DAT	Residues (mg eq/kg)[1] Parent	B-1	AB-6	AB-7	Author Report Year Study No. DocID.
US GAP Citrus fruit		**2**	**0.2**	**Min. 935**	7					**(Interval: 14 days)**
USA, 2009 Orange, FL Hamlin R090446	Tractor mounted, PTO-Driven Airblast	2	0.2	1x1658 1x1640	7	0.087 0.068 (0.078)	< 0.02 < 0.02	< 0.01 < 0.01	< 0.01 < 0.01	2011 / D.R. Hattermann, L.E.Crawford, S.Holt 350843 2012/7003656
USA, 2009 Volusia, FL Hamlin R090447	Tractor mounted, PTO-Driven Airblast	2	0.2	1x1648 1x1655	7	0.095 0.080 (0.088)	< 0.02 < 0.02	< 0.01 < 0.01	< 0.01 < 0.01	2011 / D.R. Hattermann, L.E.Crawford, S.Holt 350843 2012/7003656
GRAPEFRUIT										
USA, 2009 Lake, FL White R090459	SS Airblast	2	0.2	1x1798 1x1588	7	0.067 0.077 (0.072)	< 0.02 < 0.02	< 0.01 < 0.01	< 0.01 < 0.01	2011 / D.R. Hattermann, L.E.Crawford, S.Holt 350843 2012/7003656

CROP Country, Year Location variety Trial No.	Application				DAT	Residues (mg eq/kg)[1]				Author Report Year Study No. DocID.
	Method	No.	Rate kg ai/ha	Spray volume L/ha		Parent	B-1	AB-6	AB-7	
USA, 2009 Willacy, TX Rio Red R090461	FMC DP 50 Airblast Spayer (SR-77)	2	0.2	1x2495 1x2467	7	< 0.01 < 0.01 (<u>≤ 0.01</u>)	< 0.02 < 0.02	< 0.01 < 0.01	< 0.01 < 0.01	2011 / D.R. Hattermann, L.E.Crawford, S.Holt 350843 2012/7003656
LEMON										
USA, 2009 St. Lucie, FL Bearss R090464	Airblast Sprayer	2	0.2	1x664 1x649	7	< 0.01 < 0.01 (<u>≤ 0.01</u>)	< 0.02 < 0.02	< 0.01 < 0.01	< 0.01 < 0.01	2011 / D.R. Hattermann, L.E.Crawford, S.Holt 350843 2012/7003656
USA, 2009 Tulare, CA Pyror	Tractor-mounted, PTO-Driven	2	0.2	1x2203 1x2063	0	0.122 0.113 (0.1175)	< 0.02 < 0.02	< 0.01 < 0.01	< 0.01 < 0.01	2011 / D.R. Hattermann, L.E.Crawford, S.Holt
R090465	Airblast				1	0.086 0.112 (0.099)	< 0.02 < 0.02	< 0.01 < 0.01	< 0.01 < 0.01	350843 2012/7003656
					3	0.106 0.100 (0.103)	< 0.02 < 0.02	< 0.01 < 0.01	< 0.01 < 0.01	
GAP in Brazil: 2 x 0.2 kg/ha with >2000 L/ha										
Brazil, 2007	(n.r.)	2	0.2	2000	0	0.3				G. Casadei de Baptista nr OTSA-0484-FR
					1	0.3				
					3	0.2				
					7	0.08				
					14	0.06				

1: if different portion of commodity is analysed either include a column distinguishing marks for indicating the portions analysed

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.10. Residues of spinetoram from supervised trials on orange in the USA (for estimation of maximum residue level)

ORANGE Location, year (Variety)	Form	Application			DAT	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 with 3 times maximum 105 g ai/ha up to 210 g ai/ha /season;.					1				
Deleon Springs, FL, 2004 (Valencia)	SC	10	70-72	3	1	0.030 0.028	< 0.01 < 0.01	<u>0.030</u> 0.028	040063
Mount Dora, FL, 2004 (Valencia)	SC	11	71-72	3	1	0.011 0.022	ND < 0.01	0.011 <u>0.022</u>	040063

Table X.11. Residues of spinetoram and metabolites from supervised trials on orange in the USA (for estimation of STMR)

ORANGE Location, year (Variety)	Form	Application			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	

ORANGE Location, year (Variety)	Form	Application			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	
GAP, USA, Citrus fruits, SC or WG with 3 times maximum 105 g ai/ha up to 210 g ai/ha /season;.					*1*						
Foliar application using low spray volume (~700 L/ha)											
Deleon Springs, FL, 2004 (Valencia)	SC	10	70-72	3	1	0.030 0.028	< 0.01 < 0.01	0.011 0.014	0.016 0.024	0.057 0.066	040063
Mount Dora, FL, 2004 (Valencia)	SC	11	71-72	3	1	0.011 0.022	ND < 0.01	< 0.01 0.012	< 0.01 0.017	0.021 0.051	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.12).*

Table X.12 Parathion-methyl and paraoxon-methyl residues in soya beans and processed commodities

SOYA BEANS country, year (variety)	Application Form	kg ai/ha	kg ai/hL	water, L/ha	no.	PHI days	commodity	Residues, mg/kg parathion-methyl	paraoxon-methyl	Ref
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)

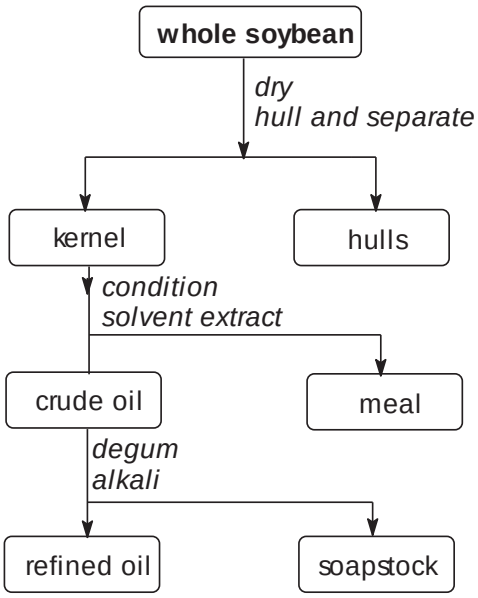


Figure X.2. Soya bean processing (ref)

(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.13 and X.14.

Table X.13 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	
			Preserves	0.50	0.40	
Xxx						

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.

A different approach is required for calculating processing factors for compounds not included in the residue definition as they may be created on processing, which have separate health based guidance values.

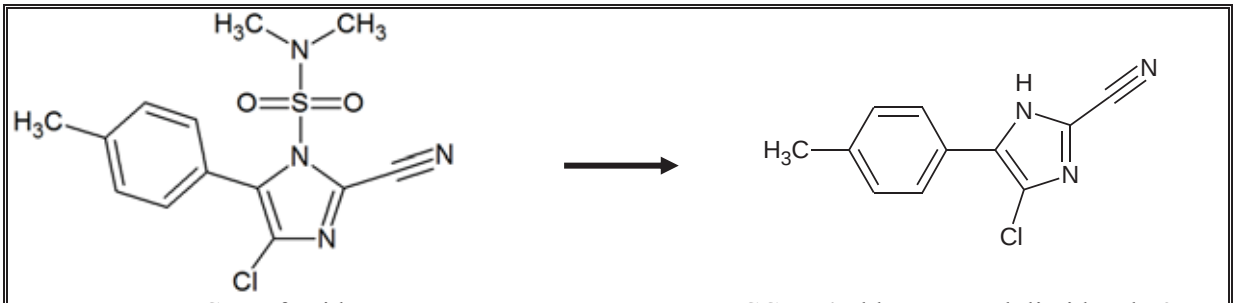
The situation is illustrated with some examples:

Example: processing grape containing cyazofamid residues

Definition of the residue for compliance with the MRLs for plant commodities: *Cyazofamid.*
Definition of the residue for long-term dietary intake from plant commodities: *Cyazofamid and CCIM, expressed as cyazofamid.*

As an ARfD was established for CCIM (in the absence of an ARfD for cyazofamid), the definition of the residue for short-term dietary intake from plant commodities is *CCIM*.

High-temperature hydrolysis of cyazofamid revealed that under pasteurisation conditions (90°C, pH 4, 20 min.), most of the cyazofamid was converted to CCIM; while under the other two conditions [baking, brewing, boiling (100°C, pH 5, 60 min); and sterilisation (120°C, pH 6, 20 min.)] tested, 100% of the test material converted to CCIM.



Cyazofamid — CCIM 4-chloro-5-p-tolylimidazole-2-carbonitrile

For estimating long-term dietary intake, the processing factors are based on the combined residues of cyazofamid and CCIM, expressed as cyazofamid, in raw and processed commodities. When residues were <0.01 in a sample, they were assumed to be 0.01 for purposes of deriving a processing factor. The method of calculation is shown with the example of processing of grape in table X.14

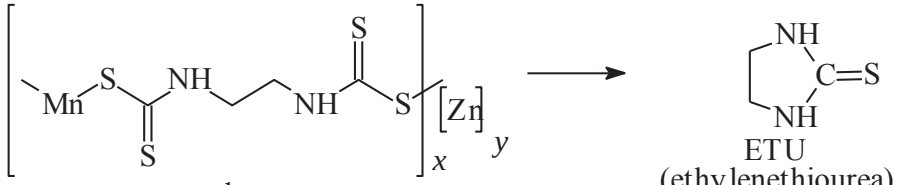
Table X.14 Calculation of processing factors and STMR-P values in case of must

Crop	Processed commodity	Long-term processing factor [a]	Short-term yield factor [b]	Long-term processing factor [a]	Short-term yield factor [b]	STMR-P (Cyazofamid + CCIM), mg/kg	STMR-P (CCIM), mg/kg	HR-P (CCIM), mg/kg
Grape	Fruit (RAC)	--	--	--	--	STMR [c] = 0.06	STMR [d] = 0.044	HR [d] = 0.47
	Must	0.3, 0.5 (2), 0.59,	0.11, 0.25, 0.3	0.59	0.3	0.035	0.013	0.14

Crop	Processed commodity	Long-term processing factor [a]	Short-term yield factor [b]	Long-term processing factor [a]	Short-term yield factor [b]	STMR-P (Cyazofamid + CCIM), mg/kg	STMR-P (CCIM), mg/kg	HR-P (CCIM), mg/kg
		1.3, 1.8, 1.9	(3), 0.33					

[a] [Cyazofamid + CCIM (cyazofamid equivalents) in the processed commodity] ÷ [cyazofamid + CCIM (cyazofamid equivalents) in the raw commodity].
[b] CCIM in the processed commodity ÷ [cyazofamid (CCIM equivalents) + CCIM in the raw commodity].
[c] Cyazofamid + CCIM (cyazofamid equivalents)
[d] Cyazofamid (CCIM equivalents) + CCIM

Example: processing of grape treated with macozeb
Ethylenethiourea (ETU) is produced from ethylenebisdithiocarbamates such as mancozeb during food processing operations such as boiling. ETU is also a metabolite and may be present in the raw agricultural commodity.



mancozeb ETU (ethylenethiourea)

The processing factor concept does not apply to residues produced during processing. The concept assumes that the residues of a compound in the processed commodity originate only from the same compound in the raw agricultural commodity (RAC).

Commodity	Dithiocarbamate residues, expressed as CS_2 mg/kg		ETU residues, mg/kg	
	Treatment 1	Treatment 2	Treatment 1	Treatment 2
Raw grapes	21 17	49 36	0.01 0.01	0.28 0.35
Dry pomace	12 14	20 18	0.20 0.21	1.3 0.90
Thick juice	2.4 2.6	1.4 1.2	0.08 0.08	4.3 4.3
Clear juice	<0.1 <0.1	<0.1 <0.1	0.19 0.23	2.4 2.6
Pasteurised juice	<0.1 <0.1	<0.1 <0.1	0.08 0.09	0.93 0.90
	PROCESSING FACTORS		PERCENTAGE YIELD	
Dry pomace	0.68	0.45	1.7 %	3.8 %
Thick juice	0.13	0.031	0.68 %	15 %
Clear juice	<0.005	<0.002	1.8 %	8.7 %
Pasteurised juice	<0.005	<0.002	0.72%	3.2 %

A percentage yield of ETU in the processed commodity may be calculated from its two origins in the raw agricultural commodity.

$$\text{Percentage yield of ETU} = \frac{100 \times ETU_{ProcCom}}{ETU_{RAC} + 0.67 \times DITH_{RAC}}$$

The 0.67 is a molecular weight adjustment that recognizes that each mancozeb unit can produce 2 molecules of CS_2 or 1 molecule of ETU.

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-on 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

Include this section only if relevant data are available. 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.9.

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. *J. Agric. Food Chem*. 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 *Salmo gairdneri* (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 *Salmo gairdneri* (Rainbow trout) in a static test. Hoechst Pfl. Fo. Biol., Germany. Rep. OEK 83/028E. Unpublished.

Notes:

a. Study references in tables require the study number (or report number).

b. Citations in the text should be of the form: Author, year, study (or report) number.

c. 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.

8. 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)

MAIN ENTRIES OF THE APPRAISAL

Plant metabolism

Rotational crop studies

Animal 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 (Table 14), with the exception of the farm animal dietary burden calculation table and the animal commodity STMR and MRL calculation table.

Table X.14 Example for presenting STMR and HR values calculated based on the results of processing studies

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$_{propylenethiourea}$

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. See further examples in section 5.13.1

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 mg/kg = 0.006 mg/kg. The method for calculating the total residue for various situations is illustrated below.

Fipronil [mg/kg]	Metabolite MB 46136 or MB 46513 [mg/kg]	Total [mg/kg]
< 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 [mg/kg]	spinosyn D [mg/kg]	Sum of spinosyns A and D [mg/kg]
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, <u>2.1</u>, 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 CS_2.*
>
> *The Meeting estimated a maximum residue level of 5 mg/kg for dithiocarbamates (as CS_2) 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].

Insert the following sentence after the residue definition.

The residue is fat-soluble. or The residue is not 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.

	Commodity	**MRL, mg/kg**		**STMR or STMR-P**	**HR or HR-P**
CCN	**Name**	**New**	**current**	**mg/kg**	**mg/kg**

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

Use the following standard statements for the long-term dietary risk assessment

The International Estimated Daily Intakes (IEDI) for [*pesticide*] was calculated from recommendations for STMRs for raw and processed commodities in combination with consumption data for corresponding food commodities. The results are shown in Annex 3.

Estimated intake within the ADI

Situation:

The IEDI is less than the ADI

The IEDI of the 17 GEMS/Food cluster diets, based on the estimated STMRs represented […]% to […]% of the maximum ADI of […] mg/kg bw, expressed as ….].

The Meeting concluded that the long-term intake of residues of [pesticide] from uses considered by the Meeting 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 IEDI calculation is conducted with STMRs recommended in previous and current Meetings. The IEDI of all of the GEMS/Food 17 cluster diets was less than the ADI.

The IEDI of the 17 GEMS/Food cluster diets, based on the estimated STMRs by the [year1] JMPR, [year2] JMPR and the present Meeting represented […]% to […]% of the maximum ADI of […] mg/kg bw, expressed as ….].

The Meeting concluded that the long-term intake of residues of [pesticide] from uses considered by the [year1] JMPR, [year2] JMPR and the present Meeting is unlikely to present a public health concern.

Estimated intake exceeds the ADI

Situation:

The IEDI of one or more of the GEMS/Food 17 cluster diets exceeded the ADI The IEDI of one or more of the GEMS/Food 17 cluster diets exceeded the maximum 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 maximum ADI (Annex 3).

The information provided to the JMPR precludes an estimate that the dietary intake would be below the maximum ADI.

Situation:

The IEDI of one or more of the GEMS/Food 17 cluster diets exceeded the ADI

The IEDI of the 17 GEMS/Food cluster diets, based on the estimated STMRs by the [year1] JMPR, [year2] JMPR and the present Meeting represented […]% to […]% of the maximum ADI of […] mg/kg bw, expressed as ….] for the GEMS/Food cluster diets [list cluster diets exceeding ADI, Gnn, Gnn and Gnn]. The IEDI for the other GEMS/Food cluster diets were in the range of [..] to [..]% of the maximum ADI.

The Meeting concluded that the long-term intake of residues of [pesticide] from uses considered by the [year1] JMPR, [year2] JMPR and the present Meeting may present a public health concern.

The dietary risk assessment may be refined by [processing data for commodity 1, commodity 2] or additional toxicology data on [subject 1, subject 2].
or
No further refinements are possible.

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. In case of a re-evaluation, only the uses evaluated by the current Meeting undergo IESTI calculation. The estimated short-term intakes for some commodities exceeded the ARfD.

The International Estimated Short Term Intake (IESTI) for [pesticide] was calculated from recommendations for STMRs and HRs for raw and processed commodities in combination with consumption data for corresponding food commodities. The results are shown in Annex 4.

The IESTI for the diets submitted to JMPR for children and general population represented [..]% to […]% and […]% to […]%, of the ARfD of [..] mg/kg bw, expressed as […], respectively. The values [...], [...] and [...]% represent the estimated short-term intake for [commodity 1], [commodity 2] and [commodity 3] respectively for the general 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 considered by the Meeting may present a public health concern for [commodity 1], [commodity 2] and [commodity 3]. The short term intake of residues of [pesticide] from uses, other than on these [..] commodities, is unlikely to present a public health concern.

The dietary risk assessment may be refined by [processing data for commodity 1, commodity 2] or additional toxicology data on [subject 1, subject 2].
or
No further refinements are possible.

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 Meeting concluded that an ARfD may be necessary, but as it has not been established. The International Estimated Short Term Intake (IESTI) for [pesticide] was not calculated. The short-term dietary risk assessment could not be finalised.

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 [year1] JMPR, [year2] JMPR had recommended STMRs and HRs for the uses presented, but was not able to finalize the risk assessment because an ARfD was not the available.

The International Estimated Short Term Intake (IESTI) for [pesticide] was calculated from recommendations for STMRs and HRs for raw and processed commodities by the [year1] JMPR, [year2] JMPR and the present Meeting in combination with consumption data for corresponding food commodities. The results are shown in Annex 4.

The IESTI for the diets for children and general population submitted to JMPR represented [..]% to [...]% and [...]% to [...]%, of the ARfD of [..] mg/kg bw, expressed as [...], respectively.

The Meeting concluded that the short-term intake of residues of [pesticide] from uses considered by the [year1] JMPR, [year2] JMPR and the present Meeting 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 [year1] JMPR, [year2] JMPR had recommended STMRs and HRs for the uses presented, but was not able to finalize the risk assessment because an ARfD was not the available.

The International Estimated Short Term Intake (IESTI) for [pesticide] was calculated from recommendations for STMRs and HRs for raw and processed commodities by the [year1] JMPR, [year2] JMPR and the present Meeting in combination with consumption data for corresponding food commodities. The results are shown in Annex 4.

The IESTI for the diets for children and general population submitted to JMPR represented [..]% to [...]% and [...]% to [...]%, of the ARfD of [..] mg/kg bw, expressed as [...], respectively. The values [...], [...] and [...]% represent the estimated short-term intake for [commodity 1], [commodity 2] and [commodity 3] respectively for the general 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 considered by the [year1] JMPR, [year2] JMPR and the present Meeting may present a public health concern for [commodity 1], [commodity 2] and [commodity 3]. The short term intake of residues of [pesticide] from uses, other than on these [..] commodities, is unlikely to present a public health concern.

The dietary risk assessment may be refined by [processing data for commodity 1, commodity 2] or additional toxicology data on [subject 1, subject 2].

or

No further refinements are possible.

Annex 1 of Appendix X

List of all countries with their 2 digit codes (ISO 3166-2)

Name	Code		Code
Afghanistan	AF	Liberia	LR
Åland Islands	AX	Libya	LY
Albania	AL	Liechtenstein	LI
Algeria	DZ	Lithuania	LT
American Samoa	AS	Luxembourg	LU
Andorra	AD	Macao	MO
Angola	AO	"Macedonia the Former Yugoslav Republic of"	MK
Anguilla	AI	Madagascar	MG
Antarctica	AQ	Malawi	MW
Antigua and Barbuda	AG	Malaysia	MY
Argentina	AR	Maldives	MV
Armenia	AM	Mali	ML
Aruba	AW	Malta	MT
Australia	AU	Marshall Islands	MH
Austria	AT	Martinique	MQ
Azerbaijan	AZ	Mauritania	MR
Bahamas	BS	Mauritius	MU
Bahrain	BH	Mayotte	YT
Bangladesh	BD	Mexico	MX
Barbados	BB	"Micronesia Federated States of"	FM
Belarus	BY	"Moldova Republic of" MD	
Belgium	BE	Monaco	MC
Belize	BZ	Mongolia	MN
Benin	BJ	Montenegro	ME
Bermuda	BM	Montserrat	MS
Bhutan	BT	Morocco	MA
"Bolivia Plurinational State of"	BO	Mozambique	MZ
"Bonaire Sint Eustatius and Saba"	BQ	Myanmar	MM
Bosnia and Herzegovina	BA	Namibia	NA
Botswana	BW	Nauru	NR
Bouvet Island	BV	Nepal	NP
Brazil	BR	Netherlands	NL
British Indian Ocean Territory	OI	New Caledonia	NC
Brunei Darussalam	BN	New Zealand	NZ
Bulgaria	BG	Nicaragua	NI
Burkina Faso	BF	Niger	NE
Burundi	BI	Nigeria	NG
Cambodia	KH	Niue	NU

Name	Code		Code
Cameroon	CM	Norfolk Island	NF
Canada	CA	Northern Mariana Islands	MP
Cape Verde	CV	Norway	NO
Cayman Islands	KY	Oman	OM
Central African Republic	CF	Pakistan	PK
Chad	TD	Palau	PW
Chile	CL	"Palestine State of"	PS
China	CN	Panama	PA
Christmas Island	CX	Papua New Guinea	PG
Cocos (Keeling) Islands	CC	Paraguay	PY
Colombia	CO	Peru	PE
Comoros	KM	Philippines	PH
Congo	CG	Pitcairn	PN
"Congo the Democratic Republic of the"	CD	Poland	PL
Cook Islands	CK	Portugal	PT
Costa Rica	CR	Puerto Rico	PR
Côte d'Ivoire	CI	Qatar	QA
Croatia	HR	Réunion	RE
Cuba	CU	Romania	RO
Curaçao	CW	Russian Federation	RU
Cyprus	CY	Rwanda	RW
Czech Republic	CZ	Saint Barthélemy	BL
Denmark	DK	"Saint Helena Ascension and Tristan da Cunha"	SH
Djibouti	DJ	Saint Kitts and Nevis	KN
Dominica	DM	Saint Lucia	LC
Dominican Republic	DO	Saint Martin (French part)	MF
Ecuador	EC	Saint Pierre and Miquelon	PM
Egypt	EG	Saint Vincent and the Grenadines	VC
El Salvador	SV	Samoa	WS
Equatorial Guinea	GQ	San Marino	SM
Eritrea	ER	Sao Tome and Principe	ST
Estonia	EE	Saudi Arabia	SA
Ethiopia	ET	Senegal	SN
Falkland Islands (Malvinas)	FK	Serbia	RS
Faroe Islands	FO	Seychelles	SC
Fiji	FJ	Sierra Leone	SL
Finland	FI	Singapore	SG
France	FR	Sint Maarten (Dutch part)	SX
French Guiana	GF	Slovakia	SK
French Polynesia	PF	Slovenia	SI
French Southern Territories	TF	Solomon Islands	SB
Gabon	GA	Somalia	SO
Gambia	GM	South Africa	ZA
Georgia	GE	South Georgia and the South Sandwich Islands	GS

Name	Code		Code
Germany	DE	South Sudan	SS
Ghana	GH	Spain	ES
Gibraltar	GI	Sri Lanka	LK
Greece	GR	Sudan	SD
Greenland	GL	Suriname	SR
Grenada	GD	Svalbard and Jan Mayen	SJ
Guadeloupe	GP	Swaziland	SZ
Guam	GU	Sweden	SE
Guatemala	GT	Switzerland	CH
Guernsey	GG	Syrian Arab Republic	SY
Guinea	GN	"Taiwan Province of China"	TW
Guinea-Bissau	GW	Tajikistan	TJ
Guyana	GY	"Tanzania United Republic of"	TZ
Haiti	HT	Thailand	TH
Heard Island and McDonald Islands	HM	Timor-Leste	TL
Holy See (Vatican City State)	VA	Togo	TG
Honduras	HN	Tokelau	TK
Hong Kong	HK	Tonga	TO
Hungary	HU	Trinidad and Tobago	TT
Iceland	IS	Tunisia	TN
India	IN	Turkey	TR
Indonesia	ID	Turkmenistan	TM
"Iran Islamic Republic of"	IR	Turks and Caicos Islands	TC
Iraq	IQ	Tuvalu	TV
Ireland	IE	Uganda	UG
Isle of Man	IM	Ukraine	UA
Israel	IL	United Arab Emirates	AE
Italy	IT	United Kingdom	GB
Jamaica	JM	United States	US
Japan	JP	United States Minor Outlying Islands	UM
Jersey	JE	Uruguay	UY
Jordan	JO	Uzbekistan	UZ
Kazakhstan	KZ	Vanuatu	VU
Kenya	KE	"Venezuela Bolivarian Republic of"	VE
Kiribati	KI	Viet Nam	VN
"Korea, Democratic People's Republic of"	KP	"Virgin Islands British"	VG
"Korea, Democratic Republic of"	KR	"Virgin Islands U.S."	VI
Kuwait	KW	Wallis and Futuna	WF
Kyrgyzstan	KG	Western Sahara	EH
Lao People's Democratic Republic	LA	Yemen	YE
Latvia	LV	Zambia	ZM
Lebanon	LB	Zimbabwe	ZW
Lesotho	LS		

Annex 2 of Appendix X

Classification for the fruit commodity groups including examples of the selection of representative commodities (adopted by CAC in 2012)

Type: 01 Fruits		Representative commodities		Member crop in subgroup
Group	Subgroup	Group	Subgroup	
001 Citrus fruits (FC 0001)	Subgroup 001A Lemons and Limes (FC 0002)	Lemon or Lime; Mandarin; Orange and Pummelo or Grapefruit	Lemon or Lime	FC 2201Australian blood lime FC 2202Australian desert lime FC 2203Australian round lime FC 2204Brown River finger-lime FC 0202Citron FC 2206Kaffir lime FC 0303Kumquats FC 0204Lemon FC 0205Lime FC 2205Lime, Sweet FC 2207Limequats FC 2208Mount White lime FC 2209New Guinea wild lime FC 2210Russell River- lime FC 2211Tahiti Lime FC 2212Yuzu
	Subgroup 001B Mandarins (FC 0003)		Mandarin	FC 0201Calamondin FC 0206Mandarin FC 2213Unshu orange
	Subgroup 001C Oranges, Sweet, Sour (FC 0004)		Orange	FC 0207Orange, Sour FC 0208Orange, Sweet FC 2214Trifoliate orange
	Subgroup 001D Pummelos (FC 0005 Pummelo and Grapefruits)		Pummelo or Grapefruit	FC 0203Grapefruit FC 0209Pummelo
002 Pome fruits (FP 0009)		Apple or Pear		FP 0226Apple FP 2220Azarole FP 2221Chinese quince FP 0227Crab-apple FP 0228Loquat FP 2222Mayhaw FP 0229Medlar FP 0230Pear FP 0307Persimmon, Japanese FP 0231Quince FP 2223Tejocote FP 2224Wild pear
003 Stone fruits (FS 0012)	003A Cherries (FS 0013)	Cherry, Sweet or Cherry, Sour; Plum or Prune	Cherry, Sweet or Cherry, Sour	FS 2230Cherry, black FS 2231Cherry, Nanking FS 0243Cherry, Sour

Type: 01 Fruits		Representative commodities		Member crop in subgroup
Group	Subgroup	Group	Subgroup	
		Plum or Peach or Apricot		FS 0244Cherry, Sweet FS 2232Choke cherry
	003B Plums (FS 0014 Plums (including Prunes))		Plum or Prune Plum	FS 0241Bullace FS 0242Cherry plum FS 0302Jujube, Chinese FS 2233Klamath plum FS 2234Plum FS 2235Plum, beach FS 0248Plum, Chickasaw FS 2236Plumcot FS 0249Sloe
	003C Peaches (FS 2001)		Peach or Apricot	FS 0240Apricot FS 2237Japanese apricot FS 0245Nectarine FS 0247Peach
004 Berries and other small fruits (FB 0018)	004A Cane berries (FB 2005)	Blackberry or Raspberry; Blueberry or Currants, Black, Red or White; Elderberry; Grape and Strawberry	Blackberry or Raspberry	FB 0264Blackberries FB 0266Dewberries FB 0272Raspberries, Red, Black
	004B Bush berries (FB 2006)		Blueberry or Currants, Black, Red or White	FB 0019Vaccinium berries FB 0020Blueberries FB 2240Agritos FB 2241Aronia berries FB 0260Bearberry FB 0261Bilberry FB 0262Bilberry, Bog FB 0263Bilberry, Red FB 2242Buffalo currant FB 2243Chilean guava FB 0021Currants, Black, Red, White FB 0278Currant, Black FB 0279Currant, Red, White FB 0268Gooseberry FB 2244European barberry FB 2245Huckleberries FB 2246Jostaberries FB 0270Juneberries FB 2247Native currant FB 2248Riberries FB 0273Rose hips FB 2249Salal FB 2250Sea buckthorn
	004C Large shrub/tree berries (FB 2007)		Elderberry	FB 2250Bayberries FB 2251Buffaloberry FB 2252Che FB 0267Elderberries

Type: 01 Fruits		Representative commodities		Member crop in subgroup
Group	Subgroup	Group	Subgroup	
				FB 2253Guelder rose FB 0271Mulberries FB 2254Phalsa FB 0274Service berries FB 2255Silverberry, Russian
	004D Small fruit vine climbing (FB 2008)		Grapes	FB 2256Arguta kiwifruit FB 2257Amur river grape FB 0269Grapes FB 2258Schisandraberry FB 1235Table-grapes FB 1236Wine-grapes
	004E Low growing berries (FB 2009)		Strawberry	FB 0265Cranberry FB 0277Cloudberry FB 2259Muntries FB 2260Partridge berry FB 0275Strawberry FB 0276Strawberries, Wild
005 Assorted tropical and sub-tropical fruits-edible peel (FT 0026)	005A Assorted tropical and sub-tropical fruits - edible peel – small (FT 2011)	Table Olives; Fig or Guava and Date	Table Olives	FT 2300African plum FT 2301Almondette FT 2302Apple berry FT 0286Arbutus berry FT 0287Barbados cherry FT 2303Bayberry, Red FT 2304Bignay FT 2305Breadnut FT 2306Cabeluda FT 2307Carandas plum FT 2308Ceylon iron wood FT 2309Ceylon olive FT 2310Cherry-of-the-Rio-Grande FT 0293Chinese olive, Black, White FT 2311Chiraulinut FT 0294Coco plum FT 0296Desert date FT 2312False sandalwood FT 2313Fragrant manjack FT 2314Gooseberry, Abyssinian FT 2315Gooseberry, Ceylon FT 2316Govemor's plum FT 0298Grumichama FT 2317Guabiroba FT 2318Guava berry FT 0299Hog plum FT 2319Illawara plum FT 2320Jamaica cherry FT 0339Jambolan FT 0340Java apple

Type: 01 Fruits		Representative commodities		Member crop in subgroup
Group	Subgroup	Group	Subgroup	
				FT 2321Kaffir plum FT 2322Kakadu plum FT 2323Kapundung FT 0290Karanda FT 2324Lemon aspen FT 2326Monos plum FT 2327Mountain cherry FT 0306Otaheite gooseberry FT 2328Persimmon, Black FT 2329Pitomba FT 2330Rumberry FT 0310Sea grape FT 2331Sete-capotes FT 2332Silver aspen FT 0311Surinam cherry FT 0305Table Olives FT 2333Water apple FT 2334Water berry FT 2335Water pear
	005B Assorted tropical and sub-tropical fruits - edible peel – medium to large (FT 2012)		Fig or Guava	FT 0285Ambarella FT 2350Arazá FT 2351Babaco FT 0288Bilimbi FT 2352Cajou (pseudofruit) FT 2353Cambucá FT 0289Carambola FT 0291Carob FT 0292Cashew apple FT 2354Ciruela verde FT 2355Davidson plum FT 0297Fig FT 2356Gooseberry, Indian FT 0336Guava FT 2357Guava, Brazilian FT 2358Guava, Cattley FT 2359Guava, Costa Rican FT 2360Guava, Para FT 2361Guayabillo FT 2362Imbé FT 2363Imbu FT 0300Jaboticaba FT 0301Jujube, Indian FT 2364Kwai muk FT 2365Mangaba FT 2366Marian plum FT 2367Mombin, Malayan FT 2368Mombin, Purple FT 2369Monkey fruit FT 2370Nance FT 0304Natal plum

Type: 01 Fruits		Representative commodities		Member crop in subgroup
Group	Subgroup	Group	Subgroup	
				FT 2371Noni FT 2372Papaya, Mountain FT 0308Pomerac FT 2373Rambai FT 0309Rose apple FT 0364Sentul FT 2374Uvalha
	005C Assorted tropical and sub-tropical fruits - edible peel – palms (FT 2013)		Date	FT 2400Acaí FT 2401Apak palm FT 2402Bacaba palm FT 2403Babaca-de-leque FT 0295Date FT 0333Doum or Dum palm FT 2404Jelly palm FT 2405Patauá FT 2406Peach palm
006 Assorted tropical and sub-tropical fruits - inedible peel (FT 0030)	006A Assorted tropical and sub-tropical fruits - inedible peel – small (FT 2021)	Litchi or Longan or Spanish Lime; Avocado; Pomegranate or Mango; Banana and Papaya; Atemoya; Pineapple; Pitaya; Prickly Pear; Kiwifruit or Passion Fruit and Muriti or Palmyra Palm	Litchi or Longan or Spanish Lime	FI 2450Aisen FI 2451Bael fruit FI 2452Burmese grape FI 2453Ingá FI 0343Litchi FI 0342Longan FI 2454Madras-thorn FI 2455Manduro FI 2456Matisia FI 2457Mesquite FI 2458Mongongo FI 2459Pawpaw, Small-flower FI 2460Satinleaf FI 2461Sierra Leone-tamarind FI 0366Spanish lime FI 0369Tamarind FI 2462Velvet tamarind FI 2463Wampi FI 2564White star apple
	006B Assorted tropical and sub-tropical fruits - inedible smooth peel – large (FI 2022)		Avocado; Pomegranate or Mango; Banana and Papaya	FI 2480Abiu FI 0325Akee apple FI 0326Avocado FI 2481Bacuri FI 0327Banana FI 2482Binjai FI 0715Cacao (pulp) FI 0330Canistel FI 2483Cupuacu FI 2484Etambe FI 0335Feijoa FI 2485Jatobá FI 2486Kei apple FI 2487Kokam

Type: 01 Fruits		Representative commodities		Member crop in subgroup
Group	Subgroup	Group	Subgroup	
				FI 2488Langsat FI 2489Lanjut FI 2490Lucuma FI 2491Mabolo FI 0345Mango FI 2492Mango, Horse FI 2493Mango, Saipan FI 0346Mangosteen FI 0349Naranjilla FI 2494Paho FI 0350Papaya FI 2495Pawpaw FI 2496Pelipisan FI 2497Pequi FI 0352Persimmon, American FI 0355Pomegranate FI 2498Quandong FI 0360Sapote, Black FI 0361Sapote, Green FI 0363Sapote, White FI 2499Sataw FI 0367Star apple FI 0312Tamarillo FI 2500Tamarind-of-the-Indies FI 2501Wild loquat
	006C Assorted tropical and sub-tropical fruits - inedible rough or hairy peel – large (FI 2023)		Atemoya and Pineapple	FI 2520Atemoya FI 2521Biriba FI 0329Breadfruit FI 2522Champedak FI 0331Cherimoya FI 0332Custard apple FI 0334Durian FI 0371Elephant apple FI 0337Ilama FI 0338Jackfruit FI 0344Mammey apple FI 2523Marang FI 0347Marmalade-box FI 2524Monkey-bread tree FI 0353Pineapple FI 2525Poshte FI 0357Pulasan FI 0358Rambutan FI 0359Sapodilla FI 0362Sapote, Mammey FI 2526Screwpine FI 2527Soncoya FI 0365Soursop FI 0368Sugar apple FI 2528Sun sapote
	006D Assorted		Pitaya and	FI 2540Pitaya

Type: 01 Fruits		Representative commodities		Member crop in subgroup
Group	Subgroup	Group	Subgroup	
	tropical and sub-tropical fruits - inedible peel – cactus (FI 2024)		Prickly Pear	FI 0356Prickly pear FI 2541Saguaro
	006E Assorted tropical and sub-tropical fruits - inedible peel – vines (FI 2025)		Kiwifruit or Passion Fruit	FI 2560Granadilla FI 2561Granadilla, Giant FI 0341Kiwifruit FI 2562Monstera FI 2563Passionflower, Winged-stem FI 2564Passion fruit, Banana FI 0351Passion fruit
	006F Assorted tropical and sub-tropical fruits – inedible peel – palms (FI 2026)		Muriti or Palmyra Palm	FI 2580Coconut, Young FI 2581Guriri FI 2582Moriche palm fruit FI 2583Muriti FI 2584Palmyra palm fruit FI 2585Salak

Annex 3 of Appendix X

Test conditions for brewing and processing tea[69]

1. Procedure for brewing tea in China

Take 3 g of green/black tea (6 g for oolong) and add 150 mL of boiling water (100 ℃) by pouring over the tea leaves. Allow the tea to brew for 5 minutes and the water extract is obtained by filtering. The remaining solid is brewed 2 other times (3 times in total). Analyse the pesticide residues in the aqueous tea infusion and the remaining solid (spent leaves).

A brew factor is calculated as follows: Divide the (residue concentration in the tea infusion (mg/kg)) by the residue concentration in the original dry tea leaves (mg/kg). Residue concentrations in tea infusion are expressed in mg per kg of dry tea used for preparing the infusion.

2. Procedure for brewing tea in Japan

In Japan, even for estimating the worst transfer rate, the amount of boiling water (90 °C) is 50 times the dry weight of leaf. The mixture is stirred for 5 min to represent the worst case scenario. That is for 1 g of green tea leaves, we use 50 mL of water.

3. Test Guideline for Pesticide Residues in Green Tea[70]

3. 1 Tea cultivation: Conventional cultivation is allowed.

3. 2. Crop management: Pesticides other than those subjects to the test may be used for the purpose of pest control, as long as they will not prohibit the residue analysis of test subjects.

3.3. Timing of test: Tests should be carried out when pesticides have to be used to control target pests.

3.4. Sampling and preparation

3.5 Analytical portion and sample size: Samples are classified into fresh leaves, processed products (such as roasted tea) and tea infusion.

Minimum sample size is 1 kg.

A. Sampling (picking tea leaves)

When new leaves start to come out on tea plants in May, three to four leaves from the tips of the plants are picked.

Old leaves should be sorted and removed to make sure that they do not get mixed into the picked samples.

[69] Yukiko Yamada: Personal communication

[70] Test Guidelines in the Republic of Korea provided by the Food Standard Division, MFDS

B. Product (roasted tea) manufacturing

1) Common requirements

a.The test is to be performed on "roasted (or parched) teas."
b.For the manufacturing sequence of roasted teas, it starts with the control sample group (non-treated with a pesticide) and proceed in the order of the groups expected to have less residue to the groups expected to have more.
c.The roasting process is performed three times and gone through the drying process to get samples for analysis of the products.
d.Sample should be carefully separated to prevent cross-contamination among adjacent samples during packaging and storage. They are sealed in polyethylene bags, labelled properly, and kept in a freezer.
e.For reference, the manufacturing yield of teas, when roasted three times, is about 21±2% of freshly plucked leaves. Generally, the more times tea leaves are roasted, the lower the yield is.

2) Detailed manufacturing depending on roasted tea type

(A) Tea manufacturing by hand

a. Washing and cutting: The tea leaves should be not washed. A number of leaves on top of one another is stacked and cut into appropriate sizes, if necessary.
b. First roasting (fixing): Fresh leaves are put into a cast-iron cauldron preheated up to 230±5 ℃ for about 7±1 min.
c. Cooling: The tea leaves are taken out immediately after the first roasting, and spread out evenly to be cooled down for 5-10 min.
d. Rolling: The roasted tea leaves are rolled by hand for 10 min, and tossed in the air to be cooled further.
e. Repeat roasting and rolling: The roasting process (2nd roasting at 175±5 ℃ for 10 min and 3rd at 95±5℃ for 10 min) and the rolling process are repeated.
f. Drying: The final heat treatment is applied to dry the leaves at the low temperature of 70±5℃ until the moisture content of final product falls to 5±1%. The drying time may be adjusted to achieve the target moisture level.

(B) Tea manufacturing by machine

a. To produce samples using a machine, at least about 5 kg of freshly green tea leaves are necessary.
b. First roasting (fixing): The tea leaves are taken into the roasting chamber preheated up to 260±10 ℃, and roasted at the rotation speed of 4-5 rpm for 9±1 min, depending on the moisture content of the leaves. At this point, the fan is left on hold for the first two to three min and run for suction. The suction and holding step are repeated at an interval of 1-2 min to release moisture.
c. Cooling: The tea leaves are taken out immediately after the first roasting, and tossed in the air for 10 min to release heat.
d. Rolling: The roasted tea leaves are rolled to rupture the cell walls of tea leaves, not their epidermis, by applying pressure. This procedure is continued for 20 min at a time.
e. Untangling: Blocks of tea leaves stuck together are untangled after rolling. This step is done by hand immediately after the rolling process so that the leaves will not stay stuck together during the drying process.
f. 1st drying: The Tea leaves are added into the roaster chamber pre-heated up to 100 ℃ and then the temperature is increased to 200-220 ℃. The leaves is dried at the rotation speed of 3-4 rpm for 10 min. The fan is left on hold for the first three to four minutes

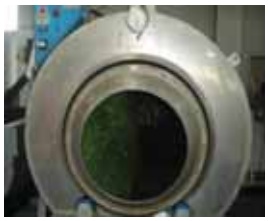
and then run for suction. The suction and holding step are repeated at an interval of 1-2 min.

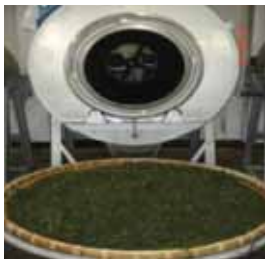
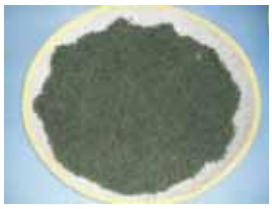
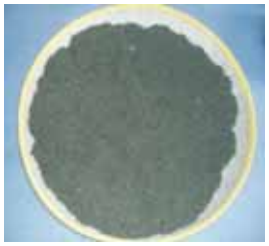
g. 2nd drying: The leaves are added into the roaster preheated up to 100 ℃, and the chamber temperature is increased gradually to 150 ℃. They are dried at the rotation speed of 3-4 rpm for 10 min.

h. Final drying: The leaves are added into the roaster preheated up to 100 ℃, and the chamber temperature is increased gradually to 120 ℃. They are dried at the rotation speed of 3-4 rpm for 15 min.

i. The moisture content of fresh leaves is between 75% and 80%, but it is reduced to 5±1% once the final drying process is completed.

Manufacturing roasted tea using a roasting machine

Process		Reference
Pluck tea leaves 	.One bud, three leaves .Moisture content: 80±2% .Variety:Small-leaf variety (*camellia sinensis var. sinensis*)	.Harvest "one bud, three leaves." (Tea plantation: 5-10 years or longer. Harvested after a third leaf comes out.)
↓		
Roast tea leaves 	.Quantity: 8±2 kg of tea leaves .Temperature:260±10℃ .Time: 9±1 min .Moisture content:55-60% .Weight diminished by 50%	.Roaster chamber should be preheated to 260±10℃ on the temperature gauge .Rotation speed: 4-5 rpm .Fan operation: Pause the fan for the first 2-3 min, then turn on for suction. Repeat suction and pause at an interval of 1-2 min (It is important to remove moisture).
↓		
Cooling 	.Purpose: Tea moisture equilibrium .Time: 10 min .Release heat from tea leaves.	.Heat should be released immediately after roasting. .Spread tea leaves out evenly.
↓		

Rolling  ↓	.Purpose: Shaping, breaking cell walls .Time: 20 min .Moisture content:50-55%	.Weight of tea leaves (after first roasting): 5 kg per rolling .Rolling time: 20 min per rolling .Break the cell walls, not epidermis, of tea leaves by applying pressure (The original form of the leaf is retained).
Untangle tea leaves ↓	.Time: 10 min	.Untangle block of tea leaves stuck together.
1st Drying  ↓	.Temperate:200-220℃ .Time: 10 min .Moisture content: 25-30%	.Roaster should be preheated up to 100℃ on the temperature gauge. .Increase chamber temperature after putting tea leaves in .Rotation speed: 3-4 rpm .Fan operation: Pause the fan for the first 2-3 min and then run for suction. Repeat suction and hold at an interval of 1-2 min.
2nd Drying  ↓	.Temperate:120-150℃ .Time: 10 min .Moisture content:15-20%	.Roaster should be preheated to 100℃ on the temperature gauge. .Increase chamber temperature gradually from 100℃ → 150℃ after putting tea leaves in. .Rotation speed: 3-4 rpm
Final Drying 	.Temperature:100-120℃ .Time: 15 min .Moisture content: 5±1%	.Roaster should be preheated to 100℃ on the temperature gauge. .Increase chamber temperature gradually from 100℃ → 120℃ after putting tea leaves in. .Rotation speed: 1-2 rpm

* Model of the roaster: TW/S-B70-9H (made in Taiwan)

C. Samples to be analysed

a. Fresh leaves: 5 g of grounded sample should be analysed. The size of the sample may be varied depending on properties of sample or the analyser.

b. Dried leaves (product): 5 g of a ground sample are taken and 15-20 mL of distilled water is added. The sample is analysed after the water is absorbed completely. The amounts of the distilled water and the sample may be varied depending on the properties of sample or the analyser.

c. Tea Infusion: Tea infusion should be boiled with distilled water and then cooled down to 80℃. 150 mL of the cooled distilled water is added to 3 g of roasted tea. The tea should be brewed for 3 min. The aqueous part of tea is used as a sample for analysis. The amounts of the water and the sample may be varied by the same proportions depending on the properties of sample or the analyser.

Appendix XI

TABLE AND SPREADSHEET EXAMPLES

CONTENTS

Table XI.1. Residue interpretation table for folpet residues on tomatoes.

Trial conditions are compared for treatments considered valid for MRL and STMR estimation. (JMPR 1998).

Crop	Country	Use pattern				Trial	folpet,
		kg ai/ha	kg ai/hL	No of appl	PHI days		mg/kg
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 (1)
			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
(b) Outdoor or field use (F), or glasshouse application (G)
(c) e.g., biting and sucking insects, soil borne insects, foliar fungi
(d) e.g., wettable powder (WP), emulsifiable concentration (EC), granule (GR)
(e) Use CIPAC/FAO Codes where appropriate
(f) All abbreviations used must be explained
(g) Method, e.g., high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, e.g., overall, broadcast, aerial spraying, row, individual plant, between the plants
(i) g/kg or g/l
(j) Growth stage at last treatment
(k) PHI = Pre-harvest interval
(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:	Crop/crop group:
Responsible body for reporting (name, address):	Submission date:
Country:	Page:
Content of ai (g/kg or g/l):	Indoor/outdoor:
Formulation (e.g., WP):	Other ai in formulation:
Commercial product (name):	(Common name and content):
Producer of commercial product	Residues calculated as:

Summary table for providing details of supervised trials (to be submitted in Excel spreadsheet Electronic attachment)

Site details							
Study reference	**Trial reference**	**Commodity**	**Country**	**Year**	**Location**	**Variety**	**Plot size (area or plant no)**
ABC-1226	1226-1	Pear	USA	2002	Soap Lake, WA	(Anjou)	6 trees
						,	

Application details									
Method	**Equipment**	**Form**	**No**	**RTI (days)**	**Rate (kg ai/ha**	**Water L/ha**	**Conc kg ai/hL**	**Date of last treatment**	**Growth stage at last treatment**
Foliar	Back pack3-nozzle hand lance	200SC	2	14	0.44 0.43	1600 1500		26.Jan.12	BBCH87

Sample details				Analytical details					
Sample size	**Field handling**	**Time to freezing (max)**	**DAT**	**[Analyte-1] Residues-a (mg/kg)**	**[Analyte-1] Residues-b (mg/kg)**	**Mean (mg/kg)**	**Method (LOQ) mg/kg**	**%Recovery% @ spike level mg/kg**	**Frozen sample storage interval**
2.4 kg 24 fruit	stalk removed	5 hours	0	0.22	0.16	0.19	0.02	80-97% @ 0.01 mg/kg	2.5 months
			3	0.12	0.14	1.13	0.02		
			7	< 0.02	< 0.02	< 0.02			

Notes:

The table can be expanded with additional columns as needed for instance to include more residue components determined individually.

Concurrent recoveries should be reported

For application detail the relevant information should be given. E.g. kg ai/ha water L/ha or water L/ha and concentration kg ai/hL.

Table XI.4. Example Table format for long-term dietary intake calculation.

	CHLOROTHALONIL (81)		International Estimated Daily Intake (IEDI)						ADI = 0 - 000 mg/kg bw						
			STMR	Diets as g/person/day			Intake as ug/person/day								
Codex Code	Commodity description	Expr as	mg/kg	G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
FS 0013	Cherries, raw	RAC	0,39	0,92	0,36	9,15	3,57	0,10	0,04	0,61	0,24	0,10	0,04	6,64	2,59
-	Peaches and nectarines, raw	RAC	0,12	2,87	0,34	2,21	0,27	0,15	0,02	5,94	0,71	1,47	0,18	15,66	1,88
FB 0269	Grape, raw	RAC	0,955	12,68	12,11	9,12	8,71	0,10	0,10	16,88	16,12	3,70	3,53	54,42	51,97
-	Grape must	PP	0,134	0,33	0,04	0,13	0,02	0,10	0,01	0,10	0,01	0,10	0,01	0,10	0,01
DF 0269	Grape, dried (= currants, raisins and sultanas)	PP	0,248	0,51	0,13	0,51	0,13	0,10	0,02	1,27	0,31	0,12	0,03	2,07	0,51
JF 0269	Grape juice	PP	0,134	0,14	0,02	0,29	0,04	0,10	0,01	0,30	0,04	0,24	0,03	0,10	0,01
-	Grape wine (incl vermouths)	PP	0,0096	0,67	0,01	12,53	0,12	2,01	0,02	1,21	0,01	3,53	0,03	4,01	0,04
FB 0275	Strawberry, raw	RAC	2,05	0,70	1,44	2,01	4,12	0,10	0,21	1,36	2,79	0,37	0,76	2,53	5,19
VA 0384	Leek, raw	RAC	17,5	0,18	3,15	1,59	27,83	0,10	1,75	0,28	4,90	0,10	1,75	3,21	56,18
-	Onions, mature bulbs, dry	RAC	0,4	29,36	11,74	37,50	15,00	3,56	1,42	34,78	13,91	18,81	7,52	43,38	17,35
-	Onions, green, raw	RAC	0,835	2,45	2,05	1,49	1,24	1,02	0,85	2,60	2,17	0,60	0,50	2,03	1,70
VB 0042	Flowerhead brassicas, raw	RAC	5	2,96	14,80	0,57	2,85	0,10	0,50	4,17	20,85	7,79	38,95	3,64	18,20
SO 0697	Peanuts, nutmeat, raw (incl roasted, excl oil, excl butter)	RAC	0,01	0,46	0,00	1,21	0,01	6,64	0,07	2,52	0,03	1,25	0,01	1,83	0,02
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (ug/person)=				187,2		374,1		283,7		302,5		254,1		570,9
	Bodyweight per region (kg bw) =				60		60		60		60		60		60
	ADI (ug/person)=				1200		1200		1200		1200		1200		1200
	%ADI=				15,6%		31,2%		23,6%		25,2%		21,2%		47,6%
	Rounded %ADI=				20%		30%		20%		30%		20%		50%

Note: Only the first 6 regional diets and a few commodities 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 fruits raw and (2) Plums, raw, the correct consumption figures for stone fruits can be obtained as: stone fruits excluding plums). For the cluster G01 the corresponding values are 10.82 and 2.40, the correct value for stone fruit raw will be 10.82-2.40=8.42. The values calculated for the 17 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.

Table XI.6 Table format for IESTI calculation for general population (example)

CHLOROTHALONIL (81)

Acute RfD= 0,6 mg/kg bw (600 µg/kg bw)

IESTI Maximum %ARfD:

															30% all	30% gen pop	20% child
Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
FS 0013	Cherries (all commodities)	highest utilisation: raw	0,39	1,8	1,000	DE	Child, 2-4 yrs	24	187,50	7,2	NR	1	0,16 - 20,9	0% - 3%	0% - 3%	0% - 3%
FS 0247	Peach (all commodities)	highest utilisation: raw with peel (incl consumption without peel)	0,12	1,1	1,000	JP	Child, 1-6 yrs	76	306,00	255,0	3	2a	0,05 - 57,91	0% - 10%	0% - 4%	0% - 10%
VA 0385	Onion, bulb (all commodities)	highest utilisation: raw without skin	0,4	0,69	1,000	JP	Child, 1-6 yrs	748	102,00	244,4	3	2b	0,15 - 12,87	0% - 2%	0% - 1%	0% - 2%
VA 0388	Shallot (i.e. dry harvested small onion) (all commodities)	highest utilisation: raw without skin	0,4	0,69	1,000	CN	Child, 1-6 yrs	480	115,81	51,4	3	2a	0,32 - 9,35	0% - 2%	0% - 1%	0% - 2%
VO 0444	Peppers, chili (all commodities)	highest utilisation: dried (incl powder)	1,5	4,4 - 44	7,000	CN	Gen Pop, > 1 yrs	1583	32,22	0,0	NR	1	0,03 - 186,44	0% - 30%	0% - 30%	0% - 7%
VO 0445	Peppers, sweet (incl. pim(i)ento) (bell pepper, paprika) (all commodities)	highest utilisation: raw with skin	1,5	4,4	1,000	CN	Child, 1-6 yrs	1002	169,85	170,0	3	2b	0,27 - 138,95	0% - 20%	0% - 9%	0% - 20%
VO 0448	Tomato (all commodities)	highest utilisation: dried	0,011 - 0,11	2,8	5,000	AU	Gen pop, > 2 yrs	61	861,10	8,0	NR	1	0,06 - 179,93	0% - 30%	0% - 30%	0% - 20%

Note: Only part of the table is shown

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.[18] 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	3	8	4	55
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.

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 photo degradation, 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 *c*GAP 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		2		4	24	11		2		2	15
Almond	5	4	2	6	2	19	3	2	2	4	2	13
Apple	20	16	6	8	6	56	12	10	4	5	4	35
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	3	8	4	55	14	10	2	5	2	33
Bean, Dried	13	16	2		2	33	8	10	2		2	22
Bean, Edible Podded	8	16	2		4	30	5	10	2		2	19
Bean, Lima, Dried	3		2		2	7	2	10	2		2	16
Bean, Lima, Green	8		2	8	2	20	5	5	2	5	2	19
Bean, Mung	3		2		2	7	2	10	2		2	16
Bean, Snap	9		2		2	13	5	10	2		2	19
Bean, Succulent Shelled	8	16	3		2	29	5	10	2		2	19
Beet, Garden	8	12	2		2	24	5	7	2		2	16
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 choi	2		2		2	6	2		2		2	6
Boysenberry	2	4	2		2	10	2	2	2		2	8
Broccoli	12	8	3	8	4	35	7	5	2	5	2	21
Broccoli, Chinese (gal Ion)	2		2		2	6	2		2		2	6
Brussels Sprouts	3	8	2	4	2	19	2	5	2	2	2	14
Buckwheat	5		2		2	9	3		2		2	7
Cabbage	12	12	6	8	4	42	7	7	4	5	2	25
Cabbage, Chinese	3	4	6		2	15	2	2	4	3	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**
Cacao Bean (cocoa)	3	8	2			13	2	5	2			9
Calabaza	2		2			4	2		2			4
Calamondin	1		2			3	1		2			3
Canola	22	16	2	8	2	50	13	10	2	5	2	32
Cantaloupe	8	12	2	8	2	32	5	7	2	5	2	21
Carambola	2	4	2		2	10	2	2	2		2	8
Carob	3	4	2			9	2	2	2			6
Carrot	12	16	6	8	4	46	7	10	4	5	2	28
Cassava, bitter or sweet	2	4	2		2	10	2	2	2		2	8
Cauliflower	11	16	2	8	2	39	7	10	2	5	2	26
Celery	12	8	3	4	4	31	7	5	2	2	2	18
Cherry, Sweet	8	12	2	3	4	29	5	7	2	2	2	18
Cherry, Tart (Sour)	8	12	2	3	2	27	5	7	2	2	2	18
Chestnut	3	4	2	4	2	15	2	2	2	2	2	10
Chickpea (garbanzo bean)	3		2	4	2	11	2		2	2	2	8
Chicory	2	4	2		2	10	2	2	2		2	8
Clover	12		2		4	18	7		2		2	11
Coconut	5	4	2			11	3	2	2			7
Coffee	5	8	2	4		19	3	5	2	2		12
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		2			4
Corn, Sweet	14	8	3	6	2	33	8	5	2	4	2	21
Cotton	12	8	2	8		30	7	5	2	5		19
Cowpea (dried shelled bean)	5		2		2	9	3		2		2	7
Cowpea (forage/hay)	3		2		2	7	2		2		2	6
Cowpea, (succulent, shelled bean)	3		2		2	7	2		2		2	6
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	12	6	4	4	37	7	7	4	2	2	22
Currant	2	8	2		2	14	2	5	2		2	11
Dandelion	1	8	2		2	13	1	5	2		2	10
Dasheen (taro)	2	4	2		2	10	2	2	2		2	8

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
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	6		2	19	2	5	4		2	13
Elderberry	3	4	2		2	11	2	2	2		2	8
Endive (escarole)	3	8	2		2	15	2	5	2		2	11
Fennel		8	2			10		5	2			7
Fig	3	4	2		2	11	2	2	2		2	8
Filbert (hazelnut)	3	4	2		2	11	2	2	2		2	8
Flax (= linseed)	10		2		2	14	6		2		2	10
Fodder beet		16	2		4	22		10	2		2	14
Garlic	3	8	2		2	15	2	5	2		2	11
Genip	1		2			3	1		2			3
Ginger	2	4	3			9	2	2	2			6
Ginseng	3	4	2			9	2	2	2			6
Gooseberry	3	8	2		2	15	2	5	2		2	11
Grape	16	16	3		6	41	10	10	2		4	26
Grape, table		16	3	8	4	31		10	2	5	2	19
Grapefruit	8	4	2	2	2	18	5	2	2	2	2	13
Grasses	12		2		4	18	7		2		2	11
Guar	3		2			5	2			2		4
Guava	2	4	2		2	10	2	2	2		2	8
Herbs		8	2			10		5	2			7
Hops	3	8	2		2	15	2	5	2		2	11
Horseradish	3	8	2		2	15	2	5	2		2	11
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	8	3		6	20	2	5	2		4	13
Kohlrabi	3	8	2		2	15	2	5	2		2	11
Kumquat	1	4	2		2	9	1	2	2		2	7
Leek	3	12	6	4	2	27	2	7	4	2	2	17
Lemon	5	8	2	6	2	23	3	5	2	4	2	16
Lentil	5	4	2		2	13	3	2	2		2	9
Lettuce, Head	13	16	6	8	3	46	8	10	4	5	2	29
Lettuce, Leaf	8	16	2	8	3	37	5	10	2	5	2	24
Lime	3	4	2		2	11	2	2	2		2	8

	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
Loganberry	2	8	2		2	14	2	5	2		2	11
Longan	1	4	2			7	1	2	2			5
Lotus Root	1	4	3			8	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	6	8	4	31	3	5	4	5	2	19
Mango	3	4	2	8		17	2	2	2	5		11
Melon		12	3		2	17		7	2		2	11
Melon, Casaba	3		3		2	8	2		2		2	6
Melon, Crenshaw	3		3		2	8	2		2		2	6
Melon, Honeydew	8		3		2	13	5		2		2	9
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	4	2	6	2	17	2	2	2	4	2	12
Muskmelons	8		3		2	13	5		2		2	9
Mustard Greens	8		2		2	12	5		2		2	9
Mustard, Chinese	2		2		2	6	2		2		2	6
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	6	8	4	46	7	10	4	5	2	28
Onion, Green	5	8	6	4	2	25	3	5	4	2	2	16
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	2	2	10
Parsnip	3	8	2		2	15	2	5	2		2	11
Passion Fruit	2	4	2		2	10	2	2	2		2	8
Pawpaw	3	4	2			9	2	2	2			6
Pea, Chinese	1		2		2	5	1		2		2	5
Pea, Dried Shelled	11	16	2	8	2	39	7	10	2	5	2	26
Pea, Edible podded	8	8	2	6	2	26	5	5	2	4	2	18
Pea, Edible Podded	3		2		2	7	2		2		2	6

	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, Field (Austrian Winter) (forage/hay)	3		2	8	2	15	2		2	5	2	11
Pea, Succulent Shelled (Pea, Garden, Succulent)	10	16	2		2	30	6	10	2		2	20
Peach	16	12	3	8	4	43	10	7	2	5	2	26
Peanut	12	4	2	8		26	7	2	2	5		16
Peanut, Perennial	3		2			5	2		2			4
Pear	11	16	6	8	4	45	7	10	4	5	2	28
Pecan	5	4	2	4	2	17	3	2	2	2	2	11
Pepper, (other than bell)	3		2		2	7	2		2		2	6
Pepper, Bell	12	16	3		2	33	7	10	2		2	21
Persimmon	3	4	6		4	17	2	2	4		2	10
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	16	2	8	2	39	7	10	2	5	2	26
Pomegranate	3	4	2			9	2	2	2			6
Potato	26	16	6	8	4	60	16	10	4	5	2	37
Pumpkin	5	8	3	4	2	22	3	5	2	2	2	14
Quince	3	8	2		2	15	2	5	2		2	11
Radish	7	8	2		2	19	4	5	2		2	13
Radish, Oriental (daikon)	2		6		2	10	2		4		2	8
Rapeseed	3	16	2		2	23	2	10	2		2	16
Raspberry, Black and Red	6	8	2		2	18	4	5	2		2	13
Rhubarb	3	8	2		2	15	2	5	2		2	11
Rice	16	8	6	6		36	10	5	4	4		23
Rice, Wild	5		2			7	3		2			5
Rutabaga	5		2		2	9	3		2		2	7
Rye	10	16	2		2	30	6	10	2		2	20
Safflower	7	4	2		2	15	4	2	2		2	10
Sainfoin	3		2		2	7	2		2		2	6
Salsify	3	8	2		2	15	2	5	2		2	11
Sesame	3	4	2			9	2	2	2			6
Shallot	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**
Sorghum, Grain	12	8	2	6	2	30	7	5	2	4	2	20
Soybean (dried)	20	16	6	8	4	54	12	10	4	5	2	33
Spices		8	2			10		5	2			7
Spinach	11	8	6		2	27	7	5	4		2	18
Squash, Summer	10	12	2		4	28	6	7	2		2	17
Squash, Winter	5	8	3		2	18	3	5	2		2	12
Strawberry	10	16	3	8	4	41	6	10	2	5	2	25
Sugar Beet	15	16	3	2		36	9	10	2	2		23
Sugarcane	8		3	8		19	5		2	5		12
Sunflower	10	16	2	8	2	38	6	10	2	5	2	25
Sweet Potato	8	4	6		2	20	5	2	4		2	13
Chard Swiss	3	8	2		2	15	2	5	2		2	11
Tangelo	3	4	2		2	11	2	2	2		2	8
Tanier (cocoyam)	2		2			4	2		2			4
Tea		8	6			14		5	4			9
Tobacco	8	4	2		2	16	5	2	2		2	11
Tomato	27	16	6	8	4	61	16	10	4	5	2	37
Triticale		16	2	4	2	24		10	2	2	2	16
Turnip, root	5	8	3		4	20	3	5	2		2	12
Turnip, tops (leaves)	5	8	3		2	18	3	5	2		2	12
Walnut, Black and English	3	8	2		2	15	2	5	2		2	11
Watercress	2	8	2		2	14	2	5	2		2	11
Watermelon	8	16	6	4	2	36	5	10	4	2	2	23
Wheat	33	16	6	12	4	71	20	10	4	7	2	43
Yam, True	3	4	3		2	12	2	2	2		2	8

1 Crops to be reconsidered after Codex classification is finalised.
2 Additional Canadian (where US trials do not overlap)
3 Number of trials for fodder crops in Europe not yet harmonised, although criteria are available that allow specifying number of trials i.e. cultivation area (ha) and production (t). Number in brackets indicate changes that will apply from 1st January 2013.
4 Japanese government revised the requirements for residue data, depending on the production volume and consumption of each crop/commodity, within the review of pesticide registration scheme. These requirements will become effective in 2014.
5 To take into account that no reduction on two trials in an OECD country is possible and that a minimum of eight trials for a comprehensive submission is required.

Appendix XIII

PRINCIPLES OF THE MANN-WHINEY AND KRUSKAL WALLIS TESTS

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 (α_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 XIII.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 XIII.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	
0.076	8	
0.082	9	
0.092	10	
0.11		11
0.13		12.5

Residues (mg/kg)	Ranks for mandarins	Ranks for oranges
0.13		12.5
0.14	14	
0.15		15
0.18	16	
∑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	

2. 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.
3. Calculate the sum of the ranks for each population.
4. Calculate the U values using the above equations ($U_1 = 17$; $U_2 = 43$).
5. Check the correctness of the calculation ($U_1 + U_2 = n_1 n_2$).
6. 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.

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 XIII.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 XIII.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		

	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 Cf and Hc values are 0.9960 and 4.4829, respectively

The H_c value follows χ^2 (chi square) distribution with **ν = k-1** degrees of freedom. If $H_c \leq \chi 2_{0.05,\nu}$ 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 $\chi^2_{0.05}$ values are:

ν	2	3	4	5	6
$\chi^2_{0.05}$	5.9915	7.8147	9.4877	11.0705	12.5916

In our example ν = 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.

CRITICAL VALUES FOR MANN-WHITNEY U-TEST AT A_2=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

Appendix XIV

ELECTRONIC ATTACHMENTS[1]

XIV.1 Annex to Appendix VII. Template for summarising supervised residue trials data.xlsx

XIV.2 Guidance IESTI 2014.pdf

XIV.3. IESTI calculation15model_final.xlsx

XIV.4. IESTI data overview.xlsx

XIV.5. IEDI calculation02_17 cluster diet.xlsx

XIV.6 OECD MRL calculator_multiple.xlsx

XIV.7 OECD MRL calculator_single compound.xlsx

XIV.8 OECD MRL Calculator White paper.pdf

XIV.9 OECD MRL Calculator User Guide.pdf

XIV.10 OECD feed calculatorV1_5.xlsx

XIV.11 Kruskal Wallis test_explanation

XIV.12 Kruskal_Wallis calculation spreadsheet

[1]: The files can be downloaded from:

http://www.fao.org/fileadmin/templates/agphome/documents/Pests_Pesticides/JMPR/Manual/Electronic_attachments.zip

SUBJECT INDEX

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The first version of this manual on the submission and evaluation of pesticide residues data for estimation of maximum residue levels in food and feed was printed by FAO in 1997 as a working document with the aim of consolidating the procedures used by the FAO Panel of experts on pesticide residues. The FAO Manual was revised in 2002 and in 2009 incorporated additional information from the JMPR Report of 1997-2009. Since then there have been many developments in the scientific evaluation process of the Joint Meeting on Pesticide Residues (JMPR), administered by FAO and the World Health Organization. The present manual incorporates all relevant information and principles that are currently used by the JMPR to estimate maximum residue levels (MRLs), supervised trials median residue (STMR) values and dietary risk from pesticide residues. The manual will constantly be revised and updated in the light of experience gained and developments in residue data evaluation. Its aim is also to improve communication between the Codex Committee on Pesticide Residues (CCPR) and its member countries and other participants in the CCPR and to explain the procedures being adopted by the FAO Panel of the JMPR.

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