If the JMPR estimate of short-term intake of a new or periodic review compound still exceeds the acute RfD for one or more food commodities a footnote will be attached to those commodities in the recommendations table

> *"The information provided to the JMPR precludes an estimate that the dietary intake would be below the acute RfD - JMPR [year] "*

CHAPTER 8

USE OF JMPR RECOMMENDATIONS BY REGULATORY AUTHORITIES

CONTENTS

Introduction
Safety assessment of pesticides
Residue studies and recommended MRLs
Interpretation of residue analytical results in comparison with MRLs

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The evaluations and appraisals of the compounds are, in most cases, based on unpublished proprietary data submitted for the purpose of the JMPR assessment In this context the JMPR documents are a unique source of information Regulatory authorities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

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 are encountered when some Member States attempt 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 that were tested and evaluated by the JMPR and the technical materials of commerce are often unknown

The purity of technical active ingredient depends on, among several factors, the route and conditions of synthesis, the purity of raw materials used for the manufacture, and the packing and storage conditions The toxicity of certain impurities can be several magnitudes higher than that of the active ingredient, and therefore their presence even in very small concentrations may substantially affect the toxicity of the pesticide product

The Joint Meeting evaluates toxicological studies on test materials that in most cases correspond to active ingredients that are sold by the companies which provided the data The purity and specifications of active ingredients that national regulatory authorities are asked to approve may or may not correspond to those that were tested and summarized in the JMPR monographs For this reason, national registration authorities should carefully consider the extent of similarity between any active ingredient being considered for registration and the technical material assessed by the Joint Meeting To be able to make this determination, registration authorities should seek information on manufacturing impurities in pesticide products, as emphasized in Sections 6 2 2 and 6 2 3 of the *FAO International Code of Conduct on the Distribution and Use of Pesticides* 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

Relevance of pesticide specifications for JMPR evaluations

The fifth edition of the FAO Manual[15] on the development and use of FAO specifications for plant protection products introduced a new procedure for data evaluation Under this new procedure the data requirements were expanded dramatically FAO in cooperation 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, FAO seeks also access to registration data from competent authorities to be able to assess whether or not

(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 will apply now only to products for which the technical materials produced by each manufacturer have been evaluated by these organizations 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 the product quality, to improve pesticide user and consumer protection as well as to reduce side effects on the environment This procedure is accepted widely now by multi-national companies as well as by manufacturers of generic compounds

The 1999 JMPR recommended that FAO and WHO specifications for the technical material using their respective procedures should be developed before pesticides are evaluated within the Periodic Review Programme of CCPR or for new pesticides Companies (sponsors) should indicate in their submissions of data to JMPR whether the pesticides used in their studies are in compliance with the new specifications An FAO or WHO specification for the technical material should be required before establishing ADIs, acute RfDs or, where relevant, recommending MRLs It was recognized that implementation of this proposal would take time

[15] FAO 1999 Manual on the development and use of FAO specifications for plant protection products Fifth Edition FAO Plant Production and Protection Paper 149

At the time of publication of this Manual (2002), the proposal is not mandatory

RESIDUE STUDIES AND RECOMMENDED MRLs

The information relating to pesticide residues (e g results of supervised trials, metabolism, animal transfer, processing studies) can be used more generally than the safety assessment of pesticides

The comparability of the trial conditions discussed in detail in chapters 5 and 6 should be assessed for deciding on the applicability of JMPR conclusions and recommendations for the particular national use conditions

Codex MRLs are intended to be used primarily to enforce and control compliance with nationally authorized uses of pesticides on commodities moving in international trade The applicability of Codex MRLs for national use depends on the relation of GAP on which the maximum residue level estimates were based to the national GAP In making decisions on comparability of national use conditions to the trial conditions described in the monographs, the results of a few supervised trials carried out under typical growing conditions of the country can be of great value

In accordance with the principles of *FAO International Code of Conduct on the Distribution and Use of Pesticides*, governments "should promote the use of safe, efficient and cost effective application methods" in order to reduce the exposure of consumers and the environment resulting from the use of pesticides When the national use conditions lead to substantially lower residues than the Codex MRL, the establishment of lower national MRLs may be considered for enforcing domestic uses since higher MRLs would encourage unauthorized use of the pesticide, which is against the principle of GAP However, for imported commodities the national authorities have an obligation to accept higher Codex MRLs which afford an acceptable level of consumer protection, in accordance with the provisions laid down in the Sanitary and Phytosanitary (SPS) agreement of the Uruguay Round of GATT (General Agreement on Tariffs and Trade)

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 make any regulatory actions

The uncertainty of the analytical results (S_R) deriving from the random variation of the consecutive procedures comprises the uncertainties of sampling (S_S), sample preparation (S_{Sp}) and analysis (S_A)

$$(S_R) = \sqrt{[(S_S)^2 + (S_{Sp})^2 + (S_A)^2]}$$

Since the average residue is the same the equation can be written as

$$(CV_R) = \sqrt{[(CV_S)^2 + (CV_{Sp})^2 + (CV_A)^2]}$$

The uncertainty of the final analytical result (CV_R) cannot be smaller than that of any step of its measurement

The experiments show that, on average, the expected minimum coefficient of variation of residue results of supervised trials is around 0 3-0 4 In this estimate the variation of replicate analyses accounted for only 10% (Ambrus, 1996b)[16]

However, much larger variations of analytical results are encountered in practice A summary of answers to the question "What are considered acceptable values for reproducibility (deviations between laboratories)?", sent out by the Working Group on Methods of Analysis of CCPR in 1987, produced the information summarized in Table 8 1

Table 8 1 Reproducibility of representative residue methods at different residue levels

Concentration, mg/kg	Coefficient of variation, %	
	Mean	Range
0 01	77	20-200
0 1	45	10-100
1	22	5-50

The figures in Table 8 1 are typical of the range of errors routinely encountered (using accepted analytical methods) in analyses for pesticide residues at the concentrations indicated In view of the variability inherent in an analytical method, a decision is needed on which analytical results are required to be sure that the residue concentration in the sampled product exceeds the MRL

Furthermore, international collaborative studies revealed that, in the comparison of an analytical result with the MRL, accuracy (influenced by mainly systematic errors) is more important than precision

In order to obtain reliable results, the laboratories performing regulatory enforcement analysis are encouraged to

- establish internal quality control measures which enable them to assess the within-laboratory variation of results,
- participate in international sample check programmes to assess the accuracy of their analysis,
- pay attention to information on storage stability of residues and the definition of residues,
- strictly adhere to Codex guidelines for preparing the portion of commodity for analysis, and
- validate the sampling procedures used for obtaining samples, and ensure proper training of sampling officers

[16] Ambrus A, Solymosne M E and Korsos I 1996 Estimation of Uncertainty of Sample Preparation for the Analysis of Pesticide Residues *J Environ Sci Health* B31 No 3 443-450

The same precautions should be applied in performing supervised trials or selective surveys to provide data for estimating maximum residue levels

CHAPTER 9

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FAO 1990 Pesticide Residues in Food 1990 - Report FAO Plant Production and Protection Paper No 102 FAO, Rome

FAO 1990 International Code of Conduct on the Distribution and Use of Pesticides FAO, Rome

FAO 1991 Pesticide Residues in Food 1991 - Report FAO Plant Production and Protection Paper No 111 FAO, Rome

FAO 1992 Pesticide Residues in Food 1992 - Report FAO Plant Production and Protection Paper No 116 FAO, Rome

FAO 1993 Pesticide Residues in Food 1993 - Report FAO Plant Production and Protection Paper No 122 FAO, Rome

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Number 4 GLP Consensus Document, Quality Assurance and GLP Environment monograph No 48, Paris (1992)

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LOQ	limit of quantification, limit of quantitation (synonymous with LOD, limit of determination)
LP	large portion consumed (kg food/day) for IESTI calculations
MRL	Maximum Residue Limit
NEDI	national estimated daily intake
NOAEL	no-observed-adverse-effect level
OECD	Organization for Economic Cooperation and Development
PHI	pre-harvest interval
RAC	raw agricultural commodity
SPS	WTO Agreement on the Application of Sanitary and Phytosanitary Measures
STMR	supervised trials median residue
STMR-P	supervised trials median residue – processed commodity
TMDI	theoretical maximum daily intake
TMRL	Temporary Maximum Residue Limit
U	unit weight of the edible portion (kg) for IESTI calculations
USEPA	United States Environmental Protection Agency
UV	ultraviolet
v	variability factor for IESTI calculations
WHO	World Health Organization of the United Nations
WTO	World Trade Organization

Appendix I

ABBREVIATIONS USED IN THE TEXT

ADI	acceptable daily intake
ai	active ingredient
acute RfD	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	CropLife International (formerly GCPF)
cv	coefficient of variation
CXL	Codex Maximum Residue Limit (Codex MRL) See MRL
EMDI	estimated maximum daily intake
EMRL	extraneous maximum residue limit
FAO	Food and Agriculture Organization of the United Nations
GAP	good agricultural practice(s)
GCPF	Global Crop Protection Federation (replaced by CLI)
GEMS/Food	Global Environment Monitoring System – Food Contamination Monitoring and Assessment Programme
GIFAP	Groupement International des Associations Nationales de Fabricants de Produits Agrochimiques (International Group of National Associations of Manufacturers of Agrochemical Products) (replaced by GCPF)
GLP	good laboratory practice
HR	highest residue in the edible portion of the commodity found in the trials used to estimate a maximum residue level in the commodity
HR-P	highest residue - processed commodity
IEDI	international estimated daily intake
IESTI	international estimated short term intake
IUPAC	International Union of Pure and Applied Chemistry
ISO	International Organization for Standardization
ISO-E	ISO – 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)

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 (Holland, 1996) 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 (acute RfD)

The acute RfD 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 evaluation It is expressed in milligrams of the chemical per kilogram of body weight

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

Critical supporting studies

Critical supporting studies are metabolism, farm animal feeding, processing, analytical methods and freezer storage stability studies

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 and HR apply

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 and acute RfD

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 after 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) (new definition)

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) (new definition)

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, or derived directly from a series of processing trials The HR-P is expressed in units of mg/kg

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) (new definition)

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 quantitation (LOQ) (new definition)

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 quantitation' and 'limit of quantification' 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) toxicological assessment of the pesticide and its residue, and

b) review of residue data from supervised trials 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

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

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)

Explanatory note The term "raw agricultural commodity (RAC)" means the same as "primary food commodity "

Processing factor (new definition)

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

Processing factor = residue level [mg/kg] in processed product – residue level [mg/kg] in RAC

Explanatory note Alternative terms sometimes used for processing factor are, "concentration factor" when residue levels increase, and "reduction factor" (inverse of processing factor) when residue levels decrease

Processed food - general definition

For the purposes of the Codex Alimentarius, the term "processed food" means the product, resulting from the application of physical, chemical or biological processes to a "primary food commodity" intended for direct sale to the consumer, for direct use as an ingredient in the manufacture of food or for further processing "Primary food commodities" treated with ionizing radiation, washed, sorted or submitted to similar treatment are not considered to be "processed foods" " (JMPR Report 1979, Annex 3)

Provisional tolerable daily intake

A value based on toxicological data It represents tolerable human intake of a former agricultural pesticide that may occur as a contaminant in food, drinking water and the environment (JMPR Report 1994, 2 3)

Explanatory note The term "tolerable" rather than "acceptable" is used to signify permissibility rather than acceptability of the intake of environmental contaminants unavoidably associated with the consumption of otherwise wholesome food Use of the term "provisional" expresses the fact that reliable data on the consequences of human exposure to these pesticides are lacking and that the submission from any source of relevant safety data is encouraged

Regulatory method of analysis

A regulatory method of analysis is a method suitable for the determination of a pesticide residue in connection 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 in order 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

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 (JMPR Report 1979, Annex 3)

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 (FAO Manual, 1997)

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