CHAPTER 7

ESTIMATING DIETARY INTAKE OF PESTICIDE RESIDUES

CONTENTS

7.1 BACKGROUND

To assess whether the maximum residue level proposed to CCPR, for use as a MRL, provides sufficient consumer safety, available residue data are combined with cultural dietary information to estimate potential residue intake by consumers. The consumer is considered to be adequately protected when estimated dietary intake of pesticide residues does not exceed the acceptable daily intake (ADI) or the acute reference dose (ARfD).

The JMPR has, from the outset, tried to estimate potential pesticide residue intake by utilising available data. In using the MRL as the residue level and the dietary patterns for the quantity of food consumed, then summing all intakes, the JMPR arrived at the Theoretical Maximum Daily Intake or TMDI. Nonetheless the JMPR was aware that TMDI calculations can result in a gross overestimation of intake. Conversely, existing uses of a pesticide, not brought to the attention of the JMPR, could result in an underestimation of the residue intake.

Until 1997 the TMDI dietary intake calculations had been carried out according to the Guidelines for predicting dietary intake of pesticide residues[44] published by the WHO in 1989. The dietary intake of any particular pesticide residue was obtained by multiplying the residue level in the food by the amount of commodity consumed from a "global" and five "cultural" diets, also known as "regional" diets. Total intake of the pesticide residue in each of the diet groups was then obtained by summing the intakes from all commodities containing the residue concerned. Intake estimation could be refined by allowing for the residue level in the edible portion of the commodity, the reduction or increase of residue levels on commercial processing such as canning and milling, and the reduction or increase in the level of residue on preparation or cooking of the food.

Based on the request of the CCPR a Joint FAO/WHO Consultation on Guidelines for predicting the Dietary Intake of Pesticide Residues[45] in 1995 reviewed the existing guidelines and recommended feasible approaches for improving the reliability and accuracy of methods for predicting the dietary intake of pesticide residues. The aim was to promote a greater acceptance of Codex MRLs by governments and, more importantly, by consumers. The report of the consultation contained recommendations for improving estimates of dietary intake, most notably the use of supervised trials median residue (STMR) levels in lieu of MRLs in the calculation of International Estimated Daily Intakes (IEDIs) and National Estimated Daily Intakes (NEDIs).

[44] WHO. 1989. Guidelines for predicting dietary intake of pesticide residues. GEMS/Food WHO, Geneva.
[45] WHO. 1995. Recommendations for the revision of the guidelines for predicting dietary intake of pesticide residues. Report of the FAO/WHO Consultation, (WHO/FNU/FOS/95.11) Geneva.

The IEDI incorporates those factors which can be applied at the international level and which comprise a subset of factors that might be considered at national level. The factors to be considered for IEDI calculations are:

- median residue data from supervised trials (STMR)
- residue definitions, which include all metabolites and degradation products of toxicological concern
- for residues at or below the limit of quantification (indicated with *), the median residue should be estimated to be the LOQ except when evidence from trials and supporting studies suggests that that residues are essentially zero
- the edible portion
- effects on residue levels due to storage, processing or cooking practices
- other known uses of the pesticide.

The National Estimated Daily Intake (NEDI) should be based on the same factors as for the IEDI, but the following additional factors based on national use pattern of the pesticides and food consumption data should also be taken into consideration, which would allow a refinement of the NEDI:

- proportion of crop or food commodity treated
- proportion of crop domestically produced and imported
- compliance monitoring and surveillance data
- total diet (market basket) studies
- food consumption data, including that of subgroups of the population.

The revised guidelines also contained sections on the risk assessment of acute hazards posed by pesticide residues and predicting dietary intake of acutely toxic pesticide residues. The guidelines have been further refined into operating procedures. See this chapter, Section 3 "*Short-term dietary intake"*.

The revised guidelines[46] were issued in 1997.

7.2 LONG-TERM DIETARY INTAKE

Long-term dietary intakes are calculated by multiplying the residue concentrations (STMRs, STMR-Ps or, where these are not available, recommended MRLs) by the 'average' daily per capita consumption estimated for each commodity, on the basis of the GEMS/Food diets[47], and summing the intakes for each food.

GEMS/Food Regional Diets, also referred to as cultural diets, are based on FAO food balance sheets from selected countries and expert knowledge. Consumption data derived from Food Balance Sheets reflect what is grown in a country plus what is imported, minus what is exported, and then divided by the number of inhabitants. GEMS/Food regional diets based on

[46] WHO. 1997. Guidelines for predicting dietary intake of pesticide residues, 2nd revised edition Unpublished document (WHO/FSF/FOS/97.7). http://www.who.int/foodsafety/publications/chem/pesticides/en/

[47] WHO. 1998. GEMS/Food Regional Diets. Regional per capita consumption of raw and semi-processed agricultural commodities. Food Safety Unit. WHO/FSF/FOS/98.3, Geneva. http://www.who.int/foodsafety/chem/gems/en/index1.html

food balance sheets include commodities that contain inedible or non-eaten portions. The consumption of the edible portion of food commodities should be used in estimating intakes rather than that of entire commodities. Corrections for wastage and home production can also improve this data. Because food balance sheets are thought to overestimate consumption of most commodities, the use of the per capita food consumption based on these sheets is generally thought to accommodate high percentile consumers (WHO 1997).

Until 2005 the JMPR used 5 regional diets. In 1997 Joint FAO/WHO Consultation on Food Consumption and Exposure Assessment of Chemicals recommended that new diets be developed based on a cluster analysis approach using major food groups. This recommendation was reconfirmed at a Joint FAO/WHO Expert Consultation on Exposure Assessment held in May 2005 in Annapolis, Maryland USA. This meeting agreed that the new diets would more accurately reflect the diversity of global food consumption patterns than the original five GEMS/Food Regional Diets[48]. Accordingly, 13 GEMS/Food Consumption Cluster Diets were developed based on FAO Food Balance Sheets. Data are currently available for 13 cluster diets with the number of countries given in brackets: A: Africa (22), B: Africa/Europe/Middle East (9), C: Africa/Middle East (10), D: Europe/Middle East (19), E: Europe (17), F: Europe (7), G: Far East (15), H: Latin America (12), I: Africa (15), J: Africa (11), K: Latin America (20), L: Far East (10) and M: Europe/Latin America (7). These Consumption Cluster Diets have been incorporated by the Dutch National Institute for Public Health and the Environment (RIVM), in cooperation with WHO/GEMS/Food, into an automated spreadsheet[49] to ensure consistency in IEDI calculations.

To use the spreadsheets, estimates made by JMPR (ADI, STMR (-P), HR (-P), and when necessary MRL values) are entered according to the manual attached to the templates. The calculations and generation of a final table are performed automatically. Great care is needed in data entry to ensure the food items are correctly matched with the corresponding residue value, taking into account, such factors as the processed proportion of a raw agriculture commodity where STMR-P values are available for the processed food, or the edible portion of the commodity if residues are available for the edible portion. To calculate processing factors, the principles described in Section 8 of Chapter 5 should be followed.

On some occasions STMR values may not be available for certain residue×commodity combinations. In such cases the MRL values may be entered in the spreadsheet to provide an intermediate estimate between the TMDI and the IEDI. Such situations should be fully explained in the report.

Notes for intake spreadsheets:

- diets are expressed in g/person/day
- daily intakes are expressed in µg/person
- the MRL is not entered unless it is used in the calculation
- data entry for meat and fat is based on 20/80% fat/muscle values for cattle and other mammalian animals and 10/90% fat/muscle values for poultry.

The procedure followed is illustrated in the example below.

[48] WHO 2008a. Dietary exposure assessment of chemicals in food Report of a Joint FAO/WHO Consultation Annapolis, Maryland, USA 2–6 May 2005, http://whqlibdoc.who.int/publications/2008/9789241597470_eng.pdf

[49] http://www.who.int/foodsafety/chem/acute_data/en/index.html

For deltamethrin, the cattle fat residue values from *dietary* exposure were a HR of 0.19 mg/kg and a STMR of 0.16 mg/kg. The cattle muscle residue values were a HR of 0.027 mg/kg and a STMR of 0.01 mg/kg. The poultry fat residue values were a HR of 0.09 mg/kg and a STMR of 0.038 mg/kg. The poultry muscle residue values were a HR of 0.02 mg/kg and a STMR of 0.02 mg/kg. The following tables illustrate the new calculation procedure for meat.

The automated excel template has the entries for 20/80% fat/muscle values for mammals and the 10/90% fat/muscle values for poultry, and performs the calculation correctly.

DELTAMETHRIN (135): International Estimate of Daily Intake ADI=0.01 mg/kg bw or 600 µg/person; 550 µg/person for Far East									
		MRL	STMR or STMR-P	Diets: g/person/day. Intake = daily intake: µg/person					
				A		E		M	
Code	Commodity	mg/kg	mg/kg	diet	intake	diet	intake	diet	Intake
MM 95	Meat (mammals other than marine)			27.7		90.2		158.3	
	Muscle (meat consumption×80%)		0.01	22.16	0.222	72.16	0.722	126.64	1.266
	Fat (meat consumption×20%)		0.16	5.54	0.886	18.04	2.887	31.66	5.066
PM110	Poultry meat			7.1		61		115.1	
	Muscle (meat consumption×90%)		0.02	5.68	0.114	48.8	0.976	103.59	2.072
	Fat (meat consumption ×10%)		0.04	1.42	0.057	12.2	0.488	11.51	0.460
		TOTAL =			1.278		5.072		8.864
		% ADI =			0%		1%		2%

The format of a spreadsheet for calculating long-term intake is provided in Tables XI.4 and XI.5 (Appendix XI). The tables are completed for an IEDI estimation for parathion-methyl and for a mixed TMDI-IEDI calculation for myclobutanil.

International estimated daily intakes (IEDIs) are derived only where STMRs or STMR-Ps are used in the calculation. Theoretical maximum daily intakes (TMDIs) use MRLs in the calculation.

$IEDI = \sum (STMR_i \times F_i)$

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

where

$STMR_i$ (or $STMR\text{-}P_i$) is	STMR (or STMR-P) for food commodity i
MRL_i is	MRL for food commodity i
F_i is	GEMS/Food regional consumption of food commodity i

JMPR intake estimates take into account JMPR recommendations. They may not always agree with a calculation that includes all current Codex MRLs because Codex MRLs whose withdrawal has been recommended by the JMPR are not included in the estimate.

Long-term dietary intakes are expressed as percentage of the ADI for a 60 kg person with the exception of the intake calculated for the diets G and L, in which a body weight of 55 kg is used[50]. 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[51]. In cases where the ADI is exceeded, JMPR indicates in its report which part of the risk assessment leaves most room for refinement (see Chapter 7.Section 6).

At the National level, further refinements of the dietary intake calculations are possible, taking into account more detailed information on food consumption, monitoring and surveillance data, total diet or reliable data on the percentage of crop treated and percentage of crop imported.

7.3 SHORT-TERM DIETARY INTAKE

In 1994 the JMPR considered the assessment of acute dietary risk in response to the CCPR's reservations about MRLs proposed for acutely toxic pesticides. The CCPR had suggested that the traditional ADI may not be appropriate for assessing risks reflecting short-term exposure to residues. Revised guidelines[52] were published in 1997 by the WHO and contained chapters on risk assessment of acute hazards and predicting dietary intake of acutely toxic pesticide residues. Procedures and practical guidelines were subsequently developed and the 1999 JMPR commenced formal routine assessment of acute dietary risk for pesticide residues in food.

High intake of a residue would occur when a large portion of a food with a high residue was consumed. The large portion size was agreed as the 97.5th percentile daily consumption for eaters of that food. Research in the UK and other countries had shown that the residue level in a unit of fruit or vegetable, e.g., a single apple or a single carrot, may be substantially higher than the residue in a composite sample representing the typical residue in the lot. This issue was accounted for through the introduction of a variability factor into the risk assessment. This concept provided the basis for the assessment of short-term dietary intake of pesticide residues.

The highest residue from the supervised residue trials at maximum GAP was generally seen as the better option than the MRL for short-term dietary intake calculations. The MRL is expressed on commodity moving in trade rather than the edible portion and the residue definition for enforcement does not necessarily match the residue definition for dietary intake estimation. The estimation of an MRL usually involves 'rounding up' to an accepted value, and rounding of values at an intermediate stage of a calculation is undesirable. Furthermore, the use of the MRL in an intake calculation may give the impression that adjusting the MRL

[50] FAO. 2003. Pesticide Residues in Food 2003- Report. FAO Plant Production and Protection Paper No. 176 FAO, Rome. Chapter 3.

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

[52] WHO. 1997. Guidelines for predicting dietary intake of pesticide residues, 2nd revised edition Unpublished document (WHO/FSF/FOS/97.7). http://www.who.int/foodsafety/publications/chem/pesticides/en/

will change the intake, but there will be no real change of dietary intake if the MRL is changed but GAP and other factors remain the same.

The highest residue in the composite sample of the edible portion from the trials used for estimating the maximum residue level is defined as the HR, expressed in mg/kg. In those cases where information is available only on the whole commodity and not on the edible portion, the HR expressed on the whole commodity may be used in the dietary intake calculations, though this is the least preferred option.

A 'high residue' is needed in the intake calculation for those processed commodities where bulking and blending are not likely to influence residues in the commodity as consumed, e.g., dried fruit or canned pineapple. In such cases the processing factor is applied to the highest residue from the supervised residue trials at maximum GAP rather than to the MRL. Similar arguments regarding rounding and residue definition apply as for the HR. The high residue in a processed commodity is referred to as the HR-P (highest residue - processed commodity).

The HR-P is the residue in a processed commodity calculated from the highest residue of the raw agricultural commodity and the corresponding processing factor.

The values provided by WHO GEMS/Food for the highest large-portion diet with the associated body weight and country for children and general population are used in the IESTI calculations.

Data on unit weights and large portion consumption (97.5^{th} percentile diets) and the mean body weights for the populations associated with the food consumption data are provided on the WHO Web site[53].

Calculations of intake recognize four different cases (1, 2a, 2b and 3). Case 1 is the simple case where the residue in a composite sample reflects the residue level in a meal-sized portion of the commodity. Case 2 is the situation where the meal-sized portion as a single fruit or vegetable unit might have a higher residue than the composite. Case 2 is further divided into case 2a and case 2b where the unit size is less than or greater than the large portion size respectively. Case 3 allows for the likely bulking and blending of processed commodities such as flour, vegetable oils and fruit juices.

LP:	Highest large portion reported (97.5^{th} percentile of eaters), in kg food per day
HR:	Highest residue in composite sample of edible portion found in the supervised trials used for estimating the maximum residue level, in mg/kg
HR-P:	Highest residue in a processed commodity, in mg/kg, calculated by multiplying the highest residue in the raw commodity by the processing factor
U	Unit weight of the whole commodity (as defined for MRL setting, including inedible parts)
U_e:	Unit weight of the edible portion, in kg, median value provided by the country where the trials which gave the highest residue were carried out
ν:	Variability factor - the factor applied to the composite residue to estimate the residue level in a high-residue unit; defined as the residue level in the 97.5^{th} percentile unit divided by the mean residue level for the lot.
STMR:	Supervised trials median residue, in mg/kg
STMR-P:	Supervised trials median residue in processed commodity, in mg/kg

See Appendix II, Glossary of Terms, for definitions of ARfD, HR, HR-P, STMR and STMR-P, and processing factor.

[53] http://www.who.int/fsf/Chemicalcontaminants/Acute_Haz_Exp_Ass.htm,

It should be noted that:

- The LP should be matched to the Codex commodity to which the HR or STMR values relate. In the case of commodities that are predominantly eaten as the fresh fruit or vegetable, the LP should relate to the raw agricultural commodity. However, when major portions of the commodity are eaten in a processed way, e.g., grains, and when information on the residue in the processed commodity is available, the LP should relate to the processed commodity, e.g., flour or bread.
- Although it was decided at the International Conference on Pesticide Residues Variability and Acute Dietary Risk Assessment in 1998[54] that the median unit weight (U_e) should be used in the IESTI equation, this value is not always available. Countries frequently use other values, such as the mean or an approximate value. JMPR uses the values that were submitted by Codex Member States to WHO GEMS/Food, on the assumption that these values represent median unit weights.

Case 1

The residue in a composite sample (raw or processed) reflects the residue level in a meal-sized portion of the commodity (unit weight, U, is below 0.025 kg). Case 1 also applies to meat, liver, kidney, edible offal, and eggs, and for grains, oil seed, and pulse commodities when the estimates are based on post-harvest use of the pesticide.

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

Case 2

The meal-sized portion, such as a single fruit or vegetable unit might have a higher residue than the composite (whole fruit or vegetable unit weight, U, is above 0.025 kg).

Case 2a

Unit edible weight of raw commodity (U_e) is less than large portion weight.

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

The Case 2a formula is based on the assumption that the first unit contains residues at the [HR × ν] level and the next ones contain residues at the HR level, which represents the residue in the composite from the same lot as the first one.

Case 2b

Unit edible weight of raw commodity, U_e, exceeds large portion weight.

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

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

[54] PSD Report of the International Conference on Pesticide Residues Variability and Acute Dietary Risk Assessment. York UK. Feb 1999. http://www.pesticides.gov.uk/uploadedfiles/web_assets/prc/WPPR_final_report.pdf

Case 3

Case 3 is for those processed commodities where due to bulking or blending the STMR-P represents the likely highest residue. Case 3 also applies to milk, grains, oil seeds, and pulses for which estimates are based on the pre-harvest use of the pesticide.

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

7.4 ACUTE REFERENCE DOSE

The acute reference dose (ARfD) of a chemical is the estimate of the amount of a substance in food or drinking-water, expressed on a body weight basis, that can be ingested over a short period of time, usually during one meal or one day, without appreciable health risk to the consumer on the basis of all the known facts at the time of the evaluation. ARfDs are derived from toxicological data obtained from feeding studies on laboratory animals. The estimated short-term dietary intake of a residue is compared with its ARfD in the risk assessment.

The JMPR WHO Core Assessment Group has already assessed many compounds and either assigned an ARfD or decided that an ARfD is unnecessary. The JMPR decided that it was inappropriate to use the ADI for a compound that has not yet been assessed for an ARfD.

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

1) an ARfD is available
2) an ARfD is unnecessary
3) the compound has not yet been evaluated for an ARfD.

When an ARfD is available the calculated IESTI values may be expressed as % of ARfD.

When an ARfD is deemed unnecessary, IESTI calculations are not necessary. In this case in the residue evaluations it is not necessary to estimate HR and HR-P values because they are not required.

When the compound has not yet been evaluated for an ARfD, HR and HR-P values should be estimated and IESTI values calculated. The ARfD section in the table heading should state: "may be necessary but has not yet been established." The final column in the IESTI tables cannot be completed (% ARfD) and entries should be indicated by a dash "–".

7.5 IESTI TABLES

For commodities where large portion diet information is available and for compounds for which ARfDs have been established, an acute risk assessment is carried out for each commodity×compound combination by assessing the IESTI as a percentage of the ARfD of the compound. If the percentage is higher than 100, the information provided to the JMPR does not allow an estimate that the acute dietary intake of the residue in that commodity would be below the acute reference dose and a note to this effect is included in the Report. See Appendix X, section "Dietary risk assessment" for standard statements depending on the results of the IESTI calculations.

An automated Excel template, similar to that described under long-term intake calculation, had been developed by Dutch National Institute for Public Health and the Environment (RIVM), in cooperation with WHO/GEMS/Food[55].

Tables XI.6 and XI.7 (Appendix XI) provide examples of the format used in the IESTI calculation spreadsheets; the examples used are for parathion-methyl. For each compound, two tables are required, one for the general population and one for children between the ages of 2 and 6 years.

The table heading should show the compound, IESTI, general population or children and the ARfD.

The commodities and the STMR, STMR-P, HR and HR-P values are taken from the recommendation tables. Only those values needed in the calculations should be entered in the IESTI tables. Note that STMR values are generally not used in IESTI calculations and should not be entered into the tables (exceptions: STMR values are used for milk, STMR values for commodities like wheat are precursors to the STMR-P values for the processed commodities).

The percentages of the ARfD are rounded to one significant figure for values up to and including 100% and to two significant figures for values above 100%.

The IESTI values in the table are expressed as 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.

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[56], the variability factor has been gradually refined based on the increased data base and information on the nature of the distribution of residues in crop units.

[55] http://www.who.int/foodsafety/publication/chem/regional_diets

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

The 2003 JMPR[57] evaluated the available information on the relation of maximum residues in crop units and the average residue in the corresponding composite samples[58]. The Meeting agreed to adopt a default variability factor of 3 for the estimation of residue levels in high-residue units in the IESTI calculations where unit weights, U, exceed 25 g (0.025 kg). The default variability factors of 5, 7 and 10 were replaced by a common default factor of 3 (JMPR report 2003). The applicability of the default variability factor of 3, which is the rounded mean (2.8) of variability factors, was confirmed by the 2005 JMPR[59] based on the evaluation of an extensive data base of residues in crop units[60]. 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[61] noted that the parameters to be used in the IESTI equation are under debate, especially within the EU. The reason for this is the different views on which level of conservatism in the calculations is appropriate. CCPR concurs with the level of conservatism that JMPR currently applies.

Summary of choice of values in IESTI calculation spreadsheets

1. Commodity, STMR, STMR-P, HR and HR-P: use the relevant values directly from the recommendations table.
2. Large portion diet: use the values provided by WHO GEMS/Food for the highest large-portion diet, body weight and country for children and general population.
3. Unit weight: choose the country, unit weight and edible portion weight from the values provided by WHO GEMS/Food. The country should be associated with the region where GAP had been used to recommend the MRL.
4. Case: decide the case from the unit weight, U, unit weight edible portion, U_e, and large portion size.

7.5.1 Animal commodities IESTI calculations

See also Chapter 6, section 12 "*Estimation of maximum residue levels and STMR values for commodities of animal origin*".

According to the recommended sampling principles (References—Pesticide Residues in Food, CODEX ALIMENTARIUS, 1993), "a lot would comply with the MRL" if:

a. the final sample (consisting of combined primary samples) of commodities other than meat and poultry products did not contain a residue above the MRL, or

b. none of the primary samples of meat and poultry products analysed contained a residue above the MRL".

This implies that a variability factor should not be used in the IESTI calculation for animal commodities.

[57] Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group. FAO Plant Production and Protection Paper, 176, 2004

[58] Hamilton DJ, Ambrus Á, Dieterle RM, Felsot A, Harris C, Petersen B, Racke K, Wong S-S, Gonzalez R, Tanaka K, Earl M, Roberts G and Bhula R. Pesticide residues in food – Acute dietary Intake. Pest Manag Sci 60:311-339 (2004).

[59] Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group. FAO Plant Production and Protection Paper, 183, 2005

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

[61] FAO. 2007. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group.. FAO Plant Production and Protection Paper No. 191 2007. FAO, Rome.

The estimation of acute intake from the consumption of animal commodities, except milk, should be performed using the Case 1 defined by the methodology. The mixed 20/80% fat/muscle values for cattle and other mammalian animals and the mixed 10/90% fat/muscle values for poultry should be used.

For milk, Case 3 should be applied (bulking or blending large portion at the STMR level).

7.6 HANDLING OF CASES WHERE JMPR ESTIMATES OF DIETARY INTAKE EXCEED THE ADI OR ARfD

Where the procedures described in this chapter have been applied to pesticides evaluated as new compounds or under the periodic review program the results are the best estimates of dietary intake of those pesticides according to the available data and methods applicable at the international level. The JMPR, by the use of footnotes, draws attention to those cases when intake estimates exceed the ADI or the ARfD.

If the JMPR estimate of long-term intake for a new or periodic review compound still exceeds the ADI for one or more of the GEMS/Food regional diets a footnote will be attached to the compound in the recommendations table:

> "The information provided to the JMPR precludes an estimate that the dietary intake would be below the ADI – JMPR [year]."

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

> "The information provided to the JMPR precludes an estimate that the dietary intake would be below the ARfD – JMPR [year]."

There is a public perception that small differences in estimated intake are real differences in terms of food safety, e.g., 120% ARfD is unacceptable whereas 80% ARfD is acceptable. However, there is conservatism in the derivation of the ARfD and in the estimation of intake. For example, a safety factor for inter-individual variation is included when the ARfD is established, and as such the ARfD is designed to protect those individuals at the upper-end of human susceptibility. There is likely to be very limited overlap between the population with the greatest sensitivity to a particular pesticide and the population with estimated intake of residues greater than the ARfD. Therefore, in cases where the ARfD is exceeded, additional considerations should be taken into account, e.g., the amount by which the ARfD is exceeded, the basis on which the ARfD has been established, and the uncertainties in the estimate of intake[62]. In cases where the ADI and/or ARfD are exceeded, the JMPR indicates in its Report which part of the risk assessment leaves most room for refinement. If no more refinements are possible, the estimated maximum residue level will not be adopted as an MRL by CCPR.

[62] FAO. 2007. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group.. FAO Plant Production and Protection Paper No. 191 2007. FAO, Rome.