

メタミドホス 推定摂取量 (単位: $\mu\text{g}/\text{人}/\text{day}$)

食品群	基準値案 (ppm)	暴露評価 に用いた 数値	国民平均		幼小児 (1~6歳)		妊婦		高齢者 (65歳以上)	
			TMDI	EDI	TMDI	EDI	TMDI	EDI	TMDI	EDI
とうもろこし	0.2	0.023	0.5	0.1	0.9	0.1	0.5	0.1	0.2	0.0
大豆	0.05	0.007	2.8	0.4	1.7	0.2	2.3	0.3	2.9	0.4
小豆類	2	0.632	2.8	0.9	1.0	0.2	0.2	0.1	5.4	1.7
ばれいしょ	0.3	0.010	11.0	0.4	6.4	0.2	11.9	0.4	8.1	0.3
やまいも(長いも)	0.1	0.02	0.3	0.1	0.1	0.0	0.2	0.0	0.4	0.1
てんさい	0.02	0.005	0.1	0.0	0.1	0.0	0.1	0.0	0.1	0.0
だいこん類(ラディッシュを含む)の根	0.03	0.006	1.4	0.3	0.6	0.1	0.9	0.2	1.8	0.4
だいこん類(ラディッシュを含む)の葉	0.05	0.010	0.1	0.0	0.0	0.0	0.0	0.0	0.2	0.0
かぶ類の根	0.30	0.073	0.8	0.2	0.2	0.1	0.2	0.1	1.3	0.3
かぶ類の葉	3	1.026	1.5	0.5	0.3	0.1	0.9	0.3	3.3	1.1
はくさい	0.2	0.029	5.9	0.9	2.1	0.3	4.4	0.6	6.3	0.9
キャベツ	0.2	0.037	4.6	0.8	2.0	0.4	4.6	0.8	4.0	0.7
ケール	1	0.198	0.1	0.0	0.1	0.0	0.1	0.0	0.1	0.0
こまつな	0.5	0.14	2.2	0.6	1.0	0.3	0.8	0.2	3.0	0.8
きょうな	1	0.213	0.3	0.1	0.1	0.0	0.1	0.0	0.3	0.1
チンゲンサイ	0.5	0.147	0.7	0.2	0.2	0.0	0.5	0.1	1.0	0.3
カリフラワー	0.3	0.038	0.1	0.0	0.0	0.0	0.0	0.0	0.1	0.0
ブロッコリー	0.7	0.132	3.2	0.6	2.0	0.4	3.3	0.6	2.9	0.5
その他のあぶらな科野菜	1	0.198	2.1	0.4	0.3	0.1	0.2	0.0	3.1	0.6
こぼろ	0.02	0.005	0.1	0.0	0.0	0.0	0.0	0.0	0.1	0.0
レタス	0.3	0.026	1.8	0.2	0.8	0.1	1.9	0.2	1.3	0.1
その他のさく科野菜	0.02	0.005	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
たまねぎ	0.2	0.026	6.1	0.8	3.7	0.5	6.6	0.9	4.5	0.6
にんにく	0.1	0.02	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
トマト	0.02	0.005	0.5	0.1	0.3	0.1	0.5	0.1	0.4	0.1
なす	0.5	0.094	2.0	0.4	0.5	0.1	1.7	0.3	2.9	0.5
きゅうり	0.02	0.005	0.3	0.1	0.2	0.0	0.2	0.1	0.3	0.1
オクラ	0.5	0.105	0.2	0.0	0.1	0.0	0.1	0.0	0.2	0.0
しょうが	0.02	0.005	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
えだまめ	0.3	0.041	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
その他の野菜	0.05	0.008	0.6	0.1	0.5	0.1	0.5	0.1	0.6	0.1
みかん	0.2	0.05	8.3	2.1	7.1	1.8	9.2	2.3	8.5	2.1
なつみかんの果実全体	1	0.084	0.1	0.0	0.1	0.0	0.1	0.0	0.1	0.0
レモン	1	●	0.3	0.3	0.2	0.2	0.3	0.3	0.3	0.3
オレンジ	1	●	0.4	0.2	0.6	0.2	0.8	0.3	0.2	0.1
グレープフルーツ	1	●	1.2	0.5	0.4	0.2	2.1	0.8	0.8	0.3
ライム	1	●	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1
その他のかんきつ類果実	0.1	0.012	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.0
かき	0.2	0.043	6.3	1.4	1.6	0.3	4.3	0.9	9.9	2.1
その他の果実	0.1	0.016	0.4	0.1	0.6	0.1	0.1	0.0	0.2	0.0
茶	2	0.467	6.0	1.4	2.8	0.7	7.0	1.6	8.6	2.0
その他のスパイス	0.5	0.02	0.1	0.0	0.1	0.0	0.1	0.0	0.1	0.0
その他のハーブ	1	0.198	0.1	0.0	0.1	0.0	0.1	0.0	0.1	0.0
計	-	-	75.2	14.1	38.6	7.1	67.0	12.1	83.6	17.1
ADI比(%)	-	-	235.2	43.9	406.8	74.8	200.7	36.2	257.0	52.5

● 個別の作物残留試験がないことから、暴露評価を行うにあたり、基準値(案)又は基準値(案) × 可食部濃度比の数値を用いた。

TMDI: 理論最大1日摂取量 (Theoretical Maximum Daily Intake)

EDI: 推定1日摂取量 (Estimated Daily Intake)

(参考)

これまでの経緯

- 平成17年11月29日 残留基準値の告示
平成20年 2月12日 厚生労働大臣から食品安全委員長あてに残留基準設定に係る食品健康影響評価について要請
平成20年 2月14日 食品安全委員会 (要請事項説明)
平成20年 2月27日 第36回農薬専門調査会幹事会
平成20年 3月 6日 食品安全委員会における食品健康影響評価 (案) の公表
平成20年 3月11日 薬事・食品衛生審議会へ諮問
平成20年 5月 1日 食品安全委員会 (報告)
平成20年 5月 1日 食品安全委員会委員長から厚生労働大臣あてに食品健康影響評価について通知
平成20年 9月19日 薬事・食品衛生審議会食品衛生分科会農薬・動物用医薬品部会

●薬事・食品衛生審議会食品衛生分科会農薬・動物用医薬品部会

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(○ : 部会長)

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

Food and Agriculture Organization of the United Nations

Rome, 2002
First edition

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^{Error! Bookmark not defined.} were published in 1997 by 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 (i.e. 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 concept provided the basis for 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 of trade rather than edible portion and the MRL compliance residue definition does not always match the dietary intake residue definition. 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 will change the intake, however 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 edible portion from the trials used for estimating the maximum residue level is defined as the HR, expressed as mg/kg. In those cases where information is available only on the whole commodity and not on the edible portion, the HR expressed on whole commodity may be used in the dietary intake calculations, but as a less preferred option.

A "high residue" is needed in the intake calculation for those processed commodities where bulking and blending are not influential, e.g. dried fruit or canned pineapple. The preference was to apply the processing factor to the highest residue from the supervised residue trials at maximum GAP rather than to the MRL. Similar arguments about rounding and residue definition apply here as for the HR case. 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.

Data on unit weights and edible portion percentages have been provided by France, the UK and the USA to WHO GEMS/Food.

Large-portion consumption data have been provided by Australia, France, The Netherlands, Japan, the UK and the USA. Mean body weights for adults and children aged 6 and under have been provided by Australia, France, The Netherlands, the UK and the USA.

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 percentile diets) and the mean body weights for the populations associated with the food consumption data are provided on the WHO web site¹³.

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), kg food/day
HR:	Highest residue in composite sample of edible portion found in the supervised trials used for estimating the maximum residue level, mg/kg
HR-P:	Highest residue in a processed commodity, mg/kg, calculated by multiplying the highest residue in the raw commodity by the processing factor
bw:	Mean body weight, kg, provided by the country from which the LP was reported
U:	Unit weight of the edible portion, kg, 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.
STMR:	Supervised trials median residue, mg/kg
STMR-P:	Supervised trials median residue in processed commodity, mg/kg

See Appendix II, Glossary of Terms, for definitions of acute RfD, HR, HR-P, STMR and STMR-P.

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 is below 0.025 kg).

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

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 is above 0.025 kg).

¹³ http://www.who.int/fsf/Chemicalcontaminants/Acute_Haz_Exp_Ass.htm

Case 2a

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

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

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 exceeds large portion weight.

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

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.

Case 3

Case 3 is for those processed commodities where bulking or blending means that the STMR-P represents the likely highest residue.

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

Acute reference dose

The acute RfD (acute reference dose) 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. Acute RfDs 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 acute RfD in the risk assessment.

The JMPR WHO Core Assessment Group has already assessed many compounds and either assigned an acute RfD or decided that an acute RfD is unnecessary.

The JMPR decided that it was inappropriate to use the ADI for a compound that has not yet been assessed for an acute RfD.

In the short-term risk assessment of a compound, there are then 3 situations with respect to the acute RfD:

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

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

When an acute RfD is 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 needed.

When the compound has not yet been evaluated for an acute RfD, HR and HR-P values should be estimated and IESTI values calculated. The acute RfD 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 (% acute RfD) and entries should be indicated by a dash “-”.

IESTI tables

An acute risk assessment is carried out for each commodity-compound combination by assessing the IESTI as a percentage of the acute RfD 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. See Appendix X, section “Dietary risk assessment” for standard statements depending on the results of the IESTI calculations.

Tables XI.6 and XI.7 (Appendix XI) are examples of the format of IESTI calculation spreadsheets; the examples are for parathion-methyl. For each compound, two tables are needed, one for the general population and one for children.

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

The commodities and the STMR, STMR-P, HR and HR-P values are taken from the recommendations table. 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 acute RfD are rounded to one significant figure for values up to and including 100% and to two significant figures for values above 100%.

The IESTI values in the table are expressed as $\mu\text{g}/\text{kg}$ bw in preference to the traditional mg/kg bw for more convenient reading; the % acute RfD is unchanged by the choice of units.

Body weights

In selecting the appropriate body weight, an *ad hoc* meeting in 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 acute RfD, 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.

Variability factors

The JMPR in 1999, after examining the available information, concluded that a variability factor ($R97.5^{\text{th}} \div \text{mean}$) of 7 for medium sized units could be used on a temporary basis until the database was further refined. The variability factor of 7 would not apply to granular soil

treatments or leafy vegetables where the factor of 10 should be retained for medium sized units.

Summary of variability factors

Commodity characteristic	v
Whole fruit or vegetable unit weight is <0.025 kg	Case 1
Whole fruit or vegetable unit weight is >0.25 kg	5
Whole fruit or vegetable unit weight is ≤0.25 kg but >0.025 kg	7
Leafy vegetables with unit weight ≤0.25 kg but >0.025 kg	10
Residue is derived from granular soil treatment with whole fruit or vegetable unit weight ≤0.25 kg but >0.025 kg	10

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 also supplied % edible portion. The unit weight on a whole commodity basis is used to decide the choice of variability factor, but the unit weight in Case 2 calculations is the edible portion unit weight. For example, the avocado unit weight is 0.3 kg and 60% of its weight is edible. Therefore the v for avocado is 5 (unit weight > 0.25 kg) and the unit weight edible portion (U) in Case 2 is 0.18 kg.

Summary of choice of values in IESTI calculation spreadsheets

1. Commodity, STMR, STMR-P, HR and HR-P: use 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^{Error! Bookmark not defined.}. The country should be associated with the region where GAP had been used to recommend the MRL.
4. Variability factor and case: decide the variability factor and case from the unit weight, unit weight edible portion and large portion size.

Animal commodities IESTI calculations

See also Chapter 6, section “Estimation of maximum residue levels and STMR values for commodities of animal origin.”

According to the recommended sampling principles¹⁴ (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 analyzed contained a residue above the MRL”.

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

The acute intake estimation from the consumption of animal commodities, except milk, should be performed using the Case 1 defined by the methodology. For milk, Case 3 should be applied (bulking or blending large portion at STMR level).

WHEN JMPR ESTIMATES OF DIETARY INTAKE EXCEED THE ADI OR ACUTE RfD

After 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 acute RfD.

If the JMPR estimate of long-term intake of 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 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].”

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.

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

PARATHION-METHYL (59): international estimate of short-term intake (IESTI) for **GENERAL POPULATION**. Acute RfD = 0.03 mg/kg bw (30 µg/kg bw)

Code	Commodity	STMR or STMR-P, mg/kg	HR, mg/kg	Large portion diet		Unit weight			Variability factor	Case	IESTI, µg/kg bw	% acute RfD, rounded	
				Country	Body weight, kg	Large portion, g	Unit weight g	Country					Unit wt, edible portion g
FP 0226	Apple		0.18	USA	65	1348	110	Fra	100	7	2a	5.4	20
	Apple juice	0.015			60						3		
VD 0071	Beans (dry)		0.05	Fra	62.3	255					1	0.2	1
VB 0041	Cabbages, Head		0.26	Fra	62.3	312	908	USA	717	5	2b	6.5	20
OR 0691	Cotton seed oil, edible	1.16		USA	65	9.1					3	0.2	1
DF 0269	Dried grapes (=Currants ...)		0.70	Fra	62.3	135.2					1	1.5	5
FB 0269	Grapes		0.41	Aus	67	513	125	Fra	118	7	2a	7.5	20
GC 0645	Maize	0.05	0.09	Fra	62.3	260				see maize flour			
CF 1255	Maize flour	0.021		Aus	67	90					3	0.03	0
OR 0645	Maize oil, edible	0.051		NI	63	43					3	0.03	0
FS 0247	Peach		0.22	Jpn	52.6	626	110	Fra	99	7	2a	5.1	20
VD 0072	Peas (dry)		0.24	Fra	62.3	445					1	1.7	6
VR 0589	Potato		0	NL	63	687	122	USA	99	7	2a	0	0
OR 0495	Rape seed oil, edible	0.10		Aus	67	65					3	0.1	0
GC 0654	Wheat	0.29	4.1	USA	65	383				see wheat bran and flour			
CM 0654	Wheat bran, unprocessed	0.64		Aus	67	37					3	0.35	1
CF 1211	Wheat flour	0.11		USA	65	365					3	0.62	2
											MAX IESTI = 20		

Table XI.7. Table format for IESTI calculation for children up to 6 years (parathion-methyl example).

PARATHION-METHYL (59): international estimate of short-term intake (IESTI) for **CHILDREN UP TO 6 YEARS** Acute RfD = 0.03 mg/kg bw (30 µg/kg bw)

Code	Commodity	STMR or STMR-P, mg/kg	HR, mg/kg	Large portion diet		Unit weight			Variability factor	Case	IESTI, µg/kg bw	% acute RfD, rounded	
				Country	Body weight, kg	Large portion, g	Unit weight g	Country					Unit wt, edible portion g
FP 0226	Apple		0.18	USA	15	679	110	Fra	100	7	2a	15.4	50
	Apple juice	0.015			15						3		
VD 0071	Beans (dry)		0.05	Fra	17.8	209					1	0.59	2
VB 0041	Cabbages, Head		0.26	Jpn	15.9	142	908	USA	717	5	2b	11.6	40
OR 0691	Cotton seed oil, edible	1.16		USA	15	6					3	0.48	2
DF 0269	Dried grapes (=Currants ...)		0.70	USA	15	59					1	2.77	9
FB 0269	Grapes		0.41	Aus	19	342	125	Fra	118	7	2a	22.6	80
GC 0645	Maize	0.05	0.09	Fra	17.8	148					see maize flour		
CF 1255	Maize flour	0.021		Aus	19	60					3	0.07	0
OR 0645	Maize oil, edible	0.051		Fra	17.8	21					3	0.06	0
FS 0247	Peach		0.22	Aus	19	307	110	Fra	99	7	2a	10.4	30
VD 0072	Peas (dry)		0.24	Fra	17.8	107					1	1.44	5
VR 0589	Potato		0	UK	14.5	279	122	USA	99	7	2a	0	0
OR 0495	Rape seed oil, edible	0.10		Aus	19	18					3	0.1	0
GC 0654	Wheat	0.29	4.1	USA	15	151					see wheat bran and flour		
CM 0654	Wheat bran, unprocessed	0.64		Aus	19	13					3	0.43	1
CF 1211	Wheat flour	0.11		Aus	19	194					3	1.13	4
											MAX IESTI =		80

Pesticide residues in food 2006

Joint FAO/WHO Meeting on Pesticide Residues

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PLANT
PRODUCTION
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PAPER

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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 on Pesticide Residues
Rome, Italy, 3–12 October 2006

WORLD HEALTH ORGANIZATION
FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS
Rome, 2006

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2.4 SHORT-TERM DIETARY INTAKE ASSESSMENT: UNCERTAINTIES IN THE INTERNATIONAL ESTIMATED SHORT-TERM INTAKE (IESTI) CALCULATION AND ITS INTERPRETATION.

Introduction

The JMPR uses the deterministic method for the International Estimated of Short-Term Intake (IESTI) of a particular pesticide from the consumption of a food commodity. This calculation was

first introduced by a WHO Consultation on exposure assessment in 1997 and further developed by the JMPR in subsequent meetings (Chapter 3; 2005 JMPR Report).

In characterizing the risks associated with the short-term dietary exposure to a pesticide from the consumption of a certain food, the IESTI is compared with the established acute reference dose (ARfD) of the compound, and the intake expressed as a percentage of the ARfD. This value can then be used to make a judgment about the potential risk associated with the consumption of that food commodity.

In a case where an IESTI calculation, for a crop/pesticide combination, results in an intake higher than 100% ARfD, the Meeting will state according to current practice: "The information provided to the JMPR precludes an estimate that the short-term dietary intake would be below the ARfD for the consumption of the commodity". Due to the uncertainties in the assessment, arising from the uncertainties in each of the parameters or assumptions used, an exceedance of the ARfD does not necessarily represent a health risk to the consumers. The establishment of an ARfD which is necessarily conservative and/or a conservative assessment of exposure will lead to an overly conservative estimate of acute dietary risk.

Some governments, regional authorities, the CCPR and the JMPR have discussed the possibilities for improvement in the methodology currently used by the JMPR in assessing the short-term dietary intake of pesticide residues.

International Estimated Short-Term Intake (IESTI)

The equations below show the IESTI calculation used currently by the JMPR for raw agricultural commodities and when post-harvest treatment of the pesticide was used in grains, oil seeds and pulses:

$$\text{Case 1: } U < 25 \text{ g} \quad \text{IESTI} = \frac{HR \times LP}{bw}$$

Case 2: $U \geq 25\text{g}$

$$\text{Case 2a: } LP > U \quad \text{IESTI} = \frac{HR \times v \times U + (LP - U) \times HR}{bw}$$

$$\text{Case 2b: } LP < U \quad \text{IESTI} = \frac{HR \times v \times LP}{bw}$$

Where:

HR = highest residue in composite samples from supervised trials conducted according to GAP, in mg/kg

v = variability factor, which gives the relationship between the 97.5th percentile of the residues in crop units and the average residue in the sampled lot of the commodity

LP = highest large portion provided (97.5th percentile of eaters), in kg of food per day

U = median unit size unit weight of the crop unit examined, in kg

Bw = mean body weight, of the selected population, in kg.

The information on each of these parameters and the limitations attached to the data provided to the Meeting are described below.

Highest residue

The highest residue (HR) is estimated from supervised trials evaluated by the Meeting that have been conducted according to GAP. The uncertainties in these values are mainly associated with the residue dataset available to the JMPR. For major commodities moving in trade, a minimum of eight residue trials are necessary for recommendations to be made, but for minor or specialty crops, as low as three trials could be acceptable. When only limited residue data is available, and the distribution of the residue population is not known, the resulting MRL recommendation can be substantially higher than the HR.

The HR used in the IESTI calculation refers to the residues of toxicological concern present in the edible portion of the crop, while the MRL refers to a residue definition relevant for enforcement purposes related to the commodity in trade. There is a concern that conducting the assessment using the HR value instead of the MRL might not assure the safety of consumers, mainly when the MRL is much larger than the HR. The incorporation of statistical calculation in the recommendation process in 2006 (General Consideration 2.10), will improve the consistency in the estimations of the MRL made by the JMPR based on the available data.

Variability factor

For crops with unit weight > 25 g (Case 2), a variability factor of 3 applied to the HR value will represent a unit with the highest residue value. The variability factor reflects the variability of residues in individual units and is defined as the 97.5th percentile of residue data within a lot divided by the mean of the lot. The factor of 3 represents the mean of variability factors estimated from a dataset of residue data from over 22000 crop units in single plots from 13 countries representing 13 crops and 25 pesticides (2005 JMPR Report). Further improvement on this estimation may be made based on new data or new approaches.

Large portion, unit weight and body weight

Data on the consumption of large portions (LP), unit weight (U) and body weight used currently by the JMPR were provided by the governments of Australia, France, The Netherlands, Japan, Sweden, South Africa, the UK and the USA and compiled by GEMS/Food. The large portion value from each country represents the 97.5th percentiles of consumers; however, the information provided to GEMS/Food does not include the method used to collect the data neither the size of the dataset which was the base of the estimated LP. Consequently, the uncertainty behind the consumption data is unknown.

In the IESTI calculation, the unit weight value (U) will determine whether a variability factor is to be applied to the HR and whether the LP will be composed by more than one crop unit (Case 2a) or will be a portion of the unit (Case 2b). The Meeting does not know whether the U values provided represent the median of units consumed in a country or a different estimation. Also, it is not clear in all cases whether that value refers to the whole commodity or the edible portion.

The body weight (bw) data provided represent the mean body weight for children and for the general population in each country. However, the correlation between the large portion and body weight of each population should be established.

The IESTI was primarily developed to assess the short-term exposure arising from the consumption of food containing residues at levels found in supervised residue trials conducted according to GAP. Some countries have been applying the IESTI equations to assess the safety of food containing residues at levels found in monitoring and/or enforcement programs. The adequacy of such an approach needs to be discussed further.

The acute reference dose (ARfD)

When setting ARfDs, the WHO panel of the JMPR uses the most appropriate data from the available toxicology database. For some compounds such as those which have specific investigations of acute toxic endpoints the ARfD that is set will have a relatively low level of uncertainty associated with it. For other compounds such as those with ARfDs based on repeat dose studies with large margins between NOAELs and LOAELs the degree of uncertainty will be large and the resulting ARfD will be conservative.

Further uncertainty and potential conservatism can occur in the ARfD if the default safety/uncertainty factor of 100 (10× for interspecies extrapolation, 10× for variability of responses in the human population) is used in the absence of specific data which support the application of chemical specific adjustment factors (CSAFs).

Attention is drawn to the fact that when the ARfD is conservative, because of a lack of appropriate toxicological data, this will be clearly stated in the relevant section of the JMPR report, together with an indication of the types of data needed to refine the estimate. The Meeting notes that since the introduction of the acute reference dose concept at the national and international level in the late 1990s, a number of conservative ARfDs which were set initially have subsequently been amended on the basis of recently generated acute toxicity data and improved guidance on the establishment of ARfDs.

Conclusions

It is recognized that the IESTI and the ARfD values are not absolute numbers but are associated with uncertainty and variability. While it is possible to reduce uncertainty, biological variability^{9,10} can only be characterized. Both are set conservatively and the degree of conservatism reflects the level of uncertainty and variability in the data. The IESTI calculation should assist the decision making process rather than be the sole determinant of acceptable or unacceptable risk. The calculation takes into account only the parameters presented to it. At present, the decision making process does not take into account important qualitative influences, e.g. the nature of the toxicological endpoint.

In order to improve the estimation process the uncertainty of the individual components of the estimation should be examined and possible ways of improvements be identified.

The Meeting recommended that FAO and WHO address the issues identified in this document, with the participation of all relevant stakeholders. The main objectives would be the improvement of the estimation of the short-term dietary intake of pesticides and of the interpretation of the outcome of the short-term assessment conducted by the JMPR. The discussion should include *inter alia* the following specific issues:

- Uncertainty and variability of the parameters used in the estimation;
- Ways to improve the consumption, unit weight and body weight data provided to the JMPR;
- Identification of additional subgroups of the population for which the assessment should be conducted, e.g., toddlers;

⁹ Uncertainty: Imperfect knowledge concerning the present or future state of an organism, system, or (sub) population under consideration. (IPCS Risk Assessment Terminology, WHO Geneva 2004).

¹⁰ Variability: Heterogeneity of values over time, space, or different members of a population, including stochastic variability and controllable variability. Variability implies real differences among members of that population. National Resource Council, Science and Judgement in Risk Assessment (National Academy Press, Washington, DC, 1994).

General considerations

- The adequacy of the IESTI equations when residues from monitoring/enforcement data are used or the need of a specific methodology for this application;
- How to improve communication between the JMPR and the risk managers and the public on the output of the risk assessment conducted by the Meeting