DIETARY RISK ASSESSMENT

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INTRODUCTION

- FAO/WHO develops scientific risk assessments to define safe exposure levels which form the basis for the development of national and international food safety standards to protect the health of the consumers and ensure fair trade practices

Ref: *(https://www.who.int/activities/assessing-chemical-risks-in-food*)

What is Dietary Risk ?

- the risk from intake of biological, chemical, and physical agents in food “
- The estimated dietary intake (EDI) is compared with the relevant toxicological reference value for the food chemical such as ADI or acute RfD.

What is Acceptable Daily Intakes (ADI)

- **ADI** is an estimate of the **amount** of a substance in food that can be ingested **daily** over a lifetime without appreciable risk
- It is established on the ff basis:

  a. data on the biochemical, metabolic, pharmacological, and toxicological studies on experimental animals and observations in humans.

  b. The no-observed adverse-effect level (NOAEL) for the most sensitive species of experimental animal.

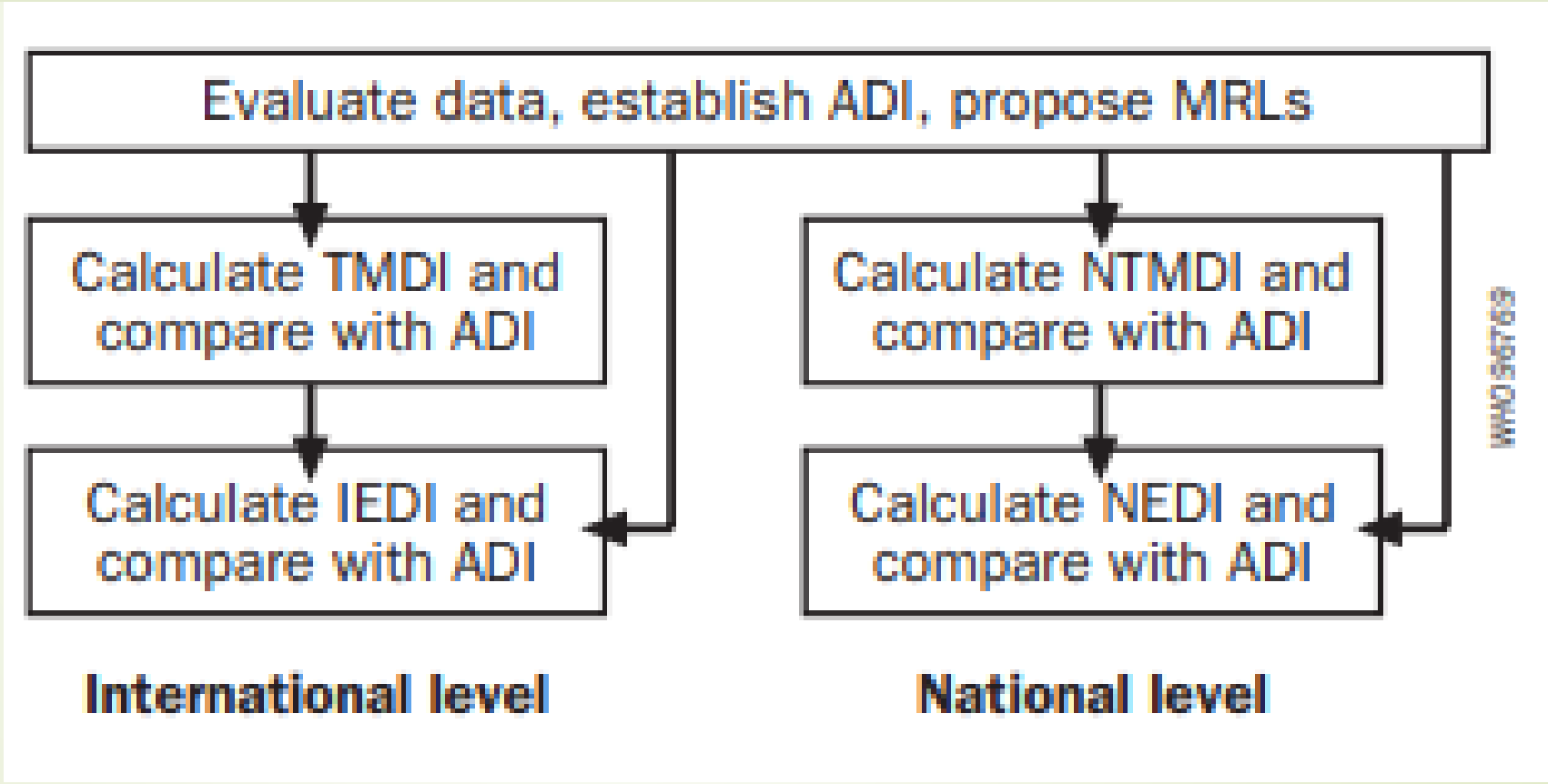
What is Acute Reference Dose (ARfD)

- The ARfD is an estimate of a substance in food that can be ingested over a short period of time, during one meal or one day, without appreciable health risk to the consumer on the basis of all known facts at the time of evaluation“ (FAO/WHO JMPR, 1998).

Why is Dietary Risk Assessment Necessary

- It provides the scientific basis for the risk management decision.
- to reach a conclusion on the acceptability of proposed MRLs and the underlying GAP.
- It ensures that the MRL established has no possible health concern.

Scheme for Dietary Intake Assessment for Pesticide Residues for Long Term Hazards



STEPS in RISK ASSESSMENT

Risk Assessment –a scientifically based process consisting of the following steps:

- (I) hazard identification,
- (ii) hazard characterization,
- (iii) exposure assessment, and
- (iv) risk characterization.

Hazard Identification and Hazard characterization

- **hazard identification** is the identification of the type and nature of adverse effects that a pesticide may cause in an organism.
- **hazard characterization** is the qualitative and quantitative description of the inherent property of a pesticide having the potential to cause adverse effects.

This should include a description of its mode of action, a dose–response assessment and the establishment of a threshold dose below which the toxic effects are no longer observed.

Risk Characterization

- The qualitative and/or quantitative estimation of the probability of occurrence and severity of known or potential adverse health effects in a given population based on hazard identification, hazard characterization and exposure assessment.

Two Types of Dietary Intake

- Long term dietary intake means lifetime intake of food containing residues of pesticides without any appreciable risk.
- Short Term Dietary Intake - the highest intake of food containing residues eaten in one sitting without any appreciable risk to human health.

Risk assessment of long term dietary intake of pesticide

- Risk Assessment of long -term dietary intakes are expressed as a percentage of the ADI for a 60-kg person or 55 kg for Filipinos

Calculation of Risk from Long Term Intake

$$NEDI = \frac{\text{proposed MRL (mg/ kg) X Consumption (Kg)}}{\text{55 Kg bw}}$$

where : NEDI = National Estimate of Dietary Intake

$$\% \text{ of ADI} = \frac{NEDI}{ADI} \times 100$$

e.g Estimation of long Term Dietary Risk for Chlorpyrifos

	Conc mg/kg	food intake (g)	Total
Onion, bulb	0,05	10	0.0005
Cauliflower	0.05	10	0.0005
Chinese cabbage	1.0	100	0.10
banana	3.0	100	0.30
Lettuce, head	0.1	100	0.01
Peppers	0.5	10	0.005
Eggplant	0.2	200	0.04
Mushrooms	0.05	100	0.005
Common beans	0.4	100	0.04
Carrot	0.5	100	0.05
Potato	0.05	100	0.005
Celery	0.05	40	0.002
Mango	0.05	400	0.02
Okra	0.05	100	0.005
TOTAL			0..538 kg
Note: All data are not true value but only for demo			

e.g. Risk assessment for chlorpyrifos

- Long Term Dietary Intake estimate at National Level

$$NEDI = \sum \frac{\text{MRL or pesticide conc. X Food Intake}}{\text{body weight (Kg)}}$$

$$NEDI = \frac{0.538\ mg}{55\ kg\ bw} = 0.00978\ mg/kg\ b.w$$

ADI: 0.01 mg/kg b.w

$$\%\ Risk = \frac{NEDI}{ADI} \times 100$$

$$NEDI = \frac{0.00978}{0.01} \times 100 = 97.8\ \%\ of\ the\ ADI$$

ADI

e.g. Risk Assessment for Pyriproxyfen on Mango

- Given:

ADI- 0.1 mg/kg bw Food intake: 9.6 g

Proposed MRL: Mango 0.02

$$NEDI = \sum \frac{\text{proposed MRL. X Food Intake}}{\text{body weight (Kg)}}$$

$$NEDI = \frac{0.02 \text{ mg/kg X } 0.0096 \text{ kg}}{55 \text{ kg bw}} = 3.5 \text{ x10-6 mg/kg b.w}$$

$$\% \text{ Risk} = \frac{NEDI}{ADI} \text{ X } 100$$

$$\% \text{ Risk} = \frac{3.5 \text{ X } 10\text{-}6 \text{ mg/kg b.w}}{0.1 \text{ mg/kg b.w}} \text{ x100} = 0.0035 \%$$

Interpretation

- If the National Estimated Dietary Intake (NEDI) of residues do not exceed the Acceptable daily Intake (ADI) for that specific pesticide -it can be concluded that the long term intake of the residues of pesticide resulting from its use is unlikely to present any public health concern.
  - NEDI < ADI ok
- If the NEDI exceed the ADI, the proposed MRL may not be accepted and should be modified in such a way that it will not pose risk to human health.
  - NEDI > ADI not ok. Modify

e.g. JMPR calculation of risk from long term dietary intake

PIRIMIPHOS-METHYL (86) International Estimated Daily Intake (IEDI). ADI=0-0.03 mg/kg bw/day

Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day. Intake = daily intake: µg/person									
			Mid-East		Far-East		African		Latin American		European	
			diet	intake	diet	Intake	diet	intake	diet	intake	diet	intake
GC 0080	Cereal grains (excluding wheat flour)	2.3	106.9	245.9	336.8	774.6	290.0	667.0	140.4	322.9	46.1	106.0
ML 0106	Milks	0.003	116.9	0.4	32.1	0.1	41.8	0.1	160.1	0.5	289.3	0.9
CM 0654	Wheat bran, unprocessed	5.1	-	-	-	-	-	-	-	-	-	-
CF 1212	Wheat wholemeal	1.6	-	-	-	-	-	-	-	-	-	-
CP 1211	White bread	0.22	215.3	47.4	76.0	16.7	18.9	4.2	37.3	8.2	117.2	25.8
CP 1212	Wholemeal bread	0.83	107.7	89.4	38.0	31.5	9.4	7.8	74.7	62.0	58.6	48.6
	Beer	0.01	-	-	-	-	-	-	-	-	-	-
	Total intake (µg/person)=			383.0		823.0		679.1		393.6		181.3
	Bodyweight per region (kg bw) =			60		55		60		60		60
% of ADI				21		51		38		10		22

Note: MRL is considered to replace STMR in 2015 FAO/WHO Expert meeting .

Short Term Intake Assessment

- Estimates of high intake of pesticide residue in one sitting based on the highest residues from the supervised trials.
- Large portion sizes and fruit and vegetable unit weights have been provided by a number of countries, but more such data are needed.
- The short-term intake is calculated for each food separately (large portion size × highest residue × a variability factor for some cases) and compared with the ARfD .
- When short-term exposure exceeds the ARfD, the risk assessors examine residue data from supervised trials with alternative GAPs to compare those alternative short-term exposures with the ARfD.
- If an estimated alternative short-term exposure does not exceed the ARfD, a maximum residue level is proposed based on GAP

Short Term Intake Assessment cont'd

- Three cases of intake calculation :

  Case 1 : food commodity unit weight ≤ 25 g

  Case 2 : food commodity unit weight > 25 g

  Case 3 : processed commodity is bulked or blended;

  including milk

  Ref: JMPR 2003 Ch. 3

Short Term IntakeAssessment cont'd

National Estimated Short-Term Intake (NESTI)

- Case 1 - food commodity unit weight ≤ 25 g

  - also applies to meat, edible offal, eggs

- NESTI = $\frac{LP \times HR}{bw}$

- LP = Large portion consumption (97.5th percentile of eater)
- HR= Highest residue found from supervised trial data

Short Term Intake Assessment cont'd

- Case 2 : food commodity unit weight > 25 g
- Case 2a unit weight, edible portion (U) < LP
- NESTI = $\frac{(U \times HR) \times V + [(LP-U) \times HR]}{bw}$

V = Variability factor

(JMPR use a default V = 3)

Short Term Intake Assessment cont'd

- Case 2b: unit weight, edible portion (U) ≥ LP

  $$NESTI = \frac{LP \times HR \times V}{bw}$$

- Case 3. Processed Commodity is bulked or blended; including milk
- $$NESTI = \frac{LP \times STMR\text{-}P}{bw}$$
- STMR-P = supervised trials median residue in processed commodity

e.g. Short term intake (ESTI) calculation for general population and children up to 6 years.

CHLORMEQUAT (015) International estimate of short term intake (IESTI) for GENERAL POPULATION
Acute RfD = 0.05 mg/kg bw Maximum % ARfD: 170%

Codex Code	Commodity	HR or HR-P mg/kg	Large portion diet Country	Body weight (kg)	Large portion, g/person	Unit weight, g	Country	Unit weight, edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	% acute RfD rounded
FP 0230	Pear	6.3	USA	65.0	693	100	FRA	89	3	2a	84.41	170%

% of ARf D = 84.41 x 100 = 170%
0.05

CHLORMEQUAT (015) : International estimate of short term intake (IESTI) for CHILDREN UP TO 6 YEARS
Acute RfD = 0.05 mg/kg bw Maximum %ARfD: 400%

Codex Code	Commodity	HR or HR-P mg/kg	Large portion diet Country	Body weight (kg)	Large portion, g/person	Unit weight, g	Country	Unit weight, edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	% acute RfD rounded
FP 0230	Pear	6.3	UNK	14.5	279	100	FRA	89	3	2a	198.55	400%

% of Acute Rf D = ESTI = 198.5 x1 00 = 400 %
ARf D 0.05

2. Summary of short-term dietary risk assessments conducted by the 2003 JMPR.

Compound		Acute RfD (mg/kg bw)	Commodity	Percentage of acute RfD	
CCPR code	Name			General population	Children £6 years
0095	Acephate	0.003	Apple	260	630
			Beans, except broad bean	60	130
			Broccoli	100	190
			Cauliflower	140	210
			Mandarin	140	400
			Nectarine	80	170
			Peach	100	170
			Pear	140	340
			Peppers, Chili	60	110
			Peppers, Sweet	200	220
			Other commodities	0-50	0-20
0145	Carbosulfan	0.02	All commodities	0-2	0-4
0096	Carbofuran [1]	0.009	Potato, Maize	0-20	0-50
0027	Dimethoate	0.02	Cabbages	320	760
			Lettuce, Head	130	200
			Peppers, Sweet	90	140
			Other commodities	0-90	1-90
0084	Dodine	0.2	All commodities	6-30	20-80
0208	Famoxadone	0.6	All commodities	0-3	0-8
0037	Fenitrothion	0.04	Maize	80	160
			Rice, husked	120	240
			Rice, polished	150	240
			Other commodities	1-30	2-80
0048	Lindane	0.06	All commodities	0	0
0049	Malathion	2	All commodities	0-2	0-7

CONCLUSION

- Dietary Risk Assessment is a pre-requisite to MRL Establishment.
- If EDI >ADI = the proposed MRL is not accepted or

  the proposed MRL may not be forwarded to step 8 in CODEX. The Philippines is following CODEX according to FPA Manual and stipulated in Food Safety Act (2013)
- Similarly, If ESTI > ARfD, the proposed MRL should be further refined using other GAPs, consumption data, etc.
- Percentages above 100 should not necessarily be interpreted as giving rise to a health concern because of the conservative assumptions used in the assessments.

END