CCP: TE 05/7

E

May 2005

منظمة الأغذية والزراعة للأمم المتحدة | 联合国粮食及农业组织 | Food and Agriculture Organization of the United Nations | Organisation des Nations Unies pour l'alimentation et l'agriculture | Organización de las Naciones Unidas para la Agricultura y la Alimentación

COMMITTEE ON COMMODITY PROBLEMS

INTERGOVERNMENTAL GROUP ON TEA

Sixteenth Session

Bali, Indonesia, 20 – 22 July 2005

THE JOINT FAO/WHO MEETING ON PESTICIDE RESIDUES (JMPR) PROCESS OF EVALUATION FOR THE ESTIMATION OF MAXIMUM RESIDUE LEVELS (MRLS): TEA

Table of Contents

	Paragraphs
I. INTRODUCTION	1
II. FUNCTIONS OF THE JMPR	2 – 5
III. DATA REQUIREMENTS FOR ESTIMATING MRLS	6 – 7
IV. JMPR PROCESS OF ESTIMATING MRLS	8 – 9
V. PROCESSING OF TEA	10 – 16
VI. DIETARY RISK ASSESSMENT	17 – 26
A. LONG-TERM DIETARY INTAKE	21 – 22
B. INTERNATIONAL ESTIMATED SHORT-TERM INTAKE (IESTI)	23 – 24
C. DIETARY RISK ASSESSMENT FOR PROPARGITE RESIDUES IN TEA	25 – 26
Long-term intake	25
Short-term intake	26

W0000

I. INTRODUCTION

1. At its last session, the Intergovernmental Group (IGG) on Tea recognized that there was a lack of global harmonization in fixing the maximum residue levels (MRLs) on tea which could constitute a barrier to trade and impose significant costs of compliance on tea exporters. Therefore, the Group decided that further actions were required in addressing the issue, including the collection of more data on MRLs for all commonly used plant protection products based on Good Agricultural Practices (GAP) and Hazard Analysis and Critical Control Point (HACCP) principles by tea producing countries. The Group would then process scientific information available on MRLs in tea for validation and documentation by the Joint Meeting on Pesticide Residue (JMPR). The collection and processing of MRL data from producing countries will be tabled at the 16th Session by the Coordinator of the IGG Working Group. This document was prepared in collaboration with the JMPR Secretary to guide the Group on the process of estimating MRLs and its relation to CODEX MRL establishment. Delegates are requested to review the documents and advise on the future course of action.

II. FUNCTIONS OF THE JMPR

2. The JMPR is an international expert scientific group administered jointly by the United Nations Food and Agriculture Organization (FAO) and World Health Organization (WHO) since 1963 with the aim of:

- evaluating the safety of pesticide residues in food and establishing acceptable daily intake levels (ADIs) and acute reference doses (ARfDs);
- estimating maximum residue levels (MRLs) in food and feed based on legally permitted uses of pesticides (GAP);
- assessing dietary risk from short and long term intake of pesticides;
- these recommendations are the basis for the establishment of Codex MRLs which are referenced by WTO under the Sanitary and Phytosanitary (SPS) and Technical Barriers to Trade (TBT) agreement as the international standards in food and feed to facilitate international trade.

3. The JMPR consists of two Panels of Experts: The Toxicology Panel (WHO Core Assessment Group) and Residues Panel (FAO Panel of Experts on Pesticide Residues).

4. The WHO Core Assessment Group is responsible for reviewing pesticide toxicological and related data and estimating No Observed Adverse Effect Levels (NOAELs) of pesticides and Acceptable Daily Intakes (ADI) of their residues in food for humans, acute reference dose (acute RfD) and characterises other toxicological criteria such as non-dietary exposures.

5. The FAO Panel of Experts on Pesticide Residues is responsible for reviewing pesticide residue data including use patterns (GAP), data on the chemistry and composition of pesticides, environmental fate, metabolism in farm animals and crops, methods of analysis for pesticide residues and for estimating maximum residue levels and supervised trials median residue values (STMRs) of pesticides in food and feed commodities.

III. DATA REQUIREMENTS FOR ESTIMATING MRLS

6. The JMPR examines the possibility of estimating maximum residue levels based on the submitted information and data, and subsequently proposes Maximum Residue Limits in commodities for pesticides used according to Good Agricultural Practice. Under GAP a pesticide is used for effective pest control but leaving a residue that is the smallest amount practicable.

7. Requirements for the estimation of MRLs include the following:

- **Physical and chemical** properties of pesticides

- **Metabolism** and degradation of pesticides after application to plants and soil – these studies suggest the residue definition in plants and animals.

- **Analytical methods** should include specialised methods and enforcement methods (usually multiresidue). These are required to determine the residue components needed for the residue definition for compliance with MRL and for estimation of dietary intake.

- **Storage stability tests** – The study should reflect those conditions to which the samples from the residue trials have been subjected. Where sample extracts have been stored for more than 24 hours prior to analysis, the stability of residues should be demonstrated with recovery studies performed under similar conditions.

- **Good Agricultural Practices (GAP)/use pattern** – It is essential, that complete current information on pesticides use under consideration is always made available. It should be summarised by the manufacturers from two aspects, (1) biological efficacy and (2) formulation and application The governments are also requested to summarise the GAP information as in Table 1.

- **Supervised trials** – Estimation of maximum residue levels is mainly based on reliable residue data from supervised trials according to GAP (see Table 2).

- **Processing Studies** – These studies are required to determine whether residues in raw agricultural commodities may be expected to degrade or concentrate during food processing. Processing studies should simulate commercial practices as closely as possible.

  Processing factor = residue level [mg/kg] in processed product/residue level [mg/kg] in raw agricultural commodities.

- Results of **National Monitoring Programmes** – This information is considered as supporting information for confirmation of practical applicability of estimated maximum residue levels and for estimating dietary intake at national level.

- **Residue definition** – The residue definition established <u>for MRL enforcement</u> purposes may not necessarily be the ideal definition for dietary intake assessment. It should be as practical as possible and preferably based on single residue components as indicators of the total significant residue, the parent compound , a metabolite or a derivative produced in analytical procedure.

  For <u>dietary intake purposes</u> it is desirable to include metabolites and photolysis products that have similar toxicity properties to the parent. The general term “transformation products” may be used to include metabolites, photolysis products and others such as products of abiotic hydrolysis.

IV. JMPR PROCESS OF ESTIMATING MRLS

8. 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 and feed commodity produced following GAP. The maximum residue level is considered by the JMPR to be suitable for establishing Codex MRLs.

Sample estimation of propargite MRL in tea (Pesticide Residues in Food – 2002 Report)

9. Propargite residues data in tea was evaluated in 2002 by the JMPR for the estimation of MRLs. The JMPR received 12 supervised trials from India, Indonesia, Japan and Kenya in 2002. Only four trials were conducted according to GAP. Summary of GAP information is shown in Table 1 and supervised residue trials in table 2.

Table 1. Summary of GAP information (Registered uses of propargite on tea)

Responsible body for reporting (name, address): Date: .....

Pesticide(s) (common name(s) : Page: .....

CCPR No(s). : Country: .....

Trade name(s) :

Main uses, e.g. insecticide, fungicide :

Table 1: Use pattern (summary of Good Agricultural Practices)

Crop	Country	Forumulation active ingredient content (ai)	Application				PHI[1], days
			Method	Rate kg ai/ha	Spray conc. kg ai/hl	Number	
Tea	Indonesia	EC570 g/l			0.11		
Tea	India	EC570 g/l	foliar	0.81	0.2	2+	7
Tea	Japan	EW570g/l	foliar		0.04	2	14
Tea	Japan	WP300g/kg	foliar		0.04		14
Tea	Kenya	EC570 g/l	foliar	0.86			
Tea	Thailand	EC200 g/l			0.05		10-15
Tea	Thailand	WP300g/kg	foliar		0.06		10-15
Tea	Thailand	EC570 g/l		0.57	0.11		

1/ Pre-harvest index.
Information on the use pattern as described on the approved label. Use rates and concentrations must be explicitly expressed in terms of active ingredient or product.

V. PROCESSING OF TEA

10. In Japan, the green tea leaves were rolled for 30 min at 90°C, rolled and twisted for 15 minutes at ambient temperature, middle rolled for 30 minutes at 34-38°C, fine rolled for 28-38 minutes at 75-80°C, and hot-air dried for 20-25 minutes at 80-90°C, simulating commercial Japanese practice.

11. In Kenya, the black tea leaves were withered at ambient temperature for 14-18 hours, macerated and fermented at ambient temperature for 90 minutes, then dried at 80-120°C to stop fermentation and to reduce the moisture content to commercial standards.

12. Instant tea was generated from the black tea by creating a strong brew, concentrating by evaporation and freeze drying. The concentrate was milled.

13. In Indonesia, black tea was processed by withering the leaves with warm air for 18 hours, rolled (30 minutes), ground in a rotorvane (0.25-1 hour), fermented by spreading on a tray at ambient temperature (1 hour) and dried under hot air (0.67-1 hour). For green tea , the leaves were

withered in a rotary dryer (7 minutes), rolled (15-20 minutes) and dried in a rotary dryer (1-2 hours). At the laboratory the green and black teas were brewed.

14. Residue data on processing studies for the production of black tea and green tea yielded processing factors of 8.5 and 3.9 for black tea and 3.9 and 2.3 for green tea. The average factor for green and black is 5.0.

Summary of supervised residue trials (see Table 2)

15. Field trials for the foliar application of propargite on tea were conducted in India, Indonesia, Japan, and Kenya. Two trials from India support the GAP of India (0.81 kg ai/ha, 7 day PHI): <0.05, 1.7 mg/kg for black tea. Two trials from Indonesia do not support the Indonesia GAP (0.11 kg ai/hl, no PHI specified) because there is no data for post treatment day 0-1. The GAP for Japan is: EW, WP, 0.04 kg ai/hl, 14 day PHI. Two trials support the GAP: 0.16, 0.26 mg/kg on fresh tea leaves. The GAP for Kenya is: EC, 0.86 kg ai/ha, with no PHI specified. No field trial data were available for a 0 or 1 day PHI. Using the processing factor 5 for the Japan samples, the ranked order of residues for tea, black and green, is: 0.05, 0.8, 1.3, 1.7 mg/kg. The Meeting agreed to withdraw the previous recommendation for an MRL for tea, green, black (10 mg/kg) and to replace it with a recommendation for an MRL for tea, green, black (5 mg/kg). The Meeting also estimated an STMR of 1.0 mg/kg.

16. The FAO Panel estimate a maximum residue level reflecting only those uses for which sufficient residue data are available.

Table 2: Supervised trials of propargite on tea

Location Year	Application				PHI days	Residues, mg/kg fresh tea leaves	Reference/comment
	Form.	No.	Kg ai/ha	Kg ai/hl			
Kericho, Kenya 1996	EW 570 g/kg	2	1.1	0.45	7 10 14 21 28	19. 18. 13 13. 15. 14 5. 8. 4.6. 2.7 0.72. 0.91. 0.73 0.33. 0.38. 0.34. 0.15	Korpalski 1997a
Sotik, Kenya 1996	EW 570 g/kg	2	0.85	0.17	7 10 14 21 28	3.6. 3.2. 2.9 1.3. 0.84. 0.93 0.10. 0.21. 0.10 0.05. 0.09. 0.25 0.06. 0.05. 0.09	Korpalski 1997a
Gambung, Indonesia, 1994	EC 570 g/kg	3	0.57	0.14	7	0.29. 0.60	Korpalski, 1996e
Gambung, Indonesia, 1994	EC 570 g/kg	3	1.1	0.28	7	2.1. 2.0	Korpalski, 1996e
Pasir Sarongge, Indonesia, 1994	EC 570 g/kg	3	0.57	0.14	7	1.0. 1.2	Korpalski, 1996e
Pasir Sarongge, Indonesia, 1994	EC 570 g/kg	3	1.1	0.28	7	2.2. 3.8	Korpalski, 1996e
Kyushu7, Japan 1994	EC 570 g/kg	2	1.5	0.04	14 21 28 35 42	0.26. 0.24 0.09. 0.09 0.07. 006 0.05. 0.05 <0.05. <0.05	Korpalski, 1996a

Table 2: Supervised trials of propargite on tea (cont'd)

Location Year	Application				PHI days	Residues, mg/kg fresh tea leaves	Reference/comment
	Form.	No.	Kg ai/ha	Kg ai/hl			
Kyushu, Japan 1994	EC 570 g/kg	2	3.0	0.08	14 21 28 35 42	0.50. 0.88	Korpalski, 1996a
Honshu, Japan 1994	EC 570 g/kg	2	1.5	0.04	14 21 23 35 42	0.14. 0.16 0.08. 0.05 <0.05. <0.05 <0.05. <0.05 <0.05. <0.05	Korpalski, 1996a
Honshu, Japan 1994	EC 570 g/kg	2	3.0	0.08	14 21 23 35 42	0.27. 0.22 0.09. 0.10 <0.05. <0.05 <0.05. <0.05 <0.05. <0.05	Korpalski, 1996a
Valparai, India 2001	EC 570 g/kg	1	0.57	0.14	0 1 3 5 7 10 14	140 110 5.2 2.4 ND ND ND	Muraleedharan 2001 Black tea (not fresh) ND: not detected
Valparai, India 2001	EC 570 g/kg	1	1.1	0.28	0 1 3 5 7 10 14	250 240 10 5.5 1.7 ND ND	Muraleedharan 2001 Black tea (not fresh) ND: not detected

VI. DIETARY RISK ASSESSMENT

17. Dietary risk assessment is necessary in order to reach a conclusion on the acceptability of proposed MRLs and the underlying GAP from a public health point of view.

18. The dietary intakes have been calculated in accordance with the revised guidelines by multiplying the residue concentrations (STMRs or recommended MRLs) by the average daily per capita consumption estimated for each food commodity on the basis of the GEMS/Food[1] Middle Eastern, Far Eastern, African, Latin American and European diets and then summing the intakes from the individual commodities:

Dietary Intake = Σ Food Chemical Concentration x Consumption[2]

[1] 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.

[2] WHO 1997b. *Food consumption and exposure assessment of chemicals.* Report of a FAO/WHO Consultation. Geneva, Switzerland, 10-14 February 1997. World Health Organization.

19. The ratio of the estimated dietary intake to the corresponding Acceptable Daily Intake (ADI) for a 60-kg person is then expressed as a percentage.

20. For dietary intake assessment, it is the median residue (STMR) from all trials at GAP for chronic dietary intake analysis and the highest residue (HR) from all supervised trials at GAP for the acute dietary intake analysis. Then the dietary intake is estimated and is compared to ADI or acute reference dose. If there are incidences of excess, the risk managers (CODEX on Pesticide Residues) have to decide to accept or reject the recommendations. The national government is asked to make refinements according to its own consumption data.

A. LONG-TERM DIETARY INTAKE

21. Long-term dietary intakes in the GEMS/Food diets are expressed as a percentage of the ADI for a 60-kg person, with the exception of the Far Eastern diet, in which a body weight of 55 kg is used.

22. The International Estimated Daily Intake (IEDI) for propargite, based on the STMR (1.0 mg/kg) estimated for tea for the five GEMS/Food Regional diets were in the range of 0.1 percent to 0.4 percent of the ADI rounded to 0 percent (Table 3). The long term intake of residues of propargite resulting from its use is unlikely to present a public health concern.

B. INTERNATIONAL ESTIMATED SHORT-TERM INTAKE (IESTI)

23. Generally, risks associated with short-term dietary intake are assessed for compounds for which STMR and HR values are estimated and for which acute reference doses (ARIDs) have been established, in commodities for which data on consumption are available. The procedures for calculating the short-term intake were defined in the 1997 FAO/WHO Geneva Consultation[1], refined at the International Conference on Pesticide Residues Variability and Acute Dietary Risk Assessment sponsored by the Pesticide Safety Directorate and at subsequent JMPR Meetings. Data on the consumption of large portions were provided by the governments of Australia and France. The consumption, unit weight and body weight data used for the short-term intake calculation were compiled by GEMS/FOOD and are available at: http://www.who.int/foodsafety/chem/acute_data/en/

24. Calculations of dietary intake can be further refined at the national level by taking into account more detailed information on food consumption, data from monitoring and surveys, on total diet or reliable data on the percentage of a crop treated and the percentage of the crop imported.

C. DIETARY RISK ASSESSMENT FOR PROPARGITE RESIDUES IN TEA

Long-term intake

25. The International Estimated Daily Intake (IEDI) for propargite, based on the STMR estimated for tea for the five GEMS/Food Regional diets were in the range of 0.1 percent to 0.4 percent of the ADI (Table 3). The long term intake of residues of propargite resulting from its use is unlikely to present a public health concern.

$IEDI_{total} = \Sigma$ [$STMR_i$ (mg/kg; processing factor already included in the STMR) x $consumption_i$ (g/person)]

Where STMR is the supervised trial median residue, that is the median of residue values from all trials conducted at GAP.

For Tea only:

Middle East, European

$IEDI_{tea}$ = $STMR_{tea}$ X consumption $_{tea}$
= 1 mg/kg x 2.3 g/person
= 2.3 µg/person

% ADI = 2.3 µg/person x 100
600 µg/person
= 0.38%

Far East

IEDI = 1.2 µg/person
% ADI = 0.22%

African , Latin American

IEDI = 0.5 µg/person
% ADI = 0.08 %
Rounded= 0%

Short-term intake

Table 3: International estimated daily intake

Propargite ADI=0.01 mg/kg bw or 600 µg/person ; 550 µg/person
Far East

		MRL	STMR	Diets: g/person/day. Intake = daily intake: µg/person									
				Mid-East		Far-East		African		Latin American		European	
Code	Commodity	mg/kg	mg/kg	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
DT 1114	tea, green, black		1	2.3	2.3	1.2	1.2	0.5	0.5	0.5	0.5	2.3	2.3
% ADI				0.4%		0.2%		0.1%		0.1%		0.4%	
Rounded				0%		0%		0%		0%		0%	

Indians have food factor of 10 g/1.5 kg = 0.67 (This is from 2g tea/cup x5cups a day).

26. The JMPR decided that an acute RfD is unnecessary for propargite. Propargite residues in tea are unlikely to present any public health concern.