FENITROTHION (037)

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EXPLANATION

Fenitrothion was evaluated for residues by the 2003 JMPR in the Periodic Review Programme of the CCPR. The 2003 Meeting recommended an MRL of 10 mg/kg for cereals (post-harvest use only) and identified some data gaps. Additional data were provided to the 2004 JMPR, together with results of supervised trials on apples, pears, beans, peas, and soya beans. The 2004 JMPR confirmed the cereal MRL also for pre-harvest uses and recommended MRLs for apple and for animal commodities. Due to an insufficient number of trials corresponding to GAPs, MRLs could not be recommended for pears, beans, peas, and soya beans.

The present Meeting received new labels for uses on soya bean and cereals, a method of analysis, and additional residue trials on soya beans. As dietary intakes calculated by the 2004 meeting of the JMPR exceeded both the ADI and ARfD the CCPR returned the recommended MRL for cereals to Step 6 several times. As a consequence the company was asked to provide alternative GAP for cereals if available.

METHODS OF RESIDUE ANALYSIS

Analytical Methods

The Meeting received information on an analytical method for the determination of parent in Brazilian soya bean residue trials. The analytical method was based on a Swedish multiresidue method[14].

The analytical method used in the Brazilian trials involves extraction of combined analytes of fenitrothion and esfenvalerate with ethyl acetate in the presence of sodium sulphate, partitioning by a mixture of cyclohexane and ethyl acetate, and cleaning by gel permeation chromatography. The analytes are determined quantitatively by gas chromatography using electron capture detectors (μ-ECD, Ni^{63} pulsing) for esfenvalerate and pulsing flame photometric detection (FPD) for fenitrothion. The validation results for fenitrothion using the method described are shown in Table 1.

Table 1. Validation results for determination of fenitrothion in dry soya bean seeds

GC detector	LOQ mg/kg	Spike mg/kg	Recovery Range (mean)	% RSD	No.	Control mg/kg	Ref
FPD	0.1*	0.1 1.0	83-86 (85) 71-74 (72)	2 2	3 3	< 0.1 (3)	SM4102 SM4202 SM4302

USE PATTERN

Fenitrothion is registered for use in many countries on a wide range of crops, see the JMPR 2004 evaluation. The Meeting received an additional label for use on soya beans in Brazil.

There are two formulations used in Brazil; one contains 500 g/L fenitrothion and the other contains a mixture of fenitrothion (800 g ai/L) and esfenvalerate (40 g/L).

[14] OHLIN, B. A capillary gas chromatographic multi-residue method for the determination of pesticides in cereals and cereal products. Pesticide Analytical Methods In Sweden. Part 1. Rapport 17/98. National Food Administration. Uppsala. 1998. p. 75-86

Table 2. Registered uses of fenitrothion on soya beans [a]

Crop	Country	Form	Application				PHI, days
			Method	Rate kg ai/ha	Spray conc, kg ai/hL	Number	
soya beans (dry/green)	Australia	EC 1000	foliar spray	0.27-0.55	ns	3	14 (WHP=14d)
	Australia	EC 1000	foliar spray by aeroplane	0.27-0.55	ns	3	14 (WHP=14d)
soya beans	Argentina	EC 1000	foliar spray	0.4-0.5	0.40-0.71	ns	14
	Argentina	EC 1000	foliar spray by aeroplane	0.4-0.5	min 2.0-3.3	ns	14
soya beans	Brazil	EC 500	foliar spray by tractor	0.5-1.0	0.17-1.0	ns (10-15d)	7
	Brazil	EC 500	foliar spray by aeroplane	0.5-1.0	1.25-3.3	ns (10-15d)	7
	Brazil [b]	EC 800 g ai/L + 40 g ai/L esfenvalerate	Foliar spray by tractor	0.2 – 0.3	0.1 – 0.2	2 (7-10d)	7 [c]
soya beans (dry/green)	Japan	EC 500	foliar spray	0.75-1.5	0.025-0.050	4	21
soya beans (dry)	Japan	EC 500	foliar spray by unmanned helicopter	0.50	6.25	4	21
soya beans (dry)	Japan	EC 500	foliar spray	0.75	2.5	4	21

a - Pesticide Residues in Food – 2004 Evaluations. Part I – Residues. Volume I. FAO Food Production and Protection Paper 182/1, p. 155. FAO. Rome, Italy.

b - new label

c - PHI is proposed to be increased to 14 days

Good agricultural practice for the post-harvest use of fenitrothion on cereals was shown in Table 35 of the 2003 JMPR residue evaluation. The previous recommendation for a maximum residue level of 10 mg/kg was based on a trial complying with Australian GAP (12 g ai/t). Since the Meeting was requested to look for alternative GAP, the current labels for post-harvest uses of fenitrothion on stored cereal grains are repeated below.

Table 3. Registered post-harvest uses of fenitrothion on stored cereal grains (for food, fodder and seed purposes) [a]

Crop	Country	Form g ai/L	Application				waiting period, days
			Method	Rate g ai/t	Spray conc, kg ai/hL	Number	
Barley	Australia [c]	EC 1000	admixture (spray) for grains stored in bulk for < 3 months	6	0.6	ns	1
	Australia [c]	EC 1000	admixture (spray) for grains stored in bulk for < 6 months	12	1.2	ns	91
	Australia [c]	EC 1000	admixture (spray) for grains stored up to 9 months	6 + methoprene (1 g ai/t)	0.6	ns	1
	Brazil	EC 500	spray	5-10	1.0-3.3	ns	14
Cereal grains	Argentina	EC 1000	spray	6	0.86-2.0	ns	1
	Australia [c]	EC 1000	admixture	6 [b]	0.6	ns	ns

Crop	Country	Form g ai/L	Application				waiting period, days
			Method	Rate g ai/t	Spray conc, kg ai/hL	Number	
			(spray) for grains stored in bulk for < 3 months				
	Australia [c]	EC 1000	admixture (spray) for grains stored in bulk for 3-6 months	12 [b]	1.2	ns	90
	Russia	EC 500	spray	10	ns	ns	ns
Maize	Brazil	DP 20	admixture (powder)	5-10	ns	ns (150 d intervals)	14
	Brazil	EC 500	spray	5-10	1.0-3.3	ns	14
Millets	Australia [c]	EC 1000	admixture (spray) for grains stored in bulk for < 3 months	6	0.6	ns	1
	Australia [c]	EC 1000	admixture (spray) for grains stored in bulk for < 6 months	12	1.2	ns	91
	Australia [c]	EC 1000	admixture (spray) for grains stored up to 9 months	6 + methoprene (1 g ai/t)	0.6	ns	1
Oats	Australia [c]	EC 1000	admixture (spray) for grains stored in bulk for < 3 months	6	0.6	ns	1
	Australia [c]	EC 1000	admixture (spray) for grains stored in bulk for < 6 months	12	1.2	ns	91
	Australia [c]	EC 1000	admixture (spray) for grains stored up to 9 months	6 + methoprene (1 g ai/t)	0.6	ns	1
Rice	Australia [c]	EC 1000	admixture (spray) for grains stored in bulk for < 3 months	6	0.6	ns	1
	Australia [c]	EC 1000	admixture (spray) for grains stored in bulk for < 6 months	12	1.2	ns	91
	Australia [c]	EC 1000	admixture (spray) for grains stored up to 9 months	6 + methoprene (1 g ai/t)	0.6	ns	1
	Brazil	DP 20	admixture (powder)	5-10	ns	ns (150 d intervals)	14
Rye	Brazil	DP 20	admixture (powder)	5-10	ns	ns (150 d intervals)	14

Crop	Country	Form g ai/L	Application				waiting period, days
			Method	Rate g ai/t	Spray conc, kg ai/hL	Number	
Sorghum	Australia [c]	EC 1000	admixture (spray) for grains stored in bulk for < 3 months	6	0.6	ns	1
	Australia [c]	EC 1000	admixture (spray) for grains stored in bulk for < 6 months	12	1.2	ns	91
	Australia [c]	EC 1000	admixture (spray) for grains stored up to 9 months	6 + methoprene (1 g ai/t)	0.6	ns	1
Wheat	Australia [c]	EC 1000	admixture (spray) for grains stored in bulk for < 3 months	6	0.6	ns	1
	Australia [c]	EC 1000	admixture (spray) for grains stored in bulk for < 6 months	12	1.2	ns	91
	Australia [c]	EC 1000	admixture (spray) for grains stored up to 9 months	6 + methoprene (1 g ai/t)	0.6	ns	1
	Brazil	DP 20	admixture (powder)	5-10	ns	ns (150 d intervals)	14
	Brazil	EC 500	spray	5-10	1.0-3.3	ns	14

a - Pesticide Residues in Food – 2003 Evaluations. Part I – Residues. FAO Food Production and Protection Paper 177, p. 523. FAO. Rome, Italy.

b - Either alone or in combination with Sumitrin Synergised Grain protectant

c - GAP information provided by national government

ns - Not specified.

RESIDUES RESULTING FROM SUPERVISED TRIALS

Residue values from the trials conducted according to maximum/alternative GAP have been used for the estimation of maximum residue levels. Those results included in the evaluation are double underlined.

A total of six trials were conducted on soya beans in three separate locations in Brazil during 2001. In each location, two trials were conducted, one using an application rate according to the GAP (0.28 kg ai/ha) and the other, at double the GAP rate (0.56 kg ai/ha). Each trial received two applications at 10 day intervals, of an EC formulation containing a mixture of fenitrothion (800 g ai/L) and esfenvalerate (40 g ai/L). Soya beans were harvested 14 days after the last application. Each sample consisted of about 1 kg of seeds obtained after manual thrashing. Samples were stored frozen at -18 ºC until analysis, which was done either immediately or within 4 months after receipt. Results of storage stability studies reviewed by the JMPR showed fenitrothion residues to be stable for at least 98 days in pulses when stored at -20 ºC. The results of supervised trials are summarized in Table 4.

The Japanese trials according to the GAP, as reported by the 2004 JMPR are included in Table 4.

Table 4. Fenitrothion residues in dry harvested soya beans

Location, year (variety)	Application					PHI	Residues, mg/kg	Reference
	Form	kg ai/ha	kg ai/hL	Interval	no.	days		
GAP, Japan	EC 500	0.5 – 1.5	-	ns	4	21		
Nagano, 1981, JB-011/JB-010 (Enrei)	DP 30	1.2	na	7-7-7 days	4	18	0.004	Kato, 1982; Shimada, 1981 [a]
Tottori, 1981, JB-011/JB-010 (Tamahomare)	DP 30	1.2	na	7-7-8 days	4	20	0.004	Kato, 1982; Shimada, 1981 [a]
Yamagata, 1990, JB-002/JB-004 (Tachiyutaka)	EC 500	1.25	0.05	7-8-6 days	4	21	≤ 0.01	Goto, et. al, 1991; Kuroda and Higuchi, 1991 [a]
Ishikawa, 1990, JB-002/JB-004 ((Enrei)	EC 500	1.25	0.05	7-7-7 days	4	21	≤ 0.01	Goto, et. al, 1991; Kuroda and Higuchi, 1991 [a]
GAP, Brazil	EC 800 g ai/L + 40 g ai/L esfenvalerate	0.2 – 0.3	0.1 – 0.2	7-10 days	2	7		
Cambé-PR Brazil 2001, SM4102 (Conquista)	EC 800 g ai/L + 40 g ai/L esfenvalerate	0.28	0.14	10	2	0 3 7 14 21	< 0.1 [b] < 0.1 ≤ 0.1 < 0.1 < 0.1	Oliveira, 2001a
Cambé-PR Brazil 2001, SM4102 (Conquista)	EC 800 g ai/L + 40 g ai/L esfenvalerate	0.56	0.28	10	2	0 3 7 14 21	< 0.1 [b] < 0.1 < 0.1 < 0.1 < 0.1	Oliveira, 2001a
Ibiporã-PR Brazil 2001, SM4202 (Conquista)	EC 800 g ai/L + 40 g ai/L esfenvalerate	0.28	0.14	10	2	14	< 0.1	Oliveira, 2001b
Ibiporã-PR Brazil 2001, SM4202 (Conquista)	EC 800 g ai/L + 40 g ai/L esfenvalerate	0.56	0.28	10	2	14	< 0.1	Oliveira, 2001b
Londrina-2001, SM4302 (Conquista)	EC 800 g ai/L + 40 g ai/L esfenvalerate	0.28	0.14	10	2	14	< 0.1	Oliveira, 2001c
Londrina-2001, SM4302 (Conquista)	EC 800 g ai/L + 40 g ai/L esfenvalerate	0.56	0.28	10	2	14	< 0.1	Oliveira, 2001c

a - From - Pesticide Residues in Food – 2004 Evaluations. Part I – Residues. FAO Plant Production and Protection Paper 179, p. 161. FAO. Rome, Italy.

b - a peak could be observed in the chromatogram, but was not quantified

FATE OF RESIDUES IN STORAGE AND PROCESSING

In storage

Four trials reviewed by JMPR in 2003 support the GAP of 6g ai/t (see table 43 reproduced below).

Table 6. Residues of parent fenitrothion and metabolite in stored wheat, after post-harvest treatment [a]

Location, year (variety), reference	Application		Storage time	Residues, mg/kg	
	Form (g ai/t)	Rate (g ai/t)		Fenitrothion	DM-FNT
Billimari, New South Wales, Australia; 1987 (ns) Turnbull and Ardley, 1987 and Ohnishi *et al.*, 1987	Liquid 1000 [b]	12	1 month 3 months	6.8 [c] 7.6	na na

Location, year (variety), reference	Application		Storage time	Residues, mg/kg	
	Form (g ai/t)	Rate (g ai/t)		Fenitrothion	DM-FNT
Ricardone, Santa Fe, Argentina; 2002 (ns) AG1 Willard, 2002b	EC 1000	6.2	Pre-treatment 1 day 14 days 58 days	0.11 5.0 3.0 1.7	< 0.01 0.12 0.72 1.6
Soldini, Santa Fe, Argentina: 2002 (ns) AG2 Willard, 2002b	EC 1000	6.4	Pre-treatment 1 day 14 days 58 days	0.67 5.6 4.2 2.8	0.42 0.58 1.4 2.5
Marcos Juarez, Cordoba, Argentina; 2002 (ns) AG3 Willard, 2002b	EC 1000	6.9	Pre-treatment 1 day 14 days 58 days	< 0.01 3.5 1.5 1.8	< 0.01 0.040 0.41 1.0
Salto, Buenos Aires, Argentina; 2002 (ns) AG4 Willard, 2002b	EC 1000	Es.	Pre-treatment 1 day 14 days 58 days	< 0.01 3.1 1.9 1.2	< 0.01 0.030 0.27 0.50

a - from - Pesticide Residues in Food – 2003 Evaluations. Part I – Residues. FAO Plant Production and Protection Paper 177, page 529, FAO. Rome, Italy, 2004

b - 1000 g ai/L, but formulation not stated.

c - Average of 3 laboratory samples, each analysed in duplicate.

na - not determined.

Es. - Estimated to be about 5.4-10 g ai/t

APPRAISAL – RESIDUE AND ANALYTICAL ASPECTS

Fenitrothion was evaluated for residues by the 2003 JMPR in the Periodic Re-evaluation Programme of the CCPR. The 2003 Meeting recommended an MRL of 10 mg/kg for cereals (post-harvest use only) and identified some data gaps. Additional data were provided to the 2004 JMPR, together with results of supervised trials on apples, pears, beans, peas, and soya beans. The 2004 JMPR confirmed the cereal MRL also for pre-harvest uses and recommended MRLs for apple and for animal commodities. Due to an insufficient number of trials corresponding to GAP, MRLs could not be recommended for pears, beans, peas, and soya beans.

The present Meeting received new labels covering uses on soya bean and cereals, a method of analysis, and additional residue trials on soya beans. Dietary intakes calculated by the 2004 JMPR exceeded the ADI and ARfD. As a consequence CCPR has returned the MRL for cereals to Step 6 several times. To resolve the issue the submission of alternative GAP data for cereals was requested.

Methods of analysis

The Meeting received descriptions and validation data for an analytical method for the determination of residues of fenitrothion in soya bean. The analytical method used in the Brazilian trials involves extraction of fenitrothion with ethyl acetate in the presence of sodium sulphate, partitioning by a mixture of cyclohexane and ethyl acetate, and cleaning by gel permeation chromatography. The analyte is determined quantitatively by pulsing flame photometric detection (FPD).

Although the method performed satisfactorily, it was only validated in the range of 0.1 – 1.0 mg/kg.

Results of supervised trials on crops

Pulses

The Meeting received information on supervised trials on soya beans from Brazil, and considered this information together with Japanese trials previously found to be matching GAP in 2004. In 2004, four trials were found to comply with Japanese GAP (foliar application, 4 times 0.025 – 0.050 kg ai/hL,

PHI 21 days). Residues found were 0.004 (2), < 0.01 (2) mg/kg. The 2004 Meeting decided that four trials (of which two showed finite residues) were not sufficient to estimate a MRL for soya bean, dry.

The present Meeting received six additional soya bean trials from Brazil. The analytical method used in these trials was not validated below 0.1 mg/kg, but the chromatograms showed well-defined peaks below that level. Two of the six trials were decline trials, in which fenitrothion peaks could be observed at day 0 indicating that the use of fenitrothion on soya beans does not result in a nil-residue situation. However, in both of the decline trials (one at GAP rate, one at double rate) no peaks were observed later than 3 days after treatment. One of the trials was according to Brazilian GAP (foliar spray treatment together with esfenvalerate, 2 treatments at 0.1 – 0.2 kg/hL, interval 7 – 10 days, PHI 7 days). Residues were < 0.1 mg/kg. At the double rate, residues found were < 0.1 mg/kg. In the remaining four trials residues were only measured 14 days after the final treatment, residues < 0.1 mg/kg.

Based on the Japanese trials (residues in rank order: 0.004 (2), <u>< 0.01</u> (2)) and using the Brazilian trials to support on the basis that current uses would not lead to detectable residues at harvest, the Meeting estimated a maximum residue level of 0.01 mg/kg, and an STMR of 0.01 mg/kg to replace the previous recommendations for soya bean.

Cereal grains

Five trials on stored wheat were performed in Australia and Argentina and reported by the 2003 JMPR. The Argentinean trials complied with the GAP of Argentina for post-harvest use on cereals: 6 g ai/t with a waiting period of 1 day. The residues found were: 3.1, 3.5, 5.0, 5.6 mg/kg. The Australian trial complied with the GAP of Australia for post-harvest use on wheat: 12 g ai/t with a waiting period of 3 months. The residue found was 7.6 mg/kg. The previous recommendation of the JMPR of 10 mg/kg (Po) was based upon the Australian trial result. In response to a request examine alternative GAP, the Meeting evaluated the available trials against Argentinean GAP.

The Meeting decided to estimate a maximum residue level for cereals based on the post-harvest use at 6 g ai/t. Residues were 3.1, <u>3.5</u>, <u>5.0</u>, 5.6 mg/kg. The Meeting decided to withdraw the previous recommendation for cereal grain of 10 mg/kg (Po). Taking into account the results of the dietary risk assessment (see below) the Meeting recommended a new maximum residue level of 6 mg/kg (Po) for cereal grain, excluding maize and estimated an HR of 5.6 mg/kg and a STMR of 4.25 mg/kg.

Fate of residues during processing

In the table below (taken from the 2004 JMPR evaluation), processing factors for wheat, barley and rice commodities are summarized. STMR-P and HR-P values were updated as the cereal grain MRL recommendation had changed.

commodity	Processing factor, range (no. of trials)	Processing factor (mean or best estimate)	STMR-P	HR-P/highest residue
Wheat bran	3.9-4.0 (2)	3.95	16.79	22.12
Wheat flour	0.21-0.26 (2)	0.235	1.00	
White bread	0.089-0.11 (2)	0.10	0.425	
Wholemeal bread	0.33-0.43 (2)	0.38	1.615	
Barley malt	0.16-0.24 (2)	0.20	0.85	
Husked rice	0.031-0.64 (22)	0.64	2.72	
Polished rice	< 0.002-0.15 (26)	0.15	0.638	
Rice hulls	0.12-10 (21)	10	42.5	56
Rice bran	0.018-7.2 (23)	7.2	30.6	40.3
Cooked husked rice	0.11 (1)	0.11	0.468	
Cooked polished rice	0.04 (1)	0.04	0.17	
Washed polished rice	0.041-0.049 (4)	0.046	0.196	
Cooked washed polished rice	0.0060-0.033 (13)	0.020	0.085	

Using the HR for cereal grains (5.6 mg/kg) and the processing factors as indicated above, the Meeting estimated a maximum residue level of 25 mg/kg in wheat bran, and 40 mg/kg in rice bran. The Meeting maintained its decision to withdraw the current recommendations for polished rice, wheat flour, white bread and wholemeal bread of 1, 2, 1 and 3 mg/kg (PoP) respectively, as the MRLs would be lower than that of the raw agricultural commodity.

Using the HR for cereal grains (5.6 mg/kg) the Meeting estimated HR-P/highest residues for wheat bran, rice hulls, rice bran, as shown in the table above.

Furthermore, using the STMR for cereal grains (4.25 mg/kg) the Meeting estimated STMR-Ps for wheat bran, wheat flour, white bread, wholemeal bread, barley malt, husked rice, polished rice, rice hulls, rice bran, cooked husked rice, cooked polished rice, washed polished rice and cooked washed polished rice, as shown in the table above.

For the purpose of undertaking a dietary risk assessment, the Meeting decided to extrapolate the processing factor for wheat flour to all other cereal flours (except maize flour as processing was considered to be different) and estimated STMR-Ps of 1 for all cereal flours except maize flour. The Meeting extrapolated the processing factor for wheat bran to buckwheat bran estimating an STMR-P of 16.79 for buckwheat bran. Since fenitrothion is used post-harvest, and the residue is a surface residue, the Meeting considered that removal of the hull and further polishing would reduce the residue in a similar way for all cereals. The Meeting therefore decided to extrapolate the processing factor for husked rice to pot barley[15], estimating an STMR-P of 2.72 for pot barley, and the processing factor for polished rice to pearled barley[15], estimating an STMR-P of 0.638 for pearled barley. Furthermore the processing factor from wholemeal bread was extrapolated to wheat bulgur[16] wholemeal, yielding an STMR-P of 1.615 and the processing factor from white bread was extrapolated to wheat macaroni and wheat pastry, yielding STMR-Ps of 0.425.

The Meeting decided to use the STMR-Ps for cooked husked rice and cooked polished rice in the dietary intake calculations for rice.

Data were only available for the transfer of fenitrothion residues into malt rather than beer (see JMPR 2004 Evaluation). The Meeting received, at a very late stage, two new studies on the processing of barley to malt. However, upon consideration of these studies the Meeting decided to maintain the existing processing factor as the results of the new studies would not have resulted in an amended estimate. As a consequence the Meeting decided not to include the new data and to extrapolate the existing processing factor for malt to barley beer, millet beer, and sorghum beer yielding a STMR-P of 0.85 for barley beer, millet beer, and sorghum beer.

Farm animal dietary burden

The Meeting estimated the dietary burden of fenitrothion in farm animals on the basis of the diets listed in Annex 6 of the 2006 JMPR Report (OECD Feedstuffs Derived from Field Crops). Calculation from highest residue, STMR (some bulk commodities) and STMR-P values provides the levels in feed suitable for estimating MRLs, while calculation from STMR and STMR-P values for feed is suitable for estimating STMR values for animal commodities. The percentage dry matter is taken as 100% when the highest residue levels and STMRs are already expressed as dry weight.

Estimated maximum and mean dietary burdens of farm animals

Dietary burden calculations for beef cattle, dairy cattle, broilers and laying poultry are provided in Annex 6. The calculations were made according to the animal diets from US-Canada, EU and Australia in the OECD Table (Annex 6 of the 2006 JMPR Report).

[15] Pot barley = hulled or husked barley; pearled barley = hulled barley with the ends of the kernel removed forming a round shape.
[16] Bulgur (wheat) = wheat that has been cooked, dried, and coarsely ground.

		Animal dietary burden, fenitrothion, ppm of dry matter diet		
		US-Canada	EU	Australia
Beef cattle	max	14.9	7.0	24.5 [a]
	mean	14.3	6.7	22.2 [b]
Dairy cattle	max	14.0	15.0	22.5
	mean	13.7	14.5	22.2 [c]
Poultry - broiler	max	19.6	11.6	14.4
	mean	19.2	10.6	13.5
Poultry - layer	max	19.6 [d]	9.9	14.1
	mean	19.2 [e]	8.9	13.2

a - Highest maximum beef or dairy cattle dietary burden suitable for MRL estimates for mammalian meat and milk

b - Highest mean beef or dairy cattle dietary burden suitable for STMR estimates for mammalian meat.

c - Highest mean dairy cattle dietary burden suitable for STMR estimates for milk.

d - Highest maximum poultry dietary burden suitable for MRL estimates for poultry meat and eggs.

e - Highest mean poultry dietary burden suitable for STMR estimates for poultry meat and eggs.

Animal commodity maximum residue levels

The calculated maximum dietary burden for dairy and beef cattle is 24 ppm. In the cattle feeding study described in 2004, no residues were found above the LOQ (0.05 mg/kg) in muscle, fat, liver or kidney at feeding levels of 10, 30 and 100 ppm. Therefore, no residues above the LOQ are to be expected at the calculated dietary burden. Residues of fenitrothion in milk were below the LOQ of 0.01 mg/kg for all dose groups.

The calculated dietary burden for poultry is 20 ppm. In the poultry feeding study no residues were detected in muscle, liver, fat and eggs (< 0.05 mg/kg) at feeding levels of 10, 30 and 100 ppm.

The Meeting confirmed its previous recommendation of maximum residue levels of 0.05* mg/kg in meat (from mammals other than marine mammals), in edible offal (mammalian), in poultry meat, and eggs. Further the Meeting recommended a maximum residue level of 0.01 mg/kg in milks. The HRs for muscle, fat, liver, kidney, poultry meat and fat are estimated to be 0 mg/kg, and the STMRs are all estimated to be 0 mg/kg.

RECOMMENDATIONS

On the basis of the data from supervised trials the Meeting concluded that the residue levels listed below are suitable for establishing maximum residue limits and for IEDI and IESTI assessment.

Definition of the residue for compliance with MRL and for estimation of dietary intake, for plant and animal commodities: *Fenitrothion.*

CCN	Commodity	MRL (mg/kg)		STMR, STMR-P (mg/kg)	HR, HR-P (mg/kg)
		New	Previous		
GC 0080	Cereal grains, excluding maize	6 (Po) [a]	10 (Po)	4.25	5.6
MO 0105	Edible offal (mammalian)	0.05*	0.05*	Liver 0 kidney 0	Liver 0 kidney 0
PE 0112	Eggs	0.05*	0.05*	0	0
MM 0095	Meat (from mammals other than marine mammals)	0.05*	0.05*	Muscle 0 Fat 0	Muscle 0 Fat 0
ML 0106	Milks	0.01*	0.01	0	
PM 0110	Poultry meat	0.05*	-	Muscle 0 Fat 0	Muscle 0 Fat 0
CM 1206	Rice bran, unprocessed	40 PoP	60	30.6	40.3
CM 0649	Rice, Husked			2.72	
CM 1205	Rice, polished			0.638	

CCN	Commodity	MRL (mg/kg)		STMR, STMR-P (mg/kg)	HR, HR-P (mg/kg)
		New	Previous		
	Cooked husked rice			0.468	
	Cooked polished rice			0.17	
	Washed polished rice			0.196	
	Cooked washed polished rice			0.085	
	Wheat flour			1	
	White bread			0.425	
	Wholemeal bread			1.615	
	Barley malt			0.85	
VD 0541	Soya beans, dry	0.01	W	0.01	
CM 0654	Wheat bran (unprocessed)	25 PoP [b]	30 PoP	16.79	22.12

* at or about the LOQ.

a - Also covers pre-harvest use of fenitrothion

b - The intake of 110% was for unprocessed wheat bran. Since this is not the edible commodity and further processing is likely to reduce the level of residues, the Meeting assumed that the intake of fenitrothion from processed wheat bran would be below the ARfD.

DIETARY RISK ASSESSMENT

In previous evaluations (JMPR 2003, 2004) the Meeting identified both long-term and short-term intake exceedances of the ADI and ARfD. The Meeting noted at the time that the intake calculations were conservative, as they did not take into account any reduction in residue obtained by processing of cereal grains, except the processing of wheat, barley and rice. Processing information on maize was identified as necessary allow a refinement of intake calculations. The present Meeting did not receive processing information on maize, as a result intake problems arising for clusters B, C and M (long-term intake) as well as for the short-term intake remain. The Meeting considered that the group MRL for cereal grains would not go forward as processing data on one of the members of that group, with significant consumption, was lacking. The Meeting therefore decided to recommend a maximum residue level for cereal grains, *excluding maize.*

Long term intake

The evaluation of fenitrothion has resulted in recommendations for MRLs and STMRs for raw and processed commodities. Consumption data were available for 37 food commodities and was used in the dietary intake calculation. The results are shown in Annex 3 of the 2007 Report of the JMPR.

The International Estimated Daily Intakes in the 13 GEMS/Food cluster diets, based on the estimated STMRs were in the range 30 – 80% of the maximum ADI of 0.006 mg/kg bw. The Meeting concluded that the long-term intake of residues of fenitrothion from uses that have been considered by the JMPR is unlikely to present a public health concern.

Short-term intake

The international estimated short-term intake (IESTI) for fenitrothion was calculated for the food commodities (and their processing fractions) for which maximum residue levels, STMRs and HRs were estimated and for which consumption data was available. The results are shown in Annex 4 of the 2007 Report of the JMPR. The IESTI varied from 0 – 80 % of the ARfD (0.04 mg/kg bw) for the general population. The IESTI varied from 0 – 110% of the ARfD for children 6 years and below. The intake of 110% was for unprocessed wheat bran. Since this is not the edible commodity and further processing is likely to reduce the level of residues, the Meeting assumed that the intake of fenitrothion from processed wheat bran would be below the ARfD. The Meeting concluded that the short-term intake of residues of fenitrothion from uses considered by the Meeting was unlikely to present a public health concern.

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