

PYRETHRINS (063)

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EXPLANATION

Pyrethrins were evaluated for residues in a periodic review by the JMPR in 2000. The JMPR recommended withdrawal of the CXL of 3 mg/kg Po for cereal grains, because no residue data were available (JMPR, 2000). The 34th Session of the CCPR in 2002 decided to retain the CXL for cereal grains, under the periodic review procedure, because it was informed by the delegation of Germany that data would be made available (CCPR, 2002).

The 2003 JMPR received information on GAP for cereals from the government of Germany. New residue supervised trials data for the post-harvest use of pyrethrins on wheat and maize were submitted by a manufacturer. The government of the Netherlands submitted GAP information for spray treatment in the field, on fruits and vegetables, and on national MRLs which were reported by the 2000 JMPR and therefore are not repeated here.

USE PATTERN

Post-harvest use of pyrethrins in mills and warehouses containing stored cereal grain is registered in Germany (Anonymous, 2003).

Table 1. Registered post-harvest uses for pyrethrins.

Crop	Country	Method, label instructions	Application rate (g ai/100m ³ space)	No.	WhP ^{1/}
Cereal grains	Germany	Cold fogging, time of action 6 hours	2.4	3	F ^{2/}
Cereal grains	Germany	Cold fogging, time of action 6 hours	0.4	10	F

^{1/} WhP: withholding period.

^{2/} F: the WhP depends on use conditions.

RESIDUES RESULTING FROM SUPERVISED TRIALS ON CROPS

The Meeting received supervised residue trials data from post-harvest use on wheat grains (Anonymous, 1978; Renner, 2000) and maize grains (Renner, 2000; Renner, 2002). Trials in 1978 and 2000 were carried out with the preparation "INSEKTENIL-Raumnebel-forte" and the 2002 trials with "INSEKTENIL-Raumnebel-forte-trocken". Both cold-fogging formulations (KN) contained pyrethrins (4 g/l) and piperonyl butoxide (22 g/l). Fog was evenly distributed in the room. Samples were drawn by sieve pipes and stored at temperatures below -18°C until analysis. The time between sampling and analysis was 1-2 months in all trials.

Samples were extracted with acetone but water was added beforehand, in amounts that took full account of the natural water content of samples, so that the acetone/water ratio was 2:1 (v/v) during extraction. For liquid-liquid partition, ethyl acetate/cyclohexane (1+1) and sodium chloride were added and excess water was separated after repeated mixing. The evaporated residue of an aliquot of the organic phase was cleaned-up by gel permeation chromatography, using a mixture of ethyl acetate/cyclohexane (1+1) as eluant. The residue-containing fraction was concentrated and, following additional silica gel mini-column chromatography, natural pyrethrins were determined by GC-ECD and piperonyl butoxide by GC-MSD. The LOQ was 0.05 mg/kg for natural pyrethrins and piperonyl butoxide in grain (wheat and maize).

The results are reported in Table 2. Double-underlined results are from treatments according to GAP and are valid for estimating maximum residue levels.

Table 2. Residues of pyrethrins and piperonyl butoxide in wheat and maize after post-harvest use.

Stored commodity, location, year; reference	Kind of storage	Application			WhP (days)	Residues (mg/kg)	
		Form	Dates, Rate (mg ai/m ³)	Duration (hours)		Pyrethrins	Piperonyl butoxide
Wheat grain, Germany, 1978; Anonymous, 1978, III-231. 2/78-1	Fogging chamber	KN	1) 08 March 1978 2) no date 3) 12 April 1978 24 Pyr. + 132 Pip.	6	Control 1	- <u>0.19</u>	- 2.6
Wheat grain, Germany, 2000; Renner, 2000, 00 10 47 027	Timber box in room 1 (160 m ³)	KN	1) 11 July 2000 2) 25 July 2000 3) 07 August 2000 24 Pyr. + 132 Pip. (3.8 g Pyr./room) (21 g Pip./room)	6	Control 0 4 7 14 21	<0.05 < <u>0.05</u> <0.05 <0.05 <0.05 <0.05	<0.05 0.18 <0.05 0.06 <0.05 <0.05
Wheat grain, Germany, 2000; Renner, 2000, 00 10 47 027	Timber box in room 2 (108m ³)	KN	1) 11 July 2000 2) 25 July 2000 3) 07 August 2000 24 Pyr. + 132 Pip. (2.6 g Pyr./room) (14 g Pip./room)	6	Control 0 4 7 14 21	<0.05 <0.05 <0.05 <0.05 < <u>0.05</u> <0.05	<0.05 0.16 0.10 <0.05 0.18 0.09
Wheat grain, Germany, 2000; Renner, 2000, 00 10 47 027	Timber box in room 3 (96m ³)	KN	1) 11 July 2000 2) 25 July 2000 3) 07 August 2000 24 Pyr. + 132 Pip. (2.3 g Pyr./room) (13 g Pip./room)	6	Control 0 4 7 14 21	<0.05 <0.05 < <u>0.05</u> <0.05 <0.05 <0.05	<0.05 <0.05 0.28 0.20 0.17 0.14
Maize grain, Germany, 2000; Renner, 2000, 00 10 47 027	Timber box in room 1 (160 m ³)	KN	1) 11 July 2000 2) 25 July 2000 3) 07 August 2000 24 Pyr. + 132 Pip. (3.8 g Pyr./room) (21 g Pip./room)	6	Control 0 4 7 14 21	<0.05 <0.05 <u>0.05</u> <0.05 <0.05 <0.05	<0.05 0.31 0.50 0.26 0.06 0.18
Maize grain, Germany, 2000; Renner, 2000, 00 10 47 027	Timber box in room 2 (108m ³)	KN	1) 11 July 2000 2) 25 July 2000 3) 07 August 2000 24 Pyr. + 132 Pip. (2.6 g Pyr./room) (14 g Pip./room)	6	Control 0 4 7 14 21	<0.05 < <u>0.05</u> <0.05 <0.05 <0.05 <0.05	<0.05 0.38 0.07 0.26 0.16 0.31
Maize grain, Germany, 2002; Renner, 2002, 01 10 47 027	Timber box in room 1 (160m ³)	KN	1) 10 Sept. 2001 2) 24 Sept. 2001 3) 08 Oct. 2001 24 Pyr. + 132 Pip. (3.8 g Pyr./room) (21 g Pip./room)	6	Control 0 4 7 14 21	<0.05 <0.05 < <u>0.05</u> <0.05 <0.05 <0.05	<0.05 0.16 0.36 <0.05 0.08 0.20
Maize grain, Germany, 2002; Renner, 2002, 01 10 47 027	Timber box in room 4 (157m ³)	KN	1) 10 Sept. 2001 2) 24 Sept. 2001 3) 08 Oct. 2001 24 Pyr. + 132 Pip. (3.8 g Pyr./room) (21 g Pip./room)	6	Control 0 4 7 14 21	<0.05 <0.05 <0.05 < <u>0.05</u> <0.05 <0.05	<0.05 0.07 0.17 0.18 <0.05 <0.05

APPRAISAL

Pyrethrins were evaluated for residues in a periodic review by the JMPR in 2000. The JMPR recommended withdrawal of the CXL of 3 mg/kg Po for cereal grains, because no residue data were available. The 34th Session of the CCPR in 2002 decided to retain the CXL for cereal grains under the periodic review procedure, because it was informed by the delegation of Germany that data would be made available. The 2003 JMPR received information on GAP for cereals from the government of Germany. New supervised residue trials for the post-harvest use of pyrethrins on wheat and maize were reported by the manufacturer.

Results of supervised trials on crops

Cereal grains. The current German label indicates that pyrethrins may be applied to stored cereal grains by cold fogging in mills and warehouses, either 3 times at 2.4 g ai/100 m³ or 10 times at 0.4 g

ai/100 m³. Four supervised trials each were available for stored wheat and maize grains according to maximum German GAP (3 x 2.4 g ai/100 m³). The residues of pyrethrins were <0.05 (3) and 0.19 mg/kg in wheat and <0.05 (3) and 0.05 mg/kg in maize. The combined residues of wheat and maize in rank order (median underlined) were <0.05 (6), 0.05 and 0.19 mg/kg.

The Meeting estimated a maximum residue level of 0.3 mg/kg, an STMR of 0.05 mg/kg and an HR of 0.19 mg/kg for the post-harvest use of pyrethrins on cereal grains and recommended withdrawal of the existing CXL for cereal grains of 3 mg/kg Po.

Residues in animal commodities

The 2000 JMPR considered that an estimate of maximum residue levels for pyrethrins in animal commodities was impossible because of the lack of adequate animal feeding studies. As cereal grains are feed items, residue concentrations in cereals must be considered in the animal dietary burden calculations when data from feeding studies with ruminants and poultry become available in the future.

RECOMMENDATIONS

The Meeting estimated the maximum residue level, STMR value and HR value shown in Table 3. The maximum residue level is recommended for use as an MRL.

Definition of the residue for compliance with MRLs and estimation of dietary intake: *total pyrethrins, calculated as the sum of pyrethrins 1 and 2, cinerins 1 and 2, and jasmolins 1 and 2, determined after calibration with World Standard pyrethrum extract.*

The residue is fat-soluble.

Table 3. Summary of recommendations.

Commodity		MRL, mg/kg		STMR or STMR-P, mg/kg	HR, mg/kg
CCN	Name	New	Previous		
GC 0080	Cereal grains	0.3 Po	3 Po	0.05	0.19

FURTHER WORK OR INFORMATION

Desirable

1. Feeding studies with ruminants (from 2000 JMPR).
2. Feeding studies with laying hens.

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Daily Intakes (IEDI) of pyrethrins, based on the STMRs estimated by the 2000 and 2003 JMPR for 11 commodities, for the five GEMS/Food regional diets were 1% of the maximum ADI of 0.04 mg/kg bw/day (Table 4). The Meeting concluded that the long-term intake of residues of pyrethrins, resulting from the uses considered by the JMPR, is unlikely to present a public health concern.

Table 4. International Estimated Dietary Intakes (IEDIs) of pyrethrins for the five GEMS/Food regional diets (ADI = 0-0.04 mg/kg bw/day).

Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day. Intake = daily intake: µg/person									
			Mid-East diet Intake		Far-East diet intake		African diet intake		Latin American diet intake		European diet intake	
GC 0080	Cereal grains	0.05	429.9	21.5	450.8	22.5	318.3	15.9	252.4	12.6	221.9	11.1
FC 0001	Citrus fruits	0.04	47.1	1.9	6.3	0.3	5.1	0.2	54.6	2.2	44.6	1.8
DF 0167	Dried fruit	0.05	0.3	0.0	0.2	0.0	0.3	0.0	0.3	0.0	0.0	0.0
VC 0045	Fruiting vegetables, cucurbits	0.04	80.5	3.2	18.2	0.7	0.0	0.0	30.5	1.2	38.5	1.5
SO 0697	Peanut	0.05	0.3	0.0	0.2	0.0	2.3	0.1	0.3	0.0	3.0	0.2
VO 0051	Peppers	0.04	3.4	0.1	2.1	0.1	5.4	0.2	2.4	0.1	10.4	0.4
VD 0070	Pulses	0.05	18.9	0.9	14.5	0.7	17.5	0.9	20.3	1.0	9.4	0.5

Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day. Intake = daily intake: µg/person									
			Mid-East diet Intake		Far-East diet intake		African diet intake		Latin American diet intake		European diet intake	
VR 0075	Root and tuber vegetables	0	61.8	0.0	108.5	0.0	321.3	0.0	159.3	0.0	242.0	0.0
VO 0448	Tomato	0.04	81.5	3.3	7.0	0.3	16.5	0.7	25.5	1.0	66.6	2.7
JF 0448	Tomato juice	0.018	0.3	0.0	0.0	0.0	0.0	0.0	0.0	0.0	2.0	0.0
	Tomato paste	0.018	5.8	0.0	0.2	0.0	0.3	0.0	0.0	0.0	4.0	0.0
Total intake (µg/person)=				31.0		24.6		18.0		18.2		18.1
Bodyweight per region (kg bw) =				60		55		60		60		60
ADI (µg/person)=				2400		2200		2400		2400		2400
% ADI=				1.3		1.1		0.8		0.8		0.8
Rounded % ADI=				1		1		1		1		1

Short-term intake

The International Estimated Short Term Intake (IESTI) for pyrethrins was calculated for 9 food commodities for which maximum residue levels were estimated by the JMPR in 2000 and 2003 and for which consumption data were available. These results are shown in Tables 5 and 6.

The IESTI represented 0-2% of the acute RfD (0.2 mg/kg bw) for the general population and 0-5% of the acute RfD for children. The Meeting concluded that the short-term intake of residues of pyrethrins, resulting from the uses considered by the JMPR, is unlikely to present a public health concern.

Table 5. Assessment of risk to the general population from the short-term dietary intake of residues of tolylfluanid (acute RfD = 0.2 mg/kg bw, i.e. 200 µg/kg bw/day).

Codex Code	Commodity	STMR or STMR-P mg/kg	HR or HR-P mg/kg	Large portion diet			Unit weight			Variability factor	Case	IESTI µg/kg bw/day	% acute RfD rounded
				Coun-try	Body wt, kg	Large portion, g/person	Unit wt, g	Coun-try	Unit wt, edible portion, g				
DF 0167	Dried fruits		0.11	FRA	62.3	138	-	-	-	-	1	0.24	0
FC 0001	Citrus fruits (grapefruit ^{1/2})		0.04	JPN	52.6	947	256	USA	125	3	2a	0.91	0
JF 0001	Citrus juice (orange juice ^{1/2})	0.0276		-	-	-	-	-	-	-	3	-	-
SO 0697	Peanuts		0.23	FRA	62.3	161	-	-	-	-	1	0.60	0
VD 0070	Pulses (peas (dry) ^{1/2})		0.05	FRA	62.3	445	-	-	-	-	1	0.36	0
VO 0051	Peppers (peppers, sweet (incl. pimiento) ^{1/2})		0.04	FRA	62.3	207	119	USA	98	3	2a	0.26	0
VR 0075	Root and tuber vegetables (Potatoes ^{1/2})		0.04	NLD	63.0	687	122	USA	99	3	2a	0.56	0
VO 0448	Tomato (fresh, juice, paste, peeled)		0.04	USA	65.0	391	123	USA	123	3	2a	0.39	0
VC 0045	Fruiting vegetables, cucurbits (watermelons ^{1/2})		0.04	USA	65.0	1939	4518	USA	2078	3	2b	3.58	2
GC 0080	Cereal grains (wheat ^{1/2})		0.19	USA	65.0	383	-	-	-	-	1	1.12	1

^{1/2} Highest consumed commodity represents the group when other consumption data are not available.

Table 6. Assessment of risk to children up to 6 years from the short-term dietary intake of residues of tolylfluanid (acute RfD = 0.2 mg/kg bw, i.e. 200 µg/kg bw/day).

Codex Code	Commodity	STMR or STMR-P mg/kg	HR or HR-P mg/kg	Large portion diet			Unit weight			Variability factor	Case	IESTI µg/kg bw/day	% acute RfD rounded
				Coun-try	Body wt, kg	Large portion, g/person	Unit wt, g	Coun-try	Unit wt, edible portion, g				
DF 0167	Dried fruits		0.11	FRA	17.8	101	-	-	-	-	1	0.62	0
FC 0001	Citrus fruits (grapefruit ^{1/})		0.04	FRA	17.8	381	256	USA	125	3	2a	1.42	1
JF 0001	Citrus juice (orange juice ^{1/})	0.0276		-	-	-	-	-	-	-	3	-	-
SO 0697	Peanut		0.23	USA	15.0	78	-	-	-	-	1	1.19	1
VD 0070	Pulses (peas (dry) ^{1/})		0.05	FRA	17.8	107	-	-	-	-	1	0.30	0
VO 0051	Peppers (peppers, sweet (incl. pimiento) ^{1/})		0.04	AUS	19.0	60	119	USA	98	3	2b	0.38	0
VR 0075	Root and tuber vegetables (potatoes ^{1/})		0.04	SAF	14.2	300	122	USA	99	3	2a	1.40	1
VO 0448	Tomato (fresh, juice, paste, peeled)		0.04	USA	15.0	159	123	USA	123	3	2a	1.08	1
VC 0045	Fruiting vegetables, cucurbits (watermelons ^{1/})		0.04	AUS	19.0	1473	4518	USA	2078	3	2b	9.30	5
GC 0080	Cereal grains (wheat ^{1/})		0.19	USA	15.0	151	-	-	-	-	1	1.91	1

^{1/} Highest consumed commodity represents the group when other consumption data are not available.

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