TOLYLFLUANID (162)

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EXPLANATION

Tolylfluanid, a fungicide, was first evaluated by the JMPR in 1988, with a subsequent residue evaluation in 1990. The compound was evaluated under the Periodic Review Programme in 2002 and the Meeting recommended a number of MRLs and the residue definition as follows.

For compliance with MRLs: *tolylfluanid.*

For the estimation of dietary intake: *tolylfluanid and N,N-dimethyl-N'-(4-methylphenyl)-sulfamide, expressed as tolylfluanid.*

Among the trial data submitted to the 2002 JMPR, the results of supervised trials on lettuce conducted in Southern France, Italy, Portugal and Spain could not be evaluated, because the closest GAP, Slovenian GAP, required a PHI of 21 days and the maximum sampling interval of these trials was 10 days. A newly registered use on lettuce was approved in Spain, which requires a PHI of 7 days. The present Meeting reviewed the results of trials conducted in Southern France, Italy, Portugal and Spain, taking into consideration the new GAP in Spain.

USE PATTERN

Information on a newly registered use of tolylfluanid on head lettuce in Spain was provided together with an official label. This information, together with registered uses on lettuce in other countries which were available to the 2002 Meeting, is summarized in Table 1.

Table 1. Registered uses of tolylfluanid on lettuce.

Crop [1]	Country	Form	Application [2]					PHI, days
			Method	Spray conc., kg a.i./hl	Water vol., l/ha	Rate, kg a.i./ha	No.	
Lettuce	Belgium	WG50	foliar	n.s.		1.25	3	[3]
Lettuce	Germany	WG50	foliar	0.1	600	0.6	6	21
Lettuce	Slovenia	WP50	foliar	n.s.		1-1.25	n.s.	21
Lettuce	Spain	WG40	foliar	0.06-0.1		n.s.	n.s.	7
Lettuce	Sweden	WG50	foliar	0.075 [4] 0.125 [5]	1000	n.s.	4-5	14
Lettuce	Uruguay	WG50	foliar	0.125		n.s.	3	5
Lettuce (G)	Poland	WG50 WP50	foliar	0.1	600-800	n.s.	Max. 3	21
Lettuce, head (G)	Netherlands	WG50 WP50	foliar	n.s.	500-1000	1.0-1.5	1	21

[1] (G), cultivation in greenhouse; without any indication, cultivation outdoor.
[2] "n.s." = not specified on the label.
[3] Not to be used after the plant weighs 40 g or when the stage "covering of the soil by the leaves" has been reached. If the plant is to be cut at a final weight of 200-250 g, the treatment has to be carried out 3 days earlier.
[4] On small plants.
[5] On larger plants.

RESIDUES RESULTING FROM SUPERVISED TRIALS ON CROPS

The results of supervised field trials on lettuce conducted in Belgium, France, Germany, Greece, Italy, Portugal, Spain and United Kingdom were submitted to the 2002 JMPR and are shown in Table 2.

Residue levels were reported for tolylfluanid and its main metabolite, *N*,*N*-dimethyl-*N'*-(4-methylphenyl)-sulfamide (DMST). The sum of tolylfluanid and DMST was calculated and expressed as tolylfluanid, on the basis of the relative molar masses of tolylfluanid (347.3 g/mol) and DMST (214.3 g/mol). When tolylfluanid and/or DMST was found to be below the limit of quantification, the sum of tolylfluanid and DMST was calculated and expressed as tolylfluanid as follows:

Tolylfluanid	DMST	Total (expressed as tolylfluanid)
<0.02	<0.02	<0.02
0.10	<0.02	0.10
<0.02	0.10	0.16
0.10	0.10	0.26

Where residues were not detected, they are shown as below the limit of quantification, e.g. <0.05 mg/kg. Residues and spray concentrations were rounded to two significant figures, except for residues near the limit of quantification for which one significant figure was used. Residue data from the trials conducted according to maximum GAP were used for the estimation of maximum residue levels. These results are double underlined. Residue data are recorded unadjusted for recovery.

Table 2. Residues in lettuce, head, from supervised trials in Belgium, France, Germany, Greece, Italy, Portugal, Spain and the United Kingdom.

Location, year, (variety); reference	Application				PHI	Residues, mg/kg		
	Form	kg a.i./ha	kg a.i./hl	No.	(days)	Tolylfluanid	DMST	Tolylfluanid + DMST [1/]
Germany, 1987, (Attraktion); 8208-87	WG50	0.6	0.1	6	0	17	14	40
					7	0.36	0.19	0.67
					14	<0.05	<0.05	<0.05
					21	<u>≤0.05</u>	<0.05	<u>≤0.05</u>
					28	<0.05	<0.05	<0.05
Germany, 1987, (Attraktion); 8209-87	WG50	0.6	0.1	6	0	29	11	47
					7	1.2	0.48	2.0
					14	0.12	<0.05	0.12
					21	<u>≤0.05</u>	<0.05	<u>≤0.05</u>
					28	<0.05	<0.05	<0.05
Germany, 1987, (Victoria Typ King); 8210-87	WG50	0.6	0.1	6	0	26	6.5	37
					7	1.0	0.20	1.3
					14	<0.05	<0.05	<0.05
					21	<u>≤0.05</u>	<0.05	<u>≤0.05</u>
					28	<0.05	<0.05	<0.05
Germany, 1987, (Victoria Typ King); 8211-87	WG50	0.6	0.1	6	0	20	5.6	29
					7	1.3	0.47	2.1
					14	0.58	<0.05	0.58
					21	<u>0.17</u>	<0.05	<u>0.17</u>
					28	<0.05	<0.05	<0.05
Germany, 1988, (Attraktion); 0215-88	WG50	0.6	0.1	6	0	17	8.2	30
					7	0.96	0.53	1.82
					14	<0.05	<0.05	<0.05
					21	<u>≤0.05</u>	<0.05	<u>≤0.05</u>
					28	<0.05	<0.05	<0.05
Germany, 1988, (Ovation); 0216-88	WG50	0.6	0.1	6	0	24	6.0	34
					7	0.39	0.21	0.73
					14	0.15	0.06	0.25
					21	<u>≤0.05</u>	<0.05	<u>≤0.05</u>
					28	<0.05	<0.05	<0.05
Germany, 1988, (Victoria King); 0217-88	WG50	0.6	0.1	6	0	30	1.3	32
					7	13	0.37	14
					14	0.63	0.06	0.73
					21	<u>≤0.05</u>	<0.05	<u>≤0.05</u>
					28	<0.05	<0.05	<0.05
Germany, 1988, (Victoria King); 0218-88	WG50	0.6	0.1	6	0	36	3.9	42
					7	2.6	0.41	3.3
					14	<0.05	<0.05	<0.05
					21	<u>≤0.05</u>	<0.05	<u>≤0.05</u>
					28	<0.05	<0.05	<0.05
Belgium, 1998, (Soraya); RA-2136/98 1622-98	WG43.5	1.125	0.19	6	0 [4/]	0.76	0.30	1.25
					0	11	1.1	13
					3	1.6	0.33	2.1
					7	1.1	0.18	1.4
					10	1.1	0.15	1.3
France (north), 1997, (Titan); RA-2121/97 0209-97	WG43.5	1.125	0.19	5	0	14	2.4	18
					7	0.38	0.10	0.54

Location, year, (variety); reference	Application				PHI	Residues, mg/kg		
	Form	kg a.i./ha	kg a.i./hl	No.	(days)	Tolylfluanid	DMST	Tolylfluanid + DMST [1/]
France (north), 1998, (Remeo); RA-2136/98 1625-98	WG43.5	1.125	0.19	6	0	34	1.3	36
					6	11	0.56	12
					8	13	0.42	14
Germany, 1997, (Nadine); RA-2121/97 0208-97	WG43.5	1.125	0.19	5	0 [4/]	2.7	0.35	3.3
					0	26	0.75	27
					3	2.5	0.52	3.3
					7	1.4	0.19	1.7
					10	0.72	0.12	0.91
Germany, 1997, (Nadine); RA-2121/97 0639-97	WG43.5	1.125	0.19	5	0 [4/]	6.9	0.47	7.7
					0	27	1.0	29
					3	0.4	0.07	0.51
					7	0.26	0.02	0.29
					10	0.15	<0.02	0.15
Germany, 1998, (Nadine); RA-2136/98 1074-98	WG43.5	1.125	0.19	6	0 [4/]	1.3	0.20	1.6
					0	9.2	0.67	10.3
					2	4.0	0.44	4.7
					7	2.0, 1.9	0.21 0.21	2.3, 2.2
					10	1.5	0.12	1.7
Germany, 1998, (Nadine); RA-2136/98 1077-98	WG43.5	1.125	0.19	6	0 [4/]	10	0.39	11
					6	2.3	0.30	2.8
					7	2.1,2.1	0.16 ,0.19	2.4, 2.4
Germany, 1998, (Nadine); RA-2136/98 1624-98	WG43.5	1.125	0.19	6	0	16	1.1	18
					5	5.8	0.71	7.0
					7	3.7	0.51	4.5
United Kingdom, 1997, (Siletta); RA-2121/97 0638-97	WG43.5	1.125	0.19	5	0 [4/]	9.8	0.34	10.4
					0	28	0.77	29
					3	12	0.45	13
					7	2.8	0.14	3.0
					10	1.8	0.10	2.0
France (south), 1996, (Massaida); RA-2066/96 0474-96	WG50	1.0	0.1	3	0 [4/]	0.03	<0.02	0.03
					0	16	1.5	18
					3	3.9	0.60	4.9
					7	0.98	0.11	1.2
					10	0.71	0.11	0.89
Italy, 1996, (Audran); RA-2066/96 0310-96	WG50	1.0	0.1	3	0 [4/]	0.08	0.02	0.11
					0	16	1.2	18
					7	3.1	0.29	3.6
Portugal, 1996, (Vanity); RA-2066/96 0421-96	WG50	1.0	0.1	3	0 [4/]	0.11	0.04	0.17
					0	16	2.3	20
					7	1.9	1.6	4.5
Spain, 1994, (Rob); RA-2090/94 0360-94	WG50	1.0	0.1	3	0 [4/]	<0.02	<0.02	<0.02
					0	17	4.6	25
					3	8.8	2.1	12.2
					5	4.0	1.2	5.9
					7	2.4	0.93	3.9
Spain, 1994, (Inverna Typ); RA-2090/94 0362-94	WG50	1.0	0.1	3	0 [4/]	1.1	0.32	1.6
					0	9.0	1.8	11.9
					3	5.1	0.85	6.5
					5	3.5	0.74	4.7
					7	2.1	0.52	2.9
Spain, 1995, (Hiverna); RA-2105/95 0005-95	WG50	1.0 [2/]	0.1	3	0 [4/]	1.5	0.36	2.1
					0	12	1.5	14
					3	7.9	0.99	9.5
					7	3.2	0.67	4.3
					10	2.3	0.46	3.1
Spain, 1995, (Francesca); RA-2105/95 0008-95	WG50	1.0	0.1	3	0	9.1	0.96	10.7
					7	6.0	0.69	7.1
Spain, 1996, (Francesca); RA-2066/96 0178-96	WG50	1.0 [3/]	0.1	3	0 [4/]	0.31	0.07	0.42
					0	15	1.3	17
					3	6.9	0.59	7.9
					7	3.8	0.40	4.4
					10	0.93	0.16	1.19

Location, year, (variety); reference	Application				PHI	Residues, mg/kg		
	Form	kg a.i./ha	kg a.i./hl	No.	(days)	Tolylfluanid	DMST	Tolylfluanid + DMST [1/]
France (south), 1998, (Batavia Nevada); RA-2039/98 1410-98	WP50	0.8	0.08	2	0 [4/]	0.10	<0.02	0.10
					0	15	1.8	18
					3	1.8	0.55	2.7
					7	0.26	0.10	0.42
					10	0.12	0.05	0.20
France (south), 1999, (Princesse); RA-2039/99 0032-99	WP50	1.0	0.1	2	0 [4/]	0.43	0.13	0.64
					0	6.7	1.2	8.6
					3	4.5	0.72	5.7
					7	2.9	0.38	3.5
					10	1.3	0.24	1.7
Greece, 1999, (Acacia); RA-2039/99 0510-99	WP50	1.0	0.1	2	0 [4/]	0.46	0.11	0.64
					0	11	1.2	13
					3	11	0.53	12
					7	4.6	0.45	5.3
					10	1.9	0.19	2.2
Italy, 1998, (Messalina); RA-2039/98 1409-98	WP50	0.8	0.08	2	0	14	2.1	17
					7	0.11	0.06	0.21
Italy, 1999, (Bionda Lenta a Montare); RA-2039/99 0033-99	WP50	1.0	0.1	2	0	5.1	0.39	5.7
					7	1.3	0.12	1.5
Portugal, 1999, (Grand Rapid); RA-2039/99 0034-99	WP50	1.0	0.1	2	0	9.7	0.77	11.0
					7	2.3	0.25	2.7
Spain, 1999, (Daguan); RA-2039/99 0031-99	WP50	1.0 [5/]	0.1	2	0 [4/]	4.8	0.95	6.3
					0	12	1.8	15
					3	12	1.2	14
					7	8.5	1.2	10
					10	8.4	1.1	10
Spain, 1999, (Daguan); RA-2039/99 0509-99	WP50	1.0	0.1	2	0 [4/]	4.0	0.68	5.1
					0	14	1.5	16
					6	9.7	1.2	12

Portion analyzed was head of lettuce in all trials.

[1/] Sum of tolylfluanid and DMST expressed as tolylfluanid.

[2/] The first application was about 9% under-dosed.

[3/] The first application was about 5% over-dosed.

[4/] Prior to last application.

[5/] The last application was about 7% under-dosed.

APPRAISAL

Tolylfluanid, a fungicide closely related to dichlofluanid, was first evaluated for toxicology and residues by the Meeting in 1988, with a subsequent residue evaluation in 1990. It was evaluated again in 2002 under the Periodic Review Programme of CCPR, when the Meeting recommended a number of MRLs and the definition of the residue as follows:

For compliance with MRLs: *tolylfluanid*

For the estimation of dietary intake: *sum of tolylfluanid and N,N-dimethyl-N'-(4-methylphenyl)sulfamide (DMST), expressed as tolylfluanid.*

Among trials data reported to the 2002 JMPR, the results of supervised trials on lettuce conducted in southern France, Italy, Portugal and Spain could not be evaluated as the closest GAP, Slovenian GAP, required a PHI of 21 days while the maximum sampling interval in these trials was 10 days. A new registered use on lettuce was approved in Spain, which requires a PHI of 7 days. The present Meeting reviewed the results of trials conducted in southern France, Italy, Portugal and Spain, taking into consideration the new registered use in Spain.

Results of supervised trials

The results of supervised trials on lettuce reported to the 2002 JMPR were evaluated in the light of the new GAP in Spain.

Lettuce, head. Trials were conducted in Belgium, France, Germany, Greece, Italy, Portugal, Spain and the United Kingdom.

The results of trials conducted in Germany in 1987 and 1988, at an application rate of 0.1 kg a.i./hl (0.6 kg a.i./ha, 6 applications), were evaluated against the GAP of Germany (0.1 kg a.i./hl, 0.6 kg a.i./ha, 6 applications, PHI of 21 days). The residues of tolylfluanid found in 8 trials that matched GAP were, in ranked order: <0.05 (7) and 0.17 mg/kg and those of the sum of tolylfluanid and DMST, expressed as tolylfluanid, were: <0.07 (7) and 0.17 mg/kg.

The trials carried out in Belgium, northern France, Germany and the United Kingdom in 1997 and 1998, at an application rate of 0.19 kg a.i./hl, were not in compliance with any GAP.

The results of trials carried out in southern France, Italy, Portugal and Spain, at an application rate of 0.08 or 0.1 kg a.i./hl, were evaluated against the GAP of Spain (0.06-0.1 kg a.i./hl, PHI of 7 days). The residues of tolylfluanid found in 15 trials that matched the GAP, and in one trial conducted in Spain with a PHI of 6 days were, in ranked order: 0.11, 0.26, 0.98, 1.3, 1.9, 2.1, 2.3, 2.4, 2.9, 3.1, 3.2, 3.8, 4.6, 6.0, 8.5 and 9.7 mg/kg and those of the sum of tolylfluanid and DMST, expressed as tolylfluanid, were (median underlined): 0.21, 0.42, 1.2, 1.5, 2.7, 2.9, 3.5, <u>3.6</u>, <u>3.9</u>, 4.3, 4.4, 4.5, 5.3, 7.1, 10 and 12 mg/kg.

The trials following German GAP showed significantly lower residues than those according to Spanish GAP. The Meeting decided to the maximum residue level on the results of trials matching Spanish GAP. The Meeting estimated a maximum residue level of 15 mg/kg, to replace the previous recommendation of 0.2 mg/kg. It also estimated an STMR of 3.75 mg/kg and an HR of 12 mg/kg.

RECOMMENDATIONS

On the basis of the data from supervised trials, the Meeting concluded that the residue levels listed in Table 3 are suitable for establishing maximum residue limits and for IEDI and IESTI assessment.

Definition of the residue for compliance with MRLs for plant commodities: *tolylfluanid*.

Definition of residue for the estimation of dietary intake from plant commodities: *tolylfluanid and N,N-dimethyl-N'-(4-methylphenyl)-sulfamide, expressed as tolylfluanid*.

Table 3. Summary of recommendations.

Commodity		Recommended MRL, mg/kg		STMR/STMR-P [1/], mg/kg	HR/HR-P [1/], mg/kg
CCN	Name	New	Previous		
VL 0482	Lettuce, head	15	0.2	3.75	12

[1/] Sum of tolylfluanid and DMST, expressed as tolylfluanid.

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Dietary Intakes (IEDIs) were calculated for the five GEMS/Food regional diets, using STMRs for 12 commodities and the STMR-Ps for various dried products estimated by the 2002 JMPR and the current Meeting (Table 4). The ADI of 0-0.08 mg/kg bw was established by the 2002 Meeting. The calculated IEDIs were 0-4% of the maximum ADI. The Meeting concluded that the intake of residues of tolylfluanid and DMST, resulting from the uses considered by the 2002 and current JMPR, was unlikely to present a public health concern.

Table 4. International Estimated Dietary Intakes (IEDIs) of tolylfluanid for the five GEMS/Food regional diets (ADI = 0-0.08 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
JF 0226	Apple juice	0.06	4.5	0.3	0	0.0	0	0.0	0.3	0.0	3.8	0.2
	Apple sauce	0.06	-	-	-	-	-	-	-	-	-	-
	Apple, canned	0.04	-	-	-	-	-	-	-	-	-	-
	Beer (arising from use on hops)	0.025	-	-	-	-	-	-	-	-	-	-
FB 0264	Blackberries	1.95	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
JF 1140	Blackcurrant juice	0.09	-	-	-	-	-	-	-	-	-	-
VC 0424	Cucumber	0.37	2.4	0.9	2.3	0.8	0.0	0.0	4.2	1.5	4.5	1.7
FB 0021	Currants, red, black, white	0.345	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.3	0.1
JF 0269	Grape juice	0.40	-	-	-	-	-	-	-	-	-	-

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
FB 0269	Grapes (fresh, wine, excluding dried grapes)	0.75	15.8	11.9	1.0	0.8	0.0	0.0	1.3	1.0	13.8	10.4
DF 0269	Grapes, dried (= currants, raisins and sultanas)	2.3	0.3	0.7	0.0	0.0	0.0	0.0	0.3	0.7	2.3	5.3
DH 1100	Hops, dry	25	0.1	2.5	0.1	2.5	0.1	2.5	0.1	2.5	0.1	2.5
VA 0384	Leek	0.97	0.5	0.5	0.0	0.0	0.0	0.0	0.3	0.3	2.0	1.9
VL 0482	Lettuce, head	3.75	2.3	8.6	0.0	0.0	0.0	0.0	5.8	21.8	22.5	2.3
	Pear juice	0.02	-	-	-	-	-	-	-	-	-	-
	Pear, Canned	0.01	-	-	-	-	-	-	-	-	-	-
VO 0445	Peppers, sweet (incl. pim(i)ento)	0.67	3.3	2.2	2.0	1.3	5.3	3.6	2.3	1.5	10.3	6.9
FP 0009	Pome fruits	0.68	10.8	7.3	7.5	5.1	0.3	0.2	6.5	4.4	51.3	34.9
FB 0272	Raspberries, red, black	1.95	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.5	1.0
FB 0275	Strawberry	0.84	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	5.3	4.5
	Strawberry, canned	0.18	-	-	-	-	-	-	-	-	-	-
VO 0448	Tomato (fresh)	0.39	44.1	17.2	5.7	2.2	14.6	5.7	25.5	9.9	34.9	13.6
JF 0448	Tomato juice	0.2	0.3	0.1	0.0	0.0	0.0	0.0	0.0	0.0	2.0	0.4
	Tomato puree	0.66	-	-	-	-	-	-	-	-	-	-
	Total intake (µg/person)=			61.4		13.1		12.4		43.7		174.1
	Bodyweight per region (kg bw) =			60		55		60		60		60
	ADI (µg/person)=			4800		4400		4800		4800		4800
	% ADI=			1.3		0.3		0.3		0.9		3.6
	Rounded % ADI=			1		0		0		1		4

Short-term intake

The International Estimated Short-Term Intakes (IESTIs) for tolylfluanid and DMST were calculated for lettuce. An acute reference dose of 0.5 mg/kg bw was established by the 2002 JMPR. The IESTI for general population was 20% of the acute reference dose and that for children was 40% (Tables 5 and 6). The Meeting concluded that the short-term intake of residues of tolylfluanid and DMST, resulting from uses on lettuce, was 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 = 0.5 mg/kg bw, i.e. 500 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
				Country	Body wt, kg	Large portion, g/person	Unit wt, g	Country	Unit wt, edible portion, g				
VL 0482	Lettuce, head	3.75	12	USA	65.0	213	754	UNK	558	3	2b	117.72	20

Table 6. Assessment of risk to children up to 6 years from the short-term dietary intake of residues of tolylfluanid (acute RfD = 0.5 mg/kg bw, i.e. 500 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
				Country	Body wt, kg	Large portion, g/person	Unit wt, g	Country	Unit wt, edible portion, g				
VL 0482	Lettuce, head	3.75	12	NLD	17.0	84	754	UNK	558	3	2b	177.12	40

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