FENVALERATE (119)

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EXPLANATION

Fenvalerate is a broad-spectrum pyrethroid insecticide consisting of four isomers (SS, RS, SR and RR), all being present at equal amounts in the technical material (see FAO Specification from 1993). The active substance was evaluated by JMPR several times between 1979 and 1991 for residues and toxicology.

In 2002 esfenvalerate, which is the purified SS-isomer (84%), was evaluated as a new compound by the JMPR for residues as well as for toxicology.

Fenvalerate was evaluated for toxicology and residues by the 2012 JMPR under the periodic review program of the CCPR, scheduled at the 43th session of the CCPR. However, no data on animal or plant metabolism, the environment, analytical methods or storage stability were submitted to the 2012 JMPR, normally required for a periodic re-evaluation of a compound.

The Meeting noted, that in 2002 esfenvalerate was evaluated by the Meeting for residues as a new compound. The JMPR Evaluation, presented in a comprehensive form, was mainly based on studies for fenvalerate. It included data on animal metabolism (lactating cows), plant metabolism (apple trees, cabbage, kidney beans, lettuce, soya bean, tomato and wheat), the environment (soil photolysis, aerobic and anaerobic soil metabolism, field dissipation and rotational crops) and livestock feeding studies (dairy cattle and laying hens). Residue analytical methods and storage stability were reported for esfenvalerate only, however all isomers of fenvalerate were covered within these studies.

The Meeting recognized that basic principles for the evaluation of key studies (animal and plant metabolism, environment, analytical methods and storage stability) have not changed significantly since 2002 and concluded that a re-evaluation of the data would result in an identical recommendation for the definition of fenvalerate residues in plant and animal commodities.

The absence of key studies normally precludes the re-evaluation of an active compound under the periodic review program by JMPR. However, the Meeting noted that its evaluation for esfenvalerate in 2002 still reflects current scientific knowledge and covers fenvalerate also. In view of the closely related chemical composition of fenvalerate and esfenvalerate the Meeting decided as an exception to apply its 2002 evaluation of esfenvalerate for decision making on fenvalerate without reiterating review of study data already reported.

RESIDUE ANALYSIS

The Meeting received no additional information on analytical methods for the determination of residues of fenvalerate.

As outlined in the 2002 Monograph for esfenvalerate, the typical laboratory practice for the analysis of both fenvalerate and esfenvalerate involves solvent extraction, cleanup by solvent partition and solid phase extraction or GPC (e.g. in DFG S19) followed by GC measurement either with ECD of mass selective detection.

The RS, SR pair elutes before the SS, RR pair on GC analysis, allowing distinction between fenvalerate and esfenvalerate via the ratio of both isomeric peaks.

Definition of the residue

The 2012 JMPR considered its evaluation for esfenvalerate in 2002 and confirmed that the recommended definition of the residue for plant and animal commodities is also applicable to fenvalerate.

Definition of the residue (for compliance with MRL and for estimation of dietary intake, plant and animal commodities): *sum of fenvalerate isomers*

The residue is fat-soluble.

USE PATTERN

Additional supervised trials residue data and GAP were submitted for mango and Chinese kale from Thailand.

Table 1 List of registered uses

Commodity	Country	Field (F), Indoor (I), Post-harvest (P)	Application	Formulation	kg ai/ha	kg ai/hl	No. of treatments	PHI (days)	Remarks
Mango	Thailand	F	foliar	EC, 350 g/L		0.0105	at infestation	7	
Chinese kale	Thailand	F	foliar	EC, 350 g/L	0.021	750	1	7	

RESIDUES RESULTING FROM SUPERVISED TRIALS ON CROPS

Trials were documented with field reports and the results of the laboratory analysis. No certificate for good laboratory practice (GLP) was provided. All samples were analysed according to Steinwandter, H. 1985 (Universal 5 min. on-line method for extraction and isolation pesticide residues and industrial chemicals. Fresenius J. Anal. Chem. 322:752-754), using extraction with acetone, partition with dichloromethane and clean-up with silica gel. Instrumental analytic was performed by GC-ECD with a stated LOQ of 0.02 to 0.05 mg/kg, however results were only expressed as fenvalerate, sum of isomers instead of separate analytical results for the RS,SR and SS, RR isomers. Recovery data for validation were provided in summarized form, with values between 70–110% with < 20% RSD.

In trials where duplicate field samples from an unreplicated plot were taken at each sampling time and analysed separately each figure is presented individually. When samples were analysed more than once mean results are listed.

When residues were not detected they are show as below the LOQ (e.g., < 0.02 mg/kg). Application rates and spray concentrations have generally been rounded to two significant figures. For residues above the LOQ results were rounded to two significant figures.

Residue values from trials conducted according to maximum GAP have been used for the estimation of maximum residue levels. In case of replicate plots the plot containing the highest residue according to GAP was selected. Those results included in the evaluation are underlined.

Conditions of the supervised residue trials were generally well reported in detailed field reports. Most trial designs used non-replicated plots. Most field reports provided data on the sprayers used, plot size, field sample size and sampling date.

Table 2 Fenvalerate - supervised residue trials

Commodity	Indoor/Outdoor	Treatment	Countries	Table
Mango	Outdoor	Foliar spray	Thailand	Table 3
Chinese kale	Indoor	Foliar spray	Thailand	Table 4

Table 3 Fenvalerate residues in mango

Location, Year (variety)	Application					Sample material	PHI, days	Residues, mg/kg	Code
	Form	Method	g ai per tree	kg ai/hL	No				
Thailand, Wisetchaichan 2007 (Namdokmai)	EC 35	Spray	0.53	0.0105	4	whole fruit	0 1 3 5 7	0.6 0.54 0.36 0.31 0.3	Fenval_001
Thailand, Suphanburi 2007 (Namdokmai)	EC 35	Spray	0.53	0.0105	4	whole fruit	0 1 3 5 7	0.71 0.49 0.46 0.37 0.48	Fenval_001
Thailand, Suphanburi 2008 (Namdokmai)	EC 35	Spray	0.53	0.0105	4	whole fruit	0 1 3 5 7	0.47 0.42 0.38 0.37 0.35	Fenval_001
Thailand, Angthong 2007 (Namdokmai)	EC 35	Spray	0.53	0.0105	4	whole fruit	0 1 3 5 7	0.57 0.53 0.53 0.46 0.43	Fenval_001

Table 4 Fenvalerate residues in Chinese kale

Location, Year (variety)	Application					Sample material	PHI, days	Residues, mg/kg	Code
	Form	Method	kg ai/ha	water L/ha	No				
Thailand, Pratumthanee 2002 (not reported)	EC 35	Spray	0.241	1146	3	leaves	0 1 3 5 7 10	3.7 1.5 0.79 0.72 0.36 0.14	Fenval_002
Thailand, Pratumthanee 2002 (not reported)	EC 35	Spray	0.231	1101	3	leaves	0 1 3 5 7 10	3.8 2.5 1.4 1.1 0.36 0.18	Fenval_002
Thailand, Kanchanaburi 2003 (not reported)	EC 35	Spray	0.24	1143	3	leaves	0 3 7 10 12 15	9.0 1.4 0.92 0.42 0.14 0.09	Fenval_002
Thailand, Ratchaburi 2003 (not reported)	EC 35	Spray	0.244	1161	3	leaves	0 1 3 5 7 10 12 15	8.0 6.1 2.7 1.9 1.0 0.46 0.25 0.11	Fenval_002
Thailand, Kanchanaburi 2004 (not reported)	EC 35	Spray	0.265	1260	3	leaves	0 3 5 7 10 12	15 4.7 2.3 1.8 0.9 0.41	Fenval_002

Location, Year (variety)	Application					Sample material	PHI, days	Residues, mg/kg	Code
	Form	Method	kg ai/ha	water L/ha	No				
Thailand, Kanchanaburi 2004 (not reported)	EC 35	Spray	0.232	1103	3	leaves	0 3 7 10 12 15	3.9 1.5 <u>0.7</u> 0.26 0.09 0.17	Fenval_002

APPRAISAL

Fenvalerate is a broad-spectrum pyrethroid insecticide consisting of four isomers (SS, RS, SR and RR) all being present at equal amounts in the technical material (see FAO Specification from 1993). The active substance was evaluated by JMPR several times between 1979 and 1991 for residues and toxicology.

In 2002 esfenvalerate, which is the purified SS-isomer (84%), was evaluated as a new compound by the JMPR for residues as well as for toxicology.

Fenvalerate was scheduled at the Forty-third Session of the CCPR under the periodic review program to be evaluated for toxicology and residues by the 2012 JMPR. However, no data on animal or plant metabolism, the environment, analytical methods or storage stability were submitted to the 2012 JMPR, studies normally required for a periodic re-evaluation of a compound.

The Meeting noted that in 2002 esfenvalerate was evaluated for residues as a new compound. The JMPR Evaluation, presented in a comprehensive form, was primarily based on studies for fenvalerate. It included data on animal metabolism (lactating cows), plant metabolism (apple trees, cabbage, kidney beans, lettuce, soya bean, tomato and wheat), the environment (soil photolysis, aerobic and anaerobic soil metabolism, field dissipation and rotational crops) and livestock feeding studies (dairy cattle and laying hens). Residue analytical methods and storage stability were reported for esfenvalerate only, however all isomers of fenvalerate were covered within these studies.

The Meeting recognized that basic principles for the evaluation of key studies (animal and plant metabolism, environment, analytical methods and storage stability) have not changed significantly since 2002 and concluded that a re-evaluation of the data would result in an identical recommendation for the definition of fenvalerate residues in plant and animal commodities.

The absence of key studies normally precludes the re-evaluation of an active compound under the periodic review program by JMPR. However, the Meeting noted that its evaluation for esfenvalerate in 2002 still reflects current scientific knowledge and covers fenvalerate also. In view of the closely related chemical composition of fenvalerate and esfenvalerate the Meeting decided, as an exception, to apply its 2002 evaluation of esfenvalerate for decision making to fenvalerate without re-reviewing study data previously reported.

Definition of the residue

The 2012 JMPR considered its evaluation for esfenvalerate in 2002 and confirmed that the recommended definition of the residue for plant and animal commodities is also applicable to fenvalerate.

Definition of the residue (for compliance with MRL and for estimation of dietary intake, plant and animal commodities): sum of fenvalerate isomers

The residue is fat-soluble.

Results of supervised residue trials on crops

The Meeting received supervised trial data for applications of fenvalerate on mango and Chinese kale conducted in Thailand. The OECD MRL calculator was used as a tool to assist in the estimation of

maximum residue levels from the selected residue data set obtained from the supervised residue trials. As a first step, the Meeting reviewed all relevant factors related to each data set in arriving at a best estimate of the maximum residue level using expert judgement. Then the OECD calculator was employed. If the statistical calculation spreadsheet suggested a different value from that recommended by the Meeting, a brief explanation of the deviation was supplied.

In trials where duplicate field samples from replicated or unreplicated plots were taken at each sampling time and analysed separately, the mean sample was taken as the best estimate of the residue from the plot.

Labels (or translation of labels) were available from Thailand, describing the registered uses of fenvalerate.

Within the periodic review program for fenvalerate only uses for mango and Chinese kale from Thailand were reported to the Meeting and evaluated.

As a consequence the Meeting withdraws its previous recommendations for fenvalerate of 20 mg/kg in alfalfa fodder, 0.1 mg/kg in beans, shells, 1 mg/kg for beans, except broad beans and soya beans, 1 mg/kg for berries and other small fruit, 2 mg/kg for broccoli, 2 mg/kg for Brussels sprouts, 3 mg/kg for cabbage, head, 2 mg/kg for cauliflower, 2 mg/kg for celery, 2 mg/kg (Po) for cereal grains, 2 mg/kg for cherries, 1 mg/kg for Chinese cabbage (type Pak-choi), 2 mg/kg for citrus fruit, 0.2 mg/kg for cotton seed, 0.1 mg/kg for cotton seed oil, crude, 0.1 mg/kg for cotton seed oil, edible, 0.02 mg/kg for cucumber, 0.02 mg/kg for edible offal (mammalian), 10 mg/kg for kale, 5 mg/kg for kiwifruit, 2 mg/kg for lettuce, head, 1 mg/kg (F) for meat (from mammals other than marine mammals), 0.2 mg/kg for melons, except watermelons, 0.1 mg/kg for milks, 5 mg/kg for peach, 0.1 mg/kg for peanut, whole, 0.1 mg/kg for peas, shelled (succulent seeds), 0.5 mg/kg for peppers, sweet (including pimento or pimiento), 2 mg/kg for pome fruit, 0.05 mg/kg for root and tuber vegetables, 0.1 mg/kg for soya bean (dry), 0.5 mg/kg for squash, summer, 0.1 mg/kg for sunflower, seed, 0.1 mg/kg for sweet corn (corn-on-the-cob), 1 mg/kg for tomato, 0.2 mg/kg for tree nuts, 0.5 mg/kg for watermelon, 5 mg/kg (Po) for wheat bran, unprocessed, 0.2 mg/kg (Po) for wheat flour, 2 mg/kg (Po) for wheat wholemeal and 2 mg/kg for winter squash.

The Meeting also withdrawn its previous recommendation given in 2004 for dried chilli pepper of 5 mg/kg, which was based on the previously estimated maximum residue level of 0.5 mg/kg for peppers, sweet (including pimento or pimiento) and a default processing factor of 10 for sweet pepper to dried chilli pepper derived in 2004.

Mango

GAP for mango in Thailand is foliar spraying at rates of 0.0105 kg ai/hl with a PHI of 7 days. In corresponding field trials conducted in Thailand residues of fenvalerate, sum of isomers in mangos (whole fruit) were (n = 4): 0.3, 0.35, 0.43, 0.48 mg/kg.

The Meeting estimated a maximum residue level, an STMR and an HR of 1.5 mg/kg, 0.39 mg/kg and 0.48 mg/kg for fenvalerate in mango, respectively.

Chinese kale

The GAP for Chinese kale in Thailand is foliar applications at rates of 0.021 kg ai/hL with a PHI of 7 days. In corresponding field trials conducted in Thailand residues of fenvalerate, sum of isomers in Chinese kale were (n = 6): 0.36, 0.36, 0.7, 0.92, 1.0, 1.8 mg/kg.

The Meeting noted that Chinese kale belongs to the Chinese broccoli commodity (VB 0401) within the Codex Classification of foods and animal feeds.

The Meeting estimated a maximum residue level, an STMR and an HR of 3 mg/kg, 0.81 mg/kg and 1.8 mg/kg for fenvalerate in Chinese broccoli, respectively.

RESIDUES IN ANIMAL COMMODITIES

Since mango and Chinese kale are not potential animal feed items, it was concluded that no evaluation of residues in livestock was needed.

RECOMMENDATIONS

Definition of the residue (for compliance with MRL and for estimation of dietary intake, plant and animal commodities): *sum of fenvalerate isomers.*

The residue is fat-soluble.

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 assessment.

CCN	Commodity	MRL, mg/kg		STMR or STMR-P, mg/kg	HR or HR-P, mg/kg
		New	Previous		
AL 1020	Alfalfa fodder	W	20		
VP 0062	Beans, shelled	W	0.1		
VP 0061	Beans, except broad beans and soya beans	W	1		
FB 0018	Berries and other small fruits	W	1		
VB 0400	Broccoli	W	2		
VB 0401	Broccoli, Chinese	3		0.81	1.8
VB 0402	Brussels sprouts	W	2		
VB 0041	Cabbages, head	W	3		
VB 0404	Cauliflower	W	2		
VX 0624	Celery	W	2		
GC 0080	Cereal grains	W	2 (Po)		
FS 0013	Cherries	W	2		
	Chinese cabagge (type Pak-choi)	W	1		
FC 0001	Citrus fruit	W	2		
SO 0691	Cotton seed	W	0.2		
OC 0691	Cotton seed oil, Crude	W	0.1		
OR 0691	Cotton seed oil, Edible	W	0.1		
VC 0424	Cucumber	W	0.02		
	Dried chili pepper	W	5		
MO 0105	Edible offal (mammalian)	W	0.02		
VL 0480	Kale	W	10		
FI 0341	Kiwifruit	W	5		
VL 0482	Lettuce, head	W	2		
FB 0275	Mango	1.5	-	0.39	0.48
MM 0095	Meat (from mammals other than marine mammals)	W	1 (F)		
VC 0046	Melons, except watermelons	W	0.2		
ML 0106	Milks	W	0.1		
FS 0247	Peach	W	5		
SO 0703	Peanut, whole	W	0.1		
VP 0064	Peas, Shelled (succulent seeds)	W	0.1		
VO 0445	Peppers, Sweet (including pimento or pimiento)	W	0.5		
FP 0009	Pome fruit	W	2		
VR 0075	Root and tuber vegetables	W	0.05		
VD 0541	Soya bean (dry)	W	0.1		
VC 0431	Squash, summer	W	0.5		
SO 0702	Sunflower, seed	W	0.1		
VO 0447	Sweet corn (corn-on-the-	W	0.1		

CCN	Commodity	MRL, mg/kg		STMR or STMR-P, mg/kg	HR or HR-P, mg/kg
		New	Previous		
	cob)				
VO 0448	Tomato	W	1		
TN 0085	Tree nuts	W	0.2		
VC 0432	Watermelon	W	0.5		
CM 0654	Wheat bran, unprocessed	W	5 (Po)		
CF 1211	Wheat flour	W	0.2 (Po)		
CF 1212	Wheat wholemeal	W	2 (Po)		
FC 0433	Winter squash	W	2		

DIETARY RISK ASSESSMENT

Long-term intake

The evaluation of fenvalerate resulted in recommendations for MRLs and STMR values for mango and broccoli. Where data on consumption were available for the listed food commodities, dietary intakes were calculated for the 13 GEMS/Food Consumption Cluster Diets. The results are shown in Annex 3 of the 2012 JMPR Report.

The IEDIs in the thirteen Cluster Diets, based on the estimated STMRs were 0-1% of the maximum ADI (0.02 mg/kg bw). The Meeting concluded that the long-term intake of residues of fenvalerate from uses that have been considered by the JMPR is unlikely to present a public health concern.

Short-term intake

The IESTI for fenvalerate calculated on the basis of the recommendations made by the JMPR represented 0–40% of the ARfD (0.2 mg/kg bw) for children and 0–20% for the general population. The results are shown in Annex 4 of the 2012 JMPR Report.

The Meeting concluded that the short-term intake of residues of fenvalerate resulting from uses that have been considered by the JMPR is unlikely to present a public health concern.

REFERENCES

Number	Author	Year	Title, Report-No.
Fenval_001	Chukiatwatana, Lamai	2008	Report on Pesticide Residue Trial, Part A, Field Report, Agricultural Toxic Substances Division Department of Agriculture Chatuchak, Bangkok 10900, Thailand
Fenval_002	Chaiyanboon, Panida	2005	Report on Pesticide Residue Trial, Part A, Field Report, Agricultural Toxic Substances Division Department of Agriculture Chatuchak, Bangkok 10900, Thailand