Australian Government

Australian Pesticides and Veterinary Medicines Authority

FENTHION

VETERINARY RESIDUES AND DIETARY EXPOSURE ASSESSMENT

A component of the reconsideration of the active constituent Fenthion, registration of products containing Fenthion and approvals of their associated labels.

MAY 2014

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Fenthion is a broad spectrum organophosphorus (OP) insecticide. Fenthion is used to control insect pests in agricultural, commercial and domestic situations and external parasites on cattle. Fenthion is also used to control pest birds in and around buildings.

The APVMA commenced the review of fenthion in 1998. The review scope included the toxicology, occupational health and safety, residues, dietary exposure and trade aspects of the active constituent approvals, product registrations and label approvals for fenthion.

The APVMA has also considered whether product labels carry adequate instructions and warning statements.

This component of the review includes the findings of the residues and dietary exposure assessment for the one fenthion product that is used on cattle to control lice, Tiguvon Spot-On Cattle Lice Insecticide (APVMA Number 33520).

Data Provided

Residues and metabolism data have been provided by Bayer CropScience and Bayer Animal Health in support of the review of fenthion. Studies have been submitted to the APVMA since 1999 and these include animal metabolism studies and animal residue data.

Conclusions and recommendations

In relation to the residues evaluation of the veterinary product containing fenthion, it is concluded that:

1) Continued registration of Tiguvon Spot-On Cattle Lice Insecticide is not supported for the following reasons:

   a) The dietary exposure to fenthion residues at the current MRLs may result in the Acceptable Daily Intake (ADI) being exceeded when food containing fenthion residues from cattle treated with Tiguvon Spot-On Cattle Lice Insecticide is consumed.

   b) In order to reduce the dietary exposure, lower MRLs need to be established. However, the submitted residues data do not enable the establishment of a meat withholding period (WHP) or a minimum re-treatment interval for Tiguvon Spot-On Cattle Lice Insecticide at lower MRLs.

2) As the continued registration of Tiguvon Spot-On Cattle Lice Insecticide is not supported the MRLs in cattle commodities are no longer relevant. It is recommended that the existing MRLs for fenthion in cattle should be deleted from Table 1 of *the MRL Standard*.

3) Fenthion is currently not registered for use in poultry, pigs and sheep so the existing MRLs in these animal commodities are no longer relevant. Therefore, it is recommended that the existing MRLs for fenthion in poultry, pigs and sheep should be deleted from Table 1 of the MRL Standard.

Standards

Upon completion of the review of fenthion, the following amendments should be made to the *MRL Standard*. These changes will also be recommended for inclusion in Food Standards Australia New Zealand (FSANZ) *Food Standards Code.*

Table 1 Recommended deletions from *Table 1 of the MRL Standard*

COMPOUND	FOOD		MRL (mg/kg)
FENTHION			
DELETE			
	MO 0812	Cattle, Edible offal of	1
	MM 0812	Cattle meat	1
	PE 0112	Eggs	*0.05
	ML 0106	Milks	T0.2
	PO 0111	Poultry, Edible offal of	*0.05
	PM 0110	Poultry meat	*0.05
	MO 0818	Pig, Edible offal of	0.5
	MM 0818	Pig meat	0.5
	MO 0822	Sheep, Edible offal of	0.2
	MM 0822	Sheep meat	0.2

1 INTRODUCTION

1.1 Background to this review

In 1998 the APVMA (formerly the NRA) began a review of fenthion as part of the former Existing Chemical Review Program. Fenthion was nominated for review because of concerns about public health, occupational health and safety, the environment and food residues. Residues data for veterinary products were received in 1999 and evaluated to determine whether these dietary exposure concerns were justified.

Fenthion (O,O-dimethyl O-4-methylthio-m-tolylphosphorothioate) is a broad spectrum organophosphorus compound. Fenthion may be absorbed through the skin, from the gastrointestinal tract or by inhalation. Once metabolised to the more toxic oxygen analogue, it acts principally by binding to and inhibiting acetylcholineesterase, affecting the nerve function in insects, humans and many other animals.

By its legislation, the APVMA must be satisfied that the use of fenthion *would not be an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues*[1] . This report considers the residues data submitted to support the current registered uses of fenthion in food producing animals and the impact of those residues on the dietary exposure to consumers.

1.2 Current Australian MRLs and residue definition

The current entries for fenthion in the *MRL Standard* that are relevant to the veterinary uses are listed below.

Table 2 Current entries in *Table 1 of the MRL Standard*

COMPOUND		FOOD	MRL (mg/kg)
FENTHION			
MO	0812	Cattle, Edible offal of	1
MM	0812	Cattle meat	1
PE	0112	Eggs	*0.05
ML	0106	Milks	T0.2
PO	0111	Poultry, Edible offal of	*0.05
PM	0110	Poultry meat	*0.05
MO	0818	Pig, Edible offal of	0.5
MM	0818	Pig meat	0.5

[1] AgVet Chemical Code Act 1994 Section 34 (1) (a)(i)

COMPOUND		FOOD	MRL (mg/kg)
MO	0822	Sheep, Edible offal of	0.2
MM	0822	Sheep meat	0.2

Table 3 Current entries in *Table 3 of the MRL Standard*

COMPOUND	RESIDUE
FENTHION	Sum of fenthion, its oxygen analogue, and their sulfoxides and sulfones, expressed as fenthion

Fenthion is currently not registered for use in poultry, pigs and sheep so the existing MRLs in these animal commodities are no longer relevant. Therefore, it is recommended that the existing MRLs for fenthion in poultry, pigs and sheep should be deleted from Table 1 of the *MRL Standard*.

1.3 Toxicological information

The Office of Chemical Safety, Department of Health and Ageing (OCS), has reviewed the available toxicology data for fenthion and confirmed the Acceptable Daily Intake (ADI) of 0.002 mg/kg bw/d. The OCSEH has also recommended an acute reference dose (ARfD) of 0.007 mg/kg bw be established for fenthion.

Table 3 Relevant health standards

COMPOUND	DIETARY STANDARD, mg/kg bw		NO OBSERVABLE EFFECT LEVEL (NOEL), mg/kg bw	SAFETY FACTOR	REFERENCE (OCS, DATE)
Fenthion	ADI	0.002	0.02	10	Nov 2008
	ARfD	0.007	0.07	10	Nov 2008

1.4 Label and maximum treatment regime for currently registered products

Currently, the only veterinary product containing fenthion that is registered for use on animals is Tiguvon Spot-On Cattle Lice Insecticide (APVMA Number 33520).

The maximum treatment regime for cattle for Tiguvon Spot-On Cattle Lice Insecticide is tabulated below:

ANIMAL	PURPOSE	DOSE RATE	CRITICAL COMMENTS
Cattle	For the control of biting and sucking lice	Up to 100 kg bw: 2.5 mL (500 mg fenthion) 110 kg to 220 kg bw: 5 mL (1000 mg fenthion) 220 kg to 550 kg bw: 10 mL (2000 mg fenthion) Over 550 kg: 20 mL (4000 mg bw fenthion) Maximum dose rate: 10 mg/kg bw for a 50 kg calf (not less than 2 weeks of age) treated with 2.5 mL of product	Apply to the rump or loins of the animal in one spot. May be used on pregnant cows
Restraints	DO NOT apply to calves less than 2 weeks old.		
Withholding periods	MEAT: DO NOT APPLY later than 10 days before slaughter for human consumption. MILK: DO NOT USE in lactating cows where milk or milk products may be used for human consumption		
Export Slaughter Interval	DO NOT USE less than 21 days before slaughter for export. The ESIs on this label were correct at the time of label approval. Before using this product, confirm the current ESI from the manufacturer on [Customer Information Line 1800 678 368 Monday to Friday 9am to 4pm EST] or the APVMA website (www.apvma.gov.au/residues/ESI.shtml)		

2 BIBLIOGRAPHY OF DATA

Residues and metabolism data have been provided by Bayer CropScience and Bayer Animal Health in support of the review of fenthion. Studies were submitted to the APVMA in 1999 and 2002 and these include animal metabolism studies and animal residue data.

Residues data relating only to the current registered veterinary use pattern has been considered in this evaluation. The following data were relied on for this veterinary residues assessment.

DATA TYPE	APVMA DATA NO.	BAYER DATA NO.	STUDY TITLE	AUTHORS	STUDY DATE
Residues	1753	32/33	Tissue Residues In Cattle.	Cox, D.	1971
Residues	1731	25	Residues In Cattle Tissues - Back fat. Report No. 41769	Anon	1974
Residues	1728	26	Residues In Cattle Tissues. Report No. 30905	Anon	1971
Residues	1729	27	Residues In Cattle Tissues. Report No. 28719	Anon	1970
Residues	1737	36	To Determine The Residues Of Fenthion In Renal Fat Tissue Of Cattle 21 Days After Treatment With Fenthion (Tigovon®) Spot On,	Gyr P	1996
Residues	1736	38	Pesticide Residues In Export Beef. Part 3. Cattle Lousicides. MRC Food Safety Program	Kearnan JF	1996
Analytical methods	1705	251	Determination of Fenthion Residues in Animal tissues by thermionic emission flame gas chromatography. Report Number 20420	JS Thornton	1968
Analytical methods	1814	14	Determination of Fenthion Residues in Animal tissues by thermionic emission flame gas chromatography. Report Number 20420	JS Thornton	1968

3 RESIDUES EVALUATION

3.1 Metabolism

The metabolism of fenthion in animals was first evaluated by JMPR in 1971 and was reviewed as part of the Codex Committee on Pesticides Residues Periodic Review Program in 1995 and this was considered adequate.

While relatively few pharmacokinetic studies have been performed in food producing species, the data are consistent with the pharmacokinetics of fenthion in rats and rabbits. Briefly, fenthion is

- rapidly absorbed following dermal application
- widely distributed in tissues with highest levels in fat, especially near the application site
- extensively metabolised
- eliminated mainly through the kidney.

In animals fenthion is mainly metabolised by oxidation to the sulfoxide, which has higher insecticidal activity than the parent compound, and subsequent oxidation to fenthion sulfone. Fenthion may also undergo oxidative desulfuration to form fenoxon. Five oxidative metabolites have been identified: fenthion sulfoxide, fenthion sulfone, fenoxon, fenoxon sulfoxide and fenoxon sulfone. No information has been submitted on the proportion of different metabolites in animal commodities, therefore it is not possible to determine a marker to total ratio for fenthion.

Further consideration of fenthion metabolism is not required within the scope of this review.

3.2 Analytical methods

Bayer CropScience Australia and Bayer Animal Health submitted methods for the analysis of fenthion in animal tissue commodities. Very few of these methods are contemporary. Review of the National Residue Survey (NRS) Annual Report Results shows that most laboratories use Gas Chromatography/Mass Spectrometry (GC/MS) or Liquid Chromatography/MS for the analysis of fenthion residues.. There are many methods currently in use across the world and throughout Australia and the evaluation of analytical methods was not required for this assessment of residues of fenthion arising from veterinary uses.

3.3 Residue definition

There are no proposed changes to the residue definition for fenthion. The residues definition of fenthion in commodities of animal origin is:
the sum of fenthion, its oxygen analogue, and their sulfoxides and sulfones, expressed as fenthion.

3.4 Residues in livestock

Fenthion MRLs for poultry, sheep and pig commodities

Fenthion is currently not registered for use in poultry, pigs and sheep, so the existing MRLs in these animal commodities are no longer relevant. Therefore, it is concluded that the existing MRLs for fenthion in poultry, pigs and sheep should be deleted from Table 1 of the MRL Standard unless it is necessary to maintain MRLs in some animal commodities as a result of residues in animal feeds being transferred to animals. These MRLs should be recommended by the Pesticides Residues component of the Fenthion Review, if they are required.

Current Fenthion MRLs for cattle commodities

Currently, the only veterinary product containing fenthion that is registered for use on animals is Tiguvon Spot-On Cattle Lice Insecticide (APVMA Number 33520). The relevant MRLs for cattle commodities are indicated below.

Table 4 Current entries in *Table 1 of the MRL Standard*

COMPOUND		FOOD	MRL (mg/kg)
FENTHION			
MO	0812	Cattle, Edible offal of	1
MM	0812	Cattle meat	1
ML	0106	Milks	T0.2

These MRLs were established using JMPR methodology and have been set in 'cattle meat' and edible offal'. The MRL for fenthion residues in milk is a temporary MRL. The metabolism data indicates that the target tissues for fenthion are fat and milk.

Fenthion residues in cattle tissues – meat WHP

For the purpose of this review, it is considered appropriate to re-evaluate the residues data for cattle. Contemporary standards require residue depletion trials to be conducted using the formulation that is to be marketed in Australia, and that animals must be treated in accordance with the critical use pattern specified on the label of the veterinary chemical product (Vet MORAG Part 5A, 2012).

A limited number of animal residues studies in cattle, performed using the currently registered use patterns, were provided in support of this review of fenthion. The currently registered use pattern for fenthion involves the administration of a maximum dose of 10 mg fenthion/kg bw topically in a spot-on formulation, with a 10 day meat WHP.

Residues data from studies where the spot-on formulation was administered, at a dose rate equal to or greater than the maximum dose rate, and where a validated analytical method was used to determine fenthion concentrations in tissues, are tabulated below.

Table 5 - Fenthion residues in cattle administered as a spot-on treatment

Rate (mg/kg bw)	Number	DAT	Fenthion residues (mg/kg)							
			Omental fat		Back fat (treated area)		Back fat (untreated area)		Renal fat	
			Range	Median	Range	Median	Range	Median	Range	Median
17.7	2	28	0.28-0.40	--	--	--	--	--	0.08-0.43	--
17.7	3	35	--	--	0.05	0.05	0.03-0.04	0.03	--	--
	3	42	--	--	0.01-0.05	0.04	0.01-0.05	0.03	--	--
11.8*	3	35	--	--	0.01-0.03	0.03	--	--	--	--
	3	45	--	--	0.02-0.07	0.03	--	--	--	--
17.7*	3	35	--	--	0.03-0.09	0.04	--	--	--	--
	3	45	--	--	<0.01-0.09	0.06	--	--	--	--
17.7	2	28	--	--	0.09-0.47	--	0.09-0.46	--	--	--
Rate (mg/kg bw)	Number	DAT	Renal/ omental fat		Muscle		Kidney		Liver	
			Range	Median	Range	Median	Range	Median	Range	Median
17.7	2	28	--	--	--	--	--	--	--	--
17.7	3	35	0.06-0.07	0.06	--	--	--	--	<0.03	--
	3	42	0.06-0.07	0.06	--	--	--	--	<0.03	--
11.8*	3	35	--	--	--	--	--	--	--	--
	3	45	--	--	--	--	--	--	--	--
17.7*	3	35	--	--	--	--	--	--	--	--
	3	45	--	--	--	--	--	--	--	--
17.7	2	28	--	--	0.02-0.04	--	0.03-0.05	--	0.01-0.02	--

DAT – Days after treatment;* two applications, one month apart

DISCUSSION

TRIAL DESIGN

Animal numbers and sampling times: The trials did not meet contemporary standards in number of animals per sampling time and the number of sampling times. Also only limited tissue samples were collected, with no study collecting and analysing all edible tissues. As the first sampling time is 28 days after treatment, this data does not support a 10 day meat WHP.

Dose rate: The currently approved label indicates that the maximum dose rate administered is 10 mg fenthion/ kg bw. None of the treatment groups were treated at this dose rate and the formulation for the product used to generate the data was not supplied.

FENTHION RESIDUES IN EDIBLE TISSUES

When cattle were administered at least 10 mg fenthion/kg bw topically in a spot-on formulation it was found that:

- Highest fenthion residues in omental fat of 0.40 mg/kg occurred at 28 days after treatment (first sampling time). Omental fat was only sampled in two animals at one sampling time and at both these times was above the proposed fat MRL of 0.1 mg/kg. Therefore, these data do not enable a meat WHP to be determined for *Tiguvon Spot-On Cattle Lice Insecticide.*
- Highest fenthion residues in renal fat of 0.43 mg/kg occurred at 28 days after treatment (first sampling time). Renal fat was only sampled in two animals at one sampling time and at both these times was above the proposed fat MRL of 0.1 mg/kg. Therefore, these data do not enable a meat WHP to be determined for *Tiguvon Spot-On Cattle Lice Insecticide*.
- Highest fenthion residues in muscle of 0.04 mg/kg occurred at 28 days after treatment. Muscle was only sampled in two animals at one sampling time. Review of the data indicates that both these values were below the proposed muscle MRL at 28 days after treatment.
- Highest fenthion residues in kidney of 0.05 mg/kg occurred at 28 days after treatment. Kidney was only sampled in two animals at one sampling time. Review of the data indicates that both these values were below the proposed kidney MRL at 28 days after treatment.
- Liver was sampled at 28, 35 and 42 days after treatment. Review of the data indicates that fenthion residues were below the proposed liver MRL at all sampling times.

CONCLUSION FENTHION RESIDUES IN EDIBLE TISSUE

As the data provided do not support the currently registered label instructions, no recommendations for use can be made. The Veterinary Residues Team is unable to recommend a meat WHP for Tiguvon Spot-On Cattle Lice Insecticide based on the submitted residues data

FENTHION RESIDUES IN MILK – MILK WHP

Tiguvon Spot-On Cattle Lice Insecticide is not currently approved for use on dairy cattle and the approved label bears the statement ‘DO NOT USE on lactating cows where milk or milk products may be used for human consumption’. Therefore a further consideration of milk WHPs is not required as part of this review of fenthion.

CONCLUSION: RESIDUES IN MILK

The use of Tiguvon Spot-On Cattle Lice Insecticide in dairy cattle is not supported by the submitted data. The VRT recommends the following statement be included under the restraints and milk withhold period headings if this product registration is to continue:

> DO NOT USE on cows which are producing or may in the future produce milk that may be used or processed for human consumption

MINIMUM RE-TREATMENT INTERVAL

Part 5A Residues of the Vet MORAG states that if a repeat dosage regimen can be reasonably anticipated in practice, even if not specified on the product label, then repeat treatments should be assessed. The currently approved label for *Tiguvon Spot-On Cattle Lice Insecticide* does not contain instructions relating to the minimum re-treatment interval. In the absence of empirical data, the VRT establishes the minimum re-treatment interval as the time required for tissue residues to decline to below the method Limit of Quantitation (LOQ), thereby minimising the likelihood of residues accumulation. As the submitted data does not demonstrate that fenthion residues in fat are below the LOQ, with a 99% confidence interval, the VRT is unable to recommend an appropriate re-treatment interval for *Tiguvon Spot-On Cattle Lice Insecticide*.

Conclusion

Continued registration of Tiguvon Spot-On Cattle Lice Insecticide is not supported from a residues perspective. Therefore, fenthion MRLs in cattle commodities are no longer relevant. It is recommended that the existing MRLs for fenthion in cattle should be deleted from Table 1 of the MRL Standard.

3.5 Dietary Risk Assessment

Dietary exposure calculations

In July 2006 the APVMA adopted the Joint FAO/WHO Expert Committee on Food Additives (JECFA) approach to setting veterinary MRLs. Therefore, it is appropriate to calculate the level of dietary exposure to fenthion residues in cattle using the JECFA food basket. However, the APVMA retains its internally harmonised approach to estimating residue intakes for food safety assessment. Therefore, dietary exposure calculations also need to be performed using the FSANZ/APVMA-agreed protocol where the National Estimated Daily Intake (NEDI) is calculated using consumption figures from the 1995 Australian National Nutrition Survey.

The Office of Chemical Safety and Environmental Health, Department of Health has recommended an Acceptable Daily Intake (ADI) for fenthion of 0.002 mg/kg bw/day. The daily dietary exposure level to fenthion residues in cattle commodities is calculated using the Theoretical Maximum Daily Intake (TMDI). Utilising the TMDI ensures that residue intake remains below the ADI at all times. Dietary exposure calculations also need to be performed using the FSANZ/APVMA-agreed protocol where the NEDI is calculated. Dietary exposure calculations for fenthion residues in cattle commodities using the JECFA food basket (TMDI) and the FSANZ/APVMA-agreed protocol (NEDI) are compared below.

Table 6 Dietary exposure to fenthion residues incorporating current and projected cattle MRLs

Iteration	Projected cattle MRLs (mg/kg)					JECFA dietary exposure (% ADI)	Estimated NEDI using MRLs (% ADI)
	Muscle	Fat	Liver	Kidney	Milk		
Current	**1**	**1**	**1**	**1**	*0.2*	*666.67*	*182.3*
Case 1	0.1	0.1	0.1	0.1	0.2	291.67	126.1
Case 2*	0.1	0.1	0.1	0.1	0.01	54.17	18.7

* Case 2 is equivalent to recent US tolerances for fenthion

The appropriate MRLs for fenthion in cattle are the highest permissible residue concentrations for each edible tissue when dietary exposure to fenthion residues, using the FSANZ/APVMA-agreed protocol and JECFA methodology does not exceed the Australian ADI (0.002 mg/kg bw/day).

Conclusion - MRLs

The currently approved MRLs are not appropriate and should be removed from the MRL Standard. Although the above table notes that when using both the FSANZ/APVMA-agreed protocol and the JECFA food basket, dietary exposure to fenthion residues through consumption of edible tissues and milk from cattle treated with fenthion does not exceed the Australian ADI when calculated using Case 2 there are insufficient residues data to establish acceptable MRLs for this product.

This review recommends that the existing MRLs for fenthion in poultry, pigs, sheep and cattle be deleted from Table 1 of the MRL Standard and that continued product registration is not supported. Therefore, a further assessment of the dietary intake of fenthion arising from veterinary uses is not required.

The assessments of dietary exposure risks arising from horticultural uses of fenthion are included in the *Fenthion Residues and Dietary Risk Assessment Report September 2012* and the *Supplementary Fenthion Residues and Dietary Risk Assessment Report October 2013*. These reports are available from the APVMA website for the fenthion review www.apvma.gov.au/products/review/current/fenthion.php.

3.6 Residues Related Aspects of Trade

The continued registration of Tiguvon Spot-On Cattle Lice Insecticide is not supported from a residues perspective. Therefore, an assessment of the residues related trade aspects for this product is not required.

4 CONCLUSIONS AND RECOMMENDATIONS

In relation to the residues evaluation for the Chemical Review of Fenthion, it is concluded that:

- Continued registration of *Tiguvon Spot-On Cattle Lice Insecticide* is not supported from a residues perspective.
- The existing MRLs for fenthion in poultry, pigs, sheep and cattle should be deleted from Table 1 of the *MRL Standard.*

4.1 Amendments to the *MRL Standard*

Upon completion of the review of fenthion, the following amendments should be made to the *MRL Standard*. These changes will also be recommended for inclusion in FSANZ's *Food Standards Code*.

Table 7 Recommended deletions from *Table 1 of the MRL Standard*

COMPOUND	FOOD		MRL (mg/kg)
FENTHION			
DELETE			
	MO 0812	Cattle, Edible offal of	1
	MM 0812	Cattle meat	1
	PE 0112	Eggs	*0.05
	ML 0106	Milks	T0.2
	PO 0111	Poultry, Edible offal of	*0.05
	PM 0110	Poultry meat	*0.05
	MO 0818	Pig, Edible offal of	0.5
	MM 0818	Pig meat	0.5
	MO 0822	Sheep, Edible offal of	0.2
	MM 0822	Sheep meat	0.2

ABBREVIATIONS

ADI	Acceptable Daily Intake (for humans)
APVMA	Australian Pesticides and Veterinary Medicines Authority
ARfD	Acute Reference Dose (for humans)
bw	bodyweight
d	day
EMA	European Medicines Agency
ESI	Export Slaughter Interval
g	gram
JECFA	Joint FAO/WHO Expert Committee on Food Additives
kg	kilogram
L	litre
LOQ	Limit of Quantitation – level at which residues can be quantified
mg	milligram
mL	millilitre
MRL	Maximum Residue Limit
NEDI	National Estimated Daily Intake
NOEL	No Observable Effect Level
NRS	National Residue Survey
VRT	Veterinary Residues Team (within the APVMA)