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Pesticide risk profile for the feeding of cereal grain to cattle and sheep

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# Abbreviations

ai	active ingredient
APVMA	Australian Pesticide and Veterinary Medicines Authority
bw	body weight
DM	dry matter
ECRP	Existing Chemical Review Program
EU	European Union
F	MRL is based on the residue in the fat portion of the tissue
FAO	Food and Agriculture Organisation of the United Nations
g	gram
GAP	good agricultural practice
ha	Hectare
HAFT	Highest average field trial
JMPR	Joint Meeting on Pesticide Residues
kg	Kilogram
LOD	Limit of detection for the analytical method, sometimes also used for
	limit of determination which is the same as LOQ
LOQ	limit of analytical quantitation
mbyp	meat by products
mg	milligram = 0.001 grams
MRL	maximum residue limit
Ν	Negligible residue (when next to US MRL)
PAFC	primary animal feed commodity
PHI	pre-harvest interval
Pow	octanol water partition coefficient
ppm	parts per million = mg/kg
PSD	Pesticide Safety Directorate
TF	transfer factor = concentration in animal tissue or milk divided by
	concentration in feed
TRR	total radioactive residue
US EPA	United States of America Environmental Protection Agency
WHP	withholding period
*	before MRL indicates that the residue is at or about the LOQ, <i>i.e.</i>
	should be less than the LOQ.

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## Potential for violative residues in cattle and sheep fed cereal grain

Chemical residues in animal feeds may be transferred to the tissues of livestock on feeding. While it is unlikely that the chemical residues present in meat and offal arising from feeding represent a concern regarding food safety they can result in disruption to trade where the relevant Australian and overseas market standards differ.

The observation of chemical product withholding periods does not guarantee that the chemical residues in the feed are such that when fed to livestock, the residues in meat and offal will meet export market requirements.

The aim of the current report is to profile the risk of violative residues in export meat and edible offal posed by the presence of pesticide residues in cereal grain and processed by-products fed to cattle and sheep.

## Assessment of currently registered chemicals that may be used on cereal crops

Estimates of residues in livestock tissues and milk are usually made on the basis of the propensity of a chemical to transfer to tissues and milk combined with anticipated animal dietary exposure.

Most experiments in the area of transfer of pesticide residues to animal tissues and milk following ingestion have been designed based on the requirements of regulators. The relevant studies required are livestock metabolism studies (lactating goat or dairy cow) and animal transfer (feeding) studies.

The feeding studies are used to determine transfer factors (TF) that are defined as the ratio of the pesticide residue in the tissue or commodity of interest (fat, muscle, liver, kidney or milk) to the residue in the diet (expressed on a dry matter intake basis).

In utilizing transfer factors derived from feeding or metabolism studies for risk assessment management purposes, the user needs to be aware of the limitations and assumptions used. The TF derived is dependent on the duration of the feeding or dosing, the concentration in the feed or dose level, the nature of the feed (if added to the feed), lactational status, bodyweight, age, sex and breed of the animal studied. For chemicals administered as a mixture, the presence of other chemicals may alter the metabolism and/or rate of excretion by induction of the various routes of decontamination. The duration of a feeding study required for the steady state concentration to be reached in tissue or milk is a function of the elimination half-life. Residue definitions set by different regulators are not always the same and residue definition is a factor that should also be taken into account when utilizing TF for managing residue risks and trade. Care must be taken in extrapolating TFs from goat metabolism studies to all ruminants as is demonstrated by endosulfan, for which the residue definition is the sum of  $\alpha$ -endosulfan,  $\beta$ -endosulfan and endosulfan sulphate, where only low levels of residues are found in goats but significant transfer to tissues occurs for cattle<sup>1,2</sup>.

<sup>&</sup>lt;sup>1</sup> Indraningsih, McSweeney, C.S. & Ladds, P.W. (1993) Residues of endosulfan in the tissues of lactating goats. *Aust. Vet. J.*, **70**, 59-62.

<sup>&</sup>lt;sup>2</sup> Reregistration Eligibility Decision for Endosulfan Case No. 0014 EPA 738-R-02-013 November 2002 Environmental Protection Agency, Office of Pesticide Programs, Special Review and Reregistration Division. (http://cfpub.epa.gov/oppref/rereg/status.cfm?show=rereg)

The transfer factors utilised here were calculated from residues reported in the scientific literature using the highest individual animal tissue divided by the nominal feed level. If the highest residue was not reported the average residue divided by the nominal feed level were used instead. In the case of milk the average residue was divided by the nominal feed level.

For the purposes of profiling risk conservative estimates of animal dietary burden (intake) are required. The APVMA "Stockfeed Guideline Document 1 Primary Feed Commodities As A Proportion of Livestock Diets" (Version 1.1 March 2002)<sup>3</sup> lists the maximum proportion of cereal grain included in animal feed as 100%. Estimates of residues in cereal grain were obtained from scaling of literature studies, MRLs or based on conservative assumptions. The dietary burden is then the residue in crop × maximum proportion in the diet. To overcome errors that may result from differences in moisture contents of feed items it is accepted practice to calculate dietary burdens for a ration on a dry matter basis. As cereal grains contain approximately 90% dry matter it was not considered necessary to correct for moisture content.

The estimated residue in animal commodities is:  $Residue = TF \times dietary \ burden \ [ppm DM \ basis]$ 

Unless stated otherwise, the following assumptions have been used in the risk assessment:

- The cereals are harvested according to good agricultural practice (label) and that the grain is derived at this time.
- The crop has been treated at the maximum rate and with the shortest interval between application and harvest permitted by the product label<sup>4</sup>.
- The maximum rate of incorporation in the ration/diet is 100%.
- That residue transfer for cattle is greater than for sheep and therefore that the transfer factors estimated from cattle feeding studies are applicable to sheep.

The potential for violative residues in animals is assessed against the Australian, Codex and US tolerances as listed in February  $2010^5$ . Other markets may have different standards however, for the bulk of Australian meat exports it is assumed that if the lower of these tolerances (or the LOQ of the analytical method if no Codex or US tolerance exists) can be met, the feeding of cereal grain will not pose an unacceptable risk.

Appendix 1 provides the details of a risk assessment for each of the compounds registered in Australia for use on cereals. The conclusion of the analysis is the risk of residue violations in meat and edible offal posed by the feeding of cereal grain and processed by-products treated with currently registered products is low for the majority of chemicals.

Based on the available information, the following pesticides are identified as requiring further investigation and/or the development of additional risk management strategies:

Pesticide	Tissue	Residue (mg/kg)		e Residue (mg/kg) Decline information locate		mation located
		Estimated <sup>1</sup>	Target <sup>2</sup>	Crop	Animal	
Bifenthrin	Fat	0.3-0.6	0.5	Yes	No	
Chlormequat	Kidney/liver	0.07	0.01	No	Yes	

<sup>3</sup> <u>http://www.apvma.gov.au/residues/Stockfeed\_Guideline\_1.pdf</u>

<sup>&</sup>lt;sup>4</sup> In general, only one or two product labels were selected per pesticide. There is a possibility that the maximum permitted rate may be higher than identified.

<sup>&</sup>lt;sup>5</sup> MRLs and approved use patterns change with time. The assessments include the most recent decisions of the Codex Alimentarius Commission (32<sup>nd</sup> Session, July 2009) with regard to Codex MRLs, US tolerances as listed in the Code of Federal Regulations at February 2010 and MRLs as they appear in Table 1 of the APVMA *MRL Standard* as at February 2010.

Pesticide	Tissue	Residue (mg/kg)		e Residue (mg/kg) Decline information loc		mation located
		Estimated <sup>1</sup> Target <sup>2</sup>		Crop	Animal	
Diclofop-methyl	Kidney	0.09	0.01	Yes	No	

residue in tissue estimated using assumptions outlined above

 $^{2}$ target residue = lowest of Australian, Codex and US MRL or in absence of these the LOQ (often assumed to be 0.01 mg/kg)

The current assessment has only identified pesticides of concern and not considered industry based QA programs that address the potential for residues in animal feeds to transfer to animals and mitigate risks; The National Vendor Declaration (NVD) form for traded livestock and the Commodity Vendor Declaration (CVD) and By-product Vendor Declaration (BVD) forms which are used for traded livestock feedstuffs.

# Appendix 1

#### 2,2-DPA (2,2-dichlorpropionic acid also known as dalapon)

- is a systemic herbicide used for the control of annual and perennial grasses and rushes. It is registered on a variety of crops including potential animal feeds sunflower, *maize*, soybean and pastures. The application rate for maize is 3.7 kg ai/ha (spray between rows). No harvest WHP is required.

There are no Codex or USA MRLs for 2,2-DPA in animal tissues. The critical Australian MRL is 0.2 mg/kg for meat (mammalian) and \*0.1 mg/kg for milks. Residues are not expected in maize at harvest (MRL for cereal grains \*0.1 mg/kg). Therefore no residues are expected to result from the feeding of maize forage or fodder to animals. Dalapon and all of its known breakdown products dissolve easily in water. They are readily washed from cells and tissues. Because dalapon is insoluble in organic solvents and lipids, it does not build up in animal tissues<sup>6,7</sup>.

It is anticipated that animal product residues will be below typical method LOQs.

#### <u>2,4-D</u>

- is a selective herbicide used widely for the control of weeds. It is registered on a variety of crops including potential animal feeds pasture and cereals. Application to *barley, rye, wheat, oats* and *triticale* is 0.85 kg ai/ha when made up to the boot stage of crop growth. A rate of 1.05 kg ai/ha is permitted for use on stubble of winter cereals and maize prior to direct drilling and sowing and to winter cereals, maize and sorghum when applied as a harvest aid or salvage spray with application at the dough stage.

No harvest WHP is required.

There are Australian, Codex and USA MRLs for 2,4-D in animal tissues however, the residue definitions that apply differ. The residue definition for Codex and Australia is parent compound. For the USA the residue definition is the sum of 2,4-D and 2,4-DCP. This added complication potentially makes comparison of the respective MRLs more difficult. The Australian MRLs are 0.2 mg/kg for meat (mammalian), 2 mg/kg for edible offal (mammalian) and \*0.05 mg/kg for milks. The critical USA tolerance is 4 mg/kg for kidney while the MRL for milk is 0.05 mg/kg. The critical Codex tolerances are 5 mg/kg for edible offal, 0.2 mg/kg for meat (mammalian) while the MRL for milk is 0.01 mg/kg. The Australian MRL for cereal grains is 0.2 mg/kg.

In an animal transfer study cows were dosed at the equivalent of 1446, 2890, 5779 and 8585 ppm in the diet for 28 days<sup>8</sup>. Residues in liver, kidney, muscle and fat for the 1446 ppm group were 0.2, 6.5, 0.24 and 0.51 mg/kg respectively. Assuming cereal grain has residues at the same level as the MRL (0.2 ppm) and using TFs from the 1446 ppm feeding study, anticipated residues in kidney and fat from feeding at 100% of the diet are  $0.2 \times 0.0045 = 0.0009$  mg/kg and  $0.2 \times 0.00035 = 0.00007$  mg/kg respectively. The LOQ for tissues was reported to be 0.05 mg/kg. The TF for milk is 0.00006 (2890 ppm feed level) giving an anticipated residue in milk of  $0.2 \times 0.0006 = 0.000012$  mg/kg.

<sup>&</sup>lt;sup>6</sup> Kuhnert M, Freytag B, Freytag HH, Fuchs V. (1992) [The tolerance and residue accumulation of sodium-2,2-dichloropropionate (Dalapon) administered over 90 days to dairy cows] *Dtsch Tierarztl Wochenschr*. 99 (4), 148-51. German.

<sup>&</sup>lt;sup>7</sup> Fertig, S. N.; Schreiber, M. M. (1961). Effects Of Herbicide Ingestion. Effect of dalapon ingestion on performance of dairy cattle and levels of residue in the milk. *J. Ag. Food Chem.* 9:369

<sup>&</sup>lt;sup>8</sup> 1998 JMPR - Pesticide Residues in Food - 1998 Evaluations, Part I Residues FAO Plant Production and Protection Paper 152/1. FAO and WHO 1999

# <u>2,4-DB</u>

- is a selective herbicide used widely for the control of weeds. It is registered on a variety of crops including potential animal feeds pasture and. Application to *barley*, *wheat* and *oats* undersown with lucerne, medic or subterranean clover is at 1.6 kg ai/ha

There are Australian but no Codex or USA MRLs for 2,4-DB in animal tissues. The Australian MRLs are 0.2 mg/kg for meat (mammalian) and edible offal (mammalian) and \*0.05 mg/kg for milks. The Australian MRL for cereal grains is \*0.02 mg/kg.

The US residue definition for plant commodities is the sum of 2,4-DB and its metabolite 2,4-D.

It is anticipated that animal product residues will be below typical method LOQs.

# alpha-Cypermethrin

- is a synthetic pyrethroid insecticide used for the control of various insects in crops. The application rates for cereals are reported in the table below together with the harvest WHPs and any label feeding restraints.

Сгор	Rate (g ai/ha)	Harvest	Feeding restraints
		WHP	
Winter cereals	24	7 days	14 days (stubble)
Maize	40	7 days	-
Rice	20	7 days	-
Sorghum	40	7 days	-

There are Australian, Codex and USA MRLs for cypermethrin in animal tissues. The relevant MRLs for cattle fat are 0.5, 0.2 and 1 mg/kg for Australia, Codex and the USA respectively. The respective milk MRLs are 1 [in the fat = 0.04 mg/kg whole milk], 0.05 F mg/kg and 2.5 mg/kg for Australia, Codex and the USA. The US also has separate MRLs for zeta cypermethrin of 1 mg/kg for cattle fat and 2.5 mg/kg in milk fat (reflecting a residue of 0.1 mg/kg in whole milk). There are Australian MRLs of 1 mg/kg for cereal grains (except wheat) and 0.2 mg/kg for wheat.

The TF for fat is  $0.1^{9,10}$ . If residues in cereal grain (except wheat) are present at the same level as the MRL, anticipated residues in fat are  $1 \times 0.1 = 0.1$  mg/kg if fed at 100% of the diet. Anticipated residues in whole milk (TF 0.003-0.1) are also 0.1 mg/kg.

Livestock residues are not anticipated to exceed international and/or domestic market standards.

# Aminopyralid

-is a herbicide used to control weeds in a variety of situations. The application rate for *barley, oats, wheat and triticale* is up to 7.5 g ai/ha.

No harvest WHP is required.

DO NOT graze or cut crops for stock food for 7 days after application.

ESI 3 days. EGI 42 days. EAFI 42 days.

 <sup>&</sup>lt;sup>9</sup> Chen-AW; Fink-JM; Letinski-DJ; Barrett-GP; Pearsall-JC (1997) Residue of cypermethrin and its major acid metabolites in milk and tissues from dairy bovines treated with cypermethrin. *J. Ag. Food Chem.* 45: 12, 4850-4855.
<sup>10</sup> 1981 JMPR Pesticide Residues in Food - 1981 Evaluations, FAO Plant Production and Protection Paper 42. FAO and WHO 1982 http://www.fao.org/ag/AGP/AGPP/Pesticid/Default.htm

There are Australian, Codex and US MRLs for aminopyralid in animal commodities. The Australian MRLs are 0.3 mg/kg for kidney, 0.03 mg/kg for other offal, \*0.0.1 mg/kg for meat and \*0.01 mg/kg for milk. The Codex MRLs are 1 mg/kg for kidney, 0.05 mg/kg for other offal, 0.1 mg/kg for meat and 0.02 mg/kg for milk. The US tolerances are 0.3 mg/kg for kidney, 0.02 mg/kg for fat, meat and other offal and 0.03 mg/kg for milk. The Australian MRL for cereal grains is 0.1 mg/kg, an MRL of 3 mg/kg for forage of cereal grains and an MRL of 0.2 mg/kg for cereal straw.

The APVMA reported: When applied to cereals at 7.5 - 10 g ai/ha (1×-1.3×) in Australia, residues of aminopyralid in grain collected at harvest, 80-117 days after treatment, were: ND (4), <LOQ (3), 0.01 (5), 0.02 (3), 0.03 (6), 0.04, 0.06, and 0.07 (3) mg/kg.

The 2006 JMPR reported: Groups of lactating dairy cows received the equivalent of 0, 32.8, 64.5, 181.5 and 644.7 ppm in the feed for 28 days. Following the dosing period, there was an additional depuration phase of 14 days, with slaughter intervals of 3, 7 and 14 days after withdrawal from dosing. Residues in whole milk following dosing at 32.8 ppm in the feed were < 0.01 mg/kg over the 28 days period. Residues reached plateau within 2 to 3 days of dosing. Residues in milk ranged <0.01-0.024 mg/kg and 0.011-0.028 mg/kg following dosing at 64.5 and 181.5 ppm, respectively. Aminopyralid residues ranged 0.023-0.127 mg/kg following dosing at 644.7 ppm. Residues had declined to < 0.01 mg/kg within 2 days of withdrawal from dosing at 32.8 ppm level of 644.7 ppm. The highest aminopyralid residues in tissues following dosing at 32.8 ppm level were: muscle < 0.01 mg/kg, fat 0.01 mg/kg, liver < 0.01 mg/kg, and kidney 0.1 mg/kg. Following dosing at 64.5 ppm, aminopyralid residues were < 0.01 mg/kg in muscle, 0.01 mg/kg in fat and liver and 0.2 mg/kg in kidney. The highest aminopyralid residues in tissues following dosing at 181.5 ppm level were 0.05 mg/kg in muscle and liver, 0.09 mg/kg in fat, and 1.5 mg/kg in kidney. The highest aminopyralid residues in tissues following dosing at 0.03 mg/kg in muscle, 0.04 mg/kg in fat, 0.06 mg/kg in liver, and 2.5 mg/kg in kidney.

It is anticipated that animal product residues will be below typical method LOQs.

#### Amitrole

-is a herbicide used to control weeds in a variety of situations. The application rate for *wheat* and *barley* is up to 1.4 kg ai/ha when used as part of the preparation for harvest. No harvest WHP is required.

There are Australian but no Codex or US MRLs for amitrole in animal commodities. The Australian MRLs, including milk, have all been set at \*0.01 mg/kg. The Australian MRL for cereal grains is \*0.01 mg/kg. As no residues are expected at harvest, no residues are expected in animals feeding on grain from treated crops.

The JMPR have stated<sup>11</sup> that "There do not appear to be any grounds for assuming that livestock grazing on plant materials growing on land that had been treated with amitrole for the control of weeds would absorb or retain significant amounts of amitrole or its metabolites".

It is anticipated that animal product residues will be below typical method LOQs.

#### Atrazine

- is a triazine herbicide used for the control of grass and weeds in crops such as sugarcane, maize, lupins, canola and sorghum. It is applied to *maize* and *sorghum* with an application rate of up to 3 kg ai/ha.

<sup>&</sup>lt;sup>11</sup> 1974 JMPR. Evaluations of some pesticide residues in food. FAO/AGP/1974/M/11; WHO Pesticide Residues Series No. 4, 1975

No harvest or grazing WHP is required.

There are no Codex animal tissue MRLs for atrazine. The US MRLs for animal tissues and milk are lower (0.02 mg/kg for cattle fat, mbyp, meat and milk) than the Australian MRLs of T\*0.1 mg/kg for edible offal mammalian and T\*0.01 mg/kg for milk. The Australian MRLs for sorghum and maize are \*0.1 mg/kg.

Feeding at 37.5 ppm in the diet for 28 days gave residues that were <0.01 mg/kg in milk and tissues at slaughter<sup>12</sup>. It is considered unlikely that detectable residues would result from the feeding of sorghum and maize grain with residues at or below the MRL to animals.

It is anticipated that animal product residues will be below typical method LOQs.

## Azimsulfuron

-is a herbicide used for control of aquatic broadleaf weeds and suppression of Barnyard grass in *rice*. Application is at up to 20 g ai/ha. A harvest WHP is not required. DO NOT graze or use for stockfeed for 2 weeks after application.

There are Australian but no Codex or US MRLs for animal commodities. The Australian MRLs for animal tissues and milk have been set at \*0.02 mg/kg. An Australian MRL has been set for rice grain at \*0.02 mg/kg and for rice straw and fodder (dry) at \*0.05 ppm.

The APVMA reported that "No animal feeding studies were included in the product submission. On the basis of non-detectable residues resulting in animal feed commodities (ie grain, forage, straw and fodder) following the proposed use on rice, it is unlikely that residues will be found in animal commodities. Metabolism studies conducted on rats show that azimsulfuron is rapidly absorbed and eliminated from animals. Following an oral dose of 1000 mg/kg of radiolabelled azimsulfuron, there was less than 1% of radioactivity remaining in the body after three days. The majority of the radioactivity was eliminated in the urine and faeces".

It is anticipated that animal product residues will be below typical method LOQs.

## Azoxystrobin

-is a strobulurin fungicide used for control of powdery mildew and rust in *barley* and *wheat* crops. Application is at up to 160 g ai/ha. The harvest WHP is 42 days.

DO NOT graze or cut for stock food for 21 days after application.

There are Australian and US but no Codex MRLs for animal commodities. The Australian MRLs for animal tissues have been set at \*0.01 mg/kg while the milk MRL is 0.005 mg/kg. The US MRLs for animal commodities are set at 0.03, 0.01 and 0.07 mg/kg for cattle fat, meat and meat by-products respectively and 0.006 mg/kg for milk. An Australian MRL has been set for barley and wheat at \*0.02 mg/kg, for barley and wheat forage at 10 ppm and for Barley and wheat straw and fodder (dry) at 3 ppm.

Residues in tissues of lactating cows were  $\leq 0.01 \text{ mg/kg}$  after feeding at levels up to 25 ppm in the diet for 28 days<sup>13</sup>. It is not considered likely that residues from feeding barley or wheat grain will exceed 0.01 mg/kg in tissues.

<sup>&</sup>lt;sup>12</sup> Atrazine Reregistration Eligibility Decision Residue Chemistry Considerations PC Code 080803; Case 0062 Environmental Protection Agency, Office of Pesticide Programs, Special Review and Reregistration Division

It is anticipated that animal product residues will be below typical method LOQs.

#### Bensulfuron-methyl

-is a selective herbicide used to control the weeds arrowhead, dirty dora and star fruit in *rice*. Application is at up to 51 g ai/ha with application early in the crop growth. A harvest WHP is not required.

There are no Australian, Codex or US MRLs for bensulfuron-methyl in animal commodities. There are Australian MRLs of \*0.02 mg/kg for rice and \*0.05 mg/kg for rice straw and fodder, dry.

The US EPA noted that<sup>14</sup> "Rice straw is fed to animals, thus exposure of humans to residues of rice straw might result if such residues are transferred to meat, milk, poultry, or eggs. However, based on the results of livestock metabolism studies in which no quantifiable residues were reported when feeding levels were approximately  $500 \times$  the potential dietary burden from feeding bensulfuron-methyl treated rice straw, the EPA has concluded that there is no reasonable expectation that measurable residues of bensulfuron-methyl will occur in meat or milk." The US MRL for rice is 0.02 mg/kg and for rice straw 0.3 mg/kg. This gives an estimated animal dietary burden of 0.038 ppm for the US (10% rice straw + 40% rice grain). It is estimated that the metabolism study was conducted at a feeding level of 19-20 ppm.

It is anticipated that animal product residues will be below typical method LOQs.

#### Bentazone

-is a benzathiadazole herbicide used for the control of dirty dora in rice. It may be applied to rice crops at 1 kg ai/ha.

A harvest WHP is not required.

Do not graze or cut for stock food for 7 weeks after application.

The Australian MRLs for tissues and milk are \*0.05 mg/kg. The Codex MRL for milk is \*0.05 mg/kg. The EU MRL for milk and cream is \*0.02 mg/kg. The Australian MRL for rice is 0.1 mg/kg. The MRLs for rice forage, fodder and straw are \*0.03 mg/kg.

Animal metabolism studies (5 to 8 day goat study, up to 1420 ppm) and a goat feeding study (35 days) at 75 and 150 ppm suggest that no detectable residues are expected with exposure of 10 to 15 ppm<sup>15</sup>. (TF for kidney was 0.04 and fat 0.002)

Note: the US EPA indicate that a lactating cow animal transfer study exists with feeding levels of 1, 5 and 20 ppm with <sup>14</sup>C bentazone and its 6 and 8-hydroxy metabolites<sup>16</sup>.

It is anticipated that animal product residues will be below typical method LOQs.

#### Benzofenap

<sup>&</sup>lt;sup>13</sup> APVMA Animal Residue Data Sheet – Azoxystrobin (October 2002)

http://www.apvma.gov.au/residues/stockfeed.shtml

<sup>&</sup>lt;sup>14</sup> [Federal Register: May 16, 1997 (Volume 62, Number 95)] [Notices] [Page 27033-27040] ENVIRONMENTAL

PROTECTION AGENCY [PF-734; FRL-5717-7] Notice of Filing of Pesticide Petitions

<sup>&</sup>lt;sup>15</sup> 1995 JMPR - Pesticide Residues in Food - 1995 Evaluations, Part I Residues FAO Plant Production and Protection Paper 137. FAO and WHO 1996

<sup>&</sup>lt;sup>16</sup> Reregistration Eligibility Decision Bentazon List A Case 0182EPA 738-R-94-029 September 1994 Environmental Protection Agency, Office of Pesticide Programs, Special Review and Reregistration Division

-is a selective pyrazole herbicide used to control weeds in rice. Application is at up to 0.6 kg ai/ha

There are no Australian, Codex or US MRLs for benzofenap in animal commodities. There are Australian MRLs of \*0.01 mg/kg for rice and \*0.02 mg/kg for rice straw and fodder, dry and for rice forage (green).

As no residues are expected in grain, none are expected in tissues of cattle and sheep.

It is anticipated that animal product residues will be below typical method LOQs.

#### Beta-cyfluthrin

- is a synthetic pyrethroid insecticide used for the control of various insects in crops. It is registered on *cereals* for the control of various insect pests. The application rate is up to 25 g ai/ha. The harvest WHP is 14 days.

There are Australian, USA and Codex MRLs for cyfluthrin. The relevant MRLs for cattle fat are 0.5, 1 and 2 mg/kg for Australia, Codex and the USA respectively. The relevant MRLs for cattle milk are 0.1, 0.04 and 5 mg/kg for milkfat (1 mg/kg in whole milk) for Australia, Codex and the USA respectively. There are Australian MRLs for cereal grains at 2 mg/kg and straw and fodder (dry) of cereal grains at 5 ppm. The US MRL for cereal grains is 4 ppm. The US has also established a range of MRLs for processed cereal products:

Barley, bran0.5 ppmCorn, field, milled byproducts0.05 ppmOat, bran0.5 ppmRice, bran6 ppmRice, hulls18 ppmRye, bran5 ppmWheat milled byproducts, except flour0.5 ppm

Residues in the animal diet from cereal grains would not be expected to lead to exposure of greater than 2 ppm in the diet. TF fat =  $0.05^{17}$ . Estimated residues in fat are  $2 \times 0.05 = 0.1$  mg/kg. The TF for milk is 0.005 giving anticipated residues of  $2 \times 0.005 = 0.01$  mg/kg.

Livestock residues are not anticipated to exceed international and/or domestic market standards following feeding with grain from treated crops.

#### Bifenthrin

- is a synthetic pyrethroid insecticide used for the control of various insects in crops. It is registered on *barley* and *wheat* for control of mites. The application rate is up to 20 g ai/ha. No harvest WHP is required.

There are Australian, Codex and USA MRLs for bifenthrin in animal tissues. The relevant MRLs for cattle fat are 2, 0.5 and 1 mg/kg for Australia, Codex and the USA respectively. The corresponding MRLs for milk are 0.5 mg/kg, \*0.05 mg/kg (cattle milk) and 1 mg/kg (milk fat, 0.1 mg/kg for whole milk). The Australian MRL for cereal grains is T2 mg/kg and for forage (green) of cereal grains 0.2 ppm and straw and fodder (dry) of cereal grains \*0.01 ppm.

Assuming residues in cereal grain are present at the MRL, the grain is fed at 100% of the diet and a maximum TF of  $0.3^{18}$  would give anticipated residues in fat of  $2 \times 0.3 = 0.6$  mg/kg.

<sup>&</sup>lt;sup>17</sup> 1998 JECFA Residues of some veterinary drugs in animals and foods. Forty-eighth meeting of the Joint FAO/WHO Expert Committee on Food Additives, 1998, FAO Food and Nutrition Paper 41/10

The TF for milk is 0.02 giving anticipated residues in milk of  $2 \times 0.02 = 0.04$  mg/kg.

Livestock residues may exceed international and/or domestic market standards.

# Bromoxynil

- is a selective herbicide used for the control of broad-leafed weeds in cereals (wheat, barley, oats and *triticale*). The application rate is up to 0.4 kg ai/ha with applications made from the three leaf to fully tillered stages of crop growth.

No harvest WHP is required.

There are no Codex animal tissue MRLs for bromoxynil. The Australian residue definition for bromoxynil is parent compound while the US definition includes a metabolite. The US MRLs for animal tissues and milk are 0.5 mg/kg for meat, 3.5 mg/kg for mbyp and 0.1 mg/kg for milk. The Australian MRL of T1 mg/kg for meat (mammalian) and T0.1 mg/kg for milk. The Australian MRL for cereal grains is \*0.2 mg/kg. No detectable residues are expected in grain at harvest and as a result no residues are expected in the tissues of cattle and sheep from the feeding of cereal grain.

In a study where bromoxynil was fed to lactating dairy cows for 4 days at 5 ppm, bromoxynil (parent compound) was not detected in milk  $(LOD 0.1 \text{ ppm})^{19}$ .

It is anticipated that animal product residues will be below typical method LOQs.

# Butafenacil

-is a pyrimidindione selective knock-down herbicide used pre-planting in *cereal crops*. Application is made pre-planting at rates up to 10 g ai/ha for wheat when butafenacil is co-formulated with triasulfuron and 16 g ai/ha for cereal grains when co-formulated with glyphosate. No harvest WHP is required.

There are Australian and US but no Codex MRLs for butafenacil in animal commodities. The Australian MRLs are \*0.02 mg/kg for edible offal (mammalian) and \*0.01 mg/kg for meat (mammalian) and milk. The Australian MRL for cereal grains (except rice) is \*0.02 mg/kg. The US residue definition is the sum of butafenacil and its metabolite CGA-293731 (1-carboxy-1methylethyl 2- chloro-5-[3,6-dihydro-3-methyl-2,6-dioxo-4-(trifluoromethyl)-1(2H)- pyrimidinyl] benzoate. The US MRLs are 0.05 mg/kg for cattle kidney and 0.5 mg/kg for cattle liver.

In a metabolism study, lactating goats were dosed for four consecutive days at a rate equivalent to feeding at 100 ppm butafenacil in the diet<sup>20</sup>. The highest <sup>14</sup>C tissue residues were found in the liver and kidney (4.4 and 0.4 mg equiv./kg, respectively). Characterization of the residual radioactivity found in the tissues and milk showed extensive metabolism of butafenacil. The principal metabolite was free acid metabolite accounting for approximately 85 % in the liver and kidney, along with smaller amounts of butafenacil, benzoic acid metabolite, and various conjugates in the other tissues.

If grain containing butafenacil at the MRL (\*0.02 mg/kg) was consumed as the entire diet, then residues in all tissues and milk would be <0.0002 mg equiv./kg. There is no reasonable expectation

<sup>&</sup>lt;sup>18</sup> 1992 JMPR - Pesticide Residues in Food – 1992 evaluations. Part II. Toxicology. WHO, WHO/PCS/93.34, Geneva, 1993

<sup>&</sup>lt;sup>19</sup> Reregistration Eligibility Decision Bromoxynil List B Case 2070EPA738-R-98-013 December 1998 Environmental Protection Agency, Office of Pesticide Programs, Special Review and Reregistration Division

<sup>&</sup>lt;sup>20</sup> Public Release Summary on Evaluation of the new active BUTAFENACIL in the products LOGRAN B-POWER HERBICIDE & TOUCHDOWN B-POWER HERBICIDE National Registration Authority for Agricultural and Veterinary Chemicals February 2002 Canberra Australia

of residues in animal commodities from feeding of grain derived from treated cereal crops to cattle and sheep.

It is anticipated that animal product residues will be below typical method LOQs.

# <u>Carbaryl</u>

- is a carbamate insecticide used for the control of various insects in crops. It is registered on *cereal crops* for control of various pests. The application rate is up to 1.1 kg ai/ha. It is also registered for grain storage (except malting barley) at rates of up to 8 ppm for storage for 3-9 months.

There are Australian, Codex and USA MRLs for carbaryl in animal tissues. The Australian and Codex residue definition is carbaryl for both plant and animal commodities. The Australian MRLs for edible offal and meat are T0.2 mg/kg while that for milk is T\*0.05 mg/kg. The Codex MRL for kidney is 3 mg/kg and liver 1 mg/kg while the MRL for meat is 0.05 mg/kg. The Codex milk MRL is 0.05 mg/kg.

The USA residue definition is the sum of carbaryl and 1-napthol expressed as carbaryl for plant commodities, the sum of carbaryl, 1-napthol, 5,6-dihydrodihydroxycarbaryl and 5,6-dihydrodihydroxynapthol expressed as carbaryl for animal tissues and the sum of carbaryl, 1-napthol, 5,6-dihydrodihydroxycarbaryl and 5-methoxy-6-hydroxycarbaryl expressed as carbaryl. The US tolerance for cattle meat is 1, fat 0.5 and that for milk 1 mg/kg.

The Australian MRL is T5 mg/kg for cereal grains.

The TF for kidney is 0.007 for the Australian/Codex residue definition and 0.012 for the US residue definition<sup>21</sup> giving rise to anticipated maximum residues in kidney from feeding cereal grain at 100% of the diet of  $0.007 \times 5 = 0.035$  mg/kg and  $0.012 \times 5 = 0.06$  mg/kg respectively for the Australian/Codex and USA residue definitions.

The TF for milk is 0.0002 for the Australian/Codex residue definition and 0.002 for the US residue definition giving rise to anticipated maximum residues in milk from feeding cereals at 100% of the diet of  $0.0002 \times 5 = 0.001$  mg/kg and  $0.002 \times 5 = 0.01$  mg/kg respectively for the Australian/Codex and USA residue definitions.

Livestock residues are not anticipated to exceed international and/or domestic market standards.

## <u>Carbofuran</u>

- is a systemic insecticide used for the control of various insects leaf hoppers and stem borer in upland *rice*. The application rate is up to 1 kg ai/ha with applications at mid-tillering to panicle initiation/emergence.

There is a harvest WHP of 6 weeks.

There are Australian, Codex and USA MRLs (expire on 31/12/09) for carbofuran in animal tissues. The relevant MRLs for meat are \*0.05 mg/kg. Milk MRLs are \*0.05, \*0.05 and 0.1 mg/kg for Australia, Codex and the USA respectively. The Australian use-pattern is such residues are expected in rice stubble/hay at harvest. This is reflected in the Australian MRL for rice of 0.2 mg/kg. The US MRL for rice is also 0.2 mg/kg.

<sup>&</sup>lt;sup>21</sup> 2002 JMPR. Pesticide Residues in Food - 2002 Evaluations – Part I: Residues Volume 1, FAO Plant Production and Protection Paper 175/1. FAO and WHO 2003 http://www.fao.org/ag/AGP/AGPP/Pesticid/Default.htm

In a feeding study with cows carbosulfan (not carbofuran) was fed to lactating dairy cattle for 28 consecutive days at rates equivalent to 1, 3, 10 and 50 ppm in the diet<sup>22</sup>. Carbofuran was not found in any milk, skim milk, cream or tissue samples at any of the 4 feeding concentrations, where the limit of detection was estimated as 0.005 mg/kg for milk and 0.01 mg/kg for tissues and cream. The metabolite 3-keto-carbofuran was detected only in one liver sample at 0.023 mg/kg from the 50 ppm group, and 3-hydroxy-carbofuran was detected in most milk samples from the 50 ppm group, at 0.007-0.030 mg/kg, and in one from the 10 ppm group (day 4, 0.007 mg/kg). Total carbamate residues reached a plateau at about 0.03 mg/kg from days 1 to 21. At the 50 ppm feeding level 3-hydroxy-carbofuran was detected in the kidneys (0.090, 0.13 mg/kg), liver (0.047, 0.060 mg/kg) and muscle (0.020, 0.030 mg/kg), but not in fat. In the 10 ppm group the 7-phenol (0.057 mg/kg) and 3-hydroxy-7-phenol (0.012 mg/kg) were found in the kidneys.

Noting the feeding study, Australian and US MRLs for animal commodities and the US MRLs for animal feeds it is apparent that carbofuran can be fed at levels of at least 45 ppm in the diet and still meet the relevant international MRLs. It is also apparent that residues in rice grain and processed products are expected to be much less than 45 ppm.

JMPR 1976<sup>23</sup>: Feed containing equal proportions of carbofuran phenol, 3-keto carbofuran phenol and 3-OH-carbofuran phenol at a total of 200 ppm was fed to 4 cows for 28 days. In milk, residues of carbofuran phenol ranged 0.03 to 0.07 mg/kg and of 3-ketocarbofuran phenol ranged 0.4 to 0.8 mg/kg between 2 and 28 days of the study. 3-OH-carbofuran phenol was <0.05 mg/kg during the study. Two cows were slaughtered at the end of the 28 day period; residues of each of the metabolites were <0.1 to 0.4 mg/kg in kidney, residues in muscle, liver and fat were <0.05 mg/kg.

It is anticipated that animal product residues will be below typical method LOQs.

#### Carboxin

-is a fungicide used on *wheat, triticale, barley* and *oats* as a seed treatment for the control of fungal smut and bunts. Application is at a maximum rate of 100 g ai/100 kg seed for wheat and barley and 50 g ai/100 kg for oats.

No harvest WHP required.

There are US but no Australian or Codex MRLs for carboxin in animal tissues. The US residue definition is the sum of carboxin and its metabolite 5,6-dihydro-3-carboxanilide-2-methyl-1,4-oxathiin-4-oxide (calculated as carboxin). The US MRLs for cattle meat and fat is 0.05, meat byproducts is 0.1 mg/kg and milk is 0.05 mg/kg. The US MRL for various cereal grains is 0.2 mg/kg. The US also has MRLs of 0.5 mg/kg for wheat and oat forage and 0.2 mg/kg for the straw and of various cereals. The Australian MRL for cereal grains is 0.1 mg/kg.

Carboxin sulfoxide (oxycarboxin) is the main metabolite of carboxin.

NOTE: US MRLs have been established for animal feed items (including bean, oat and wheat forage 0.5 ppm and cereal grain and straw 0.2 ppm) as well as for animal commodities. If the US MRLs are used to estimate the dietary burden using the US EPA Guideline, a dietary burden of 1 ppm is estimated (0.5 ppm forage, 25% DM, 25% diet each for wheat and soybean and 0.2 ppm grain, 90% DM, 50% diet). An anticipated TF is the 0.1 ppm (animal commodity tolerances)  $\div$  1 ppm (dietary burden) = 0.1 (crude estimate).

<sup>&</sup>lt;sup>22</sup> 1999 JMPR - Pesticide Residues in Food - 1999 Evaluations, Part I Residues FAO Plant Production and Protection Paper 157. FAO and WHO 2000

<sup>&</sup>lt;sup>23</sup> 1976 JMPR. Evaluations of some pesticide residues in food. AGP: 1976/M/14, 1977

Feeding cereal grain to cattle and sheep at 100% of the diet should not result in residues in tissues greater that  $0.1 \times 0.1 = 0.01$  mg/kg.

It is anticipated that animal product residues will be below typical method LOQs.

#### Carfentrazone-ethyl

-is a selective aryl triazolinone herbicide used for the control of certain broad-leafed weeds in *winter cereals* (wheat, barley, oats, triticale). The maximum application rate is 20 g ai/ha. No harvest WHP is required.

There are Australian and US but no Codex MRLs for carfentrazone ethyl in animal commodities. The Australian residue definition is parent compound while the US residue definition is carfentrazone-ethyl and its metabolite carfentrazone-chloropropionic acid (alpha, 2-dichloro-5-[-4-difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-*1*H-1,2,4-triazol-1-yl]-4-fluorobenzenepropanoicacid). The Australian animal tissue MRLs have all been set at \*0.05 mg/kg and milk at \*0.025 mg/kg. The US MRLs are 0.1 for meat and meat by-products and 0.05 mg/kg for milk. The MRL for cereal grains and cereal grain forage and fodder is \*0.05 mg/kg.

In an animal transfer study, lactating cows were fed at levels equivalent to 1, 3 and 10 ppm in the diet for 28 consecutive days<sup>24</sup>. No detectable residues (<0.005 ppm) of carfentrazone-ethyl, carfentrazone or F8426-propionic acid were found in any of the milk samples taken, except for low concentrations of carfentrazone (0.005 - 0.008 ppm) in three isolated samples from the 10 ppm dose group. No detectable residues (<0.01 ppm) of carfentrazone-ethyl, carfentrazone or F8426-propionic acid were found in any of the tissue or cream samples with the exception of kidney samples where trace amounts of carfentrazone (0.012 - 0.013 ppm) were found in samples from the 10 ppm dose group. There were no detectable residues of carfentrazone in kidney from cows fed clean feed for 7 days after dosing for 28 days, indicating that this residue was readily cleared from the kidney and excreted from the animal over a relatively short period of time.

It is anticipated that animal product residues will be below typical method LOQs.

## Chlormequat chloride

-is a plant growth regulator applied to *wheat* at the 5-7 leaf stage to produce shorter leaf internodes. The application rate is up to 308 g ai/ha for dry-land wheat and 800 g ai/ha for irrigated wheat. No WHP is required when used as directed.

There are Australian and Codex but no US MRLs for animal tissues. The Australian MRLs are 0.5 for offal and milk and 0.2 mg/kg for meat. The Codex MRLs are 0.5 mg/kg for kidney of cattle, goats, pigs and sheep, and for milk, 0.1 mg/kg for liver of cattle, goats, pigs and sheep and 0.2 mg/kg for meat of cattle pigs and sheep. The Australian MRL for wheat is 5 mg/kg.

Residues in tissues of dairy cows fed at 36 ppm in the diet for 28 days were 0.11 mg/kg for muscle, 0.05 mg/kg for fat and 0.09-0.46 mg/kg for liver and kidney<sup>25</sup>. Anticipated residues in tissues on feeding grain with residues at 5 ppm at 100% of the diet are 0.02 mg/kg for muscle, <0.01 mg/kg for fat and 0.01-0.07 mg/kg for liver and kidney. Residues in tissues declined with a half-life of <2 days when on "clean feed".

<sup>&</sup>lt;sup>24</sup> Public Release Summary on Evaluation of the new active CARFENTRAZONE-ETHYL in the product AFFINITY 400 DF HERBICIDE National Registration Authority for Agricultural and Veterinary Chemicals April 2000 Canberra Australia

<sup>&</sup>lt;sup>25</sup> 2000 JMPR. Pesticide Residues in Food - 2000 Evaluations – Part I, FAO Plant Production and Protection Paper 165. FAO and WHO 2001

Residues in whole milk were a maximum of 0.04 mg/kg for cows fed at the equivalent of 12 ppm in the diet.

Livestock residues may exceed international and/or domestic market standards.

# **Chlorpyrifos**

- is an organophosphate insecticide used for the control of various insects in crops. It is registered on *maize* and *sorghum* for the control of wireworm and is applied in-furrow at planting at 0.75 kg ai/ha (for 1 m row spacing). It is applied to *cereals* as a foliar spray at rates up to 0.75 kg ai/ha for the control of various pests including locusts (highest rate). The harvest WHP is 10 days.

There are Australian, Codex and USA MRLs for chlorpyrifos in animal tissues. The MRLs for cattle fat are T0.5, 1 and 0.3 mg/kg for Australia, Codex and the USA respectively. The MRLs for milk are T0.2 [milk in the fat] mg/kg, 0.02 mg/kg and 0.01 mg/kg (0.25 mg/kg for milk fat) respectively. There are Australian MRLs for sorghum at T3 mg/kg and other cereal grains at T0.1 mg/kg.

The maximum transfer factor for feeding cattle at 10 ppm in the diet was 0.016 for cattle fat and at 30 ppm in the diet was 0.007 for milk<sup>26</sup>. Residues from feeding sorghum, with residues of 3 ppm, at 100 % of the diet are  $3 \times 0.016 = 0.048$  mg/kg and for other grains  $0.1 \times 0.016 = 0.0016$  mg/kg. Anticipated residues for milk would be  $3 \times 0.0007 = 0.0021$  mg/kg for sorghum and  $0.1 \times 0.0007 = 0.00007$  mg/kg for other grains.

Livestock residues are not anticipated to exceed international and/or domestic market standards.

Chlorpyrifos-methyl

- is an organophosphate insecticide used for the control of various insects in stored grain. It is registered on stored grain (except rice and barley) at 5-10 ppm.

There are Australian, Codex and USA MRLs for chlorpyrifos-methyl in animal tissues. The MRLs for cattle fat are \*0.05, 0.05 and 0.5 mg/kg for Australia, Codex and the USA respectively. The MRLs for milk are \*0.05 [in the fat], \*0.01 and 0.25 (fat) mg/kg for Australia, Codex and the USA respectively. There are Australian MRLs for cereal grains at 10 mg/kg.

The maximum transfer factor for cattle fat was  $0.003^{27}$ . Residues in fat from feeding grain with residues of 10 ppm at 100 % of the diet are  $10 \times 0.003 = 0.03$  mg/kg. The maximum transfer factor for milk was 0.003. Residues in milk from feeding grain with residues of 10 ppm at 100 % of the diet are  $10 \times 0.0003 = 0.003$  mg/kg.

Livestock residues are not anticipated to exceed international and/or domestic market standards.

# Chlorsulfuron

-is a sulfonylurea herbicide applied pre-sowing or up to early post crop emergence to winter cereals (*wheat, barley, oats, triticale* and *cereal rye*). The maximum application rate is 18.75 g ai/ha. No harvest WHP is required.

<sup>&</sup>lt;sup>26</sup> 2000 JMPR. Pesticide Residues in Food - 2000 Evaluations – Part I, FAO Plant Production and Protection Paper 165. FAO and WHO 2001 http://www.fao.org/ag/AGP/AGPP/Pesticid/Default.htm

<sup>&</sup>lt;sup>27</sup> 1979 JMPR - Pesticide Residues in Food - 1979 Evaluations, Part I Residues FAO Plant Production and Protection Paper 20 Suppl. FAO and WHO 1980

There are Australian and US but no Codex MRLs for chlorsulfuron in animal commodities. The Australian MRLs are \*0.05 mg/kg for edible offal (mammalian), meat (mammalian) and milk. The US MRLs are 0.3 mg/kg for cattle, sheep and goat meat, mbyp and fat and 0.1 mg/kg for milk.

The Australian MRL for cereal grains is \*0.05 mg/kg and there is a PAFC MRL of 10 ppm. The US has a different residue definition for plant commodities (includes a metabolite, 2-chloro-5-hydroxy-N-[(4-methoxy-6-methyl-1,3,5-triazin-2-yl)aminocarbonyl] benzenesulfonamide. The US has MRLs of 0.1 mg/kg for grain, 0.5 mg/kg for straw and 20 mg/kg for forage of wheat and oats.

The log  $P_{OW}$  for chlorsulfuron is -0.99 indicating no propensity for accumulation in fat. In an animal transfer study dairy cattle were fed chlorsulfuron at dietary levels of 2, 10, and 50 ppm for 28 days<sup>28</sup>. The chlorsulfuron residue levels in milk rose within 3 days to steady-state plateaus, remaining constant during fortified feeding, and decreased to below the analytical detection limit of 0.010 ppm within 3 days of terminating the fortified feeding. Average steady-state residue levels in the milk during fortified feeding, were 0.064 ppm for cows fed at the 50 ppm dietary rate and 0.013 ppm for cows fed at the 10 ppm dietary rate. Chlorsulfuron was detected in the kidney 0.25 ppm, liver 0.024 ppm, and lean muscle < 0.010 ppm of the cow fed at the 50 ppm dietary level, but was undetected (< 0.01 ppm) in subcutaneous fat. Chlorsulfuron residues in all analysed tissue decreased to< 0.010 ppm for all cows within 8-days of returning to a diet without chlorsulfuron.

It is anticipated that animal product residues will be below typical method LOQs.

# Clodinafop-propargyl

-is a selective aryloxyphenoxypropionate herbicide used for the control of annual rye grass and other weeds in *wheat*. Application is made from the two-leaf to late tillering growth stage of the wheat at rates up to 50 g ai/ha.

No harvest WHP is required.

There are Australian but no Codex or US MRLs for clodinafop-propargyl in animal commodities. The Australian MRLs, including milk, are all \*0.05 mg/kg (residue definition parent compound). The Australian MRL for wheat is \*0.05 mg/kg and for wheat straw and fodder (dry) \*0.1 ppm. The US MRLs for wheat grain, forage and hay are 0.1 mg/kg and for wheat straw 0.5 mg/kg. The US residue definition is clodinafop-propargyl and its acid metabolite (propanoic acid, 2-[4-[(5-chloro-3-fluoro-2-pyridinyl)oxy]phenoxy]-, (2R)-).

The octanol water partition coefficient log  $P_{OW} = 3.9$  at pH 7 suggesting potential fat solubility. The US EPA proposed tolerances of 0.1 ppm for clodinafop-propargyl and the acid metabolite, CGA-193469, for wheat grain, forage, and hay and 0.5 ppm for straw and that tolerances for meat, milk and eggs are not required<sup>29</sup>.

It is anticipated that animal product residues will be below typical method LOQs.

## Clomazone

- is an isoxazolidinone herbicide used to control broad-leafed annual weeds in crops. It is registered for use on *rice* with application made post-planting at inundation of or to permanent water. The application rate is up 288 g ai/ha.

<sup>&</sup>lt;sup>28</sup> ENVIRONMENTAL PROTECTION AGENCY [PF-1072; FRL-6825-8] Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical in or on Food [Federal Register: March 8, 2002 (Volume 67, Number 46)] [Notices] [Page 10722-10727])

<sup>&</sup>lt;sup>29</sup> clodinafop-propargyl Pesticide Petition Filing 5/98 Federal Register: June 5, 1998 (Volume 63, Number 108) Page 30750-30756

A harvest WHP is not required.

There are no Australian, Codex or US MRLs for clomazone in animal commodities. The Australian MRLs for rice (\*0.01 mg/kg) and rice forage (green) and straw and fodder (dry) (\*0.01 mg/kg).

It is anticipated that animal product residues will be below typical method LOQs.

## <u>Clopyralid</u>

-is a selective pyridine herbicide used for the control of certain weeds in *wheat, barley, oats* and *triticale*. Application is made up to late tillering at rates of up to 150 g ai/ha. Do not apply later than 10 weeks before harvest.

There are Australian and US but no Codex MRLs for clopyralid in animal commodities. The Australian MRLs are 0.1 mg/kg for meat (mammalian), 5 mg/kg for kidney of cattle goats, pigs and sheep, 0.5 mg/kg for edible offal (mammalian) except kidney and 0.05 mg/kg for milk. The US MRLs are 36 mg/kg for meat by-products except liver, 3 mg/kg for liver, 1 mg/kg for fat and meat and 0.2 mg/kg for milk. The Australian MRL for cereal grains is 2 mg/kg. The US MRLs for wheat forage and straw are 9 mg/kg and for grain 3 mg/kg.

Residues in field corn, sweet corn, and popcorn grain treated at 0.28 kg ai/ha have not exceeded 1 mg/kg in grain. Residues do not concentrate in the corn milling products of starch, flour, meal, crude or refined oil, and have only slight concentration factors of 1.1 in grits and grain dust. Cannery waste from sweet corn processing contains no detectable residues of clopyralid.

Wheat, barley, and oats treated at 140 g ai/ha contained residues of clopyralid that did not exceed 3 mg/kg in grain. Residues do not concentrate in flour but do concentrate to some extent in the other milled fractions of wheat and barley.

Average clopyralid residues in tissues at the end of an experiment where calves were dosed at the equivalent of 1000 ppm in the diet for 28 days were 0.3 mg/kg in muscle, 0.2 mg/kg in fat, 1.3 mg/kg in liver and 15 mg/kg in kidney<sup>30</sup>. Anticipated residues in kidney on feeding cereal grain with residues at the MRL are  $2 \times 0.015 = 0.03$  mg/kg.

Two goats were fed radiolabeled clopyralid at rates equivalent to 230 and 69 ppm in feed for 7 days<sup>31</sup>. The residues in liver (approx. 0.04 ppm) and kidney (approx. 0.6 ppm) tissues were shown to be unchanged clopyralid. Residues in muscle and fat were too low (less than 0.02 ppm) to characterize. The milk residue averaged approximately 0.03 ppm and was shown to consist of approximately equal amounts of clopyralid and its glycine conjugate. Given that the 1000 ppm study may overestimate the TF and hence the magnitude of anticipated residues, and the results of the goat study, it is considered likely that residues in animal product resulting from feeding grain at the Australian MRL of 2 mg/kg would not result in residues above an anticipated regulatory LOQ of 0.01 mg/kg.

<sup>&</sup>lt;sup>30</sup> Draft Assessment Report (DAR) – public version- Initial risk assessment provided by the rapporteur Member State Finland for the existing active substance Clopyralid of the second stage of the review programme referred to in Article 8(2) of Council Directive 91/414/EEC, Volume 3, Annex B, B.7, February 2005.

<sup>&</sup>lt;sup>31</sup> Dow Agrosciences Technical profile, July 1998

#### Cloquintocet-mexyl

-is a crop safener used with clodinafop-propargyl (a selective herbicide used for the control of annual rye grass and other weeds in wheat). Application is made from the two-leaf to late tillering growth stage of the *wheat* at rates up to 13 g ai/ha. No harvest WHP is required.

There are Australian but no Codex or US MRLs for cloquintocet-mexyl in animal commodities. The Australian MRLs are all \*0.1 mg/kg (residue definition parent compound). The Australian MRL for wheat is \*0.1 mg/kg. The US MRL for wheat grain is 0.1 mg/kg. The US residue definition for plant commodities is cloquintocet-mexyl and its acid metabolite (5-chloro-8-quinlinoxyacetic acid).

It is anticipated that animal product residues will be below typical method LOQs.

## **Cyfluthrin**

- is a synthetic pyrethroid insecticide used for the control of various insects in crops. It is registered on *sorghum* for the control of sorghum midge. The application rate is up to 15 g ai/ha. The harvest WHP is 14 days.

There are Australian, USA and Codex MRLs for cyfluthrin. The relevant MRLs for cattle fat are 0.5, 1 and 2 mg/kg for Australia, Codex and the USA respectively. The relevant MRLs for cattle milk are 0.1, 0.04 and 5 mg/kg for milkfat (1 mg/kg in whole milk) for Australia, Codex and the USA respectively. There are Australian MRLs for cereal grains at 2 mg/kg and straw and fodder (dry) of cereal grains at 5 ppm. The US MRL for cereal grains (grain, cereal, forage, fodder and hay, group 16, forage, except rice) is 25 ppm. The US has also established a range of MRLs for processed cereal products:

Barley, bran 0.5 ppm Corn, field, 0.05 ppm Grain, aspirated fractions 150 ppm Oat, bran 0.5 ppm Rice, bran 6 ppm Rice, hulls 18 ppm Rye, bran 0.5 ppm Wheat grain 0.15 ppm

Residues in the animal diet from cereal grains would not be expected to lead to exposure of greater than 2 ppm in the diet. TF fat =  $0.05^{32}$ . Estimated residues in fat are  $2 \times 0.05 = 0.1$  mg/kg. If the ratio of US MRLs is reflective of the concentration of residues on processing, aspirated grain fractions (e.g. grain dust) could have residues of 300 ppm.

The TF for milk is 0.005 giving anticipated residues of  $2 \times 0.005 = 0.01$  mg/kg. Feeding of aspirated grain fractions at more than 1-1.5% of the diet could lead to residues in fat and milk above the Codex MRLs of 0.2 mg/kg for fat and 0.04 mg/kg for milk.

Livestock residues are not anticipated to exceed international and/or domestic market standards following feeding with grain from treated crops.

#### Cyhalofop-butyl

-is a selective aryloxyphenoxypropionate herbicide used for the post-emergent control of barnyard grass and silver top in rice. Application is made at rates up to 285 g ai/ha.

<sup>&</sup>lt;sup>32</sup> Residues of some veterinary drugs in animals and foods. Forty-eighth meeting of the Joint FAO/WHO Expert Committee on Food Additives, 1998, FAO Food and Nutrition Paper 41/10

No harvest WHP is required.

Do not graze or cut for stockfood for 8 weeks after application.

There are Australian but no Codex or US MRLs for cyhalofop-butyl in animal commodities. The Australian MRLs are all \*0.05 mg/kg (residue definition parent compound). The Australian MRL for rice is \*0.01 mg/kg and for rice forage (green) \*0.1 ppm and rice straw and fodder (dry) 0.2 ppm. The US MRLs for rice grain and rice wild grain are 0.03 ppm. The US residue definition is the sum of cyhalofop-butyl, cyhalofop acid and the di-acid metabolite.

It is anticipated that animal product residues will be below typical method LOQs.

# Cypermethrin

- is a synthetic pyrethroid insecticide used for the control of various insects in crops.

The application rates for cereals are reported in the table below together with the harvest WHPs and any label feeding restraints.

Сгор	Rate (g ai/ha)	Harvest WHP	Grazing WHP
		(days)	(days)
Winter cereals	34	21	35*
Maize	80	1	-
Sorghum	100	14	-

\*unless otherwise stated. Lower application rates have shorter do not graze intervals.

There are Australian, Codex and USA MRLs for cypermethrin in animal tissues. The relevant MRLs for cattle fat are 0.5, 0.2 and 1 mg/kg for Australia, Codex and the USA respectively. The respective milk MRLs are 1 [in the fat = 0.04 mg/kg whole milk], 0.05 F mg/kg and 2.5 mg/kg for Australia, Codex and the USA. There are Australian MRLs of 0.2 mg/kg for wheat and 1 mg/kg for other cereal grains.

If residues in cereal grain are present at 1 ppm, anticipated residues in fat are  $1 \times 0.1 = 0.1$  mg/kg if fed at 100% of the diet<sup>33,34</sup>. Anticipated residues in whole milk (TF 0.003-0.1) are also 0.1 mg/kg.

It is anticipated that animal product residues will be below international and/or domestic market standards.

# Cyproconazole

-is a conazole fungicide registered for the control of powdery mildew and rusts in *barley* and *wheat*. The application rate is up to 64 g ai/ha.

The harvest WHP is 42 days.

DO NOT graze or cut for stock food for 21 days after application.

There are Australian but no Codex or US MRLs for cyproconazole in animal commodities. The Australian MRLs have been set at 0.03 mg/kg for meat [mammalian], 1 mg/kg for edible offal (mammalian) and \*0.01 mg/kg for milk. The MRLs for barley and wheat are \*0.02 mg/kg, for forage 10 ppm and for fodder and straw dry 3 ppm.

 <sup>&</sup>lt;sup>33</sup> Chen-AW; Fink-JM; Letinski-DJ; Barrett-GP; Pearsall-JC (1997) Residue of cypermethrin and its major acid metabolites in milk and tissues from dairy bovines treated with cypermethrin. *J. Ag. Food Chem.* 45: 12, 4850-4855.
<sup>34</sup> 1981 JMPR Pesticide Residues in Food - 1981 Evaluations, FAO Plant Production and Protection Paper 42. FAO and WHO 1982 http://www.fao.org/ag/AGP/AGPP/Pesticid/Default.htm

(The log  $P_{ow}$  for cyproconazole is reported to be 2.9 indicating little propensity for transfer to fat.). The relevant TFs for liver and fat are 0.04 and 0.002 (20 ppm feeding level)<sup>35,36</sup>. Feeding at \*0.02 ppm would give rise to residues of \*0.02×0.04 = 0.0008 ppm for liver and \*0.02×0.002 = 0.00004 ppm for fat.

It is anticipated that animal product residues will be below typical method LOQs.

# Deltamethrin

- is a synthetic pyrethroid insecticide used for the control of various insects in crops. It is registered on *cereals*. The application rate is up to 13.75 g ai/ha. The harvest WHP is 7 days for cereals

There are Australian, Codex and USA MRLs for deltamethrin in animal tissues. The relevant MRLs for cattle fat are 0.5, 0.5 and 0.05 mg/kg for Australia, Codex and the USA respectively. The Australian MRL for milks is 0.05 mg/kg. The Codex MRL for milks is 0.05 F mg/kg. The US MRL is for milk fat 0.1 mg/kg reflecting 0.02 mg/kg in whole milk. The Australian MRLs are 2 mg/kg cereal grains. There are Australian animal feed MRLs of 5 ppm for fodder and forage or cereal grains, oilseeds, pulses and sweet corn and 7 ppm for rice hulls.

The TF for deltamethrin in fat is roughly  $0.03^{37}$ . Feeding of grain with residues of 2 mg/kg at 100% of the diet could result in deltamethrin residues in fat of  $2 \times 0.03 = 0.06$  mg/kg, this is less than the Australian and Codex but higher than the USA tolerances but only marginally so. Anticipated residues in milk (TF 0.009) are  $2 \times 0.009 = 0.018$  mg/kg.

Given the conservativeness of the estimates it is concluded that livestock residues should be below international and/or domestic market standards.

# Diazinon

- is an organophosphate insecticide used for the control of various insects in crops. It is registered on *cereals* for the control of various pests including grasshoppers and locusts. The application rate is up to 0.8 kg ai/ha for cereals and 1.12 kg ai/ha for sorghum. The harvest WHP is 14 days. The grazing WHP is 2 days.

There are Australian, Codex and USA MRLs for diazinon in animal tissues. The MRLs for cattle fat are 0.7 mg/kg for Australia, 2 for Codex and 0.5 mg/kg for the US. For milk the MRLs are 0.5 [in the fat], 0.0.2 F mg/kg and not specified. The Australian MRL for cereal grains is 0.1 mg/kg.

The TF for diazinon in animal fat is  $0.001^{38}$ . Feeding grain at 100% of the diet could result in fat residues of  $0.1 \times 0.001 = 0.0001$  mg/kg. No residues were detected in milk of cows dosed at the equivalent of 120 ppm in the diet.

It is anticipated that animal product residues will be below typical method LOQs.

## <u>Dicamba</u>

<sup>&</sup>lt;sup>35</sup> Evaluation of fully approved or provisionally approved products. Issue 45: Evaluation on SAN 619F (cyproconazole), August 1991, Department of Environment Food and Rural Affairs, Pesticide Safety Directorate. UK <sup>36</sup> A DVMA Trada Advise Note.

<sup>&</sup>lt;sup>36</sup> APVMA Trade Advice Note

<sup>&</sup>lt;sup>37</sup> 2002 JMPR. Pesticide Residues in Food - 2002 Evaluations – Part I: Residues Volume 1, FAO Plant Production and Protection Paper 175/1. FAO and WHO 2003

<sup>&</sup>lt;sup>38</sup> 1996 JMPR - Pesticide Residues in Food - 1996 Evaluations, Part I: Residues FAO Plant Production and Protection Paper 142. FAO and WHO 1997

- is a selective herbicide used for the control of broadleaf weeds in *cereal crops*. The application rate is up to 0.2 kg ai/ha for cereal grains and up to 0.28 kg ai/ha for grain sorghum and maize. Do not harvest, graze or cut for stock food for 7 days after application.

There are no Codex MRLs for dicamba. The US (parent + metabolite) and Australian (parent) residue definitions differ. The relevant US MRLs for animal tissues are 0.25 mg/kg for meat, 25 mg/kg for kidney and 0.2 mg/kg for milk. The Australian MRLs are meat (mammalian) at 0.05 mg/kg and milks at 0.1 mg/kg. The Australian MRL for cereal grains is \*0.05 mg/kg. The Australian use-pattern is such that no residues are expected in grain at harvest. Feeding is not expected to result in significant residues in cattle and sheep.

It is anticipated that animal product residues will be below typical method LOQs.

# Dichlorvos

- is an organophosphate insecticide used for the control of various insects in stored grain. It is registered on stored grain at 6-12 ppm with minimum out turn times of 7 days for the 6 ppm application rate and 28 days for the 12 ppm application rate.

There are Australian, Codex and USA MRLs for dichlorvos in animal tissues. The MRLs for meat are 0.05, \*0.05 and 0.02 N mg/kg for Australia, Codex and the USA respectively. The MRLs for milk are 0.02, \*0.02 and 0.02 N mg/kg for Australia, Codex and the USA respectively. There are Australian MRLs for cereal grains at 5 mg/kg.

The maximum transfer factor for feeding cattle was < 0.000005 for cattle fat<sup>39</sup>. No significant residues are expected.

It is anticipated that animal product residues will be below typical method LOQs.

## Diclofop-methyl

-is an aryloxphenoxypropinate herbicide used for control of annual grasses in *wheat, barley, oats, triticale* and *rye*. The application rate is up to 562 g ai/ha for barley and 750 g ai/ha for the other cereals.

No harvest WHP is required.

There are Australian but no Codex or US tolerances for diclofop-methyl in animal commodities. The Australian MRLs have all been set at \*0.05 mg/kg. The Australian MRL for cereal grains is 0.1 mg/kg.

The US EPA reported that for wheat/barley grain, the combined residues of diclofop-methyl and its metabolites, diclofop acid and hydroxy diclofop were non-detectable (< 0.10 ppm) in field trial studies in/on wheat and barley grain<sup>40</sup>. Wheat and barley processing data demonstrate that residues of diclofop-methyl and its metabolites, diclofop acid and hydroxy diclofop do not concentrate in bran, flour, or other processed fractions following post-emergence foliar application at 5× the label rate.

Four groups of lactating dairy cows were dosed orally *via* capsules for 28 consecutive days with diclofop-methyl at levels equivalent to 0.11, 0.33, 1.1, and 25.0 ppm in the diet. In tissues, residues

<sup>&</sup>lt;sup>39</sup> Human Health Risk Assessment Dichlorvos (DDVP) U.S. Environmental Protection Agency Office of Pesticide Programs Health Effects Division (7509C) Susan V. Hummel, Risk Assessor Date: 9 August 2000

<sup>&</sup>lt;sup>40</sup> Diclofop-Methyl Reregistration Eligibility Decision Residue Chemistry Considerations PC Code 110902; Case 2160 Environmental Protection Agency, Office of Pesticide Programs, Special Review and Reregistration Division

were highest in kidney and lowest in muscle. For the 25 ppm feed level, the combined residues were 12-23 mg/kg in kidney, 3.9-6.1 mg/kg in liver, 0.75-0.85 mg/kg in fat, and 0.32-0.57 mg/kg in muscle. Residues in whole milk plateaued by Day 4 at all dose levels. The maximum combined residues in whole milk were 0.023, 0.11, 0.21, and 2.8 mg/kg for the 0.11, 0.33, 1.1, and 25 ppm groups, respectively. Diclofop-methyl residues concentrated in milk fat, with residues in cream being 2.4-3.4× higher than in whole milk. The TF for kidney and fat were 0.9 and 0.03 respectively. Anticipated residues in kidney are  $0.1 \times 0.9 = 0.09$  mg/kg.

Livestock residues may exceed international and/or domestic market standards.

## Difenoconazole

-is a triazole fungicide that is used in apples for the control of various fungal pests in wheat and barley. The application rate is 12 g ai/100 kg seed. A harvest WHP is not required (seed dressing) Do not graze or cut for stock food for 6 weeks after sowing treated grain.

There are Australian, US and Codex MRLs for difenoconazole in animal tissues. The Australian MRLs have all been set at \*0.05 mg/kg for tissues and \*0.01 mg/kg for milk. The US MRLs for cattle fat and meat byproduct except liver is 0.1, liver 0.2, meat 0.05 and milk is 0.01 mg/kg. The Codex MRLs for edible offal are 0.2, meat fat 0.05 and milk \*0.005 mg/kg. The Australian cereal grain MRL is 0.01 mg/kg and the wheat and barley forage MRL \*0.1 ppm while the wheat and barley straw and fodder (dry) MRL is \*0.05 ppm.

The US EPA reported<sup>41</sup> "two metabolism studies were performed on ruminants (lactating goats) in a 10-day study with a dose rate of 4.17 ppm ( $14 \times$  the 0.30 ppm estimated dietary burden) and a 3-day study with a dose rate of 100 ppm ( $333 \times$  the 0.30 ppm estimated dietary burden). The total radioactive residue (TRR) in the goat tissues was used to estimate the expected residues in a feeding study with a dose rate of 0.30 ppm. The maximum residue observed was in liver, estimated to be at a level of 0.02 ppm from both metabolism studies. This value is 2.5 × below the LOQ of the proposed analytical enforcement method (0.05 ppm)."

It is considered unlikely that feeding grain, forage, fodder or straw derived from difenoconazole treated barley or wheat seed would give rise to residues at levels of concern in animal tissues.

It is anticipated that animal product residues will be below typical method LOQs.

## Diflufenican

-is a nicotinanalide herbicide used to control various weeds in *cereals* (wheat, barley, triticale, oats, rye). Application is at rates of up to 25 g ai/ha. No harvest WHP is required.

There are Australian but no Codex or US MRLs for diflufenican in animal commodities. The Australian MRLs (parent compound) are 0.1 mg/kg for edible offal mammalian and 0.01 mg/kg for meat (mammalian) and milk. The MRL for cereal grains are 0.05 mg/kg for barley, oats, rye and triticale and 0.02 mg/kg for wheat.

EFSA DAR - In a metabolism study lactating cows were dosed at 1 and 20 ppm feed with [difluorophenyl-<sup>14</sup>C]-diflufenican and 5 and 50 ppm feed with [pyridine-<sup>14</sup>C]-diflufenican for 7 days (2 doses/day). Cows were sacrificed 18-23 h after the last dose. TRR in milk reached a plateau

<sup>&</sup>lt;sup>41</sup> Difenoconazole Pesticide Tolerance Federal Register: September 15, 2000 (Volume 65, Number 180) Page 55911-55921

after 3 days at 0.01 and 0.02 mg/kg in the 20 and 50 ppm feeding studies respectively. Parent compound represented 48-52% of TRR in milk. TRR in tissues were <0.01 mg/kg for muscle, 0.07-0.08 mg/kg for fat, 0.03-0.04 mg/kg for kidney and 0.26-0.40 mg/kg for liver in the 20 and 50 ppm studies. At the 1 and 5 ppm dose levels residues in tissues were <0.01 mg/kg with the exception of liver (0.02-0.05 mg/kg) and fat (<0.01-0.03 mg/kg). Parent compound represented 82-91% of the TRR in fat. Parent residues in the highest residue liver sample were 0.02 mg/kg (about 6% TRR)

It is anticipated that animal product residues will be below typical method LOQs.

<u>Dimethenamid-P</u> - is a pre-emergent herbicide used for the control of weeds in *maize*. It is registered on maize at application rates of up to 720 g ai/ha.

A harvest WHP is not required.

DO NOT graze or cut for stock food for 4 weeks after application.

There are Australian and Codex but no USA MRLs (negligible residue) for dimethenamid in animal tissues. The Australian and Codex MRLs for animal commodities have been set at \*0.01 mg/kg. There is an Australian MRL of \*0.02 mg/kg for maize and for forage and fodder of maize and sweet corn at \*0.02 mg/kg.

It is anticipated that animal product residues will be below typical method LOQs.

#### Dimethoate

- is an organophosphate insecticide used for the control of various insects in crops. It is registered on *cereals* at application rates of up to 300 g ai/ha. The harvest WHP is 28 days.

There are Australian, Codex and USA MRLs for dimethoate in animal tissues. The Australian and Codex MRLs for animal commodities have been set at \*0.05 mg/kg while the US ones are set at 0.02 mg/kg. There is an Australian MRL of \*0.05 mg/kg for cereal grains.

A metabolism study with lactating goats dosed orally with dimethoate at a rate equivalent to feeding at 30 ppm in the diet suggests that residues are not expected in animal tissues<sup>42</sup>.

It is anticipated that animal product residues will be below typical method LOQs.

#### Diquat

- is a herbicide used for the control of weeds in various crops. It is applied to *rice, sorghum* and *winter cereals* with application rates up to 0.6 kg ai/ha.

The harvest WHPs are 5 days for rice and not required for other cereals..

The Australian and Codex MRLs for diquat in meat (mammalian) are the same at \*0.05 mg/kg. The US MRL for meat is 0.02 mg/kg. The MRLs for milk are \*0.01 mg/kg, \*0.01 mg/kg and 0.02 mg/kg respectively. The MRLs for diquat are 5 mg/kg for barley, oats and rice, 2 mg/kg for rye, triticale, wheat and sorghum and 0.1 mg/kg for maize.

No residues were detected in tissues of cows fed diquat for 28 days at 100 ppm in the diet and slaughtered on the last day of dosing (LOD  $0.01 \text{ mg/kg})^{43}$ . Residues in grain are much less than 100

<sup>&</sup>lt;sup>42</sup> 1998 JMPR - Pesticide Residues in Food - 1998 Evaluations, Part I Residues FAO Plant Production and Protection Paper 152/1. FAO and WHO 1999

ppm. This suggests that no residues would be detected in cattle and sheep tissues if fed cereal grains.

It is anticipated that animal product residues will be below typical method LOQs.

# Diuron

- is a herbicide used for the control of weeds in crop. It is applied early post-emergent from the 2 to 5 leaf growth stage. The application rate is up to 0.85 kg ai/ha for *wheat* and *barley* and up to 0.25 kg ai/ha for *triticale, oats* and *rye*.

No harvest or grazing WHP is required.

There are no Codex MRLs for diuron. The US and Australian residue definitions differ with the Australian definition including a metabolite in addition to the parent compound. The relevant US MRL for animal tissues is 1 mg/kg for cattle mbyp while the Australian MRL for edible offal of cattle is 3 mg/kg (the higher value probably reflecting the inclusion of the metabolite in the residue definition). The Australian MRL for milk is 0.1 mg/kg. The MRL for cereal grains is 0.1 mg/kg.

NOTE: US MRLs have been established for animal feed items (including alfalfa forage and hay at 2 ppm and citrus pulp dry at 4 ppm) as well as for animal commodities. If the US MRLs are used to estimate the dietary burden using the US EPA Guideline, a dietary burden of ca. 4.8 ppm is estimated. An anticipated TF is the 1 ppm (animal commodity tolerances)  $\div$  4.8 ppm (dietary burden) = 0.2 (crude estimate).

Feeding cattle and sheep cereal grain with residues at 0.1 mg/kg is expected to give rise to residues in tissues that are less than  $0.1 \times 0.2 = 0.02$  mg/kg.

It is anticipated that animal product residues will be below typical method LOQs.

## Endosulfan

- is an organochlorine insecticide used for the control of various pests in a variety of crops. The application rate for barley, oats, wheat, rye and triticale is up to 0.35 kg ai/ha to bare earth prior to crop emergence.

DO NOT graze or cut for stockfood for 10 weeks after application.

There are Australian, Codex and USA MRLs for animal commodities. The Australian and Codex MRL for fat is 0.2 mg/kg while the US MRL is 13 mg/kg. The Australian MRL for milk [in the fat] is 0.2 mg/kg, USA 2 mg/kg for milk fat and Codex 0.1 F mg/kg. There is an Australian MRL for cereal grains set at 0.1 mg/kg.

The TF for fat is  $0.3-0.4^{44}$ . Residues in fat would be  $0.1 \times 0.4 = 0.04$  mg/kg. The TF for milk is 0.02. Residues in milk would be  $0.1 \times 0.02 = 0.002$  mg/kg. The TF for cream is 0.12. Residues in cream would be  $0.1 \times 0.12 = 0.012$  mg/kg.

Livestock residues are not anticipated to exceed international and/or domestic market standards.

<sup>&</sup>lt;sup>43</sup> Reregistration Eligibility Decision, Diquat Dibromide, List A, Case 0288, EPA 738-R-95-016 July 1995 Environmental Protection Agency, Office of Pesticide Programs, Special Review and Reregistration Division. http://cfpub.epa.gov/oppref/rereg/status.cfm?show=rereg

<sup>&</sup>lt;sup>44</sup> Reregistration Eligibility Decision for Endosulfan Case No. 0014 EPA 738-R-02-013 November 2002 Environmental Protection Agency, Office of Pesticide Programs, Special Review and Reregistration Division. http://cfpub.epa.gov/oppref/rereg/status.cfm?show=rereg

Epoxiconazole

- is a fungicide used for the control of various diseases of *barley* and *wheat*. The application rate is up to 62.5 g ai/ha.

DO NOT harvest for 6 weeks after application.

DO NOT graze or cut for stockfood for 6 weeks after application.

There are Australian, but no Codex or USA MRLs for animal commodities. The Australian and MRLs are 0.05 for edible offal, \*0.01 mg/kg for meat and \*0.005 mg/kg for milk. There are Australian MRLs for barley and wheat at 0.05 mg/kg. There are Australian MRLs for barley forage, green 5 ppm, barley straw and fodder, dry 7 ppm, wheat forage, green 5 ppm and wheat straw and fodder, dry 7 ppm.

Lactating dairy cattle were dosed at 4 ppm (0.12 mg/kg bw) and 41 ppm (1.2 mg/kg bw) for 28 days. Residues in milk for the 4 ppm dose group were <0.001 mg/kg for 20 of 27 daily samples, with a maximum observable residue of 0.002 mg/kg. Residues in tissues at slaughter were <LOD except for liver for which the maximum residue was 0.04 mg/kg. For the 41 ppm dose group a detectable residue in fat of 0.02 mg/kg was observed in a single animal.

It is anticipated that animal product residues will be below typical method LOQs.

## EPTC (eptam)

-is a thiocarbamate herbicide used for the pre-emergent control of certain grasses and broad-leafed weeds and is used as a pre-plant application in crops. It is used on c*ereals* at 3.96 kg ai/ha. No harvest WHP required.

There are Australian but no Codex or US tolerances for EPTC in animal commodities. The Australian MRLs are all set at \*0.1 mg/kg. The Australian MRLs for cereal grains is \*0.04 mg/kg. As no residues are present in the crops at harvest there is no reasonable expectation of residues in animal commodities.

It is anticipated that animal product residues will be below typical method LOQs.

## Esfenvalerate

- is a synthetic pyrethroid insecticide used for the control of various insects in crops.

The application rates for *cereals* are reported in the table below together with the harvest WHPs and any label feeding restraints.

Сгор	Rate (g ai/ha)	Harvest WHP (days)
Cereals	3.5	7
Maize	25	7
Sorghum	22.5	7
Wheat, oats, barley	16.5	7
Winter cereals (wheat, barley, triticale)	15	7

There are Australian, Codex and USA (expire on 2/4/2010) MRLs for fenvalerate in animal tissues as well as Codex and US MRLs for esfenvalerate. The relevant MRLs for cattle fat are 1 (meat mammalian [in the fat]), 1 and 1.5 mg/kg for Australia, Codex and the USA respectively. The relevant MRLs for milk are 0.2 mg/kg, 0.1 F mg/kg and 0.3 mg/kg (7 mg/kg for milk fat) for Australia, Codex and the USA respectively. There are Australian MRLs of 2 mg/kg for cereal grains.

The dairy cow feeding study with [<sup>14</sup>C]fenvalerate was designed to provide residue transfer information as well as metabolism information<sup>45</sup>. The level of fenvalerate in the animal diet was 79 ppm. Approximate levels of <sup>14</sup>C and % as fenvalerate were: fat 1-3 mg/kg (90%+), milk 0.47 mg/kg (90%+), muscle 0.25 mg/kg (90%), liver 2 mg/kg (<1%) and kidney 1.4 mg/kg (17%), giving an estimated TF for fat of 3/79 = 0.04.

Anticipated residues in fat from feeding cereal grain with residues at the MRL are  $2 \times 0.04 = 0.08$  mg/kg.

Anticipated residues in milk from feeding cereal grain with residues at the MRL are  $2 \times 0.006 = 0.012$  mg/kg.

Livestock residues are not anticipated to exceed international and/or domestic market standards.

#### Ethephon

- is a plant growth regulator used on *barley* for anti-lodging. The application rate is up to 0.36 kg ai/ha.

A harvest WHP of 1 day applies.

The Codex and Australian MRLs for ethephon in edible offal are \*0.2 and 0.2 mg/kg respectively. The Codex and Australian milk MRLs are \*0.05 and 0.1 mg/kg. The US tolerance for cattle kidney is 1, meat & fat 0.02 and milk is 0.01 mg/kg .. Australia has a primary animal feed commodity MRL of 10 mg/kg. The MRL for barley is 1 mg/kg.

In a study where dairy cows were fed at up to 150 ppm in the diet for 28 days, residues in tissues were <0.1 mg/kg for muscle, <0.2 mg/kg for fat, liver and kidney<sup>46</sup>. It is considered unlikely that feeding of cereal grain would lead to residues in animal tissues that are above likely LOQs of regulatory methods.

It is anticipated that animal product residues will be below typical method LOQs.

#### Fenitrothion

-is an OP insecticide used to control Australian plague locust in *cereals*. The application rate is up to 500 g ai/ha. It is also registered as a grain protectant at a rate of 6 ppm. No harvest WHP required.

There are Australian and Codex but no US MRLs for fenitrothion in animal tissues. The relevant Australian and Codex MRLs for cattle fat are T\*0.05 and \*0.05 mg/kg respectively. The Australian MRL for milks is T\*0.05 [in the fat] mg/kg and the Codex MRL is \*0.01 mg/kg. The Australian MRL for cereal grains is 10 mg/kg.

Residues in tissues were <0.05 mg/kg in a 28 day lactating cow feeding study conducted at a feeding level equivalent to 100 ppm in the feed<sup>47</sup>. There is no reasonable expectation of finite residues in milk or tissues as a result of the feeding of cereals or their by-products.

<sup>&</sup>lt;sup>45</sup> 2002 JMPR. Pesticide Residues in Food - 2002 Evaluations – Part I: Residues Volume 1, FAO Plant Production and Protection Paper 175/1. FAO and WHO 2003

<sup>&</sup>lt;sup>46</sup> 1994 JMPR - Pesticide Residues in Food - 1994 Evaluations, Part I Residues FAO Plant Production and Protection Paper 78. FAO and WHO 1995

<sup>&</sup>lt;sup>47</sup> The NRA Review of Fenitrothion Interim Report Volume 2, June 1999, Existing Chemicals Review Program National Registration Authority for Agricultural and Veterinary Chemicals – Residues Assessment

It is anticipated that animal product residues will be below typical method LOQs.

Fenoxaprop-ethyl

-is an aryloxyphenoxypropionate herbicide used for control of certain weeds in *wheat, barley, triticale, oats* and *rye*. The application rate is up to 50 g ai/ha with application up to 10 weeks after sowing.

The harvest WHP is 10 weeks.

There are Australian and US but no Codex MRLs for fenoxaprop-ethyl in animal commodities. The Australian MRLs are 0.2 mg/kg for edible offal, 0.05 mg/kg for meat (mammalian) and 0.02 mg/kg for milk. The US MRLs are 0.05 mg/kg for animal tissues and 0.02 mg/kg for milk. The MRL for barley, rye, triticale and wheat is \*0.01 mg/kg.

The Australian and US residue definitions are the same and are the sum of fenoxaprop-ethyl and its metabolites [2-[4-](6-chloro-2-benzoxazoly)oxy]phenoxy]propanoic acid and 6-chloro-2,3-dihydrobenzoxazol-2-one], each expressed as fenoxaprop-ethyl.

The log  $P_{ow}$  is 4.58. The lack of residues in grain suggests no residues should be expected in cattle and sheep tissues or milk.

It is anticipated that animal product residues will be below typical method LOQs.

# <u>Fipronil</u>

- is a phenylpyrazole insecticide used for control of locusts. Application to *sorghum* is at 1.25 g ai/ha.

The harvest WHP is 14 days.

It is also registered as a seed treatment for *rice* and *sorghum*. The application rate is 10 g ai/100 kg seed or 12.5 g ai/ha for rice and 75 g ai/100 kg seed for sorghum.

The relevant Australian, Codex and US tolerances for fipronil in animal fat are 0.1, 0.5 (cattle meat in the fat) and 0.4 mg/kg respectively while the milk MRLs are 0.01, 0.02 mg/kg while the US MRL is 1.5 mg/kg for milkfat (representing 0.05 mg/kg in whole milk). The Australian MRL for rice is \*0.005 mg/kg and for sorghum 0.01 mg/kg.

If maximum residues in cereal grain are assumed to be at the highest MRL (0.01 mg/kg) and using the transfer factor for fat reported by the 2001 JMPR (TF = 1.1-1.2), anticipated maximum residues in fat are  $\approx 0.01 \times 1.2 = 0.012$  mg/kg<sup>48</sup>.

The TF for milk is 0.1 giving anticipated residues in milk of  $\approx 0.01 \times 0.1 = 0.001$  mg/kg. Residues from feeding cereal feed items derived from cereal crops treated with fipronil are unlikely to represent a problem.

Livestock residues are not anticipated to exceed international and/or domestic market standards.

## Flamprop-methyl

-is a herbicide used for the control of wild oats in *wheat* and *triticale*. The application rate is up to 225 g ai/ha.

No harvest WHP is required.

<sup>&</sup>lt;sup>48</sup> 2001 JMPR Pesticide Residues in Food - 2001 Evaluations – Part I, FAO Plant Production and Protection Paper 171. FAO and WHO 2002

There are Australian but no Codex or US MRLs for flamprop-methyl in animal commodities. The Australian MRLs are all \*0.01 mg/kg. The MRLs for wheat and triticale are 0.05 mg/kg.

In a study where flamprop-methyl was administered to lactating  $cows^{49}$  at low dose levels (0.3-3 mg/kg in total diet,) and the excretion of total metabolites in milk, urine and faeces were measured as well as residues in tissues, residues in milk in most cases were well below 0.001 mg/kg; in muscle samples <0.003 mg/kg. Elimination of the herbicide from the animals was rapid in every case and this, together with the low residue levels, was attributed to very efficient metabolic deesterification to the parent carboxylic acid metabolites (flamprop). This metabolite possess physical properties ideally suited for excretion via the kidneys and bile into urine and faeces and, conversely, unsuited for transport into milk.

It is anticipated that animal product residues will be below typical method LOQs.

# <u>Fludioxonil</u>

-is a fungicide used for the control of damping off caused by *Fusarium* spp. and *Penicillin* spp. in maize and sweet corn. It is applied as a seed treatment at an application rate of 5 g ai/100 kg seed. A harvest WHP is not required.

DO NOT graze or cut for stock food for 4 weeks after application (probably should read planting treated seed)

There are Australian but no Codex or US MRLs for animal tissues. The Australian MRLs have been set at \*0.05 for edible offal and \*0.01 mg/kg for meat and milk. The Australian MRL for maize and sweet corn (corn-on-the-cob) are \*0.02 mg/kg. The animal feed MRLs are \*0.02 ppm for maize fodder, maize forage and sweet corn forage and fodder.

No residues were observed above the analytical LOQ of 0.01 mg/kg (meat) and 0.05 mg/kg (liver and kidney) in an animal transfer study conducted in dairy cattle<sup>50</sup>. Lactating cows were treated with fludioxonil in gelatine capsules equivalent to 0.55, 1.6 and 5.5 ppm in feed for 28-30 consecutive days. There is no expectation of residues in tissues above regulatory method LOQs.

It is anticipated that animal product residues will be below typical method LOQs.

<u>Flurasulam</u>

is a herbicide used on *wheat, barley, oats, triticale* for the control of various weeds. The application rate is up to 5 g ai/ha. No harvest WHP is required.

DO NOT graze or cut for stock feed for 7 days after application.

There are Australian but no Codex or US MRLs for florasulam in animal commodities. The Australian MRLs for edible offal, meat and milk of \*0.01 mg/kg and for cereal grain at \*0.01 mg/kg. The MRLs for forage of cereal grains [fresh weight] and straw and fodder of cereal grains (dry) are both \*0.05 ppm.

<u>Goat metabolism:</u> Florasulam, radiolabelled as either [UL-aniline-<sup>14</sup>C]XDE-570 (A-label) or [triazolopyrimidine-9-<sup>14</sup>C]XDE-570 (TP-label), was administered daily to two lactating goats (one per treatment) at a dose level of approximately 0.48 mg/kg bw/day five consecutive days (using a

<sup>&</sup>lt;sup>49</sup> Crayford,-J-V; Harthoorn,-P-A; Hutson,-D-H (1976) Excretion and residues of the herbicide benzoylprop-ethyl, flamprop-isopropyl and flamprop-methyl in cows, pigs and hens. *Pesticide-Science*. 1976; 7(6): 559-570

<sup>&</sup>lt;sup>50</sup> Public Release Summary on Evaluation of the new active Fludioxinil in the product Maxim 100 FS Fungicide Seed Treatment National Registration Authority for Agricultural and Veterinary Chemicals April 2000 Canberra Australia

bolus gun) and was equivalent to a dietary burden of approximately 11 ppm florasulam at an average feed consumption of 2 kg/day. Approximately 24 hours after the final dose, the animals were sacrificed and samples of tissues (liver, kidney, muscle and fat), blood, gastrointestinal contents and urine from the bladder were collected.

Recoveries of the administered dose (AD) were 89% for the A-label and 83% for the TP-label. The majority of the radioactivity was excreted in the urine and faeces, accounting for a total of 99.8% of the recovered radioactivity. Residues in milk and tissues each represented <0.1% AD, and totalled 0.123% AD and 0.139% AD for the A- and TP-labels, respectively.

The highest concentration of residues in tissues was found in the kidney (0.039–0.069 ppm), followed by liver (0.023–0.033 ppm), milk (0.016–0.033 ppm), fat (0.0016–0.0017 ppm), and muscle (0.0009–0.0016 ppm). Greater than 90% of the TRRs in urine, milk, and kidney were extractable; however only 22.4–23.2% of the TRRs in liver were extracted. Unextracted residues in liver were treated with protease, which released an additional 41.8 and 56.5% of the TRRs (0.0138 and 0.013 ppm) of the A- and TP-labels, respectively. However, 32.5–43.1% of the TRRs (0.0075–0.014 ppm) in liver remained bound, and were not further analyzed.

The predominant metabolite identified in all extracts was the parent compound, representing 87.6–98.3% of the TRRs in urine, milk, and kidney, and 15.2–15.3% of the TRRs in liver. A minor metabolite representing up to 1.5% of the TRRs was tentatively identified as 5-OH-florasulam in urine, liver and kidney samples. No other metabolites were identified.

The results obtained with the two different labels indicate that no bridge cleavage occurred. The low tissue burden and high excretion rate of unmetabolized florasulam, as well as the low log Kow (1.00 at pH 4.00 and -1.22 at pH 7.0) indicate a low potential for sequestration in fatty tissues.

It is anticipated that animal product residues will be below typical method LOQs.

Flumetsulam

is a triazolopyrimidine sulfoanilide herbicide used on *wheat, barley, oats, triticale* and *cereal rye* for the control of various weeds. The application rate is up to 40 g ai/ha. No harvest WHP is required for maize. A 4 week harvest WHP applies to winter cereals.

There are Australian but no Codex or US MRLs for flumetsulam in animal commodities. The Australian MRLs are 0.3 for edible offal and \*0.1 mg/kg for meat and milk. The MRLs for maize, wheat, barley, oats, rye and triticale are \*0.05 mg/kg.

It is anticipated that animal product residues will be below typical method LOQs.

<u>Flumioxazin</u> -is a diphenyl ether herbicide use to control weeds prior to sowing of wheat, barley and oats. The application rate is 15 g ai/ha. A harvest WHP is not required. DO NOT crop or treated vegetation for 6 weeks after application.

There are Australia MRLs set at \*0.01 mg/kg for animal commodities including milk. The cereal grain MRL is \*0.05 mg/kg. The MRLs for animal feed commodities are \*0.05 mg/kg for forage of cereal grains and for straw and fodder (dry) of cereal grains.

The APVMA PRS reported a study where goats were orally dosed with 0.5 mg/kg bw  $^{14}$ C-flumioxazin for 5 days (equivalent to a nominal dose rate of 12 ppm)<sup>51</sup>. The majority of the radioactivity from oral dosing was eliminated in the urine and faeces as metabolites. Negligible residues were transferred into the milk (<0.03 mg/kg equivalents) and into tissues of the animals (<0.19 mg/kg equivalents)

It is anticipated that animal product residues will be below typical method LOQs.

# Fluquinconazole

-is a triazole fungicide used as a seed treatment for *wheat* for the control of bunts, smuts etc. It is applied at an application rate of 0.75 kg ai/tonne of seed. No harvest WHP required.

There are Australian but no Codex or US MRLs for fluquinconazole in animal commodities. The Australian MRLs are 0.2 mg/kg for edible offal, 0.5 mg/kg for meat (mammalian)(in the fat) and \*0.02 mg/kg for milk. The Australian MRL for wheat is \*0.02 mg/kg.

The TF for fat is  $0.6^{52}$ . Anticipated residues are  $<0.02 \text{ ppm} \times 0.6 = <0.012 \text{ mg/kg}$ . The TF for milk is 0.04. Anticipated residues are  $<0.02 \text{ ppm} \times 0.04 = <0.0008 \text{ mg/kg}$ .

It is anticipated that animal product residues will be below typical method LOQs.

# <u>Fluroxypyr</u>

- is a selective herbicide used for the control of broadleaf weeds in crops such as *maize, sorghum* and *winter cereals* as well as pastures. It is applied post-emergent to these crops at application rates of up to 0.3 kg ai/ha.

No harvest WHP is required.

There are no Codex animal tissue MRLs for fluroxypyr. The US (parent + metabolite) residue definition differs to that used in Australia (parent). The relevant US MRL for animal tissue is 1.5 mg/kg for cattle kidney. The relevant Australian MRL is 0.1 mg/kg for edible offal (mammalian except kidney), mammalian kidney \*0.01 mg/kg. The MRL for milk in Australia 0.1 and the US is 0.3 mg/kg. The Australian MRL for cereal grains is 0.2 mg/kg. There are animal feed MRLs of 100 ppm for forage of cereal grains and other grass-like plants and for straw and fodder (dry) and hay of cereal grains and other grass-like plants suggesting the Australian MRLs were based on feeding at this level. Feeding grain with residues 500× less than that used to set the Australian animal commodity MRLs is unlikely to lead to detectable residues in cattle and sheep tissues.

It is anticipated that animal product residues will be below typical method LOQs.

## <u>Flutriafol</u>

-is a conazole fungicide used for the control of stripe and wheat rust in wheat and powdery mildew in barley at application rates up to 125 g ai/ha.

For in furrow application:

Harvest WHP not required. Do not graze or cut for stock food for 4 weeks after application.

For foliar application.

The harvest WHP is 10 weeks for barley and 7 weeks for wheat.

<sup>&</sup>lt;sup>51</sup> Public Release Summary on Evaluation of the new active FLUMIOXAZIN in the product Pledge 500 WG Herbicide Australian Pesticides and Veterinary Medicines Authority December 2003 Canberra Australia

<sup>&</sup>lt;sup>52</sup> Evaluation of fully approved or provisionally approved products. Issue 184: Evaluation on Fluquinconazole, May 1999, Department of Environment Food and Rural Affairs, Pesticide Safety Directorate. UK

Do not graze or cut for stock food for 10 weeks (barley) or 7 weeks (wheat) after application.

The Australian MRLs are \*0.05 mg/kg for meat mammalian and milks and 0.5 mg/kg for edible offal. There are no Codex or USA MRLs for animal commodities. The Australian tolerances for barley is 0.2 mg/kg and for other cereal grains \*0.02 mg/kg.

EFSA DAR: In a metabolism study a 3 yr old Friesian cow was dosed at 2 ppm diet (as two doses per day) for 7 days. The cow was sacrificed 4 hours after the last dose. Milk production was about 10 L/day. Residues in milk reached a plateau of 0.007-0.008 mg/kg after 4 days. Flutriafol was 1% TRR in milk, 29% in liver and 7% in kidney.

A powdered formulation containing 100 g ai/ka flutriafol and 5.33 g ai/kg cypermethrin was incorporated into animal feed and administered to chickens (Rhode Island Red/White Leghorn  $\times$ ), Merino sheep, pig boars and lactating cows (Jersey/Friesian or Friesian). The level in the feed was 150 ppm flutriafol for chickens, sheep and pigs and 54.5 ppm for cows. Animals were exposed to flutriafol in feed for 7 days and then sacrificed. Additional animals were slaughtered after a further 7 or 14 days on clean feed.

No residues were detected in milk. Residue in eggs showed a steady increase to reach a maximum of 1.63 mg/kg after 7 days dosing. Following cessation of dosing residues declined steadily to be undetectable by day 14. No residues were detected in tissues of animals slaughtered after 7 or 14 days on clean feed.

Tissue	Chicken	Sheep	Pig	Cow
Heart	0.36	0.03	2.56	< 0.02
Liver	1.44	0.55	26.4	0.72
Kidney	-	< 0.02	5.22	0.03
Fat (peritoneal)	0.82	0.10	6.70	< 0.02
Muscle (loin)	-	< 0.02	1.90	< 0.02
Muscle (leg)	-	< 0.02	1.72	< 0.02
Gizzard	0.38	-	-	-
Breast meat	0.15	-	-	-
Brain	-	< 0.02	-	-

Residues of flutriafol (mg/kg) in various animal tissues following 7 days continuous dosing.

Livestock residues are not anticipated to exceed international and/or domestic market standards.

#### Glyphosate

-is a non-selective foliar herbicide used for the control of broadleaf weeds and grasses in crops such as sugarcane, *maize, sorghum* and *winter cereals* as well as pastures. It is applied prior to sowing at application rates up to 1.08 kg ai/ha.

No harvest or grazing WHPs are required.

The relevant Australian and Codex MRLs are the same at 2 mg/kg for offal. MRLs for milk are\*0.1 and \*0.05 mg/kg. The relevant USA MRL is 5 mg/kg for cattle meat byproducts. The Australian MRL for cereal grains (except sorghum, wheat and barley) is T\*0.1 mg/kg while those for barley is 10, sorghum is 15 and wheat is 5 mg/kg. There is also an MRL for wheat bran, unprocessed at 20 mg/kg. The primary animal feed commodity MRL for glyphosate is 150 mg/kg. The anticipated exposure to glyphosate is derived from feeding sorghum at 50% of the diet and wheat bran at 50% of the diet to give and anticipated feed level of  $15 \times 0.5 + 20 \times 0.5 = 17.5$  ppm.

When administered to animals glyphosate is rapidly excreted without degradation. Residues in cattle, pig and poultry meat, eggs and milk were negligible after the animals were fed with a diet containing 100 ppm glyphosate and aminoglyphosate acid<sup>53</sup>. The highest residues were in pig liver and kidney (up to 0.16 and 0.91 mg/kg, respectively) and cattle kidney (up to 1.4 mg/kg). TF cattle kidney = 0.014. Anticipated residues on feeding at 17.5 ppm in the diet are  $17.5 \times 0.014 = 0.245$  mg/kg, well below the Codex, US and Australian MRLs.

Livestock residues are not anticipated to exceed international and/or domestic market standards.

## Halosulfuron-methyl

-is a selective post-emergent herbicide used for the control of nutgrass in *maize* and *sorghum* crops. It is applied post-emergent to crops at an application rate of up to 0.0975 kg ai/ha. No harvest WHP is required.

There are no Codex MRLs for halosulfuron. The US (parent + metabolite) and Australian (parent) residue definitions differ. The relevant US MRLs for animal tissues are 0.1 mg/kg for offal while the Australian MRL for edible offal (mammalian) is 0.2 mg/kg. The Australian MRL for milk is \*0.01 mg/kg. There are animal feed MRLs of 2 ppm for maize forage and fodder, 0.1 ppm for sorghum fodder and \*0.05 ppm for sorghum forage (fresh weight). The Australian MRLs for maize and sorghum are \*0.05 mg/kg. Feeding at this level is not expected to result in significant residues in animals (<LOD mg/kg).

The US EPA reported<sup>54</sup> the details of goat and hen metabolism studies on halosulfuron-methyl. As with plants, the residue of concern in animals is halosulfuron-methyl *per se*. The current US EPA approved method for enforcement of tolerances for halosulfuron-methyl in animal commodities is based on analysis of the chlorosulfonamide half of the halosulfuron- methyl molecule; thus, it quantitates residues of parent halosulfuron- methyl as well as those metabolites containing the chlorosulfonamide acid moiety (i.e., it is not specific to halosulfuron-methyl *per se*). The US EPA decided that animal tolerances will still be expressed as halosulfuron-methyl and its metabolites determined as 3-chlorsulfonic acid, expressed as parent equivalent.

It is anticipated that animal product residues will be below typical method LOQs.

## Imazapic

-is a imidazolinone herbicide used for the control of weeds in the fallow prior to sowing of *winter crops*. It is applied at an application rate of up to 48 g ai/ha. No harvest WHP is required.

There are no Codex MRLs for imazapic. The relevant US MRLs for animal tissues are 1 mg/kg for kidney and 0.1 mg/kg for meat, fat and meat bypr except kidney while the Australian MRL for edible offal (mammalian) is \*0.05 mg/kg, for meat (mammalian (in the fat) \*0.05 mg/kg and for milk \*0.01 mg/kg. There are animal feed MRLs of \*0.05 ppm for forage of cereal grains (fresh weight) and wheat straw and fodder (dry). No MRLs have been set for cereal grains as no residues were expected. Feeding is not expected to result in significant residues in animals (<LOD).

<sup>&</sup>lt;sup>53</sup> 1986 JMPR Pesticide Residues in Food - 1986 Evaluations, Part I Residues FAO Plant Production and Protection Paper 78. FAO and WHO 1986

<sup>&</sup>lt;sup>54</sup> halosulfuron-methyl Pesticide Tolerance 4/99 Environmental Protection Agency 40 CFR Part 180 [OPP-300854; FRL-6078-5] RIN 2070-AB78

In the goat metabolism study 3 goats were exposed to <sup>14</sup>C-imazapic at doses of 0, 3.76 and 15.1 mg in gelatin capsules for seven consecutive days<sup>55</sup>. These levels were considered to be 0,  $33\times$ , and  $197\times$  of maximum residue that foraging animals would likely receive in the diet in the US. The limits of detection for imazapic were 0.02 mg/kg in fat and 0.01 mg/kg for milk and tissues. Daily milk residues were below the limits of detection as were all tissue concentrations with the exception of the kidney: 0.01 mg/kg at the low dose and 0.05 mg/kg at the high dose. Residues from the kidney consisted of 30% parent compound.

It is anticipated that animal product residues will be below typical method LOQs.

#### <u>Imazapyr</u>

-is a imidazolinone herbicide used for the control of weeds in *maize* with Clearfield® technology. It is applied at an application rate of up to 21.8 g ai/ha. No harvest WHP is required.

There are Australian and US but no Codex MRLs for imazapyr in animal tissues. The relevant Australian MRLs are \*0.05 mg/kg for edible offal (mammalian), meat (mammalian)(in the fat) and \*0.01 mg/kg for milk. The US MRLs are 0.05 mg/kg for meat, fat and meat bypds except kidney for which the MRL is 0.2 mg/kg and milk for which the MRL is 0.01 mg/kg. The MRL for maize is \*0.05 ppm.

It is anticipated that animal product residues will be below typical method LOQs.

#### Imazethapyr

-is a imidazolinone herbicide used for the control of weeds in *maize* with Clearfield® technology. It is applied at an application rate of up to 65.6 g ai/ha. No harvest WHP is required.

There are no Codex MRLs for imazethapyr in animal tissues. The relevant Australian MRLs are \*0.1 mg/kg for edible offal (mammalian), meat (mammalian) and milk while US MRL for cattle meat byproducts is 0.1 mg/kg. The MRL for maize is \*0.05 ppm. Feeding at this level is not expected to result in significant residues in animals (<LOD).

In the goat metabolism study, parent <sup>14</sup>C-imazethapyr was dosed to lactating goats at 0.25 ppm and 1.25 ppm<sup>56</sup>. Results showed <sup>14</sup>C-residues of <0.01 ppm in milk, and <0.05 ppm in leg muscle, loin muscle, fat, liver, and kidney. Additional animal metabolism studies have been conducted with CL 288511 (main metabolite in treated crops fed to livestock) in lactating goats. In these studies, lactating goats dosed at 42 ppm of <sup>14</sup>C-CL 288511 showed <sup>14</sup>C-residues of <0.01 ppm in milk, leg muscle, loin muscle, and omental fat. <sup>14</sup>C-residue levels in the liver, and kidney were 0.02 and 0.09 ppm, respectively. These studies indicate that parent imazethapyr and CL 288511-related residues do not accumulate in milk or edible tissues of the ruminant.

<sup>&</sup>lt;sup>55</sup> ERA TR 00-21-28-01e IMAZAPIC [Plateau and Plateau DG]-Human Health and Ecological Risk Assessment Final Report Prepared for: USDA, Forest Service Task No. 28 USDA/FS Contract No. 53-3187-5-12 USDA/FS Order No. 43-3187-0-0153 Submitted to: Leslie Rubin, COTR Animal and Plant Health Inspection Service (APHIS) Biotechnology, Biologics and Environmental Protection Environmental Analysis and Documentation United States Department of Agriculture Submitted by: Syracuse Environmental Research Associates, Inc. January 28, 2001

<sup>&</sup>lt;sup>56</sup> Imazethapyr; Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical in or on Food [Federal Register: January 3, 2003 (Volume 68, Number 2)] Page 370-374

**Imidacloprid** 

- is a chloronicotinyl (pyridylmethylamine) insecticide. Application to *cereals* is as a seed treatment.

The application rates for cereals are reported in the table below together with the harvest WHPs and any label feeding restraints.

Сгор	Rate	Harvest WHP (davs)	Grazing WHP (days)
Maize	0.84 g ai/1000 seeds	-	4 weeks
Sorghum	258 g ai/100 kg seed	-	4 weeks
Cereals	14 g ai/100 kg seed	-	9 weeks

There are Australian, Codex and US MRLs for imidacloprid in animal tissues. The relevant Australian and US tolerances for imidacloprid in edible offal are 0.2 and 0.3 mg/kg respectively and for milk 0.05 and 0.1 mg/kg. The Codex MRL for edible offal is 0.05 mg/kg and for milk \*0.02 mg/kg. The Australian MRLs are 0.05 mg/kg for maize, \*0.02 mg/kg for sorghum and \*0.05 mg/kg for other cereal grains.

The TF for liver is  $0.01^{57}$ . Assuming residues in grain at 0.05 ppm and feeding at 100% of the diet, residues in liver would be  $0.05 \times 0.01 = 0.0005$  mg/kg.

The TF for milk is 0.003. Anticipated maximum residues in milk are  $0.05 \times 0.003 = 0.00015$  mg/kg.

It is anticipated that animal product residues will be below typical method LOQs.

Iodosulfuron-methyl

is a sulfonylurea herbicide used for the control of various weeds in *cereals*. Application is at rates up to 10 g ai/ha.

A harvest WHP is not required.

There are Australian but no Codex or US MRLs for iodosulfuron-methyl in animal commodities. The Australian MRLs for animal commodities have all been set at \*0.01 mg/kg. The MRL for wheat is \*0.01 mg/kg.

In a dairy cow metabolism study with dosing at a rate equivalent to feeding at 14 ppm in the diet the maximum residues in fat (omental, renal and subcutaneous), milk and offal (kidney and liver) were 0.037, 0.017 and 0.16 mg equiv./kg respectively<sup>58</sup>. Residues in muscle, fat, milk and offal would be undetectable as a result of feeding 100% wheat grain containing iodosulfuron- methyl at the MRL.

It is anticipated that animal product residues will be below typical method LOQs.

## Lambda-cyhalothrin

- is a synthetic pyrethroid insecticide used for the control of various insects in crops. It is registered on *barley, wheat* and *sorghum crops* for the control of various pests. The application rate is up to 10 g ai/ha for barley and wheat and up to 17.5 g ai/ha for sorghum.

The harvest WHP is 14 days for the cereal crops listed above.

<sup>&</sup>lt;sup>57</sup> 2002 JMPR. Pesticide Residues in Food - 2002 Evaluations – Part I: Residues Volume 1, FAO Plant Production and Protection Paper 175/1. FAO and WHO 2003

<sup>&</sup>lt;sup>58</sup> Public Release Summary on Evaluation of the new active IODOSULFURON-METHYL-SODIUM in the product HUSSAR SELECTIVE HERBICIDE National Registration Authority for Agricultural and Veterinary Chemicals March 20001 Canberra Australia

There are Australian, Codex and USA MRLs for cyhalothrin in animal commodities. The relevant MRLs for cattle fat are 0.5 and 3 mg/kg for Australia and the USA respectively. The Australian MRL for milk is 0.5 [in the fat] mg/kg while the US one is 10 mg/kg for milk fat (reflecting 0.4 mg/kg in whole milk). The Codex MRLs are 3 mg/kg for fat and 0.2 mg/kg for milk. There are Australian MRLs for barley (0.2 mg/kg), sorghum (0.5 mg/kg) and wheat (\*0.05 mg/kg) and an animal feed MRL for cereal forage (green) (1 ppm).

If residues in cereal grain are fed to animals are assumed to be at the same level as the sorghum MRL, residues in fat  $(TF \ 0.3-0.5)^{59}$  would be  $0.5 \times 0.5 = 0.25$  mg/kg. The TF for milk is 0.02 giving anticipated maximum residues of  $0.5 \times 0.02 = 0.01$  mg/kg for whole milk.

Livestock residues are not anticipated to exceed international and/or domestic market standards.

## Linuron

-is a selective urea herbicide used for the control of various weeds in *wheat, barley, oats* and *maize* crops. The application rate is 0.427 kg ai/ha for wheat, barley and oats with application 3-5 weeks after sowing. For maize, application is up to 2.7 kg ai/ha and is applied soon after planting or as a directed spray.

No harvest WHP is required.

There are Australian and US but no Codex MRLs for linuron in animal commodities. The Australian MRLs are all \*0.05 mg/kg, except for edible offal (mammalian) which is 1 mg/kg, while the US MRL for cattle fat is 0.2, liver and kidney 2 and milk is 0.05 mg/kg. The MRL for cereal grains is \*0.05 mg/kg.

The UK PSD and US EPA reported several animal feeding studies<sup>60,61</sup>. In study were two dairy cows (Guernsey) were fed at 1 ppm for 30 days, residues were not found in milk, lean meat or fat (<0.05 mg/kg); liver and kidney residues ranged from 0.4-0.7 mg/kg (common moiety method = linuron and its metabolites convertible to 3,4-dichloroaniline, calculated as linuron). In a separate study, 2 dairy cows (Guernsey) were fed at 50 ppm for 30 days. Residues in milk were 0.3-0.35 mg/kg. Lean meat and fat contained *ca*. 0.5 mg linuron/kg and liver and kidney 13 mg/kg (common moiety method). No residues are expected from the feeding of cereal grains.

It is anticipated that animal product residues will be below typical method LOQs.

## Maldison (malathion)

- is an organophosphate insecticide used for the control of various insects and in *cereals*. The application rate is up to 1.1 kg ai/ha for cereals and 0.8 kg ai/ha for rice. The harvest WHP is 1 day for rice.

There are Australian and but no Codex MRLs malathion in animal tissues. The relevant Australian and USA MRLs for malathion in animal tissues are 1 mg/kg in Australia and 4 mg/kg in the US. The Australian MRL for milk is 1 [in the fat] mg/kg while the US MRL is 0.5 mg/kg for milk fat (from application to dairy cows). The MRL for cereal grains is 8 mg/kg.

<sup>&</sup>lt;sup>59</sup> Cyhalothrin. (Environmental health criteria ; 99) 1.Pyrethrins - adverse effects 2.Pyrethrins - toxicity I. Series ISBN 92 4 154299 3 (NLM Classification: WA 240) ISSN 0250-863X

<sup>&</sup>lt;sup>60</sup> Evaluation of fully approved or provisionally approved products. Issue 132: Evaluation on Linuron, May 1995, Department of Environment Food and Rural Affairs, Pesticide Safety Directorate. UK

<sup>&</sup>lt;sup>61</sup> Linuron Tolerance Reassessment Eligibility Decision Residue Chemistry Considerations PC Code 035506; Case 0047 Environmental Protection Agency, Office of Pesticide Programs, Special Review and Reregistration Division

No residues of malathion were detected in tissues in a goat metabolism study conducted at a nominal feeding level of 115 ppm<sup>62</sup>. There is no expectation of residues of malathion in tissues arising from the feeding of cereal grains derived from treated crops.

It is anticipated that animal product residues will be below typical method LOQs.

MCPA (4-chloro-2-methylphenoxy) acetic acid or in the USA 2-methyl-4-chlorophenoxyacetic acid -is a selective herbicide used for the control of broadleaf weeds in sugarcane, cereals (*barley, rye, oats, triticale, wheat*) and pastures etc. It is applied at an application rate of up to 1.05 kg ai/ha. No harvest WHP is required.

There are no Codex MRLs for MCPA in animal tissues. The Australian (parent) and US (parent + metabolite) residue definitions differ. The Australian MRL for meat (mammalian) is \*0.05 mg/kg as is the milk MRL. The US MRL for meat is \*0.1 mg/kg as is the milk MRL. The Australian MRL for cereal grains is \*0.02 mg/kg.

Cattle and sheep fed low to moderate doses of MCPA in the diet for 2 weeks showed no residues from levels less than about  $18 \text{ mg/kg}^{63}$ . The major metabolite of MCPA is 2-methyl-4-chlorophenol in the free and conjugated form, which is formed in the liver. The US has a tolerance of 300 mg/kg for pasture indicating that feeding at this level should not result in residues in animal tissues above the US MRL (i.e. the residues would be <LOQ or 0.1 mg/kg).

In a feeding study where calves were fed in the diet at 250 or 500 ppm for 28 days, residues were <LOQ in meat and fat at slaughter and <LOQ for liver at the 250 ppm feeing level<sup>64</sup>. Residues in kidney at 250 ppm feed level were 1.4 mg/kg. Residues in kidney and liver at the 500 ppm feed level were 0.14 and 2.3 mg/kg respectively. Residues at 7 days on clean feed after feeding at 500 ppm were 0.1 mg/kg in kidney. The half-life for depletion in tissues is estimated to be <2 days. Estimated TF for fat is <0.1 mg/kg  $\div$  500 ppm = <0.0002 and for offal (kidney) is 2.3 mg/kg  $\div$  500 ppm = 0.005. No residues are expected in milk of animals fed at up to 300 ppm in the diet.

It is anticipated that animal product residues will be below typical method LOQs.

#### MCPB (4-(2-Methyl-4-chlorophenoxy) butyric acid)

-is a selective herbicide used for the control of broadleaf weeds in and pastures etc. It is applied at an application rate of up to 1.68 kg ai/ha.

No harvest WHP is required.

There are no Codex or US MRLs for MCPB in animal tissues. The Australian MRLs for meat (mammalian) and milk are \*0.05 mg/kg. The Australian MRL for cereal grains is \*0.02 mg/kg. No MCPB was detected in the milk of cows fed MCPB in the ration at 50 ppm for four days (LOD 0.1 ppm)<sup>65</sup>. As no residues are expected in grain, none are expected in cattle and sheep tissues or milk.

<sup>&</sup>lt;sup>62</sup> 1999 JMPR - Pesticide Residues in Food - 1999 Evaluations, Part I Residues FAO Plant Production and Protection Paper 157. FAO and WHO 2000

<sup>&</sup>lt;sup>63</sup> MCPA. List A Reregistration Case 0017. Chemical No. 030501, 030502, 030516, 030564. Revised Product and Residue Chemistry Chapters for the Reregistration Eligibility Decision. DP Barcode: D299360

<sup>&</sup>lt;sup>64</sup> Leng. M.L., Comparative metabolism of phenoxy herbicides in animals, in Fate of pesticides in large animals edited by Ivie, G.W. and Dorough, H.W., Academic Press, New York 1977.

<sup>&</sup>lt;sup>65</sup> Bache, C.A., Lisk, D.J., Wagner, D.G. and Warner, R.G. 1964. Elimination of [(4-chloro-o-tolyl)oxy] butyric acid in urine from cows. J Dairy Sci. 47, 93-95.

#### Mefenpyr-diethyl (HOE–107892)

-is a herbicide safener used in conjunction with fenoxaprop-methyl for control of certain weeds in *wheat, barley, triticale, oats* and *rye*. The application rate is up to 13.5 g ai/ha with application up to 10 weeks after sowing.

The harvest WHP is 10 weeks.

In wheat, mefenpyr-diethyl can also be used at rates of up to 30 g ai/ha, applied up until the 5 tiller growth stage, with no harvest WHP being required when used as directed.

There are Australian and US but no Codex MRLs for mefenpyr-diethyl in animal commodities. The Australian MRLs are \*0.05 mg/kg for edible offal and meat (mammalian) and \*0.01 mg/kg for milk. The US MRL is 0.1 mg/kg for meat byproducts. The MRL for cereal grains is \*0.01 mg/kg. The Australian residue defiition is parent compound. There are US MRLs for barley (0.05mg/kg) and wheat (0.05 mg/kg). The US residue definition for plant commodities is the sum of mefenpyr-diethyl and its 2,4-dichlorophenyl-pyrazoline metabolites (HOE–094270 and HOE–113225).

The US EPA reported that the metabolism of mefenpyr-diethyl in ruminants is adequately understood<sup>66</sup>. A lactating goat was dosed with the compound at a level approximately 56-times the worst case dietary burden for 7-days. Low levels of residues of mefenpyr-diethyl and/or its 2,4-dichlorophenyl-pyrazoline containing metabolites were detected in liver and eggs.

It is anticipated that animal product residues will be below typical method LOQs.

#### Mesosulfuron-methyl

-is a pirimidylsulfonylurea herbicide used for weed control in wheat. The application rate is 9.9 g ai/ha.

Do not harvest for 8 weeks after application.

Do not graze or cut for stock food for 4 weeks after application.

The Australian MRLs for animal commodities are all \*0.01 mg/kg (including milk). The US MRL for meat by-products is 0.01 mg/kg. The MRL for wheat is \*0.02 mg/kg and for wheat forage and straw and fodder dry \*0.02 mg/kg. The US MRL for grain is 0.03 mg/kg and for grain aspirated fractions 0.6 mg/kg.

APVMA Gazette<sup>67</sup> noted that Metabolism studies indicate that the excretion of mesosulfuronmethyl in animals is rapid and extensive. Metabolism was less extensive in wheat with very low terminal residues observed in grain and straw. Residue trials conducted in Europe and Australia show residues are not expected to exceed the limit of analytical quantitation in any crop fraction (wheat grain, forage and straw) or in any animal tissues, milk and eggs.

It is anticipated that animal product residues will be below typical method LOQs.

## Metalaxyl

- is a fungicide used on a variety of crops. It is used on *maize, barley* and *wheat* as a seed treatment and is applied at rates up to 175 g ai/100 kg seed for maize and as metalaxyl-M at 3 g ai/100 kg seed for barley and wheat.

A WHP is not required.

<sup>&</sup>lt;sup>66</sup> Notice of Filing of Pesticide Petitions, Federal Register: September 26, 1997 (Volume 62, Number 187) Page 50610-50613

<sup>&</sup>lt;sup>67</sup> NRA Gazette 2, 4 February 2003 page 24 NOTICE Mesosulfuron-methyl in the product: ATLANTIS SELECTIVE HERBICIDE

There are Australian and US but no Codex MRLs for metalaxyl in animal commodities. The Australian and Codex residue definition is parent compound. The Australian MRLs for edible offal and meat are \*0.05 mg/kg while the MRL for milk is \*0.01 mg/kg. The US residue definition is the sum of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methylphenyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl equivalents. The USA MRLs are 0.4 mg/kg for fat, liver and kidney and 0.05 mg/kg for meat and meat by-products and 0.02 mg/kg for milk. The MRL for cereal grains (barley, wheat) is \*0.01 mg/kg.

In a lactating goat metabolism study conducted at a dose level equivalent of feeding at 7 ppm, radioactive residues in tissues, expressed in metalaxyl equivalents, were all  $<0.06 \text{ mg/kg}^{68}$ . It is considered unlikely that feeding of maize derived from plants grown from metalaxyl treated maize seed would generate milk or tissue residues above regulatory LODs.

It is anticipated that animal product residues will be below typical method LOQs.

#### Methabenzthiazuron

-is a urea herbicide that is used for the control of various annual broad leafed weeds in *wheat*, *barley* and *oats*. The application rate is up to 0.6 kg ai/ha for barley and oats and 1.05 kg ai/ha for wheat.

No harvest WHP is required.

There are no Australian, Codex or US MRLs for animal commodities. The Australian MRL for cereal grains is \*0.05 mg/kg indicating that residues should not occur in the harvested crop. There is no reasonable expectation of residues in animals fed grain.

It is anticipated that animal product residues will be below typical method LOQs.

## Methidathion

- is an organophosphate insecticide used for the control of insects and mites in *cereal* and forage crops. The maximum application rate is 0.56 kg ai/ha.

The harvest WHP is 6 weeks when harvesting grain for human consumption, else not required.

There are Australian and Codex but no USA MRLs for methidathion in animal tissues. The Australian (Codex) and USA residue definitions differ: methidathion (Australia, Codex), sum of methidathion, its oxygen analogue, the sulfoxide and the sulfone (USA). The Australian and Codex that apply to animal tissues are 0.5 and \*0.02 mg/kg respectively. The corresponding milk MRLs are 0.5 [in the fat] and 0.001 mg/kg. The Australian MRL for cereal grains is \*0.01 mg/kg.

No residues of methidathion were observed in tissues of cows fed at up to 50 ppm in the diet when measured by the Australian or USA residue definitions<sup>69</sup>. There is no expectation of residues in animal tissues.

It is anticipated that animal product residues will be below typical method LOQs.

## Methiocarb

<sup>&</sup>lt;sup>68</sup> 1982 JMPR Pesticide Residues in Food - 1982 Evaluations, FAO Plant Production and Protection Paper 49. FAO and WHO 1983

<sup>&</sup>lt;sup>69</sup> Methidathion Reregistration Eligibility Decision Residue Chemistry Considerations Shaughnessy No. 100301; Case No. 0034 Environmental Protection Agency, Office of Pesticide Programs, Special Review and Reregistration Division

is a carbamate molluscicide and is used in *cereals* to control snails. The application rate is up to 0.44 kg ai/ha. The harvest WHP is 7 days.

There no Australian, Codex or US MRLs for methiocarb residues in animal commodities. There is no Australian MRL for cereal grains.

The 1981 JMPR reported the results of beef and dairy cattle feeding studies where cattle were fed rations containing 10, 30 and 100 ppm methiocarb for 29 days<sup>70</sup>. Residues were detected only in the liver (animals fed 30 and 100 ppm methiocarb) and kidney (animals fed 100 ppm methiocarb). All other tissues (brain, heart, muscle and fat) showed no detectable residues. There is no reasonable expectation for residues of methiocarb in animal tissues resulting from the feeding of grain derived from treated cereal crops.

It is anticipated that animal product residues will be below typical method LOQs.

Methomyl (also thiodicarb)

- is a carbamate insecticide used for the control of heliothis and loopers in winter cereals (*wheat, oats* and *barley*), *sorghum* and *maize*. The application rate is up to 0.45 kg ai/ha. The harvest WHP is 14 days for the crops listed above.

There are Australian and Codex but no USA MRLs for methomyl (as thiodicarb) in animal tissues. The MRLs have all been set at the LOQ. The Australian MRL for cereal grains is \*0.1 mg/kg.

No residues of methomyl/thiodicarb were observed in tissues (<0.01 mg/kg) of cows fed at up to 86 ppm in the diet when measured by the Australian or USA residue definitions<sup>71</sup>. There is no expectation of residues in animal tissues.

It is anticipated that animal product residues will be below typical method LOQs.

Methoprene and S-Methoprene

is used as a grain protectant at rates of up to 1 ppm.

There are Australian and Codex but no US MRLs for methoprene in animal commodities. In the US methoprene is exempt from the requirement of a tolerance in or on all food commodities when used to control insect larvae. The Australian and Codex tolerances for cattle fat are 0.3 and 0.2 mg/kg respectively. The Australian and Codex tolerances for milk are 0.1 and 0.1 F mg/kg respectively. The Australian MRL for cereal grains is 2 mg/kg.

The TF for fat is  $0.08-0.1^{72}$ . Feeding cereal grain at 100% of the diet would give residues of  $1 \times 0.1 = 0.1$  mg/kg in fat. Note the cereal application rate rather than the cereal grain MRL has been used as the latter is much higher to reflect possible analytical results from variability in residues in grain from inhomogeneous application.

The TF for whole milk is <0.01. Feeding cereal grain at 100% of the diet would give residues of  $1 \times <0.01 = <0.01$  mg/kg in milk.

<sup>&</sup>lt;sup>70</sup> 1981 JMPR Pesticide Residues in Food - 1981 Evaluations, FAO Plant Production and Protection Paper 42. FAO and WHO 1982

<sup>&</sup>lt;sup>71</sup> 2001 JMPR Pesticide Residues in Food - 2001 Evaluations – Part I, FAO Plant Production and Protection Paper 171. FAO and WHO 2002

<sup>&</sup>lt;sup>72</sup> APVMA Animal Residue Data Sheet - Methoprene Last updated J June 2002

Livestock residues are not anticipated to exceed international and/or domestic market standards.

# Metolachlor

-is a selective herbicide used for the control of annual grasses and broadleaf weeds in *maize*, winter cereals (*wheat, barley, oats* and *triticale*) and *sorghum*. It is applied at an application rate of up to 2.88 kg ai/ha for maize and sorghum and at up to 0.36 kg ai/ha for wheat, barley, oats and triticale. No harvest or grazing WHPs are required.

There are no Codex MRLs for metolachlor in animal tissues. The Australian (parent) and US (parent + metabolite) residue definitions differ. The relevant US MRLs for animal tissues are 0.02 mg/kg for cattle meat, 0.2 mg/kg for cattle kidney and 0.02 mg/kg for milk. The Australian MRLs for meat (mammalian) and milk are \*0.05 mg/kg. Residues decline in soil and foliage with typical half-lives of 90 and 5 days respectively. The Australian MRL for cereal grains (except maize and sorghum) is \*0.02 mg/kg, for maize 0.1 mg/kg and for sorghum \*0.05 mg/kg.

The Metolachlor Registration Standard dated March, 1980, concluded that the qualitative nature of the residue in animals was adequately understood. Metolachlor is rapidly metabolized and almost totally eliminated in the urine and feces of ruminants (goats), non-ruminants (rats), and poultry. Metolachlor *per se* was not detected in any of the excreta or tissues. Finite residues were detected in animal transfer studies.

In a study cows were fed 60 ppm metolachlor in the diet for up to 28 days (equivalent to 2.4 mg ai/kg bw/day)<sup>73</sup>. Metolachlor residues in meat and fat were all below the LOQ (<0.02 mg/kg); and residues in milk were all <LOQ (<0.01 mg/kg). In contrast, finite residues of  $\sim0.4 \text{ mg/kg}$  for kidney and  $\sim0.1 \text{ mg/kg}$  for liver were reported.

Anticipated residues from the feeding grain to cattle and sheep with residues at the highest of the Australian MRLs are  $0.1 \times 0.01 = 0.001$  mg/kg for kidney, the target tissue.

It is anticipated that animal product residues will be below typical method LOQs.

## Metosulam

-is a triazolopyrimidine sulfonanilide herbicide used for the control of broad-leafed weeds in winter cereals (*barley, oats, rye, triticale* and *wheat*). It is applied at an application rate of up to 5 g ai/ha.

There are Australian but no Codex or US MRLs for metosulam in animal commodities. The Australian MRLs have all been set at \*0.01 mg/kg. The MRL for cereal grains is \*0.02 mg/kg and for forage, straw and fodder (dry) of cereal grains and other grass like plants \*0.1 ppm.

It is anticipated that animal product residues will be below typical method LOQs.

## Metribuzin

- is a herbicide used on a variety of crops. It is used on *wheat, barley* and *oats* for the control of various weeds. The application rate is up to 72 g ai/ha for oats, 278 g ai/ha for barley and 149 g ai/ha for wheat (blade wheat WA only). A harvest WHP is not required.

<sup>&</sup>lt;sup>73</sup> Revised Metolachlor and S-Metolachlor Residue Chemistry Chapter for the Tolerance Reassessment Eligibility Decision (TRED); PC codes 108801 and 108800; DP Barcode D282931; Rereg. Case 0001. Environmental Protection Agency, Office of Pesticide Programs, Special Review and Reregistration Division

There are Australian and US but no Codex tolerances for metribuzin in animal tissues. The Australian and US residue definitions differ with the Australian one being parent compound and the US one including the triazinone metabolites of metribuzin. The Australian animal commodity MRLs have all been set at \*0.05 mg/kg while the US MRLs for animal tissues have all been set at 0.7 mg/kg kg and 0.05 mg/kg for milk.

The Australian MRL for cereal grains is \*0.05 mg/kg.

The US EPA reported beef and diary cattle feeding studies where animals were fed at 3 or 10 ppm in the diet for up to 30 days<sup>74</sup>. Residues were less than the limit of detection in muscle. The TF for fat (10 ppm feed level) was 0.11 while at the 3 ppm feed level it was 0.02. It is unclear why the TF calculated for the 10 ppm feed level should be so much higher than the 3 ppm (also noting the octanol water partition coefficient). The 3 ppm transfer factor was used. The TF for milk at the 10 ppm feed level was 0.0007.

Feeding at the levels expected to arise in grain from treated crops should not lead to residues of concern in animals.

It is anticipated that animal product residues will be below typical method LOQs.

#### Metsulfuron-methyl

is a sulfonylurea herbicide used for the control of various weeds in *wheat, barley, triticale* and *rye*. Application is at rates up to 4.2 g ai/ha. A harvest WHP is not required.

There are Australian and US but no Codex MRLs for metsulfuron-methyl in animal commodities. The Australian MRLs for animal commodities have all been set at \*0.1 mg/kg. The US MRLs are 0.5 mg/kg for kidney and 0.1 mg/kg for other meat by-products, meat and fat and 0.05 mg/kg for milk.

The Australian MRL for cereal grains is \*0.02 mg/kg.

A lactating cow study reported the following disposition of metsulfuron-methyl residues (dosing regime: 0, 5, 20 or 100 ppm in the diet for 4 weeks)<sup>75</sup>. Fat and meat tissues were < 0.01 mg/kg (LOQ), except for one cow (100 ppm feeding study) with meat residues of 0.014 to 0.02 mg/kg. Liver and kidney tissues from cows fed 5 ppm were not greater than 0.053 mg/kg. Metsulfuron-methyl residues in milk samples from cows fed 5 ppm were less than 0.011 mg/kg; 20 ppm feeding resulted in residues that reached a plateau at day 7 post-treatment with residues at 0.016-0.033 mg/kg over the 4 week period.

It is anticipated that animal product residues will be below typical method LOQs.

## Molinate

-is a thiocarbamate herbicide used for weed control in *rice* crops. Application is at rates up to 5 kg ai/ha (crop salvage).

A harvest WHP is not required.

There are no Australian, Codex or US MRLs for molinate in animal commodities. The Australian MRL for rice is \*0.05 mg/kg.

<sup>&</sup>lt;sup>74</sup> Reregistration Eligibility Decision Metribuzin LIST A CASE 0181EPA 738-R-97-006 February 1998. Environmental Protection Agency, Office of Pesticide Programs, Special Review and Reregistration Division

<sup>&</sup>lt;sup>75</sup> Pest Management Regulatory Agency Decision Document E95-04 Tribenuron methyl 8 December 1995

The US EPA reported that the tolerance for residues in/on rice grain should be increased to 0.75 ppm based on combined residues of <0.73 ppm in/on grain from field trials. Molinate *per se* was <0.05 ppm (<LOQ) in/on rice grain and straw from all field trials. An adequate processing study indicated that residues concentrated in hulls and bran processed from molinate-treated rice grain; tolerances of 3.0 and 2.0 ppm respectively are required. The livestock metabolism studies indicate that molinate residues of concern are not present in tissues, milk, or eggs from animals dosed with molinate at levels greater than the theoretical maximum dietary exposure<sup>76</sup>. These diets are exaggerated and represent the maximum dietary exposure assuming all rice is treated and bears residues at the tolerance level. Tolerances for molinate residues in livestock commodities are not required based on current uses.

It is anticipated that animal product residues will be below typical method LOQs.

#### Omethoate

- is an organophosphate insecticide used for the control of mites in *cereal crops*. The maximum application rate is 34.8 g ai/ha. No harvest WHP is required.

There are Australian but no Codex or US MRLs for omethoate in animal tissues. The Australian MRLs for animal commodities including milk have been set at \*0.05 mg/kg. There is an Australian MRL for cereal grains \*0.05 mg/kg.

A metabolism study with lactating goats dosed orally with dimethoate suggests that residues of omethoate are not expected in animal tissues<sup>77</sup>.

It is anticipated that animal product residues will be below typical method LOQs.

## <u>Oryzalin</u>

- is a herbicide used for the control of various weeds in *barley* and *wheat*. The maximum application rate is 287.5 g ai/ha. No harvest WHP is required.

There are no Australian, Codex or US MRLs for oryzalin in animal tissues. There is an Australian MRL for cereal grains \*0.01 mg/kg.

EFSA reported: When administered orally to a steer at a dose of 168.3 mg/day (equivalent to approximately 49 ppm in the feed), phenyl-labelled [<sup>14</sup>C]-oryzalin was rpidly eliminated during the first 72 h then slowly for the following 8 days. The main route of elimination was the faeces (84%); about 8.5% was excreted via urine. Parent comprised 95% of the radioactivity in faeces but was not detected in urine. Radioactive residues in the milk of a cow treated with [<sup>14</sup>C]-oryzalin at the dietary concentration of 10 ppm in the feed remained low ( $\leq 0.012 \text{ mg eq/kg}$ ). The day after the last dose, the level of residues began to decrease. Residues were low in all sampled tissues of a steer treated with radiolabelled oryzalin at the dietary concentration of 10 ppm for 3 days, principally kidney and liver where the maximum radioactive residues at 24 hours after the last dose were observed (0.067).

<sup>&</sup>lt;sup>76</sup> Molinate - Revised Human Health Risk Assessment DP Barcode: D271384 PC Code: 041402 Case: 818845 Submission: S589909 19 December 2000. Environmental Protection Agency, Office of Pesticide Programs, Special Review and Reregistration Division

<sup>&</sup>lt;sup>77</sup> 1998 JMPR - Pesticide Residues in Food - 1998 Evaluations, Part I Residues FAO Plant Production and Protection Paper 152/1. FAO and WHO 1999

mg eq/kg) while residues inmuscle and fat were much lower ( $\leq 0.002$  mg eq/kg). In the tissues, oryzalin was not detected.

It is anticipated that animal product residues will be below typical method LOQs

## Oxyfluorfen

- is a diphenyl ether herbicide used for the control of weeds in various crops. It is applied prior to sowing *winter cereals* at a maximum application rate of 14 g ai/ha. There is no harvest WHP.

There are Australian and US but no Codex MRLs for oxyfluorfen in animal commodities. The Australian MRLs have all been set at \*0.01 and the US ones at 0.01 mg/kg. The Australian MRL for cereal grains is \*0.05 mg/kg.

The TF for fat is 0.035 and for milk is  $0.003^{78}$ . There is no expectation of residues in milk or animal tissues including fat.

It is anticipated that animal product residues will be below typical method LOQs.

## <u>Paraquat</u>

- is a herbicide used for the control of weeds in various crops. The application rate is up to 0.6 kg ai/ha with application in the fallow period or prior to sowing. There is no harvest WHP.

The Australian and Codex MRLs for paraquat in kidney are 0.5 and 0.05 mg/kg while in milk are \*0.01 and 0.005 mg/kg respectively. The US MRL for kidney is 0.5 mg/kg and for milk 0.01 mg/kg. The MRL for cereal grains (except rice and maize) is \*0.05 mg/kg. The MRL for maize is 0.1 mg/kg and for rice 10 mg/kg.

Residues in tissues of cattle and sheep fed at 8 ppm in the diet for 30 days were all <0.01 mg/kg<sup>79</sup>.

It is anticipated that animal product residues will be below typical method LOQs.

## Pendimethalin

-is a selective herbicide used for the control of annual ryegrass and certain broadleaf weeds in sugarcane, *cereals* etc. It is applied at an application rate of up to 0.59 kg ai/ha (pre-plant) for wheat and barley and at 1.49 kg ai/ha for maize (post-planting, pre-emergent) and rice (post-plant and flushing).

No harvest or grazing WHPs are required.

There are Australian MRLs but no MRLs for Codex and US for pendimethalin in animal tissues. The Australian MRL for animal commodities all have been set at \*0.01 mg/kg. The Australian MRL for the cereal grains listed is \*0.05 mg/kg.

The US EPA notes that animal metabolism studies in goats conducted at exaggerated feeding levels indicate that there is no reasonable expectation for residues of pendimethalin in tissues<sup>80</sup>.

<sup>&</sup>lt;sup>78</sup> Reregistration Eligibility Decision (RED) Oxyfluorfen List A Case 2490, Environmental Protection Agency, Office of Pesticide Programs, Special Review and Reregistration Division

<sup>&</sup>lt;sup>79</sup> 1976 JMPR. 1976 Evaluations of some pesticide residues in food. AGP:1976/M/14, 1977

<sup>&</sup>lt;sup>80</sup> Reregistration Eligibility Decision Pendimethalin List A Case 0187, Environmental Protection Agency, Office of Pesticide Programs, Special Review and Reregistration Division

It is anticipated that animal product residues will be below typical method LOQs.

#### Permethrin

- is a synthetic pyrethroid insecticide used for the control of various insects in crops. It is registered on *wheat, barley* and *oats* with application at rates of up to 0.1 kg ai/ha. The harvest WHP is 3 days.

There are Australian, Codex and USA MRLs for permethrin in animal tissues. The Australian and Codex residue definitions are parent compound while the USA residue definition includes some metabolites. The relevant MRLs for fat are 1, 1 and 1.5 mg/kg for Australia, Codex and the USA respectively. The relevant MRLs for offal are 0.5, 0.1 and 0.1 mg/kg for Australia, Codex and the USA respectively. The relevant MRLs for milk are 0.1 F, 0.1 F and 3 mg/kg for Australia, Codex and the USA respectively, the latter is for milk fat and represents 0.25 mg/kg on a whole milk basis. The Australian MRL for cereal grains 2 mg/kg.

The TF for fat is  $0.04^{81}$ . Residues in fat from feeding at 2 ppm could be as high as  $2 \times 0.04 = 0.08$  mg/kg.

The TF for milk is 0.002 and if fed at 2 ppm would give rise to residues in whole milk of 0.004 mg/kg, less than the relevant international standards.

Livestock residues are not anticipated to exceed international and/or domestic market standards.

#### **Phosmet**

-is an organophosphous acaricide used for the control of mites in *cereal crops*. Application is at rates up to 52.5 g ai/ha. There is no harvest WHP

There are Australian but no Codex or US MRLs for phosmet in animal commodities. The Australian MRLs are 1 mg/kg for cattle edible offal and meat (in the fat) and \*0.05 mg/kg for sheep edible offal and meat and 0.2 mg/kg for milks [in the fat]. The Australian MRL for cereal grains is \*0.05 mg/kg.

Combined residues of phosmet and its oxon in dairy cows dosed at the equivalent of 100 ppm in the feed for 21 days were 0.03-0.19 mg/kg in fat and <0.05 mg/kg in kidney, liver and muscle as well as in milk<sup>82</sup>.

It is anticipated that animal product residues will be below typical method LOQs.

#### **Picloram**

- is a selective herbicide used widely for the control of weeds. It is registered on a variety of crops including potential animal feeds pasture and *cereals*. The application rate for barley, wheat, canary grass, oats and triticale is 26 g ai/ha.

A harvest WHP is not required.

There are no Codex MRLs for picloram. The residue definition for the US and Australia is parent compound. The Australian MRL for edible offal (mammalian) is 5 mg/kg while the US tolerance for cattle kidney is 5 mg/kg. The corresponding milk MRLs are \*0.05 and 0.05 mg/kg. The Australian MRL for cereal grain is 0.2 mg/kg. Picloram does not accumulate in fat.

<sup>&</sup>lt;sup>81</sup> 1981 JMPR Pesticide Residues in Food - 1981 Evaluations, FAO Plant Production and Protection Paper 42. FAO and WHO 1982

<sup>&</sup>lt;sup>82</sup> 1976 JMPR. Evaluations of some pesticide residues in food. AGP:1976/M/14, 1977

The TF for kidney is 0.01<sup>83</sup> and milk 0.0003<sup>84</sup>. Picloram residues decline rapidly upon withdrawal of picloram from the diet when fed at 1600 ppm for 28 days such that after 3 days residues are less than the limit of analytical quantitation (0.05 mg/kg) for all tissues except kidney which had residues of 0.06 mg/kg.

It is anticipated that animal product residues will be below typical method LOQs.

#### **Picolinafen**

-is an aryloxypicolinamide herbicide for the post-emergent control of various weeds in cereal crops. It is registered for use on *winter cereals* (wheat, barley, oats, triticale and rye) at an application rate of up to 25 g ai/ha.

No harvest WHP is required.

There are Australian but no Codex or US MRLs for picolinafen in animal commodities. The Australian MRLs are 0.05 mg/kg for edible offal (mammalian), \*0.02 mg/kg for meat (mammalian) (in the fat) and \*0.01 mg/kg for milks. The MRL for cereal grains is \*0.02 mg/kg.

In a goat metabolism study where animals were dosed at the equivalent of 5 ppm in the feed, no residues were detected in milk or tissues<sup>85</sup>.

It is anticipated that animal product residues will be below typical method LOQs.

#### Pinoxaden

-is a selective herbicide used for the control of various grass weeds in *barley* and *wheat*. The application rate is up to 30 g ai/ha.

A harvest WHP is not required.

DO NOT graze or cut for stock food for 3 weeks after application.

There are Australian and US but no Codex MRLs for pinoxaden in animal commodities. The Australian MRLs for meat and offal are \*0.02 mg/kg and for milk \*0.01 mg/kg. The US tolerances are only for cattle and are 0.04 mg/kg for fat, meat and offal and 0.02 mg/kg for milk.

The Australian MRL for barley and wheat are 0.1 mg/kg. There are also MRLs for barley forage (green) 3 ppm, barley straw and fodder, dry 1 ppm, wheat forage (green) 3 ppm and wheat straw and fodder, dry 1 ppm.

The PMRA reported: Two goat metabolism studies were performed; the first one was carried out with the parent compound, pinoxaden, and the second one with a predominant plant metabolite, M4. In the first study, pinoxaden (phenyl radiolabel) was administered orally to two lactating goats (Alpine breed) at dose levels of 120.6 ppm (mg/kg feed/day) for four consecutive days. Approximately 83% of the administered dose (AD) was eliminated in excreta (feces, urine, gastrointestinal tract and rumen), 0.009% of the AD was transferred to milk and 0.260% of the AD was recovered in tissues, demonstrating low tissue burden. The highest concentrations of <sup>14</sup>C-residues were detected in kidney (2.953 ppm) and liver (1.160 ppm). The parent compound,

<sup>&</sup>lt;sup>83</sup> Kutchinski, A.H. and Riley, V. (1969) Residues in various tissues of steers fed 4-amino-3,5,6-trichloropicolinic acid, J. Agr. Food Chem. 17 (2) 283-287.

<sup>&</sup>lt;sup>84</sup> Kutchinski, A.H. (1969) Residues in milk from cows fed 4-amino-3,5,6-trichloropicolinic acid, *J. Agr. Food Chem.* 17 (2) 288-290.

<sup>&</sup>lt;sup>85</sup> PMRA Regulatory Note REG2003-Picolinafen, 17 February 2003

pinoxaden, was not detected in any of the matrices, indicating its rapid and complete metabolism in the lactating goat. The predominant metabolite detected in all the goat matrices was M2, which is the hydrolysis product of the parent molecule pinoxaden. Several minor metabolites (M3, M4, M6, M12, M13, M19, M20, M22, M23, M24, M26, M27 and M28), each representing less than 10% TRRs, were detected in feces and in some tissues and milk. In the second study, metabolite M4 was administered orally to two lactating goats (Alpine breed) at dose levels of 9.8 ppm (mg/kg feed/day) for four consecutive days. Approximately 93% of the AD was eliminated in excreta (feces, urine, gastrointestinal tract and rumen). <sup>14</sup>C-residues in milk, muscle, fat and blood were below the LOQ (0.002 ppm in milk and 0.011 ppm in tissues). Only minor fractions of the total AD were transferred to the remaining tissues (<0.1% of the AD). The highest concentrations of 14C-residues were detected in kidney (0.044 ppm) and liver (0.025 ppm). The predominant metabolite, identified in all tissues containing detectable residues, was unchanged M4. The only other metabolite identified was M10, which is the hydroxylation product of M4. M10 represented only a minor fraction of the TRRs in liver and kidney, and represented less than 10% of TRRs in feces. These results indicate that residues of pinoxaden and the major plant metabolite M4 (and by inference all metabolites sharing a similar structure) have a very low transfer into the edible tissues and milk of lactating goats.

It is anticipated that animal product residues will be below typical method LOQs

## Piperonyl butoxide (PBO)

- is a synergist used to increase the effectiveness of various synthetic pyrethroid (SP) insecticides used as grain protectants. The application rate is up to 8 ppm.

There are Australian, Codex and US MRLs for PBO in animal commodities. The Australian MRLs for animal tissues have all been set at 0.1 mg/kg. The Codex MRL for mammalian meat (fat) (except cattle) is 2 mg/kg and for cattle meat (fat) 5 mg/kg. The US tolerance for cattle tissue is 0.1 while milk fat is 0.25 mg/kg. The Australian MRL for milks is 0.05 mg/kg. There is an Australian MRL of 20 mg/kg for cereal grains.

The TF for PBO in fat is 0.004 (feeding at 100 ppm in the diet)<sup>86</sup> resulting in an anticipated maximum residue from feeding cereal grains with residues at the same level as the MRL of  $20 \times 0.004 = 0.08$  mg/kg, less than the relevant Australian and Codex MRLs. The TF for PBO in milk is 0.0001 (feeding at 100 ppm in the diet) resulting in an anticipated maximum residue from feeding cereals at 100% of the diet of  $20 \times 0.0001 = 0.002$  mg/kg, less than the relevant Australian and Codex MRLs.

Livestock residues are not anticipated to exceed international and/or domestic market standards.

<u>Pirimicarb</u> -is a carbamate aphicide used for the control of aphids in *winter cereals*. The application rate is up to 0.15 g ai/ha. The harvest WHP is 6 weeks.

The harvest WHP is 6 weeks.

There are Australian and Codex but no USA MRLs for pirimicarb in animal commodities. The Australian and Codex MRLs for meat and milk are all set at \*0.1 mg/kg. As both the Australian and Codex MRLs are set at the limit of analytical quantitation they are essentially the same.

The Australian MRL for cereal grains is \*0.02 mg/kg.

<sup>&</sup>lt;sup>86</sup> 2002 JMPR. Pesticide Residues in Food - 2002 Evaluations – Part I: Residues Volume 1, FAO Plant Production and Protection Paper 175/1. FAO and WHO 2003

In a feeding study reported by JMPR residues of pirimicarb were <0.05 mg/kg for animals dosed at the equivalent of 200 ppm in the diet<sup>87</sup>, a level of exposure much greater than would be anticipated to arise from cereal grain. The TF for milk is 0.00065 indicating a little likelihood that residues would be detected in milk.

It is anticipated that animal product residues will be below typical method LOQs.

# Pirimiphos-methyl

-is an organophosphate insecticide used for the control of insects in stored grains. The application rate is up to 4.05 ppm.

There are Australian, Codex and USA MRLs for pirimiphos-methyl in animal commodities. The Australian MRLs for animal commodities are \*0.05 mg/kg while the Codex MRLs are set at \*0.01 mg/kg. The US MRL for cattle fat and meat byproducts is 0.02 mg/kg. The Australian MRLs for cereal grains is range from 7 to 10 mg/kg.

The US EPA RED recommends animal tolerances be deleted as there is no reasonable expectation of residues<sup>88</sup>. Transfer factors for fat at a feeding level of 50 ppm (Australia, Codex) are < $0.0004^{89}$ . In a lactating goat, 91% of the labelled single dose (0.12 mg/kg) was excreted within 8 days. Maximum residue in milk was 0.026ppm. Feeding cereal grains with residues of 10 ppm are not expected to result in residues in animal commodities.

It is anticipated that animal product residues will be below typical method LOQs.

Profoxydim

-is a herbicide used for the control of certain grasses in *rice* crops. The application rate is 75 g ai/ha. A harvest WHP is not required.

DO NOT graze or cut for stock food for 28 days after application.

There are Australian but no Codex or US MRLs for profoxydim in animal commodities. The Australian MRLs are 0.5 mg/kg for edible offal and \*0.05 mg/kg for other tissues and \*0.01 mg/kg for milk. The Australian MRL for rice of 0.05 mg/kg.

The APVMA reported: When lactating goats were administered 2 forms of radiolabelled profoxydim at 10 ppm per day for 6 consecutive days, maximum radioactivity in milk was 0.01 ppm. However, none of the radioactive components in milk corresponded to profoxydim or its main metabolites. The total radioactive residue found in goat liver after 6 days was 0.31 and 0.43 ppm for 14C cyclohexenone and phenyl labelled compound respectively. Of this 0.053 and 0.086 ppm corresponded to unchanged parent compound. The total radioactive residues found in kidneys after 6 days were 0.13 and 0.15 ppm. Of this 0.002 and 0.001 ppm corresponded to unchanged parent compound. Residues were lower in muscle and in fat, at  $\leq 0.006$  and  $\leq 0.009$  ppm respectively.

<sup>&</sup>lt;sup>87</sup> 1978 JMPR - Pesticide Residues in Food - 1978 Evaluations, FAO Plant Production and Protection Paper 15 Suppl. FAO and WHO 1979

<sup>&</sup>lt;sup>88</sup> Pirimiphos-methyl (List B, Case No. 2535/Chemical ID No. 108102). Product and Residue Chemistry Chapters of the HED RED. No MRID #. DP Barcode No. D240744. Environmental Protection Agency, Office of Pesticide Programs, Special Review and Reregistration Division

<sup>&</sup>lt;sup>89</sup> 1974 JMPR. Evaluations of some pesticide residues in food. FAO/AGP/1974/M/11; WHO Pesticide Residues Series No. 4, 1975

## Propachlor

-is a herbicide used for the control of certain grasses and broad-leafed weeds in *maize, sorghum* and *sweet corn* crops. The application rate is 3.36 kg ai/ha. A harvest WHP is not required.

There are Australian and US but no Codex MRLs for propachlor in animal commodities. The Australian MRLs are 0.1 mg/kg for edible offal and \*0.02 mg/kg for other commodities including milk. The US MRLs for cattle fat and meat byproducts except kidney is 0.05, kidney 0.2 and for meat and milk 0.02 mg/kg. The Australian MRLs for sorghum of 0.2 mg/kg and for other cereal grains 0.05 mg/kg.

In an animal transfer study, dairy cattle were fed propachlor metabolites at rates of up to 50 ppm for 28 days, residues were detected in kidney (target tissue), liver, muscle, fat and milk<sup>90</sup>. A transfer factor of 0.01 was calculated for kidney.

It is anticipated that animal product residues will be below typical method LOQs.

# <u>Propanil</u>

-is an acetamide herbicide used for the control of Barnyard grass in *rice*. The maximum application rate is 5.9 kg ai/ha.

A harvest WHP is not required.

There are US and Australian but no Codex MRLs for propanil. The Australian (parent compound) and US (sum of propanil and its metabolites expressed as propanil) residue definitions differ. The Australian MRLs are \*0.1 mg/kg for cattle and sheep edible offal and meat and \*0.01 mg/kg for milk. The US MRLs are 0.1 mg/kg for cattle fat, 0.05 for meat and milk and 1 mg/kg for cattle meat bypr.

The MRL for rice is 2 mg/kg. (Note US proposed revised rice MRL from 2 ppm to be 10 ppm).

Maximum residues of propanil and metabolites convertible to 3,4-dichloroaniline (US residue) in cows dosed at the equivalent of 15 ppm in the diet were 0.31 mg/kg in liver, 0.77 mg/kg in kidney, <0.05 mg/kg in muscle, 0.1 mg/kg in fat and 0.035 mg/kg in milk<sup>91</sup>. Based on the results from a lactating goat metabolism study it is expected that propanil *per se* accounts for <10% of the residue measured as 3,4-DCA.

It is anticipated that animal product residues will be below typical method LOQs.

# Propiconazole

is a DMI fungicide used for the control of various fungal rust, scald and mildew diseases in *barley* and *wheat*. Application is at a maximum rate of 0.125 g ai/ha. The harvest WHP is 28 days.

There are Australian, Codex and US MRLs for propiconazole in animal commodities. The Australian MRLs (propiconazole) are 1 mg/kg for edible offal, 0.1 mg/kg for meat and \*0.01 mg/kg

<sup>&</sup>lt;sup>90</sup> Reregistration Eligibility Decision, Propachlor List A Case 0177, Environmental Protection Agency, Office Of Pesticide Programs, Special Review And Reregistration Division, EPA 738-R-015 November 1998

<sup>&</sup>lt;sup>91</sup> Propanil Revised Chronic Dietary Exposure Assessment (PC Code 028201); DP Barcode D281060; Case 0226. Environmental Protection Agency, Office of Pesticide Programs, Special Review and Reregistration Division

for milk. The Codex MRLs (propiconazole) for animal commodities all are set at \*0.01 mg/kg. The US residue definition is the sum of propiconazole and its metabolites determined as 2,4dichlorobenzoic acid, expressed as parent compound. The US MRLs are 2 mg/kg for liver and kidney, 0.05 mg/kg for fat and meat by-products (except liver and kidney) and 0.05 mg/kg for milk. The Australian MRL for cereal grains is \*0.05 mg/kg.

Animal transfer studies were reported by the 1987 JMPR at feeding levels of 15-100 ppm for cows and 4.5 ppm for goats resulted in undetectable parent residues in milk and tissues  $(<0.05 \text{ mg/kg})^{92}$ . After feeding cows for 14 days at 15 ppm the total residues were undetectable in milk and 0.63 mg/kg in kidney.

It is anticipated that animal product residues will be below typical method LOQs.

Prosulfocarb

-is a herbicide used for the control of certain grasses in *barley* and *wheat* crops. The application rate is 2 kg ai/ha.

A harvest WHP is not required.

DO NOT graze or cut for stock food for 10 weeks after application.

There are Australian but no Codex or US MRLs for prosulfocarb in animal commodities. The Australian MRLs are \*0.02 mg/kg for edible offal and 0.02 mg/kg for other commodities including milk. The Australian MRLs for barley and wheat are \*0.01 mg/kg.

It is anticipated that animal product residues will be below typical method LOQs.

Prothioconazole

-is a fungicide used for the control of various diseases in *barley* and *wheat* crops. The application rate is 63 g ai/ha.

DO NOT harvest for 5 weeks after application.

DO NOT graze or cut for stock food for 14 days after application.

There are Australian, Codex or US MRLs for prothioconazole in animal commodities. The Australian MRLs are 0.1 mg/kg for edible offal and \*0.01 mg/kg for other tissues and \*0.004 mg/kg for milk. The Codex MRLs are 0.2 mg/kg for edible offal and 0.01 mg/kg for other tissues and \*0.004 mg/kg for milk. The US tolerances are 0.1 mg/kg for fat, 0.2 mg/kg for edible offal and 0.02 mg/kg for meat and milk. The Australian MRLs for barley and wheat are 0.3 mg/kg.

The cattle feeding studies were conducted with the parent compound prothioconazole and JAU 6476-desthio, which is the predominant metabolite in plant materials. Ten lactating German dairy cattle (breed: Holstein Friesian; three cows/dose group and one control cow) were dosed orally (Heinemann, O, Auer, S, 2001), via capsule, for 28 consecutive days with JAU6 476-desthio at dose rates of either 0 mg/kg feed (control), 4 mg/kg feed, 25 mg/kg feed or 100 mg/kg feed. At the end of the 28-day dosing period, the cows were sacrificed within 24 hours after the last capsule treatment.

Table 85 Average residue concentrations (mg/kg) in the edible tissues of dairy cattle after 28 days of dosing with JAU 6476-desthio

0								
Dose group	M14a	M15a	M04a	Total b	M14a	M15a	M04a	Totalb
(mg/kg								

<sup>&</sup>lt;sup>92</sup> 1987 JMPR Pesticide Residues in Food - 1987 Evaluations, Part I Residues FAO Plant Production and Protection Paper 86/1. FAO and WHO 1988

feed)								
	Liver				Kidney			
4	0.01	0.01	0.02	0.04	0.01	0.01	< 0.01	0.02
25	0.05	0.03	0.15	0.22	0.06	0.06	0.03	0.14
100	0.18	0.11	0.93	0.95	0.28	0.25	0.13	0.65
	Muscle				Fat			
4	< 0.01	< 0.01	< 0.01	< 0.01	< 0.01	< 0.01	< 0.01	< 0.01
25	< 0.01	< 0.01	< 0.01	< 0.01	< 0.01	< 0.01	< 0.01	0.01
100	< 0.01	< 0.01	< 0.01	0.02	0.01	0.01	0.05	0.07

a M14: JAU 6476-3-hydroxy-desthio, M15: JAU 6476-4-hydroxy-desthio, M04: JAU 6476-desthio b Sum of M14, M15, and M04, expressed as mg/kg JAU 6476-desthio equivalents

JAU6476-desthio total residues in milk at the 4 and 25 ppm feeding levels were below the LOQ (0.004 mg/kg), whereas at the 100 ppm feeding level, total residues increased from < 0.004 mg/kg (day 1) to a plateau level (day 4 to day 29) of 0.006 to 0.010 mg/kg for two animals and of 0.013 to 0.021 mg/kg for one animal. Liquid-liquid partitioning of whole milk against n-hexane showed that M04 was in milk fat and the metabolites M14 and M15 remained in the aqueous phase. However, the total residues remained preferentially in the aqueous phase, i.e., 0.015 mg/kg with only 0.004 mg/kg in the n-hexane phase, indicating no accumulation in milk fat.

It is anticipated that animal product residues will be below international limits.

## Pyraflufen-ethyl

-is a herbicide used for the control of certain annual broadleaf weeds in winter cereal (wheat,

*barley, triticale*) crops. The application rate is 8 g ai/ha.

A harvest WHP is not required.

DO NOT graze or cut for stock food for 14 days after application.

There are Australian and US but no Codex MRLs for pyraflufen-ethyl in animal commodities. The Australian MRLs are \*0.02 mg/kg for edible offal, meat and milk. The US tolerances are 0.02 mg/kg for edible offal and milk. The Australian MRLs for cereal grains \*0.02 mg/kg.

It is anticipated that animal product residues will be below typical method LOQs.

## Pyrasulfotole

-is a herbicide used for the control of certain annual broadleaf weeds in *wheat, barley, triticale and cereal rye* crops. The application rate is 50 g ai/ha when applied with MCPA. A harvest WHP is not required.

DO NOT graze or cut for stock food for 5 weeks after application.

There are Australian and US but no Codex MRLs for pyrasulfotole in animal commodities. The Australian MRLs are 0.5 mg/kg for edible offal, \*0.01 mg/kg for meat and milk. The US tolerances are 0.35 mg/kg for liver, 0.06 mg/kg for other edible offal, 0.02 mg/kg for fat and meat and 0.01 mg/kg for milk. The Australian MRLs for cereal grains \*0.02 mg/kg.

Pyrasulfotole was administered orally via gelatin capsule to 10 lactating Holstein cows (Bos taurus) for 29 consecutive days. There were 3 animals per treatment group and a single control animal, which were dosed at 0 ppm (control), 3 ppm, 9 ppm or 30 ppm in the feed (dry weight basis).

		11 \	// 11	· 11	11			/
Matrix	Feeding	n	LOD	Min	Max	Median	Mean	Standard
	Level							Deviation
	(ppm/d)							
Milk	30a	30	0.0015	0.0042	0.0134	0.0103	0.0096	0.0024
Milk Fat	30	3	0.0003	0.0061	0.0085	0.0074	0.0073	0.0012
Milk Skim	30	3	0.0002	0.0086	0.0105	0.0090	0.0094	0.0010
Fat	3	3	0.0007	0.0017	0.0062	0.0040	0.0040	0.0022

	9	3	0.0007	<lod< th=""><th>0.0033</th><th></th><th></th><th></th></lod<>	0.0033			
	30	3	0.0007	0.0024	0.0143	0.0046	0.0071	0.0064
Kidney	3	3	0.0004	0.1748	0.2224	0.1973	0.1982	0.0238
	9	4	0.0004	0.1232	0.4240	0.2420	0.2631	0.1515
	30	3	0.0004	0.3778	0.4144	0.3811	0.3911	0.0202
Liver	3	3	0.0005	1.019	1.230	1.187	1.145	0.1113
	9	3	0.0005	0.6922	1.594	1.577	1.288	0.5159
	30	3	0.0005	1.642	1.939	1.795	1.792	0.1488
Muscle	3	3	0.0006	<lod< td=""><td>0.0010</td><td></td><td></td><td></td></lod<>	0.0010			
	9	3	0.0006	<lod< td=""><td>0.0007</td><td></td><td></td><td></td></lod<>	0.0007			
	30	3	0.0006	0.0013	0.0039	0.0025	0.0026	0.0013

It is anticipated that animal product residues will be below typical method LOQs.

Pyroxsulam

-is a herbicide used for the control of certain grass and annual broadleaf weeds in *wheat* (excluding certain durum varieties) crops. The application rate is 15 g ai/ha.

A harvest WHP is not required.

DO NOT graze or cut for stock food for 6 weeks after application.

There are Australian no Codex or US MRLs for pyroxsulam in animal commodities. The Australian MRLs are \*0.01 mg/kg for edible offal, meat and milk. There US tolerances for wheat but tolerances for anoimal commodities were determined not necessary (negligible residues). The Australian MRLs for wheat grain is \*0.01 mg/kg.

It is anticipated that animal product residues will be below typical method LOQs.

#### Sethoxydim

- is a cyclohexanedione herbicide used for the control of certain grass weeds in crops. It is approved for use on wheat at rates up to 20 g ai/ha (3-6 weeks after sowing).

A harvest WHP is not required.

Do not cut or graze for stock food for 7 weeks after application.

There are Australian and US MRLs for sethoxydim but no Codex MRLs. However, the Codex residue definition for clethodim is the "sum of clethodim and its metabolites containing 5-(2-ethylthiopropyl)cyclohexene-3-one and 5-(2-ethylthiopropyl)-5-hydroxycyclohexene-3-one moieties and their sulphoxides and sulphones, expressed as clethodim". Compariosn with the Australian residue definition indicates residues for sethoxydim will be covered by Codex MRLs for clethodim. The Codex MRLs for clethodim are \*0.2 mg/kg for edible offal and meat and \*0.05 mg/kg for milk. The Australian residue definition is sethoxydim and its metabolites containing 5-(2-ethylthiopropyl)cyclohexane-3-one and 5-(2-ethylthiopropyl)-5-hydroxycyclohexe-3-one moieties and their sulphoxides and sulphones, expressed as sethoxydim. The US residue definition is sethoxydim and its metabolites containing the 2-cyclohexen-1-one moiety. The Australian MRLs for animal commodities have been set at \*0.05 mg/kg. The US MRLs for cattle tissues are 1 mg/kg for meat by-products , 0.2 mg/kg for other tissues while the milk MRL is 0.5 mg/kg. The Australian MRL for wheat is \*0.1 mg/kg and for wheat forage green and also straw and fodder dry of \*0.1 mg/kg.

Note: The USA also has tolerances for several major animal feeds including alfalfa forage and hay (40 ppm), bean hay and clover hay (50 ppm). The tolerances suggest that sethoxydim may be fed at up to 50 ppm in the diet without exceeding the USA animal commodity MRLs. Noting the application rates for wheat and the respective MRLs it is considered unlikely that feeding wheat grain of derived feeds would lead to residues in animals above the USA MRLs.

It is anticipated that animal product residues will be below typical method LOQs.

<u>S-metolachlor</u> see metolachlor

## Spinosad

- is an antibiotic insecticide used for the control of stored grain pests cereals. The application rate is up to 1 ppm.

There are Australian, Codex and USA MRLs for spinosad in animal commodities. The Australian and US MRLs applicable to cattle meat (fat) are 2 and 50 mg/kg respectively. The respective milk MRLs are T0.1 and 7 (85 mg/kg for whole milk fat) mg/kg. The Codex MRL is 3 mg/kg for cattle fat and 2 mg/kg for fat of other mammals and 1 mg/kg for cattle milk (5 m/kg for milk fat). There is an Australian MRLs of T1 mg/kg for cereal grain.

The TF for cattle fat is  $0.5 \cdot 0.6^{93}$  giving an anticipated maximum residue in cattle fat from feeding of cereal grain at 100% of the diet of  $1 \times 0.6 = 0.6$  mg/kg.

The TF for milk is 0.05 giving an anticipated maximum residue in milk from feeding of cereal grain at 100% of the diet of  $1 \times 0.05 = 0.05$  mg/kg.

Livestock residues are not anticipated to exceed international and/or domestic market standards.

# Sulfosulfuron

-is a sulfonylurea herbicide used for the control of various weeds in *wheat* and *triticale* crops. Application is made prior to sowing at rates up to 18.75 g ai/ha. No harvest WHP is required.

There are Australian and US but no Codex MRLS for animal commodities. The Australian MRLs have all been set at \*0.005 mg/kg. The US MRLs are 0.3 mg/kg for cattle meat by-products and 0.01 mg/kg for cattle meat and 0.02 mg/kg for fat (same MRLs for sheep).

The MRLs for wheat and triticale have been set at \*0.01 mg/kg.

In a goat metabolism study, unchanged sulfosulfuron was the major terminal residue identified in liver, kidney, muscle and milk, accounting for 13 to 89 % of the total radioactive residue  $(0.0019 - 0.15 \text{ ppm})^{94}$ . Total radioactive residues in individual tissues were as follows: kidney and liver; 0.14 - 0.18 ppm, muscle; 0.0079 -0.021 ppm, fat; < 0.0022 - 0.0079 ppm, while the levels in milk ranged from 0.027 - 0.030 ppm. Parent sulfosulfuron was the major terminal residue identified in kidney, liver, muscle and milk accounting for 73 – 98 %, 81 – 86 %, 72 – 89 % and 19 – 37 %, respectively, of the extractable residues. The residues in fat were not characterized based of their low content. The low level of apparent bioaccumulation was consistent with the log P<sub>ow</sub> value of < 1 for parent sulfosulfuron (range of pH 5-9).

It is anticipated that animal product residues will be below typical method LOQs.

# Tebuconazole

<sup>&</sup>lt;sup>93</sup> 2001 JMPR Pesticide Residues in Food - 2001 Evaluations – Part I, FAO Plant Production and Protection Paper 171. FAO and WHO 2002

<sup>&</sup>lt;sup>94</sup> Public Release Summary on Evaluation of the new active SULFOSULFURON in the product MONZA HERBICIDE National Registration Authority for Agricultural and Veterinary Chemicals 1998 Canberra Australia

-is a DMI fungicide used for the control of rust and powdery mildew etc in *wheat, oats* and *barley*. The application rate is up to 125 g ai/ha. The harvest WHP is 5 weeks.

There are Australian, Codex and US MRLs for tebuconazole in animal tissues. The Australian and Codex residue definition is tebuconazole while the USA residue definition is the sum of tebuconazole and its 1-(4- chlorophenyl)-4,4-dimethyl-3-(*1*H-1,2,4-triazole-1-yl-methyl)-pentane-3,5-diol metabolite. The Australian MRLs 0.5 mg/kg for edible offal mammalian, 0.1 mg/kg for meat (mammalian) and 0.05 mg/kg for milk. The Codex MRLs are \*0.05 mg/kg for both cattle meat and cattle edible offal and \*0.01 mg/kg for milk. The US MRLs are 0.2 mg/kg for meat byp and 0.1 mg/kg for milk. The Australian MRL for cereal grains is 0.2 mg/kg.

Residues of tebuconazole were not detected (<0.05 mg/kg) in milk, muscle and fat of dairy cattle dosed at the equivalent of 250 ppm in the diet for 28 days<sup>95</sup>. The residues in liver were 0.2 mg/kg. The TF for liver is 0.0008. There is no reasonable expectation of residues of tebuconazole in meat and fat arising from feeding of grain from treated cereal crops.

It is anticipated that animal product residues will be below typical method LOQs.

#### Terbufos

-is a organophosphorous insecticide/nematicide used on *maize* and *sorghum* for the control of wireworm. Application is at rates up to 0.3 kg ai/ha. A WHP is not required.

There are Australian and Codex but no US MRLs for terbufos in animal commodities. The Australian and Codex MRLs are \*0.05 mg/kg for cattle edible offal and cattle meat. The Australian and Codex MRLs for milk have been set at \*0.01 mg/kg.

The Australian MRL for cereal grains is \*0.01 mg/kg. No residues are expected in cattle or sheep tissues.

It is anticipated that animal product residues will be below typical method LOQs.

#### Terbutryn

- is a selective herbicide used for the control of seedling broadleaf weeds in *cereals*, pasture and sugarcane. In wheat, barley, triticale and oats it is applied at rates up to 0.425 kg ai/ha. No harvest WHP is required.

There are no Codex or US MRLs for terbutryn. The Australian MRLs for meat (mammalian) (fat) and milks are 0.1 mg/kg. The Australian cereal grain MRL is \*0.1 mg/kg.

It is anticipated that animal product residues will be below typical method LOQs.

#### Thiamethoxam

- is a nitroguanidine insecticide used as a seed dressing for the control of wireworms in *sorghum* and *maize*. The application rate is up to 140 g ai/100 kg seed for sorghum and 0.49 g ai/1000 seeds for maize.

No harvest WHP required as it is a seed dressing.

<sup>&</sup>lt;sup>95</sup> 1994 JMPR - Pesticide Residues in Food - 1994 Evaluations, Part I Residues FAO Plant Production and Protection Paper 78. FAO and WHO 1995

There are Australian and USA but no Codex MRLs for thiamethoxam in animal commodities. The Australian MRLs are all \*0.02 mg/kg except milk which is \*0.005 mg/kg. The US MRLs applicable to cattle meat are 0.02 and meat byproducts 0.04 mg/kg. There are Australian MRLs of \*0.02 mg/kg for sweet corn (corn-on-the-cob), maize and sorghum.

Metabolism studies in animals demonstrated that parent thiamethoxam was a major residue in all tissues, with the exception of liver<sup>96</sup>. A dose level equivalent to 100 ppm in the feed was used in these studies. If we assume that treated produce contains residues at the MRL of \*0.02 ppm and comprises 100% of the animal diet, then scaling the residue results from the metabolism study (goats) gives an estimate of the likely residues in tissues from normal feeding of treated produce. Anticipated residues in muscle, fat, liver, kidney and milk are < 0.008 mg/kg. These values are considered to be gross overestimates of residues in tissues from consumption of treated grain.

It is anticipated that animal product residues will be below typical method LOQs.

# Thifensulfuron-methyl

-is a sulfonylurea herbicide used for the control of various weeds in *wheat, barley* and *triticale* crops. Application is made at rates up to 30.7 g ai/ha. The harvest WHP is 8 weeks.

There are Australian but no Codex or US MRLs for animal commodities. The Australian MRLs have all been set at \*0.01 mg/kg.

The Australian MRL for cereal grains (except maize and rice) is \*0.02 mg/kg.

The PMRA stated that<sup>97</sup> "Extensive residue studies show that, when applied during early growth stages at recommended application rates (two-leaf stage but before flag-leaf or shot-blade stage), no residues of parent compound are detected above the sensitivity of the analytical method (0.02 ppm) in wheat, oats and barley grain at harvest."

It is anticipated that animal product residues will be below typical method LOQs.

Thiobencarb

-is a thiocarbamate herbicide used for the control of Barnyard grass and dirty dora in *rice*. Application is at rates of up to 4 kg ai/ha. A harvest WHP is not required.

There are US but no Australian or Codex MRLs for thiobencarb in animal commodities. The Australian residue definition is parent compound while the US one is the sum of thiobencarb and its chlorobenzyl and chloro-phenyl moiety-containing metabolites. The US MRLs are 0.2 mg/kg for cattle, sheep and goat meat, fat and meat by-products and 0.05 mg/kg for milk.

The Australian MRL for rice is \*0.05 mg/kg.

It is anticipated that animal product residues will be below typical method LOQs.

Thiodicarb

<sup>&</sup>lt;sup>96</sup> Public Release Summary on Evaluation of the new active THIAMETHOXAM in the product CRUISER 350 FS INSECTICIDE SEED TREATMENT National Registration Authority for Agricultural and Veterinary Chemicals January 2001 Canberra Australia

<sup>&</sup>lt;sup>97</sup> PMRA Decision Document E90-01 Thifensulfuron

#### see methomyl

#### <u>Thiram</u>

- is a dithiocarbamate fungicide used on a variety of crops. It is used *sorghum* seed at 240 g ai/100 kg seed (QDPI board approval), on *barley* at 510 g ai/1000 kg seed (APVMA permit 5256). A harvest WHP is not required.

There are Australian and Codex but no US MRLs for thiram in animal commodities. The Australian MRL for edible offal is 2 mg/kg while the Codex MRL is 0.1 mg/kg, both as  $CS_2$ . The MRL for cereal grain is 0.5 mg/kg.

The target tissue is liver. The TF for liver (45 ppm feeding study for mancozeb)<sup>98</sup> was 0.003 giving an anticipated maximum residue from the feeding of grain at 100% of the diet of  $0.5 \times 0.003 = 0.00015$  mg/kg, less than the relevant international MRLs.

It is anticipated that animal product residues will be below typical method LOQs.

## Tralkoxydim

-is a cyclohexanedione herbicide used for the control of wild oats, annual rye grass etc in *wheat, barley, rye* and *triticale* crops. The application rate is up to 0.2 kg ai/ha. A harvest WHP is not required.

There are no Australian, Codex or US MRLs for tralkoxydim in animal commodities. The Australian MRL for cereal grains is \*0.02 mg/kg. The US MRLs are 0.02 mg/kg for grain and hay of barley and wheat and 0.05 mg/kg for wheat forage and straw.

The US EPA in its evaluation of tralkoxydim noted that<sup>99,100</sup> "Based on the results of the ruminant metabolism studies, the extensive metabolism and rapid excretion of either tralkoxydim or any of its metabolites, and ruminant consumption of commodities used in animal feed, there are no expected residues of tralkoxydim in meat or milk."

It is anticipated that animal product residues will be below typical method LOQs.

## Triadimefon

-is a fungicide used for the control of fungal diseases in *barley* and *wheat*. It is applied as a foliar spray at a maximum application rate of 125 g ai/ha. The harvest WHP is 4 weeks.

There are Australian and Codex but no US MRLs for animal tissues. The Australian/Codex residue definition is the sum of triadiment and triadimenol. The MRLs are \*0.05 mg/kg for edible offal and meat. The Australian and Codex MRLs for milk are \*0.1 and \*0.01 mg/kg respectively. The Australian MRL for cereal grains is 0.5 mg/kg.

In a lactating cow feeding studies were carried out with 1:1 mixture of triadimefon and triadimenol and at dose levels equivalent to feeding at 625, 1875 and 6250 ppm, fat contained residues up to

<sup>&</sup>lt;sup>98</sup> 1993 JMPR - Pesticide Residues in Food - 1993 Evaluations, Part I Residues FAO Plant Production and Protection Paper 124. FAO and WHO 1994

<sup>&</sup>lt;sup>99</sup> Tralkoxydim; Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical in or on Food [Federal Register: March 21, 2003 (Volume 68, Number 55)] [Page 13920-13924

<sup>&</sup>lt;sup>100</sup> Notice of Filing and Withdrawal of Pesticide Petitions [Federal Register: July 2, 1997 (Volume 62, Number 127)] [Page 35804-35812]

0.029 mg/kg at the 6250 mg/kg level and 0.016 ppm at the 1875 ppm dose level, whereas the residue level in the fat was less than 0.01 mg/kg at the 625 mg/kg feeding level<sup>101</sup>. There is no reasonable expectation of residues in cattle and sheep tissues from the feeding of cereal grains.

It is anticipated that animal product residues will be below typical method LOQs.

# **Triadimenol**

-is a fungicide used as a seed treatment for *wheat, barley* and *oats* (22.5 g ai/100 kg seed) and a foliar spray for sorghum (62.5 g ai/ha).

There are Australian and Codex but no US MRLs for animal tissues. The Australian/Codex residue definition is the sum of triadimefon and triadimenol. The MRLs are \*0.01 mg/kg for animal commodities. The Codex MRL for edible offal and milk is \*0.01 while meat is 0.02 mg/kg. The Australian MRL for cereal grains except sorghum is \*0.01 while MRL for sorghum is 0.5 mg/kg.

It is anticipated that animal product residues will be below typical method LOQs, see triadimefon above.

# Triallate

-is a thiocarbamate herbicide used for the control of various weeds in *barley, wheat* and *triticale*. The maximum application rate if 0.8 kg ai/ha with application occurring prior to sowing. No harvest WHP is required.

There are Australian but no Codex or US MRLs for triallate in animal commodities. The Australian MRLs are \*0.1 for edible offal (except kidney), 0.2 mg/kg for kidney, 0.2 mg/kg for fat and \*0.1 mg/kg for meat and milk.

The MRL for cereal grains is \*0.05 mg/kg.

In a diary cattle feeding study conducted at dose levels equivalent to 3 and 10 ppm in the diet, residues in tissues at slaughter were <0.01 mg/kg for muscle, kidney and liver for both dose groups and were 0.01 and 0.03 mg/kg in fat for the 3 and 10 ppm dose groups respectively<sup>102</sup>. Residues in milk were <0.01 mg/kg.

It is anticipated that animal product residues will be below typical method LOQs.

## Triasulfuron-methyl

-is a sulfonylurea herbicide used for the control of various weeds in *wheat, barley, oats* and *triticale* crops. Post-emergent applications are made at rates up to 11.25 g ai/ha. No harvest WHP is required.

There are Australian and US but no Codex MRLs for animal commodities. The Australian MRLs have all been set at \*0.05 mg/kg for tissues and \*0.01 mg/kg for milk. The US MRLs for cattle and sheep are 0.5 mg/kg for kidney, 0.1 mg/kg for meat, fat and meat by-products (except kidney) and 0.02 mg/kg for milk.

<sup>&</sup>lt;sup>101</sup> 1983 JMPR Pesticide Residues in Food - 1983 Evaluations, FAO Plant Production and Protection Paper 61. FAO and WHO 1985

<sup>&</sup>lt;sup>102</sup> Reregistration Eligibility Decision for Triallate List B Case 2695EPA 738-R-00-021 March 2001. Environmental Protection Agency, Office of Pesticide Programs, Special Review and Reregistration Division

The Australian MRL for cereal grains is \*0.02 mg/kg.

The US EPA reported<sup>103</sup> that "an acceptable feeding study in dairy cattle conducted at 15, 75, and 150 ppm has previously been reviewed and various animal commodity tolerances were subsequently established (milk, 0.02 ppm; meat, fat, and meat by-products of cattle, goats, hogs, horses, and sheep at 0.1 ppm)" and that "The existing [US] tolerances for triasulfuron in animal commodities are adequate to cover the use of triasulfuron on grasses [7 ppm for forage and 2 ppm for hay] with the exception of the tolerances on kidneys. Accordingly, higher triasulfuron tolerances of 0.5 ppm for the kidneys of cattle, goats, horses, and sheep are required to support the tolerances on grasses."

It is anticipated that animal product residues will be below typical method LOQs.

# Tribenuron-methyl

-is a sulfonylurea herbicide used for the control of various weeds in *fallow fields* and *pre-crop* situations. The maximum application rate is 22.5 g ai/ha. A harvest WHP is not required.

There are Australian but no Codex or US MRLs for animal commodities. The Australian MRLs have all been set at \*0.01 mg/kg.

The Australian MRL for barley, oats, sorghum and wheat is \*0.01 mg/kg and for maize \*0.05 mg/kg.

In a lactating goat study with labelled tribenuron methyl at a level of 6.7 ppm there was a total of 0.5% of the administered dose found in the assayed tissues and  $\text{organs}^{104}$ . Based on this low potential for transfer of residues to tissues, it is concluded that feeding cereal grain will not result in detectable residues in animal commodities.

It is anticipated that animal product residues will be below typical method LOQs.

## **Trichlorfon**

- is an organophosphate insecticide used for the control of various insects in crops. It is registered on *cereal crops* for the control of various pests. The application rate is up to 0.85 kg ai/ha. The harvest WHP is 2 days.

There are no Codex MRLs for trichlorfon in animal tissues. The Australian MRL for cattle fat is 0.1 mg/kg and 0.5 mg/kg for the US tolerance. The Australian MRL for milks is \*0.05 mg/kg while no milk MRL has been set in the US. The Australian MRL for cereal grains is 0.1 mg/kg.

Following peroral uptake of the trichlorfon (12.5 and 20 ppm in feed), no trichlorfon residues were detected (<0.1 ppm) in any of the examined tissues and organs (brain, heart, kidney, steak, fat) after a four week feeding period<sup>105</sup>. No detectable residues are expected in tissues of animals fed cereal grain.

 <sup>&</sup>lt;sup>103</sup> Triasulfuron; Pesticide Tolerance Federal Register: August 18, 1998 (Volume 63, Number 159) Page 44146-44152
<sup>104</sup> PMRA Decision Document E95-04 Tribenuron methyl

<sup>&</sup>lt;sup>105</sup> 1971 JMPR. Evaluations of some pesticide residues in food. AGP/1971/M/9/1; WHO Pesticide Residues Series No. 1, 1972

## Triclopyr

-is a herbicide used for the control of various weeds, including woody weeds in *fallow crops*, stubble and *sorghum*. The application rate is up to 96 g ai/ha in fallow and stubble and up to 48 g ai/ha in sorghum crops.

A harvest WHP is not required.

There are Australian and US but no Codex MRLs for triclopyr in animal commodities. The Australian and US residue definitions differ. The Australian definition is parent compound. The US definition is the sum of triclopyr and its metabolite 3,5,6-trichloro-2-pyridinol (NOTE the later is also in the US residue definition for chlorpyrifos and chlorpyrifos-methyl). The Australian MRLs are 5 mg/kg for edible offal of sheep and cattle, 0.2 mg/kg for meat (in the fat) and 0.1 mg/kg for milk [in the fat]. The US MRLs are 0.5 mg/kg for liver and kidney, 0.05 mg/kg for meat, fat and meat by-products (except liver and kidney) and 0.01 mg/kg for milk.

There are no Australian MRLs for cereal grain as no residues are expected.

NOTE: the US EPA RED suggests that feeding at 200 ppm (hay tolerance) will not lead to residues in animal commodities that exceed the US MRLs<sup>106</sup>.

It is anticipated that animal product residues will be below typical method LOQs.

# Triflumuron

-is a insecticide fungicide used as a seed treatment for wheat, barley and oats (0.6 g ai/100 kg seed.

There are Australian but no Codex or US MRLs for triflumuron in animal commodities. The Australian MRLs are \*0.05 mg/kg for relevant animal commodities. The Australian MRL for cereal grains is \*0.05 mg/kg.

It is anticipated that animal product residues will be below typical method LOQs.

# Trifluralin

-is a selective dinitroaniline herbicide used for the control of certain grasses and annual broadleafed weeds in *wheat, barley, triticale* and *rye* crops. Application is at a maximum rate of 0.384 kg ai/ha for wheat, rye and triticale and 0.6 kg ai/ha for barley. No harvest WHP is required.

There are no Codex or US MRLs for trifluralin in animal tissues although there are registrations in the US including on vegetables (except carrot) MRL 0.05 mg/kg and carrot (MRL 1 mg/kg). The Australian MRL for meat (mammalian) and milk are \*0.05 mg/kg. The Australian MRL cereal grains is 0.05 mg/kg.

The US EPA evaluation of trifluralin states that based on a goat metabolism study where animals were fed at exaggerated rates there is no expectation of finite residues of trifluralin in animal tissues<sup>107</sup>. Therefore no residues are expected to result from the feeding of cereal grain to cattle and sheep.

<sup>&</sup>lt;sup>106</sup> Reregistration Eligibility Decision Triclopyr List B CASE 2710 EPA 738-R-98-011 October 1998 Environmental Protection Agency, Office of Pesticide Programs, Special Review and Reregistration Division

<sup>&</sup>lt;sup>107</sup> Reregistration Eligibility Decision, Trifluralin, List A Case 0179, Environmental Protection Agency, Office of Pesticide Programs, Special Review and Reregistration Division EPA 738-R-95-040, April 1996

#### Triticonazole

is a DMI fungicide used as a seed treatment for *barley* and *wheat* to aid in the control of various fungal diseases. The application rate is 30 g ai/100 kg seed. No harvest WHP required.

There are Australian but no Codex or US tolerances for triticonazole in animal commodities. The Australian MRLs are \*0.05 mg/kg for animal tissues and \*0.01 mg/kg for milk. The MRL for cereal grains is \*0.05 mg/kg.