



**NATIONAL RESIDUE SURVEY**

**INFORMATION BULLETIN - September 2009**

**International Sheep Maximum Residue Limits (MRLs)**

This information bulletin provides a list of maximum residue limits (MRLs) for pesticides, veterinary medicines and contaminants that are included in the National Residue Survey (NRS) random survey for sheep matrices. Listed in the table are MRLs for Australia as defined in the Australian Food Standards Code and a number of countries to which Australian sheep products may be exported. The main purpose of this bulletin is to inform producers of the export requirements in regards to residues of pesticides, veterinary medicines and contaminants. **The critical element of this information is that Australian MRLs do not apply to other countries.** If an MRL is 'not set', in some instances, a zero tolerance applies (refer to the notes below the table for full details)<sup>#</sup>.

Organisations marketing to overseas countries should be aware that the information provided below represents the official standards, but not necessarily the marketing requirements. Marketers should refer to the contractual arrangements concerning agreed residue limits.

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Group of substances	Maximum residue limit (mg/kg) - sheep								
	Compounds	Matrix	AUSTRALIA (Food Standards Code)	CODEX	CANADA	EUROPEAN UNION	JAPAN	KOREA	UNITED STATES of AMERICA
<b>A ANABOLIC and UNAUTHORISED SUBSTANCES</b>									
<b>A1</b>	<b>Stilbenes</b>								
	dienoestrol	liver	not set	not set	not set	not set	not set	not set	not set
	diethylstilboestrol		not set	not set	not set	not set	not set	not set	not set
	hexoestrol		not set	not set	not set	not set	not set	not set	not set
<b>A3</b>	<b>Steroids</b>								
	boldenone <sup>1</sup> (17 $\alpha$ and 17 $\beta$ )	urine <sup>2</sup>	not defined	not set	not set	not set	not set	not set	not set
	methandriol		not defined	not set	not set	not set	not set	not set	not set

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<b>A ANABOLIC and UNAUTHORISED SUBSTANCES</b>											
<b>A3</b>	<b>Steroids (cont)</b>										
	Stanozolol (16-OH)	urine <sup>2</sup>	not defined	not set	not set	not set	not set	not set	not set		
	Trenbolone ( $\alpha$ and $\beta$ )	liver	not set	not set	not set	not set	not set	not set	not set		
<b>A4</b>	<b>Resorcylic acid lactones</b>										
	Zeranol	liver	not set	not set	not set	not set	P(0.02)	not set	0.02 (et)		
<b>A5</b>	<b>Beta agonists</b>										
	Cimaterol	liver	not defined	not set	not set	not set	not set	not set	not set		
	Clenbuterol		not defined	not set	not set	not set	P (0.0006)	not set	not set		
	Mabuterol		not defined	not set	not set	not set	not set	not set	not set		
	Ractopamine		not defined	not set	not set	not set	not set	not set	not set		
	Salbutamol		not defined	not set	not set	not set	not set	not set	not set		
	Zilpaterol		not defined	not set	not set	not set	not set	not set	not set		
<b>A6</b>	<b>Prohibited compounds</b>										
	Chloramphenicol	muscle	not set	not set	not set	not set	prohibited <sup>6</sup>	not detected	not set		
<b>B VETERINARY DRUGS and CONTAMINANTS</b>											
<b>B1</b>	<b>Antibacterials</b>										
	<b>Aminoglycosides</b>	Apramycin	kidney	2.0 (eo)	not set	not set	not set	P (2.0)	not set	not set	
		Dihydrostreptomycin		0.3 (eo) <sup>3</sup>	1.0	not set	1.0	1.0	1.0	1.0	not set
		Gentamycin		not set	not set	not set	not set	not set	not set	not set	not set
		Neomycin		T10.0	10.0	10.0 <sup>4</sup>	5.0	10.0	10.0	10.0	7.2
		Streptomycin		0.3 (eo) <sup>3</sup>	not set	not set	1.0	1.0	1.0	1.0	not set
	<b>Beta-lactams</b>	Amoxicillin		0.01 (eo) <sup>3</sup>	not set	not set	0.05	P (0.04)	not set	not set	
		Ampicillin		not set	not set	not set	0.05	P (0.04)	not set	not set	
		Benzyl penicillin G		0.06 (eo) <sup>3</sup>	not set	not set	0.05	P (0.06)	not set	zero (et)	
		Cloxacillin		not set	not set	not set	0.3	P (0.3)	not set	not set	
	<b>Cephalosporins</b>	Ceftiofur		not set	not set	6.0	6.0	P (6.0)	not set	not required	
		Cefuroxime		not set	not set	not set	not set	not set	not set	not set	
		Cephalonium		not set	not set	not set	not set	not set	not set	not set	
	<b>Lincosamides</b>	Lincomycin		not set	not set	not set	1.5	P (0.9)	not set	not set	
	<b>Macrolides</b>	Erythromycin		0.3 (eo) <sup>3</sup>	not set	not set	0.2	P (0.3)	not set	not set	
		Tilmicosin	not set	0.3	not set	1.0	0.3	0.3	1.2 (liver)		
		Tulathromycin	not set	not set	not set	not set	not set	not set	not set		
		Tylosin	not set	not set	not set	0.1	P (0.1)	not set	not set		
	<b>Other</b>	Dimetridazole	not set	not set	not set	not set	not set	not set	not set		
		Florfenicol	not set	not set	not set	not set	P (0.2)	not set	not set		
		Thiamphenicol	not set	not set	not set	0.05	not set	not set	not set		

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<b>B VETERINARY DRUGS and CONTAMINANTS</b>											
<b>B1</b>	<b>Antibacterials</b>										
	<b>Sulfonamides</b>	Sulfadiazine	kidney	0.1 (eo)	not set	0.1 (et) <sup>4</sup>	0.1 <sup>5</sup>	P (0.1)	0.1	not set	
		Sulfadoxine		0.1 (eo) <sup>3</sup>	not set	not set	0.1 <sup>5</sup>	P (0.1)	0.1	not set	
		Sulfafurazole		not set	not set	not set	0.1 <sup>5</sup>	not set	not set	not set	
		Sulfamerazine		not set	not set	not set	0.1 <sup>5</sup>	P (0.1)	0.1	not set	
		Sulfamethazine/ Sulfadimidine		0.1 (eo)	0.1	0.1 (et) <sup>4</sup>	0.1 <sup>5</sup>	0.1	0.1	not set	
		Sulfamethoxydiazine		not set	not set	not set	0.1 <sup>5</sup>	not set	0.1	not set	
		Sulfapyridine		not set	not set	not set	0.1 <sup>5</sup>	not set	not set	not set	
		Sulfaquinoxaline		not set	not set	0.1 (et) <sup>4</sup>	0.1 <sup>5</sup>	P (0.1)	0.1	not set	
		Sulfathiazole		not set	not set	0.1 (et)	0.1 <sup>5</sup>	P (0.1)	0.1	not set	
		Sulfatroxazole		0.1 (eo)	not set	not set	0.1 <sup>5</sup>	P (0.1)	not set	not set	
	<b>Tetracyclines</b>	Chlortetracycline		not set	1.2	1.0	0.6	1.2	1.2	12.0	
		Doxycycline		not set	not set	not set	not set	not set	not set	not set	
		Oxytetracycline		0.6	1.2	1.2 <sup>4</sup>	0.6	1.2	1.2	12.0	
		Tetracycline		not set	1.2	0.25	0.6	1.2	1.2	12.0	
<b>B2 OTHER VETERINARY DRUGS</b>											
<b>B2a</b>	<b>Anthelmintics</b>										
	<b>Benzimidazoles</b>	Albendazole	liver	3.0 (eo)	5.0	not set	1.0	not set	5.0	0.25	
		Fenbendazole		0.5 (eo)	0.5	not set	0.5	0.5	0.5	not set	
		Mebendazole		0.02 (eo) <sup>3</sup>	not set	not set	0.4	P (0.2)	not set	not set	
		Oxfendazole		3.0 (eo)	0.5	not set	0.5	0.5	0.5	not set	
		Oxibendazole		not set	not set	not set	not set	P (0.3)	not set	not set	
		Thiabendazole		0.2 (eo)	0.1	0.1 (et)	not set	0.1	0.1	0.1 (et)	
		Triclabendazole		2.0	0.1	0.25	0.1	0.1	0.1	not set	
	<b>Imidazothiazoles</b>	Levamisole		1.0 (eo)	0.1	0.1 (et)	0.1	0.1	0.1	0.1 (et)	
		Morantel		2	not set	not set	0.8	1	not set	not set	
	<b>Macrocyclic lactones</b>	Abamectin		fat	0.05 (mf)	not set	not set	0.05	P (0.04)	not set	not set
		Doramectin			0.1	not set	not set	0.1	P (0.1)	not set	not set
		Emamectin			0.002 (m) <sup>3</sup>	not set	not set	not set	P (0.002)	not set	0.01; 0.003 (m)
		eprinomectin			not set	not set	not set	not set	P (0.1)	not set	not set
		ivermectin			0.02 (mf)	0.02	0.03 (liver)	0.02	0.02	0.02	not set
		moxidectin			0.5 (mf)	0.5	not set	0.5	0.5	0.5	0.9
	<b>Salicylanilide</b>	closantel		liver	5.0 (eo)	1.5	not set	1.5	1.5	1.5	not set

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<b>B2 OTHER VETERINARY DRUGS</b>										
<b>B2c</b>	<b>Carbamates &amp; pyrethroids</b>									
	Triazines	Cyromazine/ Melamine	kidney	0.2 (eo)	0.3 (eo)	not set	0.3	0.3	not set	0.2
	Pyrimidines	dicyclanil		0.3	not set	not set	0.4	P (0.125)	not set	not set
	Benzoyl ureas	chlorflazuron	fat	not set	not set	not set	not set	not set	not set	not set
		diflubenzuron		0.05 (mf)	0.1 (m)	not set	0.1	P (0.1)	0.05 (m)	0.05
		fluazuron		not set	not set	not set	not set	not set	not set	not set
		triflumuron		2.0 (mf)	not set	not set	0.01	P (2.0)	not set	not set
	Synthetic	bifenthrin		2.0 (mf)	not set	not set	0.05	P (2.0)	not set	1.0
		bioresmethrin		not set	not set	not set	not set	P (0.5)	not set	0.5
		cyfluthrin		0.5	not set	5.0	0.05	P (4.0)	not set	2.0
		cyhalothrin		0.5 (mf)	0.4	1.0	not set	P (0.4)	not set	(λ) 3.0
		cypermethrin		0.5 (mf)	0.2 (m)	not set	0.2	P (0.2)	0.2 (mf)	1.00
		deltamethrin		0.2 (mf)	0.5 (m)	not set	0.05	not set	0.5	0.05
		fenvalerate (esfenvalerate)	1.0 (mf)	1.0 (mf)	not set	0.2	P (1.0)	1.0 (mf)	not set	
		flumethrin	not set	0.2 (mf)	not set	0.15	P (0.2)	not set	not set	
	permethrin	1.0 (mf)	1.0 (mf)	not set	not set	P (1.0)	1.0 (mf)	1.5		
	tau - fluvinate	not set	not set	not set	0.3	not set	not set	not set		
<b>B2e</b>	<b>Non-steroidal anti inflammatory</b>									
		Flunixin	liver	not set	not set	not set	not set	0.1	not set	not set
		Ketoprofen		not set	not set	not set	not set	not set	not set	not set
		Oxyphenbutazone		not set	not set	not set	not set	not set	not set	not set
		Phenylbutazone		not set	not set	not set	not set	not set	not set	not set
		Tolfenamic acid		not set	not set	not set	not set	not set	not set	not set
<b>B3 OTHER SUBSTANCES and ENVIRONMENTAL CONTAMINANTS</b>										
<b>B3a</b>	<b>Organochlorine compounds</b>									
		Aldrin/Dieldrin	fat	0.2 E(mf)	0.2 E(m)	0.2	0.2	P (0.2)	0.2 (mf)	0.3
		Chlordane (Oxychlordane)		0.2 E(mf)	0.05 E(mf)	0.1 (m)	0.05	P (0.05)	0.5 (mf)	0.3
		DDT and metabolites		5.0 E(mf)	T5.0 E(m)	1.0	1.0	P (5.0)	5.0 (m)	5.0
		Dicofol		not set	not set	0.1 (m)	0.5	0.5	not set	not set
		Endosulfan		0.2 (mf)	0.1 (m)	0.1	0.05	P (0.1)	0.1 (m)	13
		HCB		1.0 E(mf)	not set	not set	0.2	0.6	not set	0.5
		HCHs (BHC) (except γ-HCH)		0.3 E(mf)	not set	0.1 (m)	0.3	not set	not set	not set

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<b>B3 OTHER SUBSTANCES and ENVIRONMENTAL CONTAMINANTS</b>									
<b>B3a</b>	<b>Organochlorine compounds</b>								
	heptachlor (heptachlor epoxide)	fat	0.2 E(mf)	0.2 E(m)	0.2	0.2 (m)	P (0.2)	0.2 (m)	0.2
	lindane ( $\gamma$ -HCH)		2.0 E(mf)	0.1 (m)	2.0	0.02 (m)	P (0.1)	not set	7.0
	mirex		not set	not set	not set	not set	not set	not set	0.1
	PCBs		0.2	not set	not set	not set	not set	not set	3.0
<b>B3b</b>	<b>Organophosphates</b>								
	chlorfenvinphos	fat	T0.2 (mf)	not set	not set	0.01	P (0.2)	0.2 (m)	not set
	chlorpyrifos		T0.5 (mf)	1.0 (mf)	not set	not set	P (1.0)	1.0 (mf)	0.2
	chlorpyrifos-methyl		0.05 (mf)	not set	not set	0.05	P (0.3)	not set	0.5
	coumaphos		0.5 (mf)	not set	0.5	not set	not set <sup>6</sup>	not set	1.0
	diazinon		0.7 (mf)	2.0 (mf)	not set	0.05	P (2.0)	0.7 (mf)	not set
	dichlorvos		0.05 (m)	0.05 (mf)	not set	not set	P(0.02)	0.05 (m)	0.02
	dimethoate		0.05 (m)	0.05	not set	not set	P(0.05)	0.05	0.02 (mbyp)
	ethion		not set	not set	not set	not set	P (0.2)	0.2 (mf)	0.2
	famphur		not set	not set	not set	not set	P (0.1)	not set	not set
	fenitrothion <sup>7</sup>	meat	T0.05 (m) <sup>3</sup>	0.05 E(m) <sup>3</sup>	not set	not set	P (0.05)	0.05 (mf)	not set
	fenthion <sup>7</sup>		0.2 (m)	not set	not set	0.05	P (0.2)	not set	not set
	Malathion (Maldison)	fat	1.0 (mf)	not set	not set	0.02	P (2.0)	not set	4.0
	methidathion		0.5 (mf)	0.02	not set	0.02	P(0.02)	0.02	not set
	parathion-methyl		T0.05 (m)	not set	not set	0.02	P(0.05)	not set	not set
	phosmet		0.05 (m) <sup>3</sup>	not set	not set	0.1	P (0.2)	not set	0.2
	pirimphos-methyl		0.05(m)	0.01	not set	0.05	P(0.1)	0.05(m)	0.02
	prothiofos		not set	not set	not set	not set	not set	not set	not set
	temephos		3.0 (mf)	not set	not set	not set	P (3.0)	not set	not set
	trichlorfon		not set	not set	not set	0.1	P (0.1)	0.1	not set
<b>B3d</b>	<b>Chemical elements</b>								
	cadmium	liver	1.25	not set	not set	0.5	not set	not set	not set
	lead		0.5 (eo)	not set	not set	0.5 (eo)	not set	not set	not set
	mercury		not defined	not set	not set	not set	not set	not set	not set
<b>B3d</b>	<b>Mycotoxins</b>								
	Zearalenone	liver	not defined	not set	not set	not set	not set	not set	not set
	$\alpha$ -Zearalenol		not defined	not set	not set	not set	not set	not set	not set
	$\beta$ -Zearalenol		not defined	not set	not set	not set	not set	not set	not set

Group of substances	Maximum residue limit (mg/kg) - sheep								
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<b>B3 OTHER SUBSTANCES and ENVIRONMENTAL CONTAMINANTS</b>									
<b>B3f</b>	<b>Other - Fungicides</b>								
	cyproconazole	fat	0.03 (m)	not set	not set	0.05	P(0.03)	not set	0.01
	flutriafol		0.05 (m)	not set	not set	0.01	P (0.05)	not set	not set
	procymidone		T0.2 (mf)	not set	not set	0.05	P(0.2)	not set	not set
	propiconazole		0.1 (m)	0.01 (mf)	not set	0.01	P(0.08)	0.05 (m)	0.05
	quintozene		not set	not set	not set	0.01	0.01	not set	not set
<b>B3f</b>	<b>Other - Herbicides</b>								
	ethofumesate	fat	0.5 (mf)	not set	not set	0.1	0.3	not set	0.05
	metolachlor		0.05 (m)	not set	not set	not set	P(0.02)	not set	0.04
	propachlor		0.02 (mf)	not set	not set	0.05	P(0.02)	not set	0.05
<b>B3f</b>	<b>Other - Insecticides</b>								
	chlorfenapyr	fat	0.05 (mf)	not set	not set	not set	P(0.05)	not set	not set
	indoxacarb		1.0 (mf)	1.0 (mf)	not set	0.3	P(1.0)	not set	1.5

**NOTE:**

(m) meat,	(eo) edible offal	(IT) negotiated import tolerance.
(mf) meat in the fat	(E) Extraneous MRLs	
(et) edible tissue	(P) Provisional MRL	
(mbyp) meat by-product	(T) Temporary MRL	

- MRL 'not set', any detection is a violation.
- For 'not set' shown in columns for overseas markets, exporters should consult with AQIS for specific advice regarding market access requirements for the countries of interest.
- MRL 'not defined', denotes no maximum limit set, a detection is not a contravention

**1** Residues of these compounds may arise from endogenous sources.

**2** The screen is undertaken in a matrix for which Australian Standards are not established. Any detection in this matrix may indicate inappropriate use of the compound and/or the presence of residues of the compound in edible tissue.

**3** Denotes that the maximum residue limit or the extraneous residue limit is set at or about the limit of determination.

**4** Administrative MRL for which the promulgation process has been initiated.

**5** Combined total residues of all substances within the sulphonamide group should not exceed 0.1 mg/kg.

**6** Japan's Ministry of Health Labour and Welfare lists 15 chemicals for which no residues may be detected ('black list') because of high human health risks. They are: 2,4,5-T, Amitrole; Captafol; Carbadox including QCA; Chloramphenicol; Chlorpromazine; Coumafos/Coumaphos; Cyhexatin and Azocyclotin; Daminozide; Diethylstilbestrol; Dimetridazole; Metronidazole; Nitrofurans; Propham; Ronidazole.

**7** For regulatory purposes, when no MRL has been set in fat or meat (in the fat), the MRL in meat is used.

**# Australia, Canada and USA** - At present where there is no MRL a zero tolerance applies.

**# European Union** - where there is no MRL for a commodity then default value of 0.01 mg/kg applies for pesticides only. For veterinary drugs if there is no MRL then there should be no detection.

**# Japan** - if there is no residue limit applied a uniform limit of 0.01 mg/kg will then apply.

**# Korea** - If there is no national standard then Korea will apply the Codex standard. If neither are applicable, the lowest of the residue limits of the pesticide in question specified for similar agricultural products shall apply to the agricultural products which the pesticides detected.

**This table has been compiled with reference to the information obtained from the following Food/Agricultural Authorities or publications:****AUSTRALIA:**

Australia New Zealand Food Standards Code 1.4.1 (MLs) and 1.4.2 (MRLs) (Australia only), up to Amendment 111, August 2009 available on the FSANZ website. For New Zealand purposes, maximum residue limits for agricultural compounds are regulated in the New Zealand (Maximum Residue Limits of Agricultural Compounds Mandatory Food Standard 1999 (and subsequent amendments) issued under sections 11C and 11Z of the Food Act 1981.

<http://www.foodstandards.gov.au/thecode/foodstandardscode.cfm>

**CANADA:**

List of Maximum Residue Limits Regulated Under the Pest Control Products Act

Canadian MRLs established as of 16/6/09

<http://www.hc-sc.gc.ca/cps-spc/pest/protect-proteger/food-nourriture/mrl-lmr-eng.php>

Veterinary Drugs Directorate Table 1. Maximum Residue Limits (Mrls) Set By Canada Administrative Maximum Residue Limits (AMRLS) and Maximum Residue

[http://www.hc-sc.gc.ca/dhp-mps/vet/mrl-lmr/mrl-lmr\\_versus\\_new-nouveau-eng.dhp](http://www.hc-sc.gc.ca/dhp-mps/vet/mrl-lmr/mrl-lmr_versus_new-nouveau-eng.dhp)

**CODEX:**

FAO/WHO Food Stds Codex Alimentarius Pesticide Residues in Food - MRLs & Extraceous MRLs - (updated March 2009)

[http://www.codexalimentarius.net/mrls/pestdes/jsp/pest\\_q-e.jsp](http://www.codexalimentarius.net/mrls/pestdes/jsp/pest_q-e.jsp)

FAO/WHO Food Stds Codex Alimentarius Veterinary Drug Residues in Food - MRLs - (updated March 2009)

[http://www.codexalimentarius.net/mrls/vetdrugs/jsp/vetd\\_q-e.jsp](http://www.codexalimentarius.net/mrls/vetdrugs/jsp/vetd_q-e.jsp)

Summary of Evaluations Performed by the Joint FAO/WHO Expert Committee on Food Additives.

<http://jecfa.ilsa.org>

**EUROPEAN UNION:**

Maximum residue limits of **veterinary medicinal products** in foodstuffs of animal origin - Go down to the most recent date listed under the consolidated version - 2009-

<http://eur-lex.europa.eu/Notice.do?val=162315:cs&lang=en&list=185432:cs.162315:cs.&pos=2&page=1&nbl=2&pgs=10&hwds>

**Pesticide** EU-MRLs Database as of 1 September 2008

[http://ec.europa.eu/sanco\\_pesticides/public/index.cfm](http://ec.europa.eu/sanco_pesticides/public/index.cfm)

COMMISSION REGULATION (EC) No 1881/2006 of 19 December 2006 - setting maximum levels for certain **contaminants in foodstuffs**

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:364:0005:0024:EN:PDF>

**JAPAN:**

Japan - Specifications and Standards for Foods, Food additives, etc. Under the Food Sanitation Law (Abstracts),(MHW Notification, No. 370, 1959, amendment No.499

<http://www.mhlw.go.jp/english/topics/foodsafety/positivelist060228/>

Maximum Residue Limits (MRLs) List of Agricultural Chemicals in Foods

<http://www.m5.ws001.squarestart.ne.jp/foundation/search.html>

**KOREA:**

Korean Food and Drug Administration (KFDA): Korean MRLs for Pesticides, website (go to English version then to 'site map' at top right hand corner; then go (MRLs

<http://www.kfda.go.kr/>

Veterinary MRLs obtained through the Australian Government Department of Foreign Affairs and Trade, Dept. Agriculture, Fisheries and Forestry Section, Korean

**USA:**

United States Food and Drug Administration, Code of Federal Regulations

Department of Health and Human Services CFR Titles Volumes 21 (Veterinary drugs) & 40 (Pesticides); FR Titles 51, 53, 54, 55 & 57; MPI Dir 917.1, website:

<http://www.gpoaccess.gov/nara/index.html>

MRLs for Veterinary Drugs - last updated 18 August 2009

[http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=79dffe982acea9e06c35d6664fb8aeca&tpl=/ecfrbrowse/Title21/21cfr556\\_main\\_02.tpl](http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=79dffe982acea9e06c35d6664fb8aeca&tpl=/ecfrbrowse/Title21/21cfr556_main_02.tpl)

MRLs for Pesticide Chemicals - last updated 18 August 2009

[http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=2bfde6952266d018c52f77953f6287b9&tpl=/ecfrbrowse/Title40/40cfr180\\_main\\_02.tpl](http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=2bfde6952266d018c52f77953f6287b9&tpl=/ecfrbrowse/Title40/40cfr180_main_02.tpl)

MRLs for PCB - Under CPG 7111.03 - [http://www.fda.gov/ora/compliance\\_ref/cpg/cpgfod/cpg565-200.html](http://www.fda.gov/ora/compliance_ref/cpg/cpgfod/cpg565-200.html)

USA MRLs for Chlordane - [http://www.fda.gov/ora/compliance\\_ref/cpg/cpgfod/cpg575-100.html](http://www.fda.gov/ora/compliance_ref/cpg/cpgfod/cpg575-100.html)