

## CFIA Aquaculture Therapeutant Residue Monitoring List

This reference list identifies the therapeutants that are currently being monitored in imported and domestically produced aquacultured fish and crustaceans for compliance with Canadian regulatory requirements. General information on therapeutant use in aquaculture in Canada can be found in Appendix I (B) Therapeutant Use in Aquaculture - Questions and Answers.

Therapeutant Information			Regulatory Status			Action Level	
Class Name	Substance Name	Marker Residue / Metabolite	Use Status	Species	Tissue	ug/g (ppm)	ng/g (ppb)
Amphenicols	Florfenicol	Florfenicol amine	Approved <sup>1</sup>	Salmonids	Muscle	0.8 <sup>a</sup>	800 <sup>a</sup>
	Chloramphenicol		Banned <sup>2</sup>	All	N/A	DTC	DTC
	Thiamphenicol	Not accepted to be used	All	N/A	DTC	DTC	
Avermectins	Emamectin Benzoate		Approved <sup>1</sup>	Salmonids	Muscle	0.1 <sup>*</sup>	100 <sup>*</sup>
	Ivermectin		Not accepted to be used	All	N/A	DTC	DTC
Benzoylureas	Teflubenzuron <sup>h</sup>		Approved <sup>1</sup>	Salmonids	Muscle	0.3	300
					Skin	3.2	3200
Fluoroquinolones	Ciprofloxacin		Not accepted to be used	All	N/A	0.001 <sup>b</sup>	1.0 <sup>b</sup>
	Danofloxacin		Not accepted to be used	All	N/A	0.001 <sup>b</sup>	1.0 <sup>b</sup>
	Difloxacin		Not accepted to be used	All	N/A	0.001 <sup>b</sup>	1.0 <sup>b</sup>
	Enrofloxacin		Not accepted to be used	All	N/A	0.001 <sup>b</sup>	1.0 <sup>b</sup>
	Marbifloxacin		Not accepted to be used	All	N/A	0.001 <sup>b</sup>	1.0 <sup>b</sup>
	Norfloxacin		Not accepted to be used	All	N/A	0.001 <sup>b</sup>	1.0 <sup>b</sup>
	Orbifloxacin		Not accepted to be used	All	N/A	0.001 <sup>b</sup>	1.0 <sup>b</sup>
	Sarafloxacin		Not accepted to be used	All	N/A	0.001 <sup>b</sup>	1.0 <sup>b</sup>
Macrolides	Erythromycin		EDR	Fish, Crustaceans	Muscle	0.03 <sup>c</sup>	30 <sup>c</sup>
Nitrofurans	Furaltadone	3-Amino-5-morphinomethyl-oxazolidin-2-one (AMOZ)	Banned <sup>2</sup>	All	N/A	DTC	DTC
	Furazolidone	3-Amino-2-oxazolidinone (AOZ)	Banned <sup>2</sup>	All	N/A	DTC	DTC
	Nitrofurantoin	1-Aminohydantoin hydrochloride (AHD)	Banned <sup>2</sup>	All	N/A	DTC	DTC
	Nitrofurazone	Semicarbazide (SEM)	Banned <sup>2</sup>	All	N/A	DTC	DTC
Nitroimidazoles	2-hydroxymethyl-1-methyl-5-nitroimidazole (HMMNI)		Banned <sup>2</sup>	All	N/A	DTC	DTC
	Ipronidazole (IPZ)		Banned <sup>2</sup>	All	N/A	DTC	DTC
	1-methyl-2-(2'-hydroxyisopropyl)-5-nitroimidazole (IPZ-OH)		Banned <sup>2</sup>	All	N/A	DTC	DTC
	Metronidazole (MNZ)		Banned <sup>2</sup>	All	N/A	DTC	DTC
	1-(2-hydroxyethyl)-2-hydroxymethyl-5-nitroimidazole (MNZ-OH)		Banned <sup>2</sup>	All	N/A	DTC	DTC
	Ronidazole (RNZ)		Banned <sup>2</sup>	All	N/A	DTC	DTC
	Dimetridazole (DMZ)		Banned <sup>2</sup>	All	N/A	DTC	DTC

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Class Name	Substance Name	Marker Residue / Metabolite	Use Status	Species	Tissue	ug/g (ppm)	ng/g (ppb)	
Pyrethroids	Cypermethrin		Not accepted to be used	All	N/A	0.1 *	100 *	
Pyrethroids	Deltamethrin		Not accepted to be used	All	N/A	0.1 *	100 *	
Quinolones	Flumequine Oxolinic Acid		Not accepted to be used	All	N/A	DTC	DTC	
			Not accepted to be used	All	N/A	DTC	DTC	
Steroids	Boldenone (17 beta-boldenone) Methyltestosterone (17 alpha-methyltestosterone) Nandrolone (17 beta-19-nortestosterone) epi-Boldenone (17 alpha-boldenone) epi-Nandrolone (17 alpha-19-nortestosterone)		Not accepted to be used	All	N/A	DTC	DTC	
			Not accepted to be used	All	N/A	DTC	DTC	
			Not accepted to be used	All	N/A	DTC	DTC	
			Not accepted to be used	All	N/A	DTC	DTC	
			Not accepted to be used	All	N/A	DTC	DTC	
Stilbenes	Dienestrol (DIEN) Diethylstilbestrol (DES) Hexestrol (HEX)		Banned <sup>2</sup>	All	N/A	DTC	DTC	
			Banned <sup>2</sup>	All	N/A	DTC	DTC	
			Banned <sup>2</sup>	All	N/A	DTC	DTC	
Sulfonamides	Ormetoprim Sulfadiazine Sulfadimethoxine Trimethoprim		Approved <sup>1</sup>	Salmonids	Edible Tissue	0.1 *	100 *	
			Approved <sup>1</sup>	Salmonids	Edible Tissue	0.1	100	
			Approved <sup>1</sup>	Salmonids	Edible Tissue	0.1 *	100 *	
			Approved <sup>1</sup>	Salmonids	Muscle	0.1	100	
	Sulfacetamide Sulfachloropyridazine Sulfadoxine Sulfaguanadine Sulfamerazine Sulfamethazine Sulfamethiazole Sulfamethoxazole Sulfamethoxypridazine Sulfamonomethoxine Sulfamoxole Sulfanilamide Sulfapyridine Sulfaquinoxaline Sulfathiazole Sulfisoxazole			Not accepted to be used	All	N/A	DTC	DTC
				Not accepted to be used	All	N/A	DTC	DTC
				Not accepted to be used	All	N/A	DTC	DTC
				Not accepted to be used	All	N/A	DTC	DTC
				Not accepted to be used	All	N/A	DTC	DTC
				Not accepted to be used	All	N/A	DTC	DTC
				Not accepted to be used	All	N/A	DTC	DTC
				Not accepted to be used	All	N/A	DTC	DTC
				Not accepted to be used	All	N/A	DTC	DTC
				Not accepted to be used	All	N/A	DTC	DTC
				Not accepted to be used	All	N/A	DTC	DTC
				Not accepted to be used	All	N/A	DTC	DTC
				Not accepted to be used	All	N/A	DTC	DTC
				Not accepted to be used	All	N/A	DTC	DTC
				Not accepted to be used	All	N/A	DTC	DTC
				Tetracyclines	Oxytetracycline Chlorotetracycline Doxycycline Tetracycline		Approved <sup>1</sup>	Salmonids, Lobsters
Not accepted to be used	All	N/A	DTC				DTC	
Not accepted to be used	All	N/A	DTC				DTC	
Not accepted to be used	All	N/A	DTC				DTC	
Triphenylmethane Dyes	Gentian Violet	Leucogentian Violet	Not accepted to be used	All	N/A	see footnotes "f" and "g"		
			Not accepted to be used	All	N/A	see footnotes "f" and "g"		
	Malachite Green	Leucomalachite Green	Not accepted to be used	All	N/A	see footnotes "d" and "e"		
			Not accepted to be used	All	N/A	see footnotes "d" and "e"		

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### ACTION LEVEL COLUMN

For therapeutants where a predetermined guideline has been established by Health Canada (such as Maximum Residue Limits (MRLs), Administrative Maximum Residue Limits (AMRLs), interim guidelines, minimum performance Limit of Quantification, etc.), the analytical laboratory must use a validated method that is capable of providing an accurate result so that an assessment can be made on whether the product meets the applicable guideline. The residue limits for these therapeutants in the sample are identified in the "Action Level" column.

For therapeutants where a predetermined guideline has not been established by Health Canada and are not accepted for use in aquaculture in Canada, any residue detected in the sample is a violation of Article 4 (a) and/or (d) of the *Food and Drugs Act* and Section 6 (1) (a) of the *Fish Inspection Regulations*. The analytical laboratory must use a validated method and report any of these residues that are detected and positively confirmed by Mass Spectrometry (MS). The action level is indicated as "DTC" (i.e. Detected above the reporting limit) in the "Action Level" column.

### LOT ACCEPTANCE

A lot of fish is considered unacceptable when residues of a substance found in the product exceed the action level specified in this list (NOTE: for Triphenylmethane Dyes - refer to footnotes 'd', 'e', 'f' and 'g' for relevant information).

### LEGEND / EXPLANATORY NOTES

#### Colour Scheme

**Approved<sup>1</sup>** \*\*\* Veterinary drugs that are authorized for sale by Health Canada for use in food-producing aquatic animals - [http://www.hc-sc.gc.ca/dhp-mps/vet/legislation/pol/aquaculture\\_anim-eng.php](http://www.hc-sc.gc.ca/dhp-mps/vet/legislation/pol/aquaculture_anim-eng.php)  
\*\*\* Action levels presented are derived from Health Canada - Veterinary Drugs Directorate: Table 1. Administrative Maximum Residue Limits (AMRLs) and Maximum Residue Limits (MRLs) set by Health Canada: [http://www.hc-sc.gc.ca/dhp-mps/vet/mrl-lmr/mrl-lmr\\_versus\\_new-nouveau-eng.php](http://www.hc-sc.gc.ca/dhp-mps/vet/mrl-lmr/mrl-lmr_versus_new-nouveau-eng.php)

**Banned<sup>2</sup>** Banned drugs are those drugs which are prohibited for sale and use on animals (including fish) that produce food or that are intended to be consumed as food as stipulated in the *Food and Drug Regulations* (s. B.01.048 and C.01.610.1).

#### Abbreviations / Terms

**DTC - Detected above the reporting limit**

**EDR - Emergency Drug Release:** Program administered by Health Canada - Veterinary Drugs Directorate.

**Edible Tissue:** includes muscle and skin

**MRL - Maximum Residue Limit:** As stipulated in *Food and Drug Regulations*, Division 15, Table III.

**AMRL - Administrative Maximum Residue Limit:** The definition for AMRL and MRL are basically the same except AMRL is awaiting completion of the legal process for publishing in *Food and Drug Regulations*.

### FOOTNOTES

\* - Administrative Maximum Residue Limit (AMRL)

**a** - A lot of fish will be considered reject when the sum of florfenicol (parent drug) and florfenicol amine (metabolite) detected in the sample exceeds the florfenicol MRL.

**b** - As a minimum performance level of the laboratories testing for fluoroquinolones, the laboratory must have a limit of quantification (LOQ) of at least 1.0 ng/g for fluoroquinolones.

**c** - Interim action level set by Health Canada.

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d - As a minimum performance level of the laboratories testing for Malachite Green (MG) or Leucomalachite Green (LMG), the laboratory must have a limit of quantification (LOQ) of at least 0.5 ng/g for MG or LMG.

e - **MALACHITE GREEN:** The "Interim Guidelines for the Presence of Malachite Green (MG) and Leucomalachite Green (LMG) in Aquaculture Fish Products" established by Health Canada and published in the CFIA Industry Notice of March 29, 2006 are as follows:

\*\*\* Malachite green is not permitted in Canada for use during any part of the aquaculture fish production life-cycle.

\*\*\* The interim guidelines from Health Canada and CFIA's product acceptability criteria applicable to imported and domestic fish products are described below:

MG or LMG Levels	Product Action
≤ 0.50 ng/g for MG or LMG (Interim LOQ for MG or LMG)	No regulatory actions will be taken.
> 1.00 ng/g for MG or LMG	Product is unacceptable. Appropriate regulatory actions will be taken.
> 0.50 ng/g to ≤1.00 ng/g for MG or LMG (NOTE: Gathering of information will be required to determine deliberate use)	Product is unacceptable unless a review of information gathered shows there has been no deliberate use. Appropriate regulatory actions will be taken, as required.

\*\*\* For products found to contain levels > 0.50 and ≤1.00 ng/g of MG or LMG, the following approach will be used:

\*\*\* Importers will have the option of gathering information in order to provide evidence of non-deliberate use. The importers should contact the local CFIA office. On a case by case basis, the CFIA will determine when the option for gathering information is available. This will be based on the importer's Quality Management Program and/or on the presence of foreign arrangements or regulatory links with the respective foreign authorities. CFIA will take the appropriate regulatory action.

\*\*\* Federally registered processors will be required to notify the CFIA of these results and take the appropriate corrective actions according to their QMP plan. Appropriate corrective actions should include gathering information to determine if deliberate use of MG occurred during any part of the aquaculture fish production life cycle. The processor will provide their findings to the CFIA and the information will be reviewed to determine the regulatory compliance. The CFIA may complete a Compliance Verification to determine whether the QMP requirements have been met.

f - As a minimum performance level of the laboratories testing for Gentian Violet (GV) or Leucogentian Violet (LGV), the laboratory must have a limit of quantification (LOQ) of at least 0.5 ng/g for GV or LGV.

g - **GENTIAN VIOLET:** Gentian violet is not permitted in Canada for use during any part of the aquaculture fish production life-cycle.

As a result of on-going discussions with Health Canada regarding Gentian Violet as a therapeutant and as a possible contaminant, the interim guidelines for the presence of GV and LGV and CFIA's product acceptability criteria applicable to imported and domestic aquacultured fish products have been modified as follows:

GV or LGV Levels	Product Action
< 0.50 ng/g for GV and/or LGV (Interim LOQ for GV or LGV)	No regulatory actions will be taken.
<b>Sum GV &amp; LGV ≥ 1.0 ng/g</b> Specifically: GV ≥ 1.0 ng/g & LGV < 0.5 ng/g OR GV < 0.5 ng/g & LGV ≥ 1.0 ng/g OR GV ≥ 0.5 ng/g & LGV ≥ 0.5 ng/g	Product is unacceptable. Appropriate regulatory actions will be taken.
<b>GV &lt; 0.5 ng/g &amp; LGV ≥ 0.5 ng/g and &lt; 1.0 ng/g</b> OR <b>GV ≥ 0.5 ng/g and &lt; 1.0 ng/g &amp; LGV &lt; 0.5 ng/g</b>	This result will trigger a follow-up investigation for possible therapeutant use prior to making a lot decision.
<b>GV ≥ 0.5 ng/g &amp; LGV not detected at the reporting limit</b>	This result will trigger a follow-up investigation for possible post harvest contamination prior to making a lot decision.

\*\*\* When a follow up investigation is needed, laboratory reports/results (e.g. from a QMPI importer) should be forwarded to a CFIA inspector.

The CFIA Inspector will communicate with their respective Regional/Area Program Staff who will liaise with the National Manager Technical Standards (or delegate), Fish, Seafood & Production Division. The follow up investigation approach may include, but not limited to gathering evidence of non-deliberate use, collecting and reviewing additional information, etc., for an assessment and this will be determined on a case by case basis.

h - **TEFLUBENZURON:** The monitoring of teflubenzuron in aquaculture products is under review and is not applicable at this time.

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