Canadian Food Inspection Agency | Agence canadienne d'inspection des aliments

Appendix I (A) - 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 [1]	Salmonids	Muscle	**0.8** [a]	**800** [a]
	Chloramphenicol		Banned [2]	All	N/A	**DTC**	**DTC**
	Thiamphenicol		Not accepted to be used	All	N/A	**DTC**	**DTC**
Avermectins	Emamectin Benzoate		Approved [1]	Salmonids	Muscle	**0.1** [AMRL]	**100** [AMRL]
	Ivermectin		Not accepted to be used	All	N/A	**DTC**	**DTC**
Benzoylureas	Teflubenzuron [h]		EDR	Salmonids	Muscle	**0.3**	**300**
					Skin	**3.2**	**3200**
Fluoroquinolones	Ciprofloxacin		Not accepted to be used	All	N/A	**0.001** [b]	**1.0** [b]
	Danofloxacin		Not accepted to be used	All	N/A	**0.001** [b]	**1.0** [b]
	Enrofloxacin		Not accepted to be used	All	N/A	**0.001** [b]	**1.0** [b]
	Sarafloxacin		Not accepted to be used	All	N/A	**0.001** [b]	**1.0** [b]
Macrolides	Erythromycin		EDR	Fish, Crustaceans	Muscle	**0.03** [c]	**30** [c]
Nitrofurans	Furaltadone	(AMOZ) 3-Amino-5-morphinomethyl-oxazolidin-2-one	Banned [2]	All	N/A	**DTC**	**DTC**
	Furazolidone	(AOZ) 3-Amino-2-oxazolidinone	Banned [2]	All	N/A	**DTC**	**DTC**
	Nitrofurantoin	(AHD) 1-Aminohydantoin hydrochloride	Banned [2]	All	N/A	**DTC**	**DTC**
	Nitrofurazone	(SEM) Semicarbazide	Banned [2]	All	N/A	**DTC**	**DTC**
Quinolones	Flumequine		Not accepted to be used	All	N/A	**DTC**	**DTC**
	Oxolinic Acid		Not accepted to be used	All	N/A	**DTC**	**DTC**
Sulfonamides	Ormetoprim		Approved [1]	Salmonids	Edible Tissue	**0.1** [AMRL]	**100** [AMRL]
	Sulfadiazine		Approved [1]	Salmonids	Edible Tissue	**0.1**	**100**
	Sulfadimethoxine		Approved [1]	Salmonids	Edible Tissue	**0.1** [AMRL]	**100** [AMRL]
	Trimethoprim		Approved [1]	Salmonids	Muscle	**0.1**	**100**
	Sulfacetamide		Not accepted to be used	All	N/A	**DTC**	**DTC**
	Sulfachloropyridazine		Not accepted to be used	All	N/A	**DTC**	**DTC**
	Sulfadoxine		Not accepted to be used	All	N/A	**DTC**	**DTC**
	Sulfaguanadine		Not accepted to be used	All	N/A	**DTC**	**DTC**
	Sulfamerazine		Not accepted to be used	All	N/A	**DTC**	**DTC**
	Sulfamethazine		Not accepted to be used	All	N/A	**DTC**	**DTC**
	Sulfamethiazole		Not accepted to be used	All	N/A	**DTC**	**DTC**
	Sulfamethoxazole		Not accepted to be used	All	N/A	**DTC**	**DTC**
	Sulfamethoxypridazine		Not accepted to be used	All	N/A	**DTC**	**DTC**
	Sulfamonomethoxine		Not accepted to be used	All	N/A	**DTC**	**DTC**
	Sulfamoxole		Not accepted to be used	All	N/A	**DTC**	**DTC**
	Sulfanilamide		Not accepted to be used	All	N/A	**DTC**	**DTC**
	Sulfapyridine		Not accepted to be used	All	N/A	**DTC**	**DTC**
	Sulfaquinoxaline		Not accepted to be used	All	N/A	**DTC**	**DTC**
	Sulfathiazole		Not accepted to be used	All	N/A	**DTC**	**DTC**
	Sulfisoxazole		Not accepted to be used	All	N/A	**DTC**	**DTC**
Tetracyclines	Oxytetracycline		Approved [1]	Salmonids, Lobsters	Muscle	**0.2**	**200**
	Chlorotetracycline		Not accepted to be used	All	N/A	**DTC**	**DTC**
	Tetracycline		Not accepted to be used	All	N/A	**DTC**	**DTC**
Triphenylmethane Dyes	Gentian Violet		Not accepted to be used	All	N/A	**Gentian Violet notes**	
		Leucogentian Violet	Not accepted to be used	All	N/A	**"f" and "g"**	
	Malachite Green		Not accepted to be used	All	N/A	**Malachite Green notes**	
		Leucomalachite Green	Not accepted to be used	All	N/A	**"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 Quanitification, 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 notes 'd', 'e', 'f' and 'g' for relevant information).

MONITORING LIST LEGEND / EXPLANATORY NOTES

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. Established value is found in the "Action Level" column.
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* .

NOTES

"Approved 1" - Approved -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
- 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

"Banned 2" 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* . Scientific evidence has demonstrated that exposure to these substances at any level could pose a risk to human health.

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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Malachite Green and Leucomalachite Green Notes

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 - 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 ofinformation 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.

Gentian Violet and Leucogentian Violet Notes

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 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.
Sum GV & LGV ≥ 1.0 ng/g 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.
GV < 0.5 ng/g & LGV ≥ 0.5 ng/g and < 1.0 ng/g OR **GV ≥ 0.5 ng/g and < 1.0 ng/g & LGV < 0.5 ng/g**	This result will trigger a follow-up investigation for possible therapeutant use prior to making a lot decision.
GV ≥ 0.5 ng/g & LGV not detected at the reporting limit	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 liase 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.

Teflubenzuron Notes

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

Version: July 11, 2011