APPENDIX 1

APPROVED THERAPEUTANTS FOR AQUACULTURE USE

This appendix provides information on the authorized use of drugs and pesticides in the aquaculture of fish and crustaceans.

A drug used in aquaculture must be either:

1. approved by Health Canada specifically for use in fish or crustaceans;

2. authorized as an Emergency Drug Release (EDR) by Health Canada when the drug has not been approved in Canada (i.e., the drug has not been assigned a Drug Identification Number (DIN) by Health Canada);

3. authorized for testing purposes under an Experimental Studies Certificate, issued by Health Canada;

4. approved as an Investigational New Drug Submission by Health Canada for clinical trials; or

5. prescribed by a licensed veterinarian for "off-label" use (only applies to products with an assigned Drug Identification Number).

Health Canada's Veterinary Drugs Program is responsible for establishing the maximum residue limits (MRLs), administrative maximum residue limits (AMRLs) or residue limits for these drugs. MRLs are published in Table III of Division 15 of the *Food and Drugs Regulations*. Administrative MRLs or residue limits are established as policy by the Veterinary Drugs Program of Health Canada. If levels of drug residues in excess of these limits are found in fish intended for human consumption, the fish will be considered "unwholesome", according to Section 6.(1)(a) of the *Fish Inspection Regulations*.

Dosages and withdrawal times for veterinary drugs must be followed as indicated in the veterinary prescription or, in those cases where a prescription is not required, in the Compendium of Medicating Ingredient Brochures (CMIB) published and maintained by the CFIA.

When an antiparasitic product is orally administered to fish (via feed or another mechanism) it is deemed to be a drug and it is regulated by the *Food and Drugs Act* and *Regulations*.

When the same antiparasitic is applied externally to fish (not ingested) it is deemed a pesticide and it is regulated by the *Pest Control Products Act*. The Pest Management Regulatory Agency within Health Canada approves or grants emergency release permits for pesticides under the Pest Control Products Act.

The Veterinary Drugs Program of Health Canada has approved, or temporarily authorized as an EDR, the use in aquaculture of the following veterinary drug products:

PRODUCT BRAND NAME	APPROVED SUBSTANCE	RESIDUE LIMIT (µg/g)	TISSUE	SPECIES
Terramycin-Aqua	Oxytetracycline	0.2 [2]	Edible Tissue	Salmonids Lobster
Romet 30	Sulfadimethoxine	0.1 [2]	Edible Tissue	Salmonids
	Ormetoprim	0.5	Muscle	Salmonids
		1	Skin	
Tribrissen 40%	Sulfadiazine	0.1 [1]	Edible Tissue	Salmonids
	Trimethoprim	0.1 [1]	Muscle	Salmonids
Aqua Life TMS	Tricaine methanesulfonate	0.02	Edible Tissue	Salmonids
Aquaflor	Florfenicol	0.8 [1, 4]	Muscle	Salmonids
Formalin-R	Formaldehyde	n/a [5]	n/a	Salmonid eggs
Parasite-S				
Perox-Aid	Hydrogen peroxide	n/a [5]	n/a	Salmonid eggs
Calicide	Teflubenzuron	0.3 [2]	Muscle	Salmonids
		3.2 [2]	Skin	
Slice	Emamectin benzoate	0.042 [3]	Muscle	Salmonids

1. MRL (Maximum Residue Limit) Table III of Division 15 of the Food and Drugs Regulations
2. AMRL (Administrative Maximum Residue Limit)
3. EDR (Emergency Drug Release)
4. MRL is specified for the metabolite florfenicol amine.
5. Regulated biological substance, ubiquitous in nature.