Australian Government

Australian Pesticides and Veterinary Medicines Authority

Trade Advice Notice

on florfenicol for emergency use on Atlantic salmon

APVMA permit number 96499

October 2025

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Assistant Director, Communications
Australian Pesticides and Veterinary Medicines Authority
GPO Box 3262
Sydney NSW 2001 Australia

Telephone: +61 2 6770 2300

Email: communications@apvma.gov.au.

This publication is available from the APVMA website.

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Preface

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is an independent statutory authority with responsibility for assessing and approving agricultural and veterinary chemical products prior to their sale and use in Australia.

The APVMA has a policy of encouraging openness and transparency in its activities and of seeking stakeholder involvement in decision making. Part of that process is the publication of Trade Advice Notices for all proposed extensions of use for existing products where there may be trade implications.

The information and technical data required by the APVMA to assess the safety of new chemical products and the methods of assessment must be undertaken according to accepted scientific principles. Details are outlined in regulatory guidance published on the APVMA website.

About this document

This Trade Advice Notice indicates that the Australian Pesticides and Veterinary Medicines Authority (APVMA) is considering an application to vary the use of an existing registered agricultural or veterinary chemical.

It provides a summary of the APVMA's residue and trade assessment.

Comment is sought from industry groups and stakeholders on the information contained within this document.

Making a submission

The APVMA invites any person to submit a relevant written submission as to whether the application for the emergency use of AbbeyFlor Premix Concentrate for Pigs containing florfenicol for use on Atlantic salmon should be granted. Submissions should relate only to matters that the APVMA is required by legislation to take into account in deciding whether to grant the application. These grounds relate to the trade implications of the extended use of the product. Submissions should state the grounds on which they are based. Comments received outside these grounds cannot be considered by the APVMA.

Submissions must be received by the APVMA by close of business on **Wednesday, 22 October 2025** and be directed to the contact listed below. All submissions to the APVMA will be acknowledged in writing via email or by post.

Relevant comments will be taken into account by the APVMA in deciding whether to grant the application and in determining appropriate conditions of permit and product labelling.

When making a submission please include:

- contact name
- company or organisation name (if relevant)

- email or postal address (if available)
- the date you made the submission.

Please note: submissions will be published on the APVMA's website, unless you have asked for the submission to remain confidential, or if the APVMA chooses at its discretion not to publish any submissions received (refer to the public consultation coversheet).

Please lodge your submission using the public consultation coversheet, which provides options for how your submission will be published.

Note that all APVMA documents are subject to the access provisions of the *Freedom of Information Act 1982* and may be required to be released under that Act should a request for access be made.

Unless you request for your submission to remain confidential, the APVMA may release your submission to the applicant for comment.

Written submissions should be addressed to:

Residues and Trade
Veterinary Medicines
Australian Pesticides and Veterinary Medicines Authority
GPO Box 574
Canberra ACT 2601 Australia

Phone: +61 2 6770 2300
Email: enquiries@apvma.gov.au

Further information

Further information can be obtained via the contact details provided above.

Further information on Trade Advice Notices can be found on the APVMA website: apvma.gov.au.

Introduction

The APVMA has before it an application from Abbey Laboratories Pty Ltd for an emergency permit for use of AbbeyFlor Premix Concentrate for Pigs (81128) containing florfenicol for use on Atlantic salmon. The permit will be for the treatment and control of bacterial infections caused by *Piscirickettsia salmonis* in sea-penned Atlantic salmon (*Salmo salar*).

The permit is proposed for one year in the state of Tasmania only. Up to 75% of the state's production volume (approximately 56 kt of salmon) located in the south-eastern biosecurity zone has been considered for this assessment. It is likely that usage would be biased towards periods of higher temperature.

As the proposed emergency use allows for finite residues of florfenicol in salmon, the establishment of a temporary MRL and a trade consideration is required.

Trade considerations

Commodities exported

Finfish, including salmonids, are considered to be a major export commodity[1]. Residues in these commodities resulting from the use of AbbeyFlor Premix Concentrate for Pigs or similarly registered florfenicol products may have the potential to unduly prejudice international trade.

Destination and value of exports

In 2024–25 (Jul–Jun)[2], the Australian salmon industry exported a total 21,799 tons of salmon valued at $343.4 million (ABARES). Significant export markets for Australian salmon fish meat (fresh, chilled or frozen), as well as live, prepared and preserved fish included China (13,343t), Indonesia (1,680t), Japan (2,020t), Taiwan (184t), Thailand (392t), The United States (1,133t) and Vietnam (1,567t).

Australian use pattern

AbbeyFlor Premix Concentrate for Pigs (1000 g/kg florfenicol)

Table 1: Proposed use pattern

Claims:	Treatment of TRLO-EC infection caused by *Piscirickettsia salmonis* and/or aid in management of *P.salmonis* in Atlantic Salmon
Dosage and administration:	Incorporate into fish feed to deliver a dose of 10-20 mg florfenicol per kg body weight per day for 10 consecutive days. Mixing Instructions: Thoroughly mix AbbeyFlor Premix Concentrate with feed to ensure uniform distribution. Coating with an oil-based binder is recommended to improve adherence and palatability.
Withholding periods:	DO NOT USE less than 300 degree-days before harvesting fish for human consumption.
Trade advice:	EXPORT SLAUGHTER INTERVAL (ESI): DO NOT USE less than 500 degree-days before slaughter for export. Before using this product, confirm the current ESI from [registration holder/distributor name] on [insert telephone contact number] or the APVMA website (apvma.gov.au/residues).

[1] Australian Pesticides and Veterinary Medicines Authority, Veterinary Data guidelines – Overseas trade (Part5B) – APVMA Website, accessed October 2025

[2] Australian Bureau of Agricultural and Resource Economics and Sciences (ABARES) – Trade Dashboard – Salmon – Link, accessed October 2025

Results from residues trials presented to the APVMA

Publicly available data was provided demonstrating residues of florfenicol in edible tissues of Rainbow trout (*Oncorhynchus mykiss*) following treatment with florfenicol-medicated feed administered at 20 mg/kg bodyweight for 10 consecutive days. Treatment fish were housed in 2 aquaculture systems; a flow-through (FTS) or a recirculating system (RAS), each with water temperatures maintained at approximately 13°C. Skin-on fillets were taken from treated fish from each tank (n=16) and nontreated fish (n = 8) at 6, 12, 24, 48, 72, 120, 240, 360 and 480 hours post final treatment.

Analysis of florfenicol amine (FFA) in trout fillets were determined by HPLC and ultraviolet detection, using a common moiety method, converting all florfenicol residues to florfenicol-amine by acid-catalysed hydrolysis. The method reporting limit was 0.05 mg/kg.

Table 2. Florfenicol amine (FAA) concentrations in fillet tissue from Rainbow Trout treated with florfenicol-medicated feed at 20 mg/kg bw for 10 days in recirculating and flow-through systems with water temperatures of ~13 °C. (Adapted from Meinertz JR *et al.* 2014[3])

Time after treatment, hours (days)	Recirculating system FFA (mg eq./kg)					Flow-through system FFA (mg eq./kg)				
	n	Mean	Min	Max	CV (%)	n	Mean	Min	Max	CV (%)
6 (0.25)	8	9.82	5.33	15.75	23	8	11.09	7.76	16.89	23
12 (0.5)	8	11.6	5.39	15.24	24	8	11.02	7.40	15.05	24
24 (1)	8	7.07	3.73	10.61	41	8	7.7	2.90	13.95	41
48 (2)	8	2.50	0.66	3.64	46	8	2.54	1.35	5.4	46
72 (3)	8	1.00	0.66	1.85	32	8	1.21	0.65	2.03	32
120 (5)	8	0.43	0.17	0.64	57	8	0.49	0.16	1.32	57
240 (10)	8	0.25	ND	1.42	33	8	0.26	0.15	0.43	33
360 (15)	8	0.16	0.05	0.31	29	8	0.16	0.07	0.26	29
480 (20)	8	0.11	ND	0.19	25	8	0.11	0.06	0.17	25

CV = 100 × SD/mean, ND = not detected.

Based on the available data, OECD calculator estimates support a temporary MRL of 0.5 mg/kg in conjunction with a 195 degree-day (15 days × 13°C) withholding period. However, noting the limited data set and absence of residues decline data in the target species, a conservative temporary MRL of 1 mg/kg is recommended to account for the uncertainty in predicted residues. In addition, to ensure residues of florfenicol fall below 1 mg/kg, an additional 7-day safety margin will be added to the day 15 timepoint used to estimate the MRL, equating to a 300 degree-day withholding period.

[3] Meinertz JR *et al.* 2014. Florfenicol Residues in Rainbow Trout after Oral Dosing in Recirculating and Flow-through Culture Systems. Journal of Aquatic Animal Health 26:243–250

Overseas registration and approved label instructions

The applicant indicated that florfenicol products are registered for use in aquaculture internationally, in countries such as Canada, Chile, China, Japan, Norway, South Korea, The United Kingdom, and the USA.

Codex Alimentarius Commission and overseas MRLs

The Codex Alimentarius Commission (Codex) is responsible for establishing Codex Maximum Residue Limits (CXLs) for pesticides and veterinary medicines. Codex CXLs are primarily intended to facilitate international trade and accommodate differences in Good Agricultural Practice (GAP) employed by various countries. Some countries may accept Codex CXLs when importing foods. Florfenicol has not been considered by Codex. The following relevant international MRLs have been established for florfenicol.

Table 3: Codex and international MRLs

Commodity	Overseas MRLs/tolerances (mg/kg)							
	Australia	Codex [4]	EU [5]	China [6]	Japan [7]	Korea [8]	Taiwan [9]	USA [10]
Residue definition	Sum of florfenicol and its metabolites measured as florfenicol-amine	--	Sum of florfenicol and its metabolites measured as florfenicol-amine	Sum of florfenicol and florfenicol-amine	Sum of florfenicol and its metabolites measured as florfenicol-amine	--	--	Florfeniocol-amine
Salmonids	T1 (proposed)	--	1	1	1	--	--	1
Fin fish (muscle and skin in natural proportions)	--	--	1	1	--	0.2	--	--

[4] CODEX Alimentarius – MRLs for Residues of Pesticides in Food – Link, accessed October 2025

[5] European Commission – EUR-Lex– Florfenicol – Link, accessed October 2025

[6] Global Agricultural Information Network (GAIN) Report – China Publishes Maximum Residue Limits for Veterinary Drugs in Food - Link, accessed October 2025

[7] The Japan Food Chemical Research Foundation – Florfenicol – Link, accessed October 2025

[8] Korean Residue material information (Pesticides and Veterinary Drugs Information) – Florfenicol – Link, accessed October 2025

[9] Taiwan Food and Drug Administration – Standards for Pesticide Residue Limits in Foods – Link, accessed October 2025

[10] USFDA CFR Title 40 – § 556.283 Florfenicol – Link, accessed October 2025

Current and proposed Australian MRLs for florfenicol

Table 4: Current MRL Standard—Table1

Compound	Food	MRL (mg/kg)
Florfenicol		
MM 0812	Cattle meat	0.3
MO 1280	Cattle, kidney	0.5
MO 1281	Cattle, liver	3
	Pig fat/skin	1
MM 0818	Pig meat	0.5
MO 1284	Pig, kidney	1
MO 1285	Pig, liver	3

Table 5: Proposed MRL Standard—Table1

Compound	Food	MRL (mg/kg)
Florfenicol		
Add:		
WD 0893	Atlantic Salmons	T1

Potential risk to trade

Export of treated salmon containing finite (measurable) residues of florfenicol pose a risk to Australian trade in situations where (i) no residue tolerance (import tolerance) is established in the importing country or (ii) where residues in Australian commodities are likely to exceed a residue tolerance (import tolerance) established in the importing country.

A finite temporary MRL for Atlantic salmon is proposed at 1 mg/kg in support of the emergency permit with a 300 degree-day withholding period. Florfenicol residues at the proposed Australian TMRL may lead to a potential risk to trade in Atlantic salmon commodities where export markets do not have an established MRL.

As not all international markets have established florfenicol MRLs for salmon, the validated LOQ of 0.05 mg/kg presented in Meinertz JR *et al.* 2014 is considered to be the appropriate export slaughter interval (ESI) endpoint at this time. Using the highest observed residue value of 16.89 mg/kg at the 6-hour time point from the flow-through system and the longest half-life estimation of 3.0 days (half-lives ranged from 0.82 to 3.0 days in Rainbow trout at temperatures of 8-15°C, and from 1.7 to 2.6 days in Atlantic Salmon at temperatures of 3-14°C), it would take approximately 25 days for residues to decline below 0.05 mg/kg. This would equate to approximately 325 degree-days (25 days × 13°C). An additional safety factor of 14 days

(182 degree-days at the study temperature of 13°C) will be added to the estimated ESI to ensure residues fall below 0.05 mg/kg. Therefore, a 500 degree-day ESI is recommended for the permit to minimise the risk to trade from exported salmon treated following a rate of 20 mg/kg bw for 10 consecutive days.

Comment is sought from relevant industry groups on the potential risk to Australia trade from the proposed use of florfenicol on Atlantic salmon under this emergency permit.

Conclusion

Abbey Laboratories Pty Ltd has applied for an emergency permit for use of AbbeyFlor Premix Concentrate for Pigs (81128) containing florfenicol for use on Atlantic salmon.

Comment is sought on the potential for the proposed use to prejudice Australian trade.