

## Evaluation Report for Category B, Subcategory 3.3 Application

**Application Number:** 2018-1099  
**Application:** Changes to Product Labels – Application Number or Frequency  
**Product:** Salmosan Vet  
**Registration Number:** 32506  
**Active ingredient (a.i.):** Azamethiphos  
**PMRA Document Number :** 2890883

### Purpose of Application

The purpose of this application was to amend the label of the restricted product Salmosan Vet to increase the number of applications from 5 to 10 during the lifecycle of farmed Atlantic salmon to control sea lice.

### Chemistry Assessment

A chemistry assessment was not required for this application.

### Health Assessments

A toxicology assessment was not required for this application.

The use of the active ingredient, azamethiphos, in the product Salmosan Vet to control sea lice in fish farms when the number of treatments received by a fish during its lifecycle in a sea cage is increased from 5 times to 10 times, is acceptable from the occupational and bystander exposure perspective. The risks to mixers, loaders, applicators and post-application re-entry workers are not expected to exceed the current risks of using the registered product when the same personal protective equipment, application rates and methods, and label precautions and directions are followed. Risks to bystanders are not expected to be of concern as a result of the change in total number of treatments per fish lifecycle.

Residue data from trials conducted in Canada were submitted to support the use of Salmosan Vet on farmed Atlantic salmon. Azamethiphos was applied to farmed Atlantic salmon at 0.1 mg/L in seawater according to label directions, and samples were collected. As no quantifiable residues of azamethiphos were observed in muscle and skin of farmed Atlantic salmon, the current maximum residue limit (MRL) of 0.05 ppm is sufficient to cover residues resulting from the increase in the number of applications of up to 10 per fish cycle.

Following review of all available data, it was concluded that the proposed use does not represent health risks of concern for any segment of the population, including infants, children, adults and seniors.

### Environmental Assessment

When used according to label directions, the increase in the maximum number of applications over the course of the fish lifecycle from 5 to 10 applications does not represent an increase in risk to non-target organisms. When used according to label directions, the risks to non-target organisms from the use of Salmosan Vet are acceptable.

## **Value Assessment**

No value information was provided to support a change from a maximum of 5 applications of Salmosan Vet per farmed Atlantic salmon lifecycle to control sea lice to a maximum of 10 applications per fish lifecycle. An increase in the number of applications per fish lifecycle has value as it provides flexibility to the user in controlling sea lice over the multi-year lifecycle of farmed Atlantic salmon. While an increase in the number of applications of Salmosan Vet per fish lifecycle may result in increased risk of resistance of sea lice to azamethiphos, this is mitigated by resistance management statements on the product label.

## **Conclusion**

The Pest Management Regulatory Agency has completed an assessment of the information provided and has found the information sufficient to support the amendment of the label for Salmosan Vet to increase the number of applications from 5 to 10 during the lifecycle of farmed Atlantic salmon.

## **References**

<b>PMRA Document Number</b>	<b>References</b>
2861121	2018, Application for Category B.3.3 Increase in Frequency of Applications, DACO: 5.2
2861122	2017, Fish Vet Group Limited Periodic Safety Update Report for Salmosan Vet, DACO: 5.2, 7.8
2861124	2018, Data to Support the Amendment of Salmosan Label Conditions to Increase the Number of Permitted Treatments to Ten (10) per Production Cycle, DACO: 7.8

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