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Registration Decision

RD2017-13

Azamethiphos

(publié aussi en français)

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Table of Contents

| | |
|---|---|
| Registration Decision Statement for Azamethiphos..... | 1 |
| Other Information..... | 1 |
| Appendix I Comments and Responses..... | 3 |

Registration Decision Statement¹ for Azamethiphos

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of Azamethiphos Technical and Salmosan Vet containing the technical grade active ingredient azamethiphos to control sea lice on farmed Atlantic salmon.

This decision is consistent with the Proposed Registration Decision PRD2016-25, *Azamethiphos*, which contains a detailed evaluation of the information submitted in support of this registration. The evaluation found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment. See Appendix I for a summary of comments received during the consultation process as well as the PMRA's response to these comments.

Other Information

The relevant test data on which the decision is based (as referenced in PRD2016-25, *Azamethiphos*) are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

Any person may file a notice of objection² regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of the Canada.ca website (Request a Reconsideration of Decision) or contact the PMRA's Pest Management Information Service.

¹ "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

² As per subsection 35(1) of the *Pest Control Products Act*.

Appendix I Comments and Responses

1.0 Mitigation Comments

Comment

Several comments were received requesting that the skirted treatment method be removed from the product label as it is no longer used by industry.

PMRA Response

The PMRA acknowledges this request and can confirm that a decision to remove the skirted treatment method from the product label was made prior to the end of the consultation period of PRD2016-25, *Azamethiphos*.

Comment

Comments were received by a number of individuals surrounding the definition of “active lobster holding facilities” including the following points:

- Concerns were raised that the effect of azamethiphos on lobsters held in crates and lobster cars along harbour wharves and docked boats was not considered in the risk assessment.
- Concerns were raised that there are no provisions in the full registration of azamethiphos for fishermen holding lobster in and around harbours.
- Requests were made for azamethiphos treatments to either not be allowed during lobster season within one kilometer of an active fishing harbour or for the definition of ‘active holding facilities’ be expanded to include lobster cars and floating crates.
- Concerns were raised as to the definition of formal active holding facility and whether the use restrictions on these facilities are also extended to informal lobster holding facilities such as floating crates and lobster cars.
- Concerns were raised about specific harbours such as Shelburne Harbour, Lower Sandy Point and Gunning Cove. Requests for additional label restrictions were made to protect the very large number of lobster held in these harbours.

PMRA Response

After reviewing comments received on PRD2016-25, the PMRA sought out clarification on the various forms of lobster holding practices. The PMRA consulted the New Brunswick department of Agriculture, Aquaculture and Fisheries as well as the Canadian Department of Fisheries and Oceans. The PMRA further investigated the concerns regarding lobster held at informal holding facilities in and around harbor wharves, including lobster cars and floating crates.

Through collaboration with regional officers and local provincial governments, the PMRA is amending the following wording on the label of Salmosan Vet in order to provide a clearer definition of active lobster holding facility:

“DO NOT use within 1 km of any active lobster holding facilities which include active licensed lobster pounds and/or lobster tank houses as well as lobster cars/crates held within a designated

harbour authority water lot, when the ebb or flow of the tide or the prevailing current is anticipated to be moving in the direction of a lobster holding facility within 2 hours from the start of the treatment.”

In addition to the definition of active lobster holding facilities it should be noted that:

- Facilities held by holders of commercial lobster licences do not require a licence during lobster season.
- The definition of active lobster holding facilities does not include lobsters held on the sides of boats or other structures located outside of the designated harbour authority water lot.
- Boundaries of harbour authority water lots can be provided by the Department of Fisheries and Oceans.

To ensure registered products continue to meet the most modern health and environmental standards, azamethiphos will be reassessed at least every 15 years through a re-evaluation review process.

To continue to monitor for safety after they are registered, the PMRA collects pesticide incident reports from Canadians. For more information on the PMRA’s pesticide incident reporting program, please visit the Report a Pesticide Incident page in the Pesticides and Pest Management portion of the Canada.ca website.

Comment

Concerns that more frequent treatments are allowed compared to the emergency registration which could lead to increased usage and more treatments per year. Previously a limit of 2 net pens could be treated in a 24-hour period. Under the full registration this restriction has been removed which will lead to increased usage as more treatments per site per year will be possible.

Concerns that this change will result in a significant net increase in the amount of azamethiphos entering the Bay of Fundy.

PMRA Response

Based on comments received, the PMRA conducted a risk assessment based on a conservative application scenario of three salmon farms all located in a small harbour and in close proximity to one another. Based on the outcome of this conservative treatment scenario, the PMRA will be restricting the application of azamethiphos to a maximum of two net pens per day for farm sites that use 150 meter polar radius net pens. The maximum number of applications permitted per fish life cycle remains unchanged and the skirted treatment method which used a higher concentration of azamethiphos per treatment was removed from the product label. As a result, the PMRA anticipates that the total amount of azamethiphos entering the Bay of Fundy will not significantly increase.

Comment

What measures will be put in place to protect our lobsters and our economy?

What restrictions will there be on azamethiphos use in known lobster breeding and fishing areas?

What restrictions will there be on azamethiphos use in shallow areas?

PMRA Response

The PMRA has conducted a conservative risk assessment for the use of azamethiphos and has determined that no risks of concern are expected when the product is used according to the label directions. The PMRA has imposed many restrictions on the use of azamethiphos to protect lobster and the use in shallow areas. The following restrictions must be followed in all areas including those that are known lobster breeding and fishing areas.

“DO NOT apply to tarped net pens in water depths of 10 meters or less”

“DO NOT flush treatment water from a well boat with a 45 degree or 90 degree angled flushing pipe in water depths of 20 meters or less.”

“DO NOT treat more than 2 tarped net pens simultaneously”.

“When using the tarped treatment method in combination with 150 meter polar radius net pens, DO NOT treat more than two net pens per aquaculture farm site per day.”

“DO NOT use within 1 km of any active lobster holding facilities which include active licensed lobster pounds and/or lobster tank houses as well as lobster cars/crates held within a designated harbour authority water lot, when the ebb or flow of the tide or the prevailing current is anticipated to be moving in the direction of a lobster holding facility within 2 hours from the start of the treatment.”

The product will also be registered as a restricted-class product. This means that the product can only be applied by individuals who are provincially certified and trained.

Comment

A comment was received wondering if the PMRA considered Native lobster fishery in the risk assessment process. It has been a practice to set traps near salmon farms. Has this been taken into consideration?

“Throughout the summer, aboriginal/First Nation fishers set lobster traps in Shelburne Harbour. Each fisher is entitled to two traps, and often 6-8 traps are set each day. They set the traps in the inner basin of Shelburne harbour where it is protected due to the fact that they only use a smaller outboard and not a commercial fishing vessel.”

PMRA Response

When used according to the product label, azamethiphos is not expected to pose a risk to wild adult lobster. The PMRA has taken all non-target organisms near and far from salmon farms into consideration. The risk assessment indicated that adult lobster may be at risk from the use of azamethiphos. To mitigate this risk, the PMRA has added the following restrictions to the product:

“DO NOT apply to tarped net pens in water depths of 10 meters or less”

“DO NOT flush treatment water from a well boat with a 45 degree or 90 degree angled flushing pipe in water depths of 20 meters or less.”

These risk mitigation measures are intended to minimize exposure of wild adult lobster, and other non-target organisms on the ocean floor to azamethiphos.

Comment

Concerns were raised that effects of azamethiphos on shipped lobster were not highlighted by the PMRA. A 2015 study¹ by C.M. Couillard and L.E. Burrige was cited.

PMRA Response

The study on the effect of azamethiphos on shipped lobster was part of this larger study that was provided to the PMRA by the Department of Fisheries and Oceans. All information submitted to the PMRA was considered in the risk assessment. The results of this study were considered in the Proposed Registration Decision and can be found in Table 10 of PRD2016-25. The PMRA does not anticipate any effects on transported lobster due to exposure from azamethiphos. The lobster in the cited study were exposed continuously for 10 days and then subjected to live simulated transport. Based on field studies conducted by the Department of Fisheries and Oceans, concentrations of azamethiphos in the environment after an aquaculture treatment are anticipated to decline very quickly. The PMRA determined that it is highly unlikely for adult lobster to be exposed to azamethiphos continuously for 10 days and thus the effects identified in the study are not likely to occur under field conditions. Additional details surrounding the risk assessment to benthic invertebrates, including lobster, can be found in PRD2016-25, pages 23 and 24 as well as in Tables 16 to 19.

Comment

Concerns were raised that salmon farming companies encourage lobster fishermen to set traps on or near their aquaculture sites as lobsters are attracted to them; some farms are located over lobster migration routes. Has the effect of azamethiphos on lobster near or under the salmon farms been considered?

PMRA Response

The effect of azamethiphos on lobster near or under the salmon farms was investigated by the PMRA and special risk mitigation statements have been added to the product label in order to mitigate the risk to lobster near and under salmon farms including farms located over migration

routes. The following restrictions are required to mitigate the risk to lobster near and under salmon farms:

“DO NOT apply to tarped net pens in water depths of 10 meters or less”

“DO NOT flush treatment water from a well boat with a 45 degree or 90 degree angled flushing pipe in water depths of 20 meters or less.”

Additional details of the risk assessment and risk mitigation statements can be found on pages 23 and 24 of PRD2016-25.

Comment

What maximum allowable azamethiphos limits will be put in place?

PMRA Response

A maximum of 5 applications of azamethiphos is allowed per fish life cycle. The PMRA does not set maximum allowable levels of pesticides in the environment but rather sets conditions of use, including application rates, which are considered safe for the environment. The PMRA has established a maximum application rate of 0.1 mg/L. The maximum application rate of 0.15 mg/L cited in PRD2016-25 is no longer supported as the skirted treatment method was removed after PRD2016-25 was published.

Comment

Is it possible for the PMRA to implement a hazardous waste disposal initiative whereby the finfish industry can use the pesticide but they are not permitted to release the pesticides into the ocean?

PMRA Response

Based on the current risk assessment the PMRA has determined that, when used according to label directions, risks of concerns to non-target organisms are not expected. Based on this conclusion additional restrictions on the use of this product are not warranted. The PMRA will continue to monitor the use of azamethiphos and if risks from the use of the product are found unacceptable, regulatory action will be taken.

Comment

How disposal of residual pesticides in the well boats will be managed is unclear.

PMRA Response

After the treatment period, residues of azamethiphos in the treated water are flushed from the well boat. This flushing process has been taken into account in the PMRA risk assessment.

Comment

Concerns were raised that proposed registration decision is insufficiently conservative to protect the Bay of Fundy's ecosystem.

PMRA Response

The PMRA incorporated several levels of conservatism into the risk assessment for azamethiphos and determined that when used according to label directions, the use of azamethiphos is not expected to pose risks of concern to non-target organisms. The various levels of conservatism are presented throughout pages 21 to 25 of PRD2016-25.

All pesticides are tested and evaluated for safety before being registered for use by Canadians. To continue to monitor for safety after they are registered, the PMRA collects pesticide incident reports from Canadians. For more information on PMRA's pesticide incident reporting program, please visit the Report a Pesticide Incident page in the Pesticides and Pest Management portion of the Canada.ca website. If the PMRA determines that there is a concern resulting from the use of a pesticide appropriate regulatory action will be taken to reduce the risk.

Comment

Several comments were raised around the concept of buffer zones in the ocean.

PMRA Response

The PMRA agrees that the term "buffer zone" in the ocean may not best describe the mitigation measure. This term was meant to indicate an area where azamethiphos is not to be used. In light of the potential confusion with the term "buffer zone", moving forward, this term will be removed from PMRA documentation, as well as the product label, and replaced with "no-use area".

In the case of this risk assessment, the no-use area is 1 kilometer around any active lobster holding facilities which include active licensed lobster pounds and/or lobster tank houses as well as lobster cars/crates held within a designated harbour authority water lot. This 1 kilometer no use area applies only when the ebb or flow of the tide or the prevailing current is moving from the fish farm where treatment is occurring towards a lobster holding facility.

2.0 Risk Assessment Comments**Comment**

Concerns were raised that farms in close proximity to one another treating simultaneously could result in concentrations of azamethiphos greater than two simultaneous treatments at the same farm site. It was recommended that limitations be based on site size or distance between farm sites. Concerns that restrictions are on a per farm basis and not area-based; in high farm density areas, there is potential for increase in amount dispersed at one time. Regulations should reflect use and frequency based on distance between farms and application.

PMRA Response

The PMRA used data from the Department of Fisheries and Oceans (Page et al., 2015ⁱⁱ) that shows the predicted decrease in the concentration of azamethiphos over time following release from a net pen. The PMRA considered the release of two treated net pens at the same time (that is, simultaneous treatment at the same farm site) as the most conservative scenario. The estimated concentration of azamethiphos 1 hour post release from two overlapping tarped net pen treatments at the maximum application rate of 0.1 mg/L was determined to be 0.0016 mg/L. This is presented in PRD2016-25, Table 13. Pulse doses at this concentration will not pose an unacceptable risk to non-target pelagic aquatic organisms. The additive concentration from two separate farms treating at the same time was not considered in PRD2016-25 and was explored further. Consultation with provincial authorities confirmed that there are provincial regulations regarding the distance between farm sites. The smallest distance between farms was confirmed to be 300 m by the New Brunswick Department of Agriculture and Fisheries.

In order to address the concern of increased concentrations when different farms in close proximity to one another apply azamethiphos at the same time, the same data from DFO (Page et al., 2015) was used. The PMRA calculated estimated water concentrations of 4 plumes overlapping from 2 different farm sites located at the New Brunswick provincial minimum of 300 meters apart. Conservative assumptions are that the two plumes from the first farm were released at exactly the same time and overlapped with each other perfectly. It was then assumed that these plumes were carried by the ocean currents directly to a different farm site located 300 meters away at which time 2 net pens were released. It was assumed that the combined plume from the first farm overlapped perfectly with the combined plumes from the 2nd farm.

The maximum estimated concentration of azamethiphos of the 4 overlapping plumes from 2 different farm sites located 300 meters apart would be 0.203 mg/L. Following the combining of the plumes the concentration at 1 hour post release (the length of time for the combined plume to move 1 Km) was determine to be 0.00162 mg/L. This concentration is only slightly higher than the 1-hour estimated environmental concentration determined in the proposed registration decision (PRD2016-25).

The following table represents the risk assessment using the same non-target organism end-point as that which was used in PRD2016-25. The only change is the slightly higher estimated environmental concentration of 4 overlapping plumes from 2 adjacent farms.

| Organism | End-Point | Value | Uncertainty Factor | End-Point* | EEC determined for four overlapping plumes from two farms 300 m apart | RQ | RQ exceeded |
|------------------|------------------|--------|--------------------|------------|---|-----|-------------|
| Juvenile Lobster | LC ₅₀ | 0.0032 | 2 | 0.0016 | 0.0024 | 1.5 | Slightly |

* Same value was used in the risk assessment in PRD2016-25

This scenario is highly conservative and unlikely to occur under actual conditions of use for the following reasons:

- Unlikely that 2 plumes from a single farm would be released at exactly the same time
- Unlikely that the 2 plumes released would perfectly overlap and travel as one large plume
- Unlikely that 2 different farm sites would treat 4 net pens in such a manner that two overlapping plumes from the first farm will reach the second farm at the exact time that 2 net pens will be released.

The risk assessment from the 4 overlapping tarped net pens is only slightly higher than the previous risk assessment of 2 overlapping plumes from 2 skirted net pens.

Based on the conservative assumptions in the risk assessment of four overlapping tarped net pen plumes, the PMRA concludes that the risk to lobster from four overlapping tarped net pen plumes is equal to or less than the risk previously identified.

Comment

Concerns that the waters in Shelburne harbour Nova Scotia do not easily ‘flush’ with fresh oceanic water, which will lead to the accumulation of azamethiphos inside the harbour. The authors of the previously noted study (Page et al., 2015) were quoted saying that more studies are required.

PMRA Response

The risk assessment for azamethiphos as it is presented in PRD2016-25 was conservative and assumed that there would be no oceanic flushing. The PMRA does not anticipate azamethiphos to accumulate in areas that do not easily ‘flush’ including Shelburne harbour and other similar harbours. Azamethiphos breaks down quickly in water. Any amount of oceanic flushing will result in increased dispersion of azamethiphos in the harbour thus, reducing the concentration to which non-target organisms will be exposed.

As a result of the comment the PMRA reconsidered the scenario of a small harbour with low flushing to ensure that mitigation measures are sufficient. The longest half-life for azamethiphos in water of 9.8 days was used to consider dissipation in the harbour. As a conservative approach, oceanic flushing was not considered as a means of additional dissipation. Three different conservative scenarios were considered:

- Three farms in a small harbour consisting of twelve (12) 150 m polar radius net pens, treated three (3) net pens per day until all were treated
- Three farms in a small harbour consisting of twelve (12) 150 m polar radius net pens, treated two (2) net pens per day until all were treated
- Three farms in a small harbour consisting of sixteen (16) 100 m polar radius net pens, treated four (4) net pens per day until all were treated

Two additional treatments of all net pens at each farm in the harbour were then considered on a seven-day re-treatment interval. Based on this conservative scenario, short term accumulation could be possible in areas that do not flush if a large number of treatments were to be carried out

over a small area and over a short period of time. However, the PMRA determined that even with the conservative scenario, the concentrations of azamethiphos predicted with two treatments per day to 150 m polar radius net pens and four treatments per day to 100 m polar radius net pens would not pose an unacceptable risk to non-target organisms.

As a result of this risk assessment the PMRA has decided to take precautionary steps in order to mitigate the risk identified when the 150 m polar radius net pens are used by restricting the number of 150 m polar radius net pens that can be treated per day to a maximum of two (2) net pens per farm site.

The following label statements will appear on the product labels.

“DO NOT treat more than 2 tarped net pens simultaneously”

“When using the tarped treatment method in combination with 150 meter polar radius net pens, DO NOT treat more than two net pens per aquaculture farm site per day.”

Comment

A comment was received raising concerns of setting a precedent with this approval considering lack of studies on impact of azamethiphos in ocean areas, particularly the Pacific coast where farming of Atlantic salmon is done in high densities.

PMRA Response

Since it is not possible to study all species present in Canadian oceans, the PMRA uses a surrogate test species and applies uncertainty factors of up to 10 on the most sensitive test species to account for potential differences in species sensitivity to a particular pesticide. The conservatisms that were used in the risk assessment are described and outlined in PRD2016-25, pages 21 and 25. The full reference list of studies reviewed by the PMRA is presented in PRD2016-25, pages 59 to 64.

All pesticides are tested and evaluated for safety before being registered for use by Canadians. To continue to monitor for safety after they are registered, the PMRA collects pesticide incident reports from Canadians. For more information on the PMRA’s pesticide incident reporting program, please visit the Report a Pesticide Incident page in the Pesticides and Pest Management portion of the Canada.ca website. If the PMRA determines that there is a concern resulting from the use of a pesticide, appropriate regulatory action will be taken to reduce the risk.

Comment

A comment was received raising concerns by lack of analysis of real world multi-factored effects on net pens and the surrounding environment (including disease coinciding with sea lice, antifouling chemicals used on salmon open net pens, antibiotic exposure, temperature stresses, etc.). The comment was recommending more in situ research before granting registration.

PMRA Response

The environmental assessment does not assess cumulative effects or additive effects from other stressors when assessing the risk of a pest control product. For the risk assessment of azamethiphos, the PMRA did consider the effects on adult lobster exposed to sublethal concentrations of azamethiphos followed by simulated live transport.

3.0 Toxicity Comments

Comment

A number of comments were received raising concerns about research conducted by the Department of Fisheries and Oceans that shows that azamethiphos is harmful to lobster.

Azamethiphos is known to be lethal to all life stages of lobster. The following two recent studies published by DFO have shown that repeated sublethal exposure to azamethiphos causes mortality in adult male lobsters.

*Potential Exposure and Associated Biological Effects from Aquaculture Anti-Sea Lice Pesticides*ⁱⁱⁱ

Estimates of the effects of sea lice chemical therapeutants on non-target organisms associated with releases of therapeutants from tarped net-pens and well-boat bath treatments: a discussion paper^{iv}

PMRA Response

The PMRA agrees with the conclusions of the Department of Fisheries and Oceans research that azamethiphos is highly toxic to certain marine organisms including lobster. The two studies cited are very detailed and contain a significant amount of information on the lethal and sublethal effects of azamethiphos on lobster. The PMRA used all the information from the two cited studies in the risk assessment for azamethiphos, including information on sublethal effects. PRD2016-25, Table 9 shows the degree of toxicity of azamethiphos to all the non-target aquatic organisms for which toxicity data was available.

As the PMRA is committed to protecting populations of lobster, the PMRA chose to conduct the risk assessment based on the concentration of azamethiphos where no sublethal effects (behaviour, molting and reproduction) were observed. This no adverse effects concentration was determined to be 1.0 µg/L. This value comes from the study quoted in the comment titled *Potential Exposure and Associated Biological Effects from Aquaculture Anti-Sea Lice Pesticides*.

The PMRA determined that when used according to the label, azamethiphos is not expected to pose risks of concern to non-target marine organisms, including lobster.

Comment

Several commenters raised concerns about the potential effects of azamethiphos on non-target organisms including:

- non-target invertebrates (in water column or on sea floor) which are biologically similar to sea lice
- mysid shrimp
- herring and plankton and krill which are food sources for herring
- eels
- mackerel
- squid
- sand-nesting birds (piping plover)
- larger marine animals (whale, porpoise, seal and seas turtles)

PMRA Response

The PMRA's risk assessment determined that when used according to label directions, the use of azamethiphos is not expected to pose risks of concern to invertebrate communities in the water column or on the sea floor; fish, including eel, mackerel, herring and other fish species; all species of birds and all species of mammals.

Many toxicity studies were available for a variety of non-target invertebrate species and fish species. These are presented in PRD2016-25, Table 9. The PMRA does not receive studies for all organisms that could be potentially exposed. The PMRA uses the results of the studies received as surrogates for other similar species. In addition, an uncertainty factor of 10 fold is applied in order to account for potential differences within and between species.

During the risk assessment, a risk was identified for non-target invertebrates such as shrimp and lobster. The PMRA completed a full risk assessment on the impact of azamethiphos on non-target aquatic invertebrates and has required many risk mitigation measures and use restrictions in order to protect invertebrate communities including wild lobster larvae, wild adult lobster and adult lobster held in active lobster holding facilities which include active licensed lobster pounds and/or lobster tank houses as well as lobster cars/crates held within a designated harbour authority water lot. Details of the risk assessment on non-target invertebrates are outlined in PRD2016-25, pages 21 to 26.

Given the way azamethiphos is used and its fate properties, the PMRA concluded that exposure to azamethiphos would be limited for marine bird and mammal species. Azamethiphos dissipates quickly in the environment and is not expected to bioaccumulate in food sources. For more information on the fate properties of azamethiphos, please see PRD2016-25, pages 18 and 47. Further explanation of the expected risk of azamethiphos to non-target marine birds and mammals is outlined in PRD2016-25, pages 19 and 24 respectively.

Comment

A comment was received about the PMRA's conclusions being based almost exclusively on acute lethality testing. The commenter mentioned that this does not rule out the possibility of sub-lethal effects on non-target organisms (for example, shrimp and spot-prawn).

PMRA Response

The risk assessment was based on repeated sub-lethal exposure to the most sensitive species tested, adult lobster. Adult lobster was determined to be more sensitive than shrimp and spot-prawn. Risk mitigation designed to protect adult lobster will therefore also be protective of shrimp and spot prawn. The PMRA's risk assessment is conservative and is protective of populations.

PRD2016-25, Table 9, on pages 49 to 51 outline the environmental toxicological data which was used during the risk assessment for azamethiphos. A total of 45 individual end-points, including both lethal and sub-lethal, were used during the risk assessment. The PMRA determined that lobster was the most sensitive species of the 9 invertebrate species tested, including the sand shrimp (*Mysid* sp.) and the Mysid Shrimp (*Mysidopsis bahia*). Sub-lethal toxicology data therefore focused on the most sensitive species and although sub-lethal ecotoxicology data was not reviewed for shrimp and spot-prawn, the PMRA used the sub-lethal results from various stages of lobster along with uncertainty factors to account for differences in species sensitivity as a surrogate for other species including shrimp and spot-prawn. Risk mitigation measures will reduce the risk to lobster and are also expected to be protective of shrimp and spot-prawn.

Comment

A 2015 study by C.M. Couillard and L.E. Burridgeⁱ, conducted by the Department of Fisheries and Oceans, underlines the lack of research on effects of aquaculture chemicals in the field and on cumulative effects on non-target organisms.

PMRA Response

While additional field studies on effects to non-target organisms may provide additional information to supplement the risk assessment, the PMRA determined that the information available was sufficient to adequately characterize the risks associated with the use of azamethiphos. The PMRA employed a conservative risk assessment using laboratory toxicity data combined with field environmental concentration data. The PMRA does not conduct research, however; we work closely with other government departments, such as the Department of Fisheries and Oceans (DFO), who do conduct field research on pesticides. A large portion of the data used in the risk assessment for azamethiphos was completed by DFO. The DFO took thousands of measured field concentrations in order to develop a model that can be used to estimate environmental concentrations from the application of azamethiphos to net pens.

The risk assessments completed by the PMRA routinely take into consideration the potential exposure to the pesticide following the labelled use of the pesticide. The cumulative effects of other stressors are not routinely considered as part of the risk assessment. However; the cited study on the effects of azamethiphos on shipped lobster was considered in the Proposed Registration Decision PRD2016-25, Table 10.

Comment

Concerns about effect on clam beds, oyster gathering areas and shrimp/prawn fisheries due to close proximity of salmon farms in BC; no restrictions on azamethiphos to reduce or eliminate potential harm to these species.

PMRA Response

The PMRA has imposed many restrictions on the use of azamethiphos in order to protect aquatic organisms including clams, oysters, shrimp and prawn in British Columbia. The following is an excerpt found in PRD2016-25, page 25: “During the screening level risk assessment, it was determined that azamethiphos poses a negligible risk to oysters and gastropods. As lobster larvae was determined to be the most sensitive non-target invertebrate, risk mitigation applied to mitigate the risks towards lobster larvae will inherently also mitigate the risks towards other less sensitive non-target invertebrate and vertebrate species.” The product label contains many use restrictions established to reduce the risk to both lobster larvae in the water column as well as adult lobster on the ocean floor. As these restrictions are mandatory no matter where the product is used, east coast or west coast, these restrictions will mitigate the risk from the use of azamethiphos on non-target BC species as well such as oysters, clams, shrimp and prawn. The PMRA’s risk assessment is conservative and considered protective of marine populations. Further detail with respect to the risk assessment and risk mitigation requirements imposed by the PMRA may be found in PRD2016-25, pages 19 to 26.

Comment

Concerned that low dose, long term exposure effects are not adequately understood at the individual and population levels. Burrige et al. (DFO 2014) were not able to determine an LC₅₀ dosage for small crustaceans.

PMRA Response

Although unverified, the PMRA believes the quoted “Burrige et al. (DFO 2014)” study is referring to the following study:

Burrige L.E., J.L. Van Geest. 2014. A review of potential environmental risks associated with the use of pesticides to treat Atlantic salmon against infestations of sea lice in Canada. DFO Can. Sci. Advis. Sec. Res. Doc. 2014/002. vi + 39 p.

In this study, the study authors reported many LC₅₀ values for small crustaceans. However, in several instances, the concentrations of azamethiphos used, did not kill 50% or more of the individuals in the test. This means that the concentration required to kill 50% of the test animals (LC₅₀) was higher than the highest concentration tested. Therefore, although a LC₅₀ was not determined, the results of this study were still used in the risk assessment by indicating that the LC₅₀ is greater than the highest test concentration tested. This adds a level of conservatism as the study authors concluded that the LC₅₀ was greater than the highest test concentration tested yet the PMRA assumed in the risk assessment that the LC₅₀ was equal to the highest test concentration. This does not represent a lack of toxicity information on azamethiphos as the PMRA still used the data in a conservative manner. The PMRA has reviewed a very large number of toxicity studies on crustaceans far greater than what is typically required for the

registration of a pest control product in Canada. PRD2016-25, Table 9 shows over 20 different LC₅₀ values for various small crustacean species. The PMRA also has information on longer term effects of azamethiphos to crustaceans. Long term effects are generally reported as a NOEC (No Observed Effect Concentration) or LOEC (Lowest Observed Effect Concentration). The PMRA has long term data from two different studies on adult lobster which was identified as the most sensitive non-target invertebrate. The results of these studies are also presented in PRD2016-25, Table 9.

The PMRA employs a modern internationally recognized risk assessment approach when assessing the risks posed from the use of a pest control product. The PMRA determined that azamethiphos will not only breakdown quickly once it is introduced into the environment but it will also decrease in concentration quickly from ocean mixing and dilution. These processes will significantly reduce the amount of azamethiphos that non-target organisms will be exposed to. Furthermore the PMRA employed several conservative assumptions when conducting the risk assessment to account for differences within species, between species and for populations.

4.0 Tidal movement Comments

Comment

A comment pointed out that the Department of Fisheries and Oceans has shown in a studyⁱⁱⁱ that aquaculture pesticides can travel up to 10 kilometers in the ocean and that effluent plumes can be detected 3 hours after release. Plumes are affected by tides, winds and weather and areas < 20 metres in depth are “more likely to experience benthic exposure.”

PMRA Response

The PMRA agrees with this comment however the cited article covered a wide variety of pesticides. Not all of the information in the cited study is related to azamethiphos. The PMRA determined that azamethiphos breaks down quickly in the environment and that concentrations of azamethiphos decrease quickly in the ocean environment. Discussions surrounding the concentrations of azamethiphos found within the plumes can be found in PRD2016-25, page 21.

Following the risk assessment, the PMRA implemented the following mitigation measure to protect benthic organisms.

“DO NOT apply to tarped net pens in water depths of 10 meters or less”

“DO NOT flush treatment water from a well boat with a 45 degree or 90 degree angled flushing pipe in water depths of 20 meters or less.”

Comment

The below cited studies done by the Department of Fisheries and Oceans were done in New Brunswick where the tides are higher and the currents are stronger than in Nova Scotia. How can the current studies be relevant to sites in Nova Scotia? The Department of Fisheries and Oceans mentions that more studies are required.

*Potential Exposure and Associated Biological Effects from Aquaculture Anti-Sea Lice Pesticides*ⁱⁱⁱ

Estimates of the effects of sea lice chemical therapeutants on non-target organisms associated with releases of therapeutants from tarped net-pens and well-boat bath treatments: a discussion^{iv}

PMRA Response

The cited studies do mention in several areas where additional research could provide more information on specific local conditions. However, it was determined that the work done in southwest New Brunswick is expected to apply to other parts of Canada. On page 138 in the study from the Department of Fisheries and Oceans titled “*Transport and Dispersal of Sea Lice Bath Therapeutants from salmon farm net pens and well boats*”, the following conclusions were made by the study authors: “Although the work was conducted in southwest New Brunswick, the general principles and orders of magnitude dilution are expected to apply elsewhere. The models used were based on data collected from many places around the world and it should apply in other areas of Canada as well.”

Based on the conclusions from DFO and the conservative nature of the risk assessment, the PMRA believes that the exposure estimates and associated risk mitigation measures are protective of Canadian waters.

Comment

Will the effects of azamethiphos be magnified in: lower tides, weaker currents or shallower water depths?

PMRA Response

Concentrations of azamethiphos are expected to dissipate more rapidly in stronger currents and tides when compared to lower currents and tides.

The risk assessment indicated that in shallower water there was a potential risk to non-target marine organisms that live on the ocean floor. To minimise risks to non-target marine organisms in shallow water, the PMRA has added the following restrictions to the product:

“DO NOT apply to tarped net pens in water depths of 10 meters or less”

“DO NOT flush treatment water from a well boat with a 45 degree or 90 degree angled flushing pipe in water depths of 20 meters or less.”

Comment

Concerns were raised regarding the use of the term “down current” given multidirectional nature of tidal currents in the Bay of Fundy. The commenter suggested that the tidal movements are unpredictable and suggests a potential for serious mistakes exists in predicting the current movements precisely. The following suggestions were made:

- A restriction of one kilometer radius would be more appropriate
- Restrictions pertaining to holding facilities are based on proximity to salmon farms regardless of current direction.

PMRA Response

The PMRA agrees with the comment that the Bay of Fundy and other costal locations may have multidirectional tides and currents, and modified this statement accordingly in comparison with the statement which was used on the emergency registration label. The statement makes specific reference that treatments are only permitted when the prevailing tide is moving away from a lobster holding facility which includes active licensed lobster pounds and/or lobster tank houses as well as lobster cars/crates held within a designated harbour authority water lot found within 1 kilometer of the aquaculture site. Given that the ebb and flow fluctuates on a 6-hour time frame, the PMRA notes that the ebb and flow of the tide could change direction during the course of the treatment. Below is the current wording and new revised wording by the PMRA in order to ensure that the 6 hour timescale of the prevailing tide is taken into consideration.

Emergency Registration wording:

“DO NOT use within 1 km of an active lobster holding facility when the ebb or flow of the tide is moving in the direction towards the lobster holding facility.”

Revised new wording:

“DO NOT use within 1 km of an active lobster holding facility which includes active licensed lobster pounds and/or lobster tank houses as well as lobster cars/crates held within a designated harbour authority water lot, when the ebb or flow of the tide or the prevailing current is anticipated to be moving in the direction of a lobster holding facility within 2 hours from the start of the treatment.”

5.0 Policy Comments

Comment

What plans are there to study the long-term effects pesticides have on lobster larvae and the future lobster stocks?

PMRA Response

The PMRA does not conduct research on pesticides, however; we work closely with our federal and provincial partners that do conduct research in order to generate data that will inform risk assessments.

All pesticides are tested and evaluated for safety before being registered for use by Canadians.

As part of the registration process, the PMRA reviews a long list of specific studies that are required in order to conduct the risk assessment. These studies originate from many sources including data submitted by the registrant; produced by other government department and published in peer reviewed journals. Following the approval of a pesticide for use in Canada, the PMRA continues to ensure that the use of the pesticide does not pose a risk to the environment. When the PMRA becomes aware of new information that may indicate that a pesticide poses risks of concern to the environment the PMRA reviews these studies to determine if the risks continue to be acceptable. The PMRA has the authority to request new studies from the registrant if a new concern is identified.

The PMRA must complete a cyclical re-evaluation of the registered pesticide at least every 15 years to ensure that its uses continue to be acceptable. If the PMRA determines that there are risks of concern resulting from the use of a pesticide, regulatory action will be taken to reduce the risk.

To continue to monitor for safety after registration, the PMRA collects pesticide incident reports. If a concern is identified from incident reports, regulatory action will be taken by the PMRA. For more information on PMRA's pesticide incident reporting program, please visit the Report a Pesticide Incident page in the Pesticides and Pest Management portion of the Canada.ca website.

Comment

We do not understand the meaning of the following terms: "not expected", "unlikely", "may pose a risk", and "poses a negligible risk."

"When a report to approve a pesticide uses such phrases as "not expected", "unlikely", "negligible risk" and "may pose" – we, as a community are alarmed."

"Not expected" is not good enough. Unless you can say without a doubt these things will not happen you are not using the precautionary principle if you approve the registration of azamethiphos."

PMRA Response

Under the *Pest Control Products Act*, a pesticide can only be registered for use in Canada if any associated risks to health or the environment have been determined to be acceptable. Risks are acceptable if, on the basis of extensive scientific data, it has been determined that there is reasonable certainty that no harm to human health, future generations or the environment will result when the pesticide is used as directed.

It is not possible to prove scientifically that any substance is safe with absolute certainty. For example, applying results of laboratory-based toxicity studies to humans and the environment will always involve an inherent level of uncertainty. Safety factors are applied to exposures that are scientifically shown to pose no unacceptable health or environmental risks, to account for uncertainties in the risk assessment process, and to establish reasonable certainty of no harm. This approach is consistent with that of other major regulatory bodies, including the United States, Australia, and the European Union.

Comment

The onus is upon government to exercise the precautionary principle and protect what exists.

PMRA Response

PMRA's approach to evaluating pesticides for registration is precautionary. Scientists rigorously review the detailed studies and tests provided by registrants and any available information in order to determine the risks to human health and the environment, and whether or not the product has value. The health risk assessment requires that consideration be given to sensitive sub-populations such as pregnant women, infants, children and seniors; the environmental risk assessment considers factors such as risks to non-target species. If a product is found to pose a concern to human health, future generations, or the environment, it is not registered for use in Canada. Once a pesticide has been granted registration status, it becomes subject to a system of post-market risk management controls under the *Pest Control Products Act*. This includes re-evaluations and special reviews of registered pesticides, compliance and enforcement activities, and response to health and environmental incidents. If potential risks are identified in a registered product, interim measures may be implemented to address the potential risk while it is being evaluated. Registrations can be cancelled or amended any time there exists reasonable grounds to believe that the cancellation or amendment is necessary to deal with a situation that endangers human health or safety or the environment.

Many aspects of the azamethiphos assessment and decision reflect PMRA's conservative approach to risk management, as outlined in PRD2016-25, pages 22 and 23.

Comment

Commenter recommended that permission for use of azamethiphos be dependent on best practices by farm operators.

PMRA Response

The risk assessment for azamethiphos is based on current aquaculture practices. The PMRA has determined that these practices do not pose an unacceptable risk to non-target organisms. If other aquaculture practices are developed that have implications on the use of a pest control product, the PMRA will evaluate those new practices before they are allowed to be used commercially.

While Health Canada's PMRA encourages the use of Best Management Practices, sustainable production methods, and alternative pest control options, the PMRA's primary mandate is to prevent unacceptable risks to Canadians and the environment from the use of pest control products by applying a modern, evidence-based scientific approaches to assess whether the health and environmental risks of pesticides proposed for registration are acceptable, and if the products have value. Based on the risk assessment using conservative assumptions and current practice, the PMRA determined that when used according to the label, azamethiphos is not expected to pose risks of concern to human health or the environment based.

The product label also includes an IPM statement: "*Insecticide use should be based on an IPM program that includes scouting, record keeping, and considers cultural, biological and other chemical control practices.*"

Comment

Authorization of a deleterious substance: The authorization and full registration of Azamethiphos allows for a poison to be used in the marine environment. We do not feel this is keeping with obligations under section 36 of the *Fisheries Act* which prohibits deleterious substances being introduced to fish habitat.

PMRA Response

The proposed regulatory decision by the PMRA for the use of azamethiphos in aquaculture included risk reduction measures to protect human and environmental health as required by the *Pest Control Products Act*.

The Aquaculture Activities Regulations establish the conditions under which pesticides and veterinary drugs can be used to treat fish consistent with section 35 and 36 of the *Fisheries Act*.

These regulations were developed by the Department of Fisheries and Oceans, Environment Canada and the PMRA. Additional information on the regulations may be found at the following address: <http://www.dfo-mpo.gc.ca/aquaculture/management-gestion/aar-raa-eng.htm>.

Comment

Concerns based on increasing density of fish farms in Atlantic Canada and toxicity levels of azamethiphos on lobster.^v

PMRA Response

The aquaculture industry is highly regulated and there are restrictions on the distance between fish farms in Canadian waters. While the PMRA does not consider forecasted increases in scale of use in its risk assessments, the PMRA implemented mitigation that is designed to protect non-target organisms, including lobsters. The PMRA completed a risk assessment that took into consideration the reported toxicity of azamethiphos to lobster which was published in the Burrige and Van Geest study^v cited in the comment. Details of the toxicity levels to lobster and the other organisms studied and used in the risk assessment can be found in PRD2016-25, Table 9 on pages 49 to 51.

Comment

Concerns were raised about insufficient reporting of pesticide use, unclear of benefits of Aquaculture Activity Regulations.

PMRA Response

All pesticide users are legally required to comply with the *Pest Control Products Act*. Pesticides may only be used in aquaculture settings with specific restrictions to avoid, minimize and mitigate any potential detriments to fish and fish habitat. The aquaculture industry is also subject to the requirements of the Aquaculture Activities Regulations (AAR). These regulations outline mandatory notification, reporting and monitoring requirements, including the requirement to notify Fisheries and Oceans Canada of intent to use of pest control products. The reporting

requirements include sampling and monitoring, and reporting of any adverse effects. This information will allow Fisheries and Oceans Canada, Environment and Climate Change Canada, and the PMRA to monitor use intensity and environmental conditions and take action to mitigate any risks that may emerge.

Details of the Aquaculture Activities Regulations can be found at the following address: <http://www.dfo-mpo.gc.ca/aquaculture/management-gestion/aar-raa-eng.htm>.

6.0 Fate Comments

Comment

Concerns were raised about salmosan residue along shoreline where communities live.

PMRA Response

The PMRA determined that azamethiphos breaks down quickly in water and is not expected to remain in the environment for long periods of time. Residues of Salmosan Vet along shorelines where communities live are not expected.

Comment

Concerns that anything released or dumped into the ocean, does not 'go away' and that dilution is not the solution.

PMRA Response

Prior to the registration of any pesticide the PMRA carefully considers how the pesticide breaks down in the environment. Although dilution does play a role in the rapid decrease in concentration of azamethiphos in the first few hours after it is released from an aquaculture farm site, the PMRA does not consider dilution when it determines how quickly or slowly a pesticide breaks down in the environment. Azamethiphos has been shown to break down rapidly in water and therefore azamethiphos is not expected to remain in the environment for very long.

Comment

Concerns were raised regarding possible azamethiphos accumulation in the tissue of organisms.

Response

The PMRA assessed the potential for accumulation in tissues of organisms in the ecosystem and determined that azamethiphos has a low potential to bioaccumulate in the tissues of organisms. Details regarding the assessment of accumulation in the tissues of organisms can be found in PRD2016-25, Table 20, pages 55 to 56.

Comment

There is little known about the accumulation of pesticides in sediments, particularly as frequency of use increases.

PMRA Response

The PMRA reviews a large number of fate studies as well as studies on the physical and chemical properties of a pesticide before that pesticide can be registered in Canada. These studies are conducted following internationally recognized guidelines such as the guidelines published by the Organization for Economic Co-operation and Development and those published by the United States Environmental Protection Agency. By using information from these studies, the PMRA can characterise the fate of the chemical in sediments. The physical and chemical properties of azamethiphos can be found in PRD2016-25, pages 7 and 8. The PMRA determined that azamethiphos is unlikely to partition and accumulate in sediment. The publication by Burrige and Van Geest^v from the Department of Fisheries and Oceans also concluded that azamethiphos is unlikely to accumulate in sediment.

Comment

There were several requests made for the PMRA to develop criteria that takes into account their concerns in order to designate their harbours a “pesticide free zone”.

PMRA Response

The PMRA cannot designate Shelburne harbour as a pesticide free zone. The PMRA can only base any decision to prohibit the use of pesticides if the available science is unable to demonstrate that the risks to human health or the environment are acceptable. For azamethiphos, the PMRA has concluded that when used according to label instructions azamethiphos is not expected to pose risks of concern to human health or the environment.

Comment

Comments were received regarding the health concerns for people, especially children, swimming in areas, such as the harbour, public beaches or residential shorelines that are close to fish farms where treatments using azamethiphos may take place.

PMRA Response

As noted in PRD2016-25, when assessing human health risks to pesticides, the PMRA gives consideration to two key factors: the levels at which no health effects occur in animal testing and the levels to which people may be exposed. The dose levels used to assess human health risks are established to protect the most sensitive human population, for example, children. Only uses of pesticides for which exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Prior to the registration of any pesticide the PMRA also carefully considers how the pesticide breaks down in the environment. Although dilution plays a role in the rapid decrease in concentration of azamethiphos in the first few hours after it is released from an aquaculture farm site, the PMRA does not consider dilution when it determines how quickly or slowly a pesticide breaks down in the environment. In other words and specifically for azamethiphos, the information assessed by the PMRA demonstrates that it breaks down rapidly in water and therefore, is not expected to remain in the environment for an extended period. Thus, residues of azamethiphos along shorelines where communities live are not expected.

When assessing exposure and in turn risk, scientific information on the fate and breakdown of the chemical in the environment is also taken into consideration. Based on the fate of azamethiphos in sea water, residue concentrations have been shown to decrease rapidly (as does the breakdown of azamethiphos, shortly after it is released from an aquaculture farm site). Therefore, taking into account the overall information from the animal studies in addition to potential exposure to humans, exposures to adults, youth and children swimming in harbours, public beaches and residential shorelines, located in the vicinity of fish farms, are not expected to be of human health concern.

Comment

A question as to whether there was an MRL in place for salmosan was raised.

PMRA Response

MRLs ensure that exposure to pesticide residues in the diet present no concerns for human health. As indicated in PRD2016-25, *Azamethiphos*, the MRL for residues of azamethiphos in/on fish will be established at 0.05 ppm. The proposed MRL was published on 20 September 2016 (PMRL2016-47) for public consultation and will be included in the online MRL database once the decision on Salmosan Vet is finalized.

Comment

A comment was received regarding the import tolerance of 0.02 ppm for azamethiphos in muscle/skin of salmonids established by the USFDA under S512(a)(6) of the *Food, Drug and Cosmetic Act* (File Number VMF 005-969).

PMRA Response

The tolerance of 0.02 ppm has been set by the USFDA to cover residues of salmosan in edible tissue of salmonids when azamethiphos is used as a veterinary drug. The PMRA assessed residue data for salmon exposed to Salmosan Vet based on the pesticidal use of azamethiphos and found that there were no quantifiable residues in treated fish. Therefore, as there is no expectation of quantifiable residues in the treated salmon when the product is used according to the label directions, an MRL at the limit of quantitation (0.05 ppm) of the analytical enforcement method is proposed and will be included in the online MRL database once the decision on Salmosan is finalized.

Comment

Comments were received inquiring about the importation/distribution of Salmosan.

PMRA Response

“Salmosan”, like all pest control products registered under the *Pest Control Products Act*, may be imported into Canada for sale and for use. Importations of all kinds, including pest control products, must be declared to the Canada Border Services Agency (CBSA). Since 2013, the Pest Management Regulatory Agency of Health Canada has been receiving importation data weekly from the CBSA regarding importation of pest control products. Evidence of non-compliance is

pursued and, when necessary, appropriate action is taken based on this information. No enforcement action has been required in relation to “Salmosan” importation to date.

Comment

A comment was received outlining the concern from the use of Salmosan Vet without government oversight or limitations.

PMRA Response

The PMRA has conducted rigorous risk assessments based on the information available and has determined that Salmosan Vet, when used as prescribed on the label, is not expected to harm the health of Canadians or the environment. Salmosan Vet will have a Restricted product classification. This means it may only be applied by individuals who are provincially certified and trained in the application of the product and who hold a pesticide applicator certificate or licence recognized by the provincial/territorial pesticide regulatory agency where the application occurs. Once registered, the use of pest control products are subject to a system of post-market risk management controls under the *Pest Control Products Act* (incident reports, inspections) as stated above.

Comment

Several comments were received regarding Health Canada’s monitoring of the aquaculture industry on the east coast.

PMRA Response

Health Canada conducts inspections in the aquaculture industry in collaboration with federal and provincial departments responsible for the environment and the aquaculture/fisheries sector. Inspections are conducted to provide oversight on the use of emergency registration pesticides and registered pesticides used for sea lice control as well as to inspect for unregistered pesticide product use. From 2011 to 2015, a total of 308 routine monitoring inspections were completed in New Brunswick, Nova Scotia and Newfoundland and Labrador with 227 salmon samples collected and analyzed by the Health Canada Pesticide Laboratory in Ottawa. Any evidence of non-compliance with the *Pest Control Products Act* is pursued. With the exception of samples from one company in Newfoundland and Labrador, no residues were found in the remaining 224 samples. The company in Newfoundland was served with an Administrative Monetary Penalty in 2016. In addition, two companies in New Brunswick were served with Administrative Monetary Penalties in 2011 (the associated enforcement bulletins can be found in the Pesticides and Pest Management portion of the Canada.ca website.)

Health Canada will continue to conduct inspections in the aquaculture industry.

Comment

Comments were received regarding an explanation of the registration process and a request that the registration be delayed to allow for further submission of comments or that registration be denied altogether.

PMRA Response

Before a new pesticide is considered for registration in Canada, the PMRA is required under the authority of the *Pest Control Products Act* to conduct an extensive review of any data/information available on a pesticide to determine the potential risks posed to human health and the environment and the pesticide's value. Based on the studies reviewed, the risk assessments and protective label statements, if there is reasonable certainty that no harm to human health or the environment will result from use or exposure to the product, the PMRA publishes a proposed decision document summarizing its finding for a 45 day public consultation. The PMRA then consolidates and responds to the comments received during the consultation period, prior to making a final registration decision. The final decision, along with the PMRA responses to the comments from the public, is published in the Registration Decision document. Any person may file a notice of objection (based on scientific grounds) regarding the registration decision within 60 days from the date the decision is published.

For azamethiphos, the process outlined above has been followed and this decision document summarizes the concerns brought forward by stakeholders, the PMRA's response to these comments and the final decision which took into consideration stakeholder concerns.

For more information on how the PMRA regulates pesticides, please refer to the Canada.ca website (<https://www.canada.ca/en/health-canada/services/consumer-product-safety/pesticides-pest-management/public>).

ⁱ Couillard, C.M., and Burrige, L.E. 2015. Sublethal exposure to azamethiphos causes neurotoxicity, altered energy allocation and high mortality during simulated live transport in American lobster, pp 291-299. (<http://dx.doi.org/10.1016/j.ecoenv.2014.11.016>, accessed August 2017)

ⁱⁱ Page, F.H., Losier, R., Haigh, S., Bakker, J., Chang, B.D., McCurdy, P., Beattie, M., Haughn, K., Thorpe, B., Fife, J., Scouten, S., Greenberg, D., Ernst, W., Wong, D., and Bartlett, G. 2015. Transport and dispersal of sea lice bath therapeutants from salmon farm net-pens and well-boats. DFO Can. Sci. Advis. Sec. Res. Doc. 2015/064. xviii +148 p. (http://www.dfo-mpo.gc.ca/csas-sccs/Publications/ResDocs-DocRech/2015/2015_064-eng.html, accessed August 2017)

ⁱⁱⁱ DFO. 2013. Potential exposure and associated biological effects from aquaculture pest and pathogen treatments: anti-sea lice pesticides (part II). DFO Can. Sci. Advis. Sec. Sci. Advis. Rep. 2013/049. (http://www.dfo-mpo.gc.ca/csas-sccs/Publications/SAR-AS/2013/2013_049-eng.html, accessed August 2017)

^{iv} Page, F.H., and Burrige, L. 2014. Estimates of the effects of sea lice chemical therapeutants on non-target organisms associated with releases of therapeutants from tarped net-pens and well-boat bath treatments: a discussion paper. DFO Can. Sci. Advis. Sec. Res. Doc. 2014/103. v + 36 p. (http://www.dfo-mpo.gc.ca/csas-sccs/publications/resdocs-docrech/2014/2014_103-eng.html, accessed August 2017)

^v Burrige L.E., J.L. Van Geest. 2014. A review of potential environmental risks associated with the use of pesticides to treat Atlantic salmon against infestations of sea lice in Canada. DFO Can. Sci. Advis. Sec. Res. Doc. 2014/002. vi + 39 p. (http://www.dfo-mpo.gc.ca/csas-sccs/publications/resdocs-docrech/2014/2014_002-eng.html, accessed August 2017)