DEPARTMENT OF
ECOLOGY
State of Washington

Response to Public Comments

September 2018

Response to public comments on the tentative determination to deny the issuance of a National Pollutant Discharge Elimination System Permit for the Willapa Grays Harbor Oyster Grower Association to use imidacloprid for the control of burrowing shrimp.

Contents

Preface

Ecology received 3,081 comments via electronic submittals and letters during the public comment period, April 9 through May 14, 2018, on our tentative determination to deny the issuance of a National Pollutant Discharge Elimination System (NPDES) permit for applicant Willapa-Grays Harbor Oyster Grower Association to use imidacloprid for the control of burrowing shrimp. The comments received regarding the tentative decision can be found at http://ws.ecology.commentinput.com/comment/extra?id=gWPx2 for the next six months. After that, comments will be found at https://ecology.wa.gov/Regulations-Permits/Guidance-technical-assistance/Water-quality-permits-database, which is the public portal for the Permitting and Reporting Information System (PARIS) database.

Numerous comments supported the denial with generalized statements about environmental impacts. Some commenters in opposition to the permit denial provided detailed comments. The responses below are organized by category of comment. Categories include economics, ecosystem services, uncertainty, the State Environmental Policy Act or SEPA process, new science, effects to biological resources within the Sediment Impact Zone (SIZ), sediment quality standards outside the SIZ – water, and sediment quality standards outside the SIZ – sediment.

Response to Comments Related to Economics

Comments addressed the economic impact to the shellfish industry in the Willapa Bay and Grays Harbor areas if the permit was denied. Ecology acknowledges the comments and points commenters to the 2015 Final Environmental Impact Statement (FEIS), specifically Chapter 2, Section 2.6 (pages 2-16 through 2-18) describing the economic, employment, and tax base significance of the clam and oyster aquaculture industry in Pacific County, Grays Harbor County, Washington State, and the nation. Those interested in these subjects are encouraged to review the 2015 FEIS, which was adopted by reference in the 2018 Final Supplemental Environmental Impact Statement (FSEIS). Additionally, Section 2.8.5 of the FSEIS, Alternatives Considered and Eliminated from Detailed Evaluation discusses off-bottom culture, which is discussed in more detail in section 2.5.1, Oyster Culture Methods of the FEIS.

Response to Comments Related to Ecosystem Services Provided by the Control of Burrowing Shrimp

Several commenters, including the applicant, identified the ecological benefits of controlling burrowing shrimp populations in Willapa Bay and Grays Harbor. Ecology acknowledges the comments and points commenters to the FEIS, specifically Chapter 1 and Chapter 3, which contain information describing the ecosystem services of control of burrowing shrimp. The applicant noted that the FEIS included numerous discussions of the possible ecological and food web benefits of burrowing shrimp control.

Response to Comments Related to Uncertainty

A number of commenters, including the applicant, noted an increased level of uncertainty discussed in the FSEIS compared to the Draft Supplemental Environmental Impact Statement (DSEIS) regarding imidacloprid impacts. While the change reflects the process and review used to create the FSEIS under the State Environmental Policy Act (SEPA), the denial of the permit is based on the inability to authorize a SIZ, a prerequisite for issuance of an NPDES permit. The authority to deny the permit falls under NPDES rules and not substantive SEPA authority.

Ecology identified ten categories of uncertainties of which nine were discussed in the DSEIS. Pesticide resistance was identified in both public hearings and in written comments about the DSEIS. Several citations were included in these comments (see Appendix B of the FSEIS) and additional publications have been identified since completion of the FSEIS (e.g. Rix and Cutler 2017, and Crossley et al. 2018). Given the variable efficacy as reported by the applicant and the significant off-plot migration of imidacloprid to non-treated areas outside the SIZ, Ecology concluded significant uncertainty potentially having a long term effect on the ability of imidacloprid to control burrowing shrimp.

While the ten type of uncertainties described in the FSEIS represent a number of significant data gaps, other uncertainties were identified during the first EIS scoping process, in subsequent meetings and communications with Ecology, and during preparation of the FEIS. Examples are listed below:

- Research on the effects of burrowing shrimp on commercial shellfish beds has been done where oysters are the primary crop. Field research data are lacking regarding how burrowing shrimp affect clams, and the threshold for damage to clam beds. For more information refer to Chapter 2, Section 2.8.3, page 2-34 of the FEIS.
- The proposed permit would allow imidacloprid treatments from April to December. Some studies have documented seasonal or temperature related effects on imidacloprid toxicity, specifically that the pesticide has greater efficacy at higher temperatures. There is uncertainty whether imidacloprid treatments during periods of low water temperature would successfully reduce burrowing shrimp populations.
- The effects of imidacloprid on zooplankton species are largely unstudied. Under the proposed action, imidacloprid would be applied on selected commercial shellfish beds under low tide conditions when large numbers of zooplankton would not be present (see FEIS Chapter 3, Section 3.2.5). However, those communities on the leading edge of the incoming tide could be exposed to imidacloprid during the first flood tide. Applications that would be done in standing water would likely impact zooplankton when toxicity levels exceed the EPA marine acute toxicity threshold.

Response to Comments Related to SEPA Process

There were comments concerning the number of changes made to the DSEIS culminating in the FSEIS published. The changes reflect the process and review under SEPA that Ecology used to create the FSEIS. However, Ecology is denying the issuance of the permit based on the inability to authorize a SIZ, a prerequisite for issuance of an NPDES permit. The authority to deny the permit falls under NPDES rules and not substantive SEPA authority.

Response to Comments Related to New Science

A number of commenters, including the applicant, noted that no new science was offered between the development of the FSEIS and the DSEIS that provided additional evidence imidacloprid would have an adverse impact within or outside the SIZ. Specifically, the applicant stated that "[n]o reference to the public comments on the DSEIS to justify these changes, and no new studies are offered that the Department of Ecology (Ecology) had not already reviewed in its development of the DSEIS".

Ecology has received comments regarding new studies, scientific information, and research publications throughout the permit application process. Ecology received 8,287 comments during the comment period on the DSEIS via electronic submittal, letters, and testimony at public hearings. Regarding new science about imidacloprid impacts, see Appendix B and C of the FSEIS, which are the public comments received on the DSEIS, and Ecology's response to public comments received on the DSEIS. Some commenters of the DSEIS included review of new scientific information and research publications containing references and citations, which are included in both Appendix B and Appendix C of the FSEIS. Additionally, the Center for Food Safety referenced new scientific information in their submitted comments regarding the tentative determination to deny the NPDES permit for the proposed imidacloprid use, dated May 14, 2018 (see Preface for link to public comments). These comments included references to twelve additional scientific research papers regarding the environment impacts of imidacloprid. New articles are regularly being published in peer review journals which document the impact of imidacloprid. For example Hook et al. (2018) described indirect upstream imidacloprid contamination to estuarine waters which threatened marine aquaculture resources (i.e., commercial shrimp).

The DSEIS documented a number of impacts that were confirmed by new information that was presented by commenters during the DSEIS public comment period. New information is constantly being published documenting both lethal and sub-lethal impacts from neonicotinoids at levels which the applicant's imidacloprid application rate to the marine sediments and waters of the SIZ would exceed acute biologic endpoints by a several orders of magnitude.

Wood and Goulson (2017) documented that a Web of Science search (a premier search platform for peer-reviewed journal publications) using the keywords "neonicotinoids" and "water" found that nearly two-thirds of neonicotinoid articles had come out within the previous three years. The rate of new publications continues through present. For 2018 alone, a similar search using Google Scholar for the keywords "imidacloprid" and "aquatic" returned over 1320 results. A similar search for "imidacloprid" and "sediment" returned 566 results. While not all of these search results are relevant, in preparing to review public comments to the tentative determination, more than a dozen new journal articles have been identified directly related to aquatic impacts of neonicotinoids. In addition to these new publications, relevant policy decisions have been made from the new science collected since 2015.

Health Canada Pesticide Management Regulatory Agency (PMRA) has proposed a re-evaluation of imidacloprid use stating, "in aquatic environments in Canada, imidacloprid is being measured at levels that are harmful to aquatic insects;" and, for the "protection of the environment, PMRA is proposing to phase-out all agricultural and a majority of other outdoor uses of imidacloprid over three to five years." Similarly, based on "new scientific and technical knowledge" in which "concerns were identified" (EFSA 2018), the European Union (EU) voted in April 2018 to ban three neonicotinoid pesticides (including imidacloprid) three months after Ecology completed the FSEIS. This provides continuing mounting evidence of imidacloprid's negative effects to aquatic and terrestrial invertebrates.

Response to Comments Related to Effects to Biological Resources within the Sediment Impact Zone

Criteria used to evaluate the discharge and the effects to biological resources within the SIZ

The applicant and others commented about the criteria used to evaluate the discharge and the effects to biological resources within the SIZ. Ecology maintains that the Sediment Management Standards (SMS) benthic abundance criteria in (WAC 173-204-420) was developed to assess sediment toxicity to biological resources and benthic invertebrates. Although the Puget Sound Marine Criterion in SMS was developed based on Puget Sound sampling, Ecology determined that the benthic abundance criterion provided a reasonable metric to evaluate monitoring data from the experimental trials.

The criterion was considered, along with current scientific literature, in developing the approach for interpreting the non-Puget Sound marine narrative criteria in Willapa Bay. Specifically, WAC 173-204-420(3)(c)(iii), benthic abundance, sets a statistically significant "fifty percent of reference mean abundance" criterion. The applicant agreed to this approach. The applicant applied for an NPDES permit and SIZ authorization and has specified a monitoring protocol under which Ecology has performed its review.

The U.S. Environmental Protection Agency 2017 Risk Assessment (EPA 2017) chose "the lowest acceptable (quantitative) acute toxicity value of 33 µg active ingredient (ai)/L … for estimating risks to saltwater aquatic invertebrates," which was based on toxicity to mysid shrimp. They also identified "qualitative" studies with toxicity values as low as 10 µg ai/L. EPA notes that this value is "42X less sensitive than that for freshwater invertebrates." EPA then applied a Level of Concern (LOC) safety factor of 0.5 to this value, resulting in an acute toxicity standard for marine invertebrates of 16.5 µg ai/L (i.e., 33 µg ai/L x 0.5 LOC = 16.5 µg ai/L). Inclusion of a factor of safety is a standard practice in risk assessments. For instance, Smit (2014) used a factor of safety of 0.1 to propose water quality standards.

For chronic toxicity of saltwater invertebrates, the EPA Risk Assessment (2017) used data on mysid shrimp to develop a 28-day No Observable Adverse Effects Concentration (NOAEC) value of 0.163 µg ai/L and a Lowest Observable Adverse Effects Concentration (LOAEC) of 0.326 µg ai/L based on "significant reductions in length and weight." The EPA Risk Assessment (2017) includes only two chronic studies of imidacloprid effects on saltwater invertebrates. If a larger database had been available, it seems likely that lower values for chronic toxicity would have been noted for one or more invertebrate types, especially given the consistent pattern of wide variation of imidacloprid toxicity among species. For comparison, the freshwater chronic toxicity endpoint was 0.01 µg ai/L. See the literature review in FSEIS Appendix A for further details.

The applicant, in opposing the tentative determination to deny the permit application, cited to the EPA Risk Assessment (2017). In regards to the EPA development of marine endpoints, and the potential to impacts aquatic species, Ecology notes that EPA's Risk Assessment (2017) stated, "[i]midacloprid is classified as very highly toxic to both freshwater and saltwater invertebrates on an acute exposure basis." It is a standard practice for risk assessments to include a factor of safety, in this case, halving the mysid acute endpoint to account for more sensitive species. This is done to acknowledge that some untested species would be more susceptible to imidacloprid than the limited number of tested species. This is a well-established practice in toxicology. Mysid shrimp are an indicator species used in toxicity testing because of their hardy nature and ease of culture. They may therefore be more resilient to toxicants than species in the wild. As evidence, more freshwater species have been tested than marine species. Of those freshwater species, a number have been between one and two orders of magnitude more sensitive to imidacloprid, such as ostracods and mayflies.

It is expected that as other marine species are tested, there will likely be some species identified that are more sensitive to imidacloprid. For example, EPA Risk Assessment (2017) noted,

> [a]mong non-insect arthropods tested, imidacloprid appears to be most toxic to ostracods (seed shrimp) with acute EC50 values ranging from 1.0 to 3.0 µg ai/L for three species (Sanchez-Bayo et al., 2006; Qualitative). Ostracods are widely distributed in freshwater and saltwater ecosystems, are considered important components of the aquatic food web, and have been suggested as sensitive bioindicators of anthropogenic stressors, including pesticide exposure (Ruiz et al., 2013).

Results from the 2011 Cedar River trial showed impacts to ostracods and other benthic invertebrates described in the section, "[r]esponse to determining benthic community impacts-areas with sediment containing high total organic carbon." Several classes of arthropods exist in the marine environment which do not exist in the freshwater or terrestrial environments. Both Ecology and the EPA have stated that it is likely that marine species more sensitive than mysid shrimp are present in the estuarine environment but are not documented.

The EPA Risk Assessment (2017) also provides context for their endpoints in relation to other published literature, stating that the "risk findings from EPA, PMRA and EFSA [European Food Safety Authority] were comparable." The EPA Risk Assessment (2017) noted that a common theme from several of these reviews is that immobilization and ataxia (i.e., sub-lethal effects) of test organisms often occurs at concentrations one to two orders of magnitude lower than concentrations that cause lethality. Also, the EPA Risk Assessment (2017) stated, "[c]onsistent with the Agency's assessment endpoints, such severe impacts on organism mobility are considered ecologically relevant and appropriate for risk assessment purposes since organisms cannot feed, swim, or avoid predation." Given the strong evidence for adverse effects at levels lower than the EPA endpoints, and given that EPA's acute toxicity threshold is 12 times greater than the Health Canada threshold (PMRA 2016), Ecology believes the EPA marine and acute chronic endpoints are the best currently available metrics with which to evaluate impacts from the proposed permit to spray imidacloprid in Willapa Bay and Grays Harbor. The EPA endpoints allow higher concentrations than comparable risk assessments. The FSEIS, associated public comments (e.g., Audobon Nov. 1, 2017), and Ecology responses to public comment are in line with EPA's statement that imidacloprid is highly toxic to aquatic organisms even in low concentrations from indirect sources. The EPA Risk Assessment (2017) further states that "all combined use scenarios exceed the chronic risk" for saltwater invertebrates based upon terrestrial application scenarios where imidacloprid is applied terrestrially and then indirectly makes its way into water.

In summary, the applicant's overall comment that the EPA Risk Assessment (2017) criteria cannot be compared and that the proposed application of imidacloprid directly onto marine sediments would lead to less risk is inconsistent with Ecology's findings. Monitoring data from direct application to sediments resulted in concentrations in the thousands of parts per billion that likely causes immediate death of non-target invertebrates on the benthic surface and in the water of the leading edge of the incoming tide considering the acute marine endpoint is 16.5 parts per billion. The data indicate that the concentration of imidacloprid does not remain on-plot (where it was applied to sediment) but that the imidacloprid moves off-plot. Ecology concludes that the proposed application is likely to both have a direct impact on plot causing more than minor adverse effects to biological resources and that the discharge would result in an exceedance of applicable sediment quality standards off-plot, outside the proposed SIZ (WAC 173-204-415(1)(f) and 173-204-415(1)(i)).

Determining benthic community impacts - statistical methodology

Ecology has reviewed the SMS standards required to be met to issue a SIZ, taking into account the benthic abundance monitoring results from the experimental applications of imidacloprid conducted in 2011, 2012, and 2014 and relevant literature. Ecology reviewed the monitoring plans and approved of the 2014 monitoring plan with some reservation based on the low number of samples being proposed. During all three years, statistical power was low, requiring Ecology to make determinations based on best professional judgement. As stated in Ecology's April 4, 2018 memo, in order to meet the conditions detailed in WAC 173-204-420(3)(c)(iii), there must be the ability to tell the statistical difference between the major taxa abundance of treatment and reference sediments in order for Ecology to be able to determine whether a SIZ is functioning as authorized. The January 2, 2018, TerraStat memo, submitted as part of Ecology's response to comments from the DSEIS, contained a power analysis of the monitoring results which showed the submitted monitoring data is inadequate to statistically evaluate whether the benthic community data meets the benthic abundance test.

Ecology maintains that the inability to find a statistical difference cannot be presumed to mean the benthic abundance test passed SMS criteria. The applicant noted in their comments that, "of the eight field trials in Willapa Bay, seven met Ecology's stated criteria for compliance with Sediment Standards (SMS)." Ecology cannot agree that the seven monitoring trials met the statistical criterion stated in SMS and this passed the benthic abundance test. This is confirmed by TerraStat (2018 memo).

Due to natural heterogeneity of sediment types and invertebrate communities in Willapa Bay, benthic abundance values are highly variable. In order to obtain data with the required power to adequately measure the variability to statistically analyze the data, larger sample sizes and more replication of control and treatment plots are necessary (TerraStat, January 2, 2018). The power analysis of monitoring results indicates that up to 200 samples per plot are required to reach the necessary power to detect a 50% difference between the reference and the treatment plot. In the 2015 FEIS Ecology noted that the experimental monitoring approach led to a non-statistical evaluation of the benthic community data. Given that the applicant's monitoring plan relies upon a non-statistical monitoring scheme, it cannot be shown that the SIZ benthic abundance test will be met, and therefore Ecology cannot authorize a SIZ.

The applicant requested taxonomic richness be included to measure the benthic community impact within the SIZ. Ecology cannot issue or deny a SIZ authorization based upon taxonomic richness because it is not a criterion identified in SMS (WAC 173-204-420(3)(c)).

Determining benthic community impacts - areas with sediment containing high total organic carbon

The applicant noted in their comments that the 2011 Cedar River trial did not meet SIZ standards because there was more than a minor adverse effect to biological resources. The Cedar River trial site consisted of sediment that was high in organic carbon. Field and laboratory studies have documented that imidacloprid levels in sediments decline more slowly over time as organic carbon levels increase (Grue and Grassley 2013). The current permit application requests authorization to apply imidacloprid in both north and south Willapa Bay, locations known to contain sediments with higher organic carbon levels similar to the Cedar River location. Results from this area with high total organic carbon (TOC) indicated impacts to the benthic community that exceeded SMS criteria.

The 2011 Cedar River monitoring resulted in on-plot mean crustacean abundance that declined 86% after 14 days, while there was little change in the control plot. After 28 days, while there was more than a 40% increase in crustaceans at the control plot, there was a 60% decrease in crustaceans on the treatment plot. Ostracods reflected a similar trend, declining by nearly 80% at 28 days. After 28 days, six out of nine taxonomic subgroups showed a more than 60% decrease compared to before treatment numbers. Similar to the crustaceans, a 44% increase in polychaetes at the control plot after 14 days was matched by a 72% decrease at the treatment plot. At 28 days, a 75% increase in polychaetes at the control site compares to a 55% decrease at the treatment plot. In conclusion, mortality was greater than 50% and did not recover to less than 50% in 14 days.

During evaluation of the 2015 permit application, Ecology determined that the 2011 Cedar River results exceeded the "minor adverse effects" standard of the SIZ regulations (TCP memo dated April 7, 2015). The results from this location exceeded the minor adverse effects criteria in the Sediment Management Standards of WAC173-204-415. Distribution of high total organic carbon (TOC) sediments is variable at both baywide and plot scales. In areas of high TOC imidacloprid persists longer in the sediment as compared to those with low TOC. In areas of high TOC then, there is also an increased likelihood of sub-lethal impacts from the chronic exposure. Therefore, locations throughout northern and southern Willapa Bay, which have expansive, high TOC areas, and potentially areas within central Willapa Bay and Grays Harbor that also contain areas of high TOC will be similarly impacted. That is, even the reduced number of invertebrates present at 14 days likely suffer from sub-lethal impacts of imidacloprid being applied.

Summary

The applicant comments on a reference to the TCP tentative determination memo stated an SMS regulation, "that the discharge shall not have an adverse effect to the biological resources within the sediment impact zone above a minor adverse effects level". Furthermore, WAC 173-204-415(1)(f) Sediment impact zones states, "[a]dverse effects to biological resources within an authorized sediment impact zone shall not exceed a minor adverse effects level as a result of a discharge." Ecology maintains the discharge does not meet SMS.

The 2011 Cedar River site failed due to low benthic abundance, and/or, high benthic mortality indicating high TOC sediment areas are at higher risk likely above the minor adverse effects threshold. The 2014 monitoring showed 97% crab impacts (mortality or tetany), greater than the minor adverse effects threshold. The inability to statistically evaluate the monitoring data because of the lack of power to meet the SMS criterion remains problematic. Additionally, the 2012 benthic monitoring was compromised because detectable concentrations of imidacloprid were found on a control plot following application, invalidating the test assumption that a control is not to be exposed to the chemical of concern.

Ecology's position is that monitoring data gathered by the applicant cannot be used in a benthic abundance test to show that the proposed discharge will not exceed a minor adverse effect to biological resources. Also, that data indicates the proposed discharge would create a violation of WAC 173-204-415(1)(f) which states, "[a]dverse effects to biological resources within an authorized sediment impact zone shall not exceed a minor adverse effects level as a result of a discharge." Coupled with the uncertainty in the use and the toxicity of imidacloprid, the applicant has failed to adequately demonstrate that the proposed discharge will not cause an adverse effect to biological resources per WAC 173-204-420(3). Given the increasing evidence from peer-reviewed scientific literature and from federal and international risk assessments documenting concerns to marine invertebrates from levels of imidacloprid 1/100th or 1% of that proposed for application directly onto marine sediments, Ecology sees no way to reasonably condition a SIZ authorization or NPDES permit that would meet the conditions required to meet SMS.

Response to Comments Regarding Sediment Quality Standards Outside the SIZ - Water

The applicant comments regarding Ecology's conclusions of environmental impacts outside the SIZ for surface water focused on two points. The first point was that the EPA saltwater invertebrate acute and chronic toxicity values provided in the 2017 EPA Risk Assessment for Imidacloprid are not the appropriate values to be used by Ecology. The second point is that spatial averaging and dilution of the pesticide should be taken into account when evaluating results against toxicity values.

Use of EPA Risk Assessment toxicity values

As stated previously in our response regarding the criteria used to evaluate the discharge and the effects to biological resources within the SIZ, the EPA Risk Assessment (2017) endpoints are the current best available science and are relevant to evaluate the biologic impact of the direct application of imidacloprid to marine sediments. Notably, the EPA Risk Assessment (2017) establishes both acute and chronic endpoints for marine invertebrates. The development of draft EPA Risk Assessment acute and chronic endpoints (see table below), as well as Health Canada's endpoints (PMRA 2016), provide vetted surface water criteria in order to determine potential impacts to marine aquatic life related to imidacloprid application.

Table from EPA Risk Assessment (2017), Comparison of Recent Regulatory and Non-Regulatory Aquatic Risk Assessments for Imidacloprid

Endpoint Description	USEPA 2016	PMRA 2016	EFSA 2014	BCS 2016
Freshwater Invertebrates (µg ai/L)				
Acute Endpoint (Basis)	0.39 (Lowest EC50 of 0.77/2)	0.36 (Acute HC5)	0.098 (Acute HC5 of 0.49/5)	1.73 (Acute HC5)
Chronic Endpoint (Basis)	0.01 (Lowest NOAEC)	0.021 (Chronic HC5/2)	0.009 (Chronic HC5 of 0.027/3)	0.039 (Chronic HC5)
Saltwater Invertebrates (µg ai/L)				
Acute Endpoint (Basis)	16.5 (Lowest EC50/2)	1.37 (Acute HC5)	n.d.	n.d.
Chronic Endpoint (Basis)	0.16 (Lowest NOAEC)	0.33 (Lowest NOAEC)	n.d.	n.d.

In summary, the 2014 monitoring data on day zero of imidacloprid application resulted in imidacloprid values on-plot that exceeded the EPA's acute endpoint between 17 to 97 times at all monitoring sites. The 2012 experimental data reported numerous exceedances of over 250 times that of the acute endpoint. Surface water monitoring data from 2012 showed extensive distribution of imidacloprid off-plot at levels that exceed both the EPA Risk Assessment (2017) and Health Canada (PMRA 2016) acute biological endpoint criteria. The 2014 off-plot water quality data is not applicable because a single transect was shown to be inadequate to capturing the extent of off-plot distribution of imidacloprid.

Below are summaries from the FSEIS, Section 3.3.3 Surface Water-Affected Environment, in which levels of imidacloprid found in surface water both on and off-plot are further described.

- Results of the 2012 experimental trials conducted in Willapa Bay documented that concentrations of imidacloprid at more than ten times the EPA acute marine biologic criteria were observed up to 1,575 feet from the edge of the sprayed plots. Overall, imidacloprid was frequently detected off-site in drainage channels and areas covered by

the rising tide, especially in those areas located closest to the treatment plots. Off-plot concentrations were highly variable, ranging from non-detection up to concentrations of 4,200 µg ai/L.
- Surface water data collected during the 2014 trials indicate a pattern of high on-plot and low off-plot concentrations during the first rising tide. For the Cedar River sites, on-plot locations had concentrations up to 1,600 ppb, with an average value of approximately half this amount. Imidacloprid was detected at considerable distances off-plot, but at low concentrations less than 0.55 ppb. These results were based on a single transect of surface water samples and are likely not be representative of off-plot drift. Ecology believes that the 2012 studies are more representative of actual off-plot transport; however, 2014 data confirm a greater distance off-plot for movement of imidacloprid (up to 500 meters) than 2012, although concentrations were lower due to limited spatial sampling.

In conclusion, imidacloprid mixes with the surface water and moves off treated areas with incoming tides and in drainage channels. The data shows movement of imidacloprid to non-treated areas through surface water conveyance, particularly as tide water first passes over off-plot areas, will be at levels which will negatively impact aquatic invertebrates.

Spatial averaging

The applicant commented that Ecology did not present average values of imidacloprid concentrations while focusing on extreme values. Ecology identified average concentrations in the FSEIS. For example, on page 3-22, Ecology stated, "[s]urface water monitoring in 2014 reported an average concentration of imidacloprid of 796 ppb [on-plot], nearly 50 times the EPA acute marine endpoint; although reports of up to 4200 ppb (250 times the EPA endpoint) have been reported (Hart-Crowser 2013)." Further, Inverse Distance Weighing (IDW) was the method used to model the areal extent of off-plot impacts of imidacloprid. IDW is defined in Toxic Cleanup Program's (2017) Sediment Cleanup User's Manual (SCUM II) manual as an "interpolation method[s] with algorithms to interpret the influence of multiple neighboring points, their concentrations, and distances from one another when estimating a value at unsampled locations." As stated in the FSEIS, IDW is "a type of area-weighted averaging GIS tool that uses actual data calculated from monitoring." Thus, IDW is an averaging method weighed by neighboring points to better correlate site geomorphic variability (tidal channels, currents, etc.). The applicant noted that tidal elevations, drainage channels, and other physical factors occur throughout Willapa Bay that directs imidacloprid-laden waters in specific directions. The site variability and preferential flow patterns argue against averaging across spatial areas.

Ecology does not support the applicant's comments regarding averaging imidacloprid concentrations in determining off-plot impacts. The range of concentration measurements defines the breadth of potential exposures on and off-plot; averaging off-plot concentrations does not account for that. In the SMS, chemical toxicants are identified on a point-by-point basis, as invertebrates will be affected by conditions at the particular location where they reside when exposed. Individual invertebrates will come in contact with a specific concentration of imidacloprid when it washes over them. The organisms will be impacted by the imidacloprid concentration at that location, not the average concentration which represents a broader spatial area. Monitoring data indicated multiple off-plot sampling locations with documented levels of imidacloprid in surface water exceeding EPA acute endpoints, during the day of application.

When invertebrates are exposed to levels of imidacloprid several orders of magnitude above the EPA acute endpoint, their systems will be overloaded in short order because imidacloprid irreversibly binds to their receptors, and the individuals will likely suffer toxic effects. Those effects will be either lethal or sub-lethal depending upon the level of contamination at that location.

In conclusion, the impact of the proposed discharge outside the SIZ cannot exceed the Sediment Quality Standards (SQS), which corresponds to a sediment quality that will result in no adverse effects, including no acute or chronic adverse effects on biological resources and no significant health risk to humans, per WAC 173-204-320(1)(a). Ecology's review indicates that the proposed discharge will result in concentrations of imidacloprid at levels that can result in acute or chronic impact to marine invertebrates being carried by surface water up to a quarter mile outside the SIZ. The concentration of off-plot imidacloprid at levels 4 to 250 times that of the EPA acute endpoint indicates that the proposed discharge of imidacloprid will result in concentrations in surface water that will exceed the EPA acute and chronic marine endpoint in areas outside the proposed sediment impact zone. These levels of imidacloprid will result in mortality and/or reduced survival, reproduction, or growth to invertebrates that come into contact with imidacloprid concentrations in these waters. In the context of SMS SIZ standards, individual location measurements are required to evaluate effects on biological resources. Averaging sampling data would still exceed the EPA threshold, by several times, outside the SIZ boundary, but that exceedance would be by a lesser amount. Therefore, even using averaging, the effects of imidacloprid to biological resources outside the proposed SIZ would exceed SQS standards (WAC 173-204-320).

Spatial dilution

Dilution is not adequate to minimize impacts for this proposed discharge because location specific surface water concentrations of imidacloprid exceeds EPA's acute marine endpoint up to 250 times based upon the monitoring data. Since imidacloprid binds irreversibly to receptors, exposing invertebrates to doses many times higher than the acute (i.e., lethal) EPA marine endpoint will cause significant impacts to non-target invertebrates.

Most studies have examined 24 to 96 hour exposure durations at lower doses rather than higher, short-term doses that the applicant is proposing, however, several studies have looked at speed of kill. For example, scientists at Bayer (i.e., the manufacturer of imidacloprid) showed effects occurring after 10 minutes due to dermal uptake of imidacloprid (Everett et al. 2000). Others noted immobility "after a few minutes" (Schott et al. 2017). Technical fact sheets (Gervais et al. 2010) document clinical signs of impacts within 15 minutes. Ecology maintains that the EPA acute and chronic marine criteria represent the current best available science and provide relevant numbers to identify impacts from the proposed imidacloprid application.

Further, the applicant assumes that water free of imidacloprid would be diluting imidacloprid-laden water. However, incoming tidal waters passing over treated plots would continue to transport imidacloprid for an indeterminate time to up-tidal areas. Ecology has already accepted that some dilution has already occurred during collection of water quality monitoring samples. During sampling, the mouth of sampling jars were raised five cm above the sediment surface to collect water samples, therefore not capturing the maximum, initial concentration of the imidacloprid pulse that affects sediment biota. That is, monitoring data underreports the initial doses of imidacloprid that are occurring on and off-plot as collections have already been diluted by some amount before rising to a level to fill the jars.

Finally, monitoring data shows multiple impacts directly resulting from the experimental application of imidacloprid. They include the 2011 failure of the Cedar River site; the 2012 monitoring results showing a high incidence of dead commensal clams; and, the documentation of nearly every Dungeness crab surveyed suffered from tetany or died in the 2014 surveys. This shows that dilution, while occurring, is not enough to avoid impact below a minor adverse effect.

Use of Patten and Norelius 2017 and Dungeness Crab Impacts

The applicant remarked that Ecology does not take into account Patten and Norelius (2017). Ecology included an evaluation of Patten and Norelius 2017 in the FSEIS (Appendix A, page 12). During the development of the DFEIS, the applicant requested the study's inclusion, proposing text. The FSEIS review of this study noted a number of flaws and limitations in the sampling design and its conclusions. Ecology included Patten and Norelius (2017) in the FSEIS determining that Dungeness crab were impacted by imidacloprid, developing tetany which required "exposure to one or two tidal cycles of fresh estuarine water" to recover. When compared with field studies (e.g., the 2014 experimental spray monitoring which identified more than 97% of crabs surveyed being in tetany or dead), Ecology can clearly state that Dungeness crab were negatively affected by imidacloprid application.

On-plot and directly adjacent off-plot impacts were defined by 2014 surveys. Data submitted by the applicant in 2016 showed an exceedance of the SMS regulatory biological effects level demonstrated by the documented rate of juvenile Dungeness crab affected in the 2014 field trials of imidacloprid in Willapa Bay. Data collected at the 90 acre plot treated with imidacloprid in 2014 found 137 dead crab or affected crab (i.e., tetanied) out of a total of 141 crab observed (97%) in and around the edge of the treatment area. That is a rate that exceeds levels that cause more than a minor adverse effect in marine biological resources of the SMS regulations (WAC 173-204-420).

Because the applicant did not collect adequate information off-plot under realistic field conditions, there is considerable uncertainty regarding the extent of off-plot impacts due to the spatially limited data. Results are further complicated since the surveys were performed approximately 24 hours after application. With limited spatial and temporal information, Ecology determined impact near and adjacent to the areas of spray impacts to crab would be unavoidable since imidacloprid drift cannot be controlled.

Summary

Overall, Ecology's position is that the EPA Risk Assessment (2017) toxicity endpoints represent the best available values to be used to compare water column sampling results, and that modifying the water sampling data to account for dilution is not appropriate. The surface water samples incorporate a level of natural dilution caused by the incoming tidewaters at the time of collection. The samples are representative of actual conditions after pesticide application. The current available scientific literature identify both lethal and sub-lethal impacts from doses of imidacloprid to a variety of invertebrates that are exceeded by multiple times the concentrations proposed to be applied.

Response to Comments Regarding Sediment Quality Standards Outside the SIZ - Sediment

The applicant commented that Ecology incorrectly compared porewater data to the EPA Risk Assessment (2017) acute and chronic saltwater toxicity values. Ecology maintains that using EPA saltwater endpoints are reasonable proxies to evaluate potential effects from porewater concentrations of imidacloprid. The applicant states that there is a better way to evaluate the sediment porewater data outside the SIZ and analyzes the 2012 field trial data that included an extensive set of sediment porewater data collected off-plot. The applicant concludes that 97.8% of the off-plot samples were below the EPA acute toxicity criterion one day after imidacloprid application. And 78.6 % of the off-plot porewater samples were below the EPA chronic toxicity criterion 14 days after imidacloprid application. The applicant's analysis offers the best case scenario, which demonstrates that 2.2% of off-plot porewater samples exceeded the EPA acute toxicity criterion 24 hours after pesticide application, and 21.4% of off-plot porewater samples exceeded the EPA chronic toxicity criterion at 14 days after pesticide application.

Ecology noted the applicant's comments acknowledge that in a best case scenario, discharge of imidacloprid would result in a percentage of sediment porewater samples outside the SIZ exceeding the applicable SQS. The SMS requires that a permitting discharge cannot result in any exceedance of the SQS outside of the SIZ, per WAC 173-204-415(1)(i).

Ecology notes that during the 2012 monitoring, at three of five (60%) monitoring locations, imidacloprid was detected in off-plot porewater samples, exceeding both EPA marine biologic endpoints. These off-plot porewater exceedances included use of both granular (Mallet) and liquid (Nuprid) applications methods. This data further substantiates that the proposed application of imidacloprid will result in off-plot impacts.

Ecology recognized in the FSEIS that there are data gaps and uncertainties associated with conclusions about off-plot environmental impacts and would like to offer the following discussion on that topic. The current body of science regarding imidacloprid use has largely focused on spray application of imidacloprid in terrestrial environments that exposes aquatic life through indirect routes such as overspray, surface runoff, and shallow groundwater flow. As stated in Ecology's review of the EPA Risk Assessment (2017), risk quotients were based upon terrestrial agricultural use scenarios. The applicant proposes imidacloprid to be directly applied onto marine sediments, which is likely to exceed both the concentration of imidacloprid modeled, and the temporal aspects of transport from the terrestrial environment to the aqueous environment.

In all cases modeled results would grossly underestimate risk. This is confirmed by EPA's 2013 IR4 Petition for the Use of Imidacloprid on Shellfish Beds in Willapa Bay and Grays Harbor risk assessment (DeCant and Barrett 2013) that examined risk under scenarios identified in the NPDES application, i.e., direct application of imidacloprid to marine sediments. The 2013 risk assessment states, "[t]he use of the flowable and granular formulations presents a risk that exceeds all LOC's at onsite locations on an acute basis for free-swimming invertebrates and benthic invertebrates that inhabit the sediment."

Doses of imidacloprid will be higher in marine waters when applied directly to the sediment as proposed by the applicant than were estimated by the EPA Risk Assessment (2017) modeling scenarios that dealt with indirect entry of imidacloprid from terrestrial application. For all terrestrial application methods (i.e., spray) that lead to indirect entry of imidacloprid to the aqueous environment, the fraction of imidacloprid that makes it into the water is high enough to have a persistent negative impact to aquatic invertebrates.

Although the EPA Risk Assessment (2017) does state, "imidacloprid is unlikely to bioaccumulate in living tissue," this should not be mistaken for cumulative or additive toxicity which may occur. Both Rondeau et al. (2014) and Tennekes and Sanchez-Bayo (2013) describe the molecular relationship of imidacloprid to insect nervous systems. The authors state that neonicotinoid insecticides (e.g. imidacloprid) "bind virtually irreversibly" to receptors in the insect's nervous system. Toxic effects can be "reinforced with chronic exposure." Review of the 2012 imidacloprid experimental trials reported that, "the Cedar River site had 2-5 ppb of imidacloprid bound to sediment at 56 days after treatment, which was the last date monitored."

The 2012 monitoring results for porewater show multiple sites both on and off-plot that had sediment porewater concentrations above the EPA chronic criterion 14 days after imidacloprid application. The 2012 monitoring results show porewater concentrations above the EPA Risk Assessment (2017) chronic marine endpoint at numerous sites 56[1] days post-application. The combined impact of persistent imidacloprid in the biologically active zone is likely to have impacts on growth, reproduction, or other sub-lethal categories which the EPA Risk Assessment (2017) considers biologically relevant. EPA states, "[t]he focus on these effects [survival, growth, reproduction] for quantitative risk assessment is due to their clear relationship to higher-order ecological systems such as populations, communities, and ecosystems." A wide variety of sub-lethal impacts, such as immune suppression, growth, reproduction, molting success, etc., are likely to occur due to exposure to imidacloprid, but they are very difficult to document or measure outside of laboratory conditions. The monitoring results did not examine these aspects, and it cannot be assumed the impacts do not exist simply because they were not measured. The EPA 2017 Risk Assessment states, "**the potential exists for risks to fish indirectly** through reductions in aquatic invertebrates that comprise their prey base" (EPA emphasis). EPA's conclusion is that chronic impacts to invertebrates would migrate through the food chain to important ecological guilds of ecological and economic value such as forage fish, salmonids, and sturgeon. The chronic endpoint proposed by the EPA Risk Assessment (2017) aims to address these impacts.

Ecology notes the applicant's review of the 2012 sediment porewater data. The review provides additional information regarding the failure of control sites in 2012. Not only was the surface water sample contaminated with imidacloprid at the Leadbetter Control site, LC-16, (as described in the SEIS), but sediment porewater at LC-12 was also contaminated with imidacloprid at levels matching the EPA Risk Assessment (2017) chronic marine endpoint. Similarly, imidacloprid was detected in porewater at the control site, PC-12, one day after application. Thus, two separate control sites miles apart from one another confirm that imidacloprid was present on multiple control plots on, and directly after, the day of application. As stated in the FSEIS, "Under Ecology's understanding of the circumstances on this day, imidacloprid should not have been found at this site at this time since it was serving as a control, or no-spray, area for this study… [A] contaminated control sample significantly weakens the validity of the results from this

[1] This is a minimum estimate. The applicant discontinued monitoring at these sites after 56 days; therefore we do not know the full duration that porewater exceeded EPA's chronic marine endpoint at these locations.

experimental trial." Detection of imidacloprid on the control plot violates a critical assumption that there is no exposure to the chemical of concern at the control location of the experiment.

Since imidacloprid was found in the porewater of the control site after it was not found during a pre-application survey, this verifies Ecology's conclusion that imidacloprid moves off site in concentrations which results in exposing aquatic life off-plot to detectable levels of imidacloprid. Additionally, Ecology notes that detection of imidacloprid in control plots in sediment the day after sampling strongly argues against tidal dilution effectively dissipating imidacloprid. Imidacloprid appears to remain in the surface water, exposing control plot (i.e., greater than 500 meters off plot) sediments at concentrations allowing adsorption to levels that are detectable; some exceeding EPA marine endpoints.

In conclusion, the 2012 monitoring of off-plot distribution of imidacloprid provides confirmation that unavoidable off-plot impacts (i.e., impacts outside of the SIZ) will occur in violation of SMS standards WAC 173-204-415(1)(i). The applicant's review confirms that porewater concentrations exceeding EPA's marine and chronic biologic endpoints will occur for both surface water and porewater at the majority of plots where imidacloprid is applied and impacts will occur outside of the SIZ.

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