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Comparison of Aquatic Life Protective Values Developed for Pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Clean Water Act (CWA)

Technical Support Document

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Notices

This draft technical support document, "Comparison of Aquatic Life Protective Values Developed for Pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Clean Water Act (CWA)" presents analyses supporting the EPA's efforts to develop a common approach for assessing potential pesticide toxicity effects under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Clean Water Act (CWA). This document was developed to support an evaluation to assess whether aquatic life benchmarks developed by the Office of Pesticide Programs in support of registration decisions for pesticides under FIFRA are appropriate to serve as CWA aquatic life 304(a)aquatic life values, either as 304(a)(1) recommended criteria or 304(a)(2) informational benchmarks.

This technical support document does not substitute for the CWA or the EPA's regulations; nor is it a regulation itself. The document does not impose legally binding requirements on the EPA, states, tribes, or the regulated community, and might not apply to a particular situation based upon the circumstances.

The EPA may update this document in the future. This document has been reviewed in accordance with EPA policy and approved for publication. Mention of trade names or commercial products does not constitute endorsement or recommendation for use.

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Executive Summary

The U.S. Environmental Protection Agency (EPA) has undertaken an effort to harmonize aquatic effects assessment methods for pesticides to provide a common basis for evaluating the effects of these chemicals on water quality under the Clean Water Act (CWA) and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The EPA previously solicited public input through a public comment period and held national and regional stakeholder meetings early in the process of considering harmonized aquatic effects assessments for pesticides, under a project entitled "OW/OPP Common Effects Methodology" (docket number: EPA-HQ-OPP-2009-0773). In 2012, the FIFRA Scientific Advisory Panel reviewed the EPA analyses regarding potential approaches and made recommendations for the EPA to move toward a harmonized approach under FIFRA and CWA. EPA scientists from both the Office of Water (OW) and the Office of Pesticides Programs (OPP) have worked together to develop the analyses currently being released for public comment. This continued collaborative effort within the EPA ensures development of protective aquatic life values using current science while minimizing duplicative work within the agency and promoting consistency in aquatic effects assessments for pesticides. The EPA evaluated insecticides and herbicides from different chemical classes and with different modes of action to determine whether the OPP aquatic life benchmarks (ALBs) developed in support of registration decisions for pesticides under FIFRA are similarly protective as potential CWA 304(a)(1) recommended criteria, and other criteria-related values, and may thus be appropriate to serve as CWA aquatic life 304(a) aquatic life protective values, either as 304(a)(1) recommended criteria or 304(a)(2) informational benchmarks.

Currently, OPP ALBs and CWA 304(a)(1) recommended Aquatic Life Criteria (ALC) values are developed using parallel, but different, rigorously peer-reviewed methods to generate values protective of aquatic communities for both acute and chronic effects. There are several similarities in the approaches, for example both approaches: 1) use the Office of Research and Development's ECOTOXicology (ECOTOX) Knowledgebase to identify open literature toxicity studies for chemicals, 2) have similar toxicity data quality review approaches, and 3) use the same assessment endpoints including acute survival and chronic survival, growth, and reproductive effects.

The two main differences in the approaches are regarding primary data sources and the methods to calculate protective values. For data sources, OPP ALBs are extracted from the most recent publicly available pesticide ecological risk assessments and largely use registrant-submitted studies supplemented with open literature studies from ECOTOX. CWA 304(a)(1) ALC have historically been developed based on data-quality reviewed, publicly available information primarily collected from ECOTOX to fulfill the eight aquatic taxa minimum data requirements (MDRs) per the *"Guidelines for Deriving Numerical Water Quality Criteria for the Protection of Aquatic Organisms and Their Uses"* (U.S. EPA 1985) ("Guidelines") in addition to high quality, reviewed data collected under FIFRA in the form of registrant-submitted data, when available.

Both the OW ALC and OPP benchmark approaches result in robust aquatic life protective values. In support of pesticide registration decisions under FIFRA, the regulatory thresholds and ALBs are typically based on high quality data for the most sensitive acceptable aquatic plant (vascular and nonvascular), freshwater invertebrate and vertebrate species (acute and chronic data) for each taxon tested. For purposes of implementing section 304(a)(1) of the CWA, ALC recommended values are typically determined by regression analysis based on the four most sensitive genera averages in the data set to calculate the 5^{th} percentile value of the distribution represented by the tested genera averages to determine values estimated to be protective of approximately 95% of aquatic genera.

There are currently 23 pesticides with ALC, more than half of which (15) are for pesticides no longer in commerce. OPP ALBs for pesticides and selected degradates, however, address many of the currently registered pesticides in commerce. Currently, there are over 750 OPP ALBs publicly available.

The EPA investigated several methods to compare OPP ALB to values that the OW has calculated for pesticides based on ALC methods or other criteria-related approaches. The analyses show that OPP ALBs and CWA aquatic life 304(a) values are similar (within a factor of 10). Specifically, case studies for eight pesticides from several classes with existing 304(a)(1) ALC recommendations demonstrate that the most sensitive OPP ALB for a given pesticide is generally somewhat lower (more sensitive) and mostly within a factor of two of its existing 304(a)(1) ALC recommendations. The EPA also conducted analyses comparing the OPP ALBs to criteria-related values for 26 pesticides and 5 herbicides from several different classes derived using conservative methods or safety/assessment factors (*e.g.*, using the Great Lakes Initiative (GLI) approach developed for application in Great Lake states) for when data are limited and MDRs are not met. These analyses also show that OPP ALBs are similar to values (within 5-10X) developed using these criteria-related approaches applied when toxicity data are limited. This range in values is approximately the same as the inherent variability observed in repeated toxicity tests on a single species conducted within the same laboratory or across laboratories (Chapman 1998; Duke and Taggart 2000; Fairbrother 2008; Raimondo *et al*. 2007; Raimondo *et al*. 2010). These draft analyses support the conclusion that the OPP ALBs are similarly protective and appropriate for use in establishing CWA aquatic life 304(a) protective values for pesticides.

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1 Overview of the EPA Effort to Harmonize Pesticide Aquatic Effects Assessments

The Environmental Protection Agency's (EPA) objective for this effort is to harmonize aquatic effects assessment methods to provide a common basis for evaluating the effects of pesticides on water quality under the Clean Water Act (CWA) and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). This collaborative effort within the EPA ensures development of protective aquatic life values using current science while minimizing duplicative work within the agency and promoting consistency in aquatic effects assessments for pesticides. The analyses presented in this document support leveraging the most sensitive Aquatic Life Benchmarks (ALB) developed by the Office of Pesticide Programs (OPP) in support of registration decisions for pesticides as CWA aquatic life 304(a) protective values, either as 304(a)(1) recommended criteria or 304(a)(2) informational benchmarks. Case studies for select insecticides and herbicides from different chemical classes and with different modes of action described in this document demonstrate that the EPA's process used to develop OPP ALBs generates protective values for registered pesticides and would be equivalent to values developed as CWA 304(a)(1) ALC if sufficient data were available to fill the eight minimum data requirements (MDRs) and generate criteria using the Agency's traditional criteria development approach (U.S. EPA, 1985).

2 The EPA Methods for Aquatic Effects Assessments for Pesticides

2.1 Background

To develop aquatic effects assessments under the CWA and FIFRA, the EPA uses parallel but different rigorously peer-reviewed methods to generate protective values for both acute and chronic effects. Currently, EPA has derived national recommended 304(a)(1) Ambient Water Quality Criteria for the protection of aquatic life ("Aquatic Life Criteria" or ALC) for 23 pesticides[1]. For FIFRA purposes, the EPA assesses potential ecological risks of pesticides considering both terrestrial and aquatic effects data, including data underlying the ALBs, combined with exposure modeling and monitoring data. OPP ALBs are used by states and other stakeholders to evaluate water monitoring data and prioritize resources with respect to priority pollutants to ensure protection of aquatic life. The EPA currently has over 750 registered pesticides and selected degradates with at least one OPP ALB (*i.e.*, freshwater or estuarine/marine vertebrate acute and chronic, freshwater or estuarine/marine invertebrate acute and chronic, vascular aquatic plants acute and chronic, or nonvascular aquatic plants acute and chronic) along with a link to the relevant Agency action (*e.g.*, ecological risk assessment)[2].

2.2 Similarities Between OPP and OW Approaches

There are many similarities in the OPP and OW approaches to generate values protective of aquatic communities. First, both approaches rely on the EPA Office of Research and Development (ORD) Ecotoxicology (ECOTOX[3]) Knowledgebase to identify and collect open literature toxicity studies for

[1] See EPA's Aquatic Life Criteria table at https://www.epa.gov/wqc/national-recommended-water-quality-criteria-aquatic-life-criteria-table.

[2] See EPA's Aquatic Life Benchmarks at https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/aquatic-life-benchmarks-and-ecological-risk.

[3] ECOTOX (https://cfpub.epa.gov/ecotox/) is a publicly available database summarizing the ecological effects of single chemicals to aquatic and terrestrial plants and animals. ECOTOX was developed by EPA's Office of Research and Development's Mid-Continental Ecology Division (ORD/MED), which routinely conducts literature searches for pesticides undergoing Registration Review as well as for litigation-related endangered species assessments.

chemicals. Relevant literature for ECOTOX is retrieved using a comprehensive search strategy designed to locate literature worldwide on the toxicity of chemicals to a wide range of aquatic animal and aquatic plant species. ECOTOX also includes unpublished registrant-submitted data in response to FIFRA testing requirements for many chemicals. Second, the data quality review approaches for toxicity data have been harmonized for FIFRA and CWA aquatic effects assessments. For FIFRA assessments, similar to registrant-submitted studies, data identified in the open literature undergo review as specified in 2011 OPP guidance document entitled *Evaluation Guidelines for Ecological Toxicity Data in Open Literature*[4] to ensure they are consistent with standards specified in the Information Quality Act and subsequent guidelines developed by the Office of Management and Budget (OMB) on ensuring and maximizing the quality, objectivity, utility and integrity of information disseminated by federal agencies[5]. For ALC, the EPA reviews studies identified in the open literature according to its *Standard Operating Procedures for Systematic Review of Ecological Toxicity Data*[6], which is consistent with the data quality review procedures in the *Guidelines for Deriving Numerical National Water Quality Criteria for the Protection of Aquatic Organisms and their Uses*[7] (referred to as the "Guidelines"; U.S. EPA 1985) and subsequent harmonization with FIFRA procedures. Lastly, the same assessment endpoints are used under both statutes, and typically include acute survival and chronic survival, growth and/or reproductive effects.

2.3 Differences Between OPP and OW Approaches

There are two main differences in the OPP ALB and OW ALC approaches to generate protective values regarding data sources and the methods to calculate protective values.

Data Sources: Under FIFRA, primary data sources are registrant-submitted studies in response to data requirements identified in Title 40, Part 158 of the Code of Regulations (40CFR158)[8]. These studies are conducted under rigorous Good Laboratory Practice (GLP) standards as specified in 40CFR160[9]. The studies undergo extensive review and analysis by the EPA; these reviews are captured in data evaluation records (DERs), and the results of these unpublished[10] studies are subsequently captured in ECOTOX. In addition, open literature studies identified in ECOTOX are used that meet the standards specified by OMB regarding data quality using protocols identified in the EPA guidance[11]. Typically, the EPA uses ECOTOX to identify whether more sensitive toxicity endpoints are available than those derived from registrant-submitted studies. Similar to registrant-submitted studies, DERs are compiled for open literature studies as well.

Unlike FIFRA, the CWA does not give the EPA authority to require collection of test data (*i.e.*, issue data call-ins) to ensure that toxicity data are available to fulfill the MDRs for establishing ALC (U.S. EPA, 1985). The EPA has historically developed ALC for pesticides using registrant-submitted test data under FIFRA and publicly available open literature provided through ECOTOX. The EPA reviews the studies obtained

[4] https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/evaluation-guidelines-ecological-toxicity-data-open
[5] https://obamawhitehouse.archives.gov/sites/default/files/omb/fedreg/reproducible2.pdf
[6] https://www.epa.gov/wqc/aquatic-life-criteria-and-methods-toxics#sop; (U.S. EPA 822-R-24-008)
[7] https://www.epa.gov/sites/default/files/2016-02/documents/guidelines-water-quality-criteria.pdf
[8] https://ecfr.io/Title-40/sp40.26.158.g
[9] https://ecfr.io/Title-40/pt40.26.160
[10] Because of confidential business information (CBI) and other protections set forth in FIFRA Section 10, the actual studies containing raw data are not public.
[11] https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/evaluation-guidelines-ecological-toxicity-data-open

in the open literature based on the Office of Water's *Standard Operating Procedures for Systematic Review of Ecological Toxicity Data* and these reviews are captured in OW DERs, for acceptability review before use in ALC.

Effects Assessments and Protective Value Development: Under FIFRA, the EPA typically bases its regulatory thresholds and benchmark values on the most sensitive tested species as described in the 2004 *Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs*[12] ("Overview Document"). These values are frequently based on standardized test guidelines that are generally intended to meet toxicity testing requirements under FIFRA. For evaluating acute aquatic effects on freshwater taxa to make regulatory judgments under FIFRA, the EPA generally requires testing on one warm water fish, one cold water fish, and one aquatic invertebrate. Data are also required on aquatic vascular and multiple species of non-vascular plants. For evaluating chronic effects, the EPA requires chronic toxicity data for a freshwater fish and an invertebrate; ideally the species tested in the chronic toxicity tests should have corresponding acute toxicity data. Estuarine/marine (saltwater) test requirements include acute toxicity studies of a single fish and several invertebrates (crustacean; mollusc); estuarine/marine chronic toxicity tests are conditionally required depending on how the chemical is used. Depending on chemical/physical characteristics of a compound, the EPA conditionally requires subchronic and chronic toxicity testing of benthic freshwater and estuarine/marine invertebrates. As noted in the regulations, data routinely required under Part 158 may not always be sufficient to assess whether there are unreasonable adverse effects on the environment. Therefore, the Agency retains the right to call-in additional data to inform its regulatory decisions. FIFRA section 3(c)(2)(B) provides authority to issue data call-ins for additional information needed to support a registration. Also, under 40 CFR Part 158.30(b) and 40 CFR Part 158.75, the EPA may require additional information to better characterize the potential risks.

To develop ALC recommendations under section 304(a) of the CWA, the EPA typically generates a sensitivity distribution of genus average data of publicly available, high-quality data to estimate values protective of approximately 95% of aquatic genera, following the methods described in the Guidelines. For evaluating acute effects on freshwater taxa, the Guidelines approach recommends eight MDRs: three vertebrates (a salmonid, another bony fish, and an amphibian or another family of fish), five invertebrates (a planktonic crustacean, a benthic crustacean, an insect, a species from a phylum other than Chordata or Arthropoda, and a species from another order of insect or another phylum not already represented). Chronic and estuarine/marine test requirements are of similar scope with different test species.

2.4 Overview of the EPA OPP Aquatic Life Benchmarks

The EPA regulatory decisions related to pesticides under FIFRA consider both terrestrial and aquatic effects data, including those data underlying OPP ALBs, combined with exposure modeling and monitoring data in a comprehensive risk assessment. OPP ALBs are developed using toxicity values based on registrant-submitted scientific data as well as scientifically defensible acute and chronic aquatic life toxicity tests available in the open scientific literature that are reviewed by the EPA and used in the Agency's most recent publicly available ecological risk assessments for new pesticide registrations, risk assessments for currently registered pesticides, or in preliminary Problem Formulations written in support of the OPP Registration Review process[13].

[12] https://www.epa.gov/sites/default/files/2014-11/documents/ecorisk-overview.pdf
[13] https://www.epa.gov/pesticide-reevaluation/registration-review-process

For conventional pesticides, the EPA reviews studies according to criteria outlined in Standard Evaluation Procedure manuals and testing methods (*e.g.*, OCSPP Test Guidelines and Organization for Economic Cooperation and Development (OECD) Test Guidelines and Guidance Documents[14]) accepted by the scientific community and determines if they are acceptable for use in the regulatory process. This determination is based on the design and conduct of the experiment from which the data were derived, and an evaluation of whether the data fulfill the purpose(s) of the data requirement. In evaluating experimental design, the EPA considers whether generally accepted methods were used, sufficient numbers of measurements were made to achieve statistical reliability, and suitable controls were built into all phases of the experiment. In an effort to reduce duplicative testing and to create a framework for sharing of data, the OECD member countries have agreed that tests conducted in accordance with OECD Test Guidelines[15] and principles of GLP in one country must be accepted by other OECD countries for assessment purposes through the Mutual Acceptability of Data[16] agreement.

The EPA evaluates the conduct of each study in terms of whether it was conducted in conformance with the design, good laboratory practices (GLP as described in the 40CFR160) were observed, and results are reproducible. Scientifically sound studies that meet guideline specifications are classified as "acceptable" and can be used quantitatively to derive regulatory thresholds and fulfill testing requirements as specified in 40CFR158 §158.70. Studies that are scientifically sound but do not meet guideline specifications are classified as supplemental. Depending on the extent to which a study deviates from guideline specifications, it may be used quantitatively to derive risk estimates or used qualitatively to provide supporting evidence for the quantitative regulatory thresholds derived from studies classified as acceptable. Studies that are not considered scientifically sound are classified as "invalid" and have no utility in assessing toxicity or risk.

Under FIFRA, as amended, the EPA is required to review currently registered pesticides (*i.e.*, Registration Review) on a 15-yr cycle to ensure that data meet current testing requirements and to ensure that pesticides can continue to be used without causing unreasonable risks to human health and the environment. Also, if new uses of registered pesticides are proposed, then the pesticide is evaluated to determine whether the data are sufficient to support the new use as specified in the 40CFR158. As a result, regulatory thresholds (*i.e.*, benchmarks) may change as additional data are identified. Also, as new pesticides are approved by EPA, new regulatory thresholds are added to the OPP ALBs. The EPA's goal is to update these benchmarks and assessments on an annual basis.

OPP ALBs developed for ecological risk assessments are regulatory threshold concentrations below which pesticides are not expected to harm aquatic life and are considered by the EPA to be protective of community-level effects. The EPA may further refine risk assessments for federally listed threatened and endangered species assessments under the Endangered Species Act (ESA) based on the full distribution of toxicity data for a given genus, using point estimates, species sensitivity distribution approaches, or probabilistic methods. At a minimum, benchmarks are based on the single most sensitive quantitative

[14] OECD Guidelines for the testing of chemicals are a collection of the most relevant internationally agreed testing methods used by governments, industry and independent laboratories to assess the safety of chemicals. They are primarily used in regulatory safety testing and subsequent chemical notification and registration. The set of Test Guidelines is updated on a regular basis to keep pace with progress in science and countries' regulatory needs. OECD-wide networks of national coordinators and national experts provide input from scientists in government, academia, and industry. https://www.oecd.org/chemicalsafety/testing/oecd-guidelines-testing-chemicals-related-documents.htm

[15] https://www.oecd-ilibrary.org/environment/oecd-guidelines-for-the-testing-of-chemicals-section-2-effects-on-biotic-systems_20745761

[16] https://www.oecd.org/chemicalsafety/testing/mutualacceptanceofdatamad.htm

endpoint from the freshwater invertebrate and vertebrate data sets to calculate respective freshwater invertebrate and vertebrate acute and chronic benchmarks. Benchmarks are also identified for vascular and non-vascular aquatic plants. In the majority of cases, ecological risk assessments rely on a suite of registrant-submitted standardized toxicity tests with aquatic vascular and non-vascular plants and acute and chronic toxicity studies conducted with freshwater fish and invertebrates. These studies are performed on a limited number of species (one warm water fish and one cold water fish, and one freshwater invertebrate, and aquatic vascular and non-vascular plants, as noted above) intended to be representative of a broader number of taxonomic groups. However, in addition to data required to support the registration of a pesticide, open literature studies are identified through ECOTOX. In situations where additional data are available, decisions are made regarding the quality and utility of such information for use in assessing ecological risks (*e.g.*, a review of the validity and reliability of study protocols), which is consistent with the Agency's risk assessment and open literature guidance documents. The extent to which such additional data are either employed or rejected is described through a transparent, concise review (*i.e.*, DER).

Acute toxicity benchmarks rely on regression-based median lethal or median effect concentrations (*i.e.*, LC_{50} or EC_{50} values) where the measurement endpoint is typically lethality. Chronic benchmarks are based on hypothesis-based testing to identify no-observed adverse effect concentrations (NOAECs) where the measurement endpoint may be lethality (*i.e.*, impaired survival), growth and/or reproduction. While 95% confidence intervals are typically available for the regression-based endpoints, similar measures of dispersion are not typically available for NOAECs, and the nature of the effect and its magnitude (*i.e.*, percent of impairment relative to controls) at the statistically significant ($p<0.05$) lowest observed adverse effect concentration (*i.e.*, LOAEC) can vary widely. The variability of chronic NOAEC values within and across species is in part due to the spacing between test concentrations, differences in the duration of exposure, and differences in the measurement endpoint (*i.e.*, survival versus growth versus reproduction).

OPP ALBs are derived by multiplying the most sensitive toxicity values (*i.e.,* the lowest acceptable toxicity value for the most sensitive species within a taxonomic group) by their respective non-listed species Level of Concern (LOC) ratio. These LOCs are used by EPA to indicate potential risk to non-target organisms from the use of pesticides and the need to consider regulatory action. The LOC differs according to taxon and exposure duration (*i.e.*, acute versus chronic):

- Acute risk LOC of 0.5 is based on LC_{50} or EC_{50} data for acute effects for aquatic animals (this is the same as the OW factor of 2 applied to the Final Acute Value; the effect of which is to adjust the acute median lethal concentration to a minimum effect level in the range of acceptable control mortality);
- Chronic risk LOC of 1.0 based on NOAEC data for chronic effects for all animals (same adjustment factor under CWA acute ALC); and,
- Aquatic plant risk LOC of 1.0.

As noted, the OPP ALBs represent a threshold below which exposure to that pesticide would not be considered to represent a risk of concern for non-listed species. Although the acute toxicity values for aquatic animals are typically based on studies ranging in duration between 48 and 96 hours, for risk assessment purposes, the toxicity values for aquatic plants and the acute toxicity values for aquatic animals are compared to peak exposure values whereas chronic toxicity values for aquatic animals are typically compared to 21-day and 60-day exposure estimates for invertebrates and fish, respectively. As discussed in the 2014 Overview Document, the EPA is also responsible for assessing potential risk to federally listed threatened or endangered species and their designated critical habitat. Under Section

7(a)2 of the ESA, federal agencies are required to consult with the U.S. Fish and Wildlife Service and/or the National Marine Fisheries Service (collectively referred to as the "Services") to ensure that actions they fund, authorize, permit, or otherwise carry out will not jeopardize the continued existence of any listed species or adversely modify designated critical habit. For the EPA, the actions under FIFRA include the registration and registration review of pesticides. When assessing effects to listed species, the EPA uses a different process to evaluate potential impacts to individuals or populations of listed species. It may use lower, more conservative, LOCs to identify potential effects to individual listed species and/or alternative toxicity thresholds to identify potential impacts to populations of species. The EPA also evaluates potential effects to a species' habitat or food sources, which may also involve developing toxicity thresholds for these types of effects. The intent is to avoid jeopardy to the population and/or adverse modification of designated critical habitat and to formally consult with the Services in situations where there is a likely to adversely affect (LAA) determination.

2.5 Overview of the EPA CWA National Recommended 304(a)(1) Aquatic Life Criteria

The EPA typically uses the approach laid out in the Guidelines to develop national recommended 304(a) ALC. The Guidelines specifies a general assessment goal of "protection of aquatic organisms and their uses" that includes in part "prevention of unacceptable long-term and short-term effects" on aquatic species assemblages and important aquatic species. Similar to aquatic assessments under FIFRA, ALC consist of two sets of values intended to be protective of aquatic life, acute and chronic criteria. To develop ALC, the EPA reviews studies according to its *Standard Operating Procedures for Systematic Review of Ecological Toxicity Data* (https://www.epa.gov/system/files/documents/2024-09/eco-data-quality-systematic-review-sop-and-ders.pdf), which reflects the Guidelines data quality review procedures and harmonization with procedures under FIFRA, as noted above. Acute criteria, or Criterion Maximum Concentrations (CMCs), are intended to protect against acute effects from short-term exposures. Chronic criteria, or Criterion Continuous Concentrations (CCCs), are intended to protect against chronic effects on survival, growth, and reproduction that occur from longer-term exposure. The criteria include three parts: a) chemical concentration, or magnitude; b) limitations on acceptable duration of exposure; and c) limitations on frequency of allowable exceedance of the specified concentration.

The EPA's Guidelines provide that other scientifically-defensible approaches and data may be used contingent on the nature of the chemical and other factors (*e.g.*, the dominant route of exposure). Consideration of MDRs can be adjusted in the problem formulation phase of the evaluation, based on best professional judgement and data availability. In more recent ALC (2012 onward), a specific discussion of available acute and chronic data on endangered and threatened species or closely related surrogates is discussed in the criteria document. Surrogate species are the most phylogenetically-related taxonomic level possible to account for the anatomical and physiological traits conserved across taxa that influence species and taxa sensitivity to a pollutant. The EPA consults with the Services on EPA's approval of state water quality standards that may affect listed species on a state-by-state basis under CWA section 303(c).

2.5.1 Acute Criteria

The Guidelines recommends ALC be developed using acute toxicity data for a minimum of eight family MDRs with the intention of encompassing varied chemical sensitivities across organisms present in aquatic ecosystems. The eight MDRs for freshwater ALC include: 1) a salmonid; 2) a second fish family in the class Osteichthyes; 3) a third chordate family; 4) a planktonic crustacean; 5) a benthic crustacean; 6) an insect; 7) a family in a phylum other than Chordata or Arthropoda; and 8) a family from any insect

order or phylum not represented. The eight MDRs for the development of estuarine/marine ALC are: 1 and 2) two families in the phylum Chordata; 3) a family in a phylum other than Arthropoda or Chordata; 4) either the Mysidae or Penaeidae family; 5, 6, and 7) three other families not in the phylum Chordata (may include Mysidae or Penaeidae, whichever was not used above); and 8) any other family.

For an acute criterion, or CMC, the four genus mean values nearest to the 5th centile of the sensitivity distribution are used to calculate the Final Acute Value (FAV). The criteria calculation is conducted using a censored log-triangular distribution that accounts for the number of genera for which there are data. The use of the factor of two to reduce the FAV to the acute criterion is based on analysis of 219 acute toxicity tests on a range of chemicals, as described in the *Federal Register* on May 18, 1978 (43 FR 21506-18). For each of these tests, mortality data were used to determine the highest test concentration that did not cause mortality greater than that observed in the control for that particular test, which would be between 0 and 10% for an acceptable acute test. This analysis was re-analyzed by the EPA recently with the addition of new data, yielding the same general conclusion (U.S. EPA 2014). Thus, dividing the LC_{50}-based FAV by two decreases potential acute effects to a level comparable to control mortality levels. Therefore, the acute criterion is expected to protect 95% of genera in aquatic ecosystems from acute effects.

2.5.2 Chronic Criteria

When chronic values are available for the minimum eight families, the Final Chronic Value (FCV) is calculated by developing a genus sensitivity distribution in the same manner as for the FAV using the four GMCVs nearest to the 5th centile of the sensitivity distribution. The chronic values are currently typically based on 20% to 10% effect levels (*e.g.*, EC_{20} to EC_{10}) on survival, growth, or reproduction. Chronic toxicity tests used in criteria calculations generally range from one to two months in duration. If chronic values are not available for genera within eight families, but are available for at least one fish, one invertebrate, and one acutely sensitive species, then the chronic criteria may be calculated by dividing the FAV by a final acute-to-chronic ratio (FACR), based on the available paired acute and chronic values. The FCV is equal to the chronic criterion (CCC). Similar to OPP ALBs there is no additional factor applied because the genus mean averages are based on low effect levels, EC_{10} or EC_{20}.

Lastly, if the FAV and/or the FCV calculated following the Guidelines approach is not determined to be protective of a commercially or recreationally important species, the FAV and/or the FCV can be lowered to address the acute or chronic species mean value for that species, applying the duration and frequency criteria components as described above.

2.5.3 ALC Duration and Frequency Aspects

Duration recommendations for ALC are typically based on assumptions described in the Guidelines, with one hour being the typical acute criteria duration and four days the typical chronic criteria duration for water column-based criteria. The duration and frequency components of ALC are intended to ensure adequate protection of aquatic life, by establishing limits for exposures at criteria concentrations (magnitudes).

One-hour acute criteria are typically based on 48- and 96-hour toxicity test results, for invertebrates and vertebrates, respectively, the same general toxicity test designs used in FIFRA tests. The one-hour average duration for acute criteria was specified in the Guidelines because some substances can cause toxicity rapidly, noting that “one hour is probably an appropriate averaging period because high concentrations of some materials can cause death in one to three hours. Even when organisms do not die within the first hour or so, it is not known how many might have died due to delayed effects of this short of an exposure.”

Four-day chronic criteria values are typically based on 20- to 60-day toxicity tests, for invertebrates and vertebrates respectively, the same toxicity test designs used in FIFRA tests. The Guidelines state that an averaging period of four days was appropriate for use with the chronic criterion because for reasons including that "for some species it appears that the results of chronic tests are due to the existence of a sensitive life stage at some time during the test, rather than being caused by either long-term stress or long-term accumulation of the test material in the organism." This four-day duration component of the chronic water column criterion is also consistent with U.S. EPA (1991) which describes how National Pollutant Discharge Elimination System (NPDES) permit limits are derived and considers the default four-day chronic averaging period as "the shortest duration in which chronic effects are sometimes observed for certain species and toxicants." In conclusion, four-day averaging "should be fully protective even for the fastest acting toxicants." Thus, the EPA typically recommends four-day averaging periods for chronic ALC. (There are two exceptions: recently updated ALC for ammonia and selenium have longer recommended chronic water column criterion duration periods to reflect the behavior of these specific chemicals in organisms and the environment).

The frequency component of criteria has remained the same across all water column ALC, with criteria recommended not to be exceeded more than once in three years. The rationale behind the frequency component of criteria is based on the recovery of the aquatic ecosystem after an exceedance event based on an analysis of published studies.

3 Examination of Potential Approaches for Harmonizing OPP Benchmarks and CWA Section 304(a) Effects Assessment Methods for Pesticides

The current effort to harmonize effects assessments under FIFRA and CWA section 304(a) for pesticides compares the relative magnitude of values derived by OPP in support of registration decisions for pesticides under FIFRA and CWA ALC (or similar criteria-related values). The EPA examined the values resulting from the different approaches that have enough data to develop both OPP ALBs and ALC for the same pesticide. In addition, the EPA investigated two approaches for creating criteria-related values when data are insufficient to develop ALC and compared these values to OPP ALBs. The Guidelines describe the methodology the EPA has traditionally used for deriving aquatic life water quality criteria (also referred to as the Tier I approach) (U.S. EPA. 1985, 40CFR132, Appendix A).

3.1 Comparison of OPP Aquatic Life Benchmarks and CWA Aquatic Life Criteria for Pesticides

3.1.1 Acute Value Comparison

There are eight currently registered pesticides with separate acute ALC and OPP ALBs (*i.e.*, acrolein, azinphos methyl [guthion], carbaryl, chloropyrifos, diazinon, lindane, malathion, and pentachlorophenol). For these eight pesticides, OPP ALBs have been updated more recently than ALC. In seven out of the eight examples, acute ALC values are similar to (acrolein) or higher than the acute OPP ALBs (carbaryl, chloropyrifos, diazinon, lindane, malathion, and pentachlorophenol) (**Table 3.1**). The exception was azinphos methyl (guthion), which has an ALC that is lower than the OPP ALBs; however, this ALC was developed using an approach that pre-dates the Guidelines methodology. The ALC and OPP ALB for these eight pesticides are on average within a factor of two in these examples with the exception azinphos methyl (guthion) (8x) which was not derived following the Guidelines methods, as noted.

Figure 3.1 illustrates a comparison of the outcomes of OW and OPP methodologies and resulting acute values for diazinon, a data-rich organophosphate pesticide. To derive acute ALC, genus averages of toxicity tests (GMAVs) are ordered from most sensitive to least sensitive and the Guidelines algorithm (regression) is used to develop the final acute value based on the acute LC_{50} data. The final acute value is

then divided by two to yield the acute criterion value. The acute OPP ALB is derived by identifying the lowest species toxicity text (by taxon) and dividing that by two. In general, the resulting OPP ALB is somewhat lower than the ALC, because the lowest toxicity test used in deriving the OPP ALB is typically averaged with other toxicity tests for the same genus in calculating the ALC. However as noted above, the fold-difference between OPP ALB and ALC is within the typical variability observed in laboratory toxicity tests. For diazinon, the OPP ALB is lower than the ALC because the most sensitive toxicity test is one of 24 toxicity tests that are averaged together to derive the lowest genus average (GMAV).

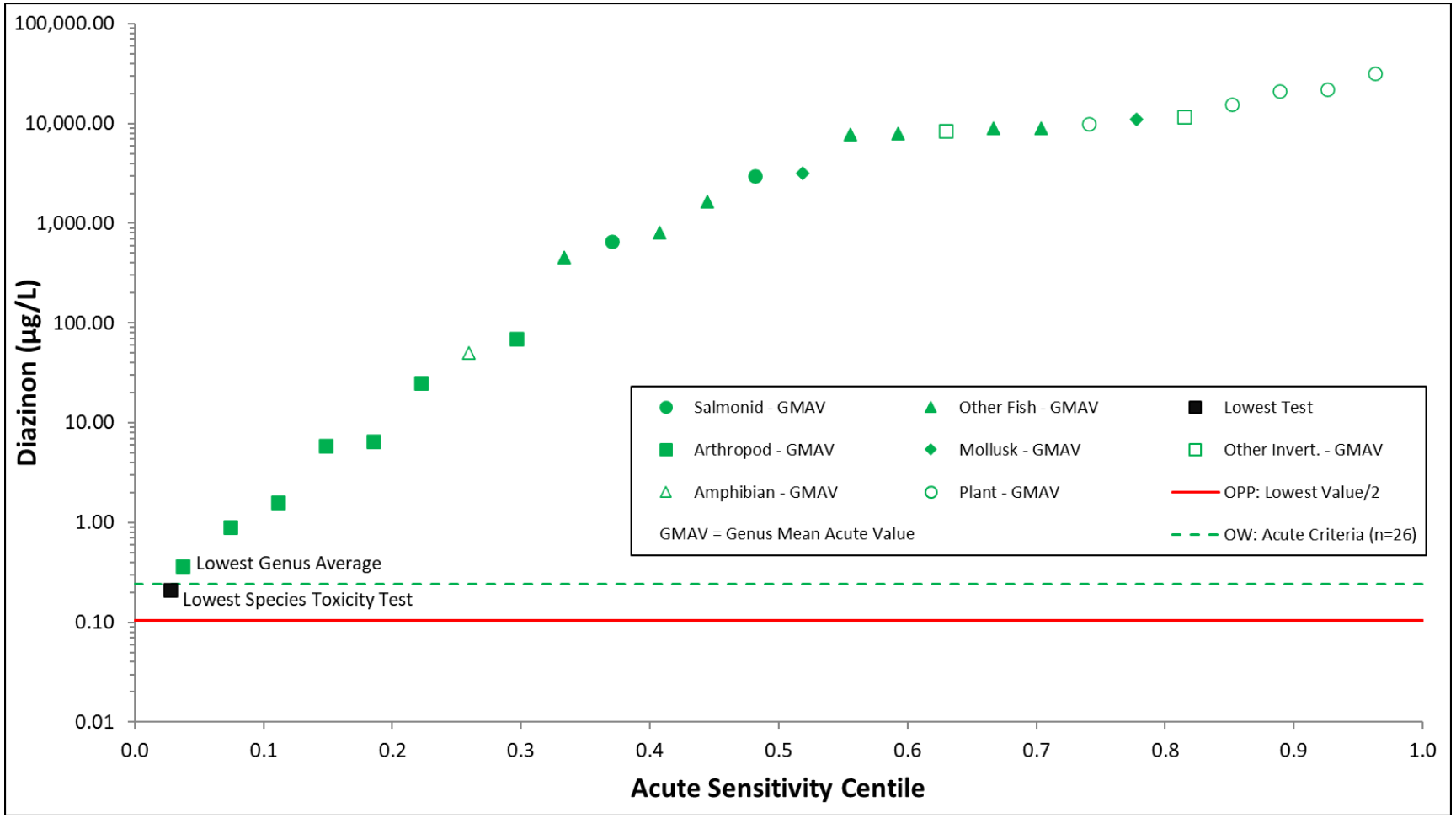

Figure 3.1: Comparison of OPP and OW acute effects assessment method for diazinon, a data rich organophosphate insecticide.
OW-generated values shown in **green** (genus averages in **green** boxes, criteria value is **green** dotted line.) OPP-generated values are **black** square (lowest toxicity test) and associated OPP ALB (**red** solid line). Note: The lowest species toxicity test (OPP approach) is one of 24 tests making up the lowest genus average (OW approach).

3.1.2 Chronic Value Comparison

There are five currently registered pesticides with separate chronic ALC and OPP ALBs (*i.e*., acrolein, carbaryl, chloropyrifos, diazinon, and pentachlorophenol). Azinphos methyl (guthion), lindane, and malathion have acute OPP ALBs and ALC but no chronic ALC. As with the acute values, OPP ALBs have been updated more recently than ALC. In four out of the five examples ALC values are the same as (diazinon and chlorpyrifos) or higher than OPP ALBs (*i.e*., chronic ALC are somewhat higher for carbaryl, chloropyrifos, and pentachlorophenol) (**Table 3.1**). The chronic ALC is lower than the OPP ALB only for acrolein where an Acute-to-Chronic Ratio (ACR) was used to derive the chronic ALC because of data limitations whereas the OPP ALB uses the most sensitive NOAEC. The factor difference between the ALC and OPP ALBs in these examples is less than 4X. This larger fold-difference for some chronic criteria compared to the acute criteria is due in part to the use of NOAECs in OPP ALB value calculations, while for CWA ALCs the EC_{20} or maximal acceptable toxicant concentration (MATC) has generally been used in the past in chronic criteria development. (For acute values the OPP ALB and ALC are based on the same effect metric, LC_{50}.)

In summary, there are limited examples to compare both chronic ALC and OPP ALBs for the same pesticide. However, in most cases where there was sufficient data and current OW methodology (*i.e.,* Guidelines) was used to derive the chronic criteria, chronic OPP ALBs were similar to or slightly lower than chronic ALC. Generally, the relative difference between the OPP ALB and ALC values were within a factor of approximately 2X across all acute and chronic criteria with Guidelines-based ALC.

Table 3.1. Comparison of the EPA's Acute and Chronic CWA Aquatic Life Criteria (ALC) and OPP Aquatic Life Benchmarks (ALB).

Pesticide	ALC date	ALB date	Acute ALC (µg/L)	Acute ALB (µg/L)	Ratio ALB/ALC (acute)	Chronic ALC (µg/L)	Chronic ALB (µg/L)	Ratio ALB/ALC (chronic)
ALC derived using Guidelines methodology								
acrolein	2009	2016	3	3.5 [v]	1.2X OW≈OPP	3	7.1 [i]	2.4X ALB > ALC
carbaryl	2012	2022	2.1	0.85 [i]	0.40X ALC > ALB	2.1	0.5 [i]	0.24X ALC > ALB
chlorpyrifos	1986	2022	0.083	0.05 [i]	0.60X ALC > ALB	0.041	0.04 [i]	0.96X OW≈OPP
diazinon	2005	2016	0.17	0.105 [i]	0.62X ALC > ALB	0.17	0.17 [i]	OW=OPP
lindane	1995	2016	0.95	0.5 [i]	0.52X ALC > ALB	NA	2.9 [v]	No ALC
pentachlorophenol	1995	2020	19 [1]	7.4 [v]	0.39X ALC > ALB	15 [1]	6.9 [i,1]	0.46X ALC > ALB
ALC derived using pre- Guidelines methodology								
azinphos methyl (guthion)	1986	2016	0.01	0.08 [i]	8X ALB > ALC	NA	0.25 [i]	No ALC
malathion	1986	2016	0.1	0.049 [i]	0.49 ALC > ALB	NA	0.06 [i]	No ALC

[v] Vertebrate value is the most sensitive ALB

[i] Invertebrate value is the most sensitive ALB

[1] ALC at pH 7.8

3.2 Comparison of OPP Aquatic Life Benchmarks and Alternative Criteria-Related Approaches When Data are Insufficient to Develop Aquatic Life Criteria

To examine harmonizing approaches when there are not enough data to develop ALC according to a strict adherence to the Guidelines approach, the EPA explored two alternative approaches for deriving criteria-related values to compare with OPP ALBs: 1) the Great Lakes Initiative (GLI) approach to develop Tier II values (U.S. EPA 1995), and 2) modified Guidelines methods for criteria development for pesticides when MDRs are not met. For information related to the derivation of the alternative approaches, see the document "Supporting Information for Comparison of OPP Aquatic Life Benchmarks, OW Aquatic Life Criteria and Alternative Criteria-Related Approaches When Data are Insufficient to Develop Aquatic Life Criteria."

3.2.1 Overview of Great Lakes Initiative Approach to Develop Criteria-Related Values to Compare to OPP ALBs

In 1995, as part of the Great Lakes Initiative (GLI), the EPA published an alternate method, called Tier II benchmarks (U.S. EPA 1995, 40 CFR Part 132 Appendix A), for deriving aquatic life protection values for Great Lakes states using assessment (or safety) factors for chemical pollutants when the Guidelines MDRs are not met. These Tier II values are protective aquatic life values that are expected to be equal to or below ALC values calculated using the Guidelines MDRs.

When fewer than eight MDRs are fulfilled, a GLI Tier II acute Secondary Maximum Concentration (SMC) can be calculated using the lowest genus mean acute value (GMAV) adjusted by an assessment factor (or Final Acute Value Factor; FAVF) to account for uncertainty due to missing data. Lower extrapolation factors correspond to datasets with higher numbers of MDRs fulfilled (**Table 3.2**). This value is then divided by two to derive the SMC. In addition, the GLI Tier II methodology specifies that datasets must at least contain acute toxicity data for a genus in the family Daphnidae. FAVFs are intended to be conservative.

FAVFs for a given chemical were calculated by first constructing 199 datasets of multiple minimum data sets (n=8) from all acceptable acute data for that chemical. Each value in a dataset represented a randomly sampled EC/LC_{50} for each of the eight MDR families described in the Guidelines. Final Acute Values (FAVs) were calculated for each of the 199 datasets (for each chemical) following Guidelines methodology. For each dataset, the lowest LC_{50} was divided by the calculated FAV and this process was repeated with sequential removal of one randomly determined LC_{50} for subsets of n=7 through n=1. When n=1, the LC_{50} must be from a genus in the family Daphniidae. Data subsets of increasing (2 through 7) size included the LC_{50} for Daphniidae plus one or more LC_{50}s from additional families randomly selected from the full dataset of n=8. Chemical specific FAVFs were then calculated as the 95th centile of the 199 LC_{50}/FAV ratios at each n. Finally, a set of final FAVFs for all chemicals was calculated as the median of all chemical specific FAVFs for subsample sizes n=1 through n=7 for all tested chemicals (Host et al. 1995), and these FAVFs, or secondary acute factors (SAF), were recommended to be applied to all datasets that were missing one or more MDR groups (**Table 3.2**).

Table 3.2 Summary of the Minimum Data Requirements (MDRs) and Corresponding Final Acute Value Factors (FAVF) based on Great Lakes Initiative (GLI) Methodology.

# Minimum Data Requirements (MDRs) Satisfied	Final Acute Value Factor
1	21.9
2	13
3	8
4	7
5	6.1
6	5.2
7	4.3

The GLI Tier II methodology allows for the calculation of a chronic value for chemicals where fewer than three ACRs have been experimentally determined. A default ACR of 18 is used when empirically derived ACRs are not available. The default ACR of 18 was derived in a manner as to provide a level of protection similar to that intended in the Tier I methodology. Once ACRs have been determined, the Secondary

ACR (SACR) is then calculated as the geometric mean of the three ACRs. If no ACRs are available, the SACR is 18 by default. The Secondary Chronic Value (SCV) is the SAV divided by the SACR.

The EPA conducted analyses using the GLI Tier II methodology for 21 pesticides with uses that are widespread based on monitoring reports from the U.S. Geological Survey (USGS) and labeled use patterns and compared the values to EPA's ALC using Tier I methodology (where possible) and EPA's OPP ALB and concluded:

- For the organophosphate and carbamate chemicals examined, the GLI Tier II-derived values are usually lower than ALBs (by approximately 4X), as expected since assessment factors were applied (see **Tables 3.4 and 3.5**).
- There is high variability among the chemicals that make up the GLI Final Acute Value Factor
    - For example, FAVFs for *individual chemicals* at n=1 range from 1.87 to 1,068 to comprise the GLI assessment factor at n=1 of 21.9 (the median of all individual chemical FAVFs).

The GLI methodology is resource intensive because a literature search and quality assurance review of all studies is required to determine the number of MDRs fulfilled to know which assessment factor is appropriate.

3.2.2 Overview of a Modified Guidelines Methods to Develop Criteria-Related Values to Compare to OPP ALBs

As part of this harmonization effort, the EPA investigated modifying the Guidelines method for criteria development using insecticide and herbicide case studies where MDRs were not met to derive criteria-related values. For insecticidal pesticides, the EPA developed criteria-related values by using an Invertebrate-only Genus Sensitivity Distribution (GSD) or Acute-to-Chronic Ratio (ACR) approach. For herbicidal pesticides, the EPA developed criteria-related values by using a Modified GSD or ACR approach including plants. This differs from EPA's standard approach to deriving ALC under the Guidelines because plants are not typically included in the GSD, due to the paucity of aquatic plant data for most chemicals in the open literature. For ALC development, plants are typically examined only to see if they are the most sensitive taxa, as noted below. The GSD values were then compared to OPP ALBs.

3.2.3 Insecticidal Pesticides

3.2.3.1 Acute Values

Case studies of 21 insecticidal pesticides that either had enough data to fulfill the eight MDRs to develop ALC or Tier I (illustrative ALC example) value or a Tier II value (based on the GLI methodology) were developed through prior analyses. Using these 21 pesticides, the EPA explored calculating sensitivity distributions (SD) with only invertebrate taxa to generate the HC_{05} values to compare with the freshwater invertebrate acute OPP ALB. The objective was to develop a method for insecticidal pesticides that focused on protecting 95% of sensitive taxa (*i.e.*, the 5th centile hazard concentration; HC_{05}) of concern. This method conserved resources by decreasing focus on non-target, insensitive taxa that may inappropriately weight the data resulting in under-protection of sensitive group. However, this method produces a value that is inherently more conservative than ALC because it reduces the number of genera (sample size) used in the calculation, as part of the "N" in the denominator of the criteria calculation.

The EPA explored the data using the GSD model following the Guidelines algorithm with all genus-level invertebrate data as this methodology is most analogous to ALC development, including dividing the acute invertebrate-only GSD calculation output by factor of two, to yield a low-effect acute values, as is done in standard ALC calculations. Generally, the case study analyses used all data underlying the OPP

ALBs even if it would be rejected or classified as qualitative according to the Guidelines due to standard data quality guideline shortcomings (*e.g.*, in a very few cases, issues such as chemical purity was <90% or did not meet study duration requirements but the data were still used for completeness of comparisons). Case study analyses were performed on mostly carbamate (C) and organophosphate (OP) pesticides to compare the invertebrate-only GSD analyses to ALC and Tier II values and OPP ALBs. The analysis focused on invertebrates since of the 16 OPs and four carbamates evaluated, the majority (94%) of acute invertebrate OPP ALBs were lower (more sensitive) than their corresponding acute vertebrate OPP ALBs by factors ranging from 4.5 to 2,614. The OP insecticide methamidophos was the one exception where the ratio was 0.73. Across all the OPs and carbamates evaluated, the chronic invertebrate OPP ALB was more sensitive than their corresponding chronic fish OPP ALB by factors ranging between 2.6 and 5,812. EPA's evaluation resulted in three groupings of pesticides based on their available data:

1. **Data-rich pesticides** either have an ALC or have sufficient data to be able to develop ALC based on the methodology in the Guidelines, because all eight MDRs are met.
    - These chemicals are carbamate insecticides (carbaryl, methomyl* propoxur*), organophosphate insecticides (OPs) (malathion, diazinon, chlorpyrifos, dichlorvos*) and the herbicide acrolein. *Methomyl, propoxur and dichlorvos do not have 304(a) criteria but have sufficient data to develop an illustrative ALC example for the purposes of these analyses only.
2. **Data-limited pesticides** values were developed using modified invertebrate-Genus Sensitivity Distribution (GSD) values and GLI Tier II values.
    - These include carbamates (oxamyl) and OPs (dimethoate, phosmet, acephate, terbufos)
3. **Data-insufficient pesticides** do not have sufficient data to generate modified invertebrate-only GSD values but values were developed using the GLI Tier II methodology.
    - These include the following pesticides: OPs (methamidophos, profenfos), a pyrethroid (fenpropathrin), and other pesticides (fenbutatin-oxide, methoxyfenozide, norflurazon, propargite, pyridaben)

3.2.3.1.1 Result of Analyses using Acute Modified Guidelines Methods and GLI Methodology for Insecticides

Similar to the comparison above for pesticides that have 304(a) national recommended ALC, in this analysis, for data-rich pesticides (where ALC or illustrative ALC values can be derived because all eight MDRs are filled) there is less than a factor of two difference between the OPP ALB and ALC for seven out of the eight pesticides. The difference between the OPP ALB and ALC for the eighth pesticide, carbaryl, is 2.5X, with the OPP ALB being lower than the ALC. The invertebrate-only (GSD) analyses showed that for data-rich pesticides, the OPP ALB and invertebrate-only GSD values are all within a factor of two except for malathion (8.5X) which does not use the toxicity study that the OPP ALB is based on due to acceptability criteria under the Guidelines. In six of the eight examples, the invertebrate-only GSD value is lower than the ALC including all of the taxa. This is largely due to the smaller sample size, or "N." Reducing the "N" decreases the calculated FAV even if the most sensitive data is the same for the ALC and invertebrate-only GSD calculations. The two exceptions are malathion which uses a methodology that pre-dates the Guidelines to derive the ALC and acrolein which has a large invertebrate-only GSD value because vertebrates, which are excluded from the invertebrate-only analysis, are more sensitive than invertebrates. The analyses with data-rich pesticides demonstrates that there are only small the difference between the OPP ALB and ALC values when similar data is used to derive the values. (See **Table 3.3** and **Figures A.1-A.7** for more information on these chemicals and relative values.)

For data-limited pesticides, the analyses show that there is more variability between the OPP ALB and the invertebrate-only GSD values. The values for two pesticides are within a factor of two (oxamyl and acephate). The values for the remaining three pesticides are greater than a factor of six where the OPP ALBs are higher than the conservative invertebrate-only GSD values. For terbufos and dimethoate, the OPP ALB is a factor of 6-10X higher than the invertebrate-only GSD values. For phosmet, the factor difference is 58X due to the use of different data in the invertebrate-only GSD value and the OPP ALB. Because the eight MDRs could not be filled to derive ALC values, the GLI Tier II methodology was applied to these pesticides. As with the invertebrate-only GSD values, the GLI Tier II calculated values were variable (1.5-7.7X, with the exception of phosmet at 22X) and all lower than the OPP ALB. With both methodologies the variability is a result of the conservative approaches, including the use of "safety" factors, and, in some cases, the use of different data compared to the OPP ALB. (See **Table 3.4** and **Figures A.8-A.12** for more information).

For data-insufficient pesticides, an invertebrate-only GSD value could not be calculated because a minimum of four invertebrate genera are required to use the Guidelines methodology. As expected, the GLI Tier II calculated values were variable (3.1-8X) and all lower than the OPP ALB except for methoxyfenozide, which used different data than the OPP ALB. This variability can be attributed to the large factors applied when few MDRs are met. (See **Table 3.5** for more information.)

Table 3.3. Comparison of acute values for data-rich pesticides in which all eight of the minimum data requirements (MDRs) are met per the Guidelines (OPP ALBs [lowest LC_{50}/2], OW ALC or illustrative ALC example, and analysis of invertebrate-only data).

Magnitude relative to ALB is the OPP ALB/OW value; a ratio < 1 means the OPP ALB value is lower than the OW value, a ratio > 1 means the OPP ALB is higher than the OW value.

Chemical sensitivity distributions presented in Appendix A.

Pesticide	Most Sensitive OPP ALB (Year published, species)	OW ALC or illustrative ALC example (Year published, # of genera, magnitude relative to ALB)	OW Genus-level Invertebrate-only $HC_{05}/2$[1] (# of genera, magnitude relative to ALB)
Carbamates			
Carbaryl	0.85 µg/L (2022; *Pteronarcella badia*)	2.11 µg/L (2012, 47 genera, 0.40X)	1.54 µg/L (20 genera, 0.55X)
Methomyl[2]	2.5 µg/L (2010; *Daphnia magna*)	4.326 µg/L (illustrative example calculated for this analysis, 8 genera, 0.58X)	2.55 µg/L (6 genera, 0.98X)
Propoxur[2]	5.5 µg/L (2009; *Daphnia magna*)	4.6 µg/L (illustrative example calculated for this analysis, 11 genera, 1.2X)	2.66 µg/L (5 genera, 2.1X)
OPs			
Malathion	0.049 µg/L (2016; *Ceriodaphnia dubia*)	0.1 µg/L (1986, "Gold Book", 0.49X)	0.418 µg/L (29 genera, 0.12X)
Diazinon	0.105 µg/L (2016; *Ceriodaphnia dubia*)	0.170 µg/L (2005, 20 genera, 0.61X)	0.097 µg/L (11 genera, 1.1X)
Chlorpyrifos	0.05 µg/L (2022; *Daphnia magna*)	0.083 µg/L (1986, 15 genera, 0.60X)	0.029 µg/L (15 genera, 1.7X)
Dichlorvos[2]	0.0334 µg/L (2021; *Daphnia pulex*)	0.032 µg/L (illustrative example calculated for this analysis, 12 genera, 1.1X)	0.023 µg/L (6 genera, 1.5X)
Other			
Acrolein (contact herbicide)	3.5 µg/L (2023; *Xenopus laevis*)	3.0 µg/L (2009, 14 genera, 1.2X)	22.87 µg/L (7 genera, 0.68X) Note the magnitude comparison is with the invertebrate ALB of <15.5 µg/L.

MDR=minimum data requirement; NA=not applicable

[1] Uses Guidelines methodology for calculating the FAV.

[2]No 304(a) ALC recommendation available but has sufficient data to develop an illustrative ALC example for the purposes of these analyses only.

Table 3.4. Comparison of acute values for data-limited pesticides (OPP ALBs [lowest LC_{50}/2], GLI Tier II calculated values, and analysis of invertebrate-only data).

Magnitude relative to ALB is the OPP ALB/OW value; a ratio < 1 means the OPP ALB value is lower than the OW value. Chemical sensitivity distributions presented in Appendix A.

Pesticide	Most Sensitive OPP ALB (Year published, species)	OW GLI Tier II value (# of MDRs filled, magnitude relative to ALB)	OW Genus-level Invertebrate-only $HC_{05}/2$[1] (# of genera, magnitude relative to ALB)
Carbamates			
Oxamyl	90 µg/L (2016; *Chironomus plumosus*)	17.3 µg/L (6 MDRs filled, 5.2X)	57.35 µg/L (4 genera, 1.6X)
OPs			
Acephate	550 µg/L (2007; *Daphnia magna*)	364.7 µg/L (7 MDRs filled, 1.5X)	1,069 µg/L (6 genera, 0.51X)
Dimethoate	21.5 µg/L (2016; *Pteronarcys californica*)	3.5 µg/L (5 MDRs filled, 6.1X)	2.15 µg/L (4 genera, 10X)
Phosmet	4.32 µg/L (2023; *Daphnia magna*)	0.20 µg/L (5 MDRs filled, 22X)	0.074 µg/L (4 genera, 58X)
Terbufos	0.085 µg/L (2023; *Daphnia magna*)	0.011 µg/L (5 MDRs filled, 7.7X)	0.014 µg/L (4 genera, 6.1X)

MDR=minimum data requirement; NA=not applicable

[1] Uses Guidelines methodology for calculating the FAV.

Table 3.5. Comparison of acute values for data-insufficient pesticides where a GLI Tier II value could be calculated but there were insufficient data to calculate either a Tier I acute value or genus-level invertebrate value.

Magnitude relative to ALB is the OPP ALB/OW value; a ratio < 1 means the OPP ALB value is lower than the OW value.

Pesticide	Most Sensitive OPP ALB (Year published, species)	OW GLI Tier II value (# of MDRs filled, magnitude relative to ALB)	OW Genus-level Invertebrate-only $HC_{05}/2$
OPs			
Methamidophos	13 µg/L (2016; *Daphnia magna*)	2.58 µg/L (4 MDRs filled, 5X)	NA (1 genus)
Profenofos	0.465 µg/L (2008; *Daphnia magna*)	0.077 µg/L (6 MDRs filled, 6X)	NA (2 genera)
Other			
Fenpropathrin (Synthetic Pyrethroid)	0.0015 µg/L (2021; *Hyalella azteca*)	0.00025 µg/L (5 MDRs filled, 6X)	NA (2 genera)
Fenbutatin Oxide (Organotin Acaricide)	0.85 µg/L (2009; *Oncorhynchus mykiss*)	0.173 µg/L (3 MDRs filled, 4.9X)	NA (1 genus)
Methoxyfenozide (Insect Growth Regulator; Diacylhydrazine)	28.5 µg/L (2013; *Chironomus riparius*)	231.3 µg/L (3 MDRs filled, 0.12X)	NA (1 genus)
Norflurazon (Pyridazine Herbicide)	4,050 µg/L (2023; *Oncorhynchus mykiss*) Note the lowest ALB is for nonvascular plants (6.03 µg/L), but the GLI Tier II value is based on *O. mykiss* so the vertebrate ALB is used in this comparison	506.3 µg/L 3 MDRs filled, 8X)	NA (1 genus)
Propargite (OS Miticide)	7 µg/L (2021; *Daphnia magna*)	2.231 µg/L (3 MDRs filled, 3.1X)	NA (1 genus)
Pyridaben (Nicotinamide Inhibitor)	0.265 µg/L (2023; *Daphnia magna*)	0.033 µg/L (3 MDRs filled, 8X)	NA (1 genus)

MDR=minimum data requirement; NA=not applicable

3.2.3.2 Chronic Values

Similar to the acute insecticide analyses, the EPA compared chronic OPP ALBs to current ALC or illustrative ALC examples if one could be derived for this analysis, as well invertebrate-only GSD values, and GLI Tier II calculated values.

The EPA examined three data-rich pesticides, one carbamate and two organophosphate insecticides, to compare chronic values for both ALC and invertebrate-only GSD values to OPP ALB. These data-rich pesticides still did not meet the MDRs to be able to calculate values using the invertebrate-only GSD, so the acute-to-chronic ratio (ACR) methodology was applied.

Comparison of OPP and OW Acute to Chronic Ratio (ACR) Approaches for Individual Taxa

There are some differences in how OPP and OW have historically calculated ACRs. The requirements of the historical OW approach are summarized from the Guidelines as follows:

- At least three ACRs are required, including one invertebrate, one fish, and at least one acutely sensitive freshwater species (for the derivation of a freshwater chronic value).
- Acute and chronic toxicity data should be from tests performed in the same laboratory using the same dilution water. When multiple acute values from the same laboratory are available, the geometric mean of those values is used.
- The maximum acceptable toxicant concentration (MATC), which is the geometric mean of the no-observe effect (NOEC) and lowest-observed effect (LOEC) concentrations, is used as the chronic value when it is available. When an MATC is not available, the best acceptable chronic value (*e.g.*, a less than value) is used.
- ACRs can be calculated using data for a marine/estuarine species and applied towards the calculation of a freshwater chronic values, provided the other requirements described above are met.

The OPP ACR approach is similar in that the acute and chronic values should be paired from studies performed under similar conditions (*e.g.*, same dilution water, test conditions). However, one major difference is that the OPP approach uses empirical no-observed adverse effect concentrations (NOAEC) values, not MATCs. In addition, the OPP ACR approach offers greater flexibility than the OW approach in that OPP does not require acute and chronic tests to be from the same laboratory. In cases where multiple acute and/or chronic values are available for the same species but paired acute and chronic data from the same laboratory/dilution water are not available, then the geometric mean of all reliable acute and/or chronic values should be used under OPP (U.S. EPA 2005).

Final ACR Determination

The OW ALC approach uses individual ACRs to determine a final ACR (FACR) by calculating the geometric mean of all acceptable ACRs. The Guidelines specify that if the ACRs appear to increase or decrease as the species mean acute values (SMAVs) increase, the FACR should be calculated as the geometric mean for those species whose SMAVs are close to the final acute value (FAV). This can occur for chemicals where acute sensitivities vary greatly across taxonomic groups based on the chemical mode of action. OPP ACRs are calculated for species within a particular taxonomic group are applied to acute values from other species within the same taxonomic group.

For purposes of this comparison, the Guidelines methodology for calculating an FACR was applied to species-specific ACRs calculated following both OW and OPP methodologies.

The chronic ACR analyses found that:

- Differences in individual ACR methodology between OW and OPP (*e.g.*, the ALC Guidelines approach of paired acute and chronic laboratory tests) reduces number of taxa available to use. See **Tables 3.6 – 3.8**.
- Invertebrate chronic OPP ALBs are similar to criteria-related values calculated using FACRs with OW and OPP methodology (most within a factor of 2, all within a factor of 5). See **Table 3.9**.

Table 3.6. Diazinon Acute-to-Chronic Ratios (ACRs) by species and calculation method.

Genus	Species	ACR		Notes
		OW-ACR	OPP-ACR	
Invertebrates				
Ceriodaphnia	*dubia*	1.112	1.709	
Daphnia	*magna*	NA	5.190	
Americamysis	*bahia*	1.586	2.295	
Fish				
Salvelinus	*fontinalis*	>903.8	>1,315	
Pimephales	*promelas*	196.2	279.6	
Jordanella	*floridae*	23.84	30.43	
Cyprinodon	*variegatus*	>2,979	3,590	
All Taxa		53.01	50.33	
All Invertebrates (FACR)		1.328	2.731	

Table 3.7. Carbaryl Acute-to-Chronic Ratios (ACRs) by species and calculation method.

Genus	Species	ACR		Notes
		OW-ACR	OPP-ACR	
Invertebrates				
Ceriodaphnia	*dubia*	1.328	1.609	
Daphnia	*magna*	1.581	2.5	
Americamysis	*bahia*	0.8530	1.178	Qualitative ACR [c]
Fish				
Gila	*elegans*	NA	3.108	ELS chronic test
Pimephales	*promelas*	23.82	42.86	Life cycle chronic test
Pimephales	*promelas*	6.256	9.326	ELS chronic test
Ptychocheilus	*lucius*	NA	2.944	ELS chronic test
All Taxa[a]		3.684	4.361	
All Taxa Final (FACR)[b]		2	2.463	
All Invertebrates		2	2.006	OW-FACR rounded up to 2 per Guidelines.

ELS=fish early life stage

[a] Of the two ACRs for *P. promelas,* only the life cycle test was included in this calculation.

[b] OW and OPP all taxa final ACRs do not include ACR for *P. promelas* (>10x spread and acutely insensitive), or qualitative ACR for *A. bahia*.

[c] As described in the carbaryl ALC document, these ACRs are treated as qualitative because control survival and number of young produced per female did not meet ASTM test requirements (U.S. EPA 2012).

Table 3.8. Malathion Acute-to-Chronic Ratios (ACRs) by species and calculation method.

Genus	Species	ACR		Notes
		OW-ACR	OPP-ACR	
Invertebrates				
Daphnia	*magna*	5.942[a]	13.22	Qualitative OW-ACR developed, because an ACR following the Guidelines could not be calculated, as there were no acute and chronic studies from same study/laboratory/test water. The resulting qualitative ACR was included because no other ACRs for invertebrate taxa were available.
Fish				
Oncorhynchus	*mykiss*	NA	4.074	
Gila	*elegans*	NA	15.46	
Pimephales	*promelas*	NA	63.18	
Ptychocheilus	*lucius*	NA	5.440	
Jordanella	*floridae*	15.98	40.58	
Lepomis	*macrochirus*	15.27	21.60	
Oryzias	*latipes*	NA	48.60	OPP ACR should be considered qualitative due to chronic test duration (14-d)
Oreochromis	*mossambica*	NA	NA	ACR not calculated because no NOAEC was available
Channa	*punctata*	NA	4.234	OPP ACR should be considered qualitative due to chronic test duration (15-d)
Cyprinodon	*variegatus*	8.5	12.75	
All Taxa FACR[a]		10.54	12.61	
All Invertebrates		5.942	13.22	

[a] OPP all taxa ACR does not include qualitative ACRs for *O. latipes* or *C. punctata* or ACR for *P. promelas* (>10x spread and acutely insensitive). OW all taxa ACR does include the "qualitative" *D. magna* ACR.

Table 3.9. Final Freshwater Chronic Values.

	OPP ALB (µg/L)		Criteria-related values (µg/L)			
	Fish	Invertebrate	Using OW-ACR (All Taxa)	Using OPP-ACR (All Taxa)	Using OW-ACR (Invertebrates)	Using OPP-ACR (Invertebrates)
Carbaryl	6.8	0.5	2.110[a]	2.103	1.537	1.532
Diazinon	<0.55	0.17	0.1699[a]	0.1244	0.09675	0.07085
Malathion	8.6	0.06	0.0847[b]	0.0708	0.1407	0.0632

[a] ALC chronic value

[b] Illustrative value calculated for this report, no 304(a)(1) ALC chronic value available

Despite having relatively robust data sets for the chronic analyses, ACRs were required to derive chronic ALC and chronic invertebrate-only GSD values for carbaryl, diazinon, and malathion. The differences in the resulting criteria-related values using the OW or OPP ACR methodologies are minimal (less than 2X difference). As with the acute values, the invertebrate-only chronic GSD values are generally lower than the ALC incorporating all the available taxa because of the small sample size (N) used in the calculation, which results in a lower value. Lastly, the lowest chronic OPP ALB are similar (diazinon and malathion) or within a factor of four (carbaryl) of the ALC (see **Tables 3.9 and 3.10**).

When three ACRs could not be fulfilled, the chronic GLI Tier II methodology was applied. As expected, the GLI Tier II calculated values were variable (1.3-42X) and all lower than the OPP ALB with one exception (methoxyfenozide which uses different data to calculate the values). The GLI Tier II calculated values include a high default ACR of 18 when data are missing in order to be able to calculate a value using that method (See **Table 3.10** for more information.)

Table 3.10. Comparison of chronic values for insecticidal pesticides (chronic OPP Aquatic Life Benchmarks (NOAEC), OW ALC / Illustrative ALC example or GLI Tier II calculated values, and invertebrate-only HC_{05} values).

Magnitude relative to ALB is the OPP ALB/OW value; a ratio < 1 means the OPP ALB value is lower than the OW value, a ratio >1 means the OPP ALB is higher than the OW value.

Note: For GLI Tier II calculated values, a default ACR of 18 is used when empirically derived ACRs are not available.

Pesticide	Most Sensitive OPP ALB (Year published, species)	OW ALC / Illustrative ALC example or Tier II value (# of ACRs filled, magnitude relative to ALB)	OW Invertebrate-only HC_{05} (# of ACRs filled, magnitude relative to ALB)
Carbaryl	0.5 µg/L (2022; estimated NOAEC value for *Pteronarcella badia* calculated using the ACR for *Daphnia magna*)	2.1 µg/L (ALC, 0.24X)	1.54 µg/L (See Table 3.7 for ACRs, 0.32X)
Oxamyl	27 µg/L (2016; *Daphnia magna*)	2.4 µg/L (GLI Tier II; 1 ACR, 11X)	NA
Diazinon	0.17 µg/L (2016, *Daphnia magna*)	0.17 µg/L (ALC, 1X)	0.097 µg/L (See Table 3.6 for ACRs, 1.8X)
Malathion[1]	0.06 µg/L (2016, *Daphnia magna*)	0.08 µg/L (illustrative ALC example calculated for this analysis; 0.75X)	0.14 µg/L (See Table 3.8 for ACRs, 0.43X)
Acephate	150 µg/L (2007, *Daphnia magna*)	40.5 µg/L (GLI Tier II; 0 ACRs, 3.7X)	NA

Pesticide	Most Sensitive OPP ALB (Year published, species)	OW ALC / Illustrative ALC example or Tier II value (# of ACRs filled, magnitude relative to ALB)	OW Invertebrate-only HC_{05} (# of ACRs filled, magnitude relative to ALB)
Dimethoate	0.5 µg/L (2016, estimated NOAEC value for *Pteronarcys californica* calculated using the ACR for *Daphnia magna*)	0.3 µg/L (GLI Tier II; 2 ACRs, 1.7X)	NA
Methamidophos	4.5 µg/L (2016, *Daphnia magna*)	0.42 µg/L (GLI Tier II; 1 ACR, 11X)	NA
Phosmet	0.75 µg/L (2023, *Daphnia magna*)	0.02 µg/L (GLI Tier II; 2 ACRs, 38X)	NA
Profenofos	0.2 µg/L (2016, *Daphnia magna*)	0.013 µg/L (GLI Tier II; 1 ACR, 15X)	NA
Terbufos	0.03 µg/L (2023, *Daphnia magna*)	0.0014 µg/L (GLI Tier II; 2 ACRs, 21X)	NA
Fenbutatin Oxide	0.31 µg/L (2009, *Oncorhynchus mykiss*). Note the vertebrate ALB is lower than the invertebrate ALB (16 µg/L)	0.06 µg/L (GLI Tier II; 2 ACRs, 5.1X)	NA
Fenpropathrin	<0.0015 µg/L (2021, *Hyalella azteca*)	0.000036 µg/L (GLI Tier II; 1 ACR, 42X)	NA
Methomyl	0.6 µg/L (2020, *Daphnia magna*)	0.47 µg/L (GLI Tier II; 2 ACRs, 1.3X)	NA
Methoxyfenozide	3.1 µg/L (2019, C*hironomus riparius*)	25.5 µg/L (GLI Tier II; 1 ACR, 0.12X)	NA
Norflurazon	770 µg/L (2023, *Oncorhynchus mykiss*). Note the lowest ALB is for nonvascular plants (5.33 µg/L), but the GLI Tier II value is based on *O. mykiss* so the vertebrate ALB is used in this comparison	56.3 µg/L (GLI Tier II; 0 ACRs, 14X)	NA
Propargite	9 µg/L (2021, *Daphnia magna*) Note the lowest ALB is for nonvascular plants (1.27 µg/L), but the GLI Tier II value is based on *D. magna* so the invertebrate ALB is used in this comparison	0.56 µg/L (GLI Tier II; 1 ACR, 16X)	NA

Pesticide	Most Sensitive OPP ALB (Year published, species)	OW ALC / Illustrative ALC example or Tier II value (# of ACRs filled, magnitude relative to ALB)	OW Invertebrate-only HC_{05} (# of ACRs filled, magnitude relative to ALB)
Pyridaben	0.044 µg/L (2023, *Daphnia magna*)	0.004 µg/L (GLI Tier II; 1 ACR, 11X)	NA

[1]No 304(a) ALC recommendation available but has sufficient data to develop an illustrative ALC example for the purposes of these analyses only.

3.2.4 Herbicidal Pesticides

Two herbicide classes (*i.e.*, triazines and organophosphorous herbicides) encompassing five case studies with varying amounts of available toxicity data were used to compare OPP ALBs to criteria-related values. The herbicide class of triazines included atrazine, propazine, and simazine; the organophosphorus herbicides included bensulide and glyphosate. The EPA's objective with the herbicidal pesticide case studies was to perform similar analyses to that for the insecticidal pesticides to develop three CWA section 304(a) ALC values to compare to OPP ALBs: 1) an ALC-equivalent value when all MDRs are met; 2) a modified HC_{05} value when MDRs may not be met; and 3) a Tier II value using the GLI methodology. This process was complicated by the fact that the Guidelines do not specify MDRs or standard acceptable toxicity tests with vascular and nonvascular aquatic plants. In the Guidelines approach, if toxicity data are available for aquatic plants the relative sensitivities of aquatic plants to animals are compared. The Guidelines state that, in most cases, "*the results of tests with plants usually indicate that criteria which adequately protect animals and their uses will probably also protect aquatic plants and their uses*." However, for herbicidal pesticides, the most sensitive taxa are often aquatic plants. Aquatic vascular and nonvascular toxicity studies are somewhat different than tests with aquatic animals, due to the issue of plants' potential ability to regrow after acute exposure to a toxic substance is ended. Further the lines between acute effects and chronic effects are less clear with plants, as some of the same endpoints can be used between acute and chronic effects for endpoints. However, as primary producers at the base of the aquatic food chain, plants should be considered systematically in assessment paradigms. There are endpoints derived from plant studies which correspond to the acute LC_{50} and chronic NOAEC values from animal studies (*i.e.*, the plant equivalent 50% inhibitory concentration or IC_{50} and the NOAEC). The major difference though is that both the plant IC_{50} and NOAEC endpoints are derived from the same study whereas in for aquatic animals, the two endpoints come from different studies. For these analyses, to be consistent with what was done for aquatic animals but different from how ALC have traditionally used plant toxicity data, the LC_{50} or IC_{50} (lethal or inhibitory concentration collectively referred to as "acute values") and the animal and plant NOAEC values (collectively referred to as "chronic values") were directly incorporated into the analyses (*e.g.*, sensitivity distributions). The data and general methods used to develop the three different ALC or criteria-related values for herbicide pesticides are described below.

Data for these analyses came from two sources. First, the EPA determined the acceptable toxicity tests from the FIFRA re-registration documents for the five herbicides. Next, the EPA performed an ECOTOX search and supplemented the re-registration data with toxicity tests deemed acceptable by ECOTOX to fulfill the MDRs prescribed in the Guidelines.

Acute ALC-equivalent values were determined if all the eight animal MDRs were met by following the Guidelines algorithm and including the plant toxicity data (LC_{50} or IC_{50}) combined with the animal data to determine the FAV. If the MDRs were met for chronic toxicity data, the same methods were applied as

the acute data. If all the MDRs were not met, but ACRs could be developed, then a chronic value was developed using the ACR method. The ACRs were determined on animal data using the less constrained OPP methodology (see above) and applied to the plant GMAV if that was the lowest value.

If the eight animal MDRs were not met, the EPA developed a modified value by using the Guidelines methodology incorporating all available acceptable animal and plant toxicity data regardless of MDR status. For this method, a minimum number of four GMAVs are required for both acute and chronic values. As for animals, low sample size (number of genera; N) in criteria calculations has a large impact on criteria estimates, which was intended in the Guidelines to incorporate the uncertainty in developing criteria with fewer data.

In addition, if the eight animal MDRs were not met, EPA developed values using the GLI methodology. For the acute value, the GLI assessment factor is dependent on the number of animal MDRs met and, in this analysis, was applied to the lowest LC_{50} (or IC_{50}) regardless of taxa type (animal or plant). The variable assessment factors in GLI methodology were also intended to address uncertainty associated when less data are available, when MDRs are not met. Similarly, the chronic value using the GLI methodology is dependent on the number of animal ACRs that can be derived, but the extrapolation factor was applied to the lowest NOAEC regardless of taxa type (animal or plant).

3.2.3.3 Acute Values

Our analyses found that the difference between the lowest OPP ALB (plant) and the ALC-equivalent value or modified $HC_{05}/2$ value ranged from a factor of 1.2 to 5.9 with an average of 3.3. The OPP ALB was lower than (atrazine) or close to (simazine) for the two herbicides with enough data to derive an illustrative ALC value. The OPP ALB was higher than the conservative GLI Tier II calculated or modified $HC_{05}/2$ values. The factor differences for the illustrative ALC or modified $HC_{05}/2$ values were also smaller than the GLI Tier II approach (8-16X). (See **Table 3.11** for more information.)

Table 3.11. Comparison of acute values for herbicidal pesticides (plant OPP ALB, OW illustrative ALC - equivalent or Tier II-equivalent values, and modified $HC_{05}/2$ values).

Magnitude relative to ALB is the OPP ALB/ OW value; a ratio < 1 means the OPP ALB value is lower than the OW value.

Chemical sensitivity distributions presented in Appendix B.

Pesticide	OPP Most Sensitive ALB (Year published, species)	OW Illustrative ALC example or Tier II values (# of MDRs filled, magnitude relative to ALB)	OW Modified $HC_{05}/2$ (# of MDRs filled, # of genera available, magnitude relative to ALB)
Chlorotriazines			
Atrazine[1]	< 1 µg/L (2016; *Oscillatoria lutea;* nonvascular plant)	5.7 µg/L (illustrative ALC example calculated for this analysis; 8 MDRs filled, 0.18X)	NA
Propazine	24.8 µg/L (2022; *Navicula pelliculosa;* nonvascular plant)	1.55 µg/L (GLI Tier II; 4 MDRs filled, 16X)	4.2 µg/L (3 MDRs, 7 genera, 5.9X)

Pesticide	OPP Most Sensitive ALB (Year published, species)	OW Illustrative ALC example or Tier II values (# of MDRs filled, magnitude relative to ALB)	OW Modified HC_{05}/2 (# of MDRs filled, # of genera available, magnitude relative to ALB)
Chlorotriazines			
Simazine[1]	6 µg/L (2023; *Arthrospira platensis;* nonvascular plant)	5.2 µg/L (illustrative example calculated for this analysis; 8 MDRs filled, 1.2X)	NA
Organophosphorus Herbicides			
Bensulide	140 µg/L (2016; *Lemna gibba;* vascular plant)	10.7 µg/L (GLI Tier II; 4 MDRs filled, 13X)	53.21 µg/L (4 MDRs, 9 genera, 2.6X)
Glyphosate	11,900 µg/L (2016; *Lemna gibba;* vascular plant)	1,607 µg/L (GLI Tier II; 4 MDRs filled, 7X)	4,908 µg/L (4 MDRs, 9 genera, 2.4X)

MDR=minimum data requirement; ACR=Acute to Chronic Ratio; NA=not applicable

[1]No 304(a) ALC recommendation available but has sufficient data to develop an illustrative ALC example for the purposes of these analyses only.

3.2.3.4 Chronic Values

As of August 2024, OPP publishes the available vascular and nonvascular plant NOAECs on their Aquatic Life Benchmarks table[17] and those ALB values were used to compare to the OW-derived chronic values for herbicides, except for atrazine which does not have a chronic plant NOAEC listed. Also, in the case of bensulide, the chronic invertebrate ALB of 11 µg/L was used in the comparison with the OW-derived chronic values as it was lower than the plant ALB. There were not enough MDRs to derive an illustrative ALC-equivalent value for these pesticides, so GLI Tier II values were calculated instead. The analyses indicate that the difference between the lowest OPP ALB and the modified HC_{05} value ranged from a factor of 1.3 to 7.9 with an average of 3.9. The range in the factor difference for the GLI Tier II approach values was larger than for the modified HC_{05} approach (1.3-36X). Similar to the acute values, the OPP ALB was higher than the conservative OW-derived Tier II and modified HC_{05} values in most case studies. (See **Table 3.12** for more information.)

[17] https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/aquatic-life-benchmarks-and-ecological-risk

Table 3.12. Comparison of chronic values for herbicidal pesticides (chronic OPP Aquatic Life Benchmarks [NOAEC], GLI Tier II calculated values, and modified HC_{05} values). Magnitude relative to ALB is the OPP ALB/ OW value; a ratio < 1 means the OPP ALB value is lower than the OW value. Chemical sensitivity distributions presented in Appendix B.
Note: For GLI Tier II values, a default ACR of 18 is used when empirically derived ACRs are not available.

Pesticide	Most Sensitive OPP ALB (Year published and species)	OW Tier II value (# of ACRs filled, magnitude relative to ALB)	OW Modified HC_{05} (# of MDRs filled, # of genera available, magnitude relative to ALB)
Chlorotriazines			
Propazine	6.5 µg/L (2022; *Navicula pelliculosa;* nonvascular plant)	0.18 µg/L (GLI Tier II; 1 ACR filled, 36X)	2.3 µg/L (3 MDRs, 7 genera, 2.8X)
Simazine	1 µg/L (*Arthrospira platensis;* nonvascular plant)	0.77 µg/L (GLI Tier II; 2 ACRs filled, 1.3X)	0.8 µg/L (3 MDRs, 13 genera, 1.3X)
Organophosphorus Herbicides			
Bensulide	11 µg/L (2016; *Daphnia magna;* invertebrate)	0.88 µg/L (GLI Tier II; 1 ACR filled, 12.5X)	1.4 µg/L (2 MDRs, 7 genera, 7.9X)
Glyphosate	1,300 µg/L (*Lemna gibba;* vascular plant)	316 µg/L (GLI Tier II; 2 ACRs filled, 4.1X)	5,087 µg/L (2, MDRs, 6 genera, 0.26X)

MDR=minimum data requirement; ACR=Acute to Chronic Ratio; NA=not applicable

3.3 Analysis of Ratios of OPP Aquatic Life Benchmarks and Alternative Criteria-Related Approaches to Develop Aquatic Life Criteria

OPP ALBs were compared to three criteria-related values by developing a ratio of one to the other. The comparative analysis focused on two classes of insecticides (organophosphates and carbamates) and two classes of herbicides (triazines and organophosphorus herbicides), with robust databases. The three different OW-estimated, criteria-related methods are:

1. Methodology for **Aquatic Life Criteria (ALC)** as outlined in the Guidelines. (Either existing ALC or Tier I (ALC-equivalent) values when there is sufficient data to be able to develop a value based on the methodology in the Guidelines.)
2. **Great Lakes Initiative (GLI) Extrapolation Factors** to calculate Tier II benchmarks (see **Section 3.2.1**)
3. Modified HC_{05} methods to conduct case studies with insecticides and herbicides where MDRs may not be met using an **Invertebrate-only** and **Herbicide-modified Genus Sensitivity Distribution** (see **Section 3.2.2**).

Table 4.1 summarizes the mean ratios of the OPP ALBs to the corresponding criteria-related value using the three different methods (*i.e.*, ALC Tier 1, Invertebrate-only GSD HC_{05}, and the GLI factor approach) for two different classes of insecticides (*i.e.*, carbamates and organophosphates) with a common mode

of action (*i.e.*, acetylcholine esterase inhibition) as well as a broader group of chemistries (*e.g.*, organochlorines, organometallics, synthetic pyrethroids, N-phenyl heterocycles, diacrylhydrazines, sulfite esters, and phenols) referred to as "Other" which include insecticides, herbicides, and fungicides representing multiple modes of action.

Given that there were no statistically significant differences between the three groups of pesticides for acute ratios derived using the three approaches, ratios were averaged across the three chemical groups and the means along with their standard deviations and standard errors are reported in **Table 3.13**. Similar analyses were conducted to the GLI factor approach.

When comparing across the three methods (*i.e.*, ALC Tier 1, Invertebrate GSD HC_{05}, and the GLI factor approach) of estimating acute values, there was no statistical difference ($p>0.05$) for the three chemical groups combined. Although the combined mean acute ratios reported in **Table 3.13** across the three methods range from 0.69 to 5.29, high variability likely reduced the ability to detect statistically significant differences between the three methods. When all the estimated acute ratios are averaged (across the three methods and three classes of insecticides) the mean ratio is 2.75. The average estimated chronic values for OPs and carbamates are close to one when comparing the ALC and GSD HC_{05} methods relative to OPP ALBs. The mean chronic ratio is higher for the GLI because it includes a high default ACR of 18 when data are missing in order to be able to calculate an ACR using that method. When all the chronic values are averaged (across the three methods and the three groups of insecticide, including the ALC chronic methodology), the mean chronic ratio is 4.81.

Table 4.1. Summary of Ratios of Acute and Chronic OPP ALBs to Corresponding Criteria Based on Tier 1 ALC, Invertebrate-only Genus Sensitivity Distribution (GSD) or Acute-to-Chronic Ratio (ACR) and Great Lakes Initiative (GLI) Tier II Methods for Two Classes of Insecticides.

Acute (OPP ALB/Criteria-related value)			
Chemical Class	**Tier 1 ALC (Mean ± SD)**	**Invertebrate GSD (Mean ± SD)**	**GLI Tier II (Mean ± SD)**
Carbamates (4)	0.71 ± 0.43 (3)	1.20 ± 0.74 (4)	5.2 (1)
Organophosphates (11)	0.70 ± 0.27 (4)[†]	3.07 ± 3.73 (7)[†]	5.29 ± 2.32 (5)[†]
Other (9)	0.69 ± 0.41 (3)	NA[††]	5.17 ± 3.12 (6)
Combined C & OP & OT (24)	0.70 ± 0.32 (10)	2.39 ± 3.07 (11)	5.22 ± 2.52 (12)
Mean Ratio across methods and insecticide classes	2.75 ± 2.19 (8)		
Chronic (OPP ALB/Criteria-related value)			
Chemical Class	**Tier 1 ALC (Mean ± SD)**	**Invertebrate ACR (Mean ± SD)**	**GLI Tier II (Mean ± SD)**
Carbamates (4)	0.24 (1)	0.325 (1)	11.25 (1)
Organophosphates (11)	0.61 ± 0.45 (3)	1.09 ± 0.94 (2)	15.07 ± 13.20 (6)
Other (9)	2.37 (1)	NA	7.54 ± 6.56 (8)
Combined C & OP & OT (24)	0.89 ± 0.90 (5)	0.84 ± 0.80 (3)	10.80 ± 9.88 (15)
Mean Ratio across methods and insecticide classes	4.81 ± 5.76 (8)		

Sample sizes are shown in parentheses (n).

[†]Excludes guthion (since utilized old methodology) and phosmet (initially utilized different data which resulted in erroneous factor); had guthion and phosmet been retained, the mean Tier 1 ALC would be 2.16 ± 3.27, the mean invertebrate GSD would be 9.98 ± 19.9, and the mean GLI Tier II would be 8.01 ± 6.97.

[††]Excludes acrolein because vertebrates are more sensitive than invertebrates.

Given the limited number of case studies with the herbicides, statistical comparisons were constrained, and unlike the carbamates and the OPs, the chlorotriazines and OP herbicides do not have a common mode of action; therefore, the ratios by method were not combined in **Table 4.2**. However, when all the estimated ratios are averaged (across the three methods and two classes of herbicides) the mean acute ratio is 7.47 and the mean chronic ratio is 8.07. Both the average acute and chronic ratios for chlorotriazines and OP herbicides for ALC and the modified HC_{05} are within or close to a factor of 5, but the ratios for the GLI method are higher due to the conservative nature of the methodology (use of assessment factors growing in magnitude as the number of MDRs met decreases) and the modification to include the herbicide data. The illustrative Tier 1 ALC are the most comparable to the OPP ALB because assessment factors are not applied as in the GLI Tier II calculations, and the impact of small sample sizes is not magnified as in the modified HC_{05}.

Table 4.2. Summary of Ratios of Plant OPP ALB to Corresponding Criteria Based on Tier 1 ALC, Modified GSD and GLI Tier II Methods for Two Classes of Herbicides.

Acute (OPP ALB/Criteria-related value)			
Chemical Class	**Illustrative Tier 1 ALC Mean ± SD (n)**	**Modified GSD HC_{05}/2 Mean ± SD (n)**	**GLI Tier II Mean ± SD (n)**
Chlorotriazine (3)	0.67 ± 0.71 (2)	5.90 (1)	16.0 (1)
Organophosphates (2)	NA	4.53 ± 4.70 (2)	10.23 ± 3.21 (2)
Mean Ratio across methods and herbicide classes	7.47 ± 5.87 (4)		
Chronic (OPP ALB/Criteria-related value)			
Chemical Class	**Illustrative Tier 1 ALC Mean ± SD (n)**	**Modified GSD HC_{05} Mean ± SD (n)**	**GLI Tier II Mean ± SD (n)**
Chlorotriazine (2)	NA	2.04 ± 1.11 (2)	18.70 ± 24.61 (2)
Organophosphates (2)	NA	4.08 ± 5.40 (2)	7.45 ± 7.14 (2)
Mean Ratio across methods and herbicide classes	8.07 ± 7.43(4)		

Sample sizes are shown in parentheses (n).

Even for pesticides with some of the most robust data sets (*i.e*., OPs and carbamates), it is challenging to identify studies that meet the MDRs specified in the Guidelines. Although the 2012 FIFRA SAP recommended the use of sensitivity distributions, identifying suitable studies with which to populate such distributions can also be challenging and could result in the need to use studies identified as qualitative studies, due to their data quality or other shortcomings, versus use of only quantitative studies in sensitivity distributions, as is strongly preferred. Some variability in the ratios (*i.e.*, large differences in the values between OPP ALBs and criteria-related values) can be attributed to the inclusion of qualitative toxicity data to calculate criteria-related values in the methods where MDRs were not met (the invertebrate-only or herbicide modified GDS or GLI Tier II approach). Another source of variability in the ratios can be attributed to the conservative nature of the alternative criteria-related methodologies used when the MDRs are not met. While the GLI Tier II approach is designed to be conservative (*i.e.*, result in a low value) depending on the number of MDRs available, the invertebrate-only and herbicide modified GDS approach is also inherently more conservative than the ALC approach due to the low genera sample size (N) used in the Guidelines algorithm. The analysis also suggests that as more data become available, the resulting values from ALC are not substantially different than the OPP ALB. In fact, in most of the limited cases, OPP ALBs are within a factor of two lower for a given pesticide than the corresponding Tier I ALC. Importantly, the ratios between ALC and criteria-related values and OPP ALBs for both acute and chronic insecticides and herbicides are no larger than differences observed due to natural variability in toxicity responses and the intra- and interlaboratory variability reported in the open literature (5-10X; Chapman 1998; Duke and Taggart 2000; Fairbrother 2008; Raimondo *et al*. 2007; Raimondo *et al*. 2010).

4 Summary and Conclusions

The EPA's objective under the Common Effects Project is to harmonize aquatic effects assessment methods for pesticides to provide a common basis evaluating the effects of these chemicals on water quality for both under the CWA and the FIFRA using best available information. After spending several years investigating the underlying methods, current evaluations have focused on maximizing efficient use of resources by leveraging existing work by OW and OPP and comparing the relative magnitudes of the effects values.

To attain this objective, EPA scientists collaborated to compare existing OPP ALBs and ALC, and other criteria-related values. However, in most cases, pesticide data are lacking to fulfill MDRs and for the development of ALC using the Guidelines methodology. For this effort, three investigative approaches of CWA section 304(a) ALC and alternative values were developed to compare with OPP ALBs.

1. Methodology to develop Aquatic Life Criteria or illustrative equivalent (Tier I) values;
2. Great Lakes Initiative methodology and assessment factors to develop Tier II values; and
3. Modified HC_{05} methodology for Invertebrate-only Genus Sensitivity Distribution (GSD) for insecticides and including plants in the GSD for herbicides and/or Acute-to-Chronic Ratio (ACR) approaches for both.

The comparative analysis focused primarily on two classes of insecticides (organophosphates and carbamates) and two classes of herbicides (triazines and organophosphorus herbicides), with relatively robust databases and compared the ratios of acute and chronic OPP ALBs to corresponding alternative criteria-related values.

In summary, the results of the EPA's analyses indicate that OPP ALB and ALC values are similarly protective of aquatic life. Most importantly, comparisons between OPP ALBs and ALC, derived using longstanding methods established to develop FIFRA and CWA protective values, respectively, indicate there is little difference between these values (most within a factor of 2), and the ALB is often somewhat lower. The alternate criteria-related approaches (invertebrate-only and herbicide modified GSD and the GLI) result in lower values as compared to the OPP ALBs due to data limitations and application of assessment (safety) factors, or application of a low sample size factor ("N") in the calculations lowers these values to account for uncertainty. However, when all the ALB/ALC ratios are averaged across the three ALC and criteria-related methods and classes of insecticides, the factor differences for the acute and chronic values are similar (within a factor of four). For herbicides, the ALB/ALC ratios averaged across the three ALC and criteria-related methods also indicate the values are similar and within an order of magnitude (mean acute ratio of approximately 7 and chronic ratio of approximately 8). These differences in values all fall within the natural variability in toxicity responses and the intra- and interlaboratory variability reported in the open literature (5-10X; Chapman 1998; Duke and Taggart 2000; Fairbrother 2008; Raimondo *et al*. 2007; Raimondo *et al*. 2010). Importantly, although the pesticides investigated in this comparative analysis have relatively robust datasets, most pesticides have more constrained data sets with little to no additional toxicity information from the open literature (*i.e.*, beyond studies submitted to the EPA in support of FIFRA registration or re-registration actions), meaning there generally would be insufficient data to meet the MDRs to develop ALC recommendations based on the Guidelines. The EPA develops informational aquatic life benchmarks under CWA Section 304(a)(2) for pollutants, typically when there are insufficient toxicity data available to develop recommended water quality criteria under CWA Section 304(a)(1).

The draft analyses presented here show that CWA section 304(a) ALC and criteria-related values and OPP ALBs are similarly protective of aquatic life. If the EPA were to use the most sensitive animal and plant OPP ALBs as CWA aquatic life 304(a) protective values, either as 304(a)(1) recommended criteria or 304(a)(2) informational benchmarks, it would provide states and Tribes with information they can consider in their water quality standards to manage potential effects of most registered pesticides on aquatic life. This would satisfy the goals of the Common Effects Project by simplifying risk communications through harmonizing aquatic life toxicity assessment approaches across the EPA, save federal government resources, and provide information for environmental protection. With the addition of new pesticide CWA section 304(a) aquatic life recommended protective values for most pesticides in commerce, which are updated regularly to include the latest science, states and Tribes would be able to consider these values in their state water quality protection programs, such as for monitoring and for developing water quality criteria. The EPA proposes that the CWA aquatic life 304(a) protective values would use the Guidelines recommended standard frequency and duration (one hour acute, 4-day chronic duration; frequency of not to be exceeded more than once in three years) if applied in state criteria or for monitoring purposes.

5 References

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Appendix A: Acute Sensitivity Distributions for Pesticides and Various Protective Values

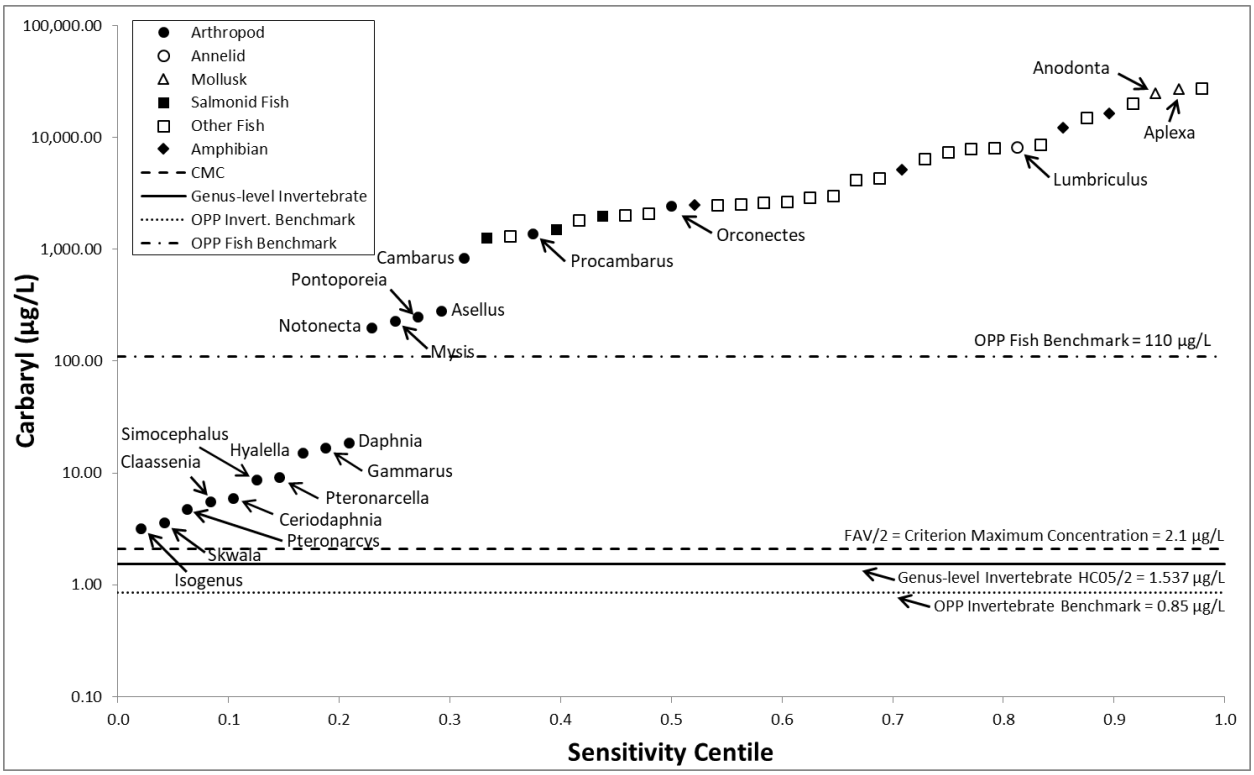

Figure A.1. Carbaryl genus-level sensitivity distribution. Symbols represent Genus Mean Acute Values (GMAVs) calculated using all quantitative data from the aquatic life criteria document for carbaryl (U.S. EPA 2012), and additional data from the OPP benchmark document for carbaryl (U.S. EPA 2007).

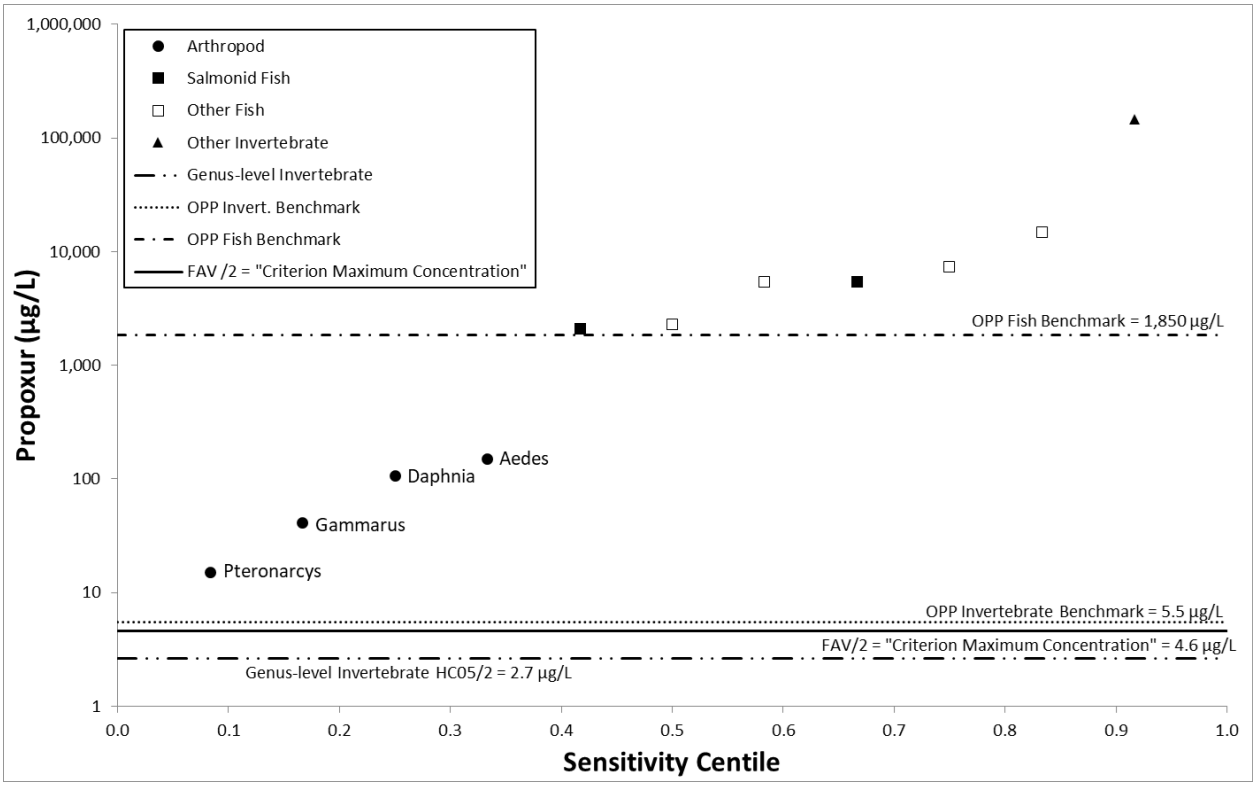

Figure A.2. Propoxur genus-level sensitivity distribution. Symbols represent Genus Mean Acute Values (GMAVs) calculated using all available data from the Office of Pesticide Program's registration review document for propoxur (U.S. EPA 2009) and an ECOTOX search conducted by Office of Water in 2013. Propoxur does not have a recommended 304(a) aquatic life criteria. The "Criterion Maximum Concentration" is an illustrative example calculated for these analyses.

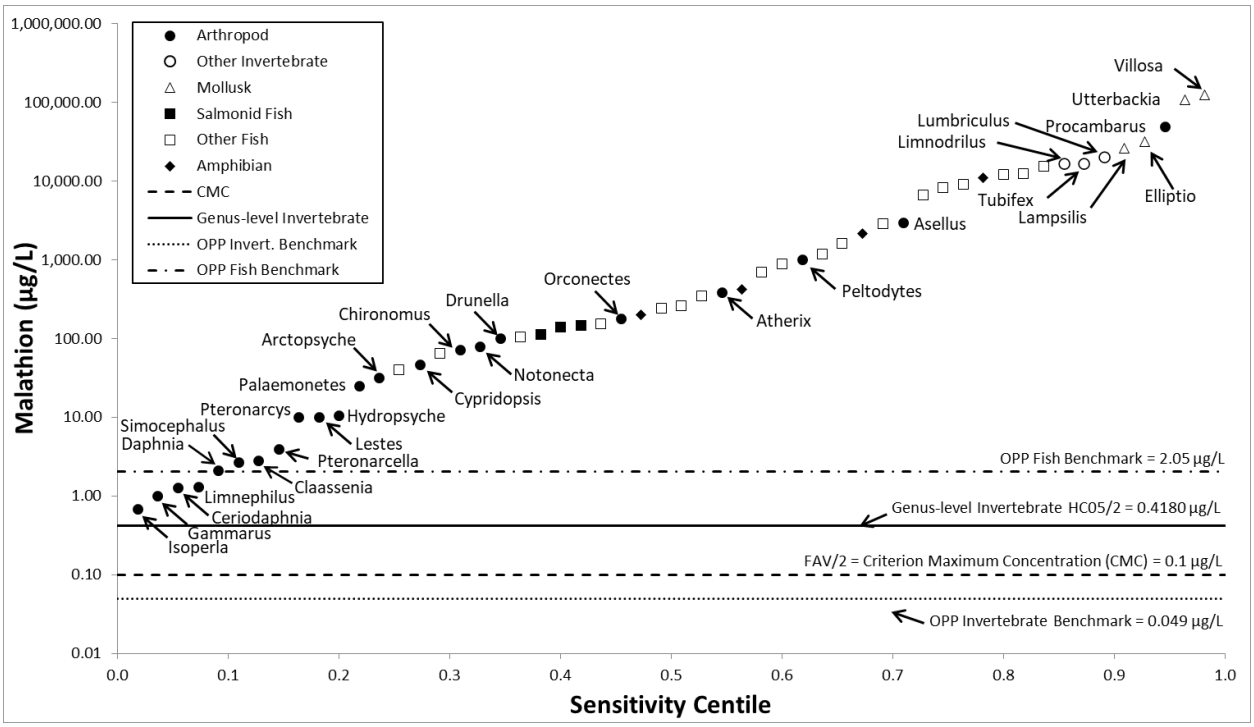

Figure A.3. Malathion genus-level sensitivity distribution. Symbols represent Genus Mean Acute Values (GMAVs) calculated using all available data from the aquatic life criteria document for malathion (U.S. EPA 1986), data from the OPP re-registration eligibility assessment document (U.S. EPA 2010) and supplemented with an ECOTOX search conducted by Office of Water in 2010. Note that the 1986 aquatic life criteria for malathion, was calculated by applying a 10x safety factor to a sensitive LC_{50} of 1.0 µg/L.

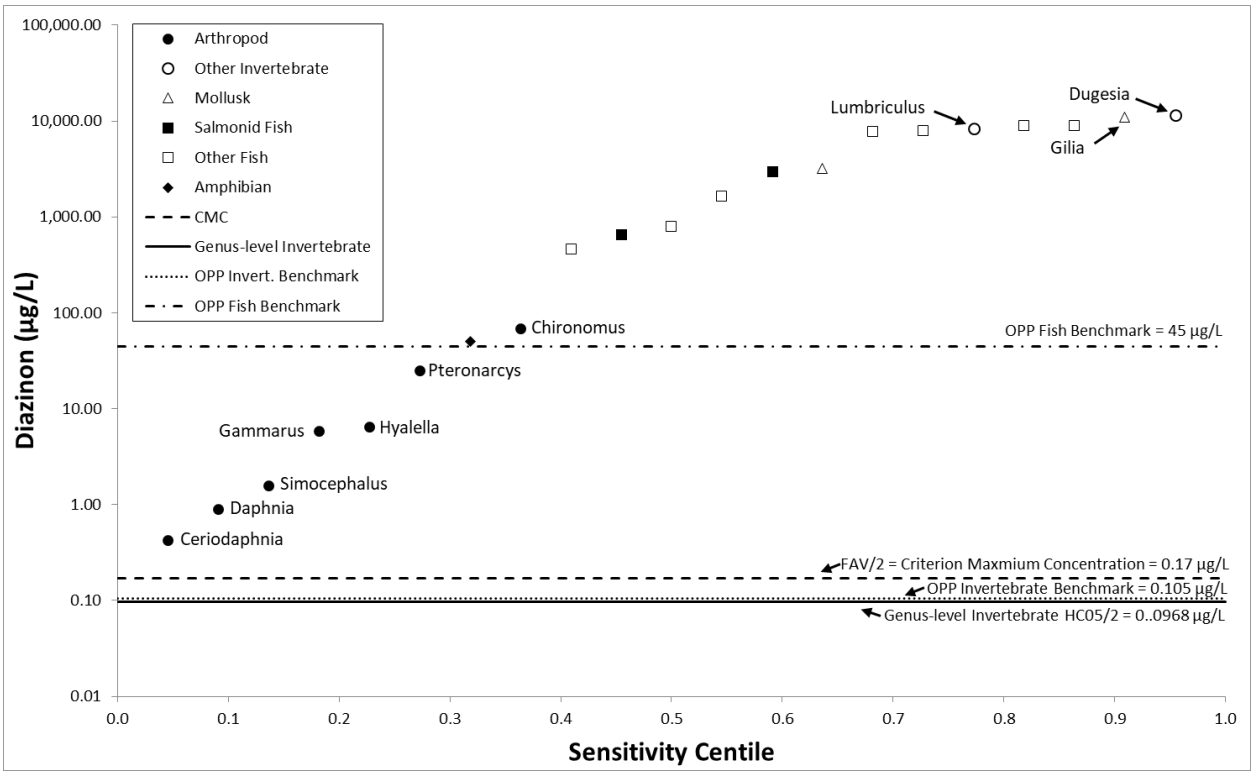

Figure A.4. Diazinon genus-level sensitivity distribution. Symbols represent Genus Mean Acute Values (GMAVs) calculated using all quantitative data from the aquatic life criteria document for diazinon (U.S. EPA 2005), data from the OPP re-registration eligibility assessment document (U.S. EPA 2007) and supplemented with an ECOTOX search conducted by Office of Water in 2010.

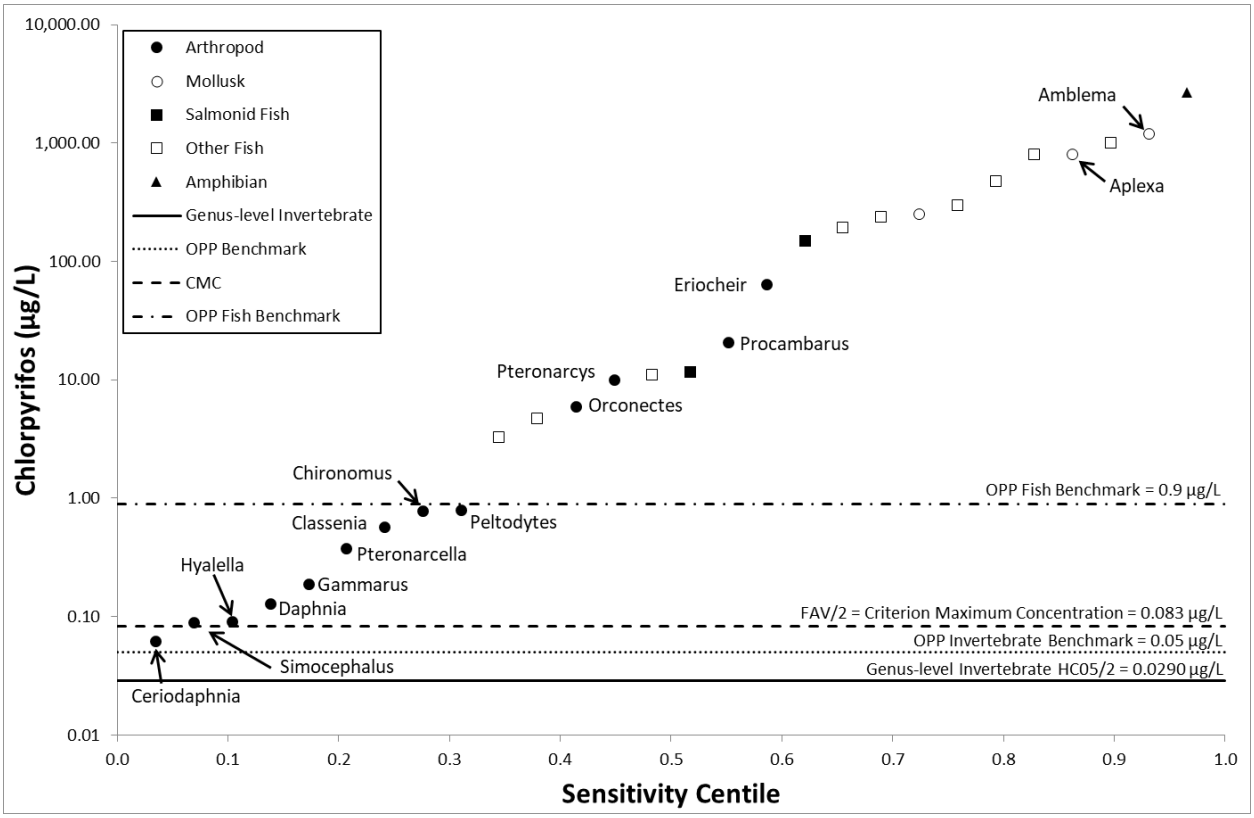

Figure A.5. Chlorpyrifos genus-level sensitivity distribution. Symbols represent Genus Mean Acute Values (GMAVs) calculated using all available data from the aquatic life criteria document for chlorpyrifos (U.S. EPA 1986), data from the OPP re-registration eligibility assessment document (U.S. EPA 2000) and supplemented with an ECOTOX search conducted by Office of Water in 2010.

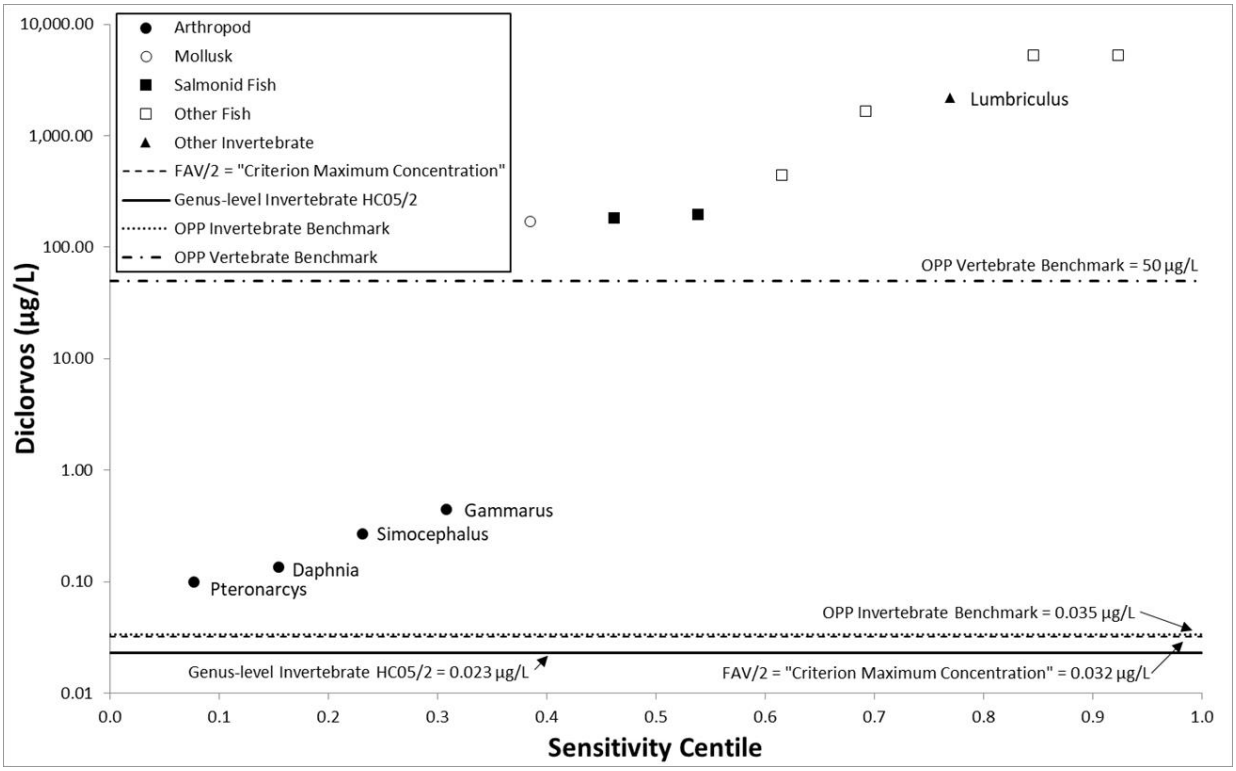

Figure A.6. Dichlorvos genus-level sensitivity distribution. Symbols represent Genus Mean Acute Values (GMAVs) calculated using all available data from the Office of Pesticide Program's registration review document for dichlorvos (U.S. EPA 2009) and an ECOTOX search conducted by Office of Water in 2013. Dichlorvos does not have a recommended 304(a) aquatic life criteria. The "Criterion Maximum Concentration" is an illustrative example calculated for these analyses.

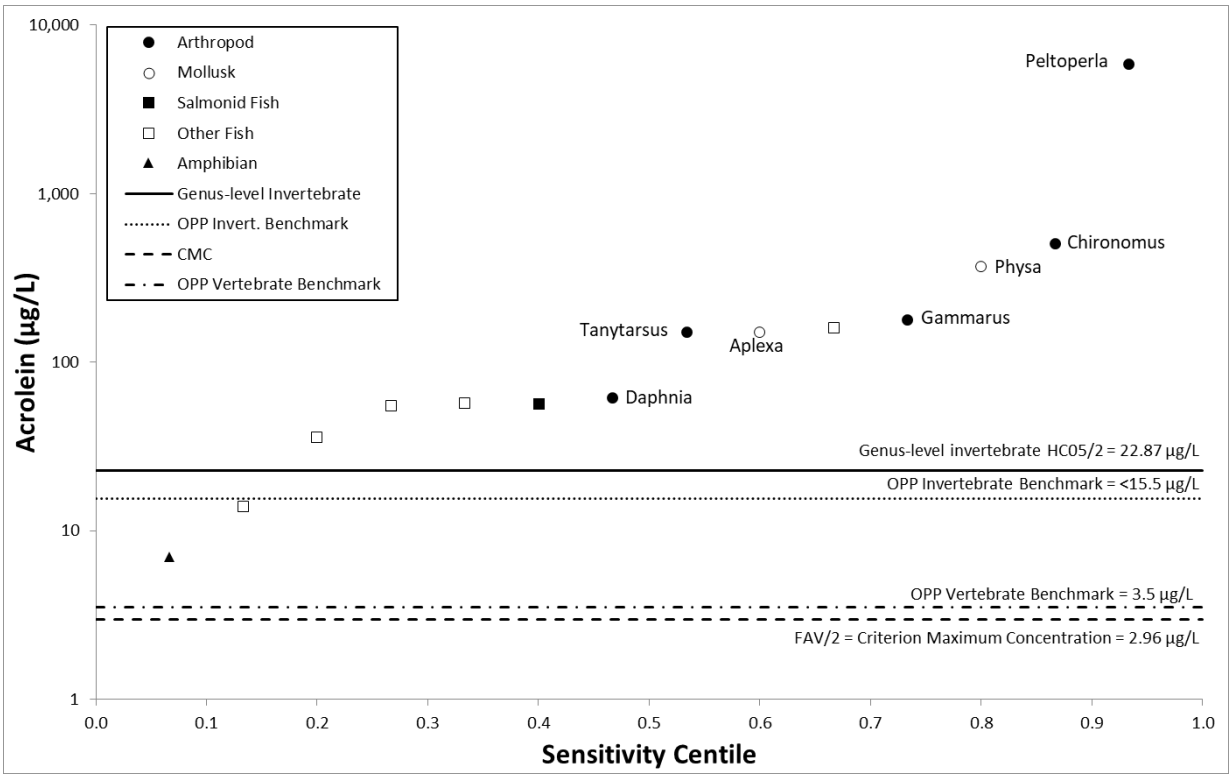

Figure A.7. Acrolein genus-level sensitivity distribution. Symbols represent Genus Mean Acute Values (GMAVs) calculated using all quantitative data from the aquatic life criteria document for acrolein (U.S. EPA 2009) and data from the OPP re-registration eligibility assessment document (U.S. EPA 2009).

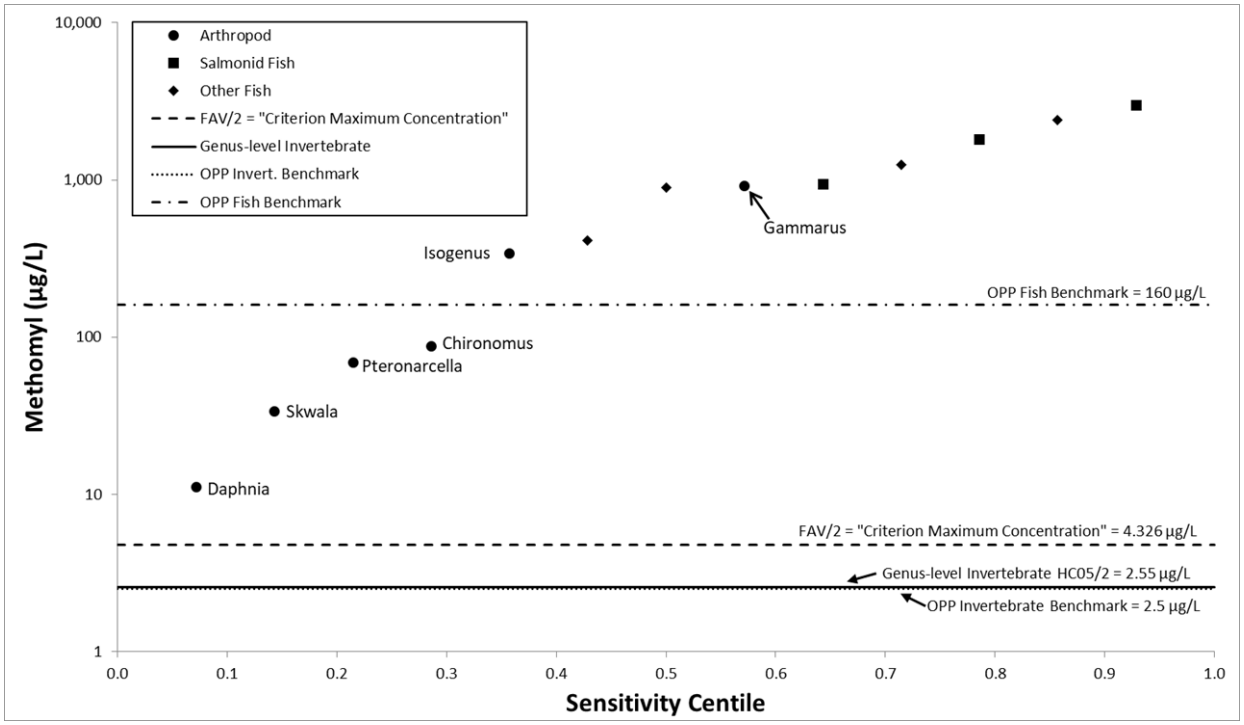

Figure A.8. Methomyl genus-level SD. Symbols represent Genus Mean Acute Values (GMAVs) calculated using all available data from an Office of Water data analysis in 2015, supplemented the Office of Pesticide Programs (OPP) registration review document for methomyl (U.S. EPA 2010). The "Criterion Maximum Concentration" is an illustrative example calculated for these analyses.

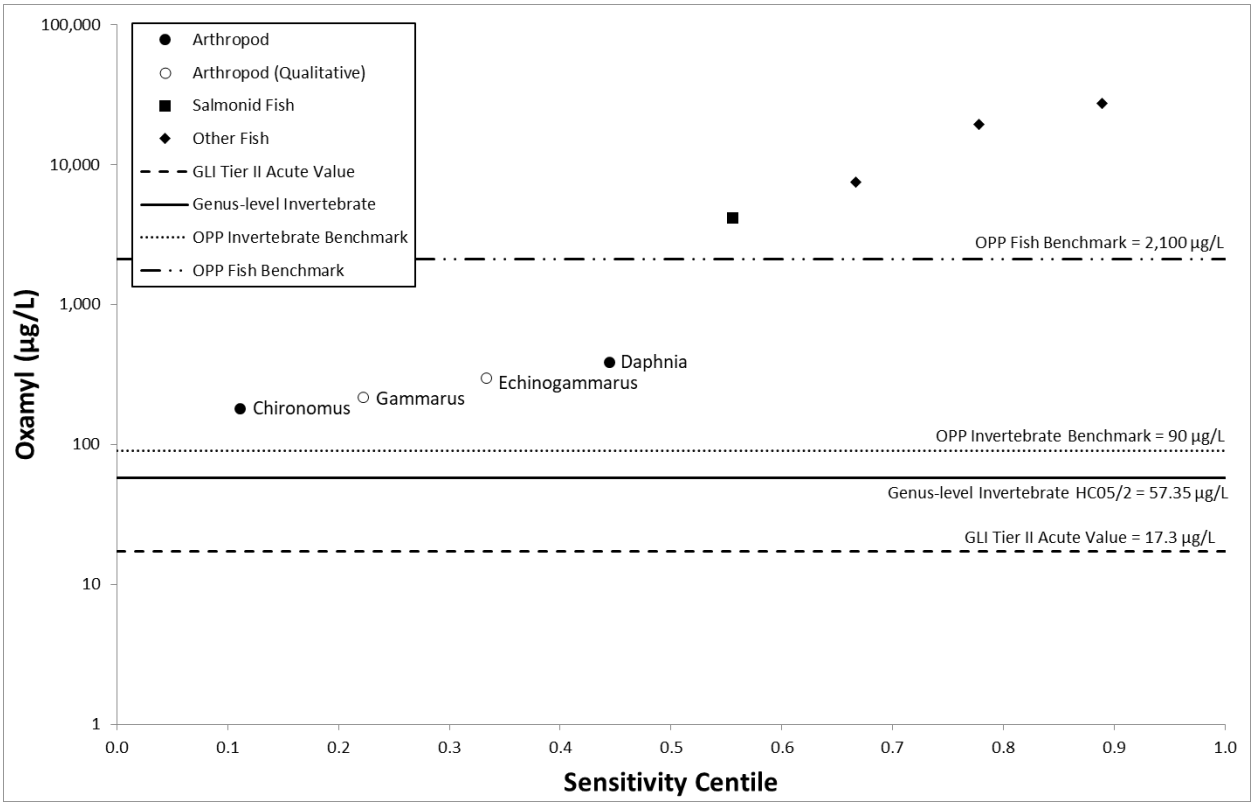

Figure A.9. Oxamyl genus-level SD. Symbols represent Genus Mean Acute Values (GMAVs) calculated using all available data from an Office of Water data analysis in 2015, supplemented the Office of Pesticide Programs (OPP) registration review document for oxamyl (U.S. EPA 2009).

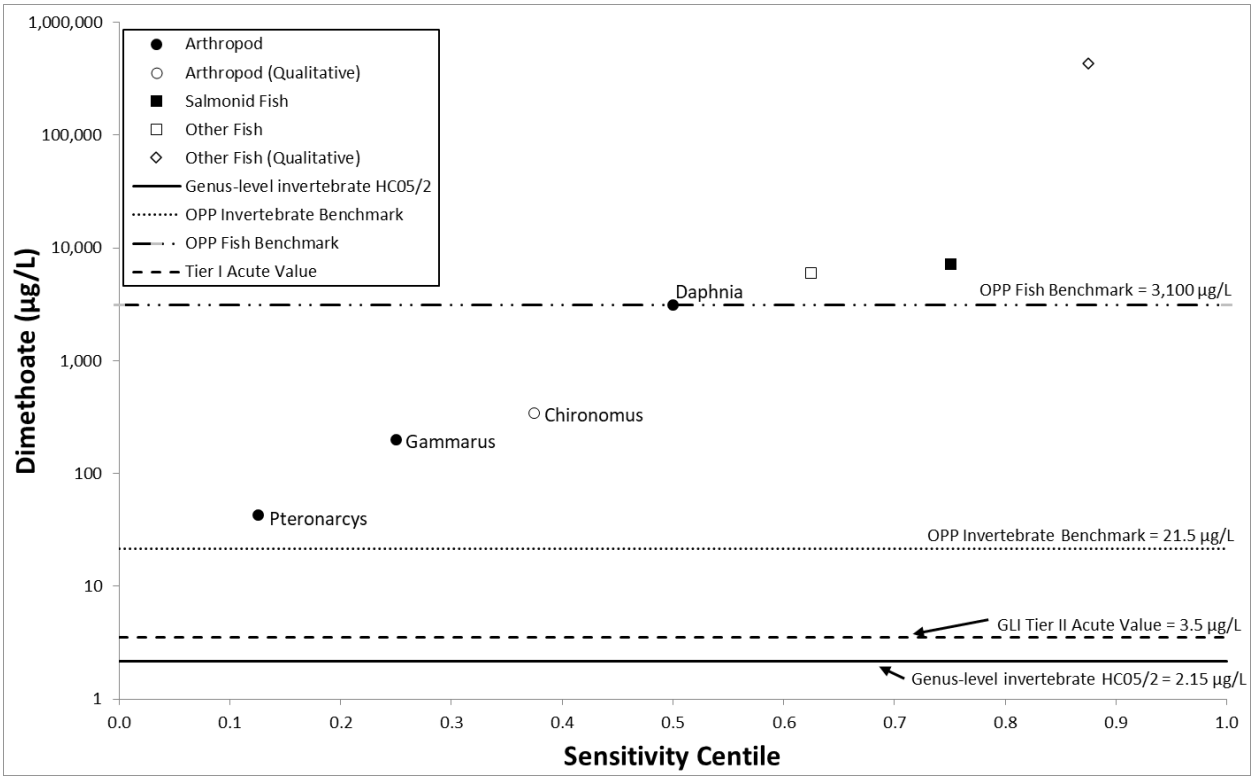

Figure A.10. Dimethoate genus-level sensitivity distribution. Symbols represent Genus Mean Acute Values (GMAVs) calculated using all available data from an Office of Water data analysis in 2015, supplemented the Office of Pesticide Programs (OPP) registration review document for dimethoate (U.S. EPA 2008).

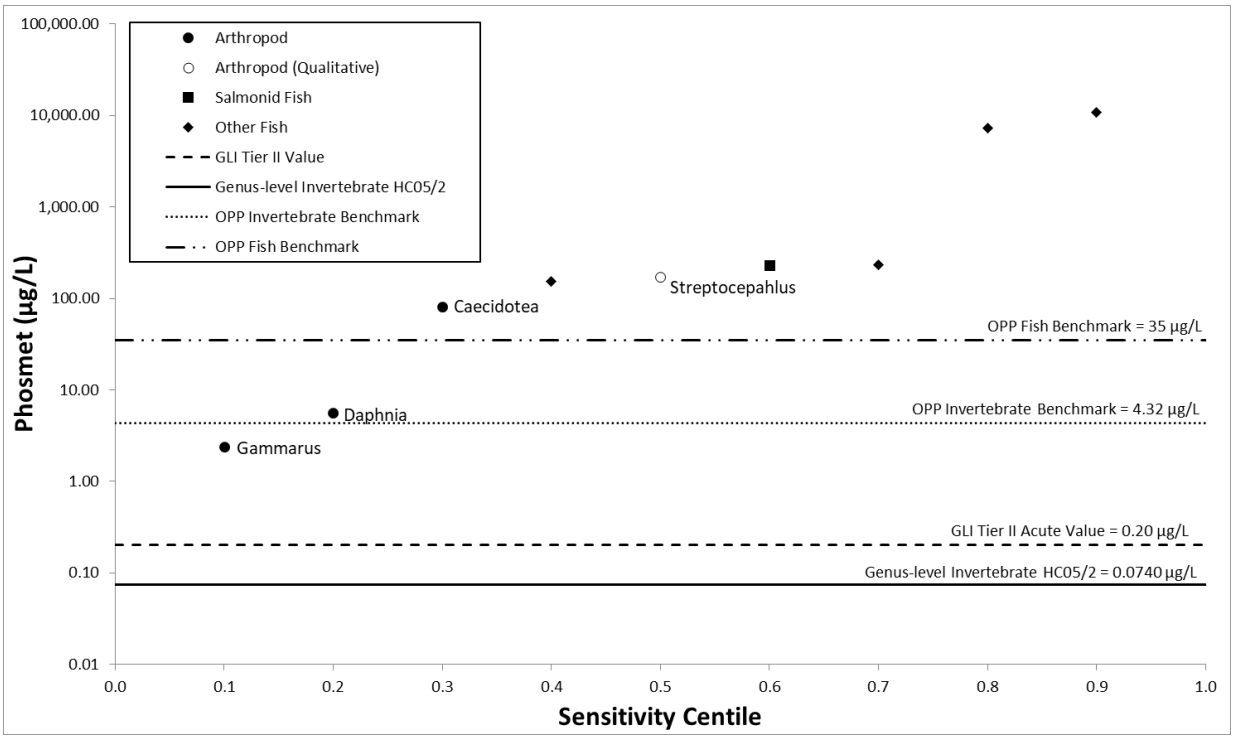

Figure A.11. Phosmet genus-level sensitivity distribution. Symbols represent Genus Mean Acute Values (GMAVs) calculated using all available data from an Office of Water data analysis in 2015, supplemented the Office of Pesticide Programs (OPP) registration review document for phosmet (U.S. EPA 2009).

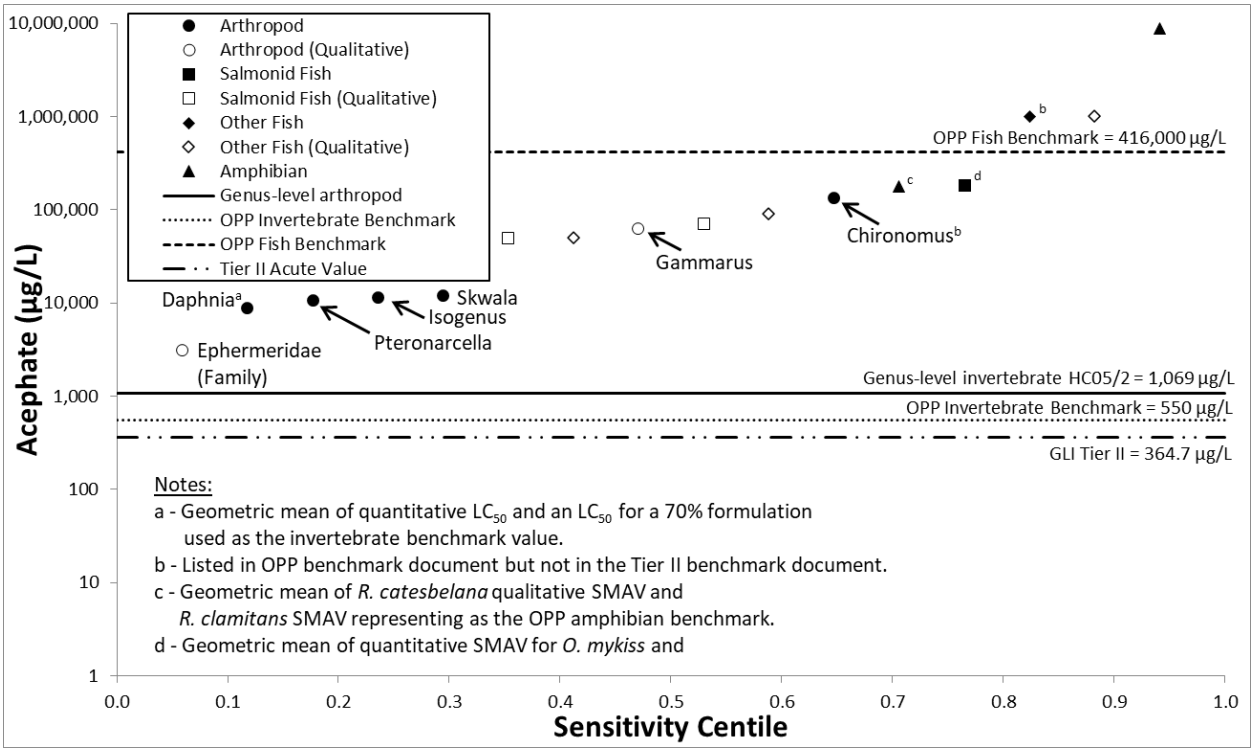

Figure A.12. Acephate genus-level sensitivity distribution. Symbols represent Genus Mean Acute Values (GMAVs) calculated using all available data from an Office of Water data analysis in 2015, supplemented the Office of Pesticide Programs (OPP) registration review document for phosmet (U.S. EPA 2007).

Appendix B: Acute and Chronic Sensitivity Distributions for Herbicides and Various Protective Values

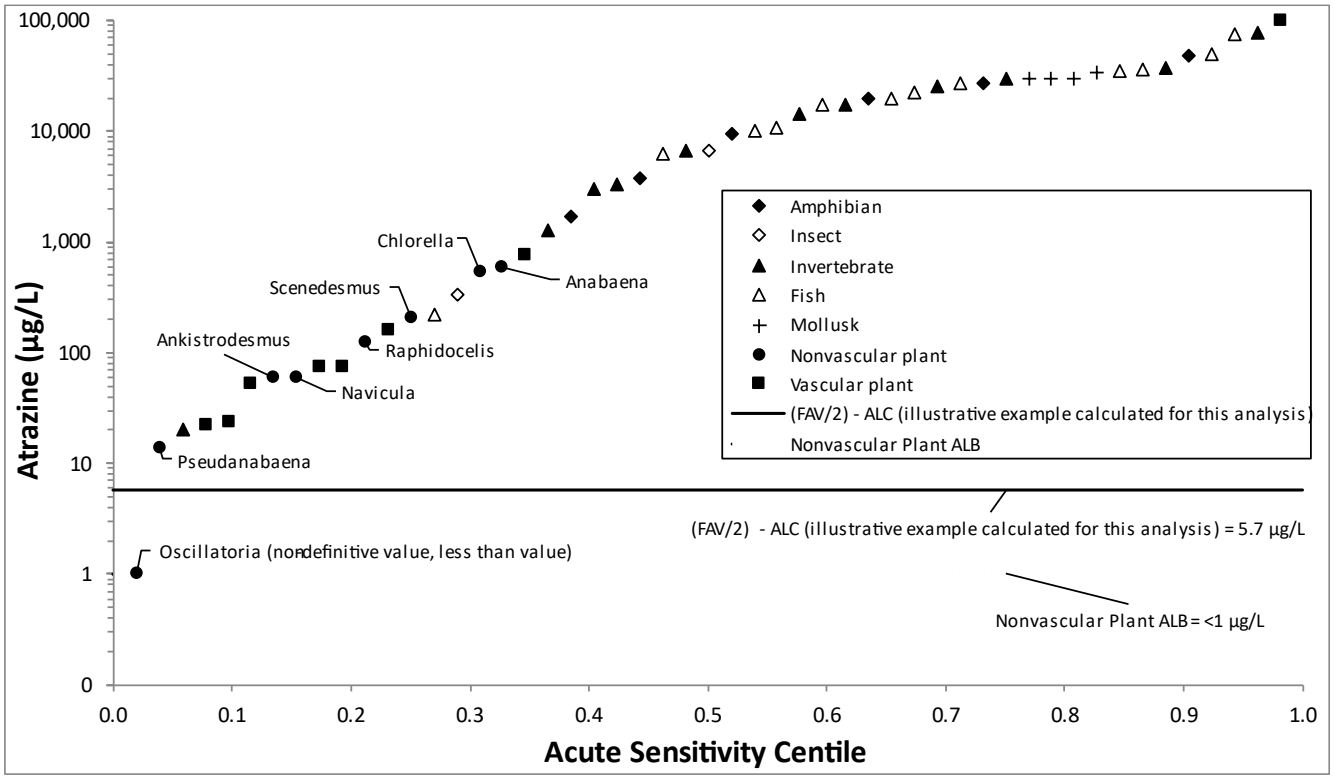

Figure B.1. Atrazine acute genus-level sensitivity distribution. Symbols represent Genus Mean Acute Values (GMAVs) calculated using all available data registration review document (U.S. EPA 2016) supplemented with data obtained by an ECOTOX search (November 2021). Atrazine does not have a recommended 304(a) aquatic life criteria, however an illustrative example ALC was calculated for this analysis.

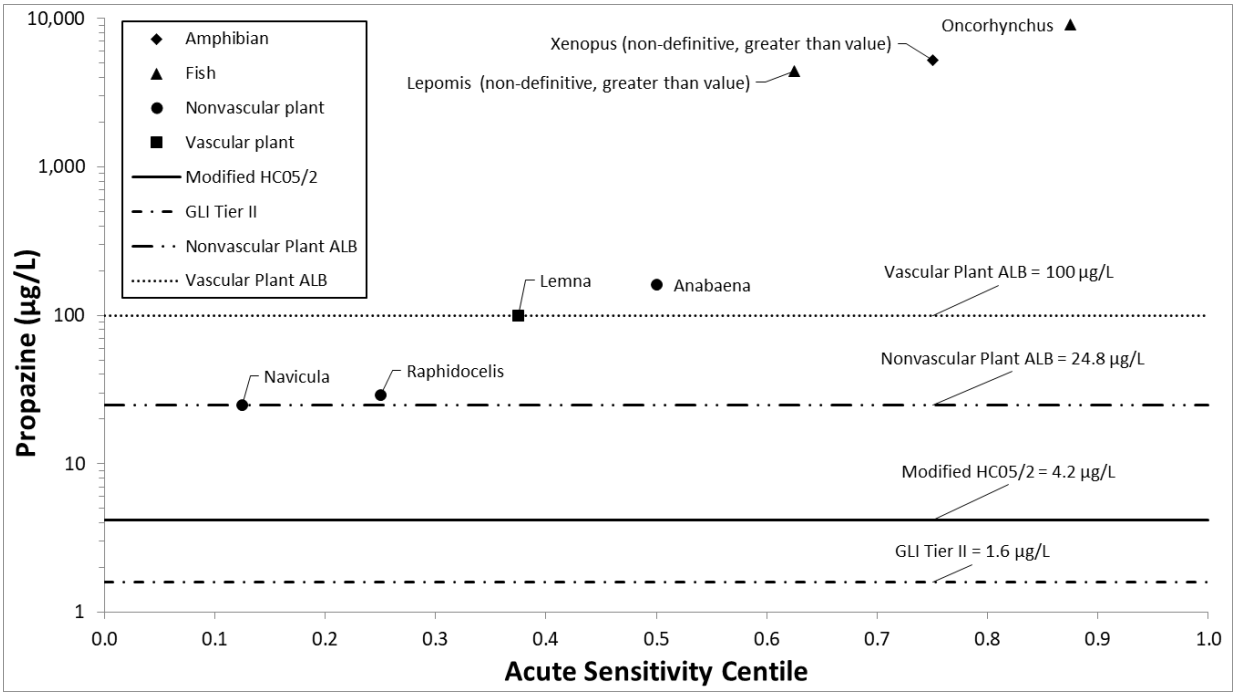

Figure B.2. Propazine acute genus-level sensitivity distribution. Symbols represent Genus Mean Acute Values (GMAVs) calculated using all available data registration review document (U.S. EPA 2016) supplemented with data obtained by an ECOTOX search (November 2021).

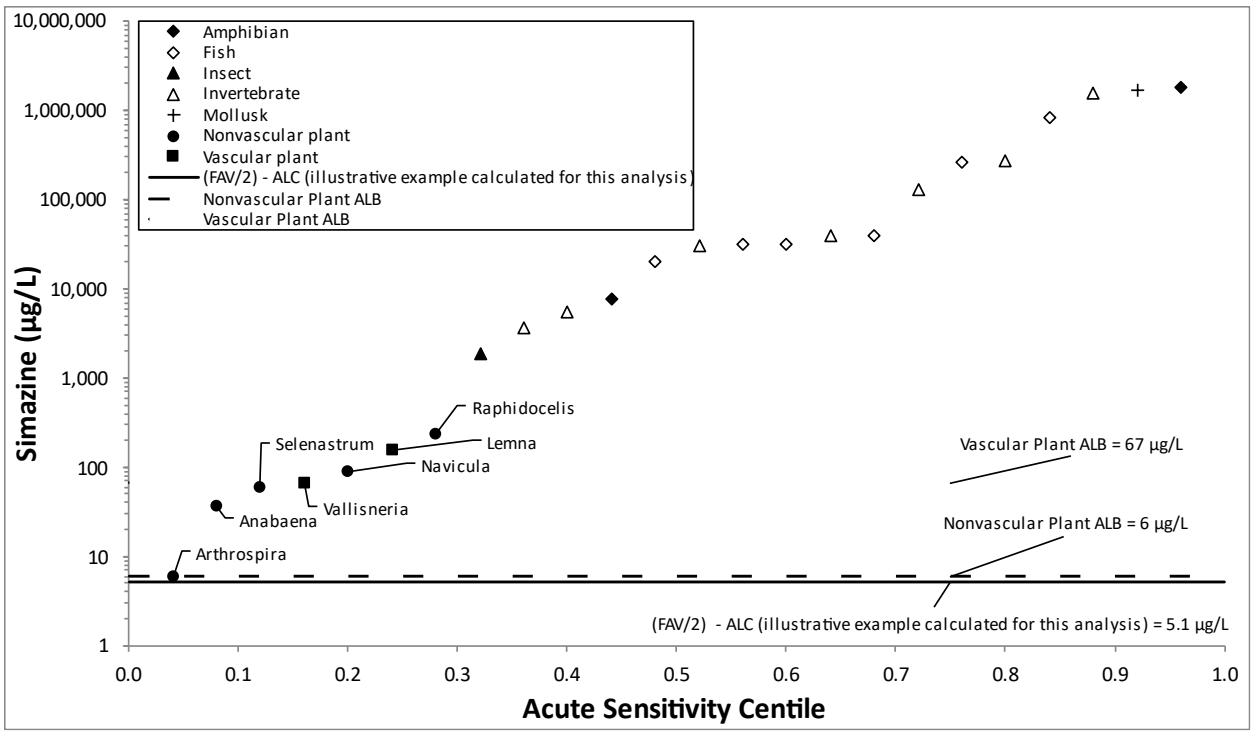

Figure B.3. Simazine acute genus-level sensitivity distribution. Symbols represent Genus Mean Acute Values (GMAVs) calculated using all available data registration review document (U.S. EPA 2009) supplemented with data obtained by an ECOTOX search (November 2021). Simazine does not have a recommended 304(a) aquatic life criteria, however an illustrative example ALC was calculated for this analysis.

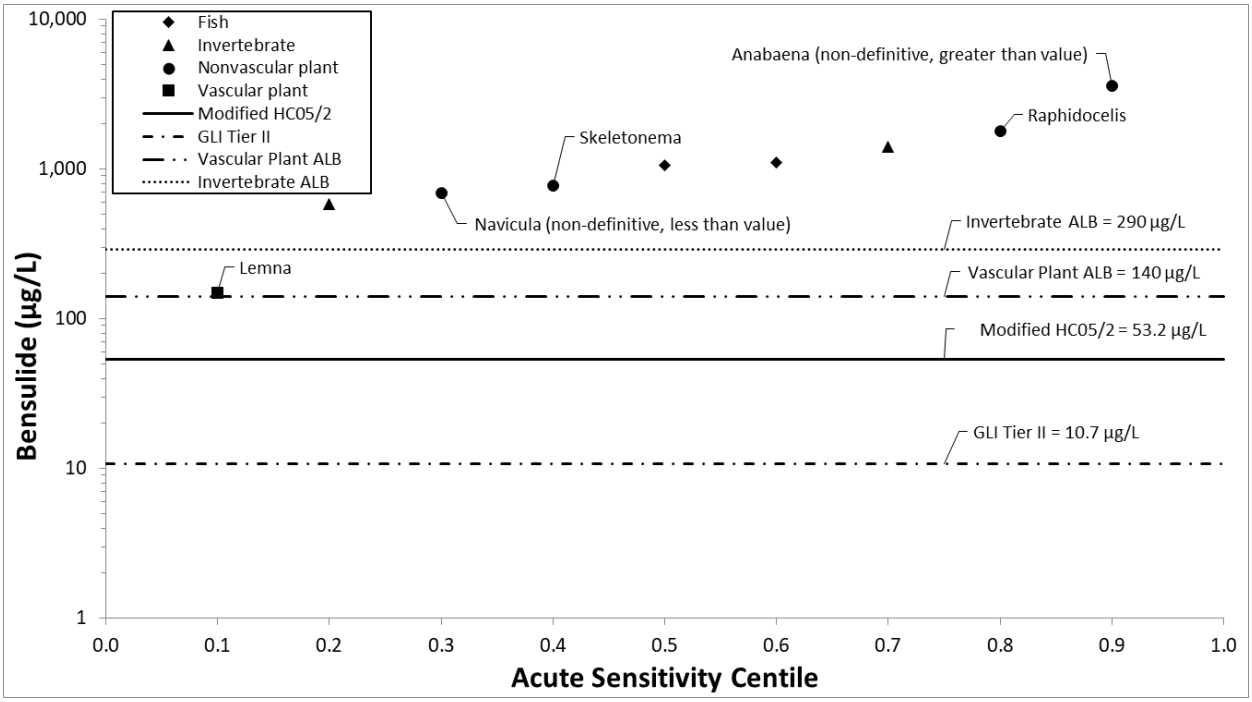

Figure B.4. Bensulide acute genus-level sensitivity distribution. Symbols represent Genus Mean Acute Values (GMAVs) calculated using all available data registration review document (U.S. EPA 2009) supplemented with data obtained by an ECOTOX search (November 2021).

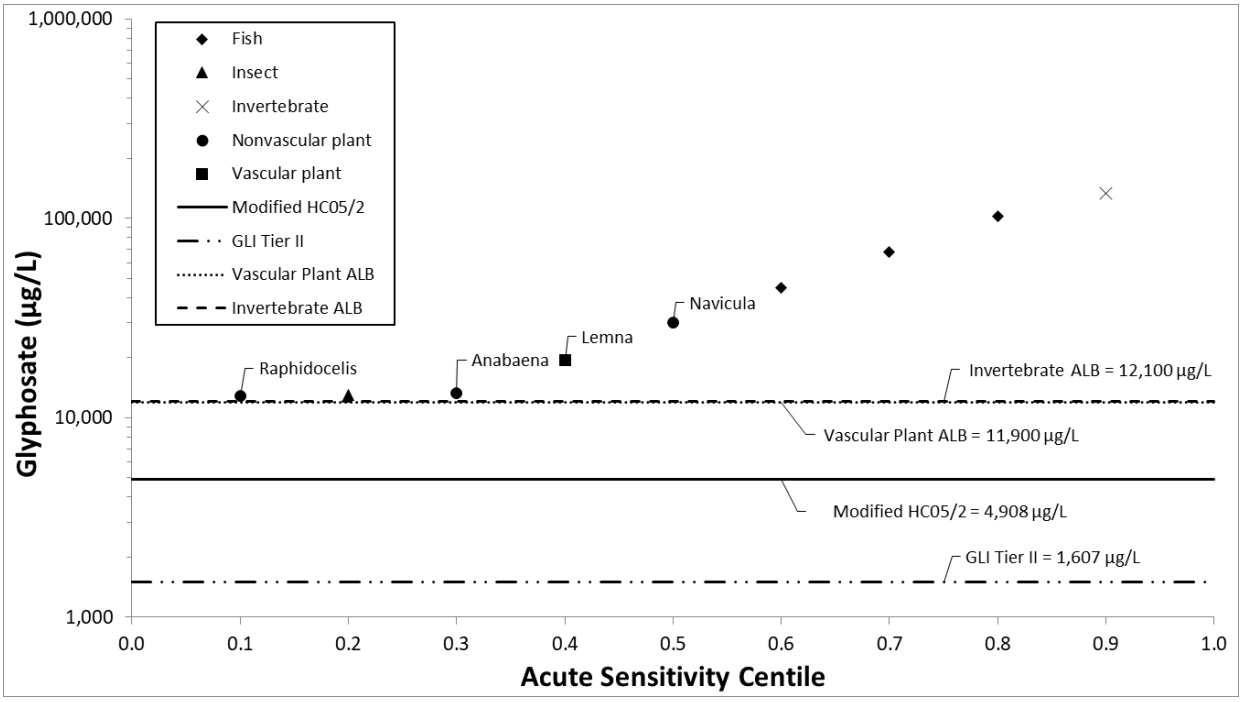

Figure B.5. Glyphosate acute genus-level sensitivity distribution. Symbols represent Genus Mean Acute Values (GMAVs) calculated using all available data registration review document (U.S. EPA 2009).

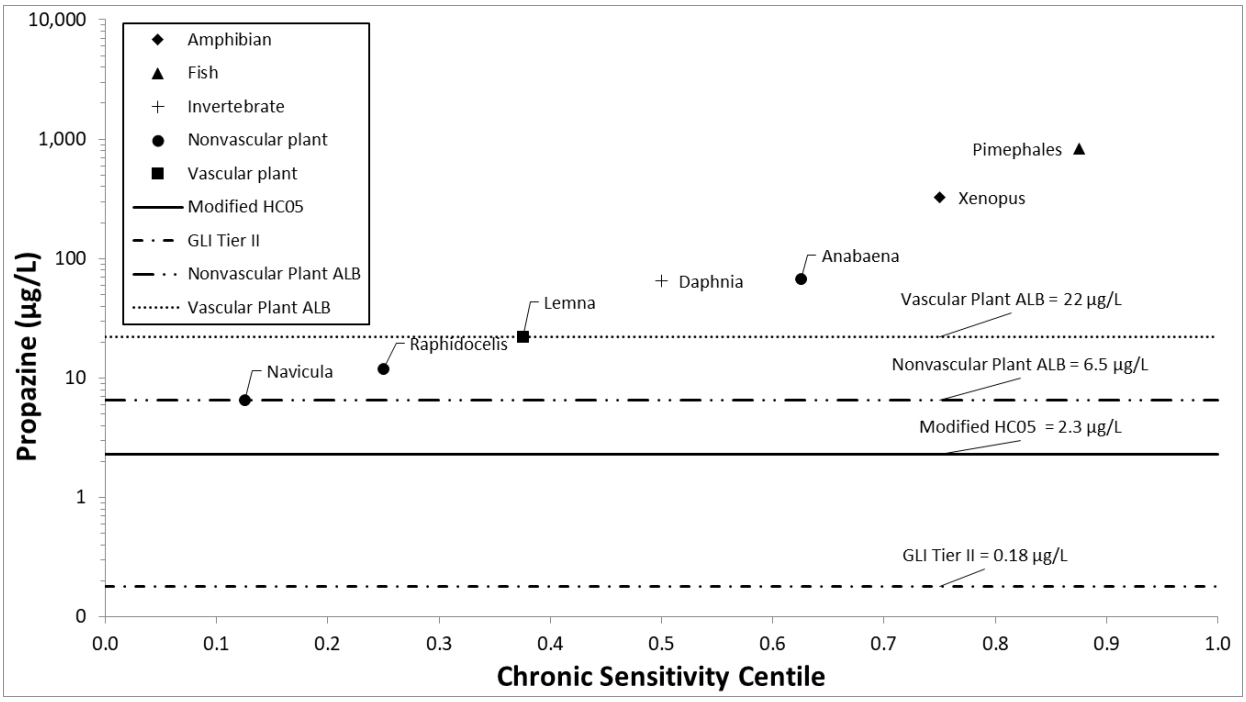

Figure B.6. Propazine chronic genus-level sensitivity distribution. Symbols represent Genus Mean Chronic Values (GMCVs) calculated using all available data registration review document (U.S. EPA 2016) supplemented with data obtained by an ECOTOX search (November 2021).

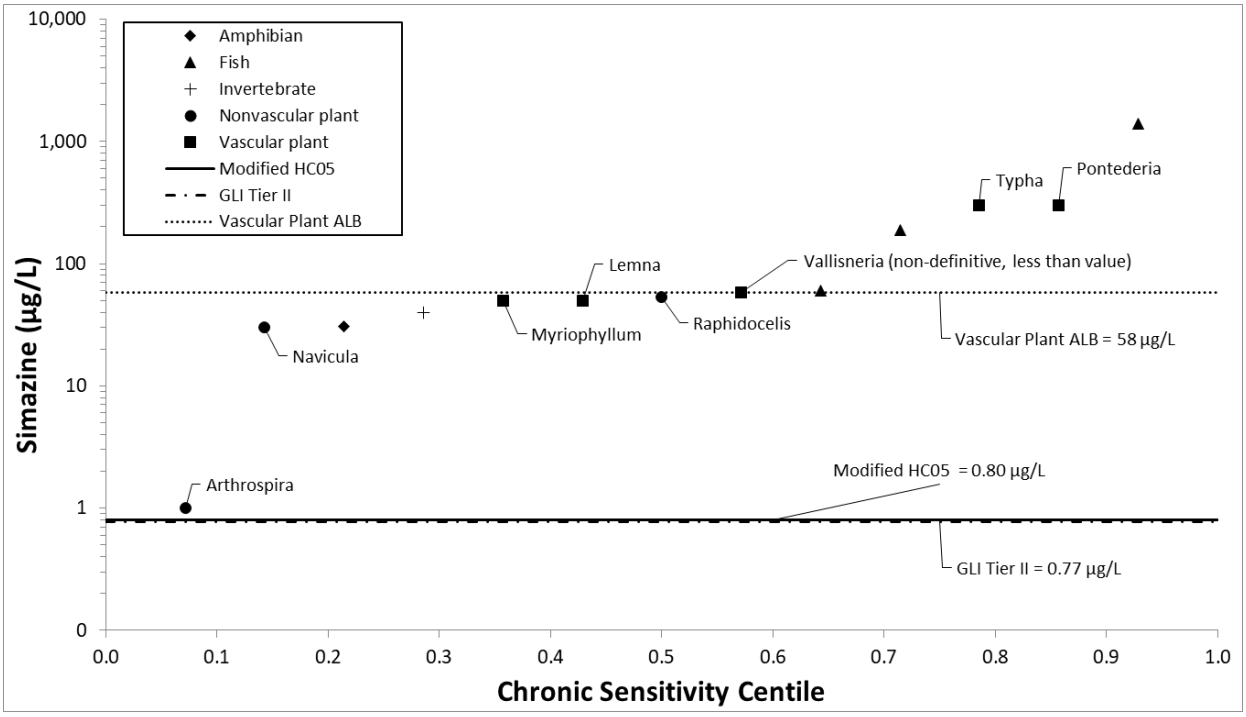

Figure B.7. Simazine chronic genus-level sensitivity distribution. Symbols represent Genus Mean Chronic Values (GMCVs) calculated using all available data registration review document (U.S. EPA 2016) supplemented with data obtained by an ECOTOX search (November 2021).

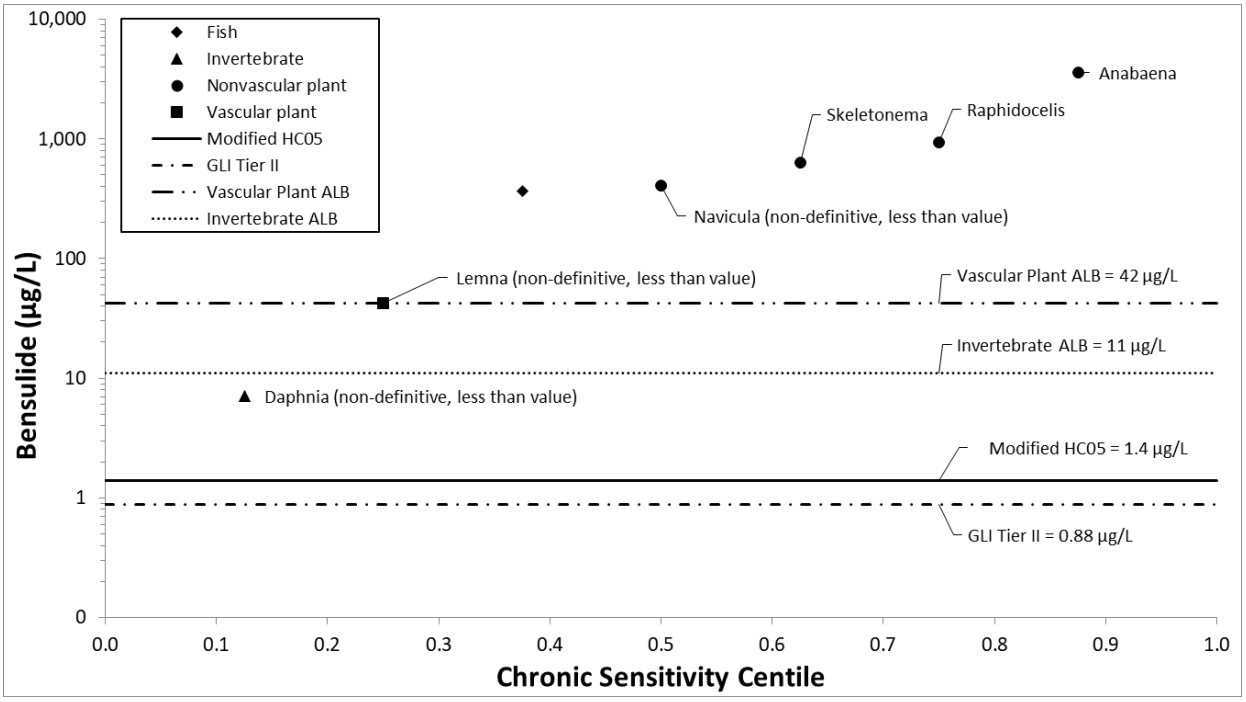

Figure B.8. Bensulide chronic genus-level sensitivity distribution. Symbols represent Genus Mean Chronic Values (GMCVs) calculated using all available data registration review document (U.S. EPA 2016) supplemented with data obtained by an ECOTOX search (November 2021).

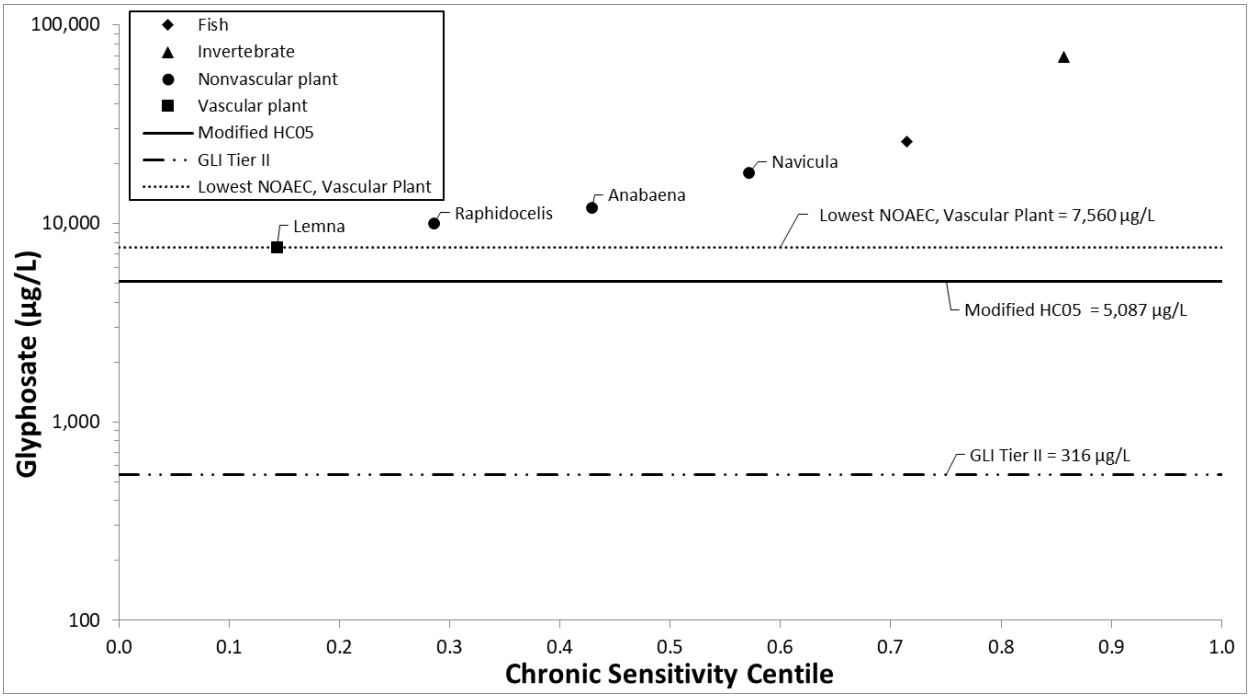

Figure B.9. Glyphosate chronic genus-level sensitivity distribution. Symbols represent Genus Mean Chronic Values (GMCVs) calculated using all available data registration review document (U.S. EPA 2009).