September 2020

Framework for Conducting Pesticide Drinking Water Assessments for Surface Water

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Office of Pesticide Programs
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Washington, DC

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List of Acronyms

BEAD	Biological and Economic Analysis Division
CFR	Code of Federal Regulations
CWS	Community Water System
DEEM	Dietary Exposure Evaluation Model
DWA	Drinking Water Assessment
DWI	Drinking Water Intake
DWLOC	Drinking Water Level of Comparison
EFED	Environmental Fate and Effects Division
EPA	Environmental Protection Agency
FFDCA	Federal Food, Drug and Cosmetics Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FIRST	FQPA Index Reservoir Screening Tool
FQPA	Food Quality Protection Act
HED	Health Effects Division
HUC	Hydrologic Unit Code
LOQ	Limit of Quantification
Mgal/d	Million gallons per day
NAWQA	USGS National Water-Quality Assessment

NWIS	USGS National Water Information System
OPP	Office of Pesticide Programs
PAD	Population Adjusted Dose
PCA	Percent Cropped Area
PCT	Percent Crop Treated
PDP	USDA Pesticide Data Program
PFAM	Pesticide in Flooded Applications Model
PRIA	Pesticide Registration Improvement Act
PRD	Pesticide Re-Evaluation Division
PRZM	Pesticide Root Zone Model
PWC	Pesticide in Water Calculator
QA	Quality Assurance
QC	Quality Control
RD	Registration Division
SAM	Spatial Aquatic Model
SAP	Scientific Advisory Panel
SBF	Sampling Bias Factor
SEAWAVE-QEX	Seasonal Wave with Streamflow Adjustment with Extended Capability
SLUA	Screening Level Use Assessment
SOP	Standard Operating Procedure
STORET	EPA Storage and Retrieval Warehouse
SUUM	Summary Use and Usage Matrix
USGS	U.S. Geological Survey
VVWM	Variable Volume Water Model
WQP	Water Quality Portal

1.0 Introduction

The Environmental Protection Agency (EPA) developed this framework to document the long-standing practices that the Office of Pesticide Programs (OPP) uses to conduct drinking water assessments (DWAs) for conventional pesticides in surface water. This framework is intended to increase consistency and transparency in the derivation of estimated pesticide concentrations in surface water for use in DWAs, and to foster cross-division coordination in the context of the statutory requirements imposed by Food Quality Protection Act (FQPA). This framework documents the standard, tiered assessment approach for estimating pesticide concentrations in surface water sources of drinking water, as well as integrating new methods, reliable data sources, and factors that refine the use of surface water monitoring data quantitively in DWAs.

This document should be followed by OPP staff as they conduct drinking water assessments. In addition, this document serves as a reference for contextual information for stakeholders and the general public on how OPP conducts drinking water assessments. This document is not a standard operating procedure (i.e., lacks technical details) and is written for a diverse audience. It is also not intended to be a comprehensive summary of all OPP guidance documents and scientific publications, but rather provides references to the associated detailed documents and ties together all the publications in a process format.

1.1. Regulatory Context

Pesticides are regulated in the United States under both the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetics Act (FFDCA). In 1996, Congress passed the Food Quality Protection Act (FQPA) which amended both FIFRA and FFDCA. Through these statutes, the EPA, OPP evaluates potential risks posed by using a pesticide to determine whether it can be used safely.

Under FIFRA, all pesticides distributed or sold in the United States must be registered by the EPA. In determining whether a pesticide can be registered in the United States, EPA evaluates the potential impact on human health and the environment. The FFDCA requires EPA to set pesticide tolerances[1] for all pesticides used in a manner that may result in a pesticide residue in or on food

[1] A tolerance is the maximum permissible level of a pesticide residue allowed in food or feed.

or animal feed, including direct application to food. FFDCA requires EPA to make a finding for each tolerance or tolerance exemption, "that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." EPA can grant tolerance exemptions based on data that indicate low exposure or little-to-no toxicity.

Aggregate exposure refers to the combined exposures to a single pesticide, and its associated transformation products, across multiple exposure routes (i.e., oral, dermal, and inhalation) and across multiple pathways (i.e., food, drinking water, and residential uses). As a result, EPA is required to estimate pesticide exposure concentrations in drinking water sources including groundwater and surface water and compare these concentrations to measures of adverse effects to humans. EPA considers potential exposure to conventional pesticides, antimicrobial and biopesticides in both sources of drinking water.

The process described for conducting a drinking water assessment was initiated in 1996 with passage of FQPA. The process has evolved since its inception, incorporating new models, data, and methods. The concepts, models, and assumptions have been vetted through various FIFRA Scientific Advisory Panels (SAPs) and in partnership with subject matter experts such as the International Life Sciences Institute (ILSI, 1999). These efforts are summarized in chronological order in the Historical Overview provided in **Appendix A (**and are described in more detail in the relevant tiering sections of this framework. EPA has developed several guidance documents and standard operating procedures (SOPs) to facilitate consistent development of DWAs (refer to **Appendix C** for a list documents).

Environmental fate scientists in EPA's Environmental Fate and Effects Division (EFED) are responsible for conducting DWAs for the human health dietary risk assessment, which includes estimating the potential concentrations of pesticides and associated transformation products identified as residues of toxicological concern in drinking water. EFED typically completes 100 or more DWAs annually to support regulatory actions. In 2017 and 2018, 148 and 114 DWAs were completed, respectively. These actions include new pesticide registrations (i.e., the first registration of an active ingredient in the United States), new use registrations (i.e., a use site added to a currently registered pesticide), and registration reviews (i.e., review of current registrations in 15-year cycles). Typically, there are six to twelve DWAs annually for new pesticide active ingredients with the remaining roughly split between new use registrations and registration reviews.

In a DWA, EFED estimates concentrations of pesticides in surface water bodies resulting from a single (e.g., corn) or multiple (e.g., corn, cotton, and turf) labeled uses of a pesticide using aquatic models such as the Pesticide in Water Calculator (PWC) and the Pesticide in Flooded Application Model (PFAM)[2]. While aquatic model inputs such as soil and weather may be localized (e.g., limited to field, county or statewide analyses), the DWA typically encompasses a large geographical scale (regional or national), representing a wide range of environmental conditions, use patterns, and agricultural practices, and thereby, a wider range of potential pesticide concentrations in drinking water sources. Since it is not feasible to directly sample for pesticide concentrations at every location and time, EPA uses data from one or more localized sites and uses model scenarios from across the country to develop conclusions about pesticide concentrations across the entire landscape.

Aquatic models are parameterized using environmental fate and transport data specific to the pesticide under evaluation to derive environmental persistence (i.e., half-lives in soil and water) and soil mobility inputs. The data are also used to help decide if transformation products may need to be considered as residues of toxicological concern. These data are considered along with the physical-chemical properties (e.g., solubility and vapor pressure) of the pesticide to complete aquatic modeling. EFED also considers available water monitoring data for pesticides already on the market when conducting DWAs.

Each regulatory action has a specific timeline and associated regulatory requirements for completion. For example, to add new food use(s) for a registered pesticide, EPA has 10 to 15 months to review and decide to register, whereas the review and decision time for a new active ingredient with food uses is 24 months under the Pesticide Registration Improvement Act (PRIA). However, in practical terms, EFED has two to six months to complete a DWA to support either of these types of new use actions, as enough time must be allotted to the EPA Health Effects Division (HED) to incorporate the information into their human health risk assessment

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[2] Water exposure models used in pesticide risk assessments: https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/models-pesticide-risk-assessment

and assess the risks before a registration decision is made.

HED incorporates the estimated pesticide concentrations from the DWA into an aggregated human health risk assessment following the guidance *General Principles for Performing Aggregate Exposure and Risk Assessments* (USEPA, 2001). Both EFED and HED utilize tiered approaches for conducting drinking water exposure and human health risk assessments. Conceptually, the HED and EFED tiered processes are aligned in terms of the level of effort, built-in conservatisms in the lower tiers, and integration of additional data to generate more realistic exposure estimates in higher tiers. However, the divisions' tiered processes differ in the details (e.g., methods, data, and assumptions) which requires coordination and collaboration across the divisions.

Collaboration is also required with other divisions within OPP. The risk management divisions: the Registration Division (RD), and the Pesticide Re-Evaluation Division (PRD) lead the regulatory decision-making process, depending on the nature of the action (i.e., whether it is for a new registration or registration review). These two risk management divisions are the liaisons with pesticide registrants, ensuring that the necessary data for the pesticide under evaluation have been provided to the respective science divisions (i.e., EFED, HED, and the Biological and Economic Analysis Division [BEAD]). BEAD provides summarized pesticide product label information, as well as usage data currently registered pesticides under evaluation. RD evaluates the product chemistry studies, and HED provides toxicity data relevant to human health for the pesticide under evaluation and all relevant transformation products. The HED chemical team also provides a Drinking Water Level of Comparison (DWLOC), which is an estimate of the maximum concentration of the pesticide and other residues of concern that may be in drinking water without triggering a risk concern for human health. As described in more detail throughout this framework, the DWLOC is an important benchmark used by EFED in the tiering process. The collaboration between OPP divisions is necessary to complete DWAs quickly and efficiently while maintaining transparency, using sound science, and meeting regulatory requirements.

1.2. Document Organization and Scope

The objective of this document is to present the tiering framework for completing a DWA. Each section of this document is dedicated to each component of the process and includes a description of the tier, the methods used to estimate drinking water concentrations, considerations in the decision-making process for advancement to the next tier, and standard practices for communicating and coordinating between EPA divisions. A summary of the tiering process is provided in the following section and in **Appendix B**. Sections in this framework document are organized as follows:

- **Section 2** describes the scoping process that occurs prior to starting a DWA.
- **Section 3** provides a description for completing a Tier 1 DWA.
- **Section 4** describes the current practices and data sources utilized in conducting Tier 2 DWAs, including an explanation of how aquatic exposure models and surface water monitoring data are used in combination to support the recommended estimated pesticide concentrations. A Tier 2 assessment may be done on a national or sometimes regional scale.
- **Section 5** describes the Tier 3 DWA, which is conducted on a regional or local scale, considers typical use information, and begins the process of identifying regions or areas of the country with and without estimated pesticide concentrations that exceed the human health DWLOCs. This section also describes the new methods and data quality considerations for using available pesticide surface water monitoring data in a robust manner by utilizing upper-bound sampling bias factors (SBFs). SBFs account for the uncertainty associated with the available non-daily pesticide surface water monitoring data and account for the spatial and temporal limitations in available pesticide surface water monitoring data.
- **Section 6** describes approaches to complete a Tier 4 DWA. This analysis is completed at the more localized level and is often site-specific. There is a high level of confidence in the reported estimated pesticide concentrations and in the agronomic and environmental conditions those estimates represent. In addition to spatially explicit modeling, monitoring data are considered on a site-specific basis.
- **Section 7** describes future direction involving alternative waterbodies for capturing the variability of drinking water supplies, and the Spatial Aquatic Model (SAM).

1.3. Overview of Tiered Approach

EPA utilizes a tiered approach to provide timely drinking water assessments and conserve resources to conduct 100 or more DWAs each year. The framework for conducting a tiered DWA is illustrated in **Figure 1.1**. As illustrated in **Figure 1.1**, EFED has defined four assessment tiers for DWAs. As the DWA transitions to higher tiers (i.e., Tier 1 through Tier 4), the more refined the DWA becomes and the more coordination and collaboration across divisions is required. Lower tiered assessments are more conservative based on the defaults or conservative assumptions, while higher tiers integrate more available data and provide more realistic estimates of environmental pesticide concentrations.

These four tiers are generally based on the level of effort, the amount of data considered, the spatial scale, and the certainty in the estimated pesticide concentration. Tier 1 requires the least amount of effort and the least amount of data; whereas, Tier 4 is resource intensive, considers a wide range of sources and types of data, and is spatially explicit, resulting in a higher confidence in the reported pesticide concentration. Each successive tier integrates more focused pesticide, spatial, temporal, agronomic, and crop-specific information. The order in which refinements are considered (i.e. the order in which the assessment is refined) is pesticide specific, depends on the nature and quality of the available data used to support the refinement, and is determined in collaboration with the broader OPP team.

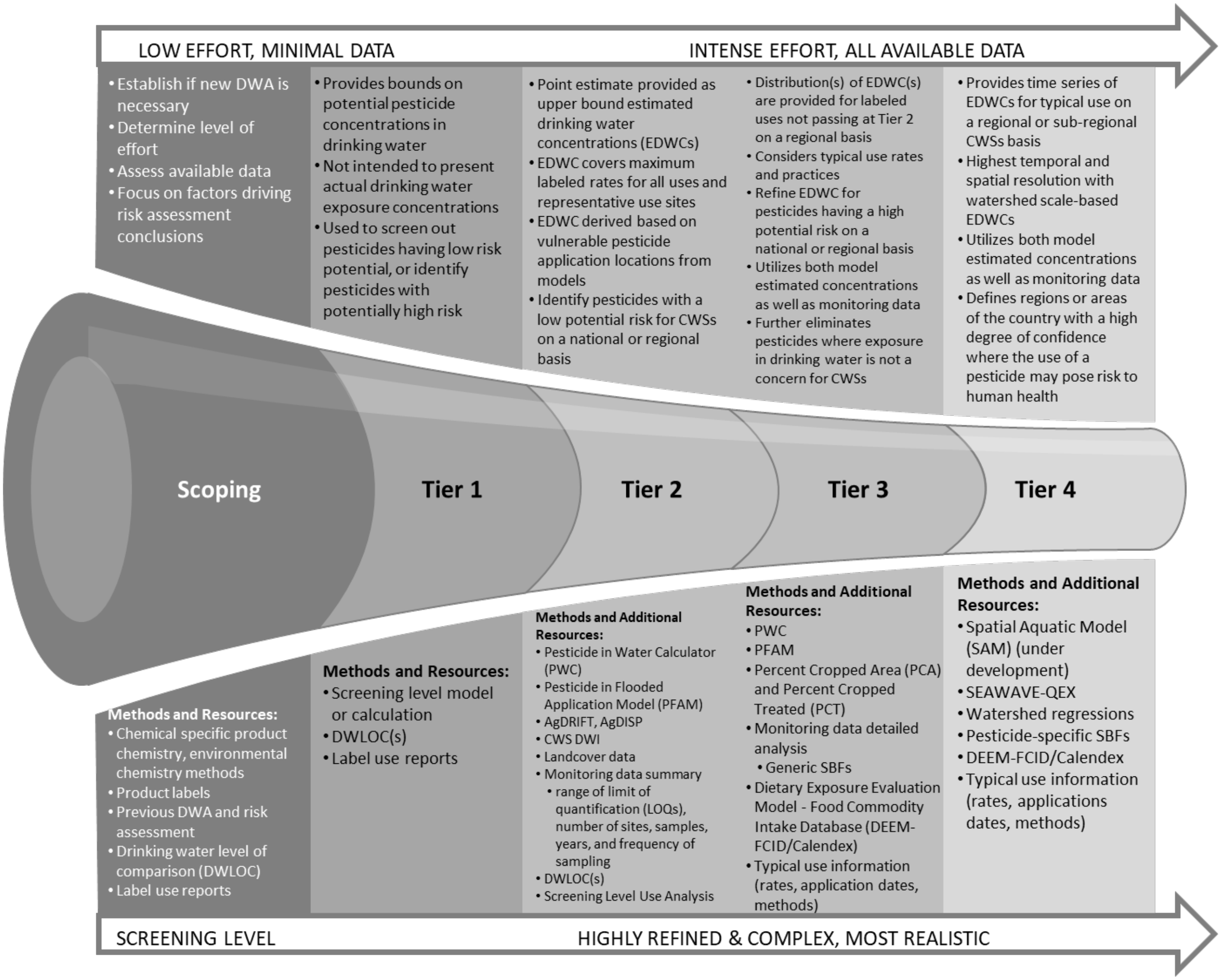


Figure 1.1. Tiered Drinking Water Assessment Framework

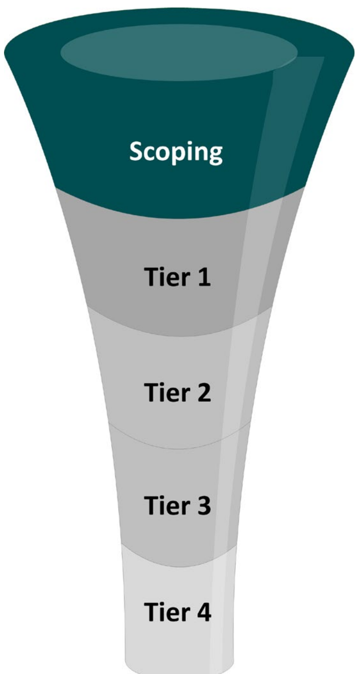
The process begins with a scoping exercise and is followed by four possible refinement tiers. The scoping process takes a holistic look at the pesticide to evaluate the level of refinement likely needed by involving EFED, HED, BEAD, and the risk management divisions (RD and/or PRD). Unless scoping indicates otherwise, the DWA begins at Tier 1. If further refinement is required (i.e., the estimated pesticide concentration is greater than the DWLOC), then the DWA proceeds to Tier 2, and so on. For pesticide concentrations lower than the DWLOC, EFED does not continue to expend resources to further refine the assessment (even when data are available to do so), if a safety finding can be made. Advancement through the tiered DWA process continues, assuming the necessary data are available to proceed to the next highest tier, until estimated pesticide concentrations no longer exceed the level of concern for human health or until a decision is made by the risk management divisions that the registration(s) need to be amended (i.e., mitigated) to reduce potential exposure.

There are some cases where lower tiers are skipped all together and work begins at Tier 3 or 4; however, most DWAs completed by EFED are categorized as Tier 1 or Tier 2 or “unrefined.” EFED estimates that only 10-20 percent of drinking water assessments move on to Tier 3. At this point, Tier 4 methods are evolving and maturing, and there have only been a few DWAs that have utilized data and methods comparable to a Tier 4 assessment.

2.0 Scoping for a Drinking Water Assessment

2.1. Introduction

Determining the scope of a DWA is an important first step in ensuring that the assessment process is efficient and results in a product that meets the statutory standards and risk management requirements. The key to a successful scoping process is early collaboration across EFED, HED, BEAD, PRD, and/or RD to agree on the nature of the assessment given the available information. This collaborative effort typically involves a holistic look at the pesticide to be assessed, the available information about the potential and actual pesticide use pattern, and the underlying environmental fate and toxicity data **(Figure 2.1**).



- Establish if new DWA is necessary
- Determine level of effort needed to complete the assessment
- Assess available data
- Focus on factors driving risk assessment conclusions
- Methods and Resources:
    - Chemical specific product chemistry, environmental chemistry methods
    - Product labels
    - Previous DWA and risk assessment
    - Drinking water level of comparison (DWLOC)
    - Label use reports

Figure 2.1. Scoping for a Drinking Water Assessment

2.1.1. Conceptual Exposure Model

More than 282 million people (87% of the total U.S. population) receive drinking water via public-supply systems [also referred to here as community water system drinking water intakes (CWS DWIs)][3] (Dieter et al., 2017). In 2015, total public-supply withdrawals from surface water accounted for 24,000 million gallons per day (Mgal/d) (61% of the total 39,200 Mgal/d withdrawals for surface water and groundwater combined) (Dieter et al., 2017). Surface water that is sourced for drinking water include rivers, streams, and impoundments such as reservoirs. CWS DWIs are distributed across the 21 major water resource regions located in the United States, 18 of which are within the conterminous 48 states (**Figure 2.2.**). Currently, only data from these 18 water resource regions are incorporated in DWAs.

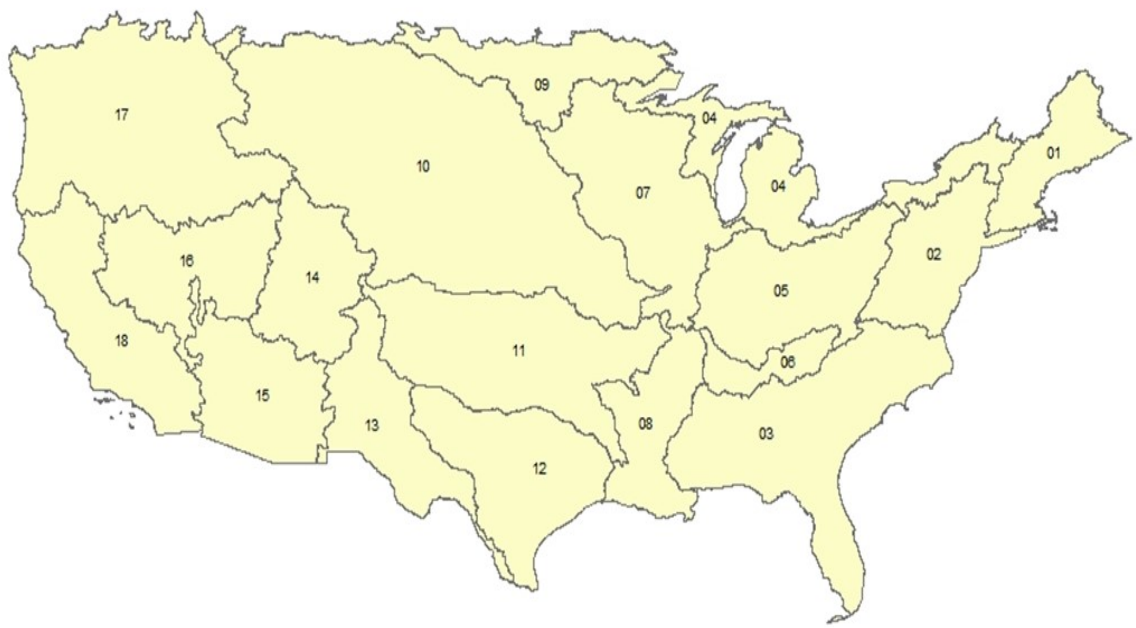


Figure 2.2. Water Resource Regions in the United States[4]

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[3] Public supply refers to water withdrawn by public and private water suppliers that provide water to a least 25 people or have a minimum of 15 connections.

[4] Map created by the Office of Pesticide Programs

The concentrations of pesticides in these surface waters used for drinking water is usually a local or regional site-specific phenomenon driven by the following factors:

- pesticide use patterns (e.g., application methods, timing, and intensity);
- pesticide physical-chemical properties (e.g., solubility);
- pesticide environmental fate properties (i.e., sorption and transformation);
- waterbody characteristics (e.g., size, flow, volume); and
- watershed characteristics (e.g., weather, soil susceptibility to runoff and/or erosion, land management practices, slope, and hydrology).

Some pesticides have relatively widespread uses and properties that are favorable to pesticide transport off-site such as high mobility and persistence. These pesticides may be detected in surface waters throughout the year, with periods of peak concentrations ranging from days to weeks during the typical application period (e.g., April-August for many uses). Other pesticides that have more localized use patterns (e.g., applied in response to specific pest pressure) or that have properties less prone to transport (i.e., less mobile and/or less persistent) may be detected infrequently in water.

Environmental fate scientists in EFED derive upper-bound (i.e., conservative) estimates of pesticide concentrations in surface waters for use in decision making. The general conceptual model adopted by EFED for pesticide dissipation and transport to surface water following application of pesticides in agricultural environments is illustrated in **Figure 2.3**.

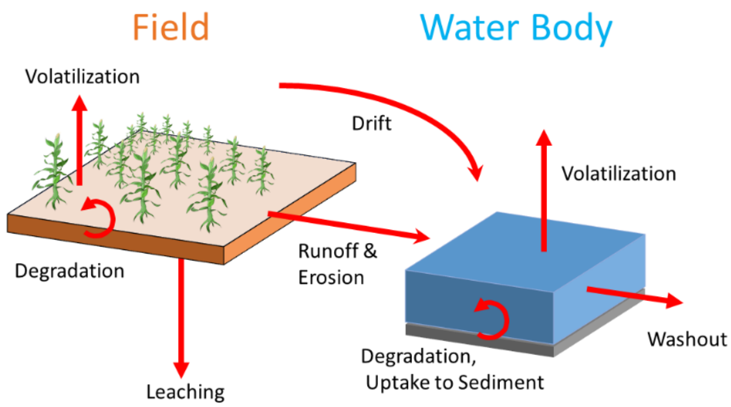


Figure 2.3 The EPA Conceptual Model for Pesticide Fate and Transport to Surface Water

To address the unique temporal and spatial patterns of pesticide occurrence, EFED most often utilizes computer models that allow for estimation of potential short- and long-term pesticide concentrations in vulnerable surface waters that may be used as drinking water. The models are parameterized based on pesticide specific physical- and chemical-properties, environmental fate and transport data, and environmental conditions. Surface water monitoring data are also integrated in DWAs, primarily for characterization, although higher tiered assessments may use surface water monitoring data quantitatively. For example, model estimates following refinement may be compared to monitoring data to ground truth the model refinements.

2.1.2. Drinking Water Treatment

The concentrations of pesticides in drinking water also depend on drinking water treatment methods such as sedimentation, flocculation, chlorination, and filtering through granular or powdered activated carbon. Data on pesticide-specific water treatment effects are sparse. Notable exceptions include organophosphates and carbamate pesticides where available data indicate the potential for standard water treatment processes to enhance transformation. Organophosphates are known to transform to a more toxic residue of concern. All evidence of drinking water treatment effects should be considered in the DWA. Considering the impact of drinking water treatment effects on the removal or transformation of the parent pesticide or residues of concern has become standard practice (USEPA, 2011). The treatment processes that are likely to occur across the country include flocculation, sedimentation, and disinfection; however, treatment methods vary by CWS and often change over time. For example, it is not uncommon for CWSs to change drinking water treatment methods throughout the year or across years. Additionally, if the pesticide or residues of concern have properties that indicate a treatment practice may affect concentrations (e.g., pesticides that hydrolyze rapidly under alkaline conditions may be impacted by water softening), the treatment method should be characterized as a potential impact where such practices occur.

While OPP acknowledges drinking water treatment methods are an important factor to consider when assessing exposure to pesticides in drinking water, treatment practices vary considerably from facility to facility and may also vary at a facility over the course of a year or across years. Therefore, drinking water treatment is generally integrated into DWAs to characterize the range of potential exposure. Variability in drinking water treatment further underscores that pesticide concentrations in drinking water are highly site-specific.

2.2. Assessment Process Summary

2.2.1. DWLOC: Important Benchmark in the Tiering Process

The DWLOC is used as a benchmark for navigating the DWA tiering process and is valuable in helping EFED determine the stopping point in refining the DWA.

The DWLOC originates from the guidance *General Principles for Performing Aggregate Exposure and Risk Assessments* (USEPA, 2001) and is used when integrating pesticide concentrations into a pesticide human health risk assessment. EPA developed the concept of "risk cup" to facilitate risk refinement when considering aggregate human health risk to a pesticide. The aggregated exposure assessment process considers exposure through multiple routes of exposure (e.g., food, water, and residential) for different sub-populations (e.g., infants, children ages 1-6, and adults) and exposure duration or types of effects [e.g., acute noncancer effects (single dose), chronic noncancer effects, and cancer]. The aggregated exposure assessments can be deterministic (levels of exposure for each pathway are point estimates), probabilistic (levels of exposure are a distribution for a given population), or a combination of the two and is dependent on the level of refinement or assessment tier.

The risk cup is the total exposure allowed for a pesticide considering its toxicity and required safety factors. The risk cup is equal to the maximum safe exposure for the duration being considered. Exposures exceeding the risk cup are of potential concern. There are risk cups for each pertinent duration of exposure (e.g., acute, short-term, chronic).

The exposure durations most commonly of interest for acute or short-term pesticide exposure risk assessments are 1-day, 4-day, and 21-day averages. For example, the relevant exposure duration for acetylcholinesterase (AChE) reversible inhibition from exposure to carbamate insecticides is 1-day, while AChE irreversible inhibition resulting from exposure to organophosphate insecticides is usually 21-days based on steady state kinetics. Moreover, a 4-day exposure duration is most relevant to the luteinizing hormone surge caused by exposure to triazine herbicides. Chronic and cancer risk assessments consider longer-term exposure concentrations such as a 365-day average or the average concentration over a lifetime of exposure.

In practice, EPA calculates the total exposure from food consumption and residential (or other non-occupational) exposures and subtracts this value from the maximum safe exposure level. The resulting value is the allowable remaining exposure without the potential for adverse health effect. Knowing this allowable remaining exposure and the water consumption for each population subgroup (e.g., infants), the allowable safe residues of concern in drinking water, also called the DWLOC, are calculated. The DWLOC provides an estimate of safe concentrations of pesticides in drinking water.

There are different types of DWLOCs to be considered. For example, HED can provide a ‘water only’ DWLOC, which does not account for aggregate exposure to the same pesticide *via* different routes of exposure such as food and inhalation. There is also an ‘aggregate’ DWLOC that subtracts out the other routes of exposure from the risk cup leaving the remaining room in the risk cup for drinking water exposure. Using this process of DWLOC calculation allows EPA to quickly determine a target maximum safe drinking water concentration, thereby quickly identifying instances where drinking water estimates require refinement.

2.2.2. Drinking Water Assessment Types

EFED conducts DWAs to support different regulatory processes as summarized below.

- For a **new pesticide**, there is no existing DWA to rely on or available monitoring data. However, generally, there is a full suite of physical, chemical and environmental fate data available as required in the Code of Federal Regulations (CFR) Part 158. Typically, for outdoor uses there are several environmental fate studies that EFED reviews prior to conducting a DWA. Generally, the most important studies to complete for exposure modeling are hydrolysis, aerobic soil metabolism, aerobic aquatic metabolism and batch equilibrium (i.e., mobility data) laboratory studies, as well as field studies. While field studies are not used directly to derive model input values, the studies help the assessor understand the environmental fate and transport in the environment for comparison to the conceptual exposure model developed based on the available laboratory data. As a screen, HED often provides a 'water only' DWLOC early in the scoping process to get a rough estimate of the level of refinement required to complete the DWA. As the risk assessment process moves forward, a refined DWLOC may be provided that considers other routes of exposure such as food or inhalation.

- For a **new use** of an already registered pesticide there is likely to be an existing DWA to consider. Generally, there are no additional environmental fate and transport data to review as part of a proposed new pesticide use. There is also typically an established DWLOC for a pesticide with existing outdoor use(s) that can be used during scoping. However, as more and more new uses are added, exposure to a pesticide from food, water, or residential routes may increase, and the DWLOC may decrease. In some cases, the DWLOC may decrease below previously estimated drinking water concentrations. In these cases, the new risk assessment will move to a higher tier to allow for refinements.

  There are some cases where a DWA does not need to be conducted for new uses, e.g., when new uses are for crops that are in the same crop group as existing uses. For example, if the proposed use is for barley at the same application rate as a registered use on wheat, then the previous DWA may be relied on since the use rates and sites are the same or considered similar and a good surrogate. In contrast, if the proposed new use is on corn and the registered use sites are fruit and vegetable crops, a new DWA is likely to be needed because the growing regions and modeling scenarios are different between corn, fruit, and vegetable crops.

- In **registration review**, EPA reexamines the safety of all registered pesticides on a 15-year cycle. With some exceptions, there are existing DWAs for pesticides with outdoor use patterns. As part of this process, EFED develops a Problem Formulation which states the approach that will be taken to complete the risk assessment and identifies any outstanding data. This includes updating the DWA, if needed, based on current science policies. Often there are new data in addition to new science policies to consider as part of registration review. Yet, that does not always mean a new DWA is needed. The new data or the change in science policy needs to be considered in the context of the previously completed DWA. That is, does new toxicity data change the DWLOC such that when compared with estimated pesticide concentration data from the previous assessment there is an overall change in the risk conclusion for the human health risk assessment? Alternatively, will an updated DWA change the human health risk assessment conclusions considering the new data or policy change? This could be, for example, the result of an increase in the modeled estimated pesticide concentrations due to a longer half-life value from new laboratory studies or identification of additional residues of concern.

2.2.3. Drinking Water Assessments Scales

EFED conducts DWAs on different spatial scales from national to regional or sub-regional levels, depending on the pesticide use under evaluation. While each pesticide is unique and thus requires an individualized approach to assessing drinking water exposure, there are general principles described in the subsequent assessment tiering sections that help risk assessors move through the different spatial scales. In summary:

- For a **national scale** DWA, a single upper end pesticide concentration is used as a starting point as described in Tier 1. This value is expected to rarely, if ever, be exceeded in the United States and is not expected to represent a pesticide concentration that would be found in drinking water.

  Alternatively, for a national scale DWA, estimated pesticide concentrations may be determined using vulnerable site-specific scenarios. These scenarios represent locations in the United States that are vulnerable to pesticide contamination and where the pesticide is expected to be used based on the use pattern. The highest estimated pesticide concentration(s) from all the use sites for the pesticide under evaluation is used as a starting point in Tier 2 and compared to the DWLOC. The estimated pesticide concentration is not an average concentration across scenarios or the United States. It is an estimated pesticide concentration resulting from a vulnerable pesticide use area somewhere in the United States. It is not intended to represent the pesticide concentration that the entire United States population is exposed to, but rather it is a concentration that individuals who consume surface-sourced drinking water in a vulnerable pesticide use area may be exposed.

- For a **regional scale** DWA, the United States is subdivided into smaller areas, most commonly on a Hydrologic Unit Code (HUC)-02 basis, to focus on areas where the pesticide concentrations may be higher than the DWLOC. Again, like the national scale, the estimated pesticide concentration at the regional scale is not an average concentration across scenarios or the region but is an estimated pesticide concentration resulting from a vulnerable pesticide use area somewhere within the evaluated region.

- A **sub-regional scale** DWA provides the highest spatial resolution of all the assessment scales, further zooming in on the vulnerable pesticide use locations where the estimated pesticide concentrations may be higher than the DWLOC. Estimated pesticide concentrations are more locally defined and generally reported on a site-, watershed-, state-specific or another sub-regional basis. Again, the estimated pesticide concentrations represent what an individual may consume from surface-sourced drinking water from geographically specific areas.

2.2.4. Incorporation of Estimated Pesticide Concentrations in the Dietary Risk Assessment

EFED can provide HED with either a point estimate or distribution (i.e. time series) of pesticide concentrations in surface water for utilization in the dietary risk assessment. A point estimate is a single value that is entered into HED's Dietary Exposure Evaluation Model (DEEM)[5]. It represents the concentration every water consumer nationally is expected to receive. This type of assessment is considered a screening level assessment because concentrations in drinking water will not be high-end estimates for all consumers but is useful because few resources are required to provide this value.

A more refined option is for EFED to provide HED with a distribution of surface water concentrations over time (i.e. time series). This is commonly provided for pesticides with a 1-day exposure duration of concern, or for pesticides with other exposure durations, such as for organophosphates and triazines. The pesticide concentration time series represent a distribution of the possible estimated drinking water concentrations in surface water over a 30-year time window

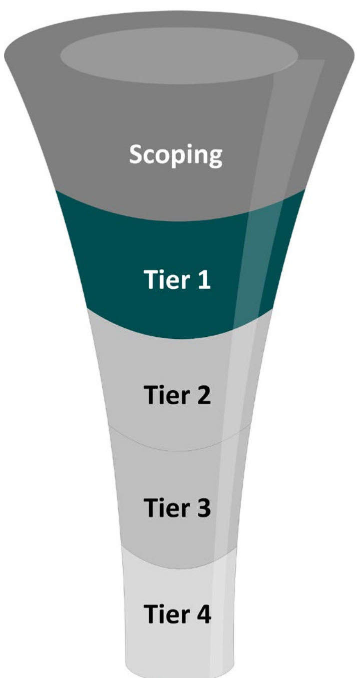
[5] DEEM-FCID/Calendex software that incorporates food consumption data used in human health dietary risk assessment for pesticides: https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/deem-fcidcalendex-software-installer#models

and are input into DEEM. A concentration from this distribution is selected for each individual consumption event, like what is done for residues on food.

3.0 Tier 1 Drinking Water Assessment

3.1. Introduction

A Tier 1 DWA provides high end pesticide surface water concentrations that are expected to rarely, if ever, be exceeded in drinking water in the United States. A Tier 1 DWA is intended, on a national basis, to screen out, with a low level of effort, pesticides that have a low potential to result in risk, and to quickly identify pesticides that require a higher level of refinement. It is designed to minimize use of resources and allow assessors time to focus on more problematic pesticides (**Figure 3.1**).



- Provides bounds on potential pesticide concentrations in drinking water
- Not intended to present actual drinking water exposure concentrations
- Used to screen out pesticides having low risk potential, or identify pesticides with potentially high risk
- Methods and Resources:
    - Screening level model or calculation
    - DWLOC(s)
    - Label use reports

Figure 3.1 Tier 1 Drinking Water Assessment

3.2. Methods

3.2.1. Modeling

In the past, EFED used the FQPA Index Reservoir Screening Tool (FIRST) to estimate pesticide concentrations in drinking water resulting from terrestrial uses (such as soybean and corn). However, FIRST is no longer used as a Tier 1 screening model. Recent Tier 1 DWAs have reported solubilities for the most soluble residue of concern or used the Tier 1 rice model to estimate upper bound pesticide concentrations for pesticides applied directly to water. Also for pesticides applied directly to water, e.g., aquatic herbicides, the target concentration in water may be utilized in the risk assessment. Otherwise, the assessment may advance to Tier 2.

3.2.2. Monitoring

For currently registered pesticides, a short summary of the available surface water monitoring data is completed and provides an understanding of measured concentrations in the environment in terms of the number, magnitude and spatial context of detections, as well as to ensure an important exposure pathway has not been overlooked. The Water Quality Portal (WQP) is a cooperative service sponsored by the United States Geological Survey (USGS), the Environmental Protection Agency (EPA), and the National Water Quality Monitoring Council (NWQMC). It contains data collected by over 400 state, federal, tribal, and local agencies. These programs are described in Appendix A of the White Paper, *Approaches for Quantitative Use of Surface Water Monitoring Data in Pesticide Drinking Water Assessments* (USEPA, 2019c). At Tier 1, if data are available, the assessor identifies the highest measured concentration, how often the pesticide is being detected and where those concentrations are occurring.

3.3. Next Steps

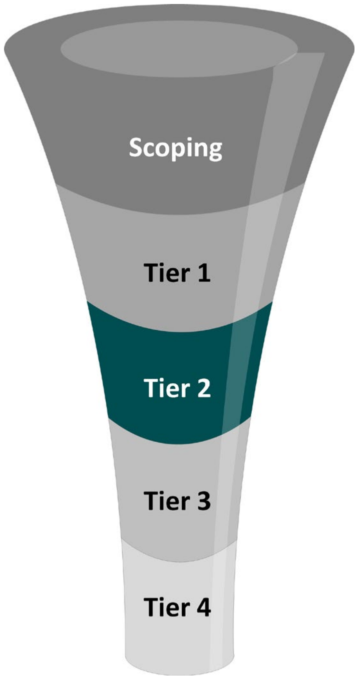
- If the Tier 1 estimated pesticide concentrations do not exceed the DWLOC, no refinements or additional work is warranted, and a Tier 1 DWA is finalized.
- If the Tier 1 pesticide concentration is greater than the DWLOC, the assessment proceeds to Tier 2.

4.0 Tier 2 Drinking Water Assessment

4.1. Introduction

Most Tier 2 level DWAs currently completed by EFED involve modeling to obtain estimated drinking water concentrations. A Tier 2 DWA is intended, with moderate effort, to screen out pesticides that have a low potential to result in risk from the labeled (proposed or already registered) uses on a national or regional basis. Tier 2 assessments are intended to provide upper bound pesticide concentrations for all labeled uses and use sites across the United States, by focusing on vulnerable locations where pesticides may be used. Assessments may consider a single use (e.g., corn) or multiple uses (e.g., corn, cotton, and turf) according to the pesticide product label. Tier 2 assessments use pesticide-specific physical-chemical properties (such as solubility and volatility) and environmental fate data (such as half-lives in water and soil) plus environmental conditions such as soil, hydrology, weather, agronomic practices, cropping patterns, and pesticide product labels to provide estimated pesticide concentrations with moderate effort (**Figure 4.1**).

EPA utilizes aquatic exposure models as well as available surface water monitoring data in the development of pesticide DWAs at the Tier 2 assessment level. EFED models allow for estimation of potential pesticide concentrations in surface water across the country. These models, described in a recent publication (USEPA, 2019) have been vetted through the FIFRA SAP process, improved over time, and currently represent the best available tools to estimate pesticide concentrations in aquatic environments. Surface water monitoring data used in Tier 2 assessments are often available from registrants, federal agencies, states, and academia, and are presented concurrently with modeled concentrations. The quantity and quality of the data are described in Tier 2 DWAs.



- Point estimate provided as upper bound estimated drinking water concentrations (EDWCs) based on vulnerable scenarios (USEPA, 2020b)
- EDWC covers maximum labeled rates for all uses and representative use sites
- Identify pesticides with a low potential risk for CWSs on a national or regional basis
- Methods and Additional Resources:
  - PWC, PFAM
  - AgDrift, AgDISP
  - CWS DWI
  - Landcover data
  - Monitoring data summary
    - Range of limit of quantification (LOQs), number of sites, samples, years, and frequency of sampling

Figure 4.1. Tier 2 Drinking Water Assessment

4.2. Methods

4.2.1. Modeling

In a Tier 2 drinking water assessment, the Pesticide in Water Calculator (PWC) and Pesticide in Flooded Application Model (PFAM) are commonly used for estimating pesticide concentrations in surface water from agriculture. The PWC is used for pesticides applied to terrestrial use sites such as corn, wheat, and soybeans. The PFAM is used for pesticides applied directly to water or in areas that are frequently flooded such as rice and cranberry growing areas. The PWC may also be used for non-agricultural sites, such as residential use.

PWC

PWC provides an efficient way to estimate surface water concentrations utilizing available environmental fate and transport data, label rate information, and a variety of environmental factors (crop growth, field soil, weather data, hydrological runoff, erosion, and pesticide applications). It couples the Pesticide Root Zone Model (PRZM5) and Variable Volume Water Model (VVWM) to simulate pesticide fate and transport from the field of application to an adjacent reservoir. PRZM5 simulates pesticide sorption to soil, in-field decay, erosion, and runoff from an agricultural field or drainage area following pesticide application(s), as well as plant interception and evapotranspiration. The VVWM estimates water and sediment concentrations in an adjacent surface water body (i.e., index reservoir) receiving the pesticide loading by runoff, erosion, and spray drift from the field. The index reservoir has dimensions and characteristics-based Shipman City Lake — a small, vulnerable midwestern reservoir located in an agricultural setting that was formerly used for source drinking water.

The PWC is the graphical user interface, previously called the Surface Water Concentration Calculator (SWCC) (Young and Fry, 2014; Young, 2014; and Young, 2019). The PRZM5 and VVWM documentation, installation files, and source code are available at the USEPA Water Models website

The PWC incorporates scenarios from across the country to model estimated pesticide concentrations in drinking water. A scenario is a combination of soil, weather, landcover, and plant/agronomic practices that affect the movement of pesticides from the field into water bodies. OPP developed new scenarios in 2020. The method for the development of PWC scenarios is described in the methods document titled, "*Creating New Scenarios for Use in Pesticide Surface Water Exposure Assessments*" (USEPA, 2020b). Non-agricultural use sites can be created on an ad-hoc basis using the same methodology. Assessors select scenarios based on the pesticide use site and the region or sub-region where the use is permitted. The scenario development method provides a well-described and transparent process, an opportunity to clearly and consistently select field scenario inputs, and to rank the millions of new scenarios by the quantity of pesticide retained in the index reservoir (i.e., OPP's definition of vulnerability), thus providing a better understanding of estimated concentrations relative to environmental conditions and use.

PFAM

The Pesticide in Flooded Application Model (PFAM, version 2) was developed specifically for regulatory applications to estimate exposure for pesticides used in flooded or intermittently flooded areas such as rice paddies and cranberry bogs. The model considers the environmental fate properties of pesticides and allows for the specifications of common management practices that are associated with flooded agriculture, such as scheduled water releases and refills. Unlike the Tier 1 rice model that assumes application to water and instantaneous partitioning between the water and sediment phases without any degradation, PFAM allows for the simulation of pesticide applications to a dry or flooded field, simulates mass transfer, sorption, degradation, and allows for discharge into a downstream waterbody. Rice scenarios are available for drinking water sources downstream from rice grown in California and Arkansas/Missouri regions. Cranberry scenarios are available for estimating concentrations in cranberry bogs in Oregon, Wisconsin, and Massachusetts; however, cranberry bogs are not sources of drinking water and these concentrations are expected to exceed what may occur in drinking water.

Concentration of the pesticide in the flood water compared to an adjacent water body depend on many factors such as the length of time the pesticide is in the flooded field, the distance the water travels between the flooded field and the receiving water body, the amount of dilution in the receiving water body, and whether the flood water is mixed with additional water that also contains the pesticide (USEPA, 2016a; USEPA, 2016b; USEPA 2016c).

4.2.1.1. Input Parameters

Pesticide Application Information

Application information is extracted from the pesticide product labels, including the maximum application rates, minimum retreatment intervals, and method and timing of application. All outdoor uses are considered for modeling. However, some uses may not be modeled because the potential for the use to result in surface water contamination is low, such as tree injections. Uses are modeled using a suite of scenarios. If label information is missing and is needed for model simulations, the RD and/or PRD divisions are engaged to determine the appropriate or intended label directions, so that model simulations reflect the intended use. Spray drift parameters are based on spray drift restrictions on the label, per the spray drift guidance (USEPA, 2013). The AgDRIFT[6] model has the capability to assess a variety of spray drift conditions from agricultural applications and off-site deposition of liquid formulation of pesticides. Aquatic spray drift buffers, droplet size, and wind speed are often required on the label. Other label restrictions such

[6] Refer to https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/models-pesticide-risk-assessment for more information on AgDRIFT and other models used in DWAs.

as states which prohibit use, are also adhered to in Tier 2 modeling.

Special Agricultural Considerations

The pesticide labels are adhered to when modeling, but sometimes the information on the label is unclear, or not in the format needed for parameterizing the aquatic models. BEAD has produced several memorandums to assist in assessing drinking water exposure with label uncertainties such as characterization of the number of applications per year or crop cycles per year, identification of application method (e.g., aerial or ground), identification of the formulation (e.g., granular or liquid), determining planting depths, and seeding rates. For more information, refer to the guidance on *Acres Planted per Day and Seeding Rates of Crops Grown in the United States* (USEPA, 2011b). BEAD should also be consulted when a labeled use does not fit the PWC or PFAM conceptual model.

Non-Agricultural Use Considerations

Several community drinking water intakes and associated watersheds occur in urban and or residential environments. EPA presented a residential exposure conceptual model to the 2008 SAP (USEPA, 2008) to assess exposure to pesticides in residential settings. This approach requires making assumptions about the area (i.e., footprint) of different potential use sites (e.g., building perimeter, utilities easements, and ornamentals) within residential or urban environments. Exposure estimates for each non-agricultural use are derived individually. It is possible that multiple urban uses and/or applications may occur within an urban watershed. In these cases, an aggregation of multiple use scenarios is necessary (more information provided in the Tier 2 output subsection: Adjustments for Non-Agricultural Uses).

Physical-Chemical Input Parameters

Environmental fate and transport properties are expected to vary across the landscape for reasons such as a range in soil and water pH and temperature across the country. However, exposure models used by OPP require a single input value. Therefore, the Tier 2 assessment incorporates conservative input parameters. EFED's input parameter guidance (USEPA, 2009) is used to set standard input values for Tier 2 models (**Table 4-1**). Generally, the environmental fate properties for Tier 2 are selected to represent the average soil sorption coefficient (K_d or K_{oc}) and the upper

90^{th} percentile confidence bound of the mean half-lives from soil, aerobic aquatic, and anaerobic aquatic metabolism studies. The half-life for each transformation study system (e.g., soil or aquatic system) is chosen in accordance with the NAFTA Kinetic Guidance. This guidance document provides a general approach for calculating and selecting representative half-life values from soil and aquatic transformation studies for risk assessment and exposure modeling purposes (USEPA, 2015). These conservative input values are generally expected to result in over-predicting concentrations in most areas.

Table 4-1. Current Modeling Input Parameter Guidance Summary (USEPA, 2009)

Input Fate Parameter (Unit)	Basis for Selection
Sorption Coefficient (K_d or K_{oc}) (mL/g)	Mean K_{oc} or K_d
Water Column Metabolism (Aerobic Aquatic Metabolism) Half-life (t½ in days)	If multiple aerobic aquatic metabolism half-life values are available, enter the 90th percentile confidence bound on the mean half-life value for the total system. If the metabolism studies are conducted at different temperatures, adjust the studies to reflect the half-life at one temperature (USEPA, 2010), then calculate the 90th percentile confidence bound on the mean half-life, and enter the corresponding temperature in the model. If a single aerobic aquatic metabolism half-life value is available, enter 3x the half-life value and the temperature the study was conducted at.. If no aerobic aquatic metabolism data are available and the pesticide shows insignificant hydrolysis, use 2x the aerobic soil metabolism half-life input value and the temperature the study was conducted at. If no aerobic aquatic metabolism data are available and the pesticide shows significant hydrolysis, enter zero (0). When both an aquatic metabolism and a hydrolysis half-life are included as inputs, the metabolism rate needs to be corrected for the hydrolysis rate at the pH and temperature of the aquatic metabolism study. This is done using the corresponding rate constants for individual studies.

Input Fate Parameter (Unit)	Basis for Selection
Benthic Metabolism (Anaerobic Aquatic Metabolism) Half-life (t½ in days)	If multiple anaerobic aquatic metabolism half-life values are available, enter the 90th percentile confidence bound on the mean half-life value for the total system. If the metabolism studies are conducted at different temperatures, adjust the studies to reflect the half-life at one temperature (USEPA, 2010), then calculate the 90th percentile confidence bound on the mean half-life, and enter the corresponding temperature. If a single anaerobic aquatic metabolism half-life value is available, enter 3x the half-life value and the temperature the study was conducted at. If no anaerobic aquatic metabolism data are available and the pesticide shows insignificant hydrolysis, use 2x the anaerobic soil metabolism half-life input value and the temperature the study was conducted at. If no aerobic aquatic metabolism data are available and the pesticide shows significant hydrolysis, enter zero (0). When both an aquatic metabolism and a hydrolysis half-life are included as inputs, the metabolism rate needs to be corrected for the hydrolysis rate at the pH and temperature of the aquatic metabolism study. This is done using the corresponding rate constants for individual studies.
Aqueous Photolysis Half-life (t½ in days @ pH 7)	Enter the maximum dark-control corrected environmental aqueous photochemical transformation half-life and the corresponding latitude. If no aqueous photolysis data are available or if there is no evidence of photolysis, enter zero (0).
Hydrolysis Half-life (t½ in days)	Use the maximum hydrolysis half-life value at pH 7. If no hydrolysis data are available, enter zero (0) and assume the compound is stable. If hydrolysis is not assumed to be stable, the aquatic metabolism half-life inputs need to be corrected for the hydrolysis rate entered so that hydrolysis is not double counted in the simulation. If the half-life is not available at an environmentally acceptable temperature, the Arrhenius equation should be used (USEPA, 1998).

Input Fate Parameter (Unit)	Basis for Selection
Soil (Aerobic Soil Metabolism) Half-life (t½ in days)	If multiple aerobic soil metabolism half-life values are available, enter the 90th percentile confidence bound on the mean half-life value. If the metabolism studies are conducted at different temperatures, adjust the studies to reflect the half-life at one temperature (USEPA, 2010), then calculate the 90th percentile confidence bound on the mean half-life, and enter the corresponding temperature. If a single aerobic soil metabolism half-life value is available, enter 3x the half-life value and the temperature the study was conducted at. If no aerobic soil metabolism data are available, assume that the compound is stable to biodegradation under these conditions, enter zero (0).

When multiple residues of concern are identified, alternative model input parameters are considered. Methods for modeling residues of concern include the Formation and Decline approach and the more commonly used Total Residue approach. The Formation and Decline approach estimates simultaneous formation and decline rate constants for parent and individual residues. The Total Residue approach does not consider temporal occurrence of individual residues, but instead the residues are summed at each sampling interval. Examples of modeling input parameters using the Total Residue approach include using the mean sorption coefficient (K_{oc} or K_d) of the most mobile compound, and the half-lives in soil and water represent the sum of the total residues of concern at each sampling interval which are then regressed with time to calculate a new half-life for each study test system.

4.2.1.2. Output Concentrations

Each Tier 2 surface water model run provides a time series of daily average pesticide concentrations, typically 30 years depending on the length of the weather file. However, for simplicity and quick reference to the DWLOC, summary statistics are also provided. For example, the 1-in-10-year daily (1-day) or annual (365-day) average pesticide concentrations are derived by ranking the single highest daily (or annual average) concentrations for each simulation year. Presently, simulations are conducted for a 30-year exposure period, therefore, the 1-in-10-year concentration is approximately the 3rd highest concentration (Young, 2019). Other summary statistics include the peak concentration, 4-day average, 21-day average, 60-day average, and entire mean of the 30-year simulation) to estimate the 90th percentile calendar year value (Young, 2019). An example of the estimated drinking water concentrations obtained from PWC is provided below (**Figure 4.2**).

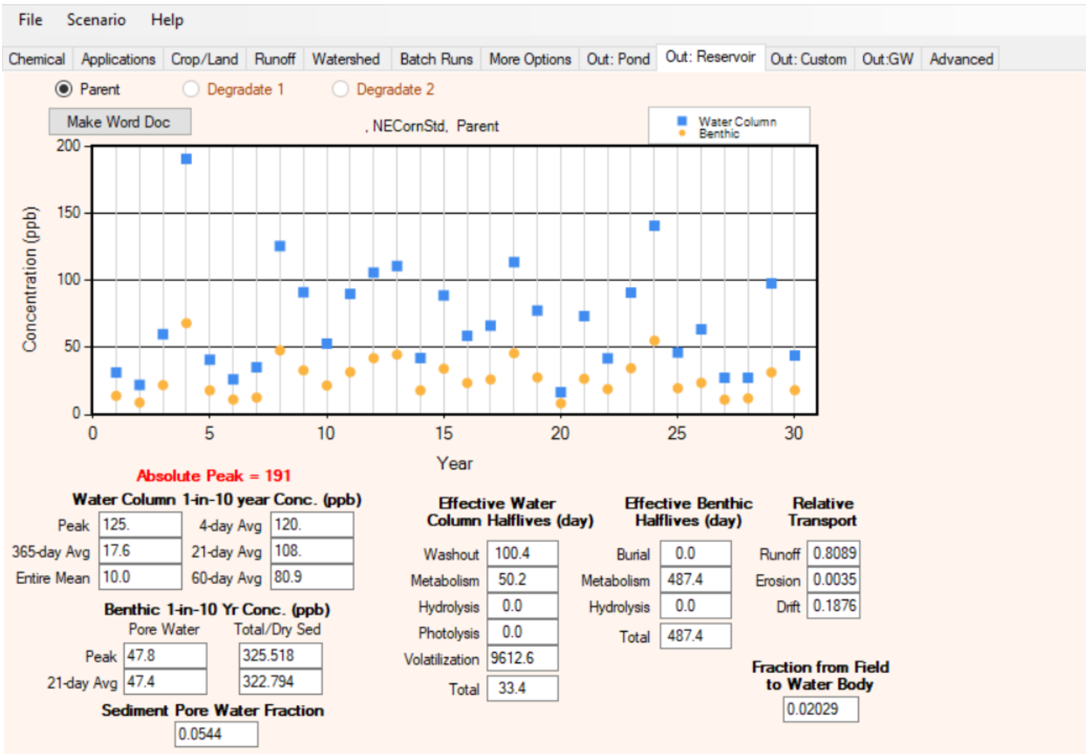


Figure 4.2 Example PWC Output

For tier 2 assessments, EFED typically provides HED with estimated drinking water concentrations that represent the 1-in-10-year daily average, the annual (365-day) average, and the entire mean of the 30-year simulation to compare to the DWLOC for acute, chronic, and cancer endpoints. An example summary table is provided in **Table 4-2.** In the event of a new use assessment, the proposed uses might result in pesticide estimates lower than estimates previously reported. In this situation, the highest concentration from the previously conducted DWA would be reported and cited in the DWA.

Table 4-2. Summary Table of Estimated Drinking Water Concentrations of a Pesticide

Drinking Water Source	Use Site; Modeled Source	Residue of Concern	Application Rate	EDWCs from Pesticide Root Zone Model – Variable Volume Water Model (PRZM-VVWM) (µg/L)		
				1-in-10 Year Concentration		30 Year Annual Average Concentration
				Daily Average	Annual Average	
Surface Water	Soybean; Index Reservoir	Pesticide X	Maximum Use Rate[a]	125	17.6	10
a) Total maximum single use rate from product labels: 0.3125 lb a.i./A (0.35 kg/ha) and 5 applications						

A time series of the PWC model output may also be utilized in the dietary assessment. An example time series with the 1-day average and 365-day moving average is shown in **Figure 4.3**. The data are separated by calendar year; vertical lines in **Figure 4.3** represent periods between January 1 and December 31 of the same calendar year. The concentrations for each calendar year are ranked from high to low. The concentrations used in a Tier 2 DWA correspond to the recurrence interval, set by EPA policy, of 10, meaning once every 10 years. These values (i.e., 1-in-10-year 1-day and 365-day average concentration and 365-day moving average) are overlaid with the original time series in **Figure 4.3**. The simulation average is also displayed.

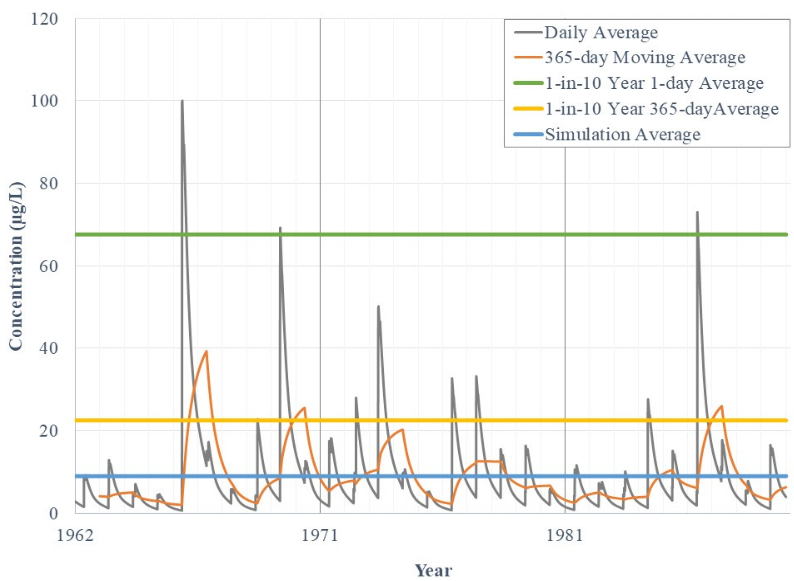


Figure 4.3 Example of a Daily and Annual Time Series of Concentrations Used for Pesticide Drinking Water Assessments

If the pesticide estimates are below the DWLOC, see the **Next Steps** section. If the estimate is above the DWLOC, then percent cropped area is generally considered at Tier 2.

4.2.1.2.1. Tier 2 Percent Cropped Area

The assumption in lower tiered assessments is that the modeled watershed supplying a CWS is entirely planted with the crop of interest [i.e., 100 % Percent Cropped Area (PCA)] and that the entire cropped area is treated with the pesticide of interest [i.e., 100 % Percent Crop Treated (PCT)]. **Section 5**, which highlights Tier 3 will touch on more in-depth methods to integrate the entire distribution of CWS PCA values and state-level usage data to define the PCT in individual CWS watersheds.

As described above, a Tier 2 assessment begins at a national scale assuming the entire CWS DWI watershed is treated with the pesticide under investigation. The next step, generally, is to consider the area of the watershed to which a pesticide may be applied. Typically, watersheds large enough to support a CWS DWI are not likely entirely cropped, nor are they comprised of only land cover classes to which the pesticide may be applied.

Landcover data in the form of a percent cropped area (PCA) adjustment factor may be considered based on CWS DWI locations (USEPA, 2014). Tier 2 PCA adjustment factors reflect the fraction of a watershed that is covered by a landcover type and/or crop. PCAs are available for major crops such as corn and wheat and crop groups such as orchards/vineyards and vegetables. All potential use sites (i.e., proposed and/or registered) are considered when selecting a PCA for use in refining the DWA. Modeled pesticide concentrations are multiplied by the PCA and the highest estimated pesticide concentrations are compared to the DWLOC. PCA adjustments can be made for point estimates as well as the full distribution of estimated pesticide concentrations. PCA can be even more refined and is later discussed in the Output Concentration section of Tier 3.

For national scale assessments, PCAs are selected which represent the highest fraction of the crop within any known drinking water watershed. If a pesticide is used on only one major crop, then the PCA for that particular crop is used. If the pesticide is used on a combination of crops, then the PCA for that particular combination of crops is used. Or, if pesticide uses include more or different crops than are captured in the existing PCA combinations, the default "all agriculture" PCA is applied. Regional *(i.e.,* HUC-2) maximum PCAs may be used for refinement but must reflect all potential pesticide use combinations for each region.

- At a **national scale**, the highest PCA for all the uses or proposed uses for all the CWS DWI watersheds across the United States is selected as a first screen.

- For typical **regional scale** assessments, the United States is divided up into smaller regions or subregions based on HUC regions (-02). There are 18 HUC-02 regions within the contiguous states (**Figure 4.4**). HUC-02 regional PCAs are available to adjust model estimated pesticide concentration(s) to account for the highest percentage of cropland within a CWS DWI watershed for major crops and crop groups within the specified HUC-02 region.

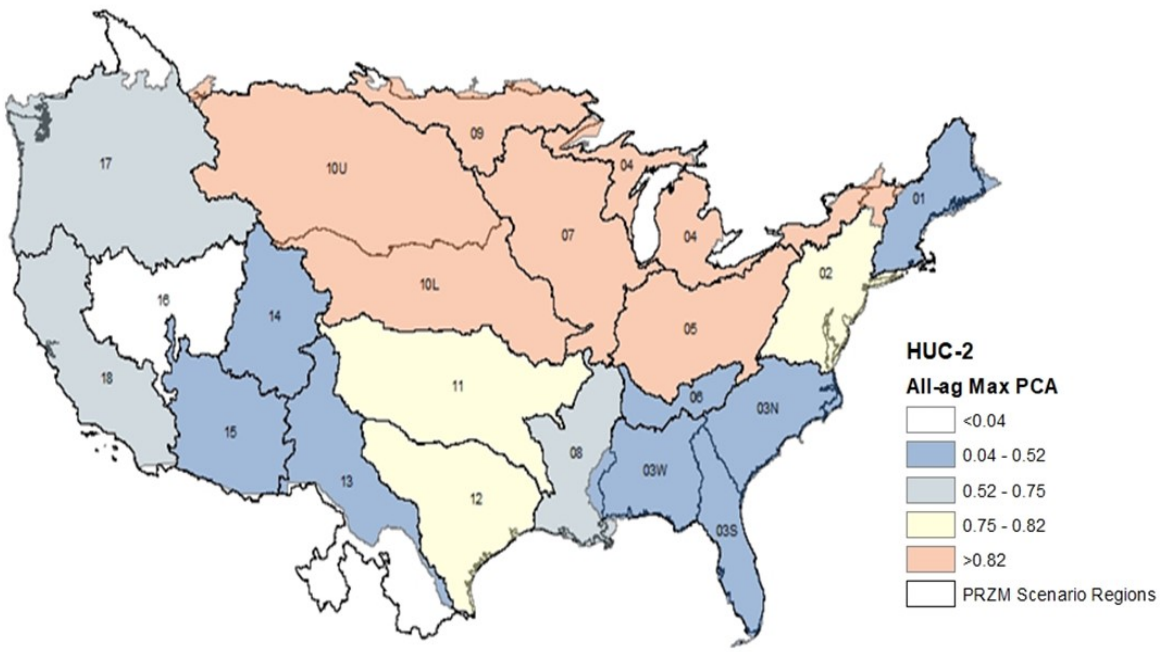


Figure 4.4 Regional/Sub-regional Agricultural Surface Water Scenarios Overlaid with HUC-02 Regional All-Ag Percent Cropped Area Adjustment Factors

There are different ways to apply regional PCAs. As an initial screen, the maximum HUC-02 regional PCA (i.e., highest PCA for all HUC-02 regions) is applied to the national-scale highest pesticide concentration estimates for all use sites and scenarios.

Alternatively, PCA adjustments may be done for all 18 HUC-02 regions to differentiate the regions where pesticide concentrations are expected to be lower than the DWLOC from those regions where pesticide concentrations may be higher. For this analysis, the highest PCA for each of the 18 regions considering all potential use sites (e.g., all-agricultural, corn-only, or corn-turf PCA) is applied to the highest estimated pesticide concentration over all the scenarios modeled (i.e., the same pesticide concentrations used at the national scale) for each respective HUC-02. It is necessary to pair the HUC-02 regional PCAs with regionally representative modeling and use scenarios.

In summary, for Tier 2 assessments, refinements begin with application of a national PCA (e.g., the highest PCA for all use sites across the contiguous states) followed by, only if needed, regional PCAs.

4.2.1.2.2. Adjustments for Non-Agricultural Uses

Several community drinking water intakes and associated watersheds occur in urban and or residential environments. Exposure estimates for each non-agricultural use are derived individually. It is possible that multiple urban uses and/or applications (e.g., ornamentals and perimeter) may occur within an urban watershed. In these cases, an aggregation of the contribution from each individual use within the watershed is necessary. For an example, refer to the 2008 FIFRA SAP on Selected Issues Associated with the Risk Assessment Process for Pesticides with Persistent, Bioaccumulative and Toxic Characteristics (USEPA, 2008).

4.2.2. Monitoring

In a Tier 2 DWA, available monitoring data from the WQP, and other state databases are generally the sources of surface water monitoring data to be evaluated. These programs are described in APPENDIX A of the *Approaches for Quantitative Use of Surface Water Monitoring Data in Pesticide Drinking Water Assessments* (USEPA, 2019c) and permit quick access to measured pesticide concentrations in surface water representing a range of potential pesticide use areas, as well as environmental conditions, to provide a contextual basis for potential environmental concentrations. Data from the USDA Pesticide Data Program (PDP) and USGS-EPA Pilot Monitoring Program (USGS-EPA reservoir), along with any registrant submitted monitoring data are also considered.

Unlike Tier 1 where the assessor identifies the highest measured concentration, how often the pesticide is detected and where those concentrations are occurring without much synthesis, in Tier 2 the assessor reports additional information in the drinking water assessment that addresses the quality and quantity of the available data. This includes an overview including total number of samples, number of sampling sites, years sampled, number of detections and the range of detections, range of detection frequency by site, and the range of level of quantification (LOQ) by dataset. Although the evaluation is done on a site-specific basis, the data may be summarized at a national scale or it may be split up at the HUC-02 level. Generally, if HUC-02 PCAs (i.e., regional scale) are considered as a Tier 2 refinement for modeling, then evaluation of the monitoring data may also be performed on a HUC-02 basis as a line of evidence to confirm differentiation of regions. In addition, the quality of the available monitoring data is described at Tier 2, including the importance of sample frequency in estimating upper bound exposure concentrations with respect to the duration of exposure considered (1- and 365-day average and 30-year average for acute, chronic, and cancer endpoints, respectively).

4.2.3. Exposure Characterization

Modeled estimated pesticide concentrations and monitoring data are complementary lines of evidence in DWAs. In general, model-estimated concentrations are expected to be higher and are given greater weight in Tier 2 due to the limited analysis of the available monitoring data, which often has limitations due to non-daily sampling frequency and geographical distributions. For example, at the Tier 2 assessment level, modeling is done for maximum label rates and minimum retreatment intervals for vulnerable use sites coupled with the index reservoir over a 30-year period to assess the impact of varying meteorological conditions on estimated concentrations.

Monitoring data reflect non-daily pesticide concentrations in surface water based on actual pesticide usage in the watershed and may not capture variability in weather over multiple years. Moreover, monitoring data are often provided for sites that are less vulnerable than the sites modeled and for surface waterbodies with different attributes (e.g., flow or size) than the index reservoir used in modeling. Therefore, non-daily ambient surface water monitoring data are expected to underestimate upper-bound pesticide concentrations in vulnerable surface drinking water sources.

While model-estimated concentrations are generally higher, monitoring data should be compared to the model estimates and to the DWLOC. If monitored concentrations exceed the model estimates, the modeling should be revisited to determine why this may be occurring, and any applied refinements reexamined.

If the modeled estimated pesticide concentrations exceed the DWLOC, refinements can be explored as part of a Tier 2 DWA. The order and the refinements considered is pesticide-specific and is generally determined based on the best professional judgement of the EFED scientist considering chemical, physical and environmental fate and transport properties of the pesticide under evaluation, the nature of the data that is available to carry out the refinement, as well as the uses and the difference between the pesticide concentration and the DWLOC. This means the EFED assessor will determine which refinement is the quickest and most effective to implement and will conduct that first and repeat this process until the estimated concentration is below the DWLOC.

4.3. Next Steps

- If the highest Tier 2 pesticide concentrations (i.e., all uses and all regions) do not result in a risk of concern for human health (e.g., do not exceed the DWLOC), no additional work is warranted.

- After using regional PCAs and distributions (i.e., time series) of pesticide concentrations, in some cases there may be use sites or regions that still have concentrations above the DWLOC. If pesticide concentrations are greater than the DWLOC after incorporating Tier 2 refinements, the assessor should consider Tier 3 refinements if the data allow. The Tier 3 assessment focuses only on the uses and/or HUC-02 regions of the country where concentrations have the potential to exceed the DWLOC. A comprehensive Tier 3 DWA requires a large amount of resources and adds much complexity to the assessment; therefore, advancement to Tier 3 should be done in consultation with the interdivisional chemical team.

5.0 Tier 3 Drinking Water Assessment

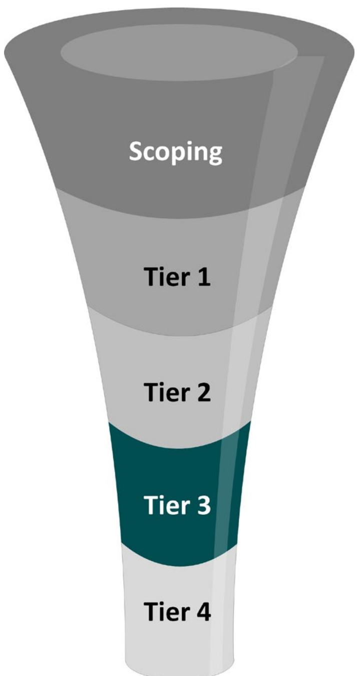
5.1. Introduction

Tier 3 drinking water assessments are less common than Tier 2 assessments and require a lot of resources and refinements. Due to the complexity of Tier 3 assessments, an additional round of review involving a panel of EFED scientists is required prior to sending pesticide concentrations to HED. The Tier 3 assessment focuses only on the uses and/or HUC-02 regions of the country where modeled concentrations derived from Tier 2 have the potential to exceed the DWLOC. The Tier 3 assessment relies on the Tier 2 modeled estimates of the 1-in-10-year daily average, 1-in-10-year annual average, and simulation average (i.e., 30-year) concentrations to identify which uses and/or HUC-02 regions need further refinement. A Tier 3 level of refinement involves an assessment of the spatial and temporal distribution of pesticide concentrations in surface drinking water sources across the country or within region(s), and may utilize additional percent cropped area (PCA) and percent cropped treated (PCT) refinements (**Figure 5.1**).

Unlike a Tier 2 DWA, which uses maximum-specified application rates and frequency and conservative half-life input values, a Tier 3 DWA relaxes conservative assumptions and becomes more environmentally realistic by considering survey usage information (e.g., reported timing of application, method, application rate, and treatment intervals) and alternative model input assumptions, such as half-life values, to describe the level of confidence in the modeled pesticide exposure concentrations.

Previous tiers rely heavily on estimated modeled concentrations, but at Tier 3 monitoring data begins to take on more weight. Available surface water monitoring data, which inherently considers actual use within the sampled watershed, are further evaluated at the Tier 3 assessment level. This includes working with BEAD to identify the most robust data available to evaluate the use(s) under consideration. Sampling bias factors (SBFs) are used to adjust non-daily measured concentrations to address the uncertainty in the sample frequency, which to date, has limited the utility of available surface water monitoring data in pesticide risk assessment. Generic SBFs can be used as surrogates for pesticide-specific SBFs as a screen to gauge if pesticide-specific SBFs should be explored as part of a Tier 4 assessment (USEPA, 2019c).

Refinements focus on relaxing conservativeness in model inputs and adding more spatial specificity to the assessment. Taken together, these refinements increase the confidence that the model estimates reflect actual concentrations that may occur in surface drinking water sources. Further analysis of the available monitoring data increases the certainty in the assessment while also becoming more spatially explicit. In a Tier 3 DWA, either model estimated (point estimate or distribution) or SBF-adjusted measured pesticide concentrations (i.e., point estimate) or a combination thereof may be used quantitatively (i.e., compared to the DWLOC) and provided to HED for consideration in the dietary risk assessment to determine the potential impact on human health. This is normally done on a regional basis.



- Distribution(s) of EDWC(s) are provided for labeled uses not passing at Tier 2 on a regional basis
- Considers typical use rates and practices
- Refine EDWC for pesticides having potential risk on a national or regional basis
- Utilize both model estimated concentrations as well as monitoring data
- Further eliminates pesticides where exposure in drinking water is not a concern for CWSs
- Methods and Additional Resources:
  - PWC, PFAM
  - PCA, PCT
  - Monitoring data detailed analysis
    - Generic SBFs
  - Dietary Exposure Evaluation Model- Food Commodity Intake Database (DEEM-FCID/Calendex)
  - Typical use information (rates, application dates, methods)

Figure 5.1. Tier 3 Drinking Water Assessment

5.2. Methods

5.2.1. Modeling

In a Tier 3 assessments, EFED uses the same aquatic exposure models, PWC and PFAM, as used in Tier 2 assessments. What distinguishes the modeling in a Tier 3 DWA from a Tier 2 DWA is the refinement of the model inputs, including assumptions related to usage, environmental fate and transport, and environmental conditions. There is no standard input parameter guidance for the selection of model input values at Tier 3. However, it begins with Tier 2 input parameter guidance and proceeds systematically based on best professional judgement.

As in Tier 2, estimated pesticide concentrations are provided as point estimates or distributions as needed by HED. Generally, Tier 3 assessments are done on a regional or sub-regional scale (e.g., state), and this is primarily driven by the availability of usage information. The more spatially explicit the usage information, the greater the confidence in the associated pesticide concentrations.

5.2.1.1. Input Parameters

As mentioned, there are no standard model input values for Tier 3 assessments. **Table 5-1** highlights the difference in model input values used in Tier 3 compared to Tier 2. This section is organized into model input parameters reflecting usage information, environmental fate and transport data, and environmental conditions and scenario selection. Generally, for a Tier 3 assessment, actual usage information is integrated along with a sensitivity analysis of the environmental fate and transport input values that have the most impact on model output values, such as aerobic soil metabolism.

Table 5-1. Refined Model Input Parameters Considered in Tier 3 compared to Tier 2

Parameter	Tier 2	Tier 3
Pesticide Use	Maximum label rates, minimum retreatment interval, and timing adjusted for cropped area adjustment for drinking water intakes.	Actual use rate, retreatment interval and timing, adjusted for percent cropped area and percent cropped treated adjustment for drinking water intakes. Sensitivity analysis on application timing if timing is not known.
Pesticide Fate	Input parameter guidance	Sensitivity analyses provide bounding estimates. Assess impact of NAFTA kinetics guidance on selecting modeling input value relative to the experimental data (NAFTA 2012; USEPA 2012).

The order of refinements considered is pesticide-specific and is generally determined based on the assessors best professional judgement considering chemical, physical and environmental fate and transport properties of the pesticide under evaluation, the nature of data available to complete the refinement, as well as the uses and the difference between the pesticide concentration and the DWLOC. Refinements should be compared to available and relevant monitoring data.

5.2.1.1.1. Usage Information

- Usage data describes actual pesticide applications. These data include information such as actual application rates for a particular use site (e.g., corn), timing of application, methods of application (e.g., aerial) and use intensity (percent cropped treated) at the state level. OPP obtains usage data from a variety of public and proprietary surveys. The key difference between use and usage is that the use represents potential applications of a pesticide (use sites and application rates as they appear on the label) while usage represents what is typically applied for a given pesticide and observed to occur in the field (from growers and users) (USEPA, 2019b). Usage data are usually obtained by market survey data.

- Crop- and location-specific application rates and timing are derived in consultation with BEAD. Generally, these data are provided on a state-by-state basis, and are used to represent regionally (e.g., HUC-02) typical (i.e., more realistic as opposed to label maximums) application conditions, including application rate (e.g., distribution of application rates including the maximum reported, median, and upper percentile rates), application intervals, number of applications, method of application (e.g., ground, aerial), and application timing. The level of confidence and the geographic scale of the data depends on how the actual usage rates are determined by BEAD and the relevant use. Typical usage rates are determined based on market survey data and represent historical use and corresponding pest pressure along with environmental factors. Therefore, the applicability of the typical usage data may be spatially limited and may also be influenced by the time frame over which such data were considered.

- Depending on availability, information from BEAD on typical tillage/soil conservation or agronomic practices may also be incorporated into the assessment; however, for modeling, exploration of alternative agronomic practices is limited. For example, spray drift buffers can be incorporated. Additionally, the assessor should consider whether the usage data indicate if the pesticide is used or not in a state or region. Such information could help rule out regions of the country where Tier 2 modeling indicated a risk, but where usage data indicates the pesticide is not actually used (as opposed to not surveyed).

5.2.1.1.2. Environmental Fate and Transport

- Generally, the environmental fate properties for Tier 2 are selected to represent the average soil sorption coefficient (K_d or K_{oc}) and the upper 90th percentile confidence bound of the mean half-lives from aerobic soil, aerobic aquatic, and anaerobic aquatic metabolism laboratory studies (**Table 4-1**). However, at Tier 3, incorporation of alternative assumptions for fate inputs can be explored and used quantitatively with an emphasis on the inputs that are known to be the key inputs driving modeled estimates and can proceed to the point that further parameter changes make no difference in the estimated pesticide concentration. Field data from terrestrial or aquatic field dissipation studies may also be evaluated for potential quantitative use at the Tier 3 level.

- While the impact of a single pesticide-specific parameter on the estimated concentrations depends on the other parameters, generally, EFED has learned over several years of conducting aquatic exposure assessments that the pesticide-specific input values including aerobic soil metabolism, aerobic aquatic metabolism, and sorption typically have the greatest effect on the estimated concentrations for surface water. Performing a pesticide-specific sensitivity analysis allows an assessor to identify and quantify the impact of model input parameters on the estimated pesticide concentration, including the limit at which further parameter changes make no difference in the estimated pesticide concentration. Metabolism rates across soils are known to vary by as much as 80x (Laskowski, 1995) for some organic compounds. The standard deviation that results from including a wide range of data may have a substantial impact on the model input values, so an average, median, or a range (i.e., minimum and maximum) of half-life values may be appropriate to consider. In addition, if uncertainty factors (i.e., 2x or 3X) are used in Tier 2 due to a limited dataset, the impact of the applied uncertainty factor(s) should be assessed to confirm the utility of additional data. Furthermore, additional data may be acquired from the open literature if not already considered.

- Environmental characteristics may influence the sorption or degradation of a pesticide and the standard inputs (which would integrate data across these variables) may not provide a good understanding of potential exposure with changes in pH conditions, for example. When this occurs, alternative assumptions on model inputs need to be explored to fully describe the potential for exposure. These types of considerations become more and more important to the DWA as it becomes more spatially refined.

5.2.1.1.3. Environmental Conditions

- There are instances where spatial refinements at the Tier 3 level focus on non-agricultural use sites where modeling scenarios are not currently available. In these cases, new scenarios can be created on an ad-hoc basis.

5.2.1.2. Output Concentrations

Estimated drinking water concentrations derived from PWC may be further refined at the Tier 3 level by applying Use Pattern Specific and non-standard PCAs, conducting Critical PCA overlap analysis, and calculating aggregate EDWCs. Additionally, percent cropped treated (PCT) can also be incorporated in Tier 3. Details on these refinements are briefly discussed in the following sections. For more detail refer t*o Integrating a Distributional Approach to Using Percent Crop Area (PCA) and Percent Crop Treated (PCT) into Drinking Water Assessment* (USEPA, 2020).

5.2.1.2.1. Use Pattern Specific and Non-Standard Percent Cropped Area (PCA)

Use of the all-agriculture PCA for crops not covered by one of the existing crop or crop pair combinations can lead to overestimation of the PCA value and resulting EDWCs. Therefore, refining with a Use Pattern Specific PCA value for any combination of crops (e.g., corn-soybean-orchard) can be calculated from the full distribution of PCA values within each watershed as the sum of their individual PCA values for each crop within that watershed. These Use Pattern Specific PCA values can be used to refine the EDWC in a similar fashion to the standard PCA values, i.e., multiplying the EDWC value by the maximum national or HUC-02 regional Use Pattern Specific PCA to give the refined EDWC value.

As an alternative to the all-agriculture PCA for crops with no relevant standard PCA value (e.g., alfalfa, sugar beets, sorghum), a conservative estimate of the PCA for these non-standard crops (i.e., miscellaneous-agriculture and non-agriculture) can be calculated as the difference between the all agriculture PCA and the sum of the standard[7] crop/group PCA values for each watershed. This is the maximum area that could be planted with any crop that does not fall into standard PCA categories. Similarly, for non-agricultural uses without a defined PCA, OPP can assume the difference between 1 and the all-agricultural PCA plus turf PCA can be attributed to urban or residential uses excluding use on turf. This will provide a conservative estimate of all non-agricultural, non-turf uses in a watershed.

The Use Pattern Specific and non-standard PCA approaches are best suited for pesticides with a limited number of uses and/or for pesticides with use patterns that do not fall within the standard crop or crop group PCAs. If the adjusted EDWCs are less than the DWLOC, then no further refinements are necessary. If this method is not applicable to the pesticide or, after applying the Use Pattern Specific PCA value the national/regional EDWC still exceed the DWLOC, the assessor can further refine by proceeding to either the Critical PCA overlap analysis or to aggregate EDWC calculations, as appropriate.

5.2.1.2.2. Critical PCA overlap analysis

The critical PCA is the ratio between the unrefined EDWC and the DWLOC and represents the PCA where the PCA-adjusted EDWC falls below the DWLOC. The critical PCA permits the quick identification of the number (or percentage) of watersheds with PCAs that would result in concentrations above the DWLOC. The critical PCA can be used as a benchmark to determine the need to consider additional refinements by comparing the location of where the crops are grown with the watersheds with a PCA greater than the critical PCA. For those watersheds with a PCA higher than the critical PCA and county overlap, aggregated EDWCs are developed (refer to the following section). Watersheds with no overlap are no longer considered for further refinement, as pesticide exposure is expected to be below the DWLOC.

5.2.1.2.3. Aggregated Estimated Concentrations

For a pesticide with multiple uses in a given CWS watershed with different EDWCs and use-specific

[7] The standard PCA crops/groups of crops are corn, cotton, orchard, soybean, vegetables, wheat and turf.

PCAs, each EDWC is adjusted by its unique PCA and then the adjusted EDWCs are added together to yield a single aggregated EDWC. This can be achieved using the 1-in-10 year concentration or using the time series data.

If none of the aggregate EDWCs exceed the DWLOC, then no further refinements are necessary. If there are still watersheds where the EDWC is greater than the DWLOC, then the aggregate EDWC values are then ranked across watersheds (either nationally or within a HUC-2 region) and compared to the DWLOC to determine the number of watersheds that still exceed the DWLOC. If warranted, the next step is to consider percent cropped treated refinements.

5.2.1.2.4. Incorporation of Percent Crop Treated (PCT)

The Percent Cropped Treated (PCT) is used to account for how much of a crop in a watershed is expected to be treated by a pesticide, rather than assuming 100% of the cropped area as treated. Pesticide concentrations are modeled on the watershed-scale, whereas PCTs are typically available at a larger scale, i.e., national or state level. This process consists of five steps, which involve calculating the state level treated acreage, allocating the treated acreage within CWS watersheds, calculating the percent crop treated values for each watershed, adjusting model estimated concentration to develop refined EDWCs, and finally comparing the adjusted EDWCs to the DWLOC.

The PCT statistics are used to calculate the number of acres treated in each state (referred to as base acres treated). Then the acres treated are allocated within each individual community water system watershed. This can be done for each combination of PCT (i.e., minimum, maximum, and average) and distribution method (i.e., upper, lower, uniform), for a total of nine separate approaches. Selecting the most appropriate approach should be determined through weight of evidence and in consultation with risk management.

PCT adjustments can be used to better understand exposure based on historical use, as well as provide a tool to facilitate the interpretation of model estimated exposure results compared to measured exposure concentrations from surface water monitoring data. For more information on these approaches, refer to USEPA, 2020.

5.2.1.2.5. Monitoring

A comprehensive analysis of all the readily available surface water monitoring data is completed at Tier 3 based on the duration of exposure concern. Generally, the data are summarized on a regional HUC-02 basis focusing on regions identified as needing further refinement in Tier 2.

Sampling bias factors (SBFs) are used to adjust non-daily measured concentrations to address the uncertainty in the sample frequency, which to date, has limited the utility of available surface water monitoring data in pesticide risk assessment (USEPA, 2019c). To prepare the data for application of a SBF, a more in-depth analysis is required that includes summarizing the number of samples, sampling timing, and frequency on a site-specific basis (i.e., the same sampling location). SBFs (short-term and long-term) are available for integration in Tier 3 DWAs for pesticides with cancer and non-cancer toxicity (USEPA, 2019c).

Prior to application of an upper bound SBF at Tier 3 as a screen, where SBFs for four pesticides can be used as a screening tool, the EFED assessor may consider if it is more efficient to move to Tier 4 and develop pesticide specific SBFs (USEPA, 2019c). Alternatively, the available surface water monitoring data are often inadequate to apply SBFs, as the uncertainty in the adjusted value is no better at estimating an upper-bound pesticide concentration for use in a DWA than the measured value.

In addition to the surface water monitoring data sources considered in Tier 2, data from state databases or other sources may be identified for use in a Tier 3 DWA. All available surface water monitoring data should be considered unless, for example, a substantial use change occurred such as the elimination of use sites or substantive reductions in application rates. Confirmation of reported sample values as well as ancillary data may be needed to make sure the most robust and accurate data are considered.

The type of monitoring program needs to be considered when evaluating the data. For example, targeted surface water monitoring data should be considered separately from ambient surface water monitoring data, as there are more ancillary data available for targeted monitoring data to help understand the potential exposure. Ancillary data include the actual pesticide use data (e.g., rate, method, and timing), and usage intensity (e.g., percent crop treated), agronomic practices (e.g., tillage, irrigation, and fertilization), and site characteristics (e.g., precipitation, temperature, and hydrologic soil group). While targeted monitoring data are ideal, the data are not treated differently than ambient monitoring data in a Tier 3 level assessment because evaluation of detailed ancillary data from a targeted monitoring study is better suited for use in a Tier 4 level assessment. More weight is generally given to targeted monitoring data in the overall DWA than ambient data.

Monitoring data sites should be mapped to provide an overview of the sampling sites in relation to CWS watersheds and/or potential use sites. Generally, this type of analysis is reserved for Tier 4 because it is resource intensive; however, national or regional maps may be created at Tier 3 to evaluate the scope of the monitoring data to determine if there are data to support a Tier 4 analysis.

5.2.1.2.6. Exposure Characterization

Both the model-predicted pesticide concentrations and the monitoring data should be compared to the DWLOC before formally providing the results to HED. Model-estimated pesticide concentrations and monitoring data are considered as complementary lines of evidence in DWAs. The regional monitoring data should be compared to the regional modeling estimated pesticide concentrations for actual usage rates within the region to ensure that the highest predicted or SBF-adjusted observed concentration is selected for quantitative use at Tier 3. It is most appropriate to compare model simulations conducted with upper bound usage rates rather than average rates with available monitoring data because state-wide average use rates (total pounds applied in the state divided by the total acres treated within the state) may not represent application rates that can occur at more localized levels, which could be higher for some locations. Use of the upper bound usage rates will capture the higher applications that may occur in localized areas.

When there are significant differences in the modeling compared to the SBF-adjusted concentrations (i.e., greater than an order of magnitude), the EFED assessor should attempt to ascertain why there are differences. When comparing modeling results with monitoring results, it should be acknowledged that the monitoring reflects a different conceptual model than the modeling simulations. For example, the monitoring data may represent a high flowing site, whereas model estimates are for the index reservoir. The EFED assessor should evaluate if there are differences in modeling parameters (i.e., usage, level of runoff or precipitation, dissipation, waterbody type, flow or size, etc.) that would result in higher modeled estimated pesticide concentrations than what is observed in the monitoring data, and determine if the monitoring data are robust enough (i.e., multiple years at a site, frequency of monitoring, adequacy of the detection limits, etc.) for quantitative use as an estimated pesticide concentration in the human health risk assessment (USEPA, 2019c).

Depending on the quality of the monitoring data, these data may be used to estimate a comparable concentration derived from modeling. For instance, if the monitoring data are targeted to a specific use pattern and the sampling was conducted in a way likely to overlap with application of the pesticide, it is possible to estimate a peak or longer term (e.g., annual average) concentration from the monitoring data and compare that with the modeled estimates.

To further help characterize the potential scope of exposure, the Screening Level Use Assessment (SLUA) and Screening Use and Usage Summary (SUUM) reports, provided by BEAD, can be used to rank uses in terms of likely exposure. The highest reported concentration either from modeling or monitoring data may be associated with a relatively small spatial footprint or low amounts of pesticide usage on a crop. This information can be relayed to the risk manager to further inform decision making. These documents can also be used to facilitate scoping to determine which uses deserve the most attention and advancement to Tier 4.

5.3. Next Steps

- After considering all Tier 3 refinements, including application of SBFs to available surface water monitoring data, if the highest Tier 3 modeled or measured pesticide concentrations do not exceed the DWLOC, no additional work is warranted, and a Tier 3 DWA is finalized.

- If, however, after considering all Tier 3 refinements there are <u>some or all areas of the country or uses with modeled or measured concentrations greater than the DWLOC</u>, the assessment should not be finalized without considering Tier 4 refinements. Tier 4 refinements focus only on uses and/or areas of the country where concentrations have the potential to exceed the DWLOC. If monitoring data are not available, or surrogate data cannot be assigned, to complete a Tier 4 assessment for the uses or the regions of interest, the assessment should be finalized as no additional work is possible. Tier 4 requires a large amount of resources and adds a great amount of complexity to the assessment; therefore, advancement to Tier 4 should be done in consultation with the interdivisional chemical team.

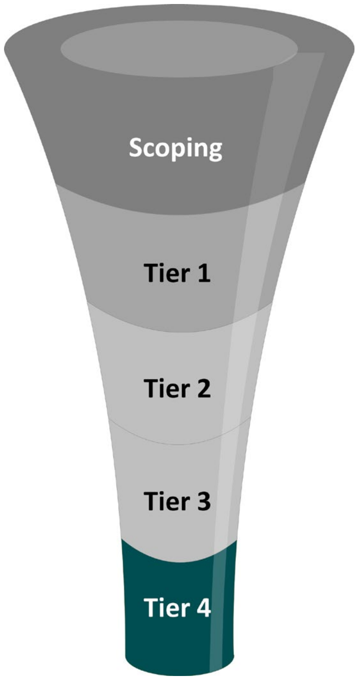
6.0 Tier 4 Drinking Water Assessment

6.1. Introduction

A Tier 4 DWA is the most highly refined, complex, and most realistic assessment and involves the most effort and analysis of all available data. Tier 4 DWAs are rare and should only be completed when Tiers 1 through 3 have resulted in risk concerns for human health. The Tier 4 assessment involves members of HED, BEAD, and RD or PRD throughout the process. It is expected that no Tier 4 DWAs will look the same since all the refinements will be pesticide and location specific (**Figure 6.1**).

A Tier 4 assessment uses both model estimated concentrations as well as monitoring data to define the estimated pesticide concentrations across the landscape and over time in the context of watersheds supporting CWSs. It provides the highest temporal and spatial resolution of all the assessment tiers. Estimated pesticide concentrations may be provided on a site-specific or watershed scale-basis; however, the results are generally summarized on a regional or sub-regional level, as it is more appropriate and there is greater confidence in the human health risk assessment conclusions when the estimated pesticide concentrations are developed for a class of water supplies, rather than an individual system.

A Tier 4 assessment describes the level of confidence in the generated pesticide concentration distribution based on the quality and quantity of the underlying data and identified factors that are driving the pesticide concentrations at a given site such as pesticide use (e.g., rate, percent use area), land use and environmental conditions (e.g., percent of watershed in runoff-prone soils, total precipitation).



- Provides time series of EDWCs for typical use on a regional or sub-regional CWSs basis
- Highest temporal and spatial resolution with watershed scale-based EDWCs
- Utilizes both model estimated concentrations as well as monitoring data
- Defines regions or areas of the country with a high degree of confidence where the use of a pesticide may pose risk to human health
- Methods and Additional Resources
    - Spatial Aquatic Model (SAM)
    - SEAWAVE-QEX
    - Watershed regressions
    - Pesticide-specific SBFs
    - DEEM-FCID/Calendex
    - Typical use information (rates, application dates, methods)

Figure 6.1. Tier 4 Drinking Water Assessment

6.2. Methods

6.2.1. Modeling

Currently, EPA does not have a model for conducting Tier 4 DWAs. However, EPA is developing the Spatial Aquatic Model (SAM) for future use in Tier 4 assessments (see **Section 7.2**). Subsequent discussions about modeling with regards to Tier 4 are conceptual in nature and are made with the understanding that SAM will be used for Tier 4 DWAs.

- The inputs and outputs used in modeling and the available surface water monitoring data considered at Tier 4 should be related to surface water sources used by CWSs, including characteristics such as use, precipitation, and soil vulnerability.

  If estimated modeled concentrations exceed the DWLOC, the attributes of the site associated with the estimated pesticide concentrations should be compared to attributes for other areas across the HUC-02 region. In addition, the individual distribution (i.e., exceedance count) should be evaluated and put into context.

6.2.2. Monitoring

As part of further analysis of the available surface water monitoring data, the co-location of monitoring sites with the pesticide use area and CWSs is evaluated. Landcover data may be used as surrogate for potential use sites, but it would not be used as a surrogate for actual pesticide use. Usage data are most commonly summarized at the state-level from proprietary survey data.

The Tier 3 analysis of monitoring data is used to identify sites suitable for input into the SEAsonalWAVEQ with EXtended capabilities (SEAWAVE-QEX; Vecchia, 2018, White Paper ATTACHMENT 5) model to estimate upper-end pesticide concentrations that may occur between sampling events. The SEAWAVE-QEX model results may be provided directly as daily concentration data to HED for use in the dietary risk assessment. The results may also be used to develop pesticide-specific SBFs to better estimate concentrations in areas of the country where monitoring data do not meet criteria for use in SEAWAVE-QEX. Use of the data should consider attributes of available monitoring data (e.g., pesticide use, weather, and runoff vulnerability) compared to areas of the country where data are either not available or are limited.

Some of the strengths of the SEAWAVE-QEX model include; 1) SEAWAVE-QEX logically deconstructs a daily pesticide concentration time series into components describing major sources of variation (seasonality, streamflow variability, and long-term trends); 2) allows, through conditional simulations, the user to reproduce the statistical characteristics of daily pesticide concentrations over a time period; 3) SEAWAVE-QEX performs well in describing near-complete monitoring data; 4) SEAWAVE-QEX function (a pulse of inputs) represents the way producers treat fields in a watershed for a given crop; 5) by using stream flow as a covariate, SEAWAVE-QEX takes into account the hydrologic landscape processes that affect pesticide transport, (i.e., infiltration and runoff or lack thereof).

The limitations of the SEAWAVE-QEX model should be clearly expressed in the assessment, including its limited use in non-flowing waters, which are important sources for drinking water in many agricultural watersheds; variance in the estimated or extrapolated maximum pesticide concentrations compared to DWLOCs; and the need for explicit statements of underlying assumptions. Other limitations include the seasonal wave component for compounds that do not have a clear seasonal pattern of use; and running the SEAWAVE-QEX model has a steep learning curve, is time and resource intensive, and it is difficult to understand by the uninitiated.

The assessor may consider developing watershed regression equations (e.g., regressions relating pesticide-specific SBFs to a watershed property, such as watershed area or precipitation) as a potential Tier 4 refinement. While previous efforts to conduct such analyses, presented in the 2019 FIFRA SAP, proved unsuccessful, future efforts may be more successful. Alternatively, a weight-of-evidence approach, relating watershed and pesticide attributes for the available monitoring sites to drinking water watersheds with missing or less robust data, could be used to provide evidence that these sites are applicable in the Tier 4 analyses. This weight-of-evidence approach should be conducted for those sites used in both SEAWAVE-QEX runs and in the development of SBFs. Any regression or weight-of-evidence analyses should consider the methods and criteria presented in the White Paper and the SAP comments on the White Paper (USEPA, 2019c).

6.2.3. Exposure Characterization

Modeled estimated pesticide concentrations and monitoring data are considered complementary lines of evidence in DWAs. However, at the Tier 4 assessment level, more weight should be given to the available surface water monitoring data if the data are from sites that either are, or represent, surface water sourced by CWSs, provided that the monitoring data can be put in context of the relative vulnerability of other CWSs. However, the characteristics of the monitoring site should be weighed against the entire distribution of CWSs. If there is an insufficient amount of robust surface water monitoring data or the data do not represent source water for CWSs, only modeled pesticide concentration estimates should be utilized.

At the Tier 4 level, spatial and temporal distributions are used to evaluate risk. Therefore, each of the distributions should be characterized based on the relative level of confidence in the data. Monitoring sampling sites can be overlaid with SAM outputs to provide further comparisons between monitoring and modeling data, as well as provide context regarding the relative vulnerabilities of the monitoring sites in relation to SAM outputs.

6.3. Next Steps

- The Tier 4 drinking water assessment is finalized.

7.0 Future Directions

EPA is currently considering additional methods for refining DWAs at higher tiers. This includes alternative waterbodies for capturing the variability of drinking water supplies and implementation of the Spatial Aquatic Model (SAM).

7.1. Alternative Waterbodies for Capturing the Variability of Drinking Water Supplies

The use of the index reservoir as a standard watershed for drinking water exposure assessment was presented to the SAP in 1998 (USEPA, 1998). The index reservoir represents potential drinking water exposure from a specific area with specific cropping patterns, weather, soils, and other factors. The current DWA paradigm takes the index reservoir and applies it around the country to estimate drinking water concentrations for pesticide uses in specific areas. While the index reservoir represents the high end of CWSs in terms of vulnerability, it does not represent the wide variety of drinking water sources and there is a desire to better understand pesticide exposure potential in a broad range of both static and flowing water bodies.

7.2. Spatial Aquatic Model (SAM)

For a Tier 4 DWA, the SAM model could be used to estimate pesticide concentrations in surface water for those HUC-02 regions that continue to exceed the DWLOC. When complete, SAM would be used to simulate the contributions of combined uses, each at its respective application rate, as the uses occur within the upstream areas supplying DWIs. SAM would also account for variations in soil, landscape, land cover, management practice, and weather within the watersheds. EPA anticipates outputs from SAM would include the length of time that concentrations exceed the DWLOC, daily estimated pesticide concentrations, and relative contributions of each pesticide use in the watershed on pesticide loading within the watershed. The goal is that the output results would no longer just represent the index reservoir but rather reflect the range of potential waterbodies used as sources of drinking water. **Figure 7.1** illustrates an example output from SAM, identifying watershed-based frequency of exceedances of the DWLOC.

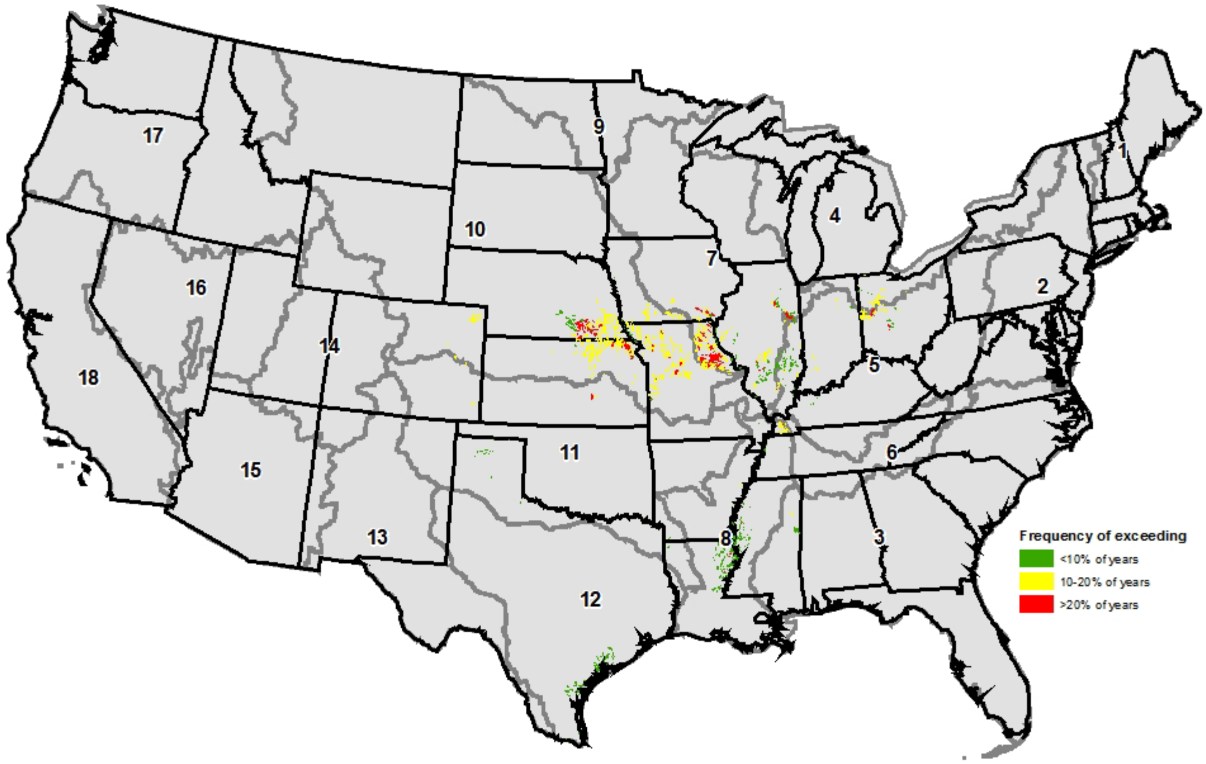


Figure 7.1 Site-Specific Refinement Illustration (red hatched areas signify the estimated concentrations that are greater than the DWLOC ranked by frequency of exceedance)

8.0 References

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Appendix A. Historical Overview

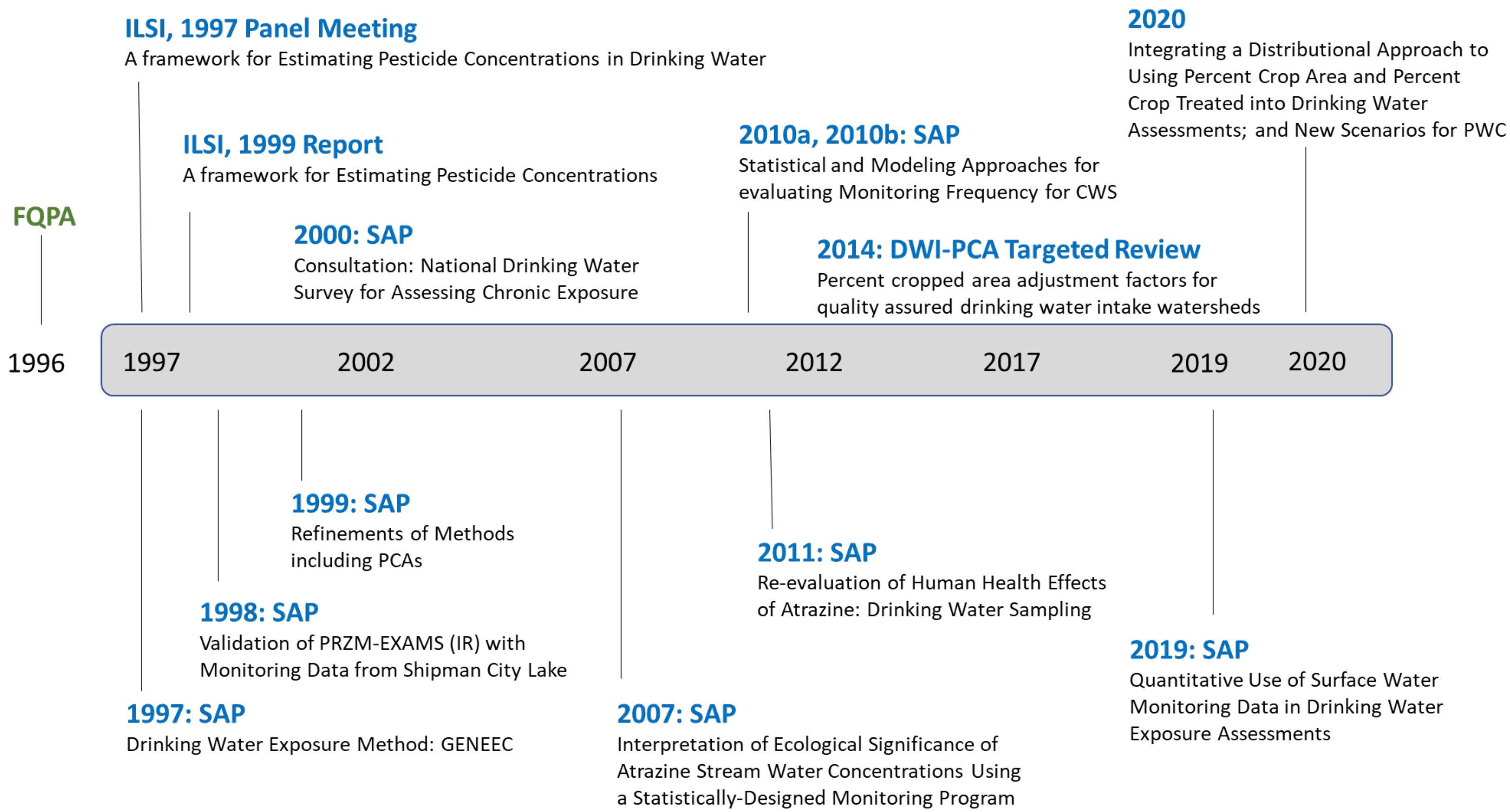

Figure A.1. Historical Overview of Principle Peer Review Events Impacting Pesticide Drinking Water Assessments

Appendix B. Drinking Water Assessment Tiering Process Summary

Table B. 1 DWA Tiering Process Summary

Tier	LOE	Divisions Involved	Purpose	Data Considerations	Quantitative Measure	Characterization
1[a]	Minimal	EFED HED	Screen out pesticides that are not likely to pose drinking water concern with minimal effort	Product chemistry Environmental fate Product labels	Upper bound concentration	• Concentrations represent upper bound concentration situation for the pesticide in water and is not intended to represent real world concentrations in drinking water sources. If, at the limit of solubility, the pesticide is not a risk concern, the DWA process ends at tier 1. • Summary of the range of observed surface water monitoring data detections.

2[b]	Moderate	EFED HED	Screen out pesticides or regions of the country that are not likely to have pesticide residues reaching levels that pose a concentration of concern	All listed above CWS DWI National or regional PCA	Estimated pesticide concentrations based on maximum label rates, standard fate input parameters, upper and lower bound exposure scenarios, index reservoir or vulnerable waterbody	• Environmental fate and transport summary for the pesticide explaining the routes of likely potential exposure, ensuring a route is not overlooked. • Models used include: PWC, Tier 1 Rice, PFAM, and AgDrift • Presents upper bound pesticide concentrations in surface water sourced by community water systems based on vulnerable use sites, maximum use rates, and cropping patterns • National or regional summary of the highest surface water monitoring data detection (and associated location and land use) observed in national and other well-known data sources; includes range in the respective limits of quantification (LOQs), number of sites samples, years of sampling, frequency of sampling. • Integrates modeling and monitoring results to describe the pesticide concentrations in surface water, explains similarities and differences in attributes of the data including use, site vulnerabilities, sample frequency, *etc.* • Identifies regions where there are no drinking water concerns.

3	High	EFED HED BEAD RD/PRD	Screen out HUC-02 regions or sub-basins within HUC-02 regions that are not likely to have pesticide residues reaching levels that pose an exposure concern	All listed above Typical use rates and practices	Provide range or distribution of PWC estimated pesticide concentrations Sampling bias factor (SBF) adjusted monitoring data by HUC-02 region (or smaller basin such as HUC-08)	• Includes model input sensitivity analysis; uses weight of evidence to support selection of model input values. • Models used include: PWC and PFAM. • EDWCs can be adjusted with PCA or PCT • Identifies and ranks uses/runs based on expected concentration considering screening level use assessment (SLUA) and national and state Use and Usage Summary (SUUM) information and crop footprint. • Presents upper bound pesticide concentrations in surface water sourced by community water systems based on vulnerable use sites, typical use rates, and cropping patterns • Presents a comprehensive analysis of monitoring data, including a summary from Tier 2 as well as censorship (i.e., measurements below the level of detection) by year, number of years, and date range of sampling. Identifies most robust data for watershed extrapolation by water resource regions (or smaller sub-basin) and applies SBFs. • Integrates modeling and monitoring results to describe exposure, similarities and differences in attributes of the data including use, site vulnerabilities, sample frequency, *etc*., considers use changes over time. • Identifies regions where there are no drinking water concerns.

4	Extensive	EFED HED BEAD RD/PRD	Screen out CWS that are not likely to have pesticide residues reaching levels that pose an exposure concern	All listed above Spatially refined usage information	Spatial Aquatic Model (SAM) chemographs SEAsonal WAVE-Q with Extended capabilities chemographs	• Estimated pesticide concentrations represent specific regions of the country. • Models used include: PWC, PFAM, and SAM. May also include other models, when appropriate, for characterization. • Identifies distributions and attributes (e.g., watershed characteristics, pesticide use) of CWS potentially impacted by pesticide use; examine likelihood of impact (e.g., exceedance counts). • Includes an assessment of SEAWAVE-QEX results including diagnostic plots, covariate data, pesticide use and site characteristics

LOE: Level of Effort

a. EFED does not currently have a standard Tier 1 approach/scenario

b. Most DWAs conducted in EFED reflect a Tier 2 approach

Appendix C. List of Guidance Documents Relevant to Drinking Water Assessments

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