Department of Pesticide Regulation

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California Notice 2024-14

TO: Pesticide Registrants and Stakeholders

SUBJECT: SURFACE WATER PROTECTION PROGRAM'S PESTICIDE EVALUATION MODEL (PREM), VERSION 6 UPDATE

The Department of Pesticide Regulation (DPR) Environmental Monitoring Branch, Surface Water Protection Program (SWPP) uses simulation models for pesticide risk characterization in product registration evaluations, post-use monitoring, and data analysis. The Pesticide Registration Evaluation Model (PREM) is used to evaluate potential aquatic impacts of pesticide products submitted to California for registration. The first public version of the model was released in 2012. Since then, SWPP continues to improve PREM by updating modeling approaches and introducing new simulation capabilities for more realistic and California-centric predictions. The latest version of the model, PREM Version 5, was published in 2017. More information on SWPP's PREM<cdpr.ca.gov/docs/emon/surfwtr/sw_models.htm> can be found on DPR's Web site.

Recently, SWPP has developed PREM Version 6 that includes several new capabilities. Below is the summary of the improvements to PREM:

- New pesticide simulation models
- K_d-based partitioning
- Biotic ligand model for copper in freshwater
- Aquatic exposure assessment for soil fumigants
- Risk characterization based on chronic toxicity
- Estimation of the percent treated area of a watershed
- Refined landscape characterization for pesticides used on residential impervious surfaces
- Exposure assessment based on use of down-the-drain products
- Pesticide applications during successive cropping
- Mitigation practices including vegetative filter strips, spray buffer zones, and rainfall restrictions

DPR thanks its stakeholders for previously submitting comments on the PREM Version 6 methodology document. Additionally, the response to comments received during the comment period is enclosed with this notice. The methodology document titled, *Methodology for Evaluation Pesticides for Surface Water Protection: PREM Version 6 Updates*, can be viewed at <cdpr.ca.gov/docs/emon/surfwtr/sw_models.htm>. A new PREM v. 6 user manual has been developed based on the outlined methodology document. The user manual titled, *Pesticide Registration Evaluation Model (PREM) User's Manual (Version 6.0)* and the executable model file will be downloadable from SWPP's PREM webpage. Until they are posted or if there are any issues with accessing the files, please contact <swpp@cdpr.ca.gov>. SWPP will use PREM Version 6 to evaluate new and future pesticide products submitted to DPR effective September 1, 2024.

If you have questions regarding PREM Version 6, please contact Dr. Anson Main by email at <Anson.Main@cdpr.ca.gov> or by telephone at 916-322-0496. If you have questions regarding the registration process, please contact Mr. Aron Lindgren by email at <Registration.Ombudsman@cdpr.ca.gov> or by telephone at 916-324-3563.

Original signed by *08/20/2024*

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Date

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DPR's Response to Public Comments on Environmental Monitoring Branch's Surface Water Program "Methodology for Evaluating Pesticides for Surface Water Protection: PREM version 6 Updates"

In May 2023, California Department of Pesticide Regulation (DPR) requested public comments on the Environmental Monitoring Branch, Surface Water Protection Program's (SWPP's) "Methodology for Evaluation Pesticides for Surface Water Protection: PREM Version 6 Updates." Comments have been received from Animal Health Institute, Bayer CropScience LP, Household & Commercial Products Association, and Western Plant Health Association. This document summarizes the comments and provides DPR's response. DPR grouped the comments by theme and summarized the comments to include all key points raised. Thus, each comment summary below represents the key points raised by one or more commenters.

General Comments and Questions on the PREM6 model

Comment #1: We appreciate the opportunity that CDPR also share the executable model and user manual in the next step to allow people test model and evaluate simulation results.

DPR Response: The executable file and user's manual for PREM6 will be available soon after the finalization and posting of this technical report. The full modeling package is expected to be released by the end of 2024.

Comment #2: PREM employs United States Environmental Protection Agency's (U.S. EPA's) eco-scenarios in California for surface water modeling. As of April 28, 2023, U.S. EPA OPP updated scenarios for ecological assessments (https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/models-pesticide-risk-assessment). The new eco-scenarios are based on latest site-specific data and organized in HUC level. We encourage DPR to also implement new eco-scenarios when model is officially released.

DPR Response: The new U.S. EPA Pesticide in Water Calculator (PWC) scenarios in the package of "dw_scenarios_v4.zip" are originally developed for drinking water ("dw") assessment based on a ranking process according to the estimated drinking water concentration (EDWC). U.S. EPA made a note that "As of April 28, 2023, OPP uses the same scenarios for both drinking and ecological assessments." But it is not clear how these scenarios would be used in ecological risk assessment.

Therefore, PREM6 continues using the previous scenarios in the package of "eco_scenarios.zip" for ecological risk assessment ("eco"). At the same time, we will evaluate the new drinking water scenarios, and watch their applications for ecological risk assessment by U.S. EPA.

Comment #3: Will DPR consider mitigation options that may not be adequately defined quantitatively in the model, but could allow for a path to registration, even if those options fail the PREM6 model?

DPR Response: Yes, for the mitigation options which are not adequately defined quantitatively in the PREM model or fail the model, SWPP will consider additional data submitted by registrants, including results from models other than PREM and field experiments for mitigation practices.

Comment #4: Could you clarify why the pond water body is selected to provide screening level exposure assessment, whereas the scenarios used in PREM6 are not screening level? If pond water body provides screening level regulatory exposure assessment, will DPR develop a refined water body (possibly representing a flowing waterbody) for refined exposure assessment?

DPR Response: The pond water body in VVWM modeling itself is not assigned to a specific tier or level of assessment.

According to U.S. EPA, when the pond is modeled with tier-2 crop *scenarios*, the VVWM results (i.e., estimated environmental concentrations, EECs, in water column and benthic region) are used for tier-2 assessment. With additional considerations such as PCA (percent crop area) and spatial distributions, the pond modeling results can also be used for tier-3 or tier-4 assessments.

In PREM6, specifically, the pond is mainly modeled for tier-2 assessment, with some options for mitigation modeling representing higher tier assessments. SWPP has evaluated other types of water body, and concluded that "*the pond was found to perform better than the endangered species water bodies in terms of reproducing the worst-case monitoring data in California*" (Xie et al., 2018).

Comment #5: As the modeled exposure estimates are expected to reflect varying exposure conditions (weather, soil, agronomic and mitigation measures, etc.), we believe it is scientifically sound to characterize both acute and chronic risks in a probabilistic manner by comparing the model-predicted full distribution of exposure to that of potential ecological effects.

DPR Response: For *registration evaluation,* PREM6 and its previous versions are mainly based on tier-2 assessments. This is also consistent with the current modeling approaches used by U.S. EPA with PWC and PFAM. Probabilistic assessments are more appropriate for *post-use risk assessment*.

Comment #6: It's not clear how Chronic Risk Assessment is used in Registration recommendations. It is important to state that the deterministic acute and chronic risk assessments proposed in PREM6 only provide one point estimate of environmental risk in time. As described in this PREM6's methodology document, they are only useful for screening purposes. U.S. EPA is using more sophisticated probabilistic methods to account for variability and/or uncertainty. The results of a screening assessment can be further refined to evaluate a more realistic exposure scenario (by incorporating distributions, mitigation, and other factors). We also appreciate DPR to provide more specific toxicological endpoints in chronic risk assessment.

DPR Response: The toxicological endpoints for acute and chronic risk assessments are evaluated by DPR's Pesticide Evaluation Branch (PEB) based on registrants' submitted data volumes. SWPP will only use the PEB reviewed and approved endpoints and compare them with the estimated environmental concentrations for risk characterization. Currently, ecological risk assessment in both U.S. EPA and DPR are mainly based on deterministic acute and chronic toxicity values. In addition, the determination of toxicological endpoints with more sophisticated probabilistic methods is beyond the scope of PREM6.

Modeling Options for Mitigation Practices

Comment #7: DPR may wish to consider allowing for the refinement of percent treated area (PTA) for banded and/or precision application methods. These application techniques may have a more favorable exposure assessment (compared to broadcast application) and should possibly be assessed separately from broadcast applications. We encourage DPR to develop guidance for the assessment of banded and precision applications. In the interim, the PREM6 model should at least allow the user to enter custom PTA values for the assessment of statewide agricultural uses via these application techniques.

DPR Response:

For the application methods mentioned in the comments, we advocate a better option is to model a "broadcast equivalent" application rate, rather than empirically modify PTA. The broadcast equivalent application rate is usually well defined in the product label, while the PTA values are associated with great uncertainty and variability.

Comment #8: Default drift fractions are identified as 0.05, 0.03, and 0.01 for aerial, air blast, and ground applications respectively. It is noted that these default values may be refined with label language as specified in section 4.2. Section 4.2 refers to the U.S. EPA 2013 draft drift guidance, but it is possible that when applying the U.S. EPA 2013 guidance to 'refine' the standard drift inputs, that the drift fractions may be larger than the standard values. We recommend aligning this section with section 4.2 to ensure that refined drift deposition values are indeed less than the default values.

DPR Response: The suggestion has been taken. PREM6 will generate a warning message if the drift fraction from the U.S. EPA 2013 guidance is larger than the default fractions (as 0.05, 0.03, and 0.01 for aerial, air blast, and ground applications, respectively).

Please note that this is essentially related to the input data preparation, rather than the model itself. For example, if a user intentionally needs to model a drift fraction larger than the default value, PREM6 will still run the simulations with user-provided inputs.

Comment #9: Table 8 provides different treatment options for each of the landscape components of the residential use conceptual watershed. Will there be flexibility for users to customize application restrictions on a case-by-case basis? For example, will users be able to select

treatment option 0, 1, or 2 for each landscape component rather than relying on pre-determined application restrictions aligning with the provided templates?

DPR Response: Yes, users can select a specific application restriction option for each surface. The templates are just provided as examples for demonstration purpose.

Comment #10: Recently, VFSMOD has been updated to improve the surface residue remobilization approach (version 4.5.2, Muñoz-Carpena 2023), where dissolved pesticide in the pore water is added to the incoming pesticide mass for the next runoff event, while the sorbed fraction stays on the soil and contributes to the equilibrium distribution at the mixing layer. This improved algorithm addresses the issue of excessive availability and remobilization of highly-sorbed pesticides that was encountered in the past version, resulting in more realistic and mechanistic simulation across products with varying mobility (Ritter et al. 2023). Therefore, we propose the addition of the new VFSMOD pesticide module as an option in PREM6 for VFS modeling.

DPR Response: The latest version of VFSMOD 4.5.2 is used in PREM6 for hydrological simulations. We are in the process of evaluating the new VFSMOD for its updated modeling capability for highly-sorbed pesticide.

Comment #11: The reviewer suggests that DPR consider the inclusion of Health Canada Pest Management Regulatory Agency (PMRA) data regarding VFS and VFSPipe. This information may be available from industry and useful for comparative purposes.

DPR Response: The PMRA scenarios are not relevant to California field conditions, and thus not appropriate for inclusion in PREM6.

Comment #12: Will DPR provide VFSMOD along with PREM6 as a model for VFS?

DPR Response: No, VFSMOD will not be provided in the PREM6 modeling package. Users should download the model from its official website.

Comment #13: It is not clear if the following two conditions are considered by the new function: 1) some products require application when soil is moist, drizzle rain (intolerable rainfall) is not prone to generate runoff but improve soil conditions for application. Therefore, completely avoiding rainy days is not suitable for these products. 2) Some pre-emergent products require application before the emergence of plants. If the current function is to postpone application date to find a completely dry day, then it's quite possible to pick up an application date after plant emergence.

DPR Response: Restricting applications by rainfall/runoff is a modeling option to generate more realistic results for the pesticide products with relevant label language. Mathematically, the purpose of this option is not to search for "a completely dry day" (as interpreted in the above comments), but an optimum date of application *within* the acceptable application window which is specified by a user. In other words, the date of application may be postponed but still within a certain period.

For the two special conditions mentioned by the reviewer: [1] PREM6 is not able to model the mitigation effects with required soil moisture for pesticide applications. The evaluation on this requirement needs to check daily soil moisture for scheduling an application, or even to introduce additional irrigation before applications, which are not currently modeled by PREM or PWC. [2] This condition can be modeled by adjusting the proposed application date according to the emergence date (predefined in the modeling scenario). Take the scenario "CA lettuce" (emergence on Feb 16) as an example: if the rainfall intolerable window is 2 days, the application window will be modeled as 5 days in PREM6 (Section 4.3). So, if the application is scheduled on or before Feb 11, PREM6 will model a pre-emergent application even with the option to consider rainfall/runoff.

Comment #14: Can DPR elaborate on the AGDISP procedure to refine the spray drift deposition? The federal pyrethroid assessment is referenced in the document as an example use of AGDISP, which included modification of wind speed/direction, spray volume/material based on product label language. However, there are much larger varieties of inputs available in AGDISP. Will DPR use standard defaults (i.e., aircraft, nozzle configurations, number of swaths, offsets, meteorology, etc.) for different application methods, and can these be provided?

DPR Response: U.S. EPA recommended the use of AgDRIFT for agricultural applications, and AGDISP for adulticide pesticides.

SWPP does not have a standard procedure for AGDISP as part of PREM. In previous evaluations on adulticides, SWPP requested that DPR's Air Program determine product-specific drift fractions by using AGDISP on a case-by-case basis. These values are used accordingly to adjust PREM input values.

Comment #15: We assume that the following year application date resets to the user-selected date and the process of checking rainfall dates begins again. In other words, if the user-specified application date was first set to crop emergence, and the year 1 application date was shifted (due to rainfall) by 2 days, the year 2 application date would start again at crop emergence and the algorithm would be restarted. Can DPR confirm this is the correct behavior of the algorithm?

DPR Response: in each year, the application date resets to the user-proposed date regardless of the actual date of application modeled in the previous year. We clarified this in the updated report (section 4.3).

Comment #16: Now that PREM has a capability to model applications by avoiding days of rainfall, will label language such as "no application shall occur if … a storm event, forecasted by NOAA or NWS, is to occur within 48 hours following application" be considered for mitigation language?

DPR Response: SWPP may consider restrictive language on pesticide product labels for agricultural uses as a mitigation practice in the PREM modeling.

Evaluation on Down-the-Drain (DtD) Products

Comment #17: The DtD model is considered to be a screening-level tool providing a registration recommendation. Will California DPR be providing a higher-tier model (i.e., landscape-scale models) if a more comprehensive evaluation is needed?

DPR Response: For registration evaluation of DtD products, higher-tier modeling is not being proposed by SWPP. However, we encourage registrants to submit refined input parameters to SWPP in order to conduct a more comprehensive evaluation. Input parameters include e-fate data, wash-off coefficients, POTW removal efficiency, etc.

For post-use risk assessment (i.e., continuous evaluation), SWPP has been developing a monitoring network (DPR study #322) to evaluate the temporal and spatial variability of DtD pesticides in wastewater influent, effluent and biosolids, and residues in surface water.

Comment #18: The exact DtD modeling approach using VVWM is unclear, and more detail is needed if VVWM is to be part of the recommended approach. For instance, it appears as if U.S. EPA Pond is being used. Is the application every day or once a year?

DPR Response: As mentioned in the report, there is a separate document with more technical details on the DtD model development: "*The DtD modeling approach has been developed under the CDPR study 315 and documented in the study report (Xie and Luo, 2022)*." (Section 3.4, the 2nd paragraph)

The pond scenario is used in PREM to predict the daily average concentrations in water column and benthic regions after discharge from a wastewater treatment plant (WWTP), as described in the report (Section 3.4, the 3rd paragraph). Pesticide applications are considered as continuous loadings to a WWTP, and the daily maximum release rate is modeled for acute ecological risk assessment (i.e., 1-in-10-year daily average concentrations).

Comment #19: Dilution in the waterbody should be considered when calculating risk quotients for a molecule and the proposed approach to set the initial concentration of the molecule in the waterbody to the WWTP outfall concentration is overly conservative. The aquatic exposure assessment model developed by Anthe et al. (2020) for imidacloprid considers dilution into the waterbody. (Anthe M., Valles-Ebeling B., Achtenhagen J., et al. (2020), "Development of an aquatic exposure assessment model for imidacloprid in sewage treatment plant discharges arising from use of veterinary medicinal products." Environmental Sciences Europe. 32:147).

Would California DPR consider applying this consideration?

For assessments that do not pass the screening assessment with the pond scenario, and thus requiring higher tier refinement, we encourage DPR to explore options for refinement that consider:

- Realistic receiving water body dimensions, potentially informed by the mentioned collaborative effort with the University of North Carolina at Charlotte.

- Realistic baseflow conditions for the receiving water body, potentially informed by assessment of gauge flow data at or nearby actual outfall locations.

DPR Response: The assumption of zero dilution in the receiving water body is based on previous studies investigating the contribution of wastewater effluent to streamflow in California. References have been provided in the technical report for the DtD model development (Xie and Luo, 2022).

In addition, we also added the new findings from the recent CDPR research contract with University of North Carolina at Charlotte (UNCC) (DPR contract #19-C0031) (CDPR, 2019). Based on the streamflow data at WWTP discharges, the UNCC study results confirmed that, under low-flow events, the receiving streamflow is significantly lower than the designed flow for most of WWTPs in California. This justifies the model assumption for no dilution as a conservative and realistic condition in California, see Section 3.4, the 3rd paragraph.

Comment #20: As noted, PREM6 provides a new pesticide use pattern for DtD products. It describes a new modeling capability to evaluate the ecological risks of indoor uses of pesticides, which are disposed of down the drain, transported through the sewer system and wastewater treatment plants (WWTP), and released with WWTP discharges into surface water. While the methodology and underlying supporting documents show indications that active ingredients present in indoor uses of pesticides are present in surface water, it has yet to be demonstrated that the presence in the surface water is traced back to indoor uses. Therefore, this update conservatively assumes that these products contribute significantly to surface water without a robust scientific basis for this assumption.

An influx of previously unevaluated products would undoubtedly strain the Environmental Monitoring Branch leading to much longer evaluation times than the current timelines.

DPR Response: Please note that not all indoor use patterns are evaluated by the model. SWPP only evaluates the use patterns that have been shown to pose a high potential of transporting AIs down the drain. As described in Section 3.4, "*The DtD products to be modeled include [1] pet products (e.g., spot-on and shampoo), [2] treated articles (e.g., impregnated fabrics and fibers, pesticide preserved garments and apparels), [3] floor drain treatment, [4] general indoor pest control on high-risk sites (e.g., foggers and sprays that are applied to pet and human beddings, floors, carpets, rugs, and upholsteries).*" In addition, additional references are added in the report to justify the selection of the use patterns for DtD evaluation (Section 3.4, the first paragraph), including (Keenan et al., 2009; Keenan et al., 2010; Moran and TenBrook, 2014; USEPA, 2016c; Teerlink et al., 2017; Sutton et al., 2019; Dery et al., 2022; Budd et al., 2023; Perkins et al., 2024).

Comment #21: Furthermore, this model has only been validated with 13 DtD products containing seven different active ingredients, which is an insufficiently robust data set to base regulatory decision-making. The reviewer has significant concerns that this overly conservative approach based on insufficient validation will overestimate the impact of these products.

The reviewer is concerned with Table 5: Comparison of registration recommendation between the DtD model and past evaluations in the Methodology for Evaluating Pesticides for Surface Water Protection: Evaluation on Down-the-Drain Products. Where are the details for pet products and shampoos? What does the term "Consistent with Previous Decision?" mean? As written, this table is nebulous at best and precludes the ability to provide comprehensive feedback.

DPR Response: We have validated the model with 12 chemicals with available monitoring data: "*As a part of the model development (Xie and Luo, 2022), the modeling approach has been validated for 12 pesticides with wastewater and surface water monitoring data available in California."* (Section 3.4, the 4th paragraph)

We also introduced the more recent efforts for model validation by comparing the modeling results with the previous registration recommendations for seven products: "*In addition, the model was also validated by applying to the previous registration evaluations for seven indoor products routed to SWPP. The modeling results generated the same registration recommendations as those from the previous case-by-case evaluations.*" (Section 3.4, the 4th paragraph)

Finally, we mentioned that "*SWPP will further test and evolve the modeling capability for DtD product as we have more data.*" (Section 3.4, the 4th paragraph)

Note that a new example (product 7) of using the DtD model to evaluate pet topical products was added to Table 5 of the technical report (Xie and Luo, 2022). See the updated table in Appendix I of this document. This is the only pet product that has been routed to SWPP for registration evaluation so far. SWPP evaluated the product by using the current version of the DtD model and recommended a "support".

Comment #22: Of the DtD uses evaluated, only a floor drain product is directly introduced in the wastewater, and all the other uses require specific events (e.g., pet washing, washing of clothes after fogging operations) to occur for the active ingredient to make its way into the wastewater possibly.

DPR Response: The event-based transport is mathematically represented in the modeling with two coefficients: the wash-off coefficient and the use extent of the product in the sewershed. Please see the technical report for model development (Xie and Luo, 2022). In summary, the wash-off coefficient defines the proportion of mass that could make its way down the drain. SWPP provides default values based on peer-reviewed studies (Table 3 in Xie and Luo, 2022), see updated values in Appendix II of this document. Registrants are welcome to submit supporting studies to modify the wash-off coefficient, especially for impregnated materials, in which case the wash-off study is easy to conduct. Also note that, the model defines the use extent factor and considers the label-allowed application interval as a model input to account for the possibility that a treated object would be washed or cleaned in a day.

Comment #23: The assumption that the concentration of DtD pesticide in sanitary wastewater (i.e., indoor) is higher than that in stormwater runoff (i.e., outdoor) for both dry and wet

conditions is implausible when compared to pesticide removal rates greater than 70% for specific actives (permethrin, bifenthrin), especially when these same active ingredients have significant non-indoor and agricultural uses that can impact stormwater runoff. It is common for storm drain discharge to be directed to WWTP in California, which results in considerable dilution even during dry conditions due to irrigation.

Additionally, a recent article by CDPR staff noted significant temporal variability associated with specific active ingredients (pyrethroids and fiproles) that impacted stormwater concentrations that should be incorporated into any model.

DPR Response: We agree with the reviewers on the variability and uncertainty of the relative contributions of sanitary wastewater (i.e., indoor) and stormwater runoff (i.e., outdoor). This is also the reason we developed separate modeling functions in PREM for indoor and outdoor uses.

Registration evaluations are generally based on conservative estimations in order to provide sufficient protection for human health and the environment. The DtD model is designed as a registration evaluation tool and intended to capture the worst-case conditions for the use of a DtD product. Other conditions such as a combined sewer system where storm drain discharge is directed to WWTP do not meet the need of conservative modeling for the purpose of registration evaluation.

Comment #24: This is also a clear indication that certain active ingredients are readily removed by wastewater treatment, i.e., effluent concentrations are much lower than the influent concentrations. While this distinction is accounted for in the models, it is imperative to emphasize that this is an active area of research upon which it is inappropriate to base regulatory decision-making.

DPR Response: The removal of active ingredients during wastewater treatment process has been considered in the model with the f_3 factor: "*the delivery factor during the wastewater treatment processes (f3)…"* (Section 3.4, the 2nd paragraph).

For new active ingredients without available data for the WWTP removal efficiency, SWPP uses the Sewage Treatment Plant (STPWIN) program in the EPI Suite v.4.11 to estimate the removal rate. The same approach is also used by U.S. EPA. The STPWIN model performance has been evaluated during the DtD model development (Xie and Luo, 2022). The results showed that the model-predicted removal rates were consistent with the observed values reported in the peer-reviewed literature.

For registered pesticides, if there are plant-scale removal data available, SWPP will consider it along with the EPI Suite predictions.

Comment #25: In particular, "any other products routed to SWPP evaluation with DtD concerns" is ill-defined, and DPR could readily expand it without stakeholder engagement or regulatory action. While we do not expect this to happen, we have concerns that it could happen. The reviewer strongly recommends that DPR include a process and requirements for adding a product, including stakeholder feedback and a scientific review of the product's inclusion.

DPR Response: Before a substance is registered as a pesticide for the first time in California, DPR is required to perform a thorough evaluation (Food & Agr. Code (FAC) § 12824. In addition, this responds to DPR's Notice of Decision (NOD) process (updated May 1, 2019), which ensures that adequate CEQA review has occurred. However, any product (including those with DtD uses) may be routed to SWPP through the Registration Branch's consultation process "*on a case by case basis*" (page 19) to address expanded uses, increased application rates, or label revisions. Importantly, SWPP maintains the ability to determine if formal evaluation is required based on review of existing data that indicate whether the active ingredient poses a threat to surface water.

Comment #26: The reviewer is also concerned about how new products, actives, and degradates will be added to the program and the time allowances necessary to develop data to support the additional registration requirements.

The guidance on how products for which DPR determines additional data are required to support this modeling approach (e.g., half-lives, ecotoxicology endpoints) that are not required by U.S. EPA will be treated needs to be clarified. U.S. EPA often does not require the submission of ecological effects data due to an incomplete exposure pathway (i.e., indoor use), and, therefore, there would be no effects on an endangered species or impact on aquatic toxicity or wastewater. It is unclear from DPR's draft guidance if this scenario has been considered or whether DPR will require the submission of data to conduct modeling not required by U.S. EPA, especially after U.S. EPA has determined that the information is not required to support registration. The reviewer is concerned that this is a significant change that needs to be adequately addressed in the draft guidance and requests that this situation be addressed before effectuating PREM6.

As this encompasses a new scope of products, will DPR now require additional data beyond current U.S. EPA requirements? If additional products are included, we request clarification as to which products specifically would be included or how they will be identified.

DPR Response: There is no additional data requirement by SWPP specific to the evaluation of a DtD product. Ecotoxicology endpoints are needed for modeling as a general requirement for all pesticides to be evaluated by SWPP.

Registrant-submitted data will be used as the primary sources to characterize model input parameters. Otherwise, for model inputs without data submitted by registrants, SWPP will estimate them with EPI Suite or use default values, as demonstrated in the technical report for model development (Xie and Luo, 2022).

Pesticide products of indoor uses have been evaluated by SWPP since 2014 based on case-by-case evaluations. They are not considered to be "a new scope of products" to SWPP. PREM6 standardizes the previous evaluations as a systematical modeling approach to the DtD products. More details on the previous evaluations are provided in the technical report for model development (Xie and Luo, 2022) and also summarized in Appendix I.

Comment #27: The reviewer notes that the model's user manual contains important details yet to be published, presenting challenges in providing comprehensive comments on specific aspects of

the Methodology and its implementation. It is reasonable to include details about input data preparation, additional data requests, or modeling results interpretation that may improve or inform a modeling effort in a user manual. However, we need clarification about why certain elements, such as professional judgment or the final reporting with registration recommendations, would be considered for inclusion in a user manual, especially as this draft document has not been provided for stakeholder review. These critical elements must be scientifically evaluated before finalization and implementation. The reviewer strongly recommends clarifying the methodology on these points and eliciting stakeholder feedback on the model user manual before effectuating PREM6.

DPR Response: The user's manual will be available soon after the finalization of the PREM6 report. It is also noteworthy that the technical details for DtD evaluations have been well documented in the previous report (Xie and Luo, 2022), which is a better reference for the DtD modeling approach than the user's manual.

The current DtD model is a product of SWPP's expanding modeling efforts since 2014. Registration evaluation reports for the DtD products evaluated by SWPP have been posted by CDPR and notified to registrants, as summarized in Appendix I of this document. To date, SWPP has received no feedback from registrants regarding the previous registration evaluations.

Comment #28: The reviewer further notes that the population and pet population estimates are temporally mismatched. The methodology specifies that the sales data set encompasses the period from 2014 to 2016, while the data about the number of pets is derived from 2018. The methodology identifies that the sales data set spans the period from 2014-2016, while the data about the number of pets is from 2018. The AVMA estimate of dogs and cats assumes that all pets use products, but not all are treated with shampoos, topicals, and collars. In addition, a growing percentage of pets are treated with oral or natural products, many regulated by FDA. The AVMA last updated the survey in 2022 and provides a population-based formula to estimate the pet population. The calculations assume that pets are located indoors and treated 12 times per year, based on the monthly use of topicals. In reality, many pets are not treated monthly since owners do not treat them during winter months, and the treatment rate is often 6 to 8 use per year. The reviewer is concerned that the values in Table 2, Conversion from label-allowed application rate to Rmax assumptions, appear overly conservative, especially for cats. The reviewer recommends that pet demographics and sales data but updated as much as possible and regularly updated to reflect changes in pet ownership over time.

DPR Response: The time span that we chose for sales data analysis is subject to the data quality. Unfortunately, the potential errors in data reporting prevent us from using data on or after 2017. Thank you for the suggestion on updating pet demographics and sales data as much as possible. SWPP is evaluating ways to fix the reporting errors in sales data and strives to update the data as much as possible.

Regarding the comments on the percentage of pets that receive topical flea and tick treatment, this factor has been taken into account by using the sales data of topical products to estimate the number of pets being treated.

The assumption of 12 applications per year follows the maximum label rate of pet spot-on products. Although the number may be smaller for some pet owners, the label does allow up to 12 applications per year, which is the maximum potential. For registration evaluation, SWPP recommends using the maximum number of applications per year based on the label. This recommendation has been consistent across all versions of PREM.

Comment #29: The reviewer is concerned that the pet bathing assumptions are not reflective of current practices. For example, many pet owners do not regularly bathe their pets indoors and may utilize exterior hoses or other outdoor water sources. Cat owners rarely bathe cats because cats regularly clean themselves. Anecdotally, members also manufacturers of pet shampoo products indicate that their sales figures are not supportive of 25% of pets being bathed monthly. Finally, there also is no consideration that many pet products are designed to be absorbed into the animal's skin and, therefore, cannot be washed from the skin if the animal is bathed. While we understand that a registrant can conduct a study and submit data to support usage, the reviewer strongly encourages DPR to utilize existing sales data and other resources to provide more realistic default assumptions.

DPR Response: The assumption of 25% dogs being washed in a 28-day interval comes from the dog wash study conducted by Teerlink et al. (2017). Although there is no further data to inform this estimate, using the assumption of 25%, along with the statewide sales data of fipronil spot-on products yielded an estimate of concentration that is comparable to the actual concentrations detected in wastewater influent in California. The same assumption is applied to cats due to a lack of reliable data to modify this estimate. SWPP understands that the assumption is on the conservative side, especially for cats; however, the National Cat Groomers Institute of America recommends a bath be given to cats once every 4-6 weeks, which is comparable to dogs.

As for the comment on the possibility for a topical skin treatment to be washed off, the dog wash studies conducted by Teerlink et al. (2017) and Perkins et al. (2024) confirmed that dog wash is a significant pathway to transport fipronil to wastewater. Using this study as a baseline, it is reasonable to classify pet topical products as a high-risk DtD use pattern and include them to the registration evaluation. Besides, SWPP only assumes a proportion of mass applied to pets would be washed off during washing events, and the wash-off coefficient is determined based on the measurement from the dog wash study.

Comment #30: The reviewer is unclear why outdoor and DtD uses were modeled using the same default pH values and why the pH value 7.45 is considered the 10th percentile. At a minimum, the discussion must be expanded to provide better guidance to users of the model.

DPR Response: The pH value 7.45 is only used in the Biotic ligand model for copper in freshwater (section 2.4). This value is not used in the evaluation on other products and use patterns such as DtD products.

Comment #31: The reviewer requests greater clarity for how site codes are being utilized. For example, lab dogs (DPR site code 56011) and cats (DPR site code 56028) would not typically receive the treatments relevant to the draft guidance. Refining the definitions, possibly in the development of CalPEST, would assist stakeholders and allow DPR to focus modeling efforts.

DPR Response: The site codes indicated in Table C2 (Xie and Luo, 2022) are used to demonstrate the method that SWPP developed to identify pet products from the pool of products registered with DPR for different use patterns. Site codes corresponding to lab dogs and cats were included because they are relevant to products used on pets. These two site codes are considered as a part of the big group of site codes that are relevant to pets.

The inclusion of lab dogs/cats in product selection had no impacts on the result. The top sales products that were finally selected and used in the model development are all topical application products designated for use on pets exclusively. These products may or may not be used on lab dogs/cats, but the point is that the products are intended to be used on pets and the mass of AI being sold can be used to estimate the maximum number of pets being treated with the AI. Whether a pet would be washed after the treatment follows another assumption, which is 25% of dogs would be washed in an application interval, according to Teerlink et al. (2017). The assumption is irrelevant to lab dogs/cats.

Comment #32: The reviewer is concerned that there is little justification for the draft document's assumption of the "General indoor pest control products (e.g., foggers, and indoor sprays to pet and human beddings, floors, carpets, rugs, and upholsteries)," pathway to DtD, especially the assumption that they are thoroughly washed off and transferred to DtD. While we understand that a registrant can conduct a study and submit data to support usage, the reviewer strongly encourages DPR to utilize existing sales data and other resources to provide more realistic default assumptions. This use must be robustly justified or removed until it can be.

DPR Response: Foggers and indoor sprays to high-risk sites have been shown to be a source of pesticides transported down the drain via washing and cleaning (Keenan et al., 2009; Keenan et al., 2010; Dery et al., 2022). SWPP believes it is an important pathway for pesticides to enter the waste stream, and therefore includes it in the registration evaluation.

However, based on the newer data coming from Dery et al. (2022) on cypermethrin foggers, along with a revisit of (Keenan et al., 2009; Keenan et al., 2010), SWPP recommends a new default value of wash-off coefficient for indoor foggers and sprays, which is 0.35 instead of the extremely conservative assumption (i.e., 1). Updates are demonstrated in Section 3.3 and Table 3 of the technical report (Xie and Luo, 2022). See the updated table in Appendix II of this document.

Comment #33: The reviewer strongly recommends that DPR train registrants using PREM6 before implementation of PREM6, especially considering that many new registrants will now be impacted by the modeling efforts by adding the DtD module.

DPR Response: A user's manual will be provided before the implementation of PREM, with detailed instructions on the use of the DtD model for registration evaluation. We routinely provide additional information as requested by registrants and answer any and all questions on the modeling.

Comment #34: There is no guidance regarding the modeling degradants of DtD products. It would be helpful to include guidance if degradants need to be modeled, and if so, what inputs are required.

DPR Response: We clarified this in the report: "*Degradate evaluation in the DtD modeling is only available for the degradation products formed in the receiving water body. Degradation and formation in the sewer system and during wastewater treatment are not modeled due to the lack of travel time and half-lives in wastewater."* (Section 3.4)

The modeling approach and instructions for degradate evaluations have been previously documented (Luo et al., 2016; Luo et al., 2019). The same approach is implemented in PREM6 for evaluating DtD products.

References

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Xie, Y. and Y. Luo (2022). Methodology for evaluating pesticides for surface water protection: Evaluation on down-the-drain products. California Department of Pesticide Regulation.

Appendix I. Updated Table 5 in the technical report (Xie and Luo, 2022) for the DtD model development (product 7 was newly added)

Table 5. Comparison of registration recommendation between the DtD model and past evaluations.

Parameter	Unit	Product 1	Product 2	Product 3	Product 4	Product 5	Product 6	Product 7
Use pattern		Impregnated socks	Floor drain	Floor drain	Indoor spray	Drinking water treatment	Animal housing treatment	Spot-on for small cats
Product AI		Copper	Fipronil	Deltamethrin	Deltamethrin	Copper	Indoxacarb	Spinetoram
R_{max_label}	µg[AI] subject^{-1} day^{-1}	1.16E+06	2.80E+04	2.55E+05	1.88E+04	NA	3.13E+06	1.74E+05
Subj/Capita	Dimensionless	1	0.02	0.02	0.25	NA	9.38E-06	0.25
$R_{max} = R_{max\_label}$ * *Subj/Capita*	µg[AI] person^{-1} day^{-1}	1.16E+06	5.39E+02	4.91E+03	4.7E+03	NA	2.94E+01	4.27E+04
$Coef_{washoff}$	Dimensionless	0.0013	1	1	1	NA	1	0.21
Interval	day	7	30	180	180	1	1	60
M	µg[AI] person^{-1} day^{-1}	2.15E+02	1.8 E+01	2.73 E+01	2.61 E+01	1.94E+05	2.94 E+01	1.49E+02
W	L person^{-1} day^{-1}	242	242	242	242	242	242	242
f_1	Dimensionless	0.01 [a]	0.76 [a]	0.022 [a]	0.022 [a]	0.338 [a]	1 [a]	0.05 [a]
f_2	Dimensionless	1	1	1	1	1	1	1
f_3	Dimensionless	0.18	0.8697	0.1238	0.1238	0.18	0.3638	0.6214
f_4	Dimensionless	1	1	1	1	1	1	1
C_R	µg[AI] L^{-1}	1.60E-03	0.05	3.08E-04	2.94E-04	48.67	4.41E-02	0.02
TOX	µg[AI] L^{-1}	0.48	0.14	0.0037	0.0037	0.48	54.2	355
RQ (Dissolved)	Dimensionless	5.24E-05	0.34	8.01E-03	7.65E-03	1.59	7.56E-04	5.07E-05
TOXSED	µg[AI]/kg[dry weight]	151000	NA	3.8	3.8	151000	720	1.6
RQ (Adsorbed)	Dimensionless	8.50E-06	NA	3.17E-03	3.03E-03	0.26	1.29E-03	1.27E-03

Recommendation		Support	Support (Watch list)	Support	Support	Denial	Support	Support
Consistent with Previous Decision?		Yes	Yes	Yes	Yes	Yes	Yes	Yes

Appendix II. Updated Table 3 in the technical report (Xie and Luo, 2022) for the DtD model development (default value of wash-off coefficient for household indoor pest control changed from 1 to 0.35)

Table 3. Values of wash-off coefficient recommended when no data is available.

Use Pattern	**Wash-off Coefficient (*$Coef_{washoff}$*)**
Pet Products (except shampoos)	0.21 OR request for wash-off study
Pet Shampoos	1
Impregnated materials	Request for wash-off study
Floor Drains	1
Household Indoor Pest Control	0.35