National Water Research Institute

Panel Report for Meeting 3

LOTT Clean Water Alliance
Reclaimed Water Infiltration Study

Based on an Independent Expert Advisory Panel Meeting
October 23, 2019

Prepared by
NWRI Independent Advisory Panel to review the
LOTT Reclaimed Water Infiltration Study

Prepared for
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Submitted:
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NOTE: This file contains Study Team responses to the Panel comments. The responses are provided in blue text throughout the document, as follows: "STUDY TEAM RESPONSE: …"

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Acronyms

COPEC	Constituent of potential emerging concern
DWEL	Drinking water equivalent level
EPA	United States Environmental Protection Agency
ERA	Ecological risk assessment
LOAEL	Lowest observed adverse effect level
HHRA	Human health risk assessment
LOTT	Lacey, Olympia, Tumwater, and Thurston County Clean Water Alliance
mgd	million gallons per day
mg/kg	milligrams per kilogram
NDMA	N-Nitrosodimethylamine
ng/L	nanogram per liter
NOAEL	No observed adverse effect level
NWRI	National Water Research Institute
Panel	Independent Advisory Panel
PFAS	Per- and polyfluoroalkyl substances
PFOA	Perfluorooctanoic acid
PFOS	Perfluorooctanesulfonate
PHGs	Public Health Goals
SAT	Soil-aquifer treatment
SF6	Sulfur hexafluoride
TDCPP	Tris(1,3-dichloro-2-propyl) phosphate

1. Purpose and History of the Panel

In 2013, the National Water Research Institute (NWRI) of Fountain Valley, California, a joint powers authority and 501c3 nonprofit, appointed local and national water industry experts to an Independent Advisory Panel (Panel) to provide a credible, third-party, science-based review of the Reclaimed Water Infiltration Study proposed by LOTT Clean Water Alliance of Olympia, Washington.

The multi-year scientific study by LOTT is focused on determining potential human and/or ecological health risks from the infiltration of reclaimed water into local groundwater—particularly, the impacts of pharmaceuticals and personal care products— and approaches to reduce those risks. The goal of the LOTT study is to help policymakers make informed decisions about future reclaimed water treatment and uses.

1.1 Project Background

The LOTT Clean Water Alliance is a wastewater utility whose members include the Cities of Lacey, Olympia, and Tumwater, and Thurston County in Washington State. Currently, most of their wastewater is treated at the Budd Inlet Treatment Plant and discharged into Budd Inlet at the southern tip of Puget Sound. As part of its long-range plan to manage wastewater, LOTT is engaged in increasing the production of Class A Reclaimed Water, the highest quality of reclaimed water as determined by the Washington State Departments of Ecology and Health.

LOTT has built a reclaimed water satellite system to produce roughly 1.5 million gallons per day (mgd) of Class A Reclaimed Water. The system includes the Martin Way Reclaimed Water Plant, which employs a membrane bioreactor for primary, secondary, and tertiary treatment. The water is then piped to the Hawks Prairie Reclaimed Water Ponds and Recharge Basins, where it circulates through five constructed wetland ponds and then flows into recharge basins to infiltrate into the underlying aquifer system. The site also serves as a public park and ecosystem for local wildlife.

LOTT also produces up to 1.5 mgd of Class A Reclaimed Water at its Budd Inlet Treatment Plant in the summer by treating the effluent with a sand filtration system. Most of this reclaimed water is used for irrigation, toilet flushing, water features, and

processes in the treatment plant. Additional sites are currently being considered for future infiltration and soil-aquifer treatment (SAT).

To address questions and concerns about reclaimed water infiltration, LOTT is engaged in a multi-year scientific study to achieve the following:

1. Provide scientific data and community perspectives to help policymakers make informed decisions about future wastewater and reclaimed water treatment and uses.
2. Ensure that the scientific study and public involvement processes are credible, objective, transparent, responsive, and responsible.
3. Foster meaningful, community-wide discussions about water quality, reclaimed water, groundwater recharge, risk assessment, and related watershed issues.

Environmental assessments, including surface water and groundwater sampling, geologic exploration and testing, and laboratory analysis, have been or will be completed during various study phases. Through the study scoping effort, preliminary information, planning data, and study needs were assessed among key project stakeholders and then sampling programs, contaminants to be monitored, sampling locations, and sampling frequency were developed. The recharge basins at the Hawks Prairie site, which have been in operation using reclaimed water since 2006, are the primary site where questions about fate and transport of residual chemicals within the aquifer system are being evaluated.

1.2 Status of the Reclaimed Water Infiltration Study

LOTT and the project team previously focused on a tracer test and groundwater quality characterization, which was conducted from January to October 2018.

The tracer test determined travel times and downgradient flow paths of the reclaimed water as it moves through the vadose zone and aquifer system, and informs groundwater modeling to characterize the longer-term fate and transport of residual chemicals in reclaimed water.

The purpose of the groundwater quality characterization was to assess water quality changes that occur over time in the subsurface as a result of reclaimed water infiltration. In particular, water quality monitoring was used to: (1) determine the effectiveness of SAT at attenuating residual chemicals and nutrients, and (2) assess the mixing and dilution that will occur as reclaimed water travels downgradient from the

recharge basins. In 2017, lysimeters and additional monitoring wells were installed at and around the Hawks Prairie Recharge Basins to support water quality modeling of the vadose zone and groundwater system.

1.3 Purpose of the Panel

The expert Panel was organized in 2013 by NWRI at LOTT's request to review the study efforts and advise the project team at specific milestones to ensure a credible, independent, transparent, and science-centered review of the scope, fieldwork methods and results, model development, and outcomes of the Reclaimed Water Infiltration Study. Background information about the NWRI Panel process can be found in **Appendix A**.

1.4 Members of the Panel

The Panel is made up of six experts in areas related to the infiltration of reclaimed water, including water reuse and public health criteria, environmental engineering, hydrogeology, human and ecological toxicology, and other relevant fields. Panel members include:

- Chair: James Crook, PhD, PE, Environmental Engineering Consultant (Boston, MA)
- Richard Bull, PhD, MoBull Consulting (Richland, WA)
- Michael Kenrick, PE, LHG, GeoEngineers (Redmond, WA)
- Edward Kolodziej, PhD, University of Washington (Tacoma/Seattle, WA)
- John Stark, PhD, Washington State University (Puyallup, WA)
- David Stensel, PhD, PE, University of Washington (Seattle, WA)

Brief biographies of the Panel members can be found in

Appendix B.

2.Panel Meeting 3

The Panel met on October 23, 2019, at LOTT's administrative offices in Olympia, Washington. This was the third time the full Panel has met to review LOTT's Reclaimed Water Infiltration Study. The purpose of the meeting was to update the Panel on several topics, including the following:

- Screening-level and refined-level human health risk assessment.
- Screening-level and refined-level ecological risk assessment.
- Fate and transport of chemical constituents of interest.

2.1 Background Material

Before the meeting, LOTT provided the following documents to the Panel for review:

- Technical Memorandum: Ecologic Risk Assessment Problem Formulation (Draft Final), prepared by Windward Environmental, LLC.
- Appendix B to the Technical Memorandum: Ecologic Risk Assessment Problem Formulation (Draft Final), prepared by Windward Environmental, LLC.
- Draft Work Plan: Groundwater Modeling and Predictive/Simulations (Task 2.1.4 continued) and Residual Chemical Fate and Transport (Task 2.1.5), prepared by HDR.
- Screening-Level Human Health Risk Assessment for the LOTT Clean Water Alliance Reclaimed Water Infiltration Study (Draft Final), prepared by Intertox, Inc.

2.2 Panel Meeting 3 Agenda and Attendees

Staff from NWRI and the LOTT project team collaborated on the agenda for Meeting 3 (in **Appendix C**). Most of the meeting was devoted to presentations by the LOTT project team.

Attendees included NWRI staff, the LOTT project team, all NWRI Panel members, the Science Task Force, and other interested stakeholders. The Science Task Force is made

up of technical experts from the Cities of Lacey, Olympia, and Tumwater, Thurston County, the Squaxin Tribe, and the Washington State Departments of Ecology and Health. A complete list of Meeting 3 attendees is included in **Appendix D**.

Time was provided for the Panel and Science Task Force to ask questions and engage in discussion after each presentation. The presentations were meant to support and/or complement data and information provided in the pre-meeting review documents.

After the presentations, the Panel met in a closed session to discuss the information presented by the LOTT project team. During the closed session, the Panel drafted a report outline and preliminary findings and recommendations, which have been expanded upon in this report.

3. Panel Findings and Recommendations

The Panel's principal findings and recommendations are derived from the pre-meeting review documents, the material presented and discussed at Meeting 3, and specific questions on human health and ecological risk management and fate and transport analysis that LOTT asked the Panel to address. The findings and recommendations are organized in the following sections:

- General Comments
- Fate and Transport Analysis
- Ecological Health Risk Assessment
- Human Health Risk Assessment

3.1 General Comments

The pre-meeting review documents were organized, thorough, and were given to the Panel with sufficient time to review them before the meeting. The Panel appreciated the excellent presentations and handouts provided before and during the meeting.

3.2 Fate and Transport Analysis

Summary of Panel Findings and Recommendations

- The fundamental steady-state modeling approach is both reasonable and acceptable.
- The Panel recommends conducting a full sensitivity analysis to understand the impacts of the steady-state assumptions.
- The Panel recommends decoupling the biodegradation and sorption analyses.
- The Panel recommends that the project team consider installing an additional downstream sampling well to test the model predictions on water quality before the groundwater flow reaches drinking water wells.

Rationale for Recommendations

The fate and transport analysis represents an amalgamation of the Tracer Study (Task 2) and the Groundwater Modeling (Task 2) efforts. As such, it synthesizes a lot of local and project information into a predictive groundwater flow and transport model. The model can be used to predict and analyze groundwater flow paths, advection travel times, and the complex processes of sorption, dispersion, and dilution that modify concentrations of residual chemicals in groundwater within the saturated zone as it moves from beneath the Hawks Prairie Recharge Basins to potential receptors such as wells, springs, and streams that receive groundwater discharged from the aquifer system.

Use of the steady-state modeling approach assumes that the seasonal variation in hydrologic inputs and outputs over the months of each season, and as the seasons vary over the years, can be treated as constant values in the model; in other words, they do not vary over time. In some senses, the natural variations, which are thus ignored, represent an element of "noise" perturbing a more dominant underlying trend or pattern which, in the case of groundwater flow, is well-represented by relatively constant values within the model domain. This confirms that it can take many years to convey water molecules and dissolved chemicals from source to receptor, with monthly or seasonal variations having a muted or attenuated impact on the system. **As such, the Panel deems the fundamental steady-state modeling approach to be both reasonable and acceptable.**

Although the steady-state modeling approach limits temporal variations within the model, a sensitivity analysis can be done by varying key individual parameters and testing the change in specific results of the modeling runs; for example, changing the infiltration rates and measuring the effect on travel time and concentration to a specific receptor. **The Panel believes that a full sensitivity analysis is needed to understand the impacts of the steady-state assumptions that cover, for example,**

variation in residual chemical concentrations, recharge facility infiltration rates, and regional recharge rates.

STUDY TEAM RESPONSE: We agree that a sensitivity analysis should be conducted, and we plan on doing so. However, it will be most efficient to focus the sensitivity analyses on specific parameters here e e ect the ost aria ilit i the o el s outcome. For Step 1 of the Fate and Transport Analysis (as outlined in the Task 2.1.5 (Fate and Transport) Work Plan), we have identified these key variables to include dispersivity, regional recharge at the Hawks Prairie facility, and effective porosity. In addition, as part of Step 2 of the Fate and Transport Analysis, sensitivity of chemical transport properties such as K_d (based on residual chemical K_{oc}, soil f_{oc}, and soil dry bulk density) and first order decay rate will be conducted on individual residual chemicals that are identified by Step 1.

The Panel also recommends that LOTT decouple the biodegradation and sorption analyses. See the Panel response to Question 6(a) from LOTT in Section 3.6.

STUDY TEAM RESPONSE: Agreed, to the extent it is possible based on available data, which will likely be limited for some chemicals. Per the Task 2.1.5 (Fate and Transport) Work Plan, this represents Step 2 in the predictive simulations of downgradient residual chemical concentrations (meaning, this analysis will be conducted on a sub-set of chemicals that are a function of potentially greater risk).

The Panel believes that LOTT can use the model to evaluate the need for sampling deep aquifer wells downstream. Uncertainties in expected travel time and concentration/attenuation revealed in a fully executed sensitivity analysis conducted on the calibrated groundwater flow and transport model should inform the frequency and duration of sampling required. **Consider installing an additional downstream well for sampling to test the model predictions on water quality at a time and place before the groundwater flow reaches drinking water wells.**

STUDY TEAM RESPONSE: LOTT is currently considering installation of up to 6 additional downgradient wells. The wells under consideration are shallow/deep aquifer paired wells located to the south, west, and east of the Hawks Prairie infiltration site. Additionally, sampling of the Lacey S29 production well is planned to assess if there is a signature of reclaimed water and if residual chemicals have arrived there.

One important outcome of the hydraulic modeling is an improved understanding of groundwater flow paths and travel times to the deep aquifer system. Because the deep aquifer is used as a drinking water source, including for production wells, an important aspect of the modeling effort would be to understand which, if any, deep aquifer wells are likely to be impacted by increased reclaimed water infiltration. Should the hydraulic modeling effort identify possible deep aquifer wells hydraulically connected to infiltration basins, the Panel recommends using such wells for assessment and monitoring purposes.

3.3 Ecological Risk Assessment – Screening Level

Summary of Panel Findings and Recommendations

- The ecological risk assessment (ERA) followed standard environmental protection agency (EPA) methodology, and the results are valid based on the methods that were used.
- The Panel recommends that the project team continue to use accepted methods for the screening-level and refined-level ERAs.
- The Panel recommends that the project team update the list of chemicals of potential ecological concern for future risk assessments as more data becomes available.

Rationale for Recommendations

The Panel commends the project team for conducting a thorough ERA study. The ERA thoroughly analyzed the species inhabiting the area of concern and identified sensitive species (species that are listed as threatened, endangered, or sensitive by the US Fish and Wildlife service and/or the Washington Department of Fish and Wildlife).

The sensitive species consist of six fish species, two bird species, and three aquatic-dependent mammal species. The study identified receptors of concern for these species and included exposure assessments.

The ERA constructed a conceptual site model and potential exposure pathways and assessments endpoints. Screening level benchmarks were not available for the chemicals identified in the analysis. Therefore, benchmarks were derived using the Ecological

Structure Activity Relationships (ECOSAR) model (EPA) and the ecotoxicology knowledgebase (ECOTOX). Benchmarks were developed for chronic exposures. Concentrations of constituents of interest (COIs) were then compared to these benchmarks. Exceedance factors were calculated by dividing measured concentrations by the benchmark. Where exceedances occurred, those chemicals were identified as constituents of potential ecological concern (COPECs). A separate analysis was also conducted to determine persistent and bioaccumulative chemicals. These chemicals were retained as COPECs irrespective of whether they exceeded benchmarks. Of the COIs evaluated, 82 were detected in reclaimed or porewater. Of these, eight chemicals were classified as COPECs for further consideration. Furthermore, 10 chemicals were classified as persistent and/or bioaccumulative.

The ERA followed standard EPA methodology. The results are valid based on the methods that were used. The project team identified the chemicals that could be a risk to ecosystems. However, because little toxicity data exists for a number of the chemicals being detected in reclaimed and porewater in the study site, caution must be advised in terms of the potential future risk of these chemicals. As more data is developed in the future, risk assessments for the COPECs identified in this study should be updated.

The Panel recommends that the project team continue to use accepted methods for the screening-level and refined-level ecological risk assessments

3.4 Human Health Risk Assessment – Screening Level

Summary of Panel Findings and Recommendations

- The human health risk assessment is conservative and protective of public health.
- The methods used in the screening-level are similar to those used by other utilities for detecting chemical concentrations in drinking water wells.
- The Panel recommends reevaluating which chemicals should be carried through to the refined risk assessment.

Rationale for Recommendations

LOTT is commended for their intent to identify and define hazards associated with residual contaminants in the reclaimed water that is infiltrated into groundwater. This water serves as a drinking water source for public utilities and private wells in the area.

The human health risk assessment is designed as a two-tiered approach. The first tier is a screening-level assessment based on risk assessments made by state and federal agencies and screening methodologies published in the peer-reviewed literature (Kroes et al., 2005; Renwick, 2005; Schwab et al., 2005; Bull et al., 2011; Yan, 2017; Reilly et al., 2019). The second tier is a refined estimate of health risks associated with chemicals identified in the screening-level risk assessment.

The Panel does not believe that the two-tiered design was required to address the probability that adverse health effects might occur as a result of water infiltrated by LOTT. In fact, a collection of existing Maximum Contaminant Levels (MCLs), Notification Levels (NLs)/Action Levels (ALs), and Health Advisories (HAs) promulgated by the EPA and/or state agencies, which are supported by recent risk assessments by CalEPA, are sufficient for most of the compounds identified as being of concern, with a few exceptions noted in the comments on those chemicals proposed for refined risk assessments.

STUDY TEAM RESPONSE: The first tier of the assessment was designed as a screening level assessment to identify those chemicals that might present a human health risk and therefore warrant further investigation in the subsequent Human Health Risk Assessment (HHRA; second tier). We recognize that there may have been some confusion about the terminology used; however, the first tier is not intended as a "h a health ris assess e t" er se, but as a conservative screening assessment to focus resources in the subsequent HHRA. To improve clarity, we have revised the descriptors applied to the two tiers a ill refer to the first tier as the " cree i e el Evaluation" a the seco as the " a ealth is ssess e t"

We agree that water quality standards (and other types of criteria) should be considered in the Screening Level Evaluation and in the HHRA. In the Screening Level Evaluation, we identified existing water quality standards for each chemical that have been published by authoritative bodies, and applied those as DWELs if they represented the most conservative value. We note however that the types of values listed (MCLs, NLs, ALs, HAs, etc.) would not have addressed all of the chemicals detected in reclaimed water or porewater, particularly the PPCP substances. Table B-1 of the Screening Level Evaluation lists identified published drinking water standards or acceptable daily intakes for the residual chemicals detected in these water sources. As shown, many of the detected compounds do not have existing values, necessitating derivation of values based on other approaches and data types (e.g., from toxicological data or therapeutic

doses). The methods used to derive health risk-based screening levels from these types of data are well standardized and applied here.

Also, as noted previously, many of the published water standards (e.g., MCLs) are not strictly health-risk based and take into consideration other types of criteria such as technical feasibility. As such, these types of values are not necessarily equivalent to purely health risk-based values when applied in a human health risk assessment. It is our opinion that values developed using relatively equivalent methods should be applied in a human health risk assessment.

To present both types of information to support risk communication for detected compounds, we propose to both (1) compare detected concentrations to existing water quality standards, where available, and (2) identify human health risk-based acceptable daily intakes for use in risk assessment.

In conducting our Screening Level Evaluation and proposing compounds for further evaluation in the HHRA, we were mindful of comments received from other reviewers (e.g., the Science Task Force) that the approach be sufficiently health protective to ensure that human health risks are not underestimated. For example, other reviewers commented that all detected compounds should be considered in the HHRA, regardless of relationship to health risk-based screening levels. We feel that our approach balances these concerns, by being both conservative (health protective) and ensuring that risks are not underestimated, and not being overly conservative as to identify compounds for further assessment that are well below levels that present a human health risk.

The consultant used the screening-level risk assessment to identify chemicals that occur below drinking water equivalent levels (DWELs). The DWEL reflects the result of a risk assessment of a chemical concentration in drinking water. Normally, if a chemical is detected at a concentration lower than the DWEL, then it would be removed from the analyte list. Therefore, the Panel suggests that only those chemicals that exceed the calculated DWELs need to be carried forward to the refined health risk assessment. Note that the consultant proposed that the refined risk assessment should also address chemicals detected at concentrations equal to or greater than 10 percent of the DWEL as well as those detected at or above the DWEL.

STUDY TEAM RESPONSE: e selecte all co o s etecte at of the

DWEL for further consideration in the HHRA in order to be conservative (health-protective), to account for the potential impact of multiple compounds that can impact the same physiological systems. Inclusion of compounds with maximum-detected co ce tratio s of a health ris -based screening level is consistent with U.S. EPA recommendations for selection of chemicals of potential concern to be carried through the risk assessment process (e.g., U.S. EPA, 2018. *Region 4 Human Health Risk Assessment Supplemental Guidance*).

The screening-level risk assessment methods are similar to those used by other utilities for detecting chemical concentrations in drinking water wells. The Panel supports the use of these methods if they are applied to their original purpose as described in the peer-reviewed literature. The threshold of toxicological concern and related methods were developed to identify which chemicals in a sample occur at a concentration that justifies an experimental effort to develop toxicological data for a risk assessment. In contrast, chemicals detected at less than the identified thresholds do not pose significant health hazards, so experimental testing is not required.

STUDY TEAM RESPONSE: We included the Threshold of Toxicological Concern (TTC) methodology in our tiered screening approach (discussed in Section 4.2.2.6 of the Screening Level Evaluation s escri e the a roach is a " efa lt" method that is recommended only for application to compounds for which very limited or no health effects data are available to support traditional risk assessment. For example, Kroes et al. (2004) (who published one of the more popular TTC schemes), state " rior to a licatio of the a roach all a aila le to icit ata o the co o sho l e collecte a e al ate he a roach sho l o l e used in cases where the available chemical-specific data are inadequate for normal risk characteri atio he is ot esi e to re lace co e tio al a roaches to risk characterization for established and well-st ie che icals " As we further indicate i o r te t " f ote the a licatio of s to har ace ticals is lar el hypothetical; none of the TTC schemes explicitly considered deliberately biologically active compounds such as pharmaceuticals in their derivation. As such, the appropriateness of application of the TTCs to pharmaceuticals is uncertain. Furthermore, both Cheeseman et al. (1999) and Kroes et al. (2004) caution against applying TTCs to EDCs. However, since Munro et al. (1996) determined that TTC schemes are protective of a broader range of compound types than industrial compounds, and since one of the goals of this project is to derive a screening-level for

each compound to aid LOTT in decision making, TTCs were derived for all pharmaceuticals for comparison purposes and for EDCs when no other data was a aila le ”

Based on this guidance, DWELs were developed in a hierarchical manner, relying first on published peer reviewed values and on values derived from published toxicity data or from therapeutic doses. Use of a TTC would be applied only as a last option in the absence of any other compound-specific data (the TTC approach is last in our hierarchy shown in Figure 4-1). However, since chemical-specific data of sufficient quality were identified for all of the compounds detected in reclaimed water or porewater, none of the DWELs was based on a TTC.

The Panel commends the conservative approach used in basing the analysis on the highest reported concentration in water that will be used as drinking water. Weight of evidence demonstrated by two or more consistent concentrations across different sample locations and events is an accepted approach to the screening-level risk assessment, and the Panel recommends using weight of evidence to set the exposure concentration at the appropriate level. For example, in the screening-level assessment, the 4-nonylphenol exceeded its DWEL in one isolated measurement of porewater in the lysimeters (510,000 ng/L), while the concentration in reclaimed water was 3,100 ng/L. The consultant should take the likelihood of human exposure to these two different water qualities into account when setting the reference concentration.

STUDY TEAM RESPONSE: We will examine the validity of water concentrations that could be in error or outliers. However, in general, it is our opinion that in screening level evaluations, comparison of maximum detected concentrations to DWELs is appropriate in part because sample collection is necessarily incomplete (i.e., it is impossible have perfect knowledge about the distribution of concentrations over an area or across a medium) and use of the maximum provides a level of conservatism to ensure that potential risks are not underestimated.

The Panel recommends that in the refined risk assessment, the exposure should be presented as a distribution of concentration present at private or production wells.

The Panel recommends expressing the concentrations of these chemicals as a percent of the bromide tracer concentrations starting with the reclaimed water to each monitoring point; this information can be used to understand if attenuation is due to

dilution or other mechanisms of attenuation.

STUDY TEAM RESPONSE: In the HHRA, we will use exposure point concentrations provided to us by HDR that are estimated based on measured concentrations and fate and transport modeling. HDR intends to show side by side the concentrations of residual chemicals (as percentage of original concentration at point of infiltration) and bromide (also as a percentage of original concentration). This is different than what is state here as " erce t of ro i e tracer co ce tratio "

From the Panel's point of view, the screening risk assessment gives rise to a series of potential actions: (1) to collect toxicological data needed to support a refined risk assessment of chemicals identified in the screening risk assessment; (2) to demonstrate that these compounds do not exceed the DWELs at production or private wells; (3) to institute controls over inputs of these chemicals to wastewater; or (4) to increase treatment to remove or reduce the concentrations of compounds that approach or exceed their calculated DWELs.

STUDY TEAM RESPONSE: The HHRA will use existing human health effects information (e.g., water quality criteria, toxicity criteria, toxicological data, therapeutic doses) to assess the potential human health significance of detected or modeled water concentrations at potential points of contact, and estimated exposures for hypothetical potentially exposed populations, as proposed in our original scope of work and described further in our refined scope of work. A number of comparisons will be made to assess the significance of measured or estimated values, including: comparisons of estimated noncancer hazards or cancer risks to acceptable values (e.g., Hazard Index of 1.0 for noncarcinogens or a range of acceptable cancer risks, such as 10^{-4} to 10^{-6}, for carcinogens) and comparison to other background sources of exposure. This information can be used to support decision-making.

The seven chemicals listed below were detected at concentrations exceeding the DWEL. The Panel questions which chemicals need to be carried through to the refined risk assessment.

STUDY TEAM RESPONSE: Each of these chemicals is discussed in turn below. Note, however, that while the Screening Level Evaluation compared maximum detected concentrations in porewater or reclaimed water to DWELs, exceedance of a DWEL at this step only means that the chemical will be considered further for possible inclusion

in the HHRA. Prior to inclusion in the HHRA, all chemicals that pass through the initial Screening Level Evaluation will undergo fate and transport modeling to predict exposure point concentrations (EPCs) at locations where exposure populations could contact water (e.g., contact with potable water in domestic supply wells or reclaimed water that discharges to surface water). If estimated concentrations at points of contact do not exceed DWELs, they will not be considered further in the HHRA.

- 1,4-dioxane exceeds the DWEL in reclaimed water. However, the concentration is below EPA's MCL based on a recent risk assessment (EPA, 2013a).

STUDY TEAM RESPONSE: 1,4-Dioxane was detected in porewater (maximum concentration 750 ng/L) and reclaimed water (maximum concentration 850 ng/L), as well as in groundwater (maximum concentration 690 ng/L), although not used as a point of comparison in the Screening Level Evaluation). 1,4-Dioxane is the subject of ongoing toxicological research and discussions regarding derivation of appropriate notification or regulatory levels at a state and federal level. U.S. EPA has not yet established a federal MCL for 1,4-dioxane. However, U.S. EPA has established a unit risk level (for carcinogenic risk) for drinking water exposure to 1,4-dioxane of 2.9 x 10^{-6} per µg/L (U.S. EPA, 2013). IRIS Listing for 1,4-Dioxane https://cfpub.epa.gov/ncea/iris2/chemicalLanding.cfm?substance_nmbr=326 , which has been correlated to a drinking water concentration at a 10^{-6} risk level of 0.35 µg/L (350 ng/L) (CA Water Boards, 2019. 1,4-Dioxane https://www.waterboards.ca.gov/drinking_water/certlic/drinkingwater/14-Dioxane.html). This is slightly below the California cancer slope factor-based value of 0.37 µg/L (370 ng/L) that is the basis for the DWEL used in the Screening Level Evaluation. California proposed a drinking water notification level for 1,4-dioxane of 1 µg/L (1,000 ng/L). e ar i this the state " he otificatio le el is slightly greater than the *de minimis* (1 X 10^{-6}) level commonly used for notification levels based on cancer risk, reflecting difficulty in monitoring 1,4- io a e at er lo co ce tratio s " Thus, the 1 µg/L level is not entirely health risk-based, and maximum-detected concentrations do exceed health risk-based values. Therefore, it is our opinion that it is appropriate to retain 1,4-dioxane for further consideration in the HHRA. In the HHRA, all available toxicity criteria and water quality criteria for 1,4-dioxane that have been published by reputable authoritative bodies will be presented and their bases discussed.

- Albuterol exceeds the DWEL of 7.5 ng/L (max concentration in reclaimed water is 11 ng/L). The oral dose is 0.1-0.2 mg/kg body weight (BW) three times per day to children from two to six years old. Infants from birth to two years have greater water consumption per unit body weight and thus much greater exposure. The Panel recommends that the project team clarify the age group used to calculate the DWEL and to use an appropriate concentration to determine if the screening level protects public health.

STUDY TEAM RESPONSE: Albuterol was detected in porewater (maximum concentration 8 ng/L) and reclaimed water (maximum concentration 11 ng/L). These concentrations exceed the DWEL of 7.5 ng/L. The DWEL is based on a lowest therapeutic dose of 0.1 mg/d for an adult, which corresponds to 0.002 mg/kg-d if an adult body weight of 80 kg is assumed. This is extrapolated to a DWEL by dividing by a conservative (i.e., health protective) composite uncertainty/modifying factor of 3,000 and multiplied by a child body weight/drinking water consumption rate ratio (10 kg/1L). All of these assumptions are conservative and were applied uniformly to the chemicals in the Screening Level Evaluation. For albuterol, the DWEL should be protective of a child exposure since the adult-based minimum therapeutic dose of 0.002 mg/kg-d is less than the child-based value of 0.3 mg/kg-d given above. Because the maximum-detected concentration of albuterol exceeded its DWEL, it was retained for further consideration in the HHRA. If EPCs for albuterol estimated via fate and transport modeling exceed the DWEL, it will be examined further in the HHRA and a modified compound-specific acceptable daily intake (ADI) will be derived for albuterol that incorporates compound-specific uncertainty factors.

- Carbamazepine was detected in reclaimed water at about twice the DWEL; however, it may not be an issue at drinking water wells, depending on attenuation.

STUDY TEAM RESPONSE: As indicated above, all compounds that passed the Screening Level Evaluation and were identified as warranting further consideration as candidates for the HHRA will undergo fate and transport modelling to predict EPCs at assumed points of contact. If these concentrations do not exceed conservative DWELs, they will not be included in the full HHRA.

- Chloramphenicol was detected in reclaimed water at about six times the DWEL.

STUDY TEAM RESPONSE: See above response regarding carbamazepine.

- Norethisterone was detected at 5.9 ng/L which is just above the DWEL of 5.0 ng/L.

The Panel recommends that the project team reevaluate the mean/median concentrations and confidence limits before carrying it forward to the refined risk assessment.

STUDY TEAM RESPONSE: See above response regarding carbamazepine.

- Primidone was detected in reclaimed water at twice the DWEL.

STUDY TEAM RESPONSE: See above response regarding carbamazepine.

- Quinoline was detected in reclaimed water at almost ten times the DWEL. Quinoline is not an organic phosphate pesticide. The Panel recommends that the project team recheck the analysis before carrying quinoline forward to the refined risk assessment.

STUDY TEAM RESPONSE: We agree, quinoline is not a phosphate pesticide but rather a chemical precursor to dyes and various chemical agents including certain pesticides. This will be corrected. The DWEL for quinoline was based on a U.S. EPA cancer slope factor of 3 $(mg/kg\text{-}d)^{-1}$ (U.S. EPA, 2001. IRIS Listing for Quinoline. https://cfpub.epa.gov/ncea/iris2/chemicalLanding.cfm?substance_nmbr=1004), that is chemical-specific and not based on whether or not the compound is a phosphate pesticide. Quinoline will be retained for further consideration in the HHRA as its maximum-detected concentration (28 ng/L in reclaimed water) exceeds its DWEL (3.3 ng/L).

The following chemicals may not have exceeded the DWEL in the reclaimed water analysis. The Panel questions which should be carried through to the refined risk assessment.

- 4-nonylphenol exceeds the DWEL only in porewater; the concentration in reclaimed water is well below the DWEL.

STUDY TEAM RESPONSE: A decision was made to include concentrations detected in porewater for purposes of comparison given the limited data availability for reclaimed water, in order to be health-protective. Also, see above response regarding carbamazepine.

- Estradiol was detected in porewater but not in the reclaimed water.

STUDY TEAM RESPONSE: A decision was made to include concentrations

detected in porewater for purposes of comparison given the limited data availability for reclaimed water, in order to be health-protective. Also, see above response regarding carbamazepine.

- Estrone has a DWEL 20 times less than the DWEL for estradiol—the Panel would like to know why. It only has 10 percent of the activity of estradiol. What is the basis for carrying this forward?

STUDY TEAM RESPONSE: The estrone value is 20% (1/5th) of the estradiol value, which is within an order of magnitude. The estradiol value is based on a California cancer slope factor whereas the estradiol value is based on a therapeutic dose, and so the two values were derived using different approaches and sets of assumptions that may vary in their relative conservatism (although they are overall selected to be health protective). Regardless, the pharmacology of estrogenic hormones is complex. As such, we will evaluate the therapeutic/ toxicologic database more closely to determine if a revised DWEL for estrone is warranted. However, we note that if the DWEL for estrone is assumed to be 1/10 that of estradiol, per the above suggestion, the DWEL would be 2.6 ng/L. The maximum detected concentrations of estrone is 1.9 ng/L in reclaimed water, which is greater than 10% of the suggested new estrone DWEL. Consequently, estrone will be retained for further evaluation in the HHRA. If fate and transport modelling to predict estrone EPCs at assumed points of contact do not exceed the revised DWEL, estrone will not be included in the full HHRA.

- Ethinyl estradiol was detected at 64 ng/L in the reclaimed water, which exceeds the DWEL of 0.083 ng/L that was calculated by the consultant. However, the consultant noted that the analytical detection limit is 5 ng/L, which is 60 times the DWEL. Therefore, an improved analytical method that is sensitive enough to detect at the DWEL concentration is needed to generate useful data for the refined risk assessment.

STUDY TEAM RESPONSE: To complete the Screening Level Evaluation, we used the analytical data that were available for the porewater and reclaimed water samples. However, since the maximum detected concentration of ethinyl estradiol exceeded the DWEL, we will retain this compound for further consideration in the HHRA. If EPCs estimated by fate and transport modeling exceed the DWEL, the HHRA will be conducted using modelled concentrations.

- NDMA is below the California reporting level (RL) and notification level (NL).

STUDY TEAM RESPONSE: NDMA was detected in porewater (maximum concentration 8.2 ng/L) and reclaimed water (maximum concentration 7.3 ng/L). These concentrations exceed the DWEL of 0.86 ng/L. The DWEL is based on a Washington MTCA GWC Method B value (https://ecology.wa.gov/Regulations-Permits/Guidance-technical-assistance/Contamination-clean-up-tools/CLARC/Data-tables) which is derived from the U.S. EPA cancer slope factor for NDMA of 51 $(mg/kg\text{-}d)^{-1}$, and is set at a cancer risk level of 10^{-6} with an assumed drinking water intake of 2 L/d and a body weight of 70 kg. The California Notification Level for NDMA is 10 ng/L, and the Response Level is 300 ng/L, while the 10^{-6}-base le el is he is ote as ei "so e hat above the *de minimis* level, to take into account the very low detection limits and their ote tial rese ce i associatio ith ri i ater treat e t" hereas the Response Level is set at a cancer risk level of 10^{-4}. The risk level is derived from a " o si ifica t ris le el" esta lishe for er alifor ia ro ositio (based on cancer) and assumes a drinking water intake of 2 L/day. We can add the California values to the table of published ADIs in the Screening Level Evaluation (Table B-1). However, since the Washington value yields a lower DWEL and is based on a published U.S. EPA cancer slope value as well as the accepted *de minimis* cancer risk level of 10^{-6}, it is our opinion that this value is appropriate to use as the DWEL for NDMA in the Screening Level Evaluation. Since maximum-detected values exceed the DWEL, NDMA will undergo fate and transport modelling to predict EPCs at assumed points of contact. If these concentrations do not exceed conservative DWELs, they will not be included in the full HHRA. If they do, the risk assessment conducted for NDMA will be conducted considering all available toxicity criteria of sufficient quality.

- PFAS is addressed by the combined PFOA/PFOS HAs based on recent assessments by EPA and California. The issue is whether they will include additional forms in a total PFAS notification/action levels.

STUDY TEAM RESPONSE: A number of risk assessments for perfluorinated compounds are underway at the state and federal level to support regulation, although federal action is lagging behind that of individual states. We will consider values proposed in these assessments in the HHRA, including California notification/response

levels, and describe the basis of our assumed values.

- Tris(1,3-dichloro-2-propyl) phosphate (TDCPP) does not exceed the DWEL in reclaimed water.

STUDY TEAM RESPONSE: TDCPP was detected in reclaimed water at a concentration equal to its DWEL, and so per the methodologies applied in the Screening Level Evaluation, TDCPP was identified for further consideration for inclusion in the HHRA. As indicated above, all compounds that pass the Screening Level Evaluation and are identified as warranting further consideration as candidates for the HHRA will undergo fate and transport modelling to predict EPCs at assumed points of contact. If these concentrations do not exceed conservative DWELs, they will not be included in the full HHRA.

3.5 Human Health Risk Assessment – Refined

Summary of Panel Findings and Recommendations

- The Panel recommends that the project team share the refined risk assessment plan with them for review before you begin work on the next phase.
- The Panel recommends that in the refined risk assessment, the exposures should be presented as a distribution of concentrations.
- The Panel recommends presenting the risk assessment for each carcinogenic contaminant evaluated instead of using the 10^{-6} lifetime risk level as a hard target.
- The Panel recommends that the project team follow the examples of EPA and the California State Water Resources Control Board for the total of PFOA and PFOS.

Rationale for Recommendations

The Panel recommends that the project team provide a detailed approach to the Panel in advance of starting the refined risk assessment. The approach should include specific methodologies and modifying factors that are used to adjust for sensitive/susceptible populations and the methodology used to project individual exposure via drinking water produced by both municipal and private wells along with the statistical confidence in these estimates. The Panel understands that exposure measurements will necessarily depend upon modeling based upon the anticipated attenuation of chemical concentrations as water travels through the aquifer(s) as depicted in Figures 9-6a-g in the Tracer Test and Water Quality Monitoring document dated October 30, 2019.

STUDY TEAM RESPONSE: A detailed scope of work for the HHRA has been prepared. In addition, HDR will conduct fate and transport modeling to predict EPCs that will be compared to DWELs. If modeled concentrations exceed DWELs, these chemicals will be evaluated further in the HHRA.

It is not clear if a formal methodology for exposure assessment has been developed to determine the range of chemical concentrations in drinking water from the aquifer. The Panel recommends that they be permitted to review the methodology before the refined risk assessment begins.

STUDY TEAM RESPONSE: See above. A scope of work describing the methodology that will be used to predict EPCs has been prepared.

The dose-response analysis underlying EPA and CalEPA Office of Environmental Health Hazard Assessment cancer risk assessments is evaluated against dose per unit of body surface area (SA) measured in milligrams per square meter (mg/m^2). Cancer risk assessments are calculated from body weight (BW) doses by multiplying by $BW^{3/4}$ (EPA 2005), reflecting a widely accepted relationship between BW and SA. The ratio of the SA of the test species to the human average SA adjusts the human dose as it is reconverted to mg/kg BW. Depending upon the test species, the conversion back to amount consumed by an individual per day is lower by as much as an order of magnitude (depending upon test species), increasing the estimate of risk. It appears that the consultant used dose/body weight as the metric and this will lead to higher values for establishing acceptable degrees of risk than would be seen in an assessment by EPA and in most states.

STUDY TEAM RESPONSE: In the HHRA, body weight (BW) scaling to the ¾ power ($BW^{3/4}$) will be applied in combination with a reduced default interspecies uncertainty factor of 3 (rather than the full default value of 10 applied in the absence of body weight scaling) to calculate animal toxicity data-based ADIs. Specifically, identified points of departures (e.g., NOAELs or LOAELs from toxicity studies) will be converted to human equivalent doses (HEDs) based on this body weight scaling approach (U.S. EPA, 2011; https://www.epa.gov/risk/recommended-use-body-weight-34-default-method-derivation-oral-reference-dose). As is not uncommon when deriving screening-level values, body weight scaling was not applied to derive HEDs and, subsequently, DWELs in the Screening Level Evaluation. Rather, the full standard default value of 10 for the interspecies uncertainty factor was applied to account for extrapolation from an animal to a human dose. We note that because of differences in the relative body weights between rats and mice (the species that are most frequently used in toxicity studies) and humans, ADIs can range from about 3-5 fold lower when derived using the body weight scaling approach compared to the approach we used. However, the body weight scaling approach effectively converts an animal study-based value to an adult human equivalent dose, which would then be converted to a DWEL using a default adult body weight of 70 kg and a drinking water ingestion rates of 2 L/d, or, effectively, multiplying the ADI by a ratio of 70/2 (i.e.,140). However, we derived DWELs by

multiplying the derived ADI (which did not incorporate body weight scaling) by a default child body weight of 10 kg and a drinking water ingestion rate of 1 L/d, or, effectively, multiplying the ADI by a ratio of 10/1 (i.e., 10). The cumulative effect is that the DWELs we derived are more conservative than those that would have been derived using the body weight scaling approach and so are health protective.

Neither the EPA nor the California State Water Resources Control Board automatically regulate at the level of 10^{-6} added lifetime risk, but by MCLs, Health Advisories (HAs), and Action Levels (AL) that are set based on policies that allow up to 10^{-4} added lifetime risk (Table 1). For this reason, the Panel recommends that LOTT not employ the 10^{-6} lifetime risk level as a hard target. It would be best to simply present the risk assessment for each carcinogenic contaminant evaluated and list the official guidance separately.

Table 1. PHGs, MCLs, HAs for selected chemicals identified in LOTT reclaimed water.

Compound	10^{-6} added risk	MCL	Notification or HA	Action Level
1-4 dioxane	0.35 µg/L[a]	1 µg/L		
NDMA	0.6 ng/L[b]		10 ng/L	100 ng/L
PFOA	0.1 ng/L[c]		70 ng/L[d]	
PFOS	0.4 ng/L[c]		70 ng/L[d]	
PFAS			70 ng/L[d]	

[a] Polhemus D., 2019
[b] U.S. EPA, 2016d
[c] Cal EPA. 2019
[d] U.S. EPA 2016a,b,& c – set at the total of PFOA and PFOS.

STUDY TEAM RESPONSE: The basis for selected DWELs for 1,4-dioxane and NDMA are described in above comment responses, and it is our opinion that the values we selected are appropriate for use in the Screening Level Evaluation. For assessment of carcinogens, we applied a 10^{-6} *de minimis* cancer risk level in the Screening Level Evaluation in order to be health protective, which is consistent with U.S. EPA guidance for selection of chemicals of interest to be evaluated in HHRAs (e.g., U.S. EPA, 2018, cited above). In the HHRA, for any

chemicals that are identified as potential carcinogens, estimated cancer risks will be compared to a range of cancer risk values that have been characterized as acceptable. Although there is no universally accepted acceptable risk standard, the U.S. EPA Superfund program established under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) generally considers risks above 1×10^{-6} (1 in 1,000,000) to be acceptable in nearly all circumstances and risks within the range of 1×10^{-4} to 1×10^{-6} (1 in 10,000 to 1 in 1,000,000) to be acceptable depending on specific site and exposure characteristics (U.S. EPA, 1989, *Risk Assessment Guidance for Superfund (RAGS), Volume I. Human Health Evaluation Manual, Part A. Interim Final*.; U.S. EPA, 1991, *Role of the Baseline Risk Assessment in Superfund Remedy Selection Decisions*). The National Contingency Plan (U.S. EPA, 1990), which provides the guidelines and procedures needed to respond to releases and threatened releases of hazardous substances, pollutants, or contaminants under CERCLA, defines the 1×10^{-6} i a illio ris le el as the " oi t of e art re" for establishing remediation goals at contaminated sites. Risks above 1×10^{-4} are nearly always considered to be unacceptable, although many occupational exposure levels (OELs) correspond to a risk level at or above this level. More specific acceptable risk levels have been identified for certain circumstances.

The Panel recommends that the project team follow the examples of EPA and the California State Water Resources Control Board for the total of PFOA and PFOS where extensive data are available unless suitable toxicological data is available to assess other PFAS chemicals. The Panel does not believe that quantification of cumulative effects would be useful at this time because the appropriate data is not available.

STUDY TEAM RESPONSE: A number of risk assessments for perfluorinated compounds are underway at the state and federal level to support regulation, although federal action is lagging behind that of individual states. We will consider values proposed in these assessments in the HHRA, including California notification/response levels, and describe the basis of our assumed values.

3.6 Panel Responses to Questions from LOTT

Risk Assessment

1. Does the Panel have any concerns about the risk assessment approach?

Panel response: See Panel response to question 1(a) below.

a. Is it (risk assessment) based on accepted methods?

Panel response

Aside from those promulgated by regulatory bodies, a number of methodologies used for screening particular categories of contaminants were taken from the scientific literature (Gaylor and Gold, 1995; Kroes et al., 2005; Schwab et al., 2005; Bull et al., 2011; Yang et al., 2017; Reilly et al., 2019). These are addressed in the section on the human health screening level risk assessment.

STUDY TEAM RESPONSE: See responses to comments above.

The Panel agrees that the screening methods to establish DWELs as a decision point parallels the original intent of this methodology.

The Panel identified some issues with the application of uncertainty factors to lowest therapeutic dose as the point of departure for the risk assessment.

STUDY TEAM RESPONSE: o r re ie of the a el s co e ts e o ot note where they have provided specific comments on these factors. We do recognize that the generic composite uncertainty factor of 3,000 applied to all minimum therapeutic doses in the Screening Level Evaluation, with an additional factor of 10 if the compound shows evidence of being an endocrine disruptor or a nongenotoxic carcinogen, is likely to be highly conservative for many compounds. As we describe in our Screening Level Evaluation report, this factor of 3,000 I based on a data analysis by U.S. EPA, wherein they conducted a statistical a al sis of a set of "lear i co o s" ith f s s a LOAELs conducted by U.S. EPA as part of the Contaminant Candidate List (CCL) Classification Process (U.S. EPA, 2012, Water: Contaminant Candidate List 3 CCL). However, any chemical retained for further consideration in the HHRA that has fate and transport model predicted-EPCs that exceed a DWEL will undergo more detailed chemical-specific toxicological assessment in the HHRA. In the HHRA, derived ADIs will use chemical-specific uncertainty factors rather than the default values applied in the Screening Level Evaluation. For each compound included in the HHRA, a narrative s ar of the che ical s to icit a the

basis of the selected ADI will be included in the final deliverable.

Refined risk assessment

No specific plan or approach was provided for the refined risk assessment. For example, will the cancer risk assessments be consistent with EPA or state agency risk assessments, or will some other standard be used? What data will be used to establish likely exposures of people using water from utilities or private wells with some confidence limits?

STUDY TEAM RESPONSE: U.S. EPA human health risk assessment guidance will be used, with consideration of other current best practices for toxicological/human health risk assessments. EPCs will be derived by HDR via fate and transport modelling. The scope of work for the HHRA describes the methods and assumptions that will be applied.

Reclaimed water has been approved and used for groundwater infiltration in indirect potable reuse, but risk assessments are rarely made; instead, formal guidelines from state or federal programs are used. While this approach has been satisfactory in the past, newly recognized contaminants and drugs are beginning to present problems for other utilities. Such concerns have been appropriately identified and are being explored by LOTT as part of this project.

Water consumed per unit of body weight differs with age, and the Panel encourages LOTT to incorporate differences in age-related water consumption. Children from birth to two years old have been identified as the group most at risk (the 1 L/day for a 10-kg child does not include the formula-fed child).

STUDY TEAM RESPONSE: A default child body weight to drinking water ratio of 10 kg/1L-d was used in the Screening Level Evaluation to be health protective. In the HHRA, several populations (including adults and children) will be considered as appropriate depending on assumed potential exposure locations and exposure scenarios, as outlined in the scope of work for the HHRA.

b. Are there significant shortcomings? (Another way this question was asked was: If the budget was higher, is there something that should be done differently or in addition to risk assessment, and if so, what and why?)

Panel response for human health risk assessment

The Panel encourages LOTT to measure and make public the data on chemicals identified in drinking water standards, not because we think they are likely to be a problem, but in the interest of transparency. Specifically, LOTT should determine if the reclaimed water meets drinking water standards.

STUDY TEAM RESPONSE: As discussed above, we will compare estimated concentrations of all chemicals considered in the HHRA to established drinking water standards and present these findings in the project deliverable.

Panel response for ecological risk assessment: There are no significant shortcomings in the ecological risk assessment. When benchmarks for specific chemicals were not available, the ECOSAR Predictive Model approach was used to estimate environmental concentrations. Concentrations were compared to toxicity endpoints and uncertainty was incorporated into the assessments.

c. Is it protective of human health?

Panel response: Yes. Practically, the parameters used to identify chemicals for further evaluation such as fate and transport evaluation or for additional treatment are protective of human health. There will always be concerns, but to go further is speculative.

The main issue in this study will be what to do with PFAS because it is regulated as the total of PFOA and PFOS occurring at concentrations much higher than that of the 10^{-6} added lifetime risk, and the other chemicals in the class are not included. Some water districts are contemplating wellhead treatment to remove PFAS if reclaimed water that was historically injected or spread in their service area contains these chemicals above the HA.

STUDY TEAM RESPONSE: As discussed above, a number of risk assessments for perfluorinated compounds are underway at the state and federal level to support regulation, although federal action is lagging behind that of individual states. We will consider recommendations proposed in these assessments in the HHRA, including comparison to California notification/response levels, and describe the basis of our assumptions.

d. Is it protective of ecological health?

Panel response: Yes. The ecological risk assessment is protective of ecological health according to the EPA, because EPA methods were used to develop the risk assessment.

A number of the chemicals found in reclaimed water do not have aquatic benchmarks because they are chemicals of emerging concern and are not currently regulated. Where this occurred, the EPA ECOSAR modeling method was used to determine toxicity based on chemical structure. Again, this is a standard method. Uncertainty was considered in this risk assessment. The chronic maximum acceptable toxicant concentration (MATC) predicted by ECOSAR for each COI was used, and the lowest MATC was divided by 10.

2. Are findings of screening-level assessment in keeping with anticipated results (i.e., what might be expected based on previous studies/existing research)?

Panel response for human health risk assessment: To date, no surprises have come out of the risk assessment. Obviously, there remain concerns about the chemical composition of historically infiltrated water into groundwater basins that arise from data and knowledge acquisition with respect to chemical occurrence and potential risks (e.g., EPA and OEHHA (CalEPA) risk assessments for PFAS in 2016 a,b,c and 2019, respectively).

STUDY TEAM RESPONSE: See responses to comments above regarding perfluorinated compounds.

Panel response for ecological risk assessment: Because a number of the chemicals found in reclaimed water did not have aquatic life criteria benchmarks, it is difficult to know whether these chemicals pose a hazard to aquatic species. Of the 82 chemicals considered, the benchmark screening classified eight as COPECs for further consideration. Because so little is known about the ecological effects of these chemicals, the results of the risk assessment need to be considered with caution. New toxicity and/or exposure data may be developed in the future, and this will need to be considered in future assessments.

3. How should background concentrations found in Task 1 be considered in regard to the human health and ecological risk assessments?

Panel response for human health risk assessment: It is important that the background occurrence (concentrations and spatial variability) of chemicals in the groundwater be established for many reasons, such as long-term historical infiltration of reclaimed wastewater, or pervasive use of septic systems regionally and within these groundwater basins. There are technical difficulties with choosing the highest measured values to represent regional background concentrations. It would be best if area-wide measures would be captured as mean or median background levels with expressions of

their variability (e.g., standard deviation or standard error of the mean). The sampling sites should be chosen, if possible, to reflect these values in available water that is as representative as possible for water that will be considered potable.

The Panel does not believe that the background concentrations of contaminants should be subtracted from their total concentrations for risk assessment purposes. This would be inconsistent with the way drinking water standards are applied.

STUDY TEAM RESPONSE: Estimated concentrations will be modeled based on concentrations in reclaimed water. Risks estimated based on these concentrations will be compared to background exposures as appropriate.

Panel response for ecological risk assessment: Background concentrations of chemicals of concern were not part of the ecological risk assessment because the goal was to determine the potential risk of chemicals emanating from the LOTT reclaimed water.
However, background concentrations may need to be considered in future risk assessments because organisms will be exposed to the total amount of each chemical; therefore, some potential for additive effects or risks could derive from consistent or pervasive background concentrations.

4. Have accepted methodologies for this type of assessment changed significantly since scoping? For example, are bioassays commonly used for this type of work?

Panel response: Accepted methodologies for this type of assessment have not changed significantly since scoping. Generally, genotoxicity bioassays are used to inform whether the risk assessment model should be linear or not, although there is more to that determination as referenced in this Panel report. In most cases, bioassays will not replace standard approaches to human health risk assessment until they can be calibrated against the *in vivo* effects of a chemical, but they remain as important screening tools for certain biological activities caused by chemicals of interest. In most cases actual analysis of the chemicals detected would be necessary for quantitative risk assessment.

5. Are the proposed approach and assumptions sufficient to account for potential cumulative effects? (note that all PFAS and hormones will be evaluated in the Human Health Risk Assessment, regardless of whether they were detected)

Panel response: There was no specific proposal for addressing cumulative risk and the Panel cannot endorse a general application of cumulative risk assessment

methods without a technical proposal. It may have some application in addressing chemicals with the same mode of action. Cumulative risk assessment methods do not extend to groups of toxicants that may produce similar pathology with a differing mode of action.
Frequently, such compounds have antagonistic effects (Bull et al., 2004). There is some basis for assessing cumulative risks for PFOA and PFOS, as demonstrated by the EPA Health Advisories (HA). For example, the combined PFOA and PFOS HA assigns a 10^{-4} added lifetime risk level at 70 µg/L of drinking water.

STUDY TEAM RESPONSE: Based on subsequent discussions with the NWRI risk assessment subcommittee, evaluation of cumulative risk has been removed from the HHRA scope of work. .

a. What are thoughts on use of a hazard index (HI) analysis to address cumulative effects?

Panel response: As far as the Panel knows, HI has only been applied to evaluation of hazardous waste sites, and not to drinking water standards. The HI evaluation usually combines chemicals of diverse toxicological characteristics. It is more appropriately applied in ambient water quality for the issues of survival and reproduction.

STUDY TEAM RESPONSE: Based on subsequent discussions with the NWRI risk assessment subcommittee, evaluation of cumulative risk has been removed from the HHRA scope of work**.**

Fate and Transport Analysis

6. Is the approach to modeling satisfactory? (infiltration/recharge discussion and climate change)

Panel response: The groundwater model provides a satisfactory approach to simulating the various aspects of groundwater movement as well as the fate and transport within the aquifer system, after infiltration water from the recharge basins has reached the water table. As such, it does not explicitly represent changes in flow and chemical concentrations that may occur within the vadose zone as infiltrated water interacts with unsaturated soil and aquifer materials that are more highly oxygenated/oxidized than below the water table. However, in the Panel's opinion, the model can be used to predict and analyze groundwater flow paths, advection travel times, and the complex processes of sorption, dispersion, and dilution that modify

concentrations of residual chemicals in groundwater within the saturated zone as it moves from beneath the Hawks Prairie Recharge Basins to potential receptors such as wells, springs, and streams that receive groundwater discharged from the aquifer system.

The primary modeling approach is both reasonable and acceptable and follows standard modeling practice. However, it is largely characterized by spatial uniformity and constancy with time, thus providing limited variability in both space and time. The assumption of uniform values for the hydraulic properties of identified geologic layers (or hydrostratigraphic units) in the model means they do not generally vary with location. This is a reasonable assumption since it is difficult to determine the spatial variations unless a lot of information is available locally, such as at the recharge facility itself, where localized variations in hydraulic conductivity of the glacial till are modeled with some degree of confidence from the data.

a. Is the proposed approach to estimating biodegradation/sorption appropriate and in keeping with accepted practice?

Panel response: The proposed approaches are consistent with accepted practice and are acceptable. As part of the predictive simulation process, the Panel recommends independently delineating the degree of contaminant attenuation expected for biodegradation and sorption processes. In particular, when predicting contaminant fate and transport, and also while actively managing water quality, it is useful to know which contaminants have attenuation profiles dominated by removal via sorption, versus those which have attenuation profiles dominated by biotransformation.

Most research concerning subsurface contaminant fate shows most consistency and stability for attenuation dominated by abiotic sorption processes, thereby allowing for a higher degree of predictive certainty as to the extent of attenuation.

By contrast, contaminants whose attenuation is dominated by biotransformation potential may be prone to more uncertainty and a higher probability of breakthrough/limited attenuation. This is because biotransformation, especially in the deep subsurface, can be seasonal, temperature dependent, require the presence of cofactors, be sensitive to the presence of co-occurring toxicants, and in general, be more variable over time and space.

Thus, the Panel recommends that when presenting modeling results, independently report the degree these two factors drive predicted attenuation outcomes. For example, a simple three-column table reporting the contaminant name and the

expected/predicted percent removal by each process would be sufficient to report out this variable.

b. Is the potential temporary nature of sorption adequately accounted for?

Panel response: The Panel has little concern over the potential temporary nature of sorption for most wastewater-derived constituents. While sorption is reversible, and an equilibrium process itself, the Panel believes that long-term saturation of sorption capacity for any specific pollutant is unlikely given the extensive size of the potential treatment system (many meters of media to the nearest downgradient well), and is not consistent with the literature as a primary driver of downgradient concentrations and transport for contaminants whose fate outcomes are dominated by sorption. In many cases, research has demonstrated that the first few centimeters of an infiltration system are responsible for most sorption-driven contaminant attenuation and this capacity does not seem to easily exhaust over time.

Attenuation mechanisms of abiotic and biotic transformation, reaction with organic matter and mineral phases, and other removal processes tend to remove organic contaminant mass from the system and govern long-term fate outcomes for sorbed contaminants.
These removal processes negate the potential adverse effects of temporary sorption for most wastewater derived contaminants whose fate is strongly tied to geomedia sorption and whose primary attenuation arises through sorption. The only possible exceptions with respect to temporary sorption are extremely persistent organics with half-lives of decades to centuries, metals, and persistent ions (e.g., perchlorate). If a contaminant of concern met such criteria and exceeds possible risk thresholds, and if its constant, long-term introduction to the system is assured, then the impact of potential temporary sorption on transport outcomes might be evaluated for this small subset of compounds.

7. Does peer review have any concerns about the modeling/fate and transport approach?

Panel response: Excepting the above comments, the Panel has no concerns about the modeling/fate and transport approach. It seems to be well-grounded in established methods.

3.6 Panel Responses to Questions/Comments from LOTT Science Task Force

1. (Question from Julie Rector, City of Lacey)

   Can the Peer Review Panel look at the tracer test results, particularly with regard to locations with reported results of non-detect? In particular, please consider the reported results for well Lacey MW-11.

Panel response:

The application of the two criteria "detection above baselines for both tracers" and "presentation of a breakthrough curve" are valid and appropriate approaches to definitive confirmation of hydraulic connectivity between basin 4/5 and the monitoring wells.

With respect to the possible detection of tracers in Lacey_MW-11, the Panel reviewed data for the nearest potential upgradient well, MW-13. Although there is no expectation for linear groundwater transport pathways, on a straight-line path MW-13 is roughly halfway from Basin 4/5 to Lacey_MW-11, and approximately 1000 feet from the basins where the tracer was applied. While the bromide data in Lacey MW-11 did exhibit characteristics of a breakthrough curve, albeit only very slightly above baseline levels (within a factor of 2X, which is not generally sufficient for statistical significance for low sample number data sets), only a single detection of sulfur hexafluoride (SF6) was reported in Lacey_MW-11, which was not confirmed by any further supporting detections of SF6. Therefore, HDR/LOTT concluded that tracer presence within Lacey_MW-11 was only possible and not confirmed. The MW-13 tracer data indicates that elevated bromide and SF6 were detected on 2/1, within about two weeks of the start of the tracer test. Further confirmation of the tracer's presence in MW-13 occurred on 2/14 and 2/22.

The subsequent single detection of SF6 in Lacey MW-11 on 2/28 is consistent with expected linear tracer velocities for the leading edge of the tracer plume estimated from the SF6 appearance in MW-13 (2/1-2/22/18). It is also consistent with the possible existence of a flow path and hydraulic connection to the infiltration basins, although not a major one. However, based the available data in Appendix E, the Panel agrees with HDR/LOTT that this possibility cannot be conclusively confirmed from the available LOTT tracer detection data and remains either possible or probable. The lack

of any supporting SF6 detection evidence in Lacey MW-11 is an important limitation to the data set, as too many things can happen to data during sampling, lab analysis, etc., to base a major conclusion on a single data point without subsequent confirmation. Confirmatory data and trend delineation (i.e., demonstrated replication and repeatability of collected data) are required to draw any sort of definitive conclusion about hydraulic connectivity, and the current data set is too limited to reach this conclusion. The measurement of wastewater-derived contaminants may present an opportunity to evaluate hydraulic connectivity.

Regarding "another interpretation for this data," both Lacey_MW-11 and Landfill MW-1, where slightly elevated levels of bromide were detected, and which subsequently decreased over time, are near a busy road (Marvin Road), and Lacey MW-11 is also close to a Fed Ex shipping facility. Especially for Landfill MW-1, the use of deicing salt, where bromide is a trace impurity, may explain these data trends. Bromide can be a trace impurity of road salts used for de-icing: https://pubs.er.usgs.gov/publication/70017709. These tracer tests occurred in mid-winter, when road salt use would be expected on busy roads. The potential for alternative, roadway-derived sources of bromide is quite possible, and may also result in seasonal bromide trends such as that observed in Landfill MW-1 and/or Lacey MW-11. This would reduce the confidence that observed bromide detections near baseline levels indicate the presence of LOTT tracer. The Panel, therefore, discounted the trace bromide detections in these wells somewhat and focused more on SF6 data. This possibility, if accurate, would indicate that the SF6 tracer data might be more definitive and accurate for these two wells in particular if confounding bromide sources are present. Existing data (background sampling data) with high conductivity or other evidence of salts or roadway-derived pollutants, might be able to further evaluate if this confounding source exists.

2. (Comment from Koenraad Mariën, Washington State Department of Health)

   Contaminants found in groundwater that were contributed by reclaimed water should not be removed from the list of COIs based on comparison values coming from a screening tool unless those values reflect our present-day knowledge base. We are seeking to contribute pollutants to a groundwater system, which is in contrast to protecting from existing contamination within a groundwater supply. Accordingly, removing chemicals from the list of COIs based on comparison levels that have been derived without considering the state of science is inappropriate. They need to be properly evaluated before they are removed from the list.

Panel response: The main issue raised by Koenraad Mariën was using risk assessments that were made based old data and old methodology. During a discussion with the Panel at Meeting 3, Mr. Marien referred to 1,4,-dioxane as an example. The Panel replied that while the Intertox report identified both the old (EPA, 1987b as identified by Intertox) and the new (EPA, 2013 as identified by Intertox) risk assessments for 1,4,-dioxane, it is not clear how the consultant assessed risk for 1,4,-dioxane in their analysis.

STUDY TEAM RESPONSE: A discussion of the basis of the 1,4-dioxane value we applied is described in a response to a comment above. As described in the Screening Level Evaluation, DWELs were based on published toxicity criteria or water quality criteria (if such values were derived by well-respected authoritative bodies) or from toxicity study data or therapeutic doses extrapolated to ADIs using standard and accepted methodologies and conservative default uncertainty or modifying factors. These values were identified by conducting a search of the regulatory, toxicological, and drug product literature, including conducting a search for toxicity data using the National i rar of e ici e s e ata ase hich ro i es literat re citatio s for toxicological studies published in peer reviewed scientific and medical journals. As such these values do consider the state of the science. From among these values, the lowest (i.e., most health protective) values of sufficient quality were selected as the basis of ADIs/DWELs applied to the detected chemicals. The values considered at each tier level and the bases for selected values are tabulated in Appendix B of the Screening Level Evaluation. In the HHRA, a more expanded description of the basis for selected toxicity values will be included for each chemical that is included in the assessment. Selection of an appropriate critical study for the derivation of toxicity criteria applied in the HHRA will ta e i to acco t s i a ce for e al ati the acce ta ilit of o e literat re studies (e.g., U.S. EPA, 2012, *Guidance for Considering and Using Open Literature Toxicity Studies to Support Human Health Risk Assessment*), including consideration of the nature of the test substance, the test organism, number of organisms tested per dose and number of dose levels evaluated, husbandry conditions, exposure method, route, and frequency of administration, length of treatment period, controls, macro- and microscopic observations of test animals, statistical methods applied, etc. In general, the study of appropriate quality that yields the lowest ADI using the above methods will be selected for use in the HHRA.

The Panel would like to point out that the current risk assessment published by EPA

(EPA 2013b-as referenced in this Panel report) was developed by a drinking water study in rodents by Kano et al. (2009), and was not based on the study of Kociba et al. (1974).

Also, the Panel notes that there are different philosophies of how to deal with chemicals with no or limited health effects data. Our current analytical capabilities are used to identify traces of contaminants in food additives, and there are methods to determine what toxicological data is needed to assess whether the additive can be approved for use in food. The decision was to use a cutoff established based on the fifth percentile of a distribution of no observed adverse effect levels (NOAELs) of many structurally related chemicals. If the contaminant does not occur in the additive at a concentration above this threshold (after the application of uncertainty factors) appropriate to the use, it would be set aside. These methods are identified in the Panel's review, but are not clearly explained or applied in the way they were intended to be used in the LOTT document. These methods are not intended to establish risk levels, but simply provide a basis for putting aside those compounds detected at concentrations lower than the cutoff value as being of much lower priority. Essentially, these methods prioritize scarce resources to provide toxicological data on chemicals most likely to be a problem.

STUDY TEAM RESPONSE: The methodology described is the TTC approach which we have described above and considered as the final tier in the hierarchical approach used to derive DWELs. As discussed above, TTCs are only recommended for application to chemicals without existing chemical-specific toxicological or health effects data. For all of the chemicals considered in this evaluation, chemical-specific data were available and so were used as the basis of DWELs, and none of the final selected DWELs was based on a TTC.

The Panel has difficulties with the two-tiered approach used. The consultant called the screening level analysis a risk assessment, but it is actually a triage method as described above. Nevertheless, the triage methodology would have a similar (possibly not identical) effect of removing chemicals from the list of immediate concern. In fact, the screening level assessment went into detail about some chemicals that really make sense only in context of making a sophisticated risk assessment, going significantly beyond the intent of the methodologies on chemicals that did not fit into this category.

STUDY TEAM RESPONSE: As discussed above, the initial tier of the

assessment was renamed the “Screening Level Evaluation” to reflect that this assessment is not intended to be a standard HHRA. Rather, the objective is to compare detected concentrations in reclaimed water to conservative health risk-based DWELs in order to select chemicals of interest for the full HHRA. If a compound is detected at a maximum concentration below the DWEL, then it is our opinion that a significant human health risk is unlikely and no further investigation is warranted. Use of this approach focuses resources in the HHRA on those chemicals most likely to present a potentially significant human health risk. However, even if a compound was detected at a concentration in porewater or reclaimed water that exceeds the DWEL (or 10% of a DWEL), it does not mean that a significant health risk is anticipated, only that the chemical warrants further evaluation in the HHRA. While an effort was made to apply the tiered approach consistently across chemicals, it is recognized that the amount and quality of data varies across chemicals depending on the scientific and public/regulatory interest focused on the chemical. However, by applying conservative assumptions, it is expected that any chemical present at a concentration that could be associated with a significant human health risk will not be overlooked.