



Memorandum

Date: June 15, 2022

To: Wendy Steffensen
Environmental Project Manager, LOTT Clean Water Alliance

From: James Crook, PhD, PE, Panel Chair

Subject: NWRI Peer Review Panel for LOTT RWIS: Comments on Draft HHRA

NOTE: The LOTT Study Team received a draft version of this memorandum on April 26, 2022. This file contains their responses to the Panel comments in blue text throughout the document.

The NWRI Peer Review Panel (Panel) that is reviewing the LOTT Clean Water Alliance Reclaimed Water Infiltration Study (RWIS) project has compiled additional comments on the Draft Human Health Risk Assessment (HHRA). These comments resulted from the Panel's review of the Draft HHRA presented during Panel Meeting 6 on March 29, 2022.

These comments are presented in the order they occur in the HHRA, broken out by section. They focus on suggestions for further improvement and refinement and do not address areas that are already very good.

Executive Summary

Exposure Point Concentration. The exposure point concentration (EPC) discussion refers to the concentrations used to represent concentrations in potable water as, "...EPCs of chemicals of interest in tap or well water were based on the maximum-estimated concentrations in the shallow and deep aquifers...". Section 3.3.2 refers to EPCs as maximum concentrations as well: "For exposure to tap or well water, the assumed EPC was the maximum-estimated concentration in each aquifer...".

During the conference call, the Panel thought the EPC was the 95th upper confidence limit (95 UCL) of the arithmetic mean of measured concentrations. The Probabilistic Risk Assessment (PRA) discussion at the end of the Executive Summary also indicates that the EPC used in the HHRA is the 95 UCL.

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Please clarify throughout the HHRA whether the EPC is the 95 UCL or the maximum concentration. If it is the maximum, please explain why the maximum was used instead of the 95 UCL.

STUDY TEAM RESPONSE: The EPC of a given chemical is calculated using as a starting value the 95% UCL of the arithmetic mean of the concentration of said chemical in reclaimed water. (Note that this approach was used for chemicals where there was sufficient data to calculate a 95% UCL. For chemicals with very limited data, the maximum concentration was used). From that starting point, the concentration in groundwater at downgradient locations is assumed to change as a function of dispersion, advection, and attenuation by other mechanisms (i.e., what is reflected in the “Attenuation Factor” approach, as has been previously discussed). As a result, downgradient EPC concentrations vary in space and time. In the HHRA, risks for each population evaluated are calculated using the maximum-estimated downgradient concentration (which corresponds to locations closest to the infiltration basins).

To clarify this, in the first formula presented in Section 3.3.2, the definition of the term C_{ochem} will be modified to: “Concentration of the residual chemical in reclaimed water (ng/L), based on the 95% UCL of the arithmetic mean reclaimed water concentration where data were sufficient for such a calculation, or the maximum detected concentration if data were not sufficient to calculate the UCL.”

Hazard Indices. Hazard indices (HIs) are still reported to two significant figures. As noted previously by the Panel, US Environmental Protection Agency (EPA) guidance recommends one significant figure.

STUDY TEAM RESPONSE: As we have previously responded, consistent with other similar efforts, we are retaining our approach of presenting risk/hazard outputs using two significant figures in order to better distinguish between doses/risks calculated for different scenarios (in the deterministic RA) or corresponding to sequential percentiles of output distributions (in the Monte Carlo PRA simulations). Further, we note that most inputs to the dose/risk calculations (e.g., EPCs and most exposure parameters as well as some toxicity criteria such as the cancer slope factor for NDMA and the state of Texas noncancer references dose for PFPeA) are estimated to at least two significant digits, which argues for retaining at least this number of significant digits in the result estimates. Regardless, in the summary discussions, we will mention that rounding risk estimates to one significant figure is recommended in some approaches to reflect the uncertainty and lack of precision in some of the inputs to the dose and risk calculations, and that, if this approach is taken, the results would round to *[value for key results inserted]*.

Lifetime Excess Cancer Risks. In this case, for non-cancer effects, using two significant figures creates the need to explain why PFPeA exceeds $HI=1$, when it does not. It is equal to 1. This comment applies to the remainder of the report, as well.

STUDY TEAM RESPONSE: See the response above for Hazard Indices, which will apply here also.



Allowable Risk Range Comparisons. The HHRA compares lifetime excess cancer risks (LECRs) to the EPA’s Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) allowable risk range. The focus of the HHRA is a drinking water evaluation, not a CERCLA evaluation.

Given that this is a drinking water evaluation, and if MCLs were to be set for these compounds, the MCL paradigm is relevant. The Panel appreciates that maximum contaminant levels (MCLs) have a different risk management/derivation paradigm than CERCLA but it should be mentioned for perspective. This comment applies to the remainder of the report, as well.

STUDY TEAM RESPONSE: We have cited the CERCLA allowable risk range to provide perspective on the ranges of cancer risk that are considered allowable by different regulatory agencies or authoritative bodies. We note that while the 10^{-6} to 10^{-4} range was originally established in the context of CERCLA, it is widely cited in other contexts to support interpretation of risk assessments conducted to meet a wide range of objectives. Similarly, as noted below, we will also add human health protection goals from the State of Oregon and Florida to provide perspective on the PRA results.

Regarding MCLs, as shown in Table 4.3 of the HHRA, none of the eight chemicals of interest evaluated in the deterministic HHRA have federal or state MCLs. Consequently, risk or hazard range corresponding to established MCLs cannot be described for these. Further, given that MCLs are set based on a number of policy-related and economic criteria, we do not think it is appropriate to speculate on what such numbers might be for these chemicals if MCLs were developed. If desired, risk or hazard ranges corresponding to MCLs for other chemicals might be mentioned as part of future risk communication efforts outside of this HHRA.

High-End Fish Consumption Rate. The Panel has concerns about the high-end fish consumption rate (FCR) added to the HHRA. Comments are in a later section that discusses the FCR.

Reporting of PRA Results. The Panel recommends that that the Executive Summary of the Draft HHRA be rewritten so that PRA findings refer to what other states have used to evaluate PRA results. It recommends focusing on a comparison to available PRA-based health protection goals rather than discussing where in the distribution various deterministic point estimates fall.

For example, the PRA paragraph could be reworked to state something along the lines of: “Results of a PRA conducted for the two chemicals with upper-bound hazard or risk estimates that slightly exceed allowable thresholds based on the deterministic risk assessment—PFPeA and NDMA, for the resident scenario—indicate that estimated HIs for PFPeA meet the human health protection goals set by Florida and Oregon (the only two regulatory agencies with PRA-based allowable HIs and LECRs).



Florida's noncancer health protection goal is an HI equal to or less than 1 at the 90th percentile. Oregon's is the same at the 90th percentile and also requires that the HI is equal to less than 10 at the 95th percentile. The HIs for the child (HI=1) and adult (HI=0.6) at the 90th percentile meet both Florida's and Oregon's health protection targets, as well as Oregon's target at the 95th percentile.

Florida's cancer health protection goals are an LECR equal to or less than 1×10^{-6} at the 50th percentile, equal to or less than 1×10^{-5} at the 90th percentile and equal to or less than 1×10^{-4} at the 99th percentile. Oregon's health protection goal is an LECR equal to or less than 1×10^{-6} at the 90th percentile and equal to or less than 1×10^{-5} at the 99th percentile. The LECR at all percentiles meets Florida and Oregon health protection goals, including at the 90th percentile (8×10^{-7}) the 95th percentile (1×10^{-6}) and the 99th percentile (3×10^{-6})."

STUDY TEAM RESPONSE: Although the Oregon and Florida PRA-based allowable risk goals relate to remediation of contaminated sites (and not drinking water), we will incorporate discussion of them and compare our results to the associated levels of acceptable risk. We note that this is comparable to the discussion of the EPA CERCLA allowable risk ranges for cancer—i.e., they provide perspective on how different regulatory agencies/ authoritative bodies interpret risk assessment results. This discussion will be included in Section 6, with a high-level summary in the Executive Summary.

Exposure Point Concentration Used in the PRA. The EPC used in the PRA (point estimate equal to the 95 UCL 200 feet downgradient of the basins) is very conservative for several reasons. Several of those have been discussed in previous comments on the HHRA. For the PRA, a distribution of arithmetic means should be used. Such a distribution clearly exists, given the EPC is a 95th upper confidence limit of the arithmetic mean (95 UCL) meaning other estimates (a distribution) of the arithmetic mean concentrations are available and could be used. Distributions are commonly used to represent EPCs in PRAs.

STUDY TEAM RESPONSE: Using a 95% UCL in the PRA is consistent with U.S. EPA guidance for a 1-dimensional (1-D) PRA. See the U.S. EPA 2001 Risk Assessment Guidance for Superfund: Volume III - Part A, Process for Conducting Probabilistic Risk Assessment (access online at https://www.epa.gov/sites/default/files/2015-09/documents/rags3adt_complete.pdf), Thus, in a PRA where probability distributions for input parameters primarily reflect parameter variability (e.g., across a population) as opposed to uncertainty—it is appropriate to conduct a 1-D PRA. For clarity, U.S. EPA recommends that a 1-D PRA be conducted as the first tier of a PRA process. If further refinement to the 1-D PRA is desired (e.g., if risk estimates exceed allowable risk ranges and one desires greater understanding of the parameter inputs that result in this exceedance), one can conduct a 2-dimensional (2-D) PRA wherein uncertainty and variability in parameter inputs are assessed separately. Because a 2-D PRA is more resource intensive than a 1-D PRA, it is recommended to be conducted after a 1-D PRA has been completed.



In discussing how to characterize the EPC term in a PRA, U.S. EPA (2001) states, “In PRA, either a point estimate (e.g., 95% UCL) or a probability distribution may be used to characterize uncertainty in the concentration term...The decision to use a point estimate, PDFv [probability distribution function for variability only], or PDFu [probability distribution function for uncertainty only], as the input for the concentration term in a Monte Carlo model will depend on the goals of the Monte Carlo simulation, as determined by the tiered process (see Chapter 2). If the goal is to characterize variability in risk, in general, a one-dimensional Monte Carlo analysis (1-D MCA) will be used and the appropriate input for the concentration term will be a point estimate that characterizes uncertainty in the mean concentration within the EU [exposure unit].” Elsewhere, U.S. EPA (2001) states, “In a 1-D MCA, a point estimate for the EPC is combined with PDFv’s for other variables to yield a probability distribution for risk.” They also note regarding this term that “The most appropriate expression of the exposure point concentration term for chronic exposure will characterize the long-term average concentration experienced by a receptor within the exposure unit” and, regarding the use of a 95% UCL, “Because an EPC is calculated from a sample [i.e., it is based on a finite set of sampling data], there is uncertainty that the sample mean equals the true mean concentration within the EU [exposure unit]; therefore, to account for associated uncertainty, the 95% upper confidence limit for the mean (95% UCL) is generally used for Superfund risk assessments.”

Given these recommendations, we concluded that given the relatively limited number of reclaimed water samples and the fact that available data sets reflect both spatial (different sample locations) and temporal (different sample times) variability, as well as uncertainty about the true distribution of sample concentrations over space and time, a PDF comprised from these data would not sufficiently capture the uncertainty and variability about the true mean of the data sets over time. Consequently, in our opinion, use of a 95% UCL as a representative of the long-term average concentration potentially experienced by a receptor in this (1-D) PRA is appropriate. We did, however, examine the estimated risks were the analysis to instead use the sampling data to establish and apply PDFs for the EPC term, instead of using the 95% UCL. We found that estimated risks at the mean or other midpoints of the distribution were sensitive to the assigned shape of the distribution (e.g., whether it is assumed to be lognormal, normal, Gaussian, or log-logistic--none of which could be strongly defended based on the limited data sets for these chemicals), but that at the upper end of the distributions (e.g., 90th to 95th percentiles), estimated risks were comparable regardless of whether a 95% UCL or a PDF was used to describe the EPC term. As such, for the reasons given above, we think use of a 95% UCL for the EPC term is appropriate at this time. In the future, if additional data are collected, use of a PDF for the EPC term in subsequent updates to the HHRA can be considered.

Introduction

The introduction contains a bullet describing the PRA (presented in Section 6 of the HHRA) without providing much background on why it was conducted. Please note that the reason the Panel suggested conducting a PRA was not because it thought the HHRA needed additional demonstration of the health protectiveness of the methods, assumptions, and



results. Rather, because the HHRA results were going to be used in the cost–benefit analysis, the Panel believed it was important to use a best estimate of potential risk to accurately estimate costs and benefits.

The best estimate (arithmetic average) of risk leads to a more accurate prediction of the benefit. Deterministic risk assessments are designed to be conservative and health protective and, thus, overestimate potential risks. When such overestimates are used to estimate costs, they overestimate the public health benefits associated with an action to mitigate those risks, which can result in more treatment than is necessary.

For example, if the conservative upper–bound estimate from a deterministic risk assessment is 10 adverse outcomes and the best estimate from a PRA is 1 adverse outcome, and the cost of reducing that to 0 adverse outcomes is \$1 million, the cost based on the deterministic assessment is \$0.1 million per adverse outcome and based on the best estimate from the PRA is 10 times more expensive—\$1 million per adverse outcome.

All adverse outcomes can be reduced regardless of cost. But there may be hundreds of adverse outcomes in the population with many other causes besides those evaluated in the risk assessment. If the average cost of preventing those is less than \$1 million per adverse outcome, say \$0.2 million, the public health benefit is greater than the average cost from the hypothetical example, but not if it is based on the deterministic upper bound. That leads to a misallocation of resources, assuming the goal of public health authorities is to reduce the largest number of adverse outcomes per dollar spent.

STUDY TEAM RESPONSE: We will edit this bullet (referring to Section 6.0) to state, “This section summarizes the methods and results of a probabilistic risk assessment (PRA) for PFPeA and NDMA for the resident scenario (the only chemicals and scenarios that exceeded risk thresholds in the conventional HHRA); this PRA was conducted to better characterize the range of exposures and risks for these chemicals and this scenario, and to provide additional information to support the cost benefit analysis.”

Section 3.3.3.5 (Fish consumption rate)

This section discusses the basis for the fish consumption rates used in the HHRA and why the rate of 330.5 grams per day likely does not represent fish consumption rates from Woodland and McAllister Creeks. For all the reasons discussed in the HHRA, these creeks cannot support such a consumption rate of locally caught fish. Based on the information presented in Pfeiffer and Anderson, Woodland Creek has median and 90th percentile sustainable productivity of 19 and 128 grams per day of resident fish, respectively; McAllister Creek has corresponding estimates of 115 and 770 grams per day.

Thus, Woodland Creek couldn’t support one person eating local fish at 330.5 grams per day. Nor could McAllister Creek, assuming median sustainable production—though it might be able to support two people based on 90th percentile productivity. Given that there are



many residences near these creeks, if they are fished it is likely that more than one or two people catch and consume fish from the creeks and that consumption rates of such fish are substantially lower than the sustainable production estimates.

While it appears that the compounds evaluated in this risk assessment do not pose an unacceptable risk even at the high consumption rate of 330.5 grams per day, using this high rate sets a precedent for applying unrealistic and non-representative exposure assumptions. Future risk assessments for different compounds may result in unacceptable risk findings if they are based on this fish consumption rate.

The Panel recommends not using this high fish consumption rate at all. However, if the high fish consumption rate must be included, the Panel recommends changing the order of discussion and evaluation of fish consumption rates. Start the discussion with more representative possible fish consumption rates from these creeks.

Even the moderate rate evaluated in the HHRA or the 95th percentile freshwater fish and estuarine fish consumption rate of 22.5 grams per day used by the EPA for Ambient Water Quality Criteria are likely high for these creeks. Consider using a rate based on Pfeiffer and Anderson that accounts for the size of the local population. If it is necessary, include the high consumption rate of 330.5 grams per day at the end of the discussion, with an explanation for why such a high rate is evaluated.

STUDY TEAM RESPONSE: We will rearrange the order of the discussion and presentation of the results of risk calculations determined using the different consumption rates, as recommended. We will also list the risk/hazard results for both the more moderate and the high-end fish consumption estimates in the results tables.

Section 5.3

As the Panel noted before, much of the HI discussion could be shortened if the Project Team follows EPA guidance and presents HIs to one significant figure. The LECR comparisons described in this section are based on the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) allowable risk range with a focus on explaining a slight exceedance of the low end of the range for NDMA. This focus may give readers the impression that the exceedance poses an unacceptable risk.

The Panel recommends focusing the discussion on the full range of risk, that the NDMA LECR is at the low end of the range, and that it is considered acceptable by EPA if this was a CERCLA site. The Panel recommends that the Project Team point out that the potential risk associated with NDMA is at the low end of the range that the EPA uses to set national drinking water standards (MCLs).

STUDY TEAM RESPONSE: See above response regarding presentation of results to two significant figures.



Section 6.0 PRA

Again, the reason the Panel recommended a PRA was to inform the cost-benefit analysis, not, "...To provide further perspective on where estimated doses of PFPeA and NDMA, and corresponding noncancer hazards and cancer risks, respectively, for the Reasonable Maximum Exposure (RME) resident fall within the range of possible exposures and risks... ." The PRA certainly provides such perspective and PRAs are often used for that purpose, but in this case the deterministic risks were already low and were derived conservatively.

STUDY TEAM RESPONSE: We will change the relevant sentence to, "To provide further perspective on where estimated doses of PFPeA and NDMA, and corresponding noncancer hazards and cancer risks, for the RME resident fall within the range of possible exposures and risks, and to provide additional information to inform the cost-benefit analysis, a probabilistic risk assessment (PRA) was conducted for these chemicals for the resident scenario."

Section 6.2 PRA Methodology

The Project Team should consider including a summary table of all the parameters used to estimate potential risk and, in that table, identify the parameters for which a distribution versus a point estimate was assumed. The details of the distributions can be presented in Table F-1.

As suggested before, consider updating the PRA to include a distribution for the EPC in place of the 95 UCL point estimate.

STUDY TEAM RESPONSE: The PRA methodology is complex and so is detailed in Section F. The objective of including this table in the Appendix as opposed to the main text was to avoid the need to include extensive explanation regarding the nature of probability distribution functions and other characteristics of PRA in the main text-- that discussion can be found in the Appendix for the interested reader. However, we will consider including a summary table as recommended in the main text, but will refer to the Appendix for more detailed explanation.

Section 6.2 PRA Results

The Panel recommends that the Project Team consider reorganizing the discussion with a focus on how the PRA outcome compares not only to EPA's allowable risk range but also the Oregon and/or Florida benchmarks.

If the discussion is reorganized, the Panel recommends that the Project Team consider shortening it with an emphasis on the results that demonstrate that potential risks fall well within various regulatory goals, using figures in addition to, or instead of, Table 6-1.

STUDY TEAM RESPONSE: See above response regarding this topic.



Appendix E

Now that the Draft HHRA includes a PRA, the Panel wonders if Appendix E is needed. It contains important information, but could the figures of the PDFs shown in this section, and the location of the deterministic assumptions on the PDFs, be included in the PRA appendix?

STUDY TEAM RESPONSE: We will move relevant information from this Appendix to the PRA appendix, and delete Appendix E.

Appendix 1F

(Page F-1) Consider using a parameter other than exposure duration to demonstrate distributions that represent uncertainty. The distribution of residence time reflects variability based on how long each household in a population remains at a particular address. A better representation of uncertainty is the EPC. There is one true arithmetic mean concentration, but we do not know it, hence the 95 UCL from the distribution of arithmetic means for the deterministic HHRA. The distribution of means represents our uncertainty about the true mean.

STUDY TEAM RESPONSE: We will revise the text as suggested.

Dose Equations

The equations do not appear to be consistent with some of the inputs shown in Table F-1. For example, the equations show the water ingestion rate separately from body weight (and those are also shown separately in the Appendix E figures), yet Table F-1 expresses the water ingestion rate as liters per kilogram-day. The text in this section (page F-3) also discusses the body weight/water ingestion rate relationship. The dose equations should be adjusted to be consistent with Table F-1 and the text.

STUDY TEAM RESPONSE: The equations are consistent with the tables. In each section, the “original” equation as applied in the deterministic RA is presented first, followed by a modified equation as applied in the PRA with a discussion of the rationale for the change. We will clarify this in the text.

Inputs

(Page F-8) As noted before, consider updating the PRA to include a distribution for the EPC.

In addition to tables with select percentiles for input distributions, figures of the output distributions for parameters represented by distributions can help readers better understand the “shape” of the distribution (see Figures in Appendix E).

(Page F10-11) The Panel recommends revising the discussion and using an ED selected from the same distribution used to estimate lifetime average daily dose (LADD) and use that ED in both the numerator and denominator of the average daily dose (ADD) equation.



Setting the ED to one year when developing the ADD distribution could lead readers to think that years of exposure were underestimated.

When estimating ED for LADD, truncate the distribution at 70 years, equal to the lifetime assumed by EPA. Table F-1 indicates the maximum ED is 87 years. An ED of 87 years and lifetime of 70 years will result in an overestimate of potential exposure and risk.

STUDY TEAM RESPONSE: Given the relatively small number of sample results describing the reclaimed water concentrations, and the variability/uncertainty introduced to this data set by both temporal and spatial factors (e.g., for NDMA, 15 reclaimed water sample results were available, of which 8 were nondetects, and these results were collected from two different locations at 8 distinct time points) as well as the sensitivity of EPC estimates to the assumed shape of the probability distribution, in our opinion it is important to apply an EPC that reflects an estimate of the long-term average, or mean, exposure concentration, and not underestimate it. As described above, we examined the effect that applying a distribution for this parameter would have on the risk estimates, and found that estimates at the upper end of the distributions (e.g., 90th to 95th percentiles) are comparable when either a 95% UCL or a PDF are used for the EPC parameter, but that estimates in the midpoints of the distribution in particular are sensitive to the assumed shape of the distribution (e.g., whether the distribution can best be described as lognormal, normal, Gaussian, log-logistic, etc., (incidentally, the EPC data fit none of these distributions well, given the limited size of the data sets)). In the future, if and when additional data are collected, periodic reassessment of risk can be considered, and these assessments, with their corresponding larger datasets, could consider distributions based on the full range of concentrations.

PRA Results

As suggested above, compare the results to benchmarks established by regulatory agencies (such as in Oregon, Florida, or the EPA) and discuss the outcome of those comparisons rather than discussing the potential risk at select percentiles. The latter discussion complicates a very clear and favorable finding.

STUDY TEAM RESPONSE: See above response regarding this topic.

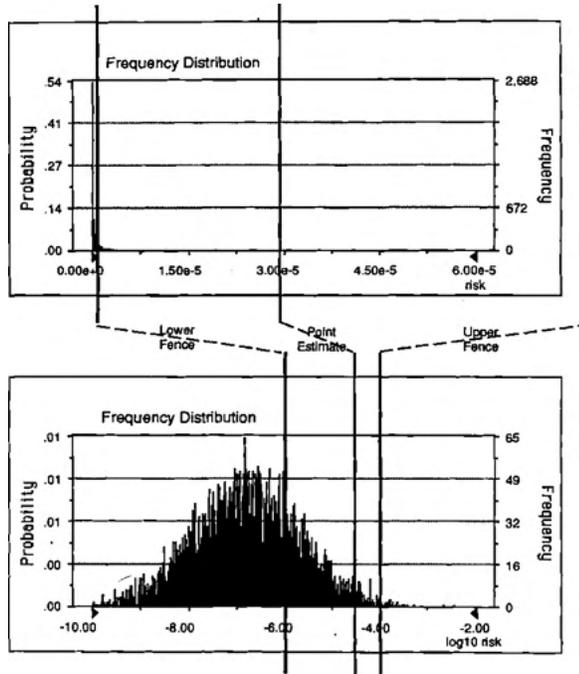
Figures F-1 through F-6

Change the x-axis from a linear to a logarithmic scale. That will make it much easier for readers to understand that most of the population has an estimated risk that is less than the lowest benchmark. See below for a hypothetical example with a potential risk that is about 100 times higher than reported in the HHRA.

STUDY TEAM RESPONSE: The figures we included are outputs from the Crystal Ball software. In our opinion, they provide a reasonable depiction of the range of estimated outputs. We will consider including other types of figures in which the risks or hazards are presented on a log-scale.



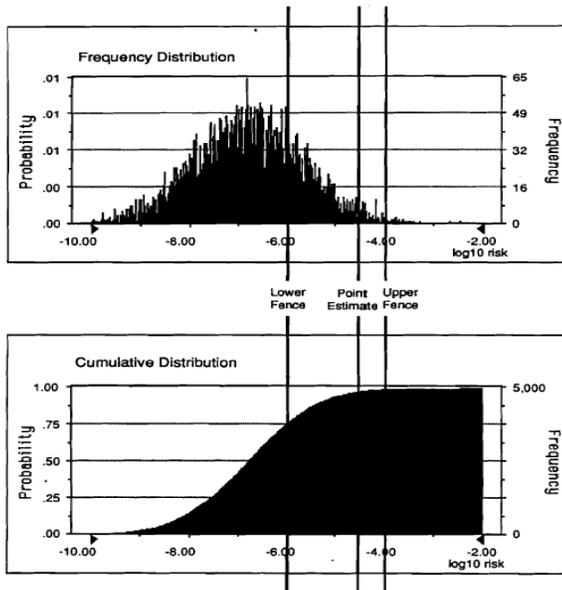
Comparison of Frequency Distributions on Linear and Logarithmic Scales



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Consider also reporting the results on a cumulative density function (CDF) figure. It can be much easier to show the risk associated with select percentiles on such figures. See below for a hypothetical example (again with potential risk about 100 times higher than reported in the HHRA).

Some Sample Output Distributions



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Below is a real-life example from a PRA conducted in Oregon that shows both LECR and HI and compares to the Oregon-specific benchmarks.

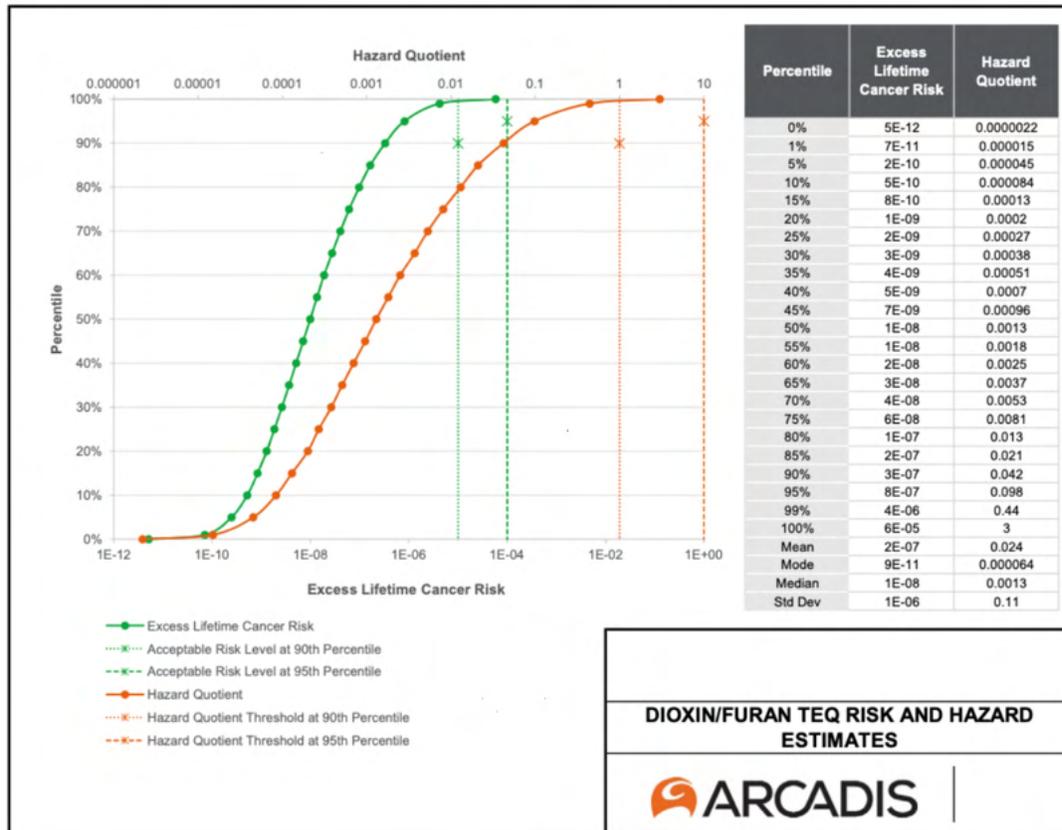


Table F-1

The Panel recommends truncating the water ingestion rate distributions. The maximums seem quite high, particularly for the LADD distribution. A long-term water consumption rate of about 0.27 L/kg-day seems high if the ED is large, which would mean the person consuming is an adult with an average weight of 80 kg, so 21 liters of water a day.

See comment above about using an ED=1 when estimating ADD.

STUDY TEAM RESPONSE: Truncating the maximum value of a beta distribution in Crystal Ball artificially shifts all other parameters of the distribution to lower values, which no longer would match the input data set that is the basis for this distribution (which is from U.S. EPA, 2019, as described in Appendix F). However, we note that these “maximum” values are extreme values at the very upper limit of the distributions, and in repeated Monte Carlo simulations, would be drawn very, very infrequently. As such, the maximum value has little impact on the simulation results. We also note that the 99.9th percentile estimates for these distributions are much lower (although these values would also be drawn very infrequently). Consequently, we have elected not to truncate these



distributions, but will add the 99.9th percentile values water consumptions distributions to Table F-1 for clarity.

Table F-2

See previous comments about using a distribution for the EPC.

STUDY TEAM RESPONSE: See above response regarding this topic.