

Response to Comments on the 2020 External Review Draft OU3 HHRA for the Smurfit-Stone/Frenchtown Mill Site

Comment #	Commenter	Topic	Comment	Response
1	PRP-Integral	Data Evaluation	On page 20, Section 3.3.2 under the Data Considerations header in OU3, non-detects (NDs) were evaluated at $\frac{1}{2}$ the sample-specific detection limit (DL) when calculating toxicity equivalents (TEQs). Summary statistics are available in the EPA Scribe database for 3 alternative TEQ values (ND = 0, ND = $\frac{1}{2}$ method detection limit [MDL], and ND = $\frac{1}{2}$ sample-specific DL); EPA used ND = $\frac{1}{2}$ DL for calculating TEQs. Although EPA has not set a policy for the preferred way to handle NDs when calculating TEQs, it recommends a sensitivity analysis be conducted to evaluate the impact of the proxy value selected for NDs when calculating TEQs, as was done in USEPA's (2019a) Final Technical Memorandum, Summary of the June 2019 Fish Sampling Event. Integral performed a sensitivity analysis comparing TEQs where ND = 0 using the TEQs calculated by EPA (i.e., using ND = $\frac{1}{2}$ DL). The relative percent difference (RPD) between the TEQs varied; the largest RPD between the lowest and highest TEQ value when evaluating different substitution methods is 200% (i.e., frequency of detects [FOD] were very low; in some cases FOD were 0%). As a result, the TEQs estimated using $\frac{1}{2}$ the DL resulted in TEQ concentrations that are higher compared to TEQs where zero was substituted, indicating that a large majority of congeners were not detected. Therefore, TEQ hazards are likely overestimated. To demonstrate the variability in TEQs when using a proxy value for NDs, Integral calculated exposure point concentrations (EPCs) and hazards for the combined Frenchtown (FRN) and St. Regis (STR) reaches (same as EPA) using EPA's calculated TEQ fish tissue concentrations. As an example, Attachment 1, Comment Table 1 (attached to original comment letter) presents the hazards calculated for the tribal fisher using rainbow trout fillet and northern pike fillet data from the 2019 sampling event for TEQD/F. When assuming ND = 0 for the TEQD/F, the hazard quotients (HQs) are significantly less (e.g., HQ = 0.6 vs. HQ = 0.1) than when the ND = $\frac{1}{2}$ DL. Further details including a summary of the results and the quantitative calculations are provided in Attachment 1, Comment Table 1 (attached to original comment letter). In summary, TEQs that represent a low frequency of detection are highly influenced by the use of proxy values for NDs, which could be overestimating hazards. We recommend EPA include a sensitivity	For Superfund site assessments, EPA Region 8 calculates the toxicity equivalent (TEQ) assuming $\frac{1}{2}$ the sample-specific detection limit (DL). This approach is consistent with evaluations conducted at other sites in the region and is supported by Montana Department of Environmental Quality (MDEQ). The summary statistics tables in the human health risk assessment (HHRA) present TEQ calculations both ways: using non-detects equal to one-half the detection limit, and non-detects equal to zero. Setting non-detects equal to zero may underestimate actual TEQ concentrations for those congeners present at a non-zero concentration below the detection limit. Text will be added within the uncertainty assessment discussing the influence of non-detects on the calculated TEQ concentrations, but a sensitivity analysis will not be added to the risk assessment.

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			analysis regarding TEQ data considerations and associated risk and hazard implications to the risk conclusions. This sensitivity analysis will help in clearly identifying risk drivers and in turn inform risk management decisions.	
2	PRP-Integral	Data Evaluation	On page 20, Section 3.3.2 under the Data Considerations header in OU3, non-dioxin-like polychlorinated biphenyls (non DL-PCBs) were calculated for OU2 and total PCB concentrations (which include dioxin and non DL-PCBs) were calculated for OU3 to evaluate exposure to PCBs. Table 3-9 of the draft OU2 HHRA lists total non DL-PCBs and total DL-PCBs as analytes for the soil contaminants of potential concern (COPCs) screening process. It is unclear why there is a total DL-PCBs analyte in addition to a TEQ DL-PCBs analyte since DL-PCBs are evaluated through a TEQ approach per USEPA (2010) recommendations. Although total DL-PCBs is not considered a COPC, it is unclear why PCB data are segregated in this manner that is inconsistent with how exposures to PCBs are evaluated in OU3. We recommend EPA provide clarification to indicate why exposure to PCBs was evaluated differently per operable unit.	Risks from exposures to polychlorinated biphenyls (PCBs) in soils were evaluated differently within the OU2 and OU3 assessments because PCB data in OU2 soils includes concentrations reported as both Aroclor mixtures and PCB congeners, whereas data for OU3 soils were only reported as Aroclor mixtures. The OU2 HHRA was revised to screen for total PCBs since DL-PCBs were included in the TEQ screening.
3	PRP-Integral	COPC Screen	In the soil and groundwater COPC screening, the data sets for each media are aggregated in its entirety; however, the EPC data sets for each media are based on individual exposure units (e.g., per well or soil grid area). Therefore, if an analyte is identified as a COPC in the aggregated data set, it is carried forward as a COPC per individual exposure unit. The maximum detected concentration for each COPC per exposure unit may be less than the overall maximum detected concentration used during the screening. Therefore, the estimated risks and hazards per exposure unit are likely overestimated as certain constituents may have screened out of the COPC selection process if the COPC selection process reflected data aggregation per an exposure unit basis. We recommend EPA include these data considerations and associated risk and hazard implications within the COPC screening section of the reports.	The purpose of the COPC screening step is merely to focus the risk evaluation. The approach included in the HHRA is a standard method for conducting a COPC screening: determining COPCs based on the entire dataset, and then calculating risk in exposure areas using EPCs for each exposure area. No changes will be made as a result of this comment.
4	PRP-Integral	Data Evaluation	In the OU3 HHRA, the data requirements are not clearly defined for how the 95UCL was calculated (in the OU3 HHRA, the 95UCL was calculated for data sets where at least five samples and two distinct detected values were available). Per the ProUCL Version 5.1.002 Technical Guide (USEPA 2015), “statistics based upon only a few detected values (e.g., < 4) cannot be considered reliable enough to estimate EPCs. When the number of detected values is small, it is preferable to use ad hoc methods rather than using statistical methods to compute EPCs and other upper limits. For data sets with low detection	As described in the HHRA, the maximum detected concentration was used as the EPC in cases where the recommended 95UCL exceeded the maximum concentration. The text in the HHRA will be updated to reflect the guidance in EPA (2015) of needing at least four detections to generate a 95UCL value.

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			frequencies, other measures such as the median or mode represent better estimates (with lesser uncertainty) of the population measure of central tendency.” We recommend EPA calculate the 95UCL when there are at least four detections consistent with USEPA (2015) recommendations and that the OU3 HHRA include its data requirements for when a 95UCL was calculated.	
5	PRP-Integral	Toxicity Values	Exposures to construction workers of one year or less are classified as subchronic exposures, per the Supplemental Guidance for Developing Soil Screening Levels for Superfund Sites (USEPA 2002). USEPA (1989, 2002) recommends that subchronic exposures should incorporate toxicity values that are based on subchronic and not chronic effects. The construction worker hazards in the HHRA are based on chronic toxicity values as presented in Appendix D. As a result, estimated HQs for the construction worker scenario are overestimated. We recommend EPA include a discussion within the uncertainty section regarding the implications resulting from the use of chronic toxicity values to evaluate the construction worker scenario (i.e., risk characterization results are overestimated).	The HHRA will be updated to use subchronic toxicity values, where available, to evaluate risk to the construction worker. The uncertainty section will also be updated to note the conclusions based on use of chronic toxicity values also.
6	PRP-Integral	Risk Characterization	The estimation of potential risks and hazards to the hypothetical future construction worker through the inhalation of soil particulates pathway is evaluated differently between OU2 and OU3. For OU2, inhalation risks and hazards are not presented for TEQ _{D/F} but are calculated for OU3 in Appendix D. Both OU2 and OU3 reports state in Section 4.2 under the Dioxin header that “there is no USEPA IRIS RfC or IRIS UR for TCDD. The USEPA RSL Tables (USEPA 2020a) provide dioxin soil screening levels for the inhalation pathway based on the California EPA RfC and UR values. However, inhalation risk based on particulate emissions from soil, estimated using the California EPA RfC value, shows that the contribution of the inhalation pathway compared to the ingestion pathway is well below 1% (USEPA 2013a).” It is unclear from this statement if further evaluation of this pathway was conducted in the HHRA with respect to inhalation exposures to TEQ _{D/F} . Furthermore, it is unclear if the statement “California EPA RfC value, shows that the contribution of the inhalation pathway compared to the ingestion pathway is well below 1% (USEPA 2013a)” also eliminates the need to evaluate potential cancer risks from TEQ _{D/F} because the California RfC is protective of both noncancer and cancer effects (as is stated for the reference dose [RfD] in Section 4.2) and/or the California UR value shows that the contribution of the inhalation pathway compared to the ingestion pathway is also below 1%. We recommend EPA update the reports to clarify if the inhalation of soil particulates pathway by a	Per the OU3 HHRA CSM, the inhalation pathway is considered complete and might be significant for the construction worker. The text will be updated to note that the contribution of the inhalation pathway is minor compared to the ingestion pathway assuming conditions where soil disturbance is minor (i.e., wind erosion). As noted in the HHRA, when soil is disturbed by mechanical forces, dust levels in air may be significant and intake of soil from inhalation of airborne dusts may become similar to or greater than the ingestion pathway. On this basis, inhalation exposures for the construction worker are evaluated quantitatively within the risk assessment.

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			hypothetical future construction worker with respect to exposure to TEQ _{D/F} is considered a complete exposure pathway warranting further quantitative evaluation in the HHRA.	
7	PRP-Integral	Data Evaluation	The conservatively estimated risks and hazards for exposure to metals in groundwater by all receptors are based on total metal concentrations. We recommend EPA include a discussion in the uncertainty section to reflect estimated risks and hazards for receptors exposed to dissolved metals in groundwater to guide risk management decisions.	As noted in the HHRA, human health exposures were evaluated using total metal concentrations. Total metals are the metrics of interest for consumption of groundwater in human health risk assessment because the low pH of the gastrointestinal systems allows metal ions to dissociate from their complexes in the gut upon ingestion. No change will be made.
8	PRP-Integral	Background Evaluation	Several of the background total metal concentrations in groundwater are greater than risk-based concentrations (RBCs). For example, the RBC for arsenic is 5.2E-02 µg/L and the average and maximum background concentration for total arsenic in groundwater is 2.92 µg/L and 6.7 µg/L, respectively. Although COPCs were not carried forward in the quantitative risk assessment if concentrations were considered below background, incremental risks due to background concentrations in groundwater were not discussed within the reports. We recommend EPA include an incremental risk evaluation for COPCs in groundwater to assist with risk management decisions.	Although conducting a comparison to background concentrations was included in the previous draft OU3 HHRA, upon further consideration of existing guidance it was determined that comparison with background levels should not be used to remove contaminants of concern from further evaluation owing to the need to fully characterize site risks (EPA 2002). Comparison to background is not a toxicological rationale for eliminating COPCs from further consideration. Comparisons of site concentrations to background concentrations should still be considered within the remedial investigation (RI) outside of the risk assessment to provide additional information to risk managers to better characterize the results presented in the risk assessment.
9	PRP-Integral	Site Characterization	Within the HHRA reports, there is minimal differentiation discussed between the two aquifer units. When there is a distinction made, the information was not presented clearly. For example, Unit 3 wells are presented as “water supply wells,” which does not indicate that these wells are screened in a distinct and deeper aquifer. We recommend EPA clearly define and describe the two aquifer units (i.e., the shallow aquifer Unit 1 and deeper aquifer Unit 3) in the HHRA reports as this information provides further clarity regarding the conceptual site model and potential pathways of exposure. Additional clarification should be	OU2 and OU3 figures identifying groundwater wells were revised to indicate Unit 1 vs Unit 3 aquifer units. The text will be revised to provide clarification, but the groundwater conceptual model report will be cited for the detailed discussion. In addition, groundwater data collected in 2020 will be incorporated into the revised risk assessment.

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			provided within the documents to distinguish between Unit 1 and Unit 3 wells when individual wells are discussed in the reports.	
10	PRP-Integral	Data Evaluation	In Attachment A-1, several updates are needed including: - The MDL and DL data columns are equivalent for every media presented in each Excel worksheet. Therefore, it is unclear if the non-detect result reflects the MDL or DL. - The dioxin, furan, and PCB fish tissue data sets are missing from the attachment. - The TEQ data table indicates “fillet sample ID” in Column C and should be updated to Sample ID. - The TEQ data table indicates rainbow trout samples were collected from sampling reach Florence. However, there is no mention of this reach in the report or figures. We recommend further clarification be provided. We recommend EPA update Attachment A-1 to include the laboratory-reported MDL and DL, and fish tissue dioxin/furan and PCB data.	The data in Attachment A-1 are consistent with the Scribe database. The value in the result column for non-detects matches the value in the “DL” column which represents the sample-specific detection limit. To improve clarity for the risk assessment, Attachment A-1 will be updated to only show the “DL” column. In addition, Attachment A-1 will be updated. As part of this update, the tabs of background groundwater and soil data will be removed, as the background screen is being taken out of the risk assessment.
11	PRP-Integral	Editorial	Section 4.2 discusses USEPA’s (2017) recommendations for evaluating human health exposures from dioxins using the noncancer RfD and considers it to be protective of both cancer and noncancer effects. However, Table 4-1 presents the cancer slope factor (CSF) for 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD). To avoid confusion, we recommend EPA remove the CSF for 2,3,7,8-TCDD from Table 4-1 in both reports and instead add a note providing the rationale from Section 4.2. Additionally, the USEPA reference should be updated to USEPA (2020a) as it is still the current recommendation indicated on EPA’s Risk Assessment for Dioxin at Superfund Sites web page.	In the revised OU3 HHRA, cancer risk will be evaluated for dioxins/furans using the CSF for TCDD (from CalEPA) shown in Table 4-1. To clarify, the recommendations for using the noncancer RfD states that cancer and noncancer effects from TCDD occur within a similar range, not that the RfD is protective of cancer effects. Consistent with the language on the EPA website, the 2012 reference dose (RfD) for TCDD will be used as a starting point to develop site-specific risk-based cleanup levels outside of the risk assessment, but this does not preclude the evaluation of potential cancer effects within the risk assessment as the CalEPA CSF for TCDD meets the criteria of a “Tier 3” toxicity value suitable for use in CERCLA risk assessment per OSWER Directive 9285.7-53 (EPA 2003). The uncertainty section will be updated to discuss the uncertainties associated with the estimated dioxin cancer risks.
12	PRP-Integral	Editorial	On Figure 3-1, the residential receptor should be identified on these figures as hypothetical.	The current note in Figure 3-1 notes that residential and worker scenarios are “hypothetical future” exposures. However, to increase clarity, the note will be revised to

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				first state that “Residents and workers represent hypothetical populations that may be exposed at the site in the future.”
13	PRP-Integral	Editorial	A time-weighted average (TWA) approach for assessing non-cancer hazards is discussed in USEPA (1991) Risk Assessment Guidance for Superfund (RAGS) Part B as opposed to the USEPA (1989) RAGS Part A guidance referenced in both reports. We recommend EPA update the reference cited in the HHRA reports.	RAGS Part A guidance discusses evaluating lifetime exposure by taking the time-weighted average of exposure over all age-groups and is a standard reference for risk assessment methodology. The reference will be retained.
14	PRP-Integral	Site Characterization	On page 33, Section 3.4.3 under the Fish header, the exposure areas for evaluating the consumption of fish reflect areas adjacent to (FRN) and downstream (STR) of the site. The underlying assumption or premise of this approach is that the former Frenchtown Mill site influences the environmental conditions in the Clark Fork River from the site to STR, which is approximately 60 river miles downstream of the site. The assumption is also not supported by any of EPA’s conceptual site models. We recommend updating the exposure area for the fish ingestion pathway to only reflect exposure areas adjacent to the site (i.e., FRN) considering the STR reach is 60 river miles downstream of the site and could be influenced by other sources.	The scope of the risk assessment focuses on evaluating potential exposures and associated risks within the current study area which includes areas within the Clark Fork River (CFR) where hazardous substances from site activities may have come to be located through typical transport processes. The areas adjacent to the site and downstream to St. Regis have been determined to be included within the current study area given that the full nature and extent to which hazardous substances from site activities have come to be located in the CFR has not been fully established. To increase clarity on this point, the nomenclature used within the HHRA will be changed from using the term “site” to “study area.” Nature and extent is outside of the scope of the risk assessment but will be considered within the RI/FS.
15	PRP-Integral	Site Characterization	The reaches presented in Figure 3-10 are reflective of the 2018 fish sampling event. We recommend presenting both the 2018 and 2019 sampling reach locations and indicate the associated fish collected at each reach within the same figure so that the 2018 and 2019 sampling reach locations can be compared with each other. See Attachment 1, Figure 1 (attached to original comment letter) for an example presentation of this information. From this example, it is clearly shown that the 2019 fish sampling event at MIS occurred upstream of the Missoula urban area as compared to the 2018 fish sampling event at MIS. Because the 2019 fish samples were collected outside of the influence of urban sources from the city of Missoula, these samples could be considered background.	As use of 2018 fish data are limited to the uncertainty assessment and not risk characterization in the HHRA, their sample locations will not be shown on a figure. The reader is referred to the EPA (2018) sampling plan for sample locations. As comparison of site concentrations to background concentrations will occur outside of the risk assessment process moving forward, specific comparison of the 2018 Missoula location compared to the 2019 Missoula location will not be included in the HHRA report.
16	PRP-Integral	Background Evaluation	On page 26, Section 3.3.6 under the COPC Screen for Fish Tissue header, and in Table 3-27, EPA calculated fish tissue TEQs in upstream	Although conducting a comparison to background concentrations was included in

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			reaches including Lolo (LOL) and two reference area reaches (Missoula [MIS] and Council Grove [COG]). The TEQs for upstream reaches were compared to TEQs calculated for reaches adjacent to (FRN) and downstream of the site (STR), together referred to as the “site reaches” by EPA. In Table 3-27, EPA did not identify any of the TEQs as COPCs in northern pike (whole body or fillet) nor TEQ_{D/F} as a COPC in rainbow trout (whole body or fillet). At the end of this COPC screening process, EPA retained all TEQs and total PCBs for quantitative evaluation “to provide risk managers with information necessary for consideration of the existing fish advisory and to account for the potential influences of other outside variables (e.g., fish age, metabolism, etc.) on the statistical tests conducted as part of the background screen.” However, EPA did not provide a discussion of the uncertainties regarding those outside variable factors in the report. Confounding factors include differences in rates of uptake, metabolism, and depuration of chemicals by fish. Additionally, chemical bioaccumulation rates within fish are highly influenced by fish age, size, species, food web, and dietary sources of contaminants. Hypothesis testing is unable to determine if statistically significant differences in chemical burdens within biological fish tissues are due to actual chemical concentration differences or variances in outside factors. Therefore, a significant level of uncertainty is inherent within the background evaluation. EPA discusses the uncertainty associated with using different fish tissue data sets (2019 vs. 2018 and 2019 combined) in Section 6.3 in relation to discussing risks and hazards associated with different reaches; however, it does not present the uncertainties inherent within the hypothesis testing approach (i.e., the variances in outside factors affecting chemical concentration burdens in fish). We recommend EPA include a discussion of the uncertainties regarding the impact of outside variable factors affecting fish tissue chemical concentrations and their associated impacts on the background evaluation in the HHRA report.	the previous draft OU3 HHRA, upon further consideration of existing guidance it was determined that comparison with upstream concentrations (i.e., background) should not be used to remove contaminants of concern from further evaluation owing to the need to fully characterize site risks (EPA 2002b). Comparison to background is not a toxicological rationale for eliminating COPCs from further consideration. Comparisons of site concentrations to background concentrations should still be considered within the remedial investigation (RI) outside of the risk assessment to provide additional information to risk managers to better characterize the results presented in the risk assessment. .
17	PRP-Integral	Background evaluation	The objective of the HHRA is to evaluate risks and hazards to current and hypothetical future receptors. Since the background evaluation did not screen out any COPCs from the quantitative risk evaluation, we recommend that EPA provide a quantitative evaluation of the incremental risks from ingestion of fish adjacent to the site at the FRN reach as compared to the upstream reaches using the 2019 data as part of	Although conducting a comparison to background concentrations was included in the previous draft OU3 HHRA, upon further consideration of existing guidance it was determined that comparison with upstream concentrations (i.e., background) should not be used to remove contaminants of concern

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			the main risk characterization section of the report as opposed to potentially discussing them in the uncertainty analysis. To demonstrate if the hazards and risks from the consumption of fish from the reach adjacent to the site (FRN) are incrementally different from the upstream reaches, Integral calculated hazards and risks for the five reaches³ using EPA's calculated TEQs and total PCBs fish tissue concentrations using the 2019 data set (i.e., EPA's OU3 Attachment A-1) for a tribal fisher ingesting rainbow trout fillet. Further details including a summary of the results and the quantitative calculations are provided in Attachment 1, Comment Tables 2 through 4 (attached to original comment letter). The incremental risk results indicate the following conclusions: - FRN hazards to a tribal fisher ingesting rainbow trout fillet impacted by TEQ_{D/F} are not incrementally different when compared to the upstream reaches and less than the EPA health guideline (HQ < 1). - FRN hazards to a tribal fisher ingesting rainbow trout fillet impacted by TEQ_{PCB} and total PCBs are not incrementally different from the upstream COG reach. Potential hazards and risks for all reaches are relatively low given that conservative (health protective) exposure and toxicity parameters were used in the evaluation. The 2019 fish sampling event at MIS occurred upstream of the Missoula urban area (see Attachment 1, Figure 1 [attached to original comment letter]). Based on the 2019 fish tissue data, the contributions from the Missoula urban area appears to be impacting the COG reach sampling area since it is directly downstream from the City of Missoula and the City of Missoula wastewater treatment plant. Therefore, it is likely that the hazard estimates for the FRN reach are reflective of the downstream impacts from the City of Missoula, City of Missoula Wastewater Treatment Plant, and other developed/urban sources since the hazards results are equivalent to the COG reach. This aligns with the statements included in Section 3.3.6 of the draft OU3 HHRA that "together these findings indicate that there may be non-Site related inputs associated with the City of Missoula contributing to the concentrations of TEQ in fish collected from the FRN/STR reaches."	from further evaluation owing to the need to fully characterize site risks (EPA 2002b). Comparison to background is not a toxicological rationale for eliminating COPCs from further consideration. Comparisons of site concentrations to background concentrations should still be considered within the remedial investigation (RI) outside of the risk assessment to provide additional information to risk managers to better characterize the results presented in the risk assessment.
18	PRP-Integral	Data Evaluation	On page 20, Section 3.3.2 under the Data Considerations header, the report presents a discussion regarding how the TEQs were calculated; however, it does not provide the toxicity equivalence factors (TEFs) or indicate which dioxin, furan, or DL-PCBs congeners act by the same	A table of the TEFs from EPA (2010) will be added to the HHRA.

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			toxicokinetic and toxicodynamic mechanisms as 2,3,7,8-TCDD. For clarity and transparency, we recommend EPA indicate the TEFs and associated congeners that are considered in each TEQ calculation (i.e., TEQ _{D/F} , TEQ _{PCB} , and TEQ _{D/F/PCB}).	
19	PRP-Integral	Data Evaluation	On page 20, Section 3.3.2 under the Data Considerations header in OU3, it is unclear how NDs were considered in the total PCB calculations as only the TEQ discussion included information regarding the treatment of NDs. Specifically, it states both on page 20 and on page A-11 that total PCB concentrations were calculated as the sum across all PCB congeners. We recommend EPA include a discussion regarding how NDs were evaluated when calculating total PCB results.	The following sentence is in the paragraph above the total PCB paragraph cited in this comment: “ <i>Risk calculations included in this risk assessment were based on evaluating NDs at ½ DL.</i> ” This sentence will be repeated in the PCB paragraph for clarity.
20	PRP-Integral	Exposure Assessment	As presented on page 21, Section 3.3.3, the fish ingestion rate of 93 g/day for a reasonable maximum exposure (RME) for a tribal fisher was assumed based on USEPA (2016a) Heritage Fish Consumption Rates of the Shoshone-Bannock Tribes. Additional details regarding the derivation of this value are not provided in the report although it is indicated on page 21 that further details can be found in Section 3.4. We recommend EPA update the report to include documentation for how the fish ingestion rate was selected for a tribal fisher.	The citation for the tribal fish consumption rate is provided in Table 3-35. For clarity, a paragraph describing the derivation of this value will be added to Section 3.4.2.
21	PRP-Integral	Exposure Assessment	As discussed on page 13, Section 3.2.1 and presented on Figure 3-1, the inhalation of soil particulates created by the use of construction equipment on upland surface soil is indicated as a complete exposure pathway for construction workers. Upon further review, the soil EPCs for this pathway reflect the surface and subsurface soil data set (Appendix D; pp. 576–579 of the PDF) as indicated in the exposure medium table title and further confirmed by the fact that the soil EPCs for the inhalation pathway are identical to the incidental ingestion (Appendix D; pp. 568–572 of the PDF) and dermal contact with soil EPCs (Appendix D; pp. 573–575 of the PDF), which are based on surface and subsurface soil. As recommended by the Supplemental Guidance for Developing Soil Screening Levels for Superfund Sites (USEPA 2002), pathways of concern for a construction worker include inhalation of fugitive dust due to traffic on unpaved roads from surface soil. We recommend EPA update the inhalation risk and hazards calculations to reflect surface soil EPCs consistent with the report text and tables and EPA recommendations.	The inhalation risk calculations for the construction worker will be updated to use an EPC generated based on surface soil data only to be consistent with the basis of the PEF used in the calculation consistent with USEPA (2002a).
22	PRP-Integral	Toxicity Values	The RfD for cadmium is used as the inhalation unit risk (IUR) for the inhalation of soil particulate risk calculations (Appendix D; pp. 576–579 of the PDF) for the construction worker scenario. As a result, the estimated risks for the construction worker are underestimated. We	The risk calculations will be updated to use the IUR of 1.8E-3 shown in Table 4-1 of the HHRA.

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			recommend EPA update the inhalation risks from cadmium for this receptor to reflect the IUR toxicity value.	
23	PRP-Integral	Data Evaluation	As stated on page 58, Section 6.3 under the Fish header, risk estimates for fish consumption are based on fish collected during the 2019 sampling event due to sampling compliance issues with the 2018 sampling event. Further details are not provided in the report. We recommend summarizing the sampling compliance issues associated with the 2018 fish sampling event in Section 3.3.2 or reference the Final Technical Memorandum Summary of the July 2018 Game Fish Sampling (USEPA 2019a) document that discussed these compliance issues so that transparency is provided regarding the data decisions that impact the risk and hazard estimates for the fish ingestion pathway.	USEPA (2019) was developed to provide the detailed analysis of the 2018 fish and includes the detailed discussion of the data quality issues. Per that memo, the 2018 fish tissue data were not included in the data considered in the quantitative risk evaluations. This document is cited in the uncertainty section and is publicly available. However, a brief summary based on the conclusions presented in the 2019 memo was added to the uncertainty section.
24	PRP-Integral	Editorial	On page 19, Section 3.3.2, the title is stated as “Data Used in the COPEC Screening.” We recommend updating the title to “Data Used in the COPC Screening” as ecological receptors are not considered in the HHRA.	The term “COPEC” will be corrected to “COPC.”
25	PRP-Integral	Editorial	For convenience of the reader, we recommend including a table that presents the soil EPCs as was completed for the groundwater (Table 3-39) and fish (Table 3-40) pathways.	Tables of the upland and floodplain soil EPCs will be added to the HHRA.
26	PRP-Integral	Editorial	Appendix D tables incorrectly indicate risk summaries for the hypothetical future resident in several locations. On page 612 of the PDF, the table title should be updated to reflect the current/hypothetical future hiker. On page 615 of the PDF, the table title should be updated to reflect the current/hypothetical future camper. On page 618 of the PDF, the table title should be updated to reflect the current/hypothetical future fisher.	These 3 table titles will be updated to the correct receptor as noted in the comment.
27	PRP-Integral	Editorial	Section 3.1.3 on page 11 under the Recreational Visitors header indicates fishing activities are restricted to the Clark Fork River (CFR). Additionally, there is no evidence presented in this HHRA to determine that the streams have been impacted by the site. We recommend updating the header on page 17 of Section 3.2.5 from “Ingestion of Fish from Impacted Streams” to “Ingestion of Fish from Potentially Impacted CFR.”	The header will be updated to “Ingestion of Fish from CFR.”
28	PRP-Integral	Editorial	In Table 2-1 and on page A-8, EPA reports that both the 2018 and 2019 fish data include lipid content data. It is not clear in the report if lipid content results were used to normalize dioxin/furans and PCBs concentrations. For example, ProUCL outputs include lipid references. If lipid content results were utilized, the process should be recognized in the report text and at a minimum discussed in Appendix A.	Appendix A will be updated to clarify that the quantitative risk calculations presented in the HHRA were done using tissue concentrations on a wet-weight unit basis and were not lipid normalized.

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29	PRP-Integral	Editorial	In Table 3-27 Fish Tissue COPC Screen, footnote “a” indicates the data are in pg/g without indicating if the data are wet or dry weight. We recommend updating the footnote to provide this additional clarification.	The footnote will be edited to note that fish tissue data are in units of pg/g wet weight.
30	PRP-Integral	Editorial	In Table 5-2, the term “fisher” should be updated to clarify if it is the tribal or recreational fisher scenario. Both the recreational and tribal fisher estimates should be reflected in the table.	The table header will be updated to clarify that the exposure parameters are specific to a recreational fisher scenario.
31	PRP-Integral	Editorial	In Section 5.4, EPA states that a diet of 50% northern pike and 50% rainbow trout was used for both the recreational fisher and the tribal fisher. However, neither the risk tables nor Appendix D presents the EPC for this mixed diet. The calculations on which this mixed diet EPC is based are not included in the document.	Separate EPCs were not generated. These additional calculations sum half of the calculated risks for consumption of northern pike and half of the calculated risks for consumption of rainbow trout. The text will be revised to clearly state how these additional risks were calculated.
32	PRP-Integral	Editorial	Figures 6-3 and 6-4 should be corrected and fully annotated. The figures have subtitles on the individual graphs that refer to the “Recreational Fisher” while the table title refers to the “Tribal Fisher.” The text indicates that these figures depict both 2018 and 2019 data and that information should be footnoted on the figures.	These figures will not be included in the revised HHRA. Although conducting a comparison to background concentrations (i.e., upstream) was included in the previous draft OU3 HHRA, comparisons of site concentrations to background concentrations will not be part of the risk assessment. Comparison of fish tissue concentrations between fish caught from locations within the OU3 study area and locations with the CFR upstream of the OU3 study area should still be considered within the RI outside of the risk assessment to provide additional information to risk managers to better characterize the results presented in the risk assessment.
33	PRP-Integral	Editorial	The title of Table 6-1 states that it is calculating hazards and risks based on a higher ingestion rate to assess uncertainty. We recommend including the actual ingestion rate used to perform these calculations in the footnotes.	The description of the results shown in Table 6-1, including the fish consumption rates and their source, are included in Section 6.1.4, which is where Table 6-1 is referenced. No change will be made.
34	PRP-Integral	Editorial	Tables 6-2 and 6-3 indicate they contain both 2018 and 2019 fish data. We recommend including the EPC and the daily intake concentrations as presented in Appendix D for the 2019 fish data ingestion pathway.	These tables summarize the risk estimates. The calculated daily intake concentrations are presented in the Appendix. No change will be made.
35	PRP-Integral	Editorial	Table 3-14 has two “b” footnotes. The second “b” footnote should be updated to “c.”	This correction will be made.
36	CFC	Site Characterization	Based on data collected in 2018 and 2019, the State of Montana has issued a do-not-eat advisory for all species and all size classes of fish	There are a number of differences between how risks were evaluated in the HHRA and

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			from the Clark Fork River in the greater Missoula area. In contrast, the EPA's HHRA model suggests only very limited dangers from fish consumption, and EPA has no plans to collect additional fish tissue data. The disconnect between State and the Federal conclusions regarding the risk to human health from the Clark Fork's fishery undermines the credibility of the entire investigation and will erode public confidence in the process. We request the following actions to help resolve the disagreement and provide the people of western Montana with a better understanding of the dangers posed by the fishery: • Further fish tissue investigations to provide statistically meaningful sample sizes for determining the magnitude and geographic extent of the risks from consuming fish of all species, size classes, and ages in the Clark Fork River. • Additional fish tissue and sediment sampling to determine the downstream extent of contamination from Smurfit and with it the appropriate downstream boundary of Operable Unit 3. • Analysis of specific dioxin/furan congeners in fish that would help determine a link, if any, to the paper making processes at Smurfit. • A comprehensive investigation of coplanar PCBs across operable units and media to evaluate EPA's assertion that the Smurfit site has never been a source of the PCBs to the Clark Fork or its fishery. The PCB removal action that has already occurred at Smurfit strongly suggests that the site should be considered a source of PCBs unless there is definitive proof to the contrary. • Adoption by EPA of the State's more protective and conservative fish consumption risk modeling assumptions and parameters including dioxin cancer risks, sample composting standards, and cancer slope factors, in consultation with Montana's fish consumption advisory board.	how risks were evaluated for the fish advisory due to different agency objectives and frameworks. Nonetheless, there is general agreement of potential risks associated with the consumption of fish collected from the CFR. The risk calculations will be updated to include evaluation of cancer risks from dioxins/furans. The RI/FS will provide additional context in characterizing the potential risks identified in the HHRA. Evaluation of source attribution is outside the scope of the HHRA. Further, evaluation of nature and extent is outside of the scope of the risk assessment which focuses on evaluation of the current study area. Further evaluation of nature and extent, including source attribution, is being conducted as part of the RI. Additional data will not be collected prior to finalization of the HHRA.
37	CFC	Aerial Deposition	Much of the area upstream of the Smurfit site was subject to decades of aerial deposition from emissions at the mill site, and EPA's own research shows Kraft liner board facilities were common sources of airborne emissions of dioxins and furans. For these reasons, we ask that all reference conditions used in the ongoing investigations be located outside of Smurfit's aerial deposition zone.	Although conducting a comparison to background concentrations was included in the previous draft OU3 HHRA, upon further consideration of existing guidance it was determined that comparison with background levels should not be used to remove contaminants of concern from further evaluation owing to the need to fully characterize site risks (EPA 2002b). Comparison to background is not a toxicological rationale for eliminating COPCs from further consideration. Comparisons of

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				site concentrations to background concentrations should still be considered within the RI outside of the risk assessment to provide additional information to risk managers to better characterize the results presented in the risk assessment. EPA recently published fact sheets on aerial deposition at the site and dioxins/furans at the site (EPA 2021a, b) that will be cited in the OU3 HHRA. Available data (MDEQ 2011) indicate that dioxins and furans in soils of Missoula are typical of rural areas elsewhere in the U.S., and well below urban areas elsewhere in the U.S. (Urban et al., 2013).
38	CFC	Background Evaluation	We are concerned about the potential impacts from known pollutant sources upstream of the Smurfit site. Stimson Lumber at the confluence of the Clark Fork and Blackfoot rivers was a well-known source of PCBs to the Clark Fork, and the S&W near Darby is a known source of dioxins and furans. It is our understanding that both of these locations, like the Smurfit site, were once owned and operated by International Paper or its corporate heirs or predecessors. EPA has argued that the State's fish consumption advisory for the Clark Fork River is not related to Smurfit because it is being driven by coplanar PCBs, not dioxins, and that the PCBs did not come from Smurfit. Even if, for the sake of argument, we took this to be true, much of the additional PCB load probably came from Stimson. To count the lingering concentrations of PCBs from Stimson towards "background" concentrations at Smurfit – and by so doing obviate the need for remediation of another site operated by the same PRP – defies common sense and is antithetical to the mission of EPA. We request an analysis of the cumulative impacts of Stimson and S&W on concentrations of dioxins, furans, and PCBs in the Clark Fork and of EPA's authority under CERCLA to require action from the responsible party common to the three Superfund sites in question.	The evaluation within the OU3 HHRA is site-specific and pertains only to the Smurfit site. Although conducting a comparison to background concentrations was included in the previous draft OU3 HHRA, upon further consideration of existing guidance it was determined that comparison with background levels should not be used to remove contaminants of concern from further evaluation owing to the need to fully characterize site risks (EPA 2002b). Comparison to background is not a toxicological rationale for eliminating COPCs from further consideration. Comparisons of site concentrations to background concentrations should still be considered within the RI outside of the risk assessment to provide additional information to risk managers to better characterize the results presented in the risk assessment. Further evaluation of nature and extent, including source attribution, is being conducted as part of the RI.
39	CFC	Flooding Concerns	High flows during the spring of 2018 provided a stark reminder that berm failure at Smurfit is an inevitability given enough time. No	Risk assessment does not/cannot account for potential future catastrophic events such as

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			assessment of risks to human health and the environment at Smurfit can be complete without consideration of the scour and transport of toxic material from the site that would occur during a high flow berm failure event. We request that berm failure be added to the analysis in the BERA and HHRA.	berm failure. This is because the concentrations of environmental contaminants can only be directly measured at the time of sampling. However, the PRPs, with EPA and MDEQ oversight, conducted a berm stability study to address these concerns. This study will be cited in the HHRA. The resiliency of potential remedies are evaluated in the Feasibility Study, which is where the potential consequences of berm failure may be considered as opposed to this HHRA.
40	CFC	General	It has now been 11 years since Smurfit closed. As we enter a second decade of esoteric debate over sample sizes and detection limits, reference conditions and aerial deposition patterns, a few simple facts remain beyond dispute: 1.6 million tons of dioxin-producing bleach pulp sit in unlined, unregulated waste dumps that are in contact with groundwater that flows to the Clark Fork River. The fish of the Clark Fork River have been rendered unfit for human consumption by the very toxins that flow from these dumps, and the aquifer will be forever off limits, thanks to manganese concentrations that exceed safe levels by a factor of 500. All of it rests in the floodplain and channel migration zone of a major river, protected only by a gravel berm that is failing and will one day be washed away. Do we really need years of additional study and meetings to determine if something needs to be done? We think not. Clean the dumps, remove the berm, and restore the floodplain. That is the only way forward at Smurfit, and for this reason we reiterate our request for EPA to move to the feasibility study phase of the project, starting at the waste management area, so that we can begin to take the steps necessary to stop the flow of pollution from Smurfit into the Clark Fork River. Your colleagues working on the Columbia Falls Aluminum Company site have taken a similar approach that could serve as a potential model for how to proceed at Smurfit.	EPA is working to finalize the risk assessments for inclusion in the RI/FS. EPA intends to move forward with the RI/FS process in accordance with CERCLA guidance.
41	MDEQ	Toxicity Values	Please be aware that any compounds present above DEQ's Water Quality Standards for human health and aquatic life will need to be addressed when making risk management decisions in the future for both surface water or groundwater.	A footnote will be added to the HHRA noting that compliance with DEQ-7 standards will be considered in the remedial investigation/feasibility study (RI/FS).
43	MDEQ	Exposure Assessment	Please note that DEQ does not support risk management decisions made based on the CTE evaluation in the risk assessment.	It is standard risk assessment practice for EPA to calculate risk using both CTE and RME scenarios. Risk management decisions occur outside of risk assessment.

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44	MDEQ	Toxicity Values	Section 4.2 (Human Toxicity Values, Manganese, page 44): DEQ agrees with the use of the EPA RSL screening level of 43 ug/L for manganese. Please note DEQ and DPHHS have developed a Manganese drinking water benchmark to protect bottle fed infants and children. This benchmark was derived to protect against neurological effects during development that have been observed in animal studies and in epidemiology studies. DEQ strongly urges EPA to recognize the RfD used in the benchmark as it moves forward in the risk assessment process for Smurfit. The current EPA oral RfD values are not based on toxicology studies, but rather on nutritional reports and even with a modifying factor, were not designed to protect the most vulnerable populations against neurological impacts. For more information, please see http://deq.mt.gov/Water/DrinkingWater/Manganese for additional information.	Based on further consideration, the RfD recommended for manganese in the EPA RSL table will be used in the HHRA. This value of 0.024 mg/kg-day incorporates subtracting out the dietary contribution from the normal U.S. diet (an upper limit of 5 mg/day) when evaluating non-food exposures to manganese. This RfD is consistent with the RfD used as the basis of the recently updated MDEQ drinking water benchmark of 0.025 mg/kg-day. This change does not alter the overall risk conclusion that manganese is a risk driver in groundwater.
45	MDEQ	Cooking Loss	Section 5.0 (Risk Characterization, Non-cancer Effects, Ingestion, page 47): Cooking Loss calculation for dioxins and PCBs. The citation for the decrease in PCB/Dioxins during cooking is cited to this document, USEPA. 2000. Guidance for Assessing Chemical Contaminant Data for Use in Fish Advisories Volume 2. Risk Assessment and Fish Consumption Limits. Third Edition. EPA 823-B-00-008. Page C-7 states the following: "EPA recommends the use of dose modification factors for setting health-based intake limits only when data on local methods of preparation and their impact on contaminant concentrations are available." Please cite the reference for a reduction of 30% and 54% for Total PCB and TEQ cooking losses, respectively, and supply the state preparation methods that those cooking losses were based on as an appendix in the HHRA. In the absence of state preparation data and studies on the specific preparation method's impact on contaminant concentrations, DEQ agrees with EPA guidance that dose modification factors should not be used.	The text will be revised to include the basis for the cooking loss values used in the risk assessment. The HHRA will also be revised to first evaluate risks from fish consumption assuming no cooking loss, then estimate risks assuming cooking loss.
46	MDEQ	Site Characterization	DEQ is concerned there is a potential data gap with the exclusion of dioxin-like PCBs from TEQ calculations in all media, except fish tissue. Please explain the rationale for not sampling dioxin-like PCBs and plans to ensure dioxin-like PCBs are not site-related and are not contributing to TEQ in OU2 or OU3.	Aroclors were measured in soils and groundwater. PCB congeners were evaluated in OU2 soils based on the presence of Aroclor concentrations above levels of concern in a localized area which has undergone a removal action. PCB Aroclors have been continuously monitored in groundwater, but risks associated with Aroclors in groundwater are below a level of concern. The uncertainty section will be updated to include a discussion of the available PCB data.

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47	MDEQ	Exposure Assessment	While the analysis does not have to be included in the risk assessment, a determination regarding whether soil remediation is required cannot be made until a soil leaching to groundwater analysis is conducted. Soil concentrations should be evaluated using Part 2 of Montana DEQ's Soil Screening Flow chart to determine whether contaminant concentrations may represent a continuing or future source of groundwater contamination.	Evaluation following MDEQ's Soil Screening Flow Chart will be considered for inclusion in the RI/FS.
48	MDEQ	COPC Screen	DEQ has concerns about the process to determine COPCs for the following reasons: no consideration of risk-based water quality standards (federal or state), the use of a 5% rule with no analysis for hot spots, the statistical analyses of background and site data to determine COPCs. In some cases, there does not appear to be sufficient data to ensure we are not prematurely screening out COPCs (e.g. surface water PAHs with DLs greater than screening levels). Please clearly describe all locations where background and site data are compared and for each location, reference a table where the data is presented (including background concentrations used with a reference to the source), along with the statistical analyses.	The approach used to determine COPCs in the HHRA that does not evaluate hot spots is consistent with RAGS (EPA, 1989). Although conducting a comparison to background concentrations was included in the previous draft OU3 HHRA, upon further consideration of existing guidance it was determined that comparison with background levels should not be used to remove contaminants of concern from further evaluation owing to the need to fully characterize site risks (EPA 2002b). Comparison to background is not a toxicological rationale for eliminating COPCs from further consideration. Comparisons of site concentrations to background concentrations should still be considered within the RI outside of the risk assessment to provide additional information to risk managers to better characterize the results presented in the risk assessment.
49	MDEQ	Background Evaluation	Appendix A, Section 2.1.2.2: DEQ does not agree with the use of the bulk fraction data for the background evaluation. Fine particles are known to be readily transported, ingested, or inhaled and typically are the fraction of soil inorganics readily sorb to as well. Therefore, bulk concentrations may not accurately capture exposure concentrations. Please conduct a background evaluation using the fine fraction soil.	Although conducting a comparison to background concentrations was included in the previous draft OU3 HHRA, upon further consideration of existing guidance it was determined that comparison with background levels should not be used to remove contaminants of concern from further evaluation owing to the need to fully characterize site risks (EPA 2002b). Comparison to background is not a toxicological rationale for eliminating COPCs from further consideration. Comparisons of site concentrations to background concentrations should still be considered

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				within the RI outside of the risk assessment to provide additional information to risk managers to better characterize the results presented in the risk assessment.
50	MDEQ	Editorial	Appendix A, Section 2.1.2.1, page A-4, last sentence: Please revise the last sentence to state, “ <i>Based on communications with the MDEQ Risk Assessor, it was...</i> ” and please delete the reference to communications with Aimee Reynolds. She has retired and is no longer with MDEQ. Please incorporate this change throughout the OU2 and OU3 Risk Assessments.	This statement and any references to specific MDEQ personnel will be removed from the HHRA.
51	MDEQ	Data Evaluation	Table 3-7: Analytes with non-detections in surface water should not be reported as 1/2 DL, but rather as <the reporting limit. It is unclear if the DL column is an MDL or a RL? Please clarify.	The values shown in the DL column represent the sample-specific detection limits.
52	MDEQ	Editorial	In Section 2.1, please edit the description of OU3 on page 4 as follows: “...the holding ponds areas within the 100-year floodplain, and parts of the CFR where hazardous substances from Site activities-historical mill operations may have come to be located.” This edit reflects language in the AOC definition of OU3.	This edit will be made.
53	MDEQ	Site Characterization	Section 2.4, regarding the sentence, “ <i>There are no current residential or commercial properties within OU3.</i> ” It is DEQ’s understanding that buildings within OU3 are currently rented for commercial/industrial use. Please verify this and update the text where needed.	To EPA’s knowledge, there are no existing buildings outside of OU2. No change will be made on this basis.
54	MDEQ	Site Characterization	Section 2.6: Please include a discussion of how the data provided in the investigations listed above are appropriate to evaluate human health risks. For example, please discuss areas where fine soil fraction data was collected vs build soil sample data and each were used to evaluate human health risks.	Appendix A provides brief summaries of the site investigations conducted to date. Citations are included to the relevant references which are available on the site webpage.
55	MDEQ	Site Characterization	Page 5, section 2.5: Please list what chemicals were used in the paper process. Were fluorinated chemicals used for water resistant properties or was a fluorination process used? Were any other special processes used? Please reference the permit, ideally include it as a reference to answer the question of what analytes had permit limits and what the limits were.	The text in Section 2.5 (Basis for Potential Human Health Concern) will be expanded, and the permit will be referenced.
56	MDEQ	Exposure Assessment	Page 11, Section 3.1.3 (Hypothetical Future Commercial/Industrial Workers): Please explain if work would ever need to be done in the floodplain on levees/berms, etc. and if so, appropriate worker/construction scenarios for the floodplain should be evaluated.	The HHRA will be updated to include evaluation of the commercial/industrial worker scenario within the floodplain.
57	MDEQ	Exposure Assessment	Regarding the Recreational Visitor population: Page 6, Section 2.4, Figure 3-1 and throughout: Swimmers, floaters and rafters should be included as receptors or a description as to why they are not given. Cold and fast rivers all around Missoula are used by swimmers, floaters and	Exposure pathways for the recreational visitor population will be expanded to include exposure to Clark Fork River surface water

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			rafters in the summer; please explain what is specific to this stretch that makes it unusable for these purposes.	and sediment while swimming/tubing in the summer months.
58	MDEQ	Data Evaluation	Section 3.2.1 (Exposures to Soil): Please define the soil depths used to evaluate each receptor. Montana DEQ considers surface soil exposure occurring from 0-2 ft and subsurface soil exposure to be 2-10 ft. Please incorporate these exposure depths into the risk assessment analysis.	Surface soil samples were collected from depths of 0 to 2.4 inches, 0 to 2 inches, 1 to 2 inches, and 0 to 6 inches over multiple sampling efforts. EPA considers exposure to surface soil to occur from 0-6 inches below the ground surface. This detail (“to a depth of 6 inches”) will be added to Section 3.2.1.
59	MDEQ	Data Evaluation	Section 3.2.4 (Ingestion of Surface Water as Drinking Water): Due to the use classification of the Clark Fork River, the water must be maintained suitable for drinking and compared to DEQ-7 human health surface water standards.	A footnote will be added to the HHRA noting that compliance with DEQ-7 standards will be considered in the RI/FS.
60	MDEQ	COPC Screen	Page 18, Section 3.3.1: Please explain how you evaluated for hot spots to ensure these were not screened out using the 5% rule over a large area.	The COPC screen also evaluates whether the detection limit exceeds the risk-based screening level for contaminants that were detected in less than 5% of all samples. Hot spot identification is considered in the sampling strategy whereby discrete soil samples (5-point composites collected over a 1-m ² area) were collected under a biased sampling strategy to target areas of most concern.
61	MDEQ	COPC Screen	Page 18, Section 3.3.1, regarding the last paragraph that begins, “ <i>If the measured level of a contaminant is not statistically...</i> ”: This method results in what appears could be a high level of uncertainty and a large number of false positives, depending on data used. Particularly as TEQ for dioxin is not just one compound and determining if it is background is more complex than a simple statistical comparison (individual compound occurrence should also be examined). Please add a full description of these topics in the uncertainty section. Including a discussion on the uncertainty introduced by not analyzing for DL-PCBs.	Although conducting a comparison to background concentrations was included in the previous draft OU3 HHRA, upon further consideration of existing guidance it was determined that comparison with background levels should not be used to remove contaminants of concern from further evaluation owing to the need to fully characterize site risks (EPA 2002b). Comparison to background is not a toxicological rationale for eliminating COPCs from further consideration. Comparisons of site concentrations to background concentrations should still be considered within the RI outside of the risk assessment to provide additional information to risk managers to better characterize the results presented in the risk assessment. The

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				discussion of PCBs evaluated in OU3 will be expanded in Section 6.1.2.
62	MDEQ	Editorial	Page 18, Section 3.3.1, regarding the following highlighted phrase: <i>“If the measured level of a contaminant is not statistically (based on an alpha of 0.05, see section 3.3.4) higher...”</i> I do not see further discussion of the statistical method used in Section 3.3.4. Please check this reference.	The comparison to background concentrations will be removed from the COPC screening process whereby this section will be deleted from the HHRA.
63	MDEQ	Background Evaluation	Page 18, Section 3.3.1, last paragraph that begins, <i>“If the measured level of a contaminant is not statistically...”</i> : Please reference the areas used for each comparison to background, the data sets used and the results. DEQ typically doesn’t allow for the use of this method except in certain cases where the media is uniform and there is sufficient data. DEQ typically compares the 95 UCL directly to the 95 UCL background level and if it is higher, that compound is a COPC.	Although conducting a comparison to background concentrations was included in the previous draft OU3 HHRA, upon further consideration of existing guidance it was determined that comparison with background levels should not be used to remove contaminants of concern from further evaluation owing to the need to fully characterize site risks (EPA 2002b). Comparison to background is not a toxicological rationale for eliminating COPCs from further consideration. Comparisons of site concentrations to background concentrations should still be considered within the RI outside of the risk assessment to provide additional information to risk managers to better characterize the results presented in the risk assessment.
64	MDEQ	Background Evaluation	Last paragraph of Section 3.3.1 on page 19: <i>“In summary, a contaminant is identified as a COPC if the maximum detected concentration exceeds an available RBC, and Site concentrations for that contaminant are significantly higher than background concentrations.”</i> Please be more specific, do you mean “site concentrations within specific, uniform media” for that contaminant are significantly higher...?	The comparison to background concentrations will be removed from the COPC screening process. As such, the highlighted sentence will be revised as follows: <i>“In summary, a contaminant is identified as a COPC if the maximum detected concentration in the medium being evaluated (e.g., groundwater, soil, fish) exceeds an available RBC.”</i>
65	MDEQ	COPC Screen	Section 3.3.2: Please include a sentence in this section indicating whether or not soil data is based on the fine or bulk fraction or both. If both were used, please indicate either in this section or a table, which soil samples represent the bulk fraction and which soil samples represent fine fraction.	A sentence will be added noting that soil data are based on the bulk fraction.
66	MDEQ	Data Evaluation	Page 20, Section 3.3.2 (Data Considerations): Please explain why data was only available for DL-PCB in fish tissue and if this is considered a data gap in the risk assessment. From the fish tissue results, it appears	It is EPA’s understanding that PCBs were not utilized in the main mill operations. Nonetheless, PCBs were included in the initial

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			the DL-PCBs could be site related. Therefore DL-PCBs should be evaluated, starting with soil samples from EU grid 74 and sediment.	site investigation studies. Aroclors have been measured in soil, groundwater, sediment and surface water. Aroclors were only detected in soils at a level of concern in isolated locations in OU2. PCB fish tissue data was necessary to address uncertainty in risk estimates for humans consuming fish caught from the Clark Fork River. Past fish sampling data was limited and lacked a comparable background and was therefore insufficient for EPA risk assessors to fully understand site-related risks to human health and ecological receptors. The uncertainty section will be revised to expand the uncertainties associated with the PCB dataset.
67	MDEQ	COPC Screen	Section 3.3.3 (Source of Risk-Based Screening Level Values): The Montana DEQ-7 Water Quality Standards for surface water and groundwater must also be used to identify compounds present above state standards. Please include this as a source and please include a comparison of surface and groundwater data to state standards.	A footnote will be added to the HHRA noting that compliance with DEQ-7 standards will be considered in the RI/FS.
68	MDEQ	COPC Screen	Section 3.3.3 (Source of Risk-Based Screening Level Values): Please discuss EPA's RSLs were also the source for screening sediment data collected at the site.	Text will be added clarifying the basis for the RSLs used to screen sediment data. RSLs will be derived based on the most conservative recreational scenario evaluated in the HHRA.
69	MDEQ	COPC Screen	Section 3.3.3 (Source of Risk-Based Screening Level Values): NRWQC for human health should also be cited as a screening level.	Text will be added clarifying the basis for the RSLs used to screen sediment data. RSLs will be derived based on the most conservative recreational scenario evaluated in the HHRA.
70	MDEQ	Editorial	Section 3.3.6, Risk-based Screen: The COPCs listed in the tabs do not match the compounds marked as COPCs in the corresponding tables. DEQ believes this is due to the background comparison provided in the tables however, DEQ suggests clarifying this discrepancy in the text to avoid confusion.	This will be clarified and updated, with the removal of the background screening analysis from the risk assessment.
71	MDEQ	COPC Screen	Table 3-20, Table 3-21, & Table 3-23: The RSL for TEQ using EPA's HQ 0.1 screening table is 4.8E-6. Table 3-20 is using the higher, non-cancer value of 5.1E-6 as a screening value. For the purposes of the COPC screening process, please update this table to reflect the screening value presented in EPA's HQ 0.1 Summary RSL table.	As dioxin/furans will be evaluated for cancer risk in the revised HHRA, the soil RSL for TEQ (TCDD) will be updated to 4.8E-06.
72	MDEQ	COPC Screen	Table 3-22: The Tapwater RSL for TEQ using EPA's HQ 0.1 Summary screening table is 1.2E-7. Table 3-22 is using the higher, non-cancer value of 1.2E-6 as a screening value. For the purposes of the COPC	As dioxin/furans will be evaluated for cancer risk in the revised HHRA, the tapwater RSL for TEQ (TCDD) will be updated to 1.2E-07.

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			screening process, please update this table to reflect the screening value presented in EPA's HQ 0.1 Summary RSL table.	
73	MDEQ	COPC Screen	Table 3-24: Please describe how surface water samples were compared to background. Table 3-24: Please explain why PCBs (the aroclors listed and dioxin like PCBs) were not analyzed for in surface water samples. Table 3-24: As commented in the text of the HHRA, compounds should also be compared to DEQ-7 and NRWQC to determine the lowest screening level, not just to EPA RSLs.	Although conducting a comparison to background concentrations was included in the previous draft OU3 HHRA, upon further consideration of existing guidance it was determined that comparison with background levels should not be used to remove contaminants of concern from further evaluation owing to the need to fully characterize site risks (EPA 2002b). Comparison to background is not a toxicological rationale for eliminating COPCs from further consideration. Comparisons of site concentrations to background concentrations should still be considered within the RI outside of the risk assessment to provide additional information to risk managers to better characterize the results presented in the risk assessment. EPA's PCB fact sheet will be cited in the HHRA. A footnote will be added to the HHRA noting that compliance with DEQ-7 standards will be considered in the RI/FS.
74	MDEQ	Exposure Assessment	Section 3.4.3 (Exposure Areas): Please include a figure showing the exposure areas as well as a figure showing the data used to evaluate exposure in each area.	Soil exposure areas are the sampling grids shown in Figures 3-4 through 3-6. These figures show the sample locations overlain on the grids (exposure areas).
75	MDEQ	Exposure Assessment	Section 3.4.3, Exposure Areas, Soil, Upland: Residential lot size should be determined using local land lot sizes and zoning restrictions and residential exposure should be considered within the smaller lot size to avoid averaging out areas of higher potential risk. Please include a discussion of the surrounding area lot sizes and zoning allowances to show the evaluation of residential exposure over 20 acres is protective of future residential use.	Soil exposure areas were determined based on the grids used for composite sampling. As noted in the Remedial Investigation Work Plan (RIWP) Addendum 7, the 20-acre grids represented the maximum spatial extent to be considered representative of the area within which a hypothetical future resident or commercial worker could be exposed. The uncertainty section will include language noting that the risk estimates presented in the

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				HHRA are not necessarily representative of smaller lot sizes.
76	MDEQ	Exposure Point Concentrations	Section 3.4.4 (Exposure Point Concentrations, Groundwater): Groundwater standards in DEQ-7 are composed of duration, frequency and magnitude. The duration is instantaneous and the frequency is not to exceed. Therefore, EPCs are not allowed to determine compliance with DEQ-7, the samples must be compared on a point-by-point basis. Use the maximum concentration from each well.	Groundwater risks were evaluated well-by-well using an EPC determined using standard EPA guidance: if the number of samples from the well was adequate, a 95UCL was calculated using ProUCL. This approach provides a protective estimate of potential chronic exposures to the human health receptors of concern and is consistent with risk assessment guidance. If the sample size from a well was too small, the maximum detected concentration was used as the EPC for that well. Compliance of groundwater with DEQ-7 standards will be discussed outside of the risk assessment process in the RI/FS.
77	MDEQ	Toxicity Values	Section 4.2 (Human Toxicity Values, Dioxin): Regarding the sentence, “No Tier 1 cancer toxicity criteria are available for TCDD.” The EPA provides carcinogenic toxicity data in the RSL tables. Please include a discussion of this and EPA’s determination on when the use of this toxicity data is appropriate. Please also provide a reference for this discussion.	In the revised OU3 HHRA, cancer risk will be evaluated for dioxins/furans using the CSF for 2,3,7,8-TCDD (from CalEPA) shown in Table 4-1.
78	MDEQ	Toxicity Values	Section 4.2 (Human Toxicity Values, Dioxin): Please note DEQ has a target cancer risk level of 1x10E-05, which may not be attained by using the IRIS RfD.	The revised OU3 HHRA will evaluate cancer risks using the CalEPA 2,3,7,8-TCDD CSF in addition to noncancer hazard using the IRIS RfD. The text will clarify that Montana DEQ uses 1E-05 to be their benchmark for cancer risk,
79	MDEQ	Risk Characterization	Section 5.0 (Risk Characterization, Cancer Effects, page 43): In the absence of calculated cancer risks, DEQ cannot determine compliance with state risk levels. Please evaluate the cancer risks for a complete evaluation of the exposure risks to dioxins. Consider using ATSDR’s CSF or Cal EPAs number.	In the revised OU3 HHRA, cancer risk will be evaluated for dioxins/furans using the CSF for 2,3,7,8-TCDD (from CalEPA) shown in Table 4-1.
80	MDEQ	Cancer risk benchmark	Regarding the cancer risk benchmark of 1E-04 in Section 5.1: Montana DEQ considers anything above 1E-5 an unacceptable risk. Please include this in the risk evaluation and bold, or highlight, cancer risks exceeding this threshold.	The text will clarify that Montana DEQ uses 1E-05 to be their benchmark for cancer risk. In the risk characterization tables (eg. Table 5-4), cancer risk results are currently shaded to note whether they exceed 1E-04 or 1E-05.
81	MDEQ	Risk Characterization	Section 5.1 (Risks from Exposures to COPCs in OU3 Soils): Language under “Cancer Effects,” above, states that COPCs in OU3 soils are considered non-carcinogenic. This is understood to mean that	In the revised OU3 HHRA, cancer risk will be evaluated for dioxins/furans using the CSF for 2,3,7,8-TCDD (from CalEPA) shown in Table

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			carcinogenic risks were not calculated for the COPCS in the OU3 Soils; however, Section 5.3 is discussing the results of both cancer and non-cancer risks. Please clarify this and provide the results of the carcinogenic risk calculations in a table for review.	4-1. Relevant text and tables will be updated accordingly.
82	MDEQ	Risk Characterization	Section 5.1 (Risks from Exposures to COPCs in OU3 Soils): Section 3.4.3 indicates that OU3 upland soils and OU3 Floodplain soils were evaluated as two separate exposure areas. Please clarify which exposure area Section 1.3 is referring to. Please also include the results of both the Upland Soils exposure area and the Flood plain soils exposure area.	There is no Section 1.3 in the HHRA. Section 5.1 discusses risks to OU3 upland and floodplain soils under the sub headers for each exposure population. For clarity, the title of Section 5.1 will be changed to, “Risks from Exposures to COPCs in OU3 Upland and Floodplain Soils.”
83	MDEQ	Risk Characterization	Section 5.1 (Risks from Exposures to COPCs in OU3 Soils, Workers): Regarding the highlighted phrase in the sentence, “ <i>Non-cancer hazards and cancer risks to hypothetical future commercial/industrial workers and hypothetical future construction workers within the OU3 upland area from incidental ingestion of and dermal contact with upland soils appear to be within usual USEPA guidelines for all EUs.</i> ” Please clarify what is meant by “appear” and provide a clear discussion of whether or not HQs were above 1. Also, please define “usual USEPA guidelines;” it is unclear what this is referring to.	This language will be updated to clearly state whether or not non-cancer hazards were above 1 and whether or not cancer risks were above the acceptable cancer risk range used by CERCLA of 1E-04.
84	MDEQ	Risk Characterization	Section 5.1 (Risks from Exposures to COPCs in OU3 Soils, Recreational Visitors): Please clarify what is meant by “appear” and provide a clear discussion of whether or not HQs were above 1. Also, please define “usual USEPA guidelines;” is this referring to the threshold of HQ being less than or equal to 1? Or is this referring to EPA’s cancer risk range?	This language will be updated to clearly state whether or not non-cancer hazards were above 1 and whether or not cancer risks were above the acceptable cancer risk range used by CERCLA of 1E-04.
85	MDEQ	Risk Characterization	Section 5.2 (Risks from Exposures to COPCs in OU3 Groundwater Wells): Please note, DEQ evaluates risk to groundwater based on a comparison of groundwater data, on a point-by-point basis to Montana’s DEQ-7 Water Quality Standards. Compounds in groundwater with concentrations above DEQ-7 standards but not determined to be risk by EPA must still be carried forward as a COC for the site.	A footnote will be added to the HHRA noting that DEQ-7 standards will be considered separately in the RI/FS.
86	MDEQ	Risk Characterization	Section 5.4 (Risks from Fish Ingestion, Recreational Fishers): Regarding the last sentence of the first paragraph (“ <i>Non-cancer HQs for the CTE recreational fisher are all below 1E+00.</i> ”), please state what meals per month this equates to. A CTE recreational fisher equates to 1.6- 8 oz. meals per month.	Fish risks were evaluated using fish consumption rates in units of grams/day. The exposure parameter tables will be updated to note what meals per month they equate to.
87	MDEQ	Risk Characterization	Section 5.4 (Risks from Fish Ingestion, Recreational Fishers): Regarding this sentence in the second paragraph (“ <i>However, the cancer risk for an RME recreational visitor consuming northern pike collected from the CFR does exceed the MDEQ criteria of 1E-05 (cancer risk = 3E-05).</i> ”	Throughout the text, the nomenclature for discussing TEQ in fish tissues will be updated as TEQ _{D/F} (dioxins and furans), TEQ _{PCB} , TEQ _{D/F/PCB} to provide increased clarity.

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			The way this statement reads is confusing. Please clarify if this is referring to cancer risks from PCBs only, not from Dioxins, which DEQ would also calculate. Please specify in the text what this is referring to.	
88	MDEQ	Editorial	Section 6.2.1 (Uncertainties in Toxicity Values): Please reference the following statement: <i>“Because of the conservative methods USEPA uses in dealing with these uncertainties, it is much more likely that the uncertainty will result in an overestimation rather than an underestimation of risk.”</i>	The following reference will be added to this sentence: EPA. 2014. Framework for human health risk assessment to inform decision making. EPA100R14001.
89	MDEQ	Editorial	Section 6.2.1 (Uncertainties in Toxicity Values): Please reference the following statement: <i>“However, data on the neurotoxicity of orally ingested manganese at relatively low doses are less consistent, albeit suggestive.”</i>	The IRIS chemical assessment summary for manganese will be cited here.
90	MDEQ	Editorial	Section 6.2.1 (Uncertainties in Toxicity Values): Please reference the following statement: <i>“Because of the conservativeness of the oral RfD for manganese, it is likely that uncertainty associated with this toxicity value will result in an overestimation rather than an underestimation of risk.”</i>	The IRIS chemical assessment summary for manganese will be cited here.
91	WQAC	Site Characterization	The data upon which the risk assessment has been made are insufficient. Problems include: a. too few samples to adequately characterize risks on and beyond the site and no recent samples in important areas such as the 140 acres of sludge ponds. b. combining samples together, which has the effect of losing important detail associated with the site given that contamination is not evenly distributed. c. need for additional dioxin testing of groundwater and surface water of the Clark Fork using high-volume sampling for dioxin-like PCBs that have detection limits above the risk-based levels. The lack of site and river sampling is hiding the potential connection of the site to the river, which limits the geographical extent of the “facility.” CERCLA’s definition of a facility is “any site or area where a hazardous substance has been deposited, stored, disposed of, placed, or otherwise come to be located,” so this type of testing is important for defining the facility site boundary to inform site remediation. For reference, we include text from WQAC letter sent to Sara Sparks and Keith Large on July 9, 2018: The WQAC discussed the May 23, 2018 Water Sample Results (Dioxin/Furans) Former Smurfit Stone/Frenchtown Mill Site at our June meeting. It was clear from looking at the results that the detection limits and reporting limits of the	Composite sampling reduces data variability and provides a reasonably unbiased estimate of mean contaminant concentrations in a specified decision unit (ITRC 2021). Groundwater monitoring has been ongoing and will continue, but additional data collection efforts to support the risk assessments are not planned at this time. Uncertainties associated with the available database are described in the uncertainty assessment. EPA has noted the recommendation for using the high-volume water sampling method but has sufficient data to complete the risk assessment. .

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			analytical method are not useful for resolving concentrations of dioxin near surface water standards. We understand this is a common situation at dioxin contaminated sites in the nation, because the standard method (EPA 8290) commonly results in detection limits of 1 pg/L at best, whereas surface water standards are 200 times or more below this detectable concentration. The human health standard for dioxin is very low, 0.005 pg/L, owing to its incredible high bioaccumulation and toxicity when accumulated in fish tissue. Dioxin is extremely expensive to sample for and we do not believe additional sampling at using the past method is likely to provide useful information about the contaminants at the Smurfit site or Clark Fork River water quality. Newer dioxin sampling methods are able to detect the presence of dioxin in surface water at lower concentrations. The Ohio River Valley Water Sanitation Commission (ORSANCO) uses a high-volume water sampling method to obtain detection limits and reporting limits 1000 times lower than the sampling method currently being used (DL below 0.001 pg/L (parts per quadrillion, ppq) for dioxin). This actually resolves pollution at and near the level of Montana DEQ-7 human health surface water of 0.005 pg/L. I (Ian Magruder, Chair of the WQAC) have personally talked with Sam Dinkins at ORSANCO who described their use of the method. He reports it has been useful for them to characterize ambient dioxin concentrations in the Ohio River at very low levels. The WQAC believes that using this method may help to resolve lingering questions about dioxin impacts to the Clark Fork from Smurfit. Given the expense of sampling dioxin we believe it would be more worthwhile to collect fewer samples using the high-volume method which provides meaningful results, than the current sampling plan which does not add much to site characterization.	
92	WQAC	Flooding Concerns	The assessment fails to include the scope of risks known to have the potential to affect the site and surrounding environment. Examples include risks associated with channel avulsion and berm failure.	Risk assessment does not/cannot account for potential future catastrophic events such as berm failure. However, the PRPs, with EPA and MDEQ oversight, conducted a berm stability study to address these concerns. Reference: https://semspub.epa.gov/work/08/1900526.pdf
93	WQAC	Site Characterization	The risk characterization in the documents we comment on here represent a gross under-sampling of the area and (given how data were combined) do not sufficiently identify hot spots or the extent of contamination (facility boundary). Consequently, the assessment very likely represents a lower level of risks than what actually exist. Further,	Soil sampling conducted to date adequately characterizes surface soil conditions at the site for risk assessment purposes. Composite sampling reduces data variability and provides a reasonably unbiased estimate of mean

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			the document completely omits potential known risks such as channel avulsion and berm failure. We believe that understanding of the site is therefore still subject to an unacceptably high level of uncertainty.	contaminant concentrations in a specified decision unit (ITRC 2021). Risk assessment does not/cannot account for potential future catastrophic events such as berm failure or river channel migration. However, the PRPs, with EPA and MDEQ oversight, conducted a berm stability study to address these concerns. Reference: https://semspub.epa.gov/work/08/1900526.pdf
94	WQAC	Future Use	Population growth trends in Missoula County indicate that this prime area of land will be subjected to development pressure in the future. Such development is a question of when, not if. Future development of the site dictates that the cleanup must be done right. This is not a problem that we can effectively bury under a layer of clean fill, pretending that it has gone away. The failure to adequately identify risks has the potential to affect the implementation and outcome of the entire Superfund process. Again, this needs to be done right now so that Missoula County and our watershed neighbors can be assured that the plans for remediation that are developed and implemented will adequately address the contamination associated with the site and lead to a solution that will protect the Clark Fork River, groundwater, land and soils, and plants and animals (including humans) living in and visiting this area, with some people depending on this area for subsistence. More details concerning what needs to be done to get this risk assessment right are provided by our colleagues from the Missoula Water Quality District, the Clark Fork Coalition, and the Frenchtown Smurfit Stone Community Advisory Group. We refer to the comments submitted by these groups to support the Missoula Water Quality Advisory Council's assertion that the risk assessment to date is insufficient, and that further work needs to be done to assure that the risk characterization is adequate to support a robust cleanup of the area.	Given that OU3 is currently undeveloped, residents, industrial/commercial workers, and construction workers were considered as hypothetical future populations. Their evaluation, and the risks characterized, account for the potential for development of the OU3 site in the future. EPA has addressed the Clark Fork Coalition, Frenchtown Community Advisory Group and Missoula Water Quality District comments submitted on the OU3 HHRA in this RTC table.
95	MVWQD	Conceptual Site Model (CSM)	Conceptual Site Models (site-wide, groundwater and air) need further development before finalizing risk assessments. Risk cannot be adequately assessed, nor pathways fully understood, until a sitewide CSM is complete, including an understanding of aerial deposition. We believe the comments that have been submitted regarding the Groundwater CSM should be addressed prior to evaluation of the risk assessments. We are fundamentally concerned that, because we don't understand the idiosyncrasies of the contaminant pathways that the risk assessments	The CSM presented in the HHRA is specific to identifying potential human receptors within OU3 and associated complete exposure pathways. This objective differs from the fate and transport CSMs being developed in other site documents. EPA recently published an aerial deposition fact sheet (EPA 2021a), which will be cited in the HHRA. In addition, the groundwater CSM (NewFields 2020) is

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			may be missing COPCs and evaluation of the most-contaminated areas (that would still be routes of exposure). Specifically: • Heterogeneity in well logs provides evidence of preferential flow paths not incorporated in any CSMs. • Background levels for metals within the Missoula aquifer are lower than those used in Smurfit Stone Assessments. Studies indicate highly variable interaction between groundwater and surface water. Variable water levels will drive changes in groundwater pathways and need to be accounted for.	currently being revised and will be cited in the HHRA as well.
96	MVWQD	Flooding Concerns	River channel migration is a risk that warrants assessment. Smurfit Stone berms impede natural river function by constricting movement of the Clark Fork River. Side channels that were active in 1955 can be identified aerially. These antecedent channels are indication of areas where there is likely preferential flow common to alluvial deposition. These preferential flows present risk of undermining of the berm through winnowing. Ten repairs between 1974 and 2007 were identified in the Missoula Conservation District 310 permit records. While most of the repairs involved adding significant armor to the bank, some of these repairs were not directly related to flood damage but rather animal burrows resulting in partial berm failure, or barbs to redirect the river's energy away from the berm that were causing erosion at normal flow. Flood analyses do not take into account the impact that ice jams, frequent on the Clark Fork River, may have in damaging the berms. Failure of internal berms, which have not been evaluated recently, and do not require permitting, could lead to increased risk of river avulsion and unpredictable erosion of sludge ponds, dumps, and contaminated soils. Considering the likelihood of channel migration, current constriction of the river, previous examples of berm failure unrelated to high flows, and highly variable state of berm maintenance, we believe the risk assessments to be inadequate by not addressing the risk of avulsion and channel migration.	Risk assessment does not/cannot account for potential future catastrophic events such as berm failure. This is because the concentrations of environmental contaminants can only be directly measured at the time of sampling. However, the PRPs, with EPA and MDEQ oversight, conducted a berm stability study to address these concerns. This study will be cited in the HHRA. The resiliency of potential remedies is evaluated in the Feasibility Study, which is where the potential consequences of berm failure will may be addressed considered as opposed to this HHRA.
97	MVWQD	Data Evaluation	Percent of fine sediments (% Fines) need to be accounted for and normalized when assessing metals and dioxin concentrations. Dioxins and heavy metals sorb to fine materials more than larger grain sediments. The surface area of smaller particles also results in greater concentrations of contaminants by volume. Fines percentages and effect on samples were not discussed in analysis of the 2016 Clark Fork River sampling or 2017 soil sampling. Nor is percent fines data readily available through SCRIBE. Fine sediment is where contaminants are most likely to be found and therefore should be targeted to identify levels of contamination across geographic areas – otherwise comparison	As noted in the RI Work Plan Addendums 7 and 9, soil and sediment samples were submitted for particle size analysis to provide preliminary information about the physical properties and type of material present where contaminants were detected. For the purposes of the OU3 HHRA, all sediment and soil samples were collected and prepped consistently in accordance with the RI Work Plan to ensure comparability. Sampling was

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			is not valid. This is commonly understood science that should have been incorporated into sampling design and quality control thresholds. Initial review of data from the 2016 Clark Fork River sediment sampling shows the samples that had the most fines also tended to have the highest TEQ values. There is also a linear relationship between fines and aluminum (graph included in original comment letter). Inclusion of the holding pond data results in more variability, likely due to the range of 93% to 3.4% fines. It is likely more contaminants of concern would have been found in sampling if fines were targeted. Within the Clark Fork River, samples cannot be compared to understand upstream, site, and downstream levels of contaminants without further standardization by further sampling of fines. Data is insufficient to determine whether there are risks in either the BERA or HHRA until adequate fine sediment sampling can occur. 2017 soil sampling data includes surface soil samples and subsurface soil samples. The subsurface samples range in fines from 97% to 0.4% fines. Surface samples range from 87% to 3.7%. This range of variability means that contaminant results from data cannot be compared. Given the toxicity of even the tiniest amount of TEQ, data cannot be normalized to account for this degree of variability. Although it was stated in a presentation regarding the BERA and HHRA that samples were reflective of environments on the site, variability does not reflect onsite use. The primary use for OU3 was for fines to settle in order to meet permit requirements. Fines variability of this degree is likely a function of sampling rather than site characteristics. Further review of data is necessary to determine what data can be compared and is reflective of contaminants on site. Without this analysis, much of the data used within the BERA and HHRA is misleading.	conducted consistent with EPA (2007). The uncertainty section will be updated to include discussion of the uncertainties associated with evaluating risks to humans based on bulk soil samples.
98	MVWQD	Site Characterization	Smurfit-Stone Facility Boundary. CERCLA's definition of a facility is "any site or area where a hazardous substance has been deposited, stored, disposed of, or placed, or otherwise come to be located." As more data is collected onsite, it is becoming clear that barriers are not in place to prevent groundwater and surface water interactions or to prevent flood waters from impacting the site and carrying contaminants downstream. The release and contamination of soils and water by pulp and paper mills has been well-documented by the EPA. Specifically, manganese is credited as the metal with the highest toxic-weighted pound equivalents (TWPE) reported by the Toxics Release Inventory (TRI) database for mills (EPA, 2006). Given that high levels of manganese have been detected in groundwater onsite, and at least four	Manganese is evaluated as a COPC in groundwater in the HHRA. Groundwater monitoring has been ongoing and will continue as part of the RI/FS. No additional sampling is planned by EPA prior to finalization of the HHRA. Further evaluation of nature and extent will occur in the RI/FS.

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			samples adjacent to or downstream of the site exceed the chronic toxicity benchmark for manganese, does the EPA believe that this contaminant is migrating offsite? If so, what are the next steps to further sample the Clark Fork River for manganese and other contaminants and assess risk?	
99	MVWQD	Sampling Design	Overall, the risk assessments need improved spatial representation of soils in both operable units. Risk assessments inform risk management decisions. We fear that inadequate sampling now will underestimate risk and carry through to the feasibility study. We disagree with taking composite samples in exposure units being represented as a 20-acre grid for upland in OU3 and 100-acre grid for the OU3 floodplain. If these areas were comprised of homogenous strata and no knowledge of potential historic use differences existed between them, then it would be a more appropriate sampling design. However, at Smurfit, even within an exposure unit, the historic uses vary. Within each type of historic use, the waste types and stratification vary. Within a single grid there could be 10 ft deep solid waste dumps, settling ponds, aeration basins, conveyances, sludge impoundments, etc. If the goal of the sampling method is to identify hot spots or delineate extent of plumes, compositing on a heterogenous site and media is not appropriate when other sampling methods exist. One such method would involve dividing the site by strata (waste layers, use types, etc.), taking grid or random samples of those strata, and then employing an adaptive cluster method, would provide more meaningful insight. When a sample comes back elevated or a new contaminant is identified, this method allows those “hot spots” to be mapped as adjacent samples are taken instead of losing the spatial information and variability in the data common with compositing large areas. Unfortunately, in the HHRA (Exposure Pathways of Chief Concern, 3.2), upland areas of OU3 and floodplain were not sampled this way. The small number of overall samples, (2014 (1-10 ft, n = 12), 2014 floodplain (5.5 - 6 feet, n=2), 2015 (0-12 feet, n = 26), and 2017 discrete 24”-30”) and inconsistency in depth and type (composite vs. discrete) renders this data set preliminary given the large geographical area sampled. Risks to construction workers was then evaluated by combining data for both surface and subsurface soils into a single dataset. We made similar comments on sampling inadequacies in OU3 in 2018 and are unaware of any new samples being taken since then. We feel the current assessment has not sufficiently characterized the soil hazards to future residents and continue to request additional sampling of OU3 including the sludge ponds, landfills, and holding ponds.	The random grid sampling captures the possibility that a receptor will likely be exposed to soils that are not delineated based on historic site uses. The composite grid sampling best represents potential exposure concentrations that a receptor may be exposed to chronically within a given exposure area. In addition, biased sampling was conducted based on site knowledge to identify areas of highest environmental concern (i.e., potential hot spot areas). These samples were collected from individual historical storage ponds and cells throughout the entire treatment chain. However, the objective of the risk assessment is to characterize the potential concentration that a receptor is exposed to over the exposure period, as opposed to evaluating a maximum concentration that could be contacted at any one time.

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100	MVWQD	Background Evaluation	Section 3.3.3.2 Results of the Background Comparisons – Sediment, HHRA 3.3.5, 3.1.2 Updated Sediment Screen, Fig 3.2. Bleaching pulp creates specific substituted CDDs and CDFs. In the 1980s in response to a lawsuit to regulate dioxins, the EPA tested wastewater and sludge from 104 mills that bleached pulp. No mills were free of dioxins and furans and these contaminants were highest in the sludges of bleached kraft pulp mills (EPA, 1990). As a result of this study and analysis of effluent and sludge from kraft pulp mills since then, the EPA has identified congeners and developed default emissions factors for these congeners deemed to be representative of the pulp wastewater and sludge categories (EPA, 2019b). The Smurfit-Stone mill produced bleached pulp and paper from 1960 through 1999. It was estimated that mill operations discharged an average of 4.8 million gallons of wastewater from the bleach plant and generated 54 tons of sludge each day. Sludge at Smurfit was pumped from the clarifier into four sludge ponds numbered 3, 4, 5, and 17. An elevated risk to residents exist for TEQ in surface soils in P17. But a clarifier wasn't built until 1969 so in earlier years this sludge was part of wastewater and wastewater ponds as well. As described in the initial site investigation in 2011, Tables 3-1 to 3-11 of the BERA, HHRA, Table 3-3 of HHRA, dioxins are COPECs onsite have been detected in OU2 and OU3 soils, floodplain soils, pond sediment, pond water, and deeper soils. More sampling is needed in areas shown to have high levels in the BERA and HHRA, namely sludge ponds (P3, P4, P5, P17) to assess the potential risk to receptors exposed to downstream surface water and sediment as these sediments and soils leave the site.	Although conducting a comparison to background concentrations was included in the previous draft OU3 HHRA, upon further consideration of existing guidance it was determined that comparison with background levels should not be used to remove contaminants of concern from further evaluation owing to the need to fully characterize site risks (EPA 2002b). Comparison to background is not a toxicological rationale for eliminating COPCs from further consideration. Comparisons of site concentrations to background concentrations should still be considered within the RI outside of the risk assessment to provide additional information to risk managers to better characterize the results presented in the risk assessment.
101	MVWQD	Conceptual Site Model	Landfill cells and sludge ponds should be evaluated as independent exposure units for human health and ecological risk. The BERA states that “the USEPA has developed this BERA to quantitatively describe the potential excess ecological risk posed by the Site in the absence of remediation”. The BERA also identifies the leaching of contaminants into groundwater and migration of contaminants from groundwater to soils, sediment, and surface as important “Fate and Transport” mechanisms for the site. In Section 3.1.1 Primary Sources of Contamination of the draft HHRA the historic use of OU3 for “storage of wastewater and solid wastes” is identified as the “primary source of contamination” of OU3 soils. It is therefore surprising that the largest repository of waste on the site, namely the buried sludge and waste, amounting to 91 acres of sludge ponds that received an estimated 20,000 tons of sludge per year, and 47 acres of other solid waste dump sites, are	The CSM shown in the HHRA is intended to highlight the complete exposure pathways from potentially contaminated media present at the site owing to site operations or waste disposal activities. The groundwater CSM (NewFields 2020) will be cited in the HHRA as well. Discrete samples (5-point composites collected over a 1-m² area) were collected under a biased sampling strategy to target areas of most concern. EPA is not currently recommending additional soil sampling to support the risk assessments.

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			omitted as a source of direct contamination of soil in the CSM. Groundwater data is sparse in characterizing the groundwater under individual sludge ponds and landfill cells.	Documentation regarding the waste management area (WMA) is located in DEQ, EPA and Missoula County files; the site was regulated beginning in the early 1980s. The PA/SI (and the appendices) conducted by EPA in 2011/2012 references documents about the older materials generated during operation including concentrations and quantities. Additional work to better understand the WMA conducted during EPA's PA/SI work effort included soil borings within the WMA. The groundwater sampling data collected at the site are being used to evaluate this potential transport pathway within the RI.
102	MVWQD	COPC Screen	In the last version of RA, the District commented that Cd should have been a COPC for groundwater due to elevated levels found in SMW--15 (6.1 on 7/10/17, 2.5 ug/L on 12/15/17, and 1.6 ug/L on 4/16/14. The District maintains Cd should be considered as a COPC because use of individual wells within this OU is possible. It is likely Cd is higher elsewhere on site, if sourced in sludge ponds and dumps.	The HHRA will be updated to include evaluation of all groundwater wells within OU3 including the floodplain. Based on this change, the maximum detected concentration of cadmium exceeds the risk-based screening level and cadmium is retained as a groundwater COPC and will be evaluated in the updated risk characterization.
103	MVWQD	Toxicity Values	The EPA established a policy in 1995 (and reaffirmed in 2013 and 2018) to consider risks to infants and children “consistently and explicitly as a part of risk assessments.” We support this policy and recognize that exposures can affect infants and children differently as a result of many factors including ingestion rates, gene-expression, biochemical and physiological function, toxicokinetic and toxicodynamic differences, and immune status. However, this policy does not appear to have been applied in the OU3 toxicity assessment for groundwater exposures to manganese. The toxicity value used in this risk assessment for Mn, based on a total dietary intake of 10 mg/day and a modifying factor of 3 is 0.047 mg/kg/day. However, the recommendation from the author of the IRIS assessment for manganese is to subtract an upper limit of 5 mg/day when evaluating non-food (e.g., drinking water or soil) exposures to manganese, leading to a RfD of 0.024 mg/kg-day”. One of the most important uncertainties and rationales for this lower RfD is based on recent peer-reviewed scientific studies indicating that infants absorb, excrete, and regulate this nutrient differently than adults. There	Based on further consideration, the RfD recommended for manganese in the EPA RSL table will be used in the HHRA. This value of 0.024 mg/kg-day incorporates subtracting out the dietary contribution from the normal U.S. diet (an upper limit of 5 mg/day) when evaluating non-food exposures to manganese. This RfD is consistent with the RfD used as the basis of the recently updated MDEQ drinking water benchmark of 0.025 mg/kg-day. This change does not alter the overall risk conclusion that manganese is a risk driver in groundwater. Risks to children were evaluated using standard EPA risk assessment methodology and guidance.

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			is evidence now that low levels of Mn in drinking water is associated with neurocognitive and neurobehavioral deficits in infants and children including lowered IQ, hyperactivity, memory deficits, and Parkinsonian-like symptoms. This recommended RfD of 0.024 mg/kg-day is also consistent with what Montana DEQ proposed when considering a Mn drinking water standard for DEQ7 in 2018 (0.025 mg/kg-day). The District requests that HQ calculations take into account Mn exposures in groundwater with the more current and protective RfD of 0.024 mg/kg-day. Additionally, we request that all other applicable RBC comparisons and RfD calculations incorporate exposures and risks to infants and children consistent with EPA's Policy on Evaluating Health Risks to Children.	
104	MVWQD	Future Use	In Section 2.4: The statement "Missoula County does not allow new building development within the 100-year floodplain" is incorrect. Though not preferred, with proper design and conditions, residential development is allowable within 100-year floodplain.	The text will be updated to state that building within the floodplain is not preferred. The HHRA will be updated to evaluate the residential and commercial/industrial scenarios within the floodplain also.
105	MVWQD	Conceptual Site Model	Section 3.1 and Figure 3-1: This flow-chart and section do not depict residential/commercial exposure to groundwater in OU3 floodplain groundwater. This pathway should be indicated as complete and evaluated quantitatively. Additionally, surface and subsurface soil should be evaluated with pertinent receptors according to all land uses permitted by local jurisdiction.	Exposure to groundwater in the floodplain was not considered a complete pathway due to building limitations within the floodplain. However, based on further consideration, this evaluation will be added in to the HHRA to account for the potential of any future landowner to build a well within the floodplain.
106	MVWQD	Background Evaluation	Section 3.3.5: OU2 and OU3 soil concentrations of dioxins and furans onsite were compared to both the urban and rural TEQ background soil levels established by the state of Montana DEQ (Table 3-13 and Tables 3-1 to 3-3). However, it is unclear which of these background values was used in determination of TEQ as a COPC. Given that unknown contributions of dioxins from the site to nearby urban areas (Missoula) and considering that the Smurfit-Stone site was a non-industrial agricultural site prior to its operation, we support comparison of site soil TEQ concentrations to the MT DEQ rural TEQ value.	Although conducting a comparison to background concentrations was included in the previous draft OU3 HHRA, upon further consideration of existing guidance it was determined that comparison with background levels should not be used to remove contaminants of concern from further evaluation owing to the need to fully characterize site risks (EPA 2002b). Comparison to background is not a toxicological rationale for eliminating COPCs from further consideration. Comparisons of site concentrations to background concentrations should still be considered within the RI outside of the risk assessment to provide additional information to risk

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				managers to better characterize the results presented in the risk assessment.
107	Missoula Co Commissioners	Site Characterization	The structure of the sampling that has been used to evaluate the site is fundamentally structured in such a way that risks are muted.	Due to the conservative bias of HHRA's, soil sampling conducted to date adequately characterizes surface soil conditions at the site for risk assessment purposes. The focus of a risk assessment is on estimating exposures that a receptor may reasonably be exposed to within a given exposure area over their entire exposure duration. Composite sampling reduces data variability and provides a reasonably unbiased estimate of mean contaminant concentrations in a specified decision unit (ITRC 2012). The 20-point/30-point composite samples were collected to provide an estimate of the mean concentration over an identified exposure area (e.g., grid). Discrete samples (5-point composites collected over a 1-m ² area) were collected under a biased sampling strategy to target areas of most concern. A weighted average was calculated to account for this bias and give more weight to the composite sample which inherently provides a better estimate of the mean concentration for each exposure area (smaller variability around the mean). EPA is not currently recommending additional soil sampling to support the risk assessments.
108	Missoula Co Commissioners	Flooding Concerns	The risk of a catastrophic channel avulsion into the site from the Clark Fork River are not evaluated.	Risk assessments are performed using available site data and presumed exposure scenarios to estimate the chronic risks posed by the contaminants present at the site. CERCLA risk assessments cannot and should not be used to estimate short-term risks from hypothetical events such as flooding, since the extent of soil disturbance, the location of such erosion, and the lateral extent of deposition cannot be known ahead of time. The impacts of potential flooding is something that is typically evaluated during the FS, which

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				follows the remedial investigation and risk assessments.
109	Missoula Co Commissioners	Conceptual Site Model	Conceptual Site Model should include updated Groundwater Conceptual Site Model and an understanding of aerial deposition.	The groundwater CSM (NewFields 2020) and aerial deposition fact sheet (EPA 2021a) will be cited in the HHRA.
110	Missoula Co Commissioners	Site Characterization	Given the evidence of impacted fish in the Clark Fork prompting the December 2020 Do-Not-Eat Advisory, the EPA should include 2018 fish data and collect additional samples downstream of the site to Noxon, to evaluate risk more completely to humans.	The 2018 fish data are incorporated into an evaluation in the uncertainty section of the HHRA, but due to data quality concerns documented within USEPA (2019), these data were not usable in the risk characterization. The risk assessment evaluates exposures and potential risks from within the current study area. The downstream location at St. Regis was selected for fish sampling based on identifying this area as a downstream location where sedimentation was likely to occur to be representative of where site-related contamination may have come to be located. The full nature and extent of contamination within the CFR is being evaluated within the RI/FS.
111	Missoula Co Commissioners	Site Characterization	Regarding sampling structure: Onsite sampling of soils and groundwater appear to be weighted heavily on grid-based sampling on 20-, 30- and 100-acre grids. We do not understand how this accurately describes the risks of the particularly toxic operations that occurred in discrete areas of the site (specifically the dumps and landfills). As stated in previous correspondence, along with provided references and photos, we are concerned that there are buried materials on this site that are contaminating groundwater or will contaminate groundwater (leaking drums and sludge from the days of bleaching pulp). We believe the risk assessment exposure units should be broken up by discrete units for each individual landfill and sludge pond. Some sites are difficult to ascertain where dumping took place and thus, require a grid-based approach. This site has very discernable boundaries of cells due to the tremendous amount of earth moving that took place (even artificially altering floodplain boundaries by filling the site with the waste that's being evaluated).	The random grid sampling captures the possibility that a receptor will likely be exposed to soils that are not delineated based on historic site uses. The composite grid sampling best represents potential exposure concentrations that a receptor may be exposed to chronically within a given exposure area. In addition, biased sampling was conducted based on site knowledge to identify areas of highest environmental concern (i.e., potential hot spot areas). These samples were collected from individual historical storage ponds and cells throughout the entire treatment chain. However, the objective of the risk assessment is to characterize the potential concentration that a receptor is exposed to over the exposure period, as opposed to evaluating a maximum concentration that could be contacted at any one time.

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112	Missoula Co Commissioners	Flooding Concerns	Regarding channel movement: The Clark Fork River meanders. Over time, our community has experienced the implications of this meandering in the loss of bridges, roads and structures. We know the best intentions to mitigate channel migration through engineering are not without their own consequences, shifting the problem upstream or downstream. Missoula's own floodplain regulations prohibit new use of riprap because of the consequences of shifting energy downstream. Plainly stated, the terms surrounding the Smurfit Stone site are masking a huge liability and risk to the ecosystem and to people. Catastrophic failure is a real threat, and that risk should be evaluated. What would the ecological and human health effects be of the Clark Fork's reoccupation of its flood plain or river channel?	Risk assessment does not/cannot account for potential future catastrophic events such as berm failure or river channel migration. The impacts of potential flooding is something that is typically evaluated during the FS, which follows the remedial investigation and risk assessments. However, the PRPs, with EPA and MDEQ oversight, conducted a berm stability study to address these concerns. This study will be cited in the HHRA. Reference: https://semspub.epa.gov/work/08/1900526.pdf
113	Missoula City-County Board of Health	Sampling Approach	The inherent ability to miss-characterize the presence of contaminants by grid-based composite sampling is concerning. We disagree with taking composite samples in exposure units being represented as a 20-acre grid for upland in OU3 and 100-acre grid for the OU3 floodplain. If these areas were comprised of homogenous strata and no knowledge of potential historic use differences existed between them, then it would be a more appropriate sampling design. However, at Smurfit, even within an exposure unit, the historic uses vary. Within each type of historic use, the waste types and stratification vary. External review by Abt Associates found "Large areas of the site are represented by a single data point, which may not be representative of the potential exposure. All of the data from 11 ponds in OU3 covering hundreds of acres were digested down to a single exposure area using one assumed value for each contaminant. The existing data may not capture the areas of contamination and potential risk when such broad areas are represented by composited samples and aggregated data." The Board is concerned that the dumps and sludge ponds are not adequately characterized. The groundwater flow is not uniform because of the disruption of the site geology and the remnant river channels that run through the site. Risk from groundwater and soils should be characterized based on historic use (evaluated by landfill cell/sludge pond cell) rather than in grids that composite and run across multiple historic uses.	Soil sampling conducted to date adequately characterizes surface soil conditions at the site for risk assessment purposes. The focus of a risk assessment is on estimating exposures that a receptor may reasonably be exposed to within a given exposure area over their entire exposure duration. Composite sampling reduces data variability and provides a reasonably unbiased estimate of mean contaminant concentrations in a specified decision unit (ITRC 2012). The 20-point/30-point composite samples were collected to provide an estimate of the mean concentration over an identified exposure area (e.g., grid). Discrete samples (5-point composites collected over a 1-m ² area) were collected under a biased sampling strategy to target areas of most concern. A weighted average was calculated to account for this bias and give more weight to the composite sample which inherently provides a better estimate of the mean concentration for each exposure area (smaller variability around the mean). EPA is not currently recommending additional soil sampling to support the risk assessments. Documentation regarding the waste management area (WMA) is located in DEQ, EPA and Missoula County files; the site was

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				well regulated beginning in the early 1980s. The PA/SI (and the appendices) conducted by EPA in 2011/2012 references documents about the older materials generated during operation including concentrations and quantities. Additional work to better understand the WMA conducted during EPA's PA/SI work effort included soil boring within the WMA. The groundwater sampling data collected at the site are being used to evaluate this potential transport pathway within the RI.
114	Missoula City-County Board of Health	Conceptual Site Model	Risk cannot be adequately assessed, nor pathways fully understood, until a sitewide Conceptual Site Model is complete. Determining risk, biological or human health, is premature when issues brought forward in the Groundwater Conceptual Site Model have not been addressed or responded to. Further, air deposition of contaminants is widely acknowledged, yet aerial deposition of contaminants is not fully discussed or included in identification of background levels. Even though current investigations are identifying contaminants at present, contamination from the site has extended beyond the site boundaries and should be included in risk assessments. Although CSMs can be updated, incorporating additional COPCs at a later stage puts the onus on the public as opposed to the PRPs to provide evidence of contamination.	The CSM presented in the risk assessment is specific to identifying potential human health receptors and exposure pathways within the current study area. This objective differs from the fate and transport CSMs being developed in other site documents. The risk assessments remain dynamic documents that can be amended as additional site information becomes available in the future if necessary. EPA has considered and investigated for aerial deposition within the risk assessment CSM and the broader RI. The groundwater CSM (NewFields 2020) and aerial deposition fact sheet (EPA 2021a) will be cited in the HHRA. Although conducting a comparison to background concentrations was included in the previous draft OU3 HHRA, upon further consideration of existing guidance it was determined that comparison with background levels should not be used to remove contaminants of concern from further evaluation owing to the need to fully characterize site risks (EPA 2002b). Comparison to background is not a toxicological rationale for eliminating COPCs from further consideration. Comparisons of site concentrations to background concentrations should still be considered

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				within the RI outside of the risk assessment to provide additional information to risk managers to better characterize the results presented in the risk assessment.
115	Missoula City-County Board of Health	Toxicity Values	The Board recommends using a more conservative RfD for Manganese in the HHRA. There is evidence now that low levels of Mn in drinking water are associated with neurocognitive and neurobehavioral deficits in infants and children including lowered IQ, hyperactivity, memory deficits, and Parkinsonian-like symptoms. According to the EPA IRIS website, “The author of the IRIS assessment for manganese recommended that the dietary contribution from the normal U.S. diet (an upper limit of 5 mg/day) be subtracted when evaluating non-food (e.g., drinking water or soil) exposures to manganese, leading to an RfD of 0.071 mg/kg-day for non-food items. The explanatory text in IRIS further recommends using a modifying factor of 3 when calculating risks associated with non-food sources due to a number of uncertainties that are discussed in the IRIS file for manganese, leading to an RfD of 0.024 mg/kg-day.” One of the most important uncertainties and rationales for this lower RfD is based on recent peer-reviewed scientific studies indicating that infants absorb, excrete, and regulate this nutrient differently than adults. This recommended RfD of 0.024 mg/kg-day is also consistent with what Montana DEQ proposed when considering a Mn drinking water standard for DEQ7 (0.025 mg/kg-day). We request risk calculations take into account Mn exposures in groundwater with the more current and protective RfD.	Based on further consideration, the RfD recommended for manganese in the EPA RSL table will be used in the HHRA. This value of 0.024 mg/kg-day incorporates subtracting out the dietary contribution from the normal U.S. diet (an upper limit of 5 mg/day) when evaluating non-food exposures to manganese. This RfD is consistent with the RfD used as the basis of the recently updated MDEQ drinking water benchmark of 0.025 mg/kg-day. This change does not alter the overall risk conclusion that manganese is a risk driver in groundwater.
116	Missoula City-County Board of Health	Site Characterization	The risk assessments remain incomplete in their failure to include what may be the most important exposure pathway: erosion and discharge of contaminated material into the Clark Fork River during high water events. Channel migration and avulsion could wash large volumes of sediment into the river and impact this resource into the future.	Risk assessments are performed using available site data and presumed exposure scenarios to estimate the chronic risks posed by the contaminants present at the site under current conditions. CERCLA risk assessments cannot and should not be used to estimate short-term risks from hypothetical events such as flooding, since the extent of soil disturbance, the location of such erosion, and the lateral extent of deposition cannot be known ahead of time. Flooding concerns will be addressed as part of the groundwater CSM revision.
117	Missoula City-County Board of Health	Future Use	Risk assessments state that Missoula County does not allow new building development within the 100-year floodplain. Though this type	The text will be updated to state that building within the floodplain is not preferred. The HHRA will be updated to evaluate the

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			of development is not preferred, it can occur within the 100-year floodplain.	residential and commercial/industrial scenarios within the floodplain also.
118	Missoula City-County Board of Health	Exposure Assessment	In December 2020, DPHHS, DEQ and FWP issued a Do-Not-Eat Fish advisory for all species of fish in the Clark Fork River downstream of its confluence with the Bitterroot based on dioxins, furans and PCBs. The Board urges EPA to further evaluate this risk by using preparation methods that may be used by ethnic populations present in this region. The Board also recommends evaluation of specific age and size class of fish species rather than by compositing samples.	The HHRA recognizes that tribal members may consume fish collected from the study area differently than a general recreational fisher. As such, the HHRA estimates risks from consumption of both fillets and whole-body fish for the tribal fisher. Game fish evaluated in the HHRA were collected to be within the state fishing size limits wherever possible. Risk calculations were conducted using both fish fillet and whole-body tissue concentrations, with cooking loss assumptions based on EPA guidance in the absence of tribal-specific information on cooking methods. However, recognizing that cooking loss will vary based on preparation and cooking techniques, the HHRA will be updated to present risks based on both assuming no cooking loss and assuming cooking loss.
119	CSKT	Exposure Assessment – Tribal	Tables 3-28 and 3-35: For the Tribal Fisher analysis, EPA evaluates risk from incidental ingestion of soil, dermal exposure to soil, and ingestion of fish (i.e., northern pike and rainbow trout). CSKT Tribal members have the treaty-reserved right to continue hunting, fishing, and gathering at usual and accustomed places both on and off the Flathead Reservation, including within the Clark Fork River (CFR) watershed. CSKT requested that EPA evaluate exposure pathways that represent additional risk to CSKT Tribal members including the ingestion of resident trout and other freshwater finfish and shellfish (i.e., crayfish and mussels); wildlife (i.e., deer, upland game birds, and waterfowl); plants (i.e., gathered roots, berries, and forbs); the non-consumptive uses of fish, wildlife, and plants; culturally important activities such as sweating practices; and, incidental ingestion and dermal contact of surface water and sediments (CSKT 2018). Plants that may be consumed by CSKT Tribal members can uptake contaminants such as metals and dioxins. In the HHRA, EPA discounts this possibility, stating that most plants do not generally absorb dioxin and most metals have little tendency to accumulate in plant tissue (HHRA, p. 16). This EPA assumption is incorrect as studies have shown	Rainbow trout and northern pike were selected as representative surrogate species of biota collected and consumed from the CFR. Unacceptable risks were predicted based on the consumption of these fish. It is reasonable to assume that concentrations and subsequent risks from consumption of bottom dwelling fish (e.g., suckers) may be similar to or greater than those of pike and trout. A qualitative discussion of fish consumption risks for species other than pike and trout will be added to the Uncertainty Section. Evidence exists that translocation of dioxins and furans from soil and sediment to above ground portions of plants is negligible due to the high molecular weight and hydrophobicity of dioxins and furans (ATSDR 1998). It is true that passive partitioning of dioxins and furans from soil and sediment into below

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			that many species of plants accumulate metals and dioxins. Plants are often used in bioremediation of sites with heavy metal contamination, specifically because they accumulate metals in their tissues. CSKT Tribal members consume various species of suckers, which are bottom-feeding species that may have different contaminant exposure via ingestion. This difference in fish-feeding behavior may impact concentrations of contaminants in fish tissue and thereby impact human health and safety through the consumption of fish.	ground portions of plants can occur; however the bioconcentration factors (BCFs) are generally quite low with few exceptions. Given the low soil/sediment-to-plant BCFs, it is expected that risks based on quantitatively evaluated exposure scenarios (residential/recreational) are protective of the plant ingestion pathway. Phytoremediation has been used with some success to reduce concentrations of dioxins and furans in contaminated soil, but these techniques require multiple types of soil amendments and the selection of highly specific plant species to be effective, which are not representative of environmental conditions. For these reasons, consumption of above ground portions of plants is not expected to be a significant exposure pathway. Regardless, a qualitative discussion of tribal plant consumption will be added to the HHRA.
120	CSKT	Exposure Assessment – Tribal	Table 3-35: EPA selected the lowest fish consumption rates from a National Cancer Institute (NCI) survey of the Shoshone – Bannock (SB) Tribes rather than the higher fish consumption rates from the NCI survey of the Nez Perce (NP) Tribe. Because CSKT fish consumption data is not available, the CSKT requested that EPA evaluate a risk envelope bounded on the upper end by NP fish consumption rates and on the lower end by SB fish consumption rates (CSKT 2018): <i>CSKT supports evaluation of Tribal subsistence fisher current and future exposure levels from Site-related contaminants based on an assumed current exposure pattern. CSKT current fish consumption rates are not available. In the absence of CSKT-specific data the Tribe will accept the use of fish consumption rates reported in fish consumption surveys of the Nez Perce Tribe (EPA 2016a) and the Shoshone Bannock Tribe (EPA 2016b). To mitigate uncertainty arising from the use of non-CSKT fish consumption rates the Tribes support evaluating a range of fish consumption rates (Table 2 [in original comment letter]). The low end of the range is defined as the Shoshone-Bannock (SB) fish consumption rates for Group 2 species. The high end of the range is defined as the Nez Perce Tribe (NPT) fish consumption rates for Group 2 species. CSKT supports evaluating both the National Cancer Institute (NCI) and</i>	As discussed with the CSKT during a meeting in Pablo, MT, EPA believes the Shoshone-Bannock Tribe consumption rates are more comparable to the fishery of the Clark Fork River since the river is not a salmon fishery. The estimated risk for subsistence fishers presented in the HHRA already exceeds acceptable levels based upon current fish consumption rates. Increasing the rate or applying a range will not change the overall conclusions of the HHRA. However, EPA agrees that the uncertainty associated with the fish consumption rates used should be characterized in the HHRA. Section 6.1.4 of the HHRA describes the uncertainty in the fish consumption rate, and evaluates tribal fish consumption risks using the Nez Perce fish consumption rates. Results of these calculations are included in the HHRA.

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			<i>the Food Frequency Questionnaire (FFQ) rates for the low end and the high end of the fish consumption range. The authors of the NPT and SB fish consumption surveys state that the NCI method results are probably closer to the true consumption rate but the FFQ consumption rates are also plausible and that the truth probably lies somewhere in between.</i> We recognize that EPA included some of the CSKT fish ingestion rate recommendations in the HHRA; however, EPA selected the lowest SB NCI fish consumption rate to assess risk from fish ingestion by a Tribal Fisher (Section 5.4) and selected the higher NP NCI fish consumption rate to assess uncertainty (Section 6.3). For this parameter, EPA relied on EPA's judgment rather than consultation with the CSKT to determine if EPA's judgement was valid and applicable to and representative of CSKT Tribal Fishers: <i>The risk estimates presented in Table 5-9 for a Tribal fisher are based on the fish consumption rates from the Shoshone-Bannock Tribes (U.S. EPA 2016a). The USEPA considers these consumption rates to best represent tribes with limited access to abundant fishers as expected within the stretch of the CFR included in OU3. (HHRA, p.56)</i> Please explain EPA's chosen methods, particularly in light of the appearance that EPA's methods were largely guaranteed to yield the lowest demonstration of risk at and from the site and highest thresholds of risk to CSKT fish consumption.	
121	CSKT	Cooking Loss	Section 5.0: EPA modifies the estimated exposure dose to Tribal Fishers by assuming cooking losses for total PCB are 30% and for TEQ are 54%. These values come from EPA's fish consumption advisories guidance (USEPA, 2000) which states that use of dose modification factors may not be appropriate for Native Americans and other fish consumers for setting health-based intake limits and should only be used when data on local methods of preparation and their impact on contaminant concentrations are available. EPA should develop data on the cooking loss associated with local CSKT methods and apply modified cooking loss value(s) in their analysis. Failing that, as EPA's (2000) guidance suggests, cooking losses should not be included in this analysis.	Risk calculations were conducted using both fish fillet and whole-body tissue concentrations, with cooking loss assumptions based on EPA guidance in the absence of tribal-specific information on cooking methods. However, recognizing that cooking loss will vary based on preparation and cooking techniques, the HHRA will be updated to present risks based on both assuming no cooking loss and assuming cooking loss occurs for dioxins/furans and PCBs.
122	CSKT	Exposure Assessment – Tribal	The HHRA does not evaluate risk to young children (Table 3-35). Young children would be exposed similarly to the rest of the CSKT community and may be at greater risk of negative impacts from the same exposure as older children and adults. CSKT and EPA proposed to	The HHRA will be revised to include the young child (aged 0 to 6 years) in the tribal fisher population scenario. Non-cancer risks will be reported for the young child for each

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			include young children in the risk assessment (CSKT, 2018 and EPA, 2018). EPA proposed evaluating young children using a fish consumption rate that is one-half an adult fish consumption rate (EPA, 2018). In addition EPA's 1995 Policy on Evaluating Health Risk to Children (reaffirmed by EPA in 2018) states that "EPA is to consider risk to infants and children consistently and explicitly as part of risk assessments generated during its decision making process" and, "that to the degree permitted by available data in each case, the Agency is to develop a separate assessment of risk to infants and children, or state clearly why this is not done." See https://www.epa.gov/children/epas-policy-evaluating-risk-children .	scenario that includes this age group. Detailed risk calculations will be included in Appendix D.
123	CSKT	Exposure Assessment – Tribal	Exposure Duration, Table 3-35: CSKT Tribal Members exercise their treaty-reserved hunting, fishing and gathering rights throughout their lifetimes. For this parameter, EPA relied on both EPA's judgment and EPA guidance for the general public (USEPA, 2014) rather than use the exposure duration values provided by CSKT (CSKT, 2018): <i>CSKT supports the following exposure durations to evaluate current and future exposure patterns for the following age groups:</i> • <i>Young Child (0-6 years): CTE – 3 years, RME 6 years</i> • <i>Child (6-16 years): CTE – 10 years, RME 10 years</i> • <i>Adult: CTE – 70 years; RME – 70 years</i>	EPA cannot justify changing the exposure durations for both CTE and RME calculations to the same duration for older children and adults, as doing so is inconsistent with how exposure durations are usually factored into risk calculations to evaluate these two types of receptors. Exposure parameters for a CTE receptor are intended to represent a measure of mean or median exposure. The differences in CTE and RME is intended to give an initial impression of the degree of variability in exposure and risk between individuals in an exposed population. The exposure durations assumed for the adult represent standard exposure durations for a resident (i.e., the most highly exposed receptor). The values for evaluating potential non-cancer effects are assumed to occur with less than lifetime exposures (i.e., <70 years). Cancer effects are evaluated by prorating the total cumulative dose over a lifetime based on the assumption that a high dose received over a short period of time is equivalent to a corresponding low dose spread over a lifetime (EPA 1989).
124	CSKT	Exposure Assessment – Tribal	Exposure Frequency (excluding fish consumption) (Table 3-35): These values, which represent the number of days/year that a Tribal Fisher is at the Site, are the same values used for the Recreational Fisher in Table 3-34 of the HHRA. For this parameter, EPA again relied on EPA's judgment rather than consultation with CSKT to determine if EPA's	The exposure frequency is intended to represent the primary time during which both a potential receptor is frequenting the study area and potential exposure to surface soils may occur. It is assumed that exposure to

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125	CSKT	Risk Characterization	Cancer Risk (Tables 5-9, 6-1): The cumulative increase in cancer risk from the contaminated site is an important factor for setting clean-up targets. The maximum cancer risk rate increase of 1-in-100,000 for Montana should be applied to the <u>cumulative</u> effect of the cancer-causing contaminants, not to each individual chemical as if they are the only toxin emitted from the site. It is vital that this principle be included in discussing acceptable increased cancer risk, especially when the allowable risk should be much lower for fish consumers using the resource for more than recreation. Additional comments regarding cancer risk are provided on page 7 of the Natural Resources Trustee comments.	In the revised OU3 HHRA, cancer risk will be evaluated for dioxins/furans using the CSF for 2,3,7,8-TCDD (from CalEPA) shown in Table 4-1. Cancer risk results presented in Section 5 tables are shaded to note whether they exceed 1E-04 or 1E-05. Cancer risks for each exposure pathway will be summed across COPCs. Previously, when total PCBs were the only COPC evaluated for cancer risk, such summing was not necessary. With the additional evaluation of cancer risk for other COPCs, the cancer risks will be summed across COPCs.
126	CSKT	Risk Characterization	Non-Cancer Hazards (Tables 5-9 and 6-1): Evaluating non-cancer hazard using time-weighted averages of the exposure estimates across older children (6-16 years) and adults rather than assessing risk to Tribal adults and Tribal older children separately underestimates non-cancer risk to Tribal older children. Presenting risk to Tribal children and adults separately allows for an understanding of how risk may differ across age groups. There are examples of Tribal HHRAs where EPA assessed non-cancer risk for adults and children separately (U.S. EPA, 2005, 2020b, 2020c).	Evaluating the TWA non-cancer hazards is consistent with how non-cancer hazards have been evaluated at other Region 8 sites in the past. The TWA approach includes exposure as a child. Appendix D will be updated to also present the non-cancer hazard estimates for a child and adult separately.
127	Trustees	Site Characterization	Request to Add Data to SCRIBES: As part of the remedial investigation /feasibility study process, the National Contingency Plan (NCP [40 CFR 300.430(b)(1)]) specifically requires the U.S. Environmental Protection Agency (EPA) to “(1) Assemble and evaluate existing data on the site, including the results of any removal actions, remedial preliminary assessment and site inspections, and the NPL listing process.” This specifically includes documents such as the Hazard Ranking System (HRS) evaluation for the Smurfit-Stone Mill Site (Site). This investigation revealed the presence of dioxin/furans and dioxin-like compounds in waste piles on the former mill property and sediment in unlined storage ponds on the former mill property.	Data collected prior to 2014 to support the Preliminary Assessment/Site Investigation are not used in the HHRA due to issues raised with data quality. EPA used those data to inform the sampling plan and focused collection on those areas identified as having potentially elevated contamination. The sampling conducted as part of RI activities are more recent, were collected in accordance with the EPA approved QAPP, and have been

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			Furthermore, these compounds were also found in fish tissues near the Site and downstream of the Site. Accordingly, there is a clear pathway from the Site to the Clark Fork river and the presence of these highly toxic compounds in the environment both on the former mill property and off of it (including in fish tissue) requires further investigation. The Trustees specifically request this data be added to the Site database (SCRIBES) and used in the BERA and HHRA. If EPA is unwilling to include this data, the Trustees request a formal response regarding why this data should not be used in evaluating Site risks.	evaluated and determined to meet the needs of the risk assessment.
128	Trustees	Site Characterization	The Trustees request that additional Site characterization, including potential locations in the Clark Fork River where hazardous substances have become located, be performed prior to finalization of the HHRA and BERA for the Site. Sampling completed to date is insufficient to adequately characterize risk to human health and the environment. Dioxins and furans are persistent highly toxic organic pollutants even at low level at or near analytic detection limits. Because of their hydrophobic nature and extremely low probability of detection, sampling methods such as surface water grab samples and groundwater samples are not adequate to characterize contamination and associated risk to human health and biota. Existing data show that there are coplanar PCBs in OU2. Further characterization is warranted to define the extent of coplanar PCBs and to identify potential pathway (both current and historic) to the river. The Trustees request that the overall Site Conceptual Model and the groundwater Site Conceptual Model be further developed and finalized to address all potential exposure pathways from the Site to the river prior to finalization of the BERA and HHRA. The NCP provides direction on collecting enough data to characterize the nature and extent of the contamination. The data collected must allow EPA to assess, “(iii) The general characteristics of the waste, including quantities, state, concentration, toxicity, propensity to bioaccumulate, persistence, and mobility, and (v) Actual and potential exposure pathways through environmental media.” 40 CFR 300.430(d)(2). The data collected then must be used to conduct a “site-specific baseline risk assessment to characterize the current and potential threats to human health and the environment that may be posed by contaminants migrating to ground water or surface water, releasing to air, leaching through soil, remaining in the soil, and bioaccumulating in the food chain.” 40 CFR 300.430(d)(4). Therefore, the NCP requires enough data to identify quantities of contamination that have been	A large amount of data has been collected and evaluated at the site since 2014. Additional data evaluations will occur, as necessary, to support the Feasibility Study. The full nature and extent to which hazardous substances from site activities have come to be located in the Clark Fork River adjacent to and downstream of the Site will be considered within the RI. Based on this, the term “site” will be replaced with “study area” within the text of the risk assessment.

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			released from the original mill property into the Clark Fork River and to determine the exposure pathways in the Clark Fork River downstream of the Site. As noted elsewhere in this comment letter, we do not believe that this data has been fully collected as required by the NCP. Further, the risk assessments are not complete until all the pathways for migration to and through surface water and bioaccumulating in the food chain have been identified, so we would request that EPA reevaluate the risk assessments as additional information is gathered as part of the process of finalizing the two Site Conceptual Models and as additional data is gathered to fully characterize the nature and extent of contamination in the Clark Fork River. The 104 Mill Study (USEPA, 1990) included samples of effluent, sludge, and pulp at the Site. 2,3,7,8-tetrachlorodibenzofuran (TCDF) was detected in samples of effluent, sludge, and pulp. Note the study had a relatively high detection limit. This study provides evidence that dioxin and furans were produced at the Site and have the potential to come to be located in the Clark Fork River sediments downstream of the Site. The Trustees strongly request that additional sampling of sediment depositional areas downstream of the Site within the Clark fork River be performed to further define the OU3 boundary and evaluate if contamination from the Site has come to be located in these areas. This type of paper mill has been shown (based on EPA studies) be a source of dioxins and furans and these depositional areas within the Clark Fork River (and likely many miles downstream from the Site, and even in the reservoirs downstream) may pose an ongoing unacceptable risk to the environment. In addition to sampling of sediment depositional areas downstream of the Site, the Trustees request high resolution analytical methods specifically targeted to quantify hydrophobic chemicals that pose a risk at low levels, such as dioxins, be used. These methods have been used for many years at other sites with known dioxin issues and are critical for informing risk management at sites where persistent organic pollutants are present.	
129	Trustees	Background Evaluation	Request for Additional Background Analysis: The Trustees understand that EPA is preparing a technical memorandum addressing air emission from the Site. The Trustees look forward to reviewing and commenting on this document. However, the Trustees suggest that airborne emissions from the Site did contain dioxins and furans and the air deposition was widespread throughout the Missoula Valley. EPA has prepared technical guidance that dioxins and furans are aerially emitted from the type of kraft paper processes used at the Site (USEPA, 1997). Therefore, the Trustees disagree with using locations within the aerial emissions area to	Although conducting a comparison to background concentrations was included in the previous draft OU3 HHRA, upon further consideration of existing guidance it was determined that comparison with background levels should not be used to remove contaminants of concern from further evaluation owing to the need to fully characterize site risks (EPA 2002b).

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			compare to background concentrations for all matrices including soil, sediment, water, and tissue. Further sampling and characterization should be performed to determine the aerial influence of the Site and to select background locations that are outside the area where aerial contamination from the Site came to be located.	Comparison to background is not a toxicological rationale for eliminating COPCs from further consideration. Comparisons of site concentrations to background concentrations should still be considered within the RI outside of the risk assessment to provide additional information to risk managers to better characterize the results presented in the risk assessment. EPA recently published an Aerial Deposition fact sheet (EPA, 2021) that will be cited in the OU2 HHRA. Available data (MDEQ, 2011) indicate that dioxins and furans in soils of Missoula are typical of rural areas elsewhere in the U.S., and well below urban areas elsewhere in the U.S. (Urban et al., 2013).
130	Trustees	Data Evaluation	The HHRA did not separate fish out by size, but rather pooled them within a species at each location. Large variations exist in TEQ concentrations between fish sizes. Although we do not know the source of this variation, it could be because of fish movement, time of residence in a particular location or the result of diet. Nevertheless, based on the variability, more sampling is warranted. For example, northern pike collected at the Frenchtown reach differed by 3.38 ng/g TEQ between sizes, 1,150% different, or 2.38 standard deviations, while rainbow trout differed by 1.37 ng/g, 1,098% difference. This pattern was similar at most locations. In many cases, the smaller size group of a species contained higher concentrations of total TEQ. Smaller fish are more abundant and easier to catch than larger/older fish, so conducting risk assessments based on size is more appropriate to accurately characterize human health risks. Furthermore, these smaller fish may be more indicative of the location where they were captured, vs larger, more mobile, older fish that may have experienced a variety of habitats in their lifetime spanning tens of miles.	Fish composites were created consistent with EPA (2000) whereby the smallest individual included in the composite was within 75% of the length of the largest fish included in the composite. Exposure point concentrations calculated based on multiple composite samples accounts for the consumption of the fish that are collected within the state catch regulations and consumed. It is not assumed that a receptor will only consume a specific size of fish over the course of their entire exposure duration. Regardless, the revised HHRA determines that unacceptable risks are associated with fish consumption for both recreational and tribal fishers, therefore additional fish data are not necessary to complete the risk assessment.
131	Trustees	Cancer Risk Benchmark	The HHRA does not accurately assess cancer risk from fish consumption. Only PCBs were evaluated for cancer effects in fish, and dioxins/furans were not assessed for cancer risk despite being categorized as probable human carcinogen. The HHRA states that non-cancer effects are protective of cancer effects, but this is because dioxins are not considered in the cancer calculations. Also, EPA is using 1E-04 as acceptable health guidelines. Montana DEQ's risk for cancer is 1E-05 and should be used in the risk calculation. The HHRA even states	In the revised OU3 HHRA, cancer risk will be evaluated for dioxins/furans using the CSF for 2,3,7,8-TCDD (from CalEPA) shown in Table 4-1. The HHRA notes that Montana DEQ uses 1E-05 to be their benchmark for cancer risk. Cancer risk results presented in Section 5

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			that cancer risk for a recreational consumer would exceed MT DEQ's 1E-05, but not EPA's 1E-04. Moreover, that cancer risk does not include TEQ from dioxins and furans. The HHRA needs to reassess cancer risk from fish consumption and include the cumulative effects from cancer-causing contaminants. If nothing else, the HHRA should acknowledge this difference from Montana standards and refrain from comments that it is a conservative estimate for risk.	tables are shaded to note whether they exceed 1E-04 or 1E-05.
132	Trustees	Cooking Loss	The HHRA assumed cooking losses for total PCBs and TEQ at 30% and 54%. This reference is from EPA's 2000 Guidelines for Fish Consumption Advisories. This guidance also states that the use of cooking loss should not be used without studies showing cooking habits of people in the area. In addition to the CSKT, the Missoula area has several ethnic communities (e.g., Hmong, and Belarusians) that consume fish in ways different from the EPA's 2000 guidelines and in potentially quantities higher than a typical recreational consumer. The HHRA should be revised using specific consumption and cooking methods for local ethnic communities and tribal consumers.	Risk calculations were conducted using both fish fillet and whole-body tissue concentrations, with cooking loss assumptions based on EPA guidance in the absence of tribal-specific information on cooking methods. However, the revised HHRA will include calculations assuming no cooking loss.
133	Trustees	Background Evaluation	The HHRA uses statistical comparisons to compare upstream locations [Missoula (MIS) and Council Grove (COG)] to locations adjacent to Frenchtown (FRN) and downstream St. Regis (STR) of the Site. In order to increase statistical power, different species size groups at a location are inappropriately pooled together. There are only two true composite replicates at each location for a given size group, so the use of statistics to show differences between locations, when within each location variation is extreme, is inappropriate. Moreover, the use of MIS and COG as representative reference areas is not appropriate, given that this area is likely influenced by the Site; directly through aerial deposition, and indirectly through adult fish movement, prey fish movement, and aquatic insect movement. See general comments and BERA comments.	Although conducting a comparison to background concentrations was included in the previous draft OU3 HHRA, upon further consideration of existing guidance it was determined that comparison with background levels should not be used to remove contaminants of concern from further evaluation owing to the need to fully characterize site risks (EPA 2002b). Comparison to background is not a toxicological rationale for eliminating COPCs from further consideration. Comparisons of site concentrations to background concentrations should still be considered within the RI outside of the risk assessment to provide additional information to risk managers to better characterize the results presented in the risk assessment. EPA recently published an Aerial Deposition fact sheet (EPA, 2021) that will be cited in the OU2 HHRA. Available data (MDEQ, 2011) indicate that dioxins and furans in soils of Missoula are typical of rural areas elsewhere

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				in the U.S., and well below urban areas elsewhere in the U.S. (Urban et al., 2013).
134	Trustees	PCBs	Despite low statistical power and small sample size, the data collected as part of the HHRA do show significantly higher concentrations of PCBs in fish adjacent and downstream of the Site. Limited sampling that occurred for coplanar PCBs in OU2 found 11 of the 12 coplanar PCBs in composite soil samples, some with high concentrations, including the same PCB congeners found in the fish tissues. The use of EPA method 8082 to look for PCBs through aroclors is not appropriate for coplanar PCBs, because it does not cover all of the congeners, and only detects down to units of ng/g. EPA's method 1668 measures down to the units in pg/g and is more appropriate for use at this Site (Dept of Ecology 2015).	Comparison between concentrations in fish collected within the OU3 study area and upstream of the OU3 study area will not be included in the revised HHRA as it was determined, upon additional consideration of EPA guidance, that comparison with background levels should not be used to remove contaminants of concern from further evaluation owing to the need to fully characterize site risks (EPA 2002b). However, evaluation of the PCB concentration data (as total PCBs) in rainbow trout does indicate lower PCB concentrations in fish collected from the Greenough and Clinton reaches (sampled in 2018; data quality review precluded the use of these data in quantitative Superfund risk assessment) compared to fish collected from within the OU3 study boundary. But concentrations in fish collected from the CFR upstream of the site at the Council Grove and Missoula locations are more generally similar with the concentrations in fish collected from within the OU3 study area. USEPA (2021b) discusses PCBs at the Site. Aroclors were evaluated in the initial investigations based on an understanding of site knowledge to identify areas where PCBs may be present at concentrations that warrant further investigation. The detection limits associated with method 8082 were determined to be appropriate to meet the site-specific Data Quality Objectives (DQOs); analytical detection limits were compared to potentially relevant human health-based screening levels. Method 1668 was then used on samples collected from areas identified for further evaluation consistent with EPA protocols. As

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				shown in the HHRA COPC Screen tables, Aroclor detection limits in soil were adequate when compared to the RSLs. Detection limits for the groundwater samples were higher than the RSLs. This represents a source of uncertainty discussed in the uncertainty section. Aroclor concentrations similar to the reported DLs result in risks from drinking groundwater in the low 1E-06 range and are not expected to substantially contribute to cumulative risk estimates.
135	J Harrington	Site Characterization	I grew up here in Western Montana, surrounded by industry who have profited-handsomely from our resources but are not held responsible for the environmental damage they leave behind. From the first meeting with the EPA in the Frenchtown firehall in 2017, the public and Natural Resource Trustees have asked that action be taken that are protective of human health and the environment, the genesis of which is a thorough and complete characterization of the site. I do not feel confident that the actions taken so far have captured the decades of environmental impact that mill activities left behind. Transparency and accountability are lacking in this process, which leads to social and environmental injustice. EPA has been sharing limited and redundant information for years, without addressing data gaps and unanswered questions. It has been asked multiple times over the years why the 2011 URS and 2013 HRN reports (USEPA, 2013b) have not been incorporated into the sampling plans, nor in the draft HHRA or BERA, without an adequate answer. The presentations of the HHRA, BERA, and the long-awaited Ground Water Site Conceptual Model were superficial, and additionally, the continued use of statements like, “only 6% of the pulp was bleached” is concerning. It has been asked again and again that the Agency report actual figures, like, 1,600,000 tons of bleached pulp was produced, but reports and presentations by the EPA on the HHRA and BERA regurgitate the, “only 6%” figure without providing context. If a stratified soil sampling plan was in place, the deeper soil horizons may reveal different concentrations than the samples taken so far, especially in the ponds holding wastewater sludge from the bleaching plant operations.	Comment noted. Data collected prior to 2014 to support the Preliminary Assessment/Site Investigation are not used in the HHRA due to issues raised with data quality. EPA used those data to inform the sampling plan and focused collection on those areas identified as having potentially elevated contamination. The sampling conducted as part of RI activities are more recent, were collected in accordance with the EPA approved QAPP, and have been evaluated and determined to meet the needs of the risk assessment. Risk assessments evaluate current and hypothetical future exposure scenarios based on current conditions, and sampling to support the risk assessments has been determined to be adequate. The objective of the multimedia sampling conducted as part of the RI is to capture the likely contaminants in the data set and determine whether they pose an unacceptable risk to human health or the environment, regardless of the quantities historically used or produced. Remedial alternatives will be evaluated in the FS, and historical damage is evaluated within the NRDA process. The data supporting a discussion about cleanup needs came from intensive soil sampling across the site. EPA approved a work plan that included two approaches to sampling.

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			On page 4 of the EIS report it states that at the time, 14 years after the mill began bleaching pulp, there were still no EPA regulations for the bleached pulp industry. The volume of wastewater from the bleaching plant alone, especially before the EPA issued any regulations for Bleaching plants in the 1960's and 1970's, should trigger a concentrated sampling event of the lower horizons in the settling and sludge ponds associated with the Bleach plant discharge. On page 27 of the 1974 EIS: <i>An average of 159 tons (based on 350 operating days) of bleached product was produced in 1973 by HW. HW reports 30,000 gallons of water are required per ton of bleached product. The discharge from the bleach plant would, therefore, average 4.8 million gallons per day (MGD). The total contaminated waste flow (not including the uncontaminated cooling water which is discharged separately) averaged 15.8 mgd (MDHES 1974).</i> The report also identifies that the mill's bleaching plant used 380 tons of chlorine monthly in 1973. It is important in attempting to understand the potential and real harm to human health and the environment that the study of the site include all areas that have been impacted by site activities.	The first approach is a targeted sampling strategy to assess areas identified as most likely to be contaminated by site operations, also known as potential source areas. This approach was implemented in OU2. As noted in the Remedial Investigation Work Plan (RIWP) (NewFields 2015), 17 target areas were identified through environmental data records, site walks, interviews with former Mill employees, and personal (NewFields' staff) experience with the site operations. Further, the RIWP specifically identified boiler emissions (possible metals, dioxins, and PAHs), areas where transformers were stored (looking for PCBs), and other areas where localized impacts may have resulted from previous operations. The second approach is a composite sampling strategy which is used for estimating concentrations in soil for risk assessment. This approach was implemented across OU1 and OU3. The composite approach provides reasonable estimates of contaminant concentrations across a defined area, known as exposure units or decision units. The risk assessment then evaluates the concentration of a contaminant across the area to determine the estimated exposure risk from each unit. For example, at a residential property, exposure units may include the front yard, the back yard, the garden, and a play area. Each of these units would be sampled separately since they are used differently and pose different exposure risks to humans (kids playing versus mowing the lawn versus planting in a garden). At Smurfit, the decision units were based on former land use or parcel boundaries. In OU1, the sampling was based on property boundaries and included 9 agricultural parcels

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				and 2 forested lands. Statistical methods were then used to determine the number of composite samples per property. In OU3, the approach was based on historical data and the boundaries of the former ponds. Samples were collected using both single point and composite methods and the rationale is detailed in the RIWP. EPA's risk managers then take the information regarding nature and extent, apply the risk assessment conclusions, and make decisions on where remediation is necessary and of what contaminants to what concentrations (cleanup standards). These decisions guide the next step in the Superfund Process: the Feasibility Study.
136	J Harrington	Aerial Deposition	The argument that there has been no impact from aerial deposition during 53 years of operation is unsupported. Why would the mill need air pollution permits if what was being discharged over the years was not a hazard to human health and the environment? In the 1974 EIS for the proposed expansion of the mill, on page 1, it states: <i>HW has applied to the AQB for a permit to expand the capacity of its pulp and paper mill from 1150 tons per day (TPD) of paper products to 1850 TPD. Operation of the expanded plant would affect air pollution from the mill, and therefore a permit is required under regulations appurtenant to the 1967 Clean Air Act of Montana. The act and subsequent regulations say there shall be no "installation, alteration, or use of any machine, equipment, device or other article which . . . may cause or contribute to air pollution ..." unless a permit is issued (MDHES 1974).</i>	Comment noted. EPA is already considering aerial deposition within the risk assessment CSMs and the broader RI. EPA recently released an aerial deposition fact sheet (EPA, 2021a) that speaks to these issues; the fact sheet will be cited in the HHRA.
137	J Harrington	Background Evaluation	My comments on the HHRA in 2018 shared the research conducted by Paul Woods Bartlett, Barry Commoner, Kim Couchot, Brian Bush, Holger Eisl and Paul Cooney on established environmental impacts involving air pollution from industry (Bartlett et al. 2000). The fact that the background areas lie within reach of aerial deposition of the mill. The background sites are not far enough away from the potential impact area of the mill to be defensible. New background sites need to be chosen and sampled. On page 19 of the EIS the sources of pollution are described:	Although conducting a comparison to background concentrations was included in the previous draft OU3 HHRA, upon further consideration of existing guidance it was determined that comparison with background levels should not be used to remove contaminants of concern from further evaluation owing to the need to fully characterize site risks (EPA 2002b). Comparison to background is not a

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			<i>Nearly every item of process equipment in a pulp and paper mill can contribute to pollution of air and water. Air pollutants generated in the pulping process are many and varied. Gases and particulates are emitted as a variety of compounds. Many of the gaseous emissions are odorous, among them hydrogen sulfide (H₂S), methyl mercaptan, (CH₃SH), dimethyl sulfide (CH₃SCH) and dimethyl disulfide (CH₃SSCH). Other gaseous pollutants emitted are sulfur dioxide (SO₂) and carbon monoxide (CO). Particulate emissions include wood fiber, sodium compounds from the recovery furnaces, fly ash, and calcium compounds. Table 1 summarizes the various pollutants and sources (MDHES 1974).</i>	toxicological rationale for eliminating COPCs from further consideration. Comparisons of site concentrations to background concentrations should still be considered within the RI outside of the risk assessment to provide additional information to risk managers to better characterize the results presented in the risk assessment.
138	CAG	Site Characterization	Identification of the concentrations and distribution of contaminants across the Mill Site is most accurately done by on-site sampling. Rather than rigorously measuring for onsite contamination, the Draft Human Health Risk Assessment discusses Exposure Pathways of Chief Concern and indirect measurements. The soil sampling conducted is insufficient. Soil sampling density was far too low to adequately determine the presence or absence of contamination across the 3000-acre site (see figures 4.4 and 4.5 attached to original comment letter: “Location of Surface Soil Samples in OU3 Upland: Smurfit-Stone/Frenchtown Mill Site, Montana” and “Location of Surface Soil Samples in OU3 Floodplain: Smurfit-Stone/Frenchtown Mill Site, Montana,” respectively). Using the scale printed on Figure 4.4, each one of the squares shown on this map represents approximately 38 acres. Using the scale printed on Figure 4.5, each one of the squares shown on this map represents approximately 92 acres. Concerns have been expressed as to the adequacy of having such large areas represented by so few samples. Representing large areas with minimal sample locations may not represent the potential risks. No new soil samples since 2017.	Soil sampling conducted to date adequately characterizes surface soil conditions at the site for risk assessment purposes. The focus of a risk assessment is on estimating exposures that a receptor may reasonably be exposed to within a given exposure area over their entire exposure duration. Composite sampling reduces data variability and provides a reasonably unbiased estimate of mean contaminant concentrations in a specified decision unit (ITRC 2012). The 20-point/30-point composite samples were collected to provide an estimate of the mean concentration over an identified exposure area (e.g., grid). Discrete samples (5-point composites collected over a 1-m ² area) were collected under a biased sampling strategy to target areas of most concern. A weighted average was calculated to account for this bias and give more weight to the composite sample which inherently provides a better estimate of the mean concentration for each exposure area (smaller variability around the mean). Due to low variability within the current data set, EPA is not currently recommending additional soil sampling to support the risk assessments.
139	CAG	Site Characterization	Soil sample data were collected in 2014, 2015 and 2016 as 5-point composite samples collected from locations across OU2 and OU3.	Composite sampling reduces data variability and provides a reasonably unbiased estimate

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			Composite sampling would tend to mask samples with high concentrations and limit their use for statistical analyses and inference.	of mean contaminant concentrations in a specified decision unit (ITRC 2021). The 20-point/30-point composite samples were collected to provide an estimate of the mean concentration over an identified exposure area (e.g., grid). Discrete samples (5-point composites collected over a 1-m ² area) were collected under a biased sampling strategy to target areas of most concern. The composite grid sampling best represents potential exposure concentrations that a receptor may be exposed to chronically within a given exposure area. The biased sampling was conducted based on site knowledge to identify areas of highest environmental concern (i.e., potential hot spot areas). However, sampling conducted to support the risk assessment is not necessarily equivalent to sampling conducted to evaluate nature and extent. Evaluation of nature and extent is outside of the scope of the risk assessment which focuses on evaluation of the current study area. Further evaluation of nature and extent is being conducted as part of the RI.
140	CAG	Site Characterization	A biased sampling approach (sampling locations selected based on site knowledge to identify areas of highest environmental concern) was used. Given that contamination may have been spread by post discharge surface flow as well as atmospheric deposition not using a sufficient number of randomized selections of sample sites across the Mill site limits any quantitative inference to identify the extent of contamination at the site. The number and spatial distribution of sites sampled should be related to the variability in the measurements.	The risk assessment is not the mechanism for characterizing the extent of contamination at a site. The risk assessment presents estimated risks to potential receptors within the study area of concern. Nature and extent of contamination is evaluated outside of the risk assessment. Nonetheless, although some site soil data was collected using biased sampling, random grid sampling was also used.
141	CAG	Site Characterization	Sampling design should have varying depths dictated by color or texture changes. Though auger bore hole logs appear to have been taken it is not clear that individual strata were sampled. Using trench sampling of strata could more accurately identify changes in soil profiles.	For the HHRA, soil depths selected for evaluation are a function of potential exposure and not necessarily of individual strata characterized by color or texture changes. The majority of potential human receptors of concern at the site are expected to be exposed only to surface soils. However, subsurface data were also collected to characterize

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				potential exposures to people during excavation activities. The HHRA evaluates subsurface exposures to construction workers who may dig down to a depth of 10 feet when constructing foundation-based buildings, such as residential homes. Further characterization of soil profiles is outside the scope of the HHRA.
142	CAG	Site Characterization	Dioxins associated with bleaching operations were found in pulp sludge and placed in unlined ponds for 38 years. There has not been adequate sampling at depths greater than 10 ft below ground surface (bgs).	Soil sampling conducted to date adequately characterizes soil conditions at the site for risk assessment purposes. Additional evaluation of the nature and extent of contamination is outside the scope of the risk assessments.
143	CAG	Site Characterization	PCBs, furans and dioxins strongly attach to soil particles, are very persistent, and can be transported via erosion and transport of contaminated soils. The BERA and HHRA soil samples were last taken in 2017, giving limited and potentially inaccurate assumptions about the current and future danger the Persistent Organic Pollutants pose to Human Health and the Environment.	Soil sampling conducted to date adequately characterizes surface soil conditions at the site for risk assessment purposes. Site activities that could be expected to increase soil contamination have not occurred since the last round of soil sampling. Finally, EPA has released a PCB fact sheet (EPA 2021c) that addresses these concerns and will be cited in the HHRA.
144	CAG	Conceptual Site Model	GW Site Conceptual Model is flawed. It ignores the significant threat of erosion of contaminated materials into the Clark Fork River. It is incomplete, resulting in a questionably vetted HHRA and BERA. You are not getting a good picture of the risk without a good GWSCM.	The CSM presented in the HHRA is specific to identifying human health receptors and exposure pathways. This objective differs from the fate and transport CSMs being developed in other site documents. However, exposure to groundwater is included in the CSM for the HHRA. Each well is evaluated individually and is not influenced by information regarding the impacts of erosion to the CFR. Additional comments on the ongoing development of the groundwater CSM are outside the scope of the HHRA.
145	CAG	Site Characterization	The Channel Migration Zone and Avulsion hazards have not been accounted for.	Risk assessments are performed using available site data and presumed exposure scenarios to estimate the chronic risks posed by the contaminants present at the site. CERCLA risk assessments cannot and should not be used to estimate short-term risks from hypothetical events such as flooding, since the

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				extent of soil disturbance, the location of such erosion, and the lateral extent of deposition cannot be known ahead of time.
146	CAG	Site Characterization	The Landfills and ponds have not been sampled to groundwater depths. The Landfills do not have an adequate number of samples. HHRA and BERA for OU3 does not address the landfills and sludge ponds. Methane generation potential in the sludge ponds and landfills should be investigated in OU3.	Documentation regarding the waste management area (WMA) are located in DEQ, EPA and Missoula County files; the site was well regulated beginning in the early 1980s. Please review the PA/SI and the Missoula County letter of July 26, 2016. The PA/SI (and the appendices) conducted by EPA in 2011/2012 references documents about the older materials generated during Mill operation including concentrations and quantities. Additional work to better understand the WMA conducted during EPA's PA/SI work effort included soil boring within the WMA. One of the goals of the RI is to sample the groundwater to determine if the WMA is leaching contaminants to the GW. EPA is requiring additional monitoring in the future because some COPCs are impacting GW.
147	CAG	Site Characterization	The early years of production produced up to 30% bleached product. The total volume of bleached product is approximately 1,600,000 tons was produced during a period of 39 years. There is a need for dioxin data at lower horizons in the sludge ponds.	Additional data will not be collected prior to finalization of the HHRA. Uncertainties associated with the available database are described in the uncertainty assessment.
148	CAG	Site Characterization	Exclusion of 104 Mill study (EPA 1990) and the 2011 URS data has not been justified and if the reasoning is not articulated, the data should be included in the HHRA and BERA.	Data collected prior to 2014 to support the Preliminary Assessment/Site Investigation are not used in the HHRA due to issues raised with data quality. EPA used those data to inform the sampling plan and focused collection on those areas identified as having potentially elevated contamination. The sampling conducted as part of RI activities are more recent, were collected in accordance with the EPA approved QAPP, and have been evaluated and determined to meet the needs of the risk assessment.
149	CAG	Site Characterization	OU3 comprises of all potential locations in the Clark Fork River where hazardous substances may be located. Sampling at locations downriver	As noted in the HHRA, the full nature and extent to which hazardous substances from site activities have come to be located in the

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			from the former mill site is necessary to fully characterize the impact of the mill.	CFR adjacent to and downstream of the site has not been fully established but will be considered within the RI.
150	CAG	Flooding Concerns	Re: calculating risks to the berm and floodplain: Continued threat of high ground water influencing materials in the dumps and sludge ponds.	Risk assessments are performed using available site data and presumed exposure scenarios to estimate the chronic risks posed by the contaminants present at the site. CERCLA risk assessments cannot and should not be used to estimate short-term risks from hypothetical events such as flooding, since the extent of soil disturbance, the location of such erosion, and the lateral extent of deposition cannot be known ahead of time. The impacts of potential flooding is something that is typically evaluated during the FS, which follows the RI and risk assessments. It is during the FS process that the EPA evaluates alternatives for cleanup against the nine criteria in the National Oil and Hazardous Substances Pollution Contingency Plan. The potential impacts of flooding would be evaluated against the criteria for compliance with applicable or relevant and appropriate requirements and long-term effectiveness and permanence.
151	CAG	Site Characterization	Groundwater is neither uniform nor homogenous and yet grab samples from surface water are being used to describe the health of the entire water system associated with the former mill.	Surface water data were collected consistent with DQOs for the site, and were evaluated in the HHRA. Groundwater monitoring has been ongoing and continues at the site. EPA uses multiple lines of evidence to evaluate impacts from the former mill on the surrounding environment. In order to perform the risk assessments, EPA analyzed a broad spectrum of information, including tissue concentration data from large fish and small fish from the Clark Fork River and its tributaries; macroinvertebrates (bugs) from on-site ponds and creeks; and small mammals on-site. Additionally, EPA considered data from sediment, surface water, sediment porewater samples, surface soil and

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				subsurface soil samples in the risk assessments. Over the course of the past 6 years, EPA has overseen collection of biannual groundwater samples from 56 monitoring wells across the Site
152	CAG	Site Characterization	It is unclear if the soil strata have been correctly profiled to make sure that each soil strata are represented.	Available soil data relevant to evaluating potential human health exposures are summarized and evaluated in the HHRA. Additional soil characterization will be in the RI.
153	CAG	Flooding Concerns	Little attention was given to a low probability flood in excess of what is calculated to be a 100-year event would breach the berm and allow flood waters to scour large portions of the site. Climate change likely has and will continue to increase the risk of erratic weather and increase the probability of floods. What is estimated to be a 100-year flood at present may well become a much higher probability event in future years.	Risk assessments are performed using available site data and presumed exposure scenarios to estimate the chronic risks posed by the contaminants present at the site. CERCLA risk assessments cannot and should not be used to estimate short-term risks from hypothetical events such as flooding, since the extent of soil disturbance, the location of such erosion, and the lateral extent of deposition cannot be known ahead of time. The impacts of potential flooding is something that is typically evaluated during the FS, which follows the RI and risk assessments. It is during the FS process that the EPA evaluates alternatives for cleanup against the nine criteria in the National Oil and Hazardous Substances Pollution Contingency Plan. The potential impacts of flooding would be evaluated against the criteria for compliance with applicable or relevant and appropriate requirements and long-term effectiveness and permanence.
154	CAG	General	It is impossible to quantify the risks without more intensive soil sampling. To date there is little data that would prove or disprove the sites impact to the Clark Fork River though State of Montana fish tissue data indicate an increase in Dioxins downstream of the site. These data were considered sufficient to issue a fish consumption advisory. It is always better to error on the side of caution when human health is at risk. Allocating resources to direct sampling of contaminants to determining the types, amounts, and locations of contaminants will give	In order to perform the risk assessments, EPA analyzed a broad spectrum of information, including tissue concentration data from large fish and small fish from the Clark Fork River and its tributaries; macroinvertebrates (bugs) from on-site ponds and creeks; and small mammals on-site. Additionally, EPA considered data from sediment, surface water, sediment porewater samples, surface soil and

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			a much clearer and defensible picture of risks and identify areas needing treatment. In conclusion, the Frenchtown CAG is in support of actions that remove the sources of contamination instead of leaving contaminants for future generations to contend with. We are asking the EPA and MTDEQ for a commitment for a thorough Risk Assessment to protect human health and the environment now and for generations to come. A resident of the area has observed that the process is driving the data instead of the data driving the process. The desired result of the Risk Assessment is an accurate representation of the impacts that the site has had and continues to have on the environment. We do not feel that the process up to this point has done enough to characterize the influence and impact that 53 years of mill operations.	subsurface soil samples in the risk assessments. Over the course of the past 6 years, EPA has overseen collection of biannual groundwater samples. Sampling conducted to support the risk assessment is not necessarily equivalent to sampling conducted to evaluate nature and extent. Evaluation of nature and extent is outside of the scope of the risk assessment which focuses on evaluation of the current study area. Further evaluation of nature and extent is being conducted as part of the RI. Risk assessments evaluate current and hypothetical future exposure scenarios, and sampling to support the risk assessments has been determined to be sufficient. The objective of the multimedia sampling conducted as part of the RI is to capture the likely contaminants in the data set and determine whether they pose an unacceptable risk to human health or the environment, regardless of the quantities historically used or produced. Remedial alternatives will be evaluated in the FS, and historical damage is evaluated within the NRDA process.
155	J Salazar	Site Characterization	...The studies EPA has conducted to date are inadequate to address fully and meaningfully the risks associated with this site. From inadequate stratification of sampling to small sample sizes to omission of some key chemicals of concern, no meaningful conclusions can be drawn concerning the levels of risk presented by this site. Upstream and downstream comparisons are invalid both because small sample size means there is no power of the test, and because aerial deposition and fish migration can move chemicals upstream.	Sampling conducted to date adequately characterizes site conditions for risk assessment purposes to evaluate the current study area. The focus of a risk assessment is on estimating exposures that a receptor may reasonably be exposed to within a given exposure area over their entire exposure duration. EPA recently published fact sheets on aerial deposition, dioxins/furans, and PCBs at the Site (EPA, 2021a, b, c) that provides additional information and will be cited in the HHRA.

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156	J Salazar	Flooding Concerns	One of the greatest inadequacies of the study design is the omission of one of the largest sources of risk associated with this site – the risk of dike failure and downstream transport of the toxic chemicals in the historic floodplain. As long as the mill’s toxic waste remains in the Clark Fork River’s historic floodplain, these risk assessments must also address the potential impacts of a dike failure followed by the river washing that waste downstream. The river will eventually reclaim its floodplain. And climate scientists predict that climate change will continue to produce bigger and bigger floods, hence the chance of such a catastrophic failure is increasing and will be even greater than historic flooding would suggest. Obviously, it is difficult to predict where the waste will wind up once it is washed downstream – but that does not mean this catastrophic scenario should be ignored. These risk assessments must assess all the possible outcomes of leaving the waste where it is (where it is subject to being washed downstream), as well as assessing the much lower risks if those wastes are moved to a location less likely to be impacted by bigger floods and dike failure. Without such an assessment, these risk assessments are missing information critical to making decisions about needed remediation actions at this site. In my view, the EPA should move quickly to require the removal of the toxic waste in the historic floodplain at the Smurfit-Stone/Frenchtown Mill site, as it has in removing the contaminated ponds at the Columbia Falls Aluminum Company Superfund site. That EPA action was taken to protect the Flathead River from the eventual failure of those ponds. The much larger area of contaminated historic floodplain at the Smurfit Stone site presents an even greater risk to the Clark Fork River.	Risk assessments are performed using available site data and presumed exposure scenarios to estimate the chronic risks posed by the contaminants present at the site. CERCLA risk assessments cannot and should not be used to estimate short-term risks from hypothetical events such as flooding, since the extent of soil disturbance, the location of such erosion, and the lateral extent of deposition cannot be known ahead of time. The impacts of potential flooding is something that is typically evaluated during the FS, which follows the RI and risk assessments. It is during the FS process that the EPA evaluates alternatives for cleanup against the nine criteria in the National Oil and Hazardous Substances Pollution Contingency Plan. The potential impacts of flooding would be evaluated against the criteria for compliance with applicable or relevant and appropriate requirements and long-term effectiveness and permanence. What the commentor refers to as the on-site toxic waste, and is referred to as the ‘waste management area’ in the HHRA is not located within the CFR 100-year floodplain.
157	V Watson	Site Characterization	...The studies EPA has conducted to date are inadequate to address fully and meaningfully the risks associated with this site. From inadequate stratification of sampling to small sample sizes to omission of some key chemicals of concern, no meaningful conclusions can be drawn concerning the levels of risk presented by this site. Upstream and downstream comparisons are invalid both because small sample size means there is no power of the test, and because aerial deposition and fish migration can move chemicals upstream.	Soil sampling conducted to date adequately characterizes surface soil conditions at the site for risk assessment purposes. The focus of a risk assessment is on estimating exposures that a receptor may reasonably be exposed to within a given exposure area over their entire exposure duration. EPA recently published an Aerial Deposition fact sheet (EPA, 2021) that provides

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				additional information and will be cited in the HHRA.
158	V Watson	Flooding Concerns	One of the greatest inadequacies of the study design is the omission of one of the largest sources of risk associated with this site – the risk of dike failure and downstream transport of the toxic chemicals in the historic floodplain. As long as the mill’s toxic waste remains in the Clark Fork River’s historic floodplain, these risk assessments must also address the potential impacts of a dike failure followed by the river washing that waste downstream. The river will eventually reclaim its floodplain. And climate scientists predict that climate change will continue to produce bigger and bigger floods, hence the chance of such a catastrophic failure is increasing and will be even greater than historic flooding would suggest. Given the evidence that water moves through this uncertified, simple gravel dike during 25 year flood events, the dike does not have to be overtopped to fail. The dike can simply liquefy and wash away. Obviously, it is difficult to predict where the waste will wind up once it is washed downstream – but that does not mean this catastrophic scenario should be ignored. These risk assessments must assess all the possible outcomes of leaving the waste where it is (where it is subject to being washed downstream), as well as assessing the much lower risks if those wastes are moved to a location less likely to be impacted by bigger floods and dike failure. Without such an assessment, these risk assessments are missing information critical to making decisions about needed remediation actions at this site. In my view, the EPA should move quickly to require the removal of the toxic waste in the historic floodplain at the Smurfit-Stone/Frenchtown Mill site, as it has in removing the contaminated ponds at the Columbia Falls Aluminum Company Superfund site. That EPA action was taken to protect the Flathead River from the eventual failure of those ponds. The much larger area of contaminated historic floodplain at the Smurfit Stone site presents an even greater risk to the Clark Fork River.	Sampling conducted to date adequately characterizes site conditions for risk assessment purposes to evaluate the current study area. The focus of a risk assessment is on estimating exposures that a receptor may reasonably be exposed to within a given exposure area over their entire exposure duration. Composite sampling reduces data variability and provides a reasonably unbiased estimate of mean contaminant concentrations in a specified decision unit (ITRC 2021). The 20-point/30-point composite samples were collected to provide an estimate of the mean concentration over an identified exposure area (e.g., grid). Discrete samples (5-point composites collected over a 1-m ² area) were collected under a biased sampling strategy to target areas of most concern. EPA recently published an aerial deposition fact sheet (EPA, 2021a) that provides additional information and will be cited in the HHRA.
159	B Sims	Flooding Concerns	The Draft HHRA lacks assessment of risks associated with climate change and the soil sampling required to determine onsite risks should flooding occur. The following narrative shown in italics is quoted from sections of the Center for Climate and Energy Solutions memo, 2021. https://www.c2es.org/site/assets/uploads/2021/01/Climate-Policy-Priorities-for-the-New-Administration-and-Congress.pdf	Risk assessments are performed using available site data and presumed exposure scenarios to estimate the chronic risks posed by the contaminants present at the site. CERCLA risk assessments cannot and should not be used to estimate short-term risks from

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			<i>“President Biden has assembled the strongest team ever to lead the government’s response to climate change. With his initial executive actions, he has already launched a wide range of efforts to dramatically strengthen that response. These include rejoining the Paris Agreement and directing agencies to initiate processes to strengthen climate-related regulations and to ensure the full consideration of science and climate related costs and benefits in federal rulemaking.” (pg. 3)</i> <i>“To better protect public and private property against rising flood risks:”</i> <i>• “Congress should codify the Federal Flood Risk Management Standard to reduce flood risk by requiring the use of protective design standards and forward-looking climate science when building or rebuilding federally-funded buildings and infrastructure, including projects funded through CDBG-DR or other programs.” (pg. 18)</i> <i>• “Congress should increase funding for the National Flood Insurance Program to update its flood insurance rate maps using forward-looking climate risk data, and to create new maps for currently unmapped areas, which account for more than half of U.S waterways and shorelines. 48 Updated maps would better assist planners and builders in determining which areas are suitable for development and increase home- and business owners’ awareness of their risks. To reduce wildfire risk.” (pg 18)</i> The HHRA documents fail to address the changed Biden Administration direction and changing environmental conditions as a result of climate change and the associated increased risk of flooding. A warmer atmosphere drives more extreme precipitation across all storm types, increasing the risk of flooding. Atmospheric Rivers are long, narrow bands of moisture in the atmosphere that extend from the tropics. They are responsible for most flood damage in the Western United States (Dettinger 2013). The amount of moisture carried by atmospheric storms from the North Pacific and released in the western US has increased from 1948–2017. The increase is linked to ocean surface warming. The most intense atmospheric river storms are becoming more frequent and increases the probability of a large magnitude flood event. Earlier this year I gave a Power Point presentation to the CAG which documented the February of 2020 atmospheric river that targeted the lower and middle Columbia River Basin. In 86 years of record the Umatilla River’s previous high peak flow near Gibbon, Oregon was 6,220 cfs. USGS stream gauge reading on February 6, 2020 was just	hypothetical events such as flooding, since the extent of soil disturbance, the location of such erosion, and the lateral extent of deposition cannot be known ahead of time. The impacts of potential flooding is something that is typically evaluated during the FS, which follows the RI and risk assessments. It is during the FS process that the EPA evaluates alternatives for cleanup against the nine criteria in the National Oil and Hazardous Substances Pollution Contingency Plan. The potential impacts of flooding would be evaluated against the criteria for compliance with applicable or relevant and appropriate requirements and long-term effectiveness and permanence.

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			over 12,000 cfs almost double the maximum flow measured over the past 86 years. An event of this nature hitting the Clark Fork River Watershed would very likely overwhelm the existing Smurfit Stone berms and significant channel adjustment would be likely.	
160	B Sims	Site Characterization	Soil sampling density appears to be far too low to adequately determine the presence or amounts of contamination across the 3000 acre site and the risks that may or may not be present (see OU3 figures 3.4, 3.5, 3.6). Direct sampling and identification of the aerial extent and concentrations of contamination are essential to assessing risks and planning remediation. Page 4 of the HHRA OU3 states: <i>“There are two main levees and several berms that were constructed using on-Site materials. The CFR levee located west of the treated water holding ponds provides flood protection, and the inner levee provides a physical barrier between wastewater solids and treated water holding ponds.”</i> Any reliance on the existing un-engineered berms to protect the site from a significant flood is questionable and likely false. Reliance on the existing estimate of the 100 year flood plain map ignores climate change and the likelihood of increased risk of flooding. The possibility of the Clark Fork River flowing through the site and eroding new channels is real and must be assessed to determine risks. In such a scenario, significant quantities of whatever is buried would be transported downstream by the river.	Sampling conducted to date adequately characterizes site conditions for risk assessment purposes to evaluate the current study area. The focus of a risk assessment is on estimating exposures that a receptor may reasonably be exposed to within a given exposure area over their entire exposure duration. EPA recently published an aerial deposition fact sheet (EPA, 2021a) that provides additional information and will be cited in the HHRA. Risk assessments are performed using available site data and presumed exposure scenarios to estimate the chronic risks posed by the contaminants present at the site. CERCLA risk assessments cannot and should not be used to estimate short-term risks from hypothetical events such as flooding, since the extent of soil disturbance, the location of such erosion, and the lateral extent of deposition cannot be known ahead of time.
161	B Sims	Exposure Assessment	One additional comment relates to the assumption regarding primary contact by people wading and swimming in the Clark Fork River. A partially false assumption is seen on page 16 of the OU3 HHRA. It states: <i>“Given water temperature, climate, and the general nature of the river adjacent to and directly downstream of the Site as dynamic and fast flowing, it is not anticipated that a person would be dermally exposed to surface water for any significant amount of time without protective gear (e.g., waders). Thus, dermal exposure to surface water is considered a complete exposure pathway for recreational visitors and tribal fishers during limited wading activities only.”</i> While it is true that there is no river access directly downstream of the Site, swimming and tubing in the river are not unusual events downstream in summer months. Several Fish Wildlife and Parks and informal access points and	Exposure pathways for the recreational visitor population will be expanded to include exposure to Clark Fork River surface water and sediment while swimming/tubing in the summer months.

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			beaches are located between the Smurfit Stone Mill Site and Superior, Montana. White water enthusiast often end up swimming rapids in the George after capsizing. I believe there is primary contact to the Clark Fork River water downstream from the site, and therefore, it should be included in the analysis.	
162	B Sims	General	I recognize the hard work and expertise of the EPA Staff who have tirelessly worked with the CAG, City/ County WQAC, Clark Fork Coalition, and State Agency representatives, and others. I also recognize the limitations inherent in the Super Fund Process that must be negotiated. However, when determining risks, it is always most accurate to take primary measurements on site to establish the level of risk. Groundwater, surface water, and fish sampling are important to establish existing risks to public health, but they do not identify specific areas needing to be addressed. PCBs and furans tend to bind to soils and may be mobilized into the river system by flooding and related erosion. Increasing the amount and the way soils were sampled coupled with a flood analysis that included increased risks due to climate change would have given a much clearer picture of locations needing to be addressed and the risks of these contaminants being transported to the river by flood flows.	Comment noted. The impacts of potential flooding is something that is typically evaluated during the FS, which follows the RI and risk assessments. It is during the FS process that the EPA evaluates alternatives for cleanup against the nine criteria in the National Oil and Hazardous Substances Pollution Contingency Plan. The potential impacts of flooding would be evaluated against the criteria for compliance with applicable or relevant and appropriate requirements and long-term effectiveness and permanence.

Commenter Key:

B Sims: Bruce Sims

CAG: Frenchtown Community Advisory Group

CFC: Clark Fork Coalition

CSKT: Confederated Salish and Kootenai Tribes of the Flathead Reservation

J Harrington: Jen Harrington

J Salazar: Jordan Salazar

MDEQ: Montana Department of Environmental Quality

Missoula Co Commissioners: Missoula County Commissioners

MVWQD: Missoula Valley Water Quality District

PRP: Potentially Responsible Party

Trustees: Montana Department of Justice Natural Resource Damage Program, Montana Fish Wildlife & Parks, Confederated Salish and Kootenai Tribes of the Flathead Reservation, U.S. Fish and Wildlife Service, U.S. Forest Service, and Kalispel Tribe of Indians

V Watson: Dr. Vicki Watson

WQAC: Missoula Public Health City-County Health Department Water Quality Advisory Council

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