
**Comments on the Environmental Protection Agency
Region 6
San Jacinto Waste Pits Proposed Remedial Action Plan:
A Scientific Peer Review**

Paul C. Chrostowski, Ph.D., QEP

CPF Associates, Inc.
7708 Takoma Avenue
Takoma Park, Maryland 20912

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ACRONYMS and ABBREVIATIONS

ABSd	=	Dermal absorption from soil/sediment
AFc	=	Adherence factor for soil/sediment
BHHRA	=	Baseline human health risk assessment
BMP	=	Best management practices
BSAF	=	Biota-sediment accumulation factor
CERCLA	=	Comprehensive Environmental Response, Compensation, and Liability Act
CY	=	Cubic yards
EPA	=	U.S. Environmental Protection Agency
FC	=	Fraction ingested from contaminated area
foc	=	Fraction organic carbon
FS	=	Feasibility Study
Hg	=	Mercury
IPC	=	International Paper Company
IRSc	=	Sediment ingestion rate
Koc	=	Organic carbon-water partition coefficient
Kow	=	Octanol-water partition coefficient
Kp	=	Sediment-water partition coefficient
LOAEL	=	Lowest observed adverse effect level
MIMC	=	McGinnes Industrial Maintenance Corporation
MNR	=	Monitored natural recovery
MW	=	Molecular weight
NCP	=	National Contingency Plan
Ng/kg	=	Nanograms per kilogram
NOAA	=	National Oceanic and Atmospheric Administration
NRRB	=	National Remedy Review Board
OCDD	=	Octachlorodibenzo-p-dioxin
O&M	=	Operation and maintenance
ORNL/RAIS	=	Oak Ridge National Laboratory Risk Assessment Information System
OSHA	=	Occupational Safety and Health Administration
PAH	=	Polycyclic aromatic hydrocarbon
PBPK	=	Physiologically based pharmacokinetic
PCBs	=	Polychlorinated biphenyls
PCDD/Fs	=	Polychlorinated dibenzo-p-dioxins and furans
PCL	=	Protective concentration level
PeCDD	=	Pentachlorodibenzo-p-dioxin
ppt	=	parts per trillion
PRGs	=	Preliminary Remedial Goals
PTW	=	Principal Threat Waste
QEP	=	Qualified Environmental Professional
RAGS	=	Risk Assessment Guidance for Superfund

RAOs	=	Remedial Action Objectives
RfD	=	Reference dose
RI	=	Remedial Investigation
ROD	=	Record of Decision
SA	=	Skin surface area
SARA	=	Superfund Amendment and Reauthorization Act
SDWA	=	Safe Drinking Water Act
SJRWP	=	San Jacinto River Waste Pits Superfund Site
2,3,7,8-TCDD	=	Tetrachlorodibenzo-p-dioxin
TCRA	=	Time Critical Removal Action
TEF	=	Toxic equivalency factor
TEQs	=	Toxicity equivalents
TrCDD	=	Trichlorodibenzo-p-dioxins
UCL	=	Upper confidence limit
USACE	=	U.S. Army Corps of Engineers

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EXECUTIVE SUMMARY

The U.S. Environmental Protection Agency (EPA) Region 6 has announced a Proposed Plan for remedial action for the San Jacinto River Waste Pits Superfund Site (“Site”) in Harris County Texas. CPF Associates was requested by McGinnis Industrial Maintenance Corporation to perform an independent objective scientific and regulatory peer review of the Proposed Plan. The Proposed Plan centers around a regulatory concept of Principle Threat Waste which was developed by EPA to streamline and focus Superfund remedies on source materials that were highly mobile and toxic and which required treatment to reduce volume, mobility, and toxicity. Our review found that Region 6’s preferred remedy does not focus or streamline the remedial action and does not specify treatment of any source materials. Further, we note that Region 6 failed to present evidence that the designated waste is highly mobile or toxic.

These problems are compounded by significant uncertainties and unwarranted reliance on subjective and often arbitrary judgment in the calculation of Preliminary Remedial Goals that were ultimately translated into criteria for characterizing waste as a Principal Threat, contrary to national EPA guidance. A detailed refined analysis shows that the Preliminary Remedial Goals could be orders of magnitude higher than those proposed by Region 6 and still be protective of human health. Region 6 also failed to adequately analyze the proposed remedial alternatives using the criteria from the National Contingency Plan and taking into account the demonstrated feasibility of containment remedies like capping at analogous sites. In developing the Proposed Plan and communicating its results, Region 6 did not comply with EPA national guidelines for transparency and failed to acknowledge scientific and engineering uncertainty in its presentation of the Proposed Plan.

In addition to problems with the Preliminary Remedial Goals and evaluation of remedial options, Region 6 also committed many scientific errors throughout the process of developing the Proposed Plan. Among them were failure to recognize that the dioxins and furans at the site have vastly different physicochemical and pharmacokinetic properties and an inaccurate analysis of the time that it could take dioxins and furans to degrade if they were allowed to

naturally attenuate. These errors need to be corrected if there is to be a credible remedy for this site.

When all of these factors are taken into account, we find that Region 6 has failed to meet the regulatory burden to develop a remedy using the criteria required by the National Contingency Plan and that a containment remedy such as Alternative 3aN would meet goals for protection of human health and the environment and compliance with Applicable or Relevant and Appropriate Requirements while being considerably more implementable, more effective in the short-term, and more cost-effective than the proposed remedy. We recommend that Region 6 withdraw the Principal Threat Waste concept and designation, select scientifically appropriate Preliminary Remedial Goals for the site, and seriously consider all of the proposed remedial alternatives using the National Contingency Plan criteria. All of this should be done in an open and transparent fashion, candidly discussing scientific and engineering uncertainties.

1.0 INTRODUCTION

On September 28, 2016, the U.S. Environmental Protection Agency (EPA) Region 6 released a Proposed Plan (“Plan”) for the San Jacinto River Waste Pits Superfund Site (“Site”) in Harris County Texas and invited comment on the Plan. This comment report responds to that invitation by presenting the results of a scientific peer review of the Plan and its underlying documentation.

1.1 Brief Site Overview

The Site contains impoundments that were used for the disposal of paper mill waste during the 1960s. Although unbeknownst at the time, paper mill waste from bleaching processes has subsequently been found to contain chemicals that are currently listed as Superfund hazardous substances¹. In March 2008, the Site was placed on the National Priorities List due to the presence of polychlorinated dibenzodioxins (“dioxins”). McGinnes Industrial Maintenance Corporation (MIMC) and International Paper Company (IPC) have been actively engaged in the investigation and management of the Site. The actions taken include a Time Critical Removal Action (TCRA) (EPA 2010a) which involved the construction of an armored cap over the impoundments located north of a bridge where Interstate 10 crosses the San Jacinto River (“Northern Impoundments”). Other activities undertaken by MIMC and IPC include monitoring and maintenance of the TCRA cap and the performance of a Remedial Investigation (Integral/Anchor 2013) and numerous other scientific studies. Region 6, in conjunction with the U.S. Army Corps of Engineers (USACE) has performed a Feasibility Study (FS) (EPA 2016a) for the Site and developed the Plan in response to the analysis presented in the FS. Important elements of the Plan include a proposed remedial alternative, remedial action objectives (RAOs), Preliminary Remedial Goals (PRGs) and designation of certain materials as principal threat wastes (PTW).

1.2 Project Scope and Approach

CPF Associates, Inc. (CPF) was requested by counsel to MIMC to undertake an independent objective scientific peer review of the Plan and its supporting documentation. CPF is a Washington DC based scientific research and consulting firm specializing in the regulatory-scientific interface of federal and state environmental and occupational health programs. The Principal Investigator for this assignment was Paul C. Chrostowski, Ph.D., QEP. Dr. Chrostowski has a B.S. in Chemistry from the University of California at Berkeley, an M.S. in Environmental Science (U.S. Public Health Service trainee) from Drexel University, and a Ph.D. in Environmental Engineering & Science from Drexel University. Dr. Chrostowski has also completed continuing education in chemical toxicology, environmental forensics, mathematical modeling, and environmental molecular diagnostics. He is a Qualified Environmental Professional (QEP # 02970014) with over 40 years of experience in the applied environmental sciences specializing in environmental impact assessment including human health and

¹ Note that EPA did not fully delineate the problem of chlorinated compounds in paper waste until 2006 (EPA 2006).

ecological risk assessment, environmental chemistry, environmental forensics, and probabilistic risk analysis. Dr. Chrostowski performed his first risk assessment at a contaminated site in 1979 and, since 1981, has performed technical and scientific work at over 350 Superfund sites. In the first decade of Superfund, Dr. Chrostowski was engaged by EPA to teach the concept of exposure assessment to its regional offices. His involvement with dioxin contamination dates back to the mid-1980s when he offered expert testimony at Times Beach Missouri. Dr. Chrostowski is a member of the Society for Risk Analysis, American Chemical Society, and International Society for Environmental Forensics.

CPF undertook to evaluate the Plan based on general principles of scientific objectivity, reliance on generally accepted science, coherence, consistency with precedent and similar actions implemented elsewhere, data analysis and use, and appropriate application of chemical, toxicological, and statistical methods. All work performed by CPF relied upon methods consistent with the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) as amended and contained in EPA guidance documents. The study was designed to be totally independent of methods used and conclusions reached by any interested party. No direction was received from the study sponsor (MIMC) regarding methods or conclusions of the study. CPF has no vested interest in the outcome of the study and has no conflict of interest with any interested party. Tasks undertaken by CPF include obtaining and analyzing pertinent documents from EPA's Administrative Record and other relevant sources, researching the scientific, engineering, and regulatory literature, performing numerical and statistical analyses on the existing Site chemical database and Region 6's PRG calculations, researching and developing scientifically justifiable alternatives to parameterization of the critical variables used by Region 6 to estimate PRGs, evaluating stability and probability of mobility of waste materials at the Site, and reviewing PTW determinations at other sites in addition to other work necessary to achieve the objectives of an independent scientific peer review.

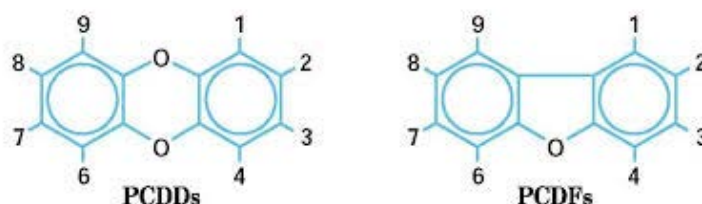
CPF recognizes the dynamic nature of the site and that additional information may be forthcoming from EPA, MIMC's environmental contractors, or the public that may impact the results of the analysis presented herein and reserves the right to modify our conclusions based on this additional information. Note also that these comments do not deal with environmental forensics or alternative sources of dioxins and furans at the site. Although these are important concepts, they are beyond the scope of this study.

In this report, CPF uses the convention that "EPA Region 6" or simply "Region 6" applies to the region-specific documents and decisions made for this site whereas "EPA" refers to other entities within the U.S. Environmental Protection Agency including headquarters, laboratories and other groups.

1.3 Dioxin Taxonomy and Nomenclature

The term "dioxin" is used throughout this report and the documents that were reviewed. The chemical nomenclature of dioxin is complex and a brief explanation is warranted here in the interests of scientific transparency. In its conventional usage, dioxin represents a family of 210 individual chemical compounds more formally designated as the polychlorinated dibenzo-p-

dioxins and furans and often abbreviated as “PCDD/Fs”. The chemical structure outlines of the PCDDs and PCDFs are shown below:



In this figure the numbers around the rings represent locations where chlorine atoms may be added to the molecules. A total of eight chlorine atoms may be added to each. The number and location of these chlorine atoms has a profound effect on the chemical and toxicological properties of the molecules. This is an illustration of the general principle of the “structure-activity relationship” which basically states that a chemical’s structure determines its physical, chemical, and biological properties. This concept is important to understanding the behavior of dioxins and is one of the fundamental axioms of risk assessment and toxicology.

Substitution on the 2,3,7, and 8-positions of the PCDD molecule yields 2,3,7,8-tetrachlorodibenzo-p-dioxin or 2,3,7,8-TCDD which is generally considered to be the most toxic member of the dioxin family. In common usage, this molecule is often referred to as “dioxin”, however, for this report, it will be referred to as 2,3,7,8-TCDD to avoid ambiguity. The reader should also be cautious in reading other documents where this important distinction has not been made. Each individual member of the 210 member dioxin family is referred to as a congener. Congeners with the same number of chlorines attached to the molecules share some properties in common and are aggregated into groups referred to as homologs. Thus, the tetrachloro dioxin homolog contains all 22 congeners with four chlorine atoms, including 2,3,7,8-TCDD. Some other chemical compounds such as polychlorinated biphenyls (PCBs) share elements of chemical structure and, thus, properties with some of the dioxins. These are known as dioxin-like PCBs (DLPCB), however, it is important to keep in mind that there are important physical, chemical, and biological distinctions between DLPCB and dioxins themselves as well as individual distinctions among the individual members of the dioxin and PCB families.

One other concept necessary for understanding the dioxin family is that of toxicity equivalents (TEQs). As its name suggests, this concept is relevant only to toxicity and not to other physical, chemical, or pharmacokinetic properties of these molecules. In the environment, dioxins usually occur as mixtures of individual congeners. Most of the congeners are not considered to be toxic and are typically not evaluated in risk assessments, although they are valuable for environmental forensics and source identification studies. Congeners that contain chlorine atoms in the 2,3,7,8-positions are considered to have varying degrees of toxicity based on *in vitro* laboratory tests². Under a specific set of carefully defined circumstances, the toxicity of

² *In vitro*, which is Latin for “in glass” refers to toxicology laboratory experiments performed in laboratory apparatus and not on observations made in living organisms.

the individual congeners is thought to be additive and a numerical estimate of the toxicity of the overall mixture may be calculated by applying toxicity equivalence factors (TEFs) to the concentrations of the individual congeners and summing the result. Mathematically, the result of this calculation is expressed as 2,3,7,8-TCDD equivalence (TEQ) or:

$$TEQ = \sum_{i=1}^n (C_i \times TEF_i)$$

In this case, TEQ has the same units as the Concentration (C) term. There are specific scientific conditions and uncertainties associated with the calculation of the TEQ (EPA 2010b) which will be fully discussed in subsequent sections of this report³. At times, the result of this calculation is erroneously referred to as “dioxin”, however, that is misleading as it does not clearly and transparently identify the concentration as a dioxin equivalent with all its associated conditions and uncertainties.

A last note about PCDD/Fs is that they are common in the environment and in most living organisms. PCDD/Fs can be generated whenever an organic material (including wood, tobacco, fossil fuels) burns in addition to being generated by some chemical processes. The dioxins are not purposefully manufactured, but, due to the prevalence of combustion sources, most, if not all, Americans have a burden of PCDD/Fs in their bodies. ATSDR (1998) quotes one large study showing that the average background 2,3,7,8-TCDD level in an unexposed population is 4.32 ± 2.53 parts per trillion (ppt) in serum lipid with a 90th percentile of ≤ 10.4 ppt. In a summary table, ATSDR (1998) further notes that the background PCDD TEQs for the general population ranges from 13.7-41.4 ppt and that of PCDFs ranges from 1.4-16.6 ppt. More recent data from the Centers for Disease Control and Prevention (Patterson et al. 2009) showed that the U.S. body burden for TEQs was 30.9 ppt lipid. Not only do these data show the ubiquity of PCDD/Fs in the human population, but they also suggest that many people with background exposures exceed the levels deemed safe using the assumptions Region 6 relied upon to calculate the PRGs. This will be discussed in depth in subsequent sections of this report.

In summary, for purposes of this report, the entire family of dioxins and furans will be referred to as PCDD/Fs, the term 2,3,7,8-TCDD will be used to indicate only that single congener, and toxicity equivalents (TEQs) will be clearly identified. The term “dioxin” will be avoided as it lacks sufficient precision unless it is used in underlying documentation.

2.0 PRINCIPAL THREAT WASTE (PTW) CONCEPT

The PTW concept was originally advanced in the 1990 revisions to the National Contingency Plan (NCP). In essence, it states that EPA expects to use “treatment to address the principal threats posed by a site, wherever practicable”. The determination of whether a material is

³ EPA (2010) states that TEFs “are most appropriate for dioxin exposures via the oral route” and that TEFs may be applied to other routes (such as dermal) as an “interim estimate or as a component of the sensitivity analysis”. These suggestions were ignored by Region 6 which included the dermal route equally with the oral route in its PRG calculations without even a discussion of the uncertainties involved.

defined as a PTW is made on a site-specific basis. In the proposed Plan for this Site, Region 6 has used PRGs to delineate the PTW. In turn, the PTW designation underpins the development and selection of the preferred remedial alternative. This section addresses the regulatory basis of PTW and PRGs and gives examples of the use of the PTW concept at analogous sites.

2.1 Regulatory Aspects

On December 21, 1988, EPA proposed revisions to the NCP, primarily to implement the Superfund Amendments and Reauthorization Act (SARA) of 1986 with a focus on the selection of remedial actions and balance in selecting cleanup standards (Freedman 1989). These proposed revisions introduced the topic of a principal threat. In the preamble, EPA suggested that a range of remedial alternatives be developed to control the source of hazardous substances at a site including treatment alternatives, engineering alternatives, and institutional controls. The range of alternatives generally should include options that remove or destroy hazardous substances to the maximum extent feasible and may include alternatives that treat the principal threats posed by a site but vary in the degree of treatment employed and in the quantity of waste that must be managed. The discussion in the preamble also made it clear that practicability was a criterion to be applied in the development of alternatives. In cases where comprehensive treatment options were less likely to be practicable, only a limited number of alternatives involving treatment of the principal threats, containment, exposure prevention or combinations of these approaches needed to be developed. EPA clearly had qualms about the wide scale application of certain treatment technologies such as thermal treatment and/or incineration and recognized that although treatment was to be preferred, it was most practicable for waste that could not be reliably contained or controlled in place.

In 1991, EPA released “A Guide to Principal Threat and Low Level Wastes” which is EPA’s leading guidance on this topic (EPA 1991a). This document follows the NCP language (including preamble) regarding PTW. It notes that the objective of characterizing a material as PTW is to “help streamline and focus the remedial investigation/feasibility study on appropriate waste management options”. The emphasis on streamlining and focus is repeated throughout the document. The guidance notes that the PTW concept is not a mandatory waste classification requirement. It also re-iterates that EPA expects to use treatment to address the principal threats posed by a site, wherever practicable. EPA defines principal threat wastes as source materials that are considered to be highly toxic or highly mobile that cannot be reliably contained. EPA explicitly states that “no threshold level of toxicity/risk has been established to equate to principal threat” although they further concede that where the toxicity and mobility of a source material combine to produce a cancer risk of 10^{-3} or greater, treatment alternatives should be evaluated. Practicability and technical feasibility are key determinants regarding disposition of a PTW. Factors for consideration in this context include availability and technical feasibility of treatment technologies, volume of material or complexity of the site, implementation of a treatment technology that could cause a greater risk, or severe environmental effects that could result from implementation. It is clear from this guidance that numerous factors need to be carefully weighed in making a PTW determination. In this guidance, EPA notes that “this concept of principal threat and low level threat waste should not

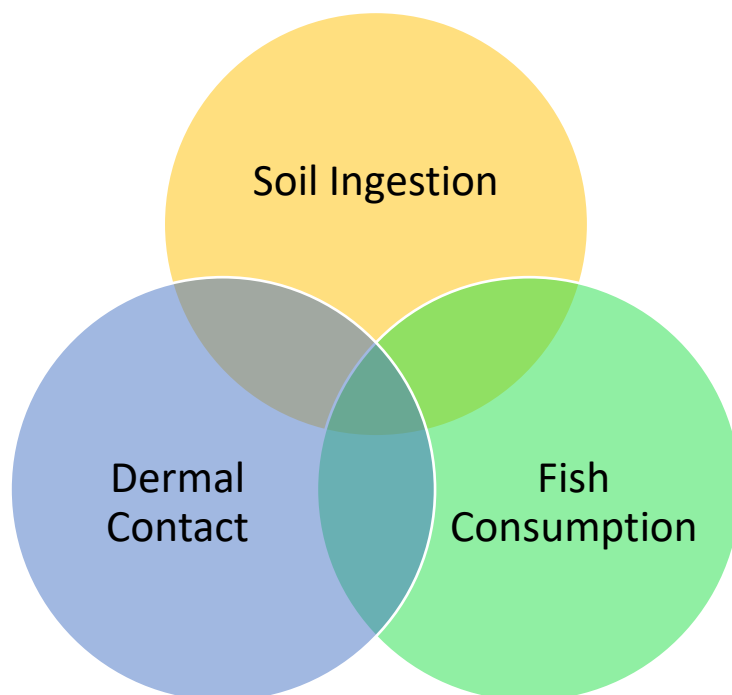
necessarily be equated with the risks posed by site contaminants via various exposure pathways.” This seems to be contrary to the position taken by Region 6 which explicitly based the PTW bright line criterion on risk assessment of site exposure pathways.

In developing rules of thumb for Superfund remedy selection, EPA (1997) further re-iterated many of the concepts regarding PTW determination. These include the expectation for treatment of PTW, use of a combination of toxicity and mobility to define a PTW, and integration of future land use into risk management options regarding PTW. EPA (1997) further goes on to state that “In some situations, it may be appropriate to contain rather than treat principal threat wastes due to difficulties in treating the wastes” and re-iterates the EPA (1991a) guidance regarding practicability and technical feasibility. No mention is made of a risk-based bright line either for identification of a PTW or for use in the management of PTW.

2.2 The Reasonable Maximum Exposure Concept

EPA policy and guidance (EPA 1989, RAGS A⁴) states that “actions at Superfund sites should be based on an estimate of the reasonable maximum exposure (RME) expected to occur under both current and future land use”. EPA continues that, if a population is exposed by more than one pathway, the combination of exposures across pathways also must represent an RME. For decades, it has been clear from this and other guidance and regulatory decisions that the RME should be plausible and well within the range of possibilities, i.e., it does not represent an extreme worst case. The PRGs calculated by Region 6 (Khoury 2016a) are based on a child from birth to six years of age simultaneously inadvertently ingesting sediment, dermally contacting sediment over a majority of his/her body surface area, and ingesting a large amount of fish solely from isolated areas of the site. In all of these calculations, the hypothetical child is assumed to be contacting sediment contaminated with chemicals of concern at a concentration representing the 95% upper confidence limit (UCL) on the mean. The overall PRGs calculated by Region 6 can be conceptually represented by a classical Venn diagram in which the exposure scenario is represented by the area of overlap of the three circles:

⁴ EPA Superfund risk assessments for baseline conditions, calculation of PRGs, and assessment of remedial alternatives, among others, are collectively referred to as “Risk Assessment Guidance for Superfund”, Parts A, B, C etc. We will use the shorthand RAGS A to refer to these documents in the text; complete citations may be found in the reference section.



In the Venn diagram, each circle can be taken to represent the proportion of the population exposed or, alternatively, the probability of exposure. Each one of these alone (individual circles) is a very low probability event (EPA 2011a, Gephart et al. 1994) and, in combination, the probability of them simultaneously occurring (area of overlap) approaches the infinitesimal. These exposure considerations and other factors will be discussed in detail in Section 4 of these comments, however, the lack of plausibility of Region 6's exposure scenario should be kept in mind.

2.3 Preliminary Remedial Goals (PRGs), Remedial Action Objectives (RAOs) and PTW

Region 6 has calculated a PRG for "dioxin" in sediment which it subsequently uses to define PTW at the site, presumably using the "highly toxic" criterion. The concept of "highly toxic" will be discussed in more depth in Section 4, however, at this point, it is pertinent to consider a definition of a PRG and the limitations associated with PRGs. The NCP and EPA guidance consider PRGs as the starting point in a process that culminates in the selection of remedial action objectives (RAOs). Specifically, the NCP notes: "Initially, preliminary remediation goals are developed based on readily available information, such as chemical-specific ARARs or other reliable information. Preliminary remediation goals should be modified, as necessary, as more information becomes available during the RI/FS. Final remediation goals will be determined when the remedy is selected." Note that the NCP clearly intends PRGs to be modified during the course of the Superfund process and also intends the remedy to inform the selection of a PRG, not the other way around. Suter et al. (2000) succinctly define PRGs as "concentrations in media that are starting points for developing cleanup target levels." The NCP notes several factors that may be used to modify PRGs including the "modifying" and "balancing" criteria

used for remedy selection, land use, factors related to technical limitations, and factors related to uncertainty. RAGS B (EPA 1991b) discusses the process for developing RAOs from PRGs: “Final remediation levels are not determined until the site remedy is ready to be selected; final remedial levels are then set out in the ROD. PRGs are refined into final remediation goals throughout the process leading up to remedy selection.”

RAGS B also discusses documentation and communication of PRGs. In the SJRWP administrative record, the first apparent mentions of PRGs are in memos from Region 6 technical staff (Khoury 2016a, Turner 2016a) to the Regional Project Manager (RPM). The development of these PRGs is far from transparent and has not been documented to the degree contemplated by RAGS B. In addition, there is no justification of the process used to derive the PRGs nor evidence that they were modified throughout the Superfund process to reflect the intent of the NCP or RAGS B. Most importantly, there is no justification of the use of a PRG to define a PTW with or without the application of an arbitrary safety factor.

The RI Report and related documentation (Integral/Anchor 2013a, Anchor 2016) developed a series of protective concentration levels (PCLs). Although this report used different nomenclature (PCL vs PRG), the intent was obviously to satisfy the NCP requirement for PRGs. The RI authors presented PCLs for a hypothetical recreational visitor and hypothetical future construction worker based on plausible present and future land use considerations. The assumptions underlying the calculations of these PCLs were fully explained in the Region 6-approved RI report and in subsequent letters from Anchor QEA to Region 6 (Anchor 2013, Anchor 2016) and the uncertainties were characterized in the baseline human health risk assessment (BHHRA) (Integral/Anchor 2013b). These PCLs were summarily rejected by Region 6 in the FS without explanation, however, our review shows that these PCLs fulfilled the NCP requirements for PRGs and could have been readily used to inform the remedy selection process.

Finally, Region 6 apparently believes that PRGs or final RAOs for chemicals with systemic non-carcinogenic effects need to be set at a hazard index (HI) of HI=1. Although this frequently may be the case, it is not required by statute, regulation, policy or guidance. The NCP [§ 300.430(e)(2)(i)(A)(1)] states, “For systemic toxicants, acceptable exposure levels shall represent concentration levels to which the human population, including sensitive subgroups, may be exposed without adverse effect during a lifetime or part of a lifetime, incorporating an adequate margin of safety”⁵. The NCP gives no further direction regarding the definition of an “adequate margin of safety” and does not define a numerical goal for achieving this margin. In RAGS B, we see that EPA has directed that the “total risk for noncarcinogenic effects is set at an HI of 1 for each chemical in a particular medium” when developing a PRG, however, gives no direction how this should be translated into an RAO.

Several EPA regions (3,4,8) have used alternative values for HIs in various Superfund decision documents. For example, EPA Region 3 has recently approved an RAO corresponding to HI=2,

⁵ This language was first used in the Safe Drinking Water Act (SDWA) as a basis for setting Maximum Contaminant Levels and Maximum Contaminant Level Goals. It was not numerically defined in the SDWA or in CERCLA.

on the basis of toxicological uncertainty in an RfD (USACE 2016). As will be seen below, there is substantial toxicological uncertainty in applying the 2,3,7,8-TCDD RfD to the TEQs at the SJRWP Site. On the basis of the logic used by Region 3, toxicological uncertainty alone could increase the SJRWP PTW bright line from 300 ng/kg to 600 ng/kg. Region 4 (EPA 2014) specifically directs developing RGOs⁶ with HQ of 3 based on statements regarding uncertainty made in RAGS A (EPA 1989). This would result in a PTW bright line of 900 ng/kg. Another regulatory interpretation is that used by the Maryland Department of the Environment (MDE 2008) which is based on orders of magnitude values for hazard indices in analogy to the orders of magnitude for cancer risks noted in the NCP. In fact the MDE explicitly considers a hot spot as a site that exceeds a HI of 100. The concept of a hot spot is not substantially different than the concept of a principal threat. Based on this reasoning, the SJRWP bright line could easily take on a value of 3,000 ng/kg. This paragraph demonstrates that the uncertainty associated with a selection of a margin of safety for a noncarcinogen can result in a substantial variability and lack of reproducibility in the outcome. All of the values cited here incorporate an adequate margin of safety and are based on regulatory guidance and usage. All are fully documented and their application is transparent. As with all Superfund regulatory risk management decisions, the selection of an adequate margin of safety and subsequent value of a target hazard index depends on transparent and justified decision-making by the risk manager rather than arbitrary selection of a value.

2.4 Region 6 Failed to Answer NRRB Questions Regarding PTW

EPA policy is that significant Superfund sediment projects require review by the EPA headquarters National Remedy Review Board (NRRB). In its review, the NRRB (2016) posed four questions to Region 6 regarding PTW and requested that the region explain fully how the site's PTW approach was consistent with CERCLA and the NCP. Three of these four questions deal with the subject of treatment:

- CERCLA § 121(b)(1) preference for treatment to the maximum extent practicable
- CERCLA § 121(d)(1) requirements regarding selection of remedies that ensure protectiveness of human health and the environment and achieve or waive applicable or relevant and appropriate requirements
- 40 CFR § 300.430(a)(1)(iii)(A) expectation that treatment be used to address the principle threats posed by a site wherever practicable
- 40 CFR § 300.430(a)(1)(ii)(E) preference for treatment to the maximum extent practicable while protecting human health and the environment, attaining ARARs, and providing the best balance of trade-offs among the NCPs five balancing criteria.

In its response to these questions, Region 6 chose not to address the questions but to make qualitative subjective statements defending their characterization of the waste as PTW. In the context of Superfund, "treatment" is defined by CERCLA § 121 as an activity that "permanently

⁶ Note that region 4 uses the term remedial goal options (RGOs) rather than RAOs.

and significantly reduces the volume, toxicity, or mobility of the hazardous substances, pollutants, and contaminants.” Region 6’s preferred remedial alternative does not involve treatment of the putative PTW in the context of CERCLA, but merely moving it from one place to another. It will not result in a decrease in toxicity. The waste is currently not mobile thus, the preferred alternative will not result in a decrease in mobility, the volume may increase depending on the addition of stabilization reagents, and the remedy will not be permanent.

2.5 Use of the PTW Concept at Analogous Sites Shows Lack of Precedent for Region 6’s Bright Line Criterion

The most common usage of the PTW concept is for sites with non-aqueous phase liquids (NAPL) and groundwater contamination. The NAPL is designated as a PTW; groundwater not containing the NAPL is considered to be a low level threat waste. At these sites, a technical impracticability (TI) boundary is often designated by an applicable or relevant and appropriate requirement (ARAR), usually a drinking water standard. Inside the boundary, a TI waiver is applied and outside the boundary an engineering control such as monitored natural attenuation is applied⁷. Land use restrictions are also a part of the remedial strategy at these sites. At the SJRWP Site, neither groundwater nor the presence of a NAPL is an issue. Recent groundwater data collected below the northern impoundments, in fact, failed to detect PCDD/F congeners (Anchor/Integral 2016). Thus, an alternative strategy, lacking a clear precedent of common usage needed to be employed by Region 6. This is the strategy of developing a bright line designation for a PTW derived from a PRG based on systemic non-cancer toxicity.

A search was conducted for analogous sites to determine how PTW concepts were applied⁸. Numerous examples were found among both EPA- and state-lead Superfund sites. As will be seen below, most of these examples involved the presence of mobile NAPLs.

The Lake Onondaga Superfund Site (Onondaga Lake Bottom Subsite) may come closest to reflecting the original strategy of PTW since much of the contamination consists of a NAPL (NYSDEC/EPA 2005). The NAPL, primarily chlorinated benzenes released during a manufacturing process, is highly mobile as evidenced by sheens, droplets, and visible liquid. The waste was also determined to be highly toxic and was characterized in the ROD as PTW. Nonetheless, EPA opted against exercising its preference for treatment on the basis of impracticability with an engineered cap being the primary remedy for the site. The ROD calls for capping almost 600 acres of contaminated sediments, about ¼ of which exceeds 30 ft in depth in a large lake that frequently freezes and turns over due to thermal gradients. NYSDEC/EPA (2005) noted that some sediment treatment would occur for materials that were dredged to improve cap effectiveness and ensure stability of the cap.

Another site where PTW was based on the presence of a NAPL was the Portland Harbor Superfund Site (EPA 2016a). The sediments at this site contained a NAPL present as globules or

⁷ The term “monitored natural attenuation” is normally used for groundwater and “monitored natural recovery” is used for sediments. For all practical purposes, these terms refer to the same processes and outcomes.

⁸ The citation of these examples should not be construed to mean that CPF supports the remedies or the underlying documentation at these sites.

blebs of product containing chlorobenzene, DDT, PAHs and other aromatic hydrocarbons. In addition, the surface sediment was associated with a cancer risk exceeding 10^{-3} and some portions of the PTW were considered to not be capable of reliable containment. Nonetheless, EPA's evaluation determined that PCDD/Fs could be reliably contained at all concentrations measured at this site.

At the Lower 8.3 Miles of the Lower Passaic River site, the human health cancer risks (from PCDD/Fs, PCBs, PAH and pesticides), clearly exceeded the PTW recommended level of 10^{-3} . Despite this, EPA proposed a remedy primarily involving sediment capping (EPA 2016b). Prior to placement of an engineered cap, enough sediment would be dredged so that the cap could be placed without causing additional flooding and to allow for continued navigational use of the federal channel. The dredged sediments would be disposed of by incineration and/or RCRA Subtitle C landfill, as appropriate. Under this alternative, approximately 90% of the 2,3,7,8-TCDD (including areas with risks greater than 10^{-3}) would be contained under an engineered cap in a river substantially larger and subject to greater flooding than the San Jacinto River.

There are some parallels between the lower Passaic River and the San Jacinto River. First, the primary chemicals of concern are dioxins although there are many more chemicals of concern in the Passaic. The Passaic sediments are also more highly contaminated, however, with surface sediments in the lower Passaic containing up to 34,100 pg/g 2,3,7,8-TCDD, 37,900 pg/g dioxin TEQs, 28,600 ug/kg PCBs, 2,806 mg/kg PAH, and 10,229 ug/kg DDT_{Tr} (Berger 2014). Second, the Passaic River is also one of the most flood-prone water bodies in the United States, subject to hurricanes, tropical storms, Nor-Easters, and tidal storm surges. From 1903 to 2014, there were 61 recorded floods on the Passaic (NWS 2016), including, most recently, Hurricanes Irene (2011) and Sandy (2012). Despite these conditions, the primary remedy is containment by capping -- EPA, New Jersey Department of Environmental Protection, and USACE agree that this remedy will be protective of human health and the environment.

The Housatonic River "Rest of River" site contains primarily PCB contaminated sediments. EPA Region 2 discussed the problem with applying the PTW concept to contaminated sediments and cited EPA's "Contaminated Sediment Remediation Guidance for Hazardous Waste Sites" (EPA 2005) as noting that treatment has frequently not been selected for contaminated sediment. EPA (2012a) continued to state "High costs, uncertain effectiveness, and/or community preferences (for on-site operations) are factors that lead to treatment being selected infrequently at sediment sites....Also [i]t should be recognized that in-situ containment can also be effective for principal threat wastes, where that approach represents the best balance of the NCP nine remedy selection criteria." This conceptual approach is equally applicable to the SJRWP Site.

At the Grasse River Superfund Site, EPA (2013) readily acknowledged that the most highly contaminated wastes could be characterized as PTW on a qualitative basis. Despite this, EPA ultimately opted against treatment and in favor of the use of an armored cap that could reliably contain the PTW on the basis of practicability and cost effectiveness.

These findings are corroborated in a report prepared by Garland (2015) that analyzed a group of sites which she felt were analogous to the SJRWP site based on geographic conditions and identifications of chemicals of concern. Her analysis identified six analogous sites throughout the United States. There is no evidence, either in Garland's report or in the various administrative records for these sites, that a bright-line toxicity based criterion was used to delineate PTW. In fact, none of these sites appear to have relied upon the PTW concept in developing a remedy as is the case in Region 6's Proposed Plan for the SJRWP site. It is quite evident, however, from inspection of the various records that many of these sites are far more hazardous than the SJRWP site since they involve NAPLs containing hazardous substances which were found to be highly mobile. Containment and institutional controls are also important components of the remedies at these sites.

One of the sites analyzed by Garland (2015), the McCormick & Baxter site in Portland, OR (EPA 2011b) bears close attention due to its potential relevance to the SJRWP site. Although the major problems at this site are associated with a creosote NAPL, the sediment remedy may be a model for a similar remedy at the SJRWP site. This sediment remedy consists of:

- Construction of a multi-layer sediment cap using sand, organophilic clay, and armoring, and
- Bank regrading and capping

As constructed, the remedy involved capping 22 acres of sediment including areas where there were NAPL seeps. The seeps were capped with organophilic clay to further prevent releases. The cap incorporated various types of armoring based on the hydraulic and physical environments. No part of this remedy depended on a PTW designation although it easily could have done so due to the mobility and toxicity of the NAPL. This remedy also did not exercise a preference for treatment but rather relied solely on *in situ* containment. Garland (2015) concluded that the cap structure was functioning as designed and that contamination of crayfish in the waters adjacent to this site had been reduced to such an extent that a consumption advisory had been lifted.

This group of analogous sites clearly shows that EPA exercises a great deal of flexibility in managing PTW at sediment sites and in selecting remedies for sites with sediment contamination, even in areas that may experience periodic flooding. As with the selection of a margin of safety, the ability of this flexibility to withstand independent review depends on the depth of justification and transparency used by the risk managers. Although some sites have relied on the existence of a cancer risk exceeding 10^{-3} as suggested in the EPA (1991a) guidance, there is no evidence that any of these sites adopted a bright line toxicity based criterion to define PTW. Finally, many contaminated sediment sites, including those with NAPLs and dynamic energetic hydraulic environments have relied on containment, institutional controls, and monitored natural recovery remedies.

3.0 SAN JACINTO RIVER WASTE PIT MATERIAL IS NOT HIGHLY MOBILE

One of the key criteria for a PTW is a high degree of mobility. In the Proposed Plan, Region 6 has failed to demonstrate that the material in the northern impoundments is highly mobile. In actuality, dioxin congeners are highly immobile and will sorb strongly to materials in the impoundments. A properly designed and maintained cap over the northern impoundments will prevent the mobility of the waste materials and any sorbed PCDD/F congeners.

3.1 PCDD/F Congener Mobility: Physicochemical Properties and Reported Environmental Behavior

In a soil or sediment environment, PCDD/Fs are generally recognized as some of the most immobile compounds known to environmental science. This is due to their high degree of hydrophobicity as well as their ability to sorb to particulate matter through a variety of other mechanisms including hydrogen bonding and van der Waals forces (e.g., Doucette & Andren 1987). EPA (2003) has cited the low water solubilities and high particulate partition coefficients as explanations for the observed immobility of PCDD/Fs in soils and sediments. One of the first comprehensive studies of this phenomenon at a contaminated site was reported by Yanders et al (1989). These investigators constructed test plots from soil at Times Beach MO that had been contaminated by 2,3,7,8-TCDD. They found no appreciable loss or vertical movement of the TCDD over a 4-year period. A follow-up study found no migration or loss of other congeners (1,2,3,4-TCDD, 1,2,3,7,8-PeCDD, OCDD and OCDF) from this soil under controlled conditions in the laboratory. This research corroborates the empirical observation at Times Beach that PCDD/Fs were persistent in contaminated soils for many years even after the site had been flooded by the Meramac River. Other studies cited by EPA (2003) concluded that the binding of PCDD/Fs to soil approaches irreversibility over time due to encapsulation of the compounds in soil organic and mineral matter.

The immobility of PCDD/Fs in marine and estuarine sediments is sufficiently established that it can often be used to date sediment cores. The immobility of PCDD/Fs in sediments has been reviewed by Ricking & Terytze (1995) in support of their hypothesis that aquatic sediments were the final sinks⁹ of PCDD/Fs. Arguably the oldest observation of dioxin congeners comes from inland sea sediments of Japan where 1,2,3,4,6,7,9-HpCDD and OCDD were detected in sediments that had been unaltered for approximately 8,120 years (Hashimoto & Wakimoto 1989). This sample was obtained at a depth of 8.75 m and dated using ¹⁴C techniques. In more recent history, Klos & Schoch (1993) used radiochemical data techniques on sediments in the Lippe region of Germany and were able to attribute the presence of PCDD/F to activities taking place during the two world wars. Sediment cores dating from between 1950 and 1960 were found to have the highest concentrations of 2,3,7,8-TCDD in the Passaic River which is

⁹ In the study of environmental fate and transport, conceptually a chemical is released from a source, travels through a migration pathway and comes to rest in a sink. At this point, the chemical will not relocate but may undergo chemical change.

subject to strong tidal influences and frequent energetic flooding (Bopp et al.1991, Tong et al. 1992). In fact recent sediment core data collected by EPA in the Passaic (Berger 2014) can be used to analyze the history of 2,3,7,8-TCDD discharge into the Passaic and accumulation in the sediments. These data show that deposition started during World War 2 (consistent with manufacturing history), reached a peak between approximately 1955 and 1972 after which it tapered off. During the time period of EPA's contamination history of the Passaic sediments with 2,3,7,8-TCDD, there were about 50 flood events on the river, yet these sediments (and their associated 2,3,7,8-TCDD) were sufficiently stable to compile deposition histories and mass balances.

Much of the behavior of PCDD/F in the environment is due to the propensity of PCDD/Fs to partition to solid materials in preference to water. This phenomenon is known as lipophilicity or hydrophobicity and is well known in environmental chemistry. EPA (1990) presents the three basic relationships describing hydrophobicity as:

Octanol-Water Partition Coefficient:

$$K_{ow} = \frac{C_{octanol}}{C_{water}}$$

Sorption Coefficient:

$$K_p = \frac{C_{solid\ phase}}{C_{water}}$$

Carbon Normalized Sorption Coefficient:

$$K_{oc} = \frac{K_p}{f_{oc}}$$

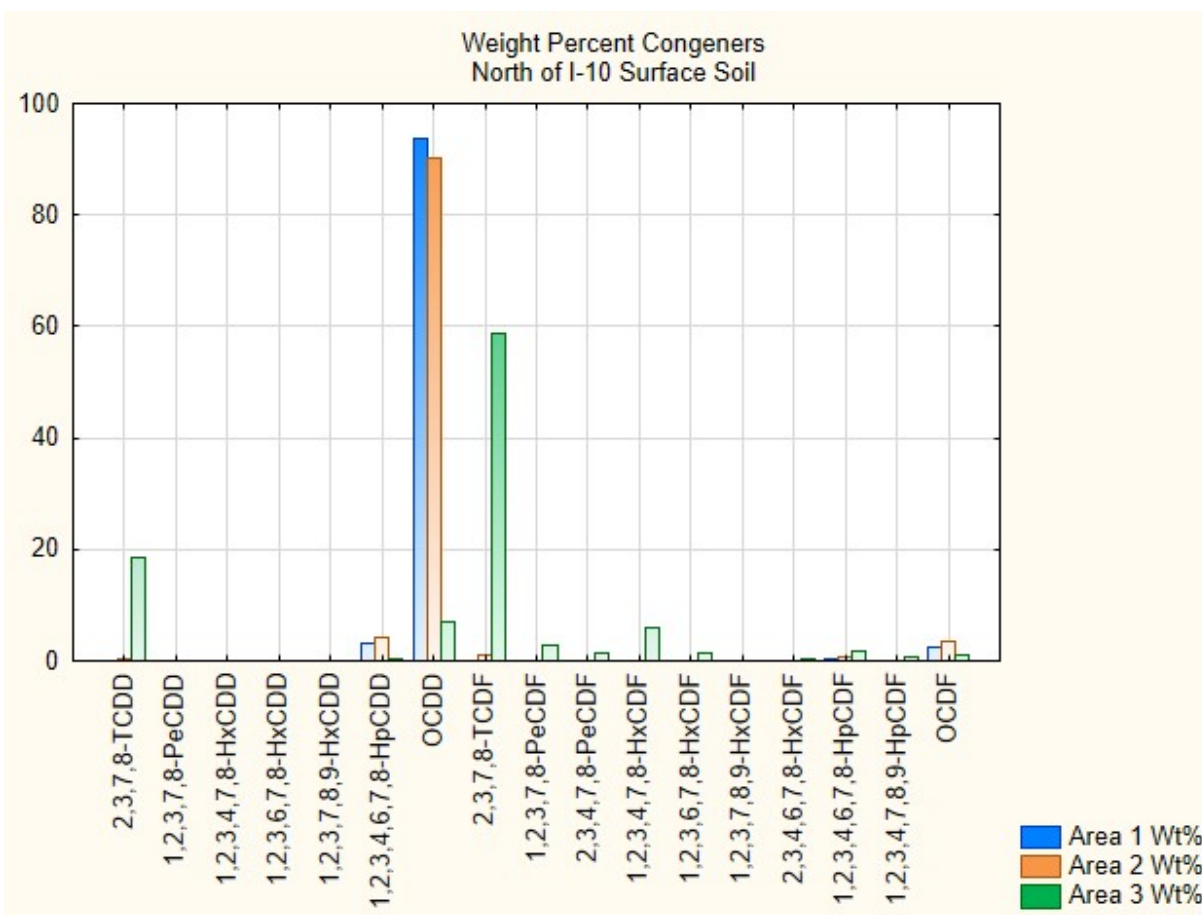
Where: K = partition coefficient

C = concentrations (self-consistent units)

f_{oc} = fraction organic carbon (dimensionless)

Based on these relationships, it logically follows that the higher the value of any of the partition coefficients, the greater the tendency of a compound to stay bound to the solid phase. The values of the partition coefficients vary widely for the different PCDD/F congeners, thus, to evaluate mobility, the exact composition of a PCDD/F mixture must be known. Our review of the RI (Integral/Anchor 2013a) shows that not all PCDD/F congeners are significant or even present in the northern impoundments as shown in the following weight percent profile:

Figure 1—Distribution of Northern Impoundment Congeners



This figure shows that OCDD and 2,3,7,8-TCDF are the dominant congeners. Other congeners with chlorine substituted in the 2,3,7,8 positions include 2,3,7,8-TCDD, 1,2,3,4,6,7,8-HpCDD, 1,2,3,7,8-PeCDF, 1,2,3,4,7,8-HxCDF, 1,2,3,6,7,8-HxCDF, 1,2,3,4,7,8,9-HpCDF, and OCDF are also present at significant concentrations. The partition coefficients for these congeners as given by EPA (2003) and Govers & Krop (1998) are shown in Table 1. In this presentation, Kp is defined as a sediment:water partition coefficient rather than a soil:water partition coefficient):

Table 1 – Dioxin Congener Partition Coefficients

Congener	Log Kow	EPA Log Koc	Log Kp (Govers & Krop 1998)
2,3,7,8-TCDD	6.8	6.4-6.66	7.29-7.86
1,2,3,4,6,7,8-HpCDD	8.00	7.80	9.48-9.97
OCDD	8.2	7.9	10.3-10.49
2,3,7,8-TCDF	6.1	5.2-7.5	7.68-7.95
1,2,3,7,8-PeCDF	6.79		8.72
1,2,3,4,7,8-HxCDF	7.0	7.4	9.37
1,2,3,6,7,8-HxCDF	7.57		9.42
1,2,3,4,7,8,9-HpCDF	8.23	5.0	
OCDF	8.0	7.4	10.5-10.96

It should be kept in mind that these are Log-transformed parameters. Thus, the Log Kow for 2,3,7,8-TCDD translates to an actual value of 6,300,000. It can readily be seen from this table that the partition coefficients for PCDD/F congeners are all very high, all over 1,000,000 times more likely to partition to a solid phase than to stay in water. In addition, it can be seen that there are substantial differences among the congeners. For example, there is a 2.1 Log difference between the lowest and highest Log Kow values for the different congeners. When translated into arithmetic space, this means that OCDD is 126 times more likely to sorb to a solid phase than 2,3,7,8-TCDF.

The reader should also note the substantial congener-specific variability regarding the values in Table 1. The importance of this will be obvious when we discuss the use of congener-specific properties rather than generic hypothetical “TEQ” properties relied upon by Region 6 in other sections of these comments.

A few additional things need to be pointed out regarding partitioning. First, not all sorption, especially for high molecular weight compounds with large electron clouds like the PCDD/F congeners, is by lipophilic:hydrophobic partitioning. This is recognized by EPA (1990) who notes that mineralogy, permeability/porosity, surface charge, and surface area of the solid phase all play a role in sorption in addition to that played by organic carbon content. PCDD/Fs have been found to sorb to mineralized clays without any organic component whatsoever (Nolan 1989). The principal author of these comments has personally observed the sorption of dissolved PCDD/F congeners onto glass surfaces in the laboratory. This material would not subsequently desorb into water, but required the use of hexane for its removal. The other thing that should be kept in mind is that partitioning is an important concept for many aspects of environmental and pharmacokinetic behavior of chemical compounds. This will become more apparent when we discuss concepts such as bioaccumulation, dermal absorption, and pharmacokinetic modeling in subsequent sections of these comments.

3.2 Paper Waste and PCDD/F Partitioning

The source of the PCDD/F congeners in the northern impoundments is paper pulp waste disposed of by Champion paper in the 1960s. PCDD/Fs and other chlorinated compounds were inadvertently produced as an unintentional byproduct of the use of chlorine (including hypochlorite) to bleach paper. Paper pulp contains primarily cellulose (approximately 45%) along with lignin (approximately 20%) and hemicellulose (approximately 20%) and other materials including water (Gurav et al. 2003). During processing, waste material may be generated for a variety of reasons including off-specification or deteriorated product (Carter 1968, Bajpai 2015). Depending on the process, between 4% and 46% of the pulp may end up as waste, with fine paper production producing more waste than coarse product such as fiberboard (Bajpai 2015). Bleaching of pulp during processing inadvertently causes chlorine to react with lignin and results in the production of chlorinated byproducts, most of which are characterized as chlorolignin in addition to lower molecular weight materials such as the PCDD/Fs. Some of these chlorinated materials persist in the waste from the operation and are often disposed of as sludge.

Thompson (1966) inspected the impoundments and waste handling operations at SJRWP. He reported that the dried sludge resembled a cheaper grade of cardboard such as used in egg cartons. Indeed the similarity between waste paper sludge and the material used to make egg cartons is striking, even to the untrained eye as shown in the Figure 2, below:

Figure 2 – Visual Comparison of Waste Paper Sludge and Egg Cartons



Thompson also noted that the material appeared to solidify rapidly and that a stable vertical wall could be cut in the impoundments. The stabilized waste material was also reported to be impermeable to rainwater. According to Carter (1966), the lignins in the pulp act as a natural glue, binding the cellulose fibers. The fibrous organic matter has been evaluated by Anchor/Integral (2011) and found to have low hydraulic conductivity, thus a limited ability for infiltrating water to penetrate the waste and contact the sorbed organic compounds. The natural stability of this material suggests that it is an ideal candidate for a containment remedy. In addition, the partitioning and sorption of PCDD/Fs to lignin and chlorolignin has been shown to exceed the partitioning to natural soil (Kukkonen 1992, Kukkonen & Pellinen 1994). In one series of tests, Kukkonen (1992) reported K_p values for 2,3,7,8-TCDD in lignin of 15.9×10^5 compared to 2.2×10^5 for chlorolignin and 0.6×10^5 for natural dissolved organic matter as a control. One of the reasons for this strong affinity of 2,3,7,8-TCDD for lignin may be due to its organic carbon content (up to 64.5% for lignin and 60.2% for chlorolignin). Since paper pulp overall has a relatively high organic carbon content compared to natural soils and sediments, this phenomenon may be generalized. For example, Abdullah et al. (2015) found organic carbon content from 18.92% to 33.67% for pulp sludge samples from 6 different mills. This certainly indicates that if a sample of typical sediment, pulp sludge, and water were treated with 2,3,7,8-TCDD, the overwhelming majority would bind to the pulp sludge rather than end up in the sediment or water. Lignin also polymerizes by oxidative coupling as it ages, which may result in an additional mechanism for strong sorption of PCDD/Fs.

This conceptual model has been confirmed at the SJRWP. Louchouart & Brinkmeyer (2009) found organic carbon contents in one of the waste pits ranging from 10% to 60%. These investigators modeled the equilibrium porewater concentrations in sediments in the Houston Ship Channel using these concepts and measured organic carbon values and predicted porewater concentrations ranging from 0.00 pg/L to 0.30 pg/L. The highest values were for OCDD, not surprising considering that this is the most prevalent congener in the Ship Channel

and the San Jacinto River sediment and also has the highest partition coefficients. These results have been corroborated by Anchor & Integral (2012) who performed a groundwater study of three well pairs surrounding the western cell of the northern impoundments and one well screened in the waste. As discussed in their report, sampling results from these wells were not contaminated by PCDD/Fs thus demonstrating how strongly bound the PCDD/Fs are to the material in the impoundment. These results have been confirmed by more recent sampling (Integral/Anchor 2016).

3.3 Stability of the SJRWP Time Critical Removal Action (TCRA) Cap

A TCRA was conducted for the impoundments which was completed in June 2011. Construction of the TCRA included a cap consisting of a geomembrane and geotextile layers covered by some 59,000 tons of rock to ultimately produce an armored cap with thickness from 12 to 24 inches. In addition, the upper three feet of waste material just below the armored cap in the western pit was stabilized by the addition of 8% Portland cement to increase stability and further prevent desorption of PCDD/Fs from the waste. It should be noted that solidification and/or stabilization of hazardous waste using Portland cement has long been advocated by EPA (EPA 1999). The TCRA design also included a thickened cap edge to reduce the potential for undercutting the cap by scour forces.

The cap is subject to on-going inspection and maintenance and has been repaired several times as a result of this. Repairs included placement of additional stone and rock and use of geotextile in an area not covered by the original plan. These repairs have added to the reliability of the original cap. There has been no evidence of a PCDD/F release from the cap to date as clearly demonstrated in Integral/Anchor (2016) and maintenance has only been necessary for a small fraction (<1%) of the cap. A recent dive team inspection performed by Region 6 (EPA 2015) underscores the stability of this cap and its effectiveness in preventing releases to the environment. The report states, “The section of the armor cap located above water (western cell) was observed to be intact with no areas of cap erosion evident. It was noted that several small areas of minor cap erosion along the central berm were evident...A review of respondent’s monthly TCRA monitoring report dated June 15, 2015 have indicated no major problematic areas needing cap repair or maintenance (emphasis added)”. The only recommendations made in the report were placement of additional armor along “small areas” and additional weed control.

Installation, operation, and maintenance of an armored cap is an engineering function that is empirical in nature rather than purely designed-based (e.g., in contrast to building a bridge). The objective is usually for a design to be implemented that then may be adjusted while being closely observed during operation and maintenance. Region 6 has presented no evidence that the cap is not performing as intended or that a modified containment structure will not perform adequately in the future. The USACE has predicted 80% erosion for Alternative 3N (not 3aN) only under unrealistic conditions that are highly unlikely to occur and contradict the “reasonable maximum” philosophy of Superfund. This will be discussed in greater depth in Section 5.

4.0 SJRWP MATERIAL TOXICITY TOO UNCERTAIN AND INSUFFICIENTLY HIGH TO BE USED AS A QUANTITATIVE PTW CRITERION

As noted above, one of the general criteria for a PTW is a characterization of highly toxic. The guidance and some precedent goes on to state that a lifetime excess cancer risk exceeding 10^{-3} can be used to give general support to that characterization. The highest cancer risk found in Region 6's risk assessment (Khoury 2016a) was 6.6×10^{-4} , thus the guidance threshold value of 10^{-3} was not exceeded and the cancer risk failed to meet the criterion. EPA Region 6 then opted for alternative methods to attempt to demonstrate high toxicity including applying an arbitrary safety factor to a PRG that, itself, did not reflect a reasonable maximum exposure.

4.1 Region 6 Failed to Use Principles of Transparency and Uncertainty in Risk Management Decision Making

Since 2001, the U.S. Government Accountability Office has periodically raised questions regarding a lack of transparency and openness in EPA decision making. In testimony before the Senate Committee on Environment and Public Works on January 23, 2009, EPA Administrator Lisa Jackson expressed a "commitment to uphold the values of transparency and openness in conducting EPA operations". She later confirmed this in an "All Hands Message" on April 23, 2009 telling all employees that "We must apply the principles of transparency and openness to the rulemaking process. This can only occur if EPA clearly explains the basis for its decisions and the information considered by the Agency..." In this case, a Superfund "Proposed Plan" or "Record of Decision" may easily be substituted for "rulemaking". Even the most casual perusal of EPA's national website yields numerous statements about EPA's commitments to openness and transparency. Despite this, the decision making process at the SJRWP Site remains murky at best. Some of the things that Region 6 has failed to explain and/or justify include:

- Its decision to apply a factor of 10 to a PRG to define PTW
- Its failure to use congener-specific physicochemical and pharmacokinetic properties
- Its decision to re-write the feasibility study
- Its decision to use a generic biota-sediment accumulation factor (BSAF) in its risk and PRG calculations despite data showing a lack of correlation between sediment PCDD/F concentrations and body burdens in aquatic life
- Its decision to reject Integral's PCLs as candidates for PRGs
- Its statements about the degradation half-lives of PCDD/F congeners
- Its failure to acknowledge the extremely high potential risks to workers and the public associated with Alternative 6N
- Its failure to utilize information in the RI and BHHRA, including a quantitative uncertainty analysis, in decision-making
- Its overall lack of acknowledgement of uncertainty in the decision-making process

The concept of uncertainty in environmental decision making is key to developing a remedy for this site. By failing to acknowledge uncertainty, Region 6 implies that all the elements of its Proposed Plan, from PRGs to PTW designation to analysis of short-term effectiveness, are certain which can convey a false sense of security to the public. In addition, the failure to incorporate uncertainty into risk management means that Region 6 has lost a valuable tool for evaluating and managing the site (Maier 2008). It should be noted that a formal uncertainty analysis was undertaken in the BHHRA, however, Region 6 did not avail itself of this analysis in developing the proposed plan nor did it undertake any uncertainty analysis in its own risk assessment or PRG calculations (Khoury 2016a, b).

EPA has required a formal uncertainty analysis in risk assessment since the publication of RAGS A in 1989. Further guidance on the integration of uncertainty into risk management was provided by EPA in a risk characterization memorandum (EPA 1992). These documents and other related guidance and policy instructs EPA risk managers to consider uncertainty at every step of the risk assessment/risk management process. In Superfund, this includes uncertainties in site physical setting, models, exposure and toxicity assessment, and risk characterization. Several studies conducted by branches of the National Academy of Sciences (NRC 1994, IOM 2013) present explicit instructions to EPA on how to manage uncertainty. In its 2013 report, the Institute of Medicine of the National Academies concludes that EPA decision documents should systematically include information on what health risk uncertainties are present and *how the uncertainties affect the decision at hand* [emphasis added]. Despite the burden clearly placed on risk managers by guidance and policy, the only mention of uncertainty in the Proposed Plan concerns uncertainty in stability of containment remedies. This lack of uncertainty characterization could only lead the naïve reader to believe that, for example, the PTW bright line of 300 ng/kg was a reliable, accurate and precise scientific fact, whereas, in reality, it could just as easily take the form of a whole spectrum of numerical values spanning several orders of magnitude.

One of the most important areas in which EPA Region 6 failed to acknowledge uncertainty regards the application of TEQs to the calculation of risks, PRGs, and the PTW bright line. The uncertainty in each of the TEFs has been assumed by EPA (2010b) to be at least \pm half a log unit. EPA guidance is also quite clear that a sensitivity analysis should be performed to characterize uncertainty when a major risk assessment includes the TEQ concept (EPA 2010b) and devotes a substantial amount of text to a detailed description of just how such an analysis should be conducted. This analysis should be utilized to identify the most important TEF and develop error bounds around its use. Performing such a sensitivity analysis is beyond the scope of these comments, but a simple illustration can be used to demonstrate the principle. Considering that there was little 2,3,7,8-TCDD at the site, we can posit that Region 6's risks were calculated mostly on the basis of TEQs. If we further assume that there is a half-log unit uncertainty in the TEFs and that this does not compound when the TEFs are applied to different congener concentrations to calculate a TEQ, then the resultant uncertainty in the calculated TEQ and associated PRG can also be taken to be one-half a log unit. Using Region 6's PRG of 30 ng/kg (Khoury 2016a), the uncertainty due to the use of TEQs alone would range from 9.5 ng/kg to 95

ng/kg. At the very least, this calculation illustrates the need for a detailed sensitivity analysis as called for in EPA (2010b) guidance; at most it strongly suggests that the uncertainty in the TEQ approach alone is too great to be used in risk management decision making.

4.2 Region 6's PRGs Only Pertain to 2,3,7,8-TCDD Despite the Predominance of Other Congeners at the Site

A quantitative sensitivity analysis was performed by CPF using the equations and parameters in the calculations of PRGs performed by Region 6 (Khoury 2016a). This analysis showed that the most important parameters were chemical specific, including toxicity criteria and BSAF, as were other, somewhat less significant parameters such as dermal absorption and oral bioavailability. Rather than use chemical-specific parameters, however, Region 6 has invented a generic hypothetical compound that they designate as a "TEQ" and to which they ascribe the physicochemical and pharmacokinetic properties of 2,3,7,8-TCDD. As shown in Figure 1, the predominant PCDD/F congeners at the site are OCDD and 2,3,7,8-TCDF, however, the chemical-specific parameters used in Region 6's calculations were all only based on 2,3,7,8-TCDD properties assigned to the hypothetical "TEQ". This introduces a significant amount of error in the use of these PRGs for any chemical other than 2,3,7,8-TCDD and obviates the use of the PRGs either to derive cleanup goals or to characterize PTW unless they are limited to application to 2,3,7,8-TCDD.

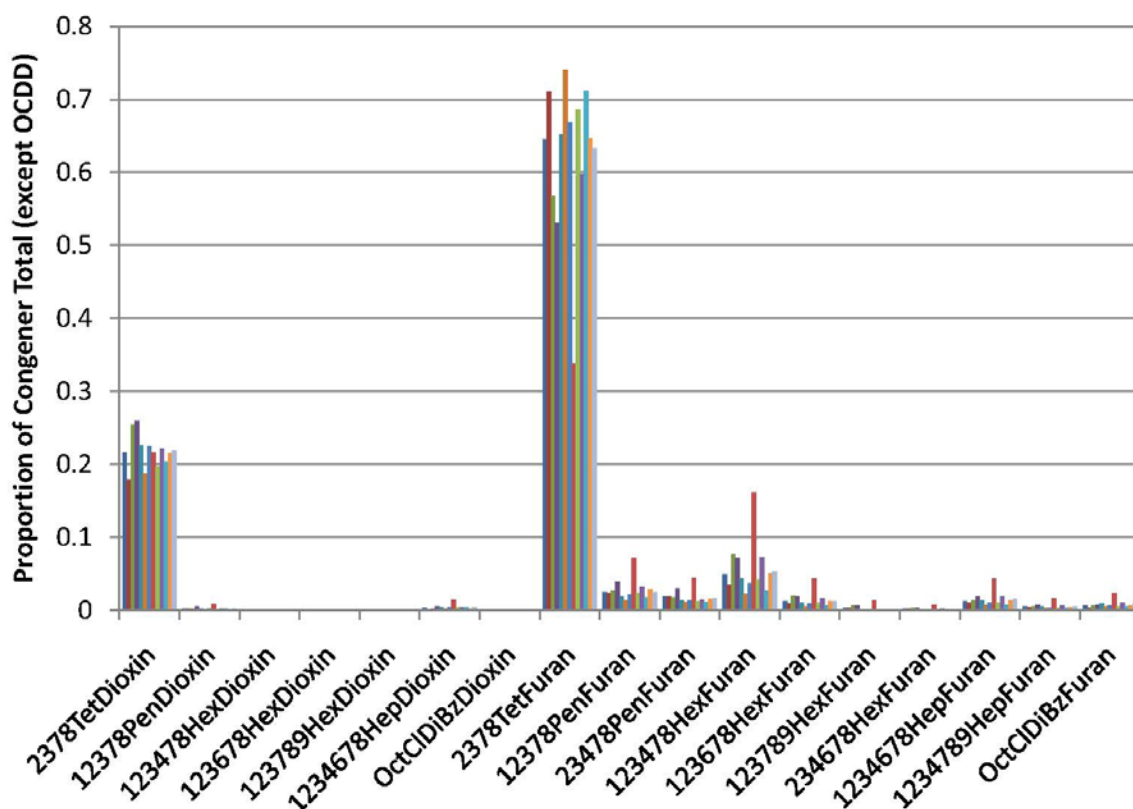
It is instructive to closely examine the chemical profile of PCDD/F congeners at the site. As shown in Figure 1 calculated from data found in Table 5-1 of the RI (Integral/Anchor 2013), in no case does 2,3,7,8-TCDD constitute a majority of the PCDD/F congeners in surface soils from the TxDOT Right-of-Way and North of I-10. Although there is substantial variability from area to area (probably caused by different PCDD/F sources and differential environmental degradation rates), in general Areas 1 and 2 have a high proportion of OCDD, followed by 1,2,3,4,6,7,8-HpCDD and OCDF; Area 3 has a high proportion of 2,3,7,8-TCDF, followed by 2,3,7,8-TCDD, OCDD, 1,2,3,4,7,8-HxCDF, and 1,2,3,7,8-PeCDF as shown in Table 2.

Data obtained from subsurface soils in these areas are similar showing overall a preponderance of 2,3,7,8-TCDF and OCDD. Figure 3, taken from Region 6's FS (EPA 2016c) shows a similar distribution:

Table 2 – Northern Areas Congener Variability (weight percent)

Congener	Area 1	Area 2	Area 3
2,3,7,8-TCDD	0.03	0.25	18.7
1,2,3,7,8-PeCDD	0.01	0.01	0.16
1,2,3,4,7,8-HxCDD	0.01	0.03	0.02
1,2,3,6,7,8-HxCDD	0.08	0.12	0.01
1,2,3,7,8,9-HxCDD	0.05	0.08	0.01
1,2,3,4,6,7,8-HpCDD	3.0	4.1	0.43
OCDD	93.7	90.2	7.0
2,3,7,8-TCDF	0.13	0.94	58.9
1,2,3,7,8-PeCDF	0.01	0.04	2.8
2,3,4,7,8-PeCDF	0.02	0.03	1.4
1,2,3,4,7,8-HxCDF	0.08	0.09	5.9
1,2,3,6,7,8-HxCDF	0.03	0.03	1.3
1,2,3,7,8,9-HxCDF	0.00	0.00	0.07
2,3,4,6,7,8-HxCDF	0.02	0.04	0.21
1,2,3,4,6,7,8-HpCDF	0.41	0.66	1.67
1,2,3,4,7,8,9-HpCDF	0.05	0.05	0.64
OCDF	2.41	3.37	0.92

Figure 3 – Congener Distribution from EPA Region 6 Feasibility Study (Excluding OCDD)
San Jacinto River - Waste Pits Dioxin Fingerprint



Note in this case, that Region 6 has deleted the OCDD column (for reasons not explained). This figure, however, does demonstrate the significance of the PCDFs compared to 2,3,7,8-TCDD. The most recent data (Integral/Anchor 2016) collected from surface sediments continues to show a preponderance of OCDD, followed by 1,2,3,4,6,7,8-HpCDD, OCDF, 2,3,7,8-TCDF, 2,3,7,8-TCDD, and 1,2,3,4,6,7,8-HpCDF in that order. Overall, 2,3,7,8-TCDD only accounts for 0.32% of the median PCDD/F concentrations sampled in this event.

If all of the congeners behaved identically, one could use a generic value for all the significant physicochemical and pharmacokinetic properties required to predict exposure and toxicity and the results would be valid. This was the technique used by Region 6 in calculating its PRGs and PTW bright line. Unfortunately, there are major differences (in some cases, orders of magnitude) among these properties that obviates this generic approach. We have already seen how sorption and mobility differs among the PCDD/F congeners. Various other parameters that control the environmental fate of chemicals also vary by orders of magnitude including biodegradation and photolytic half-lives, volatilization behavior, and water solubility. What is most important, however, in the context of this Proposed Plan, is that exposure and toxicity are also governed by basic molecular properties that dictate how these chemicals behave in the human organism. As Van den Berg¹⁰ et al. (1994) concisely stated, “Thus, human risk assessments for PCDDs and PCDFs need to consider species-, congener-, and dose-specific toxicokinetic data”. Just as a brief example of the significance of this principle of congener-specificity, an analysis of available models has shown that dermal permeability may be reliably predicted using correlations based on two independent molecular parameters – octanol:water partition coefficient and molecular weight (Wilschut et al. 1995). Based on this correlation, EPA (RAGS E) uses the following formula¹¹ to calculate dermal permeability coefficients for hydrophobic chemicals:

$$\log K_p = -2.8 + 0.66 \log K_{ow} - 0.0056 MW$$

Where K_p = dermal permeability coefficient

K_{ow} = octanol-water partition coefficient

MW = molecular weight

Variability in congener-specific values for Log K_{ow} has been discussed in Section 3.1 and Table 1, above. If the appropriate values for 2,3,7,8-TCDD and 2,3,7,8-TCDF are substituted into this relationship, we find that the permeability for 2,3,7,8-TCDD is 2.5 times greater than the permeability of 2,3,7,8-TCDF. Thus, assuming (as EPA Region 6 did in its calculations) that all congeners had the same permeability as 2,3,7,8-TCDD would alone have overestimated exposure and risk by a factor of 2.5 for one of the most important congeners at the site. In this, and related equations, molecular weight is a readily obtainable surrogate for molecular volume.

¹⁰ Note that Van den Berg is considered to be the originator of the TEQ concept and EPA's TEFs are based on his published research.

¹¹ This formula is used for illustrative purposes only; its use should not be construed as support for its accuracy or reliability.

Octanol:water partition coefficient also correlates well with molecular total surface area (which of course is also related to molecular volume). As with most physicochemical parameters, there is a significant difference in physical size among the PCDD/F congeners. For example, the total surface area among the PCDDs ranges over some 210 Å² (Doucette & Andren 1987). This means that it is physically more difficult for larger (and more hydrophobic) molecules to penetrate the skin or even cell membranes. Wilschut et al. (1995) concluded that the practical upper limit for dermal permeation was Log Kow>7, thus many of the highly chlorinated PCDD/F congeners that are present in wastes and sediments at the SJRWP Site are not likely to permeate the skin at all¹².

Congener-specific properties used in risk assessment are almost too numerous to mention. In addition to the distribution of the concentrations of the congeners, some of the important congener-specific parameters used in Region 6's (Khoury 2016a) risk assessment include bioavailability, dermal absorption, gastrointestinal absorption, biota-sediment accumulation factor (BSAF), cancer slope factor, oral reference dose, and the assumption of toxicologic additivity (TEF/TEQ). In addition, there are tacit factors that were not explicitly used in the calculations but which come into play in developing values for parameters or in more refined exposure models. For example, EPA (1992b) notes that the dermal permeability coefficient from soil is a function of the soil:water partition coefficient and the dermal permeability of the chemical from water into the skin. EPA (1992b) also notes that a more refined and time-dependent modeling concept relies on values for chemical-specific diffusion coefficients through the viable epidermis. Fundamental molecular properties involved in these and other related calculations include molecular weight, diffusivity, density, vapor pressure, Henry's law constants, water solubility, partition coefficients, and thermodynamic constants. Sophisticated structure-activity models that have been used to predict physicochemical, pharmacokinetic, and toxicity properties of PCDD/Fs include molecular polarizability, dipole moment, energy of the highest occupied molecular orbital, energy of the lowest unoccupied molecular orbital, the most negative atomic partial charge in the molecule, the most positive partial charge on a hydrogen atom in the molecule and the molecular volume (e.g., Yang, et al. 2006, Doucette & Andren 1987, EPA 2003, Lynam et al. 1998). All of these parameters are different, some by orders of magnitude, for the congeners observed at the SJRWP Site. This will be discussed in depth in Section 4.3 (BSAF) and Section 4.4 (RfD), below.

In Region 6's FS (EPA 2016c), USACE recognized the necessity to use congener-specific values in its mathematical modeling of remedial alternatives. In its RECOVERY model, for example, USACE explicitly referred to 2,3,7,8-TCDD and used parameters consistent with this designation. This is only one of several instances where USACE's analysis conflicts with Region 6's analysis.

At this point, however, it should be apparent to the reader that a fatal flaw in Region 6's PRG calculations was the assumption that all PCDD/F congeners behave identically to 2,3,7,8-TCDD and each other in the environment and in living tissue of human and aquatic life. If the TEQ concept was to be used in these calculations, it should have been applied to the concentrations

¹² Similar comments would apply to uptake by fish across the gills.

of the individual congeners in the target tissue and not to concentrations of congeners in the environment. Alternatively, the PRGs and PTW definition may be applied only to 2,3,7,8-TCDD concentrations in the environment, all other things being equal. This would result in the determination that there was little if any PTW at the Site.

4.3 Exposure Factor Uncertainty

A sensitivity analysis performed by CPF Associates identified several exposure factors used by EPA Region 6 (Khoury 2016a) to develop the PRGs as being responsible for much of the uncertainty in these calculations. In addition to toxicity, the biota-sediment accumulation factor (BSAF) was found to be highly important. Other important exposure factors include the fraction ingested from the site (FC), soil adherence factor (AF), skin surface area (SA), sediment ingestion rate (IRSc) and exposure event time (which was erroneously not considered by EPA Region 6). Each of these factors has associated scientific uncertainty and they combine in ways to propagate and magnify uncertainty in the PRG calculation. Ultimately, this combination of uncertain exposure factors represents a scenario that reflects a virtually impossible, rather than a reasonable maximum, exposure scenario.

4.3.1 Biota-Sediment Accumulation Factor (BSAF)

It is highly unusual for a site to have a PRG based on an indirect exposure pathway such as sediment→fish→human due to the uncertainties in the linkages. The PRG for this pathway, which dominates the overall PRG for sediment, involves selection and application of BSAFs that can link the amount of a PCDD/F congener in sediment to the concentration in edible fish or shellfish. The BSAF used by EPA Region 6 to calculate the PRG that is used to characterize PTW suffers from several deficiencies including: 1) failure to demonstrate a complete pathway, 2) failure to use congener-specific data, 3) use of a generic rather than site-specific BSAF, 4) use of the same BSAF for fish and shellfish, and 5) failure to transparently inform the public of the uncertainties in the BSAF and how it impacts the calculation of the PRG. The many problems associated with Region 6's application of the BSAF concept are puzzling in light of the fact that EPA's National Health and Environmental Effects Research Laboratory is internationally acknowledged to be a center of excellence regarding BSAFs. For example, EPA scientists at this center led by Burkhard et al. (2004) clearly show the relationship between BSAFs and Log Kow values which was not used by Region 6. In another publication, Burkhard et al. (2010) estimated the errors in translating BSAFs across species and across and within sites and found 90th percentile errors from 5.1X to 12X using actual empirical (not default) data. Finally, this lab at EPA has developed a large (over 10,000 entries) database of BSAF values which is available on-line as an interactive MS Access document¹³. The database contains information for the various congeners, finfish and shellfish species, and types of water bodies. As an example of its contents, a quick search by CPF revealed 27 entries for BSAFs for 2,3,7,8-TCDF in estuarine waters. These data could have been further sorted to identify fish species in the San Jacinto River (or analogous closely-related species) that are potentially consumed by local fishers.

¹³ http://www.epa.gov/medProds_Pubs/bsaf.htm

Despite the existence of this center of excellence, Region 6 opted to not avail itself of these resources and use a single default value of dubious provenance for BSAF.

While on this topic, we would be remiss in not pointing out that in Region 6's FS (EPA 2016) the USACE used different values for BSAF than Region 6 did in calculating its PRGs (Khoury 2016a). In contrast to Region 6's default value of 0.09 for all forms of aquatic life, USACE used 0.022 for blue crab, 0.044 for catfish, and 0.070 for clam, each with a specified lipid content. Thus the Proposed Plan is based on disparate value for this critical parameter, yielding widely differing results when used in the context of human health and ecological risk assessment in addition to predicting the ultimate efficacy of the proposed remedial alternatives.

4.3.1.1 *Lack of a Complete Exposure Pathway*

Integral/Anchor (2010, 2013) performed a detailed literature review analysis of bioaccumulation of PCDD/Fs in the SJR. This analysis concluded that "the majority of dioxin and furan congeners do not consistently accumulate in fish or invertebrate tissue". Integral reached these conclusions by sampling both biological tissue and sediment and subjecting the results to statistical analysis using Kendall's non-parametric rank correlation procedure. The results of this analysis are reproduced in Table 3 below:

Table 3 – Statistical Analysis of Hypothetical Sediment-Fish Tissue Association

Compound	Kendall's tau-b	p-value
2,3,7,8-TCDD	0.449	<0.001
1,2,3,7,8-PeCDD	0.144	0.0295
1,2,3,4,7,8-HxCDD	0.0603	0.362
1,2,3,6,7,8-HxCDD	-0.0627	0.345
1,2,3,7,8,9-HxCDD	-0.0405	0.542
1,2,3,4,6,7,8-HpCDD	0.0295	0.658
OCDD	0.0469	0.482
2,3,7,8-TCDF	0.299	<0.001
1,2,3,7,8-PeCDF	0.0192	0.771
2,3,4,7,8-PeCDF	0.193	0.00360
1,2,3,4,7,8-HxCDF	0.0435	0.506
1,2,3,6,7,8-HxCDF	0.0245	0.711
1,2,3,7,8,9-HxCDF	-0.0782	0.233
2,3,4,6,7,8-HxCDF	0.0028	0.968
1,2,3,4,6,7,8-HpCDF	-0.0467	0.476
1,2,3,4,7,8,9-HpCDF	-0.0506	0.440
OCDF	-0.191	0.00402

Note that, appropriately, no values were developed or analyzed for TEQs, but only for individual congeners. Of all the congener relationships in this dataset, only 5 (29%) were statistically significant at a 95% level of confidence (marked in bold). This means that any apparent

relationship between sediment concentrations and fish tissue concentrations for the other congeners could be explained as random chance or statistical noise. Even those pairs with statistically significant relationships had very weak relationships. Kendall's tau-b is a non-parametric correlation coefficient that is conceptually similar to Pearson's product moment correlation coefficient for parametric analysis. A value of zero indicates that there is no relationship between the variables, a value of +1 indicates the maximum positive relationship between the variables and a values of -1 indicates the maximum negative relationship between the variables. Of the variables with a statistically significant relationship, one (OCDF) had a negative relationship suggesting that the occurrence of higher OCDF values in sediment were associated with lower OCDF values in fish. The remaining four congeners had weak Kendall's tau values (ranging from 0.144 to 0.449) strongly suggesting that some other, currently unidentified, variable or variables had stronger associations with congener levels in fish than did sediment levels. Thus, a site-specific analysis showed only weak relationships between a few dioxin congeners in sediment and those in fish. This certainly implies a lack of a complete pathway even from sediment to fish.

It is not sufficient to merely assert that there is a human receptor at the end of an exposure pathway; this must be demonstrated using scientific evidence (Chrostowski 1994). In order to provide this evidence, the next step of the pathway analysis would have been to analyze PCDD/Fs in potential receptors. Serum or plasma PCDD/F measurements are commonly performed in environmental health studies (ATSDR 1998). If the chemical profile (fingerprint) of PCDD/F congeners in a human population matches that in the fish, the fish ingestion pathway would be deemed to be complete. This evidence is particularly important given that PCDD/Fs are ubiquitous in the human population and have an almost infinite number of sources. No such data were obtained for hypothetical fish consumers at the SJRWP Site. The results of the statistical analysis plus the absence of human body burden analysis strongly argue against a complete exposure pathway for human exposure to sediment from consumption of fish.

The decision to base the PTW determination on fish ingestion is particularly perplexing given that Region 6 apparently believes that the problem with fish is not PCDD/Fs but PCBs. Turner (2016) noted that fish PCDD/F concentration levels were already "so close to background" and that "The advisories are likely to remain in place primarily due to PCBs. Although dioxins can be found throughout the watershed, PCBs are more prevalent."

4.3.1.2 *Failure to Use Congener-Specific Data*

Region 6's inappropriate reliance on physicochemical and pharmacokinetic properties of a hypothetical "TEQ" compound rather than congener-specific data permeates their PRG calculations. With the possible exception of the reference dose, nowhere is this more problematic than the use of TEQs with BSAFs. Congener-specific effects on biouptake of PCDD/Fs into fish have been known since the mid-1980s. Region 6 (Khoury 2016b) explicitly acknowledges this. Quoting extensively from ATSDR (1998), "Measurements of the bioconcentration of CDDs tend to increase with the degree of chlorination up to TCDDs and

then decrease as chlorination continues to increase up to the OCDD congeners...The more highly chlorinated congeners, such as OCDD, appear to have the lowest bioconcentration potential either because they are less bioavailable because of their rapid adsorption to sediment particles or because of their large molecular size". Despite this, Region 6 went on to assume that a BSAF for 2,3,7,8-TCDD was appropriate to be applied to all congeners.

The evidence against this approach is overwhelming. EPA (2003) reviewed several studies where BSAFs were reported for various fish species and found differences that spanned several orders of magnitude. Three of these studies from EPA (2003) are summarized in Table 4, below:

Table 4—Congener Specific BSAFs

Compound	Carp	Pike	Lake Trout
2,3,7,8-TCDD	0.27	2.94	0.059
1,2,3,7,8-PeCDD	0.06	1.03	0.054
1,2,3,4,7,8-HxCDD	0.035	0.17	0.018
1,2,3,6,7,8-HxCDD		0.086	0.0073
1,2,3,7,8,9-HxCDD		0.018	0.0081
1,2,3,4,6,7,8-HpCDD	0.0048		0.0031
OCDD		0.002	0.00074
2,3,7,8-TCDF	0.06	1.4	0.047
1,2,3,7,8-PeCDF		0.25	0.013
2,3,4,7,8-PeCDF		0.25	0.095
1,2,3,4,7,8-HxCDF		0.036	0.0045
1,2,3,6,7,8-HxCDF	0.037	0.065	0.011
1,2,3,7,8,9-HxCDF		0.27	0.037
2,3,4,6,7,8-HxCDF		0.047	0.04
1,2,3,4,6,7,8-HpCDF	0.033	0.0009	0.00065
1,2,3,4,7,8,9-HpCDF		0.023	0.023
OCDF		0.0001	0.00099

The differences across columns are likely due to differences in biological species and water chemistry, but the differences across rows for each of the three studies is due to congener chemistry and biochemistry. In the pike study, these differences spanned 5 orders of magnitude and in the lake trout study over two orders of magnitude. This important concept was also communicated by Integral (2013) who stated "TEF is applicable to understanding toxicity, not bioaccumulation. Moreover, all 17 congeners have different properties and statistical comparison using TEQ concentrations obscures the individual chemical behaviors, uptake rates, elimination rates, bioavailability, and other controls on tissue concentrations". Despite this warning, EPA Region 6 opted to apply a generic BSAF to TEQs.

4.3.1.3 *Use and Selection of a Generic BSAF*

EPA Region 6 selected and applied a generic BSAF of 0.09 to calculate the PRGs for the SJRWP Site (Khoury 2016a,b). The value of 0.09 was cited to EPA's 2005 Combustion Guidance. These BSAFs ultimately came from EPA's (2000) dioxin reassessment and are based on an assumed fish lipid content of 7% and a sediment organic carbon content of 3% and fish species which may or may not be relevant to the SJRWP Site¹⁴. It should be noted that even EPA (2000) recommends different values for different homolog classes – hexaCDD/Fs, heptaCDD/Fs, and OCDD/F which were not used by Region 6 in development of the PRGs despite the relevance of these homologs. The rationale for Region 6's reliance on this value despite the existence of some site-specific values reported by Integral and the large database available from EPA (2003) is not apparent.

4.3.1.4 *Use of Identical BASF for Fish and Shellfish*

In calculating the PRG, Region 6 (Khoury 2016a,b) used the same value of BSAF for finfish and shellfish. This practice is contradicted by data presented in EPA (2003) and contradicts data used by USACE in EPA's FS (EPA 2016c). In one study cited by EPA (2003), the BSAF for 2,3,7,8-TCDD in blue crab was 0.055 compared to 0.081 for resident fish from the same location. Another study cited by EPA (2003) showed 2,3,7,8-TCDD BSAFs ranging from 0.04 to 0.12 in finfish and from 0.73 to 0.93 for shrimp and clams, respectively. Although these differences are not as great as the congener-specific differences, the use of a generic factor will only compound the uncertainty introduced by the use of a single BSAF. As noted above, EPA's national BSAF database has numerous values for different congeners in both finfish and shell fish.

4.3.1.5 *Failure to Evaluate and Communicate Uncertainties*

As discussed, the BSAF was one of the most significant values used in the PRG calculations. Using valid published peer-reviewed BSAF values available from EPA (2003) without altering any other factors in the calculations could raise the PRG from 30 to 130 ng/kg. If Region 6's arbitrary safety factor of 10 were to be used with this PRG, it would yield a PTW criterion of 1,300 ng/kg which would dramatically change the delineation of PTW at the site. Despite this uncertainty in the BSAF, Region 6 did not discuss this issue in its Proposed Plan nor in the supporting documentation. This is a classic failure of transparency for this site.

4.3.2 Uncertainties in Additional Exposure Factors

Region 6's selection of individual exposure factors resulted in a calculated PRG that represents a virtually impossible, rather than a reasonable maximum, exposure. This can easily be seen by consulting data presented in EPA's Exposure Factors Handbook (EFH) (EPA 2011a). For example, Region 6 assumes that a child from birth to 6 years eats 14,000 mg of fish per day, 350

¹⁴ Note that after this, the provenance of these values cannot be traced. EPA (2000) cites to Cook et al. 1990 which cannot be found in EPA 2000's reference section. Thus Region 6 is using a value of unknown quality that cannot be traced to a scientific source for one of the most important factors in its PRG calculations.

days per year. In contrast, EFH Table 10-3 does not recommend a fish ingestion value at all for children under three years and a mean of 3,200 mg/day with a 95%-tile of 13,000 mg/day for children 3 to <6 years. These recommendations are specific for fish from the Gulf region. The EFH, Table 10-1 presents data on the percentage of the population that consumes fish and shell fish by age. For finfish this ranges from 2.6% of the population at birth to 1 year to 15% of the population at 6 years for finfish and 0.66% of the population at birth to 1 year to 4.6% of the population at 6 years for shellfish. These percentages, of course, are for consumption of fish from all sources. There are no data for children consuming fish contaminated with 2,3,7,8-TCDD from the SJRWP Site (if this indeed actually occurs), so a proxy is needed. ALCOA (1998) presents data that show a fraction of total fish ingestion from the contaminated source to be 0.097 for a nearby fishery. If we apply this value to the percentages, we see that only from 0.2% to 1.4% of the population would consume fish associated with contamination from the SJRWP Site, should this consumption occur at all. When taken in conjunction with Region 6's intake rate which is higher than the 95%-tile and an exposure frequency of 350 days per year, we see that the plausibility of this scenario in an actual receptor population quickly starts to get lost, even for a reasonable maximum exposure.

Another example of an unreasonable maximum exposure concerns the area of skin that is potentially susceptible to dermal absorption of contaminants. Region 6 uses a value of 3,280 cm² in calculating the PRG According to the EFH (EPA 2011a) Table 7-9, this represents more than the total skin area of an average child from birth to six months, and a significant portion (42% to 86%) of the skin area for an older child. This implies that most of the child's skin is covered with sediment with an adherence factor of 3.6 mg/cm². In essence, this means that the child is carrying some 12 g of sediment each time she or he hypothetically visits the Site.

In calculating PRGs, Region 6 (Khoury 2016a) failed to take into account the time over which exposure could occur. The link between time and exposure is one of the fundamental principles of risk assessment and is normally represented mathematically as (NRC 1991, Chrostowski 1994):

$$E = \int_{t_1}^{t_2} C(t) dt$$

Where E= exposure (mg/kg-day)

C = concentration

t = time (days)

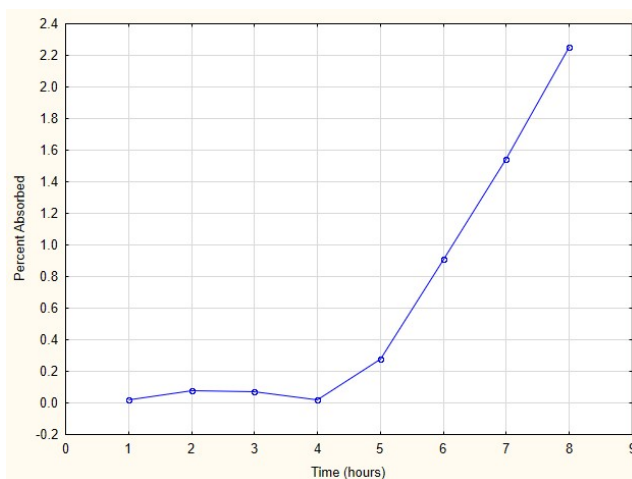
This is important for specific exposure factors and also regarding the reasonable maximum exposure concept. Most very young children spend very little time outdoors away from the home. The EFH (EPA 2011a) notes that, over the time period of birth to 6 years used by Region 6 in its PRG calculations, a child spends from 0 to 139 minutes outdoors per day, depending on age, with a weighted average of about 1 ½ hours. That, of course, is total time outdoors including recess at school, playing in a park or playground, walking or cycling through the

neighborhood, or playing with friends or family in the back yard. There are no data available to show that children actually spend time in contact with contaminated sediment at or near the SJRWP Site, however, it is not likely to encompass their entire time outdoors, especially with the implementation of land use controls. By failing to take time into account, the Region 6 PRGs tacitly assume that a child is outdoors at the Site for 24 hours per day. This clearly is not plausible and inconsistent with the concept of a reasonable maximum exposure.

The significance of time in the SJRWP exposure scenarios can be illustrated by analyzing two exposure factors – dermal absorption from soil (ABSd¹⁵) and inadvertent ingestion of sediment (IRSc). For a reference time, we follow the Oak Ridge National Laboratory Risk Assessment Information System (ORNL/RAIS)¹⁶ and use one hour as a conservative default for exposure time for a recreational use scenario.

Region 6 (Khoury 2016a) used a value of 0.03 for ABSd regardless of the time of contact with the contaminated sediment. Data published by EPA (1992), however, presents a substantially different picture. In this document, EPA (1992) summarized data from four different 2,3,7,8-TCDD absorption studies in humans and rats both *in vivo* and *in vitro*. In all four cases, the data show a strong time dependence. Figure 4 shows the data for human skin from a low organic carbon soil taken from EPA (1992).

Figure 4 -- Absorption of TCDD in Human Skin from Low Organic Carbon Soil



Structure-activity relationships for different congeners will present similar patterns although the absolute values will differ. Roy et al. (2008) in analyzing these and other newer data, concluded that there was a lag time of 7 hours before dermal absorption could be detected. In the case of a recreator at the SJRWP Site, a 7-hour exposure is highly improbable and thus dermal absorption of 2,3,7,8-TCDD is not likely to occur at all. Again, this is an illustration of an

¹⁵ Abbreviations for variables follow Khoury 2016.

¹⁶ <https://rais.ornl.gov>

unreasonable maximum exposure. At the very least, Region 6 should have taken the time course of absorption into account in calculating the PRGs.

Before leaving the topic of dermal absorption, it should be noted that the value of 0.03 for ABSd is obsolete. Newer data developed from EPA-sponsored research shows this value to be between 0.0024 for high organic soil and 0.019 for low organic soil (Roy et al. 2008). Data presented in the RI show that the total organic carbon in SJRWP Site sediments is between the low and high values from Roy et al. (2008), thus an accurate dermal absorption coefficient would also be between these values and should be used for any calculation of PRGs.

The amount of soil that a child inadvertently ingests has also been shown to be a function of time. Basically, the more time the child spends playing in the soil, the greater the amount of soil that adheres to his or her hands and is ultimately conveyed to the child's mouth. Wilson et al. (2015) investigated this phenomenon and found that sediment ingestion rates varied from 18 mg/hr to 72 mg/hr. Based on his data, a plausible reasonable maximum value for IRSc for the hypothetical child recreator at the SJWP Site sediments would be 50 mg/hr, substantially less than the 125 mg/day value assumed in the PRG calculations that did not take time into account.

In addition to time-dependent phenomena and alternative BSAF, plausible values were found in standard or site-specific references (EPA 2011a, ALCOA 1998, ORNL/RAIS) for several other exposure factors used in the PRG calculation. For example, a skin surface area (SAC) value of 2,373 cm², an adherence factor (AFc) of 0.2 mg/cm², and fraction ingested from the contaminated (FC) site of 0.097. All of these values have been used in risk assessments and their use would still be consistent with EPA's definition of a reasonable maximum exposure. When these alternative values of IRSc, SAC, AFc, FC, and BSAF are used in Region 6's equations, the resultant PRG is 600 ng/kg compared to the Region 6 value of 30 ng/kg and the PTW bright line would be 6,000 ng/kg rather than 300 ng/kg¹⁷. This shows that the numerical uncertainty, which was not acknowledged by Region 6 in the Proposed Plan, could vary by a factor of 20 times. This is akin to a weather forecaster predicting a temperature of 5° but acknowledging that it could be as high as 100°. This type of uncertainty would not be acceptable in everyday life and should not be acceptable in Superfund. It also needs to be borne in mind that these values are for 2,3,7,8-TCDD only since both Region 6's and our calculations were performed using parameters that are specific to this particular congener.

4.4 Reference Dose (RfD) Uncertainty

The PRG that Region 6 used to calculate the PTW bright line was based on systemic non-cancer effects as expressed by a toxicological reference dose (RfD). Our sensitivity analysis of the calculations shows that the RfD is one of the most important parameters in the entire set of calculations. Contrary to EPA guidance and EPA's assertions of transparency, the uncertainties in the toxicity assessment were not presented in the Proposed Plan or underlying

¹⁷ This calculation includes the sediment to fish to human pathway for illustrative purposes, despite the fact that the evidence fails to demonstrate that this is a potentially complete exposure pathway.

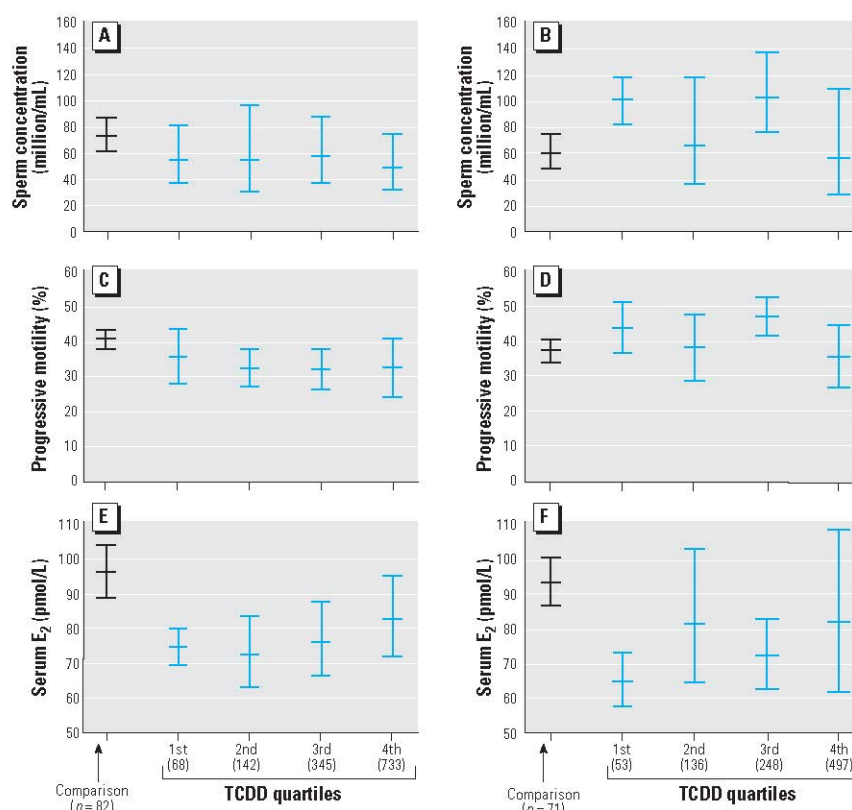
documentation (Khoury 2016a,b, Turner 2016a,b). Some of the items normally discussed in a toxicity assessment uncertainty analysis include qualitative toxicity, derivation of the toxicity values, study duration, extrapolations, biological mechanisms, selection of appropriate datasets, effect of different exposure routes, and potential for interactions (EPA 1989, 1992a, NRC 1994). This leaves the reader with the impression that there is absolute certainty in the RfD, which is certainly not the case. EPA's RfD for 2,3,7,8-TCDD has certainly been controversial. Although beyond the scope of these comments, detailed critiques are available elsewhere (e.g., Magee 2010). Our comments here will be limited to those aspects of the RfD that bear on the PRG calculations and the PTW characterization.

EPA (2012b) based the RfD on two epidemiologic studies of dioxin exposure in Seveso, Italy. One of these studies (Mocarelli et al. 2008) found an association between 2,3,7,8-TCDD exposure and decreased sperm count and motility in men who had been exposed to 2,3,7,8-TCDD as boys. The other study was based on an association between exposure to PCDD/Fs and blood thyroid stimulating hormone (b-TSH) in neonates 25 years following material exposure. In both cases, EPA identified a lowest observed adverse effect level (LOAEL) from the studies, back-calculated estimated doses from plasma chemical concentrations using a physiologically based pharmacokinetic (PBPK) model and applied safety factors to arrive at the RfD. It should be kept in mind that all of the population at Seveso was exposed to chemicals other than PCDD/Fs which included trichlorophenol, trichlorophenate and polychlorinated biphenyls, none of which were taken into account in Region 6's analysis.

In the Mocarelli et al. (2008) study, investigators measured 10 different laboratory parameters related to male fertility in two different age groups (22-31 years and 32-39 years) yielding a total of 20 data points. Statistically significant differences between controls and exposed groups were found for only 9 of the 20 data points. EPA focused in on two of the parameters that showed subtle effects at a 2,3,7,8-TCDD body burden of 68 ppt¹⁸ as shown in A and C of Figure 5:

¹⁸ PCDD/F body burden measurements are often presented as parts PCDD/F per trillion (ppt) parts whole blood, blood lipid, or blood serum.

Figure 5 – Dose-response Data from Mocarelli (2008)



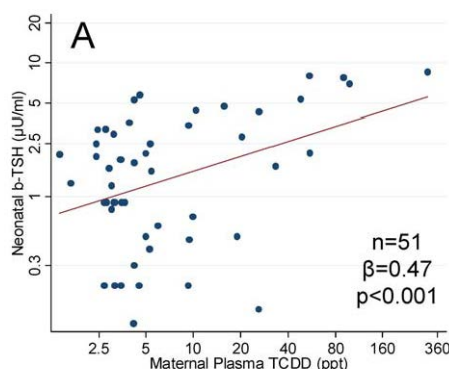
TCDD quartile distribution (adjusted mean and 95% confidence interval) of sperm concentration (A, B), total motile sperm count (C, D), and serum E₂ (E, F) for exposed men and of same-age comparison groups [A, C, E; men who were 1–9 years of age in 1976 (22–31 years of age in 1998); B, D, F; men who were 10–17 years of age in 1976 (32–39 years of age in 1998)]. Median concentrations of TCDD quartiles (shown in parentheses) are expressed as parts per trillion on a serum lipid basis in 1976.

Several factors related to toxicological uncertainty are apparent from these figures. First the magnitude of the error bars in Figure 5 (A) suggests that the apparent difference between the exposed and control groups is not statistically significant and may, in fact, be due to random error. Second, the results show an apparent unresolved paradox in that males exposed in the teens Figure 5 (B and D) show a positive effect of dioxin exposure compared to males exposed when younger Figure 5 (A, C). Third, there is no apparent dose-response relationship in Figure 5 (A, C). EPA (2012b) noted that the data were not amenable to benchmark dose modeling which represents the state-of-the-art in systemic toxicant dose-response analysis. This is likely due to the lack of a true dose-response relationship, a fundamental principal in toxicology (Klassen 1996). None of the results in this study expressed themselves clinically, i.e., there was no evidence that any of the men experienced reproductive difficulties at any age. It should also be kept in mind that this study only pertains to 2,3,7,8-TCDD and not to any other congeners.

EPA apparently intended the Baccarelli et al (2008) study to corroborate the Mocarelli et al. (2008) study since they arrived at exactly the same LOAEL although the toxicological endpoints were totally unrelated. In the Baccarelli study, although the b-TSH was elevated in the most

highly exposed area, the 95% upper confidence level of 2.31 $\mu\text{U/mL}$ was still substantially lower than the World Health Organization reference level of 5 $\mu\text{U/mL}$ ¹⁹, thus, clinical effects were not anticipated. In addition, there is a striking lack of a dose-response relationship for the underlying data. Figure 6, reproduced from Baccarelli et al's Figure 2-A, purports to show a relationship between 2,3,7,8-TCDD plasma concentrations and b-TSH levels when, for example, there is evidence of exceedance of the WHO criterion at TCDD maternal plasma levels as low as 4 ppt (within the range of typical background), no exceedances from about 5-50 ppt TCDD, and a levelling off of < 10 $\mu\text{U/mL}$ for TCDD concentrations from about 50-360 ppt.

Figure 6 - Baccarelli Dose-response Data



Note that none of these data points rise to the level of b-TSH clinical significance as described by Rowland et al. (2008). What may be of even greater importance is that many of the plasma levels, regardless of b-TSH expression, are within the range of background as reported by ATSDR (1998) and Patterson et al. (2009). In addition to the ambiguity of an endpoint, there is no suggestion of a classical dose-response relationship, despite Baccarelli's weak correlation analysis (which is itself a good illustration of the principle in epidemiology that correlation doesn't mean causation). Thus, neither of the studies used by EPA to calculate the RfD shows dose-response relationship consistent with what is known from the general toxicological literature on the PCDD/Fs. A strong dose-response relationship is one of the foundational principles of toxicology (Klaassen 1996) and necessary for demonstrating medical causation using conventional criteria (Chrostowski 2008).

The next step of EPA's RfD process was to take these toxicological data with all their attendant uncertainties and back-calculate an oral administered dose from plasma 2,3,7,8-TCDD concentrations using the Emond PBPK model (Emond et al. 2004, Emond et al. 2005, Emond et al. 2006). This administered dose ultimately translates directly into the RfD after application of

¹⁹ This level has been loosely interpreted by EPA (2012) as having some toxicological significance. "The World Health Organization has established the 5 $\mu\text{U/mL}$ standard (sic) as an indicator of potential iodine deficiency and potential thyroid problems in neonates". In fact, WHO (1994) clearly states that b-TSH of 20-25 $\mu\text{U/mL}$ is commonly employed for congenital hypothyroidism but that a value of 5 $\mu\text{U/mL}$ may be appropriate for epidemiologic studies. Thus this value was not intended to be interpreted as a toxicological threshold. In clinical practice, a level of 50 $\mu\text{U/mL}$ has been associated with an increase in the probability of congenital hypothyroidism (Rowland et al. 2008).

uncertainty (safety) factors. The Emond model has only been parameterized and validated for 2,3,7,8-TCDD and there is no basis for its use with other congeners. Differences in the pharmacokinetics of the various congeners are well known (e.g., Van Den Berg et al. 1994). The Emond model utilizes over 40 individual parameters to describe the behavior of 2,3,7,8-TCDD in the rat. Many of the values of these parameters came from earlier work of Wang et al. (1997) who used radiolabeled 2,3,7,8-TCDD and no other congeners to follow time course distribution data in female Sprague-Dawley rats.

Partition coefficients between various tissues are correlated with octanol:water partition coefficients (see Table 1) which vary over several orders of magnitude for the different congeners. The Emond model uses partition coefficients to determine distribution of 2,3,7,8-TCDD in liver, adipose tissue, rest of the body, placenta and fetus (Emond et al. 2004). As an example of the impact of congener-specific properties, EPA states that the adipose:blood partition coefficient is a highly sensitive variable in the Emond model. This coefficient may be calculated as a function of the octanol:water coefficient plus other physiological parameters. To the extent that the octanol:water partition coefficient varies among congeners, the adipose:blood coefficient will similarly vary. Milbrath et al. (2009) used a pharmacokinetic model to evaluate the transfer of PCDD/F congeners from blood lipid to milk fat in lactating mothers. Their blood lipid:milk fat partition coefficients are shown in Table 5.

Another important parameter in any pharmacokinetic model is the elimination half-life, the time it takes for one-half of an initial dose to leave the body. Milbrath et al. (2009) synthesized data on elimination half-lives of PCDD/F congeners which are also shown in Table 5. As can be seen from the table, these partition coefficients vary by a factor of 4.6 across congeners. This is only one of the partition coefficients used in the Emond model to calculate the reference dose.

Table 5 – Congener-Specific Pharmacokinetic Parameters

Congener	Elimination Half-life (years)	Blood Lipid:Milk Fat Partition Coefficient
2,3,7,8-TCDD	7.2	0.92
1,2,3,4,6,7,8-HpCDD	4.9	1.87
OCDD	6.7	3.3
2,3,7,8-TCDF	2.1	1.1
1,2,3,7,8-PeCDF	3.5	1.6
1,2,3,4,7,8-HxCDF	6.4	1.79
1,2,3,6,7,8-HxCDF	7.2	1.91
1,2,3,4,7,8,9-HpCDF	4.6	4.28
OCDF	1.4	3.4

Again, we see significant differences in both these parameters. Arguably most significant is the fact that one of the dominant congeners at the SJRWP site, 2,3,7,8-TCDF is cleared from the body at a rate 3.4 times faster than 2,3,7,8-TCDD, the compound that was used to develop the

RfD and calculate the PRGs at the SJRWP Site. Application of the Emond model to congeners other than 2,3,7,8-TCDD is beyond the scope of these comments; however, a simple illustration can show the impact of even a single congener-specific parameter. Let's assume that PCDD/Fs are eliminated from the human body using a first order process (Klaassen 1996) and that this may be evaluated using a simple one-compartment model:

$$C_t = C_o e^{-kt}$$

Where C_t = concentration of congener at time = t (years)

C_o = initial concentration following exposure

k = elimination rate constant (years⁻¹)

Converting the half-lives from Milbrath (Table 5) to rate constants, assuming an initial unit concentration, and using EPA Region 6's exposure duration of 26 years (Khoury 2016), we find that the concentration of 2,3,7,8-TCDD after this time would be 460 times higher than the concentration of 2,3,7,8-TCDF when the two congeners started with the same concentration.

In a PBPK model such as the Emond model, these parameters are combined and, thus, the uncertainty associated with an individual parameter is propagated and multiplied in the output. The resulting uncertainty in the model output could easily cause uncertainty of over an order magnitude in the resultant RfD that is independent of, but combines with, the uncertainty in toxicity equivalence.

4.5 Arbitrary Factor of 10, TCDD Dose-Response Relationship, and Definition of Highly Toxic

Region 6 applied a safety factor of 10 to the PRG to substantiate its conclusion that the wastes in the Northern Impoundments are PTW. Region 6 provided no policy, regulation, guidance or science to support this decision. A close examination of the dose-response curves for 2,3,7,8-TCDD from the Mocarelli et al. (2008) study that was used to calculate the RfD, in fact, underscores from a scientific standpoint, the arbitrary nature of this safety factor. The reader's attention is drawn to cases A and C in Figure 5, above. These figures show that there is no increase in toxicity with increasing dose for both sperm concentration and progressive motility, the two laboratory parameters used by EPA to derive the RfD. Even if the dose (expressed as serum concentration) is increased from 68 ppt to 733 ppt (over a factor of 10), there is no statistically significant concomitant increase in outcome. The effect from the Baccarelli et al. (2008) study may be even more striking. The graphical analysis presented in this publication shows no increase in toxicity (represented by neonatal b-TSH concentrations) as 2,3,7,8-TCDD concentrations increase an order of magnitude from 5 to 50 ppt. In fact one would have to increase maternal plasma 2,3,7,8-TCDD by some 140 times to get something even close to a 10-fold increase in toxicity. Even at this level (marginally < 10 µU/mL), however, there is a low probability of clinical hypothyroidism occurring in children when compared to the clinical threshold of 50 µU/mL (Rowland et al. 2008). Overall, the information contained in the dose-response graphical analyses of the studies relied upon by EPA to derive the RfD shows that

there is no evidence-based rationale for selecting a safety factor of 10 and that a safety factor of 100 could just as readily been used without any ramifications to public health.

Even if there was absolute certainty in the calculation of the RfD, it would be difficult to imagine how the use of this RfD could lead to a characterization of SJRWP material as “highly toxic”. As noted above, the effects identified in the two epidemiologic studies that were the basis for the RfD were very subtle and certainly not consistent with a definition of high toxicity. Neither of the studies was based on clinical effects and there is no medical or clinical evidence either of reproductive failure or hypothyroidism in humans at the doses chosen by EPA (2012b) to represent the LOAEL. In addition, the LOAELs chosen by EPA to calculate the RfD overlap with naturally occurring background values of PCDD/Fs in the general population (ATSDR 1998).

In this context, it should be noted that EPA (2012b) divided the LOAEL by a factor of 30 to derive the RfD. To calculate the PTW bright line, Region 6 multiplied the PRG by a factor of 10. This means that the resultant exposure, even if all the other calculations were certain, would still be below the toxicological level at which an adverse effect (LOAEL) for subtle subclinical effects would occur by a factor of three. This hardly fits a definition of “highly toxic” as that term is commonly understood in common usage implying something that can result in severe irreversible injury or death at typical administered doses.

EPA has not developed a definition of “highly toxic” for purposes of characterizing PTW (or indeed for any other related purpose), however, definitions have been developed by other federal regulatory agencies. The most common definition is that used by the Occupational Safety and Health Administration²⁰ (OSHA) and the Consumer Product Safety Commission (CPSC)²¹ which is based on an LD50 of 50 mg/kg in a laboratory rat. One can take the highest cancer risk calculated by Region 6 (Khoury 2016a) and back-calculate a daily dose of 2.5 mg/kg using the Tier 3 oral cancer slope factor. This dose is well below the regulatory definition used by OSHA or CPSC. EPA’s doses may be toxic in the sense that there is some finite probability of an adverse health effect greater than that expected in the absence of exposure, but there is no support for them to be considered highly toxic.

4.6 Alternative PRGs

Although the use of PRGs to characterize a principal threat is contrary to EPA guidance and, in this case, scientifically flawed, it is instructive to see what PRGs would look like if standard default assumptions or alternative reasonable maximum exposure concepts were used in their calculation. Since there is a poor correlation between PCDD/Fs in sediment and that in fish and since Region 6 has failed to demonstrate that a sediment→fish→human exposure pathway is complete, a standard PRG would not include this pathway but would be limited to dermal contact and inadvertent ingestion of sediment plus inhalation of particulate matter emitted by wind erosion. The ORNL/RAIS recreator receptor scenario is the basis of this PRG. This scenario assumes that a recreator contacts sediments for 75 days per year for a 1 hour event over a

²⁰ See 29 CFR 1918.28 App A Health Hazard Definitions

²¹ Federal Hazardous Substances Act 15 USC §§ 1261-1278. August 12, 2011 version.

standard 26 year exposure period (6 years as a child and 20 years as an adult). All of the exposure factors in the ORNL/RAIS PRG model are purposefully biased to be conservative (health protective) as per EPA's reasonable maximum exposure concept (although the probability of this exposure occurring is almost infinitesimally small). The results of this calculation yield a child PRG of 240 ng/Kg, an adult PRG of 215,000 ng/Kg with a combined life-cycle PRG of 778 ng/Kg. In addition, we calculated PRGs for various default hypothetical worker receptors. The results are shown in Table 6.

Anchor (2013) took land use into account in calculating PRGs²² in accordance with EPA guidance (EPA 1995). The reasonably anticipated future land use at the site, which can easily be regulated by institutional controls, would limit access to workers only. Their analysis calculated an outdoor commercial worker PRG of 1,300 ng/kg. Other PRGs for a variety of receptors were presented in Appendix H of the RI report (Integral/Anchor 2013) and are also shown in Table 6.

Table 6 - Summary of Alternative PRG Calculations

Receptor	Source	PRG (ng/kg)
Site-specific outdoor commercial worker	Anchor 2016	1,300
Site-specific recreational fisher	Integral/Anchor 2013	3,479
Site-specific recreational visitor	Integral/Anchor 2013	1,740
Default recreator	CPF Associates	778
Default outdoor worker	CPF Associates	800
Default composite worker	CPF Associates	724
Default excavation worker	CPF Associates	79,200
Child	EPA Region 6 (Khoury 2016)	30
Child	CPF sensitivity analysis using Region 6 approach	600

As expected, in general the site-specific PRGs are higher than the regulatory defaults. The Region 6 PRG is clearly an outlier due to the factors discussed in these comments. All of these alternative PRGs are protective and fit EPA's reasonable maximum exposure concept. All should be compared to the 95% UCL on the mean exposure point concentrations that are appropriate to the particular exposure scenario. Selection among the various PRGs depends mostly on the appropriateness of the receptor. The use of institutional controls as components of the remedy argues against a recreational or visitor receptor. It is a simple matter to control access to the site and the presence of an exposure barrier as in Alternative 3aN will add an extra margin of safety. Depending on the exact institutional control/land use restriction, one of the worker receptor scenarios would be most appropriate.

These PRGs of course, only pertain to 2,3,7,8-TCDD and have bearing only on the calculation of RAOs and not designation of a PTW. These calculations are all based on a HI of 1. Due to

²² Termed "PCLs" in the source documents.

uncertainties in the toxicology behind the RfD, the lack of severity of an effect, and the fact that substantial dermal absorption is not likely to occur during a 1-hour exposure period, an HI of 2 or 3 would be more appropriate and the PRGs would be adjusted upward accordingly. The resulting RAOs would be much higher than the maximum surface sediment 2,3,7,8-TCDD concentration of 23.9 ng/Kg found in 2016 by Integral and would likely apply only to a small portion of the northern impoundments area.

5.0 SJRWP MATERIAL CAN BE RELIABLY CONTAINED

Neither Region 6's FS nor the Proposed Plan demonstrated that the waste pit materials could not be reliably contained on-site. Rather, Region 6 substituted subjective judgment in ignoring containment cap engineering design and the large amount of information available from other sites where these remedies have been used in similar situations.

5.1 Containment Alternatives (2N through 5aN) Can Meet RAOs in Concept. Their Efficacy is a Matter of Engineering which Can Be Managed through Remedial Design

There is no underestimating the importance of engineering design on any containment remedy. On EPA's Clu-In website, Reible (2004) has noted that "Retention of contaminants for decades, centuries, or longer may be expected if the cap can be properly placed and retained over these time periods...It is likely to be feasible to design a cap to be stable under almost any hydraulic forces". This is as true for the SJRWP Site as it is in general and it appears that Region 6 has given insufficient attention to engineering in evaluation of remedial alternatives. Most of the existing uncertainties in the containment alternatives are a matter of simple environmental and civil engineering practice that can easily be managed through the remedial design process that is implemented following issuance of the ROD. Our review shows that all of the containment alternatives will meet the RAOs in concept if sufficient attention is paid to design, evaluation, and implementation of caps as described by Reible (2004):

- Determination of appropriate performance criteria
- Evaluation of mechanisms compromising cap or chemical containment effectiveness
- Evaluation of required armoring layer characteristics
- Identification of appropriate cap material including potential amendments to encourage fate processes
- Evaluation of appropriate cap placement approaches

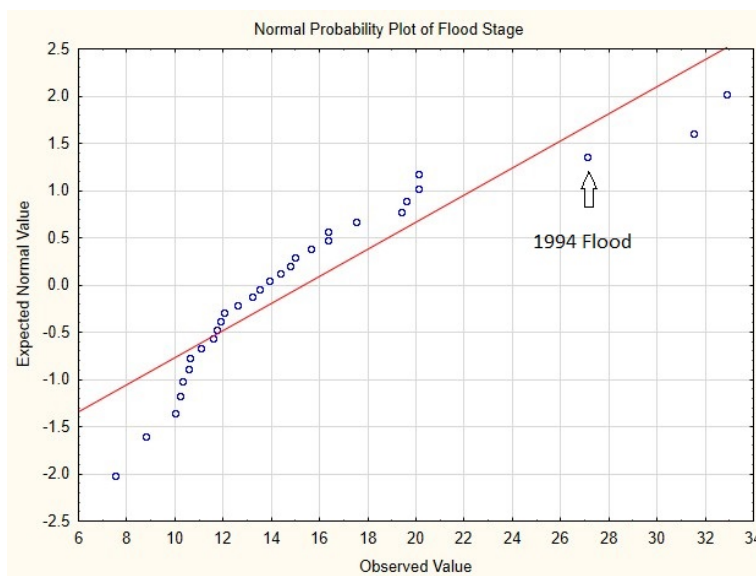
Each of these elements can (and should) be components of the remedial design process.

Rather than focusing on engineering, Region 6 has appeared to rely on several unsubstantiated concepts in evaluating the containment alternatives including emphasizing the significance of very low probability events (hydrologic and operation and maintenance) and assumptions regarding the degradability of the PCDD/Fs.

In the Region 6 FS (EPA 2016c), the USACE analyzed a severe hypothetical event in which a river flow with a discharge of 390,000 cfs occurred simultaneously with a peak storm surge, in other

words Hurricane Ike would occur at the same time as the 1994 flood. Both of these are rare events. Anchor (2012) analyzed the hydrograph of the San Jacinto River and found that the 100-year flood represented a flow of 372,000 cfs. In other words, the flow rate used by the USACE was greater than that experienced in a 100-year flood. Based on this, the probability of the modeled flow rate occurring on any given day is less than 3×10^{-5} . We evaluated flooding for the past 90 years on the San Jacinto using data obtained from NOAA (2016)²³. The resulting probability plot is shown in Figure 7:

Figure 7 – San Jacinto River Flood Hydrograph



This hydrograph is a probability plot of the occurrence of flood stage based on an underlying normal (Gaussian) distribution. The higher the location on the vertical scale, the lower the probability of occurrence. Thus, the scenario evaluated by the USACE is based on a flow too high to be represented on this graph and is a very rare event that can be represented by a daily probability of 9.1×10^{-5} . If one makes the assumption that a peak storm surge and a flood are unrelated events, the joint probability would be about 3×10^{-9} that they would occur simultaneously on a given day. Region 6 uses the result of this modeling effort to dismiss Alternative 3N, however, as we will see below, USACE is much less dismissive and, in fact, presents an engineering solution (which is represented in Alternative 3aN) to scouring of the cap in this scenario. That proposed solution could easily be implemented during remedial design.

5.1.1.1 Efficacy of O&M

Region 6 also appears to assume without evidence that operation and maintenance (O&M) of the cap will fail and the Proposed Plan devotes a substantial amount of discussion to what Region 6 believes are failures in O&M. What Region 6 fails to recognize here is that O&M of any significant civil engineering project is a dynamic and iterative process. One would be hard

²³ In which we describe a storm surge as equal to or exceeding NOAA's action stage of 8 ft.

pressed to find any major structural project in the U.S. that did not have modifications to its maintenance over years of operation as more information became known about the structure and its relationship to its environment. What is important is that there is a legal commitment to inspection and maintenance that evolves as time passes. An example that immediately comes to mind is the new San Francisco Bay Bridge that has been built to replace the structure damaged by the 1989 Loma Prieta earthquake. After the bridge had been built at a cost of \$6.4 billion, it was discovered during O&M that there were corrosion problems with some structural members. This is being remedied by application of an engineering solution. There were no adverse consequences (accidents, injury, and property damage) from the routine discovery and remediation of this problem. This type of a commitment to O&M and iterative improvement is already in force at the SJRWP Site and it can be reiterated and strengthened as part of the remedy and Record of Decision. It should be kept in mind when discussing the current and future operation of any cap that Region 6 has uncovered no evidence of a release from the TCRA cap since it was constructed.

5.1.2 Over-Estimation of Time for Natural Renovation to Occur

Region 6 also appears to base its judgements regarding the time over which a cap may need to be stable on the degradation rates of PCDD/Fs. In the FS (EPA 2016c), Region 6 states, “Dioxins/furans are highly persistent chemicals and will not break down for hundreds of years. While there is considerable uncertainty regarding biodegradation of dioxins/furans, Region 6 estimates that, for dioxins that are not exposed to sunlight the dioxin half-life ranges from 25 to 100 years.” Region 6 (Khoury 2016c) then proceeds to take the upper end of this range to estimate that it would take between 450 years and 750 years for the “dioxin” in the sediment to reduce from a putative 40,000 ppt to various proposed cleanup levels. The origin of the half-life range is obscure at best and misleading at worst. Region 6 cites to EPA’s Clu-In website, but that site merely restates what Region 6 wrote in the FS²⁴. In a memorandum, Region 6 (Khoury 2016c) notes that his source of information was ATSDR’s 1998 Toxicological Profile for dioxin, a secondary and almost 20-year old source, which cited to a statement made by Paustenbach et al. (1992) who derived it from documents dealing with risk assessment rather than environmental fate. Nonetheless, as originally developed it clearly was a default value that only applies to 2,3,7,8-TCDD in subsurface soil rather than to a variety of congeners in sediment.

Since the early 1990’s a vast amount of progress has been made in understanding PCDD/F degradation, both biological and chemical in the environment, including books and review articles devoted to the subject (Wittich 2013, Field & Sierra-Alvarez 2008). The biochemical pathways responsible for the degradation of dioxins to innocuous products are well known as are the conditions under which degradation occurs. Arguably the most significant of these developments is the understanding that PCDD/Fs degrade by microbial reductive dechlorination in anaerobic sediment environments and laboratory environments. This development has been extensively reported upon since the early 2000s (Vargas et al. 2001)

²⁴ https://clu-in.org/contaminantfocus/default.focus/sec/dioxins/cat/Chemistry_and_Behavior/

when it was found that PCDDs undergo anaerobic biodegradation in sulfate-reducing, methanogenic, and iron-reducing sediments. Reductive dechlorination as a biodegradation mechanism was explored by Bunge et al. (2003) and attributed to *Dehalococcoides* species. In 2004, *D. ethenogenes* was found to degrade PCDDs (Fennell et al. 2004). In 2014, *D. mccartyi* strain 195 was found to degrade 1,2,3,7,8-PeCDD to generally non-toxic trichlorodioxins (Zhen et al. 2014). In 2010, Taş et al. delineated the genomics of *Dehalococcoides* spp and found numerous species capable of dehalogenating organic molecules including PCDDs and PCBs. All of this research has been published subsequent to the documents cited by Region 6 and none of it was taken into account by Region 6. Possibly most perplexing is why Region 6 has not considered enhanced monitored natural recovery (MNR) using genetically engineered *Dehalococcoides* spp or zero valent iron *in situ* to accelerate PCDD/F degradation if it is found to be too slow in the uncapped perimeter or other readily accessible areas.

In addition to qualitative information about biodegradation, two very important quantitative principles have emerged from all of this research: that PCDD/F degradation is both a site-specific phenomenon and a congener-specific phenomenon. Wittich (2013) shows degradation rates for PCDD/Fs that range from several days to well over one hundred years. This is a consequence of site-specificity and primarily depends on the nature and abundance of particular consortia of microorganisms and well as chemical factors such as nutrients and electron acceptors. As with many factors involving PCDD/Fs, there is a strong congener-specific variation of biodegradation rates. Wittich (2013), for example, presents data showing that 1,2,4,6,8-PeCDF had a half-life of 1.0 years in sediment whereas 1,2,3,4,6,7,8-HpCDD had a half-life of 4.1 years under the same experimental conditions. Lynam et al. (1998) evaluated reductive dechlorination degradation rates for PCDD/F congeners using molecular orbital theory and found that these rates were congener-specific and could be modeled using conventional thermodynamics. This is in direct contradiction to the approach used by Region 6 (Khoury 2016c) that applied a single degradation rate constant to the particular mixture of many congeners represented by TEQs.

There is recent evidence suggesting that degradation is already occurring at the SJRWP Site. At the Lower Passaic River Superfund site which has been discussed elsewhere in these comments, EPA (Berger 2014) used site-specific empirical data to estimate the half-life for 2,3,7,8-TCDD to be approximately 30 years. In the Baltic, Sinkkonen & Paasivirta (2000) found the ratio of 2,3,7,8-TCDD half-life to 2,3,7,8-TCDF half-life to be 1:0.7 meaning that, based on EPA's half-life for Passaic River sediments, we would expect one-half of the prominent 2,3,7,8-TCDF at the SJRWP Site to degrade in about 20 years.

In addition to ignoring decades of more recent research into PCDD/F biodegradation mechanisms and rate constants, Region 6 (Khoury 2016) used an erroneous mathematical model to predict the time it would take for the PCDD/Fs in the sediments to reach cleanup goals. Without justification, Region 6 (Khoury 2016c) used an integrated form of a chemical kinetics model based on the assumptions that: 1) the process is pseudo first order, 2) that there is only one product to the reaction, and 3) that there is only one reaction. In reality, the case

for the PCDD/Fs is of parallel and consecutive reactions which are well-known in environmental chemistry and engineering (Smith 1970, Pilling & Seakins 1995, Kim et al. 2009).

Although not explicitly stated by Region 6, the differential form of the rate equation used in the calculations is:

$$\frac{dC}{dt} = -k_1 C$$

Where C = the concentration of degrading substrate

k_1 = first order rate constant

t = time

We can examine the ramifications of this calculation by hypothesizing that 2,3,7,8-TCDD is degrading by reductive dechlorination. In a reductive dechlorination process, 2,3,7,8-TCDD can lose chlorines in two positions yielding 1,2,3-TrCDD and 1,2,4-TrCDD. The formation of each of these products from 2,3,7,8-TCDD has its own rate constant (and half-life) and is described by a somewhat different form of the differential rate equation:

$$\frac{dC}{dt} = -(k_1 + k_2)C$$

Where k_1 and k_2 represent the rate constants associated with the two trichlorinated dioxin products.

If we assume that all 40,000 ppt “dioxin” is 2,3,7,8-TCDD (consistent with Region 6 usage) and use the data from Kim et al (2009) in this formulation, we find that it will take only 74 years for the cleanup level of 220 ppt noted by Region 6 (Khoury 2016c) to be attained rather than the 750 years predicted by Region 6. One of the reasons for this large difference is Region 6’s tacit assumption that 2,3,7,8-TCDD is being totally mineralized rather than being degraded to the non-toxic TrCDD products. Further, the degradation reactions are sequential or consecutive. For example, PeCDD → TCDD → TrCDD etc. The kinetics of consecutive reactions are very complex, even for pseudo first-order processes. For example, let’s call the concentration of PeCDD “A”, the concentration of TCDD “B” and the concentration of TrCDD “D” in the above sequence. The degradation in this case can be represented by three simultaneous differential equations:

$$\frac{dA}{dt} = -k_1 A$$

$$\frac{dB}{dt} = k_1 A - k_2 B$$

$$\frac{dD}{dt} = k_2 B$$

Rather than the simple form used by Region 6, the integrated form analytical solution in terms of the yield of “B” (y_B) is:

$$y_B = \frac{k_1}{k_1 - k_3} \left\{ \left(\frac{A}{A_o} \right)^{k_3/k_1} - \frac{A}{A_o} \right\}$$

Parameterization and solution of this equation is beyond the scope of these comments, however, it is well within the scope of environmental engineering practice and may be used along with other equations in the sequence to accurately predict the biodegradation or chemical reduction of PCDD/Fs.

In Integral/Anchor (2016), the investigators found a decrease in surface sediment TEQs from 92.4 ng/kg in 2010 to 17.52 ng/kg in 2016. If this follows a pseudo-first order process, as assumed by Region 6, we may calculate a half-life of about four years which is consistent with that reported by Wittich (2013) for various congeners in sediments. These are promising data which should be pursued to determine their significance both for the design of a cap and MNR at the site. In addition, there is substantial data showing that PCDD/Fs undergo chemical reductive dechlorination in addition to biochemical reductive dechlorination (Kim et al. 2008). The applicability of these processes to enhanced MNR, should enhancements be applied to uncapped areas, should be investigated prior to deciding on a final remedy. Under no circumstances is there justification for using a default obsolete half-life value and an erroneous mathematical model to make decisions regarding selection of remedial alternatives, especially when site-specific empirical data are readily available. In fact, the more recent science regarding PCDD/F degradation underscores the effectiveness of MNR or enhanced MNR as a sediment remedy for these contaminants.

5.1.3 Complexity and Failure Probability of Alternative 6N

Even without taking the erroneous assumptions discussed above into account, it is easy to see that the USACE evaluation effort in Region 6’s FS (EPA 2016c) supports containment remedies. Here, we use Alternative 3aN (with an upgraded cap, institutional controls, groundwater monitoring, and MNR) as an example. Time constraints prohibit doing the same analysis for the rest of the containment alternatives, however, it is likely that one would reach similar conclusions for the others. Since the ultimate outcome of MNR based on reductive dechlorination is detoxification, this remedy would also satisfy the NCP’s preference for treatment (reduction in toxicity).

USACE concluded that Alternative 3N is expected to be “highly effective in controlling the flux of contaminants and reducing the exposure concentration of contaminants in the water column. The exposures and flux at the site will be much less than from the surrounding sediments at concentrations below the PCL (*sic*)”. The USACE also evaluated the effects of remediation (CERCLA short-term effectiveness criterion) and found that “Enhancement of the TCRA cap under Alternative 3N would be expected to produce very little impacts...full removal under Alternative 6N would be expected to significantly increase short-term exposures to contaminants.” USACE concluded that over a 500-year period, Alternative 3N is predicted to

release between 0 mg (*sic*) and 2.18 mg of 2,3,7,8-TCDD depending on the input assumptions used. On the other hand, Alternative 6N could release between 3×10^{-16} mg and 10,200 mg of 2,3,7,8-TCDD, again depending on the inputs used²⁵.

The lower values for some Alternative 6N scenarios are contingent on the successful operation of best practices that have yet to be defined. The USACE's suggested best practices for placement involve "carefully placing the sand material in two equal layers which considerably reduces mixing with the contaminated materials and resuspension. This results in the top 6 inches of material, including the mixed layer, remaining clean and increasing the barrier between the contaminated residuals and the water column". USACE shows the depth of the mixed layer as 10 cm (3.9 inches), two sand layers of 5 cm and 15 cm (2 and 5.9 inches) and a residual layer of 3 cm (1 inches)²⁶, each with prescribed porosities and TOC content. The idea of heavy equipment operating over a large area in an uncertain environment with the precision needed to attain this specification precision in practice is a laudable goal, but probably not attainable in the field. Insofar as other best practices, the USACE has stated "it will be necessary to prepare a contingency plan as part of the Remedial Design in order to develop best practices to prevent, contain, or manage such release." USACE does caution us, however, that "it may be necessary to conduct the work by removing only small portions of the cap at a time, and provide cover for any residuals before starting the next area" which may be considered to constitute a best practice, albeit one that adds complexity and uncertainty to the efficacy of the remedy. In general, however, no mention is given regarding the content of these desired best practices including quality assurance/quality control, performance goals, or consistency with standards.

The Region 6 FS (EPA 2016c) contains a table that analyzes releases from analogous sites that employed best management practices (BMPs) for dredging activities. These studies found a substantial release of contaminants for all 6 sites that were reviewed. In the case of the Passaic River, up to 6% of the dredged PCDD/F was estimated to be released to the water column using dredging BMPs and a silt curtain. In its study of dredging contaminated sediments at Superfund sites, the National Research Council (NRC 2007) concluded that although it was not a guarantee, the adoption of BMPs could help to ensure appropriate implementation of a remedial project. For the reader of the Proposed Plan to be able to evaluate the effectiveness of the BMPs, they need to be presented in detail, critically reviewed, and their probability and consequences of failure assessed.

Regardless of the exact releases, the best practice alternatives will result in adding complexity to a remedial alternative that is already highly complex. As discussed elsewhere in these comments, increasing complexity breeds the probability of increasing failure. Given these and other related conclusions in the USACE analysis, there is little justification for selecting Alternative 6N in preference to Alternative 3aN.

²⁵ See EPA 2016c, Table 16-10. The performance of this model and validity of the results have not been independently validated by CPF.

²⁶ We have preserved the number of significant figures used by USACE in performing dimensional conversions.

5.2 Containment/Entombment Remedies are Commonly Used for Sediment Sites

The United States has had a traditional general focus on capping and monitored natural recovery (MNR) for management of contaminated sediments (Forstner & Aplitz 2007, EPA 2005). The National Research Council (NRC 2007) found that capping after the implementation of dredging was often necessary to meet cleanup objectives. Capping technologies are well developed and have a long track record of use. One of the earliest dioxin sites, the Conservation Chemical Site in Missouri, was remediated by capping the entire site in 1987. EPA's own information on sediment capping is detailed and comprehensive²⁷. The use of capping as a major remedial alternative for contaminated sediment at hazardous waste sites is fully consistent with EPA guidance (EPA 2005). We have discussed some examples above where the PTW concept has been used with capping remedies. Notable among these is the Lower Passaic River, a dioxin site, where capping is the major component of the selected remedy. A complete listing of sites where containment through capping has been incorporated into a decision document is beyond the scope of these comments, however, Table 7 below presents a sampling of these remedies:

Table 7 – Example Sediment Capping Remedies

Site	Cap Size (acre)	Contaminants of Concern
Pine Street Canal	7.8	PAH
GM Central Foundry	2	PCB
Grasse River	284	PCB
Onondaga Lake	425	Hg, chlorobenzenes
Tennessee Products	7.1	PAH
Fox River	387	PCB
McCormick & Baxter	23	Dioxin, As, PAH
Montrose Chemical	300	DDT, PCB
Wykoff/Eagle Harbor	4.8-54 (separate areas)	Hg, PAH
Pacific Sound Resources	58	PAH, PCBs, PCDD/Fs
Welch Creek Domtar	18	PAHs, PCDD/Fs

Even these few illustrative examples show that capping has been used for a variety of contaminants over a variety of areas and in a variety of sediment situations from salt water to flowing freshwater streams and lakes. Similar to the SJRWP Site, armoring and the use of cement or other pozzolanic reagents for stabilization have been used at these and other sites, including those where PCDD/Fs and related chemicals such as PCBs were chemicals of concern.

In addition to the implementation of these containment remedies at other sites, there is a substantial record of successful O&M of sediment containment remedies elsewhere. This includes armor rock repair in the St. Lawrence River (PCBs, PCDD/Fs), intertidal armor

²⁷ <https://clu-in.org/contaminantfocus/default.focus/sec/Sediments/cat/Remediation/p/1>

maintenance in the St. Paul Waterway (PCBs), subtidal armor maintenance at Eagle Harbor (PAH, Hg), and the Georgia-Pacific Whatcom Creek site (Hg). The latter has been, in fact, cited in the media as an example of a demonstration project to derive information about the practicability and design of capping (Harder & Ham 2007). It should be noted that the remedial action at two of these sites where O&M has been successful are driven by mercury which is orders of magnitude more mobile than PCDD/Fs.

6.0 REGION 6 FAILED TO ACKNOWLEDGE THE SERIOUS DEFICITS IN SHORT-TERM EFFECTIVENESS OF THE PREFERRED ALTERNATIVE

The NCP requires an analysis of the impacts of short-term effectiveness of remedial alternatives to include:

- Short-term risks that might be posed to the community during implementation of an alternative
- Potential impacts on workers during remedial action and the effectiveness and reliability of protective measures
- Potential environmental impacts of the remedial action and the effectiveness and reliability of mitigative measures during implementation.

Region 6's preferred Alternative 6N is a significant complex construction undertaking that, in fact, may be without precedent in the history of Superfund. Region 6 proposes excavating and transporting some 152,000 cubic yards (CY) of material that it has characterized as a principal threat, highly toxic and mobile waste. It is axiomatic that complex systems are more prone to failure than simple systems. In his seminal paper on this topic, Richard Cook unequivocally states "Complex systems are intrinsically hazardous systems" (Cook 2000). Cook goes on to explain that failures in complex systems can only be prevented using a variety of technical (e.g., backup systems), human (training, knowledge) and organizational and institutional (policies and procedures, work rules, team training) components. Every operation in a complex system will have an error rate which depends on a variety of factors. In a multistep system, the errors in individual steps propagate to result in an overall failure rate. Thus, the overall probability of failure in a complex system is a function of the number of steps in implementing the system. This is true even for operations with highly trained operators (nuclear power plants, chemical manufacturing) (e.g., Gertman & Blackman 1994).

USACE found Alternative 6N to potentially result in the release of significantly more contamination than Alternative 3aN especially if there was to be a failure in the even more complex (and largely undefined) best practices during or after construction. The various engineering unit operations involved in Alternative 6N include barge unloading, sediment rehandling, dewatering, disposal of contaminated water, sediment stockpiling, transloading, shipping to an off-site facility (location unknown at this point) and management at the off-site facility. Throughout this process, the sediment will maintain its principal threat characteristics as defined by Region 6. Handling of the "highly toxic" principal threat waste is expected to involve 11,800 hours of heavy equipment operations and approximately 13,300 truck trips. It is highly unlikely that such a complex remedy including many process steps will not result in a

release of principal threat highly toxic materials into the environment. Although Region 6 has not provided any details of this remedy, let us assume that the waste will be disposed of at a permitted facility in Texas. The closest facility to the Site is the U.S. Ecology facility in Robstown, TX which is about 230 miles from the Site. If 13,300 trucks make this trip, they will accumulate a total of 3.1 million vehicle miles. Based on data compiled by Rhyne (1994) over the lifetime of this project, this could result in some 87 accidents. The probability of a hazardous materials release from one of these accidents will vary by geography and roadway type but could be as high as 0.10 (Rhyne 1994) which means that approximately 9 of the accidents would result in a release of “highly toxic” materials into water, air, or soil. It should also be noted that some 2% of truck/truck accidents involves a flammable substance (as could occur if the truck hauling PTW collided with a truck hauling petroleum) which would further complicate the nature of the release and any response action. Aside from releases of hazardous materials during transport, there are very real risks of traffic accidents that can result in death, injury, and/or damage to property. These accidents and their consequences could obviously pose a risk to the community that would not occur with a containment remedy such as Alternative 3aN, however, these risks and associated risks to workers were not evaluated by Region 6. Similar risks would also be associated with rail or barge transport.

EPA (1991c) RAGS C has developed detailed guidance for assessing the risks of the NCP’s short-term effectiveness criteria. This guidance includes information on remediation technologies and potentially significant releases. Based on the information contained in this guidance, unit operations associated with waste handling could result in fugitive emissions of particulates and volatiles to air, runoff or leaching of contaminants to surface or groundwater, and seepage or runoff to nearby soil. In addition to the hazards posed by transportation noted above, Region 6 should have at least noted the hazards posed by handling of the waste at the site.

In addition to EPA guidance, the National Research Council (NRC 2007) in its report on sediment dredging at Superfund sites recommended to EPA that “improved risk assessment that specifically considers the full range and real-world limitations of remedial alternatives is needed to allow valid comparisons of technologies and uncertainties. Each remedial alternative offers a unique set of risk-reduction benefits, possibly with the creation of new exposure pathways and associated risks. The effects of adverse environmental conditions, such as those leading to chemical release and production of contaminated residuals, need to be accounted for in a quantitative comparison of net risk reduction associated with different alternatives.” Despite these recommendations, Region 6 did not perform this type of analysis in support of its Proposed Plan or the BMPs that it assumes will be a part of implementation of this plan.

In this regard, Region 6 has failed to meet its mandate for assessing short-term effectiveness risks under the NCP, has not followed EPA’s own guidance which clearly calls for quantitative risk assessments in the case of potential highly toxic materials release, has not followed the recommendations made to EPA by the National Research Council, and has failed to be transparent in its communications with the public concerning potential hazards associated with the preferred remedy.

7.0 USE OF PTW AT THE SJRWP SITE DOES NOT “HELP FOCUS AND STREAMLINE THE REMEDY SELECTION PROCESS”

The PTW concept was first advanced as one of a group of Superfund reforms undertaken in the early 1990s. These reforms including related concepts such as the Superfund Accelerated Cleanup Model and Presumptive Remedies which were designed to respond to criticisms from the Government Accountability Office and others regarding the amount of time it was taking to develop and implement effective remedies at Superfund Sites. As discussed above, EPA notes that the objective of characterizing a material as PTW is to “help streamline and focus the remedial investigation/feasibility study on appropriate waste management options”. The emphasis on streamlining and focus is repeated throughout the document. An oft cited example is the short-term removal of waste-filled buried drums from a site allowing the remainder of the remedy to focus on contaminated media in the long-term. There is no evidence in the Proposed Plan that the preferred remedy will streamline or focus on management of PTW at the site. Rather, the Proposed Plan treats the PTW designation merely as another RAO to be attained. The Preferred remedy is, in fact, highly complex rather than streamlined and focused, especially when compared to the alternatives involving containment.

Further, the clear intent of the PTW concept is to satisfy the statutory preference stated in CERCLA § 121 for remedial actions “in which treatment which permanently and significantly reduces the volume, toxicity, or mobility of the hazardous substances, pollutants, and contaminants is a principal element.” The Preferred Remedy includes excavation of contaminated material, stabilization, and disposal in an off-site landfill. Thus, this alternative clearly does not satisfy the statutory preference for treatment, but merely moves the waste material from one place to another. In theory, dioxin-containing soil may be treated by a variety of methods including thermal, chemical, and physical processes. None of these are considered in this remedial alternative. The FS states, “Several treatment technologies, including thermal (incineration and in-pile thermal desorption) and chemical (solvated electron technology and base catalyzed decomposition) processes were also considered for use at the Site but were not included in a remedial alternative”. Region 6 then goes on to point out exactly why these treatment options are not feasible. Their conclusions here are certainly supported by decades of Superfund experience. *Ex situ* treatment of the large volume of waste involved (approximately 152,000 CY) which may be mostly native sediment is, in fact, not practicable, certainly not cost-effective, and may not even be possible from an engineering standpoint. On the other hand, leaving the sediments *in situ* to undergo MNA avoids most of the problems associated with *ex situ* treatment. Simple cost-effective enhancements such as amending the sediment with engineered consortia of microorganisms or zero valent iron could also be used *in situ* if the natural degradation process was found to be too slow in areas where such enhancements were feasible.

It does beg the question, however, if the Preferred Remedy does not focus or streamline the process and does not involve CERCLA’s statutory preference for treatment, why the PTW designation was made in the first place.

8.0 DISCUSSION AND CONCLUSIONS

The Proposed Plan centers around a regulatory concept of PTW which was developed by EPA to streamline and focus Superfund remedies on source materials that were highly mobile and toxic and which required treatment to reduce volume, mobility, and toxicity. Our scientific peer review found that Region 6's preferred remedy does not focus or streamline the remedial action and does not specify treatment of any source materials. Rather, the preferred alternative creates complexity. With increasing complexity comes a proportionate risk of failure. In some instances, the consequences of failure are likely to be more severe than the putative health risks the remedy is intended to avert. As we have seen with Alternative 6N, there is a very real probability of traffic incidents that could result in death, injury, and/or property damage. These are actuarial risks—millions of such accidents occur in Texas every year. The only necessary predicate for these risks is transportation by motor vehicle. In contrast, the risks associated with the SJRWP Site are purely conditional and conjectural. A child would need to simultaneously contact the site and eat fish contaminated by 2,3,7,8-TCDD at the 95% UCL of concentration at the site regularly for a period of six years to even experience the possibility of exposure at a dose 30 times lower than the LOAEL for subclinical effects. Under this scenario, the risk would be effectively zero.

Further, we note that Region 6 failed to present evidence that the designated waste is highly mobile or toxic. These problems are compounded by significant uncertainties and unwarranted reliance on subjective judgment and unsubstantiated assumptions in the calculation of PRGs that were ultimately translated into criteria for characterizing waste as a Principal Threat, contrary to EPA guidance. Some of the problems with the PRGs, such as the failure to account for the physicochemical and pharmacokinetic properties of individual PCDD/F congeners, are fatal scientific flaws which render the PRGs useless at best and misleading at worst. A detailed refined analysis shows that the PRGs could be orders of magnitude higher than those proposed by Region 6 and still be protective of human health. The application of a safety factor of 10 to the PRG to characterize a PTW is purely arbitrary and results in an exposure dose that is still below the LOAEL for a subclinical effect. This condition could hardly be termed "highly toxic" by any definition.

Despite the fact that containment remedies such as capping and entombment, especially when combined with stabilization, land use restrictions, and MNR have a long track record of widespread application as sediment remedies in the United States, Region 6 failed to seriously consider these remedies. Alternative 3aN meets all of the NCP criteria and has a better chance of working. This is demonstrated by the fact that the current TCRA cap, which is proposed to be upgraded to translate into a permanent remedy, already has been effective in preventing releases of PCDD/Fs to the environment. Alternative 3aN is also considerably more focused and streamlined than the preferred remedy. In Superfund, as in most large scale engineering projects, the law of parsimony also holds – the simpler the remedy, the greater the chance of its effectiveness and the fewer the chances for failure.

Region 6 also failed to effectively communicate the Proposed Plan in a transparent fashion. Some of Region 6's assumptions are purely arbitrary and not justified at all in the Proposed Plan. The selection of the safety factor of 10 to translate from a PRG to PTW is an example. Others contradict site-specific conditions. An example of this is the poor correlation between sediment PCDD/Fs and body burdens of PCDD/Fs in finfish and shell fish. Still others have no basis in scientific fact, such as the assertion that the degradation half-life for PCDD/Fs at the site is between 25 and 100 years. This is in addition to administrative and process issues, such as a lack of justification for Region 6 rejecting a competent FS written by Anchor QEA and substituting its own FS. All of this is compounded by Region 6 failing to acknowledge the uncertainty underlying its conclusions and decisions, thus giving the public the impression that the Proposed Plan is reliable and accurate to a reasonable degree of scientific and engineering certainty.

When all of these factors are taken into account, we find that Region 6 has failed to meet the regulatory burden to develop a remedy using the criteria required by the National Contingency Plan and that a containment remedy such as Alternative 3aN would meet goals for protection of human health and the environment and compliance with Applicable or Relevant and Appropriate requirements while being considerably more implementable, more effective in the short-term, and more cost-effective than the proposed remedy. We recommend that Region 6 withdraw the PTW concept and designation, select scientifically appropriate PRGs for the site, and seriously consider all of the proposed remedial alternatives using the NCP criteria. This reconsideration certainly needs to consider a quantitative risk assessment of the short-term effectiveness as in RAGS C and the scientific literature. All of this should be done in an open and transparent fashion, candidly discussing scientific uncertainties.

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