DEPARTMENT OF ECOLOGY
State of Washington

Dioxins, Furans, and Dioxin-Like PCB Congeners: Addressing Non-Detects and Establishing PQLs for Ecological Risk Assessments in Upland Soil

Implementation Memorandum #11

To: Interested Persons

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11.0 Purpose

This memorandum is an interpretation from the Washington State Department of Ecology (Ecology) for:

1) Evaluating detection limits and non-detects for the purposes of summing congeners for site evaluations; and

2) Establishing a PQL for dioxin-like congeners, specifically for:

   a. Chlorinated dibenzo-p-dioxins (PCDDs) (TCDD is a member of this class);
   b. Chlorinated dibenzofurans (PCDFs); and
   c. Dioxin-like polychlorinated biphenyls (PCBs).

This memorandum addresses Ecological Risk Assessment and the Terrestrial Ecological Evaluation (TEE) under MTCA (WAC 173-340-7490 through -7494). The recommended PQLs for dioxins/furans and dioxin-like PCBs (both congener-specific and summed TEQ values) are listed in Table 3. To address non-detects and establish PQLs for sediments, please consult Ecology's *Sediment Cleanup Users Manual II (SCUM II)* (Ecology, 2015), which can be found at: www.ecy.wa.gov/programs/tcp/smu/sed_standards.htm.

Note: Maximum recommended PQLs for dioxins/furans and dioxin-like PCBs (both congener-specific and summed values) are listed in Table 1 of this memorandum.

11.1 Acronyms and Abbreviations

BDL	Below Detection Limit
CDD	Chlorinated Dibenzo-p-Dioxins
CDF	Chlorinated Dibenzofurans
CRQL	Contract Required Quantitation Limit
EDL	Estimated Detection Limit
GC	Gas Chromatograph
HRGC	High Resolution Gas Chromatography
HRMS	High Resolution Mass Spectrometry
KM	Kaplan-Meier
LOL	Limit of Linearity
MTCA	Model Toxics Control Act
ND or (<)	Not Detected
PCB	Polychlorinated biphenyls
PCDD	Chlorinated dibenzo-p-dioxins
PCDF	Chlorinated dibenzofurans
PQL/QL	Practical Quantitation Limit
QAPP	Quality Assurance Project Plan
QC	Quality Control
SCUM II	*Sediment Cleanup Users Manual II*
TEF	Toxicity Equivalency Factor

11.2 Addressing Non-Detects in Datasets

Datasets that contain analyte values below-detection limit (BDL) are known as *censored datasets*. Censored datasets present difficulties for many standard estimation procedures and statistical tests. For example, the mean cannot be estimated unless numerical values are assigned to the BDL data. The values assigned to BDL data can therefore significantly impact the calculated mean of the dataset (Ecology, 1992).

When a laboratory reports a target analyte as ND or <, a numeric reporting limit is also provided. This means that the analyte is not present at or above the numeric reporting limit. However, the analyte could be present at a lower concentration. In fact, the laboratory may even have positively identified it — although not reported it — at that lower concentration (Scholz and Flory, 1999). Many of the terms used by laboratories are interchangeable and several refer to the same thing, but some have significantly different meanings. It is helpful to understand these terms to make informed decisions based on laboratory results, when a compound is reported as ND. It is also important to use a consistent approach to describe: a) when reported laboratory data should be considered NDs, and b) how to interpret ND data.

As a result, this section of the memorandum (Section 11.2) provides guidance on how to address NDs for the purposes of summing congeners.

11.2.1 Definitions of Laboratory Reporting/Detection Limits

Laboratories use different terms and definitions to describe reporting/detection limits. Ecology recommends using the following definitions for the treatment of NDs and evaluating data. A summary is provided in Table 1.

- **Limit of Linearity (LOL):** This is the concentration at or above the upper end of the calibration curve at where the relationship between the concentration of the analyte and the instrument response ceases to be linear (Scholz and Flory, 1999).

- **Practical Quantitation Limit (PQL/QL):** MTCA defines the PQL/QL as the lowest concentration that can be reliably measured within specified limits of precision, accuracy, representativeness, completeness, and comparability during routine laboratory operating conditions, using department approved methods (Ecology, 2007a).

Note: The PQL/QL is the minimum level of a substance for which the question "how much of the substance is present" can be answered with a high degree of certainty. PQL/QLs are often determined by evaluating performance results of inter-laboratory studies where artificial samples are analyzed to test each laboratory's ability to accurately measure a substance using a specific method (Ecology, 1995).

- **Estimated Detection Limit (EDL):** This is the minimum concentration required to produce a signal to noise (S/N) ratio which is at least 2.5 times the background signal ("noise") level. This is the limit at which an analyte can be positively identified. The SW-846 Method 8290 for dioxins/furans by High Resolution Gas Chromatography/High Resolution Mass Spectrometry (HRGC/HRMS) requires that EDLs be used for reporting limits. For HRGC/HRMS the EDL should be reported to determine if the analyte is positively identified. Congener-specific EDLs should be reported for each congener analyzed.

> **Note**: The EDL is the concentration required to produce a signal with a peak height of at least 2.5 times the background signal ("noise") level. When using HRGC/HRMS it is important to require the reporting of this level in order to determine analytes that are positively identified in the sample.

Table 1: Summary of laboratory limits for dioxin analyses

Laboratory Term	Region	Definition
LOL (Limit of Linearity)	Region of less certain quantitation	Concentrations at or above the upper end of the calibration curve where the relationship between the quantity of the analyte and the instrument response ceases to be linear.
PQL (Practical Quantitation Limit)	Region of known quantitation and identification of analyte	The lowest concentration that can be reliably measured during routine laboratory operating conditions.
EDL (Estimated Detection Limit)	Region that represents estimated quantitation and positive identification of analyte	The lowest concentration at which an analyte can be positively identified. This concentration is calculated at 2.5 times the signal-to-noise ratio.
Noise	Region of unknown identification and quantitation	Unable to differentiate between the blank and the sample.

11.2.2 How to Qualify Data

Low concentration data should be reported to the user as quantified, estimated, or censored. A summary is provided in Table 2.

- If an analyte is present above the PQL and below the LOL, it is identified, quantified, and unqualified.
- If an analyte is present below the PQL and above the EDL, it is identified and the concentration is estimated with a "J" qualifier (USEPA, 2011a).
- If an analyte is not detected (below the EDL), it is considered censored with a "U" qualifier (USEPA, 2011a).
- If an analyte is detected, and all of the identification criteria are met except for the mass-ion abundance ratio (m/z ratio), this is considered an Estimated Maximum Possible Concentration (EMPC) value. See Section 6.19 (step 3) of *R10 Data Validation and Review Guidelines for Polychlorinated Dibenzo-p-Dioxin and Polychlorinated Dibenzofuran Data (PCDD/PCDF) Using Method 1613B, and SW846 Method 8290A* (USEPA, 2014) for a determination if the sample should be qualified with either a "UJ" or "J."

As a result, values that are detected above the EDL are considered identified in the sample of concern. Therefore, the congener-specific detection limit in a sample is at the EDL, which is expressed as 2.5 times the signal-to-noise ratio. It is important to note that detecting a concentration above the EDL is not the only criteria needed to positively identify an analyte. The criteria needed to unambiguously identify a gas chromatograph (GC) peak are as follows (USEPA, 2011a):

- Retention times and relative retention times
- Peak identification
- Signal-to-noise ratio
- Ion abundance ratios
- Polychlorinated Diphenyl ether interferences

The laboratory used should provide a list and definition for each qualifier used. For specific explanations of all criteria needed to positively identify an analyte, please see: *National Functional Guidelines for Chlorinated Dibenzo-p-Dioxins (CDDs) and Chlorinated Dibenzofurans (CDFs) Data Review* (USEPA, 2011a).

Table 2: Example of data qualifiers based on EPA's Contract Laboratory Program National Functional Guidelines for Organic Data Review (USEPA, 2011a)

Qualifier	Definition
U	The analyte was analyzed for, but not detected. The value preceding the "U" may represent the adjusted Contract Required Quantitation Limit (see DLM02.X, Exhibit D, Section 1.2 and Table 2) of the sample-specific estimated detection limit (EDL; see Method 8290A, Section 11.9.5).
J	The analyte was positively identified. The associated numerical value is the approximate concentration of the analyte in the sample (due either to an issue with the quality of the data generated because certain QC criteria were not met, or the concentration of the analyte was below the adjusted CRQL).
UJ	The analyte was not detected (see definition of "U" flag, above). The reported value should be considered approximate.
R	The sample results are unusable due to the quality of the data generated because certain criteria were not met. The analyte may or may not be present in the sample.

11.2.3 How to Assign a Value to Non-Detected Congeners

The current MTCA rule has language that addresses what to do when determining compliance with cleanup levels at sites that have samples with "undetected" concentrations. When specifically discussing the procedures that involve dioxin-like congeners (PCDDs, PCDFs, PCBs), Ecology describes actual practice at most dioxin/furan contaminated sites in its *Concise Explanatory Statement and Responsiveness Summary for the Amendment of Chapter 173-340 WAC, Model Toxics Control Act Cleanup Regulation* (Ecology, 2007b):

> *Because of the limited number of samples with full dioxin/furan congener analysis and the difficulty of applying the default approach to mixtures, actual practice at most dioxin/furan contaminated sites is to use the following alternative statistical procedure under WAC 173-340-740(7)(f)(v):*
>
> - *For congeners that occur at the site but not in the sample of concern, assign one-half the detection limit for compliance calculations; and*
>
> - *For congeners not detected in any samples at a site, assign a value of zero for compliance calculations (assuming Ecology approved detection limits were used).*

Please note that this does not preclude Ecology Cleanup Project Managers from following other alternative statistical procedures, such as the Kaplan-Meier (KM) Product Limit Estimator. Ecology recognizes that substitution for the detection limit for non-detected or "censored values" has the potential to produce biased results (see Helsel et al., 2006; Shepard, 2013; Smith et al.,

2006). Because of this, Ecology is including the EPA recommendation of additional methods for the treatment of non-detected congeners (USEPA 2011b):

1. Kaplan-Meier (KM) Product Limit Estimator in cases where:
    a. Some fraction of the congeners are non-detect; and
    b. There are at least three detected congeners.

2. Simple Substitution where:
    a. Less than three congeners are detected.
        i. Substitution of zero for lower bound estimates.
        ii. Substitution of one-half the detection limit for a "middle of the road" value.

Before accepting a laboratory as qualified to conduct the analysis, review the Laboratory Quality Assurance Project Plan (QAPP) to verify that the laboratory can meet the PQLs in Table 3 for each congener. Appendix A of this memo includes a Dioxin/Furan/PCB Laboratory Statement of Work containing recommended laboratory guidelines.

11.3 Establishing PQLs for Soil for the TEE

In WAC 173-340-700(6) (d), Natural background and analytical considerations, MTCA states:

> *In some cases, cleanup levels calculated using the methods specified in this chapter are less than natural background levels or levels that can be reliably measured. In those situations, the cleanup level shall be established at a concentration equal to the practical quantitation limit or natural background concentration, whichever is higher. See WAC 173-340-707 and 173-340-709 for additional information.*

Essentially, this means that the final cleanup level for the terrestrial ecological exposure pathway is the highest of the following (Ecology, 2007a):

- A calculated risk based value protective of receptors (plants, soil biota, and wildlife).
- Natural background for soil.
- The practical quantitation limit.

As a result, the PQL remains an important factor when determining cleanup levels. In 1993, Ecology issued "Implementation Memo No. 3" which was a summary of a laboratory survey that included the achievable PQLs at that time (Ecology, 2001). Until this memorandum is updated, the PQLs listed in Table 3 are recommended. These congener-specific recommended PQLs were multiplied by their respective Toxicity Equivalency Factors (TEFs), and then added up for a "TEQ-based" PQL. Table 4 lists laboratory-specific PQLs for both dioxin/furan congeners and the sum value. These PQLs listed are median-based, and were calculated from: a) a laboratory survey (Ecology, 2012) that was used for the *Sediment Cleanup Users Manual II* (Ecology, 2015), and an additional survey that was developed from Ecology contract lab required values (listed as "Proposed Minimum Values").

These PQLs have been based on the following methods:

a) EPA Method 1613B/8290A or CLP-SOW Method DLM02.2 (HRGC/HRMS) for PCDD and PCDF, and

b) EPA Method 1668A/B or CLP-SOW Method CBC01.2 (HRGC/HRMS) for PCBs (USEPA, 2011c).

Table 3: PQLs for PCDD, PCDF, and dioxin-like PCB congeners for soil. These include congener-specific (and sum) median soil quantitation limits and toxicity equivalency factors for mammals, avians, and fish. The PCDD and PCDF values were based on laboratory survey and contract values listed in Table 4.

Analyte	Quantitation Limit (QL) (ppt)	Mammalian TEF	Avian TEF	Fish TEF	TEF Adjusted QL (Mammals) (ppt)	TEF Adjusted QL (Avian) (ppt)	TEF Adjusted QL (Fish) (ppt)	Sum QL (Mammals) - 2,3,7,8 (TEQ)	Sum QL (Avian) - 2,3,7,8 (TEQ)	Sum QL (Fish) 2,3,7,8 (TEQ)
2,3,7,8 TCDD	0.605	1	1	1	0.605	0.61	0.605			
1,2,3,7,8 PeCDD	1.945	1	1	1	1.945	1.95	1.945			
1,2,3,4,7,8 HxCDD	2.5	0.1	0.05	0.5	0.25	0.13	1.25			
1,2,3,6,7,8 HxCDD	2.5	0.1	0.01	0.01	0.25	0.03	0.025			
1,2,3,7,8,9 HxCDD	2.5	0.1	0.1	0.01	0.25	0.25	0.025			
1,2,3,4,6,7,8 HpCDD	2.5	0.01	0.001	0.001	0.025	0	0.003			
1,2,3,4,6,7,8,9 OCDD	5	0.0003	0.0001	1E-04	0.002	0	5E-04			
2,3,7,8 TCDF	0.665	0.1	1	0.05	0.067	0.67	0.033			
1,2,3,7,8 PeCDF	2.5	0.03	0.1	0.05	0.075	0.25	0.125			
2,3,4,7,8 PeCDF	2.5	0.3	1	0.5	0.75	2.5	1.25			
1,2,3,4,7,8 HxCDF	2.5	0.1	0.1	0.1	0.25	0.25	0.25			
1,2,3,6,7,8 HxCDF	2.5	0.1	0.1	0.1	0.25	0.25	0.25			
2,3,4,6,7,8 HxCDF	2.5	0.1	0.1	0.1	0.25	0.25	0.25			
1,2,3,7,8,9 HxCDF	2.5	0.1	0.1	0.1	0.25	0.25	0.25			
1,2,3,4,6,7,8 HpCDF	2.5	0.01	0.01	0.01	0.025	0.03	0.025			
1,2,3,4,7,8,9 HpCDF	2.5	0.01	0.01	0.01	0.025	0.03	0.025			
1,2,3,4,6,7,8,9 OCDF	5	0.0003	0.0001	1E-04	0.002	0	5E-04			
	43.2							5.3	7.4	6.3
3,3',4,4' TetraCB (77)	10.5	0.0001	0.05	1E-04	0.001	0.53	0.001			
3,4,4',5 TetraCB (81)	10.5	0.0003	0.1	5E-04	0.003	1.05	0.005			
2,3,3',4,4' PeCB (105)	10.5	3E-05	0.0001	5E-06	3E-04	0	5E-05			
2,3,4,4',5 PeCB (114)	10.5	3E-05	0.0001	5E-06	3E-04	0	5E-05			
2,3',4,4',5 PeCB (118)	10.5	3E-05	1E-05	5E-06	3E-04	0	5E-05			
2',3,4,4',5 PeCB (123)	10.5	3E-05	1E-05	5E-06	3E-04	0	5E-05			
3,3',4,4',5 PeCB (126)	10.5	0.1	0.1	0.005	1.05	1.05	0.053			
2,3,3',4,4',5 HxCB (156)	10.5	3E-05	0.0001	5E-06	3E-04	0	5E-05			
2,3,3',4,4',5' HxCB (157)	10.5	3E-05	0.0001	5E-06	3E-04	0	5E-05			
2,3',4,4',5,5' HxCB (167)	10.5	3E-05	1E-05	5E-06	3E-04	0	5E-05			
3,3',4,4',5,5' HxCB (169)	10.5	0.03	0.001	5E-05	0.315	0.01	5E-04			
2,3,3',4,4',5,5' HpCB (189)	10.5	3E-05	1E-05	5E-06	3E-04	0	5E-05			
	126.0							1.4	2.6	0.1

Note: Mammalian TEFs derived from Vandenberg et al., 2006.
Avian and Fish TEFs derived from Vandenberg et al., 1998.
Yellow highlight is for emphasis only.

Table 4. Recommended congener-specific (and sum) dioxin PQLs calculated from prior laboratory survey results in addition to Ecology contract lab proposed minimum values. Note that one high and low PQL was removed from the survey prior to calculating a median value to allow for limitations of current laboratory technology.

Congener	Survey Laboratory 1	Survey Laboratory 2	Survey Laboratory 3	Survey Laboratory 4	Survey Laboratory 5	Survey Laboratory 6	Survey Laboratory 7	Survey Laboratory 8	Survey Laboratory 9	Survey Laboratory 10	Survey Laboratory 11	Proposed Minimum Value	Congener-Specific Median Value
2,3,7,8 TCDD	1	1	1	1	0.2	0.5	0.5	1	0.71	0.2	0.2	0.2	0.605
1,2,3,7,8 PeCDD	5	5	5	5	1	2.5	2.5	1	1.39	1	1	1	1.945
1,2,3,4,7,8 HxCDD	5	5	5	5	1	2.5	2.5	2.5	2.24	1	1	1	2.5
1,2,3,6,7,8 HxCDD	5	5	5	5	1	2.5	2.5	2.5	2.33	1	1	1	2.5
1,2,3,7,8,9 HxCDD	5	5	5	5	1	2.5	2.5	2.5	2.53	1	1	1	2.5
1,2,3,4,6,7,8 HpCDD	5	5	5	5	1	2.5	2.5	2.5	10,3	1	1	1	2.5
1,2,3,4,6,7,8,9 OCDD	10	10	10	10	2	5	5	5	21.2	2	2	2	5
2,3,7,8 TCDF	1	1	1	1	0.2	0.5	0.5	1	0.83	0.2	0.2	0.2	0.665
1,2,3,7,8 PeCDF	5	5	5	5	1	2.5	2.5	2.5	2.33	1	1	1	2.5
2,3,4,7,8 PeCDF	5	5	5	5	1	2.5	2.5	2.5	2.06	1	1	1	2.5
1,2,3,4,7,8 HxCDF	5	5	5	5	1	2.5	2.5	2.5	1.9	1	1	1	2.5
1,2,3,6,7,8 HxCDF	5	5	5	5	1	2.5	2.5	2.5	1.8	1	1	1	2.5
2,3,4,6,7,8 HxCDF	5	5	5	5	1	2.5	2.5	2.5	1.95	1	1	1	2.5
1,2,3,7,8,9 HxCDF	5	5	5	5	1	2.5	2.5	2.5	2.61	1	1	1	2.5
1,2,3,4,6,7,8 HpCDF	5	5	5	5	1	2.5	2.5	2.5	3.41	1	1	1	2.5
1,2,3,4,7,8,9 HpCDF	5	5	5	5	1	2.5	2.5	2.5	4.84	1	1	1	2.5
1,2,3,4,6,7,8,9 OCDF	10	10	10	10	2	5	5	5	17.6	2	1	2	5

Low PQL (removed)

High PQL (removed)

Median of PQLs (minus removed PQLs)

43.22

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APPENDIX A

Laboratory Statement of Work

The following statement of work includes minimum laboratory submittal requirements for dioxin/furan/PCB analyses under EPA Method 1613/1668 for cleanup under the Model Toxics Control Act, WAC 173-340.

General

1. Provide documentation that the sum of the Congener-Specific Laboratory Quantitation Limits is no greater than the established Practical Quantitation Limit (Table 3) of:

    a. 43.2 ng/kg (17 Dioxin/Furan Congeners)
    b. 126 ng/kg (12 Dioxin-like PCB Congeners)
    c. 169.2 ng/kg (29 Dioxin-like Dioxin/Furan/PCB Congeners)

2. Use appropriate TEF Methodology and sum congeners for the receptors (if requested) for both congener-specific and a 2,3,7,8 TCDD (TEQ):

    a. Mammals
    b. Avians
    c. Fish

3. Must be able to analyze samples within the method holding times.

4. Provide the Quantitation Limit for each result. The PQL is based on the lowest validated standard in calibration curve and equivalent to "Minimum Level ML" in 1668 and 1613.

5. Must provide Congener-Specific Estimated Detection Limits (2.5 times the signal-to-noise ratio).

6. Report down to the Estimated Detection Limit, based on 2.5 times the signal-to-noise ratio for HRMS analyses. Provide this value for each analyte.

Qualifiers

1. Report and qualify detected values that are below the PQL as estimates ("J").

2. Do not report below the EDL for HRMS analytes. Where the EDL is above the PQL due to interference, raise any values that are between the PQL and the EDL to the value of the EDL and qualify "UJ."

3. An Estimated Maximum Possible Concentration (EMPC) value is calculated and reported if all qualitative identification criteria are met except for the mass-ion abundance ratio (m/z ratio). See (USEPA, 2014 - Section 6.19 (step 3)) for further information on whether the sample should be qualified with either a "UJ" or "J."

4. Qualify results that contain interference from Polychlorinated Diphenyl Ethers (PCDPE) with either a "UJ" or "J". If the interference is significant (>25%) of the compound peak, the sample result is flagged as "UJ". If the interference is minimal (<25%), the compound is reported and flagged as "J."

5. The qualifiers used for dioxin, furan, and dioxin-like PCB congener data by HRGC/HRMS are defined as (note that the detection limit is at 2.5 times the signal-to-noise ratio):

    a. "J" – The analyte was positively identified. The associated numerical result is an estimate.
    b. "U" – The analyte was analyzed for, but not detected.
    c. "UJ" – See above (steps 2 through 4).

Analyte Identification

1. Provide the Chemistry Abstract Service Registry Number (CAS RN) for each analyte.

2. Name PCB congeners using the naming convention at: www.epa.gov/osw/hazard/tsd/pcbs/pubs/congeners.htm

3. Modify the naming convention to a 7-character format that uses leading zeroes for congener number below 100 (e.g. PCB-008). This format is needed for compatibility with Ecology's EIM database.

4. Number coeluting congeners in ascending order (e.g.: PCB-040/041/071). Records for coeluting congeners must have no CAS number.

5. PCDDs, PCDFs, and Dioxin-like PCBs must be resolved according to the criteria stated in the method, or analyzed and reported from a confirming column. Where congeners coelute, and the coelutions are not resolved, the data must be flagged to indicate the potential coelutions.