UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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MEMORANDUM

Date:

Subject: *Region 5 Land and Chemical Division Toxic Substances Control Act & Great Lakes National Program Office Sediment Remediation Memorandum of Agreement on TSCA Approvals for Dredging and Disposal of Sediments Containing PCBs*

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To: File

The attached Memorandum of Agreement (MOA) outlines the process for addressing Toxic Substances Control Act (TSCA) contaminated sediments for Great Lakes National Program Office (GLNPO) sediment remediation projects. This MOA documents the mutual agreement of Region 5 Land and Chemical Division (LCD) and GLNPO and establishes a process for review and approval of projects involving TSCA contaminated sediment remediation. Approval of this MOA will streamline GLNPO sediment remedial projects involving TSCA wastes and save time/resources of both divisions over the coming years.

This process has already be successfully implemented at the following sediment remediation projects: Buffalo River, Sheboygan, Raisin River, Lincoln Park Phases 1 and 2 and Ottawa River.

Region 5 LCD RRB TSCA Remedial Program & Great Lakes National Program Office Sediment Remediation Memorandum of Agreement on TSCA Approvals for Dredging and Disposal of Sediments Containing PCBs

I. Introduction and Applicability

This Memorandum of Agreement (MOA) is entered into between the Land and Chemicals Division (LCD) Remediation and Reuse Branch (RRB) and the Great Lakes National Program Office (GLNPO) in order to facilitate the remediation and disposal of Polychlorinated Biphenyls (PCB) regulated under the Toxic Substances Control Act (TSCA) at sediment cleanup projects in Region 5. This MOA documents the mutual agreement of Region 5 RRB and GLNPO and establishes a process for TSCA review and approval of projects involving PCB contaminated sediment remediation under the Section 118(c)(12) of the Clean Water Act, 42 U.S.C. §1268(c)(12), for the dredging and disposal of sediments containing TSCA regulated PCB Remediation Waste.

This MOA will apply at GLNPO cleanup projects involving PCB Remediation Waste as defined in 40 Code of Federal Regulations (CFR) 761.3. This MOA does not apply if the project involves materials which do not meet the definition of PCB Remediation Waste (e.g. material is at as-found concentrations < 50 ppm from a release which occurred prior to April 18, 1978). GLNPO will consult with LCD RRB if GLNPO believes a project involves PCB materials which do not meet the definition of PCB Remediation Waste (see Template 1 Attachment F for supporting information GLNPO should provide to RRB during such consultation).

This MOA process allows for the disposal of PCB remediation Waste to be addressed using one of three options (the process is diagramed in the flowchart in Figure 1):

- Option 1: Performance-Based Disposal – 40 CFR §761.61(b)
- Option 2: Risk-Based Disposal Approval – 40 CFR §761.61(c)
- Option 3: Coordinated Approval – 40 CFR §761.77(c)

Option 1

Performance based disposal (40 CFR §761.61(b)), presented in more detail in section II.6.a below, specifically requires either:

- all sediments with PCBs >1ppm to be disposed of in a TSCA approved landfill or,
- all PCB contaminated sediments >50ppm must be disposed of at a TSCA-approved landfill and all PCB contaminated sediments >1ppm and < 50 disposed of in facility permitted under Clean Water Act Section 404, or the equivalent of such a permit as provided for in regulations of the U.S. Army Corps of Engineers at 33 CFR part 320 USACE 33 CFR pt 320 facility (confined disposal facility).

Option 2

Risk-Based Disposal Approval (40 CFR §761.61(c)), presented in more detail in section II.6.b below, will only apply to GLNPO projects if:

- a non-commercial landfill or a new, dedicated disposal facility is proposed for disposal of dredged sediments; or
- human health and/or ecological risk scenarios not already addressed by the LCD/GLNPO risk assessment documents found in Attachments A through F exist at the site.

Option 3

Coordinated Approval (40 CFR §761.77(c)), presented in more detail in section II.6.c below, applies when neither Option 1 nor Option 2 applies. Given past and current GLNPO sediment remediation projects, Option 3 is the scenario that will apply at most, if not all GLNPO sites with PCB contamination >50ppm. This MOA addresses the Coordinated Approval Process further in section II and in Attachments A-F.

See the Regulatory Background in Attachment H for additional information.

II. **TSCA Approval Process Agreement**

LCD RRB recognizes that GLNPO is the lead EPA program for projects under Section 118(c)(12) of the Clean Water Act. LCD RRB will provide support, technical assistance, and review under TSCA as needed and as outlined in the sections below.

LCD and GLNPO agree that:

1. GLNPO is the lead program for carrying out projects under their authority including the GLLA. GLNPO has the expertise and the ability to develop appropriate remedial actions that are protective of human health and the environment in Great Lakes Areas of Concern.

2. LCD RRB human health and ecological risk assessors have worked with their GLNPO counterparts on an initial, one-time exercise to confirm and memorialize that GLNPO's process for determining cleanup levels will not pose an unreasonable risk of injury to health or the environment. The agreed upon processes are presented in Attachments A (BSAF determination), B (Human Health) and C (Ecological).

3. GLNPO will notify LCD of proposed projects requiring review under TSCA prior to the Remedial Design stage of the project so that LCD may appoint a project manager to coordinate with GLNPO. That LCD project manager will

be the LCD point of contact for issuing the TSCA coordinated or risk-based approval for the project.

4. Dredged sediments will be disposed of based on the concentrations determined in-situ. Sediments cannot be excavated and then characterized for disposal.

5. Sediments temporarily stored for dewatering purposes will be stored in a location meeting the containment requirements of 40 CFR §761.65(c)(9) and liquid PCB Remediation Wastes (i.e. sediment dewatering decantate) will be decontaminated to the standards in 40 CFR §761.79(b) or otherwise disposed of according to 40 CFR §761.60(a) or (e) or a risk-based approval under 40 CFR §761.61(c).

6. GLNPO and its Non-Federal Sponsor (NFS) will utilize one of the three options below for approvals and management of TSCA regulated PCB Remediation Waste:

   a. Option 1 – Performance Based Disposal

      A formal TSCA program approval for disposal is not required if the project meets the following Performance Based Disposal conditions:

      - all PCB impacted materials above 1 ppm will be removed;
      - no residual PCB > 1 ppm will be capped or remain in place;
      - all dredged materials are disposed of in a TSCA approved 40 CFR §761.75 Chemical Waste Landfill; or
      - all PCB contaminated sediments ≥50 ppm are disposed of at a TSCA-approved landfill and all PCB contaminated sediments >1 ppm and < 50 ppm are disposed of in accordance with a permit that has been issued under section 404 of the Clean Water Act, or the equivalent of such a permit as provided for in regulations of the U.S. Army Corps of Engineers (USACE) at 33 CFR Part 320 or in accordance with a permit issued by the U.S. Army Corps of Engineers under section 103 of the Marine Protection, Research, and Sanctuaries Act, or the equivalent of such a permit as provided for in regulations of the U.S. Army Corps of Engineers at 33 CFR Part 320 (for example, a U.S. Army Corps of Engineers Confined Disposal Facility (CDF) permitted under an authority noted above).

GLNPO and its NFS will document compliance with Performance-Based Disposal under 40 CFR §761.61(b) by providing a memo[1] to the LCD RRB TSCA Remedial Program. LCD RRB TSCA will review the memo to

[1] See Model Memo Appendix G, Template 2.

determine compliance with 40 CFR §761.61(b). LCD RRB will respond to GLNPO with a memo indicating agreement or a need for further action.

b. Option 2 – Risk-Based Disposal

GLNPO's NFS will submit a Risk-Based Disposal Application for LCD RRB review and approval under 40 CFR §761.61(c) if any of the following conditions apply:

- it is proposed to dispose of dredged sediments ≥ 50 ppm in a facility other than a permitted §761.75 TSCA Chemical Waste or a RCRA Subtitle C commercial landfill whose operating permit allows disposal of ≥ 50 ppm PCB Remediation Waste and/or;
- dredged sediments < 50 ppm will be disposed of in a facility other than: 1) a permitted RCRA Subtitle D commercial landfill whose operating permit allows disposal of < 50 ppm PCB Remediation Waste or, 2) a facility permitted under section 404 of the Clean Water Act, USACE Section 103 of the Marine Protection, Research, and Sanctuaries Act, or equivalent permit as provided for by USACE at 33 CFR Part 320 or;
- a new, dedicated disposal facility is proposed for disposal of dredged sediments; or
- human health and/or ecological risk scenarios not already addressed by the LCD/GLNPO risk assessment documents found in Attachments A through C exist at the site (e.g. different receptors, exposure pathways, etc.).

The Risk-Based Disposal Approval request should include information as described in the notification required by 40 CFR §761.61(a)(3), as well as information requested in Option 3 below for Coordinated Approvals. LCD RRB will request additional information from GLNPO and its Partners as needed to assist RRB in its review.

c. Option 3 – Coordinated Approval

GLNPO's NFS will request a Coordinated Approval under the provisions of 40 CFR §761.77(c) from the LCD RRB TSCA Remedial Program if the following conditions apply:

- the remedial cleanup level (either on a point-by-point basis or a Surface Weighted Average Concentration (SWAC)) is calculated in accordance with Attachments A through C;
- dredged sediments ≥ 50 ppm will be disposed of in a permitted §761.75 TSCA Chemical Waste or a RCRA Subtitle C commercial landfill whose operating permit allows disposal of ≥ 50 ppm PCB Remediation Waste;
- dredged sediments < 50 ppm will be disposed of in a permitted RCRA Subtitle D commercial landfill whose operating permit allows disposal

of < 50 ppm PCB Remediation Waste or in a CDF permitted under section 404 of the Clean Water Act, USACE Section 103 of the Marine Protection, Research, and Sanctuaries Act, or equivalent permit as provided for by USACE at 33 CFR Part 320.

The Coordinated Approval request will include information identified in 40 CFR §761.77(a)(1) including:

- a copy of the signed agreement, for example: a GLLA project agreement
- information regarding the project scope (e.g., the remedial investigation and feasibility study, the project application from the non-federal sponsor);
- project cleanup level;
- identification of sediment disposal destinations;
- documentation that the disposal destinations are permitted to receive such waste; and
- post-remedial sampling plans designed to verify how the cleanup level will be met

Recordkeeping and reporting for purposes of TSCA must be conducted under 40 CFR Part 761, Subparts J and K as applicable to the project.

7. GLNPO will provide public notice and information to local communities regarding the project including information on the remediation, management and disposal of PCB Remediation Waste requiring a TSCA approval under the Coordinated or Risk-Based approval options as outlined above. GLNPO will share information on the level and type of public involvement anticipated for the project during GLNPO's initial notification to LCD RRB under this MOA.

8. GLNPO will adhere to all state and local requirements for disposal of PCB impacted sediments. In some cases, such requirements may be more stringent than federal TSCA requirements.

For the Great Lakes National Program Office

Chris Korleski
Director
Great Lakes National Program Office

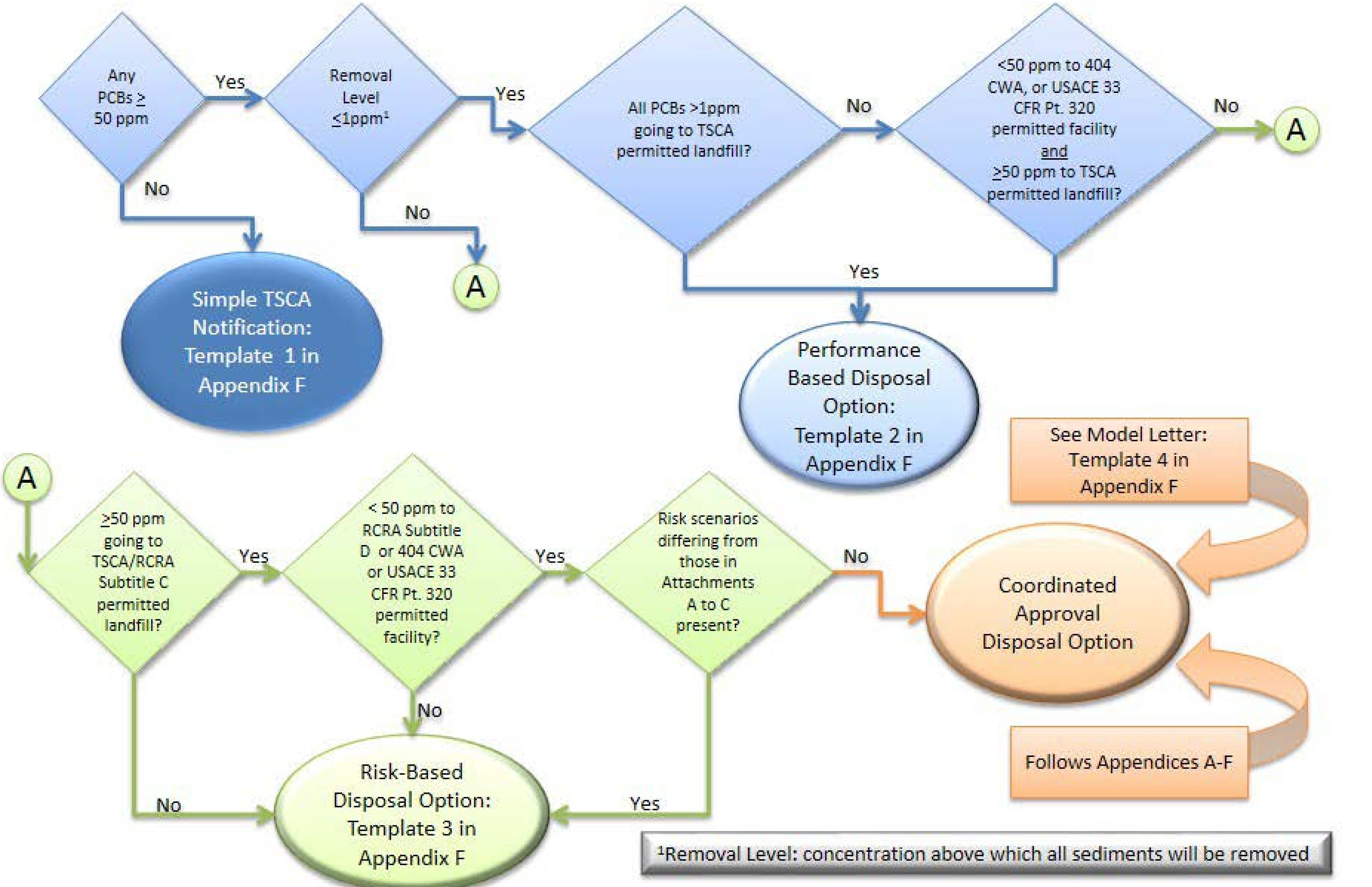
Date: 8/10/15

For the Land and Chemicals Division

Margaret M. Guerriero, Director
Land and Chemicals Division

Date: 8/17/2015

Figure 1: Region 5 TSCA Remedial Program & Great Lakes National Program Office Sediment Remediation Process



Attachment A: Great Lakes National Program Office – Great Lakes National Program Office and Region 5 TSCA Template for Calculation of Biota-Sediment Accumulation Factors

A biota-sediment accumulation factor (BSAF) describes the empirical relationship between PCB concentrations in fish tissue and sediment, ideally co-located, where the sediment concentrations represent the source of contamination to the fish. When site-specific data are available, they should be utilized to generate site-specific BSAFs. If the site specific data are inadequate or non-existent, then literature based BSAFs should be calculated. The processes for determination of a site-specific BSAF and/or a literature based BSAF are presented below.

The first step in calculation of either human health (Attachment B) or ecological (Attachment C) cleanup goals is the calculation of a site-specific or selection of a literature based BSAF.

The BSAF is defined by the equation:

$$BSAF = \frac{C_{fish} / f_{lipid}}{C_{sed} / f_{oc}}$$

Where:

C_{fish} = Chemical concentration in fish (mg/kg) fresh/wet weight
f_{lipid} = fraction of lipid in fish or edible portion of fish (usually as %)

C_{sed} = Chemical concentration in sediment (mg/kg) dry weight
f_{oc} = fraction of organic carbon in sediment sample (usually as %)

Development of a site-specific BSAF:

In order to determine whether a site-specific BSAF can be calculated, the following data should be gathered and reported:

- Fish tissue data – list all species available for at least the last 5 years, the number of samples, tissue type (fillet, whole-body, skin on/skin off, etc.) as well as any relevant metadata (quality, who took the data, etc.).
- Fish lipid data – often, this parameter is analyzed at the same time and in the same samples as PCB chemistry, but not always. If both lipids and PCBs are within the same dataset, report the lipid data with the PCB fish data, so that each fish tissue concentration is normalized by its own lipid fraction. Otherwise, gather and report on all the available fish lipid data for at least the last 5 years (including, year analyzed, species and tissue type)
- PCBs in sediment – ideally surface sediment concentrations taken at the same time as fish tissue are available, if so this should be highlighted. Regardless, a summary of the PCB data, including both grabs and cores for the last 5 years should be provided.

- Total organic carbon (TOC) – as with the above parameters, the available TOC data for at least the last 5 years should be summarized. Where possible, each sediment concentration sample should be normalized by its own foc/%TOC values.
- Geospatial information – summarize spatial data parameters for sediment and fish samples and if they are already available as a GIS data layer.

Table A1 is a suggested format for presentation of fish PCB and lipid data, while Table A2 is a suggested format for presentation of sediment data. When the sediment chemistry and fish samples locations are co-located, the tables can be combined into one summary table.

PCB data - Congeners vs. Aroclors: As part of the data gathering step, the type of PCB analytes assessed should also be reported (i.e. congeners, Aroclors, homologs, etc). The preference is for congener data, where available, and then Aroclors if the congener data are not sufficient and/or available. Regardless of whether the data are congeners or Aroclors, the total PCB value should be used in the assessment. When the data are available to do so, total PCB concentrations should be calculated from individual PCBs using the same methodology with respect to handling non-detects.

Table A1: Data Reporting Summary (for fish PCB and lipid data only)

Fish Species	Source	Year	Whole body or fillet	Total PCB Fish Tissue Concentration (C_{fish})	PCB type (Aroclor or congener or homolog)	Fish Lipids (f_{lipid})	GIS info	Notes (metadata, other issues)

Geographical information system (GIS)

Table A2: Data Reporting Summary (sediment PCB and organic carbon)

Sample ID or Location	Source		Sample type (grab or core) & Depth (ft)	Total PCBs (C_{sed})	PCB type (Aroclor or congener or homolog)	Fraction TOC (f_{oc})	Normalized PCBs (C_{sed} / f_{oc})	GIS info	Notes (metadata, other issues)

Geographical information system (GIS)

➔ After the data are collected and summarized, they should be provided to EPA, to make the decision on whether a site-specific BSAF can be calculated.

<u>Selection of a literature-based BSAF</u>:

If the decision is made to use a literature based BSAF, the following BSAF database should be consulted: http://www.epa.gov/med/Prods_Pubs/bsaf.htm. Table A3 presents a format for presentation of the human health and ecological literature-based BSAFs.

Human Health BSAF selection: At least two different species should be selected, one a bottom-feeding fish and the other a pelagic/sport fish species. The appropriate species can be chosen from those available in the database to represent these categories of fish. Also using the site-specific data gathered from above, choose a BSAF that has similar levels of TOC and lipid.

Ecological BSAF selection: BSAFs should be selected for at least two trophic levels of fish representing either a top level predator or bottom-feeding fish (whichever is best for the site) and for forage fish. The latter represent smaller species and/or juveniles of a size class normally consumed by piscivorous birds and mammals.

Table A3: Literature-Based PCBs BSAFs for Use in Deriving Risk-Based Sediment Concentrations

Site/data source	Species Scientific Name	Species Common Name	Fillet/whole body/Age Class	Total PCBs in Sediment (avg mg/kg oc)	BSAF[a]
Human Health					
Median or average or some other relevant statistic that may be appropriate					
Ecological					
Median or average or some other relevant statistic that may be appropriate					

[a]Bolded BSAF selected for use in calculating sediment RBCs.

<u>Considerations:</u>

Burkhard *et al.* (2010) evaluated scenarios in which BSAFs were applied from one location, species, and/or site to another location, species, and/or site using PCB BSAF information available in the USEPA BSAF data sets. The authors reported results for each BSAF comparison scenario for fish, mussels, and decapods. Burkhard *et al.* did not present a specific quantitative formula for predicting BSAFs at one location from another. However their results (Table A4) indicated (but were not limited to) the following:

- A ±2.9-fold range around a PCB BSAF determined for a given fish species at one site captures approximately 50% of the true BSAFs for the same species at a different site.
- A ±10-fold range around any BSAF (PCB, polychlorinated dibenzodioxins/furans [PCDD/F], polycyclic aromatic hydrocarbons [PAH], or chlorinated pesticide) determined for a given fish species at one site will have approximately a 90% probability of capturing the true BSAF for the same chemical and the same species at a different site.

Table A4: Summary of across-site comparisons of BSAF presented in Burkhard et al. (2010).

	All compounds (PCBs, PCDD/Fs, pesticides)				PCBs only	
BSAF Comparison	Median[1]	Average (percentile)	90th percentile[2]	n	Median[1]	n
Same fish species at different sites:	2.9-fold	2.5-fold (82nd)	10-fold	2673	2.9-fold	2034
Different fish species at different sites:	3.1-fold	4.5-fold (74th)	6.7-fold	710	3.3-fold	513

[1]Burkhard et.al, suggests that when comparing smallmouth bass at one site to smallmouth bass at another, 50% of comparisons would be +/- 2.9-fold of the BSAF

[2] Burkhard et.al, suggests that when comparing smallmouth bass at one site to smallmouth bass at another, 90% of comparisons would be +/- 10-fold of the BSAF.

These findings should be considered when calculating literature-based BSAFs sediment sites

Attachment B: Great Lakes National Program Office – Great Lakes National Program Office and Region 5 TSCA Template for Estimation of Human Health PCB Risk-Based Concentrations for Sediment

Background: There are projects that involve both GLNPO and also the TSCA program, where there are contaminated sediments greater than 50 ppm of PCBs. Sediment remediation processes require that human health be considered during the feasibility stage where cleanup goals are calculated. Under TSCA, in some cases, PCB contaminated sediments must go through the risk-based disposal approval option. This template outlines how to develop cleanup goals that will be satisfactory to both the GLNPO and the TSCA programs.

Overview: The template calls for a two step process, where the first step involves development of an appropriate biota to sediment accumulation factor (BSAF) (see Attachment A). In this step, site-specific data are gathered and summarized to determine whether to do a site-specific BSAF or use a BSAF available from the literature. In the second step the BSAF is used in conjunction with specified exposure and toxicity assumptions to develop cleanup goals.

Step One – BSAF development: See Attachment A of this document.

Step Two - Cleanup Goal Calculation:
Using the risk equation for estimating cancer risk, rearranged to solve for fish tissue concentration and setting risk to 10^{-6}, gives the following:

$$CF = \frac{(AT * BW * 1E\text{-}06)}{(IR * FI * ED * EF * CSF)}$$

Where:

- CF = concentration in fish
- AT = averaging time
- BW = body weight
- IR = ingestion rate
- FI = fraction ingested
- ED = exposure duration
- EF = exposure frequency
- CSF = cancer slope factor

And for non-cancer risks, setting the hazard index to one, provides the following equation:

$$CF = \frac{(AT * BW * RfD * 1)}{(IR * FI * ED * EF)}$$

Where:

- CF = concentration in fish

AT = averaging time
BW = body weight
IR = ingestion rate
FI = fraction ingested
ED = exposure duration
EF = exposure frequency
RfD = reference dose

Using the above two equations, two different exposure scenarios will be considered: the average sport fisher and the reasonable maximum exposure (RME), represented as a subsistence fisher. The following variables for each of the exposure scenarios are provided below, so that acceptable fish tissue concentrations can be calculated.

Variables to be Used for Calculating Acceptable Fish Tissue Concentrations

Variable	Value to be used for the Average Scenario	Value to be used for the RME Scenario	Notes
IR (g/day)	10.9 (50^{th} percentile)	38.7 (95^{th} percentile)	From West; also EPA 1995 (GLWQI TSD); Exposure Factors Handbook
FI (%)	1	1	
ED (years)	30	30	
EF (days/year)	350	350	(based on 50 weeks of meals)
AT (days)	ED * 365	ED * 365	
BW (kg)	70	70	
CSF (no units)	2	2	IRIS
RfD	2 E-05	2 E-05	IRIS

IRIS = U.S. EPA's Integrated Risk Information System

Then the four fish tissue values (cancer and noncancer for average and RME scenarios) resulting from this calculation are then converted to a sediment cleanup goal using the BSAF equation, rearranged to solve for concentration in sediments (CS):

$$CS = \frac{CF * TOC}{L * BSAF}$$

Where:

CS = concentration in sediments
L = lipids

As a result, there will be a range of cleanup goals, spanning cancer and noncancer endpoints, two different fish species, and average and reasonable maximum exposure scenarios. The following table should be used in reporting the cleanup goals, using consistent units for PCBs in sediments.

Cleanup Goal Reporting Table

Fish Species	**Average Exposure**	**RME Exposure**
- Sport Fish	Cancer:	Cancer:
List species assessed	NC:	NC:
-Bottom-feeding fish	Cancer:	Cancer:
List species assessed	NC:	NC:
Uncertainties & Concerns: *List any variable or aspect of the analysis that was of concern or contributed to uncertainty. Examples include limited data available for a parameter, mismatched years of data for calculating a site-specific BSAF, or assumptions made for a variable with insufficient data, such as TOC.*		

Site specific BSAF used? ____Yes ______No Values used_________

Attachment C Great Lakes National Program Office and Region 5 TSCA Template for Estimation of Ecological PCB Risk-Based Concentrations for Sediment

This attachment presents a process, that when applied at sediment sites, will allow for a streamlined calculation of ecological risk-based concentrations for sediment (ERBCs). This streamlined process is only designed for use at sediment sites where polychlorinated byphenyls (PCBs) are present in sediments. The sediment project team should evaluate the calculated ERBCs along with human health RBCs (where appropriate) as one line of evidence in the selection of a project-specific clean up goal.

Overview: This template calls for a three-step process, where the first step involves development of an appropriate biota to sediment accumulation factor (BSAF) (see Attachment A). In this step, site-specific data are gathered and summarized to determine whether to derive a site-specific BSAF or use a BSAF available from the literature. In step 2, exposure factors and ecological toxicity reference values are derived. The third and final step combines the BSAF from step 1 with the specified exposure and toxicity assumptions (step 2) to develop cleanup goals.

1. **Estimation of biota-sediment accumulation factor (BSAF)**—See Attachment A
2. **Selection of endpoints, exposure pathways/parameters and protective concentrations in fish (RBC_{fish})**—Concentrations of PCBs in fish tissues should be based on specific target risk levels protective of the endpoint evaluated. For purposes of this streamlined evaluation, the endpoints will be:
    - Protection of fish
    - Protection of piscivorous birds
    - Protection of piscivorous mammals
3. **Estimation of ERBCs from RBC_{fish} and BSAF**—Using Steps 1 and 2, PCB ERBCs should be derived from acceptable concentrations of PCBs in fish (RBC_{fish}) and the relationship between PCBs in fish tissue and in sediment (BSAF).

Step 2: Selection of endpoints, exposure pathways/parameters and protective concentrations in fish (RBC_{fish})—Ecological RBCs must be derived using approaches and assumptions consistent with USEPA risk assessment guidance (USEPA, 1992; USEPA, 1997b; USEPA, 1998). A streamlined exposure assessment and toxicity assessment are presented below for use directly in calculating ecological risk based concentrations in sediments.

Exposure Assessment

Derivation of risk-based PCB cleanup goals protective of ecological health should focus on the following receptors and exposure pathways:

- Fish—Exposure by direct uptake from sediment and food.
- Piscivorous birds and mammals—Exposure by direct uptake from sediment and food.

To streamline the process, GLNPO and TSCA staff have agreed to general exposure parameters (Table C1 and C2) for the receptors suggested as representative of these trophic groups and exposure pathways.

- Smallmouth bass, a terminal predator representing upper trophic level fish.
- Belted kingfisher, representing piscivorous birds.
- Mink, representing piscivorous mammals.

Table C1: General exposure parameters for suggested picivorous receptors.

Species	BW Body Weight (kg)[a]	FIR Food Ingestion Rate (kg/day-dry) [b]	$BSAF_{forage\ fish}$[c]	Percent Solids of $Tissue_{forage\ fish}$[c] (fraction)	$Lipid_{forage\ fish}$[c] (fraction)
Belted kingfisher	0.158	0.024	4.9	0.24	0.05
Mink	1.4	0.053	4.9	0.24	0.05

[a]USEPA 1993
[b] Nagy (2001) regression equation format = dry matter g/day/g body weight = a(grams body weight)^{b}/g body weight
[c]Suggested value based on forage fish as a general group. Shoul be changed to site-specific values if the data are available to support their development.

Group	*a*	*b*
belted kingfisher	0.849	0.663
mink	0.102	0.864

Table C2: Exposure parameters for Smallmouth Bass

$BSAF_{SMB}$	$Lipid_{SMB}$ (fraction)	Mean Area Wide Sediment TOC (fraction)
site-specific or literature value	**0.033**	**site-specific**

Toxicity Assessment

Unlike human health evaluations, U.S. EPA has no approved ecotoxicological database. The toxicity literature search used to support a streamlined risk evaluation is found in Attachment D. Since the intent of this document is to streamline calculation of ERBCs for sediment sites, this evaluation can be used as is. With time, it will need to be reviewed and updated as the science of ecotoxicology advances. Additionally, this toxicity assessment will need revision if, at a given site, different or additional receptors are evaluated. However, the same endpoints (e.g. 25th and 50th percentile NOEC/NOAELs and LOEC/LOAELS) should be used.

A literature search was conducted to derive toxicity reference values (TRVs) for fish, birds, and mammals and the results are presented in Table C3. They measure the effects of PCBs on survival, growth, and reproduction. The TRVs were no observed effect concentrations (NOECs) and lowest observed effect concentrations (LOECs) for fish, and no observed adverse effect levels (NOAELs) and lowest observed adverse effect levels (LOAELs) for birds and mammals. Potential TRVs for smallmouth bass, belted kingfisher, and mink were used to calculate the 25th and 50th percentiles of the distribution. The use of the 25th and 50th percentiles and the NOEC/NOAEL and LOEC/LOAEL provide a range of conditions that bound the reasonable uncertainty in the effects data.

Table C3: Suggested Toxicity Reference Values (TRVs)

Receptor	TRV		
	NOEC/NOAEL	**LOEC/LOAEL**	**Units**
25th percentile TRVs			
Smallmouth bass	17	22	mg/kg-ww
Belted kingfisher	0.18	0.75	mg/kg-bw/day
Mink	0.12	0.13	mg/kg-bw/day
Median TRVs			
Smallmouth bass	32	113	mg/kg-ww
Belted kingfisher	0.29	1.6	mg/kg-bw/day
Mink	0.26	0.35	mg/kg-bw/day

Step 3 - Estimation of ERBCs from RBCfish and BSAF

Calculation of ecological risk based concentrations in sediments ($ERBC_{sed}$) is accomplished by rearranging standard ecological risk assessment upper trophic level equations. The rearranged equation for calculation of sediment concentrations protective of upper trophic level fish represented by smallmouth bass is:

$$ERBCsed = \left(\frac{TRVww/Fraction_{lipid}}{BSAF_{smb}}\right) Fraction_{toc}$$

Where:
TRVww = toxicity reference value from table C3 wet weight
Fraction lipid = fraction of lipid in fish (whole body) Table C2
$BSAF_{smb}$ = biota-sediment accumulation factor for smallmouth bass (site specific)
$Fraction_{toc}$ = fraction of total organic carbon in sediments (site specific)

The rearranged equation for calculation of sediment concentrations protective of piscivorous birds and mammals, as represented by belted kingfisher and mink is:

$$\boldsymbol{ERBCsed} = \left(\frac{\dfrac{\left(\left(\dfrac{(TRV_{ww} * BW)}{FIR}\right) * Fraction_{solids}\right)}{Fraction_{lipid}}}{BSAF_{forage\ fish}}\right) * Fraction_{toc}$$

Where:
TRVww = toxicity reference value from table C3 wet weight
BW = Body weight (kg) From Table C1
FIR = Food ingestions rate From Table C1
Fraction solids = From Table C1
Fraction lipid = From Table C1
$BSAF_{forage\ fish}$ = From Table C1

Fraction toc = fraction of total organic carbon in sediments (site specific)

Uncertainties & Concerns:

Briefly discuss any variable or aspect of the analysis that was of concern or contributed to uncertainty. Examples include limited data available for a parameter, mismatched years of data for calculating a site-specific BSAF, or assumptions made for a variable with insufficient data, such as TOC.

Attachment D: Great Lakes National Program Office and Region 5 TSCA Ecological Toxicity Reference Values Literature Review

This Attachment presents the information that has been reviewed and approved for use as is by both GLNPO and TSCA ecological assessors. The information supports what is presented for direct use in Attachment C. Tables D1, D2 and D3 present the literature values suggested for use for fish, piscivorous birds and mammals respectively.

Fish Toxicity Reference Values

Toxicity studies that relate PCBs in fish tissue to adverse effects were identified from a search of electronic databases and reference sources, including the following:

- Environmental Residue-Effects Database (2003)
- ECOTOX Database (USEPA, 2003)
- Jarvinen and Ankley (1999), a compilation of tissue residue no observed effect concentrations (NOECs) and lowest observed effect concentrations (LOECs)
- Scientific literature searches through search engines such as BIOSIS and Science Direct

Databases were searched for fish dose-response studies in which tissue concentrations were measured.

Studies were selected for review if whole-body tissue concentrations and measured survival, growth, or reproductive effects data were available. Studies reporting residue concentrations in tissues other than whole-body (for example, egg or other organ tissues) were reviewed when relevant endpoints were measured. All life stages, including eggs, were considered. Fish-egg tissue residue toxicity reference values (TRVs) were converted into adult whole-body tissue residue TRVs using conversion factors reported in literature.

The acceptability of fish toxicity studies was determined through best professional judgment, taking into account the following:

- Was the observed toxicity a result of a single constituent? Studies using field-collected fish with background constituent concentrations in tissue cannot attribute toxicity to one specific constituent unless there is strong evidence that all other constituents in the tissue are below toxic levels.
- What is the ecological relevance of the exposure duration? Chronic studies measuring exposure for 30 days or longer were preferred.
- Did the measured endpoint in the study directly measure the growth, survival, or reproductive success of the test organism?

PCB Aroclors

For PCBs (as Aroclors), the proposed TRVs are derived from NOECs and LOECs for the individual Aroclor mixture with the highest toxicity for comparison with total PCB concentrations (sum of Aroclors). Twenty papers on the potential adverse effects of PCB mixtures on fish were reviewed. Details of the studies are summarized in Table D-1. The potential mechanisms of exposure included dietary ingestion, water exposure, gavage, and maternal transfer. Concentrations in whole-body tissue were reported in 16 reviewed studies (Duke et al., 1970; Fisher et al., 1994; Hansen et al., 1971, 1973, 1974, 1975; Hattula and Karlog, 1972; Hendricks et al., 1981; Lieb et al., 1974; Matta et al., 2001; Mauck et al., 1978; Mayer et al., 1977, 1985; Nebeker et al., 1974; Powell et al., 2003), and egg tissue concentrations were reported in four reviewed studies (Fisher et al., 1994; Freeman and Idler, 1975; Mac and Seelye, 1981; McCarthy et al., 2003).

Adverse effects on growth, mortality, reproduction, and behavior were reported in both laboratory-raised and field-collected fish. Five additional studies measuring the toxicity of PCBs to fish were reviewed; however, the studies were excluded from the TRV selection process because they did not meet the criteria used for TRV literature selection. Specifically, studies in which no toxic effects were reported (Kuehl et al., 1987) were excluded from the TRV selection process. In addition, studies that reported endpoints that were not related to growth, mortality, reproduction, and behavior, such as enzymatic activity, were not included in the TRV selection process (Melancon and Lech, 1983). DeFoe et al. (1978) was not included in the TRV selection process because no tissue concentrations were reported at a time when effects were observed. Finally, Rhodes and Casillas (1985) was excluded from the TRV selection process because fish were exposed to a mixture of constituents in the laboratory.

Several studies were evaluated to derive conversion factors between egg tissue residues and maternal adult tissue residues. Three papers that report PCB concentrations in maternal adults relative to eggs were identified (Miller, 1993; Niimi, 1983; Russell et al., 1999). Russell et al. (1999), and Miller (1993) report only egg and maternal adult fillet data, which is not directly usable to derive a whole-body concentration for comparison with site-specific fish data; therefore, PCB egg to adult conversion factors were based on data from Niimi (1983). Niimi (1983) reports whole-body maternal adult (with eggs) and unfertilized egg constituent concentration data for PCBs (quantified using a 4:1 Aroclor 1254:1260 analytical standard) from rainbow trout, white sucker, white bass, smallmouth bass, and yellow perch collected from Lake Ontario and Lake Erie. Niimi (1983) notes that the constituent concentrations in fertilized eggs would be two to three times lower than those reported for unfertilized eggs because of water uptake prior to egg hardening. Therefore, because available egg TRV papers report fertilized egg data, to derive egg-adult conversion factors, egg concentration data reported in Niimi (1983) were conservatively divided by two to approximate fertilized egg concentrations. Because Niimi (1983) showed that the ratio of constituents in eggs to constituents in maternal adults was dependent on species, species-specific (that is, salmonids and trout species) egg-to-adult conversions were used if a species was the same or closely related to one of the species reported in Niimi (1983) (that is, rainbow trout). If no species-specific conversion was available, an average egg-to-adult conversion across the five species (that is, rainbow trout, white sucker, white bass, smallmouth bass, and yellow perch) reported in Niimi (1983) was used (list value).

Table D-1 presents the fish PCB effects concentrations reported in the reviewed studies. Whole-body tissue residues of PCBs in nine species (rainbow trout, brook trout, Atlantic salmon, sheepshead minnow, lake trout, spot, pinfish, goldfish, and coho salmon) were associated with adverse effects on growth, survival, behavior, or reproduction in 16 of the reviewed studies. Whole-body tissue residue LOECs ranged from 1.53 mg/kg for fry mortality of field-collected brook trout (Berlin et al., 1981) to 645 milligrams per kilogram on wet-weight basis (mg/kg ww) for growth and mortality of fingerling coho salmon (Mayer et al., 1977). In the study reporting the lowest LOEC (Berlin et al., 1981), field-collected eggs were exposed to three levels of PCB concentrations via diet and water for 176 days, and fry mortality was observed at all exposure levels. The concentration in fry tissue exposed to the lowest level was 1.53 mg/kg ww PCBs after 176 days of exposure (Berlin et al., 1981); however, the field-collected eggs contained 7.6 mg/kg ww PCB and 4.7 mg/kg ww dichlorodiphenylethylene (DDE), and possibly other, uncharacterized organic constituents that could have contributed to the reported toxicity. The next lowest LOEC was based on Fisher et al. (1994), in which live fry body weight was significantly reduced in Atlantic salmon following egg exposure to a PCB Aroclor mixture in water for 48 hours. The reported egg concentration of 1.53 mg/kg ww PCBs was converted into an adult tissue whole-body concentration of 7.2 mg/kg ww using a conversion factor of 4.69 (Niimi, 1983).

Whole-body tissue residue NOECs ranged from 0.98 mg/kg ww for growth of juvenile Chinook salmon (Powell et al., 2003) to 120 mg/kg ww for growth of rainbow trout (Mayer et al. 1985). Only the lowest NOEC of 0.98 mg/kg ww was below the lowest LOEC. In this study, Powell et al. (2003) measured no effect on juvenile Chinook salmon growth where whole-body tissue residues ranged from 0.74 to 0.98 mg/kg following 4 weeks of exposure to Aroclor 1254 in water.

Wildlife TRVs

Studies that relate dietary concentrations or bird egg concentrations of PCBs to adverse effects in wildlife were identified from a search of electronic databases and from a review of original studies identified in the following review sources:

- Agency for Toxic Substances and Disease Registry (ATSDR)
- ECOTOX database (USEPA electronic database)
- BIOSIS electronic database
- TOXNET database (National Library of Medicine)
- IRIS database (USEPA electronic database)
- U.S. Fish and Wildlife Service (USFWS) Contaminant Review Series electronic database
- Oak Ridge National Laboratory database (Sample et al., 1996)

For wildlife, only those studies in which relevant survival, growth, and reproduction were measured were reviewed. Selecting NOAELs and LOAELs based on the available reviewed literature were prioritized using the following guidelines:

- The preferred exposure duration was subchronic or chronic, or conducted during a critical life stage such as reproduction, gestation, or development. Acute studies were considered but not preferred.

- Only studies with mortality, growth, and/or reproductive effect endpoints were used for birds and mammals.

- Doses received by food ingestion were preferred over administration of the dose using drinking water, gavage, oral intubation, or injection because the non-dietary exposure route cannot be directly related to environmental exposure to the bird or mammal. Drinking water studies may overestimate dietary risk because gastrointestinal absorption may be higher for constituents ingested via drinking water (Sample et al., 1996). In some cases, however, TRVs based on studies with doses administered via injection, oral intubation, gavage, or drinking water were selected because no other studies are available.

- Preferred TRVs were based on results that were evaluated statistically to identify significant differences from control values. Studies were not considered if negative control groups were not included.

- In general, laboratory studies were preferred to studies using field-collected prey because controlled test conditions provide greater certainty that the observed response can be related to the constituent dose. The presence of multiple constituents and other environmental factors may result in adverse effects that complicate the interpretation of field study results (USEPA, 2003).

For the site-specific dietary TRVs, a daily dose is expressed as mg/kg body weight per day (mg/kg bw/d). Most studies reported toxicity results as the constituent concentration in food associated with adverse effects, although some presented results as a daily dose. The daily exposure dose was derived from a food concentration using the animal's body weight (kg) and ingestion rate (kilograms per day [kg/d]) as reported in the study or using values published elsewhere.

Avian TRVs

PCB Aroclors

Oral toxicity of PCB Aroclors to birds via food or capsule ingestion was evaluated in 21 studies (Ahmed et al., 1978; McLane and Hughes, 1980; Lowe and Stendell, 1991; Britton and Huston, 1973; Scott et al., 1975; Cecil et al., 1974; Peakall et al., 1972; Peakall and Peakall, 1973; Dahlgren et al., 1972; Tori and Peterle, 1983; Hill and Shaffner, 1976; Custer and Heinz, 1980; Platonow and Reinhart, 1973; Risebrough and Anderson, 1975; Fernie et al., 2000, 2001; Fisher et al., 2001; Bird et al., 1983; Haseltine and Prouty, 1980; Kreitzer and Heinz, 1974; Stickel et al., 1984).

In the studies reviewed, reproduction (measuring endpoints such as adult fertility, hatchability, eggshell thickness, egg production, eggshell weight, embryo development, courtship behavior, onset of nest initiation, clutch size, and embryo mortality and viability), avoidance behavior, adult growth, and mortality were observed in seven bird species exposed orally to PCB Aroclor mixtures. These endpoints were measured in the following bird species: American kestrels, chickens, turtle doves, mourning doves, pheasants, Japanese quail, mallard ducks, common gackles, red-winged blackbirds, brown-headed cowbirds, and starlings. Table B-2 summarizes the NOAELs and LOAELs derived from the dietary PCB studies reviewed. LOAELs ranged from 0.46 mg/kg bw/d for reproduction of American kestrels (Lowe and Stendell, 1991) to 34.4 mg/kg bw/d for avoidance behavior of Japanese quail (Kreitzer and Heinz, 1974). The lowest calculated LOAEL of all studies reviewed was based on eggshell weight and thickness in American kestrels fed 0.46 mg/kg bw/d Aroclor 1248 (Lowe and Stendell, 1991). However, Lowe and Stendell (1991) did not report the overall effect of eggshell thinning on reproductive success (for example, hatchability, offspring viability) or the critical degree at which eggshell thinning would affect reproductive success (eggshell thickness of the experimental group was 5 percent different from the control). The next lowest LOAELs were reported in Britton and Huston (1973), who reported reduced hatchability in chickens fed 0.58 mg/kg bw/d PCBs Aroclor 1242 following 6 weeks of dietary exposure.

NOAELs ranged from 0.061 mg/kg bw/d for reproduction (i.e., egg production, and hatchability) of chickens (Scott et al., 1975) to 3.9 mg/kg kg/d for reproduction (egg production and eggshell thinning) of mallards (Risebrough and Anderson, 1975). NOAELs below the lowest LOAEL of 0.50 mg/kg bw/d were reported in four studies based on reproduction and ranged from 0.061 to 0.41 mg/kg bw/d (Scott et al., 1975; Platonow and Reinhart, 1973; Britton and Huston, 1973; McLane and Hughes, 1980). At the highest NOEC of 0.41 mg/kg bw/d, no effects on eggshell thickness, egg production, hatching success, and fledging success were reported in screech owls exposed to dietary PCBs for two generations (McLane and Hughes, 1980). Table D-2 presents all of the NOAELs and LOAELs calculated for PCBs from the literature reviewed.

Mammal Toxicity Reference Values

PCB Aroclors

Fourteen papers on the potential adverse effects of PCBs on mammals were reviewed (Aulerich and Ringer, 1977; Aulerich et al., 1985, 1986; Bleavins et al., 1980; Brunström et al., 2001; Harris et al., 1993; Heaton et al., 1995; Hornshaw et al., 1983; Jensen et al., 1977; Kihlstrom et al., 1992; Restum et al., 1998; Ringer, 1983; Tillitt et al., 1996; Wren et al., 1987). The potential mechanism of exposure included dietary ingestion of laboratory or exposed field-collected diets. The most comprehensive studies of PCB toxicity in a wildlife mammalian species have been conducted with mink, and only mink studies were reviewed for PCBs. Mink also appears to be one of the most sensitive mammalian species tested (Fuller and Hobson, 1986) and, therefore, is considered a good surrogate for assessing risk to other mammals. Four additional studies on the toxicity of PCBs to mink or ferret were reviewed; however, these studies were excluded from the TRV selection process because they did not meet the TRV literature selection criteria. Specifically, studies in which no toxic effects were measured (Bleavins et al., 1984; Henny et al., 1981) or in which no dietary dose was reported (O'Shea et al., 1981) were not included in the TRV selection process. Studies that reported endpoints that were not related to growth, mortality, reproduction, and behavior (that is, hematology and liver pathology) were not included in the TRV selection process (Heaton et al., 1995). In addition, Platonow and Karstad (1973) was excluded from the TRV selection process because no data were presented in the paper and no true controls were used.

Table D-3 presents all of the NOAELs and LOAELs calculated for PCBs from the literature reviewed. Adverse effects on maternal growth, kit growth, kit survival, gestation length, whelping success, and reproductive failure were measured in mink following exposure to PCBs. LOAELs ranged from 0.037 mg/kg bw/d for reproduction in mink (Restum et al., 1998) to 2,000 mg/kg bw/d for growth of mink (Harris et al., 1993).

NOAELs ranged from 0.070 mg/kg bw/d for reproduction in mink (Hornshaw et al., 1983) to 480 mg/kg bw/d for growth of mink (Harris et al., 1993). The lowest LOAELs, ranging from 0.037 to 0.077 mg/kg bw/d PCBs, were reported in studies in which adverse reproductive effects (including reduced kit body weight, delay in the onset of estrus, and reduced whelping success) were observed in mink fed field-collected carp from the Great Lakes region over a chronic period (Restum et al., 1988; Hornshaw et al., 1983). In the studies, mink were fed a prepared diet containing various percentages of field-collected fish; thus, these studies only have quantitative relevance to mink exposed to constituent mixtures similar those found in the Great Lakes fish. In addition, there is uncertainty associated with these LOAELs because the field-collected fish contained other organic constituents (such as dioxins, DDE, dichlorodiphenyldichloroethane, chlordane) that likely could have contributed to the reproductive toxicity reported in mink. The next lowest LOAEL of 0.089 mg/kg bw/d was reported in Brunström et al. (2001) in which offspring growth was reduced in mink fed a Clophen A50 PCB mixture for 18 months.

TABLE D1: Whole-body Tissue Residue Fish TRV Studies

Analyte	NOEC (WB)	LOEC (WB)	CF	NOEC (egg)	LOEC (egg)	Units (ww)	Source	Endpoint	Test Species	Lifestage	Exposure Mode	Exposure Duration	Endpoint Effect	Chemical Form	Notes
PCBs (Aroclor 1254)	0.98					mg/kg	Powell et al. 2003	growth, survival	Chinook salmon	juvenile	diet	4 wks			whole body burdens ranged from 0.74 to 0.98 over the 13 period following treatment; only no-effect level reported; no effect on growth, survival, or survival following immunological challenge
PCBs (Aroclor 1254)		1.53				mg/kg	Berlin et al. 1981	mortality	Brook trout	fry	water and diet	176 days	fry mortality		field collected eggs from Lake Michigan with starting egg residues of 7.6 ug/g PCBs and 4.7 ug/g DDE; mortality is estimated
PCBs: Aroclor mixture (egg)[a]		7.2	4.69		1.53	mg/kg	Fisher et al. 1994	reproduction (egg exposure)	Atlantic salmon	egg (converted to WB)	water	48 hours	live fry body weight		growth was significantly reduced at day 176; no effect on reproduction was observed; adult concentration was estimated using egg:adult conversion factor of 4.69 based on rainbow trout data in Niimi (1983); see text for detail on use and derivation of conversion factors
PCBs: Aroclor 1254 (egg)[a]		7.7	4.69		1.64	mg/kg	Hendricks et al. 1981	reproduction (egg exposure)	Rainbow trout	egg (converted to WB)	maternal transfer	60 days	fry growth		eggs were exposed via maternal transfer from gravid females fed 200 ug/g PCBs for 60 days; adult concentration was estimated using egg:adult conversion factor of 4.69 based on rainbow trout data in Niimi (1983); see text for detail on use and derivation of conversion factors
PCBs (Aroclor 1254)	8					mg/kg	Lieb et al. 1974	growth, mortality	Rainbow trout	14 weeks	food	32 wks			only no-effect level reported
PCBs: Aroclor 1254 (egg)		8.7	2.71		3.2	mg/kg	McCarthy et al. 2003	reproduction (egg exposure)	Atlantic croaker	egg	maternal transfer to eggs	2 wks during reproduc-tion (adults)	reduction in larval growth rate and impaired response to startle stimulus		parental fish fed dietary PCBs-eggs exposed via maternal transfer; residues not clearly presented; adult concentration was estimated using egg:adult conversion factor of 2.71 based on average data reported in five species in Niimi (1983); see text for detail on use and derivation of conversion factors
PCBs (Aroclor 1254)	1.9	9.3				mg/kg	Hansen et al. 1973	reproduction	Sheepshead minnow	adult		28 days	decreased fry survival		
PCBs (Aroclor 1268)	15					mg/kg	Matta et al. 2001	reproduction	Mummichog	adult	food	~6 wks	fertilization and hatching success, larval survival		two generations of progeny observed; only no-effect level reported
PCBs (Aroclor 1254)	17					mg/kg	Duke et al. 1970	mortality	Pinfish	juvenile	water	48 hours			only no-effect level reported

PCBs: Aroclor mixture (egg)[a]		26.2	4.69		5.59	mg/kg	Fisher et al. 1994	reproduction (egg exposure)	Atlantic salmon	egg (converted to WB)	water	48 hours	retarded phototropism behavior in alevins		predator avoidance affected significantly at 14.16 mg/kg ww; adult concentration was estimated using egg:adult conversion factor of 4.69 based on rainbow trout data in Niimi (1983); see text for detail on use and derivation of conversion factors
PCBs:Aroclor 1254 (egg)[a]	21	32	7.04	3	4.5	mg/kg	Mac and Seelye 1981	reproduction (egg exposure)	Lake trout	sac-fry (converted to WB)	water and diet	48 days	fry mortality		field collected eggs from Saugatuck, Michigan with unknown organics; no effect on fry growth was observed; LOEC is residue at 48 days and NOEC is control residue at 48 days; only one group was treated with 50 ng/L (water) and 0.72 mg/kg (diet) Aroclor 1254; adult concentration was estimated using sac fry:adult conversion factor of 7.04 based on rainbow trout data in Niimi (1983); see text for detail on use and derivation of conversion factors; elevated control mortality (12.5%); PCB exposure was via both food and water simultaneously
PCBs (Aroclor 1260)	32					mg/kg	Mayer et al. 1977	growth, mortality	Channel catfish	fingerling	food	193 days			only no-effect level reported
PCBs (Aroclor 1254)	27	46				mg/kg	Hansen et al. 1971	mortality	Spot		water	20 days			mortality did not appear directly related to body burden; bb increased with exposure duration; NOEC (catfish)= 32
PCBs (Aroclor 1254)	60					mg/kg	Powell et al. 2003	mortality	Chinook salmon	juvenile	oral gavage	96 hrs			only no-effect level reported
PCBs (Aroclor 1254)	31	71				mg/kg	Mauck et al. 1978	growth	Brook trout	fry-exposure to eggs	water	10 d prior to hatch and 118 d after hatch	reduced growth		residue measured at 118 days; growth effect reported at 48 days but disappeared at 118 days.
PCBs (Aroclor 1016)	77					mg/kg	Hansen et al. 1975	reproduction	Sheepshead minnow	fry	water	2 wks	fertilization and hatching success, larval survival		intermittent-flow toxicity test; no effect: fertilization success, survival of embryos to hatching, or survival of fry; only no-effect level reported
PCBs (Aroclor 1016)		106				mg/kg	Hansen et al. 1974	mortality, behavior	Pinfish		water	33 days	loss of equilibrium; erratic swimming		significant reduction in survival (50% mortality relative to 6% in control)
PCBs (Aroclor 1254:1260 mixture)	120					mg/kg	Mayer et al. 1985	mortality	Rainbow trout	young	water	90 days			mortality observed; not significantly different; dose was 1:2 ratio of Aroclor 1254:1260; only no-effect level reported
PCBs (Aroclor 1254:1260 mixture)	70	120				mg/kg	Mayer et al. 1985	growth	Rainbow trout	young	water	90 days		1:2 ratio of Aroclor 1254:1260	

PCBs (Aroclor 1254)	71	125				mg/kg	Mauck et al. 1978	mortality	Brook trout	fry-exposure to eggs	water	10 d prior to hatch and 118 d after hatch	fry survival		reduced fry survival; 21 to 100% mortality; tissue residue measured at 118 days; Median hatching time and egg hatchability were not affected. Larval growth was initially reduced, but not by the end of the test
PCBs (Aroclor 1016)	77	200				mg/kg	Hansen et al. 1975	mortality	Sheepshead minnow	fry	water		fry survival		
PCBs (Clophen A50)		250				mg/kg	Hattula and Karlog 1972	mortality	Goldfish		water	5-21 days		PCBs dissolved in acetone (0.5 mL/L)	LOEC is lethal body burden
PCBs:Aroclor 1254 (egg)[a]		365	4.69		77.9	mg/kg	Freeman and Idler 1975	reproduction (egg exposure)	Brook trout	egg	water	21 days	reduced hatchability	Aroclor 1254	75% hatching at LOEC and 92% hatching in control; concentration in back muscle of dose fish with affected hatchability was 32.8 mg/kg ww; adult concentration was estimated using egg:adult conversion factor of 4.69 based on rainbow trout data in Niimi (1983); see text for detail on use and derivation of conversion factors
PCBs (Aroclor 1254)		458, 361 (female)				mg/kg	Nebeker et al. 1974	reproduction	Fathead minnow		water		reduced spawning		terminal residue; egg hatchability and fry survival was not affected
PCBs (Aroclor 1254)		645				mg/kg	Mayer et al. 1977	mortality	Coho salmon	fingerling		~260 days			all fish died w/in 265 days of dose; no stats, no control
Calculated PCB 25th percentile	17	22													
Calculated PCB 50th percentile	32	113													

Highlighted TRVs are closest TRVs to 25th and 50th percentiles

NC -- TRVs not reported in database because study only injection dose was reported (no WB tissue residues were reported)

[a] Concentrations in egg tissues or sac-fry tissues were converted into whole-body adult tissue concentrations using conversion factors reported in the literature; see text for additional detail on conversion factors.

[b] Whole body tissue concentrations were converted to wet weight assuming 80% moisture in the organism

TABLE D2: Bird Dietary TRV Studies Evaluated

Analyte	NOAEL (mg/kg bw/d)	LOAEL (mg/kg bw/d)	Source	Endpoint	Test Species	Chemical Form	Exposure Mode	FI (kg dw or L/day)	Wet or Dry?	FI Default?	Nagy bird guild	Body Weight (kg)	BW Default?	% Moisture	NEC wet (ppm)	NEC dry (ppm)	LEC wet (ppm)	LEC dry (ppm)	Exposure Duration	Effect Endpoint	Notes
PCBs (Aroclor 1254)	0.054		Ahmed et al. 1978	mortality, growth, reproduction	White leghorn males	Aroclor 1254	food	0.0034	W			2.56			40				20 wks	fertility, hatchability, growth, mortality	no control values given
PCBs (Aroclor 1248)		0.35	Lowe and Stendell 1991	reproduction	American kestrel	Aroclor 1248	food	0.0136	D	1	6	0.13	E	10%			3	3.3	5.5 months	eggshell weight and thickness	only one dose used
PCBs (Aroclor 1248)	0.49		McLane and Hughes 1980	reproduction	Screech owl	Aroclor 1248	food	0.0266	D	1	5	0.181	B	10%	3	3.33			2 generations	Eggshell thickness, egg production, hatching success, fledging success	egg tissue concentrations also reported in study
PCBs (Aroclor 1242)	0.29	0.58	Britton and Huston 1973	reproduction	White leghorn chickens	Aroclor 1242	food	0.0997	W	3		1.71	C		5		10		6 weeks + 5 weeks untreated	hatchability	significant effects on hatchability
PCBs (Aroclor 1242)		0.60	Hill et al. 1975a	reproduction	Japanese quail	Aroclor 1242	food	0.0048	D	1	3	0.09	B	10%			10	11.111	45 days	eggshell thinning	only one dose used
PCBs (Aroclor 1248)	0.061	0.61	Scott et al. 1975	reproduction	White leghorn chickens	Aroclor 1248	food	0.105	W			1.71	C		1		10		8 weeks	egg production and egg hatchability	egg residues also reported
PCBs (Aroclor 1232)		1.2	Cecil et al. 1974	reproduction	White leghorn hens	Aroclor 1232	food	0.0997	W	3		1.71	C				20		9 weeks + 7 weeks untreated then mated	hatchability, embryo abnormality, embryo mortality	only one dose used; no discussion of statistical significance
PCBs (Aroclor 1254)		1.4	Peakall et al. 1972; Peakall and Peakall 1973	reproduction	Ringed turtle-dove	Aroclor 1254	food	0.0202	D	1	1	0.155	D	9%			10	10.989	2 generations	Hatching success in second generation	egg tissue concentrations also reported in study
PCBs (Aroclor 1254)		1.6	Dahlgren et al. 1972	reproduction	Ring-necked pheasant	Aroclor 1254	gelatin capsule					1.135	B				1.7857		Once per week for 16 weeks	Egg hatchability	dose reported in mg/kg/wk-daily dose derived from weekly dose [(7 mg/ week)/7]
PCBs (Aroclor 1254)		1.6	Tori and Peterle 1983	behavior	Mourning dove	Aroclor 1254	food	0.0168	D	1	1	0.119	B	10%			10	11.1	42 days (+30 days untreated following 2 wks post exposure)	reduced courtship behavior, fewer successful pair bonds formed (both statistically	unbounded LOAEL

																				significant); also delay onset of nest initiation	
PCBs (Aroclor 1254)	2.5		Custer and Heinz 1980	reproduction	Mallard	Aroclor 1254	food	0.1082	W	2		1.082	B		25				~ 1 month	Reproductive success	
PCBs (Aroclor 1254)	0.29	2.9	Platonow and Reinhart 1973	reproduction	White leghorn chickens	Aroclor 1254	food	0.0997	W	3		1.71	C		5		50	50.0	39 wks (14 wks for 50 ppm group)	hatchability	statistically significant effect observed; LOAEL is residues where instantaneous depression of hatchability and embryotoxicity is observed; NOAEL is where hatchability of fertile eggs is unaffected; however, at NOAEL fertility and egg production are significantly reduced (study attributes it to mating inactivity and not PCB exposure)- uncertain NOAEL
PCBs (Aroclor 1254)	3.9		Risebrough and Anderson 1975	reproduction	Mallard	Aroclor 1254	food	0.1082	W	2		1.082	B		39				4 months	Egg production, eggshell thinning	
PCBs (Aroclor 1248: 1254:1260 mixture)		7	Fernie et al. 2000, 2001	reproduction	American kestrel	1:1:1 ratio of Aroclor 1248:1254:1260	food												100 days until eggs hatched	egg laying in second generation (exposed *in ovo*); also some effect on clutch size and fledgling success	body weight normalized dose estimated in study; no stats- egg laying endpoint: 91% in controls laid a clutch of eggs; 75% in test group
PCBs (Aroclor 1248: 1254:1260 mixture)		7	Fisher et al. 2001	reproduction	American kestrel	1:1:1 ratio of Aroclor 1248:1254:1260	food												1 mo prior to mating through mating period	courtship behavior	body weight normalized dose estimated in study; no adverse effect on male sexual behavior and no change in female sexual

																					behavior or frequency of copulation; study performed along with Fernie et al. 2000; 2001
PCBs (Aroclor 1254)		9.5	Bird et al. 1983	reproduction	American kestrel	Aroclor 1254	food										33		62-69 days	decreased sperm count and sperm concentration	endpoint is not a direct measure of reproductive success; assumed 80% moisture from day old dead chicks in diet
PCBs (Aroclor 1254)		12.0	Kreitzer and Heinz 1974	behavior	Japanese quail	Aroclor 1254	food	0.0048	D	1	3	0.09	B	10%			200	222.2	8 days treated + 6 days untreated	avoidance response (depressed response to stimuli)	statistically significant effect; only one dose used
PCBs (Aroclor 1242)		15	Haseltine and Prouty 1980	reproduction	Mallard	Aroclor 1242	food	0.1082	W	2		1.082	B				150		12 weeks	hatchability, embryo mortality, egg viability, embryo abnormalities	egg tissue concentrations also reported in study
PCBs (Aroclor 1254)	NC	NC	Stickel et al. 1984	mortality	common gackles, red-winged blackbirds, brown-headed cowbird, starling	Aroclor 1254	food											1500	birds fed until 50% of birds died	study not useful-presents LT50 in four bird species at an extremely high dietary PCB concentration	
Calculated PCB 25th percentile	0.18	0.75																			
Calculated PCB 50th percentile	0.29	1.6																			

For 2,3,7,8-TCDD, the highlighted TRVs are considered the most suitable TRVs of the available values. For PCBs, the highlighted TRVs are the closest TRVs to 25th and 50th percentiles.

NC = TRV not calculated in database because more preferable studies were available for TRV selection (see notes)

FI = food ingestion rate

NEC = No effect concentration in exposure medium

LEC = Low effect concentration in exposure medium

W = wet weight basis

D = dry weight basis

Default ingestion rates:
1 - Nagy 2001
2 - Heinz et al. 1987
3 - NRC 1984
4 - NRC 1994
5 - EPA 1993

Nagy bird group allometric equation
1- all birds: FI (kg/d dw) = [0.638*((bw(g))^0.685)]/1000
2- Passerines: FI = [0.630*((bw(g))^0.683)]/1000
3- Galliformes: FI = [0.088*((bw(g))^0.891)]/1000
4- Omnivorous birds: FI = [0.670*((bw(g))^0.627)]/1000
5- Carnivorous birds: FI = [0.849*((bw(g))^0.663)]/1000

Default body weight:
A - NRC 1994
B - Dunning 1993
C - NRC 1984
D - Sample et al. 1996
E - EPA 1993

6- Eurasian Kestrel: FI =(22.1/211)*bw(kg)

F - Pattee 1984

TABLE D3

Mammal Dietary PCB TRV Studies Evaluated

Analyte	NOAEL (mg/kg bw/d)	LOAEL (mg/kg bw/d)	Source	Endpoint	Test Species	Exposure Mode	FI (kg dw or L/day)	Wet or Dry?	FI Default ?	Body Weight (kg)	BW Default ?	% Moisture	NEC wet (ppm)	NEC dry (ppm)	LEC wet (ppm)	LEC dry (ppm)	Chemical Form	Exposure Duration	Effect endpoint	Notes
PCBs (total PCBs)		0.037	Restum et al. 1998	Reproduction	Mink	food	0.20			1.34	B				0.25			multi-generational	kit body weight, onset of estrus (as indicated by vulvular swelling), decrease in females whelping	uncertainty-other organics in field collected fish-dioxins, DDE, DDD, chlordane (effects may not be just result of PCB exposure); LOAEL calculated assuming 200 g fd/ day; most sensitive reproductive endpoints
PCBs (Aroclor 1254)		0.074	Hornshaw et al. 1983	Reproduction	Mink	food				1.34	B							290 days	kit survival to 4 wks (0%)	uncertainty-unknown organics in field collected fish; LOAEL effect was observed in mink fed field collected perch and white sucker (~0.66 ppm) from Lake Heron and Lake Erie assuming 150 g fd/ day
PCBs (Aroclor 1254)	0.070	0.077	Hornshaw et al. 1983	Reproduction	Mink	food				1.34	B							250 days	kit body weight	uncertainty-unknown organics in field collected fish; LOAEL-effect was observed in mink fed field collected perch scrap (~0.66 ppm) from Lake Erie

																				assuming 150 g fd/ day. NOAEL- no sign. effect on kit body weight for mink fed other field collected fish (concentrations in sucker were highest- used to calculate NOAEL)
PCBs (Clophen A50)		0.089	Brunström et al. 2001	reproduction	Mink	food				1.12					0.1		Clophen A50	18 months	kit growth	Clophen A50 mixture
PCBs (Aroclor 1254)		0.13	Wren et al. 1987b	Reproduction	Mink	food	0.18	W	1	1.34	B				1			6 mos	reduced kit growth rate	
PCBs (total PCBs)		0.13	Heaton et al. 1995a; Tillitt et al. 1996	Reproduction	Mink	food												182 days (including reproduction)	kit body weight at 3 and 6 weeks, gestation length, kit survival	uncertainty- TEQs also detected (3.6 mg/kg bw/d at LOAEL) and unknown other contaminants in field collected fish; most sensitive reproductive endpoints
PCBs (Aroclor 1254)	0.077	0.17	Hornshaw et al. 1983	Reproduction	Mink	food				1.34	B							250 days	kit survival at birth (0%)	uncertainty- unknown contaminants in field collected fish; LOAEL- effect was observed in mink fed field collected carp (~1.5 ppm) from Saginaw Bay (Lake Heron) assuming 150 g fd/ day; NOAEL- no sign. effect on kit survival was observed in mink fed other field collected fish- whitefish, perch, alewife, sucker (concentrations in perch were highest-

																				used to calculate NOAEL)
PCBs (Aroclor 1254)		0.22	Ringer 1983	reproduction	Mink	food	0.15	W		1.34	B		1		2			4 and 9 months prior to giving birth	# offspring/ female, decrease in pup body weight	no stats; at LOAEL: # offspring/ female = 0.3; at NOAEL: # offspring/ female = 4.3; at control: # offspring/ female = 4.1 - 6.0
PCBs (Aroclor 1254)	0.13	0.26	Aulerich and Ringer 1977	Reproduction	Mink	food	0.18	W	1	1.34	B		1		2			4 months	Number of kits born alive (0% at 4 wks)	
PCBs (Clophen A50)	0.27		Brunström et al. 2001	Growth	Mink	food				1.12			0.3				Clophen A50	18 months	maternal bw	Clophen A50 mixture
PCBs (total PCBs)	0.26	0.32	Heaton et al. 1995a	Growth	Mink	food												182 days (including reproduction)	maternal body weight	uncertainty-TEQs also detected (6.8 and 10.7 mg/kg bw/d at NOAEL and LOAEL) and unknown other contaminants in field collected fish; most sensitive reproductive endpoints
PCBs (Aroclor 1254)		0.39	Aulerich et al. 1985	Reproduction	Mink	food	0.13	W	1	0.87	B				2.5			88-102 days	Number of kits whelped and born alive (0%)	
PCB (mixture composition not reported)		0.51	Jensen et al. 1977	Reproduction	Mink	food	0.13	W	1	0.87	B				3.3			66 days	Number of kits born alive	PCB composition not known
PCBs (Aroclor 1242)		0.65	Bleavins et al. 1980	Reproduction	Mink	food	0.18	W	1	1.34	B				5			8 months	Reproductive failure	
PCBs (Aroclor 1254)		1.31	Hornshaw et al. 1986	Weight gain in adults	Mink	food	0.18	W	1	1.34	B				10			4 weeks	Weight gain in adults	
PCBs (Aroclor 1254)		1.64	Kihlstrom et al. 1992	Reproduction	Mink	food												3 months	All whelps stillborn	
PCBs (Aroclor 1254)	1.2	1.8	Aulerich et al. 1986	growth	Mink	food												28 days	female growth	mink fed rabbit prey exposed to PCBs; LOAEL and NOAEL are average between male and female

																				mg/kg bw/d dose. Mortality was also recorded for a 28 day exposure but insufficient data to calculate an LOAEL.
PCBs (Clophen A50)		2.0	Kihlstrom et al. 1992	Reproduction	Mink	food												3 months	All whelps stillborn	
PCBs (Aroclor 1254)	1.5	2.4	Aulerich et al. 1986	growth	Mink	food												28 days	male and female growth	mink fed mink cereal diet. A mortality test was also run and recorded for a 28 day exposure but insufficient data to calculate an LOAEL.
PCBs (Aroclor 1016)		2.6	Bleavins et al. 1980	Reproduction/Mortality	Mink	food	0.18	W	1	1.34	B				20			8 months	Birth weight and growth rate of kits, and 25 % adult female mortality	
PCBs (Aroclor 1232)	480	2000	Harris et al. 1993	growth	Mink	injection (ip)												single injection + 14 days (untreated)	body weight gain	single injection (5 dose levels)
Calculated PCB 25th percentile	0.12	0.13																		
Calculated PCB 50th percentile	0.26	0.35																		

For 2,3,7,8-TCDD, the highlighted LOAELs are considered the most suitable TRVs, based on the NOAEL presented in Table 6. For PCBs, the highlighted TRVs are the closest TRVs to 25th and 50th percentiles.

NC = TRV not calculated in database because more preferable studies were available for TRV selection

NEC = No effect concentration in vehicle

LEC = Low effect concentration in vehicle

W = wet weight basis

D = dry weight basis

FI = food ingestion rate

DWI = drinking water ingestion rate

Default ingestion rates:

1 - Bleavins and Aulerich 1981

Default body weight:

A - EPA 1993

B - Bleavins and Aulerich 1981

Attachment E: Great Lakes National Program Office and Region 5 TSCA Going from the Clean Up Goals to Removal Level

Choosing a Cleanup Goal

In attachments B and C, the specific processes that GLNPO will follow to derive protective cleanup goals (CUG) are described. At the end of these, a potential of 14 cleanup goals will be available to project managers that span from human health to ecological endpoints, with varying toxicity and exposure assumptions inherent in the range. This attachment describes how GLNPO will go from the potential 14 to selecting the ultimate cleanup goal and how it relates to the removal level described in the flowchart shown in Figure 1.

Unlike other programs where risk is the metric for defining a remediation, the Great Lakes Legacy Act works only in the Great Lakes Area of Concern and is therefore focused upon Beneficial Use Impairments or BUIs. BUIs are not defined via a risk-based approach but instead on how environmental contamination can affect the use and functioning of an area. Based on a BUI approach, there are 6 GLLA Remedy Objectives similar to Superfund's 9 criteria that are prioritized to both define the goals of a remediation and on whether that remediation is successful. They are:

1. Short and long term reductions in contaminants of concern (COCs) in sediments (and porewater and water as appropriate).
2. Improvement in the benthic and biologic community.
3. Short and long term reductions of COCs in biota (e.g., fish, benthos & birds).
4. Reductions in sediment-related toxicity.
5. Improvement in habitat quality.
6. Volume, area and mass remediation of sediment contamination.

These remedy objectives are used in a similar fashion to the 9 criteria in that they help determine which is the most feasible and appropriate target for the site in question, as significant factors that affect which cleanup goal is appropriate will vary from site to site. Therefore, it is ultimately a site-specific and decision as to how the 14 potential cleanup goals are narrowed down to the chosen cleanup goal(s).

Translating from Cleanup Goal to Removal Level

As shown in Attachment A, B and C, the PCB cleanup goals are most often based on fish consumption, either by humans or ecological endpoints of interest. Therefore, GLNPO uses appropriate models to estimate how the PCBs in sediments are transported into fish tissue and to make estimates of fish tissue concentrations of PCBs (shown in detail in Attachment A). Then, based on human fish consumption patterns and the relationship between sediment and fish tissue concentrations, GLNPO calculates a sediment clean up goal that would result in protective fish tissue concentrations. This same logic is applied to the evaluation of bioaccumulation of PCBs into whole fish and the potential for adverse impacts on piscivorous birds and mammals.

The resulting PCB CUGs (i.e., human health and wildlife) are intended to reduce PCB concentrations in fish. Therefore, the sediment CUGs needs to represent a sediment concentration that fish (which are mobile within the cleanup zone) would be exposed to as they move throughout their lifetime. The sediment CUGs applicable to fish exposure are in most cases, best estimated as a surface average or surface-weighted average concentration (SWAC) within the cleanup zone.

Therefore, the chosen cleanup goal(s) are most often applied as a SWAC to the site and different removal levels (e.g., the concentration that determines where to start dredging) are assessed for their ability to achieve the chosen SWAC cleanup goal. It is almost always the case that a removal level will not be the same concentration as the SWAC cleanup goal, but will depend on the contamination distribution at a site. For example, a removal level of 1 ppm PCBs might translate into a post-remedial SWAC of 0.2 ppm PCBs. Again, the numeric relationship between a removal level and cleanup goal will depend on site-specific characteristics.

Attachment F Great Lakes National Program Office and Region 5 TSCA Model Language Templates

Template 1 – Informal Email Consultation

Email from: GLNPO Project Manager
To: Peter Ramanauskas, LCD RRB

Email should contain the following information:

- Project name/location
- Summary of GLNPO sampling efforts and data for the project including: time span of sampling, extent of sampling, data summary (maximums and averages).
- Notification that GLNPO believes all available data indicates no PCB present above 50 ppm and MOA does not apply to the project.
- A statement that if PCB sediments greater than or equal to 50 ppm are found, GLNPO will notify RRB per the MOA.

cc: Marc Tuchman, Great Lakes Legacy Act Program Manager
GLNPO contacts

Template 2 – Performance Based Disposal Memorandum

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 5

DATE:

SUBJECT: Notification of TSCA Performance Based Disposal (40 CFR 761.61(b)) of PCB Remediation Waste Sediments from Great Lakes Legacy Act [Project Name] Project, [Location]

FROM: Insert Name Here
Technical Assistance and Analysis Branch Chief
Great Lakes National Program Office

TO: Jose Cisneros
Remediation and Reuse Branch Chief
Land and Chemicals Division

This memo is intended to notify the Land and Chemicals Division Remediation and Reuse Branch (RRB) of a Great Lakes Legacy Act (GLLA) sediment dredging project involving Polychlorinated Biphenyl (PCB) Remediation Waste regulated under the Toxic Substances Control Act (TSCA) 40 Code of Federal Regulations (CFR) Part 761.

The Great Lakes National Program Office (GLNPO) and its Non-Federal Sponsor for the subject remedial project intend to manage all dredged PCB Remediation Waste sediments for disposal in accordance with the TSCA Performance Based Disposal provision found at 40 CFR §761.61(b). The project cleanup level is ≤ 1 ppm on a point-by point basis and will be confirmed through post-dredging verification sampling. Dredged sediments will be disposed of at the [insert landfill name] TSCA approved 40 CFR §761.75 Chemical Waste Landfill. [Optional: PCB Remediation Waste sediments containing PCBs at concentrations < 50 ppm will be disposed of at the [insert name] disposal facility operating under [identify which: section 404 of the Clean Water Act, or the equivalent of such a permit as provided for in regulations of the U.S. Army Corps of Engineers at 33 CFR part 320 or in accordance with a permit issued by the U.S. Army Corps of Engineers under section 103 of the Marine Protection, Research, and Sanctuaries Act, or the equivalent of such a permit as provided for in regulations of the U.S. Army Corps of Engineers at 33 CFR part 320].

The project is scheduled to begin dredging activities on [date]. If RRB has any questions or concerns, please contact [name] of my staff at [number].

cc: Marc Tuchman, Great Lakes Legacy Act Program Manager
GLNPO contacts

Template 3 – Risk Based Approval Model Cover Letter

Peter Ramanauskas
USEPA REGION 5
77 West Jackson Boulevard
Mail Code: LU-9J
Chicago, IL 60604-3507

Subject: [Insert Site Name Here]
Application for Risk-Based Disposal Approval in Accordance with 40 CFR §761.61(c)

Dear Mr. Ramanauskas:

The [insert name of non-federal sponsor(s)], in cooperation with the USEPA Great Lakes National Program Office, are requesting a Toxic Substance Control Act Risk-Based Disposal Approval for the [insert site name] Area of Concern in accordance with the requirements of both 40 CFR §761.61(c) for the removal of sediments containing polychlorinated biphenyls (PCBs) and the Region 5 LCD RRB TSCA Remedial Program & Great Lakes National Program Office Great Lakes Legacy Act Sediment Remediation Memorandum of Agreement on TSCA Approvals for Dredging and Disposal of Sediments Containing PCBs (MOA).

In accordance with the MOA, we are submitting/have previously submitted/submitted under separate cover/have attached the following information:

- a copy of the signed project agreements
- information regarding the project scope (e.g., the remedial investigation and feasibility study, the project application from the non-federal sponsor);
- project cleanup level, clean up goal and/or removal level;
- identification of sediment disposal destinations;
- post-remedial sampling plans designed to verify how the cleanup level will be met
- description and evaluation of human health and/or ecological risk scenarios not already addressed by the risk assessment documents found in Attachments A & B of the MOA
- information as required by 40 CFR §761.61(a)(3)

The [insert name of non-federal sponsor] appreciates the guidance and assistance provided by the Region 5 TSCA Program and we look forward to receiving written agency approval of our application in the near term. If you have any questions or need additional information to provide the approval, please contact me [insert contact name(s) here].

Sincerely,

Insert non-federal sponsor name(s)
and contact information

cc: Marc Tuchman, Great Lakes Legacy Act Program Manager
GLNPO contacts

Template 4 – Coordinated Approval Model Letter

Peter Ramanauskas
USEPA REGION 5
77 West Jackson Boulevard
Mail Code: LU-9J
Chicago, IL 60604-3507

Subject: [Insert Site Name Here]
Application for Coordinated Approval in Accordance with 40 CFR §761.77(c)

Dear Mr. Ramanauskas:

The [insert name of non-federal sponsor(s)], in cooperation with the USEPA Great Lakes National Program Office, are requesting Toxic Substance Control Act Coordinated Approval for the [insert site name] Area of Concern in accordance with the requirements of both 40 CFR §761.77(c) for the removal of sediments containing polychlorinated biphenyls (PCBs) and the Region 5 LCD RRB TSCA Remedial Program & Great Lakes National Program Office Great Lakes Legacy Act Sediment Remediation Memorandum of Agreement on TSCA Approvals for Dredging and Disposal of Sediments Containing PCBs (MOA).

In accordance with the MOA, we are submitting/have previously submitted/submitted under separate cover/have attached the following information:

- a copy of the signed project agreements
- information regarding the project scope (e.g., the remedial investigation and feasibility study, the project application from the non-federal sponsor);
- project cleanup level, clean up goal and/or removal level;
- identification of sediment disposal destinations;
- documentation that the disposal destinations are permitted to receive such waste; and
- post-remedial sampling plans designed to verify how the cleanup level will be met

The [insert name of non-federal sponsor] appreciates the guidance and assistance provided by the Region 5 TSCA Program and we look forward to receiving written agency approval of our application in the near term. If you have any questions or need additional information to provide the approval, please contact me [insert contact name(s) here].

Sincerely,

Insert non-federal sponsor name(s)
and contact information

cc: Marc Tuchman, Great Lakes Legacy Act Program Manager
GLNPO contacts

Attachment G Great Lakes National Program Office and Region 5 TSCA Regulatory Background

The regulations at 40 CFR Part 761, Subpart D, establish requirements for the storage and disposal of PCBs. The regulation at 40 CFR §761.3 defines "PCB remediation waste" as "waste containing PCBs as a result of a spill, release, or other unauthorized disposal, at the following concentrations: Materials disposed of prior to April 18, 1978, that are currently at concentrations ≥ 50 ppm PCBs, regardless of the concentration of the original spill; materials which are currently at any volume or concentration where the original source was ≥ 500 ppm PCBs beginning on April 18, 1978, or ≥ 50 ppm PCBs beginning on July 2, 1979; and materials which are currently at any concentration if the PCBs are spilled or released from a source not authorized for use under this part. PCB remediation waste means soil, rags, and other debris generated as a result of any PCB spill cleanup, including, but not limited to: (1) Environmental media containing PCBs, such as soil and gravel; dredged materials, such as sediments…"

In the case of many GLLA cleanups, PCB releases to the receiving body of water may have occurred at multiple locations, times, and source concentrations with limited or no information available as to the source concentrations or dates of release. The June 28, 1998 preamble to the Mega Rule states, "[r]esearch has shown that sediments can be the depository for chemicals and other pollutants, including PCBs, discharged into surface waters from both point and non-point sources….Dredged material containing PCBs, such as sediments, settled sediment fines, and aqueous decantate from sediment, is included in the definition of 'PCB remediation waste' and is regulated for disposal under TSCA at the concentration at which it is found." (63 FR 35410) Thus, sediments at concentrations both above and below 50 ppm are considered PCB remediation waste and must be managed for disposal under 40 CFR §761.61.

The May 1998 *Response To Comments Document On The Proposed Rule -- Disposal Of Polychlorinated Biphenyls* (page 101) states that while sediments are included in the definition of "PCB remediation waste", the self-implementing cleanup provisions at 40 CFR §761.61(a) cannot be used to remove sediments from marine or freshwater ecosystems (*see* 40 CFR §761.61(a)(1)(B)), including ponds, lakes, and streams that are located wholly on the owner or operator's property. The risks from dredging operations can vary greatly from site to site, and EPA does not have broadly-applicable data to support inclusion of this activity as a self-implementing option. Sediments must be disposed of in accordance with the performance-based disposal requirements at 40 CFR §761.61(b) or under a risk-based disposal approval pursuant to 40 CFR §761.61(c). It must be noted that while the self-implementing cleanup provisions cannot be used to remove sediments from marine or freshwater ecosystems, the 1998 preamble to the Mega Rule states that even though "Section 761.61(b)(3) provides a disposal option specific to dredged material containing <50 ppm PCBs…dredged material falls within the definition of PCB remediation waste, and as such the other disposal options of §761.61(a), (b), and (c) are available for management and disposal of dredged material containing PCBs at any concentration, as long as the applicable requirements are met." (63 FR 35410)

Therefore, depending on the scope of the remedial project, GLNPO and the project Non-Federal Sponsor (NFS) would need to comply with 40 CFR §761.61(b) or (c) when carrying out a GLLA project to remediate PCB impacted sediments. These provisions, and a discussion of the applicability and use of the Coordinated Approvals process in these cases, are examined below.

Performance-Based Disposal – 40 CFR §761.61(b)

The performance-based disposal option at 40 CFR §761.61(b)(2)(i) allows for disposal of non-liquid PCB Remediation Waste (i.e. sediments): 1) in a high temperature incinerator approved under 40 CFR §761.70(b), 2) by an alternative disposal method approved under 40 CFR §761.60(e), 3) in a chemical waste landfill approved under 40 CFR §761.75, or 4) in a facility with a coordinated approval issued under 40 CFR §761.77.

The performance-based disposal option at 40 CFR §761.61(b)(3)(i) and (ii) also allows one to manage or dispose of material containing < 50 ppm PCBs that has been dredged or excavated from waters of the United States "[i]n accordance with a permit that has been issued under section 404 of the Clean Water Act, or the equivalent of such a permit as provided for in regulations of the U.S. Army Corps of Engineers at 33 CFR part 320" or "[i]n accordance with a permit issued by the U.S. Army Corps of Engineers under section 103 of the Marine Protection, Research, and Sanctuaries Act, or the equivalent of such a permit as provided for in regulations of the U.S. Army Corps of Engineers at 33 CFR part 320."

Section 761.61(b) only addresses disposal of waste. Section 761.61(b) does not require removal of PCB remediation waste at any specified concentration nor does this paragraph provide for procedures to demonstrate that cleanup at a site is complete . To be completely unregulated for disposal off-site without an approval from EPA, waste must contain <1 ppm, and that concentration must not be the result of dilution during remediation (i.e., by mixing with clean soil during excavation).

Risk-Based Disposal Approval – 40 CFR §761.61(c)

This provision of the TSCA Regulation states that "[a]ny person wishing to sample, cleanup, or dispose of PCB remediation waste in a manner other than prescribed in [the other sections of 40 CFR §761.61], must apply in writing to the Regional Administrator …. EPA will approve such an application if it finds that the method will not pose an unreasonable risk of injury to health or the environment."

Thus, should the GLNPO project entail disposal of PCB remediation waste in a manner other than as allowed for under the performance-based provisions at 40 CFR §761.61(b), or in a manner other than outlined in this Memorandum of Agreement, GLNPO should work with the NFS of that particular remedial project and have that NFS submit a risk-based disposal approval application to LCD RRB.

Coordinated Approval – 40 CFR §761.77(c)

This provision states: "A person…conducting PCB remediation activities may apply for a TSCA PCB Coordinated Approval. The EPA Regional Administrator may approve the request if the EPA Regional Administrator determines that the activity will not pose an unreasonable risk of injury to health or the environment and the person: ... Has a permit or other decision and enforcement document issued or otherwise agreed to by EPA…which exercises control over the management of PCB wastes, and that person is in compliance with all terms and conditions of that document …." (40 CFR §761.77(c)(1)(i)

Of the Coordinated Approval, EPA's 1998 *Response to Comments on the Proposed Mega Rule* document (cited previously) states: "The provision is there as a mechanism to avoid redundancy and wasted time and resources in obtaining a TSCA PCB approval when another, equally protective permitting process has addressed, or is about to address, the risks of injury to health or the environment associated with the mismanagement of PCB waste."

"The determination as to whether waste management documents issued under another statute are sufficient to reduce or eliminate risks can only be made on a case-by-case basis since waste management scenarios often vary from incident to incident or from site to site. To obtain this determination, EPA must first be asked to evaluate the non-TSCA prescription, as is often done for CERCLA and RCRA actions, for example."

And further:

"Under the provision at §761.77, if the TSCA PCB waste requirements have been satisfied, the Regional Administrator could issue a TSCA PCB Coordinated Approval, which would be the equivalent of a TSCA PCB approval….EPA believes that state and other federal programs are protective of health and environment, even though a line-by-line comparison would identify differences in approaches. In order to assess the similarities between TSCA PCB and other requirements, TSCA officials will need to review non-

> TSCA waste management documents and determine to what extent those requirements reduce or eliminate unreasonable risks of injury from PCBs, and whether concerns commonly experienced in the management of PCB wastes have been addressed. TSCA officials will eventually be able to streamline this process and reduce the amount of time and effort required to process TSCA PCB Coordinated Approvals as they gain more experience with and insight into non-TSCA waste management activities." (Emphasis added)

This MOA is intended to provide a streamlined process between LCD and GLNPO which addresses the issues identified in the underlined statements above. LCD and GLNPO human health and ecological risk assessors have agreed that the processes outlined in Appendices A through E to calculate and determine a final project specific remedial cleanup goal and verify that the cleanup goal is met through the use of a Surface Weighted Average Concentration (SWAC) will reduce or eliminate unreasonable risks of injury to human health and the environment from PCBs.

Attachment H: Great Lakes National Program Office and Region 5 TSCA Works Cited and/or Relevent Literature

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Skinner, L. C., B. Trometer, A. J. Gudlewski. 2009. *Data Report for Residues of Organic Chemicals and Four Metals in Edible tissues and Whole Fish for Fish Taken from the Buffalo River, New York.*

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