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Standard Operating Procedure (SOP) for Selecting and Prioritizing Chemicals for PPRTV Development

CONTENTS

PPRTV SCOPING TEAM

Title	Staff Members
STSC ADMINITRATIVE DIRECTOR	Teresa Shannon
STSC CO-DIRECTORS	Phillip Kaiser and Beth Owens
NCEA BRAB & CRAB BRANCH CHIEFs	Jason Lambert Belinda Hawkins
NCEA CINCINNATI DIVISION DIRECTOR	Annette Gatchett
OSRTI SPB BRANCH CHIEF	Mike Scozzafava
OLEM HQ OH2R2AF TOXICITY WORKGROUP CO-CHAIRS	Michele Burgess Keith Fusinski
OLEM SENIOR SCIENCE ADVISOR	Kathleen Raffaele

ACRONYM DESCRIPTIONS

IRIS	Integrated Risk Information System. IRIS assessments cover hazard identification and dose response steps of risk assessment. The assessment may cover one chemical, a group of structurally or toxicologically related chemicals or a chemical mixture.
NCEA	National Center for Environmental Assessment. NCEA is within the United States Environmental Protection Agency's (EPA) Office of Research and Development (ORD). The three main NCEA divisions are in located in Cincinnati, OH, Washington, DC, and Research Triangle Park, NC. The STSC and ERASC are led out of NCEA-Cincinnati.
PPRTV	Provisional Peer-Reviewed Toxicity Value. PPRTVs are toxicity values derived for use in the Superfund Program. PPRTVs are derived after a review of the relevant scientific literature using established Agency guidance on human health toxicity value derivations.
OH2R2AF TOXICITY WORKGROUP	OLEM Human Health Regional Risk Assessors Forum Toxicity Workgroup. The OH2R2AF Toxicity Workgroup is a sub-workgroup of the OLEM Human Health Regional Risk Assessors Forum that is managed out of the Office of Superfund Remediation and Technology Innovation. The mission is to identify issues with respect to the use and reporting of toxicity values for regional risk assessors; to provide technical direction in the selection of toxicity values for OLEM programs.
OLEM	Office of Land and Emergency Management. OLEM provides policy, guidance and direction for the Agency's emergency response and waste programs; develops guidelines for the disposal of hazardous waste and underground storage tanks; provide technical assistance to all levels of government to establish safe practices in waste management; administer the Brownfield's program which supports state and local governments in redeveloping and reusing potentially contaminated sites; manage the Superfund program, which responds to abandoned and active hazardous waste sites and accidental chemical releases; and encourages innovative technologies to address contaminated soil and groundwater.
QUARTERLY REPORT	Quarterly reports are completed for each of the two technical support centers for which the HHRA program has main responsibility: the Superfund Health Risk Technical Support Center (STSC) and the Ecological Risk Assessment Support Center (ERASC). Reports from the STSC and ERASC are developed and integrated into one master quarterly report covering the

	activities of all five of the ORD technical support centers. The reports serve as an important resource to keep OLEM and regional risk assessors apprised of activities, developments, and applications with respect to assessments and other technical advice and evaluation. As such they aid efficiency, consistency and communication of assessment information.
STSC	Superfund Health Risk Technical Support Center. STSC provides technical support to EPA program (i.e, OLEM) and regional offices in the area of Superfund human health risk assessment. Examples include the development of Provisional Peer-Reviewed Toxicity Value (PPRTV) assessments, scientific consultations, and support for interpreting EPA publications and other guidance, and risk assessment methods research on chemical pollutants.
TECHNICAL SUPPORT CENTERS	A network of Regional forums and specialized Technical Support Centers (TSCs) providing technical assistance to Regional Remedial Project Managers, Corrective Action Staff, and On-Scene Coordinators.

1. STANDARD OPERATING PROCEDURE (SOP) FOR CANDIDATE SELECTION AND PRIORITIZING CHEMICALS FOR PPRTV DEVELOPMENT

Representatives from the STSC, OLEM and the OH_2R_2AF Toxicity Workgroup will form a PPRTV Scoping Team that will collaborate to nominate, select a candidate chemical list, and prioritize the chemicals for PPRTV development on an annual basis. The goals of selecting and prioritizing the chemicals requested for PPRTV development are twofold: (1) emphasize development of high-quality deliverables based on the most current OLEM and Regional priorities/needs; and (2) optimize the expenditure of fiscal resources and human capital for assessment activities related to priority chemicals.

Two processes will be described in this SOP. The first is the standard annual nomination and selection procedure. The second is for an emergency request for an accelerated addition of a chemical for development. The annual prioritized list of chemicals will be released by June to all parties listed as the Scoping Team for the upcoming fiscal year. Discussions on changes will be conducted with the Scoping Team and after consensus by all parties will be distributed to OLEM and OH_2R_2AF. Distribution will occur quarterly during the calls with OLEM and OH_2R_2AF and documented in the recorded notes.

2. STANDARD ANNUAL PROCEDURE

A step-by-step process is used to compile chemicals of interest, narrow down, and prioritize candidate chemicals for new PPRTV development as well as chemicals eligible for updating an existing PPRTV (on a 5-year cycle). The steps are as follows:

1. Nomination Forms:
   In January of each year OLEM, the Lead Region for Superfund, and STSC will be asked to prepare nomination forms for PPRTV assessments. Each nominated chemical should be accompanied by a short description of the need for a PPRTV assessment. For example, found at several Superfund sites, or is potentially a major source of exposure to a population of interest. The nomination form is attached as Attachment 1. All forms should be submitted to the STSC by January 30.

   Prior to Step 2, all nominated chemicals that are on the IRIS agenda, or update, will be removed. In addition, each nominated chemical will be evaluated considering current resources (i.e., what can be done given the budget and available staff).

2. Candidate Chemical Selection and Prioritization:
   Annually the PPRTV Scoping Team (consisting of representatives from the STSC, OLEM and the OH_2R_2AF Toxicity Workgroup) will review chemical nomination forms (Attachment 1). Nominated chemicals will have an initial scoping and preliminary

literature search to determine the potential to support a PPRTV derivation. Using information from this initial scoping and preliminary literature search as well as information from the nomination forms, the Scoping Team will evaluate the requested chemicals based on the following set of criteria (Attachment 2):

- Number of Superfund sites with the chemical and concentrations.
- Number of times a PPRTV for that chemical was requested through the STSC within the past 5 years.
- Data to support development of values (PPRTV and\or Screening Values). If a chemical's data set is considered unlikely to support PPRTV derivation, it would become an Appendix Screening Value candidate. If data are not available to support PPRTV or Screening Value (e.g., read-across based surrogates) derivation, another chemical from the candidate list would be selected for the PPRTV agenda.
- PPRTV Update Request.

3. PPRTV updates:
   In addition, all currently available PPRTVs will be reviewed to determine eligibility for update (i.e., >5 years old). Selection criteria for update action are the same as under the chemical selection process outlined above under 2.

The schedule for the nomination and selection process is as follows:

■ Call for nominations	January (30 days)
■ Perform initial scoping and preliminary literature search	February\March
■ Scoping Team Selection and Prioritization	March\April (adjust assessment agenda as needed)
■ OLEM and NCEA management review and approve list	May
■ Release the Final Chemical List to OLEM and Chairs of the OH_2R_2AF Toxicity Workgroup	June
■ Initiate work on list	June

Steps in the process are as follows:

A. A nominated chemical list is developed by the STSC from the call for chemical nominations, including the nominations compiled by the STSC from the hotline. This will include information on the need and who requested the chemical.
B. After consideration of current resources, an initial scoping and preliminary literature search is performed for the list of nominated chemicals.

C. Chemicals are screened for data and information. The Scoping Team reviews the information on the chemicals and prioritizes based on the chemical prioritization criteria outlined above.
D. OLEM and NCEA review and approve list.
E. The final list is released to OLEM and Chairs of the OH_2R_2AF Toxicity Workgroup. If a chemical did not make the Final Chemical List the Regional requestor will be notified by the Scoping Team with the rational for non-selection.
F. Work begins.

3. FAST TRACK PROCEDURE

If an "Fast Track" need is raised by a Region outside of the normal annual nomination, candidate chemical selection, and prioritization process the following steps will be followed:

1. Formal request for support must be submitted to the STSC Hotline or OLEM.

2. The STSC will immediately raise the request to OLEM HQ and the OH_2R_2AF Toxicity Workgroup for review and consideration. Emergency requests for PPRTV development will go through the same criteria as described under steps 1 and 2 of the annual procedure above. Additionally, consideration for PPRTV development will include discussions on: (1) which chemical(s) in the selected/prioritized list for that given FY will be postponed; (2) specialized expertise needs; and (3) size of the chemical's data base and resource needs.

3. Decisions and outcomes based upon "fast track" deliberations among the groups listed above, after consensus by OLEM and NCEA management, will be drafted and transmitted in a memo from OLEM to all relevant stakeholders (e.g., OH_2R_2AF Toxicity Workgroup, STSC, and original requesting office). This memo may include but is not limited to: (1) PPRTV document development decision(s); (2) anticipated timeline(s) for chemical(s) added to the prioritized list, and/or (3) referral to the IRIS Program, ATSDR, etc.

4. REPORTING

Regular communication with OLEM and the Regions (through the OH_2R_2AF Toxicity Workgroup) will be through monthly or bi-monthly calls. Once the Final Chemical List is determined and approved by OLEM and NCEA management, it will be disseminated to OLEM and Chairs of the OH_2R_2AF Toxicity Workgroup. Regular updates will occur on the monthly calls. Any changes, or consideration for changes, in the chemical list will be noted on those calls.

Selected candidate and prioritized chemicals are subject to change based on the following factors:

- Based on initial literature search no animal or human data are found and the surrogate approach is not applicable.
- The literature search reveals that the scope of the document would be more than double the contract hours to develop and/or human resources necessary to complete the document. This would diminish the amount of resources available to complete the annual goal.
- A fast track chemical has been added to the list.

Any changes to the prioritization list will be coordinated by OSRTI Science Policy Branch Chief and NCEA Division Director prior to implementation.