6: Proposed TRVs using Screening PPRTVs as the Authoritative Source

Background

DEQ and Oregon Health Authority (OHA) are currently reviewing the inhalation toxicity reference values (TRVs) used in DEQ's air quality programs. Oregon Administrative Rules (OAR), adopted by the Oregon Environmental Quality Commission, specify sources of toxicity information considered to be authoritative in terms of their scientific rigor and comprehensive methods for deriving TRVs (OAR 340-247-0030). There are four authoritative sources in rule: the U.S. Environmental Protection Agency (EPA), U.S. Agency for Toxic Substances and Disease Registry (ATSDR), California's EPA (CalEPA), and Oregon DEQ in consultation with the Air Toxics Science Advisory Committee (ATSAC).

DEQ considers TRVs generated by two main programs at the EPA, the Integrated Risk Information System (IRIS) Program as well as the Provisional Peer-Reviewed Toxicity Value (PPRTV) Program. PPRTVs are toxicity values that are primarily developed for chemicals of concern in EPA's Superfund Program (EPA 2024a). PPRTVs are derived from a robust review of the scientific literature using EPA methods, sources of data, and derivation guidance (EPA 2024b). To date, over 400 chemicals have PPRTV assessments available (EPA 2024c), and DEQ considers all of these PPRTV assessments when reviewing and updating DEQ inhalation TRVs. In 2008, EPA started developing **screening PPRTVs** for chemicals when the data do not meet all the requirements for deriving a PPRTV (EPA 2024a).

The purpose of this document is to provide background on the EPA screening PPRTVs and how DEQ is proposing to use these screening values during the 2025 Toxic Air Contaminant Review and Update Rulemaking.

When EPA Derives Screening PPRTVs

The EPA has the following information on their website about screening PPRTVs and how these screening values incorporate more uncertainty than other PPRTVs:

> "Screening PPRTVs are derived using the same methodologies and undergo the same development and review processes (i.e., internal and external peer review, etc.) as provisional values [PPRTVs]; however, the screening values are presented in an appendix and characterized such that users of screening PPRTVs are made aware that there is more uncertainty associated with these screening values than for the values presented in the main body of a PPRTV assessment" (EPA 2024a).

The EPA lists the following circumstances where they may derive a screening PPRTV:

> "When some useful human or animal toxicity data are available, but…
> - The data are published in non peer-reviewed sources.
> - The data are published and peer-reviewed, but have associated uncertainties such as:
>   - The composite Uncertainty Factor is greater than 3,000.
>   - The principal study is not comprehensive (e.g., few or one endpoint examined).

- Other: the principal study has a small number of animals tested, poor study design, incomplete reporting, etc.

When no useful human or animal toxicity data are available for a chemical…

- An expert-driven read-across approach can be applied" (EPA 2024a).

DEQ Proposal

In existing DEQ rule, TRVs are not based on screening PPRTVs. In this 2025 rulemaking, DEQ is proposing to use screening PPRTVs as the TRV when no other TRVs are available from another authoritative sources. **Despite the greater uncertainty behind screening PPRTVs compared to other PPRTVs, they allow DEQ to protect public health from additional toxic air contaminants for which some toxicity information is known.** DEQ proposes to use screening PPRTVs as the TRV for 14 toxic air contaminants (Table 1). DEQ is seeking feedback on this proposal during the current Toxic Air Contaminant Review and Update Rulemaking.

Table 1. Toxic Air Contaminants where DEQ is proposing to use a screening PPRTV as the TRV.

Chemical Abstract Services Registry Number (CAS RN)	Chemical Name, TRV Category, and Proposed TRV	EPA Explanation on Why they Derived a Screening PPRTV
156-60-5	*trans*-1,2-Dichloroethene • Noncancer chronic TRV, 40 µg/m^3	Total uncertainty factor of 3,000; subchronic study used to derive the screening chronic PPRTV; the inhalation database only includes 3 studies and none of the studies included immune function assays, and the PPRTV document states that the lack of these assays represents a major source of uncertainty; there are no multigenerational reproductive toxicity studies – pages 36-38
110-54-3	Hexane • Cancer TRV, 5 µg/m^3	PPRTV document states that there is "suggestive evidence for carcinogenic potential" when following the *EPA 2005 Guidelines for Carcinogen Risk Assessment* and because of this descriptor, the quantitative inhalation unit risk is provided as a screening value – pages 42-54
62-75-9	N-Nitrosodimethylamine • Noncancer chronic TRV, 0.04 µg/m^3	PPRTV document states the screening value is very uncertain because data did not include weights of individual animals; however, this screening value might be supported by the similarity of the estimated equivalent inhalation daily dose at the point of departure with the information from the study used to derive the oral toxicity value – page 24
79-00-5	1,1,2-Trichloroethane (Vinyl trichloride) • Noncancer chronic TRV, 0.2 µg/m^3	Total uncertainty factor of 3,000; critical study has not been peer reviewed; confidence in the database is low due to the lack of reproductive and developmental toxicity testing and absence of supporting chronic-duration systemic toxicity studies; overall confidence in the screening chronic PPRTV is low – pages 15-16

Chemical Abstract Services Registry Number (CAS RN)	Chemical Name, TRV Category, and Proposed TRV	EPA Explanation on Why they Derived a Screening PPRTV
156-59-2	cis-1,2-Dichloroethene {cis-1,2-Dichloroethylene} • Noncancer chronic TRV, 40 µg/m^3	Analogue approach: *trans*-1,2-dichloroethene (DCE) was selected as the analogue for *cis*-1,2-DCE for derivation of a screening chronic PPRTV; the screening chronic PPRTV for *trans*-1,2-DCE was derived by applying a total uncertainty factor of 3,000 and those same uncertainty factors were applied here for *cis*-1,2-DCE – pages 68-69
64-18-6	Formic Acid • Noncancer chronic TRV, 0.3 µg/m^3	Total uncertainty factor of 30,000, but "by convention the maximum UF for screening values is 10,000"; some examples of uncertainty include extrapolating from subchronic to chronic exposure duration and a lack of developmental toxicity and multigenerational reproduction studies of inhaled formic acid – page 33
78-83-1	Isobutanol (Isobutyl Alcohol) • Noncancer chronic TRV, 400 µg/m^3	Toxicologically relevant effects identified in inhalation studies are limited to a non-peer-reviewed study; total uncertainty factor of 1,000 – pages 41-43
108-87-2	Methylcyclohexane • Noncancer chronic TRV, 100 µg/m^3	PPRTV document states "the available inhalation studies have limitations precluding their use in deriving provisional toxicity values (unpublished, not peer-reviewed, written primarily in a foreign language);" total uncertainty factor of 3,000 – pages 49-52
192-97-2	Benzo[e]pyrene • Noncancer chronic TRV, 0.002 µg/m^3	Analogue approach: Benzo[a]pyrene was the only potential analogue with an inhalation toxicity value and was selected as the candidate analogue compound for chronic inhalation exposure of benzo[e]pyrene; total uncertainty factor of 3,000 – pages 47-75
198-55-0	Perylene • Noncancer chronic TRV, 0.002 µg/m^3	Analogue approach: Of the 29 structural candidates, only benzo[a]pyrene has a relevant inhalation noncancer toxicity value; total uncertainty factor of 3,000 – pages 44-56
77-73-6	Dicyclopentadiene • Noncancer chronic TRV, 0.3 µg/m^3	Total uncertainty factor of 3,000; data in principal study (formation of hyaline droplets) is semiquantitative and not amenable to benchmark dose modeling – pages 38-41
75-86-5	2-Methyllactonitrile (acetone cyanohydrin) • Noncancer chronic TRV, 2 µg/m^3	Total uncertainty factor of 3,000; no acceptable two-generation reproductive or developmental toxicity studies; using data from a subchronic-duration study for the chronic screening PPRTV – pages 29-30
92-52-4	Biphenyl • Noncancer chronic TRV, 0.4 µg/m^3	A 1977 study by Cannon Laboratories, Inc. was selected as the principal study; this study is unpublished but was submitted to EPA under the Toxic Substances Control Act; study predates current Good Laboratory Principles ; PPRTV document states "Monsanto Chemical Co. (1983) and WHO (Boehncke et al.,

Chemical Abstract Services Registry Number (CAS RN)	Chemical Name, TRV Category, and Proposed TRV	EPA Explanation on Why they Derived a Screening PPRTV
		1999) reported similar respiratory effects in mice and rats."; total uncertainty factor of 3,000; used data from subchronic-duration study; no acceptable two-generation reproduction or developmental studies – pages 34-40
60-34-4	Methyl hydrazine • Noncancer chronic TRV, 0.02 µg/m^3 • Cancer TRV, 0.001 µg/m^3	Noncancer chronic: Total uncertainty factor of 3,000; examples of uncertainty include no acceptable two-generation reproduction or developmental studies and a no-observed-adverse-effect level cannot be determined with the available data – pages 32-34 Cancer: Data from the 1-year bioassay conducted by Kinkead et al. (1985) were used as the basis for the quantitative cancer assessment, as this was the only study that demonstrated increased incidences of tumors after inhalation exposure; individual animal data was not available; incidence of hemangiomas in the high-dose group was illegible in the report; mode of action for tumors produced by methyl hydrazine has not been elucidated so default linear methodology was applied – pages 35-38

For all the TRVs in Table 1, an alternative TRV is not available from our other authoritative sources: ATSDR, CalEPA, DEQ in consultation with ATSAC, or other programs at the EPA. None of the screening PPRTVs in Table 1 are in existing DEQ rule.

References

EPA. 2024a. "Basic Information About Provisional Peer-Reviewed Toxicity Values (PPRTVs)." https://www.epa.gov/pprtv/basic-information-about-provisional-peer-reviewed-toxicity-values-pprtvs.
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