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EPN Comments on Carbon Trichloroethylene Draft Risk Evaluation
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The Environmental Protection Network (EPN) is an organization comprised of over 500 U.S. Environmental Protection Agency (EPA) alumni volunteering their time to protect the integrity of EPA, human health and the environment. We harness the expertise of former EPA career staff and confirmation-level appointees to provide insights into regulations and policies proposed by the current administration that have a serious impact on public health and environmental protections.

EPN is submitting these comments to the Science Advisory Committee on Chemicals (SACC) to aid in their review of the Trichloroethylene (TCE) draft risk evaluation during their scheduled March 24-27, 2020, meeting.

TCE, like a number of other chemicals in the First 10 for which risk evaluations have been conducted, is one of a group of organochlorine chemicals classified as Volatile Organic Compounds (VOCs), based on its ability to easily transition from a liquid state to a vapor or gas. It is a high-volume production and use solvent with a wide range of commercial and consumer uses.

For TCE, EPA conducted a Toxic Substances Control Act (TSCA) Work Plan assessment in 2014. Thus, this is the second time in recent years that a draft risk assessment for TCE has undergone public comment and peer review. EPA also conducted Work Plan assessments under the old law for 1-Bromopropane, Methylene Chloride and N-Methylpyrrolidone (NMP). Initial risk assessments also were prepared for 1,4-Dioxane and the Cyclic Aliphatic Bromide Cluster (HBCD), but these were not subjected to public comment or external peer review. All six of these assessments have now been updated, revised and expanded to reflect the risk evaluation mandates of the 2016 "amended" TSCA and the EPA Risk Evaluation Rule, and have been subjected to a repeat (for 4) or initial (for 2) round of public comment and peer review.

As one might expect, the pre-amended TSCA risk assessments provide a valuable resource for judging the adequacy and integrity of the risk evaluations for these six chemicals developed in the post-2016 era and, by extension, for other chemicals being assessed now and in the future. Comparison of pre-and post-amended TSCA assessments allow for judging the appropriateness and adequacy of literature identification, selection and application, as well as rigor in the identification, interpretation and application of new information arising in the intervening years. Furthermore, there are other criteria by which a risk evaluation is to be judged. Does the evaluation reflect application of scientifically-sound principles and best practices? Has EPA adhered to its own agency-wide guidance in the conduct of the assessment? In the simplest of terms, are conclusions reached logical and evidence-based, and do they make sense?

As a reminder, TSCA § 26(h) and (i) require EPA to use scientific information, technical procedures, measures, methods, protocols, methodologies and models consistent with the best available science and to base its decisions on the weight of the scientific evidence. As EPN carried out its review of this draft risk evaluation, it discovered a number of instances where the agency failed to adhere to this prescription. Comments on some of these instances follow.

1. Political Intervention in the Scientific Enterprise — A Thumb on the Scale

As EPN does each time when reviewing and preparing comments on draft risk evaluations, it began its TCE review with a pre-screen of sections of the document addressing aspects that had been identified previously as areas of concern. When scrutinizing the information on human health hazards, we focus on adequacy of the database(s), derivation of the Benchmark Margin(s) of Exposure (MOE), and selection of the critical endpoint(s) of toxicity and related dose-response data, which serve as the basis for calculation of the Point(s) of Departure (POD).

As we screened this information in the TCE draft risk evaluation, we were struck by the tortured logic being applied to justify the choice of endpoints for the quantitative assessment of acute and chronic non-cancer effects.

Our puzzlement vanished with the publication of Elizabeth Shogren's February 28, 2020, article via Reveal from the Center for Investigative Reporting. This article reported that the initial draft evaluation forwarded to the Office of Management and Budget for interagency review continued to rely on fetal heart defects as the most sensitive endpoint, but that the White House directed EPA not to use this endpoint for a determination of unreasonable risk. We view this intervention by the current administration into the scientific assessment of a high-profile chemical as one of the most egregious acts we have witnessed in our collective century-plus years of experience at the agency. It raises the spectre that less-visible manipulations have occurred in earlier draft risk evaluations and prospects of the same for risk evaluations to come. The credibility of the once-promising amended TSCA risk evaluation program for existing chemicals is now shattered.

2. Risk Characterization → Risk Determination → Risk Management

In EPA's 2014 TCE TSCA Work Plan Risk Assessment, risks from its use in large and small commercial operations and consumer solvent degreasing, consumer use as a spray-applied protective coating for arts and crafts, and commercial use as a spot remover at dry-cleaning facilities were assessed. This risk assessment was used to support two proposed rules under TSCA § 6 (81 FR 91592; December 12, 2016; 82 FR 7432; January 19, 2017) to ban these uses of TCE.

In the December 12, 2016, notice, EPA proposed to prohibit TCE's manufacture, processing, and distribution in commerce for use in aerosol degreasing and for use in spot cleaning in dry-cleaning facilities; to prohibit commercial use of TCE for aerosol degreasing and for spot cleaning in dry-cleaning facilities; and to require manufacturers, processors, and distributors, except for retailers, to provide downstream notification of these prohibitions throughout the supply chain (e.g., via a Safety Data Sheet (SDS)) and to keep limited records.

In the January 17, 2017, notice, EPA proposed to prohibit TCE's manufacture (including import), processing, and distribution in commerce for use in vapor degreasing; to prohibit the use of TCE in vapor degreasing; to require manufacturers (including importers), processors, and distributors, except for retailers, of TCE for any use to provide downstream notification of these prohibitions throughout the supply chain; and to require limited recordkeeping.

After the change in administrations, both proposals were withdrawn and no risk mitigation was implemented. Now, an updated risk characterization has been completed and coupled with risk determinations for all relevant commercial and consumer conditions of use (COUs). EVERY commercial COU has been declared to present an unreasonable risk of injury to health to workers and, in most cases,

also to occupational non-users (ONUs) in the same setting. With regard to consumer COUs, all but one has been deemed to present an unreasonable risk of injury to health to consumers and also, for the vast majority of uses, to bystanders.

To us the picture is crystal clear. All but one trivial condition of use has been shown to pose a danger to the public health, in both the occupational and consumer setting. It is time to proceed directly to rulemaking with a proposal to ban ALL further import, manufacture, and distribution of TCE for commercial and consumer uses in the U.S., followed by promulgation of the ban on all uses on an expedited timeline.

3. The Timing of Public Comment and Peer Review

"As EPA explained in the Risk Evaluation Rule (82 FR 33726 (July 20, 2017)), it is important for peer reviewers to consider how the underlying risk evaluation analyses fit together to produce an integrated risk characterization, which forms the basis of an unreasonable risk determination. EPA believes peer reviewers will be most effective in this role if they receive the benefit of public comments on draft risk evaluations prior to peer review. For this reason, and consistent with standard agency practice, the public comment period will precede peer review on this draft risk evaluation" (Page 40).

Seriously? This purportedly preferred sequence of public comment and peer review has not been realized even once since the draft risk evaluations for any of the First 10 chemicals have been released over the past year. The two-day lead time before a virtual prep meeting and the three weeks or so granted for public comments to reach the peer review committee before it meets is clearly inadequate for submitters to prepare meaningful comments on these substantial and consequential assessments. This time around, for TCE, the comment period runs from February 26 until April 27, 2020, with the peer review committee meeting scheduled for March 24-27, right in the middle of the public comment period. Comments must be submitted to EPA by March 18, 2020, in order for the SACC to receive them, leaving the committee less than a week to digest them. This pattern has been, and will continue to be, an unacceptable execution of transparency.

As EPN has said before, and feels compelled to repeat once again, the agency is implementing a schedule for review that is inconsistent with best management practices. We continue to be concerned that this process deprives the SACC of scientific and policy input that would be valuable in informing its review of draft risk evaluations and, thus, greatly reduces the value of the public comment process. This recurrence reinforces the view that the current agency approach values a calendar deadline for a decision over the integrity of the information going into the decision and represents yet another example of its disdain for the scientific enterprise. Furthermore, the process appears to be a mechanism to discourage comments from the stakeholder community that wishes to see a standardized risk evaluation process followed.

4. Conditions of Use to Be Assessed

The 2014 final TCE TSCA Work Plan Chemical Risk Assessment document identified three major categories of occupational uses (intermediate in the manufacturing of refrigerant, and solvent degreaser for large and small commercial settings) and three major categories of consumer uses (spotting agent, solvent degreaser, and plastic clear protective coating spray (hobbyists, arts/crafts)) as COUs worthy of inclusion in the assessment. Three other consumer uses (film cleaner (hobbyists), toner aid (home office), and mirror edge sealant (hobbyist/home maintenance)) were excluded based upon assumption of low potential for human exposure.

The 2017 TCE Scoping document identified more than 20 categories of use, reflecting over 50 subcategories of use. The six categories of use included in the 2014 assessment were included in the 2017 scope. One consumer COU (paints and coatings-diluent in solvent-based paints and coatings) identified in the 2017 Scoping document was excluded during problem formulation because data suggested that TCE is no longer a component of such products. One more consumer COU was excluded from the final list (lace wig and hair extension glues) because, after consultation with the Food and Drug Administration (FDA), it was determined that it falls outside the scope of EPA's jurisdiction. *However, in spite of the COU being treated as outside of EPA's regulatory jurisdiction, it does not mean that exposure attendant to that use should be excluded from the exposure assessments for consumers in the relevant subpopulation*.

The final list of consumer COUs includes the three consumer uses that had been excluded from the 2014 list. *This is seen to be a wise choice because these three COUs, along with all but one other assessed consumer COUs (pepper spray) were determined to pose an unreasonable risk to consumers and also to bystanders, and, therefore, are targets for risk management, most appropriately a ban on all those uses.*

5. Systematic Review

EPN is aware that the National Academies of Sciences (NAS) has begun its review of the draft guidance document entitled "Application of Systematic Review in TSCA Risk Evaluations." However, this review will not be completed before the First 10 draft risk evaluations will have gone through a round of public comment and peer review. This presents a significant challenge to the integrity of these 10 risk evaluations and, indeed, to the entirety of the Existing Chemicals review program.

Feedback on the draft guidance is needed now. Questions on Systematic Review should be added to the charge for TCE, particularly in the areas where the Office of Pollution Prevention and Toxics (OPPT), and, quite frankly, the agency as a whole, has not yet developed a credible approach for dealing with risk of bias or evidence integration, although we must admit Appendix G of the TCE document holds some promise as an example of the latter.

6. **Occupational and Consumer Exposure Assessment**

For occupational acute and chronic exposure scenarios, central tendency and high-end inhalation exposure to workers and ONUs were estimated. Acute and chronic dermal exposure was estimated only for workers. Each exposure scenario was evaluated with and without use of personal protective equipment (PPE).

Consumer exposure scenarios: only acute (i.e., short term or daily) inhalation exposure to consumers and bystanders was estimated for three scenarios (high intensity, moderate intensity, low intensity) based upon duration of use, weight fraction of TCE in the product, and mass used. Acute dermal exposure was estimated only for consumers. No chronic exposure scenarios resulting from long-term use of household consumer products were evaluated, although it is likely that consumers use some TCE-containing products on multiple occasions over time and are exposed to continuous levels of TCE in indoor air.

Once again, while EPA acknowledges that exposure via the inhalation and dermal routes to workers and consumers will most likely be occurring simultaneously, it continues to ignore the reality of concurrent exposure by multiple routes and pathways, evaluating the exposures via inhalation and dermal contact separately. Furthermore, the agency continues to ignore known exposures occurring via routes and pathways not directly related to the COUs (including ambient and indoor air and drinking water) and that there is no guarantee that PPE will be used throughout the work shift. This obviously results in an underestimate of

risk to the populations of concern. *Risk determinations for all occupational and consumer COUs should be based upon aggregation of all exposures and, for workers, the assumption that no PPE is being used.*

As EPN has argued repeatedly, assessment of aggregate exposure within a COU, coupled with exposures known to exist outside a COU should always be implemented as a benchmark of a credible and responsible exposure assessment. To do otherwise is to deny reality, irresponsible, and unethical.

TCE also presents an additional challenge when it comes to the consideration of *cumulative* exposure assessment. As the TCE draft risk evaluation points out, TCE shares virtually all of its metabolites with tetrachloroethylene (aka perchloroethylene or Perc; see Table 3.4 on Pages 204-205). TCE also exhibits many of the same endpoints of concern as Perc (neurotoxicity; kidney and liver toxicity; and cancer, immunotoxicity, developmental, and reproductive toxicity) (see EPA's 2012 TCE IRIS document). Given this reality, the TCE exposure assessments and risk determinations should also take into account cumulative exposures to Perc (and to the other chlorinated compounds listed in Table 3.4 where metabolites, endpoints, COUs, and ambient exposures co-exist.

The Perc draft risk evaluation will soon be issued for public comment and peer review. It, too, should incorporate the same approach: aggregate exposure assessment within a COU, coupled with exposures known to exist outside a COU and cumulative exposure assessment to TCE (and to the other chlorinated compounds listed in Table 3.4) where metabolites, endpoints, COUs, and ambient exposures co-exist. We already know, without conducting a detailed examination and comparison, that TCE's and Perc's COUs have significant potential for overlap; their COU categories are virtually identical as are many of the subcategories.

7. Environmental Assessment

EPN's comments on the TCE draft risk evaluation's section on environmental hazard and risk are summarized below. A detailed analysis of the environmental assessment can be found in Appendix A.

In general, we are inclined to accept that modeling based on physical and chemical properties and fate parameters support the view that TCE is not expected to partition to biosolids and sediment in sewage treatment plants. The modeling is based on concepts and values that are fairly well understood and accepted. This approach supports no further investigation of environmental exposure pathways for terrestrial organisms, which would be mainly exposed to TCE via scenarios involving diet and drinking water. Since TCE is expected to volatilize from soils and water to air, consequent concerns about exposure to terrestrial organisms would therefore not be great.

We agree with EPA's risk evaluation of TCE to conduct no further analysis beyond what was done in the problem formulation document (§ 2.5.3.3 in USEPA, 2018d) for environmental exposure pathways for land application of biosolids and sediment and water or soil pathways for terrestrial organisms. Physical and chemical properties confidently predict TCE will be mobile in soil and migrate to water, or volatilize to air. TCE is not expected to partition to biosolids during wastewater treatment.

We do, however, strongly support the need to closely assess the exposures, hazards, and risks posed by TCE to aquatic species.

While we agree TCE is not expected to accumulate in aquatic organisms, we also agree that EPA data indicate TCE presents hazards to aquatic organisms. Since algae are considered separately (see Appendix A for comments on algae), we agree aquatic invertebrates are the most sensitive species for acute exposures, with toxicity values ranging from 7.8 mg/L to 33.85 mg/L (geometric mean = 16 mg/L). Toxicity values for

chronic aquatic exposures were 7.88 mg/L (fish) and 9.2 mg/L (aquatic invertebrates). The data also indicate TCE presents hazards to aquatic plants. The range of toxicity values among algal species was wide, the lowest being 0.03 mg/L.

EPA calculated the concentrations of concern (COCs) for aquatic species (Section 3.1.5) based on environmental hazard data for TCE using geometric means and statistical modeling of toxicity values for multiple species. *We think EPA instead should have used both acute and chronic toxicity values for the most sensitive species within each major taxonomic group, e.g., algae, aquatic invertebrates, and fish.* This view is based on the fact that TSCA clearly requires EPA to protect all exposed aquatic, benthic, and terrestrial species against adverse effects from exposure to industrial chemicals. Modeling chemical toxicity is useful to investigate groupings and trends in toxicity data and, where no data exist, to generate toxicity data using structure-activity relationships. Nevertheless, valid testing results are always preferable to results of modeling, particularly where the models work to reduce apparent toxicity, e.g., by using averaged results of individual studies in place of results from studies of the most sensitive species, and, consequently, minimizing levels of concern for adverse effects to the natural environment.

8. Adequacy of Databases for Hazard Assessment and Derivation of PODs

a. Adequacy of the Database

For occupational/commercial COUs EPA assessed acute/short-term and chronic risk to workers and ONUs. Worker exposure routes included inhalation and dermal, ONUs inhalation only. The exposed populations evaluated were both male and female workers (≥ 16 years or older) and female workers of reproductive age (≥ 16 years to < 50 years).

For all consumer COUs, the user was assumed to be an adult (≥ 21 years of age) or in one of two youth age groups (11-15 years and 16-20 years), while a non-user bystander could be of any age. Consumers were assessed for both acute/short-term inhalation and dermal exposure, bystanders only for acute/short-term inhalation exposure. No chronic assessments were conducted.

The toxicology database is adequate for evaluating and characterizing TCE toxicity and selecting endpoints for the purposes of this risk assessment. We have no recommendations for modifications to the Benchmark MOEs based upon database deficiencies. Routes (inhalation, dermal) and durations (acute, chronic) of exposure as well as (sub)populations (all age groups) to be protected are clearly identified.

b. Derivation of PODs

EPA identified a number of health hazards stemming from exposure to TCE, including: acute overt toxicity, liver toxicity, kidney toxicity, neurotoxicity, immunotoxicity (including sensitization), reproductive toxicity, developmental toxicity, and cancer. Data from studies describing all endpoints except for overt acute toxicity were available to characterize their dose-response relationships, to perform dose-response analysis for the selected PODs, and to quantify risks for specific exposure scenarios. Since adequate data on dose response relationships for acute overt toxicity were lacking, data on other endpoints were used to fill that void.

Acute non-cancer PODs are summarized in Table 3.13 on page 252. Chronic non-cancer PODs are summarized in Table 3.14 on page 253. The cancer POD is shown in Table 3.15 on page 254. The estimate of the inhalation unit risk for TCE is 2.20×10^{-2} per ppm ([4×10^{-6} per $\mu g/m^3$] rounded to one significant

figure), based on human kidney cancer risks reported by Charbotel et al. (2006) and adjusted 4-fold upward for potential additional risk for non-Hodgkin lymphoma (NHL) and liver cancer.

It is abundantly clear from scrutinizing the summary of the hazard data presented in Section 3.2 and reading a number of the key studies, that the fetal cardiac defects reported in Johnson et al. (2003) and re-affirmed in subsequent publications are the most sensitive endpoints identified across the non-cancer effects of concern. Yes, it is true that this study raised some concern among the peer reviewers and others during the evaluation of the draft risk assessment that was finalized as the 2014 TSCA Work Plan Chemical Risk Assessment. However, the agency communicated with the authors and received clarification on the questions that had been raised.

Subsequent to the issuance of the 2014 TSCA risk assessment, a study was conducted, purportedly to replicate the Johnson et al. study. Submitted to the agency (Charles River Laboratories, 2019) and published in the public literature in 2019 (DeSesso, et al. 2019), it was said to show no significant increases in the same fetal heart defects noted in the Johnson et al. study. The reason for this could well be because the Charles River study did not look for the atrial septal defects and valve defects that the Johnson et al. study describes. As EPA notes, "The majority of cardiac malformations observed in the Johnson study were not [ventricular septal defects (VSDs)] … while the Charles River study only identified VSDs in controls and TCE-treated offspring. Of note, two major categories of heart malformations identified in the Johnson study that are absent from even the positive control group of the Charles River study are atrial septal defects and valve defects. The Charles River study methodology appeared to be focused primarily on identification of VSDs."

We would submit that the Charles River Laboratories study does not rebut the findings of Johnson et al. If you do not look, you cannot see.

In summary, the PODs derived from the Johnson et al. study should be used in the assessment of all acute and chronic occupational exposure scenarios and all acute consumer exposure scenarios.

As currently articulated in the draft risk evaluation, it would appear that EPA is employing a new and unvetted policy of selecting the most "representative" over the most sensitive endpoint, an approach at odds with longstanding agency-wide risk assessment practices.

EPN is deeply concerned that the draft risk evaluation for TCE includes a new policy, never before used by EPA. The factors selected for consideration under this new policy do not include sensitivity and appear to be arbitrary and capricious, designed to provide the agency with complete discretion to ignore the most sensitive endpoint. On page 257, EPA documents how this new policy is used to select a much less sensitive endpoint than congenital heart defects as the basis for acute and chronic non-cancer PODs. EPA uses a few of the factors identified for this new representativeness policy to justify selection of the immunosuppression study for acute effects and the autoimmune study for chronic effects, but does not evaluate those same factors for the congenital heart defects study.

The congenital heart defects study would score very high, even using these arbitrary and capricious factors. In addition to providing the most sensitive endpoint, this study has the lowest cumulative uncertainty factor and highest relevance to the endpoint of interest and human exposure scenarios of all the studies chosen for derivation of the POD. The low cumulative uncertainty factor is backed by the positive weight of evidence supporting this study, with epidemiology and mechanistic studies compensating for the mixed evidence from animal studies. On pages 222 and 232, EPA documents that communication with authors of the study, and flaws in an industry study alleviated concerns about data quality and the strength of the results. In addition, the congenital heart defects study has high relevance to human exposure scenarios since EPA

concluded on page 234 that the most susceptible life stage for TCE is the pregnant woman and developing fetus.

It is critically important that EPA not replace the protective public health policy of selecting the most sensitive endpoint with this arbitrary and capricious "representative policy." There is no scientific justification for this new policy, which could have wide-ranging effects, undermining the reference doses and cancer potency factors developed for all chemicals, not just TCE.

Detailed Assessment of Draft Risk Evaluation Sections on Environmental Hazard and Risk

Algal Hazard and Risk Issues for TCE

EPA used a species sensitivity distribution (SSD) model to generate cumulative probability distributions of toxicity values. The model incorporated data from nine algal species. For purposes of environmental risk assessment, EPA selected and used a chemical concentration (HC_{05} = 52,000 ppb) as a hazard level that was extrapolated from the algal SSD by using a specified percentile of the distribution. (Etterson, M. 2019, Species Sensitivity Distribution (SSD) Toolbox. Duluth, MN: USEPA). *We believe that it is inappropriate for EPA to override the more sensitive algal concentration of concern (COC) (3 ppb) by using the SSD projections in assessing risks.*

We would point out that TCE reduced the growth and metabolism of *Pseudokirchneriella subcapitata* (now named *Raphidocelis subcapitata*), a freshwater green algal species, starting from 0.05 mg/L and 0.02 mg/L, respectively, with the mean hazard level = 0.03 mg/L.

EPA acknowledges that the algal SSD only includes EC_{50}s to compare between high- and medium-quality studies of nine species, and it does not capture some of the lowest reported toxicity values. *We believe it would be more environmentally protective to include results from testing these more sensitive species.* EPA specifically excludes lowest observed effect concentrations (LOECs) and no observed effect concentrations (NOECs), e.g., the chronic value (ChV) of 0.03 mg/L for algal growth and metabolism derived from Labra et al. (2010, Water, Air, and Soil Pollution, 213 (1-4): 57-70). Again, given the great difference between the acute and chronic values and the need to protect the most sensitive species, *we think it's very important to use only the algal COC of 3 ppb.*

In this regard, we would ask whether TSCA mandates protecting 95% of all species or 100% of all species. Given the very wide range of separation (four orders of magnitude) between the algal COC (3 ppb) and the SSD-generated algal HC_{05} (52,000 ppb) for TCE, we think it's important to address the sensitivity of all algal species. Guiry [J. Phycol. 48,1057–1063 (2012)] conservatively estimated there are 72,500 algal species, discounting diatoms whose numbers have been estimated to be over 200,000 species. TSCA obligates protection of the most sensitive species, and *EPN thinks the more protective approach would be to use the 3 ppb COC, and to not use the statistically derived HC_{05} of 52,000 ppb.*

For comparative purposes, we would point out that approaches for setting ChVs for aquatic invertebrates and fish have traditionally made use of the maximum acceptable toxicant concentration (MATC) concept to help set water quality regulations for protecting aquatic life. MATCs are usually reported as geometric means between a NOECs and LOECs. Again, given the need to protect all algal species, and the very wide range between the algal EC_{50} and HC_{05} for the same species, *we think it is critically important to firmly establish the COC at 3 ppb, and to not use the statistically derived HC_{05} of 52,000 ppb, as reported in Table 3-1.*

EPA used algal data for nine species to produce an SSD, which was then used to calculate an HC_{05} of 52 mg/L (or 52,000 ppb). As stated previously, this HC_{05} estimates a concentration that EPA maintains is hazardous for 5% of species. EPA maintains that HC_{05} can also be used, in addition to the algal COC, to

estimate the concentration of TCE that is expected to protect 95% of algae species. We would ask EPA to provide further explanation for the basis and methods for extrapolating from COC-based adequate-quality results of testing nine species to protecting 95% of all of the approximately 72,500 algal species, i.e., 0.95 x 72,500 algal species = 68,875 species. While the basis and methods may well be appropriate for extrapolating effect levels over four orders of magnitude for the same species, we'd be very much interested in reviewing the logic of this approach.

The paper (Labra et al., 2010) used to set the 3 ppb algal COC was evidently not used in developing the algal COC, and EPA explained that omission by pointing out that Labra et al. (2010) had data quality limitations, and that the SSD used only medium- or high-quality studies. Nevertheless, we think a more environmentally-protective approach would have been to include Labra et al. (2010) in developing the SSD because the effect levels for growth and metabolism (ca. 30 ppb) reported in Labra et al. were orders of magnitude below those used in the SSD.

While we acknowledge that the algal testing results reported by Ando et al. (2003) were of considerably lower quality than Labra et al. (2010), they found effect levels (*Volvulina steinii* 10-day LOEC: 3 ppb) that were more sensitive by a factor of 10 than those Labra et al. (2010) reported. Again, acknowledging the weaknesses found in both Labra et al.'s and Ando et al.'s studies, we nevertheless think they demonstrate the existence of effects to different algal species occurring at concentrations that are orders of magnitude lower than those used in EPA's algal SSD. To our minds, this argues for the importance of not diminishing the merits of results from testing more sensitive species.

Also, data from Labra et al. (2010) resulted in a ChV (3 ppb) used in EPA's TCE report. Had the Ando et al. (2003) study been more rigorous, it would have resulted in a ChV of 0.3 ppb. The SSD resulted in an HC_{10} of 52,000 ppb based on toxicity testing designed with relatively short durations (typically 96 or fewer hours) compared to the 10-day duration reported by Ando et al. (2003). While their results were not used quantitatively during data integration, we think they are useful in pointing out the need for not diminishing the 3 ppb COC based on Labra et al. (2010). This is because the data demonstrate that algal effects at unusually low TCE concentrations to different species are real and should be incorporated in, not diminished by, SSD analyses in EPA's TCE risk evaluation and would be more protective of the natural environment.

Environmental Risk

EPA used COCs in assessing environmental risks. COCs are threshold concentrations below which adverse effects on aquatic life are expected to be minimal.

Risk quotients (RQs) were then used in identifying potential risks to aquatic environments. An RQ is derived by dividing a measured or predicted environmental concentration by the appropriate COC.

For aquatic environments, RQs compare a predicted environmental concentration (PEC) with a COC: PEC/COC = RQ. Where an RQ equals or exceeds 1, it indicates a potential risk. Acute risk requires no extended exposure duration; chronic risk requires exposure for 20 or more days of continuous release.

As required by TSCA, in assessing the risks TCE poses to the environment, EPA focused on 11 COUs. These included processing as a reactant, open-top vapor degreasing, repackaging, adhesives, sealants, paints and coatings, industrial processing aid, other industrial uses, other commercial uses, process solvent recycling and worker handling of wastes, and wastewater treatment plants.

Table 4-1 (pages 264-267, lines 220-231) indicates at least 30 instances where RQs ≥ 1 appear to have been met or exceeded, indicating potential risks to the aquatic environment. TCE releases from processing, repackaging, degreasing, and various adhesives and coatings were major sources of potential risk. The following paragraphs summarize those apparent risks to the aquatic environment.

Processing as a Reactant

One processing-as-a-reactant facility (Proxair Technology Center, Tonawanda, NY) had chronic RQs = 3.81 with 20 days' exceedance. EPA used algal SSD to argue that this was not an appreciable risk to most algal species and therefore judged it was not a problem for aquatic environmental risk. We disagree with this finding because the Exposure and Fate Assessment Screening Tool (E-FAST) exposure modeling indicates in one instance, for algae, the RQ at this facility was 56.33 times greater than the algal COC (3 ppb) with 350 days' exceedance; in another instance, RQ was 1,000 times greater than the algal COC, with 20 days' exposure. EPA used algal SSD to argue that this was not an appreciable risk to most algal species and therefore argued it was not a problem for aquatic environmental risk. *Again, we disagree with this finding because we think the algal SSD works to diminish protection for the more sensitive algal species.*

At the Proxair facility, aquatic risks were also identified for chronic exposure, with RQ = 3.81 times greater than the chronic COC (788 ppb), with 20 days of exceedance. We agree this presents potential chronic risk to the aquatic environment.

Repackaging

One repackaging facility (Hubbard-Hall, Inc., Waterbury, TC) had algal risk where the RE = 1.13.04 with 20 days' exceedance. Assuming Hubbard-Hall released TCE 250 days/year, the RQ would be 9.06 with 194 days of exceedance. EPA used SSD to generate an algal COC of 52,000 ppb and argue that, for most algal species, these releases would not pose a risk. We disagree with EPA's position to not use the COC for the more sensitive species because it is less protective of the aquatic environment. No other risks were identified at this site.

Open-top Vapor Degreasing

Three of 64 open-top vapor degreasing sites had acute RQs ≥ 1, and chronic or algal RQs ≥ 1 with 20 or more days of exceedance.

One site (U.S. NASA Michoud Assembly Facility, New Orleans, LA) had RQ = 3.11, and a chronic RQ = 12.61 with 20 days of exceedance, and an algal RQ = 3,312.50 with 20 days of exceedance. Given 260 days of release, the algal RQ = 255.21, with 260 days of exceedance. EPA again used the algal SSD to argue that risk to the most sensitive algal species might not apply to algal species as a whole: "there may be risk for some of the most sensitive species of algae at this site, but not for algae species as a whole" (page 261, line 124). We again disagree with this approach because we think it is less protective of the natural environment.

Another site (GM Components Holding, LLC, Lockport, NY) had an algal RQ = 3.66 with 117 days of exceedances; assuming 20 days per year of release, the RQ = 48.16 with 20 days of exceedance. EPA again used the algal SSD to argue that risk to algal species as a whole was not a problem. Again, we disagree with this approach because we think it works to be less protective of the natural environment.

A third site (Akebono Elizabethtown Plant, Elizabethtown, KY) had an algal RQ = 1.62 with 27 days of exceedance, assuming 260 days per year of release. EPA again used the SSD-derived value of 52,000 ppb in

place of the algal COC (3 ppb) to argue that risk to algal species as a whole was not a problem. We disagree yet again with EPA's approach because we think it has the effect of being less protective of the natural environment.

Adhesives, Sealants, Paints, and Coatings

One site (Raytheon Company, Portsmouth, RI) out of 54 facilities had algal RQs ≥ 1 (as high as 44.44) with 20 or more days' exceedance. Assuming 250 days per year of releases, the RQ = 3.61 with 250 days' exceedance. Clearly this poses a risk to the aquatic environment. EPA again used the algal SSD to generate a toxicity value of 52,000 ppb for use in place of the COC (3 ppb) to argue that risks to "algal species as a whole" were not a problem. No other aquatic organisms appear to be at risk for this condition of TCE use.

Other Industrial Uses

Three of the 21 other industrial uses had algal RQs ≥ 1. One facility (Eli Lilly and Company - Lilly Tech Center, Indianapolis, IN) had algal RQ = 3.01, assuming 250 days of release per year, and that RQ was exceeded 35 days.

Another site (Washington Penn Plastics, Frankfort, KY) had an algal RQ = 2.51, assuming 250 days of release per year; the algal COC (3 ppb) was exceeded 22 days.

The third site (Keeshan and Bost Chemical Co., Inc., Manvel, TX) had an algal RQ of 66.67 with 20 days of exceedance, assuming 20 days of release per year. Assuming 350 days per year of release, this site has an algal RQ of 3.17 with 350 days of exceedance (pages 262, lines 162-165). With both of these release assumptions, Keeshan and Bost was exceeding the algal COC every day they were releasing TCE. This is clearly a risk to algae. EPA again used the SSD-derived value of 52,000 ppb in place of the algal COC (3 ppb) to argue that risk to algal "*species as a whole*" was not a problem. We continue to disagree with EPA's approach to assessing risks to algae because we think it has the effect of being less protective of the natural environment.

Industrial Processing Aid

One site out of six had an algal RQ ≥ 1 with 20 or more release days per year of exceedances. That facility (Entek International LLC, Lebanon, OR) had an algal RQ = 46.11 assuming 20 days per year of release. The algal COC (3 ppb) was exceeded for 20 days. Assuming TCE was released for 300 days per year, the algal RQ = 3.10 with 140 days of exceedance. EPA again used the SSD-derived value of 52,000 ppb in place of the algal COC (3 ppb) to argue that risk to algal "*species as a whole*" was not a problem. We continue to disagree with EPA's approach to assessing risks to algae because we think it has the effect of being less protective of the natural environment.

Other Commercial Uses

One site out of nine facilities had an algal RQ ≥ 1 with 20 or more days per year of exceedances (page 262, lines 185-193). That facility (Park Place Mixed Use Development, Annapolis, MD) had an algal RQ ≥ 1, as high as 36.67, assuming 20 days per year of release; the algal COC (3 ppb) was exceeded for 20 days. Assuming the facility released TCE 250 days per year, the RQ would be 3.00 with 250 days of exceedance. Again, EPA used the SSD-derived value of 52,000 ppb in place of the algal COC (3 ppb) to argue that risk

to algal "*species as a whole*" was not a problem. We continue to disagree with EPA's approach to assessing risks to algae because we think it has the effect of being less protective of the natural environment.

Process Solvent Recycling and Worker Handling of Wastes

Three of five facilities had algal RQs ≥ 1 with 20 or more days per year of exceedances (page 262, lines 195-207). One facility (Clean Water of New York, Inc, Staten Island, NY) had an algal RQ as high as 46.08 with 20 days of exceedance. Assuming that facility released TCE for 250 days per year, the RQ = 3.92, with 250 days of exceedance. This is clearly a potential risk to aquatic algae.

Assuming the second facility (Veolia ES Technical Solutions LLC, Middlesex, NJ) released TCE 20 days per year, the algal RQ = 11.91 with 20 days' exceedance.This appears to be a potential risk to aquatic algae.

Assuming the third facility (Clean Harbors Deer Park LLC, La Porte, TX) released TCE 250 days, the algal RQ = 2.86 with 110 days of exceedance. This is clearly a potential risk to aquatic algae.

For these three facilities, again EPA used the SSD-derived value of 52,000 ppb in place of the algal COC (3 ppb) to argue that risk to algal "*species as a whole*" was not a problem. We continue to disagree with EPA's approach to assessing risks to algae because we think it has the effect of being less protective of the natural environment.

Wastewater Treatment Plants (WWTPs)

One out of nine WWTPs had algal RQs ≥ 1 with 20 or more days of exceedance (page 263, lines 209-218). That facility (New Rochelle STP, New Rochelle, NY) had an algal RQ = 4.26 assuming 20 days per year of release. The algal COC (3 ppb) was exceeded 20 days. Assuming this facility released TCE 365 days per year, the RQ = 0.23 with zero days exceedance. Since WWTPs are likely to be operating with more than 20 days of release, the latter risk assessment is more likely to represent actual conditions, and therefore would pose little or no risk to aquatic algal species. We are inclined to agree with EPA that the New Rochelle STP appears to present little or no risk to aquatic algal species.

Risk Estimation for Sediment

EPA did not quantitatively assess exposure to sediment-dwelling organisms because TCE is not expected to partition to sediment, based on physical-chemical properties (Section 4.1.3, page 275). TCE is expected to remain in aqueous phases and not adsorb to sediment due to its water solubility (>1280 mg/L) and low partitioning to organic matter (log K_{OC}= 1.8-2.17). Limited sediment monitoring data for TCE that are available suggest that TCE is present in sediments, but because of its relatively low partition coefficient for organic matter (log K_{OC} = 1.8-2.17) and because it biodegrades slowly [19% biodegradation in 28 days (ECB 2004)], TCE concentrations in sediment pore water are expected to be similar to the concentrations in the overlying water or lower in the deeper part of sediment where anaerobic conditions prevail. Thus TCE detected in sediments is likely from the pore water. *We agree with EPA's assessment and decision not to further pursue characterizing risks due to TCE exposure to sediment-dwelling organisms.*

Risk Estimation for Terrestrial Organisms

EPA did not quantitatively assess exposure to terrestrial organisms through soil, water, or biosolids (Section 4.1.4, pages 275-276). TCE is not expected to partition to soil but is expected to volatilize to air, based on its physical-chemical properties. Review of hazard data for terrestrial organisms shows potential hazard;

however, physical and chemical properties do not support an exposure pathway through water and soil pathways to terrestrial organisms.

TCE is not anticipated to partition to biosolids during wastewater treatment. TCE has a predicted 81% wastewater treatment removal efficiency, predominantly due to volatilization during aeration. Any TCE present in the water portion of biosolids following wastewater treatment and land application would be expected to rapidly volatilize into air. Bolstering this analysis, TCE was not detected in EPA's Targeted National Sewage Sludge Survey (TNSSS) nor was it reported in biosolids during EPA's Biennial Reviews for Biosolids, a robust biennial literature review conducted by EPA's Office of Water (U.S. EPA, 2019; 5933985). Furthermore, TCE is not expected to remain in soil, because it is expected to either volatilize into air or migrate through soil into groundwater.

TCE is expected to volatilize to air, based on physicochemical properties. However, the emission pathways to ambient air from commercial and industrial stationary sources or associated inhalation exposure of terrestrial species were considered to be outside of the scope of the risk evaluation, because stationary source releases of TCE to ambient air are adequately assessed and any risks effectively managed when under the jurisdiction of the Clean Air Act (CAA).

We agree with EPA's decision not to further assess exposure and resulting risks to terrestrial organisms through soil, water, or biosolids.

Environmental Risk Conclusions

Risks to aquatic organisms (Section 4.5.1, pages 354-355) like fish and invertebrates were identified near one open-top vapor degreasing facility (U.S. NASA Michoud Assembly Facility, New Orleans, LA) and one facility that processes TCE as a reactant (Table 4-53). These facilities had an acute RQ ≥ 1, or a chronic RQ ≥ 1 and 20 days or more of exceedance for the chronic COC. Risk to the most sensitive species of algae were identified near facilities with 20 or more days of exceedances for 461 of these facilities, and more than 100 days exceedances for 10 facilities. The U.S. NASA Michoud Assembly Facility had a surface water concentration modeled for this facility that was 3.11 times higher than the acute COC of 3,200 ppb, indicating risk to aquatic organisms from acute exposures. That NASA facility also had a chronic RQ of 12.61 with 20 days of exceedance. In other words, the surface water concentration was 12.61-fold higher than the COC of 788 ppb for 20 days. Therefore, EPA identified risk to aquatic organisms at this site for acute and chronic exposures to TCE. However, as a taxonomic group, EPA judged that 95% of algae species would not experience risk from this level of TCE exposure. They had RQs ³1 using the algal COC of 3 ppb, but RQs <1 using the algae HC_{05} of 52,000 ppb). These facilities were not included in Table 4-53 in this section, but are in Table 4-1 for reference.

We think relegating algal risk data "for reference" in Table 4-1 is a mistake because it ignores risks to the more sensitive aquatic algal species. Again, in contrast with EPA's approach to minimize risk to aquatic algae, we think the data from the above scenarios clearly represent significant potential risks to algae, as well as aquatic invertebrates and fish.