HSIA
halogenated solvents industry alliance, inc.

September 19, 2017

Document Control Office (7407M)
Office of Pollution Prevention and Toxics (OPPT)
Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, DC 20460

Re: Trichloroethylene [EPA-HQ-OPPT-2016-0737]
Tetrachloroethylene [EPA-HQ-OPPT-2016-0732]
Methylene Chloride [EPA-HQ-OPPT-2016-0742]
Carbon Tetrachloride [EPA-HQ-OPPT-2016-0733]

Dear Sirs:

The Frank R. Lautenberg Chemical Safety for the 21st Century Act (LCSA) amended the Toxic Substances Control Act (TSCA) and established several regulatory timelines. Under TSCA § 6(b)(4)(D), EPA released scoping documents for the first ten chemicals targeted for evaluation under LCSA, including the chlorinated solvents trichloroethylene (TCE), tetrachloroethylene (perchloroethylene or PCE), and methylene chloride (dichloromethane or DCM). The general comments included in this submission are also applicable to the scoping document for carbon tetrachloride (CTC).

The Halogenated Solvents Industry Alliance, Inc. (HSIA) represents producers, distributors and users of chlorinated solvents. HSIA appreciates the opportunity to comment on problem formulation for the above-referenced scoping documents, as solicited in the notice announcing their release. 82 Fed. Reg. 31592 (July 7, 2017). In that notice, EPA acknowledged that the initial scoping documents did not achieve the quality anticipated for future scoping documents:

> "The first 10 chemical substances were not subject to prioritization, the process through which EPA expects to collect and screen much of the relevant information about chemical substances that will be subject to the risk evaluation process. As a result, EPA had limited ability to process all the information gathered during scoping for the first 10 chemicals within the time provided in the statute for publication of the scopes after initiation of the risk evaluation process. Hence, the scope documents for the first 10 chemicals are not as refined or specific as future scope documents are anticipated to be. In addition, there was insufficient time for EPA to provide an opportunity for comment on drafts of these scope documents, as it intends to do for future scope documents."

One of the challenges for EPA in developing the required scoping documents was doing so prior to release of the final *Procedures for Chemical Risk Evaluation under the Amended Toxic Substances Control Act (Risk Evaluation Rule)*, 82 Fed. Reg. 33726 (July 20, 2017). Due to the acknowledged limitations of the initial scoping documents, EPA announced that it would:

> "publish and take public comment on a Problem Formulation document which will refine the current scope, as an additional interim step, prior to publication of the draft risk evaluations for the first 10 chemicals."

Typically, as will be discussed below, EPA treats Planning and Scoping and Problem Formulation as separate, albeit iterative, activities. The above statement indicates that EPA clearly has concerns with the quality of the Planning and Scoping element released in June and hopes to address those concerns through creation of a Problem Formulation document. Both elements are important in designing a credible risk assessment (or risk evaluation under LCSA). Recognizing that aspect, HSIA is pleased to submit the following comments for consideration by EPA in its development of the problem formulation documents for the four chlorinated organics (TCE, PCE, DCM, and CTC) found on the initial list of 10 chemicals under consideration.

General Recommendation

HSIA would strongly recommend that, in development of the problem formulation documents for the four chlorinated organics, EPA give serious consideration to its own guidance document *Framework for Human Health Risk Assessment to Inform Decision Making*. Although briefly mentioned in the Risk Evaluation Rule, there is no mention of the document in the June scoping documents for the four chlorinated compounds. We find this surprising, as application of the framework would appear to address many of the limitations acknowledged by EPA. As summarized in the 2014 document:

> "[t]he Framework for Human Health Risk Assessment to Inform Decision Making lays out a Framework for conducting human health risk assessments in support of decision making at EPA. It focuses on the planning and scoping and problem formulation steps, drawing on NRC (2009) and other advisory groups, and EPA experience. For example, the Framework addresses recommendations in the Silver Book (NRC 2009) on assuring the utility of risk assessment, which the Framework terms as being fit for purpose. . . [T]he NRC's 1983 four-step risk assessment paradigm is maintained, but there is increased emphasis on interaction between risk assessors and risk managers in planning the assessment to maximize utility. Emphasis on utility is maintained throughout the process, beginning with planning and scoping and continuing through the evaluation of the applicability of the risk assessment in informing decisions."

and

> "[a]pplication of the Framework, with its emphasis on problem formulation and the utility of the risk assessment, ultimately will result in better, more transparent choices among risk management options. This Framework builds on Agency guidelines, policies and guidance and is directed at improving risk assessment products but does not overturn or in any way change existing science policy decisions."

Specific Recommendations

Although the four chlorinated organics from the initial list of ten chemicals under consideration were not subjected to the LCSA prioritization process anticipated for chemicals considered in the future, it must be noted that all have been in commerce for decades and all should be considered "data-rich." As such, they all have a history of already being heavily regulated/controlled under a variety of existing federal and state programs. This makes them somewhat unique, particularly when compared against chemicals newly introduced into commerce, and raises some interesting problems in evaluating them under LCSA.

As mentioned earlier, the initial scoping documents for the four chlorinated organics were released prior to issuance of the Risk Evaluation Rule. In the preamble to that rule, which became effective on

September 18, EPA provided clarification on several issues that were problematic/unclear in the draft version released under the previous administration. In the following sections, HSIA addresses several of these specific issues in hopes that EPA will consider them during development of the problem formulation documents.

EPA's interpretation of its regulatory mandate under LCSA

In the Risk Evaluation Rule, EPA's clarified its regulatory mandate under LCSA:

> "EPA interprets the mandates under section 6(a)–(b) to conduct risk evaluations and any corresponding risk management to focus on uses for which manufacturing, processing, or distribution in commerce is intended, known to be occurring, or reasonably foreseen to occur. . . ."

HSIA agrees with this position. As will be seen in several of the following recommendations, further broadening of that mandate for chemicals that are already subjected to extensive regulation presents serious conflicts both in assessing potential human health and environmental risks and in any subsequent risk management decisions. The focus should be restricted to chemicals in commerce from this point forward.

EPA should use discretion in its selection of conditions of use

One of the most contentious issues associated with the evaluation of risk under LCSA is "conditions of use." The issue focuses on the question "should any/all actual/potential uses of a chemical in the past/present/future be considered in the risk evaluation?" LCSA does not require the Agency to conduct full risk evaluations based on all conditions of use and nowhere in the law is "conditions of use" preceded by "all." Expansion of the term "conditions of use" beyond the intent of Congress may distract from and negatively impact EPA's ability to conduct meaningful risk evaluations in a timely manner.

EPA should exclude certain *de minimis* conditions of use

The four chlorinated organics included on the initial list are all used as intermediates in the synthesis of other chemicals. These are the largest uses of CTC and TCE. Such feedstock use takes place within closed systems in restricted-access facilities where workers are operating under Occupational Safety & Health Administration (OSHA) regulations with appropriate personal protective equipment (PPE). Given the nature of the chlorinated organics, a leak detection and repair (LDAR) program is typically in place and fugitive emissions are monitored. The only potential human exposure would be to on-site workers, whose risks are managed under a facility's health and safety program, which falls under the jurisdiction of OSHA. Potential off-site exposures would only occur at or beyond the facility fence-line, and air modeling of fugitive emissions typically shows maximum air concentrations occurring very close to the release point (*i.e.*, within the facility). In the preamble to the Risk Evaluation Rule, EPA addresses the issue of *de minimis* exposures such as these with the following rather ambiguous language:

> "EPA may, on a case-by-case basis, exclude uses that EPA has sufficient basis to conclude would present only '*de minimis*' exposures. This could include uses that occur in a closed system that effectively precludes exposure, or use as an intermediate."

Given our understanding of the use of these solvents as intermediates, HSIA believes there is a sufficient basis to exclude this "condition of use" from further consideration in the risk evaluation.

EPA should consider a tiered approach to address *de minimis* and/or heavily regulated exposures

For those situations where EPA is not comfortable excluding certain "conditions of use" based on anticipated *de minimis* exposures, HSIA recommends that the Agency consider a tiered approach for screening potential risks as an initial step in the risk evaluation. Although our preference would certainly be to exclude those *de minimis* and/or heavily regulated "conditions of use" during the scoping/problem formulation stage, we support EPA's recognition in the Risk Evaluation Rule that in order to efficiently carry out the LCSA Congressional mandate, EPA must maintain the flexibility to issue a decision on specific "conditions of use" in a tiered, staged approach.

Legacy sources of exposure should not be addressed under LCSA

HSIA recommends that legacy sources of exposure should be excluded from the risk evaluation process under LCSA. Legacy sources of exposure typically refer to historical releases of a chemical to the environment associated with misuse or disposal. Although legacy environmental sources of exposure certainly exist for the four chlorinated organics, they have been effectively managed for decades under various federal programs (*i.e.*, CERCLA, RCRA, CAA, etc.). Many states also have stringent programs for addressing legacy contamination from these chemicals. Management of legacy contamination through the various federal and state programs is already risk-based and adding an additional risk-management program to the existing mix would be duplicative and not needed. The following statement from the preamble to the Risk Evaluation Rule indicates that EPA feels it could "exercise its discretion" on decisions relating to exclusion of a particular condition of use.

> "During the scoping phase, EPA may also exclude a condition of use that has been adequately assessed by another regulatory agency, particularly where the other agency has effectively managed the risks."

From a practical perspective, it is difficult to conceive how risks from a legacy source of exposure would even be managed under LCSA. For the four chlorinated organics, once a legacy exposure source (*i.e.*, existing environmental contamination) is discovered, responsibility for management of any human health or environmental risk would be assumed by the state. If the source was sufficiently large and generated a sufficiently high Hazard Ranking Score (HRS), it could be classified as a Superfund site under CERCLA.

Protection from workplace exposures to chemicals is the primary responsibility of OSHA, not EPA

As noted above, EPA has exclusionary discretion for "a condition of use [*i.e.*, exposure] that has been adequately assessed by another regulatory agency, particularly where the other agency has effectively managed the risks." As originally enacted and as updated by LCSA, TSCA requires EPA to consult and coordinate with other federal agencies "for the purpose of achieving the maximum enforcement of this Act while imposing the least burdens of duplicative requirements on those subject to the Act and for other purposes."[1] It has been clear since passage of the Occupational Safety and Health Act in 1970 that workplace protection is the primary responsibility of OSHA.

The LCSA eliminated the requirement in TSCA § 6(a) that EPA protect "against [unreasonable] risk using the least burdensome requirements," but did not materially change the existing framework that

[1] TSCA § 9(d).

requires unreasonable risks to be addressed under statutory authority other than TSCA wherever possible. EPA's longstanding interpretation of this framework is as follows:

> "Under section 9(a)(1) of TSCA, the Administrator is required to submit a report to another Federal agency when two determinations are made. The first determination is that the Administrator has reasonable basis to conclude that a chemical substance or mixture presents or will present an unreasonable risk of injury to health or the environment. The second determination is that the unreasonable risk may be prevented or reduced to a sufficient extent by action taken by another Federal agency under a Federal law not administered by EPA. Section 9(a)(1) provides that where the Administrator makes these two determinations, EPA must provide an opportunity to the other Federal agency to assess the risk described in the report, to interpret its own statutory authorities, and to initiate an action under the Federal laws that it administers.
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> "Accordingly, section 9(a)(1) requires a report requesting the other agency: (1) To determine if the risk may be prevented or reduced to a sufficient extent by action taken under its authority, and (2) if so, to issue an order declaring whether or not the activities described in the report present the risk described in the report.
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> "Under section 9(a)(2), EPA is prohibited from taking any action under section 6 or 7 with respect to the risk reported to another Federal agency pending a response to the report from the ether Federal agency. There would be no similar restriction on EPA for any risks associated with a chemical substance or mixture that is not within the section 9(a)(1) determinations and therefore not part of the report submitted by EPA to the other Federal agency."[2]

It was clear from the outset that TSCA is to be used only when other statutes fail to provide a remedy for unreasonable risks. When TSCA was enacted in 1976, Representative James Broyhill of North Carolina indicated that "it was the intent of the conferees that the Toxic Substance [Control] Act not be used, when another Act is sufficient to regulate a particular risk."[3] TSCA § 9(a) is substantively unchanged by the LCSA. The House Energy and Commerce Committee Report states: "H.R. 2576 reinforces TSCA's original purpose of filling gaps in Federal law that otherwise did not protect against the unreasonable risks presented by chemicals," and further clarifies that "while § 5 makes no amendment to TSCA § 9(a), the Committee believes that the Administrator should respect the experience of, and defer to other agencies that have relevant responsibility such as the Department of Labor in cases involving occupational safety."[4]

EPA applied this statutory directive in determining that the risk from 4,4' methylenedianiline (MDA) could be prevented or reduced to a significant extent under the OSH Act, and referring the matter for action by OSHA.[5] And in an analysis of TSCA § 9, EPA's Acting General Counsel concluded that

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[2] 4,4'-Methylenedianiline; Decision to Report to the Occupational Safety and Health Administration, 50 Fed. Reg. 27674 (July 5, 1985). EPA also has acted under § 9(a) to refer 1,3-butadiene and glycol ethers to OSHA, 50 Fed. Reg. 41393 (Oct. 10, 1985) and 51 Fed. Reg. 18488 (May 20, 1986), respectively, and to refer dioxins in bleached wood pulp and paper products to the Food and Drug Administration, 55 Fed. Reg. 53047 (Dec. 26, 1990).

[3] 122 Cong. Rec. H11344 (Sept. 28, 1976).

[4] H. Rep. No. 114-176 (114th Cong., 1st Sess.) at 28.

[5] 50 Fed. Reg. 27674 (July 5, 1985).

"Congress expected EPA – particularly where the Occupational Safety and Health Act was concerned – to err on the side of making referrals rather than withholding them."[6]

If EPA were to identify a category of exposure deemed to present a risk that is unreasonable, these considerations indicate that referral under § 9(a) would be the appropriate course.[7] It is clear from Section 9(a) that TSCA is to be used only when other statutes fail to provide a remedy for unreasonable risks.

EPA codified this principle in the Risk Evaluation Rule, 40 C.F.R. §702.39. EPA should adopt the OSHA permissible exposure limits (PELs) as the appropriate screening levels for potential risks to workers. If the 90th percentile estimates from the 8-hour time-weighted average (TWA) exposure concentrations are at or below the OSHA PELs, EPA should conclude a condition of no significant risk for worker exposures. However, it is possible that EPA could, if scientifically appropriate, decide to apply more recent American Conference of Governmental Industrial Hygienists (ACGIH) threshold limit values (TLVs) to evaluate potential risks to workers.

Occupational exposure limits, such as OSHA PELs and ACGIH TLVs, are derived to be protective for occupational exposures. The values are typically based on occupational epidemiology studies and, therefore, are especially relevant for worker populations. For example, occupational studies by their very nature include consideration of the healthy worker effect.[8] Occupational exposure limits also consider other factors unique to the workplace, such as technical feasibility. In general, occupational exposure limits should be considered protective for worker exposures. Such limits and their bases should be part of worker risk evaluations under the new TSCA.

Risk evaluations conducted under LCSA should be state-of-the-art

There have been significant developments in the science of risk assessment and in our understanding of mode of action for cancer and other apical endpoints in recent years. HSIA is encouraged that EPA has acknowledged these developments in the Risk Evaluation Rule and appears committed to including them in risk evaluations conducted under LCSA. Many of these developments are the result of concerns with EPA's IRIS program. HSIA believes that the following are necessary components of a state-of-the-art risk evaluation and should be part of the problem formulation documents.

Systematic Review: Although several of the chemicals from the initial list of ten to be evaluated under the amended TSCA are relatively data-rich, it is essential that a systematic review be undertaken to ensure that all existing hazard data are considered. The IRIS evaluation of TCE, for example, was completed in 2011 and an examination of that document reveals that many of the studies referenced are now more than a decade old. Although EPA indicated that many of the principles of systematic review were considered

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[6] Memorandum to Lee M. Thomas from Gerald H. Yamada, June 7, 1985, p. 2.

[7] As noted above, TSCA § 9(a) provides that if the Administrator has reasonable basis to conclude that an unreasonable risk of injury is presented, and he determines, in his discretion, that the risk may be prevented or sufficiently reduced by action under another federal statute not administered by EPA, then the Administrator shall submit a report to that agency describing the risk. In the report, the Administrator shall request that the agency determine if the risk can be prevented or sufficiently reduced by action under the law administered by that agency; if so, the other agency is to issue an order declaring whether the risk described in the Administrator's report is presented, and is to respond to the Administrator regarding its prevention or reduction. The Administrator may set a time (of not less than 90 days) within which the response is to be made. The other agency must publish its response in the Federal Register. If the other agency decides that the risk described is not presented, or within 90 days of publication in the Federal Register initiates action to protect against the risk, EPA may not take any action under § 6 of TSCA.

[8] A healthy worker effect is based on observations in occupational epidemiology studies that workers usually exhibit lower overall death rates than the general population because the severely ill and chronically disabled are ordinarily excluded from employment (Li *et al.* 1999).

during the TCE IRIS evaluation, there have been significant developments in that process over the past decade. At the very least, the systematic review should consider all existing hazard data and, consistent with current approaches, publish acceptance criteria, including criteria to assess study quality, which are then used in the selection of key studies.

HSIA would recommend that a similar approach be applied to exposure data used for the risk evaluation. For example, a systematic review of air monitoring data should exclude data generated prior to the effective date of a National Emission Standard for Hazardous Air Pollutants which limited the emissions of a particular chemical from covered sources. Although EPA provides a fairly lengthy discussion on systematic review in the preamble to the Risk Evaluation Rule, it did not codify a definition for systematic review. Many of the elements of systematic review do, however, appear in the codified definition of "weight of scientific evidence" provided below.

Consideration of Best Available Science: HSIA strongly endorses the use of best available science in risk evaluations conducted under LCSA. Although Section 702.33 of the Risk Evaluation Rule provides a detailed definition of "best available science," the overarching principal is science that is reliable and unbiased. Several of the chlorinated solvents have suffered from EPA's reliance on scientific studies that were considered substandard by the scientific community. HSIA is hopeful that EPA's commitment to consideration of best available science, when combined with a formal systematic review process, will yield risk evaluations that are reliable.

Consideration of New Data: HSIA supports EPA's position on the acceptance of new data for consideration in the risk evaluation.

> "EPA does not intend to preclude the generation of new scientific information to inform risk evaluations, however, as mentioned in the discussion of reasonably available information, the extent to which EPA will consider any newly generated information in a risk evaluation will depend on the statutory deadlines."

Application of Weight of Scientific Evidence Approach: As discussed above, Section 702.33 of the Risk Evaluation Rule defines "weight of scientific evidence" as:

> ". . . a systematic review method, applied in a manner suited to the nature of the evidence or decision, that uses a pre-established protocol to comprehensively, objectively, transparently, and consistently, identify and evaluate each stream of evidence, including strengths, limitations, and relevance of each study and to integrate evidence as necessary and appropriate based upon strengths, limitations, and relevance."

Similar language regarding the "weight of scientific evidence" was included in the scoping documents for TCE , PCE , DCM and CTC released in June 2017 [excerpt from the TCE scoping document follows]:

> "EPA will be evaluating the weight of the scientific evidence for both hazard and exposure. Consistent with this approach, EPA will also use a systematic review approach. As such, EPA will use explicit, pre-specified criteria and approaches to identify, select, assess, and summarize the findings of studies. This approach will help to ensure that the review is complete, unbiased, reproducible, and transparent."

Whether or not a definition for systematic review is codified in the Risk Evaluation Rule is less important than EPA's commitment to integrate the process into risk evaluations conducted under LCSA. HSIA strongly supports that commitment for both hazard and exposure data.

Peer Review: Although the proposed Risk Evaluation Rule only provided lip-service to the concept of peer review, HSIA strongly supports EPA's commitment to the peer review process as described in the preamble to the final rule:

> "In addition to any targeted peer review of specific aspects of the analysis, the entire risk assessment will also undergo peer review [emphasis added], as it is important for peer reviewers to consider how the various underlying analyses fit together to produce an integrated risk characterization, which will form the basis of an unreasonable risk determination. "

EPA's commitment to the peer review process under TSCA has, to date, been uneven. Although the TSCA Work Plan Chemicals Assessment for TCE, conducted in 2012, was subjected to external peer review, the final document contained an exposure scenario (*i.e.*, condition of use) that was not even included in the draft. Despite lack of peer review for that condition of use, EPA used the results of the risk assessment as the basis for a proposed ban.

Public Comment Period: LCSA requires that EPA allow for no less than a 30-day public comment period on a draft risk evaluation, prior to publishing a final risk evaluation. HSIA recommends that EPA allow at a minimum a 60-day public comment period following release of the draft problem formulation documents given their obvious importance in setting precedent for the program moving forward. Indeed, a public meeting to review and discuss public comments on the draft problem formulation documents could greatly facilitate agreement on the final product (*i.e.*, the risk evaluation).

Clearly, the scenarios examined in the 2014 TSCA Work Plan Chemicals Assessments should be re-evaluated. Language in the scoping documents for TCE and DCM, released by EPA in June 2017, indicates that conditions of use previously evaluated in 2014 TSCA Work Plan Chemical Risk Assessments may not be re-evaluated under the Risk Evaluation Rule. HSIA urges EPA to reconsider this position as part of problem formulation, for several reasons. First, as already mentioned, between publication of the peer-reviewed draft assessment for TCE in 2012 and release of the final version in 2014, EPA introduced a new "condition of use" (*i.e.*, spot cleaning) which was not subjected to peer review. Second, the Risk Evaluation Rule, which promulgated the procedure(s) to be followed in conducting a risk evaluation to satisfy requirements under LCSA, was not published until July 20, 2017, three years after finalization of the Work Plan Chemical Assessments for TCE and MC. All significant "conditions of use" should be evaluated in compliance with the Risk Evaluation Rule, which requires significant aspects not addressed or applied in the previous risk assessments, such as consideration of best available science and application of a weight of the scientific evidence approach.

To facilitate EPA's review of these uses, HSIA is submitting comments on the earlier proposed rules (and related risk assessments) to the relevant dockets.

EPA's approach for evaluating environmental impacts under LCSA is problematic

Under LCSA, EPA is required to evaluate potential chemical impacts on the environment and HSIA has serious concerns about the approach described in the final Risk Evaluation Rule. The scoping documents for the four chlorinated organics state that:

> ". . . manufacturing, processing, use and disposal . . . . . can result in releases to air, water, sediment and soil. EPA expects to consider exposures to the environment and ecological receptors that occur via these exposure pathways or media . . . . . in conducting the risk evaluation . . . ."

The Risk Evaluation Rule appears to expand the potential scope for the evaluation of environmental impacts even further. Under §702.43(4) (*i.e.*, Considerations for environmental risk evaluations), the rule states:

> "For environmental evaluations specifically, EPA plans to include a discussion of the nature and magnitude of the effects, the spatial and temporal patterns of the effects, implications at the species, population, and community level, and the likelihood of recovery subsequent to exposure to the chemical substance."

In addition to being concerned about the level of effort required to carry out such an activity, HSIA is concerned that such an evaluation would have to be location-specific. If, for example, EPA is interested in evaluating potential environmental impacts from a manufacturing facility, those impacts will have to be based on either measured or modeled media concentrations. The fate and transport of chemicals into air, soil, sediment, and surface water is known to be influenced by factors that are location- and site-specific and any adverse impacts will be applicable to that specific facility only. The air modeling of emitted chemicals from a manufacturing facility into environmental media surrounding that facility, for example, will be influenced by many factors, including local meteorology, terrain, proximity to surface water bodies, and distance to the facility boundaries, among others.

As described, the evaluation of environmental impacts under LCSA could result in a situation where a "condition of use" is found to be associated with unacceptable environmental impacts, yet the "condition of use" would only be relevant at a specific facility. That same "condition of use" could be acceptable at another facility operating under the exact same conditions, creating a real risk management dilemma.

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HSIA appreciates the opportunity to provide these comments on this important step of problem formulation.

Respectfully submitted,

Faye Graul

Faye Graul,
Executive Director