UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

General Comments of Safer Chemicals Healthy Families on Risk Evaluation Scoping Efforts for Ten Chemical Substances under the Toxic Substances Control Act

Submitted via Regulations.gov (March 15, 2017)

1,4-Dioxane. Docket ID No.: EPA-HQ-OPPT-2016-0723.

1-Bromopropane. Docket ID No.: EPA-HQ-OPPT-2016-0741.

Asbestos. Docket ID No.: EPA-HQ-OPPT-2016-0736.

Carbon Tetrachloride. Docket ID No.: EPA-HQ-OPPT-2016-0733.

Cyclic Aliphatic Bromide Cluster (Hexabromocyclododecane or HBCD). Docket ID No.: EPA-HQ-OPPT-2016-0735.

Methylene Chloride. Docket ID No.: EPA-HQ-OPPT-2016-0742.

N-Methylpyrrolidone (NMP). Docket ID No.: EPA-HQ-OPPT-2016-0743.

Pigment Violet 29 (Anthra[2,1,9-def:6,5,10-d'e'f]diisoquinoline-1,3,8,10(2H,9H)-tetrone). Docket ID No.: EPA-HQ-OPPT-2016-0725.

Trichloroethylene (TCE). Docket ID No.: EPA-HQ-OPPT-2016-0737.

Tetrachloroethylene (also known as Perchloroethylene). Docket ID No.: EPA-HQ-OPPT-2016-0732.

Safer Chemicals Healthy Families (SCHF) submits these comments on the Environmental Protection Agency's (EPA's) scoping process for the initial ten chemicals selected for risk evaluations under the newly enacted Frank R. Lautenberg Chemical Safety for the 21st Century Act (LCSA).[1]

These comments address general issues common to the 10 chemicals and supplement chemical-specific comments that SCHF is submitting to several EPA dockets. SCHF and many of its partner organizations also offered comments on the 10 chemicals at EPA's February 14 public meeting.

SCHF is a coalition of national, state and local organizations committed to assuring the safety of chemicals used in our homes, workplaces and in the many products to which our families and children are exposed each day. SCHF and its partners took a leadership role during the LCSA legislative process, advocating the most protective and effective legislation possible to reduce the risks of toxic chemicals in use today.

LCSA is the first major overhaul of the 1976 Toxic Substances Control (TSCA) and a potentially important step forward in evaluating and reducing the risks of chemicals to health and the

[1] 82 Federal Register 6545 (January 19, 2017).

environment in the US. If EPA takes forceful and proactive steps to implement the new law, it can deliver significant health and environmental benefits to the American people. However, if EPA rolls back the protections mandated by Congress, the law's promise will not be realized and the threats that chemical risks now pose to our communities and the environment will continue unchecked. SCHF will engage constructively with EPA and other stakeholders on an implementation path that maximizes the health and environmental protections of LCSA but will hold EPA accountable if it fails to carry out the law as enacted by Congress.

The following organizations have endorsed and are supporting the SCHF comments:

Alaska Community Action on Toxics

Alliance of Nurses for Healthy Environments

Asbestos Disease Awareness Organization

Autism Society of Minnesota

Breast Cancer Action

Breast Cancer Prevention Partners *(formerly Breast Cancer Fund)*

Center for Environmental Health

Clean and Healthy New York

Clean Production Action

Clean Water Action

Conservation Minnesota

Earthjustice

Ecology Center

Environmental Health Strategy Center

Healthy Building Network

Healthy Legacy

LDA Minnesota

League of Conservation Voters

Learning Disabilities Association of America

Maryland Public Interest Research Group

Minnesota Center for Environmental Advocacy

Mitchell Environmental Health Associates

National Medical Association

Natural Resources Defense Council

NC Conservation Network

Oregon Environmental Council

Physicians for Social Responsibility

Safer States

Science and Environmental Health Network

Toxic-Free Future

U.S. Public Interest Research Group (PIRG)

Vermont Public Interest Research Group

WE ACT for Environmental Justice

Women for a Healthy Environment

Women's Environmental Institute

SUMMARY OF KEY POINTS

Through LCSA, Congress established a new framework under TSCA section 6(b) for conducting timely, comprehensive and science-based risk evaluations for chemicals of concern. The law provides that EPA's evaluations must be strictly risk-based and must result in a definitive determination whether the evaluated substance as a whole presents an unreasonable risk of injury to health and the environment, without regard to costs and other non-risk factors.

Congress wanted EPA to launch the risk evaluation process expeditiously. Accordingly, in section 6(b)(2)(A) of TSCA, it directed EPA to assure that evaluations are initiated within six months of the law's enactment on 10 substances drawn from the 2014 TSCA Workplan list. EPA designated these 10 substances on December 19, 2016,[2] and is now developing scoping documents for its evaluations. The February 14 public meeting convened by the Agency was a positive step to obtain stakeholder input on the scoping documents, and the opportunity to submit written comments will enable stakeholders to share additional data and perspective.

EPA's initial risk evaluations will provide an early test of the effectiveness of new law. It is therefore critical that they reflect the best information on hazard and exposure available, are based on a comprehensive understanding of the chemicals' conditions of use, and employ sound, precautionary methodologies and protocols that fully capture the risks they pose to health and the environment.

SCHF's chemical-specific comments reflect the results of our own extensive research on several of the 10 chemicals and are intended to point EPA to information about exposure and use that should inform its scoping documents. As these comments show, EPA's preliminary use and exposure profiles for the 10 chemicals – while a positive and helpful step – overlook critical data-sources and fail to capture important conditions of use and pathways of exposure. We urge EPA to redouble and expand its efforts to characterize the chemicals' conditions of use as it develops its scoping documents.

The SCHF general comments augment our submissions on individual chemicals by offering our recommendations for how EPA should structure the scoping process and subsequent risk evaluations so they promote the purposes of LCSA and maximize human health and environmental protection. We also take issue with industry suggestions at the February 14 public meeting that we believe are **not** grounded in the new law and will weaken the scoping and risk evaluation processes if adopted.[3]

Our principal recommendations are as follows:

- ✓ *Risk evaluations must address the entire life cycle and conditions of use of the evaluated chemical. This interpretation is compelled by the broad definition of "conditions of use"*

[2] 81 Federal Register 91927

[3] Several of the issues we address are also raised by EPA's proposed January 19 risk evaluation procedural rule (82 FR 7562) and will be addressed in our comments on that proposal.

in section 3(4) to include all phases of a chemical's life cycle and by the explicit requirement in section 6(b)(4)(A) that a risk evaluation must address "the conditions of use" of the subject chemical. EPA's scoping documents must describe all known conditions of use during the chemical's life-cycle and outline steps to identify additional uses if necessary

- ✓ *Risk evaluations under TSCA will be meaningful and effective only if they are based on sufficient information to characterize the nature, duration and magnitude of exposure for all conditions of use and identify the chemical's health and ecological effects for all end-points and routes of exposure. Because the 10 chemicals did not undergo prioritization under the new law and were selected for risk evaluation shortly after its enactment, EPA's ability to characterize hazard and exposure will be constrained by data gaps. We recommend that the scoping process be designed to identify the information that EPA is lacking and initiate efforts to obtain that information under EPA's expanded information collection authorities as expeditiously as possible.*

- ✓ *EPA scoping documents must broadly describe all the chemical's "conditions of use" and assure that all sources of exposure that may contribute to total risk are considered in its evaluations. For example, where it is "known" or "reasonably foreseen" that a chemical is being used for purposes not identified in labeling or marketing materials or being handled in a manner inconsistent with the practices described in Material Safety Data Sheets (MSDS), these activities will constitute "conditions of use" as defined in the law. Similarly, the definition would encompass the chemical's presence as an impurity or byproduct in waste streams or products, future uses that can be reasonably anticipated, and legacy environmental releases that are contributing to ongoing exposure.*

- ✓ *Aggregate and cumulative exposure assessment must be an essential element of risk evaluations whenever total risk is a function of multiple pathways of exposure or the combined impacts of multiple chemicals of similar toxicity. This approach is consistent with past EPA practice and guidance and inherent in the LCSA emphasis on examining total risk across a chemical's lifecycle and conditions of use. Scoping documents must explain how EPA will assess aggregate and cumulative exposure and identify the information that will inform this assessment.*

- ✓ *EPA lacks authority to "tier" risk evaluations or designate uses as "low risk" at the scoping stage. The scoping process is not intended to make initial judgments about risk and could not realistically perform this function given its limited duration. If uses are dropped from the risk evaluation based on a cursory review at the scoping stage, the risk evaluation itself will be inadequate because critical exposure and hazard information pertaining to these uses will not be considered and their contribution to aggregate exposure and risk will not be taken into account.*

- ✓ *An important step during the scoping process should be identifying communities where, because of proximity to manufacturing, processing or disposal facilities, contaminated sites or air or water emissions and discharges, exposure to the subject chemical is likely to be elevated. Several readily available information sources can help pinpoint such communities. Residents of at risk communities frequently have important information about exposure conditions and indicators of elevated adverse health outcomes that can inform both the scoping and risk evaluation processes. After it identifies such communities, EPA should reach out to and establish communications with community groups at the scoping stage or during the risk evaluation itself.*

- ✓ *If EPA identifies discontinued uses of a chemical during the scoping process, they should be subjected to Significant New Use Rules (SNURs) to avoid their resumption before the evaluation is complete. Once a SNUR is in place, EPA would have to be notified before the use is re-commenced and would be able to either allow or restrict the use in light of the analysis of hazard and exposure in its risk evaluation. Otherwise, the use would escape EPA evaluation and restriction*

I. THE SCOPING DOCUMENT AND RISK EVALUATION MUST CAPTURE THE ENTIRE LIFE-CYCLE AND ALL THE CONDITIONS OF USE OF THE EVALUATED CHEMICAL

In its risk evaluation proposal, EPA has properly concluded that risk evaluations must –

> "encompass **all** manufacture, processing, distribution, use and disposal activities that constitute the conditions of use within the meaning of TSCA section 3. That is to say, a risk evaluation must encompass **all** known, intended and reasonably foreseen activities associated with the chemical substance."[4]

This interpretation is compelled by the broad definition of "conditions of use" in section 3(4) to include all phases of a chemical's life cycle and by the explicit requirement in section 6(b)(4)(A) that a risk evaluation must address "the conditions of use" of the subject chemical. Equally important, as EPA notes, the goal of the evaluation under section 6(b)(4)(A) is to determine whether the "chemical substance" as a whole presents an unreasonable risk, not whether discrete uses present such a risk.[5] This reflects Congress' desire for definitive and comprehensive risk evaluations covering a chemical's entire use and exposure profile, as opposed to partial evaluations that defer unaddressed risks to future resolution.

[4] 82 FR 7565 (emphasis added)

[5] The description of the scoping process in section 6(b)(4)(D) does not, as some have argued, provide discretion for EPA to narrow the scope of risk evaluations. This provision simply requires EPA to enumerate the hazards, exposures and conditions of use it has identified so that it can structure and plan the risk evaluation, provide the public with a clear roadmap of how it will conducted and give stakeholders an opportunity to identify hazard and exposure scenarios that may be unknown to the Agency. This organizing and public information function does not imply an ability to exclude uses or hazards from the risk evaluation that should be addressed to provide the comprehensive life-cycle assessment that Congress envisioned.

EPA's comprehensive approach is essential for policy as well as legal reasons. Picking and choosing among a chemical's conditions of use could result in overlooking risk scenarios of significant concern due to resource constraints, political pressures or lack of information. If EPA could meet the statutory deadline for completing evaluations on the basis of a partial characterization of uses, exposure pathways and risks, it would have no obligation under the law to address the remaining risk scenarios, despite their significance. The resulting gap would weaken protection of health and the environment. In some cases, focusing on a subset of uses could even lead to a determination that the chemical does not present an unreasonable risk although a comprehensive evaluation would support a different conclusion. In such cases, the public would erroneously conclude that the chemical is safe.

In addition, aggregating exposures across uses – a necessary step to avoid understating risks and identifying and protecting potentially exposed or susceptible subpopulations – cannot be accomplished effectively if some uses are dropped from consideration at the outset of the evaluation. This would mean that pathways that contribute to aggregate exposure would be ignored, and that the evaluation would underestimate total exposure and risk, providing the public with a misleading characterization of the chemical's risks throughout its life cycle.

We recommend strongly that, as EPA has concluded, all conditions of use of a chemical across its life cycle must be described in its scoping documents and then addressed in its subsequent risk evaluations.

II. THE SCOPING DOCUMENT MUST INCLUDE A ROADMAP FOR FILLING DATA GAPS ON HAZARD AND EXPOSURE THAT WILL WEAKEN THE QUALITY OF THE RISK EVALUATION UNLESS ADDRESSED

Risk evaluations under TSCA will be meaningful and effective only if they are based on sufficient information to characterize the nature, duration and magnitude of exposure for all conditions of use and identify the chemical's health and ecological effects for all end-points and routes of exposure. EPA's proposed risk evaluation and prioritization rules properly underscore the importance of assuring that adequate information is in hand before risk evaluations are initiated, using TSCA authorities to fill data gaps where necessary.

As EPA notes in these proposals,[6] the ideal time for filling data gaps is at the pre-prioritization stage, so that the Agency can proceed toward a risk evaluation confident that it will have sufficient information to perform a robust examination of hazard, exposure and risk. However, this was not possible for the initial 10 chemicals selected for risk evaluation because they did not undergo prioritization under the new law and had to be selected for risk evaluation shortly after enactment of the LCSA.

[6] 82 FR 4825, 4831 (January 17, 2017) (Proposed Procedures for Prioritization of Chemicals for Risk Evaluation); 82 FR 7562, 7569 (January 19, 2017) (Proposed Procedures for Chemical Risk Evaluation).

This means that EPA's ability to characterize hazard and exposure for the full range of end-points and conditions of use will be constrained by data gaps. Our own research on the 10 chemicals confirms that these data gaps are significant and will weaken the quality of EPA's risk evaluations unless filled. We therefore recommend that the scoping process be designed to identify the information that EPA is lacking and initiating efforts to obtain that information as expeditiously as possible.

It is not realistic to expect industry to fill data gaps voluntarily: the track record of industry submission of information on the initial 10 chemicals has been disappointing and very little voluntary testing was conducted under the original TSCA. EPA should therefore plan on using its mandatory information collection authorities under TSCA to fill data gaps where voluntary submissions are not timely or adequate. The LCSA expands these authorities and streamlines the process for exercising them, removing the barriers to information development that hamstrung EPA under the old law.

For example, section 4 now authorizes EPA to issue orders where necessary to "perform a risk evaluation." Such orders can be used to require industry to develop new information on the frequency, levels and duration of exposure for a chemical's conditions of use. Or a testing order can be issued to obtain data on a hazard end-point not adequately characterized by existing data. To collect existing information, EPA can add the 10 chemicals to its section 8(d) reporting rule for unpublished "health and safety studies." Alternatively, EPA can use its subpoena authority under section 11. EPA should specify in the scoping document its roadmap and timetable for filling data gaps using these authorities.

Some of the additional information EPA requires industry to develop may not be available within the 3.5 year timeframe for completing risk evaluations under TSCA. In the absence of these data, EPA may still be able to reach sound conclusions about a use or exposure pathway by applying well-grounded default assumptions or extrapolation methods. Similar approaches may be possible for hazard end-points that lack complete toxicological data.

In these instances, however, EPA should still require information collection and testing, so that a fuller risk characterization can be conducted at a later date. EPA's proposed risk evaluation rule provides that EPA may reevaluate an unreasonable risk determination based on a risk evaluation if new information so warrants.[7] Thus, if new hazard or exposure information that industry is required to develop supports different or more extensive conclusions about a chemical's risks, the risk evaluation for the chemical should be reopened and modified.

Where the data available for a risk evaluation are incomplete, it is critically important that EPA not equate the absence of data with the absence of risk. For example, if EPA lacks data to

[7] Section 702.45(e) of the proposed risk evaluation rule provides that EPA "may reassess a final unreasonable risk determination at any time based on information available to the Agency." Thus, if new hazard or exposure information that industry is required to develop supports different or more extensive conclusions about a chemical's risks, the risk evaluation for the chemical should be reopened and modified.

assess a chemical's carcinogenicity, its risk evaluation needs to clearly state that cancer risk has not been addressed, that the chemical may or may not present such a risk, and that this end-point is outside the scope of its evaluation because of the absence of data. EPA should make the same disclaimers for conditions of use that cannot be adequately characterized, even by using default assumption or extrapolation methods, because basic information about the nature of the use and scope and extent of exposure is unavailable.

III. EPA MUST BROADLY DEFINE CONDITIONS OF USE IN ORDER TO ASSURE THAT ALL ACTIVITIES AND SOURCES OF EXPOSURE THAT MAY CONTRIBUTE TO TOTAL RISK ARE IDENTIFIED IN ITS SCOPING DOCUMENT

The term "conditions of use" is defined in section 3(4) to mean –

> "the circumstances, as determined by the Administrator, under which a chemical substance is intended, known or reasonably foreseen to be manufactured, processed, distributed in commerce, used or disposed of."

This is a broad definition and indicates that a wide range of activities throughout a chemical's life cycle must be identified in EPA's scoping document and then addressed in its risk evaluation. At the February 14 public meeting, however, industry parties argued that certain exposure scenarios are **not** conditions of use and therefore should **not** be considered during the scoping process. These arguments represent a serious misreading of the statutory definition and would result in incomplete and inadequate risk evaluations, as explained below:

Label Recommendations. Industry claimed that uses of a chemical that are not identified in labeling or marketing materials or are inconsistent with the handling practices described in labeling or Material Safety Data Sheets (MSDSs) are not "conditions of use" because they are not "intended" by the manufacturer or processor. However, section 3(4) defines "conditions of use" to include not just "intended" but "known or reasonable foreseen" activities that occur as a result of manufacture, processing, use, distribution in commerce or disposal of a chemical. This would plainly encompass applications of the chemical not explicitly advertised or identified by the seller but known or reasonably anticipated to occur within a processing or end-use sector, as evidenced by Internet postings, articles in trade or general publications or anecdotal reports by consumers or workers. It would also encompass use of the chemical without safeguards such as ventilation or personal protective equipment when the absence of these safeguards has been reported in the medical or occupational health literature, surveys of work sites or residences or technical bulletins. For several chemicals that EPA is already evaluating such as TCE, PERC, DCM and NMP, solvent or vapor degreasing, paint removal and dry cleaning applications are known to occur at construction job sites, small commercial establishments and homes where the use of personal protective equipment and other precautions is uneven at best and non-existent at worst. To presume that these limitations on exposure are in place and protecting workers and consumers in the face of contrary evidence would be to read the terms "known" and "reasonably foreseen" out of the statutory definition of "conditions of use."

Byproducts and Impurities. Some industry members also suggested that the presence of a chemical in a product or waste stream as an impurity or byproduct does not constitute a condition of use and should not be considered when evaluating the chemical's exposure potential. However, whether or not an impurity or byproduct performs a commercial purpose or is generated intentionally, its existence will generally be "known" or "reasonably foreseen" by the manufacturer and constitute one of the "circumstances under which [the] chemical substances is . . . manufactured, processed, distributed in commerce, used or disposed of." The exposures associated with impurities or byproducts can be significant and their contribution to overall exposure and risk should be accounted for in EPA's scoping documents and risk evaluations.

Future Uses. A chemical's conditions of use should also include future applications, manufacturing or processing conditions and exposure and release pathways that are "reasonably foreseen" based on new product or plant expansion announcements or use scenarios for chemicals with similar characteristics. The LCSA legislative history underscores EPA's responsibility to "consider future or reasonably anticipated risks in evaluating whether a chemical substance or mixture presents an unreasonable risk" and notes that this "authority and mandate" derive from the LCSA definition of "conditions of use."[8]

Legacy Releases and Contamination. Legacy environmental releases of a chemical often contribute significantly to current exposure, particularly in communities impacted by groundwater, surface water, drinking water or soil contamination or proximity to waste sites. Such releases would qualify as "conditions of use" under the law because they define the "circumstances under which a chemical substance is . . . known . . . to be disposed of." And even if these releases are best addressed under other laws like CERCLA or RCRA, their incremental contribution to overall exposure by an impacted community or vulnerable subpopulation is clearly relevant to whether the aggregate risk posed by a chemical is "unreasonable" and must be considered in meeting EPA's obligation to protect "potentially exposed or susceptible subpopulations."

Non-TSCA Products. Exposures from TSCA-exempt uses such as personal care products or biocides should also be included in scoping documents and risk evaluations because of the need to account for their contribution to aggregate risk, even though regulatory authority over these products is not available under TSCA but derives from other laws administered by EPA or agencies such as FDA. This is now standard practice in implementing the Food Quality Protection Act (FQPA).

IV. SCOPING DOCUMENTS SHOULD PROVIDE A ROADMAP TO HOW EPA WILL ASSESS AGGREGATE AND CUMULATIVE EXPOSURE

[8] Detailed Analysis and Additional Views of Democratic Senators, June 7, 2016. Congressional Record S3516.

Determining risk based on all relevant pathways and sources of exposure for the general population and vulnerable subpopulations is inherent in the new law's focus on the total risk posed by a chemical throughout its life-cycle as distinct from the discrete risk associated with a particular condition of use. Thus, under section 6(b)(4)(F)(i), EPA must "integrate and assess available information on hazards and exposures for *the conditions of use* of the chemical substance" and, under section 6(b)(4)(F)(iv), must "take into account, where relevant, the likely duration, intensity frequency and number of exposures under *the conditions of use* of the chemical substance" (emphasis added). This focus on characterizing exposures across a chemical's conditions of use necessarily requires the Agency to identify all sources of exposure that may affect the general population or specific subpopulations and to determine the overall levels, frequency and duration of exposures by each population or subpopulation resulting from this combination of pathways.

This approach is commonly described as "aggregate exposure assessment" and EPA has applied it successfully in several programs. For example, the 1996 FQPA directs EPA to examine aggregate exposures when issuing or renewing tolerances for pesticides in food and EPA has longstanding guidance for doing aggregate risk and exposure assessments to meet this requirement.[9]

EPA scoping documents should include a roadmap to conduct an aggregate exposure assessment whenever total risk by the general population or a vulnerable subpopulation is a function of the combined exposures resulting from multiple pathways or uses. They should further identify **all** uses and pathways that contribute to **total** exposure by the general population or significant subpopulations so that EPA has the necessary information for assessing aggregate exposure. In the evaluation itself, EPA would then characterize the magnitude of each use or pathway's contribution to total exposure – quantitatively if possible but qualitatively if not. Based on this characterization, the evaluation would determine whether the chemical presents an unreasonable risk based on the **combination** of uses and pathways, even if in isolation the risk associated with an individual use or pathway may not be unreasonable.[10]

Scoping documents should also address whether and how EPA will use "cumulative exposure" methodologies for TSCA risk evaluations. This, too, is an area that EPA has addressed in several guidance documents.[11] The Agency defines "cumulative risk" as "the combined risks from

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[9] https://www.epa.gov/sites/production/files/2015-07/documents/aggregate.pd

[10] EPA should also abandon its presumed safety threshold model for non-cancer effects, as recommended in the expert *Science and Decisions* report of the National Academy of Sciences..

[11] E.g., *Guidance on Cumulative Risk Assessment of Pesticide Chemicals That Have a Common Mechanism of Toxicity.* U.S. Environmental Protection Agency, Office of Pesticide Programs, Washington, DC. (2002) Available at http://www.epa.gov/oppfead1/trac/science/cumulative_guidance.pdf; *Framework for Cumulative Risk Assessment,* U.S. Environmental Protection Agency, Office of Research and Development, National Center for Environmental Assessment, Washington, DC. EPA/600/P-02/001F (2004). Available at http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=54944.

aggregate exposures (i.e., multiple route exposures) to multiple agents or stressors" and has explained that:

> "In cumulative risk assessments that examine risks posed by multiple chemicals, exposure assessments evaluate a population's chemical exposures through multiple routes of exposure over time. Such assessments may encompass multiple exposure timeframes in which the timing and intensity of exposures to different chemicals are examined relative to each other. It is also important to determine whether the exposures to multiple chemicals can lead to toxicokinetic interactions or toxicodynamic interactions. In addition to providing information about multiple chemical exposures in the general population, these exposure assessments identify potentially susceptible or vulnerable subpopulations in the study area and potentially unique pathways of exposure in those subpopulations."[12]

We recommend that EPA scoping documents should provide for cumulative risk assessments whenever the evidence demonstrates that a defined population or subpopulation is exposed to multiple chemicals that have common modes of toxicity. In this situation, total risk to the relevant population or subpopulation will be a function of combined exposure to these different chemicals and their interaction with each other, which could be additive or synergistic depending on the circumstances. A compelling case for examining cumulative risks will exist where EPA is in parallel conducting risk evaluations on multiple chemicals within a class that have similar chemical structures, conditions of use and adverse health effects. An example of such a grouping is the four solvents (TCE, PERC, DCM and NMP) among the initial 10 chemicals: not only is it likely that workers and consumers are exposed to all or some of these solvents simultaneously but their common hazards (i.e. neurotoxicity, reproductive toxicity) are likely to magnify the risks of such concurrent exposures. Failure to consider cumulative risk scenarios would result in understatement of these risks and under-protection of exposed populations.

While the LCSA does not directly mention cumulative risk, section 26(c) of TSCA authorizes EPA to implement any provision of the law with respect to "categories," a term broadly defined to allow grouping of chemicals by toxicity, use, exposure pathways or chemical structure. By designating the four solvents among the initial 10 chemicals as a "category", EPA would be able to align its risk evaluations so they assess cumulative risks across the category in determining if the chemicals pose unreasonable risks.

V. EPA LACKS AUTHORITY TO "TIER" RISK EVALUATIONS OR DESIGNATE USES AS "LOW RISK" AT THE SCOPING STAGE

At the February 14, 2017 public meeting, industry argued that EPA should adopt a "tiered" approach to risk evaluation, with a "screening level" assessment at the scoping stage and then a more rigorous and comprehensive "full" evaluation for those uses or pathways that warrant

[12] EPA National Center for Environmental Assessment, *Concepts, Methods and Data Sources for Cumulative Health Risk Assessment of Multiple Chemicals, Exposures and Effects: A Resource Document,* at xxviii (August 2007).

closer examination. Uses and exposure pathways that are eliminated at the scoping stage, industry asserted, should be deemed not to present an "unreasonable risk" or treated as "low priority."

The Agency should reject these approaches as lacking any basis in the LCSA and as fundamentally unworkable.

The scoping process is intended to organize and array the available information on conditions of use, exposure pathways and hazards and to outline a strategy and set of methodologies for analyzing this information. It is not intended to make initial judgments about risk and could not realistically perform this function in any case. Conducting a preliminary risk analysis – whether for "screening" purposes or otherwise – of the multiple hazards, uses and exposure pathways associated with most high-priority chemicals would be a daunting task that is simply not feasible within the 6 month scoping process. If uses are dropped from the risk evaluation based on a cursory review at the scoping stage, the risk evaluation itself will be inadequate because critical exposure and hazard information pertaining to these uses will not be considered and the contribution of the uses to aggregate exposure and risk will not be taken into account.

Nor is a tiered approach to risk evaluation allowable under the statute. Under section 6(b)(4)(A), a risk evaluation is to be performed for the chemical as a whole, not individual uses. The only mechanism for determining that a chemical or individual conditions of uses do not present an unreasonable risk is completion of a full risk evaluation that meets all the requirements of section 6(b)(4)(F). An informal finding of low risk during the abbreviated scoping process is not a sufficient basis for this determination. Similarly, low priority designation under section 6(b)(1)(4)(ii) is aimed at chemicals, not individual uses, and requires a showing that the chemical lacks the potential for unreasonable risk under **all** its conditions of use. There is no basis to apply the "low priority" label to a specific use based on a limited evaluation during the scoping process, particularly where the remaining uses are known to present risks.

VI. DURING THE SCOPING PROCESS, EPA SHOULD USE CDR AND OTHER INFORMATION TO IDENTIFY COMMUNITIES WHERE SIGNIFICANT EXPOSURE TO THE CHEMICAL IS LIKELY

An important step during the scoping process should be identifying communities where, because of proximity to manufacturing, processing or disposal facilities, contaminated sites or air or water emissions and discharges, exposure to the subject chemical is likely to be elevated. Several information sources can help pinpoint these communities.

For example, reports submitted under EPA's Chemical Data reporting (CDR) rule must identify the sites where a chemical is manufactured and imported and describe the activities conducted at these sites. Reports filed for the Toxics Release Inventory (TRI) will likewise identify sites where a subject chemical is released into environmental media or disposed of in amounts above reportable quantities and describe the nature of these releases and their amounts. EPA

also has extensive data-bases on CERCLA "Superfund" sites that identify the chemicals contributing to soil or groundwater or drinking water contamination and often contain monitoring and other information describing the pathways, locations and levels of environmental releases. The same information is available for many Brownfields sites and for hazardous waste management and disposal facilities regulated under RCRA Subtitle C.

Collection and analysis of this information at the scoping stage will enable EPA to zero in on environmental justice communities or other population groups at increased risk from exposure to the chemical. This will in turn lead to identifying "potentially exposed or susceptible subpopulations" for which EPA must make determinations of unreasonable risk in its evaluations and protect from unsafe exposures under section 6(a) rules where such risks are present. In addition, EPA will have a stronger basis for identifying the pathways contributing to aggregate or cumulative exposures and the magnitude of such exposures. As a result, the scoping documents will be better able to outline the Agency's strategy for aggregate and cumulative exposure assessment.

Citizens of at risk communities frequently have important information about exposure conditions and indicators of elevated adverse health outcomes that can inform both the scoping and risk evaluation processes. After it identifies such communities using the sources and tools described above, EPA should reach out to and establish communications with community groups at the scoping stage or during the risk evaluation itself.

VII. IF EPA IDENTIFIES DISCONTINUED USES OF A CHEMICAL DURING THE SCOPING PROCESS, THEY SHOULD BE SNURED TO AVOID THEIR RESUMPTION BEFORE THE EVALUATION IS COMPLETE

In its own research on some of the 10 chemicals, SCHF has identified significant uses that have been discontinued. These former uses may not meet the definition of "conditions of use" in section 3(4) of TSCA if they are not contributing to ongoing exposure and EPA may in any case be reluctant to expend resources to address them during its risk evaluation. Nonetheless, such uses might be resumed during or after the risk evaluation process and the follow-up section 6(a) rulemaking, in which event they would avoid any scrutiny or regulation. Not all such uses will be of high concern and some may remain inactive, but the possibility exists that a resumed use could result in significant exposure at levels that would be considered unsafe based on EPA's risk evaluation. Because the use is outside the scope of the evaluation, however, EPA would lack the tools to eliminate these risks.

One mechanism to address this scenario is to use EPA's authority to issue significant new use rules (SNURs) under section 5(a)(2) of TSCA. Where a use has been discontinued, it would qualify as a "new use" based on EPA's well-established interpretation of its SNUR authority. The use would likely also be considered "significant" in light of the known health and environmental concerns identified when the chemical was first included in the Workplan list or during the scoping process for the evaluation. Thus, the basis for "significant new use" designation would

be clear-cut and the resources required for the SNUR rulemaking would be minimal. Once the SNUR is in place, EPA would have to be notified before the use is re-commenced and would be able to either allow or restrict the use in light of the analysis of hazard and exposure in its risk evaluation.

We urge EPA to identify discontinued uses during the scoping process and then to subject them to a SNUR.

CONCLUSION

We appreciate the opportunity to participate in the scoping process for the 10 chemicals and provide our recommendations on how to design and implement that process to assure that EPA's risk evaluations are comprehensive, science-based and protective of human health and the environment. We look forward to continue working with EPA on the 10 chemicals.

Respectfully submitted,

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On behalf of:

Alaska Community Action on Toxics
Alliance of Nurses for Healthy Environments
Asbestos Disease Awareness Organization
Autism Society of Minnesota
Breast Cancer Action
Breast Cancer Prevention Partners
(formerly Breast Cancer Fund)
Center for Environmental Health
Clean and Healthy New York
Clean Production Action
Clean Water Action
Conservation Minnesota
Earthjustice
Ecology Center
Environmental Health Strategy Center
Healthy Building Network
Healthy Legacy
LDA Minnesota
League of Conservation Voters
Learning Disabilities Association of America
Maryland Public Interest Research Group
Minnesota Center for Environmental Advocacy
Mitchell Environmental Health Associates
National Medical Association
Natural Resources Defense Council
NC Conservation Network
Oregon Environmental Council
Physicians for Social Responsibility
Safer States
Science and Environmental Health Network
Toxic-Free Future
U.S. Public Interest Research Group (PIRG)
Vermont Public Interest Research Group
WE ACT for Environmental Justice
Women for a Healthy Environment
Women's Environmental Institute