Before the United States
Environmental Protection Agency

Trichloroethylene: Regulation of Certain Uses
Under TSCA §6(a)
(Docket EPA-HQ-OPPT-2016-0163)

Comments of the Chemical Users Coalition

The U.S. Environmental Protection Agency recently issued for comment a proposed rule under Section 6 of the Toxic Substances Control Act ("TSCA"), at 81 Fed. Reg. 91592 (December 16, 2016), that would prohibit the manufacture, processing, distribution, and commercial use of trichloroethylene ("TCE") for aerosol degreasing and for spot cleaning in dry cleaning facilities. (Hereinafter, the "TCE1 Rule".) This proposed rule raises important precedential issues for the TSCA program, as modified by the Frank R. Lautenberg Chemical Safety for the 21st Century Act ("LCSA"). The Chemical Users Coalition ("CUC") appreciates the opportunity to provide comments concerning those issues.

CUC is an association of companies from diverse industries that are interested in chemical management policy from the perspective of those who use, rather than manufacture, chemical substances.[1] CUC believes in the importance of aligning protection of health and the environment with the pursuit of technological innovation, two goals that can and must be made compatible if our society is to achieve sustainable economic development. Aligning these goals is particularly important in the area of chemical management policy, which necessarily addresses how core technologies and products should be adapted to address emerging information about health and environmental risk.

CUC supported passage of the Frank R. Lautenberg Chemical Safety Act ("LCSA") and has a strong, continuing interest in implementation of the new law to assure that it results in an effective and efficient TSCA program. In commenting on the TCE1 Rule, CUC is focusing on specific statutory interpretations of TSCA and regulatory strategies set forth in EPA's proposed rule and preamble that may set important precedents for the program. Specifically, these comments address (a) EPA's interpretation of its Section 9 obligations; (b) the rationale for EPA's decision to regulate commercial users of TCE; and (c) a recommendation for EPA to undertake alternatives assessment for a set of solvents, including TCE, perchloroethylene, methylene chloride and 1-bromopropane.

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[1] The members of CUC are Intel Corporation, Procter & Gamble Company, American Honda Motor Corporation, Lockheed Martin Corporation, HP Incorporated, IBM Company, The Boeing Company, General Electric Company, and Airbus Americas S.A.S.

1. EPA's Interpretation of Section 9(a) is Inconsistent with the Statute

In the preamble to the proposed TCE1 Rule, EPA explains that it decided not to invoke the process set forth in Section 9(a) to determine whether another federal agency could sufficiently address the unreasonable risks identified in the proposed rule. Specifically, EPA did not send a Section 9(a) report to the Consumer Product Safety Commission ("CPSC") and the Occupational Safety and Health Administration ("OSHA") for the TCE aerosol degreasing products or to OSHA for the dry cleaning spot cleaner products that are covered by the proposal.

The rationale EPA has offered for this decision does not withstand scrutiny.[2] EPA should reconsider its decision on this matter, focusing on whether the unreasonable risks identified in the rulemaking "may be prevented or reduced to a sufficient extent" by these agencies, in the areas of their jurisdiction and expertise, based on the specific facts in the rulemaking record. EPA should not, as it has done in the preamble to the proposal, rely on a set of generic arguments that would essentially dismiss these agencies from ever being appropriate agencies for a Section 9(a) referral under TSCA. Such an approach would effectively write Section 9 out of the statute.

a. Structure and purpose of Section 9(a)

Section 9 of TSCA addresses the relationship of the statute to other federal laws, both at EPA and in other agencies, which have overlapping jurisdiction over chemical substances. Section 9 was part of the original TSCA statute, and was not substantially changed by the LCSA. The purpose of Section 9 is to create mechanisms for EPA to engage with other federal agencies and EPA programs, through a transparent process, to decide when it makes sense for the EPA TSCA program or some other federal program to address an unreasonable risk in a specific area. As stated in the Conference Report for the original TSCA statute in 1976, the purpose of Section 9 is "to assure that overlapping or duplicative regulation is avoided while attempting to provide for the greatest possible measure of protection to health or the environment."[3]

The process for EPA's engagement with other agencies is set forth in Section 9(a). The statute says that when EPA determines that a chemical substance presents an unreasonable risk, as specified under the statute, and determines (in the Administrator's discretion) that the risk "may be prevented or reduced to a sufficient extent" under a law not administered by EPA, the Agency must provide a report to the agency responsible for that law. The report must describe what constitutes the unreasonable risk, including the activities that EPA believes would

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[2] Since EPA did not invoke the Section 9(a) process with CPSC and OSHA, there is no record to evaluate whether those agencies could, would or should have properly addressed the risk issues identified in this rulemaking, and thus CUC takes no position on whether regulatory action by these agencies is appropriate in this case.

[3] H.R. Conf. Rep. No 94-1679, at 84 (1976).

present that risk. EPA's report also requests the other agency to provide a response about whether it could take action sufficient to prevent or reduce the identified risk, as well as the agency's view of whether the identified risk is an unreasonable risk. Where the other agency (a) determines that the identified risk is not an unreasonable risk; or (b) initiates action under its law to protect against the unreasonable risk, EPA may not take further action under Section 6(a) or Section 7 of TSCA.[4]

The LCSA made some modifications to Section 9, but it did not substantially change the general framework for Section 9(a) referrals to other agencies. It is worth noting, however, that the LCSA included a new Section 9(a)(5), which makes clear that EPA is not relieved of its risk management responsibilities under Section 6 for risks that "are not identified in a report" submitted to another agency under Section 9(a). As will be explained in more detail later in these comments, this language affirms that Congress anticipated that Section 9(a) referrals would be targeted to the jurisdictional scope of specific agencies.

Historically, EPA has addressed Section 9 on only a few occasions in Section 6 rules, and has not previously provided general guidance regarding implementation of Section 9. It now appears that EPA is using this rulemaking to establish a policy on implementation of Section 9 that effectively reads it out of the statute.

b. EPA's rationale for not initiating a Section 9(a) referral is flawed

EPA offers three rationales for why a Section 9(a) referral was not made for the uses in the proposed TCE1 Rule. First, EPA argues that its proposed rule is addressing "exposure to populations in both workplaces and consumer settings" and that TSCA is the only federal law that provides the authority "to prevent or sufficiently reduce these cross-cutting exposures."[5] The Agency further notes that neither CPSC nor OSHA can "bar the manufacture, processing and distribution [of chemical substances] for these uses" as EPA proposes to do.[6] Based on these conclusions, EPA concludes that neither CPSC nor OSHA can sufficiently address the identified unreasonable risk, as a matter of law.

In focusing on a generic argument related to legal authority, EPA is missing the point of its Section 9(a) obligations. It was self-evident in 1976 and 2016 that agencies like CPSC and OSHA had specific areas of jurisdiction that were not as expansive as TSCA's reach. If the 9(a) referral obligation turned exclusively on the theoretical jurisdiction of the respective agencies, TSCA would be superior to the other statutes every time, and Section 9 would be superfluous. Congress

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[4] The statute includes further specifics regarding the timelines, deadlines and public transparency regarding this process.

[5] 81 Fed. Reg. 91592 (December 16, 2016) ("FR Notice"), at 91619.

[6] Id.

would not enact such a meaningless provision. Further, Congress would not keep that same provision intact 40 years later in the LCSA, including a provision (as noted above) that anticipates that EPA would be making Section 9(a) referrals to other agencies addressing a subset of the uses that contribute to an overall unreasonable risk.

Thus the question presented in the context of this rulemaking is whether CPSC and OSHA can, as a matter of fact, sufficiently reduce the unreasonable risks identified in this rulemaking that are within the areas of their jurisdiction, using their available regulatory tools. As an example, the exposure of concern for spot cleaning in dry cleaning uses is solely an occupational risk, well within OSHA's jurisdiction. Similarly, the question of "sufficiency" of CPSC or OSHA action under Section 9(a) does not turn on the question of whether these agencies can take precisely the same actions that EPA is considering under Section 6(a). These agencies may have additional tools within their program scope that are just as effective, or even superior to, the regulatory options that EPA may take under TSCA.[7] These questions would be a subject for consideration in a Section 9(a) referral.

Second, EPA argues that OSHA does not have authority over the working conditions of state and local employees, which makes its regulatory authority inherently insufficient. There could be situations where this limitation in OSHA's authority would be a legitimate consideration in deciding whether a Section 9(a) referral made sense. In the context of this rule, however, it is not self-evident that state and local governments routinely operate dry cleaning establishments. The central point to note on this argument is that EPA's conclusion on this subject is unsubstantiated. Unless and until EPA provides information that supports this conclusion, EPA cannot rely upon it.

Third, EPA notes that the LCSA changes to the unreasonable risk standard of Section 6 "reduce the likelihood that an action under the CPSA [Consumer Product Safety Act], FHSA [Federal Hazardous Substances Act], or the OSH Act would reduce the risk of these uses of TCE so that the risks are no longer unreasonable under TSCA."[8] In making this argument, EPA focuses on the fact that the CPSC and OSHA authorities require considerations of cost, societal burden, and technological or economic feasibility, while TSCA risk management is guided by an unreasonable risk standard that only considers risk-based factors. This characterization is not entirely accurate as Section 6(c)(2) and Section 6(g)

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[7] It is worth noting that these agencies are likely to have superior implementation capabilities in the areas of their expertise, compared to that of EPA. Within EPA's Regional offices, the TSCA program has one of the smallest contingents of compliance and enforcement staff in the Agency, most of which have developed expertise on the implementation of TSCA programs for the PCBs, asbestos and lead regulations, which do not involve substantial work with consumer products or industrial workplace settings.

[8] FR Notice, at 91619.

of TSCA call for consideration of a variety of non-risk factors in selecting appropriate risk management measures.

The more fundamental flaw, however, in this conceptual argument by EPA is that it proves too much. EPA is essentially saying that referrals to CPSC and OSHA will never be justified, making Section 9(a) a meaningless provision. If Congress had intended the result suggested by EPA, it would have removed Section 9(a) from the statute when enacting the LCSA Section 6 unreasonable risk standard. It did not do so. The logical conclusion is that Congress wanted EPA to take its responsibilities under Section 9(a) seriously, expecting the Agency to review the facts in individual rulemakings and make case-by-case decisions about when a Section 9(a) referral is warranted. EPA has not done that here.

c. EPA is attempting to establish a broad policy on Section 9 that will eliminate its practical utility in future rulemakings

As noted above, the conceptual, statutory-based arguments that EPA is articulating in the TCE1 Rule preamble to avoid a Section 9(a) referral in this case would logically apply to virtually any other Section 6 rule under consideration. In fact, EPA provides the same set of arguments for avoiding a Section 9(a) referral, sometimes using identical wording, in the two other Section 6 rules it recently proposed – the rule on TCE for vapor degreasing and the rule on NMP and methylene chloride for paint stripping.[9]

CUC is concerned that EPA is essentially creating a general policy aimed at avoiding Section 9(a) referrals for all of its Section 6 rules. Using the statutory-based generic arguments presented in the preamble to this rule, EPA appears to be on a path of creating standard "boilerplate" preamble language that will become a routine insertion into the preambles for future Section 6 rules. We recognize that there will be situations where EPA will be able to develop a sound rationale for not invoking the Section 9(a) process. The process set out in Section 9(a), however, should be taken seriously and referrals to other agencies should be addressed on the merits of individual chemical risks and uses of concern. EPA cannot simply interpret Section 9(a) out of the statute.

2. EPA has not established a reasonable rationale for regulating commercial users of TCE

For both the aerosol degreasers and the dry-cleaning spot cleaners, EPA is proposing a regulatory response that has three elements: (a) a ban on manufacture (including import), processing and distribution of TCE-based products; (b) a ban on commercial use of these products for these purposes; and (c) notification to customers about these bans. In evaluating the options to EPA's proposed approach, the Agency recognizes that an option

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[9] *See* TCE Vapor Degreasing Rule, at 82 Fed. Reg. 7432 (January 19, 2017), and the NMP/MC Paint Stripping Rule, at 82 Fed. Reg. 7464 (January 19, 2017).

that just bans manufacture, processing and distribution, coupled with customer notification, "could reach the risk benchmarks for TCE."[10]

In both contexts, however, EPA insists that commercial users of these products must be regulated directly in order to assure protection of workers and consumers. The basis for this decision is an Agency belief that commercial users of the regulated products will seek to evade the restrictions by "diverting" TCE from other permitted uses for use as aerosol degreasers or dry cleaning spot cleaners. In one formulation of this concern, EPA states that not regulating commercial users directly "would leave open the likelihood that commercial users or consumers could obtain off-label TCE for aerosol degreasing. (emphasis added)"[11] Yet, EPA also concludes that "TCE is not a critical chemical for chemical degreasing and that substituting alternate chemicals would not be overly difficult."[12] The Agency further states, "A wide variety of effective substitutes for TCE in spot cleaning applications indicates that producers and users can readily shift from TCE to less hazardous chemical substitutes." The logic in EPA's justification for regulating commercial users, as stated, is at least unclear. The fact that something could happen does not establish that there is a likelihood that it will happen. What is even more problematic in EPA's analysis is that the Agency presents – but ignores - data indicating that there should be no compelling economic or technological motivation to try to evade the regulatory requirements, based on the availability of effective, readily-available alternatives.

EPA has a fundamental responsibility to provide compelling evidence before suggesting that commercial users will press their suppliers to manufacture, process and distribute banned products and thereby violate the law. The members of CUC are users of chemical substances under TSCA, and certainly do not engage in such practices. In this rulemaking, EPA has not offered any tangible evidence that commercial users of TCE will, or are likely to, encourage suppliers to provide them with TCE products that would violate federal law. Instead, EPA has offered only an assumption that those practices will occur, while at the same time providing a record, as noted above, indicating that there would not be strong incentives for any company to undertake such a practice.

There is another core element of TSCA that EPA has ignored in this analysis. Under Section 15(2) of the statute, it is unlawful to "use for commercial purposes a chemical substance or mixture which such person knew or had reason to know was manufactured, processed or distributed in commerce" in violation of Section 5 or 6, or any rule or order issued under those sections of the law. In the context of this rule, once EPA prohibits the manufacture, processing, and distribution of TCE for the uses specified in this regulation, commercial users of these products would be facing a parallel restriction on "use" of these products as a matter of law. There is no evidence in the record for this rule that

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[10] FR Notice, at 91605 for aerosol degreasers; a similar statement for spot cleaners is found in the FR Notice, at 91610.

[11] FR Notice, at 91605.

[12] FR Notice, at 91606.

EPA has considered this aspect of the TSCA statute in developing its rationale for regulating commercial users of these products.

Based on these considerations, EPA has not established that regulation of commercial users of TCE is justified to address the unreasonable risk identified in this rule. In addition, for future consideration, EPA should not attempt to regulate commercial users of chemical substances based on a simplistic, unsubstantiated assumption that commercial users have a habit of violating the law.

3. EPA should conduct an alternative assessment on the chemical substances that are likely to replace TCE in these applications

In the preamble of the proposed TCE1 Rule, EPA acknowledges that several of the likely replacements for TCE are chemical substances that have been identified as priorities for regulatory action under the mandates of the LCSA. On December 19, 2016, EPA published an initial list of 10 chemical substances that would be the subject of risk evaluations under the new provisions of Section 6.[13] Several of the substances on this list are common industrial solvents that could be used as replacements for TCE in the applications covered by the proposed TCE1 Rule. Specifically, 1-bromopropane and perchloroethylene may be replacements for TCE in dry cleaning spot cleaners, and methylene chloride, 1-bromopropane and perchloroethylene may be replacements in aerosol degreasers.

The preamble further indicates that 25% of TCE users will substitute perchloroethylene or 1-bromopropane for TCE in both the aerosol degreaser and dry cleaning spot cleaning markets.[14] EPA does not recommend the use of these chemicals as alternatives but recognizes that such substitution could occur. While EPA states that "all substitutes are expected to be less hazardous than TCE", the Agency also admits that it "has not developed risk estimates related to the use of substitutes."[15] As a record, for these statements, EPA has provided general profiles of existing hazard and exposure information on the alternatives to TCE for the two applications in the rule.[16]

EPA should conduct, and seek comment on, a more systematic comparative analysis of the chemical substances that have been identified as TCE replacements for these applications. The profiles that EPA has developed to date on these chemicals are useful but don't begin to offer the kind of rigor and product-specific data (e.g., concentrations of the respective chemicals in alternative products) that would be needed to conduct a

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[13] Section 6(b)(2)(A) required EPA to identify, and initiate risk evaluations on, 10 chemical substances.

[14] *See* FR Notice at 91602 and 91608.

[15] FR Notice, at 91602.

[16] EPA, "Analysis Report of Chemical Alternatives in Support of Risk Management Options for Use of TCE in Aerosol Degreasing and for Spot Cleaning in Dry Cleaning Facilities," EPA Document #740-R1-6001 (Draft Final, October 2016).

scientifically credible comparison. Without such an analysis, EPA may be pushing companies and consumers to move toward "regrettable substitutes" that will become candidates for future regulation by the Agency for these same applications.

Increasingly, policymakers have been adopting strategies and methodologies for conducting "alternatives assessment" on chemical substitutes as a means of evaluating hazard, exposure, resource and performance data through a systematic (and publicly transparent) process. An alternatives assessment on the chemical substances used in aerosol degreasing and dry cleaning spot cleaning would inform EPA's decision on the TCE1 rule and further advance its risk evaluations on the other solvent substances contained in the "initial list" for risk revaluation under the new Section 6 process.

Respectfully submitted,

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