



HSIA

halogenated
solvents
industry
alliance, inc.

March 15, 2013

TSCA Work Plan Chemicals Program
Environmental Protection Agency

Re: EPA-HQ-OPPT-2012-0723; CAS No. 79-01-6

Dear Sirs:

The Halogenated Solvents Industry Alliance, Inc. (HSIA) represents US producers and users of trichloroethylene (TCE, CAS No 79-01-6). TCE was identified in an initial group of seven “Work Plan Chemicals” for which the Environmental Protection Agency (EPA) recently completed risk assessments on which it solicits public comment. 78 Fed. Reg. 1856 (January 9, 2013).

HSIA has participated extensively in EPA risk assessments and rulemakings for TCE since its formation in 1980. HSIA welcomes the opportunity to submit these comments, which (i) demonstrate that exposures from use of TCE in small vapor degreasers are already more than adequately regulated under the Clean Air Act (CAA) and other relevant statutory authority, (ii) question the focus on a handful of auto and consumer and hobbyist arts and craft products, and (iii) show that EPA’s assessment of the risks posed are based on outdated exposure data and inappropriate inferences as to potential health effects.

Most importantly, HSIA believes that this exercise is *ultra vires* and could lead to a misallocation of EPA and private sector resources away from pressing environmental concerns. As discussed more fully below and in the attached technical comments, the risk assessments are largely based on use and exposure information that predate comprehensive regulation of the most important source of TCE emissions, vapor degreasing. This may be because EPA and its contractors failed to note that this sector is now controlled by emission limits that provide an “ample margin of safety to protect public health” as required by CAA § 112(f)(2).¹ Concern about “bystanders” would appear to be misplaced, as vapor degreasing

¹ 40 CFR Part 63, Subpart T. EPA is required, within eight years of publication of a national emission standard for a particular major source category, to conduct a “residual risk” review for that category to ensure an

occurs in occupational settings. And it would be a clear overreach of EPA's authority for it to assert the power to regulate to protect workers in occupational settings when this responsibility has been delegated by Congress to the Occupational Safety and Health Administration (OSHA) for over 40 years since passage of the Occupational Safety and Health Act of 1970.

EPA clearly believes the Toxic Substances Control Act (TSCA) to be in need of revision: "The American public has the right to expect that the chemicals manufactured, imported, and used in this country are safe and the EPA needs an effective law that gives us the tools necessary to provide the public with this assurance. The time is now to fix this badly outdated law. TSCA must be updated and strengthened so that the EPA has the tools to do our job of protecting public health and the environment."² TSCA has not been amended by Congress, however, and the language of the current statute cannot be read to give EPA the regulatory authority implicitly asserted in these Work Plan assessments.³

That said, we note that EPA recognized that "industrial settings [are] believed to be better controlled and monitored," and appropriately excluded TCE use in large commercial/ industrial solvent degreasing and as an intermediate (mostly in refrigerant manufacturing) from the scope of the Work Plan assessment. EPA might also wish to emphasize the significant reductions in TCE use over the past 25 years, emissions having dropped from 56 million pounds in 1988 to 2.6 million pounds in 2011 (see table at p. 5 of enclosed Technical Comments).

A. Statutory Framework – Regulation under TSCA § 6

Perhaps for the reasons summarized above, the assessment is silent as to the statutory authority under which EPA might base regulatory action to address the alleged risks from use of TCE in the applications identified. It appears, however, that EPA will be "determining, on the basis of final risk assessments, which chemical or chemicals may be appropriate for restrictions or bans authorized by Section 6 of TSCA."⁴

EPA may regulate a substance under TSCA § 6 only when "there *is* a reasonable basis to conclude" that the substance presents "an unreasonable risk of injury to health" (emphasis added). Thus, regulation under TSCA § 6 must be preceded by a determination that there is

ample margin of safety and to adopt more protective standards where a particular standard does not reduce lifetime excess cancer risks to the most exposed individual to less than one in a million. CAA § 112(f)(2).

² Testimony of James J. Jones, Acting Assistant Administrator, Office of Chemical Safety and Pollution Prevention, Environmental Protection Agency, before the Committee on Environment and Public Works and the Subcommittee on Superfund, Toxic and Environmental Health, United States Senate (July 24, 2012).

³ As the Supreme Court has stated, "Congress does not . . . hide elephants in mouseholes." *Whitman v. Am. Trucking Association*, 531 U.S. 457, 468 (2001).

⁴ *EPA to Focus on Existing Chemicals in 2013*, BNA Daily Environment Report, p. 2 (January 22, 2013).

an actual risk to health and that the benefits of regulation outweigh its costs. EPA has not identified the metrics it used to determine that TCE presents an “unreasonable risk” under TSCA § 6 and that the benefits of such regulation would outweigh its cost. A review of the evidence demonstrates that neither standard is met in the case of TCE.

In addition, TSCA § 6 requires:

“If the Administrator determines that a risk of injury to health or the environment could be eliminated or reduced to a sufficient extent by actions taken under another Federal law (or laws) administered in whole or in part by the Administrator, the Administrator may not promulgate a rule under subsection (a) of this section to protect against such risk of injury unless the Administrator finds, in the Administrator’s discretion, that it is in the public interest to protect against such risk under this chapter. In making such a finding the Administrator shall consider (i) all relevant aspects of the risk, as determined by the Administrator in the Administrator’s discretion, (ii) a comparison of the estimated costs of complying with actions taken under this chapter and under such law (or laws), and (iii) the relative efficiency of actions under this chapter and under such law (or laws) to protect against such risk of injury.”⁵

This provision is of special significance as EPA considers use of TCE in small vapor degreasers. EPA has already adopted a national emissions standard under CAA § 112 specifically to regulate emissions of TCE and five other chlorinated solvents from vapor degreasing operations.⁶ It required both major and area source batch and in-line cleaning machines to apply maximum achievable control technology (MACT) to meet emission standards.

More recently, EPA adopted facility-wide annual emission limits for these sources, in order to provide an “ample margin of safety to protect public health” as required by § 112(f)(2).⁷ These standards impose facility-wide limits based on application of cancer potency factors to estimated emission rates, as follows:

“To develop the proposed risk-based alternatives, all emission rates in the assessment data base were first converted to MC [methylene chloride]-

⁵ TSCA 6(c)(1); 15 U.S.C. § 2605(c)(1).

⁶ 40 CFR Part 63, Subpart T, initially adopted at 59 Fed. Reg. 61805 (December 2, 1994) (the “degreasing NESHAP”).

⁷ 72 Fed. Reg. 25138 (May 3, 2007). EPA is required, within eight years of publication of a national emission standard for a particular major source category, to conduct a “residual risk” review for that category to ensure an ample margin of safety and to adopt more protective standards where a particular standard does not reduce lifetime excess cancer risks to the most exposed individual to less than one in a million. CAA § 112(f)(2).

equivalents based on the relative cancer potency of the [hazardous air pollutants, or HAPs] emitted. The cancer-potency-weighted MC-equivalent emission rate was calculated as the estimated emissions for the HAP in [kilograms per year] or [pounds per year] times the unit risk estimate (URE) for the HAP divided by the URE for MC.”⁸

Moreover, the NESHAP limits emissions from batch vapor solvent cleaning machines (the type of open-top degreaser typically used by small facilities) to 150 kilograms per square meter (of the open face) per month.

In sum, CAA § 112(f) requires EPA to adopt standards that reduce lifetime excess cancer risks to the most exposed individual to less than one in a million for vapor degreasing, and EPA has done this. Regrettably, the Work Plan assessment fails to consider the degreasing NESHAP at all. If it had, EPA could have addressed how any TSCA authority realistically could achieve greater public health protection for vapor degreasing sources of TCE than EPA already is required to achieve and is achieving under current law. Before moving forward, in any event, TSCA § 6 requires the Administrator to find “that it is in the public interest to protect against such risk under [TSCA]. . . consider [ing] (i) all relevant aspects of the risk, . . . (ii) a comparison of the estimated costs of complying with actions taken under [TSCA and CAA § 112], and (iii) the relative efficiency of actions under [TSCA and CAA § 112] to protect against such risk of injury.”

1. Existence of Health Risk

A principal driver of the instant risk assessment is a mathematical demonstration of risk from data generated from high-dose animal studies. In reliance on conservative policy assumptions, the available human and animal evidence suggesting that such an extrapolation may not reflect reality was accorded no weight. A more solid scientific basis is required to support regulation under TSCA § 6.

Regulations adopted under TSCA § 6 must be based on “substantial evidence in the rulemaking record . . . taken as a whole,” as opposed to the more deferential standard of review prescribed in the Administrative Procedure Act.⁹ The decision of the U.S. Court of Appeals for the Fifth Circuit in *Gulf South Insulation v. Consumer Products Safety Commission*,¹⁰ in which the court applied the substantial evidence test to set aside the Commission’s ban of urea formaldehyde foam insulation, indicates the degree of certainty in the evidence required to support regulation under this strict standard of judicial review. The court found that a risk assessment based on a single data set, incorporating mathematical

⁸ 71 Fed. Reg. 47670, 47680 (August 17, 2006).

⁹ TSCA § 19(c)(1)(B)(i), 15 U.S.C. § 2618(c)(1)(B)(i).

¹⁰ 701 F. 2d 1137 (1983) (“*Gulf South*”).

extrapolation from high levels in rats to low levels in humans, does not constitute substantial evidence. Moreover, the court identified at least two assumptions from the Commission's risk assessment that were "of questionable validity" – that at identical ambient exposure levels the effective dose is the same for rodents as for humans, and that there is no threshold below which the chemical poses no risk of cancer.¹¹ These same two assumptions form the basis for the risk estimates in the TSCA Work Plan TCE assessment.

"Substantial evidence," then, means more than mathematical calculations based on conservative policy assumptions to the exclusion of all other scientific data. To justify regulation under TSCA § 6, there must be scientific evidence indicating a real risk of injury to health, not the mere possibility of risk. As the Supreme Court held in interpreting the Occupational Safety and Health Act, an agency cannot justify pervasive regulation on the basis of the mere possibility of some human risk.¹²

2. Economic Factors

Under TSCA § 6, the determination that an unreasonable risk is presented requires that any real risk identified be weighed against the costs associated with reducing it:

"In general, a determination that a risk associated with a chemical substance or mixture is unreasonable involves balancing the probability that harm will occur and the magnitude and severity of that harm against the effect of proposed regulatory action on the availability to society of the benefits of the substance or mixture, taking into account the availability of substitutes for the substance or mixture which do not require regulation, and other adverse effects which such proposed action may have on society."¹³

The higher the cost to society of regulation, the more serious the risk must be before EPA may regulate under TSCA § 6. Section 6(c)(1) requires EPA to consider specifically not only health effects and human exposure, but also the benefits of the substance for various uses, the availability of substitutes, and the economic consequences of any rule, including the effect on the national economy, small business, and technological innovation.

Congress recognized that regulation under TSCA § 6 could have severe economic consequences, and intended that these be accorded great weight in deciding whether to act under § 6:

¹¹ 701 F.2d at 1147, n. 19.

¹² *Industrial Union Dept., AFL-CIO v. American Petroleum Institute*, 448 U.S. 607 (1980).

¹³ H. Rep. No. 1341, 94th Cong., 2d Sess. 14, *reprinted in* H. Comm. On Interstate and Foreign Commerce, Legislative History of the Toxic Substances Control Act ("Legislative History") at 422 (1976); *see also* 122 Cong. Rec. S3499 (March 26, 1976), Legislative History at 212 (statement of Sen. Magnuson).

“[A TSCA § 6] requirement may remove a substance from the market or impose lesser restrictions on its availability and such a requirement is not of limited duration. Thus, the effect on society may be far reaching. As a result regulatory effect will be of greater significance in a determination of unreasonable risk for purposes of section 6 than for a determination for purposes of section 4 or 5(g) [T]he requirements for a determination of unreasonable risk for purposes of Section 4 or 5(g) are less demanding.”¹⁴

The Work Plan assessment contains none of the economic analysis that would be required to support a TSCA § 6 rulemaking. We note, however, that TCE is the solvent of choice for manufacturing a range of products to specification across the medical, electronics, aerospace, and many other industries. It is the best solution for many cleaning applications, and in some cases is the only solution. Aqueous cleaning, for example, is not an option where there is no tolerance for corrosion, rusting, and pitting of the substrate being cleaned. Alternative cleaning methods may leave residues, which are not acceptable in applications such as medical instruments and implants.

Forced substitution of TCE by aqueous or other solvent cleaners can also harm the environment. TCE is typically recycled as part of a controlled process, leaving only filters and sludge to be disposed of. Aqueous systems require much greater water usage and can produce large amounts of contaminated waste water, which when discharged can cause significant problems for publicly owned treatment works (POTWs).

Furthermore, a number of alternatives to TCE pose greater risks of flammability and/or toxicity. Acetone is highly flammable at room temperature; vapors from acetone in a degreasing machine can readily be ignited by sparks, which are commonly produced when metal parts being cleaned strike one another. Hexane and n-propyl bromide (nPB), also used as substitutes in certain operations, can result in significant risk of neurotoxicity.¹⁵

Airless degreasers have major operational disadvantages, as a number of equipment manufacturers have commented. Moreover, they are not an option in many applications. A number of companies in Pennsylvania clean the narrow tubes they manufacture in large (40-

¹⁴ H. Rep. No. 1341, 94th Cong., 2d Sess. 14-15, Legislative History at 422-23.

¹⁵ “UC Berkeley research scientist Michael Wilson studied auto mechanics disabled by a neurotoxic blend of hexane and acetone used as a brake cleaner. The product had been substituted for chlorinated solvents The next reformulation was no better: Hexane was swapped out for bromopropane, known to cause sterility, Wilson said.” (<http://www.universityofcalifornia.edu/news/article/22772>, reporting on UC Centers for Occupational and Environmental Health (COEH), Green Chemistry, Cornerstone to a Sustainable California (2008), p. 16; http://coeh.berkeley.edu/docs/news/green_chem_brief.pdf). See also Samukawa, M, Ichihara, G., Nobuyuki, O, Kusunoki, S., “A case of severe neurotoxicity associated with exposure to 1-bromopropane, an alternative to ozone-depleting or ozone-warming solvents.” *Arch. Intern. Med.* 172: 1257-1260 (2012) (use of nPB in metal degreasing operations identified as causing severe peripheral neuropathy in an exposed worker).

50 feet) custom-built equipment. No airless system is available that meets such requirements. These considerations led EPA to exempt narrow tube manufacturing facilities from the degreasing NESHAP.

B. Statutory Framework – Referral under TSCA § 9

As indicated above, TCE does not appear to present an unreasonable risk of injury to health for purposes of regulation under TSCA. Even if it were deemed to do so, however, TSCA § 9 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. Worker Exposure

The Work Plan TCE assessment addresses potential risks to workers and bystanders as a result of its use in vapor degreasing. As noted above, worker health and safety falls under the jurisdiction of OSHA. In an analysis of TSCA § 9, EPA’s Acting General Counsel concluded that “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.”¹⁶

OSHA has regulated occupational exposure to TCE for many years. The current workplace limits are 100 parts per million (ppm) as an 8-hour time-weighted average (TWA), 200 ppm as an acceptable ceiling concentration, and 300 ppm as an acceptable maximum peak (5 minutes in any 2-hour period) above the acceptable ceiling concentration for an 8-hour shift.¹⁷ OSHA should be given an opportunity to consider whether a lower workplace standard would be appropriate. Otherwise, if EPA were to go forward with regulation under TSCA, there would be a potential for conflicting and overlapping regulation. OSHA’s existing limits would remain in place, regardless of EPA’s action, and OSHA’s enforcement of its own standards is mandatory (subject to prosecutorial discretion). OSHA may not, however, enforce an EPA regulation under the general duty clause of the Occupational Safety and Health Act, even if the EPA regulation afforded greater protection, as long as an OSHA standard on the same substance is in effect.

It is also significant that EPA is not authorized to establish ambient concentration limits under TSCA § 6.¹⁸ EPA thus cannot limit employee exposure directly, but could only do so indirectly, *e.g.*, by controlling the amount of substance used in a product or prohibiting

¹⁶ Memorandum to Lee M. Thomas from Gerald H. Yamada, June 7, 1985, p. 2.

¹⁷ 29 CFR § 1910.1000 Table Z-2. HSIA members recommend compliance with Threshold Limit Values (TLVs) published by the American Conference of Governmental Industrial Hygienists (ACGIH). For TCE, the current TLVs are 10 ppm as an 8-hour TWA and 25 ppm as a Short Term Exposure Limit.

¹⁸ H. Rep. No. 1341, 94th Cong., 2d Sess. 34 (1976), *reprinted in* Legislative History at 441.

