



# HSIA

halogenated  
solvents  
industry  
alliance, inc.

March 30, 2012

TSCA Work Plan Chemicals Program  
Environmental Protection Agency

Re: EPA-HQ-OPPT-2011-0516; CAS Nos 75-09-2, 79-01-6

Dear Sirs:

The Halogenated Solvents Industry Alliance, Inc. (HSIA) represents US producers and users of the chemicals dichloromethane (DCM or methylene chloride, CAS No 75-09-2) and trichloroethylene (TCE, CAS No 79-01-6). DCM and TCE were recently identified in an initial group of seven "Work Plan Chemicals" for which the Environmental Protection Agency (EPA) intends to complete risk assessments in 2012. EPA asked that any relevant information be submitted by March 30, 2012 to be included in its review process.<sup>1</sup>

HSIA has participated extensively in EPA risk assessments and rulemakings for DCM and TCE since its formation in 1980. HSIA welcomes the opportunity to submit these comments, which we believe demonstrate conclusively that EPA should recognize that the potential risks posed by these compounds have been thoroughly reviewed and that manufacture, use, and disposal of these substances is more than adequately regulated under the Toxic Substances Control Act (TSCA) and other relevant statutory authority.

It appears that selection of DCM as a priority, in particular, may have omitted to take into account the exhaustive reviews and rulemakings initiated by EPA following its designation under TSCA § 4(f), discussed in § III below. The recent IRIS assessment, discussed in § I below, concludes that the potential hazard posed by DCM is even lower than EPA's estimates at the time of the 4(f) review, when it was judged to have "low carcinogenic hazard." We are mystified as to the rationale for considering further risk management steps for DCM in these circumstances. Before considering further risk management options, EPA should review the exhaustive catalog of federal regulation of DCM available in the attached OECD Risk Reduction Monograph.<sup>2</sup>

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<sup>1</sup> <http://www.epa.gov/oppt/existingchemicals/pubs/workplan.html>. These comments are a response to that rather uninformative notice in the abbreviated time frame provided. HSIA reserves the right to comment on any risk assessments of these compounds before they are adopted by EPA.

<sup>2</sup> Organisation for Economic Co-operation and Development, Risk Reduction Monograph No 2: Methylene Chloride, Background and National Experience with Reducing Risk (OECD Environment Monograph Series No 101 (1994)).

For TCE, while there was no priority review under TSCA § 4(f), § IV below makes clear that the regulatory structure governing current use and disposal is more than adequate. Nothing in the new IRIS assessment suggests that TCE poses a substantially greater potential cancer hazard than EPA previously assumed. The only issues with TCE relate to legacy contamination before there were restrictions on disposal of spent solvent wastes.

I. Both DCM and TCE Have Been the Subject of Comprehensive IRIS Reviews Completed in the Preceding Six Months

The 567-page final IRIS assessment for DCM was released four months ago.<sup>3</sup> It contained an inhalation unit risk estimate, EPA's standard measure of carcinogenic potency, of  $1.0 \times 10^{-8} (\text{ug}/\text{m}^3)^{-1}$ . This value is *lower* than the  $4.7 \times 10^{-7} (\text{ug}/\text{m}^3)^{-1}$  estimate previously reflected in IRIS.<sup>4</sup> We question how new information resulting from a comprehensive review intended to guide all of EPA's regulatory programs can be considered the basis to consider more stringent risk management steps when that new information indicates *less* hazard than previously assumed.

The situation for TCE is more complex. The 1200-page final IRIS assessment was released six months ago.<sup>5</sup> EPA first produced a draft Toxicological Review in 2001. The draft was seriously flawed, as revealed in a 2002 Science Advisory Board review and reflected by an interagency request to the National Research Council of the National Academy of Sciences to provide independent guidance on scientific issues to support an objective and scientifically balanced health risk assessment. The report that resulted<sup>6</sup> led to issuance of a substantially revised draft in 2009. The revised draft was improved in some respects but departed substantially from the Academy's guidance in others.

In the meantime an exhaustive assessment of the impacts of TCE contamination of drinking water at a major Marine Corps base was published by yet another committee of the

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<sup>3</sup> Toxicological Review of Dichloromethane (Methylene Chloride) (CAS No. 75-09-2) In Support of Summary Information on the Integrated Risk Information System (IRIS) (November 2011) (EPA/635/R-10/003F).

<sup>4</sup> Potential carcinogenicity drives risk management for carcinogens, as the levels considered by EPA to pose an "acceptable" cancer risk are invariably lower than those derived from other toxicity endpoints. We address the inhalation, as opposed to oral, values in these comments as most environmental regulation of chlorinated solvents addresses their emissions.

<sup>5</sup> Toxicological Review of Trichloroethylene (CAS No. 79-01-6) In Support of Summary Information on the Integrated Risk Information System (IRIS) (September 2011) (EPA/635/R-09/011F).

<sup>6</sup> Assessing the Human Health Risks of Trichloroethylene, Key Scientific Issues (National Academies Press 2006) (hereafter "2006 Report").

National Research Council.<sup>7</sup> This report places every cancer outcome reviewed in relation to exposure to TCE, perchloroethylene, or a mixture of the two into categories, taken directly from a 2003 report entitled *The Gulf War and Health* by the National Institute of Medicine. For TCE, the highest category any cancer outcome received was “limited or suggestive evidence of an association.”

The final IRIS assessment, on the other hand, takes the position that there is convincing evidence of a causal association between TCE exposure in humans and kidney cancer. Although the 2009 Report is referenced in the Toxicological Review, this major inconsistency was not explained or addressed. Moreover, the epidemiologic study on which this conclusion was primarily based was used as the basis for estimating the TCE slope factor, even though the 2006 Report concluded that “[t]here appear to be insufficient epidemiologic data to support quantitative dose-response modeling for trichloroethylene and cancer.”

That said, even with its deficiencies, nothing in the new IRIS assessment suggests that TCE poses a substantially greater potential cancer hazard than EPA previously assumed. The now-preferred inhalation unit risk estimate is  $4.1 \times 10^{-6} (\text{ug}/\text{m}^3)^{-1}$ . This may be compared to the screening level previously used by EPA of  $2 \times 10^{-6} (\text{ug}/\text{m}^3)^{-1}$ , which was 2-fold lower, or to the screening level prior to that, based on an oral slope factor in EPA’s 2001 draft IRIS assessment which was subsequently withdrawn.<sup>8</sup> The withdrawn value was equivalent to a 65-fold *higher* unit risk than the subsequent screening level, and thus very significantly higher than the current value as well. Nothing in the new IRIS assessment would appear to warrant selection of TCE as a priority for further risk assessment.

## II. EPA Should Establish Criteria for Listing in the Work Plan beyond the Appearance of a Substance on Lists

The criteria published by EPA for identifying substances in the Work Plan are so broad as to be nebulous:

- Chemicals identified as potentially of concern for children’s health.
- Chemicals identified as persistent, bioaccumulative, and toxic (PBT).
- Chemicals identified as probable or known carcinogens.

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<sup>7</sup> Contaminated Water Supplies at Camp Lejeune, Assessing Potential Health Effects (National Academies Press 2009) (hereafter “2009 Report”).

<sup>8</sup> Interim Recommended Trichloroethylene (TCE) Toxicity Values to Assess Human Health Risk and Recommendations for the Vapor Intrusion Pathway Analysis, Memorandum from Susan Parker Bodine, Assistant Administrator for Solid Waste and Emergency Response (January 15, 2009).

- Chemicals used in children's products.
- Chemicals used in consumer products.
- Chemicals detected in biomonitoring programs.<sup>9</sup>

Indeed, these are the same criteria identified a year ago when EPA announced the Chemical Action Plan (CAP) program.<sup>10</sup> For five of the eight chemicals listed under the CAP program, EPA indicated that it would initiate a TSCA § 5(b)(4)(A) listing that would identify them as substances that present or may present an unreasonable risk of injury to health or the environment. We understand that EPA submitted certain of the CAPs to the Office of Management & Budget (OMB) for clearance, and that no such clearance has been received. Hence, careful scrutiny is in order for another, apparently similar program created out of TSCA without clear statutory support.

Under the CAP program, EPA never identified the metrics it would use to determine when a chemical "may present" an "unreasonable risk" and qualify for listing under the statute. This opacity shielded the Agency's scientific and policy bases from public scrutiny and limited the effectiveness of Congressional oversight and judicial review. Failure to identify criteria may have been a factor in OMB declining to clear the program. In any event, the selection of the 83 chemicals in the TSCA Work Plan, and particularly of the seven chosen for priority risk assessment, does not provide comfort that sensible criteria are being applied.

### III. Adequate Regulation of DCM Has Already Been Achieved under TSCA

#### A. Regulation

In 1985, EPA initiated a priority review of risks of human cancer from exposures to DCM, using its authority under TSCA § 4(f).<sup>11</sup> Unlike the current Work Plan activity, invocation of TSCA § 4(f) gave EPA a clear focus. Based upon the results of the review, EPA was statutorily required to decide whether to initiate action under TSCA §§ 5, 6, or 7 to prevent or reduce significant risk of serious or widespread harm or to publish a finding that such risk (if any) as exists is not unreasonable.

TSCA § 5, which governs notifications of manufacture of new chemicals and manufacture and processing of chemicals for significant new uses, was largely irrelevant to DCM, as was § 7, which authorizes civil actions for relief from imminent hazards. The

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<sup>9</sup> <http://www.epa.gov/oppt/existingchemicals/pubs/workplan.html#assess>.

<sup>10</sup> <http://www.epa.gov/oppt/existingchemicals/pubs/chempridiscguide.html>.

<sup>11</sup> 50 Fed. Reg. 20126 (May 14, 1985).

alternative appeared to be rulemaking under TSCA § 6, referral to other agencies under TSCA § 9, or publication of a finding that any risk posed by DCM exposure is not unreasonable.

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.” Thus, regulation under TSCA § 6 must be preceded by a determination that there is an actual risk to health and that the benefits of regulation outweigh its costs. A review of all of the evidence demonstrated that neither standard was met, and EPA proceeded with referral to other agencies under TSCA § 9.

As a result of these referrals, the Consumer Product Safety Commission (CPSC), the Occupational Safety & Health Administration (OSHA), and the Food & Drug Administration (FDA) adopted regulations of DCM uses under their respective jurisdictions that remain in effect today. In brief, CPSC adopted cautionary labeling for household products containing DCM that would meet or exceed the requirements of the Federal Hazardous Substances Act:

“Front Panel

“CAUTION: Vapor Harmful, Read Other Cautions  
and HEALTH HAZARD INFORMATION on Back Panel

“[Or equivalent language]

“Back Panel

“Contains methylene chloride, which has been shown to  
cause cancer in certain laboratory animals. Risk to your  
health depends on level and duration of exposure.

“[Or equivalent language]

“[The back panel labeling given above would be placed separately from use precaution information such as the following.]

“Use this product outdoors, if possible. If you must use it  
indoors, open all windows and doors or use other means to ensure  
fresh air movement during application and drying. If properly used,  
a respirator may offer additional protection. Obtain professional advice  
before using. A dust mask does not provide protection against vapors. Do  
not use in basement or other unventilated area.”<sup>12</sup>

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<sup>12</sup> 52 Fed. Reg. 34698 (September 14, 1987).

After a rulemaking that lasted ten years, OSHA adopted a standard under § 6(b)(5) of the Occupational Safety and Health Act lowering the workplace exposure limit for DCM from 500 parts per million (ppm) to 25 ppm as an 8-hour time-weighted average (TWA). In addition, it established a short-term (15-minute) exposure limit (STEL) of 125 ppm and an action level for concentrations of airborne DCM of 12.5 ppm (8-hour TWA).<sup>13</sup>

FDA also took action following initiation of the priority review. DCM had been used as an ingredient of aerosol cosmetic products (principally hair sprays). FDA determined that any cosmetic product containing DCM as an ingredient would be deemed adulterated.<sup>14</sup> At the same time, FDA decided to maintain the limit (10 ppm) it had established on the amount of DCM that can remain after processing of spices, hops extract, and decaffeinated coffee.<sup>15</sup>

EPA itself has adopted a number of national emission standards that limit emissions of DCM, which is a Hazardous Air Pollutant (HAP) listed in Clean Air Act (CAA) § 112. These include, for only the more important commercial applications of DCM, National Emission Standards for Organic Hazardous Air Pollutants from the Synthetic Organic Chemical Manufacturing Industry,<sup>16</sup> for Halogenated Solvent Cleaning,<sup>17</sup> for Aerospace Manufacturing and Rework Facilities,<sup>18</sup> for Shipbuilding and Ship Repair (Surface Coating),<sup>19</sup> for Wood Furniture Manufacturing Operations,<sup>20</sup> for Pharmaceuticals Production,<sup>21</sup> for Flexible Polyurethane Foam Production,<sup>22</sup> for Flexible Polyurethane Foam Fabrication Operations,<sup>23</sup> for Paint Stripping and Miscellaneous Surface Coating Operations at Area Sources,<sup>24</sup> for Flexible Polyurethane Foam Production and Fabrication Area Sources,<sup>25</sup> and for Chemical Manufacturing Area Sources.<sup>26</sup>

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<sup>13</sup> 29 CFR § 1910.1052; 62 Fed. Reg. 1494 (January 10, 1997).

<sup>14</sup> 21 CFR § 700.19; 54 Fed. Reg. 27328 (June 29, 1989).

<sup>15</sup> 21 CFR § 173.255.

<sup>16</sup> 40 CFR Part 63, Subpart F.

<sup>17</sup> 40 CFR Part 63, Subpart T.

<sup>18</sup> 40 CFR Part 63, Subpart GG.

<sup>19</sup> 40 CFR Part 63, Subpart II.

<sup>20</sup> 40 CFR Part 63, Subpart JJ.

<sup>21</sup> 40 CFR Part 63, Subpart GGG.

<sup>22</sup> 40 CFR Part 63, Subpart III.

<sup>23</sup> 40 CFR Part 63, Subpart MMMMM.

<sup>24</sup> 40 CFR Part 63, Subpart HHHHHH.

Most significantly, 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.<sup>27</sup> It is unclear how any TSCA authority realistically could achieve greater public health protection for sources of DCM than EPA already is required to achieve under current law.

## B. Uses

### Consumer Paint Stripping

DCM historically has comprised 60 to 80 percent of the organic nonflammable paint strippers on the market. There is no substitute for DCM in these products. Even flammable organic paint strippers usually contain 30 to 40 percent DCM to enhance stripping effectiveness. Some varnishes and lacquers can be stripped with a combination of hydrocarbon and oxygenated solvents such as toluene, xylene, mineral spirits, acetone, and methanol, but such solutions are not as effective as those containing DCM.

Strippers based on caustic soda (sodium hydroxide) are not viable alternatives to organic strippers because they are not effective at room temperature and present a significant danger of injury upon skin or eye contact. Caustic strippers can also damage wood surfaces and destroy the patina on antique furniture and veneers.

Heat guns are satisfactory on some wood products such as moldings, but are not effective on furniture having curved surfaces. Moreover, decomposing coatings give off noxious and possibly toxic fumes.

### Industrial Paint Stripping

Some coatings can be stripped in dip tanks containing hot caustic soda solutions and activators. This procedure usually requires a longer soak time and is not effective on all coatings. Some of the modern coatings are extremely difficult to strip and require activated DCM solutions. As indicated above, caustic solutions present a significant danger of injury upon skin or eye contact.

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<sup>25</sup> 40 CFR Part 63, Subpart OOOOOO.

<sup>26</sup> 40 CFR Part 63, Subpart VVVVVV.

<sup>27</sup> CAA § 112(f)(2).

Cryogenic stripping with liquid nitrogen is a possible alternative, but would not be effective for all coatings and would present a significant danger of injury upon skin contact.

Sand blasting is another alternative with limited application. It can damage the substrate from which the coating is being removed, particularly if the substrate consists of a soft metal like aluminum. It also requires safety equipment for operator protection.

Pyrolysis and molten salt bath techniques are possible alternatives for paint racks and hooks. However, their high capital costs and energy demands are disadvantageous, and they may present a thermal hazard.

### Commercial Furniture Strippers

Many small, independent furniture stripping shops throughout the country depend on DCM-based strippers for their continued existence. No acceptable alternative for antique furniture stripping has been developed.

Hot caustic soda dip tanks are used to some extent in stripping, but this process raises the grain of the wood and changes its appearance and loosens the glue joints, making it unacceptable for fine wood furniture and antiques. Moreover, veneers cannot safely be stripped with this process. This technique is satisfactory only for stripping wood prior to repainting where the surface appearance is not critical.

Of the organic chemicals, benzene, chloroform, propylene dichloride, acetone, and n-methyl pyrrolidone have been used, but have generally been replaced by DCM on the basis of flammability, toxicity, and stripping efficiency. Substitution of a flammable stripper for DCM could result in significantly increased insurance rates, judging from inquiries received from a number of insurers. Reportedly, some shops would not be able to obtain insurance if they used flammable strippers. Moreover, DCM-based strippers, because of their greater effectiveness, cannot be replaced in certain furniture stripping applications.

### Military Maintenance

All of the nonflammable organic strippers defined by military and government specifications are DCM-based. At this time, there are no reasonable alternatives that meet the specifications.

### Aerosols

Prior to EPA's announced concern over use of CFCs in aerosols, relatively little DCM was used in this application. Thereafter, DCM became more widely used, and serves several important functions in aerosol applications in a variety of production formulations. It is a very strong solvent, a flammability suppressant, a vapor pressure depressant and a viscosity



thinner, and it provides good atomization and high evaporation rate. No single alternative has all these technical qualities.

### Cold Cleaning

DCM is used alone or in combination with flammable, less expensive hydrocarbon solvents to raise the flash point of safety solvent blends for various cold cleaning jobs. Its high evaporation rate and superior solvency are important properties in these applications and are not matched by nonflammable substitutes. A change to flammable solvents can result in an increased risk of fire-related injuries or deaths and in substantially increased insurance rates.

### Vapor Degreasing

DCM is ideal for low temperature vapor degreasing applications because it will not harm heat-sensitive parts, will not bake on heat-sensitive soils, and can be used with a heat pump to conserve energy and reduce costs. TCE and perchloroethylene are possible alternatives in other vapor degreasing applications, but use of these solvents can require costly equipment modification to accommodate the increased heat input needed.

### Polyurethane Foam Blowing and Fabrication

DCM has been widely used in polyurethane foam manufacture and fabrication.

### Pharmaceuticals Processes

The pharmaceutical industry uses DCM in pill coating, as a reaction medium and recrystallization solvent, and perhaps in other proprietary operations. Alternative pill coating solvents and techniques exist, but they require substitution of flammable solvents (*e.g.*, ethanol) resulting in increased fire risks. An alternative reaction medium or extraction solvent would have to combine chemical inertness, special solvency for reactants, ease of separation, and nonflammability. Accordingly, replacement of DCM in such operations could require extensive research and process equipment changes and might not be feasible in some cases.

### Cellulose Triacetate Fiber

DCM was at one time critical in cellulose triacetate fiber production. The fiber industry has undertaken extensive efforts to find alternative solvents or processes but we do not have current information on the success of these efforts.

### Electronics Manufacturing

Most DCM consumed in the electronics industry is used in the manufacture of printed circuit boards. Many processes for “stripping” solvent-based photoresist depend on pure or formulated DCM. Major research costs would be required to find a substitute for DCM processing of ultra-fine line circuitry. In other electronics applications, water-based photoresist can be used. Solvent-based photoresist equipment is not usable in the aqueous process, and replacing this equipment for an aqueous system would be very expensive. Aqueous systems may also require increased process control to maintain proper chemical balance. There are a significant number of small printed circuit board specialty businesses that depend on solvent photoresist know-how and very low equipment investments to manufacture small lot orders profitably. Recapitalization to an aqueous process and departure from their solvent technology base could seriously threaten their existence.

### Coffee Decaffeination

Processes designed specifically for DCM probably could not use an alternative solvent. DCM is reported to preserve flavor better than alternatives. Super critical carbon dioxide is in use in Europe, but would require major equipment changes costing millions of dollars, according to domestic coffee marketers. Other methods are reported to be in use, but they significantly increase manufacturing costs and may involve the use of chemicals whose toxicity has not been tested as thoroughly as that of DCM.

### IV. Trichloroethylene is Also Adequately Regulated

The regulation and use of TCE, compared to DCM, is quite straightforward. As acknowledged in the IRIS assessment, almost all TCE is used in vapor degreasing, where it has long been the solvent of choice for a variety of technical factors. Even in the industry sectors identified separately (*e.g.*, aerospace manufacturing and rework), TCE is used in vapor degreasing. Vapor degreasing with TCE and other chlorinated solvents is already adequately regulated. The National Emissions Standard for Halogenated Solvent Cleaning, adopted by EPA in 1994 and updated in 2006, imposes strict controls on emissions of TCE from vapor degreasing operations throughout American industry.<sup>28</sup>

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.

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<sup>28</sup> 40 CFR Part 63 Subpart T. Like DCM, TCE is a listed “Hazardous Air Pollutant” in CAA § 112.

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, also used as substitutes in certain operations, can result in significant risk of neurotoxicity and/or reproductive effects. "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 [n-propyl bromide], known to cause sterility, Wilson said."<sup>29</sup>

Airless degreasers have major operational disadvantages. Moreover, they are not an option in many applications. A number of companies that were granted an exemption from certain Subpart T requirements clean the narrow tubes they manufacture in large (40-50 feet) custom-built equipment. No airless system is available that meets such requirements.

In sum, forced substitution of TCE in vapor degreasing would not have any beneficial effect on public health, but would drive more of the industrial economy, and associated manufacturing jobs, offshore.<sup>30</sup>

## V. Conclusion

HSIA is puzzled as to how DCM and TCE came to be identified in a group of seven priority "Work Plan Chemicals" for which EPA intends to complete risk assessments in 2012. Comprehensive risk assessments for DCM and TCE were just issued in the past six months by the EPA program office charged with developing such guidance for use across all EPA program offices. Those assessments showed lower potency for DCM, and similar potency for TCE, to earlier assessments. Moreover, both compounds are among the most thoroughly studied and heavily regulated of all industrial chemicals. It would seem more

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<sup>29</sup> <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](http://coeh.berkeley.edu/docs/news/green_chem_brief.pdf).

<sup>30</sup> TCE exposure is also regulated in the workplace. The Occupational Safety and Health Administration (OSHA) has established a permissible exposure limit (PEL) of 100 ppm for an 8-hour time-weighted-average (TWA), 200 ppm (ceiling), and 300 ppm (peak). 29 CFR § 1910, Table Z. These limits are out of date, and HSIA member companies recommend compliance with the threshold limit value (TLV) of 10 ppm for an 8-hour TWA recommended by the American Conference of Governmental Industrial Hygienists.

appropriate for EPA to use its limited resources to review substances that have not already been the subject of so much regulatory attention.

Respectfully submitted,

*Faye Graul / wcn*  
Faye Graul  
Executive Director

Enclosure