HSIA
halogenated
solvents
industry
alliance, inc.

March 15, 2013

TSCA Work Plan Chemicals Program
Environmental Protection Agency

Re: EPA-HQ-OPPT-2012-0725; CAS No. 75-09-2

Dear Sirs:

The Halogenated Solvents Industry Alliance, Inc. (HSIA) represents US producers and users of dichloromethane (DCM or methylene chloride, CAS No 75-09-2). DCM 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).

The DCM assessment focuses on "risks due to occupational and residential use of paint strippers containing DCM." Specifically, the assessment is focused on exposures to workers employed by "small commercial shops," *i.e.*, those employing fewer than ten workers. HSIA welcomes the opportunity to submit these comments, which (i) demonstrate that occupational and consumer exposures from use of DCM in paint stripping are already more than adequately regulated under the Toxic Substances Control Act (TSCA) and other relevant statutory authority, and (ii) show that EPA's assessment of the risks posed are based on outdated exposure data and inappropriate inferences as to potential health effects.[1]

I. Adequate Regulation of DCM Has Already Been Achieved under TSCA and other Statutory Authorities

A. Statutory Framework – Regulation under TSCA § 6

The assessment is silent as to the statutory authority under which EPA might base regulatory action to address the alleged risks from use of DCM in paint stripping. It appears,

[1] EPA appropriately excluded DCM use in adhesives, pharmaceuticals, metal cleaning, chemical processing, aerosols (propellant use), and polyurethane foam from the scope of the Work Plan assessment.

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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."[2]

In 1985, EPA initiated a priority review of risks of human cancer from exposures to DCM, using its authority under TSCA § 4(f).[3] Under the statutory language of TSCA, there is a substantial difference between the amount of evidence and extent of analysis required to support a decision to initiate a priority review under § 4(f) and that required to justify regulatory action under § 6. Section 4(f) is triggered when "there *may be* a reasonable basis to conclude" that a substance presents "a significant risk of serious or widespread harm" (emphasis added).

In contrast, 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 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 DCM 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 DCM and paint stripping.

Moreover, 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."[4]

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

[3] 50 Fed. Reg. 20126 (May 14, 1985).

[4] TSCA 6(c)(1); 15 U.S.C. § 2605(c)(1).

EPA itself, in the years following the § 4(f) review, 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, notably, National Emission Standards for Organic Hazardous Air Pollutants for Paint Stripping and Miscellaneous Surface Coating Operations at Area Sources,[5] a standard which covers the very risk upon which the Work Plan assessment is focused. If this risk is significant, EPA *must* adopt more protective standards under the Clean Air Act.[6] 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.

1. Existence of Health Risk

The basis for EPA's TSCA § 4(f) review was the mathematical demonstration of risk from data generated by a single high-dose animal study. 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. Whether or not this was an appropriate response to the statutory mandate of § 4(f), 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.[7] The decision of the U.S. Court of Appeals for the Fifth Circuit in *Gulf South Insulation v. Consumer Products Safety Commission*,[8] 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 one data set, incorporating mathematical 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.[9] These same two assumptions form the basis for the risk estimates in the TSCA Work Plan DCM assessment.

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[5] 40 CFR Part 63, Subpart HHHHHH.

[6] 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).

[7] TSCA § 19(c)(1)(B)(i); 15 U.S.C. § 2618(c)(1)(B)(i).

[8] 701 F. 2d 1137 (1983) ("*Gulf South*").

[9] 701 F.2d at 1147, n. 19.

"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.[10]

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."[11]

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 greater weight in deciding whether to act under § 6 than under § 4:

> "[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."[12]

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

[11] 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).

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

The Work Plan assessment contains none of the economic analysis that would be required to support a TSCA § 6 rulemaking. We note, however, that 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. And decomposing coatings give off noxious and possibly toxic fumes.

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.

B. Statutory Framework – Referral under TSCA § 9

As indicated above, DCM 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." Notably, the Work Plan DCM assessment addresses potential risks to workers and consumers as a result of paint stripping use. Worker and consumer health and safety fall under the jurisdictions, respectively, of the Occupational Safety and Health Administration (OSHA) and the Consumer Product Safety Commission (CPSC). 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."[13]

Indeed, as part of its TSCA § 4(f) review, EPA issued an advance notice of proposed rulemaking (ANPR) in which it announced that it would be conducting, in consultation with other federal agencies, a comprehensive and integrated regulatory investigation of DCM.[14] Thereafter, EPA reported on how "the integrated regulatory investigation led to significant exposure reductions in the major chlorinated solvent use applications, and established a precedent for future cooperative regulatory endeavors."[15] The notice indicated that an Interagency Work Group, chaired by EPA's Office of Toxic Substances, had been formed "to determine whether DCM presents a significant risk to human health or the environment, and to determine if regulatory actions are needed to limit exposures to DCM." The notice then described risk management actions completed by each agency, as well as a discussion of ongoing risk control activities.

It is regrettable that the current TSCA Work Plan activity is apparently being conducted without reference to the successfully completed DCM TSCA review. As a consequence, how EPA intends to use the risk assessment it has developed is unclear, as is the authority under which EPA is acting.

OSHA has regulated occupational exposure to DCM for many years. Following the § 4(f) review, 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).[16] 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 standard 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.

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

[14] 50 Fed. Reg. 42037 (October 17, 1985).

[15] 56 Fed. Reg. 24811 (May 31, 1991).

[16] 29 CFR § 1910.1052; 62 Fed. Reg. 1494 (January 10, 1997).

It is also significant that EPA is not authorized to establish ambient concentration limits under TSCA § 6.[17] 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 a particular use of the substance under § 6. This is potentially much more burdensome economically than ambient standards, which permit each employer subject to the standards to achieve the necessary reduction in exposure in the most cost-effective manner. Yet Executive Order 13563 requires agencies to achieve their objectives by using the least costly regulatory alternative.[18]

There is also a long history of CPSC involvement with DCM, beginning in the mid-1970s. Following the TSCA § 4(f) referral, CPSC adopted cautionary labeling for household products containing DCM, including paint strippers, 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]

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

[18] Improving Regulation and Regulatory Review, 76 Fed. Reg. 3821-3823 (January 21, 2011). In pertinent part, E.O. 13563 states:

"This order is supplemental to and reaffirms the principles, structures, and definitions governing contemporary regulatory review that were established in Executive Order 12866 of September 30, 1993. As stated in that Executive Order and to the extent permitted by law, each agency must, among other things: (1) propose or adopt a regulation only upon a reasoned determination that its benefits justify its costs (recognizing that some benefits and costs are difficult to quantify); (2) tailor its regulations to impose the least burden on society, consistent with obtaining regulatory objectives, taking into account, among other things, and to the extent practicable, the costs of cumulative regulations; (3) select, in choosing among alternative regulatory approaches, those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity); (4) to the extent feasible, specify performance objectives, rather than specifying the behavior or manner of compliance that regulated entities must adopt; and (5) identify and assess available alternatives to direct regulation, including providing economic incentives to encourage the desired behavior, such as user fees or marketable permits, or providing information upon which choices can be made by the public."

> "[The back panel labeling given above would be placed separately from use precaution information such as the following.]
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> > "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."[19]

In light of the foregoing activities, considerations of avoiding unnecessary duplication and utilizing established expertise weigh in favor of invoking the Administrator's referral authority under TSCA § 9(a) even if EPA were to proceed under TSCA. If EPA were to identify a category of exposure deemed to present a risk that is unreasonable, these considerations indicate that referral under § 9(a) would be the appropriate course.[20] It is clear from Section 9(a) that TSCA is to be used only when other statutes fail to provide a remedy for unreasonable risks. Representative James Broyhill of North Carolina indicated that "it was the intent of the conferees that the Toxic Substance Act not be used, when another act is sufficient to regulate a particular risk."[21] EPA applied this statutory directive in determining that the risk from 4,4' methylenedianiline (MDA) could be prevented or reduced to a significant extent under the Occupational Safety and Health Act, and referring the matter for action by OSHA.[22]

The Food & Drug Administration (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.[23] At the same time, FDA decided to maintain the

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[19] 52 Fed. Reg. 34698 (September 14, 1987).

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

[21] 122 Cong. Rec. H11344 (Sept. 28, 1976).

[22] 50 Fed. Reg. 27674 (July 5, 1985).

[23] 21 CFR § 700.19; 54 Fed. Reg. 27328 (June 29, 1989).