September 15, 2010

Mr. Bob Barish
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Re: Feasibility Advisory Committee – Trichloroethylene

The Halogenated Solvents Industry Alliance, Inc. (HSIA) represents producers and users of trichloroethylene (TCE), a chlorinated solvent widely used in vapor degreasing and other applications. HSIA has previously commented in relation to the potential health effects of TCE. In these comments, we address the feasibility (or, rather, the complete infeasibility) of the 0.4 part per million (ppm) 8-hour time-weighted average (TWA) permissible exposure limit (PEL) recommended by the Health Expert Advisory Committee.

Vapor degreasing remains an important part of the California manufacturing economy. According to data collected by the federal Environmental Protection Agency as it developed national emissions standards in 2006, there were 589 vapor degreasing operations in California, over half of the 1094 total nationwide.[1]

The adoption of PELs by Cal/OSHA for toxic materials is governed by Section 144.6 of the Labor Code. It provides that, in setting standards, the Standards Board shall:

> "… adopt that standard which most adequately assures, *to the extent feasible*, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to a hazard regulated by such standard for the period of his working life. Development of standards … shall be based upon research, demonstrations, experiments, and such other information as may be appropriate. In addition to … health and safety protection for the employee, other considerations shall be the latest available scientific data in the field, the reasonableness of the standards, and experience gained under this and other health and safety laws."

Emphasis added.

Evidence of Feasibility

There appears to be no evidence of feasibility in the record of this proceeding. The two TCE links on the website concern potential carcinogenicity and related matters, and neither the discussion nor the references reflect any consideration of feasibility. It should be obvious, however, from even the briefest review of the existing workplace limits/recommendations, some of which do take feasibility into account, that 0.4 ppm would be extreme. Existing limits/recommendations, expressed as 8-hour TWAs, range from 100 ppm (federal Occupational Safety & Health Administration (OSHA) § 1910.1000 (Table Z) to 25 ppm (existing Cal/OSHA) to 10 ppm (American Conference of Industrial Hygienists (ACGIH) Threshold Limit Value (TLV). Thus, on its face the recommended TWA is 250 to 25 times lower than existing workplace limits.

[1] Degreaser Distribution by State, SIC and Urbanization, EPA-HQ-OAR-2002-0009-0057.2. TCE is the predominant chlorinated solvent used in degreasing.

To assist in your review of feasibility, we enclose two reviews. The first is a recently published modeling effort by scientists with the National Institute for Occupational Safety & Health and others.[2] For trichloroethylene, Table 5 shows a median of 7 ppm for measured data and a median of 30 ppm for "predicted intensity," a term which is not defined but appears to reflect the authors' best estimate of historic (for TCE from 1950) workplace exposure. The authors note that "[f]or trichloroethylene, the large difference in percentage of reported versus predicted levels exceeding the current ACGIH TLV and the higher percentage of predictions above the 1% SVP [saturation vapor pressure] threshold were due predominately to estimates derived from the earlier decades (*i.e.*, 1950s – 1970s)." It should also be noted that before 2006 the ACGIH TLV for TCE was 50 ppm or higher.

The second enclosure is a review of more recent (2001 – 2009) samples from the OSHA compliance industrial hygiene database.[3] While the data cover a very wide range (<1 – 3292 ppm), the majority of the values are between 5 and 50 ppm.

Legal Standard for Review

Section 144.6 closely mirrors Section 6(b)(5) of the federal Occupational Safety and Health Act ("OSH Act"), which reads:

> "The Secretary, in promulgating standards dealing with toxic materials or harmful physical agents under this subsection, shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life. Development of standards under this subsection shall be based upon research, demonstrations, experiments, and such other information as may be appropriate. In addition to the attainment of the highest degree of health and safety protection for the employee, other considerations shall be the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws. Whenever practicable, the standard promulgated shall be expressed in terms of objective criteria and of the performance desired."

Decisions of the U.S. Supreme Court and the federal appellate courts construing this substantially similar statutory language make clear that "feasible" means "capable of being done, executed, or effected," both technologically and economically.[4] "To show that a standard is technologically feasible, OSHA must demonstrate 'that modern technology has at least conceived some industrial strategies or devices which are likely to be capable of meeting the PEL and which the industries are generally capable of adopting.'"[5] To show economic feasibility, "OSHA must 'provide a reasonable assessment of the likely range of costs of its standard, and the likely effects of those costs on the industry,' so as to 'demonstrate a reasonable likelihood that these costs will not threaten the existence or competitive structure of an industry, even if it does portend disaster for some marginal firms.[6]

Cal/OSHA has not shown, nor is there any evidence in the record to support, that a PEL of 0.4 ppm for TCE is either technologically or economically feasible. Based on the information provided in this comment, we submit that it is not possible for Cal/OSHA to conclude that a PEL of 0.4 ppm is feasible for TCE.

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[2] Hein *et al.*, Statistical Modeling of Occupational Chlorinated Solvent Exposures for Case-Control Studies using a Literature-Based Database, Ann. Occup. Hyg. (in press) (2010).

[3] Memorandum from Rae M. Kligys to W. Caffey Norman, Trichloroethylene Exposure Levels in U.S. Workplaces (Sept. 14, 2010).

[4] American Textile Manufacturers Institute, Inc. v. Donovan, 452 U.S. 490, 508-09 (1981) (Cotton Dust).

[5] AFL-CIO v. OSHA, 965 F.2d 962, 980 (11th Cir. 1992) (PELs Update), quoting United Steelworkers v. Marshall, 647 F.2d 1189, 1207 (D.C. Cir. 1980), *cert. denied*, 453 U.S. 913 (1981). In sum, Cal/OSHA must "show the ability of technology to meet specific exposure standards in specific industries." *Id.* at 981.

[6] *Id.* at 982, quoting United Steelworkers v. Marshall, 647 F.2d 1189, 1266, 1272 (D.C. Cir. 1980), *cert. denied*, 453 U.S. 913 (1981).

Moreover, § 11350 of the Government Code provides, in part, as follows:

> "(b) In addition to any other ground that may exist, a regulation . . . may be declared invalid if . . . the agency's determination that the regulation is reasonably necessary to effectuate the purpose of the statute . . . is not supported by substantial evidence."

This mirrors the "substantial evidence" test imposed on federal OSHA under § 6(f) of the OSH Act, which reads, in part:

> "The determinations of the Secretary shall be conclusive if supported by substantial evidence in the record considered as a whole."

"Substantial evidence" has been defined as "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion."[7] Under the substantial evidence test, a court "must take a 'harder look' at OSHA's action than we would if we were reviewing the action under the more deferential arbitrary and capricious standard applicable to agencies governed by the Administrative Procedure Act."[8]

Unintended Consequences of Cal/OSHA Adopting a PEL for TCE that Is Not Feasible

One of the results of adoption of an infeasible PEL for TCE can be predicted, based on recent past experience in California. It has been called "regrettable substitution" by the authors of a recent California Green Chemistry report. The example concerns compounds that were used as replacements in automotive brake cleaners for chlorinated solvents that were banned in that application by the California Air Resources Board:

> "Between 1995 and 2003, California auto repair workers were exposed to hexane, a well-known neurotoxic chemical found in automotive brake cleaners and many other commercial products. In 2000, several workers developed a neurological disorder that caused decreased function of their arms and legs. Each year, millions of cans of hexane-based products were sold in California as an alternative to chlorinated solvents, which were also hazardous but were more heavily regulated in the state.
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> "The use of hexane, which continues today, highlights problems that are universal to current chemical and product management:
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> > "• Uncontrolled use: Hexane was introduced without restrictions into the California market and used in higher volume and with fewer worker protections than anticipated by manufacturers.
> >
> > "• Disproportionate impact: The most highly exposed workers were those in entry-level jobs, held mainly by Latino and Asian immigrants.
> >
> > "• Lack of authority: Agencies lacked the authority to obtain sales data from manufacturers. As a result, they could neither assess the scope of the health threat nor identify specific workers at risk. Agencies also lacked the authority to phase-out the use of these products.
> >
> > "• Regrettable substitution: The phase-out of chlorinated solvents, though appropriate, occurred without an effective strategy for managing substitutes, resulting in the introduction of a new hazard, in the form of hexane.

[7] Universal Camera Corp. v. NLRB, 340 U.S. 474, 477 (1951).

[8] Asbestos Information Ass'n/N. Am. v. OSHA, 727 F.2d 415, 421 (5th Cir. 1984).

> "• Barriers to safer alternatives: Safer, water-based cleaners were available but appeared more expensive than hexane-based products, whose true costs were externalized to the public. These costs included worker diseases, air pollution, and the disposal of 6 million aerosol cans of hazardous product waste each year into public landfills.
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> "A comprehensive chemicals policy would simultaneously address this full set of problems by pairing the regulation of known hazards directly with the evaluation and adoption of safer alternatives."[9]
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> One of the authors of this report was quoted thereafter:
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> "One initiative goal is to prevent the unintended health consequences of chemical substitutions. 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 or nPB], known to cause [present a risk of] sterility, Wilson said.
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> "The current approach to managing chemicals is akin to an emergency response system, which is not enough. You also need to have a prevention system in place, Wilson said."[10]

The introduction of nPB into the vapor degreasing market as a "drop-in replacement" for TCE is entirely predictable; it is the stated objective of at least one supplier:

> "Acceptable methods of cleaning with EnSolv include **vapor degreasing**, **ultrasonics**, **dip tanks**, **flushing** or **cold cleaning**.
>
> "It is the ideal, **environmentally friendly**, drop in **replacement solvent for Trichloroethylene (TCE)**, **Perchloroethyelene (PERC)** and a number of other commonly used, hazardous or designer industrial solvents. . . ."[11]

Unlike most other regulatory authorities, Cal/OSHA has regulated nPB by adopting a PEL of 5 ppm, based on reproductive effects as described in assessments from 2003-04. Since that time, however, concern about nPB has shifted to neurotoxic effects and potential carcinogenicity. For example, there have been a number of case reports of severe neurotoxicity in workers exposed to nPB. Many of the case subjects needed hospitalization and the reversibility of the effects is still in question. A publication by Majersik *et al.* provides a complete clinical analysis of the effects and indications of the slow recovery, if any, observed in patient follow- up.[12] Thereafter, two cases

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[9] 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.

[10] http:/www.universityof california.edu/news/article/22772.

[11] http://www.envirotechint.com/products/degreasing/details/ensolv. The listed "benefits of EnSolv" include:

> "• Non Chlorinated"
>
> "• Non Hazardous Air Pollutant"
>
> "• Non Ozone Layer Depleting (atmospheric life span of only 11-19 days)"
>
> "• Non Hazardous Waste (not regulated by DOT for transportation)"
>
> "• Non Hazardous Decomposition"

[12] Majersik *et al*., Severe Neurotoxicity Associated with Exposure to the Solvent 1-Bromopropane (n-Propyl Bromide), Clinical Toxicology 45: 270-276 (2007).

were reported involving workers exposed to nPB (in vapor degreasing and dry cleaning, respectively) who were diagnosed with clinical manifestations of nPB.[13] A recently published study showing neurophysiological effects in workers exposed to a range of levels allowed the authors to calculate the lowest dose level at which female workers would be likely to experience measurable adverse effects.[14] This exposure is 1.28 ppm (presumably an 8 hour time-weighted average), well below the 5-ppm PEL established by Cal/OSHA.

Moreover, a draft report of two-year carcinogenesis studies of nPB, which was unanimously approved by the NTP Technical Reports Review Subcommittee,[15] shows:

- Clear evidence of carcinogenicity in female F344 rats (adenomas in large intestine and equivocal evidence for skin tumors)
- Some evidence of carcinogenicity in male F344 rats (adenomas in large intestine, skin tumors, and equivocal findings for mesotheliomas and pancreatic adenomas)
- Clear evidence of carcinogenicity in female B6C3F1 mice (lung tumors)
- No evidence of carcinogenicity in male B6C3F1 mice

Standard methodology for the calculation of cancer potency and risk estimation (the linearized multistage model) applied to the incidence of mouse lung tumors in the NTP study yields a q1* term (the 95% confidence limit of the linear term resulting from the model) of 1.95×10^{-3} per ppm (lifetime exposure).

Widespread substitution of nPB for TCE in vapor degreasing could lead to a tremendous upswing in case reports of neurotoxicity in workers. Cal/OSHA should carefully consider this important issue as it ensures that any PEL it adopts for TCE is technologically and economically feasible, as required by California law.

Conclusion

The PEL recommended by the Health Expert Advisory Committee for TCE clearly is not feasible. HSIA stands ready to assist Cal/OSHA as it moves forward to set a PEL that California industry, using TCE in modern equipment, is generally capable of achieving.

Respectfully submitted,

Faye Graul
Executive Director

Enclosures

[13] Perrone *et al*., Neurologic Illness Associated with Occupational Exposure to the Solvent 1-Bromopropane – New Jersey and Pennsylvania, 2007 – 2008, Morbidity and Mortality Weekly Report 57(48): 1300-1302 (2008).

[14] Li *et al*., Dose-Dependent Neurologic Abnormalities in Workers Exposed to 1-Bromopropane, J. Occup. Environ. Med 52: 769-777 (2010).

[15] NTP Technical Report 564 (Board Draft).