

- Proposed rule addresses paint stripping with methylene chloride (dichloromethane or DCM).
- Will be in first round of rulemaking under TSCA § 6 since 1989, among first rules to interpret “unreasonable risk” under revised TSCA.
- SBAR meeting held June 15, 2016; EPA disclosed intent to take over regulation of DCM in workplace/consumer applications.
- Clearly raises novel legal or policy issues arising out of legal mandates for purposes of E.O 12866.

- TSCA § 6(c)(2)(C) – in adopting a specific condition of use EPA must consider whether “technically and economically feasible alternatives” that benefit health or the environment, compared to use to be restricted, will be “reasonably available as a substitute when the proposed prohibition or other restriction takes effect.”
- Given the information EPA has received from the small businesses that rely on and use this chemical, it is clear that a true substitute is not available at this time (and presumably will not be “reasonably available as a substitute when the proposed prohibition or other restriction takes effect”).
- TSCA § 26(l)(4) – where risk assessment completed prior to date of enactment, § 6(a) rule must be consistent with “the scope of the completed risk assessment for the chemical substance and consistent with other applicable requirements of § 6.”

- Under TSCA § 6(b)(4)(F) the risk evaluation must:
  - “integrate and assess available information on hazards and exposures for the conditions of use of the chemical substance, including information that is relevant to specific risks of injury to health or the environment . . . .;”
  - “take into account, where relevant, the likely duration, intensity, frequency, and number of exposures under the conditions of use of the chemical substance;” and
  - “describe the weight of the scientific evidence for the identified hazard and exposure.”

§ 26(h): “In carrying out sections 4, 5, and 6, to the extent that the Administrator makes a decision based on science, the Administrator shall use scientific information, technical procedures, measures, methods, protocols, methodologies, or models, employed in a manner consistent with the best available science, and shall consider as applicable—

- (1) the extent to which the scientific information, technical procedures, measures, methods, protocols, methodologies, or models employed to generate the information are reasonable for and consistent with the intended use of the information;
- (2) the extent to which the information is relevant for the Administrator’s use in making a decision about a chemical substance or mixture;
- (3) the degree of clarity and completeness with which the data, assumptions, methods, quality assurance, and analyses employed to generate the information are documented;
- (4) the extent to which the variability and uncertainty in the information, or in the procedures, measures, methods, protocols, methodologies, or models, are evaluated and characterized; and
- (5) the extent of independent verification or peer review of the information or of the procedures, measures, methods, protocols, methodologies, or models.”

§ 26(i): “The Administrator shall make decisions under sections 4, 5, and 6 based on the weight of the scientific evidence.”

- Characterization of DCM as “likely carcinogenic in humans” based entirely on IRIS Assessment, but no discussion of concerns raised by HSIA and other commenters.
- IRIS Assessment, like the IARC classification, used a “strength of the evidence” approach; TSCA § 26(i) requires “decisions under sections 4, 5, and 6 [to be] based on the weight of the scientific evidence.”
- Characterization ignores robust data base of five occupational cohort studies, including an exhaustive study of Eastman Kodak employees: “In summary, the Kodak research was well designed, thoughtfully conducted, and appropriately expanded over time. Findings were consistently negative for causes of death hypothesized to be related to methylene chloride exposure, such as ischemic heart disease and cancers of the lung and liver, as well as for any other specific cause of death.” Dell *et al.* (1999).
- The epi studies also do not support an association between DCM and brain cancer. A recent comprehensive study found no association between exposure to DCM and glioma risk. Ruder *et al.* (2014).

- Acute risk based on bathtub refinishing scenario, which was initial focus of EPA concern. There have been 14 deaths associated with asphyxiation from use of DCM refinishing bathtubs in spaces with little or no ventilation.
- Risk is being addressed by Consumer Product Safety Commission (CPSC), which has invited comment on a petition submitted by HSIA, 81 Fed. Reg. 60298 (Sept. 1, 2016).
- HSIA's petition asks the Commission to expand its 1987 Statement of Interpretation and Enforcement Policy regarding labeling of household products containing DCM, so that it addresses acute hazard as well as the chronic hazard already addressed. The label submitted by HSIA went beyond precautionary language and stated "Do Not Use To Strip Bathtubs," with a corresponding pictogram.
- CPSC staff has already approved the expanded cautionary language, which formulators are using.
- Under the Federal Hazardous Substances Act, further regulation of these household products is precluded absent a finding that the cautionary language contained in the Commission's Statement is ineffective.

- Work Plan Assessment relies on incorrect baseline for exposure to DCM from paint stripping, particularly the occupational exposure scenarios. Inadequacies described in draft Assessment include:
  - “The principal limitation of the worker exposure data is the uncertainty in the representativeness of the data. EPA reviewed a number of published exposure studies with inherent data limitations including: number of facilities, job sites, or residences; most often, limited number of sites investigated.”
  - “An additional data limitation for occupational exposure estimation is the age of the identified exposure studies. Most of the exposure studies were conducted in the 1990s, with some pre-dating the 1990s; some studies were more recent. Some references have discussed a trend to reduce the use of DCM in paint stripping products (i.e., OSHA promulgated new exposure limits for DCM in 1997). *These factors can limit the representativeness of 1990 and older data with regards to present day workplace conditions and exposures.*”

- It is remarkable that EPA would even consider using pre-1997 exposure data in an assessment of occupational exposures to DCM.
- In that year 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), a 95% reduction.
- The statement “it is not known, but it is possible, that actual exposure distributions could be declining during the monitoring period considered in this assessment” is puzzling, considering that entire applications of DCM were lost as a result of the lower workplace limit,
- In sum, where DCM continues to be used, including in paint stripping, exposures must be kept below 12.5 ppm to avoid triggering the action level. There is no basis for EPA to assume that DCM is being used throughout the United States in what would be flagrant violation of the OSHA standard.

- NESHAP for Paint Stripping and Miscellaneous Surface Coating Operations at Area Sources, 40 C.F.R. Part 63, Subpart HHHHHH, requires paint stripping operations using DCM to:
  - Institute management practices to (i) ensure there is a need for paint stripping; (ii) ensure there is no alternative paint stripping technology that can be used; (iii) reduce inhalation exposure from paint strippers; (iv) optimize application conditions to reduce DCM evaporation; and (v) practice proper storage and disposal of paint strippers
  - Develop and implement a written plan to minimize the use and emissions of DCM (if facility uses more than one ton of DCM annually)
  - Maintain copies of annual usage of DCM paint strippers on site at all times
  - Maintain a copy of current DCM minimization plan on site at all times (if facility uses more than one ton of DCM annually)

- The exposure data in the assessment predate the compliance dates of the NESHAP (ranging from January 2008 to January 2011). Most significantly, the assessment seems to have been conducted without reference to the extensive reporting and recordkeeping requirements of the NESHAP.
- Under the NESHAP, every facility must make initial notification and report annually to EPA the location of each paint stripping operation, identifying the method employed and substrates stripped, whether the source is in compliance, and whether it plans to use more than one ton of DCM post-compliance.
- Even more extensive information on DCM content and usage are required to be maintained by the operator and accessible to EPA.
- It is remarkable that the Work Plan assessment was apparently compiled without utilizing the data already in the hands of EPA and other permitting authorities.

- The Assessment uses a screening level modeling approach to assess hazard and exposure.
- This does not meet OMB Information Quality Act guidelines for a “highly influential scientific assessment” to support TSCA § 6 rulemaking. Screening level assessments are considered inappropriate to support regulations intended to reduce risk because they do not accurately estimate risk or quantify exposures.

- Take into account exposure under the conditions of use
- Describe weight of the scientific evidence for identified hazard and exposure
- Use of scientific information, employed in a manner consistent with the best available science
- Consider variability and uncertainty in the information
- Consider extent of independent verification or peer review of the information
- Screening level assessment
- Hazard assessment based on “strength of evidence” as opposed to “weight of evidence”
- Exposure assessment based on workplace limits in effect 20 years ago that are 20 times higher than current limits, and ignores available EPA data
- No formal or informal uncertainty analysis



# Acceptable Exposure Limit (AEL): Methylene chloride

Existing chemical acceptable exposure limit (AEL) is:

- Derived from the lowest risk estimate and appropriate UF to provide margin of safety
- Calculated for acute and chronic exposures and non-cancer and cancer effects
- Selected to be protective of all risks (for methylene chloride this is based on cancer risk)

## Non-cancer

$$AEL_{non-cancer\ 8hrTWA} = \frac{POD(acute\ or\ chronic)}{MOE_{benchmark}(acute\ or\ chronic)} * Duration\ Adjustment$$

$AEL_{non-cancer\ 8\ hr\ TWA}$  for acute exposures = 1.3 ppm

$AEL_{non-cancer\ 8\ hr\ TWA}$  for chronic exposures = 2 ppm

## Cancer

$$AEL_{cancer\ 8hrTWA} = \frac{Cancer\ benchmark(10^{-6})}{IUR} * \frac{Lifetime(24hrs\ X\ 365days\ X\ 70\ yrs)}{Working\ Career(8hrs\ X\ 250days\ X\ 40\ yrs)} = 0.2\ ppm$$



# Exposure Estimates: Methylene Chloride

Industry	Acceptable exposure limit (8 hr TWA, ppm)	Acute high-end estimated exposure (8 hr TWA, ppm)	Chronic high-end estimated exposure (8 hr TWA ppm)
Professional Contractors	0.2	858	431
Automotive Refinishing	0.2	120	64
Furniture Refinishing	0.2	364	169
Aircraft Paint Stripping	0.2	1,095	551
Graffiti Removal	0.2	342	139
Other workplace settings (immersion stripping)	0.2	2,015	1009



# EPA's Authority to Regulate Occupational Risks

- SERs were interested in more information about EPA's authority to regulate occupational hazards and risks, compared to OSHA
- OSHA authority extends only to private sector employers
  - Public sector employees conducting paint removal are not subject to OSHA
- TSCA restrictions are consistent with OSHA hierarchy of hazard control (eliminate/substitute hazard; engineering controls; best practices administrative controls; personal protective equipment)
- TSCA authority can address the risks from methylene chloride and NMP in paint removal that cut across worker, public sector and consumer settings
- EPA is working closely with OSHA; both agencies feel TSCA is the appropriate authority to address the risks that EPA has identified, including those that occur in workplaces
  - See letter of support from Department of Labor in Appendix E

- “OSHA lacks direct jurisdiction over state and local government workers.”
- “OSHA does not cover self-employed workers, military personnel and uniquely military equipment, systems, and operations, and workers whose occupational safety and health hazards are regulated by another federal agency.”
- “[S]ince 1976, there has been an annual rider to OSHA's appropriation that prohibits the agency from expending appropriated funds to issue standards for or conduct enforcement activities against certain small farming operations.”



# Potential Regulatory Options - Methylene Chloride

1. Regulatory Option #1: Prohibit manufacturing, distribution, and use of methylene chloride as a paint remover
2. Regulatory Option #2: Allow certain commercial uses with worker protections and other requirements to protect the public
  - Worker protections: Personal protective equipment (PPE) or air exposure limit
    - PPE:
      - APF 1,000 would be in most scenarios, with APF 10,000 when immersion methods of paint removal are used. APF is the workplace level of respiratory protection that a respirator or class of respirators is expected to provide to employees.
      - A respiratory protection program includes training, medical monitoring, re-fitting, and other components of respirator protection programs
      - Workers nearby (occupational bystanders) would be required to wear respirators as well, or be excluded from the area
    - **As an alternative, work places could meet an air exposure limit of 0.2 ppm**
      - Potentially could use engineering controls such as ventilation to reduce the respirator APF needed
  - Other requirements:
    - Downstream notification by manufacturers, processors, and distributors of the prohibitions for this use
    - **Packaging of paint removers containing methylene chloride in volumes no less than 55-gallon drums**
    - Bystanders (such as residents of homes) must stay out for up to 24 hours after work is completed

- § 9(a) – Laws not administered by EPA:
  - If unreasonable risk can be sufficiently reduced under a law not administered by EPA, EPA shall publish and submit to the other agency a report and request it to determine if it can reduce the risk under such other law. The other agency must respond to EPA and publish its response.
  - Other agency must either decide that there is no such risk or initiate rulemaking within 90 days of its response
- § 9(b) – Laws administered by EPA:
  - If risk can be sufficiently reduced under another law administered by EPA, then EPA must use that other authority unless it determines that it is in the public interest to proceed under TSCA.
  - In making public interest determination, EPA must compare the estimated costs and efficiencies of the actions to be taken under TSCA and action to be taken under such other law.

- In 1985 EPA initiated a priority review of risks of cancer from DCM, using its authority under TSCA § 4(f), and made referrals to OSHA and the CPSC, under whose jurisdictions fall worker and consumer health and safety, respectively.
- This comprehensive regulatory framework provides adequate protections with respect to the same potential adverse impacts and potential exposure pathways targeted by the current EPA initiative. Taking action that would lead to the removal of products from the marketplace on the false assumption that workers and consumers fail to comply with existing requirements is not consistent with TSCA as initially enacted or as revised.
- As noted above, OSHA has regulated occupational exposure to DCM for many years. Following the § 4(f) review, OSHA adopted a standard lowering the workplace exposure limit for DCM from 500 ppm to 25 ppm.
- Under the Federal Hazardous Substances Act, further regulation of DCM-based household products is precluded absent a finding that the cautionary language contained in the Commission's Policy Statement is ineffective.

- Original history is clear: “it was the intent of the conferees that the Toxic Substance [Control] Act not be used, when another act is sufficient to regulate a particular risk.”
- Recent House report: “TSCA's original purpose [is] filling gaps in Federal law that otherwise did not protect against the unreasonable risks presented by chemicals,” and “the Administrator should respect the experience of, and defer to other agencies that have relevant responsibility such as the Department of Labor in cases involving occupational safety.” Colloquy:
  - “Mrs. BLACKBURN. It is my understanding that, as a unified whole, this language, old and new, limits the EPA's ability to promulgate a rule under § 6 of TSCA to restrict or eliminate the use of a chemical when the Agency either already regulates that chemical through a different statute under its own control and that authority sufficiently protects against a risk of injury to human health or the environment, or a different agency already regulates that chemical in a manner that also sufficiently protects against the risk identified by EPA. Would the chairman please confirm my understanding of § 9?
  - “Mr. SHIMKUS. The gentlewoman is correct in her understanding.
  - “Mrs. BLACKBURN. As the EPA's early-stage efforts to regulate methylene chloride and TCE under TSCA § 6 illustrate, they are also timely. EPA simply has to account for why a new regulation for methylene chloride and TCE under TSCA is necessary. . . .”

- As already noted, under the Clean Air Act EPA has adopted regulations for DCM in paint stripping that protect public health with an ample margin of safety.
- Strangely, the Assessment appears to have been conducted without reference to the NESHAP, resulting in great uncertainty in its estimates of DCM releases, exposures, and population exposed, all of which could be eliminated by using data required to be reported to EPA under the NESHAP.
- Has EPA compared the estimated costs and efficiencies of the actions to be taken under TSCA against the NESHAP or any action that might be taken to strengthen the NESHAP?

OMB should not clear proposed rule:

- Assessment does not comply with TSCA §§ 6, 26:
  - Not best available science or based on weight of scientific evidence
  - Screening level hazard/exposure assessments
  - Exposure assessment greatly overstates exposure/risk
- No justification for usurping OSHA authority over workplace and CPSC jurisdiction over consumer products, or ignoring existing EPA regulation of same sources