Labor on TSCA Risk Evaluation

January 12, 2023
U.S. Environmental Protection Agency Risk Evaluation Workshop

Outline

1. EPA's corrected risk evaluation approach
2. Assumption of PPE in risk evaluation and OSHA's respiratory protection standard
3. Assumption of OSHA compliance in risk evaluation
4. Industrial hygiene practice

We Applaud EPA's Decision to Correct Scientifically Indefensible Assumptions Initially Used in the First Ten Risk Evaluations

In its final risk determination for Methylene Chloride, EPA states:

EPA has determined that the appropriate approach… is to ***make an unreasonable risk determination for… a whole chemical substance, rather than making unreasonable risk determinations separately on each individual condition of use*** evaluated in the risk evaluation.

EPA has determined that the risk determination explicitly state that it ***does not rely on assumptions regarding the use of personal protective equipment (PPE)*** in making the unreasonable risk determination under TSCA section 6"

Reasons for which the Use of Personal Protective Equipment Must not be Assumed

Hierarchy of Controls

Introduction

Following the industrial hygiene hierarchy of controls model can help most anyone work safely with most any material in a manner that reduces risks to acceptable levels. There are five components of the hierarchy of controls that flow from most protective to least: elimination, substitution, engineering controls, administrative controls, and personal protective equipment (PPE) and clothing. Each concept has distinct benefits and potential pitfalls, which is why AIHA does not typically support proposed product bans but favors the hierarchy of controls approach.

1. **Eliminate asbestos from the process**
    a. Steps one and two in the hierarchy of controls are really the same. Elimination and substitution both amount to removing asbestos from the process. In "Asbestos Part 1: Chrysotile Asbestos; Regulation of Certain Conditions of Use Under Section 6(a) of the Toxic Substances Control Act (TSCA)" EPA states that replacements are available for:
        i. Vehicle friction breaks
        ii. Chlor-alkalai plants
        iii. Sheet gaskets

    It would appear that elimination or replacement is viable in all three major areas. We recognize and encourage the use of "replacement risk analysis" to determine the environment, health, and safety downside of any of these changes and an assessment of the relative risks based upon the relevant comparative hazards associated with all materials.

2. **Substitute the asbestos material with an asbestos-free product, if a replacement is needed.**

    The banning of asbestos is not eliminating risks but rather substituting new risks. This means that any alternative methodology should undergo the same level of scrutiny as applied to asbestos so it can be assured that any excess risk is actually lowered rather than introducing new risks that may be as detrimental as those associated with the use of asbestos. Note that membrane cell technology involves per- and polyfluoroalkyl substances (PFAS) chemicals, which have their own health risks.

    Efforts to replace asbestos-containing gasket materials have been an ongoing effort since at least the 1970's in the chemical industry. In many cases, the use of asbestos-containing gaskets has been eliminated. Asbestos-containing gaskets can withstand high temperatures and pressures and are very resistant to the corrosive properties of many chemicals. Before banning asbestos gaskets, EPA should be sure that suitable alternatives exist that can withstand these extreme conditions. A failure of a gasket could easily result in severe injuries or even death to workers near the failure and to offsite communities. For example, asbestos gaskets are used on chlorine tank cars which can be located in communities throughout the country. A chlorine leaking railcar due to a failed gasket could be catastrophic.

3. **Engineer design changes**
    a. Engineering changes tend to be long-range, although they may not be as long-range as the overall process changes described above. The best changes will not require modification of worker behavior and will be relatively maintenance non-intensive.

4. **Administrative controls: Post warning signs and apply labels for asbestos-containing areas and materials**
    a. Control access to areas containing asbestos products
    b. Administrative controls rely heavily on worker behavior, management and supervisory commitment, and the quality of training. United States Occupational Safety and Health Administration (OSHA) specifically prohibits the use of job rotation, which is a main administrative control when seeking to reduce worker exposures.

5. **Personal protective equipment and clothing**
    a. This is the last line of defense and is not recommended unless the more effective controls are in the planning stage or have been shown not to be effective. Issues such as the quality of training, worker compliance, day-to-day and worker-to-worker variation, and the condition of PPE all come into play. This aspect of the hierarchy of controls should be used with caution when working with a high-hazard material such as asbestos.

Risk Evaluation

Risk of inhalation of asbestos

AIHA suggests that EPA's risk evaluation of chrysotile asbestos was not performed properly and was expected to be revised in accordance with the comments on the EPA TSCA process issued by the NAS. AIHA submitted public comments on the scope of Part 2 of the asbestos risk evaluation planned by EPA with the recommendations to address the methodological issues determined by NAS prior to any further activities or regulatory actions on asbestos. The current version of EPA's rulemaking does not respond to the recommendations of various scientific organizations regarding the methodological problems encountered in the previous EPA documents.

American Industrial Hygiene Association:

"[PPE]is the last line of defense and is not recommended unless the more effective controls are in the planning stage or have been shown not to be effective."

NIOSH

"Employers should not rely on PPE alone to control hazards when other effective control options are available."

Centers for Disease Control and Prevention

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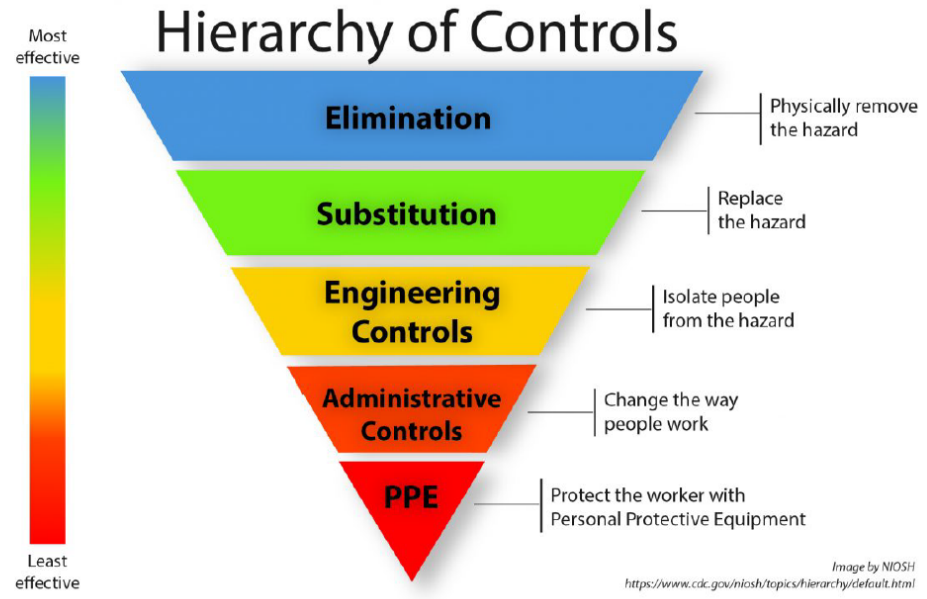
Hierarchy of Controls

Controlling exposures to hazards in the workplace is vital to protecting workers. The hierarchy of controls is a way of determining which actions will best control exposures. The hierarchy of controls has five levels of actions to reduce or remove hazards. The preferred order of action based on general effectiveness is:

1. Elimination
2. Substitution
3. Engineering controls
4. Administrative controls
5. Personal protective equipment (PPE)

Using this hierarchy can lower worker exposures and reduce risk of illness or injury.



Where possible, elimination or substitution is the most desirable followed by engineering controls. Administrative or work practice controls may be appropriate in some cases where engineering controls cannot be implemented or when different procedures are needed after implementation of the new engineering controls. Personal protection equipment is the least desirable but may still be effective.

Type of Control	Examples
Elimination/Substitution	▪ Substitute with safer alternatives. [See Transitioning to Safer Chemicals: A Toolkit for Employers and Workers]
Engineering Controls (implement physical change to the workplace, which eliminates/reduces the hazard on the job/task)	▪ Change process to minimize contact with hazardous chemicals. ▪ Isolate or enclose the process. ▪ Use of wet methods to reduce generation of dusts or other particulates. ▪ General dilution ventilation. ▪ Use fume hoods.
Administrative and Work Practice Controls (establish efficient processes or procedures)	▪ Rotate job assignments. ▪ Adjust work schedules so that workers are not overexposed to a hazardous chemical.
Personal Protective Equipment (use protection to reduce exposure to risk factors)	▪ Use chemical protective clothing. ▪ Wear respiratory protection. [See the Respiratory Protection Safety and Health Topics page] ▪ Use gloves. ▪ Wear eye protection.

OSHA:
“Personal protection equipment is the least desirable”

It is *illegal* to rely on respiratory protection unless engineering controls are or will be used to the full extent feasible

- 1910.134(a)(1)In the control of those occupational diseases caused by breathing air contaminated with harmful dusts, fogs, fumes, mists, gases, smokes, sprays, or vapors, the primary objective shall be to prevent atmospheric contamination. ***This shall be accomplished as far as feasible by accepted engineering control measures*** (for example, enclosure or confinement of the operation, general and local ventilation, and substitution of less toxic materials). ***When effective engineering controls are not feasible***, or while they are being instituted, ***appropriate respirators shall be used*** pursuant to this section.
- Hence, *any assumption that respiratory protection is used is either* ***an assumption that employers are violating the law*** *or* ***an assumption that it is entirely infeasible to achieve any additional protection by use of engineering controls.***

Other Assumptions

From the Final Risk Evaluation for C.I. Pigment Violet 29

OSHA requires and NIOSH recommends that employers utilize the hierarchy of controls to address hazardous exposures in the workplace… EPA generally assumes compliance with OSHA requirements for protection of workers, including the implementation of the hierarchy of controls... EPA does not have reasonably available information to support this assumption for each condition of use; however, EPA does not believe that the Agency must presume, in the absence of such information, a lack of compliance with existing regulatory programs and practices. Rather, EPA assumes there is compliance with worker protection standards unless case-specific facts indicate otherwise, and therefore existing OSHA regulations for worker protection and hazard communication will result in use of appropriate PPE in a manner that achieves the stated APF

The flaw in this reasoning is that there are ***absolutely no OSHA regulations whatsoever that govern C.I. Pigment Violet 29 or most of the chemicals on the TSCA inventory. Therefore, to assume employers are in compliance is to assume they do nothing at all.***

If is a substance is not on this list, it does not have a full OSHA standard requiring the hierarchy of controls

- **1910.1001 - Asbestos.**
- **1910.1003 - 13 Carcinogens**
- **1910.1017 - Vinyl chloride.**
- **11910.1018 - Inorganic arsenic.**
- **910.1024 - Beryllium.**
- **1910.1025 - Lead.**
- **1910.1026 - Chromium (VI).**
- **1910.1027 - Cadmium.**
- **1910.1028 - Benzene.**
- **1910.1029 - Coke oven emissions.**
- **1910.1043 - Cotton dust.**
- **1910.1044 – 1,2-dibromo-3-chloropropane.**
- **1910.1045 - Acrylonitrile.**
- **1910.1047 - Ethylene oxide.**
- **1910.1048 - Formaldehyde.**
- **1910.1050 - Methylenedianiline.**
- **1910.1051 - 1,3-Butadiene.**
- **1910.1052 - Methylene Chloride.**
- **1910.1053 - Respirable crystalline silica.**

Hierarchy of Controls

- All of these standards require hierarchy of controls as a means to control *to* the PEL, not below the PEL.
- The PEL and other provisions are in place to address “significant risk”, not unreasonable risk.[1] In almost all cases, “feasibility” places the risk level ***above*** the significant risk level.

[1] Significant risk is a legal concept developed by the solicitor of labor pursuant to a footnote to Industrial Union Department, AFL-CIO v. American Petroleum Institute (the Benzene Case). It allows ***much more risk*** than unreasonable risk under TSCA.

Z- Tables

- Z-tables contain exposure limits for about 600 chemicals that are 50-60 years out of date (based on 1960s science and/or 1960s guesswork) and carry ***no requirements whatsoever to follow the hierarchy of controls or even to measure workplace air to determine whether exposures exceed these ancient limits.***
- Exposure at or just below the Z-table limits are likely to pose unreasonable risk. OSHA says:
  - OSHA recognizes that many of its permissible exposure limits (PELs) are ***outdated and inadequate for ensuring protection of worker health.*** Most of OSHA's PELs were issued shortly after adoption of the Occupational Safety and Health (OSH) Act in 1970, and have not been updated since that time… (https://www.osha.gov/annotated-pels)
- Unlike full OSHA standards, the ***Z-Tables do not carry air monitoring requirements and do not mandate compliance with the hierarchy of controls in any form. The mere presence of an exposure limit for a substance on a Z-Table, should not, by itself lead EPA to assume that the hierarchy of controls is being followed.***
  - Many employers will not need to use respiratory protection to comply with Z-tables because ***the limits are so outdated that compliance does not necessarily require respirators, even in the absence of robust engineering controls.***
  - Some employers may currently use respiratory protection to comply with Z-Tables; if so, they may also follow the requirement to use all feasible engineering controls. They may conduct air monitoring as part of the assessment required by the respiratory protection standard (29 CFR 1910.134).
- ***It cannot be assumed that any employer has taken any particular course of action to comply with Z-Tables.***

5(a)(1) General Duty Clause

Since 2011, OSHA has issued only 28 general duty clause citations for airborne chemical exposures.

In the rare case that general duty clause citations have been issued, the following conditions have been true:

- A clinical health effect (usually acute, hence no protection against chronic diseases like cancer) has already been experienced by workers consistent with “serious physical harm.”
- Chemicals were well-studied chemical and exposure was at very high levels to establish “recognized hazard.”
- Citations were issued because evidence documented workers at the facility were physically harmed, not just because airborne exposure exceeded a limit.

Source: AFL-CIO *Death on the Job Report* (2022)

5(a)(1) General Duty Clause

- All involved harm that had already occurred
- Acute and not chronic harm

Assuming compliance with the General Duty Clause should not lead to an assumption of any particular method of compliance or of control of exposure to concentrations low enough to prevent unreasonable risk of harm that is other than acute and severe.

Whether “Occupational Non-Users” (ONUs) are exposed more or less than those who work with a chemical is an empirical question, not subject to general assumptions

A study of urinary Bisphenol A found that the geometric mean level of BPA in the urine of maintenance workers (n=42) was 156 µg/g. This was higher than such occupational users as flaker operators (23.2 µg/g, n=68) and kettle operators (69.5 µg/g, n=126).

Hines, C.J., Jackson, M.V., Deddens, J.A., Clark, J.C., Ye, X., Christianson, A.L., Meadows, J.W. and Calafat, A.M., 2017. Urinary bisphenol A (BPA) concentrations among workers in industries that manufacture and use BPA in the USA. *Annals of work exposures and health*, 61(2), pp.164-182.

Hazard Communication Standard

- The OSHA Hazard Communication Standard (29 CFR 1910.1200) has training and information requirements but no control requirements
- Because OSHA does not enforce control recommendations on safety data sheets, there should be no assumption that such recommendations are followed.
- Recommendations on safety data sheets are often too vague to follow:
  - “Use adequate ventilation” or “Use in a well-ventilated area”
  - “Use respiratory protection”
  - “Use chemical protective gloves”
- ***Cannot assume that any controls are put in place based on assuming compliance with this standard***

Industrial Hygiene Practice

- Many workplaces do not employ staff industrial hygienists or use industrial hygiene consultants, especially small workplaces
- EPA should not assume that any industrial hygiene practice that is not mandated by regulation is universal or will continue into the future
- In assessing worker exposure, EPA *should* ***assume that there are workplaces in which non-mandatory industrial hygiene practices, (i.e., respirators to protect against a chemical that has no OSHA standard), are not applied… and that any workplace using voluntary industrial hygiene practices today could drop them tomorrow.***