

Letter from the Editors

September 2020

Dear Colleague,

In this issue of *Trends*, we explore the topic of Occupational Stewardship, which refers to the proactive approach employers take to ensure a safe work environment for employees.

Our issue begins with an exploration of notable achievements and remarkable events in the nearly 50-year history of the Occupational Safety and Health Administration (OSHA). With a focus on work-related exposures, the second article examines the risk evaluations developed so far under the Toxic Substances Control Act (TSCA) and their significant findings with implications for risk management decisions in the workplace. Article three addresses the need for greater protection of sensitive worker subpopulations, discussing OSHA programs aimed at the protection of all workers and a case study approach for protecting pregnant and soon-to-be-pregnant workers.

Gradient contributors to this *Trends* issue include David Dodge, M.S., DABT, CIH; Dr. Lisa Bailey; and Jiaru Zhang, M.P.H. Bill Hubbard, Esq., of Thompson Hine contributed the guest editorial on navigating the legal implications of the COVID-19 pandemic in the workplace.

We hope this issue of *Trends* brings clarity to the nuanced subject of Occupational Stewardship.

Yours truly,

*Chris Long*

*Kurt Herman*

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# 50 Years of OSHA

By David Dodge, M.S., DABT, CIH

*In the face of many obstacles, OSHA has made great strides in its mission to “ensure safe and healthful working conditions” throughout its 50-year history.*

In the federal government, no agency embodies the theme of occupational stewardship more than the Occupational Safety and Health Administration (OSHA). The Occupational Safety and Health Act, which created OSHA, was enacted in 1970 to ensure safe and healthful conditions for workers. Prior to OSHA, an estimated 14,000 deaths in the workplace and 390,000 new cases of

***OSHA’s legal standards are arguably its most effective tools for protecting workers.***

occupational disease each year had become a major concern that demanded governmental attention. OSHA has now been carrying out its mission for nearly 50 years, from establishing baseline federal health and safety standards in 1971 to responding to the

current COVID-19 pandemic (see timeline). It has done so with notable successes that have improved the lives of many workers, but also with regulatory restrictions, political and legal opposition, and budgetary constraints that have led to setbacks and gaps in coverage. While a summary of all of OSHA’s activities is beyond the scope of this article, some of OSHA’s more notable areas of emphasis – standard setting, worker rights, and responses to tragic events – are discussed here.

OSHA began by adopting a number of existing standards to establish a baseline for safety and health protection in U.S. workplaces. This included the adoption of existing Threshold Limit Values (TLVs) recommended by the private, non-governmental entity, the American Conference of Governmental Industrial Hygienists (ACGIH). This helped to address the responsibility given to OSHA to set legally enforceable Permissible Exposure Limits (PELs) and other standards to protect workers in the workplace. Because of regulatory requirements, the process

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# 50 Years of OSHA

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that OSHA must go through to issue a standard is extensive and lengthy. Thus far, OSHA has been successful in promulgating 32 substance-specific PELs and many other types of standards, prioritizing carcinogens and other hazards prominent in U.S. industries. The first substance-specific PEL developed or updated by OSHA was for asbestos in 1972, and others now include vinyl chloride, inorganic arsenic, lead, ethylene oxide, benzene, methylene chloride, hexavalent chromium, silica, and beryllium. OSHA has also developed several non-chemical worker protection standards, such as for hearing conservation, blood-borne pathogens, confined spaces, and fall protection. OSHA's legal standards are arguably its most effective tools for protecting workers.

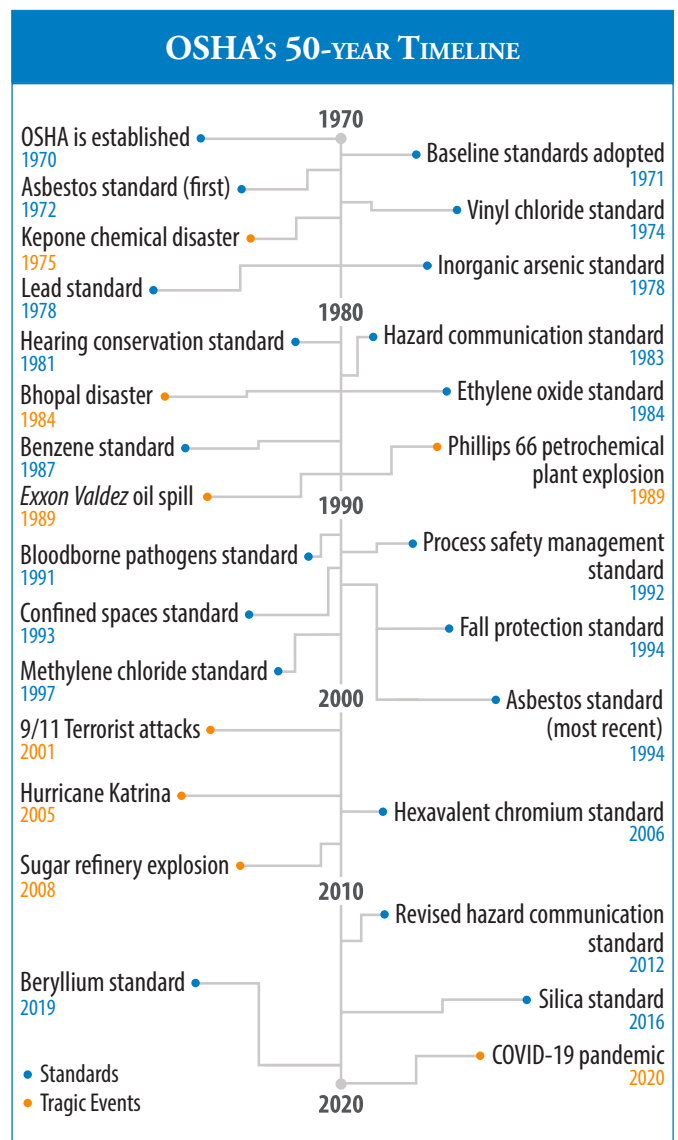
Workers' rights have been another major area of emphasis by OSHA. In 1980, the Supreme Court affirmed an OSHA protection that workers had the right to refuse an assigned task on the basis of danger to life or health, without being discriminated against. Also in 1980, OSHA issued a rule requiring that workers and their doctors have access to worker medical and exposure records. In 1983, OSHA implemented the Hazard Communication Standard, giving workers the right to

know about the chemicals they may be exposed to in the workplace and their hazards. It has since been expanded and revised, including in 2012, when OSHA modified the standard to harmonize the U.S. approach with

*Perhaps the greatest threat to occupational health that OSHA has faced – a virus posing health risks to every industry in the nation – is happening now.*

international requirements.

The 50-year history of OSHA has also been filled with tragic events that have prompted OSHA to respond. OSHA has sent staff to help protect cleanup and recovery workers from health and safety hazards after events such as the *Exxon Valdez* oil spill in 1989, the 9/11 terrorist attacks, and Hurricane Katrina in 2005. Incidents such as the Bhopal disaster in India in 1984 prompted OSHA to increase inspections of chemical plants and other facilities in the U.S. Some incidents have led OSHA to develop new standards and procedures, or address deficiencies of existing ones. The mishandling of the pesticide Kepone at a manufacturing plant in Virginia in the mid-1970s led to poisonings of workers and environmental pollution, causing OSHA to address its weaknesses in inspections and responses to complaints. An explosion at a petrochemical plant in Texas in 1989 led OSHA to issue the Process Safety Management standard in 1992 to reduce the risk of deadly fires and explosions in workplaces. In response to several industrial combustible dust incidents, including a deadly explosion at a sugar refinery in



Georgia in 2008, OSHA initiated rulemaking to address the fire and explosion hazards of combustible dust. Perhaps the greatest threat to occupational health that OSHA has faced – a virus posing health risks to every industry in the nation – is happening now. OSHA is responding to the COVID-19 pandemic by providing guidance and resources for employers and workers to minimize exposure to the virus in the workplace.

Despite challenges, the activities of OSHA since its inception have contributed to a significant reduction in work-related deaths, injuries, and illnesses. The toll of occupational hazards on workers, however, remains significant. The occupational landscape continues to evolve and encounter novel and unexpected hazards, as evidenced most starkly by the current pandemic. To best serve the working population of the U.S., OSHA will continually need to manage its constraints, adapt to the times, and direct its efforts to the greatest good.

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# Worker Risk Evaluations Under TSCA: What We Know So Far

By Lisa Bailey, Ph.D.

*U.S. EPA's TSCA risk evaluations inform best practices for worker safety, which will have far-reaching implications for industry and consumers alike.*

Under the Lautenberg Chemical Safety for the 21<sup>st</sup> Century Act (LCSA) amendments to the Toxic Substances Control Act (TSCA), the U.S. Environmental Protection Agency (U.S. EPA) recently released draft risk evaluations for the first 10 chemicals designated as high priority (*e.g.*, asbestos, trichloroethylene [TCE],

perchloroethylene [PCE], carbon tetrachloride) ([U.S. EPA](#)). Two evaluations (methylene chloride and 1-bromopropane) were recently finalized (U.S. EPA 2020a,b), with the remaining evaluations due to be finalized by the

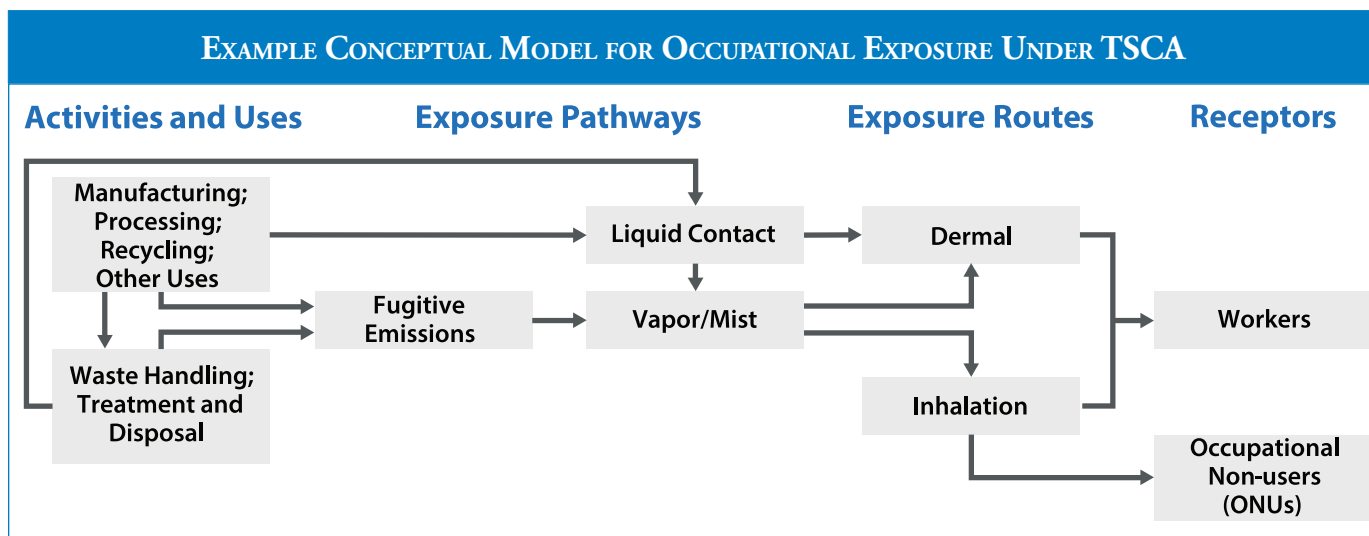
end of 2020. In April 2020, U.S. EPA published draft scopes of work for 20 additional high-priority chemicals (including several chlorinated compounds, phthalates, and formaldehyde), with final risk evaluations scheduled to be published by December 2022. The scopes describe the chemical uses and exposure pathways that will be evaluated for workers and consumers, and how human and environmental risks will generally be evaluated for the full life cycle of the chemicals. U.S. EPA has included conceptual models of the exposure pathways in the scoping documents (see **Figure below**).

*Information from the recent evaluations provides an opportunity for employers to make proactive decisions about potential workplace risks associated with these chemicals.*

From the first 10 chemical risk evaluations, we are beginning to understand how U.S. EPA will determine relevant chemical uses and evaluate risks for these uses. Thus far, the evaluations have focused on risks from worker exposures (including occupational non-users [ONUs]), and consumer exposures (*i.e.*, from use of products containing these chemicals). U.S. EPA has not evaluated risks for the general population *via* releases to ambient air, water, and soil because these exposure pathways are considered to be adequately managed under programs of other environmental statutes (*e.g.*, Clean Air Act [CAA], Safe Drinking Water Act [SDWA], Resource Conservation and Recovery Act [RCRA]). Some notable features of the recent worker risk evaluations are as follows:

- A lifetime cancer risk of  $10^{-4}$  (1 in 10,000) is considered acceptable for workers and ONUs (as opposed to the  $10^{-6}$  [1 in 1,000,000] risk that is considered acceptable for the general population), with consideration of personal protective equipment (PPE) in a subset of the risk calculations. This assumption often results in risks at exposure concentrations lower than the current Occupational Safety and Health Administration (OSHA) Permissible Exposure Limits (PELs), the implications of which are not yet clear.
- Regulatory toxicity assessments were conducted for some chemicals (*e.g.*, asbestos), but for others (*e.g.*, PCE, carbon tetrachloride) U.S. EPA applied values derived in the most recent Integrated Risk Information System (IRIS) toxicity assessments.

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# What's New at Gradient

## Awards and Announcements

**Dave Mayfield and Tim Verslycke** have been awarded the Society of Environmental Toxicology and Chemistry (SETAC) Exceptional Paper Award for their publication, [“Scientific Integrity Issues in Environmental Toxicology and Chemistry: Improving Research Reproducibility, Credibility, and Transparency.”](#)

## Publications

**Bailey, L.A., L.R. Rhomberg.** 2020. Incorporating ToxCast™ data into naphthalene human health risk assessment. *Toxicol. In Vitro.* DOI:10.1016/j.tiv.2020.104913.

Cox, L.A. Jr., **J.E. Goodman, A.M. Engel.** 2020. Chronic Inflammation, Adverse Outcome Pathways, and Risk Assessment: A Diagrammatic Exposition. *Regul. Toxicol. Pharmacol.* DOI:10.1016/j.yrtph.2020.104663.

**Goodman, J.E., L.E. Kerper, R.L. Prueitt, C.M. Marsh.** 2020. A critical review of talc and ovarian cancer. *J. Toxicol. Environ. Health.* 23(5):183-213

Lynch, H.N., **J.E. Goodman.** 2020. Target sites: Skin. *Information Resources in Toxicology (Fifth Edition).* (Ed.: Wexler, P.), Elsevier, Amsterdam, Netherlands, p585-588.

Mihajlov, I., **M.R.H. Mozumder,** B.C. Bostick, M. Stute, B. Mailloux, P.S.K. Knappett, I. Choudhury, K.M. Ahmed, P. Schosser, A. van Geen. 2020. Arsenic contamination of Bangladesh aquifers exacerbated by clay layers. *Nat. Commun.* 11:2244.

**Mozumder, M.R.H.,** B.C. Bostick, H.M. Selim, M.A. Islam, E.M. Shoenfelt, T. Ellis, B. Mailloux, I. Choudhury, K.M. Ahmed, A. van Geen. 2020. Similar retardation of arsenic in gray Holocene and orange Pleistocene sediments: Evidence from field-based column experiments in Bangladesh. *Water Res.* DOI:10.1016/j.watres.2020.116081.

**Mozumder, M.R.H.,** H.M. Michael, I. Mihajlov, M.R. Khan, P.S.K. Knappett, B.C. Bostick, B. Mailloux, K.M. Ahmed, I. Choudhury, T. Koffman, T. Ellis, K. Whaley-Martin, R. San Pedro, G. Slater, M. Stute, P. Schosser, A. van Geen. 2020. Origin of groundwater arsenic in a rural Pleistocene aquifer in Bangladesh depressurized by distal municipal pumping. *Water Resour. Res.* DOI:10.1029/2020WR027178.

**Tuit, C.B., A.D. Wait.** 2020. Sampling and Analysis. *Environmental Science Deskbook: Environmental Law Series.* (Ed: Conrad, J.W.), Thomson Reuters, Eagan, Minnesota.

## Upcoming Presentations

**Virtual. September 15-17, 2020.** PSX 2020.

- **“PBT: Predicting Persistent, Bioaccumulative, and Toxic Properties.”** J. Kneeland.

**Virtual. September 21-22, 2020.** International Society of Exposure Science (ISES) 30<sup>th</sup> Annual Meeting.

- **“Probabilistic Modeling of Leaching from Coal Ash Impoundment Liners: A Case Study in Science Informing Policy Development.”** A. Dale, J. Kondziolka, C. de Lassus, A. Bittner, B. Hensel.

**Virtual. November 15, 2020.** American College of Toxicology 41<sup>st</sup> Annual Meeting.

- **“Toxicity Assessment of Pharmaceutical Dye Sunset Yellow FCF (aka FD&C Yellow No. 6).”** J. Cohen, I. Mohar, T. Lewandowski.



## By The Way...

As of 2019, life expectancy in the United States has declined for the third year in a row, largely because of higher mortality rates for people between the ages of 25 and 64.

Source: <https://www.businessinsider.com/us-life-expectancy-declined-for-third-year-in-a-row-2019-11>



## Gradient Webinar

Join Gradient's *Trends* authors on October 28<sup>th</sup> for a live webinar for further discussion on this Occupational Stewardship issue.

[Please click here for information about this event.](#)

# Hidden Worker Health & Safety Hazards

By Jiaru Zhang, M.P.H.

*OSHA and companies are working to better protect often overlooked sensitive worker subpopulations.*

One of the biggest assets to any company is its employees. However, “one size fits all” Environmental Health and Safety (EHS) programs may not adequately protect all employee subpopulations, including, for example, those who are immunocompromised, pregnant, aging, or non-English speakers. As discussed below, the Occupational Safety and Health Administration (OSHA) has recognized the need to better protect all workers, regardless of health status, age, and ethnicity/language. In addition, a case-study approach for protecting pregnant and soon-to-be-pregnant workers is discussed as a specific example of how to address worker subpopulations.

In 2016, OSHA published a report titled “Recommended Practices for Safety and Health Programs” that shared proactive best practices to protect all workers (OSHA, 2016). Recommendations included involving workers in EHS policy creation; removing barriers to participation, such as language; implementing an anonymous reporting system; encouraging reporting of close calls/near misses; conducting incidence investigations; conducting regular inspections; and identifying chemical, physical, biological, and ergonomic hazards, such as work-related musculoskeletal disorders associated with an aging workforce, etc.

For small- and medium-sized companies, OSHA offers a free and confidential On-Site Consultation Program that does not result in penalties or citations but instead is intended to help companies identify existing and potential workplace hazards, pro-

vide review of safety and health management programs and even conduct occupational health sampling (at no cost), and offer expert advice. In fiscal year 2018, OSHA made over 26,000 visits to companies under this program. For those

companies that operate exemplary EHS programs, OSHA consultants may recommend them for OSHA’s Safety and Health Achievement Recognition Program (SHARP). Acceptance into SHARP designates a company as a model for protecting worker health and safety, which can boost employee morale and attract new talent over its competitors. Additionally, a SHARP certificate exempts companies from OSHA’s programmed inspections for a number of years. Alternatively, companies that do not undergo the On-Site Consultation Program may apply for OSHA’s Voluntary Protection Program (VPP), which offers similar

recognition and inspection exemption benefits.

As an example of how to better protect one of these often-overlooked worker subpopulations, Gradient has developed and conducted conservative screening-level analyses aimed at protecting pregnant and soon-to-be-pregnant workers from developmental and reproductive toxicity (DART). In certain facilities, workers routinely work with or are in the vicinity of potentially hazardous chemicals in their day-to-day activities. However, not all chemicals have established occupational exposure limits (OELs), and, in the U.S., existing OELs do not always consider DART effects. Additional DART analyses have been conducted in order to help occupational physicians decide whether workplace activities should be restricted to protect fathers, mothers, and developing children. According to our analyses, 18% of the 1,700 chemicals/products that were evaluated were classified as known or suspected DART agents, but approximately half of these lacked established OELs. These results suggest a need to evaluate DART effects for this subpopulation, so that risk managers can take informed protective action if needed.

While there has been progress, more research and work are needed to protect sensitive worker subpopulations. Additional emphasis is particularly important on emerging concerns, such as COVID-19, in which immunocompromised and aging workers are disproportionately affected.

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## References:

Occupational Safety and Health Administration (OSHA). 2016. Recommended Practices for Safety and Health Programs. OSHA 3885. 40p. October. Accessed on July 14, 2020 at <https://www.osha.gov/Publications/OSHA3885.pdf>.

*...in the U.S., existing OELs [occupational exposure limits] do not always consider DART [developmental and reproductive toxicity] effects.*

## By The Way...

Dr. Alice Hamilton (1869-1970) is widely credited as the pioneer of occupational health science, spearheading initiatives to make workplaces safer for all Americans.

Source: <https://www.pbs.org/newshour/health/celebrating-life-alice-hamilton-founding-mother-occupational-medicine>

**Do you have a scientific topic that you would like Gradient to write about in Trends? Send us your ideas for future Trends topics:** [trends@gradientcorp.com](mailto:trends@gradientcorp.com).

# Guest Editorial: Opening Pandora's Box: Protecting Your Business by Ensuring a Safe Environment for Employees and Customers

By Bill Hubbard, Esq.

*COVID-19 will be with us for the foreseeable future, meaning businesses must prepare themselves for associated legal action from their employees or customers.*

It seems like years ago, but it was only in March that states started issuing “stay-at-home” or “shelter-in-place” orders to flatten the curve of COVID-19 cases. Orders varied state by state, sometimes city by city, and businesses had to decipher whether they were an essential business, permitted to remain open. By April, “reopening” orders were issued, establishing a phased approach permitting businesses to open if they followed occupancy, social distancing, face covering, and other requirements. Reopening orders varied among states even more than the stay-at-home orders, forcing businesses to determine what safeguards were mandated or recommended. By late June, new hotspots appeared and some states paused their reopening plans or re-closed bars, restaurants, and other businesses to thwart COVID-19 outbreaks.

Throughout all of this, businesses have had to balance their financial health with the health of their employees and customers, all while attempting to avoid liability. Their concern is warranted because COVID-19 exposure lawsuits have already been filed across the country. While the predicted explosion of lawsuits has not yet materialized, the statute of limitations for such claims of a year or more means we are likely to see an influx of cases in years to come. The federal government has been considering legislation providing businesses with immunity from COVID-19 lawsuits, but to date none has been adopted. Various states, including AL, AR, GA, IA, KS, LA, MS, NC, OH, OK, UT, and WY, have begun enacting legislation to narrow the liability limits related to and stemming from COVID-19, though all vary and are in various stages of adoption.

## Employee Claims

Whether or not an employee can recover for COVID-19 disease under workers compensation varies state by state. Employees generally need to prove a causal connection between their job and the disease. However, some states, like Illinois, have passed legislation creating a rebuttable presumption that first responders or front-line workers who contracted COVID-19 did

so in the course of their employment. Workers' compensation statutes often include exclusivity provisions, which bar an employee from bringing a personal injury lawsuit. In most states, however, there is an exception to the exclusivity provision, which permits an employee to sue an employer when the employer committed an intentional tort, allowing the employee to recover for damages beyond those available under workers' compensation. The intentional tort standard varies per state, but it is generally very high, requiring that the employer must have had the intent to injure or the belief that the injury was substantially certain to occur.

## Customer and Contractor Claims

A customer or contractor exposed to COVID-19 could file a lawsuit based on negligence, which requires a plaintiff to prove that the business had a duty, which it breached, causing the plaintiff's injury. Causation requires a plaintiff to prove that they contracted COVID-19 at the business. Because the virus is so widespread, it will be difficult to prove causation; however, efforts at contact tracing may provide plaintiffs with evidence as to where they were likely exposed. As to duty, every business must operate in the same manner as a reasonably prudent business in the same position (industry and geographic location), requiring the plaintiff to prove the business was not acting reasonably.

Acting reasonably requires vigilance in keeping abreast of the changing governmental mandates and best industry practices. Luckily, trade associations, industry groups, and consultants have created guidance documents and published best practices that a business should follow (see, e.g., industry-specific guidance from the American Industrial Hygiene Association [AIHA, 2020] and chemical trade association resources [Society of Chemical Manufacturers & Associates, 2020]). COVID-19 will be with us for the foreseeable future, and every business can protect itself from COVID-19 liability by acting to ensure a safe environment for employees, customers, and contractors.

*Bill Hubbard is a Partner in the Cleveland office of Thompson Hine, specializing in product liability litigation. He can be reached by email at [Bill.Hubbard@ThompsonHine.com](mailto:Bill.Hubbard@ThompsonHine.com).*

## References:

American Industrial Hygiene Association. 2020. Back to Work Safely. Accessed on July 29, 2020 at <https://www.backtoworksafely.org/>

Society of Chemical Manufacturers & Associates. 2020. COVID-19 Resources. Accessed on July 29, 2020 at <https://www.socma.org/resource-center/covid-19/>

# Worker Risk Evaluations Under TSCA: What We Know So Far

*continued from pg. 3*

- Air monitoring data from manufacturing facilities were considered in the risk evaluations, with the 95<sup>th</sup> percentile applied to high-end and the 50<sup>th</sup> percentile applied to central-tendency worker risk estimates. U.S. EPA also used the 50<sup>th</sup> percentiles from worker air monitoring data as worst-case estimates for some ONU scenarios (assumed to be bystanders and not direct handlers of chemicals); however, it is uncertain how conservative this is.
- Exposure models were applied to estimate dermal exposures for several chemicals, resulting in unreasonable risks in some cases, even considering PPE (*e.g.*, methylene chloride, PCE, TCE).

Information from the recent evaluations provides an opportunity for employers to make proactive decisions about potential workplace risks associated with these chemicals, including 1) communicating with workers about the potential exposures and risks that have been characterized by U.S. EPA and how they compare to exposures and risks based on industry data, and about the importance of using PPE; 2) identifying the types of exposure information (*e.g.*, personal air monitoring data) they should be collecting if they do not already have adequate exposure information for their workers (including for ONUs); and 3) interacting with U.S. EPA in framing future risk evaluations, or revisions to the draft risk evaluations, so that accurate exposure information (including industrial hygiene data, information on uses, institutional controls, and PPE) is made available to U.S. EPA and reliable risk estimates can be generated for their workers.

We have yet to see how U.S. EPA will use the risk evaluations to make risk management decisions for the workplace. Since several risk evaluations reported risks at exposure concentrations below the OSHA PELs, how U.S. EPA's risk management decisions intersect with OSHA regulations to guide the mitigation process will have important implications for chemical manufacturers and downstream users.

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## References:

- (a) [U.S. EPA](#). Office of Chemical Safety and Pollution Prevention. 2020. Risk Evaluation for Methylene Chloride (Dichloromethane, DCM) (CAS No. 75-09-2). EPA-740-R1-8010. 753p. June.
- (b) [U.S. EPA](#). Office of Chemical Safety and Pollution Prevention. 2020. Risk Evaluation for 1-Bromopropane (n-Propyl Bromide) (CASRN: 106-94-5). EPA-740-R1-8013. 486p. August.

## The next issue will focus on:

*Product Stewardship & Proposition 65*

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