Lessons Learned
Solutions for Workplace Safety and Health

CASE STUDY 5

Regulating methylene chloride:
a cautionary tale about setting health standards
one chemical at a time
NIOSH estimates 20,000 cancer deaths and 40,000 new cases of cancer per year can be attributed to exposures at work.
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Regulating Methylene Chloride:
A Cautionary Tale about Setting Health Standards
One Chemical at a Time

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On June 30, 2000 a 35-year-old female worker from a North Carolina cushion company was carried to the local emergency room because she could no longer walk without assistance. Days before, headaches had progressed into severe numbness and burning sensations in her feet, legs, thighs, and lower back.

Her job at the cushion company was to glue foam cushion pieces together with a spray adhesive containing 55 percent (by weight) 1-bromopropane, which had been introduced into the workplace not long before workers started to get sick.

One case of this neurological illness turned into many as similarly exposed and sick workers from other cushion manufacturing companies were reported. Months and years later, these workers' neurological symptoms still persist.

The sad irony: the companies had switched to a 1-bromopropane-based adhesive in place of one containing methylene chloride in response to the Occupational Safety and Health Administration's new methylene chloride standard.

How could a system of regulating toxic hazards to protect workers result in additional sick workers?

Since the earliest days of the Occupational Safety and Health Administration (OSHA), the agency has realized the severe limitations of issuing regulations substance by substance, and hazard by hazard. Yet despite this understanding, OSHA regulates exposures to only a small fraction of the tens of thousands of chemicals on the market in the United States today. And the majority of existing health standards allow "acceptable" workplace exposures based on evidence from the 1950s, despite scientific findings that reveal health effects at exposures well below current legal limits.

OSHA’s methylene chloride health standard is a success story: it is comprehensive in scope to protect workers, it survived legal challenges and a threatened Congressional review, and it is based on early signs of harm revealed by animal toxicology studies. Yet despite these successes, the methylene chloride standard clearly reveals lessons learned about the politicization of science to delay regulation, the inherent dangers of a substance-by-substance system of regulating toxic hazards, and the missed opportunity for workplace health regulations to stimulate innovation of safer chemistries.
OSHA's standard setting: Early attempts to remedy problems through substance-specific regulations

The primary mechanism that the 1970 Occupational Safety and Health Act (OSHA) established to protect workers was OSHA's capacity to regulate through specific occupational health and safety standards. Section 6 (b)(5) of the OSHA specifically addresses the need for OSHA, in regulating toxic materials or harmful physical agents, to promulgate the standard that "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."

Those who drafted the law realized that if the OSHA Act was to effectively protect workers, it was imperative that OSHA quickly adopt existing national consensus limits or federal standards for exposures to chemical agents. Within one year of the OSHA Act's passage, Permissible Exposure Limits (PELs) for roughly 450 hazardous agents were established. These interim standards were based on assessments by a private professional organization: the American Conference of Governmental Industrial Hygienists' (ACGIH) 1968 threshold limit values (TLVs). Formal rulemaking ensued, and during the first years of OSHA, the agency devoted much of its resources to setting more comprehensive and permanent health standards for a number of occupational carcinogens, including asbestos in 1972, vinyl chloride and a group of 14 other chemicals in 1974, coke oven emissions in 1976, and benzene, dibromochloropropane, inorganic arsenic, and acrylonitrile in 1978. Yet with a rate of roughly two final regulations in the first nine years of the agency, OSHA quickly learned that issuing rules for hazardous chemicals one at a time could achieve only meager results in the context of the sheer number of chemicals to which workers were exposed.

Back in the day: OSHA tries (and fails) to regulate many carcinogens at once

By the late 1970s, OSHA was under significant pressure by Congress, organized labor, and environmental groups to speed up the standard-setting process. With nearly a decade of experience, the agency had also reflected on the need to resolve and streamline decision-making for specific issues of science policy that were encountered repeatedly during public hearings for each proposed standard—and yet again in the courts as nearly every standard was subsequently challenged by industry. Issues continually debated included, for example: (1) whether there is a threshold (no-effect) exposure for carcinogenic effects of chemicals; (2) whether it's possible to extrapolate from animal data to human risk; and (3) the importance of studies that demonstrate a health risk versus those that find no effect. As a result of these scientific challenges, OSHA issued its Generic Carcinogen Policy in 1980.

The preamble of the Generic Carcinogen Policy acknowledged that "to follow the past system and procedure for each and every individual substance and hazard would be, we believe, beyond the abilities of an agency, no matter how large a staff it may have." To accelerate the rule-making process for carcinogens, the Generic Carcinogen Policy established binding scientific policy determinations, regulatory procedures, and specific provisions that govern OSHA's regulation of carcinogens. Priority was placed on issuing protective health regulations based on early evidence revealed through animal studies, rather than on waiting for conclusive epidemiologic studies documenting effects in humans. Moreover, positive study results (i.e., evidence demonstrating harm) were prioritized over negative results (i.e., evidence demonstrating no harm). Thus a key principle in the policy was prevention—an orientation consistent with OSHA's highly protective mandate concerning worker health. As explained by OSHA, "To wait for years..."
for science to provide further depth of understanding to the complex issues of cancer causation or cure, without having today some consistent and workable system for the reduction or prevention of human exposures to those toxic substances for which there is evidence of a carcinogenic potential to workers, would be inconsistent with OSHA’s statutory obligations and unacceptable to all.”

The policy outlined a process for OSHA to screen candidate substances and to set priorities for regulation. For substances prioritized as highest-risk “Category I potential carcinogens,” a priority-setting mechanism was established whereby OSHA would select 10 substances for comprehensive rule-making at any one time. For all Category I substances, OSHA would require the resulting permanent health standards to reduce exposure to the lowest feasible level. If there was a suitable substitute, no occupational exposure would be permitted. In 1980, OSHA issued a candidate list of 204 substances for further scientific review under the terms of the policy.

**Threats to new and innovative chemicals policy: The US Supreme Court’s Benzene Decision and a new “deregulatory” philosophy**

The Generic Carcinogen Policy had real potential to comprehensively address carcinogenic exposures in workplaces. It set in motion a general policy that the only safe exposure to carcinogens was no exposure, and that the only factor that should limit efforts to reduce exposure was technological feasibility.

However, the policy was weakened almost as soon as it began. A few months after the Generic Carcinogen Policy was established, the US Supreme Court issued what has become known as the Benzene Decision—a decision that dramatically affected OSHA’s ability to regulate hazards in the workplace. In this 1980 decision, the Supreme Court stated that before OSHA promulgates a permanent health standard, the Secretary of Labor is required to make a determination, first, that a workplace is unsafe due to the presence of a “significant risk” to workers, and second, that this risk can be eliminated or lessened by the promulgation of a standard or a change in a standard.

The Supreme Court offered general guidance for future OSHA rule-making by noting that the significant risk requirement is not meant to be a mathematical straightjacket and that responsibility fell on OSHA to determine what it considers to be a significant risk, based largely on policy considerations. The Court provided only one concrete example of significant risk: “If the odds are one in a billion that a person will die from cancer by taking a drink of chlorinated water, the risk clearly could not be considered significant. Yet on the other hand, if the odds are one in a thousand that regular inhalation of gasoline vapors that are two percent benzene will be fatal, a reasonable person might well consider the risk significant and take appropriate steps to decrease or eliminate it.” With guidance to regulate risks somewhere in the range from one in one thousand to one in one billion, the Supreme Court gave OSHA broad discretion to determine how stringently to protect the health of workers from cancer risks considered significant. Yet, subsequent OSHA standards have tended to control exposures only to risks at the upper end of this range. What started with the new Reagan administration’s interpretation of the Supreme Court ruling—that a significant occupational health risk is defined as one cancer death per 1,000 workers exposed to a specific agent over a lifetime—has defined OSHA’s own interpretation of acceptable risk levels ever since.

Under the Generic Carcinogen Policy, significant risk did not have to be demonstrated in order for OSHA’s Category I substances to be regulated to the lowest feasible PEL. However, the Benzene Decision opened the possibility that any subsequent rulemaking on these substances might be overturned by the courts. With a new Republican administration in the White House, the government decided not to pursue implementation of the policy and thereby risk legal challenge.
In January 1981, OSHA published changes to the Generic Carcinogen Policy in response to the Benzene Decision. These changes modified the regulatory requirement for Category 1 substances such that exposure levels would be set on a substance-by-substance basis, considering the significance of the risk present and using all relevant evidence and statutory provisions. In 1983 OSHA issued a partial stay on the policy while it reviewed its criteria and process requirements for developing lists of chemicals considered candidates or priorities for regulation. Despite attempts by labor groups, industry groups, and the Office of Management and Budget (OMB) to either revive or completely kill the policy, no action was subsequently taken. OSHA still has the opportunity to revive this policy as an important model, moving the agency towards comprehensively regulating known and suspected carcinogens. Yet the requirements under the Benzene decision, despite attempts by OSHA to revise the policy accordingly, still remain one of the primary barriers.

OSHA’s additional attempts to comprehensively and expeditiously regulate toxic chemical exposures

By the late 1980s, as OSHA approached its 20th birthday, the agency had established just 13 permanent standards covering 26 substances—efforts that significantly lagged behind progress by other organizations that evaluate health data and set exposure limits. For example, by 1987 the ACGIH had set TLVs for 168 additional substances that were not regulated by OSHA. ACGIH also revised downward 234 of the roughly 450 TLVs from the 1969 list that OSHA adopted into law in 1971 based on more recent evidence of harm at lower exposure levels.

Similarly, over this same period the National Institute for Occupational Safety and Health (NIOSH) had developed and published Recommended Exposure Limits (RELs) for 160 substances. Unfortunately, NIOSH is not a regulatory body and its standards are not legally enforceable. While the OSHAct directs OSHA to use NIOSH recommendations in the promulgation of new or revised health and safety standards, OSHA has acted on only a handful of NIOSH’s recommendations.

In 1989 OSHA issued the Air Contaminants Standard, in which it promulgated 212 additional PELs and 164 updated PELs based for the most part on ACGIH’s TLVs. Yet in 1992, the US 11th Circuit Court of Appeals vacated the standard because OSHA had failed to establish that each regulated substance posed a significant risk as required under the Supreme Court Benzene Decision and because OSHA did not meet its burden of establishing that the new PELs were either economically or technologically feasible. OSHA’s request for a rehearing was denied, and a request for an appeal to the Supreme Court was rejected by the US Solicitor General. As a result, in June 1993 OSHA revoked the updated PELs, and thus the PELs reverted back to the levels set prior to issuance of the Air Contaminants Standard.

Despite OSHA’s efforts to regulate chemicals more broadly through the Generic Carcinogen Standard and the Air Contaminants Standard, the majority of current workplace health standards remain woefully out of date and workers are being legally exposed to chemicals at levels known to cause harm. To date, OSHA has issued roughly 30 permanent health standards for toxic substances, a small fraction of the chemicals used in commerce today. The last permanent health standard that
OSHA established was the hexavalent chromium standard in 2006.

At the end of a long regulatory battle, the PEL in the final hexavalent chromium rule was five times less protective than the limit OSHA had initially proposed. An examination into the industry-funded data that were used as the primary basis for the revised PEL suggests that the data were analyzed in such a way as to cover up evidence that very low levels of chromium can cause cancer. As a consequence, the final standard considered it “acceptable” that from one to nearly five workers for every 100 workers exposed to hexavalent chromium at the new PEL over the course of their working life will die of lung cancer. Yet OSHA did not update its own standard until pressure mounted based on even more troubling evidence of the chemical’s carcinogenicity from the National Toxicology Program (NTP).

In February 1985, NTP published its results from two animal carcinogenicity studies on methylene chloride. Based on its two-year inhalation study using rats, NTP found “some evidence” for males and “clear evidence” for females of the carcinogenicity of methylene chloride for mammary gland cancers. NTP’s second inhalation study examining effects in mice revealed “clear evidence” of the carcinogenicity of methylene chloride for lung and liver cancers among both males and females.

The methylene chloride rule: Delays and regrettable substitutions through substance-by-substance, risk-based regulation

Over 60 years ago, methylene chloride (also known as dichloromethane) was introduced as a replacement for more toxic and flammable solvents. Its non-flammability and strong solvent capability contributed to the broad use of methylene chloride in a variety of products and processes. It was widely used in paint removers, degreasing agents, adhesives, and aerosol propellants. It was also used as a blowing agent in flexible urethane foams, as a process solvent in the manufacture of pharmaceuticals and food products, and as a fumigant for grains and fruits. While overall use of methylene chloride has declined in recent years, it is still used in most of these applications today.

Like the vast majority of legal exposure limits, the exposure limit for methylene chloride was established in 1971 based on a 1946 ACGIH threshold limit value (500 ppm 8-hour time-weighted average, or TWA). This initial exposure limit was established to protect workers from methylene chloride’s ability to irritate the skin and eyes as well as to affect the central nervous system. By the mid-1970s scientific evidence revealed that levels of methylene chloride far below the 500-ppm limit produced levels of carboxyhemoglobin (COHb) that robbed the blood of its ability to deliver oxygen, which in turn could cause heart disease or aggravate preexisting heart disease. Based on this evidence, in 1975 the ACGIH lowered the recommended threshold limit value to 100 ppm, and in 1976 the National Institute for Occupational Safety and Health established a REL (8-hour time-weighted average) of 75 ppm.

Yet OSHA did not update its own standard until pressure mounted based on even more troubling evidence of the chemical’s carcinogenicity from the National Toxicology Program (NTP).

Labor petitions and OSHA (finally) sets a standard

The NTP toxicological studies prompted review and action on methylene chloride exposure across a number of federal regulatory agencies, including OSHA. Yet OSHA’s response was not of its own accord, but rather was instigated by a petition from labor. In July 1985, The United Auto Workers (UAW) used the NTP study results to petition OSHA to issue a hazard alert and an emergency temporary standard for methylene chloride. The petition, which was subsequently joined by six other unions, also called for OSHA to begin work on a permanent standard requiring a radical reduction in allowable workplace exposure levels for methylene chloride.

In April 1986, NIOSH published a Current Intelligence Bulletin on methylene chloride in which it recommended methylene chloride be regarded as a “potential occupational carcinogen.” The foreword of the report stated, “Although the potential for methylene chloride induced cancer in humans has not been determined, the probability of a population of exposed workers developing cancer...
could be decreased by reducing exposure. Therefore, NIOSH recommends that occupational exposure to methylene chloride be controlled to the lowest feasible limit.”

This recommendation mirrored the original OSHA Generic Carcinogen Standard that called for action before evidence of harm in humans.

Sixteen months after labor’s call for action and NIOSH’s recommendation to reduce exposures, OSHA denied the petition for an emergency standard, but agreed to launch a permanent standard-setting process. A few days later, in November 1986, OSHA announced its Advanced Notice of Proposed Rulemaking to revise the occupational health standard for methylene chloride.

After multiple delays—and 12 years after NTP’s studies sounded the alarm—OSHA finalized its methylene chloride rule.

After multiple delays—and 12 years after NTP’s studies sounded the alarm—OSHA finalized its methylene chloride rule. The standard, which went into effect April 10, 1997 for most industries, reduced the legal exposure limit from 500 to 25 parts per million in air over an 8-hour workday and established a short-term exposure limit of 125 ppm for 15 minutes. It also established requirements for exposure monitoring, worker training, engineering controls, designation of restricted areas, spill and leak prevention, and medical surveillance for high-risk employees. The standard made clear that if engineering controls and workplace practices did not reduce methylene chloride to an acceptable level, workers must use full face-piece supplied-air respirators because methylene chloride vapors penetrated standard filter cartridge respirators. The updated standard was based primarily on the NTP results showing the carcinogenic effect of methylene chloride in mice, with support from a variety of occupational epidemiologic studies demonstrating increased risk of cancers of the biliary tract/liver, prostate gland, and brain, as well as suggestive evidence for an effect on cardiovascular mortality.

Since the Benzene Decision, and despite the Supreme Court’s broad interpretation of significant risk—the threshold for implementing any regulatory action—OSHA has steadfastly interpreted significant risk as one extra case of cancer or other health consequence per 1,000 workers over the course of a working life (45 years). In the case of the methylene chloride standard, the residual lifetime risk of cancer at the new PEL was 3.6 per 1,000 workers. Thus even after OSHA established more stringent exposure limits, a significant number of deaths as a result of cancer caused by methylene chloride exposure were still to be expected. OSHA acknowledged in the rule itself that a significant risk remains at 25 ppm, but the PEL was considered what was currently “feasible” (an issue addressed further below).

Thus, workers who assume that exposures at the new PEL are no longer dangerous are sadly mistaken. OSHA’s residual cancer risks for workers are orders of magnitude greater than risks EPA “accepts” for the broader public. This essentially translates into acceptance of a large number of illnesses and deaths among workers while society is willing and able to prevent these same outcomes among the general public.

Want to delay and derail worker health protections? Debate the nuances of risk assessment

Delays in finalizing the methylene chloride standard came in many forms, but all were due in part to continued science policy debates that were different from those the 1981 Generic Carcinogen Policy sought to alleviate. The new debates were rooted in the requirement of the Benzene Decision to demonstrate the significance of methylene chloride’s risk to workers through risk assessment.

Risk assessment is a tool that uses modeling and prediction to evaluate the potential for exposure to a chemical hazard to cause disease. It requires numerous assumptions and judgments about exposures, human behavior, and how a chemical moves through and is metabolized by the body to exert its toxic effect. Because of uncertainties in these assumptions, risk assessments conducted by different scientific groups can result in widely different results. On top of this, political and financial interests can also influence the risk assessment process.
OSHA’s risk-assessment-based standard-setting process also limits a comprehensive understanding of risks and prevention opportunities because the preventability of the exposure is rarely considered in establishing “acceptable” exposure levels. This one-chemical-at-a-time risk assessment doesn’t evaluate the possibility of cumulative or interactive exposures or effects. Thus, as practiced, risk assessment uses highly uncertain data to arrive at a single estimate at the expense of a broader, more nuanced understanding of risk.38

In developing the methylene chloride rule, there was extensive industry testimony and comments on narrow technical issues like these: Which animal model is the most representative of methylene chloride’s mode of action in humans? Is there a documented physiological mechanism or mechanism(s) that demonstrates methylene chloride’s carcinogenic effect? What pharmacokinetic model best represents how methylene chloride is metabolized in animals versus in humans? Extensive resources and time were spent soliciting and responding to comments critiquing the validity of scientific knowledge and assumptions OSHA made in its final risk assessment.12 Then, in 1995, after OSHA had closed the record and proposed its updated methylene chloride rule, the Halogenated Solvents Industry Alliance introduced a handful of new studies that it had sponsored.

The studies were in effect, industry’s last-ditch effort to downgrade methylene chloride’s cancer risk. In summarizing the studies, the executive director of the Halogenated Solvent Industry Alliance stated that this new evidence showed that mice “are uniquely sensitive at high exposure levels to methylene chloride–induced lung and liver cancer, and . . . other species, including humans, are not at similar risk.”39 OSHA has a responsibility to examine and consider all available evidence to justify its decisions whether to regulate. As a consequence, OSHA reopened the record to receive and respond to comments about the study.

The studies were found to have significant problems in design and conduct which limited the validity of the results.34 OSHA ultimately rejected these arguments and the proposed standard was left intact. Yet more time had been lost and more workers had been exposed to a cancer-causing chemical. Given the high burden OSHA faces to
implement permanent health standards for chemicals, this strategy of “manufacturing uncertainty” has worked extremely well in delaying actions.\(^{37}\)

The primacy of engineering controls: technological feasibility trumps preventing hazards at their source

OSHA was also required to demonstrate that the methylene chloride standard could be met “to the extent feasible,” as defined in the OSHAct. Feasibility has two components: (1) technological feasibility; and (2) economic feasibility. The analyses needed to demonstrate feasibility, along with the process of responding to public comments, are further reasons that it took so long to finalize the methylene chloride standard. For a standard to be considered “technologically feasible,” OSHA must demonstrate that industry can meet the PEL either through the application of existing control technology or through new and improved technologies not fully developed.\(^{40,41}\)

Thus the courts saw a role for OSHA standards to stimulate innovation as a “technology-forcing” authority.\(^{42,43}\) The courts even noted that such technology forcing could adversely affect laggard companies that were not adopting technologies to appropriately protect workers. These court decisions were consistent with the industrial hygiene hierarchy of controls that places substitution as the most effective means to protect workers, followed by engineering controls, administrative controls and as a last resort, personal protective equipment. But despite these health-protective interpretations of technological feasibility, it is the more recent debates over economic feasibility that have stymied regulatory actions.

While the agency could consider innovation as reducing long-term costs of compliance, OSHA is often constrained in examining economic feasibility as a result of economic reviews conducted by OMB, and also by the Regulatory Flexibility Act, the Paperwork Reduction Act, and the Small Business Regulatory Enforcement Fairness Act. The latter act requires that OSHA convene and gather input from a Small Business Advocacy Review Panel that comprises several Small Entity Representatives, officials from the Small Business Administration’s Office of Advocacy, and officials from OMB’s Office of Information and Regulatory Affairs. OSHA officials noted that the agency “increased flexibility of compliance in response to comments made by the Small Business Administration and small businesses, themselves—OSHA gave small employers more time to implement the standard’s requirements; eliminated a requirement for written compliance plans; and altered training requirements.” A report by the Center for Progressive Reform has found that the requirement to comply with these laws significantly delays regulation without producing any clear benefits to industry or health.\(^{44}\)

As a result of these review requirements, OSHA interpreted its feasibility analysis with caution. This was in part to avoid costly challenges by industry that would require significant human and economic resources of an already resource-constrained agency. In the case of methylene chloride, rather than designing a regulation that stimulated research and technological innovation to eliminate the use of the chemical, the standard relied on less protective hazard control approaches, such as engineering controls (e.g., using ventilation equipment to remove the offending agent to the outdoors).\(^{45,48}\) These controls are standard in most of our current regulatory approaches that seek to manage risk—that is, reduce exposure to the chemical of concern rather than reduce the intrinsic hazard of the substance by investing in strategies that discover, design, and adopt safer alternatives.

The unintended consequences of chemical-by-chemical, agency-by-agency approaches to chemicals management

Our failure to advance a worker health and safety system that incentivizes the development and design of safer chemistries can result in continued harm to workers when employers seek substitutes for regulated chemicals. Although OSHA expected industries to use engineering controls to comply with its methylene chloride standard, in fact many companies abandoned the use of methylene chloride due to the perceived costs of these controls.\(^{46}\)

OSHA was not the only federal agency that affected employers’ use of methylene chloride. The Food and Drug Administration (FDA), the Consumer Product Safety Commission (CPSC), the Department of Housing and Urban Development (HUD), and the Environmental Protection Agency
(EPA) all issued actions responding to the NTP studies and epidemiologic literature about methylene chloride’s potential carcinogenicity. The FDA issued a final rule on June 29, 1989 banning methylene chloride in cosmetic products, primarily hair sprays.\(^6\) The CPSC fell short of issuing a final rule regarding methylene chloride, but issued a “statement of interpretation and enforcement policy” requiring that by September 14, 1988, all manufacturers, importers, packagers, and private labelers of consumer products must indicate on all products that inhalation of methylene chloride has produced cancer in laboratory animals and must specify relevant use precautions.\(^{18}\) HUD issued restrictions on using methylene chloride during residential de-leading. EPA undertook its own risk assessment of methylene chloride and in May 1985, determined that the chemical was a probable human carcinogen.\(^{25}\)

EPA’s subsequent actions were primarily stimulated by the 1990 Clean Air Act Amendments (CAAA), and resulted in contradictory outcomes. One component of the CAAA required EPA to phase out ozone-depleting chemicals by 2000. In 1994, EPA determined that methylene chloride was one of the many “acceptable” chemical substitutes for a number of industrial applications, even though the Agency acknowledged concerns about its toxicity.\(^{19}\) In the ensuing years, EPA also set restrictive air emissions through technology standards for dozens of hazardous air pollutants, including methylene chloride, as part of its regulatory obligation under Title III of the CAAA. Thus, while EPA obligated industries to eliminate their use of ozone-depleting chemicals (which could involve switching to methylene chloride), the agency’s actions to reduce hazardous air pollutant emissions sent another message to employers to reduce or eliminate methylene chloride use.

From the point of view of many employers, engineering controls to reduce methylene chloride exposures were not a feasible means for regulatory compliance, given the array of federal agency actions. For example, employers could not simply vent methylene chloride vapors to the outside because of EPA’s new and more restrictive emission standards. If occupational health regulations restrict methylene chloride emissions inside where it affects workers, and environmental regulations restrict venting emissions outside because of air quality protections, a reasonable solution might be to replace methylene chloride altogether.

And that’s just what many companies did. In response to methylene chloride regulations as well...
as regulations associated with EPA’s ban on ozone-depleting chemicals, chemical companies and equipment manufacturers identified a new market for a broad array of old and new alternatives, including substitute chemistries, mechanical and equipment innovations, as well as modernized manufacturing processes.50

There are many examples of companies that successfully transitioned to using safer alternatives to methylene chloride and often experienced financial benefits as a result.50 Yet, there are also tragic cases of companies that fell prey to the opportunistic marketing of replacement chemicals that were largely untested and unregulated—such as 1-bromopropane.

Substituting an untested chemical for a bad one: the tragic mistake called 1-bromopropane

In the early to mid-1990s, 1-bromopropane, also known as n-propyl bromide, was used primarily as an intermediate in the production of a range of chemicals. By the mid- to late 1990s, as EPA’s and OSHA’s methylene chloride regulations as well as bans on the use of specific ozone-depleting solvents began to take effect, 1-bromopropane blasted onto the scene as an alternative to methylene chloride. It was introduced and marketed as a non-flammable, non-toxic, fast-drying and inexpensive solvent that was effective in a variety of applications, such as refrigeration, metal cleaning, and vapor and immersion degreasing applications, as well as in adhesive resins.1,3,51-54 1-bromopropane became a favored replacement solvent in some applications because it worked well, it was a quick, drop-in substitute, and there were no regulations governing workplace or environmental emissions and minimal toxicity testing to suggest any hazard.53,54

Despite some signals as early as 1981 that 1-bromopropane was mutagenic, no comprehensive toxicity testing of the chemical had been conducted.2,55 A broader literature on the hazards of 1-bromopropane began to emerge in 1998. That year, the first report of the neurotoxicity of 1-bromopropane from animal studies was published.53 A year later, the first case report of neurotoxicity in a worker was published.56 In that case report, a 19-year-old worker who used 1-bromopropane for metal degreasing and cleaning had developed progressive weakness in his legs and right hand, had difficulty swallowing, and at the time of admission to the hospital in February 1998 could no longer stand without assistance.56

One worker after another who used a 1-bromopropane-based spray solvent in a job manufacturing cushions similarly experienced the neurotoxic effects of 1-bromopropane.1,3 For many of these workers, symptoms persisted for years, and some of these workers also experienced reproductive effects, which unfortunately were some of the earliest signals of reproductive harm from the chemical.1,3,57-58 Many cushion-manufacturing employers had recently introduced 1-bromopropane as an alternative to methylene chloride.1,59

Prompted by cases of sick workers, NIOSH launched a series of health hazard evaluations at a number of cushion-manufacturing workplaces that used 1-bromopropane during the period 1998-2000, and recommended enhancing engineering controls to reduce exposure levels.58,60,61 In 2003, and on the basis of limited data, NTP’s Center for the Evaluation of Risks to Human Reproduction concluded that 1-bromopropane is toxic to the developmental and reproductive health of animals.

At the request of OSHA in 1999, NTP also studied the carcinogenicity of 1-bromopropane and found evidence of carcinogenicity.62,51 In an unpublished analysis by a former Director of Health Standards at OSHA, the NTP results reveal that 1-bromopropane is roughly four times as potent a carcinogen as methylene chloride.63

Yet to date, neither EPA nor OSHA has established regulations to minimize health risks from exposure to 1-bromopropane. In 2006, the ACGIH set a time-weighted average TLV for 1-bromopropane at 10 ppm. As of late 2010, NIOSH is in the process of establishing a REL for 1-bromopropane.

On May 9, 2010, OSHA published its regulatory review of the methylene chloride standard. While none of the comments submitted highlighted the problems of substituting 1-bromopropane for methylene chloride, OSHA’s final report did acknowledge potential health hazards with some substitutes: “The use of substitutes for MC [methylene chloride] has increased in certain industries. These substitutes may pose their own health hazards. Therefore, based on public comments, OSHA
will consider putting out guidance recommending that, before a substitute for MC is used, the toxicity of that substitute should be checked on the EPA and NIOSH websites. While such guidance would be a step forward, it remains to be seen whether OSHA will pursue these hazard communication efforts.

More than a decade to regulate one chemical? At what cost?

While OSHA finally prevailed in finalizing the methylene chloride rule, this accomplishment came at a cost to worker health due to regulatory delays and our substance-by-substance system of regulation. The high burden on OSHA to demonstrate significant risk on a chemical-by-chemical basis opens the door for scientific challenges (with or without merit) that delay preventive actions. Regulation of one chemical without thinking about alternatives opens the door for unregulated chemicals to be used in substitution.

While substitution is the preferred approach to protect not only workers but also the broader public from chemical hazards, it is dangerous to pick substitutes without a thorough overhaul of our system to manage the safety of chemicals in commerce. Designed correctly, chemical regulations can stimulate scientific research and technological innovation.

Yet as things currently stand in the United States, employers are left to their own devices to find alternatives to newly regulated chemicals. Such employers can easily fall prey to chemical sales personnel who are eager to sell them a promising substitute that is considered “safe” simply because no testing has proven it hazardous. Given that complete basic toxicological screening data is available for only a small percentage of the tens of thousands of chemicals listed as being in commerce in the United States, stories like 1-bromopropane will be played out again and again until new approaches to comprehensively manage these hazards are identified.

OSHA estimated that the permanent methylene chloride standard would reduce exposure-related deaths by at least 97 percent for more than one-quarter of a million US workers, and prevent the deaths of 34 workers per year on average. Thus the 12 years that it took to enact the standard (not including the additional time for small businesses to comply with the regulation) and the decision not to issue an emergency standard (as originally recommended by labor) inadvertently resulted in continued exposures to workers that caused or will cause an estimated 408 deaths. Moreover, by OSHA’s own estimates, for each year that the new standard was delayed, as many as 30,000 to 54,000 workers may have suffered central nervous system and cardiovascular system damage. Clearly, lengthy rule-making processes are not healthy for workers.

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The road not taken: Toxics use reduction and a comprehensive chemicals policy

While OSHA debated the mechanisms of action of methylene chloride and their relevance to humans, agencies in Massachusetts were implementing a pioneering new approach to reducing chemical hazards—toxics use reduction (TUR). Under the 1989 Toxics Use Reduction Act, manufacturers using more than 10,000 pounds per year (less for chemicals of high concern) of some 900 chemicals are required to undertake a yearly accounting of how those chemicals enter, are used in, and are released from their facility as waste (liquid or solids that are captured and transferred offsite) or emissions (e.g., releases to air, water or ground). Every two years, the firms are required to undertake a planning process to identify alternatives to reduce or eliminate those chemicals. In reviewing alternatives, firms are required to include workers and consider environmental, consumer, and occupational health hazards to ensure that risks are not shifted. Firms pay a small fee on chemical use that funds the regulatory program but also funds voluntary, confidential technical assistance and training, and research support at the Toxics Use Reduction Institute at the University of Massachusetts Lowell.
This model of regulatory requirements to understand chemical use and opportunities for prevention (without any requirement to act), coupled with support to firms to institute changes, has led to significant results in just the first 10 years of the program: an 80 percent reduction in chemical emissions; a 67 percent reduction in chemical waste; and a 40 percent reduction in toxic chemical use, while saving firms millions of dollars.38

The TUR approach focuses on alternatives and solutions to toxic chemical concerns, even though perfect information is not available. For example, while the US EPA has struggled to finalize a risk assessment on trichloroethylene (TCE), a suspect carcinogen widely used in degreasing, Massachusetts has reduced the use of this chemical by 95 percent in degreasing operations by testing alternatives, which have been evaluated for safety, to ensure they work as effectively as TCE.

One example of the success of the TUR approach took place at Crest Foam, a small polyurethane foam manufacturer. The company eliminated the use of 190,000 pounds per year of methylene chloride by installing a foaming process that uses carbon dioxide instead of trichlorofluoromethane (CFC-11) or methylene chloride. The alternative is not only more efficient and less costly than methylene chloride, but also saved the company tens of thousands of dollars in permitting and emission control equipment costs.65

While the TUR model demonstrates that a solutions-based approach to chemical hazards can reduce risks and save money, it does not entirely eliminate the roadblock of quantitative risk assessment. A lengthy debate about these challenges in the European Union led, in 2007, to an entirely new chemicals policy called REACH—Regulation, Evaluation, and Authorization of Chemicals. REACH requires manufacturers and importers of chemicals to provide to authorities information on chemical toxicity, uses, and exposure; and to inform chemical users of hazards and prevention measures. In addition, REACH requires companies to seek permission to continue to use chemicals of high concern. While REACH is still in the early years of implementation, it is an effort to address the challenges outlined in this paper, in order to more effectively understand and prevent chemical hazards.

Following the passage of REACH, several US states have initiated their own comprehensive chemicals policies. While they differ in nature, they focus on prioritizing the universe of chemicals into lists of higher and lower concern, requiring or encouraging the shift to safer alternatives, and disclosing the chemical ingredients and toxicity of products.

Indeed, many leading-edge firms are undertaking their own efforts to prioritize chemicals of concern and find safer alternatives. While some firms are considering the lifecycle impacts (that is, including the impacts to workers, consumers and the environment of upstream production and downstream disposal) of substitutes, many others are still focused only on direct hazards to consumers.

In 2009, the US EPA released principles for reforming the US federal toxics law, the 1976 Toxics Substances Control Act (TSCA), a law that was originally seen as a response to the limits of the OSHAct for protecting workers from toxic exposures. While TSCA has been criticized for the high burdens it places on EPA to gather hazard data and take action, for new chemicals the law authorizes EPA to collect data and prevent exposures when a substance “may present an unreasonable risk or substantial exposure”—even before that substance has been manufactured. This worker health provisions has provided some added measure of protection for workers, though new chemicals on the market since 1980 represent less than 5 percent by volume of the total on the market today.

As Congress begins to debate the new Safe Chemicals Act, introduced in the House in June 2010, it is imperative that worker health considerations be front and center. Indeed, while the law includes only some limited reference to substitution, there are several provisions that specifically address worker health. Nonetheless, given the eight-year reform process in Europe leading to REACH, and the six-year process that led to the original TSCA, it is unlikely that changes to federal chemicals policy will occur any time soon.

Many leading-edge firms are undertaking their own efforts to prioritize chemicals of concern and find safer alternatives.
Lessons Learned

The long history of the methylene chloride standard also shows us that it is possible to issue protective regulations based on the weight of the evidence at any one time. OSHA relied on early warnings of harm from animal studies and did not delay acting to protect workers until conclusive evidence from epidemiologic studies emerged. Yet there were delays. It took OSHA over a decade to issue this one permanent health standard. Meanwhile tens of thousands of workers remained exposed to levels of methylene chloride known to cause harm, and hundreds of workers will meet or have met an early death. Reasons for these delays are numerous and include manufactured uncertainties and a broad range of time-intensive obligations set forth by the OSHAct, Congress, the courts and the Executive Office of Management and Budget.

Yet one obligation in particular, the requirement of the Supreme Court’s Benzene Decision to demonstrate the significance of methylene chloride’s risk to workers through risk assessment, offered a forum for the politicization of science that continues to plague rule-making processes to this day. While OSHA ultimately “won” the risk and economic assessment game in the case of methylene chloride and was able to meet its various legal and administrative obligations while keeping intact a rule to better protect workers, the extensive resources spent on dueling scientific and economic assessments could have been used to help small and medium-sized businesses identify and implement safer alternative chemicals—stimulating innovation and saving lives.

It thus appears that the Benzene Decision stands firmly in the way of a more efficient and more effective rulemaking process on toxics in workplaces. Or does it? The challenge facing occupational health policy is to think about toxic substances differently. We need to identify leverage points that better address the entire system of chemicals uses and alternatives, and so protect workers, consumers and the environment.

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### CASE STUDY 5 — TIMELINE

<table>
<thead>
<tr>
<th>YEAR</th>
<th>EVENT</th>
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<tbody>
<tr>
<td>1971</td>
<td>OSHA adopts ACGIH’s 8-hour time-weighted average (TWA) 500 ppm as the Permissible Exposure Limit (PEL) for methylene chloride (interim standard). The exposure limit was originally established in 1946.</td>
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<tr>
<td>1975</td>
<td>ACGIH lowers its Threshold Limit Value (TLV) for methylene chloride from 500 ppm to 100 ppm.</td>
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<td>1976</td>
<td>NIOSH recommends reducing the 8-hour TWA for methylene chloride from 500 ppm to 75 ppm.</td>
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<tr>
<td>1980</td>
<td>(January) OSHA issues its Generic Carcinogen Policy.</td>
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<td>1980</td>
<td>(July) The Supreme Court issues what is now known as the Benzene Decision, requiring OSHA to make a determination that a workplace is unsafe due to the presence of a “significant risk” to workers, and that this risk can be eliminated or lessened by the promulgation of a standard or change in a standard.</td>
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<tr>
<td>1981</td>
<td>OSHA revises its Generic Carcinogen Policy to be more consistent with the Supreme Court’s Benzene decision.</td>
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<tr>
<td>1983</td>
<td>OSHA issues a partial stay on its Generic Carcinogen Policy, which remains in effect today.</td>
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<tr>
<td>1985</td>
<td>(February) NTP reports bioassay results showing clear evidence of methylene chloride’s carcinogenicity in mice and rats.</td>
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<td>1985</td>
<td>(May) EPA’s risk assessment on methylene chloride determines the chemical is a “probable human carcinogen.”</td>
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<td>1985</td>
<td>(July) UAW and others petition OSHA to issue an emergency temporary standard, develop guidelines for handling methylene chloride, and initiate rulemaking, for a permanent standard.</td>
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<tr>
<td>1986</td>
<td>(April) NIOSH publishes its Current Intelligence Bulletin, classifies methylene chloride as potential occupational carcinogen and recommends control of exposures to the lowest feasible level.</td>
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<tr>
<td>1986</td>
<td>(November) OSHA denies petition for a current standard and days later initiates rulemaking on a permanent standard.</td>
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<td>1988</td>
<td>CPSC issues a “statement of interpretation and enforcement policy” requiring hazard labeling for consumer products containing methylene chloride.</td>
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<tr>
<td>1987</td>
<td>OSHA issues its Air Contaminants Standard updating and/or establishing PELs for nearly 400 chemicals.</td>
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<td>1989</td>
<td>FDA issues final rule to ban methylene chloride in cosmetic products.</td>
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<td>1992</td>
<td>US 11th Circuit Court of Appeals vacates the Air Contaminants Standard because OSHA failed to establish that each regulated substance posed a significant risk and that the new PELs were either economically or technologically feasible.</td>
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<tr>
<td>1994</td>
<td>EPA determines that methylene chloride is an acceptable chemical substitute for ozone-depleting chemicals targeted for phase-out. In the years that follow, EPA also sets restrictive air emission technology standards for methylene chloride.</td>
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<tr>
<td>1997</td>
<td>OSHA’s final methylene chloride rule is issued, lowering the permissible exposure limit to 25 ppm and sets a short-term exposure limit is 125 ppm for 15 minutes.</td>
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<tr>
<td>1998</td>
<td>OSHA’s methylene chloride rule is amended to support temporary medical removal protection benefits and start-up dates for compliance for specific applications.</td>
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<tr>
<td>1998</td>
<td>First cases of neurological illness occur in workers using 1-bromopropane as a substitute for methylene chloride.</td>
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<tr>
<td>2003</td>
<td>NTP concludes that 1-bromopropane is toxic to the developmental and reproductive health of animals.</td>
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<tr>
<td>2009</td>
<td>NTP issues draft technical report demonstrating evidence of carcinogenicity of 1-bromopropane in mice and rats.</td>
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Acknowledgments

We are deeply grateful to Dr. Adam Finkel (University of Pennsylvania), who was instrumental in both the design and review phases of this case study, given his experience as OSHA Director of Health Standards when the methylene chloride standard was issued and his current research and analysis of the hazards associated with 1-bromopropane. We also thank Dr. Cora Roelofs (University of Massachusetts Lowell) who also helped to review this case study and whose science policy research on methylene chloride over the last decade is featured prominently here.

References

CASE STUDY 5: Regulating Methylene Chloride


40. Society of the Plastics Indus., Inc. v. OSHA, 509 F.2d 1301, 1308 (2nd Cir.) 1975.


Every day, 14 workers die on the job, and each year more than four million are seriously injured or sickened by exposures to toxic agents. Real change in the nation’s approach to workplace safety and health is desperately needed.

This case study is one in a series of six featured in the full report, Lessons Learned: Solutions for Workplace Safety and Health. The series includes:

- **Case Study 1**
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  When my job breaks my back: shouldering the burden of work-related musculoskeletal disorders
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Through these case studies, the report identifies strategies for real change—approaches that can protect workers while stimulating innovation in safer forms of production that can also protect the communities in which we all live. Copies of the full report, executive summary, as well as the individual case studies can be downloaded from the Lowell Center for Sustainable Production’s website, by clicking on the links above.