

# Client Alert

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Environment, Land and Resources Department

## Federal TCE Review May Trigger Cleanup and Exposure Issues

On July 27, 2006, the National Research Council (NRC) of the National Academy of Sciences released a widely-anticipated report (NAS Report) on the toxicity of trichloroethylene (TCE). The release of the NAS Report marks a milestone in the regulation of TCE and likely will galvanize regulatory officials, activists, and the plaintiffs' bar, which have been seeking to reinvigorate TCE as a basis for regulatory action and toxic tort litigation. The regulated community should monitor carefully these, and related, developments, and prepare for a potentially new paradigm where the link between TCE and cancer is considered to be stronger than previously thought, and exposure to TCE through vapor pathways is more prominent than in the past, when the overriding focus was on exposure to TCE in water. Companies should be positioning themselves now to respond to these shifting fundamentals.

### Overview

The NAS Report was commissioned by the White House, Department of Defense, United States Environmental Protection Agency (EPA), and other agencies to offer independent guidance following a controversial draft TCE toxicity evaluation EPA issued in 2001. The NAS Report supports EPA's finding that TCE is a potential human carcinogen, based on the NAS's review of the toxicological literature on the

subject. However, the NAS noted that some of the human epidemiology studies relied upon in previous risk assessments are "weak;" NAS relied primarily on animal toxicity studies in reaching its conclusions.

While acknowledging that additional research is required to evaluate fully the risk of exposure to TCE, the NAS Report urges EPA and other federal agencies to finalize their toxicity reassessment without such research, and EPA intends to do so within six months. The main conclusion of the NAS Report – that the weight of evidence on cancer and other health risks from TCE exposure has strengthened since 2001 – has significant legal and policy implications.

On a parallel track, EPA is re-evaluating the extent to which TCE rises out of groundwater and soil as a vapor, potentially placing people in overlying buildings at risk. EPA is concerned that tools traditionally used to estimate exposure to TCE vapors may understate such exposure significantly. Scientific understanding of the intrusion of vapors from chemicals like TCE (vapor intrusion) into indoor spaces including homes is evolving significantly. EPA is expected to issue final guidance on vapor intrusion this year that recognizes that the model widely relied upon to determine the presence of vapors in indoor air underestimates exposure. The guidance is expected to recommend new decision criteria and more site-

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specific sampling methodologies, which could require sites across the country to be re-evaluated for TCE contamination.

Correspondingly, pressure is likely to increase on EPA from politicians, other agencies, and non-governmental organizations (NGOs) to issue national standards quickly for TCE exposure and for the clean-up of contaminated sites. EPA has been awaiting the publication of the NAS Report to complete its toxicity assessment, and as a result of the delay, regulators in key states have begun to develop their own widely varying risk, clean-up and vapor intrusion TCE standards. The divergence of standards has led Sen. Hillary Rodham Clinton (D-NY) and other lawmakers to promote interim national guidelines. Industry leaders have complained that divergent state standards complicate remediation efforts, property transfers and other transactions at sites across the country.

The evolution of TCE toxicity and vapor intrusion issues has not escaped the attention of the plaintiffs' bar. Already, plaintiffs' attorneys and the press have begun to call TCE the "next big thing." Regardless of the rhetoric, the stakes – from new clean-up costs to property damage and personal injury suits – are large. Potentially responsible parties should re-evaluate their current approaches to TCE-containing sites, in light of potential toxic tort liability, and potentially increased data collection and clean-up requirements.

## **TCE: Historical Use and Scope of Exposure**

TCE is a volatile organic compound that has been used widely since the early 1900s by the military and industry as a degreasing agent for machine parts and aircraft. It is still used by small and large dry cleaners and in consumer products such as adhesives, typewriter correction fluid, paint and spot removers. In 2004

alone, EPA's Toxic Release Inventory reported that more than six million pounds of TCE were released into the environment.

TCE is a common contaminant of air, soil and water at thousands of current and former manufacturing facilities, military installations, and waste sites around the country; it is one of the most common groundwater pollutants, and has been found at 60 percent of the sites on the Superfund National Priorities List (NPL). Exposure to TCE occurs in several ways, including ingestion and dermal contact (from drinking or showering in water containing TCE) and inhalation (from breathing air containing TCE vapors).

## **Federal TCE Risk Assessment and Human Health Standards**

EPA issued its last TCE risk assessment in 1985, in which it evaluated inhalation and ingestion exposure pathways and concluded that TCE was a probable human carcinogen. Subsequent risk assessments were prepared in draft form, but never completed. EPA's most recent draft risk assessment (2001) was criticized heavily by government and industry for finding TCE "highly likely to produce cancer in humans," for recommending stringent new cancer slope factors treating TCE as if it were two to 40 times more carcinogenic than previously thought, and for supporting its conclusions with limited scientific data.

At the request of its interagency sponsors, the NRC reviewed the scientific material on TCE, including the 2001 EPA draft risk assessment, related comments that provided the catalyst for the study, relevant literature and information from interested parties, and held public meetings. The NRC did not conduct any new studies evaluating TCE's toxicity, nor did it present a formal risk assessment in putting together its report, *Assessing the Human Health*

*Risks of Trichloroethylene: Key Scientific Issues.*

The NAS Report underscores EPA's 2001 findings that TCE exposure may cause cancer, reproductive and developmental problems, impaired neurological function and autoimmune disease. It found that animal and human studies support the conclusion that TCE is a potential cause of kidney and liver ailments, including cancer. However, the NAS Report also noted that: the level of exposure needed to produce kidney damage is not clear; the liver data are inconsistent; only heavy exposure to TCE may produce liver damage; and there were weaknesses in EPA's analysis of the epidemiological data on TCE and cancer. The NAS Report indicated that exposure to TCE at levels faced by the general public is not likely to induce liver cancer; and, as the population generally is exposed at doses lower than those in animal and occupational studies, forthcoming studies must be more refined.

The NAS report called for additional research, in the following areas:

- epidemiological studies to characterize the mechanisms by which TCE causes cancer and other health problems in humans;
- the incremental health effects of varying doses of TCE (the NAS report recommends that EPA use its linear cancer model, where cancer risk rises in proportion to dose and clearly define the linear extrapolation procedure);
- the increased risk to high-exposure occupations or heavily contaminated locales;
- the effect of TCE on sensitive populations (and an understanding of which populations are most sensitive);
- how exposure to other chemicals in conjunction with TCE could affect human health;
- whether people with conditions such as diabetes or obesity could be more susceptible to adverse effects from TCE; and

- the interplay between TCE and alcohol (the NAS Report found insufficient evidence to support the magnification of risks from combined TCE and alcohol exposure as proposed by EPA in its 2001 draft assessment).

The NRC recommended that federal agencies finalize their risk assessment with currently available data so that risk management decisions can be made expeditiously. EPA intends to move forward aggressively on a new risk assessment of TCE using its 2001 assessment as a base and hopes to complete the effort within six months. Whether the final risk assessment for TCE will include the same range of estimated cancer slope factors as the draft – 0.02 to 0.4 milligrams per kilogram per day (mg/kg-d) – is unclear. However, recent evidence reportedly points to alleged reproductive effects at lower TCE levels than those associated with cancer effects. Thus EPA potentially could assert that it has scientific support to increase the 1985 TCE toxicity factors even more aggressively than proposed in the 2001 assessment, although the NAS's criticism of human epidemiology studies (which were a key driver in the prior assessment) could limit EPA's flexibility in that regard. Also, several of the more active states (California, Colorado and New York) may impose stricter standards before EPA has a chance to issue its final assessment on TCE.

## **Developments in the Regulation of Vapor Intrusion and Indoor Air**

Vapor intrusion occurs when volatile compounds present in soil or groundwater evaporate and move beneath the foundation of a building and then, when the pressure inside is lower than outside, move inside the building (through cracks, openings

for sump pumps, pipes, electrical wiring, heating, ventilation and/or air conditioning systems). Vapor intrusion is not a new issue; however, regulatory agencies responsible for the investigation and cleanup of contaminated properties have traditionally focused more on soil and groundwater contamination. For years, it was believed that vapors in buildings

rarely reach levels that present health concerns, especially at sites where groundwater contamination has been addressed. However, as summarized in the following chart compiled from unofficial EPA statements,<sup>1</sup> certain agency staff are promoting the belief that the problem is more common, persistent and pervasive than previously believed.

Issue	Prior Agency Assumption	Emerging Agency Position
<b>Groundwater</b>	High concentrations of a contaminant such as TCE would have to be present in groundwater for indoor air problems to result.	Recent studies demonstrate that indoor air problems can exist when levels of groundwater contamination are low. While TCE quickly evaporates from water, it can stick to soil particles for a long time and pose a continuing source of vapor contamination after groundwater has been remediated.
<b>Soil Vapor</b>	Soil vapors collected at foundation depth, near a building, are a proxy for soil vapor conditions beneath the foundation of the building.	Vapor levels beneath the foundation can be more than a hundred times greater than levels in nearby soil, as the foundation can trap vapors and allow them to accumulate and concentrate.
<b>Attenuation / Dilution</b>	The ratio of vapor levels in soil or groundwater to those inside a building is high, and the ratio increases the deeper one samples.	The foundation is not as effective or consistent at blocking vapors from entering a building as previously thought. Attenuation factors vary significantly; no single ratio can be used reliably to screen for indoor contamination at all sites.
<b>Wind Effect</b>	Only subsurface vapors pose an indoor contaminant problem	Wind can blow vapors from the ground near buildings into the structure and pose an indoor contaminant problem

Within the next year, EPA is expected to finalize its *2002 Draft Guidance for Evaluating the Vapor Intrusion to Indoor Air Pathways from Groundwater and Soils*, likely soon after the revised TCE risk assessment is available. Significant changes in the measurement of vapor intrusion pathways and related human health exposure are anticipated. EPA's final vapor intrusion guidance is expected to incorporate new evidence regarding vapor intrusion and use more accurate attenuation factors, more direct sampling and rely more heavily on professional judgment in determining whether to do indoor sampling. For example, sampling requirements may change to require multiple measurements from groundwater, soil gas, sub-slab gas, and indoor and outdoor air. Some have suggested that EPA promote the use of a decision matrix. A matrix potentially offers a more refined analysis than a decision tree, as it may be possible to compare indoor vapor levels to sub-slab vapor levels and use an actual, measured attenuation or dilution factor to determine whether to take further action (and what action to take).

The 2002 draft guidance does not propose clear standards for indoor air, and different EPA regions use widely-varying approaches for identifying TCE levels of concern in indoor air. On one extreme, Region 2 references an indoor air TCE concentration of 0.041 ppv by volume (or 0.22 ug/m<sup>3</sup>), which corresponds to a 1x10<sup>-5</sup> cancer risk under the most conservative cancer slope factor used in the draft guidance. While acknowledging that the draft EPA guidance can generate this potential range of TCE indoor air values, Region 8 has noted that when using an alternative cancer risk slope factor, the same draft guidance produces TCE levels for indoor air ranging from 0.43 to 43 ug/m<sup>3</sup>, depending on the cancer risk level used (*i.e.*, 1x10<sup>-6</sup> to 1x10<sup>-4</sup>). Region 8 also notes that if the most conservative values are used, the implication is that

1x10<sup>-6</sup> cancer risk levels "are lower than typical background levels of TCE in indoor air."<sup>2</sup> The draft guidance also recommends use of a decision tree structure, by which sampling data at each step (groundwater, soil gas, and indoor air) would inform investigators whether they should continue to the next step of testing and analysis. While some criticized the draft guidance as overly conservative, others, including some of EPA's own scientists, raised concerns about its reliance on the Johnson and Ettinger model.

The Johnson and Ettinger model estimates the extent of vapor intrusion into a building by considering variables such as the type of contaminant, the level and depth of contamination, the type of geologic material the vapor will travel through (usually, water, soil or rock), and other factors. The model makes a series of important assumptions: *e.g.*, vapors enter buildings through cracks in the walls and foundations, vapor velocities decrease rapidly with increasing distance from the structure, soil properties and the distribution of the contaminant are homogenous, and water movement and biodegradation do not affect vapor movement, to name a few. In addition, the model does not account for site-specific details such as wind levels and background contamination, nor does it require direct measurement of indoor air quality. In recent years, the model has received heavy criticism by experts who allege it under-predicts vapor intrusion levels.

## **Varying State TCE Standards Complicate Matters**

In the absence of a final EPA risk assessment on TCE and final guidelines on vapor intrusion, numerous state environmental agencies have adopted their own TCE guidelines. The maximum residential indoor TCE vapor levels recommended by governmental authorities range significantly: 1.2 ug/

m3 (California), 5.0 ug/m3 (New York and New Jersey), 14 ug/m3 (Michigan).

Whether these standards will change in light of the NAS Report and EPA's forthcoming risk assessment remains to be seen. EPA's draft risk assessment guidance does not supersede state guidance, and the states have the right to set more stringent standards than the federal MCL. EPA guidance on vapor intrusion is applicable only to sites that are under EPA oversight.

Notably, policy-makers in California and New York, both of which have a large number of TCE-contaminated sites that are not currently subject to EPA guidelines, have focused on TCE contamination and vapor intrusion in recent years. In November 2004, the California Environmental Protection Agency (CEPA) revised its indoor air concentrations for residential and non-residential buildings (to 1.2 ug/m3 and 2.0 ug/m3, respectively), and in January 2005, the California Department of Toxic Substances Control (DTSC) released interim guidance on the evaluation of vapor intrusion. Meanwhile, the California Senate is considering a bill that, if passed, would require by January 1, 2008 the posting of a list of sites with vapor intrusion contamination on the CEPA Web site.

The New York State Assembly held a hearing on vapor intrusion and issued a report in March 2005 that urged testing of residential areas near contaminated sites, steps to protect air quality where vapor intrusion exists, long-term monitoring and mitigation, and cleaning up contamination sources. In May 2006, the New York legislature passed a bill requiring landlords to inform tenants if they are at risk from TCE vapor intrusion. The New York State Department of Health and Department of Environmental Conservation are expected to release imminently draft policies regarding vapor intrusion.

## Implications of Recent TCE Developments

It is likely that changes in federal and state regulations will follow soon after EPA's final risk assessment for TCE and the issuance of revised vapor intrusion guidelines. These changes potentially may lead to lower maximum standards for TCE in water, air and other media, and stricter cancer slope factors, as well as changes in vapor sampling methodology (based on the premise that the presence of indoor TCE vapors is greater than previously believed).

TCE monitoring and remediation activities have been conducted for many years; however, sites that were previously considered to be relatively free of contamination may be reevaluated to meet new standards. Certain states already have begun to reassess sites, and EPA is contemplating a survey of TCE-contaminated NPL sites nationwide in order to determine if they need to be reprioritized because of vapor intrusion.

Companies, developers and contractors will need to consider their potential toxic tort exposure, and potentially-increased data collection and clean-up requirements under a new regime. Arguably, human exposure could have been occurring at levels that exceed the new standards for years or decades; limiting that exposure could be expensive.

Developers of property overlying contaminated groundwater should anticipate that simply remediating the groundwater itself may not satisfy regulators that the risk of TCE contamination has been addressed adequately. As the scope of sampling expands, regulators will focus on the mitigation of actual, measured vapor levels within a structure. This may result in increased use of institutional

and engineering controls, such as vapor barriers (to seal cracks and other openings in floors, walls and ductwork), ventilation systems, and manipulation of the pressure differentials between indoor and outdoor space. Such controls are often costly and require maintenance. Existing property owners and developers of new structures have an interest in which engineering controls are accepted by the responsible regulatory agencies, how their performance will be monitored, and how to transfer legal responsibility for the long-term maintenance of the controls when a property is sold. These types of exposures may generate a response from current occupants, for which the responsible regulatory agencies may require a formal public participation process.

Lawsuits regarding exposure to TCE in water have been common for several decades; we expect the plaintiffs' bar will attempt to make exposure to TCE vapors a more central issue in such lawsuits, or bring claims based solely on vapor intrusion theories. Courts have become increasingly willing to certify toxic torts as class actions; there have been substantial jury verdicts and settlements related to TCE (some approaching \$100 million). With the publication of the NAS report, more such lawsuits may be in the offing.

While change in TCE regulation may be inevitable, much can be done to affect this change, and prepare for it. Like-minded companies should coordinate with trade organizations and build coalitions to work with state and federal officials on implementation of the new standards and new institutional and engineering controls. Additionally, interested parties can begin to reassess potential TCE liability, consider strategic sampling and preventative and/or mitigation measures, and explore and develop contractual, statutory and common law defenses.

#### **Endnotes**

- <sup>1</sup> The information in the chart is based on our interpretation of unofficial statements by EPA staff. *See, e.g.,* Walter Mugdan, *Vapor Intrusion: The Next Big Thing*, Vol. 30, No. 4 ALI-ABA Bus. L. Course Materials J. (Aug. 2006).
- <sup>2</sup> *See* EPA Region 8 Technical Publication, dated Jan 26, 2005.

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