



CENTER FOR PUBLIC ENVIRONMENTAL OVERSIGHT

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May 29, 2012

Mathy Stanislaus
Assistant Administrator
Office of Solid Waste & Emergency Response
U.S. Environmental Protection Agency

Dear Mathy:

As you may know, Region 9 EPA has developed an Interim Removal Action Level (RAL) for short-term exposure to trichloroethylene (TCE), and it is seeking guidance from headquarters about its applicability. It is based on the non-cancer findings in EPA's September 2011 Toxicological Review of TCE. Though the RAL was developed in response to construction activity at the MEW Superfund Study Area here in Mountain View, it may have applicability at a wide range of sites across the country.

When the Center for Public Environmental Oversight learned that the MEW Responsible Parties were submitting lengthy documents challenging the proposed/interim RAL, we asked our technical consultant, Peter Strauss, to review them. We are always concerned when Responsible Parties inject themselves into toxicological debates because, to our knowledge, they *never* argue for more protective standards.

Here is Peter's memo, developed in consultation with our Community Advisory Board for the MEW Superfund Study Area and the Moffett Field National Priorities List site. Based upon Peter's analysis, CPEO and our Community Advisory Board recommend that EPA headquarters act quickly to adopt Region 9's approach, which appears to be justified by scientific evidence.

Sincerely,

A handwritten signature in black ink that reads "Lenny Siegel".

Lenny Siegel
Executive Director

MEMORANDUM

TO: Lenny Siegel
FROM: Peter Strauss
DATE: Tuesday, May 22, 2012
SUBJ: **Removal Action Levels (RALs) for TCE**

In late 2011, as a consequence of construction activities at the MEW Superfund Site in Mountain View, EPA Region 9 staff began talking with building owners about establishing an Interim Removal Action Level (RAL) for TCE. The site has elevated levels of TCE in soil and shallow groundwater and is subject to a vapor intrusion mitigation strategy. One element of this strategy imposes requirements on new construction and major modification as well as activities that significantly disturb the subsurface. The construction activities taking place in some of the buildings are major renovations with penetrations into the slab to place utility lines, thus having the possibility to disturb the underlying soil and creating a pathway for vapor to reach indoors. Furthermore, ventilation systems are not fully operable during construction. EPA is therefore attempting to establish guidelines about when and how to conduct sampling, and what levels would constitute an exceedence of allowable short-term or acute exposure. It has stated that:

In light of this information [i.e., finalization of the Toxicological Review of TCE in September 2011] and as a matter of good construction practice, EPA recommends that you take this interim removal action level into account and that the buildings be maximally ventilated while workers are inside the building and subsurface conduits remain open to ensure that workers are protected from Site contaminants. EPA also recommends that the Sampling Plan include monitoring for TCE in air and contingency measures if the interim removal action level is exceeded while subsurface conduits remain open and there is potential exposure to workers.

Background on the Proposed Interim RAL

The RALs are chemical-specific concentrations for individual contaminants that may be used to support a decision by EPA to undertake a removal action or to undertake some additional type of action, including increased monitoring. They are not meant to define a protective level and should not be confused with Regional Screening Levels (formerly PRGs) or with cleanup levels or cleanup standards. EPA guidance states, “When based on an RfC (reference concentration) or RfD (reference dose), the OSWER policy calls for setting RALs at levels that correspond to a hazard quotient of 3” because of uncertainty in the non-carcinogenic values (EPA 2008). The reference concentration is the estimated level at which continuous inhalation is unlikely to have deleterious effects on humans, including sensitive populations. It is generally used as the basis for establishing noncancer health endpoints.

Region 9 developed the Interim RAL for TCE of $15 \mu\text{g}/\text{m}^3$ by applying the reference concentration (RfC) of $2 \mu\text{g}/\text{m}^3$, developed in the 2011 Toxicological Review and published in IRIS. This is for a continuous 24-hour exposure. The site-specific remediation goal for the site is $5 \mu\text{g}/\text{m}^3$ for TCE, ($2 \mu\text{g}/\text{m}^3$ adjusted for a ten-hour workday). This is equivalent to a hazard quotient of 1. The RAL was developed by multiplying $5 \mu\text{g}/\text{m}^3$ (i.e., the hazard quotient) by three, producing an indoor air concentration of $15 \mu\text{g}/\text{m}^3$ for workplaces in the MEW area.

Somewhat unique to TCE, the noncancer health endpoints include kidney effects, neurological effects, immunological effects, and congenital cardiac effects. While the first three are the result of chronic exposure at around $2 \mu\text{g}/\text{m}^3$, the fourth effects occur in a window of time of 21 days during the first trimester of pregnancy. Thus, EPA Region 9 believes that based upon the Toxicological Review, a short-term standard is needed. They have requested that EPA headquarters clarify how the RfC should be used in the establishment of such a standard.

The Responsible Parties Response

The MEW companies and the Mountain View Commercial Owners Group (hereafter referred to as the Companies) performed an independent analysis of EPA's Interim RAL, and they have sent a letter to EPA Headquarters objecting to the imposition of this short-term exposure guideline. They are concerned with "EPA Region 9's conclusion and communication to others that very short-term exposure to TCE at the MEW site should be limited to concentrations as low as 15 micrograms per cubic meter ($\mu\text{g}/\text{m}^3$) in air vapor and that short-term exposure above this level may have teratogenic effects." (A teratogen is defined as any agent or factor that induces or increases the incidence of abnormal prenatal development.) In the Toxicological Review, EPA identified Congenital Cardiac Defects as one of the health endpoints likely to be caused by exposure to TCE. They dispute the fact that the RfC developed in the Toxicological Review applies to short-term effects. Furthermore, they argue that the study design of the Toxicological Review did not attempt to address teratogenic effects, and that any short-term standards are inappropriate.

Furthermore, the companies state that the RAL under consideration is inconsistent with current short-term exposure screening levels that are used by other agencies of the federal government. They are concerned that "as applied at the MEW Superfund site, $15 \mu\text{g}/\text{m}^3$ of TCE in indoor air (referred to herein as the 'short-term RAL') would trigger the cessation of work or modified duty (e.g., the use personal protective equipment) for commercial, industrial and construction workers." They request that these proposed RALs be reviewed by Headquarters and made consistent with other government standards.

Issues

There are four important issues that need to be resolved.

The first issue is whether the information in the IRIS file can be used to determine acute or short-term health effects. The Companies' analysis states, "There is no indication in the EPA toxicity review document or in the on-line IRIS file for TCE indicating the RfC is intended for anything other than chronic exposure averaging." In most cases, the Toxicological Reviews are meant to establish reference levels for long-term chronic exposure. Additionally, guidance from EPA on setting RALs also indicates that they should be used for long-term chronic exposures. However, it is difficult to overlook the fact that for one health endpoint, a specific window of relatively short-term exposure may elicit the deleterious effect. Region 9 has requested guidance from Headquarters about whether and how the reference concentrations should be applied to short-term exposures.

The second issue deals with what health endpoints should be used in developing the RAL. The Companies maintain that the explicit identification of TCE as a teratogen and the identification of a corresponding and appropriate exposure averaging time was not a focus or goal associated with the EPA (2011) TCE toxicological review. The Companies' analysis states that: "A thorough and objective weight-of-evidence analysis would likely conclude that TCE should not be identified as a teratogen." It also states, "Because of the importance of the issue in the possible derivation and use of a RAL for risk management and risk communication, the issue of a causal link between TCE exposure and developmental effects warrants a more focused evaluation." The Toxicological Review indicates multiple non-cancer health endpoints, including neurological effects, immunological effects, and kidney effects, as well as teratogenic effects. The approach used in the Toxicological Review was to select a value supported by multiple effects. As noted above, the RfC of 2 $\mu\text{g}/\text{m}^3$ is based in part on critical heart malformations, occurring within a window of 21 days during the first trimester. It does not appear that this warrants further analysis except when new information is developed. The RfC recently published (September 2011) included the latest information.

The third issue is consistency with other allowable acute and short-term exposure values. The Companies cite several studies that have acute exposures several orders of magnitude higher than the proposed Interim RAL, but those values are out of date and unprotective. These include recommendations by the National Advisory Committee for Acute Exposure Guideline Levels for Hazardous Substances (NAC AEGLE Committee) for the general public of 410,000 $\mu\text{g}/\text{m}^3$ as an 8-hour average (NAC 2009). AEGLEs represent threshold exposure limits and are applicable to emergency exposure periods ranging from 10 minutes to 8 hours. However, the AEGLE is an interim value, awaiting peer review. The values were developed in 2004. The Agency for Toxic Substances and Disease Registry (ATSDR) has developed an acute duration inhalation minimal risk level (MRL) of 11,000 $\mu\text{g}/\text{m}^3$ and an intermediate inhalation MRL (15-364 days) of 540 $\mu\text{g}/\text{m}^3$ based on neurological effects (ATSDR 1997). However, these values considered only neurological effects and were developed in 1997. OSHA permissible exposure is 8-hour time-weighted average (TWA) of 537,000 $\mu\text{g}/\text{m}^3$, with 1,612,000 $\mu\text{g}/\text{m}^3$ as a 5-minute maximum short-term exposure limit (STEL) allowable in any 2-hour period in the workplace. The National Institute for Occupational Safety and Health (NIOSH) recommends an exposure limit of 134,000 $\mu\text{g}/\text{m}^3$ as a 10-hour TWA. I do not doubt that the Companies have correctly cited these other data; however, they do not include the new data developed in the 2011 Toxicological Review, especially as it relates to Congenital Cardiac Defects.

The fourth, policy issue is perhaps the most important. This dispute shines a bright light on what the 2011 Toxicological Review does not say. For more than a decade, EPA has been attempting to develop new standards for TCE. After developing the basis for standards in 2011, practical considerations must come into play. Indeed, Region 9's attempt to develop an interim RAL as construction on contaminated land is taking place is a practical response to protecting the public (in this case, workers). No matter how the above issues are resolved, there needs to be a point at which EPA can recommend that short-term contamination is too high, and one must take measures to prevent this. Because the Interim RAL would be used as guidance in a construction project, and not imposed as a stop work level, in my view, EPA has appropriately attempted to protect the public.

Some might ask whether the Interim RAL should be applicable because one would not expect pregnant women to be part of the construction workforce. This assumption, particularly when applied to the wide range of people at a typical commercial construction site, is out of date and inappropriate. This logic would violate the civil rights of women. More important, even if there

were a voluntary restriction of access to females who were pregnant, because of the “effects window,” it would be difficult to know who is pregnant within the first trimester. Moreover, once established, this RAL would be applied to general industrial and commercial operations in the future, not just construction.

Recommendations

I recommend that EPA headquarters act quickly to adopt Region 9’s approach, which appears to be justified by scientific evidence. It is likely that a decision will come after the current construction at the MEW buildings ends. Nevertheless, there will be activities at this site and elsewhere subject to the RAL. The RAL is not only used to establish actionable levels, but also to design sampling protocols to detect the short-term exposures. The CAB may be interested in writing a short letter to EPA to this effect. In the interim, I also recommend that these RALs be applied (and accepted by the Companies) as voluntary guidelines.