



March 31, 2017

Docket DOC-2017-0001  
Office of Policy and Strategic Planning  
U.S. Department of Commerce  
HC Hoover Building  
Room 5863  
1401 Constitution Avenue N.W.  
Washington, DC 20230

Re: Impact of Federal Regulations on Domestic Manufacturing, Request for Information, Docket DOC-2017-0001 (82 *Fed. Reg.* 12786, March 7, 2017)

Dear Sirs:

The Chemical Products and Technology Division of the American Chemistry Council (ACC/CPTD)<sup>1</sup> wishes to call the Department's attention to policy guidance issued in 2014 by the U.S. Environmental Protection Agency's Office of Solid Waste and Emergency Response (OSWER)<sup>2</sup> that is having a significant impact on the redevelopment of land for manufacturing or other purposes. This guidance – related to remediation of sites contaminated with trichloroethylene (TCE) – is being implemented by several EPA regions and states currently, and has the potential to dramatically impact progress towards productive use of lands nationally. The potential impact is highlighted by the recent addition of a subsurface intrusion component to the Hazard Ranking System for placement on the National Priorities List (NPL) under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA).<sup>3</sup>

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<sup>1</sup> ACC represents the leading companies engaged in the business of chemistry. ACC members apply the science of chemistry to make innovative products and services that make people's lives better, healthier and safer. ACC is committed to improved environmental, health and safety performance through Responsible Care®, common sense advocacy designed to address major public policy issues, and health and environmental research and product testing. ACC's Chemical Products and Technology Division is composed of a wide range of more than 60 self-funded product and sector groups that are focused on specific chemistries and related technologies. Members participating in these groups include large and small manufacturers, formulators, downstream users, distributors, suppliers and other trade associations.

<sup>2</sup> US EPA. Memo from Robin H. Richardson (Acting Director, Office of Superfund Remediation and Technology Innovation. Compilation of Information Relating to Early/Interim Actions at Superfund Sites and the TCE IRIS Assessment (August 27, 2014). (Richardson memo) OSWER is now known as the Office of Land and Emergency Management (OLEM).

<sup>3</sup> 82 *Fed. Reg.* 2760, January 9, 2017.



Despite the fact that the 2014 guidance established Agency policy for early mitigation at remediation sites, and for interpreting scientific data on developmental effects, it was not subject to public notice and comment. In response to subsequent calls for review of the policy, EPA has argued that the guidance memo is “not a regulation nor a rule,” while simultaneously noting that it “operationalized the [EPA Integrated Risk Information System (IRIS)] TCE Assessment.”<sup>4</sup> ACC/CPTD believes that such “operationalization” is clearly covered by Executive Order 13771 which indicates that --

[f]or purposes of this order the term "regulation" or "rule" means an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or to describe the procedure or practice requirements of an agency.<sup>5</sup>

As such, we urge the Department to consider the 2014 guidance memo in its review of regulations that adversely impact domestic manufacturers.

### **EPA’s Assessment of the Non-Cancer Effects of TCE Differs from Other Authoritative Groups**

EPA’s 2011 IRIS assessment for TCE reestablished cancer potency factors and lowered the chronic (lifetime) reference concentration (RfC - for inhalation) and reference dose (RfD – for water consumption) for non-cancer effects significantly.<sup>6</sup> The non-cancer reference values are based primarily on developmental effects (fetal heart malformations, or FHM) reported in studies from a single laboratory. The results are inconsistent with GLP studies conducted in other laboratories. Published reviews of the studies that observed these effects have described numerous limitations in the methodology, including the use of non-standard statistical methods, the failure to run concurrent control experiments, and the pooling of control groups.

In reviewing the same data, the National Research Council dismissed the FHM findings because of the unusually flat dose-response curve and the inconsistency of the results with those from other, better conducted studies.<sup>7</sup> Similarly California’s Office of Environmental Health Hazard Assessment (OEHHA) rejected the FHM studies because they did not produce a

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<sup>4</sup> Letter from Enrique Manzanilla, Director Superfund Division, EPA Region 9, to Mr. Mike Mielke, Silicon Valley Leadership Group (November 19, 2015).

<sup>5</sup> Executive Order 13771. Presidential Executive Order on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

<sup>6</sup> US EPA. IRIS Toxicity Profile for Trichloroethylene (CASRN 79-0 1-6). Washington DC, USEPA (2011).

<sup>7</sup> National Research Council (NRC). Assessing the Human Health Risks of Trichloroethylene: Key Scientific Issues. Washington, DC: National Academies Press. (2006).



meaningful or interpretable dose-response relationship.<sup>8</sup> OEHHA also noted that the results are not consistent with earlier developmental and reproductive toxicological studies done outside this lab in other animal species. More recently, in a 2014 update of the assessment of the fetal heart data, seven of 11 EPA scientists characterized the confidence in the dose-response evaluation of the cardiac data as “low,” a conclusion which differs significantly from that of the 2011 IRIS assessment.<sup>9</sup> Despite the clear concern about the FHM studies expressed by most scientists -- including many within the Agency -- EPA has made no attempt to update or correct its assessment.

### **EPA Guidance Memos Establish Short-Term Action Levels**

Following the release of the IRIS assessment for TCE, EPA’s Region 9 and 10 issued policy guidance outlining investigation approaches and response measures to address inhalation exposures to TCE in indoor air from the subsurface vapor intrusion pathway.<sup>10,11</sup> In both cases, the policy established action levels based on the RfC from the 2011 IRIS assessment and provided guidance on “accelerated and urgent response actions.” As a result of confusion generated by the release of guidance from the two regional offices, OSWER subsequently issued its 2014 guidance memo which indicated that the Agency “expects to take early actions” based on the IRIS RfC. The 2014 memo further noted –

[I]n most cases, it is assumed that a single exposure at any of several developmental stages may be sufficient to produce an adverse developmental effect, but the RfC for a single exposure hasn’t been determined yet by EPA.<sup>12</sup>

Despite acknowledging that the RfC was developed to protect against chronic (i.e., lifetime) exposure to TCE, the memo has been interpreted to require action based on sampling results in excess of the RfC collected over 1 to 24 hours.

The application of the low levels dictated by the RfC to acute (short-term) exposures to TCE outlined in the 2014 memo has dramatically expanded the number of buildings requiring

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<sup>8</sup> Office of Environmental Health Hazard Assessment (OEHHA). Public health goals for chemicals in drinking water – trichloroethylene. OEHHA. Sacramento, CA (2009).

<sup>9</sup> TCE developmental cardiac toxicity assessment update (undated). (Document ID EPA-HQ-OPPT-2012-0723-0045 available at <http://www.regulations.gov>)

<sup>10</sup> Memo from Enrique Manzanilla, Director Superfund Division, EPA Region 9. EPA Region 9 Response Action Levels and Recommendations to Address Near-Term Inhalation Exposures to TCE in Air from Subsurface Vapor Intrusion (July 9, 2014).

<sup>11</sup> Memo from Joyce C. Kelly, Office of Environmental Assessment, EPA Region 10. OEA Recommendations Regarding Trichloroethylene Toxicity in Human Health Risk Assessments (December 13, 2012).

<sup>12</sup> Richardson memo, at 2.



investigation at remediation sites and the number of indoor air samples to be collected and analyzed in these buildings. Concerns among federal, state, and local authorities regarding the potential for future vapor intrusion exposures have resulted in calls for cleanup of groundwater contamination beyond that otherwise required by CERCLA or state requirements. Public outreach about potential TCE exposure from EPA and state authorities has generated unnecessary confusion and concern.

### **Operationalization of the Guidance Memos has had a Significant Economic Impact**

Enforcement of the very low levels indicated by the RfC has resulted in unnecessary evacuations of residences, dramatic expansion of the number of buildings requiring investigation and the number of indoor air samples to be collected and analyzed, and calls for remediation of groundwater not used as drinking water. According to an April 2014 memo from EPA Region 9, the Agency's decision to expand the area to be monitored at remediation sites in the South Bay region in California based on TCE vapor intrusion concerns increased the number of residences requiring investigation from 96 to more than 358 and the numbers of commercial buildings to be investigated from 59 to in excess of 270.<sup>13</sup> Estimates developed by CH2M Hill suggest that long-term (30 years) vapor intrusion monitoring in a typical non-residential building would cost \$159,000 (~\$5,000/year) –assuming no mitigation.<sup>14</sup> This number is estimated to double to \$314,000 if early mitigation and subsequent long term monitoring are required – EPA's preferred approach. The costs for mitigation and monitoring are expected to be higher for residential structures – assuming more frequent sampling and a lower threshold for requiring mitigation.

Based on the estimates above, the policy outlined in EPA's April 2014 memo will increase the costs of remediation of non-residential buildings in the South Bay region by up to \$48 million over 30 years. The cost for monitoring/mitigation for residences in the South Bay region likely would exceed \$100 million over the 30-year period. At a single site - the Middlefield-Ellis-Whisman (MEW) Superfund site in Mountain View, California, - the investigation of vapor intrusion alone is expected to cost \$19 million. This cost is on top of the \$150 million already spent on site cleanup.

In light of the significant impact that EPA's policy guidance relating to addressing TCE exposure from subsurface vapor intrusion has had, and will continue have, we urge the Department to consider the OSWER and regional guidance memos as part of its review of the impact of federal regulations on domestic manufacturing. Please feel free to contact me at

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<sup>13</sup> Briefing Memo from Melanie Morash, Remedial Project Manager, to Enrique Manzanilla, Director, Superfund Division (April 29, 2014).

<sup>14</sup> Presentation by Chris Lutes CH2M Hill at EPA Workshop at AEHS 2015.



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[srisotto@americanchemistry.com](mailto:srisotto@americanchemistry.com), or at 202-249-6727, if you have questions about the above information.

Sincerely,

***Steve Risotto***

Stephen P. Risotto

Senior Director

