February 21, 2008

Charles Auer, Director
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, NW
Washington, DC 20460

RE: Supplemental Information on the Benzene Voluntary Children's Chemical Evaluation Program (VCCEP) Assessment; Response to Tier 3 Recommendations

Dear Mr. Auer:

The American Chemistry Council Benzene, Toluene, and Xylene (BTX) VCCEP Consortium (the "Consortium") provides the attached supplemental information on the benzene VCCEP assessment prepared by Julie Panko of ChemRisk. This supplemental information addresses the comments EPA raised in its VCCEP Data Needs Assessment of Benzene on the benzene VCCEP exposure assessment. The Consortium believes that this additional information fully responds to EPA's questions and comments regarding the VCCEP exposure assessment.

The Consortium also acknowledges that EPA has recommended several additional VCCEP Tier 3 animal toxicology studies for benzene. Specifically, EPA has recommended a developmental neurotoxicity study and an adult neurotoxicity screening battery via the oral route and potentially modifying the protocols to also address the Agency for Toxic Substances and Disease Registry's (ATSDR) Priority Data Needs (PNDs). The Consortium has carefully evaluated the recommendation for these Tier 3 studies, and the fact that important new data are being developed. We do not believe generating these additional animal toxicology data will provide any meaningful contribution to the overall risk characterization or risk assessment of benzene, especially because epidemiology data are the best basis for assessing benzene risks.

As the benzene VCCEP hazard and risk assessment indicated, and the Agency is well aware, benzene has been extensively reviewed, and it has well established cancer and noncancer risk levels derived from human epidemiology data. In addition to the extensive human epidemiology data on benzene, there are numerous animal toxicology studies including studies on neurotoxicity and developmental toxicity. It is highly unlikely that these additional animal data would change the overall human hazard and risk assessments of benzene given the human data and existing risk reviews and

assessments. Further, there are extensive exposure and risk management regulations and practices to limit benzene exposure in the workplace, in the general environment and in the home, with additional regulations being implemented. (See Section 4 of the Benzene VCCEP Assessment Document). New regulations have been announced since that document was prepared, including reductions in benzene content of fuel, further emissions controls on benzene sources and mandates to use less benzene-containing petroleum products in fuels.

The EPA and ATSDR interest in developing oral animal toxicology data on benzene also does not appear to be supported by the benzene exposure assessment, which shows that inhalation is clearly the main route of exposure. The Consortium's extensive exposure assessment evaluated benzene exposure from drinking water, food and other sources and it showed that the oral exposures are significantly lower than the inhalation route of exposure. Based on the scope of existing data and control measures, there appears to be little potential value in developing these additional oral animal toxicology data, and therefore the Consortium respectfully declines EPA's recommendations for Tier 3.

If you have any questions regarding this supplemental information or the Consortium's decision regarding the Tier 3 recommendations, please contact me at 703-741-5609 or at Christopher_Bryant@americanchemistry.com.

Sincerely yours,

Chris Bryant, Managing Director
Chemical Products & Technology Division

cc: Jim Willis, Director
Chemical Control Division
Office of Pollution Prevention and Toxics

Ward Penberthy, Assistant Director
Office of Pollution Prevention and Toxics

Attachment

ChemRisk®

February 10, 2008

Andrew Jaques
Director, CHEMSTAR
American Chemistry Council
1300 Wilson Blvd
Arlington, Virginia 22209

RE: RESPONSES TO EPA BENZENE VCCEP DATA NEEDS LETTER

Dear Andrew,

This letter provides our responses to comments made by USEPA in their VCCEP Data Needs Letter for Benzene with respect to the Benzene VCCEP Exposure Assessment. The EPA comment is provided first in italics, followed by our response.

1. *EPA also notes that there was an over dependency on the information supplied by the TEAM study with the assessment's focus on indoor benzene exposure and in minimizing the effects of personal exposure to those that lived by fixed sources. As stated in the Federal Register for VCCEP, "Similarly, a complete reliance on the biomonitoring data for an exposure assessment, given the quality concerns raised by stakeholders, would be insufficient" and that "Sponsors will bear a special responsibility in defining and describing the essential exposure issues associated with each chemical." (Vol. 65, No. 248. pg. 81711). It is the responsibility of the sponsor to fully address ambient air exposures, especially in areas that pose a high cumulative risk, such as Texas, versus relying on portions of the TEAM study in negating these effects.*

In evaluating the contribution of benzene exposures from ambient air, ChemRisk relied upon numerous studies beyond those of the TEAM study. These included 17 studies conducted from 1994-2000 (See Tables 7.10, 7.11 and 7.12 of the submission document), as well as a specific evaluation of ambient air benzene concentrations in urban areas (where motor vehicle traffic contributes significantly to the ambient air concentrations of benzene) and areas with stationary sources which emit benzene (i.e., Harris County, TX) (See Tables 7.3, 7.4, 7.5).

Several of the published studies evaluated the relationship between outdoor air, indoor air and personal air concentrations of benzene[123]. In each of these studies, the relationship between the

[1]Weisel, C.P.; J. Zhang; B. Turpin; M.T. Morandi; S. Colome, Stock, T.H., and Spektor, D.M. (2005) Research Report : Relationships of Indoor, Outdoor, and Personal Air (RIOPA). Part 1 Collection Methods and Descriptive Analyses. Health Effects Institute. Number 130 Part 1, November 2005.

[2] Buckley T.J., Weaver, V.M., Payne-Sturges, D.C. and Kim, S. 2005. VOC Exposure in an Industry-Impacted Community. NUATRC Research Report Number 4. Mickey Leland National Urban Air Toxics Research Center.

three values was personal air>indoor air>outdoor air; with strong correlations between personal and indoor air sample concentrations and weak or no correlation between personal and outdoor air benzene concentrations. Thus, these studies support the conclusions of the TEAM study that personal exposures to benzene result from exposures close to the person. Weisel et al., studied urban residential indoor air concentrations of VOCs in Los Angeles, CA, Houston, TX and Elizabeth NJ because of the potential influence of outdoor air concentrations from mobile sources and stationary sources. This study included the evaluation of approximately 100 residences in each city, with reported median indoor air concentration of benzene of 2.19 $\mu g/m^3$ and the 95th percentile concentration of 10 $\mu g/m^3$. These concentrations are within the range of 1 – 13 $\mu g/m^3$ reported from other studies published in the literature and within the typical and high end indoor benzene concentrations used in the VCCEP assessment to characterize children's benzene exposure from the indoor air. Further, while the outdoor concentrations were not predictive of personal exposures, Kwon et al., (2006)[4] reported that the outdoor benzene concentrations in the residential areas studied by Weisel et al. are predicted based on proximity to roadways and gas stations.

2. *There were also discrepancies in the use of 1996 NATA data measurements in comparison to top benzene emitters using 2003 TRI data in the development of typical urban and rural exposures. All of the urban and rural facilities not controlled by the sponsors, (Holcim, US Sugar and GP) were not even emitting benzene in 1996. The two top urban sponsors listed on page 103 of submission, US Sugar Corp in Palm Beach County, Florida and the Holcim plant in Michigan had no reported emissions of benzene in 1996. The top rural benzene source, Georgia-Pacific in Bedford County, Virginia had no TRI benzene releases in 1996. However, the 1999 emissions inventory would include reported benzene emissions from U.S. Sugar, who opened a 600,000 ton per year refinery in 1998. It would be of interest to note if ambient air concentrations did increase in this area as to whether the NATA is an accurate predictor of ambient air concentrations of benzene. The data used to represent the typical urban and rural concentrations was in error and used for all other estimates of outdoor ambient air exposure to children. It is also not transparent that the NATA data measurements accurately depict ambient air concentrations of benzene, especially with fluctuating levels and the chemicals ½ life.*

The 2003 TRI data was used as a guide to identify locations within the US that may have higher outdoor air concentrations of benzene due to benzene emissions from stationary sources. TRI reporting facilities can change from year to year and the opening or closure of one facility and the subsequent air emissions from such can also change, as well as off-set one another. Therefore, the TRI data was used to identify counties for which we expected outdoor benzene concentrations to be higher and thus allowed a targeted search the NATA database to obtain benzene concentrations. The EPA has taken steps to compare the modeled estimates to measured values and reports that the chemical constituent with the highest correlation between

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[3] Phillips, M.L., Esmen, N.A., Hall, T.A., and Lynch, R. 2004. Determinants of exposure to volatile organic compounds in four Oklahoma cities. Journal of Exposure Analysis and Environmental Epidemiology, 1-12.

[4] Kwon, J., C. Weisel; B. Turpin; J. Zhang; L. Korn; M. Morandi; T. Stock; S. Colome. (2006). Source Proximity and Outdoor Residential VOC Concentrations: Results from the RIOPA Study. Environ. Sci. Technol. 40: 4047-4082.

modeled and measured values is benzene; with a modeled to measured ratio of 0.93 (http://www.epa.gov/ttn/atw/nata/draft6.html#secV.B accessed 12/17/07). As such, the NATA estimates are reasonably predictive for the time period under consideration. Because the NATA modeled estimates are based on an emission inventory from 1996 and 1999, we took additional steps to understand whether the NATA estimates were consistent with more recent measured data and to do so, we reviewed the EPA's AirData database. NATA modeled estimates from 1996 for Harris County TX were compared to measured data from 2003 and found to be consistent for both the mean and 95th percentile values. Therefore, we used the average of the mean measured values of 4.4 $\mu g/m^3$ for Harris County TX as the high end estimate of outdoor benzene air concentrations. This value is also consistent with, albeit higher than other measurements of outdoor benzene air concentrations reported in the literature for urban areas where there is contribution from both mobile sources and stationary emission sources of benzene. For instance, Weisel et al reported mean benzene concentrations from Elizabeth, NJ, Los Angeles, CA and Houston TX were 2.15 $\mu g/m^3$, accordingly the use of a value of 4.4 $\mu g/m^3$ to represent the high end outdoor air concentrations of benzene is well supported.

3. *Finally, EPA notes that the sponsor excluded consideration of available data from the on-going monitoring programs implemented as a result of the Texas air quality study conducted in 2000. Texas increased Auto GCs for ambient air measurement, expanding the number from three to a dozen in Harris County. Texas followed in 2002 with the mass monitoring of both continuous and episodic emissions from sources of Highly Reactive Volatile Organic Chemicals (HRVOC). (TCEQ, Texas Commission on Environmental Quality, "Central Registry," "Speciated Emissions Inventory." "Air Emission Event Reports," 2004, "PCQ", 2005; available on TCEQ website* ftp://ftp.tnrcc.state.tx.us)

The Auto GC data collected by TCEQ consists of 10 monitors sited throughout Harris County, TX, 3 which are operated by the TCEQ and 7 which are owned/operated by private interests. The Auto GC instruments collect and analyze the outdoor ambient air for more than 60 volatile organic compounds that are considered highly reactive and associated with the formation of ground level ozone. The Auto GC instruments sample and analyze the outdoor air once every hour. Benzene is one of the chemicals analyzed on an hourly basis and the results for the 3 monitors operated by the TCEQ are publicly available. The Auto-GC sampler data for benzene collected during 2006 was downloaded and analyzed. Nearly 23,000 1-hr benzene concentrations were included in this data set (See Table 1). The daily average for the 3 sites ranged from 0.37 - 5.3 $\mu g/m^3$, with an average of 1.4 $\mu g/m^3$. The 95th percentile of the daily averages was 2.88 $\mu g/m^3$ and the 99th percentile was 4.0 $\mu g/m^3$. Thus, while we did not specifically consider the Auto-GC data in the outdoor benzene concentration analysis, the high end concentration of 4.4 $\mu g/m^3$ that was used in the VCCEP exposure assessment is consistent with , in fact higher than, the upper bound concentration associated with the 2006 air monitoring data for benzene in Harris County. For these reasons, the outdoor ambient air concentrations used in the assessment have not been underestimated.

Table 1. Summary of 2006 Auto GC Data for Benzene – Harris County, TX

N=22,966	Daily Average Benzene Concentration ($\mu g/m^3$)
Min	0.38
Max	5.37
95th	2.89
99th	4.03

In addition to comments on the exposure data and analysis EPA also raised concerns regarding the environmental fate data provided in Section 5, Chemical Overview. In responding to this concern, it should be noted that the physicochemical and environmental fate information provided was for the general benefit of the reader and was not used quantitatively in the exposure assessment. Where data are sufficient and representative, it is usually preferable to use measured environmental concentrations to conduct an exposure assessment rather than relying on modeled values based on hypothetical scenarios.

Regarding EPA's preference for Level III fugacity data over Level I, it is important to recognize that when developing Level III data that assumptions about environmental release information have an enormous impact on the modeling results. The model's default emissions assumptions of 1000 kg/hour into each environmental compartment should not be used when actual emissions information exists, such as the TRI data. The TRI data[5] indicate that the vast majority of benzene emissions are to the air (93%); 5.3 % are to underground injection, with the remaining <2% going into other media such as surface water and land (see Table 5.11 of the submission). Using these emissions data would suggest that the appropriate emissions into each compartment would be approximately 1 kg/hour into surface water, 2 kg/hour to soil, and 325 kg/hr into air. When the Level III fugacity model is run with these emission rates, the benzene is predicted to primarily partition into the air compartment ranging from 75 to 89 % depending on the use of default or measured ½ life values for benzene in air and water. These results clearly demonstrate that the vast majority of benzene partitions to the air, which further supports the overall conclusions of exposure assessment that inhalation is the primary source of exposure. While Level III fugacity modeling is useful when measured values for various chemical properties are known, but little is known about actual releases of a chemical, it is not useful for estimating environmental concentrations unless there is a single source of release and a defined release area. In fact, EPA states, "EPA does not believe that the environmental media concentration results from this analysis are useful for quantitative risk assessment." (http://www.epa.gov/oppt/exposure/pubs/eqchpv.htm).

EPA also mentioned biodegradation in its VCCEP Data Needs Assessment and inquired to available data on this endpoint. Appendix D of the Benzene VCCEP Submission, the OECD

[5] The Benzene VCCEP Submission included 2003 TRI data. The most recent TRI data (2005) indicate similar overall emissions.

SIDS dossier for benzene, includes the results of several well conducted biodegradation studies (see Section 3.5, Biodegradation). These data indicate that benzene is readily biodegradable.

Sincerely,

Julie Panko

Julie M. Panko, CIH
Managing Health Scientist