BILL WHITE
MAYOR

OFFICE OF THE MAYOR
CITY OF HOUSTON
TEXAS

July 11, 2008

Michael Honeycutt, Ph.D.
MC 168
Manager, Toxicology Section
Texas Commission on Environmental Quality
PO Box 13087
Austin, Texas 78711-3087

Re: City of Houston Comments on DSD for 1,3-Butadiene

Dear Michael,

The City of Houston is grateful for the invitation to comment on the TCEQ Development Support Document (DSD) for 1,3-Butadiene. Dangerous levels of 1,3-butadiene measured at Milby Park in Houston have the City very concerned about the impact of exposure to these elevated concentrations on its citizens and the surrounding community.

The TCEQ proposes a carcinogenic Effects Screening Level (ESL) of 9.1 ppb and a noncarcinogenic ESL of 4.5 ppb for 1,3-butadiene, the lower of which (4.5 ppb) is proposed to be the working level. The TCEQ's proposed level decreases the current ESL of 5.0 ppb by 0.5 ppb. This is much less of a decrease than the City expected. The City is opposed to TCEQ's proposed 1,3-butadiene ESL of 4.5 ppb and in favor of lowering the ESL to the EPA recommended level of **0.15 ppb at $1x10^{-5}$ risk level**, for several reasons:

1) Important local research indicates 1,3-butadiene is posing an unacceptable cancer risk in Houston,
2) EPA advocates the use of a lower more health protective value and use of a different level introduces inconsistency within the state,
3) Studies referenced in the DSD to support the higher carcinogenic ESL are flawed,
4) Cumulative risk from other carcinogenic air toxics prevalent in Houston is not considered in ESL development, and
5) Use and purpose of the ESL is not consistent with the risk level used to develop the ESL.

These reasons are discussed below.

1) **Important local research indicates 1,3-butadiene is posing an unacceptable cancer risk in Houston**

The most important reason that the City advocates a lower, more conservative ESL consistent with the EPA is that recent epidemiological data indicate that the high concentrations found in the Houston Ship Channel (HSC) area are strongly correlated with increased incidence of certain childhood leukemias. A University of Texas School of Public Health (UTSPH) study reported that higher 1,3-butadiene levels (≥1.15 ppbV vs. <0.266 ppbV) were associated with acute lymphocytic leukemia, acute myeloid leukemia, and all leukemias in children.[1]. The trend of increasing 1,3-butadiene concentrations and increasing leukemia rates was statistically significant for children for the cancers listed in Table 1.

Table 1. Cancers having statistically significant associations with 1,3-butadiene in the UTSPH study

Cancer Type	Houston 1,3-Butadiene Level*	Rate Ratio of Increased Incidence	p-value	p-value for trend
Hodgkin's Disease	1	1.00		0.099
	2	1.53	0.171	
	3	1.67	0.152	
	4	1.80	0.071	
All Leukemia	1	1.00		0.017
	2	1.10	0.530	
	3	1.19	0.292	
	4	1.40	0.024	
Acute Lymphocytic Leukemia	1	1.00		0.041
	2	1.09	0.629	
	3	1.11	0.528	
	4	1.38	0.051	
Acute Myeloid Leukemia	1	1.00		0.026
	2	1.50	0.359	
	3	1.79	0.217	
	4	2.53	0.033	

* level 1 = <0.266 ppbV; level 2 = 0.266 – 0.381 ppbV; level 3 = 0.382 – 1.14 ppbV; level 4 = ≥ 1.15 ppbV

[1] Walker KM, Coker AL, Symanski E, Lupo PJ. (2006) **A preliminary investigation of the association between hazardous air pollutants and lymphohematopoietic cancer risk among residents of Harris County Texas.** University of Texas Health Science at Houston, School of Public Health http://www.houstontx.gov/health/UT-main.html

These data approximately translate into the following concentration and incidence rates per 1 million people shown in Table 2.

Table 2. Leukemia incidence in children from UTSPH study

Concentration*	Approximate Leukemia Incidence in HSC Area per Million People (Children age <20 yrs)		
1,3 BD ppbV	all leukemia	acute lymphocytic leukemia	acute myeloid leukemia
0	45.1	34.6	4.7
0.266	47.7	36.7	6.3
0.382	52.1	38.1	7.8
1.15	60.2	46.6	10

* BD concentrations presented on low end of range in UTSPH study

If the baseline level is assumed to correspond to the incidence numbers associated with 0 1,3-butadiene concentrations, the *increased* incidence is found by subtracting the baseline from the other levels (Table 3):

Table 3. Increased leukemia incidence in children from UTSPH study

Concentration	Approximate *Increased* Leukemia Incidence in HSC Area per Million People (Children age<20 yrs)		
1,3 bd ppbV	all leukemia	acute lymphocytic leukemia	acute myeloid leukemia
0	0	0	0
0.266	2.6	2.1	1.6
0.382	7	3.5	3.1
1.15	15.1	12	5.3

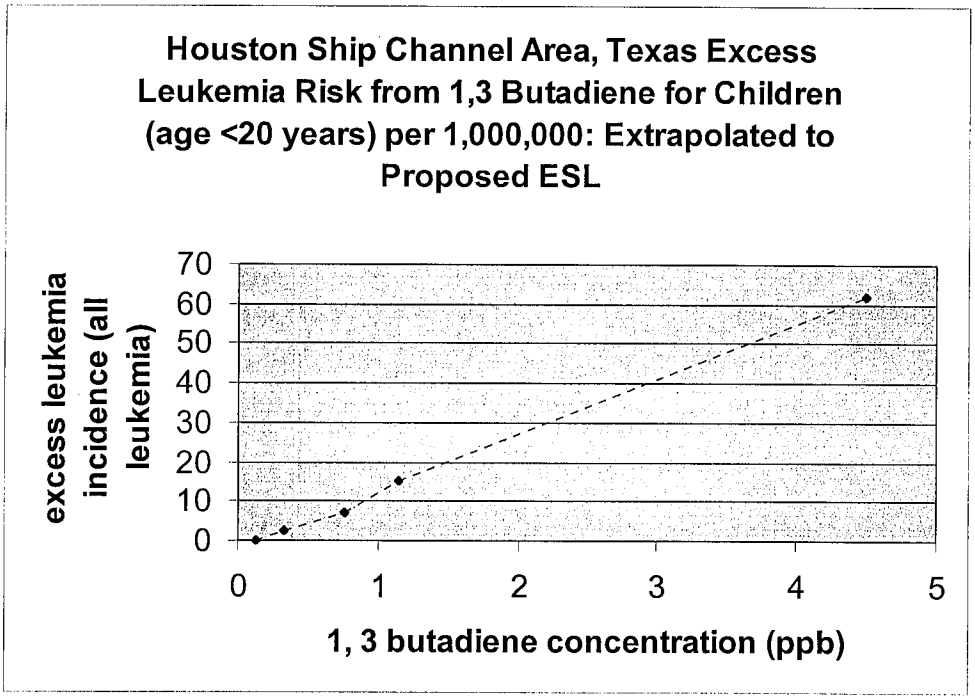
From these estimates, concentrations above 1.15 ppbv result in an increased incidence of **15 cases per million children, or risk of $15x10^{-6}$ ($1.5 x10^{-5}$ / ($\mu g/m^3$)) from 1,3-butadiene alone**. This estimated cancer incidence risk exceeds the TCEQ level of $1x10^{-5}$ and the EPA risk goal of $1x10^{-6}$. This area also has high concentration of other air toxics (see comment 4). The EPA recommended range is $1x10^{-6}$ to $1x10^{-4}$ with a goal of $1x10^{-6}$ as found in the Clean Air Act.[2]

In a simple extrapolation of the UTSPH data regressed for all leukemia cases as related to 1,3-butadiene, it is possible that 1,3-butadiene concentrations at 4.5 ppb would result in over 60 excess leukemia cases in children (age < 20 years) in a million people, if the incidence remained linear (Figure 1). **This would result in 60 $x10^{-6}$ risk or $6x10^{-5}$ risk.** Although this extrapolation is based on limited data and some key assumptions, the

[2] US Federal Register, 54CFR Volume 38, Part 44. 1989

results indicate that a more conservative health protective standard (as recommended by EPA) is the best course of action while further in depth studies in the HSC area are conducted.

Figure 1. Excess leukemia risk from 1,3-butadiene for children in HSC area



The UTSPH report was not referenced by the TCEQ in the DSD. Although the findings are on a pilot study level, a more comprehensive UTSPH study funded by the National Institutes of Health (NIH) and supported by the City of Houston is currently being conducted (Symanski personal communication, June 2008). Unlike the adult male worker study referenced in the DSD, the UTSPH pilot study findings apply to the general population and most directly to the Houston community. The City of Houston feels that the pilot study findings indicate that the proposed 1,3- butadiene ESL is not protective and should be lowered to the EPA recommended concentration level.

The City believes that the UTSPH pilot study findings will likely be verified with the more in depth current UTSPH findings because:

- The National Institutes of Health granted funding for the current study. This is an indication that the pilot findings were found to be credible and of significant interest.
- Results from the exposure to a child receptor represent the simplest category of human exposure because issues with confounding factors associated with travel to work, occupation, smoking or previous exposure are not relevant.

2) **EPA advocates the use of a lower more health protective value and use of a different level introduces inconsistency within the state**

The state is proposing to use a different 1,3-butadiene air standard than that used and advocated by the EPA. The state's value is:

- less conservative than the EPA's,
- not based on local cancer incidence and
- will result in inconsistent regulation within Texas.

The inhalation unit risk (IUR) value in EPA Integrated Risk Information System (IRIS) remains $3x10^{-5}/(\mu g/m^3)$. The Office of Air Quality Planning & Standards (OAQPS) also recommends this toxicity value. Neither EPA IRIS nor EPA OAQPS has plans to change the 1,3-butadiene IUR values and there are no ongoing EPA reassessments for 1,3-butadiene (personal communication by email with Roy L. Smith, Ph.D. Office of Air Quality Planning & Standards, June 23, 2007).

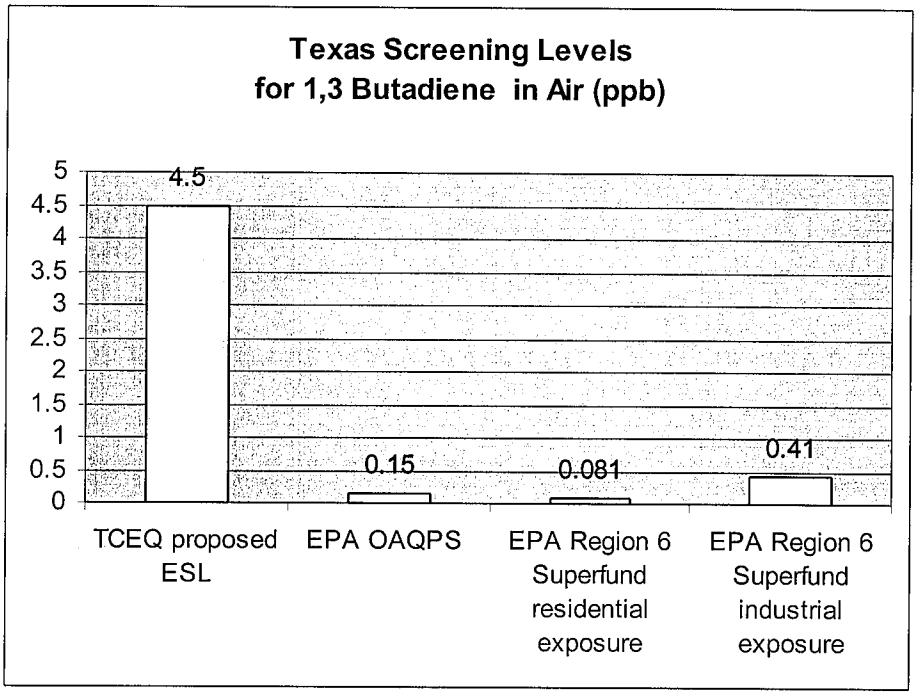
The 1,3-butadiene concentration corresponding to the EPA IUR is, for risk level of

$1x10^{-5}$, is 0.15 ppb and the TCEQ proposes to use 4.5 ppb at the same risk level. The proposed TCEQ number is 30x less conservative than what EPA advocates. Within the state of Texas, according to EPA OAQPS, EPA regulated sites will be assessed using 0.15 ppb value at $1x10^{-5}$ risk level, based on unit risk, while the rest of the state will be assessed using the 4.5 ppb value at $1x10^{-5}$ risk level.

In addition, EPA Superfund sites within the state will be assessed using the IUR from EPA IRIS and OAQPS of $3x10^{-5}$ b/$(\mu g/m^3)$ but at the screening level the risk of $1x10^{-6}$ including exposure parameters is used (http://epa-prgs.ornl.gov/chemicals/index.shtml). EPA Region 6 uses air inhalation risk screening levels set at $1x10^{-6}$, in part to account for exposures from multiple chemicals. The Houston area also has exposures from multiple chemicals and therefore, the lower risk value of $1x10^{-6}$ should be used in Houston (see comment 4).

EPA Region 6 screening level 1,3-butadiene concentrations for air for Superfund sites is 0.04 ppb for residential exposure and 0.18 ppb for industrial exposure. Other EPA region sites using OAQPS standards will use a screening concentration of 0.15 ppb if they screen at $1x10^{-5}$ risk or 0.015 if they screen at $1x10^{-6}$ risk, while TCEQ proposes a screening level concentration of 4.5 ppb (Figure 2).

Figure 2. Comparison of existing with proposed screening levels for 1,3-butadiene in Texas



3) Studies referenced in the DSD to support the higher carcinogenic ESL are flawed

Several reasons given for a higher carcinogenic ESL in the DSD require further clarification or correction. The page number where the inconsistency is located and our comments are listed below.

Page 8, Figure 1.

The source of the data for the national average for urban/suburban areas in the Measured Ambient Concentrations (ppb) block is not referenced.

Data on the NATA website (http://www.epa.gov/ttn/atw/nata1999/tables.html) for 1999 county average for all sources from the county level emission summaries is given in micrograms per cubic meter and converts to 0.05 ppb for rural areas and 0.37 ppb for urban areas. Although in the same ballpark, these are not the same numbers as in the block in Figure 1 and repeats the question, "Where is this data from?" Furthermore, a more suitable metric for the DSD would be ambient concentrations for Texas with a separate measure for Harris County.

The caption in Figure 1 states that "USEPAs current acceptable cancer risk range (is) based on an outdated epidemiology study."

The SEER study published in 2001 analyzes data from 1973 to 1998 and is the latest report cited on EPA's IRIS website (http://www.epa.gov/NCEA/iris/subst/0139.htm#carc). The TCEQ uses re-analyses of the UAB study originally conducted on workers from 1943 -1991 to update the USEPA 2002 assessment. If there are "no other epidemiology

studies that would be appropriate to evaluate human cancer risk from BD exposure," is data collected only as late as 1991 sufficient to revise the ESL in 2008? The City advocates lowering the ESL to the EPA recommended values and believes that revising the ESL to a higher concentration based on the re-analyses of this older data is a mistake.

Page 45, last sentence
"Cheng et al. (2007) results support the presence of a relationship between high cumulative exposure and leukemia and high intensity of exposure and leukemia."

A reanalysis of a worker mortality study is not an appropriate surrogate for risk to the community.
Cheng et al. conducted a reanalysis of 1,3-butadiene exposure data collected by Delzell on synthetic rubber industry workers who died of leukemia. These types of worker studies are limited in detecting incidence of leukemia due to the healthy worker effect. Workers who had contracted leukemia, diagnosed or not, would not be counted unless they had died. Additionally, worker exposure is based on an 8-hour work day whereas residents are exposed for a much longer time period each day.

When determining an ESL, the outcome to be measured should be incidence of disease, not mortality. Therefore, if incidence had been measured in the Cheng or Delzell studies, the number of workers with leukemia would likely have been much higher. That would lower butadiene exposure estimates and show a relationship at a lower concentration.

Although TCEQ accounts for differences in a worker mortality study and risks to a general population through numerical adjustments and models, it is not clear that the data used to establish the models or adjustment factors is sufficient to capture the variables that can occur within a community. Therefore, the City suggests that the TCEQ develop an appropriate epidemiology study in the Houston-Galveston area to answer these questions.

Page 53. second paragraph.
"Toxicokinetic and toxicodynamic evidence indicates children are not more susceptible to chemical leukemogenesis than adults for acute myeloid leukemia and acute nonlymphocytic leukemia…

Inhalation studies should be used when determining an air concentration limit.
This statement may be true for toxicokinetic and toxicodynamic evidence where cancer patients contract leukemia from chemotherapy, but the DSD is addressing inhalation exposures, not oral or intravenous injections. Epidemiological studies would make the better comparison as in the UTSPH study above.

Children are affected more than adults by 1,3-butadiene exposure and leukemia.
The UTSPH study discussed in Section 1 above indicates a relationship with higher 1,3-butadiene levels ($\geq$1.15 ppbV vs. <0.266 ppbV) and acute lymphocytic leukemia, acute

myeloid leukemia, and all leukemias. It is possible that this association was not found in the studies referenced by the TCEQ because:

- The relationship found by UTSPH was in children while the cornerstone study on which TCEQ bases the 9.1 ppb 1,3-butadiene carcinogenic level (Delzell *et al.* 1995; 1996) addressed exposure in adult male workers only.
- The statistical trend is stronger for adults (lower p-values) when specific cancers and leukemias are tracked as opposed to combining all cancers into a larger group as has been done in previous studies.

In the UTSPH study, the same associations with 1,3-butadiene and leukemias in children were not found for adults. However, when distance from the Ship Channel was examined, a significant increasing trend of acute myeloid leukemia in males was detected with proximity to HSC. It is likely then, that if specific types of leukemias had been analyzed in the Delzell studies that associations at lower butadiene concentrations may have been detected.

Page 55
4.2.5.2 Estimating Risks for the General Population from Occupational Workers

"No reliable data" claim in Grant paper is an incorrect use of terminology.
TCEQ bases their claim that "There are no reliable data linking BD exposures at low concentrations typical for the general population to increased mortality from any cause in Texas" on the TDSHS report referenced in the Grant et al. paper. However, there are problems with the TDSHS report.

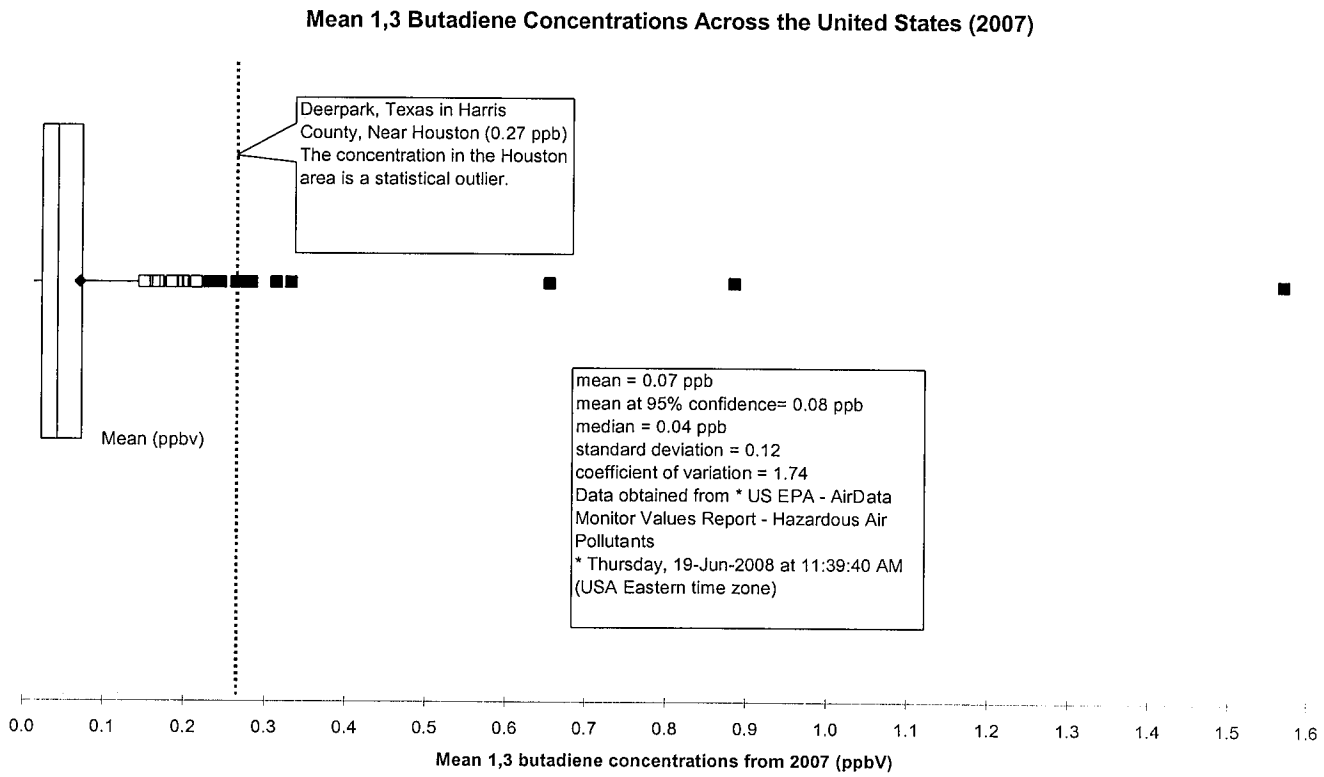
When calculating the standard mortality ratio (SMR) and standard incidence ratio (SIR), TDSHS uses Texas statistics instead of local information. The communities selected for this analysis are located close to industry and are generally more minority-populated and younger than the rest of Texas and would be expected to have different morbidity and mortality statistics.

Secondly, there are several limitations pointed out in the report: non-specific death certificate information, people moving in and out of the community, long latency period, lack of recent data, and limited power.

Therefore, a more accurate statement would be that there is insufficient data, not "no reliable data," linking BD to mortality from "any cause" in Texas. There is a key difference in the meaning of these statements.

The importance of looking at data from the Houston-Galveston area in developing a statewide ESL is further illustrated in the boxplot below. Although the national 2007 mean 1,3-butadiene concentration is 0.07 ppb, the mean concentration for the Deer Park monitor in the Houston-Galveston area is 0.27 ppb, a statistical outlier. If canister data were available for the Houston Milby Park monitor it would also be an outlier based on 2007 auto GC data.

Figure 3. Boxplot of mean 1,3-butadiene canister concentrations in the U.S. with outliers



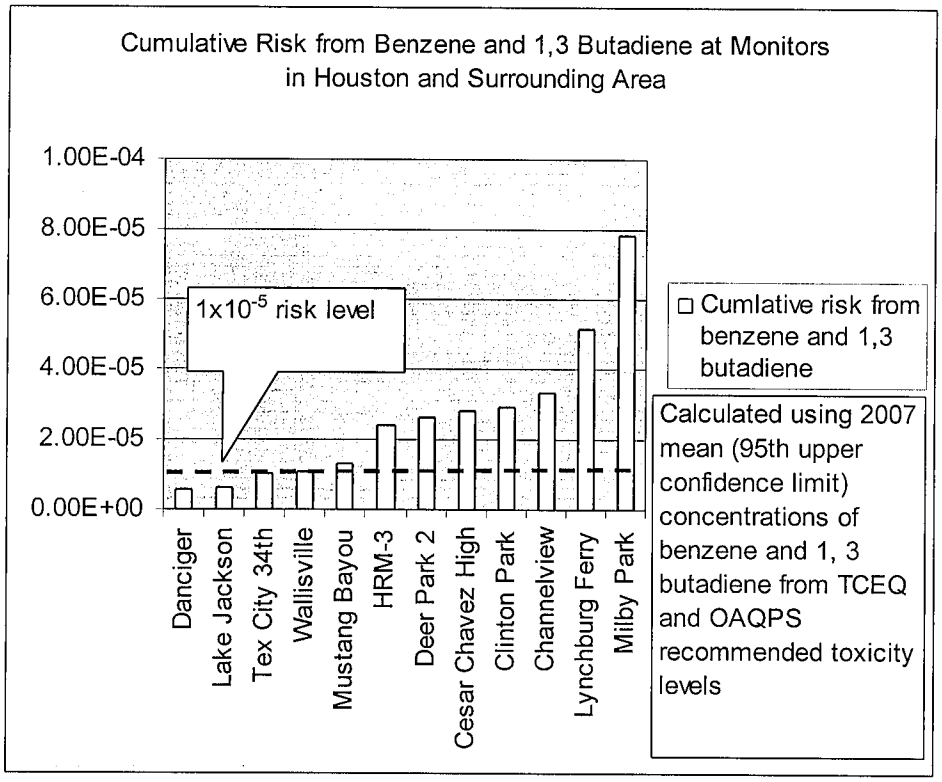
4) Cumulative risk from other carcinogenic air toxics prevalent in Houston is not considered in ESL development

Citizens of the City of Houston and surrounding community are exposed to several criteria pollutants and air toxics simultaneously. Regulation of a single pollutant without consideration of exposure from others is ineffective in protecting human health. For example, when the risk from two main air toxics of concern in Houston are combined, the cumulative risk exceeds the $1x10^{-5}$ risk level for all but two locations. There are 7 pollutants posing a definite risk in Houston and the surrounding area as identified by experts on the Mayor's Task Force on the Health Effects of Air Pollution.[3] (Institute for Health Policy, 2006), therefore the risk will be even higher than those shown below.

---

[3] Institute for Health Policy. University of Texas School of Public Health. 2006. A Closer Look at Air Pollution in Houston: Identifying Priority Health Risks
http://www.greenhoustontx.gov/reports/UTreport.pdf

Figure 4. Cumulative risk for benzene and 1,3-butadiene at Houston area monitors



5) Use and purpose of the ESL is not consistent with the risk level used to develop the ESL

The City of Houston understands the purpose of the Effects Screening Level for an air constituent to be

a) the limit at which industrial air permits cannot be exceeded at a specified downwind receptor location
b) an air monitor annual average ambient limit, above which the area is placed on the Air Pollutant Watch List. Permits in the watch list area are more stringently reviewed.

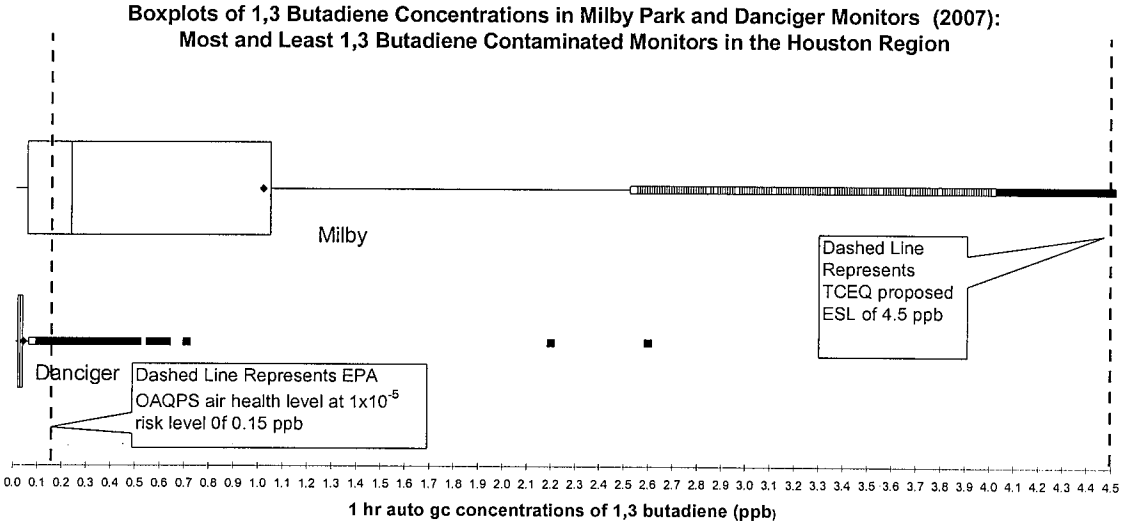
As the City of Houston outlined in comments on MERA earlier this year, there are many problems with the application of the ESL in the permit process (e.g., no model validation or verification, no measured receptor concentrations, no consideration for neighboring emission points etc.) in a) above.

A main point of departure, however, between the TCEQ and the City is in the fundamental understanding of the interpretation of the ESL in b) above. The City is in agreement with the state that the risk limit of $1x10^{-5}$ used to set the ESL is used to identify serious areas of concern, i.e., hot spot areas that are anomalies. We agree that extra resources in manpower and mobile monitors, should be allocated to remedy these anomalous areas expeditiously.

The problem arises when the TCEQ will not acknowledge that anything below this level is in need of improvement. In effect, the TCEQ does not use the ESL in b) above except as a bright line ambient standard.

The TCEQ repeatedly stands in the path of cleaner air in Houston when the city government initiates measures to make improvements in air quality. The City and multiple air experts, as documented in the Rice University report[4], feel that a health protective risk level of $1x10^{-6}$ should be our goal, especially in light of the additive risk of our several air pollutants. The figure below shows the Milby Park 1,3-butadiene concentrations from 2007 in a boxplot with the ESL and the OAQPS limits marked. The ESL set at $1x10^{-5}$ is so high that only a minority of sites and hours in a year exceed it, yet Milby Park has some of the highest 1,3-butadiene concentrations in the United States.

Figure 5. Boxplot of mean 1,3-butadiene auto GC concentrations at two Houston area monitors



It appears that the TCEQ would like the public to believe that everything below the ESL is acceptable even though the vast majority of observations at this monitor fall between EPA's health level and TCEQ's hotspot level. The City of Houston would like support from the TCEQ in improving our air quality. As in the case of the MCL in drinking water, the TCEQ should consider an MCLG for air, with a goal set to be more health protective (e.g, $5x10^{-6}$ or $1x10^{-6}$).

[4] Rice University 2006. The Control of Air Toxics: Toxicology Motivation and Houston Implications http://www.greenhoustontx.gov/reports/controlofairtoxics.pdf

Again, I appreciate the opportunity to comment and am happy to discuss this matter with you further.

Sincerely,

Loren Raun

Loren Raun, Ph.D.
City of Houston
Mayor's Office