TEXAS COMMISSION ON ENVIRONMENTAL QUALITY

Protecting Texas by Reducing and Preventing Pollution

May 28, 2013

EPA Docket Center (EPA/DC)
U.S. Environmental Protection Agency
Mail Code 2822T
1200 Pennsylvania Ave, NW
Washington, DC 20460

Attn: Docket ID No. EPA–HQ–OA–2013–0133

Re: Draft Policy Papers Released for Public Comment: Title VI of the Civil Rights Act of 1964: Adversity and Compliance with Environmental Health-Based Thresholds, and Role of Complainants and Recipients in the Title VI Complaints and Resolution Process

Dear Sir or Madam:

The Texas Commission on Environmental Quality (TCEQ) appreciates the opportunity to respond to the United States Environmental Protection Agency's (EPA) proposal published in the April 26, 2013, edition of the *Federal Register* entitled: "Draft Policy Papers Released for Public Comment: Title VI of the Civil Rights Act of 1964: Adversity and Compliance with Environmental Health-Based Thresholds, and Role of Complainants and Recipients in the Title VI Complaints and Resolution Process."

Enclosed please find the TCEQ's detailed comments relating to the EPA proposal referenced above. If you have any questions concerning the enclosed comments, please contact Mr. Anthony Tatu, Environmental Law Division, Office of Legal Services, (512) 239-5778, or at anthony.tatu@tceq.texas.gov.

Sincerely,

Zak Covar
Executive Director

Enclosure

TCEQ Comments on Draft Policy Papers Released for Public Comment: Title VI of the Civil Rights Act of 1964: Adversity and Compliance with Environmental Health-Based Thresholds, and the Role of Complainants and Recipients in the Title VI Complaints and Resolution Process

I. Further justification is needed for the proposed changes to Title VI guidance regarding consideration of environmental health-based thresholds

Given the lack of opportunity for EPA to apply the rebuttal presumption following issuance of its 2000 *Draft Guidance*, the TCEQ is concerned with EPA's first proposed policy change: eliminating application of the rebuttable presumption when investigating allegations about environmental health-based standards.

More specifically, eliminating the rebuttable presumption presents EPA, as well as a recipient agency, with the potentially untenable situation where there may not be any actual adverse human health effects clearly attributable to such regulatory actions (*e.g.*, air permit, Superfund remedy selection, etc.), yet there is a determination of adverse impact (albeit the first step in analyzing a finding of non-compliance under EPA's Title VI administrative complaint process).

In eliminating the rebuttable presumption, EPA describes other factors in its proposal that will be included in its evaluation of adverse impact: "existence of hot spots, cumulative impacts, particularly sensitive populations, misapplication of environmental standards or the existence of site-specific data demonstrating an adverse impact despite compliance with the health-based standard." As discussed in further detail below, TCEQ believes reliance on such broad terminology without further elaboration is counter to the goal of 'elucidating the analytical framework' for reviewing Title VI complaints, particularly given the highly complex and technical nature of underlying environmental regulations where health impacts are already taken into consideration.

TCEQ supports EPA continuing to validate and evaluate its existing programs that can help address Title VI issues. For example, EPA has continued to emphasize the importance of addressing disproportionate impacts of air toxics, characterizing exposure and risk distributions in geographic hot spots via the National Air Toxics Program. With this goal in mind, EPA has developed tools and guidance to model air toxics risks at finely resolved spatial units using Geographic Information Systems (GIS). These tools are designed to estimate cancer and non-cancer risks from multiple air toxics emitted from multiple sources at a community resolution (Turaga et al. 2011). Further, EPA has also published guidance documents for conducting community-scale risk assessments as part of the Air Toxics Risk Assessment Reference Library series (EPA 2006).

TCEQ considers EPA health-based values (e.g., RfD, RfC, NAAQS) to be sufficiently health-protective (if not overly conservative in some cases) such that the absence of adversity should continue to be a rebuttable presumption when health-based thresholds are met. Collectively, EPA technical support documents wherein health-protective

criteria are derived constitute a considerable body of evidence demonstrating this to be a reasonable presumption, which should require rebuttal by convincing scientific evidence to the contrary.

Thus, the rebuttable presumption of no adverse effects when NAAQS and/or other health-based thresholds (e.g., RfDs) have been met should not be discarded in favor of a policy position that calls into question implementation of many federal laws under EPA's own jurisdiction.

In addition, TCEQ notes that while the proposed guidance is not binding, the statement that "EPA is mindful of its broad discretion afforded to federal agencies in the enforcement of federal statutes, including enforcement of federal financial assistance recipients' obligations under Title VI" suggests that EPA resolution of a Title VI complaint can impact a recipients' federal assistance in such a way where application of EPA's guidance is binding.

A. There is no scientific basis for eliminating the rebuttable presumption

The draft guidance proposes to eliminate the rebuttable presumption of no adverse effects when NAAQS and/or other health-based comparison values (e.g., Reference Doses, or RfDs) have been met. As an initial matter, TCEQ is concerned because the proposed changes encompass not only health-based standards promulgated by EPA (e.g., NAAQS), but also other health-based reference values (e.g., RfDs) that may be generated by regulatory agencies, such as TCEQ. This is an expansion of the information to be considered when determining if a claim has validity. The draft guidance appears to conclude that past, present, and future actions by regulatory agencies based on such criteria cannot be presumed to be adequately health-protective. As a general practice, the methods used to derive health-based criteria such as reference doses (RfDs), reference concentrations (RfCs), and similar values (e.g., Slope Factors (SFo) and Unit Risk Factors(URFs)) are conservative and produce health-protective values orders of magnitude lower than those that produce adverse health effects. These health-based values tend to overestimate risk, especially when combined with reasonable maximum exposure assumptions, such as those used for the Superfund program. The proposed guidance is fundamentally inconsistent with the derivation of health-protective values by EPA and other agencies, which are designed to protect public health including sensitive subpopulations in addition to providing an adequate margin of safety. This proposed guidance also undermines the practical utility of these values for environmental policy and risk management decisions.

Throughout the draft guidance the term "health-based thresholds" is used. The TCEQ interprets this to mean NAAQS, RfDs, TCEQ ReVs and other heath-based toxicity factors. However, this term has a specific meaning in toxicological and risk assessment literature. In particular the term "threshold" is used to describe the dose or exposure below which no deleterious effect is expected to occur. The existence of a threshold for the vast majority of chemicals is a cornerstone of toxicology.

B. The criteria proposed in the draft guidance are overly vague

Hot Spots

The proposed guidance includes vague criteria which can be arbitrarily and capriciously applied in the affirmative to a given situation to conclude that a regulatory agency charged with protecting public health has caused an adverse impact where none can be scientifically demonstrated. For example, "hot spot" is not defined but may be interpreted to simply mean appreciably higher concentrations of an emitted chemical in close proximity to a facility compared to distant locations. However, levels at both locations may afford the same level of health protection in that they are orders of magnitude below those which cause adverse health effects. This term could also be used to describe natural random geographical variation in the prevalence and/or incidence of a health outcome (e.g., due to a disproportionate number of elderly individuals or smokers in an area) where no causation exists and confounding by known risk factors cannot be adequately taken into account. Without a proposed definition, TCEQ must speculate as to the possible meaning of the term, and thus these comments may not be comprehensive.

Sensitive populations

Another vague criterion with potential for misapplication is the presence of sensitive populations as they are considered in the establishment of the health-based standard. This is because many potentially sensitive subpopulations are often not explicitly discussed or evaluated in EPA chemical toxicity assessments. However, it must still be recognized that all such populations are implicitly considered and accounted for when considering potentially sensitive subpopulations as a group through various means in the derivation of health-based thresholds (e.g., intra-human variability uncertainty factors, use of lower statistical bounds for points of departure, database uncertainty factors, etc.). Furthermore, such groups are included in many studies used to establish NAAQS values. Also, the proposed guidance is unclear as to whether a realistic assessment of the conditions at issue, which finds no appreciable potential for adverse effects even in sensitive populations, can offset the presence of such populations.

In addition, it is unclear whether "particularly sensitive populations" refers to populations known to be more sensitive to a particular chemical as opposed to those simply assumed to potentially be more sensitive in general. The term "sensitivity" could refer to health problems generally due to factors other than the chemical-specific considerations (e.g., socioeconomics, access to health care and diagnosis), whether a population can be deemed particularly sensitive simply based on considerations such as number of chemicals and proximity to industry as opposed to inherent biological factors (e.g., genetic differences conferring metabolic differences), etc.

Site-specific data

Lastly, the type of site-specific data to be evaluated which could be construed (or misconstrued) to demonstrate an adverse impact despite compliance with health-based thresholds is not defined or even discussed. Furthermore, TCEQ is concerned that an objective, scientifically-sound, evaluation of site-specific data allegedly demonstrating an adverse impact (e.g., health effects) may be challenging for EPA. This is because, for example, while causal inference is particularly important in such a demonstration, due

to potential problems at EPA ,the National Academy of Sciences (NRC 2011) expressed its concerns about EPA process by highlighting best practices for assessing causation strength of evidence (among other elementary concepts and approaches) in their comments to EPA.

C. TCEQ Practice for Deriving Health-Based Comparison Values

As discussed in more detail below, TCEQ's practice for deriving and utilizing health-based comparison values is scientifically based and peer reviewed. Therefore, TCEQ does not support any detailed guidance for development and use of such values and thresholds for the Title VI Compliant and Resolution Process.

Cumulative Exposure

The draft guidance asserts that factors including cumulative impacts and presence of particularly sensitive populations may not be considered in the establishment of health-based comparison values. To the contrary, TCEQ routinely considers cumulative exposures when deriving health-based comparison values (e.g., Air Monitoring Comparison Values, or AMCVs used in air monitoring and the Effects Screening Levels (ESLs) used in air permitting) and is required in many instances to do so by statute. The TCEQ currently addresses cumulative exposures primarily through air permitting and through its extensive monitoring of ambient air.

The TCEQ Toxicology Division calculates safe concentrations of chemicals in air that are written into enforceable permits. The TCEQ's 2012 guidelines for developing these levels were peer-reviewed outside of the agency by world-renowned experts in inhalation toxicology and risk assessment. The guidelines—and the ESLs calculated from them—are scientifically-sound assessments of a chemical's potential for adverse health effects. The method for deriving these ESLs (described in detail online at http://www.tceq.texas.gov/toxicology/esl/guidelines/about.html) addresses both cumulative and aggregate exposures. The risk-management goal for cancer-causing chemicals is 1 in 100,000, the theoretical extra cancer risk (above the background cancer risk of about 1 in 3) that a chemical may cause over a lifetime of exposure in the most sensitive portions of the population. This risk level is ten times more stringent than the highest level that EPA deems acceptable. When developing ESLs, the TCEQ derives a scientifically-sound, safe level, and then reduces that number by 70 percent for evaluating air permit applications.

The TCEQ's extensive air monitoring network helps verify that its permitting process has been effective for multiple emission sources even in the most industrialized areas of Texas. The TCEQ benefits from the largest stationary monitoring network in the country. Many of these monitors are placed in areas with densely packed sources, such as industrial areas, which represent a worst-case scenario of aggregate exposure—giving the agency high confidence that policies and practices that work in those areas will work equally well in less industrial areas.

Monitors provide reliable data on aggregate and cumulative exposure as they measure the air concentrations due to emissions from all sources (such as industrial sites, mobile sources such as cars, and area sources such as gas stations). Many monitors are also placed in communities and provide real time continuous monitoring of ambient air. In addition, there is an interactive process when selecting monitoring sites, and TCEQ involves multiple opportunities for stakeholder/community participation and follows EPA's criteria for siting. The vast majority of the monitors in the state showed annual average concentrations under the 1-in-100,000 screening level for carcinogenic chemicals. Actual monitoring data verify acceptable exposure levels and the ESLs are inherently conservative and health-protective.

The TCEQ also uses cumulative risk assessments from other organizations, such as EPA's National-Scale Air Toxics Assessment (NATA), to identify areas with computer-modeled concentrations above a level of concern. Although NATA is based on a theoretical model of reported emissions rather than actual monitored concentrations, the assessment helps the TCEQ identify other potential issues. Finally, in the limited areas (about 0.08 percent of the state) where actual monitored concentrations of chemicals indicate a potential concern, the TCEQ uses the Air Pollutant Watch List to reduce ambient (outdoor air) levels. The list considers possible sources of the chemical of concern. More information can be found online at http://www.tceq.texas.gov/toxicology/AirPollutantMain/APWL_index.html. Therefore, the resulting health-based comparison values adequately address cumulative exposure.

Sensitive Subpopulations

Regulatory and scientific study definitions of susceptible, vulnerable, and sensitive subpopulations vary. The TCEQ defines susceptible as a capacity characterized by biological or intrinsic factors (e.g., metabolic factors, genetic polymorphisms, toxicodynamics, pre-existing disease, lifestage, and gender) that may modify the effect of a specific exposure, leading to a higher health risk at a given exposure level (Hines et al. 2010, Snodgrass 1992, USEPA 2011c). Thus, individuals in a susceptible subpopulation may experience adverse health effects at lower levels of exposure than the general population or more severe effects at the same exposure level.
In some cases, studies are available for sensitive subpopulations. These may include children, older adults, pregnant women, or individuals with preexisting health conditions (e.g., studies in asthmatics after inhalation exposure to irritants). Critical life stages or windows of susceptibility should be identified, if possible, for chemicals. Studies based on sensitive members of the population are often used as key studies, especially if the critical effect in sensitive subpopulations is observed at lower concentrations/doses than in the general population. If a toxicity assessment is conducted where the critical effect was measured in a sensitive population or the potential increased sensitivity of children or other sensitive subpopulations was accounted for through use of appropriate uncertainty factors, then these subpopulations are protected.

As a matter of course, the TCEQ protects sensitive subpopulations when deriving health-based toxicity factors utilized in air permitting and air monitoring activities. The approach is outlined in extensive detail in the TCEQ Guidelines to Develop Toxicity Factors (http://www.tceq.texas.gov/toxicology/esl/guidelines/about.html). In addition, the potential for odors as a nuisance condition, and effects on vegetation, are also considered when deriving the toxicity factors.

Most dose-response assessments have inherent uncertainty because the process requires some scientific judgment, use of default assumptions, and data extrapolations. Therefore, the acute and chronic Reference Values (ReVs) are derived with the application of uncertainty factors (UFs) to account for a lack of knowledge and true heterogeneity or diversity. For the intraspecies (i.e., person-to-person) uncertainty factor, the aspects considered in assessing the potential for differences in toxicity among the human population and deciding on a specific value include: (1) the mode/mechanism of action, (2) the toxicological endpoint observed, (3) what is known/unknown about toxicokinetic/toxicodynamic differences among individuals, (4) the range of response among humans and subpopulations (i.e., differences due to mass or activity pattern), (5) whether toxicological (e.g., dose-response) data exist on effects in a susceptible human population, and (6) sensitivity. The TCEQ uses best scientific judgment on a chemical-by-chemical basis in determining the most appropriate values to apply to account for potential intrahuman variability. The resulting health-based comparison values are, therefore, adequately protective of both the general population and sensitive subpopulations.

References:

EPA, 2006. Air Toxics Risk Assessment Reference Library Volume 3, Community-Scale Assessment. Accessed from http://www.epa.gov/ttn/fera/risk_atra_vol3.html. on.

National Research Council (NRC). 2011. Review of the Environmental Protection Agency's Draft IRIS Assessment of Formaldehyde. Washington, DC: The National Academies Press.

Texas Commission on Environmental Quality (TCEQ). (2012). Guidelines to develop toxicity factors. (RG-442). Retrieved from http://www.tceq.texas.gov/publications/rg/rg-442.html

Turaga R. M R., Noonan D., Bostrom A (2011). Hot spots regulation and environmental justice. Ecological Economics 70: 1395-1405.

II. Role of Complainants and Recipients in the Title VI Complaints and Resolution Process

While TCEQ recognizes EPA's efforts to strike a balance between providing greater involvement for complainants in the complaint process while working with recipients, the TCEQ offers the following comments:

A. With regard to Alternative Dispute Resolution (ADR) efforts, it is not clear if EPA intends to offer, at EPA's expense, complainants and recipients the opportunity to engage in binding or non-binding ADR. Likewise, will complainants and recipients have an opportunity to weigh in during the ADR selection process?

B. TCEQ suggests that mediation be considered as a tool for resolving issues raised in a complaint.

C. When EPA in its discretion elects to engage complainants who want to provide input on potential remedies as well as potential terms of a settlement agreement, the TCEQ notes that any potential remedy and/or settlement term must be within the scope of a recipients' jurisdiction and authority. And while suggested remedies and/or settlement terms will be forwarded to the recipient for further discussion with the EPA, such a three-way exchange may prompt frustration with either the complainant or the recipient, depending on how a complaint is finally concluded. In addition, in exercising EPA's discretion, the TCEQ urges that complainant input occur early in the process.