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Approaches to Derive Odor-Based Values

Toxicology Division

Office of the Executive Director
TEXAS COMMISSION ON ENVIRONMENTAL QUALITY

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Acronyms and Abbreviations

Acronyms and Abbreviations	Definition
AMCV	Air Monitoring Comparison Value
ESL	Effects Screening Level
$^{acute}ESL$	acute health-based Effects Screening Level for chemicals meeting minimum database requirements
$^{acute}ESL_{odor}$	acute odor-based Effects Screening Level
FIDO	Frequency, intensity, duration, offensiveness
ODT_{50}	Odor detection threshold, concentration where 50% of the volunteers participating in an odor panel detected the odor
µg	microgram
µg/m^3	micrograms per cubic meter
mg	milligrams
mg/m^3	milligrams per cubic meter
ppb_v	parts per billion by volume
ReV	Reference Value
TCEQ	Texas Commission on Environmental Quality
TD	Toxicology Division
USEPA	United States Environmental Protection Agency

Odor-Based Effects Screening Levels (ESLs) and Air Monitoring Comparison Values (AMCVs)

1.0 Air Quality and Protection of Welfare from Odor Nuisance

Odor is one of the leading (70-80%) causes of complaints received by environmental regulatory agencies in North America and Europe (Leonardos, 1996; Nicell, 2009; Shusterman, 1992). Noxious, unpleasant odors may impair intended property use, interfere with business operations, cause discomfort or induce adverse health effects in humans and animals on the property (Nicell, 2009). Frequent exposure to high concentrations of odorous chemical (i.e., with unpleasant odors), typically three to five times greater than the odor detection threshold (defined below), may cause a variety of indirect health effects, including headache, nausea, anorexia, vomiting, dizziness, shortness of breath, and certain types of mental stress (Cone and Shusterman, 1991; Nicell, 2009; Schiffman and Williams, 2005; Shusterman, 1999; 2001; Wilhite and Dydek 1989, 1991). In addition, a number of studies suggest that odorants may be irritating to the respiratory tract and, after relatively longer exposure durations, can worsen asthma for some people (Cain and Murphy, 1980; Sakula, 1984; Shim and Williams, 1986; Stein and Ottenberg, 1958). The potential impact of unpleasant odors on welfare and quality of life for exposed individuals mandates effective regulation of chemical emissions to prevent nuisance odorous conditions.

Texas is the only state in the United States that regulates odor nuisance based upon the use of odor-based values. The Texas Commission on Environmental Quality (TCEQ) is required by the Texas Clean Air Act [Chapter 382 of the Texas Health and Safety Code (THSC)] to conduct air permit reviews and ensure that the construction of a facility or modification of an existing facility will use at least the best available control technology and be protective of human health and physical property. Federal standards, such as the National Ambient Air Quality Standards (NAAQS), may be used to evaluate the impacts of some pollutants. Similarly, the TCEQ has state standards for specific chemicals, including hydrogen sulfide and sulfuric acid. If there is no federal or state standard to regulate specific chemical emissions, the TCEQ Toxicology Division develops chemical-specific screening values to evaluate chemical concentrations in ambient air. Chemical-specific Effects Screening Levels (ESLs) are used to evaluate modeled emissions originating from proposed facilities in the air permits program. Air Monitoring Comparison Values (AMCVs) are used to evaluate monitored concentrations of chemicals measured in ambient air at various stationary and mobile sites state-wide (http://gis3.tceq.state.tx.us/geotam/index.html). For more information on ESLs and AMCVs specifically, please see the TCEQ Guidelines to Develop Toxicity Factors (TCEQ 2015).

The intent of an odor-based value is regulation of odor with the intention to prevent odor nuisance conditions, rather than prevention of odor detection. Odor nuisance generally occurs when short-term emissions from a source are of character, duration, intensity, and frequency to constitute a nuisance condition as described in TCEQ guidance (Odor Complaint Investigation

Procedures, TCEQ 2007). Briefly, when the TCEQ investigates an odor complaint, evidence is gathered to evaluate four primary characteristics of odor (FIDO procedure, TCEQ 2007):

- frequency (how often an odor is experienced);
- intensity (how strong is the odor);
- duration (the duration that the odor is experienced); and
- offensiveness (how unpleasant the odor is to most people).

Given that these characteristics are the primary basis upon which the TCEQ will evaluate odor complaints, it is important for odor-based values to be derived with the intention of preventing odor nuisance conditions.

2.0 Chemicals for Which Odor-Based Values are Derived

The TCEQ develops odor-based values for chemicals that are malodorous. (i.e., that smells very unpleasant, obnoxious, disagreeable, or pungent).

Odor data would be considered integral in deriving odor-based values for chemicals. When available data suggest that the chemical possesses an offensive, pungent odor character, odor values help to prevent nuisance odors, which would likely occur at concentrations significantly lower than those that induce adverse health effects. In the case where odor data is unavailable for a malodorous chemical a surrogate odor value may be considered for that chemical.

Alternatively, some chemicals will have odor-based values that are quite high, such that adverse health effects may occur long before odor is detected or recognized. Based on scientific judgment, odor-based values may not be developed for these chemicals. This procedure is analogous to the approach used for the derivation of vegetation ESL values, where a vegetation value is not derived if it is estimated to be significantly higher than the health-based value (TCEQ 2015). Based on scientific judgment odor-based values may not be developed for chemicals whose odors are not unpleasant (e.g., ketones, esters, alcohols, or alkanes (TCEQ 2007)), although historical information where frequent odor complaints are received for a chemical will be considered.

3.0 Deriving a Proposed Odor-Based Value

The TCEQ evaluates available chemical-specific data for chemicals proposed for derivation, and conducts an analysis to determine whether development of an odor-based value is needed to prevent odor nuisance conditions. The analysis for determining the defensibility of generating an odor-based value includes the following steps:

1. Identify data describing odor character
2. Determine if the chemical is from a class of chemicals known as malodorous

3. Search for available odor threshold data (recognition or detection as discussed in Section 4.0).

4.0Sources of Data

Odor values are typically set at an effect level, which may be recognition or detection thresholds, meaning some individuals may detect odors at these levels. The data sources for odor values are quite broad. Initial data collection includes basic physical-chemical properties, chemical structure and notes regarding descriptions of odor character. The definitions of odor threshold values are as follows:

- Detection Threshold (Absolute Threshold): the concentration at which 50% of the volunteers participating in an odor panel detected the odor (ODT_{50}).
- 50% Recognition Threshold: the concentration at which 50% of the odor panel defined the odor as being representative of the odorant being studied.
- 100% Recognition Threshold: the concentration at which 100% of the odor panel defined the odor as being representative of the odorant being studied.

The TCEQ derives odor -based values from odor detection thresholds, which are the lowest concentration of a chemical perceived, but not recognized, by test individuals (Cone and Shusterman, 1991). The TCEQ generally uses the ODT_{50}, which is the concentration of chemical that 50% of test subjects detect odor. When odor detection thresholds are not available, an odor recognition threshold may be used as the basis of an odor-based value. Furthermore, if available data indicates the chemical of interest actually has a pleasing odor at low concentrations but an offensive odor at higher concentrations, a higher ODT_{50} or an odor recognition value may be used for the odor-based ESL.

The more a chemical concentration exceeds its 50% detection or recognition threshold, the higher the percentage of people exposed to that chemical will perceive the odor. People typically perceive an odor as unpleasant when the concentration has exceeded the ODT_{50} by 3 to 5 fold or exceeded the odor recognition threshold (Wilhite and Dydek, 1989, 1991). As stated previously, persistent or recurrent exposure to strong, unpleasant odors may indirectly cause health effects such as headache and nausea in some individuals (Cone and Shusterman 1991, Nicell 2009, Schiffman and Williams 2005). Chemical concentrations that are below a 50% detection threshold are less likely to be odorous, but perception of their odor by some individuals cannot be ruled out.

In order to identify and interpret the odor threshold values for chemicals, TCEQ staff conducts a comprehensive literature search of published odor thresholds. Some of these thresholds that the

TCEQ adopts are derived from original research, and some are compiled from literature reviews. Any updated study is considered when developing an odor-based value, as discussed in the following sections.

Reported odor threshold data often differ considerably. In fact, it is not uncommon for reported odor threshold values to range over several orders of magnitude for the same chemical. For example, 26 values were reported for hydrogen sulfide, ranging from 0.072 - 1,400 parts per billion by volume (ppb_v), a factor of 10,000. Major factors that contribute to variability in the odor thresholds are due to differences in types of data sources, differences in experimental methodology, and human olfactory response characteristics, which exhibit a great deal of inter-individual variables.

In a report, "Odor Threshold for Chemicals with Established Occupational Health Standards", the American Industrial Hygiene Association (AIHA 1989) reviewed and critiqued odor threshold data for 182 chemicals that have a threshold limit value (TLV). The project developed a set of criteria for acceptability of odor threshold measurement techniques to evaluate the experimental odor threshold determinations reported in the literature. The criteria are briefly summarized below:

- Panel size of at least six people per group
- Panelist selection based on odor sensitivity
- Panel calibration
- Consideration of vapor modality (air or water)
- Diluent in accord with compound
- Presentation mode that minimizes additional dilution (ambient) air intake
- Analytical measurement of odorant concentration
- Calibration of flow rate and face velocity (olfactometers)
- Concentration presentation series that reduces olfactory fatigue
- Repeated trials
- Forced-choice procedure
- Concentration steps increasing by a factor of two or three

Of the 182 odorants with a TLV, the AIHA review resulted in 110 compounds from 36 reference sources that had odor threshold values that met the evaluation criteria (AIHA 1989). The AIHA approach was then used by the USEPA (USEPA 1992) to conduct critical reviews of published odor threshold values for the chemicals listed as hazardous air pollutants (HAPs) in the 1990 Clean Air Act Amendments. The analysis resulted in 57 odorous HAPs from 16 reference sources with acceptable odor threshold values (USEPA 1992).

van Harreveld et al. (1999) reported that since the early 1990s, the introduction of improved instrument calibration, improved panel screening procedures, and the adoption of n-butanol as a reference material have enabled more objective odor measurements compared to odor studies conducted prior to the 1990's. Additionally, in a National Advisory Committee for Acute Exposure Guideline Levels for Hazardous Substances (NAC/AEGL Committee) meeting, van Doorn et al. (2002) stated that odor thresholds reported more than several decades ago were probably not obtained under the same conditions of methodological precision compared to modern olfactometer methods. van Doorn et al. (2002) further indicated that modern performance tests, such as using forced choice dynamic olfactometry, has improved the objectivity, sensitivity, repeatability, and reproducibility of odor threshold determinations. Standardized odor measurement practices published by the American Society of Testing and Materials (ASTM E679), Dutch Standard (NVN 2820), Australia/New Zealand Standard (AS/NZS4323.3:2001), and European Committee for Standardization (CEN) Standard (CEN 13725); as well as the Japanese Triangle Odor Bag Method are considered the standard olfactometry methods (Ruijten et al. 2009, van Doorn et al. 2002, McGinley 2002, Mahin 2003). These standard methods are considered objective, quantitative, dependable, and reproducible (St. Croix Sensory 2005). The following are some of the latest publications describing standardized methods of measuring odor:

- The American Society of Testing and Materials (ASTM) Standard of Practice E679-04: Standard Practice for Determination of Odor and Taste Threshold by a Forced-Choice Ascending Concentration Series Method of Limits (ASTM 2004).

- The European Committee for Standardization (CEN) Standard CEN 13725:2003: Air Quality – Determination of Odour Concentration by Dynamic Olfactometry (CEN 2003).

- The Australian/New Zealand Standard. AS/NZS4323.3:2001: Stationary source emissions. Part 3: Determination of odour concentration by dynamic olfactometry. Standard Australia, Sydney, Australia (AS/NZS 2003).

- The Dutch Standard NVN 2820: Air Quality, Sensory Odour Measurement Using an Olfactometer (Netherlands 1995). The Japanese Triangle Odor Bag Method (Iwasaki 2003, Nagata 2003).

- An 8-station vapor delivery device (VDD8), ascending concentration approach. (Cain et al. 2007; Cometto-Muñiz and Abraham 2008).

- Air and Waste Management Association (AWMA) EE 6 Subcommittee on the Standardization of Odor Measurement. Guidelines for odor sampling and measurement by dynamic dilution olfactometry (AWMA 2002).

- Others such as those reported by McGinley (2001) and St. Croix Sensory (2005).

The above methods are considered reliable approaches for measuring odor (Ruijten et al. 2009, Hoshika et al. 1993; van Doorn et al. 2002; Nagata 2003; van Harreveld 1999, 2003; McGinley 2001). Furthermore, The NAC/AEGL Committee (van Doorn et al. 2002) and the Netherlands National Institute for Public Health and the Environment (Ruijten et al. 2009) have defined the quality levels for all odor thresholds reported in the literature, placing emphasis on study methods and controls.

Studies comparing odor thresholds for compounds determined by the above methods indicate that the detection thresholds obtained using the Japanese triangle method [e.g., odor threshold values from Nagata (2003)] appear to generally agree with those obtained using the European or Dutch standard methods. However, one difference noted in the approach utilized by Nagata (2003) is the assembly of odor panelists, which were pre-screened to ensure that sensitive panel members were selected for the study. This method has resulted in the observation that some odor thresholds originating from this particular study are lower than those in other studies, likely due to the use of the pre-screened panelists, which can potentially lead to the risk of bias (Iwasaki, 2003). In addition, there are differences between directed tests (i.e., the odor panelist is concentrating on detecting odor) and undirected tests (the subjects have no indication the object of the exercise is to detect odor). There can be a four-fold increased detection threshold for an undirected test compared to a directed test (Amoore 1983). Therefore, the potential risk of bias must be considered when selecting a final odor-based value.

5.0 Integration of Data to Determine the Final Odor-Based Value

Following collection of all available odor data, a number of issues must be considered in order to select the most appropriate value based on professional judgment. Professional judgment in this context refers to the application of knowledge and training to the evaluation of available data using an evidence integration approach. After collecting available odor data, a broad evaluation of those data must be conducted to determine what approach (es) need to be considered in the derivation of an odor-based value.

In some cases, there may be only one odor threshold value for a chemical of interest; however, there is often more than one value available. The odor threshold values can vary widely and the apparent reason for this variance, as discussed above, may be unknown or multifactorial. When evaluating available odor data, the TCEQ takes note of the range of values observed for a given chemical. Likewise, basic information regarding the odor characteristics is considered (i.e., malodorous or offensive only at high concentrations). Study quality is considered, which includes the publication date, method used to collect threshold values, risk of bias, and use of experimental controls. In addition to considering the study quality and characteristics, the TCEQ evaluates any outlier odor thresholds that should be excluded from the analysis, if scientifically defensible. If the observations appear to cluster around a particular range of values, that could strengthen the choice to select a threshold that is based on the central tendency of the values (e.g., geometric mean).

As part of the integration of available data, identification of previously used odor-based values is useful. The TCEQ may have historically used a value based on older studies, in which odor complaints have never been reported, indicating no odor nuisance issues have occurred when regulating at the level of that ESL. Agency records can be reviewed to determine if a chemical of interest is emitted in the state and which facilities have reported emitting it by investigating available emissions inventory data available from the Air Quality Division Emissions Assessment Section (http://www.tceq.texas.gov/airquality). From these data, the identification of specific facilities emitting the chemical of interest may be determined. Using facility-specific identifiers, it is possible to evaluate whether there were complaints regarding a specific chemical while using this chemical-specific odor-based value by querying the TCEQ Complaints database (http://www2.tceq.texas.gov/oce/waci/index.cfm). Further information may be acquired upon consultation with knowledgeable regional investigators or other air section staff to determine whether a facility or chemical has been the subject of complaints.

Similarly, air monitoring data provide measured concentrations of a chemical that are detected in ambient air. If values are frequently measured above a proposed odor-based value, further investigation is needed to determine whether emissions of the chemical in question have been associated with potential issues (i.e., complaints or enforcement cases). Ultimately, if the chemical has never been the subject of odor complaints or enforcement cases regarding odor, and the proposed odor value is appreciably lower than historical values, it is likely that the proposed value may be unnecessarily conservative. When that is the case, the historical value may be retained.

During the process of deriving a final, odor-based value, individual pieces of chemical-specific data must be considered in the context of all available data. This process is called evidence integration. The evidence integration process is intended to facilitate the generation of scientifically defensible odor-based values using data from a wide range of sources.

6.0 Conclusion

Overall, the selection of final odor values will be driven by an analysis of the available data, as well as professional judgment. In this context, professional judgment refers to the application of knowledge and training to the evaluation of available data using an evidence integration approach. The ultimate goal is regulation of odor to prevent odor nuisance conditions, rather than prevention of odor detection. The TCEQ has procedures to investigate odor nuisance conditions using agency-established guidance (i.e., FIDO procedure, TCEQ 2007).

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