TEXAS CHEMICAL COUNCIL
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July 22, 2009

Toxicology Division, MC 168
Texas Commission on Environmental Quality
P.O. Box 13087
Austin, TX 78711-3087

RE: Technical Comments - Interim Guidelines for Setting Odor-Based Effects Screening Levels

Dear Sir or Madam:

The Solvents Industry Group ("SIG")[1] of the American Chemistry Council and the Texas Chemical Council (TCC) appreciate this opportunity to comment on the Interim Guidelines for Setting Odor-Based Effects Screening Levels (ESL) proposed by the Texas Commission on Environmental Quality (TCEQ).

I. Executive Summary

After a thorough review of the proposed odor-based ESL guidelines, SIG and TCC have concluded that TCEQs revised position on the acceptability of odor threshold information for ESL determination incorporates many commendable improvements on the treatment of historical test data. We believe, however, that additional enhancements are needed to improve clarity, scientific integrity, and encourage data collection by chemical manufacturers and formulators who may wish to sponsor additional testing. Moreover, the TCEQ should also proactively promote and facilitate new research and testing by assuring affected companies and institutions that any new test data will be used in a clear and consistent fashion to develop an ESL_{odor} value.

We cannot, for the reasons set forth below, support the proposed guidelines for odor based ESLs in its current form. The proposed guidance significantly lacks detail and the guideline is inadequately conceived in several areas. As stakeholders, we have a significant interest in the development of odor based ESL guidelines and urge the TCEQ to fully consider these comments. SIG and TCC are convinced that the issuance of the guidance in its current form, without addressing our recommended changes, could impede the ESL development process by discouraging affected parties from sponsoring new odor-related research or identifying meaningful management measures.

[1] SIG represents major U.S. manufacturers of hydrocarbon and oxygenated solvents and was formed to address health, safety, and environmental issues affecting both the producers and users of those materials. Current members include: The Dow Chemical Company, ExxonMobil Chemical Company, Shell Chemical LP and Eastman Chemical Company.

These comments address in detail the following topic areas:

- Additional Guidance Required in Several Key Topic Areas
- More Descriptive Details Needed on the Four Designated Methods
- The Criteria Used to Identify Acceptable Odor Threshold Data Should Incorporate Greater Flexibility
- The Definition of an Odor Threshold Needs to be Modified
- Odors Detected by Field Investigators Need to be Evaluated in a More Objective Fashion
- A New Approach is Needed When Examining Odor Threshold Values Determined Prior to 1990
- Evergreen Provisions Need to be Incorporated into the Guidance

II. Additional Guidance Required in Several Key Topic Areas

The odor-related ESL policies being developed by the TCEQ have generated a significant amount of interest from stakeholders through the U.S.. The high visibility associated with these policy initiatives demands that the TCEQ do all it can to issue clear and concise guidelines that can be readily understood by all affected parties. As such, the current re-issuance of the odor guidance provides an excellent opportunity for the TCEQ to provide some critical background information that was omitted from the initial odor based ESL guidelines.[2] This additional guidance would help clarify the TCEQ's position on three critical issues that are recognized to be significant determinants of odor perception and awareness.

1. A more detailed explanation is needed of the four factors used to characterize odors and odorants: detectability, intensity, hedonic tone, and odor quality. This discussion should include a detailed examination of the importance of odor quality and odor character (i.e., pleasantness vs. unpleasantness), since this is generally considered to be the most important factor dictating whether an individual living in a community setting will respond unfavorably. Information concerning odorant properties will be of particular value to those who are unfamiliar with odor testing methodologies and the four factors used to describe an odor.

2. Odor perception, especially in regards to community odor concerns and complaints, has received a tremendous amount of attention by the scientific community. It is a particularly important consideration in those circumstances where there is a discrepancy between the concentration causing a nuisance complaint and any documented odor threshold values

[2] Guidelines to Develop Effect Screening Levels, Reference Values and Unit Risk Factors. Texas Commission on Environmental Quality, Chief Engineer's Office, Toxicology Section. RG-442. November, 2006. http://www.tceq.state.tx.us/files/rg-442.pdf_4452928.pdf

determined under controlled conditions.[3] Reviewing the recent findings on odor awareness and perception will help eliminate confusion and explain how discrepancies can develop and be resolved. Any such discussion should acknowledge TCEQ's understanding of the problem and demonstrate that there is a strong cognitive and emotional component to odor awareness. It is important that those affected by these guidelines recognize how attitudes and expectations can influence a claim of odor annoyance or odor acceptability.

3. The proposed guidelines fail to contain any descriptive details concerning the use of field olfactometry as an alternative method of making objective threshold determinations under actual ambient conditions. This technique could provide inspectors and plant operators with a very easy to use, cost effective, and well accepted approach for collecting odor intensity information under actual use conditions.[4] Field olfactometry has been in use for many years by State authorities throughout the U.S. . There are several standardized approaches for the use and application of a field olfactometer. Independent analysis has shown that odor threshold measurements by field olfactometry are in good agreement with the results obtained by the standardized dynamic olfactometry methods discussed in the proposed guidelines.[5] Field olfactometry can provide the TCEQ and manufacturing facilities with a convenient way of verifying the ESL_{odor} values developed using laboratory data. In addition, the threshold values collected under ambient conditions will help resolve disputes concerning odor detection in the field versus odor measurement in the laboratory.

III. More Descriptive Details Needed on the Four Designated Methods

The revised guidelines describe four standard approaches for obtaining an acceptable odor threshold value, but fail to provide the details needed to fully understand and appreciate how the methods compare and contrast. To improve their overall effectiveness, the proposed guidelines need to be expanded to include an analysis of the similarities, differences, and key operating principles governing the use of these idealized methods for collecting odor threshold information. The additional detail will aid sponsors wishing to conduct studies to improve the accuracy and upgrade the quality of existing odor threshold values. Similarly, the methodological details will help ensure that any new test data submitted by a sponsor to the TCEQ will conform to expectations and be readily adopted.

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[3] Sucker, Kristen, Both, Ralf, Bischoff, Michael, Guski, Rainer, and Winneke, Gerheard. Odor frequency and odor annoyance. Part I: assessment of frequency, intensity and hedonic tone of environmental odors in the field. International Archives for Occupational and Environmental Health 81:671-682, 2008.

[4] McGinley, Charles. Standardized odor measurement practices for air quality testing. Air and Waste Management Symposium on Air Quality Measurement Methods and Technology. November, 2002. http://www.fivesenses.com/ Documents/Library/ 38%20Standard%20Odor%20Measure%20for%20Air%20Qual.pdf

[5] McGinley, Michael and McGinley, Charles. Comparison of field olfactometers in a controlled chamber using hydrogen sulfide as the test odorant. International Water Association 2nd International Conference on Odour and VOCs. September, 2003. http://www.nasalranger.com/media/39%20Comparison%20of%20Field%20Olfactometers %20with%20H2S%20in%20Chamber.pdf

A description of key aspects is particularly important for two of the proposed methods, CEN 13725 and ASTM E679-04. These methods were intended as uniform standards in Europe and the United States, respectively, but did not necessarily achieve that status. Because these two methods are not identical, with significant differences in both the operation of the dynamic olfactometer and the magnitude of the vapor dilution steps, the guidelines need to be more explicit and categorically state what conditions are acceptable and unacceptable for a threshold test to be valid.[6] Without further detail and explanation, the guidelines for acceptable approaches may cause more confusion than they eliminate, simply because many of the publications are not freely available on the internet and are difficult to obtain in the United States.[7] Clear guidance is needed on this matter to facilitate the scientific community and interested stakeholders responding to TCEQ requests for technical information on chemicals undergoing ESL evaluation.

IV. The Criteria Used to Identify Acceptable Odor Threshold Data Should Incorporate Greater Flexibility

Additional latitude is needed in this selection and identification of acceptable test methods for odor threshold determination. The current proposed guidance does not provide sponsors, researchers, or testing laboratories with enough flexibility in their design of test protocols for odor threshold determination. Although the TCEQ has identified four standardized approaches for assessing an odor threshold, the approaches are highly region specific and tailored to the testing capabilities in specific parts of the world. Only one of the four methods was developed in the U.S., and this method has not been widely adopted.[8] The TCEQ should accept other available approaches for odor threshold determination. For instance, the methods proposed by the Air & Waste Management Association (AWMA) EE-6 subcommittee on odor, are a well established approach. [9] In fact, the AWMA method not only contains far more methodological detail than the ASTM method, but has been proffered as a substitute to the seldom used ASTM method.

The proposed guidelines fail to justify the use of some methodological standards in preference to others. For instance, the odor detection standard developed in the Netherlands has been issued in Dutch not English, so critical evaluation of the approach is impractical by most Americans. Likewise, the methodological approach developed, validated, and issued by the

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[6] McGinley, Charles. Standardized odor measurement practices for air quality testing. Air and Waste Management Symposium on Air Quality Measurement Methods and Technology. November, 2002. http://www.fivesenses.com/Documents/Library/38%20Standard%20Odor%20Measure%20for%20Air%20Qual.pdf

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

[8] Smeets, Monique, Bulsing, Patricia, van Rooden, Sanneke, Steinmann, Ranijita, de Ru, J. Alexander, Ogink, Nico, van Thriel, Christoph, and Dalton, Pamela. Odor and irritation thresholds for ammonia: A comparison between static and dynamic olfactometry. Chemical Senses, 32:11-20, 2007.

[9] Guidelines for Odor Sampling for Point, Area and Ambient Sources with Evaluation using the Dynamic Dilution Olfactometry. AWMA EE-6 Subcommittee on the Standardization of Odor Measurements. June, 2008. http://www.fivesenses.com/ee6/files/GuidelineDoc%20suggested%20Revision%20from%20Anna%20Bokowa%20-%20June2008.doc

governments of New Zealand and Australia are not mentioned, despite their use in many laboratories within these countries.[10] In fact, many researchers in the U.S., who routinely perform odor threshold determinations in conjunction with established lines of psychophysical research, do not strictly adhere to the procedures outlined in ASTM E679-04 or any of the other standards described in the proposed guideline.[11] Despite the slight deviations, these investigative approaches comply with the overall intent of the standardized approaches and yield perfectly acceptable odor threshold information.

Instead of issuing a list of acceptable approaches, the TCEQ should consider listing the essential criteria of a well conducted odor threshold determination. This type of generic guidance will eliminate the ambiguities that are found when different methods are compared, and help promote the collection of new test data. Generic guidance will also insure that all relevant studies are considered during ESL development, including those showing small, but insignificant, differences from the standardized approaches. By listing the essential components of a well conducted study, the TCEQ will encourage the development and use of rapid screening methods that are able to provide superior information on the chemicals where odor thresholds are either substandard or absent. Such methods have already been identified and their use by a greater number of testing laboratories needs to be encouraged.[12]

V. The Definition of an Odor Threshold Needs to be Modified

The TCEQ previously issued guidelines defining odor detection threshold as the concentration of a gas or vapor, "at which 50% of the volunteers participating in an odor panel detected the odor".[13] However, odor threshold values obtained using the proposed methods do not provide data that meets the TCEQ's definition. The odor thresholds determined using the proposed approaches do not measure an absolute threshold as defined by TCEQ guidelines. Instead, many of the proposed methods, especially those used outside the U.S., define odor threshold as the gas or vapor concentration that is detected on 50% of the test trials.

This difference in definition is important and can directly impact the magnitude of the odor threshold, as shown in a recent analysis performed by Dalton and Smeets.[14] A review of TCEQs original guidance on ESL_{odor} also noted this discrepancy in odor threshold definitions and pointed out that the TCEQ definition was inconsistent with the classical definition and the

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[10] Australian/New Zealand Standard Air Quality - Determination of odour concentration by dynamic olfactometry. AS4323.3 2001. http://www.cschi.cz/odour/files/world/An%20interlaboratory%20odour%20study%20US%20EPA%202003.pdf

[11] Dalton, Pamela. Personal Communication, July, 2009.

[12] Wise, Paul, Bien, Nancy, and Wysocki, Charles. Two Rapid Odor Threshold Methods Compared to a Modified Method of Constant Stimuli. Chemical Perception, 1:16-23, 2008.

[13] Guidelines to Develop Effect Screening Levels, Reference Values and Unit Risk Factors. Texas Commission on Environmental Quality, Chief Engineer's Office, Toxicology Section. RG-442. November, 2006. http://www.tceq.state.tx.us/files/rg-442.pdf_4452928.pdf

[14] Dalton, Pamela and Smeets, Monique. Olfactometry: the Human Nose as Detection Instrument. In Hedge A (Ed.). Handbook of Human Factors and Ergonomic Methods. 1st ed. CRC Press, 2004.

traditional means of calculating an odor threshold.[15] Again, most testing laboratories have defined an odor threshold as the concentration that an average person can detect half of the time, not as the concentration that can be detected by 50% of the population.

VI. Odors Detected by Field Investigators Need to be Evaluated in a More Objective Fashion

The proposed guidelines indicate that an acute ESL_{odor} value may be set at the lowest measured value if air monitoring staff or field investigators detect an odor at a concentration that is below the geometric mean from adequately collected and compiled threshold studies. We strongly urge the TCEQ to reconsider this policy and either eliminate or drastically modify the circumstances when field detection, without the use of standardized field olfactometry measures, supersedes studies performed under controlled test conditions. We believe that using subjective odor determinations in preference to values measured using the best standard of practice is an arbitrary and capricious policy that we cannot endorse. There are simply too many uncontrolled variables that can impact odor detection under these conditions.

As described earlier, most modern methods for assessing odor threshold are aimed at assessing the concentration that an average person can detect 50% of the time. It follows from this definition that a field investigator will be able to detect odors on half of his/her visits to a facility emitting a volatile chemical or gas at concentrations at or near the threshold value. If left in place, this policy of supplanting test data with field data undermines the whole purpose of the guidance, which is to establish solid reference values for odor threshold.

As an alternative, the TCEQ can issue strict guidelines describing the exact conditions that need to be in place for field data to supplant test data. This would necessarily include descriptions of odor quality, measurements using a field olfactometer, and the application of secondary dispersion modeling under actual climatic conditions to ensure proper source attribution. Sample collection and analysis in the laboratory should also be considered as a means of verifying the actual composition of any odors detected under field conditions. Once again, the position as outlined lacks scientific merit and suggests a systematic misunderstanding of the odor threshold concept and the laws of probability. We urge the TCEQ to reconsider the ramifications of this aspect of the proposed guidance.

[15] Cain, William. Comments on Review Draft. Report of the Peer Review Meeting on Development of Effects Screening Levels, Reference Values, and Unit Risk Factors for the Texas Commission on Environmental Quality (TCEQ). Appendices. October, 2005. http://www.tceq.state.tx.us/files/FinalAppendixes.pdf_4417399.pdf

VII. A New Approach is Needed When Examining Odor Threshold Values Determined Prior to 1990

The proposed guidelines for handling odor threshold data collected prior to 1990 can be dramatically improved. Instead of assuming that all studies performed prior to 1990 are necessarily defective and that the lowest threshold value from this era is the most accurate, the TCEQ can establish criteria of acceptability or institute a system that numerically adjusts the threshold values according to predefined weighting scheme. The system being proposed does not take advantage of the fact that although some older data may be potentially unfounded, there is an abundant amount of useful information that can be analyzed and used effectively if handled correctly. In fact, some experts believe that the only odor threshold values that are defective are those collected more than 50 years ago, and that less dated information can be utilized after an appropriate examination.[16] Likewise, there are many studies performed prior to 1990 that are perfectly well suited for establishing odor ESL. For example, all of the studies cited by Nagata, and used to justify the inclusion of the Japanese triangle odor bag method in the list of acceptable methods, were performed in the twelve year interval from 1976 to 1988.[17]

Rather than taking a one-dimensional approach, the TCEQ can develop a set of evaluation criteria to examine and compile older information. Factors such as data consistency, degree of variation from the geometric mean, adherence with the spirit and essential elements of current standards, analytical verification, appropriateness of the psychophysical methods, and other factors deemed important can all be used to rate, rank, and normalize the values from studies performed over twenty years ago.

Analysis and adjustment of imperfect odor threshold data is not a new concept. Devos and others have used such an approach to evaluate and normalize odor threshold values compiled from older, non-standardized, methods.[18] There is also an abundant amount of qualitative and quantitative structure activity information that can be incorporated into any decision making on the adequacy of older studies.[19] A comparison of measured values against other members of the chemical series can help determine their validity, as can the use of established quantitative structure activity relationships for the various chemical categories. Using a weight of evidence approach, the biases and imprecision of threshold studies from past eras can be effectively examined and accounted for in the ESL_{odor} development process.

VIII. Evergreen Provisions Need to be Incorporated into the Guidance

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[16] van Doorn, Reind, Ruijten, Marc and van Harreveld, Ton. Guidance for the Application of Odor in Chemical Emergency Response. Presented at the NAC/AEGL-Meeting September 2002. August, 2002.

[17] Nagata, Yoshio. Measurement of Odor Threshold by Triangle Odor Bag Method. Odor Measurement Review. Japan Ministry of the Environment, pp. 118-127, 2003. http://www.env.go.jp/en/air/odor/measure/02_3_2.pdf

[18] Devos M, Patte F, Rouault J, Laffort P, van Gemert LJ. Standardized human olfactory thresholds. Oxford: IRL Press; 1990.

[19] Cometto-Muñiz, J. Enrique and Abraham, Michael. Human olfactory detection of homologous *n*-alcohols measured via concentration–response functions. Pharmacology, Biochemistry and Behavior. 89:279-291, 2008.

To ensure their reliability, accuracy, and overall robustness, the guidelines need to be reexamined and updated at regular intervals. This will ensure that the most recent information has been identified, and relied upon by the TCEQ. Although general informational exchanges can be accomplished through routine updates to the guidelines, special remarks or critical changes in odor policy should take place without delay on an as needed basis. The TCEQ should commit to using the best possible science in assessing odors and odorants by incorporating specific language in the proposed guidelines concerning these types of information updates. This will assure all affected parties that the TCEQ is actively monitoring new developments and that any meaningful events affecting the measurement or analysis of odor threshold values will be conveyed.

IX. Conclusions

The SIG and TCC applauds the efforts of the TCEQ to improve how it assembles and analyzes existing odor threshold information into a more systematic and deliberate assessment of the odor detection threshold for individual substances. We believe, however, that more can be done to improve the science behind ESL_{odor} development. As discussed above, the guidelines should embrace a scientifically sound, consistent, and defensible approach that can be used by interested stakeholders.

In this regard, the TCEQ should focus on three topic areas where the proposed guidelines are believed to be seriously flawed. These include i) the use of an inappropriate odor threshold definition to describe what is being measured in most standardized tests; ii) the inappropriate use of anecdotal odor assessments by field investigators to supplant the data collected with a test panel under controlled conditions; and iii) a failure to use a standard weight of evidence approach to examine and evaluate the odor information collected using older, less standardized, techniques. Each of these three topic areas is considered to be a critical area of improvement for the proposed guidelines.

SIG and TCC remain committed to working with TCEQ on these issues and look forward to continued dialogue in this area. If you have any questions, please contact Leslie Berry at (703) 741-5612 or Leslie_Berry@americanchemistry.com or Mike McMullen at (512) 646-6404 or mmcmullen@txchemcouncil.org.

Sincerely,

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