

Peer Review TCEQ Guidelines for Developing Odor and Vegetative ESLs

Introduction

In 2006, the Toxicology Division (TD) of the Chief Engineer's Office released a technical guide (RG-442) used by the Texas Commission on Environmental Quality (TCEQ) to develop Effects Screening Levels (ESLs), inhalation Reference Values (ReVs), and inhalation Unit Risk Factors (URFs). Although this document was primarily written as guidance for the TCEQ staff, it also documented the processes used to develop ESLs, ReVs, and URFs for any interested person with training in inhalation toxicology and risk assessment. ESLs are chemical-specific air concentrations set to protect human health and welfare. Short-term ESLs are based on data concerning acute health effects, the potential for odors to be a nuisance, and effects on vegetation, while long-term ESLs are based on data concerning chronic health and vegetation effects. Welfare-based ESLs (odor and vegetation) are set based on effect threshold concentrations. Health-based ESLs, however, are calculated from ReV and URF toxicity factors. ReVs and URFs are based on the most sensitive adverse health effect relevant to humans. Derivation of a ReV or URF begins with a toxicity assessment involving hazard identification and dose-response assessment based on the chemical's mode of action. The resulting ReVs and URFs are then used to calculate ESLs that correspond to no significant risk levels.

The Texas Clean Air Act (Chapter 382 of the Texas Health and Safety Code (THSC)) specifically mandates the TCEQ to conduct air permit reviews of all new and modified facilities to ensure that the operation of a proposed facility will not cause or contribute to a condition of air pollution. Because of the comprehensiveness of the language in the THSC, the methods were developed so that ESLs could be derived for as many air contaminants as possible, even for chemicals with limited toxicity data.

Since 2006, new scientific developments in toxicology and risk assessment have resulted in changes to some risk assessment approaches, and the TD has derived some ReVs and ESLs through methods not specifically discussed in (but consistent with) the existing guidance (<http://www.tceq.texas.gov/toxicology/dsd/final.html>). As a result, the TD has prepared revised guidelines that will be entitled "Guidelines to Develop Inhalation and Oral Cancer and Non-Cancer Toxicity Factors." The Guidelines are presented in seven chapters. In Chapter 1, several fundamental topics are addressed including legal authority and regulatory use, consideration of cumulative risk, problem formulation, and public participation opportunities. Chapter 1 also provides an introduction to the different toxicity values and their use in calculating health-based inhalation ESLs, introduces and explains the use of Air Monitoring Comparison Values (AMCVs), and the use of toxicity factors in remediation projects. Chapter 2 describes how welfare-based ESLs are determined (i.e., odor- and vegetation-based values). Chapter 3 discusses common procedures used to develop both acute and chronic toxicity values for the inhalation routes and chronic toxicity factors for the oral routes of exposure. Chapter 4 addresses the procedures that are unique to the derivation of acute inhalation ReVs, and Chapter 5 addresses the procedures that are unique to the derivation of chronic toxicity factors. Chapter 6 provides

procedures for the treatment of chemical groups and mixtures and Chapter 7 discusses procedures for using epidemiology studies to develop toxicity factors.

General Guidance to Reviewers

Reviewers are asked to consider all aspects of the methodology and evaluate strengths and weaknesses of the methods based on the specific questions described below, keeping in mind that TCEQ may need to develop toxicity factors even when there may be a less-than-desirable level of data in a chemical's database. Where possible, try to put the strengths and weaknesses in perspective by indicating their relative magnitude. Reviewers are asked to avoid emphasizing minor technical details or making tutorial comments. Reviewers should identify scientific uncertainties and suggest ways to reduce or eliminate those uncertainties.

For the evaluation of welfare-based ESLs, the reviewers will mainly review Chapter 2. In particular, the reviewers are asked to focus on the significant revisions made since the 2006 document, including an expanded approach to developing odor-based ESLs and additional consideration of the differences between children and adults when assessing risk.

Vegetative Charge Questions

General Issues

1. Are the overall approaches outlined for developing vegetative ESLs adequate?
2. Are other available alternate approaches more appropriate?

Vegetation ESLs

1. Are the criteria for deciding whether or not to develop a vegetation ESL appropriate?
2. Is it appropriate to focus vegetation ESL development on plant species native to or grown in the state of Texas?
3. Is it appropriate to base the vegetative ESL on the LOEL in the most sensitive species as opposed to the NOAEL in the most sensitive species?
4. Is it appropriate to base the vegetative ESL on relatively moderate adverse effects plant damage as opposed to milder vegetative effects?
5. Are there other issues specific to developing vegetative ESLs that have not been adequately addressed in the document?

Odor Charge Questions

General Issues

1. Are the overall approaches outlined for developing acute odor ESLs (Figure 2-1) adequate?
2. Are other available alternate approaches more appropriate?

Odor ESLs

1. Have the definitions of the quality levels (Levels 1, 2, and 3) for odor threshold values been described correctly? Have these quality levels been appropriately used in the development of odor ESLs?
2. Is the use of the geometric mean of all equivalent odor threshold values (for Level 1 and Level 2 data) an appropriate approach for developing the odor ESLs?
3. The TCEQ has determined that if nuisance odors have actually been reported at concentrations lower than the geometric mean, then lowest odor threshold value will be used for the odor ESL. Is this decision appropriate?
4. Is it appropriate to adopt the acute odor ESL for longer exposure durations?
5. Is the process for developing generic odor ESLs in the absence of chemical-specific data appropriate (see Figure 2-4)?
 - a. Use of data on correlation between chain length and odor to generate odor ESL equations that will estimate an odor ESL in absence of good odor data (see Table 2-1).
 - b. For chemicals that are from groups with poor correlation between odor threshold and carbon chain length, the geometric mean of the OT50 of that group is used as the generic odor-based ESL (see Table 2-2).
6. Are there other issues specific to developing odor ESLs that have not been adequately addressed in the document?