

2009 Innovations Awards Program APPLICATION

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ID # (assigned by CSG): 09- S-29TX

Please provide the following information, adding space as necessary:

State: Texas

Assign Program Category (applicant): Natural Resources/Environmental Protection (Use list at end of application)

1. Program Name **TCEQ's Effects Screening Levels (ESLs)**
2. Administering Agency **Texas Commission on Environmental Quality**
3. Contact Person (Name and Title) **Michael Honeycutt, Ph.D., Director, Toxicology Division**
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8. Web site Address: **<http://www.tceq.state.tx.us/implementation/tox/esl/ESLMain.html>**
9. Please provide a two-sentence description of the program. **The TCEQ developed new scientific guidelines for deriving Effects Screening Levels (ESLs), which are safe levels of chemicals in air. The new ESL guidelines incorporate the latest scientific methods and models to ensure that ESLs meet the highest scientific standards.**
10. How long has this program been operational (month and year)? Note: the program must be between 9 months and 5 years old on March 2, 2009 to be considered. **Since November, 2006.**
11. Why was the program created? What problem[s] or issue[s] was it designed to address? **The TCEQ's old program for developing ESLs had been severely criticized in the news media and in the scientific literature. The TCEQ's new ESL program was designed to incorporate the latest scientific methods and models to address these concerns and ensure that new ESLs are of the highest scientific quality. The Toxicology Division finalized the new ESL guidelines in November 2006. ESLs are designed to address several important issues of public health significance. Unlike other state, federal, and international agency guidelines, the TCEQ's new ESL guidelines evaluate a chemical holistically - examining the potential to cause adverse short-term health effects, long-term adverse health effects, nuisance odor conditions, and effects on plants. Several areas in Texas are highly industrialized with numerous facilities in close proximity having air permits, and ESLs are used to set health-protective air permit emissions limits for air contaminants. Additionally, TCEQ collects ambient air monitoring data from the largest state monitoring network in the country, and also conducts extensive mobile air monitoring. ESLs are used to evaluate the vast amount of ambient air monitoring data that TCEQ collects from a health effects perspective. ESLs are also used in setting health-protective soil remediation cleanup levels. As previously mentioned, the new ESL guidelines incorporate the latest scientific methods, including two new methods for addressing the challenge of setting safe short-term air concentrations for chemicals with limited toxicity data which were the subject of a paper written by the Toxicology Division and published in a peer-reviewed journal.**

12. Describe the specific activities and operations of the program in chronological order.

In October 2003, the Toxicology Division began the process of documenting the new guidelines for deriving ESLs with particular emphasis on incorporating the latest, most up-to-date scientific methods and models. After developing the proposed ESL guidelines, they were posted on the TCEQ website for public comment, and then underwent an independent scientific peer review organized by Toxicology Excellence for Risk Assessment (TERA), an organization internationally-renowned for conducting peer reviews. Written comments received from the public were provided to the peer-review panel. TERA assembled a panel of eight independent distinguished experts from around the country who met in Austin in June 2005 to hear public comment on the proposed guidelines and discuss their analysis of the proposed ESL guidelines. In October 2005, TERA published the expert peer reviewers' findings, which were very positive overall, and the report on the peer review meeting is posted on their and TCEQ's websites. TCEQ ensured a transparent process with ample opportunity for input from the public, who provided comments both before and after revisions were made to the guidelines pursuant to peer reviewer comments. TCEQ revised the proposed ESL guidelines to respond to the peer reviewers' and public comments. The revised ESL guidelines were then posted on TCEQ's website for a second 30-day public comment period in June 2006. After addressing all scientific comments through appropriate revisions, the Toxicology Division finalized the new ESL guidelines in November 2006. The Toxicology Division uses the new ESL guidelines to develop ESLs for individual chemicals. Proposed new ESLs for individual chemicals undergo public comment and may also undergo external peer review. TCEQ's new ESL guidelines ensure that new ESLs meet the highest scientific standards.

13. Why is the program a new and creative approach or method? **The new ESL guidelines assess a chemical's toxicity holistically, evaluating the potential for short- and long-term health effects, odor, and plant effects, unlike other state, federal, and international agency guidelines. In addition to the new ESL Guidelines incorporating the latest scientific methods, the Toxicology Division developed two new methods for setting safe short-term air concentrations for chemicals with limited toxicity data. These creative new approaches for assessing short-term toxicity and deriving health-protective short-term air concentrations were the subject of a scientific paper written by Toxicology Division staff entitled, *Evaluation of Acute Inhalation Toxicity for Chemicals with Limited Toxicity Information*, which was published in a prestigious peer-reviewed journal (Regulatory Toxicology and Pharmacology). Other environmental organizations are now beginning to use our ESLs and the methods we developed during the process.**

14. What were the program's start-up costs? (Provide details about specific purchases for this program, staffing needs and other financial expenditures, as well as existing materials, technology and staff already in place.) **The external scientific peer review for the ESL guidelines cost approximately \$90,000. The Toxicology Division's fourteen highly-trained toxicologists are the primary staffing resource needed for the ESL program, and use USEPA's Benchmark Dose Modeling software and other computer programs/software (e.g., BEIR IV excess cancer risk spreadsheets, interspecies dosimetric software). Significant funding also had to be made available for obtaining numerous scientific articles and external expert peer review of highly technical and complex ESL derivations if necessary.**

15. What are the program's annual operational costs? **Approximately \$75,000 to \$150,000 per year, depending on the number of chemicals requiring external scientific peer review or advanced toxicological analyses.**

16. How is the program funded? **Appropriations from the state legislature.**

17. Did this program require the passage of legislation, executive order or regulations? If YES, please indicate the citation number. **No**

18. What equipment, technology and software are used to operate and administer this program? **Various computer programs including USEPA's Benchmark Dose Modeling software, interspecies dosimetric software (e.g., USEPA's Regional Deposited Dose Ratio model, CIIT's Multiple Pass**

Particle Dosimetry model), and specialized spreadsheets created by contractors (e.g., BEIR IV excess cancer risk and multiplicative relative risk model spreadsheets).

19. To the best of your knowledge, did this program originate in your state? If YES, please indicate the innovator's name, present address, telephone number and e-mail address. **Yes. Michael Honeycutt, Ph.D., TCEQ, PO Box 13087 MC-168, Austin, TX, 78711-3087**

20. Are you aware of similar programs in other states? If YES, which ones and how does this program differ? **California has a similar program, but Texas' ESLs also evaluate odor potential and effects on plants. California's doesn't.**

21. Has the program been fully implemented? If NO, what actions remain to be taken? **Yes**
Briefly evaluate (pro and con) the program's effectiveness in addressing the defined problem[s] or issue[s]. Provide tangible examples. **The new ESL program has been fully implemented and the Toxicology Division has been using the new ESL guidelines to develop chemical-specific ESLs. TCEQ's new ESL program has effectively addressed the criticisms and ensures that new ESLs meet the highest scientific standards. To date, new ESLs for 24 individual chemicals or mixtures have been finalized, including several of significant public health importance (e.g., benzene, 1,3-butadiene, formaldehyde), and the Toxicology Division is continuously developing new ESLs under the guidelines. TCEQ's new ESLs are of the highest scientific quality and have been well received in the scientific and regulatory communities. For example, in November 2008, the Canada Ministry of the Environment published a "Science Discussion Document on the Development of an Air Standard for 1,3-Butadiene." In that document, the Canada Ministry of the Environment deemed the 1,3-butadiene assessment recently published by the TCEQ in August 2008 as the most current, scientifically-sound assessment after reviewing chemical assessments from Health Canada and Environment Canada, the Province of Quebec, the USEPA, the Swedish Institute of Environmental Medicine, the United Kingdom, the World Health Organization, and the States of California, Louisiana, Massachusetts, Michigan, Minnesota, New Jersey, New York, North Carolina, Ohio, and Texas. Other countries that are using TCEQ's ESLs include: Australia, Austria, Israel, Belgium, Canada, Mexico, Taiwan, and the Netherlands.**

22. How has the program grown and/or changed since its inception? **Based on valuable experience gained in implementing the ESL program and deriving new ESLs, the Toxicology Division is considering even further improvements of the program and additional elaboration and clarification on existing procedures and methodologies contained in the new ESL guidelines. The Toxicology will implement these improvements in the next two to three years.**

What limitations or obstacles might other states expect to encounter if they attempt to adopt this program? **Expert scientific/technical staff are required for implementation of the program. The Toxicology Division employs fourteen highly-trained toxicologists to implement the ESL program.**