Sunset Management Recommendation 1.2: Commission Vote on Acceptable Level of Health-Based Risk

# Background

The Sunset Advisory Commission Staff <u>Report</u> with Commission Decisions on the Texas Commission on Environmental Quality (TCEQ) (2022-23, 88th Legislature) contains the Sunset Advisory Commission's statutory recommendations to the Legislature and management recommendations for TCEQ to implement. Management Recommendation 1.2 from the report states "[d]irect TCEQ's commission to vote in a public meeting on the acceptable level of healthbased risk used in the development of toxicity factors for permitting and other regulatory actions." The referenced "acceptable level of health-based risk" is interpreted to mean the acceptable individual-chemical excess cancer risk, or target risk level, used in permitting and other regulatory actions.

# Target Risk Levels and the Development of Toxicity Factors

Target risk levels (TRLs) represent levels of chemicals that are considered to confer no significant risk from long-term exposure. TRLs are set by policy makers and risk managers as a necessary step in the process of developing cleanup levels, screening levels, and acceptable chemical concentrations in air or other media using a risk-based decision-making process. Based on this risk level, the risk assessor can then establish the corresponding long-term, health-protective concentration of a chemical in a given environmental media (e.g., air, soil, water).

TRLs apply specifically to cancer risk because many carcinogens are considered to cause some risk at any exposure concentration higher than zero. TRLs describe cancer risk numerically as a probability, such as one extra cancer case for every 100,000 similarly exposed persons, which is also expressed as  $1 \times 10^{-5}$ . A risk estimate of  $1 \times 10^{-5}$  means that 1 additional case of cancer (above the background population cancer rate) might occur among 100,000 exposed persons because of a given (typically lifetime) chronic exposure to a chemical.

Establishing TRLs requires consideration of risk/benefit tradeoffs. Setting an excess risk level that is too high (as judged based on relevant considerations) can result in under-protection that leaves too many at an appreciable risk of an adverse health effect, albeit perhaps still at a relatively low risk probability. For example, an excess cancer risk of 1 in 1,000 is relatively low compared to background cancer risk of approximately 330 in 1,000 (or 1 in 3). By contrast, setting an acceptable excess risk level that is very low (relatively speaking) can result in little health benefit in terms of risk reduction but may be associated with substantial costs. For example, reducing levels of a carcinogen in soil at a remediation site, or in ambient air in a particular area, to a 1 in 1,000,000 ( $1 \times 10^6$ ) excess risk level (if even possible due to background concentrations) will likely cost significantly more compared to reducing carcinogen levels to a 1 in 100,000 ( $1 \times 10^6$ ) risk level, but would not significantly reduce the total lifetime cancer risk for exposed individuals. For example, since background lifetime cancer risk is around 330,000 in 1,000,000, switching from a TRL of 1 in 100,000 to 1 in 1,000,000, a reduction of only 0.0009% in total lifetime risk.

The TCEQ *Guidelines for Developing Toxicity Factors* (RG-442) uses a 1 in 100,000 (1 x 10<sup>-5</sup>) excess cancer risk. This excess risk level is then used to establish the concentration (i.e., dose) of a chemical that is considered acceptable in environmental media, such as the long-term concentration in ambient air. Although that cancer risk level was informally discussed with and approved by individual TCEQ Commissioners at the time that the *Guidelines* were first written (2006-2007), they were not officially approved and voted on by the Commissioners. Therefore, a proposal to set a TRL of 1 in 100,000 for use in setting screening levels for the TCEQ air

permitting program and for comparing to ambient air monitoring data will be sent to the Commission for their approval at a Commission open meeting.

## **Relevant Considerations for Setting a TRL**

The TCEQ takes its responsibility to protect public health very seriously, which is a primary consideration in selecting a TRL. Within that context, there are several other important relevant considerations. The United States Environmental Protection Agency (EPA) set an acceptable lifetime excess cancer risk range of  $1 \times 10^{-6}$  to  $1 \times 10^{-4}$  in the National Contingency Plan (NCP; 40 CFR Section 300.430); that is, 1 in 1,000,000 to 1 in 10,000 (EPA 1990). Texas has consistently set a TRL of  $1 \times 10^{-5}$ , using it for the air program (as noted above), for the Texas Risk Reduction Program (TRRP) rule for site remediation, and for the Texas Surface Water Quality Standards (30 TAC Chapter 307). Consistency within and across agency programs and/or rules helps provide clarity and avoid continuous debate with external parties about what level of excess risk should be considered acceptable (e.g., for each chemical in an environmental medium). Used in conjunction with a chemical's toxicity factor (e.g., inhalation unit risk factor) to calculate a health-protective media concentration (e.g., in ambient air), the TRL of 1 in 100,000 (1 x 10<sup>-5</sup>):

- Represents the logarithmic center of EPA's acceptable excess risk range.
- Accounts for potential exposure to multiple carcinogens while remaining below the upper end of EPA's acceptable risk range (1 in 10,000 or 1 x 10<sup>-4</sup>);
- Allows for action for pollutants monitored by the TCEQ that exceed the TRL (e.g., under the Air Pollutant Watch List to reduce emissions in the area) well before reaching the upper end of EPA's acceptable risk range (e.g., in terms of concentration and duration); and
- Insignificantly contributes to an individual's lifetime cancer risk (e.g., increases total risk from approximately 33,000 in 100,000 to 33,001 in 100,000, a *de minimis* increase of 0.001%).

These considerations support the conclusion that a TRL of 1 in 100,000 ( $1 \times 10^{-5}$ ) is reasonable from a regulatory perspective and is protective of human health as a matter of TCEQ policy for use in agency programs, rules, and guidance.

## Proposal

The TCEQ Executive Director proposes to set a target cancer risk level of 1 in 100,000 (1 x 10<sup>-5</sup>) for setting screening levels that are used in TCEQ's air permitting program and compared to ambient air monitoring data. This proposal is being directed to the Commission with the recommended action of posting for 30 days of public comment. After considering the comments, the Executive Director plans to appear again to request adoption of a final policy.

## How To Submit Comments:

e-mail: tox@tceq.texas.gov or mail (must be received at the TCEQ no later than 10/3/2023) to:

## **Regular mail:**

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

### Mail delivery services:

Toxicology Division, MC 168 Texas Commission on Environmental Quality 12100 Park 35 Circle, Bldg. F Austin, TX 78753