# Procedures for Evaluating Inhalation Risks

## Discussion Questions

The Environmental Protection Agency has published updated procedures for inhalation risk assessments.

- Does the new EPA guidance provide a solid scientific foundation for evaluating revisions to the MTCA rule? In other words, are these procedures consistent with current scientific information?
- Is there additional scientific information and regulatory guidance on this issue that Ecology should consider during the rulemaking process?

## Background Information

The Model Toxics Control Act (MTCA) Cleanup Regulation includes policies and procedures for establishing cleanup levels based on inhalation exposure (WAC 173-340-750). These procedures were developed in 1990 and are based on the methodologies included in the *Risk Assessment Guidance for Superfund (RAGS) Part A*[1] (referred to as Part A). The current MTCA equation for air cleanup levels based on carcinogenic effects is summarized in Figure 1 below. The MTCA rule includes similar procedures for calculating air cleanup levels based on non-cancer effects.

EPA published revisions to the Superfund procedures for evaluating health risks resulting from inhalation exposure in early 2009. The updated guidance (*Risk Assessment Guidance for Superfund: Volume I: Human Health Evaluation Manual (Part F, Supplemental Guidance for Inhalation Risk Assessment)*[2]) is attached to this review (See Attachment 1). Part F is designed to promote consistent implementation of EPA's procedures for assessing inhalation risks[3]. Key differences between the MTCA rule and the updated EPA guidance include the following:

- EPA recommends that risk assessors use the air concentration of a chemical as the exposure metric (e.g., ug/m$^3$) when evaluating inhalation risks. This differs from RAGS Part A and MTCA equations that use intake (mg/kg-d) as the exposure metric.
- EPA recommends that risk assessors not use inhalation toxicity values generated using simple route-to-route extrapolation.

Ecology is currently considering potential revisions to the MTCA cleanup rule. As part of that process, Ecology is evaluating whether and how to update the rule based on recent EPA guidance materials. There appear to be several relatively straight-forward changes to the MTCA rule that are based on the Part F procedures. One option is shown in Figure 2.

[1] EPA. 1989. Risk Assessment Guidance for Superfund. Volume I. Part A. Office of Emergency and Remedial Response, Washington D.C. EPA-540/1-89/-002.
[2] EPA. 2009. Risk Assessment Guidance for Superfund. Volume I: Part F, Supplemental Guidance for Inhalation Risk Assessment. Office of Superfund Remediation & Tech. Innovation. Washington D.C. EPA-540-R-070-002.
[3] EPA. 1994. Methods for Derivation of Inhalation Reference Concentrations and Application of Inhalation Dosimetry

Figure 1 – Current MTCA Equation for Air Cleanup Levels Based on Carcinogenic Risks[4]

$$\text{Air cleanup level (ug/m}^3\text{)} = \frac{\text{RISK x ABW x AT x UCF}}{\text{CPF x BR x ABS x ED x EF}}$$

Where

| | | |
|---|---|---|
| RISK | = | Acceptable cancer risk level (1 in 1,000,000) (unitless) |
| ABW | = | Average body weight over the exposure duration (70 kg) |
| AT | = | Averaging time (75 years) |
| UCF | = | Unit conversion factor (1,000 ug/mg) |
| CPF | = | Carcinogenic potency factor[5] as specified in WAC 173-340-708(8) (kg-day/mg). Ecology generally uses toxicity values for published in the Integrated Risk Information System (IRIS) database.[6] WAC 173-340-708(8) includes procedures for calculating CPF values when such values are not available in the IRIS database.[7] |
| BR | = | Breathing rate (20 $m^3$/day) |
| ABS | = | Inhalation absorption fraction (1.0) (unitless) |
| ED | = | Exposure duration (30 years) |
| EF | = | Exposure frequency (1.0) (unitless) |

**Figure 2**

**Example to Illustrate Possible Revision Based on EPA Inhalation Risk Guidance**

$$\text{Air cleanup level (ug/m}^3\text{)} = \frac{\text{RISK x AT}}{\text{IuR x ED x EF x ET}}$$

Where:

| | | |
|---|---|---|
| RISK | = | Acceptable cancer risk level (1 in 1,000,000) (unitless) |
| AT | = | Averaging time (70 years) |
| IuR | = | Inhalation unit risk factor as specified in WAC 173-340-708(8) (ug/$mg^3$) |
| ED | = | Exposure duration (30 years) |
| EF | = | Exposure frequency (1.0) (unitless) |
| ET | = | Exposure time (1.0) (unitless) |

[4] WAC 173-340-750 includes a similar equation for calculating air cleanup levels based on non-cancer health effects.

[5] **"Carcinogenic potency factor"** or **"CPF"** means the upper 95th percentile confidence limit of the slope of the dose-response curve and is expressed in units of (mg/kg-day)-1. When derived from human epidemiological data, the carcinogenic potency factor may be a maximum likelihood estimate. (WAC 173-340-200)

[6] EPA's methods for developing inhalation reference concentrations are described in *Methods for Derivation of Inhalation Reference Concentrations and Application of Inhalation Dosimetry* (EPA, 1994). Part F was prepared to facilitate implementation of the 1994 guidance materials at Superfund sites.

[7] The rule notes the complexity in calculating inhalation toxicity values: "…[t]he procedure to derive a human equivalent concentration of inhaled particles and gases shall take into account, where available, the respiratory deposition and absorption characteristics of the gases and inhaled particles. Where adequate pharmacokinetic and metabolism studies are available, data from these studies may be used to adjust the interspecies scaling factor."