REGULATION 5.20 Methodology for Determining the Benchmark Ambient Concentration of a Toxic Air Contaminant

Louisville Metro Air Pollution Control District Jefferson County, Kentucky
Pursuant To: KRS Chapter 77 Air Pollution Control
Relates To: KRS Chapter 77 Air Pollution Control
Necessity and Function: KRS 77.180 authorizes the Air Pollution Control Board to adopt and enforce all orders, rules, and regulations necessary or proper to accomplish the purposes of KRS Chapter 77. This regulation establishes the methodology for determining the benchmark ambient concentration of a toxic air contaminant.

SECTION 1 Use of Benchmark Ambient Concentration

A benchmark ambient concentration (BAC) of a toxic air contaminant (TAC) developed pursuant to this regulation shall be used to determine compliance with the environmental acceptability goals established in Regulation 5.21.

SECTION 2 Determination that a TAC is a Carcinogen

2.1 A TAC shall be determined to be a carcinogen for purposes of determining the BACc if:

2.1.1 A carcinogenic unit risk estimate (URE) or a concentration representing a specific level of additional lifetime cancer risk for the TAC is listed by a source in sections 3.3.1 to 3.3.3,

2.1.2 The TAC is designated as “known to be a human carcinogen” or “reasonably anticipated to be a human carcinogen” in the most recent *Report on Carcinogens* published by the National Toxicology Program (NTP),

2.1.3 The TAC is designated as a Group 1 (carcinogenic to humans), Group 2A (probably carcinogenic to humans), or Group 2B (possibly carcinogenic to humans) agent or mixture by the International Agency for Research on Cancer (IARC),

2.1.4 The TAC is designated as a carcinogen by the Agency for Toxic Substances and Disease Registry (ATSDR), or

2.1.5 After providing an opportunity for public review and comment, the District determines that the TAC should be considered to be a carcinogen for purposes of determining the BAC_C because:

2.1.5.1 The TAC is "known to be a human carcinogen": There is sufficient peer-reviewed evidence of carcinogenicity from studies in humans indicating a causal relationship between exposure to the TAC and human cancer,

2.1.5.2 The TAC is "reasonably anticipated to be a human carcinogen": There is limited peer-reviewed evidence of carcinogenicity from studies in humans indicating a causal relationship between exposure to the TAC and human cancer, but alternative explanations, such as chance, bias, or confounding factors, could not adequately be excluded,

2.1.5.3 There is sufficient peer-reviewed evidence of the TAC's carcinogenicity from studies in experimental animals indicating an increased incidence of malignant or a combination of malignant and benign tumors: (1) in multiple species, (2) at multiple tissue sites, (3) by multiple routes of exposure, or (4) to an unusual degree with regard to incidence, site, or type of tumor, or age at onset, or

2.1.5.4 There is less than sufficient peer-reviewed evidence of the TAC's carcinogenicity in humans or laboratory animals, but:

2.1.5.4.1 The TAC belongs to a well-defined, structurally-related class of substances whose members are listed in the most recent *Report on Carcinogens* published by the NTP as known or reasonably anticipated to be a human carcinogen, or

2.1.5.4.2 There is convincing relevant information that the agent acts through mechanisms indicating it would likely cause cancer in humans.

2.2 In making a determination pursuant to section 2.1.5:

2.2.1 Conclusions regarding carcinogenicity in humans or experimental animals shall be based on relevant peer-reviewed scientific evidence, including dose response, route of exposure, chemical structure, metabolism, pharmacokinetics, sensitive subpopulations, genetic effects, and other data relating to mechanism of action or factors that may be unique to a given substance.

2.2.2 For a TAC to be determined to be a known human carcinogen, evidence from peer-reviewed studies of humans is required. This may include traditional cancer epidemiology studies, data from clinical studies, or data derived from the study of tissues from humans exposed to the TAC and useful for evaluating whether a relevant cancer mechanism is operating in humans.

2.3 Notwithstanding any provision of section 2.1, the Board may determine, through rulemaking pursuant to Regulation 1.08, that a TAC is not a carcinogen for the purpose of determining the BACc.

2.3.1 In making a determination pursuant to section 2.3, the Board shall rely upon a determination by one of the sources listed in sections 2.1 or 3.3 that a TAC is not a carcinogen for purposes of determining the BACc under the STAR Program. This provision does not limit the Board's statutory authority under KRS Chapter 77 to grant a variance.

2.3.2 In making a determination pursuant to section 2.3, conclusions regarding carcinogenicity in humans or experimental animals shall be based on relevant peer-reviewed scientific evidence, including dose response, route of exposure, chemical structure, metabolism, pharmokinetics, sensitive sub populations, genetic effects, and other data relating to mechanism of action or factors that may be unique to a given substance, traditional cancer epidemiology studies, data from clinical studies, or data derived from the study of tissues exposed to the TAC.

2.4 Any person may petition the Board pursuant to section 2.3 to make a determination that a TAC is not a carcinogen for the purpose of determining the BAC_C. The petition shall include a statement of the reasons why the TAC should not be treated as a carcinogen for the purpose of determining the BAC_C.

2.5 In making a determination pursuant to section 2.3, the Board shall revise this regulation and list any TAC determined not to be a carcinogen in this section.

2.5.1 Ethyl Acrylate (January 18, 2012).

SECTION 3 Determination of the BACc

3.1 The benchmark ambient concentration for a TAC determined to be a carcinogen (the BAC_C shall be calculated as follows:

$$BAC_C = \frac{1 \times 10^{-6}}{URE}$$

Where:

BAC_C = a concentration representative of an additional lifetime cancer risk of 1 in 1,000,000 ($1 \otimes 10^{-6}$), in units of micrograms per cubic meter ($\mu g/m^3$),

URE = the upper-bound excess lifetime cancer risk estimated to result from continuous exposure to an agent at a concentration of 1 $\mu g/m^3$ in air, in units of $(\mu g/m^3)^{-1}$. The URE shall be determined according to the methodology in section 3.3, and

$1x10^{-6}$ = An upper bound additional lifetime cancer risk of 1 in 1,000,000.

3.2 If a source in sections 3.3.1 to 3.3.3 lists a concentration of a carcinogen, expressed in $\mu g/m^3$, as representative of an additional lifetime cancer risk of $1x10^{-6}$, that concentration may be used as the BAC_C.

3.3 A URE or a BAC_C directly shall be derived as follows :

3.3.1 If a URE for the TAC is included in the EPA's Integrated Risk Information System (IRIS) that URE shall be used to determine the BAC_C.

3.3.2 If a URE for a TAC has not been derived pursuant to section 3.3.1 but a URE for that TAC has been developed by the California Office of Environmental Health Hazard Assessment, that URE, found in the column "Inhalation Unit Risk $(\mu g/m^3)^{-1}$", shall be used to determine the BAC_C.

3.3.3 If a URE for a TAC has not been derived pursuant to section 3.3.1 or 3.3.2 but an Initial Risk Screening Level (IRSL) for that TAC has been developed by the Michigan Air Quality Division, that IRSL shall be used as the BAC_C.

3.3.4 If a URE, or a BAC_C directly, has not been derived pursuant to sections 3.3.1 to 3.3.3, the URE may be derived using:

3.3.4.1 The methodology in EPA's *Guidelines for Carcinogen Risk Assessment* (March 2005), and *Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens* (March 2005);

3.3.4.2 The methodology in EPA's *Air Toxics Risk Assessment Reference Library, Volume 1, Technical Resource Manual, Chapter 12 Inhalation Toxicity Assessment*, (April 2004);

3.3.4.3 The methodology in EPA's *Guidelines for Carcinogen Risk Assessment*, Review Draft (July 1999);

3.3.4.4 The methodology in EPA's *Guidelines for Carcinogen Risk Assessment*, 51 Fed. Reg. 33992-34003 (September 24, 1986);

3.3.4.5 The methodology in *R 336.1231 Cancer Risk Assessment Screening Methodology (2) (b) and (3)* of the *Michigan Administrative Code*; or

3.3.4.6 An alternative cancer risk assessment methodology that can be demonstrated to the District to be more appropriate based on biological grounds and that is supported by peer-reviewed scientific data.

3.3.5 If a URE for a TAC has not been derived pursuant to sections 3.3.1 to 3.3.4, the BAC_C shall be the default value 0.0004 $\mu g/m^3$.

3.4 An annual average time period shall be used to determine a BAC_C.

SECTION 4 Determination of the BAC_{NC}

The benchmark ambient concentration for the noncarcinogenic effects of a TAC (the BAC_{NC}) is the concentration that is likely to be without an appreciable risk of deleterious effects during a lifetime. The BACnc shall be determined as follows:

4.1 If a Reference Concentration (RfC) for a TAC has been developed by the EPA and included in IRIS, that RfC shall be used as the BAC_{NC}, in units of $\mu g/m^3$.

4.1.1 An annual average time period shall be used to determine the BAC_{NC} pursuant to this section.

4.2 If a BAC_{NC} for a TAC has not been determined pursuant to section 4.1 but a Reference Exposure Level (REL) has been developed by the California Office of Environmental Health Hazard Assessment, that REL, expressed in units of $\mu g/m^3$, shall be used as the $BAC_{NC.}$

4.2.1 An annual average time period shall be used to determine the BAC_{NC} pursuant to this section.

4.3 If a BAC_{NC} for a TAC has not been determined pursuant to section 4.1 or 4.2, but an Oral Reference Dose (RfD) for that TAC has been developed by EPA and included in IRIS, that RfD shall be used to calculate the BAC_{NC} as follows:

$$BAC_{NC} = Oral\ RfD \times \frac{70\ kg}{20\ \frac{m^3}{day}}$$

Where:

BAC_{NC}= Benchmark Ambient Concentration for the noncarcinogenic effects of a TAC, in units of $\mu g/m^3$,

RfD = Oral Reference Dose, in units of µg/kg-day,

70 kg = The average body weight of a human, and

20 m^3/day = The average daily inhalation rate for a human.

4.3.1 An annual average time period shall be used to determine the BAC_{NC} pursuant to this section.

4.4 If a BAC_{NC} for a TAC has not been determined pursuant to sections 4.1 to 4.3 but an Initial Threshold Screening Level (ITSL) for that TAC has been developed by the Michigan Air Quality Division, that ITSL, expressed in units of $\mu g/m^3$ shall be the $BAC_{NC.}$.

4.4.1 The average time period listed for a specific ITSL shall be used to determine the BAC_{NC} pursuant to this section.

4.5 If a BAC_{NC} for a TAC has not been determined pursuant to sections 4.1 to 4.4 but an occupational exposure level (OEL) exists for that TAC, the OEL may be used to calculate the BAC_{NC} as follows:

$$BAC_{NC} = \frac{OEL}{100}$$

Where:

BAC_{NC}= Benchmark Ambient Concentration for the noncarcinogenic effects of a TAC, in units of $\mu g/m^3$,

OEL = Occupational Exposure Level, that, for the TAC, is the lowest value of either the National Institute of Occupational Safety and Health (NIOSH)-recommended exposure level listed in the current edition of the NIOSH pocket guide to chemical hazards or the time-weighted average Threshold Limit Value listed in the current edition of the American Conference of Governmental and Industrial Hygienists Threshold Limit Value booklet, in units of $\mu g/m^3$, and

100 = A composite safety factor to account for differences in susceptibility between the healthy, adult worker population compared to the general population that is more diverse and may contain individuals or

subpopulations more sensitive to the effects of the toxic air pollutant (safety factor of 10). Additionally, the composite safety factor accounts for the difference in exposure duration (in hours per week and years working versus a lifetime) for the worker population compared to the general population:

$$\frac{1}{10} \times \frac{40\ hours/week}{168\ hours/week} \times \frac{30\ years}{70\ years} \approx \frac{1}{100}$$

4.5.1 An 8-hour average time period shall be used to determine the BAC_{NC} pursuant to this section based upon a time-weighted OEL.

4.6 If a BAC_{NC} for a TAC has not been determined pursuant to sections 4.1 to 4.5 but a 7-day, inhalation, no observed adverse effect level (NOAEL) or lowest observable adverse effect level (LOAEL) is available for that TAC, the NOAEL or LOAEL may be used to calculate the BAC_{NC} as follows:

$$BAC_{NC} = \frac{NOAEL}{35 \times 100} \times \frac{Hr\ Exposed/Day}{24\ Hr/Day}$$

$$BAC_{NC} = \frac{LOAEL}{35 \times 100 \times UF} \times \frac{Hr\ Exposed/Day}{24\ Hr/Day}$$

Where:

BAC_{NC} = Benchmark Ambient Concentration for the noncarcinogenic effects of a TAC, in units of $\mu g/m^3$,

NOAEL = No observed adverse effect level (inhalation study), in units of $\mu g/m^3$,

LOAEL = Lowest observed adverse effect level (inhalation study), in units of $\mu g/m^3$,

35 = A safety factor to account for using a NOAEL or LOAEL from a 7-day exposure period to estimate a NOAEL or LOAEL for a lifetime study,

100 = A standard composite safety factor comprised of a safety factor of 10 to account for differences between animals and humans and a safety factor of 10 to account for the differences between individuals in the human population, and

UF = Uncertainty Factor, a value from 1 to 10, applicable when using a LOAEL (lowest effect) instead of a NOAEL (no effect), determined by the District on a case-by-case basis, considering the type and severity of effect. For example, a value of 1 would be used when the lowest effect was a skin rash; a value of 10 would be used when the lowest effect was death.

4.6.1 If approved by the District, the BAC_{NC} may be determined on a case-by-case basis using a NOAEL or LOAEL from repeated dose studies other than 7-day studies. An annual average time period shall be used to determine the BAC_{NC} pursuant to this section.

4.7 If a BAC_{NC} for a TAC has not been determined pursuant to sections 4.1 to 4.6 but a 7-day oral NOAEL or oral LOAEL is available for that TAC, the oral NOAEL or oral LOAEL

may be used to calculate the BAC_{NC} as follows:

$$BAC_{NC} = \frac{Oral\ NOAEL}{35 \times 100} \times \frac{W_A}{I_A} \times \frac{b}{a}$$

$$BAC_{NC} = \frac{Oral\ LOAEL}{35 \times 100 \times UF} \times \frac{W_A}{I_A} \times \frac{b}{a}$$

Where:

BAC_{NC}	=	Benchmark Ambient Concentration for the noncarcinogenic effects of a TAC, in units of μg/m^3,
NOAEL	=	No observed adverse effect level (oral study), in units of μg/kg-day,
LOAEL	=	Lowest observed adverse effect level (oral study), in units of μg/kg-day,
35	=	A safety factor to account for using a NOAEL or LOAEL from a 7-day exposure period to estimate a NOAEL or LOAEL for a lifetime study,
100	=	A standard composite safety factor comprised of a safety factor of 10 to account for differences between animals and humans and a safety factor of 10 to account for the differences between individuals in the human population,
UF	=	Uncertainty Factor, a value from 1 to 10, applicable when using a LOAEL (lowest effect) instead of a NOAEL (no effect), determined by the District on a case-by-case basis, considering the type and severity of effect. For example, a value of 1 would be used when the lowest effect was a skin rash; a value of 10 would be used when the lowest effect was death,
W_A	=	Body weight of experimental animal in kilograms (kg),
I_A	=	Daily inhalation rate of experimental animal in m^3/day,
b	=	Absorption efficiency (percent absorbed) by the oral route of exposure, and
a	=	Absorption efficiency (percent absorbed) by the inhalation route of exposure.

4.7.1 If approved by the District, the BAC_{NC} may be determined on a case-by-case basis using an oral NOAEL or oral LOAEL from repeated dose studies other than 7-day studies. An annual average time period shall be used for the BAC_{NC} determined pursuant to this section.

4.8 If a BAC_{NC} for a TAC has not been determined pursuant to sections 4.1 to 4.7 but an inhalation LC_{50} from a study that is 4 or more hours in duration is available for that TAC, the LC_{50} may be used to calculate the BAC_{NC} as follows:

$$BAC_{NC} = \frac{LC_{50}}{500 \times 100}$$

Where:

BAC_{NC} = Benchmark Ambient Concentration for the noncarcinogenic effects of a TAC, in units of μg/m^3,

LC_{50} = Concentration of material used in an inhalation study that causes death of 50% of the group of test animals when administered as a single dose in a specific time period, in units of μg/m^3,

500 = A factor to account for using an LC_{50} to estimate a no observed adverse effect level (NOAEL) for a lifetime study, and

100 = A standard composite safety factor comprised of a safety factor of 10 to account for differences between animals and humans and a safety factor of 10 to account for the differences between individuals in the human population.

4.8.1 An annual average time period shall be used to determine the BAC_{NC} pursuant to this section.

4.9 If a BAC_{NC} for a TAC has not been determined pursuant to sections 4.1 to 4.8 but an LC_{50} from a 1-hour inhalation study is available for that TAC, the 1-hour LC_{50} may be used to calculate the BAC_{NC} as follows:

$$BAC_{NC} = \frac{(1 - HR)LC_{50}}{500 \times 100 \times 40}$$

Where:

BAC_{NC} = Benchmark Ambient Concentration for the noncarcinogenic effects of a TAC, in units of μg/m^3,

LC_{50} = Concentration of material used in an inhalation study that causes death of 50% of the group of test animals when administered as a single dose in a specific time period, in units of μg/m^3,

500 = A factor to account for using an LC_{50} to estimate a no observed adverse effect level (NOAEL) for a lifetime study,

100 = A standard composite safety factor comprised of a safety factor of 10 to account for differences between animals and humans and a safety factor of 10 to account for the differences between individuals in the human population, and

40 = A safety factor to account for the uncertainty of using a one-hour inhalation LC_{50} compared to an exposure duration of four hours or more.

4.9.1 An annual average time period shall be used to determine the BAC_{NC} pursuant to this section.

4.10 If a BAC_{NC} for a TAC has not been determined pursuant to sections 4.1 to 4.9 but an animal oral LD_{50} is available for that TAC, the LD_{50} may be used to calculate the BAC_{NC} as follows:

$$BAC_{NC} = \frac{LD_{50\ (mg/kg)}}{500 \times 100 \times 40 \times 0.167} \times \frac{W_A}{I_A}$$

Where:

BAC_{NC} = Benchmark Ambient Concentration for the noncarcinogenic effects of a TAC, in units of $\mu g/m^3$,

LD_{50} = Amount of material administered in a single dose by a route other than inhalation, e.g., oral, that causes death of 50% of the group of test animals, in units of μg/kg,

500 = A factor to account for using an LC_{50} to estimate a no observed adverse effect level (NOAEL) for a lifetime study,

100 = A standard composite safety factor comprised of a safety factor of 10 to account for differences between animals and humans and a safety factor of 10 to account for the differences between individuals in the human population,

40 = A safety factor to account for the uncertainty of estimating an LC_{50} from an LD_{50},

0.167 = A factor to convert the daily dose to a 4-hour time frame (4 ÷ 24 = 0.167),

W_A = Body weight of experimental animal in kilograms (kg), and

I_A = Daily inhalation rate of experimental animal in m^3/day.

4.10.1 An annual average time period shall be used to determine the BAC_{NC} pursuant to this section.

4.11 If a BAC_{NC} for a TAC has not been determined pursuant to sections 4.1 to 4.10, the BAC_{NC} shall be the default value of 0.04 $\mu g/m^3$.

4.11.1 An annual average time period shall be used to determine the BAC_{NC} pursuant to this section.

4.12 A BAC_{NC} shall not be derived from a methodology in section 4.3, 4.7 or 4.10 unless the District determines that the use of oral toxicity data is appropriate. The use of oral toxicity data is not appropriate when:

4.12.1 Groups of chemicals have different toxicity by the two different routes (e.g., metals, irritants, and sensitizers),

4.12.2 A first-pass effect by the respiratory tract is expected,

4.12.3 A first-pass effect by the liver is expected,

4.12.4 A respiratory tract effect is established, but dosimetry comparison cannot be clearly established between the two routes,

4.12.5 The respiratory tract is not adequately studied in the oral studies, or

4.12.6 Short-term inhalation studies, dermal irritation, in vitro studies, or characteristics of the chemical indicate potential for portal-of-entry effects at the respiratory tract, but the studies themselves are not adequate for the development of a BAC.

SECTION 5 Consideration of Acute Noncancer Effects

If the District determines that compliance with the BAC_{NC} over the applicable averaging time does not provide adequate protection from the acute effects of a TAC, the District may establish an acute BAC_{NC} (BAC_{NCA}) using a shorter averaging time and a methodology consistent with the guidance provided in EPA's *Air Toxics Risk Assessment Reference Library, Volume 1, Technical Resource Manual, Section 12.6 Acute Exposure Reference Values* (April 2004).

Adopted v1/6-21-05, effective 7-1-05; amended v2/7-19-06; v3/7-20-11, v4/01/18/12.