

**Louisville Metro Air Pollution Control District  
Preliminary  
Regulatory Impact Assessment**

**Regulation 5.20  
*Methodology for Determining Benchmark Ambient Concentration  
of a Toxic Air Contaminant*  
Version 3/External**

**Purpose of the Draft Proposed Action:**

The draft proposed action provides that the Air Pollution Control Board (Board), through rulemaking pursuant to APCD Regulation 1.08, may amend Regulation 5.20 and determine that a Toxic Air Contaminant (TAC) is not a carcinogen for purposes of determining a Benchmark Ambient Concentration (BAC) to demonstrate compliance with the Environmental Acceptability goals established in Regulation 5.21 of the District's Strategic Toxic Air Reduction (STAR) program. In addition, the proposed amendment reconciles existing provisions of Section 4 regarding the use of oral toxicity data to establish a noncarcinogenic BAC. The remaining draft proposed changes are administrative ones designed to improve readability, for example by removing redundant or outdated provisions.

**Estimated Costs and Savings:**

There are no anticipated costs or savings to regulated entities at this time. In the future, there may be some savings to regulated sources emitting a TAC currently considered a carcinogen, if the Board determines that the particular TAC is not a carcinogen.

**Feasibility of All Alternatives:**

Regulation 5.20 is part of the STAR program. The District evaluated not amending the regulation, but determined that the amendments are necessary to ensure that STAR is based on the most current scientific information.

The STAR program relies on the expertise of other agencies to estimate risk. Regulation 5.20 establishes a number of sources as authoritative, including the U.S. EPA, the National Toxicology Program (NTP), the International Agency for Research on Cancer (IARC), the Agency for Toxic Substances and Disease Registry, and the California and Michigan air regulatory agencies, for determining when a TAC is a carcinogen for purposes of determining the BAC. However, because scientific knowledge “is not only uncertain, but also dynamic,”<sup>1</sup> it

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<sup>1</sup> *Role and Use of Science at EPA* (“Scientific knowledge is not only uncertain, but also dynamic. Through research that is designed to reduce uncertainties, our understanding increases and, as a result, we change our assumptions about the impacts of environmental problems and how they should be addressed.”), available at [www.epa.gov/epahome/science.htm](http://www.epa.gov/epahome/science.htm).

is not unusual for an authoritative source to change its conclusions based on new scientific information. To avoid becoming outdated, the STAR program must be able to take such changes into account, particularly to address the strict hierarchy of governmental and quasi-governmental agencies established in Regulation 5.20 and used to determine whether a TAC is a carcinogen for purposes of determining the BAC.

Like the District in STAR, many of the authoritative sources used or relied upon by the District in Regulation 5.20 use and rely on listings and determinations by other agencies. As a result, a chemical may be derivatively listed as a carcinogen by one or more agencies based on a determination by another or de-listed based on a subsequent analysis by yet another. However, given the autonomy and independence of these authoritative sources, and their respective missions and resources, an action to list or de-list a chemical by one agency rarely occurs at the same time as another. This lag in listing and de-listing, coupled with the strict hierarchy currently established in Regulation 5.20, may result in absurd and punitive results in the limited situations where one or more -- but not all -- of the sources listed in Regulation 5.20 have delisted a chemical after further scientific review. Such is the case with ethyl acrylate; in fact, the agency that developed the carcinogenic unit risk estimate (URE) on which the  $BAC_C$  was based has withdrawn the URE for the carcinogenic effects of ethyl acrylate. This puts a source that emits ethyl acrylate in the anomalous position of having to comply with a more stringent standard (the default  $BAC_C$  of  $.0004 \mu\text{g}/\text{m}^3$ ) as a result of a determination that should result in a less stringent standard (the  $BAC_{NC}$  of  $48 \mu\text{g}/\text{m}^3$ ). Although the District anticipates that there will be very few cases where it will propose changing the classification of a TAC, the amendment provides a necessary tool in implementing the STAR Program. If the proposed action is adopted, the District will propose delisting ethyl acrylate as a carcinogen and regulating it as a noncarcinogen in a future rulemaking.

The District received several informal comments expressing concern over the proposal in the prior draft that would have authorized the District to rely on de-listing determinations by one or more of the agencies listed in Regulation 5.20. To address this concern, the current draft requires the District to propose de-listing as part of a public rulemaking process. Amended section 2.3 now provides that “[t]he Board may determine through rulemaking pursuant to Regulation 1.08 that a TAC is not a carcinogen for purposes of determining the BAC.” The District’s formal rule making process includes these additional steps:

1. The District proposes a draft regulation that is typically released to stakeholders for informal comments.
2. A committee of the Board approves the draft, beginning the formal public review process.
3. A legal notice is published, announcing the beginning of a 30-day written formal public comment period.
4. The Board holds a public hearing on the proposed regulation.
5. Following the public hearing and consideration of all public comments, the Board may:
  - a. Adopt the proposed regulation;
  - b. Reject the proposed regulation;
  - c. Modify the proposed regulation;

- d. Seek additional public comment; or
  - e. Take no action.
6. After adoption, the District begins implementing the new regulation.

Importantly, use of the rulemaking process required by KRS 77.185 and implemented through Regulation 1.08 will provide a high level of public accountability and important safeguards against arbitrary decision-making since the Board, rather than the District, will accept or reject the proposed change at a public hearing following an opportunity to provide written and oral comments. The District seeks comment on whether or not this proposed change has succeeded in resolving the concerns expressed.

**Comparison with Any Minimum or Uniform Standards:**

There are no federal requirements relating to this regulation. This regulation is part of the District’s STAR program regulating air toxics.

**Report on Public Outreach Efforts:**

This draft proposal to amend Regulation 5.20 is part of a package of proposed amendments to the STAR regulations that was released for informal external review on March 17, 2010, and sent to: all members of the 2009 STAR Advisory Group; all persons who have requested to be informed of proposed changes to STAR regulations; all persons who have requested to be notified of proposed changes to any District regulations; EPA Region 4; and the Kentucky Division for Air Quality. The District received written informal comments on the draft proposal and is responding to those comments in a separate Comment/Response document. The public will have an opportunity to comment at a meeting of the appropriate committee of the Air Pollution Control Board, during the formal public comment period, and at a public hearing prior to consideration by the full Board.