CASE STUDY SUMMARY

Interpretation of 24-hour sampling data: Methods for Developing 24-hour Ambient Air Quality Criteria based on toxicological and implementation considerations

Describe the problem formulation(s) the case study is designed to address. How is the method described in the case useful for addressing the problem formulation?

The Ontario Ministry of the Environment (MOE) sets science-based ambient air quality criteria or AAQCs to evaluate regional air quality data. An AAQC is a desirable concentration of a contaminant in air that is unlikely to adversely affect human health or the environment. . The term “ambient” is used to reflect general air quality independent of location or source of a contaminant.

Ontario’s 24-hour AAQCs are based on health effects and are set at concentrations that are protective against effects that may occur during continuous lifetime exposure. In comparison, the Texas Commission on Environmental Quality develops reference values to be used as 24-hour Air Monitoring Comparison Values (AMCVs), to compare to measured 24-hour ambient air concentrations, although the TCEQ also develops acute 1-hr and chronic AMCVs to evaluate 1-hr measured concentrations of chemicals or calculated annual average concentrations, respectively. This case study describes the Ontario approach and discusses how the Ontario AAQCs and Texas AMCVs may be applicable, depending on the science and implementation considerations.

The MOE currently employs two approaches to assign an averaging time of 24 hours to AAQCs meant to be protective in continuous lifetime exposures: 1) based on concerns about effects that may develop after short-term exposures (e.g., developmental); or 2) through conversion of an AAQC with an annual averaging time. These two approaches for setting 24-hour AAQCs are described below.

In this case study we aim to demonstrate how both toxicological and implementation considerations may influence the setting the averaging time of an AAQC and, in turn, the interpretation of 24-hour air quality data.

Provide a few sentences summarizing the method illustrated by the case study.

Generally, AAQCs are used in monitoring programs to assess air quality resulting from the contributions of a contaminant to air from all sources. AAQCs may also be adopted or adapted as regulatory air standards in Ontario, which are used mostly to evaluate the modelled contributions of a contaminant to air by a single regulated source. Air standards are used to assess regulatory compliance, identify needs for abatement and also to inform permitting decisions. While the focus of this problem formulation is on the AAQC component of our air quality program, it will also be relevant to air standards.

The MOE develops 24-hour AAQCs based on an assumed continuous lifetime exposure. Therefore, if the 24-hour AAQC is met, then no adverse effects are expected to a person continuously exposed over a lifetime.

Establishing 24-hour AAQCs for Continuous Lifetime Exposures

Approach 1– Effects Caused After Short-term Exposure

The MOE may set 24-hour AAQCs directly based on adverse effects when short-term exposures may be sufficient to cause the effect. For example, this approach may be relevant for developmental effects resulting from prenatal exposure (e.g. dioxins), or with critical windows of exposure (e.g., manganese) .

Approach 2 - Conversion from Annual AAQCs

Similar to what is done by the Texas Commission on Environmental Quality (TCEQ), the MOE assigns annual averaging times to AAQCs to protect against adverse health effects elicited after long-term air exposures. If the annual AAQC is met then no effects are expected over continuous lifetime exposures. However, the annual AAQC does not allow assessment of short-term periods of elevated exposure that may cause a different effect from that used to set the annual AAQC or increase the risk of the same effect used to set the annual AAQC. Another limitation of the annual AAQC is that air quality can only be assessed after sufficient air quality data are collected to reflect an annual average. That is, longer averaging times require more sampling and longer delays in order to get enough data to compare to an air quality criterion.

To address the limitations of the annual AAQC, the MOE converts the annual AAQC to a 24-hour value using a conversion factor and the *converted* 24-hour AAQC is used to assess 24-hour air quality data. Conversion factors were originally derived from empirical data of monitored ambient air levels of sulphur dioxide (SO_2) in urban areas, and also near point sources, and atmospheric dispersion modelling of specific sources. The urban ambient air data, acquired in eight of the largest U.S. cities, together with Ontario data available at that time, showed a relationship between a 1 hour average and an annual average exposure at the respective monitoring locations. **The MOE used this information to select a conversion factor of 5 to convert from an annual to a 24-hr average and a conversion factor of 3 to convert from a 24-hr to a ½ hr average.** These generic conversion factors are derivable from an exponential equation (i.e. the commonly used power law) that has also been used for other averaging times (i.e. 1 hr value, ½ hour and 10 minutes), which the MOE references in its local air quality regulation:

$$C_{long} = C_{short} \left(t_{short}/t_{long}\right)^{p}$$

Where C_{long}= the concentration for the longer averaging time

C_{short}= the concentration for the shorter averaging time

T_{short} = the shorter averaging time (in minutes)

T_{long} = the longer averaging time (in minutes)

and, p = the power law exponent, 0.28

A review of the various literature sources for, and assumptions made by, different regulatory bodies in selecting the basis for the exponent, and the value for *n* to use in the commonly used power law is discussed in greater detail in the case study. Briefly, this conversion is based on a general relationship between emissions and meteorological influences, based on empirical monitoring data; it reflects variability in emissions and resulting exposures, rather than how a chemical's toxicity varies with duration.

The conversion factor is relied on to ensure that if the shorter-term AAQC for a compound (i.e.., the converted 24 hour AAQC) is met, as observed in monitored 24-hour data, then a AAQC with longer-term exposures (e.g., an annual average effects-based AAQC) will not be exceeded, and no effects are expected over long-term continuous exposures. This way, an 'equivalency' or 'link' between the converted 24-hour AAQC and the effects-based annual AAQC is established. That is, the converted 24-hour AAQC is a health protective value for long term exposure, rather than a value that can be used to estimate health risk directly associated with a single 24-hour exposure. That said, the converted 24-hour AAQC is also likely protective against potential adverse effects associated with short-term exposures, as long as the conversion does not result in a converted 24-hour AAQC that is above a concentration of concern for the short-term exposure associated effect.

An additional assessment would be required to evaluate the potential for short-term effects if the converted 24-hour AAQC were exceeded on repeated occasions.

The methodology of creating a converted 24-hr AAQC would be applicable for all chemicals with assigned annual AAQCs, which are designed to protect against adverse health effects elicited after long-term air exposures (i.e., carcinogens, and most non-carcinogens). As mentioned above, those chemicals with a critical window of exposure (i.e., divalent and trivalent chromium, manganese, dioxins), would not normally be assigned an annual averaging time, and thus would not be applicable to the development of a converted 24-hr AAQC.

Comment on whether the method is general enough to be used directly, or if it can be extrapolated, for application to other chemicals and/or problem formulations. Please explain why or why not.

Both approaches are general enough to be used directly as benchmarks for the evaluation of air quality data based on an assumption of continuous lifetime exposure.

Approach 1 may be directly applied by other agencies through consideration of specific effects and critical windows of exposure.

Approach 2 may be applied after selection/validation of appropriate conversion factors in other jurisdictions / air sheds and contaminants. With regard to the MOE, the province-wide application of the 5-fold annual-to-24 hour conversion for AAQCs is supported by urban data sets. Urban ambient air monitoring data includes the contribution of diverse emitting sources to general air quality and hence supports the conversion of an annual AAQC to a 24-hr AAQC, which can be used to interpret air quality data in the absence of annual data. This methodology has thus been utilized for a wide range of ambient air contaminants in diverse settings within Ontario.

In addition to utilizing these conversion factors for environmental assessments, the MOE uses it as a tool when comparing ambient air quality concentration levels from other jurisdictions. Specifically, when converting a guideline developed by another jurisdiction for use in MOE, if there are no details available about the specific averaging time conversion factors used by other jurisdictions in order to derive the guideline, or if no conversions were performed by a jurisdiction, then MOE conversion factors may be used. It should be noted, however, that if the agency used a specific averaging time conversion factor to derive their guideline, for the sake of consistency the MOE first applies the inverse of the other agency's conversion factor, and then applies MOE conversion factors, if necessary.

Discuss the overall strengths and limitations of the methodology.

Approach 1:

The MOE's 24-hour AAQC can be used to set targets for air quality and can be used to readily assess air quality relative to these targets, when compared to single 24-hr monitored data points. If the 24-hour AAQC is met then no adverse effects are expected over a continuous lifetime exposure. Another strength of this approach is that it is based on chemical-specific data. As well, while this approach also protects for the potential adverse effects from single or rare short-term peaks in exposure, the 24-hour AAQC is not appropriate for assessing the health risk associated with single or rare exposures above the AAQC. This gap is filled by the direct development by the TCEQ of a short-term effects-based value. The ministry currently evaluates single or rare exposures above the 24-hour AAQC on a case-by-case basis.

Approach 2:

<u>Strengths</u>

A strength of this approach is that it is science-based, using empirically derived conversion factors from measurements of several contaminants in air. The use of a conversion factor of 5 to convert an annual to a 24-hour number has generally been found to be protective, with varying levels of conservatism depending on the emissions and air dispersion scenario. However, meteorological anomalies may not be captured under this conversion method, or in physical situations where regional ambient air variability may not apply due to local topography (i.e., specific local areas exposed to air tunnel-like effects, as with mountain valleys).

Another strength of the approach is that the converted 24-hour AAQC is protective against effects in both long-term and short-term exposure (provided that short-term effects do not occur at concentrations less than five times the annual AAQC (i.e., the converted 24-hr AAQC)). Theoretically, if short-term adverse effects which may occur within 24-hours at levels less than a value equal to 5x the annual AAQC were of concern, then an additional short-term AAQC specific to that other effect would be warranted.

Assuming the minimal data requirements to set an annual AAQC for long-term exposure are available, no other data are necessary to create the converted 24-hour AAQC.

Limitations

The converted 24-hour AAQC is not directly linked to an effect and instead provides an indication whether the effects-based annual AAQC may be exceeded. This limitation does not impact this AAQC's use as an air quality target but has been criticized when used to set regulatory air standards for evaluating the contributions to air of regulated emitters. MOE's stakeholders have argued that compliance with an air standard should not be evaluated based on a converted value. In response, the MOE introduced annual air standards, for the first time, for six contaminants in 2011. However, the MOE will continue to use converted AAQCs to evaluate ambient air quality.

The converted 24-hour AAQC is not appropriate for interpreting single or rare exposures above the AAQC. In such cases, the MOE evaluates exposure on a case-by-case basis. This limitation is further explored below by comparison of converted 24-hour AAQCs to the proposed 24-hour AMCVs developed by the TCEQ.

The conversion factors applied are based on analysis of monitoring information for a selected group of chemicals, with the assumption that the conversion factor derived from this analysis is applicable to all chemicals in air. This limitation is balanced by the selection of a value from the dataset that could be considered conservative in most scenarios.

Outline the minimum data requirements and describe the types of data needed.

To derive 24-hour AAQCs, the MOE undertakes an approach similar to other comparable jurisdictions; specifics may change, but the underlying goal is to base the AAQC on the most sensitive relevant adverse health effect reported in the medical and toxicological literature, and have it set at a level designed to protect sensitive individuals in the population by the inclusion of margins of safety and conservatism, via usage of uncertainty factors or extrapolation to a target risk value. Thus, the minimum data requirements are similar to those for developing other chronic exposure limits – adequate data from subchronic or chronic exposure to identify a point of departure for an effect relevant to humans; shorter duration studies may provide the point of departure if they identify a lower effect level. Uncertainty factors are used to address data gaps, as for other chronic exposure limits.

HOW THIS ASSESSMENT ADDRESSES ISSUES RAISED IN SCIENCE & DECISIONS:

A. Describe the dose-response relationship in the dose range relevant to human exposure.

The MOE takes into consideration a number of dose-response factors in determining whether to assign a 24-hour or annual average to an effect-based AAQC designed to protect for long-term exposure. These include the following:

1. Patterns and duration of exposure. Is exposure episodic with short term peaks or does it involve long-term repeated exposure to relatively low concentrations?

2. Nature of the relevant critical effect(s), including critical windows of exposure. Developmental effects are of particular interest in this context, given the relatively short critical window of exposure during pregnancy.

3. Mode of action for critical effects including relevant dose metrics (i.e., whether, for example, the effect is likely to be associated with area under the blood concentration time curve or Cmax – i.e., the maximum concentration in blood).

As such, this approach uses standard UFs in the development of an AAQC, be it 24-hour or annual, and so does not generally attempt to describe the human dose-response in the range of human exposures.

B. Address human variability and sensitive populations?

C. Address background exposures and responses?

D. Address incorporation of existing biological understanding of the likely mode of action (MOA)?

E. Address other extrapolations, if relevant – insufficient data, including duration extrapolations, interspecies?

F. Address uncertainty.

For B-F: While such issues are addressed in the establishment of the effects-based AAQCs, they are not revisited in the assignment of averaging time or in the derivation of a conversion-driven 24-hour averaged AAQC. The purpose of this case study is to obtain comments from the panel the strengths and limitations of the approaches employed by the MOE in interpreting 24-hour monitoring data, and not in the development of an effects-based AAQC.

G. Allow the calculation of risk (probability of response for the endpoint of interest) in the exposed human population?

While both approaches are intended to identify a safe dose level, the 24 hours AAQC developed through the two approaches above are treated differently, with regard to risk assessment.

The 24-hour AAQCs developed through Approach 1 are specific to the assessment of risks from long-term continuous exposures and are directly linked to an adverse health effect being considered; so they may be used in assessments of long-term risk.

In comparison, as the converted 24-hour AAQCs developed though Approach 2 are not *directly* linked to an adverse health effect, they are not appropriate for risk calculations. In these cases, the monitored value would be *converted back to an annual equivalent* (i.e, divided by 5), to get an equivalent annual average value from which long-term risk calculations (e.g. cancer probability) could be calculated.

H. Work practically? If the method still requires development, how close is it to practical implementation?

Both methods are already implemented in Ontario. As discussed above, the practicality of the converted 24-hour AAQCs is one of the strengths of this approach.