Preliminary Comments on the Policy Assessment from Dr. H. Christopher Frey

Chapter 5 – Preliminary Conclusions on Adequacy of the Current Primary NO2 Standards

1. *What are the Panel's views on staff's preliminary conclusions regarding adequacy of the current standards and on the public health policy judgments that support those preliminary conclusions? Does the discussion provide an appropriate and sufficient rationale to support staff's preliminary conclusion that it is appropriate to consider retaining the current standards, without revision, in this review?*

Chapter 5 provides an appropriate and sufficient rationale to support a recommendation to the Administrator that it is appropriate to retain the current primary NAAQS for nitrogen dioxide.

- Current scientific evidence, including evidence for asthma exacerbation related to short-term exposures based on controlled-human exposure studies, strengthens conclusions reached in the last review. The strengthening is based on more specific integration of evidence, rather than new evidence. Supporting evidence is available from epidemiologic studies, including some studies conducted since the last review. With regard to epidemiology, uncertainty remains as to the potential for confounding by traffic-related air pollutants.
- Current scientific evidence for respiratory effects related to long-term exposures is stronger since the last review, although there are uncertainties related to the potential role of co-pollutants.
- The current scientific evidence supports the choice of NO_2 as the **indicator** for ambient gaseous oxides of nitrogen. For example, controlled human and animal exposure studies provide specific evidence for health effects following exposure to NO_2. Epidemiologic studies also provide support for NO_2 as associated with adverse effects. NO_2 also serves as a good indicator of exposures to oxides of nitrogen, since reductions in exposures to NO_2 would reasonably be related to reductions in exposures to oxides of nitrogen more broadly.
- With regard to **averaging time**, the existing 1-hour and annual averaging times address short-term and long-term exposures to NO_2. Controlled human and animal studies provide scientific support for a one hour averaging time as being representative of an exposure duration that can lead to adverse effects. Epidemiologic evidence provides further support for the 1-hour averaging time.
- Epidemiologic studies provide support for a longer average time representative of an association between long-term exposures, or repeated short-term exposures, and asthma development.
- There is very limited support for adverse effects at **levels** below the current standards for either the 1-hour or annual averages. Available epidemiologic studies that might provide such support suffer from two key problems: (a) they are subject to uncertainty regarding copollutant confounding; and (b) they represent air quality situations that would likely violate the current standard.
- Thus, there is a scientific basis to state that there is strong evidence for the selection of NO_2 as the **indicator** of oxides of nitrogen, for the selection of one hour and annual **averaging times** to represent short-term and long-term exposures, respectively, and that there are notable adverse effects at **levels** that exceed the current standard, but not at levels that are below the current standard.

- The **form** of the standard is the most difficult to assess scientifically. A key factor in making a decision regarding the form is often "programmatic stability" which is intended to avoid situations in which compliance with the standard is subject to highly stochastic variable factors that are beyond human control, such as meteorological variability. For the one hour current standard, the form is based on the 98th percentile of daily maximum 1 hour concentrations, which corresponds to the 7th or 8th highest daily maximum 1 hour concentration in a year. This form limits but does not eliminate exposures at or above 100 ppb NO_2. A scientific rationale for this form is there is uncertainty regarding the severity of adverse effects at a level of 100 ppb, and thus some potential for maximum daily levels to exceed this benchmark with limited frequency may nonetheless be protective of public health. As such, however, the choice of form appears to be more of a policy than scientific judgment. The policy judgment regarding protecting public health with an adequate margin of safety is at the discretion of the Administrator.

2. *What are the Panel's views on the areas for additional research that are identified in Chapter 5? Are there additional areas that should be highlighted?*

Key areas of uncertainty that have come up during the current review cycle for the Nitrogen Oxides Primary NAAQS have included:

- In a letter from CASAC to the Administrator of September 9, 2015 (EPA-CASAC-15-002), CASAC stated that "quantitative risk assessment based on the epidemiologic evidence would be challenged by considerable uncertainty due to the inability to distinguish the contributions of NO_2 from the contributions of other highly correlated pollutants." There is an ongoing need for research in multipollutant exposure and epidemiology to attempt to distinguish the contribution of NO_2 exposure to human health risk.
- There is generally a need to continue to characterize "adversity" and "clinically" significant outcomes when interpreting the results of controlled exposure and epidemiologic studies (e.g., see also EPA-CASAC-15-001)
- There is very likely to be an ongoing need for meta-analysis of multiple studies, to incorporate possible future studies.
- Issues of seasonal differences in NO_2 exposures, and distinguishing between ambient and indoor exposures, need to be addressed to aid in better inferences of health effects (e.g., see EPA-CASAC-15-001). As noted in the CASAC response to charge questions regarding the second draft of the ISA, "There can be more interpretation from studies of indoor exposure and for studies undertaken in different seasons. The indoor exposure studies can be informative because they do not have the same mix of copollutants as the outdoor exposure studies. More consideration of the modes of action associated with the various copollutants would also be of use."
- Information that helps explain variability in ambient NO_2 concentrations is an ongoing need, including air quality monitor site characteristics (e.g., location in a street canyon), available traffic counts, fleet mix data, and historical emissions information and trends. The representativeness of the available ambient data should be determined. New information on near-road oxides of nitrogen levels is critical for better quantifying near-road impacts. The time series of near-road monitoring data will increase between now and the next review cycle and should be analyzed and evaluated.

- There is also a need to continue to address issues of equity and environmental justice related to the distribution of exposures among and between communities of varying socioeconomic status. Such distributions may also be highly related to identification of groups at higher risk for adverse effects as a result of combinations of exposure scenarios, populations, lifestages, and socioeconomic factors. More research on effect modification with regard to such factors is an ongoing need. For example, as noted in EPA-CASAC-15-001, "There is substantial evidence that groups in poverty or who are non-white experience higher exposures to NO_2, but the epidemiological evidence is still lacking. It is important to clearly show how the exposure differences follow socioeconomic status (SES) or racial gradients, because for those that are considered causal or likely to be causal, there is high potential for larger health effects even if the epidemiological evidence of a direct effect modification is lacking."
- Scientific information to support quantification of ambient concentration and exposure benchmarks is an ongoing need. As noted in EPA-CASAC-15-002, "EPA should evaluate whether there is a basis for positing a benchmark lower than 100 ppb for use in interpreting the short-term exposure estimates."
- As stated in EPA-CASAC-15-002, "quantitative uncertainty analysis methods are recommended for characterizing and comparing these potential sources of uncertainty." There will be an ongoing need to quantify uncertainties.
- EPA should continue to explore ways to improve quantitative methods for estimating exposure and develop or collect data needed to support such methods.
- As noted in EPA-CASAC-15-002, "The available controlled human exposure data do not rule out that adverse effects could occur at NO_2 concentrations below that of the current 1-hour standard. Therefore, other means for inferring concentrations that may be associated with adverse effects at 1-hour average NO_2 concentrations below 100 pbb (such as based on epidemiologic data) should be explored and taken into account when considering benchmark concentrations and interpreting results from the exposure assessment." This is an ongoing need.
- Although in this review there was not sufficient new scientific information to support a substantial update of previously conducted risk assessments, it is possible that the state of science could further develop between now and the next review cycle. Thus, there may be an ongoing need to develop exposure quantification methods, models, and data to make use of information that may arise, or new interpretations of existing information.