Lowest Measured Level (LML) Assessment for Rules without Policy-Specific Air Quality Data Available

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Inherent in any complex Regulatory Impact Analysis (RIA) are multiple sources of uncertainty. Health benefits analysis relies on an array of data inputs—including air quality modeling, health impact functions and valuation estimates among others—which are themselves subject to uncertainty and may also in turn contribute to the overall uncertainty in this analysis. There are a variety of methods to characterizing the uncertainty associated with the human health benefits of air pollution, including quantitative and qualitative methods. When evaluated within the context of these uncertainties, the health impact and monetized benefits estimates in an RIA can provide useful information regarding the magnitude of the public health impacts attributable to reducing air pollution.

Reductions in premature mortality typically dominate the size of the overall monetized benefits. Therefore, most of the uncertainty characterization generally focuses on the mortality-related benefits. Typically, EPA employs two primary techniques for quantifying this uncertainty. First, because this characterization of random statistical error may omit important sources of uncertainty, we employ the results of an expert elicitation on the relationship between premature mortality and ambient $PM_{2.5}$ concentration (Roman et al., 2008); this provides additional insight into the likelihood of different outcomes and about the state of knowledge regarding the benefits estimates. Second, when we have air quality modeling specific to the policy we are evaluating and it can be used as an input to the health impact and economic analysis, we use Monte Carlo methods for characterizing random sampling error associated with the concentration response functions from epidemiological studies and economic valuation functions.[1] Both approaches have different strengths and weaknesses, which are fully described in Chapter 5 of the PM NAAQS RIA (U.S. EPA, 2006).

In addition, some RIAs, including the PM NAAQS RIA (2006d) and Ozone NAAQS RIA (2008a), also contain a suite of sensitivity analyses that evaluate the sensitivity of the monetized benefits to the specification of alternate mortality cessation lags and income growth adjustment factors. Cessation lags and income growth adjustments are simply multipliers applied to the valuation function, which generally affect monetized benefits estimates in the same manner. Thus, it is possible for readers to infer the sensitivity of these parameters by referring to those previous analyses.[2] Other RIAs contain unique sensitivity analyses that are specific to the

[1] Currently, we are unable to characterize the random sampling error from the underlying studies when applying national average benefit-per-ton estimates.

[2] For example, in the PM NAAQS RIA, the use of an alternate lag structure would change the $PM_{2.5}$-related mortality benefits discounted at 3% discounted by between 10.4% and –27%; when discounted at 7%, these benefits change by between 31% and -49%. When applying higher and lower income growth adjustments, the monetary value of $PM_{2.5}$ and ozone-related premature changes between 30% and -10%; the value of chronic

input parameters of that analysis, such as blood lead level (U.S. EPA, 2008b) or rollback method (U.S. EPA, 2010a). Other sources of uncertainty, including the projection of atmospheric conditions and source-level emissions, the projection of baseline morbidity rates, incomes and technological development are typically unquantified in our RIAs. For these sources, we typically provide a qualitative uncertainty characterization associated with these input parameters.

One particular aspect of uncertainty has received extensive quantitative and qualitative attention in recent RIAs: the existence of a threshold in the concentration-response function for $PM_{2.5}$-related mortality. A threshold is a specific type of discontinuity in the concentration-response function where there are no benefits associated with reducing $PM_{2.5}$ levels in areas where the baseline air quality is less than the threshold. Previously, EPA had included a sensitivity analysis with an arbitrary assumed threshold at 10 µg/m^3 in the PM-mortality health impact function in the RIA to illustrate that the fraction of benefits that occur at lower air pollution concentration levels are inherently more uncertain. A threshold of 10 µg/m^3 does not necessarily have any stronger technical basis than any other threshold, and we could have instead assumed a threshold at 4, 7.5, or 12 µg/m^3 for the sensitivity analysis. In addition to identifying the most support for a non-threshold model, the underlying scientific evidence does not support any specific "bright line".

Based on our review of the current body of scientific literature, EPA now estimates PM-related mortality without applying an assumed concentration threshold. EPA's Integrated Science Assessment for Particulate Matter (U.S. EPA, 2009b), which was recently reviewed by EPA's Clean Air Scientific Advisory Committee (U.S. EPA-SAB, 2009a; U.S. EPA-SAB, 2009b), concluded that the scientific literature consistently finds that a no-threshold log-linear model most adequately portrays the PM-mortality concentration-response relationship while recognizing potential uncertainty about the exact shape of the concentration-response function.[3] Since then, the Health Effects Subcommittee (U.S. EPA-SAB, 2010) of EPA's Council concluded, "The HES fully supports EPA's decision to use a no-threshold model to estimate mortality reductions. This decision is supported by the data, which are quite consistent in showing effects down to the lowest measured levels. Analyses of cohorts using data from more recent years, during which time PM concentrations have fallen, continue to report strong

endpoints change between 5% and -2% and the value of acute endpoints change between 6% and -7%. (U.S. EPA, 2006)

[3]It is important to note that uncertainty regarding the shape of the concentration-response function is conceptually distinct from an assumed threshold. An assumed threshold (below which there are no health effects) is a discontinuity, which is a specific example of non-linearity.

associations with mortality. Therefore, there is no evidence to support a truncation of the CRF." For a summary of these scientific review statements and the panel members please consult the Technical Support Document (TSD) Summary of Expert Opinions on the Existence of a Threshold (U.S. EPA, 2010c).

Consistent with this finding, we have conformed the previous threshold sensitivity analysis to the current state of the PM science by incorporating a new "Lowest Measured Level" (LML) assessment. While an LML assessment provides some insight into the level of uncertainty in the estimated PM mortality benefits, EPA does not view the LML as a threshold and continues to quantify PM-related mortality impacts using a full range of modeled air quality concentrations. Unlike an assumed threshold, which is a modeling assumption that reduces the magnitude of the estimated health impacts, the LML is a characterization of the fraction of benefits that are more uncertain. It is important to emphasize that just because we have greater confidence in the benefits above the LML, this does not mean that we have no confidence that benefits occur below the LML.

While the LML of each study is important to consider when characterizing and interpreting the overall level PM-related benefits, EPA believes that large cohort-based mortality estimates are suitable for use in air pollution health impact analyses. When estimating PM mortality impacts using risk coefficients drawn from the Harvard Six Cities and the American Cancer Society cohorts there are innumerable other attributes that may affect the size of the reported risk estimates—including differences in population demographics, the size of the cohort, activity patterns and particle composition among others. The LML assessment provides a limited representation of one key difference between the two studies. For the purpose of estimating the benefits associated with reducing $PM_{2.5}$ levels, we utilize the effect coefficients from Pope et al. (2002) for the American Cancer Society cohort and from Laden et al. (2006) for the Harvard Six Cities cohort.

Analyses of these cohorts using data from more recent years, during which time PM concentrations have fallen, continue to report strong associations with mortality. For example, the Krewski et al. (2009) follow-up study of the American Cancer Society cohort had an LML of 5.8 $\mu g/m^3$. As we model mortality impacts among populations exposed to levels of $PM_{2.5}$ that are successively lower than the LML of each study, our confidence in the results diminishes. As air pollution emissions continue to decrease over time, there will be more people in areas where we do not have published epidemiology studies. However, each successive cohort study has shown evidence of effects at successively lower levels of $PM_{2.5}$. As more large cohort studies follow populations over time, we will likely have more studies with lower LML as air quality levels continue to improve. Even in the absence of a definable threshold, we have more confidence in the benefits estimates above the LML of the large cohort studies. To account for the uncertainty in each of the studies that we base our mortality estimates on, we provide the LML for each of the cohort studies. However, the finding of effects at the lowest LML from the recent Krewski et al (2009) study indicates that confidence in $PM_{2.5}$-related mortality effects down to at least 5.8 $\mu g/m^3$ is high.

In the recently proposed Transport Rule RIA (U.S. EPA, 2010b), we included the new LML assessment in which we binned the estimated number of avoided $PM_{2.5}$-related premature mortalities resulting from the implementation of the Transport Rule according to the projected 2014 baseline $PM_{2.5}$ air quality levels. This presentation is consistent with our approach to applying $PM_{2.5}$ mortality risk coefficients that have not been adjusted to incorporate an assumed threshold. A very large proportion of the avoided PM-related impacts occurred among populations initially exposed at or above the LML of each study, which gave us a high level of confidence in the PM mortality estimates. This assessment summarized the distribution of avoided PM mortality impacts according to the baseline $PM_{2.5}$ levels experienced by the population receiving the $PM_{2.5}$ mortality benefit. Approximately 80% of the avoided impacts occurred at or above a baseline annual mean $PM_{2.5}$ level of 10 $\mu g/m^3$ (the LML of the Laden et al. 2006 study); about 97% occur at or above an annual mean $PM_{2.5}$ level of 7.5 $\mu g/m^3$ (the LML of the Pope et al. 2002 study). This assessment confirmed that the great majority of the impacts associated with the Transport Rule occurred at or above each study's LML.

For the Transport Rule, policy-specific air quality modeling data for the year 2014 was available as an input into the benefits analysis. For some rules, especially New Source Performance Standards (NSPS) or National Emissions Standards for Hazardous Air Pollutant (NESHAP) rules, policy-specific air quality data is not available due to time or resource limitations. For these rules, we provide the following LML assessment as a characterization of the baseline exposure to $PM_{2.5}$ levels in the U.S. Many of the upcoming NSPS and NESHAP rules have compliance dates between 2013 and 2016 and represent marginal improvements in air quality levels. Although it the data is not a perfect match, we believe that the air quality data from the Transport Rule is a reasonable approximation of the baseline exposure in the U.S. for upcoming NSPS and NESHAP rules.[4]

[4] Because the Transport Rule is not yet promulgated, the baseline exposure obtained from this modeling data would slightly overestimate the fraction of the population exposed to air quality levels below the LML. As additional rules continue to reduce the ambient $PM_{2.5}$ levels over time, a larger fraction of the population would be exposed to air quality levels below the LML. However, the emission reductions anticipated from the rules without air quality modeling available are comparatively small and represent marginal changes. We intend to update this

For rules without air quality modeling, we generally estimate the monetized benefits and health impacts using benefit-per-ton estimates (Fann, Fulcher and Hubbell, 2009). Using this method, we are unable to estimate the percentage of premature mortality associated with the specific rules' emission reductions at each $PM_{2.5}$ level. However, we believe that it is still important to characterize the uncertainty associated with the distribution of the baseline air quality. As a surrogate measure of mortality impacts, we provide the percentage of baseline exposure at each $PM_{2.5}$ level. If air quality levels in the baseline are above the LML, the marginal changes anticipated from these rules would likely also lead to post-policy air quality levels above the LML. Therefore, we have high confidence that the magnitude of the benefits estimated for these rules, as the marginal changes would also be above the LML.

It is important to note that baseline exposure is only one parameter in the health impact function, along with baseline incidence rates population, and change in air quality. In other words, the percentage of the population exposed to air pollution below the LML is not the same as the percentage of the population experiencing health impacts as a result of a specific emission reduction policy. The most important aspect, which we are unable to quantify for rules without air quality modeling, is the shift in exposure associated with the specific rule. Therefore, caution is warranted when interpreting the following assessment.

A very large proportion of the population is exposed at or above the lowest LML of the cohort studies (Figures 1 and 2), increasing our confidence in the PM mortality analysis. Figure 1 shows a bar chart of the percentage of the population exposed to various air quality levels in the pre- and post-policy policy. Figure 2 shows a cumulative distribution function of the same data. In addition, Figure 2 also demonstrates that policy had a greater impact on reducing exposure to the portion of the population in areas with high $PM_{2.5}$ levels relative to the portion of the population at low $PM_{2.5}$ levels. Both figures identify the LML for each of the major cohort studies. As the policy shifts the distribution of air quality levels, fewer people are exposed to $PM_{2.5}$ levels above the LML. Under baseline conditions, about 96 percent of the population is exposed to annual mean $PM_{2.5}$ levels of at least 5.8 $\mu g/m^3$, which is the lowest air quality level considered in the most recent study of the American Cancer Society cohort by Krewski et al. (2009). Using the Pope et al. (2002) study, the 85% of the population is exposed at or above the LML of 7.5 $\mu g/m^3$. Using the Laden et al. (2006) study, 40% of the population is exposed above the LML of 10 $\mu g/m^3$. As we model mortality impacts among populations exposed to levels of $PM_{2.5}$ that are successively lower than the LML of the lowest cohort study, our confidence in the

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LML assessment as necessary to correspond with the successively lower baseline air quality levels anticipated as the result of promulgating significant upcoming rules.

results diminishes. However, the analysis above confirms that the great majority of the impacts occur at or above the lowest cohort study's LML. It is important to emphasize that we have high confidence in $PM_{2.5}$-related effects down to the lowest LML of the major cohort studies, which is 5.8 µg/m^3. Just because we have greater confidence in the benefits above the LML, this does not mean that we have no confidence that benefits occur below the LML.

Figure 1: Percentage of Adult Population by Annual Mean $PM_{2.5}$ Exposure (pre- and post-policy)

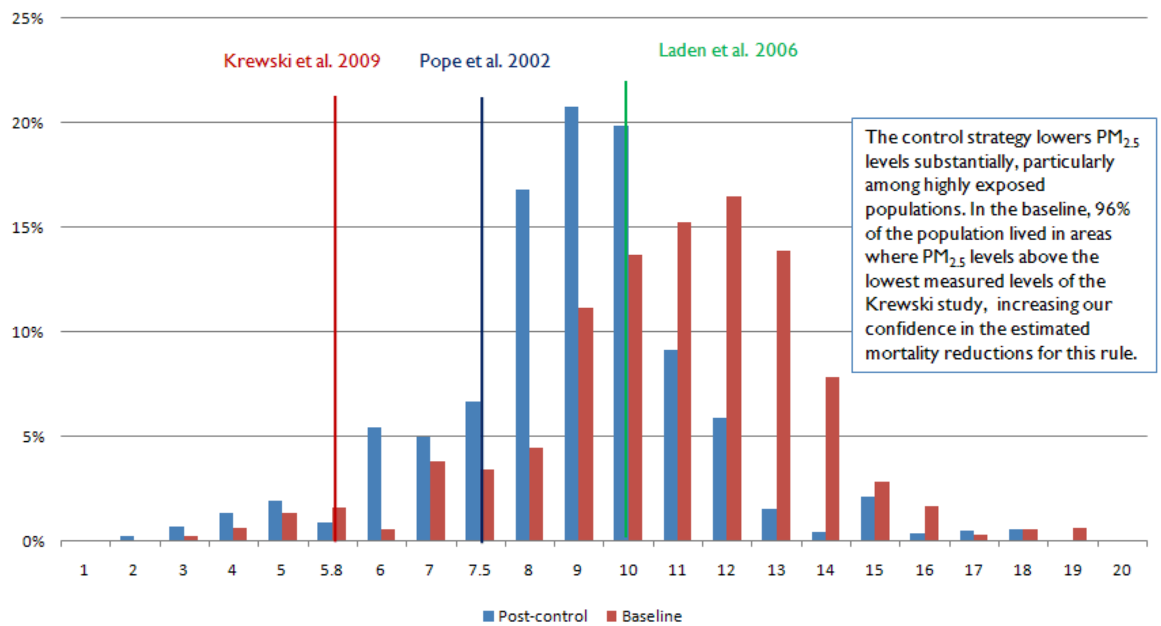
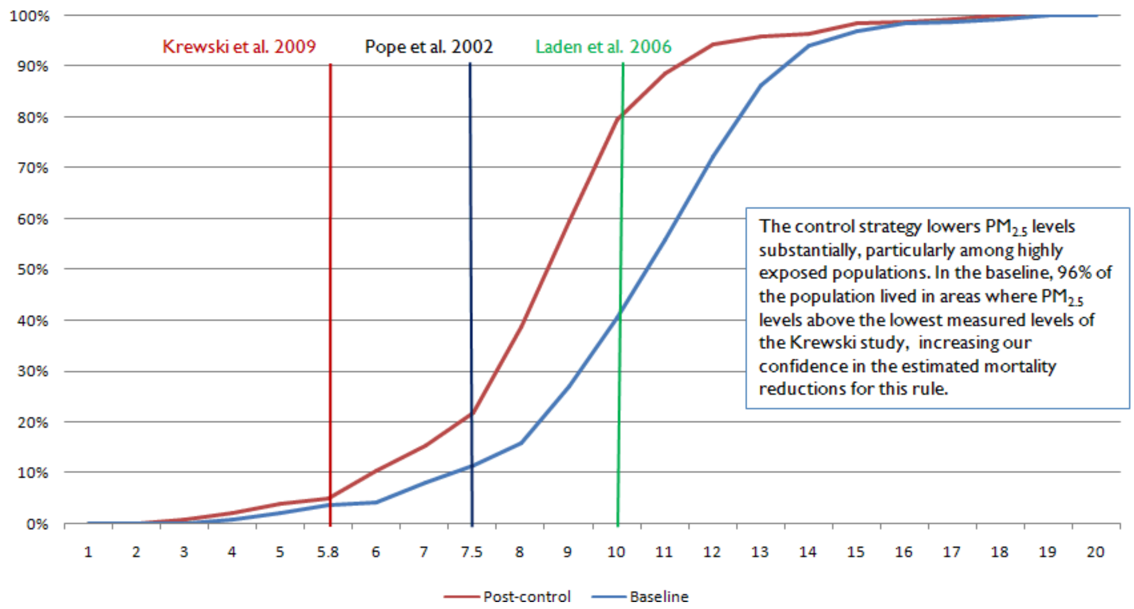


Figure 2: Cumulative Distribution of Adult Population at Annual Mean $PM_{2.5}$ levels (pre- and post-policy)



There are several important differences between the assessment conducted for the Transport Rule and the assessment presented here. If you compare the graphics in the Transport Rule to those provided here, you will notice that these graphs show a larger percentage of the population below the LML. It is imperative to point out that the Transport Rule graphics represented mortality impacts attributable to the Transport Rule, whereas these graphics represent exposure. Mortality impacts are the result of the incremental change in exposure between the baseline and control. However, the baseline population exposure at lower air quality levels is so much larger than the impacts among these same populations. In other words, the population exposed to lower $PM_{2.5}$ levels are not receiving very much of the air quality benefit between the base and the control case.

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