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AMERICAN LUNG ASSOCIATION.

Comments of the American Lung Association on

EPA's OAQPS Staff Paper – First Draft, on the Review of the National Ambient Air Quality Standards (NAAQS) for Particulate Matter (PM): Policy Assessment of Scientific and Technical Information, August 2003

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The American Lung Association appreciates this opportunity to comment on EPA's first draft Staff Paper on the review of the PM NAAQS. We commend the Agency for providing an early opportunity for public review and comment on their presentation of the science, on the initial policy recommendations, and on additional analyses that should be performed to clarify issues.

We believe EPA staff have done an excellent job in the synthesis and interpretation of the scientific database on the health effects of particulate air pollution. The conclusions of the CD and Staff Paper are well within the mainstream of scientific opinion.

The weight of the scientific evidence from hundreds of scientific studies clearly supports strengthening the air quality standards for fine particles as recommended by EPA staff scientists.

An extensive, federally funded research program has generated literally thousands of new scientific publications on the health effects of fine particles since the 1997 review. A million dollar independent audit, replication, and reanalysis of the major long-term studies (the Harvard Six Cities Study and the American Cancer Society (ACS) Cohort Study) reconfirmed the results of the original studies reporting a link between fine particle air pollution and premature death, when controlling for other risk factors. The ACS study was recently enlarged and extended, further substantiating the air pollution – morality relationship. An important analysis of short-term study mortality based on the Harvard Six City data was also re-analyzed and replicated.

Hundreds of new peer-reviewed studies have reported associations between particle pollution and declines in lung function, respiratory symptoms, school absenteeism, increased use of asthma medications, emergency room visits, hospitalizations, strokes, low birth weight babies, infant mortality and premature death in cities across North America and throughout the world. The National Morbidity, Mortality and Air Pollution Study, designed very conservatively to address earlier criticisms, found mortality and hospitalizations for the elderly increased in association with daily increases in PM_{10} air pollution. Our understanding of potential toxicological mechanisms, including possible cardiovascular effects of air pollution has increased dramatically. Over three dozen "time series" studies of short-term effects were recently re-analyzed to address a statistical glitch and their major conclusions were unchanged.

Children, the elderly, and those with pre-existing heart disease, lung disease, and diabetes have emerged as those at greatest risk.

The Clean Air Act requires EPA to establish National Ambient Air Quality Standards (NAAQS) for common air pollutants at levels that will "protect public health with an adequate margin of safety."

Overwhelming evidence of adverse health effect means that EPA must act to protect public health.

In preparing the next draft of the Staff Paper, CASAC and EPA should preserve and strengthen the policy options that have been laid out in the draft Staff Paper.

We support establishment of separate standards for fine and coarse particles, in line with the rationale laid out in the draft staff paper. We believe the health evidence justifies stringent annual average and 24-hour standards for both fine and coarse particles. Our specific comments on each of the standards follows.

Annual average $PM_{2.5}$ standard. *EPA has proposed to retain an annual average $PM_{2.5}$ standard, and has suggested a range from the current standard of 15 µg/m^3 down to 12 µg/m^3. The staff has questioned the appropriateness of "spatial averaging." This standard is intended to protect against short-term as well as long-term exposure to fine particles.*

An annual average standard is an appropriate averaging time for a fine particle standard in light of the long-term cohort studies showing chronic effects, and the mean concentrations observed in the short-term studies.

The Lung Association agrees that the upper end of the range should be no higher than 15 µg/m^3, the level of the current annual average standard. The well-substantiated long-term studies clearly demonstrate increased risk of premature death at levels well below 15 µg/m^3, and even lower than 12, the lower end of EPA's proposed range**.** A tighter standard is appropriate. The upper end of the range should not be raised.

Each microgram that EPA lowers the annual average standard will save thousands of lives each year and avert tens of thousands of illnesses. From a public health perspective, the highest priority must be paid to strengthening the annual average fine particle standard.

We are pleased that EPA has proposed a range that contemplates tightening the annual average standard, down to the level of 12 µg/m^3, the level of California's recently promulgated $PM_{2.5}$ annual average standard. We believe the range should extend below 12**,** to ensure that the standards incorporate an adequate margin of safety, particularly given that increased mortality is present down to the lowest levels studied in the ACS and Six Cities Studies (9 µg/m^3 in the ACS cohort study, and 11 µg/m^3 in the Six Cities

Study). These mortality studies are bolstered by morbidity studies that lend coherence and consistency to the epidemiologic findings. Newly available short-term studies link $PM_{2.5}$ to mortality from cardiovascular and respiratory causes, hospital admissions, emergency room visits for asthma, doctor visits, and respiratory illness, symptoms, and reductions in lung function at levels well below the current annual average standard. The long-term mean 24-hour $PM_{2.5}$ concentrations range from 14 $\mu g/m^3$ down to 8.5 $\mu g/m^3$, lending further support for a range than extends below 12 $\mu g/m^3$. **In short, the lower end of the range should extend down to 10 $\mu g/m^3$, and there is no justification whatsoever for increasing the upper end of the proposed range**.

EPA's risk analysis should examine the potential health benefits of standard levels below the lower end of the proposed range, to better inform the question of the adequacy of the proposed range.

We are pleased that EPA is reconsidering the appropriateness of spatial averaging. We are concerned that spatial averaging as currently structured provides a potential loophole that states could use to avoid designating areas as nonattainment, by averaging out high concentration monitors with other monitors that are below the standards. There are few safeguards that would prevent states from taking undue advantage of this loophole. "Averaging out" high concentrations of fine particles would leave the people who live in the near the monitors that record the highest concentrations unprotected. In the past, concentrations above the level of the standard at any monitor were sufficient to trigger nonattainment designation, and we found no justification to deviate from this practice when EPA adopted the fine particle standards in 1997. **Spatial averaging should be rejected.**

24-hour $PM_{2.5}$ standard. *EPA has proposed to retain a 24-hour standard for $PM_{2.5}$, with a range of 50 to 30 $\mu g/m^3$, below the current standard of 65 $\mu g/m^3$. EPA says that a 24-hour standard is justified to limit the occurrence of peak concentrations. However, EPA has proposed to retain the 98^{th} percentile form of the standard.*

PM is a pollutant that often occurs in short bursts, due to transient increases in pollution or daily traffic patterns. Exposure to these high, shorter- term levels has been found to result in serious health effects, even when the annual average is within standards.

Dozens of studies have reported associations between daily increases in $PM_{2.5}$ and total mortality, cardiovascular mortality, respiratory mortality, hospital admissions for cardiovascular causes, respiratory causes, COPD, and asthma, and with respiratory symptoms. The vast majority of these studies reported effects at levels well below the current 24-hour standard. This led EPA to establish an Air Quality Index warning level at 40.5 $\mu g/m^3$, well below the level of the current 24-hour standard.

A tighter 24-hour $PM_{2.5}$ standard is clearly justified to protect against short-term spikes in fine particle pollution. CASAC should not allow a weakening of the proposed range. The annual average standards, at their current level, and even at the lower end of EPA's proposed range, are not sufficient to prevent exposures to high daily concentrations of $PM_{2.5}$ in the range that are known to cause adverse effects. This is

because high daily concentrations on the order of (25-90 $\mu g/m^3$) can still occur, even when attaining the annual average standard.

A more stringent annual average standard would lower this distribution somewhat but concentrations greater than 25 $\mu g/m^3$, and even 40 $\mu g/m^3$, would still be commonplace in many areas, affecting the health of millions of people. Furthermore, an annual average standard alone may not lead to the development of control strategies for seasonal source categories such as agricultural burning or residential wood combustion that are likely to contribute to high daily concentrations.

If EPA selects a 24-hour standard at the upper end of the proposed range, it will have the appearance of tightening the standard without providing substantial additional public health protection. Only a few additional counties (2 percent) are unlikely to meet the combined annual and 24-hour standard of 15/50 $\mu g/m^3$, compared to a standard of 15/65 $\mu g/m^3$, or even a 15 $\mu g/m^3$ annual standard alone. The upper end of the range is too high.

Not only does the upper end not provide the required protection of public health, the lower end of the proposed range is too high to provide a margin of safety for susceptible people such as children, the elderly, and those with pre-existing respiratory and heart conditions. **The Lung Association believes the lower end of the range must extend at least down to 25 $\mu g/m^3$**, the level of the 24-hour $PM_{2.5}$ standard proposed by the State of California in 2002. This level was derived by examining the distributions of $PM_{2.5}$ in the daily mortality studies, and providing an additional margin of safety. It is significant that California proposed a "not to be exceeded" form for their 24-hour standard.

The 98th percentile form of the standard ignores too many exceedance days. EPA must explore alternative forms of the 24-hour standard. Alternative forms might include the single exceedance form, the fourth highest concentration over 4 years, and the 99th percentile form. If the purpose of the 24-hour standard is to prevent exposure to high daily concentration, a form of the standard that allows multiple exceedances – more than 21 exceedance days over a three-year period – cannot possibly fulfill its objective. The selection of the 98th percentile form is arbitrary, particularly given that the standard is based on three years of monitoring data, and that we are increasingly moving toward continuous monitoring.

If the intent of the 24-hour standard is to protect the public against short-term peaks, then a standard that permits 21 days of unlimited levels of air pollution fails to protect the public against those peaks. More critically, if one day of bad air is sufficient to sicken or even kill, why should any community have to endure multiple days of deadly air before regulatory action is triggered, particularly if the intent of the short-term standard is to protect against these kind of events?

The public should not have to suffer through multiple spikes of potentially deadly air because of a faulty standard that was ostensibly intended to protect them from that very thing.

Additional analysis of the form of the standard is needed. We would like to see EPA perform a more rigorous analysis of 24-hour concentrations. How many areas where monitors attain the annual average standard do 24-hour readings exceed 25 $\mu g/m^3$? How many days each year do such excursions occur and how high do concentrations get? How many people are affected and what are the increased risks to public health? EPA's analysis of these questions should be based on data from federal reference monitors as well as continuous monitors. In particular, additional analysis of the monitoring data is needed to better understand the geographic extent and public health considerations of the 98th percentile form of the standards.

Annual Average $PM_{10-2.5}$ Standard. *EPA has proposed to establish a new standard for "coarse particles," defined as PM_{10} minus $PM_{2.5}$, with a range for the annual average standard from 30 down to 13 $\mu g/m^3$. EPA is suggesting that the appropriateness of spatial averaging needs to be explored for the coarse particle standard. EPA is also suggesting that an annual average standard may be unnecessary, and that at 24-hour standard may be sufficient.*

The Lung Association agrees that there should be a separate set of coarse particle standards, and that fine and coarse particles represent distinct pollutants. There are a growing number of new studies estimating morbidity and mortality risks associated with increases in $PM_{10-2.5}$. Almost all are positive, and a number statistically significant. Importantly, a recent study reported reductions in lung function growth associated with long-term exposure to coarse as well as fine particles. A distinct coarse particle standard is clearly justified.

The Lung Association believes an annual average form of the $PM_{10-2.5}$ standard is warranted, to protect against long-term average concentrations. We note that in its 2002 review of the PM standards, the State of California strengthened its annual average PM_{10} standard from 30 $\mu g/m^3$, down to 20 $\mu g/m^3$, in an effort to limit long-term exposures to coarse particles. A short-term standard alone cannot protect against chronic effects reported in the literature.

The upper end of the proposed range is too high. The upper end of the proposed range is equivalent to a PM_{10} standard of 60-75 $\mu g/m^3$ (assuming that coarse particles represents 40-50 percent of PM_{10}, depending on the region of the country), well above the current level of the PM_{10} annual average standard of 50 $\mu g/m^3$. This seems unreasonable in light of the weight of evidence on the adverse effects of PM_{10} accumulated since the standards were set in 1987.

In a similar vein, the lower end of the range should be lowered. The 2002 California annual average PM_{10} standard of 20 $\mu g/m^3$ is equivalent to a $PM_{10-2.5}$ standard of about 10 $\mu g/m^3$. This suggests that EPA should consider extending the lower end of their proposed range downward somewhat.

As we argued for fine particles, the Lung Association believes that spatial averaging lets hot spots off the hook, and decreases the likelihood that the health of the public is protected. **We oppose spatial averaging for coarse particles.**

As with fine particles, the risk analysis needs to explore health impacts below the lower end of the proposed range, to assess the adequacy of the range to protect public health.

24-Hour $PM_{10-2.5}$ Standard. *EPA has proposed to establish a 24-hour coarse particle standard within the range of 75 to 30 µg/m^3, with a 98th percentile form.*

The Lung Association supports a 24-hour coarse particle standard, but the upper end of the range is too high and the bottom of the range should be lowered. A number of short-term studies have reported statistically significant associations of coarse particles with hospital admissions, respiratory effects, and mortality, at levels ranging from 33 µg/m^3 down to about 11 µg/m^3. This suggests that both the upper and lower ends of the proposed range are too high to protect against these effects. We further note that the upper end of the range is roughly equivalent to the current PM_{10} standard of 150 µg/m^3, (60-75 µg/m^3 $PM_{10-2.5}$ equivalent depending on assumptions), indicating a very weak standard. By comparison, the California 24-hour PM10 standard is 50 µg/m^3, equivalent to a $PM_{10-2.5}$ standard of 20-25 µg/m^3, below the level of the proposed ranges.

In addition**, the 98th percentile form of the standard allows too many high pollution days**, as we explained for fine particles. EPA should consider alternative forms of the standard that allow fewer exceedance days.

The Lung Association agrees with EPA that the health evidence justifies setting a separate standard for coarse particles. We strongly support setting both an annual average and a 24-hour average standard.

If coarse particles comprise 40-50 percent of PM_{10}, it appears that the upper end of the proposed range for the annual average standard is equivalent to a PM_{10} concentration of 60-75 µg/m^3, well above the current annual average PM_{10} standard. This endpoint is unjustifiably high in light of the wealth of evidence on adverse effects of PM_{10}.

Similarly, for the 24-hour coarse particle standard, the upper end of the proposed range is too high as compared to the current PM_{10} standard. We believe the short-term studies reporting associations of coarse particles with hospital admissions, respiratory effects and mortality at concentrations ranging from 33 µg/m^3 down to 11 µg/m^3 suggest that both the upper and lower end of the range are too high to protect against these effects.

In summary, we believe the draft Staff Paper provides a strong rationale for strengthening both the annual average and the 24-hour fine particle standards. EPA needs to consider lowering the bottom end of the ranges to ensure that a margin of safety is given sufficient consideration. Further, EPA needs to consider alternative forms of the standard that do not allow for so many exceedance days to occur. We further support establishment of

long- and short-term coarse particle standards, albeit with more stringent ranges than proposed.

Additional Analyses. In preparation for the next draft of the Staff Paper, we would like to see additional analyses done to inform the decision-making process. Specifically:

1. Health risk analysis of levels below the proposed ranges.

There is no way to evaluate the adequacy of the ranges without looking at the health implications of levels below the proposed range.

2. Analysis of alternative forms of the 24-hour standard, such as the single exceedance form, the 4th highest concentration over three years, and the 99th percentile form.

EPA has not provided justification for its selection of the 98th percentile form of the 24-hour standards. Alternative forms of the standard would be more effective at meeting the stated goal of the short-term standard – to prevent exposure to short term spikes that are not prevented by the annual average standard.

3. Analysis of specific health implications of the 98th percentile form.

In how many areas where monitors attain the annual average standard do readings exceed 25µg/m^3? How many days each year do such excursions occur and how high do concentrations get? How many people are affected and what are the increased risks to public health?

4. Analysis of the spatial averaging issue.

How many more people would be protected if the spatial averaging loophole is eliminated?

Risk Assessment. We note that the sensitivity analysis explores the impacts of seven alternative assumptions, but six of the seven models examined results in lower risk estimates than the base case. This reflects a lack of balance in the selection on alternative cases to analyze. A more balanced approach would examine other cases for the sensitivity analysis – for example use of risk functions from the Harvard Six Cities Study, and assessment of health risks down to background concentrations – that might indicate increased risks over the base case.

We believe it would be extremely inappropriate to adopt any of the weakening assumptions explored in the sensitivity analysis as part of the base case for the next round of analysis.

In summary, we believe the first draft Staff Paper provides a sound interpretation of the recent science on the adverse health effects of PM, and presents appropriate, well-

justified rationales for the proposed ranges. The Lung Association believes that tighter ranges and alternative forms of the standard as discussed above are well justified, and that no weakening of the ranges should be entertained at this time.