

Children's Health Protection Advisory Committee

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September 10, 2012

Lisa P. Jackson, Administrator
United States Environmental Protection Agency
1200 Pennsylvania Ave, NW
Washington, DC 20460

RE: National Ambient Air Quality Proposed Standards

Dear Administrator Jackson,

Thank you for your continued commitment to children's health. We appreciate the opportunity to comment on the recently proposed new National Ambient Air Quality Standards (NAAQS) for PM_{2.5}.

The Environmental Protection Agency (EPA) *Proposal to Revise the Air Quality Standards for Particle Pollution (Particulate Matter)* released on June 14, 2012 would decrease the annual primary standard for fine particles (PM_{2.5}) to within the range of 12 µg/m³ to 13 µg/m³. The Children's Health Protection Advisory Committee (CHPAC) has been briefed on the history of rule making for the NAAQS PM standards, the Clean Air Scientific Advisory Committee (CASAC) review, and other background documents relating to the proposed standards. The CHPAC includes representatives with a variety of perspectives and backgrounds in children's environmental health. Based on this expertise, CHPAC submits the following comments on the proposed standards.

The standards address a range of topics including exposures to coarse particles, air quality, monitoring, and short term standards. This letter focuses on the recommendation of an appropriate annual standard for PM_{2.5} because it is one of the most important decisions affecting children's health. We commend EPA for the thorough review and discussion of the scientific literature about effects of particulate matter on health reflected in the Integrated Science Assessment. Despite this review, CHPAC is concerned that children's health may not have been sufficiently addressed in the rule making process. This letter presents our comments on the following topics: the range of proposed standards; how available knowledge about effects during early life stages are incorporated and evaluated in the review; and the lack of a charge statement to the CASAC that specifically focused on children's health impacts. In this letter, we discuss these points and make recommendations regarding consideration of children's health when creating regulatory standards.

I. Consideration of the Full Range of PM_{2.5} Standards Recommended by the CASAC and EPA Staff

We are concerned that the proposed rule does not include the full range of concentrations identified by the CASAC and EPA staff as being supported by current scientific knowledge. The CASAC recommended a range of 11 to 13 $\mu\text{g}/\text{m}^3$. In the September 10, 2010 letter to the Administrator, the CASAC concluded that there is no evidence of a threshold for response to PM_{2.5} and there is scientific evidence supporting consideration of the range from 11 to 13 $\mu\text{g}/\text{m}^3$ for the annual standard, which was included in the EPA staff recommendation. While there is no recognized threshold for children's health impacts from PM_{2.5} exposure, CHPAC believes an annual health standard of a range down to 11 $\mu\text{g}/\text{m}^3$ is an improvement over the current regulations and would further protect children's health. CHPAC recommends that you adopt the standard of 11 $\mu\text{g}/\text{m}^3$, a conclusion that is supported by the EPA science assessment and CASAC review.

II. Incorporating Children's Specific Health Impacts in Scientific Evaluation

We commend the EPA Science Assessment and the CASAC review for recognizing and citing the impacts of PM_{2.5} on children's health. While we sincerely appreciate the scientific review, we draw your attention to the lifelong consequences on lung structure and function that may result from fetal and early life exposures to PM_{2.5}. We have mentioned previously, and as you certainly are very well aware, children are very different than adults in regard to the health effects that can occur with fine particulate matter exposure. For instance, the narrower airways of infants and children tend to increase particle deposition in the lung relative to adults. Given that the lungs undergo significant structural and maturational changes during the first six years of life, and continue to mature through adolescence, we are particularly concerned about the significance of prenatal and early life PM_{2.5} exposures on lung development. Such exposures have the potential to affect the overall growth and function of the respiratory system in infants and children, effects that can persist into adulthood and affect the risk for developing adult lung disease. As documented in the EPA Science Assessment, there is consistent evidence that PM_{2.5} contributes to morbidity in children at current ambient concentrations. Exposure at different stages of childhood may result in different disease presentations depending on the stage of maturation of the lung. Given the impacts on children's lung development and potential for long term health impacts, CHPAC recommends that EPA thoroughly analyze effects on lung development from early life exposure to PM_{2.5} and consider framing and supporting additional research in this area.

III. Consideration of Children's Health in the Rule Making Process

During the process of establishing NAAQS for PM_{2.5}, EPA was informed that studies of children's health and exposure needed to be addressed more fully. The EPA policy review noted that the courts responded to concerns raised in 2006 about the annual PM_{2.5} standard of 15 $\mu\text{g}/\text{m}^3$ given the findings of children's respiratory morbidity studies. The courts consequently stated that EPA was unreasonably confident that the standard was protective. Current EPA documents, including the policy review, cite children's health studies and identify children as a group particularly sensitive to PM_{2.5}. Since children's health has been a specific concern to those involved in evaluating PM_{2.5}, CHPAC expects EPA to describe the extent to which children are protected at the lower and upper proposed standards and how such health concerns might be used to select a value for risk management.

We are concerned that the manner in which current reviews are structured will tend to put greater weight on adult effects and ask you to consider other ways to assess evidence for the standard-setting process. CHPAC urges EPA to place the same weight on studies examining impacts on children's health as that of adult studies. For example, in the EPA Policy Assessment for the Review of the Particulate Matter NAAQS, EPA cites numerous children's studies, but when translating the epidemiologic scientific evidence to create the now proposed standards, it models and extrapolates based on data from four adult studies (Figure 2-8). CHPAC recommends that EPA also model and extrapolate based on data from children's health studies to better inform standards that would protect both children and adults from adverse health outcomes. CHPAC recommends that this be done as an integral part of the risk analysis even if there is stronger evidence from adult studies. For example, EPA could have used the children's health studies cited in Figure 2-8 to further model and extrapolate to obtain concentrations that would be protective of children's health. The fact that there may be stronger evidence from adult studies does not mean that standards based on adult studies will be protective for children and consequently will meet the standard requisite to protect public health with an adequate margin of safety.

Moreover, CHPAC believes that the process would be strengthened if EPA would explicitly seek review and advice on the extent to which EPA has appropriately incorporated and addressed children's health concerns in recommending a specific PM_{2.5} standard. The NAAQS are unique among all EPA standards because they have a statutorily mandated scientific body, the CASAC, constituted to provide advice to the Administrator. In doing so, the CASAC has focused on the charge questions provided by the agency. However, EPA's charge to the CASAC did not specifically mention children's health, nor did it identify concerns raised by the courts. In addition, the charge in Section 2.3.3.1 asked about multiple different susceptible populations, but did not address the potential linkages between childhood health impacts and subsequent disease development. The CHPAC applauds you for making children's health a priority of your administration, and we urge you to include the following points in all future charges to each CASAC: 1) An explicit review and explanation of the approach to assessing impacts on children in the development of the scientific and policy documents throughout the process, and 2) To consider whether there are early life exposures and effects that may warrant a different standard from that which would be proposed based on studies of adult exposures.

IV. Conclusions and Recommendations

Children are a vulnerable population, due to unique sensitivities during early lifestages to PM_{2.5} exposures. While far more studies assess adult morbidity and mortality due to PM_{2.5} exposures, many epidemiologic studies report that exposures in childhood can significantly affect morbidity and subsequent respiratory health in adulthood. Therefore, when creating regulatory standards, children's health impacts due to PM_{2.5} exposure deserve individualized and focused attention. In order to appropriately incorporate children's health into the rule making process, CHPAC recommends the following:

1. EPA consider the full range identified as scientifically justified by the CASAC and EPA staff, specifically 11 to 13 µg/m³;
2. EPA adopt the low end of this range, 11 µg/m³; to best protect children's health;

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For future standards, CHPAC recommends that

3. EPA analyze the health effects of concern for children and the concentrations that would be requisite to protect public health for children with an adequate margin of safety, even if there is stronger evidence for adults;
4. EPA consistently charge appropriate scientific review committees to weigh, balance, and integrate children's environmental health into the decision making process to set regulatory standards.

Thank you for your consideration of our recommendations and suggestions.

Sincerely,



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CHPAC, Co-Chair



Pamela Shubat, Ph.D.
CHPAC, Co-Chair

cc: Gina McCarthy, Assistant Administrator, Office of Air and Radiation
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