



Plan for Review of the National Ambient Air Quality Standards for Lead

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February 2006

DISCLAIMER

This plan for the review of the national ambient air quality standards (NAAQS) for lead (Pb) is an informational document that summarizes background information on EPA's NAAQS review process and the schedule for the ongoing review of the Pb NAAQS. This document also includes staff views as to the planned organization and content of a key document, the *Lead Staff Paper* that will be prepared by OAQPS staff as part of this review. As such, some elements of this plan may be modified to reflect information developed during this review and to address advice and comments received from the Clean Air Scientific Advisory Committee and the public throughout this review.

Table of Contents

1	INTRODUCTION	1
1.1	Overview of Review Process	1
1.2	Scope of Pb NAAQS Review Plan	3
1.3	Summary of Past Pb NAAQS Reviews	3
2	LEAD NAAQS REVIEW SCHEDULE AND STATUS	4
3	LEAD STAFF PAPER DEVELOPMENT	6
3.1	Organization and Content	6
3.2	Air Quality Characterization and Analyses	7
3.3	Lead-Related Health Effects and Primary Standards	7
3.3.1	Policy-Relevant Assessment of Health Effects Evidence.....	7
3.3.2	Human Exposure Analysis.....	8
3.3.3	Human Health Risk Assessment.....	9
3.3.4	Approach to Staff Review of Primary Standards.....	10
3.4	Lead-Related Environmental Effects and Secondary Standards	11
3.4.1	Policy-Relevant Assessment of Lead Environmental Impacts	11
3.4.2	Environmental Effects Analysis	12
3.4.3	Approach to Staff Review of Secondary Standards.....	12
	REFERENCES	14

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1 INTRODUCTION

The U.S. Environmental Protection Agency (EPA) is presently conducting a review of the national ambient air quality standards (NAAQS) for lead (Pb). This plan for the Pb NAAQS review presents the schedule for key milestones in this review, and provides background information on the NAAQS review process, a brief summary of past Pb NAAQS reviews, and the status of current review activities. This document also focuses on the development of a key document in the review process, the *Lead Staff Paper: Policy Assessment of Scientific and Technical Information in the Review of the Lead NAAQS* (Pb Staff Paper), and discusses the planned organization and content of that document. As such, this plan is intended to serve as an informational document to help interested parties understand the status and plans for EPA's ongoing Pb NAAQS review.

1.1 Overview of Review Process

Sections 108 and 109 of the Clean Air Act (Act) govern the establishment and periodic review of the NAAQS. These standards are established for pollutants that may reasonably be anticipated to endanger public health and welfare, and whose presence in the ambient air results from numerous or diverse mobile or stationary sources. The NAAQS are to be based on air quality criteria, which are to accurately reflect the latest scientific knowledge useful in indicating the kind and extent of identifiable effects on public health or welfare which may be expected from the presence of the pollutant in ambient air.¹ The EPA Administrator is to promulgate and periodically review, at five-year intervals, "primary" (health-based) and "secondary" (welfare-based) NAAQS for such pollutants. Section 109(b)(1) of the Act defines a primary standard as one "the attainment and maintenance of which in the judgment of the Administrator, based on such criteria and allowing an adequate margin of safety, are requisite to protect the public health." Section 109(b)(2) of the Act directs that a secondary standard is to "specify a level of air quality the attainment and maintenance of which, in the judgment of the Administrator, based on such criteria, is requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of [the] pollutant in the ambient air."²

Based on periodic reviews of the air quality criteria and standards, the Administrator is to make revisions in the criteria and standards and promulgate any new standards, as may be appropriate. The Act also requires that an independent scientific review committee advise the

¹ The cost of attaining the NAAQS is not to be taken into account in setting the standards, but rather is considered in the development of control strategies designed to implement the standards.

² Welfare effects, as defined in section 302(h) of the Act include, but are not limited to, "effects on soils, water, crops, vegetation, man-made materials, animals, wildlife, weather, visibility and climate, damage to and deterioration of property, and hazards to transportation, as well as effects on economic values and on personal comfort and well-being."

Administrator on the criteria and standards as part of this NAAQS review process. Since the early 1980's, this independent review function has been performed by the Clean Air Scientific Advisory Committee (CASAC), a standing committee of EPA's Science Advisory Board.

The process generally used by EPA for conducting periodic reviews of the criteria and NAAQS for a given pollutant includes the preparation of two key documents, an Air Quality Criteria Document (AQCD) and a Staff Paper, followed by the proposal and promulgation of decisions as to whether to retain or revise the existing standards. The AQCD, prepared by EPA's National Center for Environmental Assessment in Research Triangle Park (NCEA-RTP) within the Office of Research and Development (ORD), provides a critical assessment of the latest available scientific information upon which the NAAQS are to be based. Drawing upon the AQCD, staff in EPA's Office of Air Quality Planning and Standards (OAQPS) within the Office of Air and Radiation (OAR) prepares a Staff Paper that evaluates policy implications of the key studies and scientific information contained in the AQCD and presents the conclusions and recommendations of the staff for standard-setting options for the EPA Administrator to consider. The Staff Paper is intended to help "bridge the gap" between the scientific assessments contained in the AQCD and the judgments required of the Administrator in determining whether it is appropriate to retain or to revise the primary and secondary NAAQS. In conjunction with the Staff Paper, OAQPS staff conducts various policy-relevant assessments of air quality data and health and/or environmental effects to help inform staff's conclusions and recommendations. Drafts of the AQCD and the Staff Paper and related assessments are made available for public comment and CASAC review. The final versions of these documents incorporate changes made in response to CASAC advice and recommendations and public comments.

Based on the information in these documents, the Administrator proposes decisions on whether to retain or revise the NAAQS, taking into account CASAC advice and recommendations and public comments. The Administrator's proposed decisions are published in the *Federal Register*, with a preamble that presents the rationale for the decisions and solicits public comment. The Administrator makes final decisions after considering comments received on the proposed decisions. The Administrator's final decisions are promulgated in a *Federal Register* notice that addresses significant comments received on the proposal.

NAAQS decisions involve consideration of the four basic elements of a standard: indicator, averaging time, form, and level. The indicator defines the pollutant to be measured in the ambient air for the purpose of determining compliance with the standard. The averaging time defines the time period over which air quality measurements are to be obtained and averaged, considering evidence of effects associated with various time periods of exposure. The form of a standard defines the air quality statistic that is to be compared to the level of the standard (i.e., an ambient concentration of the indicator pollutant) in determining whether an area attains the standard. The form of the standard specifies the air quality measurements that are to be used for compliance purposes (e.g., the mean average over 90 days), the monitors from which the measurements are to be obtained (e.g., one or more population-oriented monitors in an area), and whether the statistic is to be averaged across multiple years. These basic elements of a standard are the primary focus of the staff conclusions and recommendations in the Staff Paper and in the subsequent rulemaking. These four elements taken together determine the degree of public health and welfare protection afforded by the NAAQS.

1.2 Scope of Pb NAAQS Review Plan

The review of the Pb criteria was initiated in November 2004 by NCEA-RTP with a general call for information published in the *Federal Register*. In January 2005, NCEA-RTP released a work plan for the review and revision of the Pb AQCD (EPA, 1986a) and its corresponding addendum (EPA, 1986b) and supplement (EPA, 1990). This Pb NAAQS review plan is intended to update and go beyond the scope of the earlier Pb AQCD work plan. That work plan focused on key issues to be addressed in the preparation of a revised Pb AQCD, the organization and content of the revised AQCD, and the schedule for its preparation.

Beyond updating the status for the preparation of the Pb AQCD, this plan addresses the preparation of a Pb Staff Paper and the subsequent rule making. Following a brief summary of past Pb NAAQS reviews, this plan presents an updated schedule for key milestones through completion of the Pb NAAQS review and the status of current review activities. The remainder of this plan then focuses on the development of the Pb Staff Paper and related health and environmental assessments. The planned organization and content of the Pb Staff Paper are outlined; key policy-relevant issues are identified; plans for preparing health and environmental assessments of scientific and technical information contained in the Pb AQCD are briefly summarized; and general approaches are discussed for drawing upon the available evidence and assessments to develop staff recommendations on whether, and if so, how, it may be appropriate to revise the primary and secondary Pb NAAQS.

Since this plan is being prepared prior to completion of the Pb AQCD, it anticipates various issues that might emerge during the review of that document and allows for various approaches that might be appropriate for the health and environmental assessments planned in conjunction with the preparation of the Pb Staff Paper. Thus, this plan represents current staff views and may be modified to reflect information developed during this review and to address advice and recommendations received from the CASAC and public comments.

1.3 Summary of Past Pb NAAQS Reviews

On October 5, 1978 the EPA promulgated primary and secondary NAAQS for lead under section 109 of the Act (43 FR 46246). Both primary and secondary standards were set at a level of $1.5 \mu\text{g}/\text{m}^3$ as a quarterly average (maximum arithmetic mean averaged over a calendar quarter). This standard was based on the 1977 Pb AQCD (USEPA, 1977).

In 1986, the first periodic review of the Pb air quality criteria and standards was undertaken with the development of the 1986 AQCD (USEPA, 1986a) and Addendum to the 1986 AQCD (USEPA, 1986b). In 1990 a supplement to the 1986 AQCD/Addendum was published (USEPA, 1990). Based on information contained in the AQCD documents, an OAQPS Staff Paper (USEPA, 1990) and Exposure Assessment (USEPA, 1989) were prepared. Following the completion of these documents, the agency did not propose any revisions to the 1978 Pb NAAQS.

2 LEAD NAAQS REVIEW SCHEDULE AND STATUS

Key milestones in the ongoing Pb criteria and standards review are summarized below in Table 1. This schedule is consistent with the decision made by the U.S. District Court, Eastern District of Missouri, Eastern Division that ordered completion of this lead review by September 1, 2008 (Missouri Coalition for the Environment v. EPA, Civil Action No. 4:04-CV-00660 (ERW) (E.D. Mo. Sept. 14, 2005)). The court-ordered schedule requires EPA to complete the initial draft of the AQCD no later than December 1, 2005; finalize the AQCD no later than October 1, 2006; prepare an initial draft of the SP no later than January 1, 2007; finalize the SP no later than November 1, 2007; have the proposed rulemaking notice signed no later than May 1, 2008; and have a final rulemaking concerning any revisions to the lead NAAQS signed no later than September 1, 2008. In order to meet this schedule for final rulemaking, EPA has advanced the target dates for some of these milestones. The schedule below represents EPA's best judgment of the target dates necessary for meeting the court-ordered deadlines. Accordingly, EPA intends to adhere closely to this schedule.

As shown in Table 1, EPA initiated this review in November 2004 with a call for information. A work plan for the preparation of the Pb AQCD was released in January 2005 for CASAC and public review and consultation with CASAC on the AQCD work plan occurred in March 2005. EPA also held a series of workshops on several draft chapters of the Pb AQCD to obtain broad input from the relevant scientific communities in August 2005. These workshops on air quality, modeling, risk assessment, and environmental effects helped to focus the preparation of the first draft Pb AQCD. The first draft of the AQCD was released for CASAC and public review December 1, 2005. The CASAC panel will meet on February 28 and March 1, 2006 to conduct a peer review of the first draft Pb AQCD.

Table 1. Key Milestones in the Pb NAAQS Review

Major Milestones	Completed/Future Target Date(s)
Call for Information	November 9, 2004
CASAC Teleconsultation on AQCD Development Plan	March 28, 2005
Peer Review Workshops for AQCD	August 4-5 and 16-19, 2005
First Draft AQCD for CASAC and Public Comment	December 1, 2005
CASAC Meeting on First Draft AQCD	February 28 and March 1, 2006
Plan for Human Health and Ecological Risk Assessments for CASAC and Public Comment	Late April 2006
CASAC Consultation on Plan for Human Health and Ecological Risk Assessments	Late May 2006
Second Draft AQCD for CASAC and Public Comment	Late May 2006
CASAC Meeting on Second Draft AQCD	July 2006
Complete Final AQCD	October 1, 2006
First Draft SP and First Draft Human Health and Ecological Risk Assessment Reports for CASAC and Public Comment	Late November 2006
CASAC Meeting on First Draft SP and First Draft Human Health and Ecological Risk Assessment Reports	Late January 2007
Second Draft SP and Second Draft Human Health and Ecological Risk Assessment Reports for CASAC and Public Comment	Mid-June 2007
CASAC Meeting on Second Draft SP and Second Draft Human Health and Ecological Risk Assessment Reports	Late July 2007
Complete Final SP and Final Human Health and Ecological Risk Assessment Reports	Late September 2007
Publish Proposal Notice in Federal Register	Late February 2008
Final Promulgation Noticed Signed by Administrator	September 1, 2008

Consistent with the above schedule, OAQPS staff is now preparing plans for the human health and ecological risk assessments. As discussed below, the health-related assessment plan will include discussions of the planned scope and methods to be used in conducting an exposure analysis and health risk assessment. The ecological risk assessment plan will focus on the scope and methods that will be used to conduct analyses of Pb-related environmental impacts. After consulting with the CASAC and considering public comments on these plans, OAQPS staff will conduct the assessments and incorporate initial results into the first draft Pb Staff Paper and accompanying reports. The first draft Pb Staff Paper and first draft assessment reports will be released for CASAC review and public comment after the release of the second draft Pb AQCD, and will be based on information in the second draft Pb AQCD to the extent possible.

3 LEAD STAFF PAPER DEVELOPMENT

3.1 Organization and Content

The policy assessment to be presented in the Pb Staff Paper will be based on staff's evaluation of the policy implications of the scientific evidence contained in the Pb AQCD and the results of qualitative and quantitative analyses. Taken together, this information will inform staff conclusions and recommendations on the elements of the Pb standards under review. While the Pb AQCD focuses on new scientific information available since the last review, it appropriately integrates that information with scientific criteria from previous reviews. The quantitative analyses to be presented in the Pb Staff Paper (and to be described in more detail in a number of technical support documents) are based on the most recently available air quality information, so as to provide current characterizations of Pb air quality patterns and estimated health and welfare effects risks related to exposure to ambient Pb concentrations.

Following an introductory chapter, the Pb Staff Paper will be organized into three main parts: the characterization of ambient Pb air quality data and multimedia issues; Pb-related health effects and primary Pb NAAQS; and Pb-related welfare effects and secondary Pb NAAQS. The content of these parts is summarized here and discussed more fully below.

- The characterization of ambient Pb air quality data and deposition of lead to other media will include information on Pb properties, current Pb air quality patterns, historic trends, and background levels, as well as providing a frame of reference for subsequent discussion of current and alternative Pb NAAQS and alternative forms of Pb standards.
- Health-based information will include an overview of key policy-relevant health effects evidence, major health-related conclusions from the Pb AQCD, and an examination of issues related to the quantitative assessment of evidence from dosimetric, toxicologic, human exposure, and epidemiological studies. Results from the planned health assessment (i.e., an exposure analysis and quantitative risk assessment) will be presented. This part will conclude with a discussion of the adequacy of the current primary standard; staff conclusions as to potential alternative indicators, averaging times, levels, and forms; and staff recommendations on ranges of alternative primary standards for consideration by the Administrator.

- Welfare-based information will include an overview of key policy-relevant welfare effects evidence and major welfare-related conclusions from the Pb AQCD. This part will include a discussion of the adequacy of the current secondary standard; results from any environmental assessments; staff conclusions as to potential alternative indicators, averaging times, levels, and forms; and staff recommendations on ranges of alternative secondary standards for consideration by the Administrator.

3.2 Air Quality Characterization and Analyses

Ambient Pb air quality information, generally based on air quality data available from EPA's Air Quality System database, and information in Chapters 2 and 3 of the Pb AQCD will be presented in Chapter 2. This chapter will summarize the chemical and physical properties of ambient ground-level Pb, including discussions of methods and measurements for Pb concentrations in various environmental and biological media. The multimedia aspects of lead will be also considered. The main sources of anthropogenic lead will be discussed in relation to point source emissions and current lead levels in fuel. Spatial patterns of Pb in the affected areas around important sources of ambient lead (e.g. smelters) as well as causes of re-entrainment of artifact lead (e.g. traffic). Finally, background Pb levels will be characterized, and issues pertaining to anthropogenic versus geologic sources of lead will be discussed.

3.3 Lead-Related Health Effects and Primary Standards

In presenting the staff's review of the primary Pb NAAQS, Chapter 3 will present a policy-relevant assessment of the health effects evidence evaluated in the Pb AQCD. To put this information into a public health perspective, staff plans to conduct a quantitative assessment of public health impacts attributable to Pb, including an exposure analysis and health risk assessment, to be presented in Chapters 4 and 5, respectively. This assessment will provide quantitative estimates of human exposure to ambient Pb and of the risk to public health associated with current Pb levels, with attainment of the current standard, and with attainment of alternative Pb standards. A Health Assessment Plan is being prepared that outlines the scope and methods being considered for use; staff intends to modify this plan, as appropriate, based on input received through a consultation with CASAC and from public comments. The complete assessment will be documented in a Human Health Risk Assessment Report; these technical support documents will include detailed descriptions of the assessment methods and results. Chapter 6 will present staff conclusions and recommendations on the various elements of the primary Pb NAAQS and will also include a summary of key uncertainties and related staff research recommendations.

3.3.1 Policy-Relevant Assessment of Health Effects Evidence

An assessment of key policy-relevant health evidence on the known and potential health effects associated with exposure to ambient Pb (including exposure resulting from transport of ambient-sourced Pb into non-air media such as soil and indoor dust), will be presented in Chapter 3. This chapter will discuss key policy-relevant findings on Pb-related health effects evaluated in Chapters 4 through 6 of the Pb AQCD, placing particular emphasis on the integrative synthesis presented in Chapter 7 of that document. Critical health endpoints

associated with lead exposure, including the role of pre-existing health conditions in increasing the susceptibility of specific populations to lead-related health effects will be discussed. Chapter 3 will also cover the issue of concurrent (exogenous) lead exposure versus artifact (endogenous) exposure in the context of lead exposure and risk assessment.

This assessment will also address a number of key issues relevant to the staff's interpretation and quantitative assessment of available toxicological and epidemiological evidence, so as to provide a foundation for a quantitative exposure analysis and health risk assessment. Such issues include: (a) consideration for the range of exposure metrics used in characterizing lead exposure (e.g., blood serum, total blood, urine, teeth and bone lead concentrations), (b) interpretation and relevance of the wide range of health effects identified in laboratory animal and epidemiological studies, (c) judgments as to the severity of health effects reported in these studies; and (d) interpretation of epidemiological studies reporting associations between adverse health effects and Pb exposure. In considering the epidemiological evidence, additional issues will be addressed, such as: (a) approaches used to evaluate the role of co-pollutants and potential confounding in Pb-effects associations; (b) temporality in associations between lead exposure and health effects (e.g., concurrent versus artifact exposure and identification of critical exposure windows); and (c) questions related to the form of concentration-response relationships with special emphasis on behavior in lower-exposure regions.

3.3.2 Human Exposure Analysis

Characterization of human exposures to ambient Pb (and lead transported from air to non-air media) will be discussed in Chapter 4, drawing from information generally presented in Chapter 3 and 4 of the Pb AQCD. Chapter 4 will include discussion of factors that affect exposure to lead in ambient air and non-air media. The central focus of this chapter will be on the exposure analysis developed to assess lead exposures for different segments of the US population. The exposure analysis will cover exposure scenarios of interest in the lead NAAQS context including key point source scenarios and potentially, the re-entrainment of anthropogenic lead contained in roadway dust with subsequent impacts to adjacent residential areas. Results from each of the exposure scenarios will be placed in the broader national-context by estimating the number of individuals represented by each scenario. Exposure estimates will be used as an input to the risk assessment for health endpoints for which exposure-response functions are available and will provide information on population exposures exceeding levels of concern that may be identified for various other health endpoints.

The exposure analysis will likely use some form of fate/transport modeling to predict lead concentrations in key contact media resulting from air deposition. These media concentrations (including ambient air lead concentrations associated with inhalation) will then be inputted to a biokinetic model to predict lead doses to critical compartments possibly including total blood, serum blood and bone. The development of the overall modeling framework to support exposure analysis will consider key factors including: (a) lead speciation and particle size distribution in the context of air dispersion, deposition and transport in non-air media, (b) temporal precision required to capture important variation in lead exposure (temporal precision will also reflect dose-response data for key health endpoints), (c) the need to model/consider past

(artifact) lead exposure and the resulting endogenous exposure along with concurrent lead exposure, (d) background non-ambient air related lead exposure (e.g., paint and water) and (e) variation in inter-individual and intra-individual behavior related to lead exposures. The issue of model verification will also be discussed specifically from the standpoint of increasing confidence in model predictions made as part of the NAAQS assessment. The complete set of results and a detailed description of the methods used in this risk assessment will be presented in the Health Risk Assessment Report.

3.3.3 Human Health Risk Assessment

The characterization of human health risks attributable to exposure to ambient Pb levels will be presented in Chapter 5, based primarily on controlled human exposure and epidemiological studies evaluated in Chapters 5, 6 and 7 of the Pb AQCD. The human health risk assessment that will be presented in this chapter will be designed to assess population risks for a number of exposure scenarios selected to represent the range of scenarios of potential concern in the lead context. Risk estimates will be generated for public health risks associated with current Pb levels and with attainment of the current Pb standard and potential alternative standards. To the extent possible given data availability and resources, uncertainty and variability related to lead exposure and risk will be characterized. Public health risks associated with health endpoints for which the available evidence is judged to be inadequate to support quantitative risk assessment will be characterized qualitatively.

EPA is considering a variety of options for conducting the lead risk assessment, ranging from identifying the number (or percentage) of individuals falling within specific exposure ranges of concern (i.e., risk bins), to estimating actual health effect increments and their distribution across the study population (e.g., distribution of IQ loss). EPA may also elect to focus the human health risk assessment on the most sensitive endpoints/subpopulations combinations if it is judged that this information will provide an adequate basis for making judgments on whether the current standard or alternative standards will protect public health with an adequate margin of safety.

A number of issues related to the selection and application of appropriate concentration-response functions and critical health effects levels for use in this assessment will need to be addressed including: (a) overall quality of studies including statistical significance and treatment of confounders, (b) consideration for artifact (endogenous) lead exposure reflected in specific exposure metrics such as bone lead, (c) relevance of attributes associated with the epidemiological studies to the risk scenario under evaluation (lead species, pre-existing lead exposures, prevalence of confounding factors in the target study population) and (d) the shape of concentration-response functions in the exposure range of interest. Particular attention will also be given to plans to conduct sensitivity analyses to characterize uncertainties in the assessment and the influence of various assumptions made to conduct the assessment. The complete set of results and a detailed description of the methods used in this risk assessment will be presented in the Health Risk Assessment Report.

3.3.4 Approach to Staff Review of Primary Standards

Chapter 6 will present staff conclusions and recommendations for the Administrator to consider in deciding whether the existing primary Pb standard should be revised and, if so, what options for a revised standard might be appropriate. Staff conclusions and recommendations on the primary standard will be based on the information contained in the Pb AQCD, focusing particularly on the assessment and integrative synthesis of information presented in Chapter 7 of that document, and on the staff evaluations and assessments discussed in the preceding chapters of the Pb Staff Paper.

In recommending a range of primary standard options for the Administrator to consider, it is recognized that the final decision will be largely a public health policy judgment. A final decision must draw upon scientific information and analyses about health effects and risks, as well as judgments about how to deal with the range of uncertainties that are inherent in the scientific evidence and analyses. Staff's approach to informing these judgments is based on a recognition that the available health effects evidence generally reflects a continuum consisting of ambient levels at which scientists generally agree that health effects are likely to occur through lower levels at which the likelihood and magnitude of the response become increasingly uncertain. This approach is consistent with the requirements of the NAAQS provisions of the Act and with how EPA and the courts have historically interpreted the Act. These provisions require the Administrator to establish primary standards that are requisite to protect public health and are neither more nor less stringent than necessary for this purpose. The provisions do not require that primary standards be set at a zero-risk level, but rather at a level that avoids unacceptable risks to public health.

In this review, a series of questions will frame the staff's approach to reaching conclusions and recommendations, based on available evidence and information, as to whether consideration should be given to retaining or revising the current primary Pb NAAQS. The staff's review of the adequacy of the current primary standard begins by considering whether the currently available body of evidence assessed in the Pb AQCD suggests that revision of any of the basic elements of the standard would be appropriate. This evaluation of the adequacy of the current standard will involve addressing questions such as the following:

- To what extent does newly available information reinforce or call into question evidence of associations with effects identified in the last review?
- To what extent does newly available information reinforce or call into question any of the basic elements of the current Pb standard?
- To what extent have important uncertainties identified in the last review been reduced and have new uncertainties emerged?

To the extent that the evidence suggests that revision of the current standard would be appropriate, staff will then consider whether the currently available body of evidence supports consideration of standards that are either more or less protective by addressing the following questions, taking into account multimedia, multipathway exposures:

- Is there evidence that associations, especially likely causal associations, extend to air quality levels that are as low as or lower than had previously been observed, and what are the important uncertainties associated with that evidence?
- Are health risks estimated to occur in areas that meet the current standard; are they important from a public health perspective; and what are the important uncertainties associated with estimated risks?

To the extent that there is support for consideration of revised standards, staff will then identify ranges of standards (in terms of averaging times, levels and forms) that would reflect a range of alternative public health policy judgments, based on the currently available evidence, as to the degree of protection that is requisite to protect public health with an adequate margin of safety. In so doing, staff will address the following questions, taking into account multimedia, multipathway exposures:

- Does the evidence provide support for considering different exposure indices or averaging times?
- What range of levels and forms of alternative standards is supported by the evidence, and what are the uncertainties and limitations in that evidence?
- To what extent do specific levels and forms of alternative standards reduce the estimated risks attributable to Pb, and what are the uncertainties in the estimated risk reductions?

Based on the evidence, estimated risk reductions, and related uncertainties, the staff will then make recommendations as to ranges of alternative standards for the Administrator's consideration in reaching decisions as to whether to retain or revise the primary Pb NAAQS.

3.4 Lead-Related Environmental Effects and Secondary Standards

In presenting staff's review of the secondary Pb NAAQS, Chapter 7 will first discuss key policy-relevant findings on Pb-related welfare effects evaluated in the draft Pb AQCD, including environmental effects on wildlife, vegetation and ecosystems. An Environmental Risk Assessment Plan is being prepared that outlines the scope and methods being considered for use; staff will finalize this plan based on input received through a consultation with CASAC and from public comments. The complete assessment will be documented in an Environmental Risk Assessment Report; this technical support document will include a detailed description of the assessment methods and results. Chapter 8 will present staff conclusions and recommendations on the various elements of the secondary Pb NAAQS, and will also include a summary of key uncertainties and related staff research recommendations.

3.4.1 Policy-Relevant Assessment of Lead Environmental Impacts

An assessment of key policy-relevant evidence on the known and potential environmental effects associated with exposure to ambient Pb, alone and in combination with other pollutants

and stressors that are routinely present in ambient air, will be presented in Chapter 7. This chapter will discuss key policy-relevant findings on Pb-related welfare effects evaluated in Chapters 8 of the Pb AQCD. Consideration will be given to how newly available information changes, if at all, our understandings from the last review of the nature and/or significance of Pb welfare effects and the Pb exposure levels associated with such effects.

3.4.2 Environmental Effects Analysis

Staff is planning an assessment of key policy-relevant information on the known and potential environmental effects associated with ambient Pb exposure. This assessment, to be presented in Chapter 7, will draw upon the most relevant information contained in the Pb AQCD and other significant research evaluated therein and will build upon the limited qualitative assessment performed during the last review.

3.4.3 Approach to Staff Review of Secondary Standards

Staff conclusions and recommendations for the Administrator to consider in deciding whether the existing secondary Pb standard should be revised and, if so, what revised standard would be appropriate will be presented in Chapter 8. Staff conclusions and recommendations on the secondary standard will be based on the information presented in Chapter 8 of the Pb AQCD and on staff analyses and evaluations discussed in the preceding chapters of the Pb Staff Paper.

In recommending a range of secondary standard options for the Administrator to consider, staff recognizes that the final decision will be largely a public policy judgment. A final decision must draw upon scientific evidence and analyses about effects on public welfare, as well as judgments about how to deal with the range of uncertainties that are inherent in the relevant information. This approach is consistent with the requirements of the NAAQS provisions of the Act and with how EPA and the courts have historically interpreted the Act. These provisions require the Administrator to establish secondary standards that are requisite to protect public welfare from any known or anticipated adverse effects associated with the presence of the pollutant in the ambient air. In so doing, the Administrator seeks to establish standards that are neither more nor less stringent than necessary for this purpose. The provisions do not require that secondary standards be set to eliminate all welfare effects, but rather at a level that protects public welfare from those effects that are judged to be adverse.

In this review, a series of questions will frame the staff's approach to reaching conclusions and recommendations, based on available evidence and information, as to whether consideration should be given to retaining or revising the current secondary Pb NAAQS. The staff's review of the adequacy of the current standard begins by considering whether the currently available body of evidence assessed in the Pb AQCD suggests that revision of any of the basic elements of the NAAQS would be appropriate. This evaluation is done for each category of Pb-related welfare effects identified in the Pb AQCD as being associated with the presence of Pb in the ambient air. Staff's review of the adequacy of the current Pb standard for

each effects category involves addressing the following questions, while taking into account multimedia, multipathway exposures:

- To what extent does the available information demonstrate or suggest that Pb-related effects are occurring at current ambient conditions or at levels that would meet the current standard?
- To what extent does the available information inform judgments as to whether any observed or anticipated effects are adverse to public welfare?
- To what extent is the current secondary standard likely to be effective in achieving protection against any identified adverse effects?

To the extent that the evidence suggests that revision of the current secondary Pb NAAQS would be appropriate, the staff then identifies ranges of standards (in terms of exposure indices, averaging times, levels, and forms) that would reflect a range of alternative policy judgments as to the degree of protection that is requisite to protect public welfare from known or anticipated adverse effects. In so doing, the staff addresses the following questions taking into account multimedia, multipathway exposures:

- Does the available information provide support for considering different Pb exposure indices?
- Does the available information provide support for considering different averaging times?
- What range of levels and forms of alternative standards is supported by the information, and what are the uncertainties and limitations in that information?
- To what extent do specific levels and forms of alternative standards reduce adverse impacts attributable to Pb, and what are the uncertainties in the estimated reductions?

Based on the available information, estimated reductions in adverse impacts, and related uncertainties, the staff will make recommendations as to ranges of alternative standards for the Administrator's consideration in reaching decisions as to whether to retain or revise the secondary Pb NAAQS.

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