United States
Environmental
Protection Agency

Project Work Plan for Revised Air Quality Criteria for Lead

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CASAC Review Draft

Project Work Plan for Revised Air Quality Criteria For Lead

National Center for Environment Assessment
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This document is an external draft for review purposes only and does not constitute U.S. Environmental Protection Agency policy. Mention of trade names or commercial products does not constitute endorsement or recommendation for use.

PREFACE

This project work plan has been prepared as a managerial and management information tool for the U.S. Environmental Protection Agency's National Center for Environmental Assessment Division in Research Triangle Park, NC. It may be modified and amended from time to time, as necessary, to reflect actual project requirements and progress. As a result, any proposed schedules and outlines, or any lists of technical coordinator assignments, authors, or reviewers are subject to change.

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I. INTRODUCTION

A. LEGISLATIVE BACKGROUND

Two sections of the Clean Air Act (CAA) govern the establishment, review, and revision of National Ambient Air Quality Standards (NAAQS). Section 108 (42 U.S.C. 7408) directs the Administrator of the U.S. Environmental Protection Agency (EPA) to list certain air pollutants that may be reasonably anticipated to endanger public health or welfare and to issue air quality criteria for them. These air quality criteria (scientific bases for NAAQS) are to reflect the latest scientific information useful in indicating the kind and extent of all identifiable effects on public health or welfare that may be expected from the presence of a given "criteria" pollutant in ambient air.

Section 109(a) of the CAA (42 U.S.C. 7409) directs the Administrator of EPA to propose and promulgate primary and secondary NAAQS for pollutants identified under Section 108. Section 109(b)(1) defines a primary standard as one that, in the judgment of the Administrator, is requisite to protect the public health (see inset) based on the criteria and allowing for an adequate margin of safety. The secondary standard, as defined in Section 109(b)(2), must specify a level of air quality that, in the judgment of the Administrator, is requisite to protect the public welfare (see inset) from any known or anticipated adverse effects associated with the presence of the pollutant in ambient air, based on the criteria.

PUBLIC HEALTH EFFECTS

- Effects on the health of the general population, or identifiable groups within the population, who are exposed to pollutants in ambient air
- Effects on mortality
- Effects on morbidity
- Effects on other health conditions including indicators of:
    - pre-morbid processes,
    - risk factors, and
    - disease

PUBLIC WELFARE EFFECTS

- Effects on personal comfort and well-being
- Effects on economic values
- Deterioration of property
- Hazards to transportation
- Effects on the environment, including:
    - animals
    - climate
    - crops
    - materials
    - soils
    - vegetation
    - visibility
    - water
    - weather
    - wildlife

Section 109(d) of the CAA (42 U.S.C. 7409) requires periodic review and, if appropriate, revision of existing criteria and standards. If, in the Administrator's judgment, the Agency's review and revision of criteria make appropriate the proposal of new or revised standards, such standards are to be revised and promulgated in accordance with Section 109(b). Alternatively, the Administrator may find that revision

of the standards is inappropriate and conclude the review by leaving the existing standards unchanged. Section 109 of the Clean Air Act (42 U.S.C. 7409) also requires that the criteria and NAAQS be reviewed by an independent scientific review group, those review responsibilities being met by the Clean Air Scientific Advisory Committee (CASAC) of EPA's Science Advisory Board (SAB).

B. REGULATORY BACKGROUND

On October 5, 1978 the EPA promulgated primary and secondary NAAQS for lead, under Section 109 of the CAA (43 FR 46258). The primary standard and the secondary standard are the same: 1.5 $\mu g/m^3$ as a quarterly average (maximum arithmetic mean averaged over a calendar quarter). The standards were based on the EPA's 1977 Air Quality Criteria for lead. Subsequent regulations reducing the use of lead additives in gasoline were promulgated in 1985 (50 FR 9386), leading to substantial reductions in ambient air lead concentrations.

In 1986, the EPA published a revised Air Quality Criteria Document for Lead (Lead AQCD). The 1986 AQCD assessed newly available scientific information on the health and welfare effects associated with exposure to various concentrations of lead in ambient air. The 1986 AQCD reviewed literature through 1985 for information relevant to derivation of air quality criteria for lead. The document was principally concerned with the health and welfare effects of lead, but other scientific data were also discussed in order to provide a better understanding of the pollutant in the environment. Thus, the 1986 document included chapters that discussed the atmospheric chemistry and physics of the pollutant; analytical approaches; environmental concentrations; human exposure and dosimetry; physiological, toxicological, clinical and epidemiological aspects of lead health effects; and lead effects on ecosystems. An Addendum to the 1986 Lead AQCD was also published along with it in 1986 (U.S. Environmental Protection Agency, 1986). Subsequently, a supplement to the 1986 Lead AQCD/Addendum was published by EPA in 1990 (U.S. Environmental Protection Agency, 1990). That 1990 supplement evaluated still newer information emerging in the published literature concerning (1) lead effects on blood pressure and other cardiovascular endpoints and (2) the effects of lead exposure during pregnancy or early postnatally on birth outcomes and/or on the neonatal physical and neuropsychological development of affected children.

The evaluations contained in the 1986 Lead AQCD/Addendum and the 1990 Supplement provided scientific inputs to support decision-making with regard to review and, as appropriate, revision of the Lead NAAQS and they were drawn upon by EPA's Office of Air Quality Planning and Standards (OAQPS) in preparation of an associated Lead Staff Paper. After consideration of evaluations contained in these documents, EPA chose not to propose revision of the Lead NAAQS.

Changes in relative contributions of various lead sources and exposure pathways to human exposures in the United States, and EPA actions to reduce such exposures also provide important background for this review. Since 1978, the amount of lead emitted into the air nationally has markedly declined. From 1982 to 2002, for example, lead emissions into the air decreased by 93 percent, and the average air quality concentration of lead decreased by 94 percent from 1983 to 2002 (http://www.epa.gov/airtrends/lead2.html). Total lead emissions into the air decreased from about 220,000 tons in 1970 to less than 4,000 in 1999. This decline is mainly attributable to EPA's regulatory efforts to reduce the content of lead in gasoline (http://www.epa.gov/airtrends/lead2.html), which has substantially altered basic patterns of air lead emissions in the United States. Emissions from stationary sources have also been greatly reduced (http://www.epa.gov/airtrends/lead2.html, Fig. 2-11); however, given the even greater reductions in emissions from transportation sources, industrial processes (including smelters and battery manufacturers) now constitute a larger percentage of remaining lead emissions to the atmosphere (*id.*, Fig. 2-12). (See generally (http://www.epa.gov/airtrends/lead2.html). In short, lead emissions into the atmosphere decreased greatly in the 1980's and 1990's, a trend that has continued to the present. As a consequence, airborne lead now represents only a relatively small component of total exposure to lead, such that the principal sources of U.S. lead exposure in the most sensitive population (young children) are through non-inhalation pathways (such as lead in deteriorating paint, food, drinking water, dust, and historically contaminated soil).

Since the 1980's, EPA has played a major role in working to reduce the main sources of lead exposure for most children, including deteriorating lead-based paint, lead contaminated dust, and lead contaminated residential soil (http://www.epa.gov/lead/). For example, EPA has established standards for lead-based paint hazards and lead dust cleanup levels in most pre-1978 housing and child-occupied facilities, and is now developing standards for those conducting renovation activities that create lead-based paint hazards and for the management and disposal of lead-based debris (http://www.epa.gov/lead/regulation.htm). Also, EPA has developed standards for management of lead in solid and hazardous waste, oversees the cleanup of lead contamination at Superfund facilities, and has issued regulations to reduce lead in drinking water (http://www.epa.gov/lead/sources.htm). Beyond specific regulatory actions, the Agency's Lead Awareness Program continues to work to protect human health and the environment against the dangers of lead by conducting research and designing educational outreach efforts and materials (http://www.epa.gov/lead/).

Since the 1980's, EPA has also promulgated regulations under section 112 of the Act, 42 U.S.C. § 7412, to address emissions of lead components and other toxic pollutants from both primary lead smelters and secondary lead smelters (40 CFR Subparts X and TTT). Under section 112(d), these emission standards are to require "the maximum degree of reduction in emissions" that are "achievable."

EPA promulgated section 112(d) standards for secondary lead smelters on June 23, 1995 (60 Fed. Reg. 3587) and revised them on June 13, 1997 (62 Fed. Reg. 32209) followed by promulgation of section 112(d) standards for primary lead smelters on June 4, 1999 (64 Fed. Reg. 30194).

C. PROJECTED SCHEDULE

On November 9, 2004, EPA's National Center for Environmental Assessment Division in Research Triangle Park, NC (NCEA-RTP) announced official initiation of the current periodic review of air quality criteria for lead. More specifically, under processes established in Sections 108 and 109 of the CAA, the EPA began by announcing in the Federal Register (69 FR 64,926) the formal commencement of the review with a call for information. In addition, EPA has prepared this Lead AQCD Work Plan, a draft of which is now being made available for review by CASAC and the public, to communicate the process and timeline for development of a revised Lead AQCD. After carefully assessing and evaluating pertinent new studies, the EPA will first prepare preliminary draft chapters for a revised criteria document and subject them to expert review at public workshops. After consideration of comments received at the workshops, appropriate revisions will be made in the draft materials and a First External Review Draft of the entire revised document will be made available for review and comment by CASAC and the public. EPA expects that, after consideration of CASAC and public comments, it will be necessary to prepare a Second External Review Draft of the revised Lead AQCD for further review by CASAC and the public before EPA completes the final version of the Lead AQCD. Publication of the final document and its availability to the public will be announced in the Federal Register. Table 1 shows the projected schedule for the criteria document revision process.

Drawing upon evaluations in the Lead AQCD and other lead exposure/risk analyses, the EPA's Office of Air Quality Planning and Standards (OAQPS) staff will prepare a draft Lead Staff Paper assessing policy implications of key information in the Lead AQCD and posing possible options for the EPA Administrator to consider regarding whether to retain or, if appropriate, revise the Lead NAAQS. The draft Staff Paper and analyses will also be made available for review by CASAC and the public. Taking into account CASAC and public comments, final revisions will be made in the Lead Staff Paper, and it will provide information for decisions to be made by the EPA Administrator regarding possible retention or revision of the Lead NAAQS.

Table 1. Proposed Schedule for Development of Revised Lead Air Quality Criteria Document (Pb AQCD)[1]

Major Milestones		Target Dates
1.	Literature Search	Ongoing
2.	Federal Register Call for Information	November 2004
3.	Prepare Draft Pb AQCD Project Work Plan	Nov-Dec 2004
4.	Release Draft Project Plan for Public Comment/CASAC Review	January 2005
5.	Public Comment Period	Jan/Feb 2005
6.	CASAC/SAB Public Meeting to Review Project Work Plan	March 2005
7.	Workshop Drafts of Pb AQCD Chapters	May/June 2005
8.	Peer Consultative-Review Workshop(s)	July/August 2005
9.	Release First External Review Draft	January 2006
10.	Public Comment Period (90 days)	Feb-April 2006
11.	CASAC/SAB Public Review Meeting *(First Ext. Rev. Draft)*	April 2006
12.	Release Second External Review Draft	September 2006
13.	Public Comment Period (60 days)	Oct-Nov 2006
14.	CASAC/SAB Public Review Meeting (*Second Ext. Rev. Draft*)	December 2006
15.	Final Lead AQCD	February 2007

[1] Proposed schedule may be modified from time to time, as necessary, to reflect actual project requirements and progress.

II. SCIENTIFIC BACKGROUND AND KEY ISSUES

Numerous issues were identified by authors and reviewers of the 1986 Lead AQCD/Addendum and the 1990 Supplement (U.S. Environmental Protection Agency, 1986, 1990) as being relevant to the development of lead criteria. Additional issues were identified in the course of public discussion and CASAC review of draft versions of those earlier AQCD materials and/or the associated Lead Staff Paper, and some further issues have begun to emerge since then as being of potential public health concern. By way of introduction to the types of issues anticipated to be considered in the current lead criteria review, the next several sections each open with concise presentation of some pertinent background information on a given general category or topic, followed by listing of a number of the more important issues as illustrative of the types of questions to be considered in the current review of lead criteria. Many of these issues were addressed by previous reviews. This review will consider any newly available evidence as it may pertain to potential affirmation or revision of previously-stated key findings or conclusions.

A. LEAD AS A MULTIMEDIA ENVIRONMENTAL CONTAMINANT

Lead is a toxic metal that can produce a variety of physiological and, ultimately, pathological effects in humans and can also have adverse effects on the environment. As illustrated in Figure 1, human exposure occurs through multiple pathways, including primarily ingestion of lead in media such as food, water, soil, and dust, as well as inhalation of airborne lead. Because health effects in humans are associated with varying levels of lead in the blood and because all exposure pathways contribute to blood lead levels, health risks are a function of total exposure. Thus, the evaluation of potential health risks associated with exposures to concentrations of lead in the air must also take into account estimated exposures and blood lead impacts of lead derived from other media (e.g., food, water, etc.). As a result, considerable attention will be accorded in the revised Lead AQCD to delineation of information useful in facilitating understanding of lead as a multimedia environmental contaminant, including characterization of relative contributions of various exposure pathways to lead burdens in humans and ecosystems and relationships of such lead burdens to consequent human health and environmental effects.

Examples of important key issues related to delineation of lead as a multimedia environmental contaminant are provided below.

1. *Physical and Chemical Properties of Lead and Measurement Methods*

- What are important chemical and physical features of inorganic lead and organic lead compounds encountered in the environment?

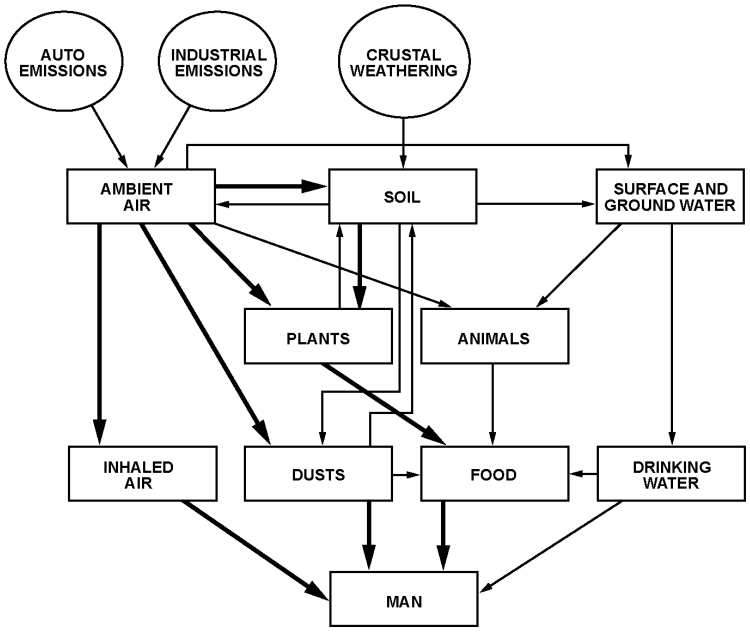

Figure 1. Principal pathways of lead from the environment to human consumption. Heavy arrows are those pathways discussed in greatest detail in the 1986 Lead AQCD.

Source: U.S. Environmental Protection Agency, Air Quality Criteria for Lead, Volume II of IV, EPA/600/8-83/028bF (June 1986).

- What are key features of sampling and analytic methods employed for measurement of lead in environmental and biological media?
- What are appropriate quality assurance/quality control approaches to help ensure reliability of such measurements?

2. ***Sources, Emissions, Transport, and Environmental Fate of Atmospheric Lead***

- Long-Term Historic Trends in Atmospheric Lead Emissions and Environmental Contamination.
- What are more recent trends in atmospheric emissions in the United States since the 1970's?
- How important is the downward deposition of lead onto surfaces accessible by humans?
- What are the spatial concentration patterns of anthropogenic lead emissions and how do these differ from natural emissions?
- What fraction of observed U.S. ambient air lead concentrations can be attributed to anthropogenic emission sources?
- To what extent does long-range transport of lead emitted in other countries contribute to U.S. ambient air lead levels?

3. *Multimedia Human Exposure and Dosimetry*

- What are the main multimedia/exposure pathways accounting for human environmental lead exposures in the United States since the 1970's?
- What are current typical lead concentrations currently encountered by sensitive U.S. populations via different major exposure pathways, e.g., air, food, water, etc.?
- What is the current status of population-based information on total human lead exposure and spatial and temporal patterns of exposures of sensitive population groups?
- What tissue or fluid lead concentrations can serve as useful biomarkers of short- or long-term lead exposure?
- What other types of biomarkers are useful as indices of short- or long-term lead exposures?
- How do social factors (e.g., human activity patterns and variable avoidance behaviors) affect lead exposures of sensitive population groups?
- What genetic/physiologic factors influence lead exposure and the magnitude of lead uptake/biological retention?
- What are features of currently available biokinetic models that are useful for projecting likely impacts of multimedia human lead exposures (via air, food, water, etc.) on internal body burdens as indexed by blood lead levels, etc?

B. HEALTH EFFECTS OF EXPOSURE TO LEAD

Decision-making underlying establishment of the 1978 primary Lead NAAQS took into account consideration of the following key issues:

(1) Determination of blood lead (PbB) concentrations associated with unacceptable risk of adverse health effects, especially in infants and young children as key sensitive population;

(2) Characterization of PbB distributions typical of U.S. pediatric populations;

(3) Determination of target level for average PbB concentration to keep PbB levels of given percentage of sensitive population group below concentrations associated with unacceptable health risks;

(4) Characterization of typical relative contributions of different multimedia lead exposure pathways (food, water, air, soil, etc.) to U.S. pediatric PbB levels; and

(5) Determination of allowable air lead concentrations (i.e., the NAAQS) , taking into account average contributions from other multimedia lead exposure pathways (e.g., via food, water, etc.).

One of the most controversial and intensely debated issues was the first listed above, i.e., the determination of blood lead levels associated with unacceptable risk of adverse health effects. This

determination was based on the 1977 Pb AQCD characterization of health effects associated with acute and more chronic exposure to lead resulting in internal lead body burdens indexed across a wide range of blood lead levels in adults and, of most concern, in young children, infants, and the unborn (in-utero) fetus. This included qualitative delineation of types of lead effects documented by clinical and epidemiological observations (as also supported by experimental animal studies) and characterization of quantitative dose-response relationships. The latter included estimation of lowest-observed effect levels for induction of: (a) clearly adverse, clinically evident classical signs and symptoms of acute lead poisoning, such as (1) indications of life-threatening lead encephalopathy (serious central nervous system damage most often seen in infants and young children and often leading to permanent severe mental retardation and learning disabilities among survivors) documented to be associated with acute high-level lead exposures resulting in very high blood-lead levels or (2) other signs of peripheral nerve damage (as indexed, for example, by slowed nerve conduction velocities), anemia, indications of renal damage and/or gastrointestinal symptoms (e.g., colic) observed in young children at somewhat lower blood lead levels (the occurrence of a sufficiently severe constellation of the above types of acute lead poisoning signs and symptoms typically warranting chelation and other types of immediate medical treatment). It also included (b) much more subtle and difficult to detect indications in asymptomatic infants and children of less severe but still serious nervous system impacts (as indexed by IQ decrements or various other types of sensitive tests of neurobehavioral or psychomotor functions) and/or more moderate red blood cell impacts reported to occur at still lower blood lead levels but seen as likely collectively constituting adverse health effects; and (c) much smaller magnitude biological or pathophysiological effects of lead unlikely to be of medical concern (e.g., initial biochemical impacts on heme synthesis that occur starting at very low blood lead levels and increase in magnitude as blood lead levels become more elevated). Subsequent studies assessed in the 1986 Lead AQCD/Addendum and the 1990 Supplement provided further evidence substantiating the above types of findings and reported observed effect levels for neurobehavioral impacts that extended to still lower PbB values than previously reported.

Among the more important health-related issues that are anticipated to be considered in the current Lead NAAQS review as part of the basis for decisions on the primary Lead NAAQS are those listed below.

1. **Biological Mechanisms of Action**
   - What are mechanisms and time-courses associated with lead-induced subcellular, cellular, and tissue injury, repair, and/or remodeling?
   - What are the effects of age, gender, and pre-existing disease on cellular and tissue responses to lead-induced injury?

- In particular, to what extent does lead affect heme synthesis at varying lead exposure levels and what are consequent impacts on various tissue or organ system functions?

2. **Effects of Repeated Short-term, Prolonged, or Long-term Lead Exposure on Potential Histopathologic, Pathophysiologic and Clinical Sequelae of Disease**

- What levels and/or patterns of lead exposure are associated with retardation of growth rate in fetuses, infants, and children?
- What levels of exposure (indexed by blood, bone, teeth lead levels) early in development are associated with induction of neurological/neurobehavioral deficits?
- To what extent do lead-induced neurobehavioral/growth effects early in development persist and have long-term sequelae?
- To what extent does long-term lead exposure contribute to postmenopausal osteoporosis, formation of cataracts, or other health problems encountered most typically in older population groups?
- What evidence exists for genotoxic, carcinogenic, and/or co-carcinogenic effects of lead?

3. **Sensitive Populations and Factors that Enhance Susceptibility**

- What environmental and host factors (e.g., demographic, socioeconomic, genetic) are associated with increased vulnerability or susceptibility to short- and long-term exposure to lead?
- Does lead exposure exacerbate pre-existing health conditions? If so, what is the nature of enhanced health effects in persons with pre-existing health conditions who are exposed to lead?
- What are the quantitative relationships between ambient lead exposures and the frequencies of occurrence of these effects?

C. ECOLOGICAL EFFECTS OF EXPOSURE TO LEAD

Lead occurs in various forms in the environment. Ionic lead (Pb^{2+}), lead oxides and hydroxides, and lead-metal oxyanion complexes are the general forms of lead released into soil, groundwater, and surface waters. Pb^{2+} is the most common and reactive form of lead, forming mononuclear and polynuclear oxides and hydroxides. The form of lead in the environment greatly influences the bioavailability and toxicity to various biota.

Lead can accumulate in the terrestrial environment in soils, microorganisms, and plants. The forest canopy is the functional interface between 90 percent of the Earth's biomass and the atmosphere. Scavenging of atmospheric lead by foliage is a significant entry route of Pb into terrestrial ecosystems. Soil-borne lead can be directly toxic to soil microorganisms and disrupt decomposition and mycorrhizal

processes. Once captured, lead persists within terrestrial ecosystems for decades, if not centuries. Lead can enter adjacent aquatic systems by interactions between the terrestrial and aquatic environment.

Lead can also accumulate in sediments of aquatic ecosystems and serve as a source of contamination to benthic organisms over long periods of time. Aquatic macrophytes can accumulate lead from sediments and introduce lead into the aquatic food chain through the activities of plant grazers. Uptake of lead directly from the water column can also contribute to total lead body burdens in pelagic aquatic species. Lead can move up the food chain and ultimately impact human health through consumption of lead-tainted fish and shellfish.

The previous review (U.S. Environmental Protection Agency, 1986) indicated that remaining uncertainties in available data for a number of environmental effects categories increased the difficulties associated with characterizing qualitative or quantifiable risks to various components of agronomic, forested, and natural ecosystems. The following issues tend to center around addressing such uncertainties and provide an overall framework for assessing new scientific information that should likely be considered to support selection of an appropriate secondary lead NAAQS protective of crops, natural vegetation, and ecosystem components and processes.

1. **Exposure Dynamics:** monitoring to determine ambient lead concentrations encountered in urban and rural farm/forest areas, exposure patterns (episodes), concentrations vs flux, relationship between chamber and field exposure data, plant uptake;

   a. Modeling

   - What is the state of the science in modeling lead concentration gradients and deposition velocities across plant canopies, plant communities, or multiple ecological resource landscapes?
   - How precise and accurate are these models?
   - How well can these models be extrapolated temporally and spatially within or across different forest types, crops, watersheds, basins, ecophysiographic regions, the urban-rural interface, etc.?
   - Can passive samplers be useful to "fill in the gaps" in model-derived lead concentrations at remote areas where continuous lead monitoring is not routinely performed?

   b. Exposure Regimes

   - How do episodic exposures (predisposition) alter plant or animal responses to chronic, cumulative lead exposures?
   - How do we translate results from controlled exposure studies which are typically conducted with single species/organisms (e.g., tree seedlings or crops) to whole trees, forest stands, farm land, lakes, estuaries, ecosystems, watersheds, airsheds, or ecophysiographic regions?
   - Can data from remote sensing platforms be useful in understanding local, regional, national, and global lead transport and deposition?

2. **Plant/Animal Response and Mode of Action:** biological, chemical and physical responses, especially cellular biochemical/physiological mechanisms; individual plant sensitivity/ genetic composition; site/habitat influences; pest, disease, and abiotic stress interactions;

   a. Plants

   - Is there new information regarding the mode of action of lead once it enters a plant?
   - Are there genetic markers that can be identified using state-of-the-art molecular biological methodologies that differentiate lead tolerant and intolerant cultivars and species?
   - What is known about lead's effects on ecosystem components singly and in combination with other air pollutants?
   - How does lead, both singly and in combination with other air pollutants, influence plant-pathogen and plant-pest interactions?

   b. Wildlife

   - Are lead exposure effects on wildlife similar to human exposure effects?
   - Has lead altered the nutritional content of forage for domestic animals or wildlife populations?
   - What is known about lead's effects on faunal ecosystem components singly and in combination with other air pollutants?

   c. Aquatic organisms

   - How important is lead uptake from sediments in lead accumulation in aquatic plants and animals?
   - How important is methylation in lead mobility and bioavailability in aquatic systems?
   - To what extend is lead biomagnified up the food chain?

3. **Ecosystems:** exposure/response relationships of sensitive individual plant species and forest trees to lead under ambient conditions; impact of lead exposure on interspecific competition on both above- and below-ground interactions and on ecosystem products and services.

   a. Biodiversity

   - Does lead influence the biodiversity of ecological systems?

   b. Terrestrial-Aquatic Interface

   - Have terrestrial ecosystem effects of lead exposure affected aquatic ecosystems?
   - Has lead altered the nutrient cycling in forested catchments that may manifest themselves as changes in water chemistry at the stream and watershed levels?

4. **Assessment:** assessment of economic impacts on products (crops, forests, fish, shellfish, etc.) and ecosystem services, benefits derived from control of lead exposures.

   a. Economics

   - Have new and innovative methods evolved since the last criteria document for monetizing ecosystem services and non-consumptive use products (e.g., aesthetics, recreation, plant nutritional quality for wildlife)?

- To what extent can credible estimates be derived for economic impacts of lead on consumptive-use ecosystem products (e.g., crop yields, fish yields, shell fisheries, and timber)?

b. Scaling Up

- What recent advances, if any, now allow for localized or spatiotemporally disparate data sets to be aggregated for regional ecological effects assessments?
- Can critical loads be determined for sensitive ecosystem components?

III. ORGANIZATIONAL STRUCTURE AND PREPARATION/REVIEW PROCESS

A. ORGANIZATION AND CONTENT OF REVISED LEAD DOCUMENT

The updated Lead AQCD will critically evaluate and assess scientific information on the health and welfare effects associated with exposure to the concentrations of this pollutant in ambient air. The revised document is not intended to be an exhaustive review of the literature. Rather, the cited references will reflect the current state of knowledge on the most relevant issues pertinent to decisions on possible Lead NAAQS revision. Although emphasis will be placed on the presentation of health and welfare effects data, other scientific data will also be presented and evaluated in order to provide a better understanding of the nature, sources, distribution, measurement, and concentrations of lead in ambient air, as well as the measurement of population exposure to lead.

The focus of the selected scientific information in the text will be on literature published since the previous review of the air quality criteria for lead. Emphasis will be placed on studies conducted at or near lead concentrations found in ambient air. Other studies may be included if they contain unique data, such as the documentation of a previously unreported effect or of a mechanism for an observed effect; or if they were multiple-concentration studies designed to provide exposure-response relationships.

Key findings and conclusions from the 1986 Lead AQCD/Addendum and 1990 Supplement will briefly be summarized at the outset of discussion of a given topic, with appropriate reference back to the previous materials. Important prior studies will be more specifically discussed if they are open to reinterpretation in light of newer data and are judged to be potentially useful in decisions on revision of the standards for lead. Generally, only information that has undergone scientific peer review and has been published (or accepted for publication) in the open literature will be considered in the criteria document. Exceptions may be made depending on the importance of the subject information and its pertinence to criteria development for Lead NAAQS, as determined in consultation with CASAC.

The proposed structure of the document will begin with an Executive Summary and Conclusions. Chapter 1 (Introduction) will present information on the legislative background and purpose of the document, provide a brief introduction to key issues to be addressed, and present an overview of the organization of the document. Chapter 2 will provide information on the physics and chemistry of lead, as well as sampling and analytic methods for measurement of lead concentrations in various environmental and biological media. Chapter 3 will cover sources, emissions, transport, and deposition/fate; and Chapter 4 will cover environmental concentrations, patterns, and multimedia exposure pathways. Chapter 5 will discuss dosimetric issues, focused mainly on modeling of multimedia exposure impacts on human internal lead burdens, as indexed by blood or bone lead concentrations. Chapters 6 and 7 will discuss toxicologic studies of lead health effects in humans and laboratory animals,

as well as clinical and epidemiologic studies. Chapter 8 will then provide an integrative synthesis of key information regarding human lead exposures and health effects. Chapter 9 will deal with ecological and other environmental effects of lead. The proposed chapter topics are provided in the inset below. See Appendix A for a more detailed outline of proposed contents to be included in the revised Lead AQCD.

Chapter Topics for Revised Air Quality Criteria for Lead

Executive Summary	
Chapter 1	Introduction
Chapter 2	Chemical and Physical Properties and Measurement
Chapter 3	Sources, Emissions, Transport, and Deposition
Chapter 4	Environmental Concentrations and Pathways to Human Exposure
Chapter 5	Models of Human Exposure, Uptake, and Biokinetic Distribution of Lead
Chapter 6	Toxicologic Effects of Lead in Laboratory Animals
Chapter 7	Epidemiological and Clinical Studies of Lead Effects in Humans
Chapter 8	Integrative Synthesis of Human Exposure and Health Risks
Chapter 9	Environmental Effects of Lead

B. METHODS AND PROCEDURES FOR DOCUMENT PREPARATION

Responsibilities for developing the revised Lead AQCD will be essentially the same as those used for recent criteria documents, with additional emphasis being placed on more extensive coordination and collaborative inputs from various participating EPA units. Briefly, the respective responsibilities are as follows. The Research Triangle Park Division of EPA's National Center for Environmental Assessment (NCEA-RTP) will have lead responsibility for preparation of the updated Lead AQCD. The Director of NCEA-RTP has appointed a project manager and team with responsibility for developing the present project work plan for preparation of the document. Development of the plan has been facilitated by input from other EPA program and policy office staff among those listed on the EPA Lead Criteria Work Group (see Appendix B). This resulting draft project plan is being made available for CASAC and public review and will then be revised, as appropriate. It will also be further updated, as appropriate, to reflect any major future changes and/or progress in its implementation.

A literature search has been ongoing to collect references on the health and ecological effects of lead. Additional literature searches are also underway for other respective areas to be covered in the criteria document; and NCEA-RTP has developed an information base to access the references and provide quality assurance and quality control functions. Specific chapter or section authors are being selected on the basis of their expertise in the subject areas and their familiarity with the relevant literature.

Both EPA and non-EPA scientific experts will be involved in this effort. The main focus of the revised criteria document will be on evaluation and interpretation of data that deal with the effects of airborne lead on human health and welfare. One or more peer consultation workshops will be convened to discuss draft criteria document chapters and will focus on the selection of studies included in the chapters, the potential need for additional information to be added to the chapters, and the quality of the summarization and interpretation of the literature. The respective authors of the draft chapters will revise them on the basis of the workshop discussions. After resolution of outstanding issues and comments derived from the workshops, NCEA-RTP will release the First External Review Draft of the revised Lead AQCD for public comment and CASAC review. Then, revisions will be made on the basis of the public comments and CASAC review. EPA expects that it will be necessary to make a Second External Review Draft available for further CASAC and public review before EPA completes and releases the final version of the revised Lead AQCD. Preparation of an updated Lead Staff Paper, drawing upon key findings and conclusions from the Lead AQCD and other related exposure/risk analyses, will be carried out by EPA's Office of Air Quality Planning and Standards (OAQPS).

C. PERSONNEL

Dr. Robert W. Elias will serve as the NCEA-RTP project manager responsible for overall coordination of the Lead AQCD preparation effort. Drs. Lester D. Grant and J. Michael Davis will provide overall technical guidance for the health effects aspects and Dr. Timothy Lewis for the ecological effects aspects of the document. Other NCEA-RTP project team members who are to provide overall coordination and technical inputs for individual chapters are as follows: Dr. Joseph Pinto for the chapter on lead chemistry and measurement methodologies; Dr. Robert Elias, Dr. Joseph Pinto, Ms. Beverly Comfort, and Mr. William Ewald for the chapter on environmental concentrations, patterns, and potential exposures; Dr. Robert Elias for the chapter on lead biokinetic modeling; Drs. Lori White, James Brown, Srikanth Nadadur, and J. Michael Davis for the chapter materials dealing with toxicological effects in laboratory animals and humans; Drs. Dennis Kotchmar and Ji Young Kim for review and evaluation of epidemiological studies; and Dr. Timothy Lewis for the chapter on environmental effects. Additional technical assistance on air quality, health effects, and ecological effects will be obtained from EPA scientists in EPA's National Exposure Research Laboratory (NERL), National Health and Environmental Effects Research Laboratory (NHEERL), and the Office of Air Quality Planning and Standards (OAQPS), as appropriate and needed. As needed, scientific expertise will also be obtained from outside EPA, utilizing contractual arrangements with non-EPA experts. Members of NCEA-RTP's project team and other EPA and non-EPA personnel expected to contribute to the document are listed in Appendix C; examples of the pool of experts that EPA expects to tap to assist in development of the Lead AQCD as

potential authors or contributors of written materials or serving in peer consultative or reviewer roles for review of workshop draft or external reviews draft materials are also listed in Appendix C.

D. APPROACH

Discussions will be held between NCEA/RTP staff and EPA workgroup members to help identify key issues and approaches to addressing them. Non-EPA experts will also be consulted to help identify and refine key issues to be addressed and pertinent new literature to be considered. Discussions will also be held with the authors at the initial stages of document development to acquaint them with detailed guidelines and specifications. Subsequent meetings with authors may be conducted to facilitate continuity within and between chapters. Periodic coordination meetings will be held to facilitate flow of information on document preparation progress, to obtain feedback on evolving draft materials, and to determine any needed modifications in planned actions.

The authors will be provided copies of the previous 1986 Lead AQCD/Addendum and the 1990 Supplement (U.S. Environmental Protection Agency, 1986). New sections for the updated document will each first summarize key findings and conclusions from those prior document materials, including reference to "key" studies. Once this background information is presented, the remainder of the given section will be updated with discussion and interpretative evaluation of the newer literature. In cases where no new information is available, the summarization of key findings from the previous criteria document will suffice. The primary focus in the main Lead AQCD chapters will be on interpretive evaluation of the most pertinent evidence with reference being made to more descriptive summarization of details of particular studies provided in separate annexes to be appended to the main Lead AQCD.

A list of references published since the last review of lead criteria (mainly after completion of the 1986 Lead AQCD/Addendum and 1990 Supplement) will be made available to the authors. The references will be selected from information data base searches conducted by EPA and from any materials submitted in response to the November 2004 call for information. Hard copies of these references will be supplied upon request. Additional references may need to be added to the list (e.g., missed or recently published papers or "in press" publications). As an aid in selecting pertinent new literature, the authors will also be provided with a summary of issues that need to be addressed in the preparation of the revised Lead AQCD. These will include issues identified by authors and reviewers of the previous lead document materials, raised in public discussions, workshops, or CASAC comments received by EPA and/or raised via interactions involving EPA Lead Workgroup members. The list of issues may be further augmented in the course of preparation or review of draft materials for the revised Lead AQCD.

E. PUBLIC AND SCIENTIFIC REVIEW

1. Review and Revision of Consultative Review Workshop Draft

When working drafts of the main chapters (other than the Executive Summary) of the document have been completed by the authors, one or more workshops will be convened by the NCEA-RTP Project Team. The workshops will include the document authors, EPA Work Group participants, and external reviewers chosen on the basis of scientific expertise within specific areas covered. The workshops will be open to the public, as announced in a Federal Register Notice.

2. Public Review of External Review Drafts

After the workshop consultative review process is completed, the authors, contributing reviewers, and NCEA-RTP Project Team will resolve how to address comments received and will revise the draft chapters in preparation for their inclusion in the First External Review Draft (ERD) of the Lead AQCD. After clearance by the U.S. EPA, the draft document will be released for public comment as announced in a Federal Register Notice. Electronic and printed copies of the ERD will be made available for review during a specified time period, usually of 60 to 90 days; written comments are solicited during this time. A similar procedure will be followed for public and CASAC review of a Second External Review Draft that EPA expects to be necessary before completion of the Final Lead AQCD.

3. Review by Clean Air Scientific Advisory Committee

At the time the First External Review Draft is released to the public, that draft document will also be sent to the Clean Air Scientific Advisory Committee (CASAC) of EPA's Science Advisory Board (SAB). CASAC members and consultants (see Appendix D) will review the draft document and discuss their comments in a public meeting announced in the Federal Register. At the meeting, the NCEA-RTP Project Team plans to present an overview of the main features of the document, a summary of key issues raised by public comments received on the document, and the charge to the committee, as well as being prepared to discuss proposed revisions, if indicated. Based on CASAC's past practice, EPA expects that key CASAC advice and recommendations for revision of the document will be summarized by the CASAC Chair in a letter to the EPA Administrator. EPA will take into account any such recommendations, as well as CASAC and public comments at the meeting and any written comments received, in revising the draft Lead AQCD. As noted earlier, EPA expects that it will be necessary to prepare a Second External Review Draft for further CASAC review and public comment. After appropriate revision, the final document will be made available on an EPA website and subsequently printed, with its public availability being announced in the Federal Register.

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APPENDIX A

PROPOSED CONTENTS OF REVISED AIR QUALITY CRITERIA FOR LEAD

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APPENDIX B

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APPENDIX D

U.S. EPA SCIENCE ADVISORY BOARD
CLEAN AIR SCIENTIFIC ADVISORY COMMITTEE MEMBERS
Fiscal Year 2005

The Clean Air Scientific Advisory Committee (CASAC) has a statutorily mandated responsibility to review and offer scientific and technical advice to the Administrator on the air quality criteria and regulatory documents that form the basis for the national ambient air quality standards (NAAQS), which currently include standards for lead (Pb), particulate matter (PM), ozone (O_3), and other photochemical oxidants, carbon monoxide (CO), nitrogen oxides (NO_x) and sulfur oxides (SO_x). To perform such reviews, in each case the Committee forms a review panel consisting of CASAC members and augmented by selected consultants with expertise in scientific or technical areas pertinent to the given pollutant or pollutant class under review.

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