EPA United States Environmental Protection Agency

Draft Plan for Review of the Primary National Ambient Air Quality Standard for Nitrogen Dioxide

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Draft Plan for Review of the Primary National Ambient Air Quality Standard for Nitrogen Dioxide

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and

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DISCLAIMER

This draft plan for the review of the primary national ambient air quality standard for nitrogen dioxide is an informational document prepared for external review purposes and does not constitute U.S. Environmental Protection Agency policy. This plan also serves as a management tool for the U.S. Environmental Protection Agency's National Center for Environmental Assessment and the Office of Air Quality Planning and Standards in Research Triangle Park, North Carolina. This information 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. Mention of trade names or commercial products does not constitute endorsement or recommendation for use.

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1. INTRODUCTION

The U.S. Environmental Protection Agency (EPA) is conducting a review of the primary (health-based) and secondary (welfare-based) national ambient air quality standards (NAAQS) for nitrogen dioxide (NO_2). The purpose of this document is to communicate the plan for reviewing the primary NAAQS for NO_2. The review of the secondary NAAQS for NO_2, to be conducted in conjunction with the review of the secondary NAAQS for sulfur dioxide (SO_2), will be addressed in a separate plan to be released in the spring of 2007.[1]

This review plan is organized into six chapters. Chapter 1 presents background information on the review process, the legislative requirements for the review of the NAAQS, and past reviews of the NAAQS for NO_2. Chapter 2 presents the current review schedule. Chapter 3 presents a set of policy-relevant questions that will serve to focus this review on the critical scientific and policy issues. Chapters 4 through 6 discuss the planned scope and organization of the key assessment documents, the planned approaches for preparing the documents, and plans for scientific and public review of the documents. As the assessments proceed, the plan described here may be modified to reflect information received during the review process.

1.1 OVERVIEW OF THE REVIEW PROCESS

The Agency has recently decided to make a number of changes to the process for reviewing the NAAQS (described at http://www.epa.gov/ttn/naaqs/). This new process, which is being applied to the current review of the NAAQS for NO_2, contains four major components. Each of these components is described in this section. The first component is an integrated review plan. This plan will specify the schedule for the review, the process for conducting the review, and the key policy-relevant science issues that will guide the review. The final integrated review plan will be informed by input from CASAC, outside scientists, and the public.

[1] A separate plan for the review of the primary NAAQS for SO_2 is now also being prepared for release in spring of 2007.

The second component of the review process is a science assessment. Under the new process, a concise synthesis of the most policy-relevant science will be compiled into an integrated science assessment (ISA). The ISA for this review of the NO_2 NAAQS will critically evaluate and integrate scientific information on the health effects associated with exposure to oxides of nitrogen (NO_x) in the ambient air. It will focus on scientific information that has become available since the last review and will reflect the current state of knowledge on the most relevant issues pertinent to the review of the primary NO_2 NAAQS. The ISA will be supported by a more detailed and comprehensive assessment of the scientific literature, which will be compiled into a science assessment support document (SASD). Together, the ISA and SASD will replace the Air Quality Criteria Document from previous NAAQS reviews.

The third component of the review process is a risk/exposure assessment. For the review of the NO_2 standard, we plan to focus on conducting an exposure assessment drawing upon the information in the ISA. This exposure assessment will develop, as appropriate, quantitative estimates of human exposure associated with current ambient levels of NO_2 and with levels that just meet the current standard and possible alternative standards. A concise exposure assessment report will be prepared that focuses on key results, observations, and uncertainties.

The fourth component of the revised process will be a policy assessment/rulemaking. Under the new process, a staff paper, such as that prepared in previous NAAQS reviews, will not be prepared. Rather, a policy assessment reflecting Agency views will be published in the Federal Register as an advance notice of proposed rulemaking (ANPR). The ANPR will be accompanied by supporting documents, such as air quality analyses and technical support documents, as appropriate. Issuance of a proposed and final rule will complete the rulemaking process.

1.2 LEGISLATIVE REQUIREMENTS

Two sections of the Clean Air Act (CAA) govern the establishment and revision of the NAAQS. Section 108 (42 U.S.C. 7408) directs the Administrator to identify and list "air pollutants" that "in his judgment, 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" and to issue air quality criteria for those that are listed. Air quality criteria are intended 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 [a] pollutant in ambient air . . . ."

Section 109 (42 U.S.C. 7409) directs the Administrator to propose and promulgate "primary" and "secondary" NAAQS for pollutants listed under section 108. Section 109(b)(1) 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."[2] A secondary standard, as defined in section 109(b)(2), must "specify a level of air quality the attainment and maintenance of which, in the judgment of the Administrator, based on such criteria, is required to protect the public welfare from any known or anticipated adverse effects associated with the presence of [the] pollutant in the ambient air."[3]

The requirement that primary standards include an adequate margin of safety was intended to address uncertainties associated with inconclusive scientific and technical information available at the time of standard setting. It was also intended to provide a reasonable degree of protection against hazards that research has not yet identified. See *Lead Industries Association v. EPA*, 647 F.2d 1130, 1154 (D.C. Cir 1980), cert. denied, 449 U.S. 1042 (1980); *American Petroleum Institute v. Costle*, 665 F.2d 1176, 1186 (D.C. Cir. 1981), cert. denied, 455 U.S. 1034 (1982). Both kinds of uncertainties are components of the risk associated with pollution at levels below those at which human health effects can be said to occur with reasonable scientific certainty. Thus, in selecting primary standards that include an adequate margin of safety, the Administrator is seeking not only to prevent pollution levels that have been demonstrated to be harmful but also to prevent lower pollutant levels that may pose an unacceptable risk of harm, even if the risk is not precisely identified as to nature or degree.

In selecting a margin of safety, the EPA considers such factors as the nature and severity of the health effects involved, the size of sensitive population(s) at risk, and the kind and degree

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[2] The legislative history of section 109 indicates that a primary standard is to be set at "the maximum permissible ambient air level . . . which will protect the health of any [sensitive] group of the population," and that for this purpose "reference should be made to a representative sample of persons comprising the sensitive group rather than to a single person in such a group" [S. Rep. No. 91-1196, 91st Cong., 2d Sess. 10 (1970)].

[3] Welfare effects as defined in section 302(h) [42 U.S.C. 7602(h)] 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."

of the uncertainties that must be addressed. The selection of any particular approach to providing an adequate margin of safety is a policy choice left specifically to the Administrator's judgment. See *Lead Industries Association v. EPA*, supra, 647 F.2d at 1161-62.

In setting standards that are "requisite" to protect public health and welfare, as provided in section 109(b), EPA's task is to establish standards that are neither more nor less stringent than necessary for these purposes. In so doing, EPA may not consider the costs of implementing the standards. See generally *Whitman v. American Trucking Associations*, 531 U.S. 457, 465-472, 475-76 (2001).

Section 109(d)(1) requires that "not later than December 31, 1980, and at 5-year intervals thereafter, the Administrator shall complete a thorough review of the criteria published under section 108 and the national ambient air quality standards . . . and shall make such revisions in such criteria and standards and promulgate such new standards as may be appropriate . . . ." Section 109(d)(2) requires that an independent scientific review committee "shall complete a review of the criteria . . . and the national primary and secondary ambient air quality standards . . . and shall recommend to the Administrator any new . . . standards and revisions of existing criteria and standards as may be appropriate . . . ." Since the early 1980's, this independent review function has been performed by the Clean Air Scientific Advisory Committee (CASAC) of EPA's Science Advisory Board.

1.3 HISTORY OF REVIEWS OF THE PRIMARY NAAQS FOR NO_2

On April 30, 1971, EPA promulgated identical primary and secondary NAAQS for NO_2, under section 109 of the Act, set at 0.053 parts per million (ppm), annual average (36 FR 8186). In 1982, EPA published *Air Quality Criteria for Oxides of Nitrogen* (EPA, 1982), which updated the scientific criteria upon which the initial NO_2 standards were based. On February 23, 1984, EPA proposed to retain these standards (49 FR 6866). After taking into account public comments, EPA published the final decision to retain these standards on June 19, 1985 (50 FR 25532).

On July 22, 1987, EPA announced that it was undertaking plans to revise the 1982 air quality criteria (52 FR 27580). In November 1991, EPA released an updated draft air quality criteria document for CASAC and public review and comment (56 FR 59285). The draft document provided a comprehensive assessment of the available scientific and technical

information on heath and welfare effects associated with NO_2 and other NO_x. The CASAC reviewed the document at a meeting held on July 1, 1993 and concluded in a closure letter to the Administrator that the document ". . . provides a scientifically balanced and defensible summary of current knowledge of the effects of this pollutant and provides an adequate basis for EPA to make a decision as to the appropriate NAAQS for NO_2" (Wolff, 1993).

The EPA also prepared a draft Staff Paper that summarized and integrated the key studies and scientific evidence contained in the revised air quality criteria document and identified the critical elements to be considered in the review of the NO_2 NAAQS. The Staff Paper received external review at a December 12, 1994 CASAC meeting. The CASAC comments and recommendations were reviewed by EPA staff and incorporated into the final draft of the Staff Paper as appropriate. The CASAC reviewed the final draft of the Staff Paper in June 1995 and responded by written closure letter (Wolff, 1995). In September of 1995, EPA finalized the document entitled, "Review of the National Ambient Air Quality Standards for Nitrogen Dioxide: Assessment of Scientific and Technical Information" (EPA, 1995).

Based on that review, the Administrator announced her proposed decision not to revise either the primary or secondary NAAQS for NO_2 (60 FR 52874; October 11, 1995). The decision not to revise the NAAQS for NO_2 was finalized after careful evaluation of the comments received on the proposal. The level for both the existing primary and secondary NAAQS for NO_2 is 0.053 parts per million (ppm) (100 micrograms per cubic meter of air [ug/m^3]), annual arithmetic average, calculated as the arithmetic mean of the 1-hour NO_2 concentrations.

2. REVIEW SCHEDULE

On December 9, 2005, EPA's National Center for Environmental Assessment in Research Triangle Park, NC (NCEA-RTP) announced the initiation of the current periodic review of the air quality criteria for NO_x and the NO_2 NAAQS and issued a call for information in the Federal Register (70 FR 73236). Table 2-1 outlines the schedule under which the Agency is conducting this review.

Table 2-1. Proposed Schedule for Development of Revised NO_x Integrated Science Assessment (ISA) and NO_2 Primary Standard [1]

Stage of Review	Major Milestone	Draft Target Dates
Integrated Plan	Literature Search	Ongoing
	Federal Register Call for Information	December 2005
	Prepare Draft NO_2 NAAQS Work Plan	February 2007
	Workshop on science/policy issues	February 2007
	CASAC consultation	April 2007
	Prepare final integrated NO_2 NAAQS Work Plan	May 2007
Science Assessment	Prepare first draft of ISA	August 2006-August 2007
	CASAC/public review first draft ISA	August 2007-October 2007
	Prepare second draft of ISA	October 2007-February 2008
	CASAC/public review second draft ISA	February 2008-March 2008
	Prepare final ISA	May 2008-July 2008
Risk/Exposure Assessment	Prepare assessment methodology	January 2007-August 2007
	CASAC/public consultation on methodology	August 2007-October 2007
	Prepare first draft risk and/or exposure assessments	October 2007-March 2008
	CASAC/public review of the first draft	March 2008-May 2008
	Prepare second draft of risk and/or exposure assessments	May 2008-September 2008
	CASAC/public review of second draft	September 2008-November 2008
	Prepare final assessments	November 2008-January 2009
Policy Assessment/Rulemaking	Prepare draft ANPR	July 2008-February 2009
	Interagency review of ANPR	February 2009
	CASAC review/public comment on ANPR	March 2009-April 2009
	Proposed rulemaking	August 2009
	Final rulemaking	May 2010

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

3. KEY POLICY-RELEVANT ISSUES

3.1 HISTORICAL PERSPECTIVE

The most recent review of the NAAQS for NO_2, completed in 1996, concluded that exposure to NO_2 is associated with a variety of acute, as well as chronic, health effects. In addition, the 1977 Clean Air Act Amendments specifically direct EPA to review criteria on the health effects of short-term (1- to 3-hr) exposures to NO_2. Therefore, in order to evaluate the need for both a short-term and a long-term standard for NO_2, the most recent review of the NAAQS for NO_2 analyzed the relationship between short-term and annual average levels. This analysis indicated that areas of the United States that meet the existing annual standard for NO_2 would also not exceed short-term NO_2 levels of potential concern. This analysis, together with the uncertainty surrounding the evidence for health effects following short-term, low-level exposure to NO_2, resulted in EPA's conclusion that the existing NO_2 primary NAAQS provided adequate protection from short-term health effects. Therefore, a separate short-term standard was not developed. The current level for both the primary and secondary NAAQS for NO_2 is an annual arithmetic average of 0.053 parts per million.

3.2 ISSUES TO BE CONSIDERED IN THE CURRENT REVIEW

In this review, a series of policy-relevant questions will frame our approach to determining whether the current primary NAAQS for NO_2 should be retained or revised. The answers to these questions, and the resulting conclusions regarding the corresponding policy issues, will inform the decision of whether to retain or revise the current annual standard and/or whether to set a separate short-term (e.g., 1 to 3 hr) standard.

The first step in reviewing the adequacy of the current primary standard is to consider whether the available body of scientific evidence, assessed in the ISA, supports or calls into question the scientific conclusions reached in the last review regarding health effects related to exposure to NO_2 in the ambient air. This evaluation of the newly available scientific evidence will address a series of questions including the following.

- Has new information altered the scientific support for the occurrence of health effects at levels of NO_2 found in the ambient air?

- To what extent does newly available information reinforce or call into question evidence for associations between short-term exposure to NO_2 and adverse health effects?
- To what extent does newly available information reinforce or call into question evidence for associations between long-term exposure to NO_2 and adverse health effects?
- What do recent studies focused on the near-roadway environment tell us about health effects of NO_2?
- At what levels of NO_2 exposure do health effects of concern occur?
- To what extent have important uncertainties identified in the last review been reduced and/or have new uncertainties emerged?
- What are the air quality relationships between short-term and long-term exposures to NO_2?

If the evidence suggests that revision of the current standard might be appropriate, we will consider whether the available body of evidence supports consideration of options that are either more or less stringent than the current standard. The following questions will inform this determination.

- Is there evidence for the occurrence of adverse health effects at levels of NO_2 lower than those observed previously? If so, at what levels and what are the important uncertainties associated with that evidence?
- Do exposure estimates suggest that exposures of concern for NO_2-induced health effects will occur in areas that meet the current primary standard for NO_2? If so, are these exposures of sufficient magnitude such that the health effects might reasonably be judged to be important from a public health perspective? What are the important uncertainties associated with these exposure estimates?

If there is support for consideration of revised primary standards, the Agency will identify ranges of options for alternative standards in terms of the level, indicator, form, and averaging time. The following questions will inform the identification of any such alternative standards.

- Does the evidence and air quality and exposure assessments provide support for considering different exposure indices or averaging times?

- What range of levels is supported by the evidence and air quality and exposure assessments, and what are the uncertainties and limitations in that evidence and exposure assessment?
- What is the range of forms supported by the evidence and air quality and exposure assessments, and what are the uncertainties and limitations in that evidence and air quality and exposure assessment?

4. SCIENCE ASSESSMENT

4.1 SCOPE AND ORGANIZATION

The science assessment for NO_x will consist of the ISA and the SASD. The ISA will critically evaluate and integrate the scientific information on exposure and health effects associated with NO_x in ambient air.[4] The SASD, which evaluates and summarizes relevant studies, will provide a detailed basis for developing the ISA. The SASD will include scientific evidence organized by health outcome in the discipline areas of epidemiology, toxicology, and dosimetry as well as human exposure and atmospheric science relevant to the review of the primary NAAQS. The ISA will draw from this evidence and synthesize the current state of knowledge on the most relevant issues pertinent to the review of the NAAQS for NO_2. Information from other scientific fields will be integrated into the health effects evidence if it contributes to a better understanding of population exposure and/or risk or to a better understanding of the nature, sources, distribution, measurement, and/or concentrations of NO_x in ambient air. The ISA discussions will be designed to focus on the key policy questions described in Chapter 3 of this document.

The focus of the ISA and the SASD will be on literature published since the previous review of the air quality criteria for NO_x. Key findings and conclusions from the 1993 Air Quality Criteria Document (AQCD) for NO_x will be briefly summarized at the beginning of the ISA. The results of recent studies will be integrated with previous findings. Important older studies will be more specifically discussed if they are open to reinterpretation in light of newer data. Generally, only information that has undergone scientific peer review and that has been published (or accepted for publication) in the open literature will be considered. However, exceptions may be made depending on the importance of the subject information and its relevance to the review of the NO_2 NAAQS, as determined in consultation with CASAC. Emphasis will be placed on studies conducted at or near NO_x concentrations found in ambient air. Other studies may be included if they contain unique data such as the documentation of a

[4] Note that evidence related to environmental effects of NO_x will be considered separately in the science assessment conducted as part of the review of the secondary NAAQS for NO_2 and SO_2.

previously unreported effect, documentation of the mechanism for an observed effect, or information on exposure-response relationships.

4.2 ASSESSMENT APPROACH

Introduction

The NCEA-RTP is responsible for preparing the SASD and the ISA for NO_x. Expert authors include EPA staff with an extensive base of knowledge in their respective fields and extramural scientists contracted to the EPA.

Literature Search

The NCEA-RTP uses a systematic approach to identify relevant studies for consideration. A Federal Register Notice is published to announce the initiation of a review and request information from the public. An initial publication base is established by searching MEDLINE and other databases using as key words the terms nitrogen oxides, nitrogen dioxide, NO_x, NO_2, HNO_3, nitric acid, PAN, or total reactive nitrogen. This search strategy is periodically reexamined and modified to enhance identification of pertinent published papers. Additional papers are identified for inclusion in the publication base in several ways. First, EPA staff reviews pre-publication tables of contents for journals in which relevant papers may be published. Second, expert chapter authors are charged with independently identifying relevant literature. Finally, additional publications that may be pertinent are identified by both the public and CASAC during the external review process. The studies identified will include research published or accepted for publication by a date determined to be as inclusive as possible given the relevant target dates in the NAAQS review schedule. Some additional studies, published after that date, may also be included if they provide new information that impacts one or more key scientific issues. The combination of these approaches should produce the comprehensive collection of pertinent studies needed to form the basis of the ISA.

Criteria for Study Selection

In selecting epidemiologic studies for the present assessment, EPA will consider whether a given study contains information on (1) short- or long-term exposures at or near ambient levels of NO_x; (2) health effects of specific NO_x species or indicators related to NO_x sources (e.g.,

motor vehicle emissions, combustion-related particles); (3) health endpoints and populations not previously extensively researched; (4) multiple pollutant analyses and other approaches to address issues related to potential confounding and modification of effects; and/or (5) important methodological issues (e.g., lag of effects, model specifications, thresholds, mortality displacement) related to NO_x exposure effects. Among the epidemiologic studies, particular emphasis will be focused on those relevant to standard setting in the United States. Specifically, studies conducted in the U.S. or Canada will be generally accorded more text discussion than those from other geographic regions. In addition, emphasis in the text will be placed on discussion of (1) new, multi-city studies that employ standardized methodological analyses for evaluating NO_x effects and that provide overall estimates for effects based on combined analyses of information pooled across cities; (2) new studies that provide quantitative effect estimates for populations of interest; and (3) studies that consider NO_x as a component of a complex mixture of air pollutants.

A set of explicit criteria will also be used to select experimental studies for discussion. The selection of research evaluating controlled exposures to laboratory animals will focus primarily on those studies conducted at or near ambient NO_2 concentrations and those studies that approximate expected human exposure conditions in terms of concentration and duration. In discussing the mechanisms of NO_2 toxicity, studies conducted under atmospherically relevant conditions will be emphasized whenever possible. The selection of research evaluating controlled human exposures to NO_x will mainly be limited to studies where subjects were exposed to less than 1 ppm NO_2. For these controlled human exposures, emphasis will be placed on studies that (1) investigate potentially susceptible populations such as asthmatics, particularly studies that compare responses in susceptible individuals with those in age-matched healthy controls; (2) address issues such as dose-response or time-course of responses; (3) investigate exposure to NO_2 separately and in combination with other pollutants such as O_3 and SO_2; (4) include control exposures to filtered air; and (5) have sufficient statistical power to assess findings.

Content and Organization of the SASD

The SASD will be focused on accomplishing two goals. The first goal will be to identify scientific research that is relevant to informing key policy issues. The second goal will be to

produce a base of evidence containing all of the publications relevant to the NO_x review. In order to provide the policy context for this presentation of the scientific research, the introduction to the SASD will present information on the legislative background and purpose of the document, highlight key points from the last review of the NAAQS for NO_2, provide a brief introduction to the key issues to be addressed in the current review, and present an overview of the organization of the document. Subsequent sections of the SASD will provide information on (1) the chemistry of NO_x and the related chemistry of SO_x, as well as sampling and analytic methods for measurement of NO_x and SO_x;[5] (2) environmental concentrations and human exposure to NO_x; (3) dosimetry; (4) toxicologic studies of NO_x health effects in laboratory animals; (5) human clinical studies examining health effects following controlled exposure to NO_x; and (6) epidemiologic studies of health effects from short- and long-term exposure to NO_x. More detailed information on various methods and results for the health studies will be summarized in tabular form in the annex. These tables will generally be organized to include information about (1) concentrations of NO_x levels and averaging times; (2) description of study methods employed; (3) results and comments; and (4) quantitative outcomes for NO_x measures.

In assessing the scientific quality and relevance of epidemiologic, animal toxicologic, and human controlled exposure studies, the following considerations will be taken into account: (1) to what extent are the aerometric data and exposure metrics of adequate quality and sufficiently representative to serve as credible exposure indicators; (2) were the study populations adequately selected and are they sufficiently well-defined to allow for meaningful comparisons between study groups; (3) are the health endpoint measurements meaningful and reliable; (4) are the statistical analyses appropriate, properly performed, and properly interpreted; (5) are likely covariates (i.e., potential confounders or effect modifiers) adequately controlled or taken into account in the study design and statistical analyses; and (6) are the reported findings internally consistent, biologically plausible, and coherent in terms of consistency with other

[5] Separate from the review of the primary NAAQS, a review of the secondary NAAQS also will be conducted. Acidifying compounds move through soil, vegetation, and surface waters, setting off a cascade of adverse ecological effects. Thus, to adequately assess the impacts of acidic deposition on ecological resources, it is prudent to combine the assessment of NO_x and SO_x environmental effects. To support both the primary and secondary NAAQS reviews, a combined discussion of the atmospheric chemistry and measurement techniques for NO_x and SO_x will be performed. Further, the atmospheric chemistry of NO_x and SO_x are intricately linked; thus, discussion of their combined chemistry is more effective than a separate discussion of each pollutant.

known facts. Consideration of these issues will inform our judgments on the relative quality of individual studies and will allow us to focus the assessment on the most pertinent studies.

Content and Organization of the ISA

The organization of the ISA for NO_x will be consistent with that used in the integrative chapter of the criteria document for O_3 (U.S. Environmental Protection Agency, 2006). The ISA will contain information relevant to considering whether it is appropriate to retain or revise the current annual standard and whether it is appropriate to consider setting a separate short-term exposure standard. The content of the ISA will be guided by a series of policy-relevant questions that were derived from the previous review of the NAAQS for NO_2, as well as policy-relevant questions based on new scientific information. These policy-relevant questions are related to two overarching issues. The first issue is whether new evidence reinforces or questions the evidence presented and evaluated in the last NAAQS review. The second issue is whether uncertainties from the last review have been addressed and/or whether new uncertainties have emerged. The specific questions that stem from these issues are listed below by topic area.

A. Air Quality and Atmospheric Chemistry: The ISA will present and evaluate data related to ambient concentrations of NO_x; sources leading to the presence of NO_x in the atmosphere; and chemical reactions that determine the formation, degradation, and lifetime of NO_x in the atmosphere.

- What are the strengths and weaknesses of various methods for measuring NO_2? To what extent are these methods subject to interference from NO_x oxidation products or other substances? Are there products that might be toxicologically significant, such as nitro-PAHs?
- Based on recent air quality and emissions data, what are current concentrations and emissions of NO_2? What spatial and temporal patterns can be seen in the air quality data for NO_2?
- Using air quality and emissions data on NO_x and atmospheric chemistry models, what are likely policy relevant background concentrations of NO_2?

- Because ambient monitoring data are sparse for NO_2, are there other techniques that can be used to better define the range of concentrations and the spatial and temporal variability of NO_2 over the U.S.? Are satellite retrievals or three dimensional chemical transport models useful? Can satellite data be used on a regular basis to improve the characterization of NO_x emissions?

B. Exposure: The ISA will evaluate the factors that influence exposure to NO_x and the uncertainties associated with extrapolation from ambient concentrations to personal exposures to NO_2 of ambient origin.

- Do new data provide evidence to examine different exposure indices or averaging times specifically addressing the long-term standard and the need for a short-term standard (i.e., 1 to 3 hours)?
- What are the uncertainties when extrapolating between stationary NO_x monitoring instruments and personal exposure to NO_2 of ambient origin, especially for susceptible groups? Issues include measurement error in outdoor ambient monitors, the use of monitors for estimating community concentrations, and their use as a surrogate for personal exposure to NO_2 of ambient origin.
- What do measurements of ambient concentration of NO_2 represent? To what extent do they provide an estimate of ambient exposures for health studies, an indicator of personal exposure to NO_2, and/or an indicator of personal exposure to other gaseous pollutants (including CO and HONO) and particle phase pollutants generated by traffic?
- What influence do the patterns of NO_2 exposure, for both indoor and outdoor sources, have on evaluation of health effects? What is the exposure pattern for indoor sources such as gas stoves (i.e., peak, repeated peak, and average NO_2) and how does it relate to ambient NO_2 patterns?
- What data are available to interpret both short- and long-term NO_2 exposures (e.g., 1 hour, 24 hours, 2 weeks, longer periods)? This includes such information as air

exchange rates, indoor sources, distance to highways, and methods for measuring personal exposures to NO_2.

C. Health Effects: The ISA will evaluate the literature related to respiratory effects such as airway responsiveness, pulmonary function, lung inflammation, decreased host defense, emergency department visits, hospitalizations, and mortality. The available literature on cardiovascular effects of NO_x exposure also will be evaluated. Other health effects also may be evaluated. Health effects that occur following both short- and long-term exposures will be evaluated in epidemiologic, human clinical, and toxicologic studies. Efforts will be directed at identifying the lower levels at which effects are observed.

Short-Term Exposure:

- What do controlled human exposure, animal toxicologic, and epidemiologic studies indicate regarding the relationship between short-term, repeated exposures to NO_2 and health effects of concern (e.g., lung function decrements and respiratory symptoms) in healthy individuals and in those with preexisting disease states (e.g., asthmatics)?
- How do results of recent studies expand current understanding of the relationship between repeated, short-term exposure to NO_x and lung function changes or lung function development? What are the lowest levels of NO_x at which these lung function effects are observed?
- What are the effects of NO_x exposure on small airway function in humans (e.g., small-airway resistance, gas-exchange surface and oxygen diffusion capacity, ventilation-perfusion mismatches) and what is the potential clinical relevance of these effects?
- What is the nature and time-course of lung inflammation in healthy persons and in persons with pre-existing lung disease (e.g., asthma)?
- What is the influence of NO_x on host defense against infectious disease?
- Is exposure to NO_x associated with mortality (total, respiratory or cardiovascular), hospital admissions, or emergency department visits as assessed using population-level datasets? What are the lowest ambient NO_x concentrations at which these

associations are observed? The utility of the statistical methods applied will be evaluated (i.e., time series studies). As discussed above, the potential effects of exposure error on epidemiologic outcomes will be evaluated.

- To what extent does exposure to NO_2 contribute to health effects in the cardiovascular, renal, or other systems?
- What is the nature of health effects in persons exposed to multipollutant mixtures that contain NO_x in comparison to exposure to NO_x alone?
- Does exposure to NO_2 (or other NO_x) perturb the biologic function of endogenous NO (e.g., by generating unwanted or excessive reactive nitrogen species)?

Long-Term Exposure:

- Does the scientific evidence support the occurrence of health effects from long-term exposure (e.g., months to years) at ambient levels that are lower than previously observed? If so, what uncertainties are related to these associations and are the health effects in question important from a public health perspective?
- How do results of recent studies expand current understanding of the relationships between repeated, short-term exposure to NO_x and lung function or lung function development? What are the lowest levels of NO_x at which these lung function effects are observed?
- Can long-term exposures to NO_2 result in chronic effects manifested as permanent lung tissue damage, reduction in baseline lung function, or impaired lung function development?
- To what extent does long-term NO_x exposure promote development of asthma or chronic lung disease? What is the relationship between long-term NO_x exposure and shortening of human life span via promotion of such diseases?
- What annual and seasonal patterns of NO_x exposure are most instrumental in promoting potentially harmful health effects?
- What is the nature and time-course of lung inflammation in healthy persons and in persons with pre-existing lung disease (e.g., asthma)?

D. Causality: The ISA will evaluate the evidence for and against a causal relationship between observed health outcomes and NO_x exposure. The ISA will place emphasis on studies conducted at typical ambient levels.

- Does the evidence base contain new information to evaluate the case for or against a causal relationship between health effects and NO_2 exposure?
- What information is available regarding the health impacts of a decrease in ambient levels of NO_x?

E. Uncertainties: The ISA will evaluate uncertainty in the scientific data, particularly in relation to observed epidemiologic findings.

- How do confounding by coexposure to other pollutants (e.g., O_3, PM, SO_2, and CO) and meteorological factors influence the uncertainty of the evidence base for both short- and long-term exposures? The possibility that NO_2 ambient concentrations may serve as a surrogate for personal exposure to vehicle exhaust pollutants, including gases and particles, will be addressed.
- What are the uncertainties due to other confounding factors in epidemiologic studies (e.g., demographic and lifestyle attributes, genetic susceptibility factors, occupational exposure, and medical care)?
- What is the shape of the concentration-response model (e.g., linear vs. threshold models) and associated community risks?
- What uncertainties surround the evidence for long-term effects such as life shortening and development/progression of disease?

F. Biological Mechanisms of Action: The ISA will evaluate the data examining mechanisms for the health outcomes associated with exposure to NO_x.

- Is there new information related to the biological mechanism of action?

- What are the potential mechanisms of response to NO_x, with a focus on physical-chemical characteristics, response pathway(s), and exposure-dose-response relationships?
- What are the inherent interspecies differences in sensitivity to NO_x and in NO_x dosimetry in different regions of the respiratory tract?
- What are the interspecies differences in basic mechanisms of lung injury and repair?
- What NO_x reaction products can be found in the respiratory tract cells, tissues, or fluids as biomarkers of NO_x exposure?
- What are the mechanisms and time-courses of NO_x-induced cellular and tissue injury, repair, and remodeling?
- What are the effects of age, gender, and pre-existing disease on cellular and tissue responses to NO_x-induced injury?
- Which NO_x-induced health effects are sufficiently characterized to be quantitatively compared across species?
- What is the state of knowledge of laboratory animal-to-man extrapolation of effects? Is a credible qualitative extrapolation possible for short- and for long-term exposures?

G. Susceptible Populations: The ISA will examine health outcome data to identify specific groups that are more susceptible to the adverse effects of NO_x exposure than normal healthy adults (e.g., patients with COPD, children, and asthmatics). The host and environmental factors that are responsible for differential susceptibility to NO_x will be investigated.

- Is preexisting respiratory or cardiovascular disease in conjunction with advanced age an important factor in susceptibility to mortality associated with exposure to NO_x?
- Regarding morbidity health endpoints, to what extent are children and asthmatics more sensitive than the general population to NO_x exposure?
- Is susceptibility to the effects of short-term NO_x exposure associated with long-term NOx susceptibility?

- What host and environmental factors (e.g., demographic, socioeconomic, and genetic) are associated with susceptibility to short- and long-term exposure to NO_x?

H. Public Health Impact: The ISA will present concepts related to the potential for defining adverse health effects. To accomplish this, the implications for public health of different health effects will be discussed. This will include, as appropriate, an estimation of the potential number of persons at risk for each health effect.

4.3 PUBLIC AND SCIENTIFIC REVIEW

Review of the Scientific Assessment Support Document

The draft SASD will undergo peer review by external reviewers chosen on the basis of scientific expertise. The broad approach for the peer review includes the following steps: (1) review of text and associated figures and tables; (2) review the presentation of the epidemiologic literature, particularly focusing on the areas of confounding and measurement error; (3) review the summary of the evidence base and integration of the data; (4) review the discussions of strength of associations, robustness, consistency, and coherence; (5) review the discussions on uncertainty; (6) review the clinical and public health perspectives; and (7) identify new issues and literature. Peer reviewers will be required to submit written comments which, along with public comments received, will be considered by EPA for revision of the SASD.

Review of the Integrated Scientific Assessment

Drafts of the ISA will be reviewed by CASAC of EPA's Science Advisory Board (SAB). The SASD will also be made available to CASAC in order to assist with their review of the ISA. CASAC members (see Appendix A) and consultants will review the draft document and discuss their comments in a public meeting announced in the Federal Register. 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. In revising the draft ISA for NO_x, EPA will take into account any such recommendations. EPA will also consider comments received, from CASAC or from the public, at the meeting

itself and any written comments received. EPA anticipates preparing a second draft of the ISA for 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.

5. RISK/EXPOSURE ASSESSMENT

5.1 SCOPE AND ORGANIZATION

The exposure assessment for NO_2 will estimate human exposures associated with current ambient levels of NO_2, with ambient levels that just meet the existing standard, and with ambient levels that just meet any alternative standards under consideration. This assessment will initially draw upon the information presented in the ISA, focusing on exposure and dose metrics that are consistent with health effects of concern. Based on our current understanding of the available evidence, as discussed in the previous criteria document (US EPA, 1993) and in more recent assessments (WHO, 2005; CalEPA, 2006a, 2006b, 2007) and workshops (EPA Workshop on Interpretation of Epidemiologic Studies of Multipollutant Exposure and Health Effects, December 2006), we do not anticipate that there will be sufficient exposure-response or concentration-response data to support a quantitative health risk assessment for NO_2. However, if initial versions of the ISA or initial results from the exposure assessment suggest that a quantitative risk assessment might be appropriate, a scope and methods plan will be developed describing our proposed approach to such an assessment. This plan would be the subject of a consultation with the CASAC NO_x panel and made available to the public for review and comment.

5.2 HISTORICAL PERSPECTIVE

In the previous review of the NAAQS for NO_2, exposure was assessed in a qualitative manner. This qualitative assessment targeted long-term air quality trends as indicated by analysis of ambient monitoring data (US EPA, 1995). An annual standard of 0.053 ppm was retained to protect against long-term exposures and resultant health effects. However, the variability in ambient concentrations and, therefore, the potential for exposure to short-term peak concentrations was also considered. Because at the time of the standard review a few studies indicated the possibility for adverse health effects due to short-term exposures of 0.15-0.20 ppm, the frequency of 1-hour ambient concentrations in excess of 0.15 ppm to 0.30 ppm was

estimated. CASAC concluded that the minimal occurrence of short-term peak concentrations at or above 0.20 ppm indicated that the annual standard would provide adequate health protection against short-term exposures (Wolff, 1995).

5.3 EXPOSURE ASSESSMENT APPROACH

Document Preparation

The exposure assessment will be prepared by EPA's Office of Air Quality Planning and Standards (OAQPS) with technical support from OAQPS contractors.

Overview

A tiered approach will be employed, beginning with an air quality analysis and progressing to a more refined exposure assessment if appropriate. This approach will be informed by the previous review of the NAAQS for NO_2 (US EPA, 1995), recent guidelines from the World Health Organization (2005), and the NO_2 review conducted by the California Environmental Protection Agency (CalEPA, 2006a; 2006b, 2007).

Air Quality Analysis

The first step in this process will be to conduct an air quality analysis relying largely on the information provided in the SASD and the ISA. This analysis will include information on NO_2 properties, current NO_2 air quality patterns, historic trends, and policy-relevant background levels.[6] It will provide a frame of reference for subsequent discussions of current and possible alternative standards. General steps in the process include the following.

- Obtain recent year ambient monitoring data (e.g., 2003-2006)
- Estimate number of exceedances (if any) of the current annual NO_2 standard
- Estimate number of exceedances of several short-term peak air quality indicators (e.g., 1-hour and daily exceedances ranging from 0.10 to 0.20 ppm) given attainment of the current annual NO_2 standard and possibly of alternative standards. Major locations evaluated could include the Los Angeles Consolidated Metropolitan Statistical Area (CMSA), Houston, other

6 Policy-relevant background is defined as the distribution of NO_2 concentrations that would be observed in the U.S. in the absence of anthropogenic (man-made) emissions of NO_2 in the U.S., Canada, and Mexico.

locations that may contain higher than average number of peak concentrations, and an aggregate of all other areas. Criteria will be developed for selection of appropriate areas to include. New prediction equations are to be developed using ambient monitor data to approximate minimum, mean, and maximum estimates for the number of exceedances of one-hour air quality indicators given attainment of the current and alternative annual standards for NO_2.

- Evaluate the relationship between annual average concentrations and 1-hour peak concentrations across multiple years. Similarly, the relationship can be explored between daily average and annual average concentrations and between hourly peak concentrations and daily average concentrations.

Screening-level Exposure Assessment

Depending on the outcome of the air quality analysis, a screening-level exposure assessment may be performed. The purpose of this assessment would be to better understand the relationship between ambient concentrations, local sources, and human exposure. The approach would involve the development of screening-level exposure metrics to estimate variability in human exposure rather than assuming that ambient concentrations are equal to exposures. This screening-level exposure estimation would consider several factors, including those listed below.

- Factors that may contribute to greater personal exposures (short- and long-term) including the impacts of important sources of NO_2 (e.g., roadways, outdoor point sources such as gas utilities, and indoor sources such as gas stoves) and the impacts of human behavior (e.g., time spent outdoors, time spent near roadways, and activity level).
- Factors that may contribute to lessened personal exposures (short- and long-term) including the decay of NO_2 indoors and the time spent indoors.
- Exposure levels experienced by susceptible populations (e.g., asthmatic children) relative to those experienced by the general public
- Population living in areas exceeding the screening-level exposure metrics

Refined Exposure Assessment

Although the above screening-level assessment represents an improvement over the assumption that exposures are equal to ambient concentrations, it relies on a number of

simplifying assumptions which introduce uncertainty into the estimates. Depending on the relationship between these screening-level exposure estimates and the exposure-response information, or health effects benchmarks, for health effects of concern, more refined estimates of exposure may be developed. The purpose of a more refined exposure assessment would be to incorporate personal human attributes, such as time-location-activity patterns and human physiology, more realistically. The general approach of this assessment would be to estimate population exposures to ambient NO_2 in a number of urban areas across the U.S. Areas included in the analysis would be selected with the goal of achieving variation in population, geography, demographics, climate, and NO_2 air quality. Exposure estimates would be generated for current NO_2 levels, for levels assuming attainment of the recent NAAQS, and for levels assuming attainment of any alternative standards under consideration.

The exposure assessment would take into account several important factors including the magnitude and duration of exposures, frequency of repeated high exposures, and breathing rate of individuals at the time of exposure. Estimates would be developed for multiple indicators of exposure including 1) counts of people exposed one or more times to a given NO_2 concentration while at a specified breathing rate and 2) counts of person-occurrences of particular exposures, which accumulate across all people in the population of interest.

A new version of EPA's Air Pollutants Exposure (APEX) model (also referred to as the Total Risk Integrated Methodology/Exposure (TRIM.Expo) model) would be used in this analysis. APEX is a Monte Carlo simulation model that can be used to simulate a large number of randomly sampled individuals within each urban area thus generating area-wide estimates of population exposure. APEX simulates exposures in indoor, outdoor, and in-vehicle microenvironments while taking into consideration the movement of individuals through time and space. Human activity data needed for this analysis would be drawn from the Consolidated Human Activity Database (CHAD), which is developed and maintained by ORD's National Exposure Research Laboratory (NERL). A key issue would be the development of an approach for creating longitudinal activity sequences for individuals based on a cross-sectional activity database that includes 24-hour records.

5.4 CRITERIA FOR SELECTION OF ASSESSMENT APPROACH

Criteria will be established to determine the level of detail warranted and the specific design of the exposure assessment. The factors listed below will inform these decisions.

- outcome of the ambient air quality analysis
- weight-of-evidence, as provided in the ISA, from new clinical studies with relevant exposure-response data, particularly those conducted at or near current ambient concentrations
- weight-of-evidence, as provided in the ISA, from new epidemiological studies that evaluate the relationship between short-term repeated peak exposures and health outcomes
- new information regarding susceptible populations identified in previous reviews (e.g., those with pre-existing respiratory disease and children 5-12 years of age) or information regarding newly identified (i.e., since the previous review) susceptible populations
- information regarding the relative contribution to exposure of indoor sources versus outdoor sources
- information on the potential impact of roadway concentrations on nearby residents and on specific microenvironmental concentrations (e.g., while traveling inside motor vehicles)
- existence of the data required to perform the analyses in the more refined tiers of the assessment

5.5 UNCERTAINTY AND VARIABILITY

APEX is a Monte Carlo simulation model which explicitly incorporates the inherent variability of the model input data. Developing appropriate distributions representing variability and uncertainty in various model inputs (e.g., air exchange rates, NO_2 decay rates, physiological parameters) would be a key part of a refined modeling effort. The primary difficulty in performing an uncertainty analysis is the quantitative characterization of the uncertainties of the model inputs and model formulation. Information is often available to characterize the variability of model inputs, and sometimes to characterize the variability and uncertainty combined. However, it is often more difficult to estimate the uncertainty separately from the variability. In the case of a possible APEX NO_2 application, the data are sufficient to provide

reasonable bounds or ranges for the uncertainties of most of the model inputs. If we were to conduct a refined analysis, we would plan to assess the impacts of the uncertainties of the model inputs across these ranges, and use these results to inform a discussion of model uncertainties.

A 2-dimensional Monte Carlo Latin hypercube sampling approach could be used as a combined variability and uncertainty analysis for APEX. Essentially, a Monte Carlo approach entails performing many model runs with model inputs randomly sampled from specified distributions reflecting variability and uncertainty of the model inputs. The 2-dimensional Monte Carlo method allows for the separate characterization of the variability and uncertainty in the model results (Morgan and Henrion, 1990), taking into account the uncertainty and the variability of all of the APEX inputs.

The methods for assessing input parameter uncertainty and model formulation or structure uncertainty are different. It is difficult to incorporate the uncertainties due to the model formulation into a quantitative assessment of uncertainty in a straightforward manner. The preferred way to assess model formulation uncertainty is by comparing model predictions with measured values, while having fairly complete knowledge of the uncertainty due to input parameters. In the absence of measurements that can be used to estimate model uncertainty, one must rely on informed judgment. Our approach to assessing model formulation uncertainty would be to partition this uncertainty into that of the components, or sub-models, of APEX. For each of the sub-models within APEX, we would discuss the simplifying assumptions and those uncertainties associated with the sub-models which are distinct from the input data uncertainties. Where possible, we would evaluate these sub-models by comparing their predictions with measured data. Otherwise, we would formulate an informed judgment as to a range of plausible uncertainties for the sub-models. We would quantitatively assemble the different types of uncertainties and variability to present an integrated analysis of uncertainty and variability.

5.6 PUBLIC AND SCIENTIFIC REVIEW

CASAC of EPA's Science Advisory Board (SAB) will be consulted on the assessment approach at a public meeting. Drafts of the exposure analysis will also be reviewed by CASAC. CASAC members and consultants (see Appendix A) will review the draft document and discuss

their comments in a public meeting announced in the Federal Register. 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. In revising the draft exposure analysis for NO_2, EPA will take into account any such recommendations. EPA will also consider comments received, from CASAC or from the public, at the meeting itself and any written comments received. EPA anticipates preparing a second draft of the exposure analysis for 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.

6. POLICY ASSESSMENT/RULEMAKING

Based on the information in the ISA and the exposure assessment report, the Agency will develop an ANPR that reflects EPA views regarding the need to retain or revise the NAAQS for NO_2. The ANPR will identify conceptual evidence- and risk-based approaches for reaching policy judgments, discuss what the science and exposure assessment say about the adequacy of the current standards, and present any preliminary exposure information associated with alternative standards. The ANPR will also describe a range of policy options for standard setting including a description of the underlying interpretations of the scientific evidence and risk/exposure information that might support such alternative standards and that could be considered by the Administrator in making NAAQS decisions. Such a policy assessment will help to bridge the gap between the Agency's scientific assessment and the judgments required of the Administrator in determining whether it is appropriate to retain or revise the standards. The use of an ANPR will provide an opportunity for both CASAC and the public to evaluate the policy options under consideration and to offer comments and recommendations to inform the development of a proposed rule. Issuance of a proposed and final rule will complete the rulemaking process.

7. REFERENCES

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APPENDIX A

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

FISCAL YEAR 2007

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), carbon monoxide (CO), nitrogen dioxide (NO_2) and sulfur dioxide (SO_2). To perform such reviews, in each case the Committee forms a review panel consisting of CASAC members 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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