



EPA United States
Environmental
Protection Agency

Draft Integrated Plan for Review of the Primary National Ambient Air Quality Standards for Sulfur Dioxide

Notice

This document is a preliminary draft. It has not been formally released by EPA and should not at this stage be construed to represent Agency policy. It is being circulated for comment on its technical accuracy and policy implications.

April 2007

Draft Plan for Review of the Primary National Ambient Air Quality Standards for Sulfur Dioxide

U. S. Environmental Protection Agency
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and

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DISCLAIMER

This draft plan for the review of the primary national ambient air quality standards for sulfur 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 sulfur dioxide (SO₂). The purpose of this document is to communicate the plan for reviewing the primary NAAQS for SO₂. The review of the secondary NAAQS for SO₂, to be conducted in conjunction with the review of the secondary NAAQS for nitrogen dioxide (NO₂), is being addressed in a separate plan.

This integrated review plan is organized into six chapters to address all of the major components of the review. Chapter 1 presents background information on the review process, the legislative requirements for the review of the NAAQS, past reviews of the NAAQS for SO₂, and the scope of the current review. 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.

This review plan is a draft document and will be subject to consultation at a public meeting with the Clean Air Scientific Advisory Committee (CASAC)¹ of EPA's Science Advisory Board. The final review plan will be informed by comments received from CASAC and the public. Public comments are also being solicited on this plan.

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 SO₂, contains four major components. Each of these components is described in this section. The first component is an integrated

¹Members of the CASAC and members of the CASAC NO_x/SO_x Primary Standard Review Panel are listed in the Appendix.

1 review plan. This plan will specify the schedule for the review, the process for conducting the
2 review, and the key policy-relevant science issues that will guide the review.

3 The second component of the review process is a science assessment. Under the new
4 process, a concise synthesis of the most policy-relevant science will be compiled into an
5 integrated science assessment (ISA). The ISA for this review of the SO₂ NAAQS will critically
6 evaluate and integrate scientific information on the health effects associated with exposure to
7 sulfur oxides (SO_x) in the ambient air. It will focus on scientific information that has become
8 available since the last review and will reflect the current state of knowledge on the most
9 relevant issues pertinent to the review of the primary SO₂ NAAQS. The ISA will be supported
10 by a more detailed and comprehensive assessment of the scientific literature, which will be
11 compiled into a science assessment support document (SASD). Together, the ISA and SASD
12 will replace the Air Quality Criteria Document from previous NAAQS reviews.

13 The third component of the review process is a risk/exposure assessment. For the review
14 of the SO₂ standard, we plan to focus on conducting an exposure assessment drawing upon the
15 information in the ISA. This exposure assessment will develop, as appropriate, quantitative
16 estimates of human exposure associated with current ambient levels of SO₂ as well as with levels
17 that just meet the current standard and possible alternative standards. A concise exposure
18 assessment report will be prepared that focuses on key results, observations, and uncertainties.

19 The fourth component of the revised process will be a policy assessment/rulemaking.
20 Under the new process, a staff paper, such as that prepared in previous NAAQS reviews, will not
21 be prepared. Rather, a policy assessment reflecting Agency views will be published in the
22 Federal Register as an advance notice of proposed rulemaking (ANPR). The policy assessment
23 will consider the available scientific evidence and exposure/risk analyses, together with related
24 limitations and uncertainties, and will focus on the basic elements of an air quality standard:
25 indicator, averaging time, form,² and level. These elements, which serve to define each standard,
26 will be considered collectively in evaluating the public health protection afforded by the
27 standards. The ANPR will be accompanied by supporting documents, such as air quality
28 analyses and technical support documents, as appropriate. Issuance of a proposed and final rule
29 will complete the rulemaking process.

² The “form” of a standard defines the air quality statistic that is to be compared to the level of the standard in determining whether an area attains the standard.

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.”³ 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.”⁴

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

³ 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)].

⁴ 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.”

1 pollution at levels below those at which human health effects can be said to occur with
2 reasonable scientific certainty. Thus, in selecting primary standards that include an adequate
3 margin of safety, the Administrator is seeking not only to prevent pollution levels that have been
4 demonstrated to be harmful but also to prevent lower pollutant levels that may pose an
5 unacceptable risk of harm, even if the risk is not precisely identified as to nature or degree.

6 In selecting a margin of safety, the EPA considers such factors as the nature and severity
7 of the health effects involved, the size of sensitive population(s) at risk, and the kind and degree
8 of the uncertainties that must be addressed. The selection of any particular approach to
9 providing an adequate margin of safety is a policy choice left specifically to the Administrator's
10 judgment. See *Lead Industries Association v. EPA*, supra, 647 F.2d at 1161-62.

11 In setting standards that are "requisite" to protect public health and welfare, as provided
12 in section 109(b), EPA's task is to establish standards that are neither more nor less stringent
13 than necessary for these purposes. In so doing, EPA may not consider the costs of implementing
14 the standards. See generally *Whitman v. American Trucking Associations*, 531 U.S. 457, 465-
15 472, 475-76 (2001).

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

27 28 **1.3 HISTORY OF REVIEWS OF THE PRIMARY NAAQS FOR SO₂**

29 On April 30, 1971, the EPA promulgated primary NAAQS for SO₂. These primary
30 standards, which were based on the findings outlined in the original 1969 Air Quality Criteria for
31 Sulfur Oxides, were set at 0.14 parts per million (ppm) averaged over a 24-hour period, not to be

1 exceeded more than once per year, and 0.030 ppm annual arithmetic mean. In 1982, EPA
2 published the Air Quality Criteria for Particulate Matter and Sulfur Oxides along with an
3 addendum of newly published controlled human exposure studies, which updated the scientific
4 criteria upon which the initial standards were based (EPA, 1982). In 1986, a second addendum
5 was published presenting newly available evidence from epidemiologic and controlled human
6 exposure studies (EPA, 1986). In 1988, EPA reviewed and revised the health criteria upon
7 which the SO₂ standards were based. As a result of that review, EPA published a proposed
8 decision not to revise the existing standards (53 FR 14926). However, EPA specifically
9 requested public comment on the alternative of revising the current standards and adding a new
10 1-hour primary standard of 0.4 ppm.

11 As a result of public comments on the 1988 proposal and other post-proposal
12 developments, EPA published a second proposal on November 15, 1994 (59 FR 58958). The
13 1994 re-proposal was based in part on a supplement to the second addendum of the criteria
14 document, which evaluated new findings on short-term SO₂ exposures in asthmatics (EPA,
15 1994a). As in the 1988 proposal, EPA proposed to retain the existing 24-hour and annual
16 standards. The EPA also solicited comment on three regulatory alternatives to further reduce the
17 health risk posed by exposure to high 5-minute peaks of SO₂ if additional protection were judged
18 to be necessary. The three alternatives included: 1) Revising the existing primary SO₂ NAAQS
19 by adding a new 5-minute standard of 0.60 ppm SO₂; 2) establishing a new regulatory program
20 under section 303 of the Act to supplement protection provided by the existing NAAQS, with a
21 trigger level of 0.60 ppm SO₂, one expected exceedance; and 3) augmenting implementation of
22 existing standards by focusing on those sources or source types likely to produce high 5-minute
23 peak concentrations of SO₂. On May 22, 1996, EPA's final decision, that revisions of the
24 NAAQS for sulfur oxides were not appropriate at that time, was announced in the Federal
25 Register. In that decision, EPA announced an intention to propose guidance, under section
26 303 of the Act, to assist states in responding to short-term peak levels of SO₂. The basis for the
27 decision, and subsequent litigation, is discussed below in Chapter 3.

28
29

1 **1.4 SCOPE OF THE REVIEW**

2 The focus for the current review will be on evidence related to the health effects of SO₂,
3 alone and in combination with other pollutants. The principal atmospheric transformation
4 products of SO₂ (sulfuric acid and sulfates) are components of ambient particulate matter (PM)
5 and are currently reviewed and addressed under the NAAQS for PM. This will continue to be
6 the case in the next review of the NAAQS for PM and; therefore, it is appropriate to focus the
7 present review on gaseous SO_x. Gaseous SO_x species other than SO₂ occur in the atmosphere at
8 much lower concentrations than SO₂. Furthermore, previous reviews of the air quality criteria
9 for SO_x have not identified evidence for health effects caused by ambient or near ambient air
10 concentrations of gaseous SO_x other than SO₂. Therefore, this review will focus on SO₂ as an
11 indicator of gaseous SO_x. However, the possible influence of other atmospheric pollutants,
12 including sulfate, on the interpretation of the role of SO₂ in health effects studies will be
13 considered.

14

2. REVIEW SCHEDULE

In May of 2006, 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 SO_x and the SO₂ NAAQS and issued a call for information in the Federal Register (71 FR 28023). Table 2-1 outlines the schedule under which the Agency is currently conducting this review.⁵

Table 2-1. Proposed Schedule for Development of Revised SO_x Integrated Science Assessment (ISA) and SO₂ Primary Standard

Stage of Review	Major Milestone	Draft Target Dates
Integrated Plan	Literature Search	Ongoing
	Federal Register Call for Information	May 2006
	Prepare Draft SO ₂ NAAQS Work Plan	February 2007
	Workshop on science/policy issues	February 2007
	CASAC consultation	March 2007
	Prepare final integrated SO ₂ NAAQS Work Plan	April 2007
Science Assessment	Prepare first draft of ISA	September 2007
	CASAC/public review first draft ISA	December 2007
	Prepare second draft of ISA	April 2008
	CASAC/public review second draft ISA	July 2008
	Prepare final ISA	September 2008
Risk/Exposure Assessment	Prepare assessment methodology	October 2007
	CASAC/public consultation on methodology	December 2007
	Prepare first draft risk/exposure assessment	May 2008
	CASAC/public review of the first draft	July 2008
	Prepare second draft risk/exposure assessment	November 2008
	CASAC/public review of second draft	January 2009
Policy Assessment/Rulemaking	ANPR	April 2009
	CASAC review/public comment on ANPR	June 2009
	Proposed rulemaking	October 2009
	Final rulemaking	July 2010

⁵ This schedule is subject to change pending issuance of a court-ordered schedule that will govern the completion of the review.

3. KEY POLICY-RELEVANT ISSUES

3.1 HISTORICAL PERSPECTIVE

The first NAAQS for SO₂ was established in 1971. At that time, a 24-hour standard of 0.14 ppm, not to be exceeded more than one time per year, and an annual standard of 0.03 ppm were judged to be both adequate and necessary to protect the public health. The most recent review of the NAAQS for SO₂, completed in 1996, retained the existing standards. The 1996 review focused on the question of whether an additional short-term standard (e.g., 5-minute) was necessary to protect against short-term, peak exposures. Based on the scientific evidence, the administrator judged that repeated exposures to 5-minute peak SO₂ levels (≥0.60 ppm) could pose a risk of significant health effects for asthmatic individuals at elevated ventilation rates. The Administrator also concluded that the likely frequency of such effects should be a consideration in assessing the overall public health risks. Based upon an exposure analysis conducted by EPA, the Administrator concluded that exposure of asthmatics to SO₂ at levels that can reliably elicit adverse health effects is likely to be a rare event when viewed in the context of the entire population of asthmatics. Therefore, 5-minute peak SO₂ levels were judged not to pose a broad public health problem when viewed from a national perspective, and a 5-minute standard was not promulgated. In lieu of a 5-minute standard, EPA announced an intention to propose guidance to assist states in responding to short-term peak levels of SO₂.

The American Lung Association and the Environmental Defense Fund challenged EPA's decision not to establish a 5-minute standard. On January 30, 1998, the Court of Appeals for the District of Columbia found that EPA had failed to adequately explain its determination that no revision to the SO₂ NAAQS was appropriate and remanded the decision back to EPA for further explanation. In response, EPA has collected and analyzed additional air quality data focused on 5-minute concentrations of SO₂. These air quality analyses conducted since the last review will help inform this review, which will address issues raised in the Court's remand of the Agency's last decision. No further Agency action has been taken.

3.2 ISSUES TO BE CONSIDERED IN THE CURRENT REVIEW

The first step in reviewing the adequacy of the current primary standard is to consider whether the available body of scientific evidence supports or calls into question the scientific conclusions reached in the last review regarding health effects related to exposure to SO₂ 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/substantiated the scientific support for the occurrence of health effects at levels of SO₂ found in the ambient air?
- Does new information impact conclusions from the previous review regarding the effects of SO₂ on susceptible populations?
- To what extent does newly available information reinforce or call into question evidence for associations between short-term (e.g., 24-hour average, 5-minute peak) exposures to SO₂ and adverse health effects?
- To what extent does newly available information reinforce or call into question evidence for associations between long-term exposure to SO₂ and adverse health effects?
- At what levels of SO₂ 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 longer-term exposures to SO₂?

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 SO₂ 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 levels of concern for SO₂-induced health effects will occur in areas that meet the current primary standard for SO₂? If so, are these

1 exposures of sufficient magnitude such that the health effects might reasonably be
2 judged to be important from a public health perspective? What are the important
3 uncertainties associated with these exposure estimates?

4 If there is support for consideration of revised primary standards, the Agency will identify ranges
5 of options for alternative standards in terms of the indicator, averaging time, form, and level.

6 The following questions will inform the identification of any such alternative standards.

- 7 • Does the evidence, including air quality and exposure assessments, provide support
8 for considering different exposure indices or averaging times?
- 9 • What is the range of levels that is supported by the evidence, and what are the
10 uncertainties and limitations in that evidence?
- 11 • What is the range of forms supported by the evidence, and what are the uncertainties
12 and limitations in that evidence?

13

4. SCIENCE ASSESSMENT

4.1 SCOPE AND ORGANIZATION

The science assessment 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 SO₂ in ambient air.⁶ The SASD, which evaluates and summarizes relevant studies, will provide a detailed basis for developing the ISA. The SASD will include scientific evidence relevant to the review of the primary NAAQS. This information will be organized by discipline in the areas of atmospheric sciences, ambient monitoring, exposure assessment, dosimetry, clinical studies, toxicology and epidemiology. The ISA will draw from the evidence presented in the SASD and synthesize the current state of knowledge on the most relevant issues pertinent to the review of the NAAQS for SO₂. Discussions in the ISA will focus on the key policy questions described in Chapter 3 of this document. The ISA will synthesize information on the health effects of SO₂ drawing from the disciplines noted above. These discussions will be placed in the context of the atmospheric environment (i.e, those aspects that consider the nature, sources, distribution, measurement, and/or concentrations of SO_x in ambient air). The ISA will also evaluate available information relevant to assessing human exposures and risks to public health associated with these exposures.

The focus of the ISA and the SASD will be on literature published since the previous review of the air quality criteria for SO₂. Key findings and conclusions from the 1982 Air Quality Criteria Document and First Addendum (EPA, 1982), the 1986 Second Addendum (EPA, 1986), and the 1994 Supplement to the Second Addendum (EPA, 1994a) 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

⁶ Note that evidence related to environmental effects of SO_x will be considered separately in the science assessment conducted as part of the review of the secondary NAAQS for NO₂ and SO₂.

1 information and its relevance to the review of the SO₂ NAAQS, as determined in consultation
2 with CASAC. Emphasis will be placed on studies conducted at or near SO₂ concentrations
3 found in ambient air. Other studies may be included if they contain unique data such as the
4 documentation of a previously unreported effect, documentation of the mechanism for an
5 observed effect, or information on exposure-response relationships.

8 **4.2 ASSESSMENT APPROACH**

9 **Document Preparation**

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

14 **Literature Search**

15 The NCEA-RTP uses a systematic approach to identify relevant studies for consideration.
16 A Federal Register Notice is published to announce the initiation of a review and to request
17 information from the public. An initial publication base is established by searching MEDLINE
18 and other databases using as key words the following terms: sulfur oxides, sulfur dioxide, SO_x,
19 SO₂, and reduced sulfur gases. This search strategy is periodically reexamined and modified to
20 enhance identification of pertinent published papers. Additional papers are identified for
21 inclusion in the publication base in several ways. First, EPA staff reviews pre-publication tables
22 of contents for journals in which relevant papers may be published. Second, expert chapter
23 authors are charged with independently identifying relevant literature. Finally, additional
24 publications that may be pertinent are identified by both the public and CASAC during the
25 external review process. The studies identified will include research published or accepted for
26 publication by a date determined to be as inclusive as possible given the relevant target dates in
27 the NAAQS review schedule. Some additional studies, published after that date, may also be
28 included if they provide new information that impacts one or more key scientific issues. The
29 combination of these approaches should produce a comprehensive collection of pertinent studies
30 for review in the SASD and to form the basis of the ISA.

1 **Criteria for Study Selection**

2 In selecting epidemiologic studies for the present assessment, EPA will consider whether
3 a given study contains information on (1) short- or long-term exposures at or near ambient levels
4 of SO₂; (2) health effects of specific SO_x species or indicators related to SO₂ sources; (3) health
5 endpoints and populations not previously researched; (4) multiple pollutant analyses and other
6 approaches to address issues related to potential confounding and modification of effects; and/or
7 (5) important methodological issues (e.g., lag of effects, model specifications, thresholds,
8 mortality displacement) related to SO₂ effects. Among the epidemiologic studies, particular
9 emphasis is focused on those relevant to standard setting in the United States. Specifically,
10 studies conducted in the United States or Canada will be generally accorded more text discussion
11 than those from other geographic regions. In addition, emphasis in the text is placed on
12 discussion of (1) new, multi-city studies that employ standardized methodological analyses for
13 evaluating SO₂ effects and that provide overall estimates for effects based on combined analyses
14 of information pooled across cities; (2) new studies that provide quantitative effect estimates for
15 populations of interest; and (3) studies that consider SO₂ as a component of a complex mixture of
16 air pollutants.

17 A set of explicit criteria will also be used to select experimental studies for discussion.
18 The selection of research evaluating controlled exposures of laboratory animals will focus
19 primarily on those studies conducted at or near ambient SO₂ concentrations and those studies that
20 approximate expected human exposure conditions in terms of concentration and duration.
21 In discussing the mechanisms of SO₂ toxicity, studies conducted under atmospherically relevant
22 conditions will be emphasized whenever possible. The selection of research evaluating
23 controlled human exposures to SO₂ will mainly be limited to studies where subjects were
24 exposed to less than 1 ppm, which represents the upper end of the range of interest that was
25 identified in the previous review of the NAAQS for SO₂. For these controlled human exposures,
26 emphasis will be placed on studies that (1) investigate potentially susceptible populations such
27 as asthmatics, particularly studies that compare responses in susceptible individuals with those in
28 age-matched healthy controls; (2) address issues such as dose-response or time-course of
29 responses; (3) investigate exposure to SO₂ separately and in combination with other pollutants;
30 (4) include controlled exposures to filtered air; and (5) have sufficient statistical power to assess
31 findings.

1 **Content and Organization of the SASD**

2 The SASD will be focused on accomplishing two goals. The first goal will be to identify
3 scientific research that is relevant to informing key policy issues. The second goal will be to
4 produce a base of evidence containing all of the publications relevant to the SO₂ NAAQS review.
5 In order to provide the policy context for this presentation of the scientific research, the
6 introduction to the SASD will present information on the legislative background and purpose of
7 the document, highlight key points from the last review of the NAAQS for SO₂, provide a brief
8 introduction to the key issues to be addressed in the current review, and present an overview of
9 the organization of the document. Subsequent sections of the SASD will provide information on
10 (1) the atmospheric chemistry of SO₂ as well as the sampling/analytic methods for measurement
11 of SO₂⁷; (2) environmental concentrations and human exposure to SO₂; (3) dosimetry; (4)
12 toxicologic studies of SO₂ health effects in laboratory animals; (5) human clinical studies
13 examining health effects following controlled exposure to SO₂; and (6) epidemiologic studies of
14 health effects from short- and long-term exposure to SO₂. More detailed information on various
15 methods and results for the health studies will be summarized in tabular form in the annex.
16 These tables will generally be organized to include information about (1) concentrations of SO₂
17 and averaging times; (2) description of study methods employed; (3) results and comments; and
18 (4) quantitative outcomes for SO₂ effect estimates.

19 In assessing the scientific quality and relevance of epidemiologic, animal toxicologic, and
20 human controlled exposure studies, the following considerations will be taken into account:
21 (1) to what extent are the aerometric data and exposure metrics of adequate quality and
22 sufficiently representative to serve as credible exposure indicators; (2) were the study
23 populations adequately selected and are they sufficiently well-defined to allow for meaningful
24 comparisons between study groups; (3) are the health endpoint measurements meaningful and
25 reliable; (4) are the statistical analyses appropriate, properly performed, and properly interpreted;
26 (5) are likely covariates (i.e., potential confounders or effect modifiers) adequately controlled or
27 taken into account in the study design and statistical analyses; and (6) are the reported findings
28 internally consistent. Consideration of these issues will inform our judgments on the relative

⁷ This section of the SASD will also provide information on NO₂ in order to support the reviews of the primary and secondary NAAQS for both SO₂ and NO₂. The atmospheric chemistry of NO_x and SO_x are intricately linked. Therefore, discussion of their combined chemistry is more effective and more efficient than a separate discussion of each pollutant.

1 quality of individual studies and will allow us to focus the assessment on the most pertinent
2 studies.

3

4 **Content and Organization of the ISA**

5 The organization of the ISA for SO₂ will be consistent with that used in the integrative
6 chapter of the criteria document for O₃ (U.S. Environmental Protection Agency, 2006). The ISA
7 will contain information relevant to considering whether it is appropriate to retain or revise the
8 current annual standard and whether it is appropriate to consider setting a separate short-term
9 peak exposure standard. The content of the ISA will be guided by a series of policy-relevant
10 questions that were derived from the previous review of the NAAQS for SO₂, as well as policy-
11 relevant questions based on new scientific information. These policy-relevant questions are
12 related to two overarching issues. The first issue is whether new evidence reinforces or calls into
13 question the evidence presented and evaluated in the last NAAQS review. The second issue is
14 the extent to which uncertainties from the last review have been addressed and/or whether new
15 uncertainties have emerged. Specific questions that stem from these issues are listed below by
16 topic area.

17

18 A. Air Quality and Atmospheric Chemistry: The ISA will present and evaluate data related
19 to ambient concentrations of SO₂; sources leading to the presence of SO₂ in the
20 atmosphere; and chemical reactions that determine the formation, degradation, and
21 lifetime of SO₂ in the atmosphere.

22

- What are the strengths and weaknesses of various methods for measuring SO₂?

23

- Based on recent air quality and emissions data, what are current concentrations and emissions of SO₂? What spatial and temporal patterns can be seen in the air quality data for SO₂?

24

25

26

- Using air quality and emissions data as well as atmospheric chemistry models, what are the likely policy relevant background concentrations of SO₂?

27

28

1 B. Exposure: The ISA will evaluate the factors that influence exposure to SO₂ and the
2 uncertainties associated with extrapolation from ambient concentrations to personal
3 exposures to SO₂ of ambient origin.

- 4 • What information is available to assess SO₂ exposures of various averaging times?
- 5 • What are the uncertainties when extrapolating between stationary SO₂ monitoring
6 instruments and personal exposure to SO₂ of ambient origin, especially for
7 susceptible groups? Issues include measurement error in outdoor ambient monitors,
8 the use of monitors for estimating community concentrations, and their use as a
9 surrogate for personal exposure to SO₂ of ambient origin.
- 10 • What do measurements of ambient concentration of SO₂ represent? To what extent
11 do they provide an estimate of ambient exposures for health studies, an indicator of
12 personal exposure to SO₂, and/or an indicator of personal exposure to other
13 pollutants?
- 14 • What influence do the patterns of SO₂ exposure have on evaluation of health effects?
- 15 • What data are available to interpret SO₂ exposures? This includes such information
16 as air exchange rates and methods for measuring personal exposures to SO₂.

17
18 C. Health Effects: The ISA will evaluate the literature related to respiratory effects (e.g.,
19 airway responsiveness, pulmonary function, lung inflammation, emergency department
20 visits, hospitalizations, and mortality) and cardiovascular effects. Other health effects may
21 also be evaluated. Health effects that occur following both short- and long-term exposures
22 will be evaluated in epidemiologic, human clinical, and toxicologic studies. Efforts will be
23 directed at identifying the lowest levels at which effects are observed.

24
25 Short-Term Exposure:

- 26 • What do controlled human exposure, animal toxicologic, and epidemiologic studies
27 indicate regarding the relationship between short-term (e.g., 24-hour average),
28 repeated exposures to SO₂ and health effects of concern in healthy individuals and in
29 those with preexisting disease states (e.g., asthmatics)?

- 1 • What does the available evidence from human and animal toxicologic studies as well
2 as epidemiologic studies suggest regarding the potential health effects of short-term
3 peak exposures (e.g., 5-minute exposures) in healthy individuals and in those with
4 preexisting disease states such as asthmatics?
- 5 • How do results of recent studies expand current understanding of the relationship
6 between repeated, short-term exposure to SO₂ and lung function changes or lung
7 function development? What are the lowest levels of SO₂ at which these lung function
8 effects are observed?
- 9 • What are the effects of SO₂ exposure on small airway function in humans (e.g., small-
10 airway resistance, gas-exchange surface and oxygen diffusion capacity, ventilation-
11 perfusion mismatches) and what is the potential clinical relevance of these effects?
- 12 • What is the nature and time-course of health effects of concern in healthy persons and
13 in persons with pre-existing lung disease (e.g., asthma)?
- 14 • Is exposure to SO₂ associated with mortality (total, respiratory, and/or cardiovascular),
15 hospital admissions, and/or emergency department visits as assessed using population-
16 level datasets? What are the lowest ambient SO₂ concentrations at which these
17 associations are observed? What are the uncertainties associated with this data?
- 18 • To what extent does exposure to SO₂ contribute to health effects in the cardiovascular,
19 reproductive, or other systems?
- 20 • What is the nature of health effects in persons exposed to multipollutant mixtures that
21 contain SO₂ in comparison to exposure to SO₂ alone?

22

23 Long-Term Exposure:

- 24 • Does the scientific evidence support the occurrence of health effects from long-term
25 exposure (e.g., months to years) at ambient levels that are lower than previously
26 observed? If so, what uncertainties are related to these associations and are the health
27 effects in question important from a public health perspective?

- 1 • Can long-term exposures to SO₂ result in chronic effects manifested as permanent lung
2 tissue damage, reduction in baseline lung function, or impaired lung function
3 development?
- 4 • To what extent does long-term SO₂ exposure promote development of asthma or
5 chronic lung disease? What is the relationship between long-term SO₂ exposure and
6 shortening of human life span via promotion of such diseases?
- 7 • What annual and seasonal patterns of SO₂ exposure are most instrumental in
8 promoting potentially harmful health effects?
- 9 • What is the nature and time-course of lung inflammation in healthy persons and in
10 persons with pre-existing lung disease (e.g., asthma)?

11

12 D. Causality: The ISA will evaluate the evidence as a basis for making inferences about the
13 causal nature of associations between SO₂ exposure and observed health outcomes. The
14 ISA will place emphasis on studies conducted at typical ambient levels.

- 15 • Does the evidence base contain new information to evaluate the case for or against a
16 causal relationship between health effects and SO₂ exposure?
- 17 • What information is available regarding the health impacts of a decrease in ambient
18 levels of SO₂?

19

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

- 22 • How do confounding by coexposure to other pollutants and by meteorological factors
23 influence the uncertainty of the evidence base for both short- and long-term
24 exposures?
- 25 • To what extent are the observed health effects associations attributable to SO₂ versus
26 the pollutant mixtures that SO₂ may be representing? For example, ambient SO₂
27 concentrations may be serving as a surrogate measure for long range transport of
28 particles.

- 1 • What are the uncertainties due to other confounding factors in epidemiologic studies
2 (e.g., demographic and lifestyle attributes, genetic susceptibility factors, occupational
3 exposure, and medical care)?
- 4 • What is the shape of the concentration-response curve (e.g., linear vs. threshold
5 models) and what are the associated community risks?
- 6 • What uncertainties surround the evidence for long-term effects such as life shortening
7 and development/progression of disease?

8

9 F. Biological Mechanisms of Action: The ISA will evaluate the data examining
10 mechanisms for the health outcomes associated with exposure to SO₂.

- 11 • Is there new information related to the biological mechanism of action?
- 12 • What are the potential mechanisms of response to SO₂, with a focus on
13 physical-chemical characteristics, response pathway(s), and exposure-dose-response
14 relationships?
- 15 • What are the inherent interspecies differences in sensitivity to SO₂ and in SO₂
16 dosimetry in different regions of the respiratory tract?
- 17 • What are the interspecies differences in basic mechanisms of lung injury and repair?
- 18 • What SO₂ reaction products can be found in the respiratory tract cells, tissues, or fluids
19 as biomarkers of SO₂ exposure?
- 20 • What are the mechanisms and time-courses of SO₂-induced cellular and tissue injury,
21 repair, and remodeling?
- 22 • What are the effects of age, gender, and pre-existing disease on cellular and tissue
23 responses to SO₂-induced injury?
- 24 • Which SO₂-induced health effects are sufficiently characterized to be quantitatively
25 compared across species?
- 26 • What is the state of knowledge of laboratory animal-to-man extrapolation of effects?
27 Is a credible qualitative extrapolation possible for short- and for long-term exposures?

- 1 G. Susceptible Populations: The ISA will examine health outcome data to identify specific
2 groups that are more susceptible than normal healthy adults to the adverse effects of SO₂
3 exposure (e.g., patients with COPD, children, and asthmatics).
- 4 • Is preexisting respiratory or cardiovascular disease in conjunction with advanced age
5 an important factor in susceptibility to mortality associated with exposure to SO₂?
 - 6 • Regarding morbidity health endpoints, to what extent are children and asthmatics
7 more sensitive than the general population to SO₂ exposure?
 - 8 • Is susceptibility to the effects of short-term SO₂ exposure associated with long-term
9 SO₂ susceptibility?
 - 10 • What host and environmental factors (e.g., demographic, socioeconomic, and genetic)
11 are associated with susceptibility to short- and long-term exposure to SO₂?
- 12
- 13 H. Public Health Impact: The ISA will present concepts related to the potential for defining
14 adverse health effects. To accomplish this, the implications for public health of different
15 health effects will be discussed. This will include, as appropriate, an estimation of the
16 potential number of persons in sensitive sub-populations that are at increased risk for
17 each health effect.
- 18
- 19

20 **4.3 PUBLIC AND SCIENTIFIC REVIEW**

21 **Review of the Scientific Assessment Support Document**

22 The draft SASD will undergo peer review by external reviewers chosen on the basis of
23 scientific expertise. The broad approach for the peer review includes the following steps: (1)
24 review of text and associated figures and tables; (2) review the presentation of the epidemiologic
25 literature, particularly focusing on the areas of confounding and measurement error; (3) review
26 the summary of the evidence base and integration of the data within each discipline; (4) review
27 the discussions of strength of associations, robustness, and consistency within each discipline;
28 (5) review the discussions on uncertainty; (6) review the clinical and public health perspectives;
29 and (7) identify new issues and literature. Peer reviewers will be required to submit written

1 comments which, along with public comments received, will be considered by EPA for revision
2 of the SASD.

3

4 **Review of the Integrated Scientific Assessment**

5 Drafts of the ISA will be reviewed by CASAC. The SASD will also be made available to
6 CASAC in order to assist with their review of the ISA. CASAC will review the draft document
7 and discuss their comments in a public meeting announced in the Federal Register. Based on
8 CASAC's past practice, EPA expects that key CASAC advice and recommendations for revision
9 of the document will be summarized by the CASAC Chair in a letter to the EPA Administrator.
10 In revising the draft ISA for SO₂, EPA will take into account any such recommendations.
11 EPA will also consider comments received, from CASAC or from the public, at the meeting
12 itself and any written comments received. EPA anticipates preparing a second draft of the ISA
13 for CASAC review and public comment. After appropriate revision, the final document will be
14 made available on an EPA website and subsequently printed, with its public availability being
15 announced in the Federal Register.

16

5. RISK/EXPOSURE ASSESSMENT

5.1 SCOPE AND ORGANIZATION

A tiered approach to assessing exposure will be employed, beginning with an air quality analysis and progressing to a more refined exposure assessment if appropriate. The approach taken will be informed by the analyses and conclusions from the previous SO₂ NAAQS review (US EPA, 1982; 1986; 1994), subsequent analyses of air quality data focused on 5-minute concentrations of SO₂, recent guidelines from the World Health Organization (2005), and the ISA for SO_x. If appropriate, the exposure assessment will estimate human exposures associated with current ambient levels of SO₂, with ambient levels that just meet the existing standards, 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. The general assessment methodology is discussed below and will be discussed in more detail in a separate scope and methods document which will be reviewed by CASAC at a public meeting in conjunction with the review of the first draft of the ISA.

Based on our current understanding of the available evidence, we do not anticipate that there will be sufficient exposure-response or concentration-response data to support a quantitative health risk assessment for SO₂. However, if the draft ISA or initial results from the exposure assessment suggest that a quantitative risk assessment might be appropriate, a detailed plan describing our proposed approach for conducting the risk assessment will be included in the scope and methods document described above.

5.2 HISTORICAL PERSPECTIVE

In the previous review of the NAAQS for SO₂, it was judged that repeated exposures to 5-minute peak SO₂ levels ≥ 0.60 ppm could pose a risk of significant health effects for asthmatic individuals at elevated ventilation rates (e.g., while exercising). Therefore, the exposure analysis focused on exercising asthmatics and the potential for exposure to short-term peak concentrations of SO₂. Based upon the results of that analysis, it was concluded that exposure of

1 asthmatics to SO₂ at concentrations that can elicit adverse health effects is likely to be a rare
2 event when viewed in the context of the entire population of asthmatics. Therefore, 5-minute
3 peak SO₂ concentrations were judged not to pose a broad public health threat when viewed from
4 a national perspective.

7 **5.3 EXPOSURE ASSESSMENT APPROACH**

8 **Document Preparation**

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

12 **Air Quality Analysis**

13 The first step in this process will be to conduct an air quality analysis, initially relying on
14 the information provided in the SASD and the ISA. This analysis will include information on
15 SO₂ properties, current SO₂ air quality patterns, historic trends, and policy-relevant background
16 levels.⁸ It will provide a frame of reference for subsequent discussions of current and possible
17 alternative standards and for additional air quality analyses relevant to human exposure. General
18 steps in the process include the following.

- 19 • Obtain recent year ambient monitoring data
- 20 • Estimate number of exceedances (if any) of the current SO₂ standards
- 21 • Estimate number of exceedances of short-term air quality indicators given attainment of the
22 current SO₂ standards and possibly of alternative standards.
- 23 • Evaluate the relationship between short-term (e.g., 5-minute) peak concentrations and
24 concentrations using other averaging times (e.g., hourly, daily, annual), where such data are
25 available.
- 26 • Identification of point sources of potential concern and their locations

⁸ Policy-relevant background is defined as the distribution of SO₂ concentrations that would be observed in the U.S. in the absence of anthropogenic (man-made) emissions of SO₂ in the U.S., Canada, and Mexico.

1 **Screening-level Exposure Assessment**

2 Depending on the outcome of the air quality analysis, a screening-level exposure
3 assessment may be performed. The purpose of this assessment would be to better represent the
4 relationship between ambient concentrations, local sources, and human exposure. The approach
5 would involve the development of exposure metrics that capture additional variability in human
6 exposure rather than assuming that ambient concentrations are equal to exposures. The analysis
7 would be informed by the personal exposure and microenvironmental concentration data
8 summarized in the SASD and the ISA, the results of the air quality analysis described above, and
9 the following factors.

- 10 • The relationship between local point source emissions of SO₂ and human behavior (e.g., time
11 spent outdoors within close proximity to point sources and activities performed)
- 12 • The decay of SO₂ indoors and the amount of time spent by people indoors
- 13 • Exposures experienced by susceptible populations relative to those experienced by the
14 general public
- 15 • Population density in areas with potentially high exposure concentrations

16

17 A simplified exposure modeling framework could be employed to incorporate these and
18 other factors with the potential to impact personal exposures. Newly developed model input
19 would be in the form of concentration distributions and probability functions.

20

21 **Refined Exposure Assessment**

22 Although the above screening-level assessment represents an improvement over the
23 assumption that exposures are equivalent to ambient concentrations, it relies on a number of
24 simplifying assumptions that introduce uncertainties into the exposure estimates. Depending on
25 the relationship between these screening-level exposure estimates and the exposure-response
26 information or health effects benchmarks for health effects of concern, more refined estimates of
27 exposure may be developed. The purpose would be to more realistically incorporate personal
28 human attributes, such as actual time-location-activity patterns, and to better account for human
29 physiology. The general approach for this assessment would be to estimate population exposures
30 to ambient SO₂ in a number of areas across the United States where the screening assessment
31 indicates the potential for exposures of concern. Areas included in the analysis would be

1 selected with the goal of improving on the amount of variability that is captured and explained in
2 our exposure estimates. Factors that would be considered when making these choices include
3 the population residing in the area, geography, demographics, climate, and SO₂ air quality.
4 Exposure estimates would be generated using current SO₂ ambient concentrations, ambient
5 concentrations that meet the current standards (for any areas not in attainment), and ambient
6 concentrations that meet potential alternative standards.

7 A refined exposure assessment would take into account several important factors
8 including the magnitude and duration of exposures, frequency of repeated high-level exposures,
9 and breathing rate of individuals at the time of exposure. Estimates would be developed for
10 multiple indicators of exposure including, 1) counts of susceptible individuals exposed one or
11 more times to a given SO₂ concentration while at a specified breathing rate and 2) counts of
12 person-occurrences of particular exposures, which accumulate across all people in the population
13 of interest.

14 A new version of EPA's Air Pollutants Exposure (APEX) model (also referred to as the
15 Total Risk Integrated Methodology/Exposure (TRIM.Expo) model) would be used in this
16 analysis. APEX is a Monte Carlo simulation model that can be used to simulate a large number
17 of randomly sampled individuals within each urban area thus generating area-wide estimates of
18 population exposure. APEX simulates exposures in indoor, outdoor, and in-vehicle
19 microenvironments while taking into consideration the movement of individuals through time
20 and space. Human activity data needed for this analysis would be drawn from the Consolidated
21 Human Activity Database (CHAD), which is developed and maintained by ORD's National
22 Exposure Research Laboratory (NERL).

23 Additional modeling may also be performed to provide data for input to APEX. For
24 example, finer spatial (e.g., within census tract) and temporal resolution (e.g., 5 minute) in air
25 quality concentrations may be required to better estimate exposures in particular areas where
26 local point sources are identified. Due to limitations in currently available ambient
27 concentrations derived from air quality monitors, the only way to obtain this level of detail is
28 through air quality modeling.

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 air quality analysis (e.g., and of the screening-level exposure analysis if conducted)
- 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., asthmatics at an increased ventilation rate) or information regarding newly identified (i.e., since the previous review) susceptible populations
- information on the potential impact of point sources on nearby residents
- existence of the data required to perform the analyses in the more refined tiers of the assessment

5.5 UNCERTAINTY AND VARIABILITY

At each stage of the assessment, an evaluation of the uncertainties will be performed and the relative degree of confidence in the results will be determined. Similar to the exposure assessment described above, a tiered approach will be employed that begins with a qualitative uncertainty analysis and progresses to a quantitative analysis only if warranted and if data are available to support such an analysis. The first step in the uncertainty analysis will be to identify the components of the exposure assessment, determine whether uncertainty can be evaluated for each of those components, and provide a rationale for why this is the case. The second step will be to perform a qualitative uncertainty analysis for the appropriate components of the exposure assessment. This qualitative analysis will result in a matrix describing, for each area of uncertainty, both the magnitude (minimal, moderate, major) and the direction of influence (under- or over-estimate) on exposure estimates. If sufficient data are available, and if the

1 magnitude of uncertainty is judged significant, a quantitative assessment of uncertainty will then
2 be performed for selected components of the exposure assessment.

3 There are two primary sources of uncertainty that would be addressed in a quantitative
4 analysis. The first is uncertainty associated with the model inputs (e.g., use of air quality data,
5 time-location-activity diaries, microenvironmental factor distributions). The second is
6 uncertainty associated with model formulation (e.g., algorithms included in the model). Each of
7 these is described in more detail below.

8 In the case of model inputs, information is often available to characterize variability.
9 In some cases, information is also available to characterize the combination of variability and
10 uncertainty. However, information is often not available to estimate uncertainty separately from
11 variability. APEX is a Monte Carlo simulation model that explicitly incorporates the variability
12 inherent in the model input data. A 2-dimensional Monte Carlo Latin hypercube sampling
13 approach could be used as a combined variability and uncertainty analysis for APEX. A Monte
14 Carlo approach entails performing a large number of model runs with inputs randomly sampled
15 from specified distributions that reflect the variability and uncertainty of the model inputs. The
16 2-dimensional Monte Carlo method allows for the separate characterization of variability and
17 uncertainty in the model results (Morgan and Henrion, 1990). If this approach were taken,
18 developing appropriate distributions representing both variability and uncertainty in model inputs
19 (e.g., air exchange rates, SO₂ decay rates, physiological parameters) would be a key part of the
20 effort.

21 In the case of model formulation, the preferred approach would be to compare model
22 predictions with measured values, while having relatively complete knowledge of the uncertainty
23 associated with input parameters. In the absence of measurements that can be used to estimate
24 model uncertainty, the analysis must rely on informed judgment. The approach would be to
25 partition the model formulation uncertainty into that of the components, or sub-models, of
26 APEX. For each of the sub-models, we would discuss the simplifying assumptions and the
27 uncertainties associated with those assumptions. Where possible, we would evaluate these sub-
28 models by comparing their predictions with measured data. Where this is not possible, we would
29 formulate an informed judgment regarding a range of plausible uncertainties for the sub-models.

30
31

1 **5.6 PUBLIC AND SCIENTIFIC REVIEW**

2 CASAC will be consulted on the scope and methods plan for the exposure assessment at
3 the same time that they are asked to review the first draft of the ISA. The two will be discussed
4 together at a single public meeting. Similarly, CASAC will be asked to review the first draft of
5 the exposure assessment and the second draft of the ISA at a single public meeting. After
6 appropriate modifications have been made to the exposure assessment, a second draft will be
7 reviewed by CASAC at a separate public meeting. Each of these meetings with CASAC will be
8 announced in the Federal Register.

9 Based on CASAC's past practice, EPA expects that key CASAC advice and
10 recommendations for revision of the exposure assessment will be summarized by the CASAC
11 Chair in a letter to the EPA Administrator. In revising the draft exposure assessment for SO₂,
12 EPA will take into account any such recommendations. EPA will also consider comments
13 received, from CASAC or from the public, at the meeting itself and any written comments
14 received. After appropriate revision, the final document will be made available on an EPA
15 website and subsequently printed, with its public availability being announced in the Federal
16 Register.

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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’s views regarding the need to retain or revise the NAAQS for SO₂. The ANPR will identify conceptual evidence-based approaches for reaching policy judgments, discuss the implications for the adequacy of the current standards of the science and exposure assessments, and present 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.

The final decision to retain or revise the NAAQS is largely a public health policy judgment. A final decision should draw upon scientific information and analyses related to health effects, population exposure and risks, and judgments about the appropriate response to the range of uncertainties that are inherent in the scientific evidence and analyses. The Agency’s approach to informing these judgments is based on a recognition that the available health effects evidence generally reflects a continuum consisting of ambient levels at which scientists generally agree that health effects are likely to occur through lower levels at which the likelihood and magnitude of the response become increasingly uncertain. The ANPR 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 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. The Agency will also solicit public comment on the proposed rule in order to inform the final rule. Issuance of a final rule will complete the rulemaking process.

7. REFERENCES

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12 Global Update 2005. Summary of Risk Assessment. World Health Organization.

1 **APPENDIX**

2
3 **U.S. EPA SCIENCE ADVISORY BOARD**
4 **CLEAN AIR SCIENTIFIC ADVISORY**
5 **COMMITTEE MEMBERS**

6
7 **FISCAL YEAR 2007**

8
9
10 The Clean Air Scientific Advisory Committee (CASAC) has a statutorily mandated
11 responsibility to review and offer scientific and technical advice to the Administrator on the air
12 quality criteria and regulatory documents that form the basis for the national ambient air quality
13 standards (NAAQS), which currently include standards for lead (Pb), particulate matter (PM),
14 ozone (O₃), carbon monoxide (CO), nitrogen dioxide (NO₂) and sulfur dioxide (SO₂).
15 To perform such reviews, in each case the Committee forms a review panel consisting of
16 CASAC members augmented by selected consultants with expertise in scientific or technical
17 areas pertinent to the given pollutant or pollutant class under review.

18
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