Overview of the Environmental Protection Agency's Process for Reviewing the National Ambient Air Quality Standards

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1 INTRODUCTION

This document is intended to describe the general process followed by the U.S. Environmental Protection Agency (EPA) in reviewing the national ambient air quality standards (NAAQS).[1] It describes the phases of a review, the documents associated with each phase, the general timing and sequence of document development, the role of the Clean Air Scientific Advisory Committee (CASAC), and public involvement opportunities. An overview and key concepts are presented in Chapter 2. Chapters 3, 4 and 5 provide a more in-depth description of each phase of the review, including the Planning Phase, the Assessment Phase, and the Regulatory Decision-Making Phase, respectively. While not exhaustive, this document serves as a reference to provide clarity regarding the different steps in a NAAQS review. The EPA intends to maintain this document as a reference for the public and the CASAC, with periodic updates as appropriate.

There are two types of NAAQS: "primary" (health-based) and "secondary" (welfare-based).[2] The Clean Air Act (CAA) governs the establishment, review, and revision of these standards.[3] It specifies that the NAAQS are to be based on air quality criteria that "accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of the pollutant in ambient air." The pollutants for which NAAQS are established are therefore termed "criteria" pollutants, of which there are currently six: carbon monoxide (CO), lead (Pb), oxides of nitrogen, ozone (O_3) and

[1] EPA's process for reviewing the NAAQS is subject to revision and adaptation as appropriate for individual reviews and based on experience, the issues arising in a particular review, and stakeholder input. This document is intended to provide a general description, rather than prescribe specific requirements that would be adhered to each review, and to be updated on an ongoing basis.

[2] Under the Clean Air Act, welfare effects include but are not limited to "effects on soils, water, crops, vegetation, manmade 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" (CAA 302(h)).

[3] Appendix A summarizes these legislative requirements.

related photochemical oxidants, particulate matter (PM), and sulfur oxides (SO_X).[4] [5] The CAA requires periodic reviews of the air quality criteria and the standards themselves.[6]

The EPA's process for NAAQS reviews includes assessing the current scientific information (i.e., the air quality criteria); conducting quantitative analyses of air quality, exposure and risk, as warranted; and evaluating policy options regarding the standards, all of which contribute to the Agency's decisions in each review. As part of this process and in accordance with the CAA, the Administrator receives advice from an independent scientific review committee, the CASAC. The EPA also invites the public to participate throughout the process. The public may provide comments on planning for the review, the assessments that inform the Administrator's decisions, and on the Administrator's proposed decisions. Together, the scientific and technical assessments, CASAC advice and public input inform the Administrator's judgments, as required under the CAA, whether to retain or revise the current standards.

The chapters that follow provide more details regarding the various elements of the NAAQS review process and the roles of various partners contributing to it. For each review, the EPA will provide additional pertinent detail in the documents accompanying that review. However, this overview document can serve as a general reference for CASAC and the public regarding typical procedures in each review.

[4] The CAA describes criteria pollutants as those pollutants "emissions of which, in [the Administrator's] judgment, cause or contribute to air pollution which may reasonably be anticipated to endanger public health or welfare"; "the presence of which in the ambient air results from numerous or diverse mobile or stationary sources"; and for which the Administrator "plans to issue air quality criteria…." (42 U.S.C. § 7408(a)(1)).

[5] The current NAAQS are listed at: *https://www.epa.gov/criteria-air-pollutants/naaqs-table*.

[6] The Act requires the Administrator to complete a review, making revisions as appropriate, "at five-year intervals" and also authorizes review and revision, as appropriate, "more frequently."

2 REVIEWING THE NAAQS: AN OVERVIEW

2.1 PHASES OF THE REVIEW AND ROLES OF KEY EPA OFFICES

Each review of the air quality criteria and NAAQS has three phases, a **Planning Phase**, an **Assessment Phase** and a **Regulatory Decision-Making Phase** (Figure 2-1). The planning phase begins with a Call for Information for the Agency to consider in the review followed by a workshop when warranted. In the assessment phase, the Agency generally develops three types of assessments: a science assessment, one or more[7] risk/exposure assessment(s) and a policy assessment. In the regulatory decision-making phase, the Agency publishes a proposed notice for public comment and then publishes a final decision notice, as well as the EPA's responses to public comments on the proposed decision. The documents prepared in all three phases, summarized below, are announced in the *Federal Register*[8] and made available to the public on an Agency web site maintained for this purpose (*http://www.epa.gov/naaqs*).

[7] The EPA may develop assessments for human exposure and health risk and/or for environmental exposures and welfare risk. Thus, in some reviews there may be multiple risk and/or exposure assessments. Alternatively, in some reviews, the new scientific evidence, technical information, and available methods/tools do not provide support for updating exposure/risk analyses to address previously identified limitations or uncertainties or to provide additional insight beyond those provided by the assessment in prior review. In such cases, the EPA may conclude that development of a new assessment for the review is not warranted, and the PA will consider the exposure and risk information from the assessment conducted in the prior review.

[8] The *Federal Register* is a daily gazette and system for publishing government documents and ensuring the American public access to government information. In NAAQS reviews, notices of document availability, opportunities for public comment and proposed and final decisions are published in the *Federal Register*. The *Federal Register* is available online at: *www.federalregister.gov*.

Figure 2-1. Overview of the NAAQS review process and its phases.

Two main offices of the EPA guide the review: the Office of Air and Radiation (OAR) and the Office of Research and Development (ORD). The critical offices within OAR and ORD include the Office of Air Quality Planning and Standards (OAQPS) and the Center for Public Health and Environmental Assessment (CPHEA), respectively (Figure 2-2). The OAQPS leads the overall NAAQS review and development of the risk/exposure and policy assessments (REA and PA), while the CPHEA leads the review of the criteria with development of the science assessment.

Office of Air and Radiation (OAR)
- *Office of Air Quality Planning and Standards (OAQPS)*
  - Health and Environmental Impacts Division (HEID)
  - Air Quality Assessment Division (AQAD)

Office of Research and Development (ORD)
- *Center for Public Health & Environmental Assessment (CPHEA)*
  - Health & Environmental Effects Assessment Division (HEEAD)
  - Integrated Climate Sciences Division (ICSD)

Figure 2-2. The EPA offices with primary roles in NAAQS review activities.

2.1.1 The Planning Phase

Following the Call for Information, the EPA develops detailed planning documents for each review. Currently, the EPA's plans for each review are presented to the public in an **Integrated Review Plan** (IRP).[9] The IRP is prepared jointly by the CPHEA and OAQPS. In general, the IRP contains background material, such as the history of the existing criteria and standards and the projected timeline for the review, as well as key scientific, technical or policy aspects of plans for the new review.

For efficiency and to facilitate timely input from the CASAC and the public, the IRP is composed of three volumes. Volume 1 provides background information and serves as a reference for the public and the CASAC. Volume 2 addresses the general approach for the review, identifying key policy-relevant issues that will guide the review, and also addresses planning for the science assessment, including key considerations in its development. Volume 3 is the planning document for quantitative risk and exposure analyses to be considered in the policy assessment. All three volumes of the IRP are publicly available, and the key aspects of plans for the assessments in the new review (Volumes 2 and 3) are the subject of CASAC consultation and public comment.

2.1.2 The Assessment Phase

In the assessment phase, the EPA prepares the science assessment, risk and exposure assessment(s), and the policy assessment. A list of these assessments is shown here, followed by a fuller description of each in section 2.2.

- **Integrated Science Assessment (ISA)**[10]**—**The ISA and its associated materials provide a comprehensive assessment of the current scientific literature on health and welfare effects associated with the presence of the pollutant in the ambient air, emphasizing information that has become available since the last such assessment to reflect the current state of knowledge. The ISA forms the scientific foundation for each NAAQS review.
- **Risk/Exposure Assessment (REA)—**Based on the updated scientific information presented in the ISA, the EPA develops quantitative assessments

[9] Development of the IRP for some NAAQS reviews may be informed by a science policy workshop to help the Agency identify issues and questions to frame the review.

[10] The ISA and its associated materials function in the NAAQS review process today as the Air Quality Criteria Document (AQCD) did in reviews of the past.

of exposure and/or risk of health and/or welfare effects, which may vary significantly in scope and content, as warranted. The results and their implications are discussed in the policy assessment, with the full detailed REA presented as an appendix to the policy assessment, as in recent reviews, or in a companion document, as appropriate.

- **Policy Assessment (PA)**[11]**—**The PA evaluates implications of the current scientific evidence, air quality information, and exposure and risk analyses for the current standard(s) and potential alternative standards, and frames policy options for consideration by the Administrator. Review of the PA by the CASAC facilitates CASAC advice to the Administrator, as provided for in the CAA, on the existing standards and any revisions that may be appropriate to consider.

The EPA makes drafts of these assessments available for CASAC review and public comment and prepares final documents with consideration of the CASAC reviews and public comments.

2.1.3 The Regulatory Decision-Making Phase

The regulatory decision-making phase of the review process generally follows issuance of the final PA and consideration of conclusions presented therein. In this phase, the Agency develops and publishes a notice of proposed decision to communicate to the public the Administrator's proposed decisions regarding the standards review and considerations underlying the proposed decisions. When the proposed decision is to revise the existing NAAQS or establish new NAAQS, the notice presents the proposed regulatory changes. Regardless of whether a change to the NAAQS is proposed, the notice outlines the supporting rationale for the decision, based on the underlying scientific evidence and quantitative exposure and risk information as well as associated uncertainties. A public comment period, during which one or more public hearings are generally held, follows publication of the proposed decision. Taking into account comments received on the proposed decision,[12] the Agency develops a notice of final decision, including any regulatory revision. Publication of the final decision generally completes the review.

[11] The PA functions like the Staff Paper in past reviews.

[12] The Agency responds to all timely significant comments on the proposal at the time of the final action.

The relative order of document development in the three phases is illustrated by a generic NAAQS review timeline in Figure 2-3 below.[13] The following sections address the role of CASAC (section 2.2) and public input (section 2.3), and key concepts in the review and establishment of NAAQS (section 2.4). Subsequent chapters provide a more in-depth discussion of each phase of the review.

[13] Figure 2-3 is a generic timeline and may not reflect the specific schedule for activities in a given review.

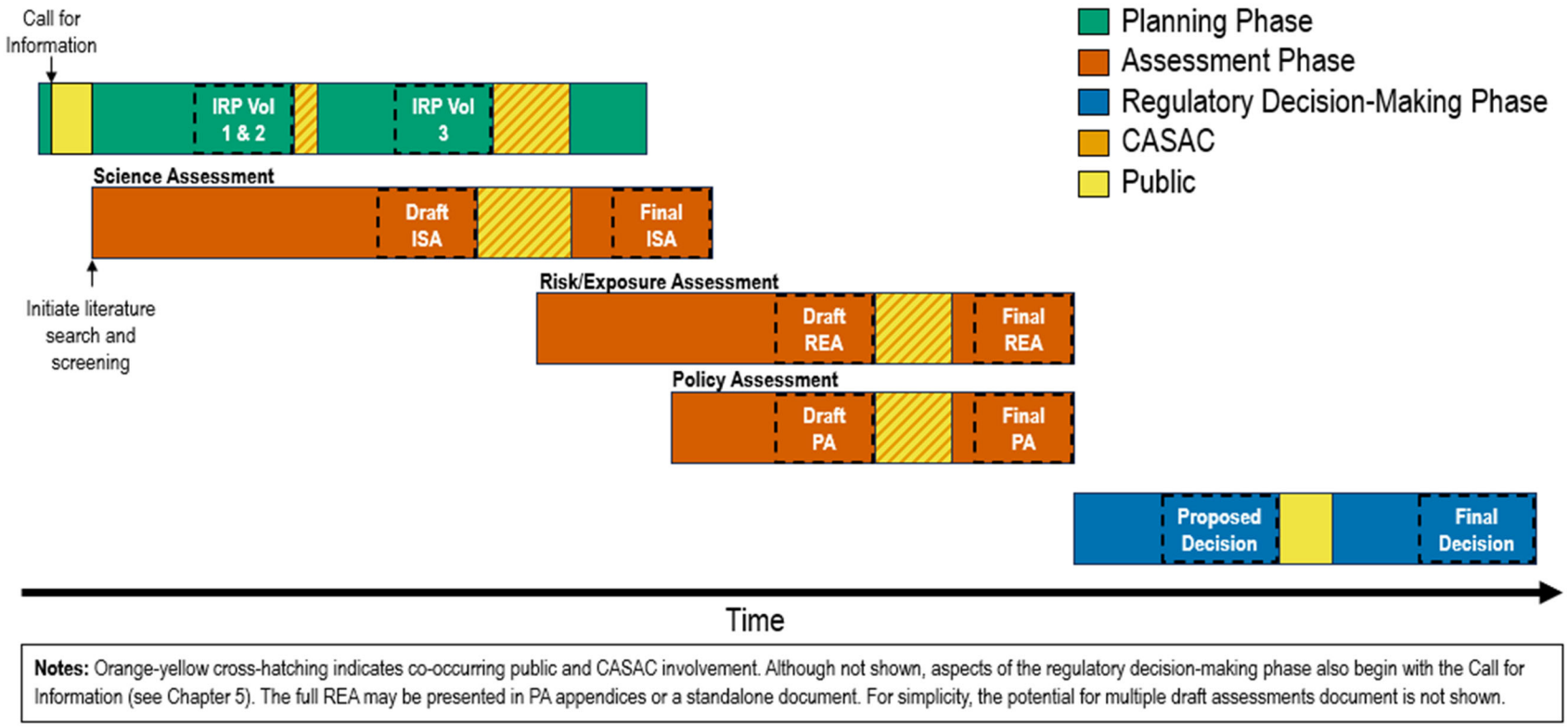

Figure 2-3. Generic timeline and sequencing of phases for a NAAQS review and points of public and CASAC involvement.

2.2 ROLE OF THE CASAC

The CASAC provides advice to the EPA Administrator in each NAAQS review in fulfillment of the CAA requirement for an independent scientific review committee, as summarized in Appendix A.[14] The Administrator appoints the members of the CASAC, as required by the CAA, which specifies that the independent scientific review committee be composed of "seven members including at least one member of the National Academy of Sciences, one physician, and one person representing State air pollution control agencies" (CAA, section 109(d)(2)(A)). Under the CAA, the Committee is required to review the air quality criteria and national primary and secondary ambient air quality standards and make recommendations to the Administrator regarding any new standards or revisions to the criteria and standards as appropriate. The nomination process and appointment of the CASAC is managed through the EPA's Science Advisory Board (SAB) Staff Office.[15] For each review, the SAB Staff Office typically selects a pollutant-specific panel of experts to assist the seven-member CASAC. These individuals are nationally and/or internationally recognized for their expertise and research in the field of air pollution related to the criteria pollutant under review, and generally include one or more members of the CASAC. Together, these CASAC members and the pollutant-specific experts form the "CASAC Panel" for that review. However, while the CASAC Panel provides input to the CASAC, ultimately it is the seven-member CASAC that officially advises the EPA Administrator on the air quality criteria and standards.

During each review, typically the CASAC and CASAC Panel review the key planning and assessment documents, including the IRP, the ISA, the REA, and the PA. The role of the CASAC and the public in the planning and assessment phases is summarized in Table 2-1, and described separately in further detail in this section and

[14] Since the early 1980s, this independent review function has been performed by the Clean Air Scientific Advisory Committee (CASAC) of the EPA's Science Advisory Board (SAB). The CASAC charter (available on the "About the CASAC" webpage, accessible from *https://epa.gov/casac*) provides more information on the objectives and scope of the CASAC's activities and a description of duties, as well as other administrative guidance. The CASAC charter is renewed every two years in accordance with the provisions of the Federal Advisory Committee Act (FACA).

[15] Information about this process is available on the EPA's CASAC membership web page: *https://casac.epa.gov/ords/sab/r/sab_apex/casac/mnp?session=666951693277*.

section 2.3, respectively. With the exception of Volume 1 of the IRP, which is a reference document for the review, all of the planning documents and assessments undergo consideration by the CASAC and are available for public comment.

Table 2-1. Role of CASAC review and public comment during planning and assessment phases.

Phase	Contents of each Document or Assessment	CASAC Review and Public Input
Planning	**Integrated Review Plan**	
	Volume 1, Background Document, includes a summary of the review history for the criteria pollutant(s) under review, review milestones, and the anticipated timeline.	Serves as a reference to the CASAC and the public regarding the pollutant and NAAQS under review.
	Volume 2, Planning for the Review and the Integrated Science Assessment, describes planning considerations for the overall review, including policy-relevant issues or questions, and for development of the ISA, including key scientific questions.	Subject of a consultation with the CASAC Panel and public comment. Panel member input (at the public meeting and in post-meeting comments) and public comments are considered in developing the drafts of the ISA and PA, respectively.
	Volume 3, Planning Document for Quantitative Exposure/Risk Analyses, describes key planning considerations for REA, including information or tools that might support new/updated analyses.	Subject of a consultation with the CASAC Panel and public comment. Panel member input (at the public meeting and in post-meeting comments) and public comments are considered in developing the draft REA(s).
Assessment	***Integrated Science Assessment.***[1] The ISA describes a comprehensive review, synthesis, and evaluation of the most policy-relevant scientific information on the pollutant(s) under review, including key science judgments important to the design and scope of air quality, exposure and risk analyses, as well as other aspects of the NAAQS review.	Subject to review by the CASAC and public comment. Advice and comments from the CASAC and public comments on the draft ISA are considered by the EPA in developing the final ISA.
	Risk and Exposure Assessment.[1] [2] The REA evaluates human or environmental exposures and health or welfare risks associated with air quality conditions meeting the existing and potential alternative standards, as appropriate.	Subject to review by the CASAC and public comment. Advice and comments from the CASAC on the draft REA are considered in developing the final REA.
	Policy Assessment.[1] The PA evaluates the policy implications of information from the ISA and quantitative exposure/risk analyses to frame policy options for consideration by the Administrator.	Subject to review by the CASAC and public comment. In its review, the CASAC also provides its advice to the Administrator on the existing standards or revisions that may be appropriate to consider, per the CAA. Advice and comments from the CASAC on the draft PA and its conclusions are considered by OAQPS staff in developing the final PA, which also includes a summary of CASAC advice.

1 More than one draft of a document may be developed, as warranted by the available scientific and quantitative information and CASAC advice in its review.
2 The REA may be presented as appendices to the PA, as in recent reviews, or in a separate document depending on the review.

During the planning phase, the EPA receives input from the CASAC Panel on key aspects of the review plans via a consultation on information in the IRP, which includes the policy-relevant questions that will guide the review, the scope of ISA, and planning of quantitative analyses for the REA, among other aspects. As recognized earlier in this Chapter, the EPA engages in such consultations on Volumes 2 and 3 of the IRP. In these consultations, the CASAC Panel convenes at public meetings that are announced in the *Federal Register*. Members of the public are also invited to provide comments (orally and/or in writing) to the CASAC Panel at the consultation meeting. At the public meeting, the Panel members discuss the volumes and individual Panel member comments are also conveyed to the Agency after the meeting.[16] The Panel members' views provided in these consultations inform the EPA's planning for the scientific, technical and policy assessments in each review.

During the assessment phase, the CASAC Panel reviews drafts of the ISA, REA and PA and discusses their comments in one or more public meetings. Simultaneous with releasing a draft document to the public, the EPA provides the document to the SAB Staff Office for distribution to the CASAC Panel. With transmittal of the document, the EPA also provides a series of charge questions to guide review of each assessment. In some cases, these charge questions are similar from review to review (e.g., "Is the information presented in the draft PA technically sound, clearly communicated and appropriately characterized?"). In other cases, charge questions may be specific to the document and criteria pollutant under review and thus vary across reviews. The CASAC Panel convenes at public meetings that are announced in the *Federal Register* and that offer the opportunity for the public to provide oral and/or written comments.

In fulfilling their role in review of the draft assessment documents, the CASAC Panel prepares draft advisory reports, summarizing comments and recommendations to the EPA in the context of addressing the charge questions on the draft documents. The draft reports include a draft letter for transmitting the report that also highlights the most important recommendations and includes specific responses to the charge questions. A draft of each report is made available to the public and to the seven-

[16] There are not consensus comments of the Panel (or of the CASAC) developed for consultations.

member CASAC. The draft report is discussed, deliberated on, and finalized by the Panel at a public meeting. The seven-member CASAC joins this meeting and seeks clarifications and revisions on the draft report from the Panel. At the end of the meeting, the seven-member CASAC votes on adopting the Panel's draft report. Once adopted, the final report, which includes the letter from the CASAC, responses to the Agency charge questions, and the individual Panel member comments, is transmitted to the EPA. In this way, the final report conveys CASAC advice on the draft documents to the Administrator.[17]

In completing its review of the ISA, which provides the scientific evidence base for the NAAQS review, the CASAC generally considers whether the document (once revised to address comments) will be suitable for the EPA to rely on in NAAQS decision-making. The CASAC letter on the draft PA additionally conveys the CASAC recommendations regarding the standards being reviewed. Together, the letters on the various assessment documents reflect the CASAC's statutory mandate to advise the Agency on both the criteria and the standards.

Section 109(d)(2)(C) of the CAA identifies several other advisory functions for the CASAC, including advising the EPA on information gaps in NAAQS reviews and relevant related research, and advising on relative contributions to air pollution concentrations of natural as well as anthropogenic activity. These areas are generally addressed in the PA and considered by the CASAC in its review of a draft PA. Another function also identified for the Committee is advising on "adverse public health, welfare, social, economic, or energy effects" associated with strategies for NAAQS attainment and maintenance (CAA 109(d)(2)(C)(iv). In situations where strategies for attaining the NAAQS could result in adverse public health or welfare effects (e.g., because control of one pollutant could lead to increases in another), that possibility can be addressed as part of the CASAC's advice on the criteria and standards. However, as noted in Appendix A, costs of implementing the standards cannot be considered in the NAAQS-setting process. Accordingly, any advice on "social, economic and energy effects" of achieving the

[17] The letter is addressed to the EPA Administrator from the CASAC Chair, who may or may not also chair the pollutant-specific Panel. If the CASAC Chair is not the chair of the pollutant-specific panel, the chair of that panel also signs the letter.

standard cannot be considered by the Administrator during a NAAQS review. Consistent with this requirement, the EPA's practice is not to solicit and the CASAC does not provide advice on these topics during NAAQS reviews.[18]

2.3 PUBLIC INVOLVEMENT

The EPA provides multiple opportunities for public involvement during a NAAQS review. The EPA begins each review with a broad Call for Information from the public. When announcing the availability of Volumes 2 and 3 of the IRP and drafts of the ISA, REA and the PA in the *Federal Register*, the EPA also solicits public comment on these documents. The *Federal Register* notices describe the process by which the public can submit comments on each document to the relevant docket[19] and specifies the period during which comments are to be submitted. The Agency considers these comments in completing the final documents for the review. Further, the *Federal Register* announcements of CASAC and CASAC Panel meetings on these documents also invite the public to share views for consideration in the deliberations over the documents.

During the regulatory decision-making phase, the Agency solicits public comment on the proposed decision(s) and also provides an opportunity for delivery of oral comments at a public hearing. The comment period during which the public may submit comments to the regulatory docket on a proposed NAAQS decision generally ranges from 45 to 90 days, although variations may occur. As described in Chapter 5, the Administrator considers comments received from the public in reaching decisions in the review.

[18] The means by which the CASAC, supplemented by a panel with appropriate expertise, could provide advice on these topics is beyond the scope of NAAQS reviews and, thus, of this document.

[19] A docket is a collection of documents made available by an agency for public viewing. Often associated with an opportunity for public comment, EPA dockets consist of materials used in a rulemaking or other agency action. These may include documents specifically referenced in the *Federal Register*, public comments received, and other information used by the Agency to explain or support its decisions. In each NAAQS review, the EPA maintains two dockets, one for the review of the air quality criteria (the ISA docket) and one for the review of the NAAQS (the regulatory docket).

2.4 FUNDAMENTAL ASPECTS OF NAAQS REVIEWS

There are several fundamental aspects of NAAQS reviews that are integral to the Administrator's policy judgments and decisions in any review and also play a role in the assessments that inform the Administrator's decision-making in a review.

2.4.1 Elements of a Standard, Design Values, and Air Quality Characterization

Each NAAQS is defined by four elements: indicator, averaging time, form and level. The **indicator** of a standard is the chemical species or mixture that is to be measured in determining whether a standard is met.[20] For example, the indicator of the primary standard for sulfur oxides is sulfur dioxide, and the NAAQS for PM include standards with two different indicators, particles with nominal mass median diameter less than or equal to 2.5 and 10 micrometers ($PM_{2.5}$ and PM_{10}, respectively). The **averaging time** is the time period over which measurements of the chemical are averaged (e.g., one hour in the case of the primary sulfur dioxide standard). The **form** describes the relevant mathematical or statistical treatment of the dataset of ambient air measurements, such that together with the averaging time, it defines the air quality statistic that is to be compared to the level of the standard in determining whether a standard is met. For example, the form of the primary standard for sulfur oxides is the annual 99th percentile daily maximum 1-hour concentrations averaged over three years.[21] Lastly, the **level** is the value of the standard in terms of the chemical concentration, averaged and handled as specified by the form and averaging time. For example, the level of the 1-hour primary standard for sulfur oxides is 75 parts per billion. Thus, the primary standard for sulfur oxides is met at an ambient air quality monitoring site when the three-year average of the annual 99th percentile of the daily maximum 1-

[20] The sampling and analysis methods for measurement of the pollutant consistent with the indicator for the standard are specified in regulation.

[21] As other examples, the form of the annual $PM_{2.5}$ NAAQS is the 3-year average of the weighted annual mean $PM_{2.5}$ concentrations, while the form of the current 3-month Pb NAAQS is a 3-month average concentration not to be exceeded during a 3-year period.

hour average concentrations is less than or equal to 75 parts per billion (as determined in accordance with relevant data handling regulations).[22]

The public health or welfare protection provided by NAAQS is evaluated based on consideration of the four elements of each NAAQS collectively. A metric called a **design value** facilitates such consideration. The design value is an air quality statistic calculated in terms of the indicator, averaging time, and form of the standard, as specified by any data handling regulations specific to the standard. The EPA calculates and annually publishes design values for each ambient air monitoring site with data meeting relevant regulatory requirements (*https://www.epa.gov/air-trends/air-quality-designvalues*). When a design value is greater than the level of the NAAQS, the monitor is described as violating the NAAQS; when the design value is at or below the level of the NAAQS, the NAAQS is met.

Pollutant concentrations vary spatially with location, reflecting factors such as the influence of source types, emissions magnitude and pollutant chemistry and transport. Therefore, the design values will also vary with location. This variation can contribute to a given urban area having a location with a design value above a given standard level and other locations well below it.

As recognized in section 4.2 below, the REA in a review focuses on characterizing exposures and risks estimated to be associated with air quality conditions that meet the existing or potential alternative standards. For example, when evaluating health protection or risk, such as in a health REA focusing on specific urban areas, the EPA generally characterizes the exposure and risk associated with the patterns of air quality across the area that meet different standards, as determined by pollutant concentrations at their highest point in the area yielding a design value equal to the level of the standard being considered. In these air quality scenarios (characterized by a design value equal to the standard level of interest), there is not a uniform level of air quality at that concentration across a geographic area. Rather, there is a pattern of air quality for which the location of the highest concentration just meets the standard, and

[22] The primary standard for sulfur oxides is specified in the code of federal regulations at 40 CFR 50.17 (*https://www.ecfr.gov/current/title-40/chapter-I/subchapter-C/part-50/section-50.17*).

concentrations at surrounding locations will be lower.[23] This air quality pattern includes temporally and spatially varying pollutant concentrations to which people may be exposed in their daily activities.[24] Based on the exposure and risk estimates for such air quality scenarios, the Administrator can consider the extent of protection for public health or welfare associated with the standards in reaching decisions on standards that provide the requisite protection (as further discussed in sections 2.4.2 and 2.4.3).

2.4.2 The Primary Standard

In accordance with the CAA,[25] primary (health-based) standards must "specify a level of air quality the attainment and maintenance of which, in the judgment of the Administrator [...] and allowing an adequate margin of safety, are requisite to protect the public health." Further, consistent with the legislative history, primary standards are established to protect the public health, with an adequate margin of safety, including the health of at-risk populations.[26] The requirement in the Act for public health protection with "an adequate margin of safety" is intended to address uncertainties associated with inconclusive evidence and to provide a reasonable degree of protection against hazards that research has not yet identified. In addressing the requirement to protect the public health with an adequate margin of safety, the EPA considers such factors as the nature and severity of the health effects involved, the size of the sensitive population(s),[27] and the kind and degree of uncertainties. Selecting any particular

[23] How much lower the lower concentrations may be and the spatial distribution of these concentrations depend on many factors specific to the meteorology and pollutant source characteristics in an area.

[24] These exposure concentrations are generally evaluated in an REA in terms of an exposure metric identified in consideration of the health effects evidence for that pollutant. Such an exposure metric for an REA may have some general similarity to the averaging time and form of the pollutant standard (e.g., short-term or long-term in nature); but it generally differs in any of a number of ways.

[25] Further detail on legislative requirements and history, as well as relevant court decisions, is provided in Appendix A.

[26] In this context, at-risk populations refers to persons comprising the sensitive group or lifestage rather than to a single person in such a group or lifestage.

[27] As used here and similarly throughout this document, the term population (or group) refers to persons having a quality or characteristic in common, such as a specific pre-existing illness or a specific age or life stage. Identification of such sensitive groups (called at-risk groups or at-risk populations) involves consideration of susceptibility and vulnerability.

approach to providing an adequate margin of safety is a policy choice left specifically to the Administrator's judgment.

2.4.3 The Secondary Standard

In accordance with the CAA,[28] secondary (welfare-based) standards must "specify a level of air quality the attainment and maintenance of which, in the judgment of the Administrator [...] is requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of [the] pollutant in the ambient air" (CAA section 109). Although the CAA defines "welfare effects," it does not define "public welfare." In addressing effects that are adverse to the public welfare, the EPA considers not just whether there is a welfare effect caused by the pollutant under review (and under what air quality conditions), but what implications it might have for the public welfare. Determining which effects are "adverse" to the public welfare, and under what conditions, requires policy judgments about the societal impacts of the various welfare effects (e.g., effects on soils, waterbodies, crops, vegetation, visibility) and the kind and degree of associated uncertainties. Aspects of the evidence and quantitative exposure/risk information important to this consideration include the extent and severity of the effect under relevant air quality conditions, among other factors. Such factors inform the Administrator's judgments regarding the level of protection necessary to address the potential for adversity to the public welfare. Altogether, the Administrator's decisions on secondary standards must provide the requisite protection of the public welfare from known or anticipated adverse effects.

2.4.4 Role of Policy Judgment in Standards Decisions

As governed by the CAA, the Administrator's final decisions in reviews of NAAQS are largely public health and public welfare policy judgments. Such judgments are informed by the understanding that the health and welfare effects evidence generally reflect a continuum consisting of exposure concentrations at which scientists generally agree that health or welfare effects are likely to occur, through lower exposure concentrations at which the likelihood and magnitude of the response become

[28] Further detail on legislative requirements and history, as well as relevant court decisions, is provided in Appendix A.

increasingly uncertain. Decisions on particular elements of the NAAQS may also involve other judgments, such as about the weight to be placed on extreme or unusual data and the benefits of stability for air quality management. This approach is consistent with the CAA requirements and how the courts have interpreted the Act. The CAA provisions require the Administrator to establish standards that are requisite. The term "requisite" means sufficient but not more than necessary. The CAA does not require that standards be established at zero-risk levels or at background concentrations. Thus, in light of all of the relevant considerations, and in accordance with the CAA, the Administrator establishes the NAAQS such that, in the Administrator's judgment, the primary NAAQS are sufficient to protect public health with an adequate margin of safety and secondary NAAQS sufficient to protect the public welfare against any known or anticipated adverse effects associated with the presence of such air pollutant in the ambient air.

3 REVIEW PLANNING

Planning for the review begins with the EPA's *Federal Register* announcement concerning the new review and extends through development of Volume 3 of the IRP (Figure 2-3). As recognized in Chapter 2, planning for the review is a joint responsibility of the CPHEA and the OAQPS. The initial stages of planning in a review are summarized in section 3.1, and section 3.2 describes key aspects of the 3-volume IRP.

3.1 INITIAL PLANNING

Each NAAQS review is initiated with a **Call for Information** published in the *Federal Register*. The Call for Information announces initiation of the review and invites the public to submit scientific studies and related information pertinent to the review of the air quality criteria and standards review; it may also solicit comments from the public on policy-relevant issues important to address in the review. The public is directed on how to submit any comments on the review and the specified time period within which to do so.

As a part of the early planning in a review, the CPHEA and OAQPS staff look to the last review to identify issues and information particularly relevant to the new review and areas of particular uncertainty.[29] Together, these help focus the new review. The CPHEA and OAQPS staff also review key uncertainties and data gaps identified in the previous review (e.g., in the PA and decision notices).[30] Particular attention is given to uncertainties and data gaps documented in the PA for the last review, including those identified by both staff and by the CASAC.

As warranted, the EPA may also seek initial input from experts representing a variety of scientific disciplines relevant to a specific review (e.g., via a workshop to discuss key scientific- and policy-relevant issues being and/or to be considered in the

[29] The PA for each review identifies key uncertainties, data gaps and areas for future research, and the notices of proposed and final decisions in the review note uncertainties particularly relevant to the NAAQS decisions.

[30] As they identify studies for the new review, the staff also considers studies identified in the last review after completion of the ISA. These include studies that were submitted by public commenters on the proposed decision and which the EPA provisionally considered at that time.

review.[31] Workshop discussions may then inform planning for the review and development of the ISA.

3.2 INTEGRATED REVIEW PLAN

The three volumes of the IRP are: Volume 1, which is a background document; Volume 2, which addresses the general approach for the review and the plan for developing the ISA; and, Volume 3, the REA planning document. An overview of each of these documents is provided below.

3.2.1 Volume 1: Background Document

Volume 1 of the IRP provides background on the criteria and standards for the subject pollutant in the review. More specifically, it includes a history of past reviews and decisions, including key aspects of the Administrator's decisions and judgments concerning the specific NAAQS being reviewed. This volume also covers the general milestones for the review, including release of the various review documents, and the anticipated timeline for the review, noting any factors that may influence this timeline (e.g., a court ordered deadline or consent decree).

Volume 1 generally includes appendices with additional information for reference by the CASAC and the public. For example, these may include information on ambient air quality monitoring and data handling requirements for the criteria pollutant under review,[32] and a summary of the development process for the ISA, consistent with the process presented in the Preamble to the ISAs (U.S. EPA, 2015). Volume 1 serves as a reference document for the CASAC and is released by the EPA with Volume 2.

[31] The decision on whether to hold a workshop has typically depended on the criteria pollutant under review, as well as the resources and timeline associated with the review. As an example, expert input may be more important in reviews with a substantial volume of new scientific evidence since the last review, in a review with complex quantitative analyses, and/or in a review where new information has emerged that may alter the approach for the review.

[32] In addition to information on monitoring and data handling regulations, the appendices may summarize recent air quality information, drawing on documents presenting an overview of recent air quality for each criteria pollutant that are updated on an annual basis (e.g., *Overview of Ozone (O_3) Air Quality in the United States*) at https://www.epa.gov/air-quality-analysis/naaqs-review-analysis.

3.2.2 Volume 2: Planning for the Review and the Integrated Science Assessment

Volume 2 of the IRP summarizes the general approach for the review, including policy-relevant topics, and describes key planning considerations for developing the ISA. The policy-relevant topics are used to frame consideration of the scientific evidence and technical information in the PA. The key ISA planning considerations include identification of scientific questions to guide the development of the ISA.

In describing the general approach for the review, Volume 2 recognizes that a critical aspect of the assessments in the review is to provide the Administrator with the information needed to make decisions, as required under the CAA, regarding whether the standards under review should be retained or revised. In this context, Volume 2 generally presents an initial set of the "policy-relevant" questions the OAQPS staff addresses in its consideration of the available scientific evidence, quantitative risk and exposure analyses, and any associated uncertainties in the PA. Policy-relevant questions in each review generally revolve around consideration of the extent to which air quality conditions associated with the current and/or potential alternative standards have the potential to be associated with exposures and risks of concern for the public health or welfare. Questions may also relate to the individual elements of the standard (i.e., indicator, form, averaging time, level). Generic examples of some of these policy-relevant questions, which may evolve with the initial stages of the PA development, are presented in Table 3-1.

Table 3-1. Generic policy-relevant questions considered in a PA for a primary and/or secondary NAAQS review.

- At what exposure levels do health/welfare effects occur? Is there evidence of effects at exposure levels lower than those previously observed, and what are the important uncertainties associated with that evidence?
- Does the currently available information alter or strengthen our understanding of the health/welfare effects associated with exposure to the criteria pollutant?
- What populations/ecosystems/ecosystem components are most at risk for this criteria pollutant?
- Is there new evidence on factors that influence relationships between criteria pollutant concentrations, exposures and health/welfare effects?
- Does the current risk and exposure information indicate exposures of concern associated with air quality conditions that just meet the NAAQS? Are these risks and exposures of sufficient magnitude such that the health effects might reasonably be judged to be important from a public health/welfare perspective? What are the important uncertainties associated with these risk and exposure estimates?
- To what extent have important uncertainties identified in the last review been reduced and/or have new uncertainties emerged?
- To what extent does the newly available information call into question support for any of the basic elements of the standard (i.e., indicator, form, averaging time, level)?

With regard to planning for the ISA, Volume 2 describes plans for the ISA organization and scope. It also identifies specific scientific questions to focus on in considering the available scientific information, in light of the overarching policy-relevant questions for the review. These scientific questions may cover topics such as: pollutant sources, atmospheric chemistry, and ambient air concentrations; human exposure, toxicokinetics, and biomarkers; health effects; at-risk lifestages and populations; and welfare effects, including ecological effects, materials damage, and visibility impairment, among other topics.

Consultation with the CASAC Panel and comments from the public on Volume 2 (see sections 2.1, 2.2 and 2.3 above) provide early input to the EPA in its planning for a review. Such input may pertain to policy-relevant issues important to consider in the review (e.g., beyond those identified by the EPA or that may warrant further investigation or focus), as well as to the scope and specific scientific questions to focus the evaluation of the scientific evidence. Together, input in these areas at the planning stages informs development of the draft ISA and PA.

3.2.3 Volume 3: Planning Document for Quantitative Exposure/Risk Analyses

Volume 3 of the IRP serves as the planning document for quantitative risk and exposure analyses considered for the review. These analyses are generally intended to provide quantitative estimates of human exposure and health risk, and/or of environmental exposures and welfare risk, for air quality conditions of interest in the review. Decisions on analyses to be undertaken in each review are informed by the scientific evidence for the subject pollutant, as characterized by the ISA, the extent to which there is newly available evidence indicating different effects or effects under different exposure conditions than was known in the last review, and the availability of relevant data and modeling tools.

Volume 3 presents a critical evaluation of the extent to which newly available scientific evidence, tools, or methodologies provide support for and warrant the conduct of quantitative risk and exposure analyses that would inform the review. As warranted, this document discusses initial planning for such analyses. Aspects of this discussion may include how the analysis approaches from prior NAAQS review(s) may be refined, based on newly available evidence, and/or consideration of new analyses appropriate to be conducted in the review.

With regard to both health and welfare assessments, Volume 3 generally begins with a comprehensive review of the analyses conducted in the last review, a summary of key uncertainties and limitations associated with the analyses, and a description of how the analyses were considered by the Administrator in reaching decisions in the last review. Additionally, the EPA staff considers scientific evidence newly available in the review and how it may inform risk and exposure analyses, including information related to inputs for risk and exposure assessments and/or methods or tools for modeling exposure and/or risk. Where the available information indicates it is appropriate to consider a new type of analysis and/or analysis focused on a newly identified health or welfare effect or endpoint, the document discusses relevant approaches. As a result of these considerations, several tasks may be identified as appropriate to consider. These include:

- *Updating quantitative analyses from the previous review*. This may be appropriate to reflect more recent advances in methodologies or tools and any

new scientific information that together may yield important updates to the exposure/risk information from the prior review.

- *Conducting new quantitative analyses*. This may arise from advancements in the scientific literature and/or evolution of the modeling tools, or health or welfare effects newly identified by the current evidence (or for which quantitative assessment is newly supported), that would result in new or different quantitative analyses from those in the prior review.
- *Excluding quantitative analyses conducted in the prior review.* At times, the EPA may judge it unnecessary to repeat analyses or carry forward approaches from previous reviews. This may be when significant uncertainties have been identified in a prior analysis, affecting its usefulness in decisions of the prior review, and newly available information has not been identified that might address these uncertainties.[33]
- *Relying on quantitative analyses conducted in the previous review.* This may be the appropriate approach when new information or improved approaches are not available to support appreciably updated analyses (e.g., when there are no or very limited advancements in the scientific evidence, methodologies, or analysis tools), such that new or updated analyses would not be expected to provide appreciably different information from prior assessments.

Consultation with the CASAC Panel and public comments on Volume 3 assist the EPA in its planning decisions for quantitative analyses that may be appropriate to conduct in a review. The timing of Volume 3, generally coinciding with the public availability of the draft ISA (and the associated CASAC review), also ensures that the REA planning takes into account the current scientific evidence, including availability of any new evidence. Comments received at this planning stage are taken into account in development of any quantitative analyses and draft REA.

[33] When there are numerous analyses that might be conducted in a criteria pollutant or review, the EPA recognizes the need to prioritize with regard to scientific support and potential influence on decision-making. By focusing the quantitative analyses performed in a review on those that are most policy-relevant and for which the scientific support is strong, they can be of greatest utility to the decision making by the Administrator. Accordingly, by such a focus, the EPA can ensure the analyses conducted in a review are appropriately comprehensive and technically sound, while recognizing the potential constraints of time and resources.

4 ASSESSMENTS

The subsections below describe the three types of assessments that inform NAAQS reviews. Section 4.1 briefly summarizes the science assessment presented in the ISA. Assessments of exposure and risk, which are based on the scientific information presented in the ISA, are described in section 4.2. Lastly, the PA is described in section 4.3.

4.1 SCIENCE ASSESSMENT

The Integrated Science Assessment provides the scientific evidence base for the Agency's decision-making in each NAAQS review, and fulfills the EPA's responsibilities under the CAA for review of the air quality criteria. The ISA characterizes the currently available scientific evidence of the health and welfare effects associated with the presence of the pollutant in ambient air, including any recent advances in scientific knowledge in these areas. The general process for developing an ISA is described in the Preamble to the Integrated Science Assessments (U.S. EPA, 2015).[34] Individual ISAs (e.g., U.S. EPA, 2024a) build on that general process to reflect advances in assessment methods; advice from the CASAC; and comments from outside scientific organizations, stakeholder groups, and other members of the public. The reader is referred to those documents for greater detail on the ISA process. Here, the EPA provides only a broad overview of the science assessment, along with key aspects of its role in NAAQS reviews.

The ISA is a comprehensive review, synthesis, and evaluation of the most policy-relevant science (e.g., epidemiology, controlled human exposure, animal toxicology, atmospheric science, exposure science, environmental science, and ecology). The fundamental process for developing an ISA includes several elements: literature searches; study selection; evaluation of individual study quality; evaluation, synthesis, and integration of the evidence; and development of causality determinations and other scientific conclusions. The ISAs build on the data and conclusions of previous NAAQS

[34] The Preamble to the ISA, as well as more general information about the ISAs, are available to the public on the Integrated Science Assessment webpage (*https://www.epa.gov/isa*).

reviews through review of the available scientific evidence, with a focus on studies published since the literature search publication cutoff date for studies included in the prior ISA. Important older studies may be discussed to reinforce key concepts and conclusions. Older studies may also be the primary focus in some subject areas or scientific disciplines where research efforts have subsided and/or where these older studies remain the definitive works available in the literature.

Scientific judgments made in the ISA on topics such as causality, populations at higher risk than the general population (at-risk populations) and quantitative exposure-response relationships, are important to the design and scope of air quality, exposure and risk analyses, as well as other aspects of the NAAQS review. For example, the ISA's findings related to three general questions are particularly relevant: *What are the effects? Who {or What} is affected? Under what exposure conditions?* Answers to these questions are conveyed by the scientific findings in the ISA, including its characterization of limitations and associated uncertainties in the evidence. As described below, these findings inform the development of other aspects of the NAAQS review process and provide the scientific foundation for the Agency's decisions in each review.

With regard to the first question: *What are the effects?,* the ISA presents a comprehensive characterization of the evidence to identify what health or welfare effects are associated with the presence of the criteria pollutant in ambient air. In reaching conclusions in this regard, the ISA uses a weight-of-evidence framework for characterizing the strength of the available scientific evidence supporting causal relationships between criteria pollutant exposures and specific health and welfare effects. The EPA weighs the array of scientific evidence and reaches conclusions about the extent of scientific support for a causal relationship between exposures to the air pollutant and specific effects. Application of this framework provides for one of five causality determinations, as summarized in Table 4-1.[35] These determinations reflect the

[35] Rationale and details associated with these determinations are presented in the Preamble to the ISA (U.S. EPA, 2015). The EPA sponsored a study with the National Academies of Science, Engineering, and Medicine (NASEM) to evaluate the current ISA framework for reaching causality determinations (NASEM, 2022). NASEM was generally supportive of the framework used in the ISA, with several recommendations for improvement subsequently reflected in Appendix A of Volume 2 of the IRP for nitrogen oxides (U.S. EPA, 2024b). The NASEM recommendations, together with CASAC Nitrogen

EPA's conclusions on the health and welfare effects of the criteria pollutant as supported by the scientific evidence. These conclusions inform the consideration of health and welfare effects evidence in subsequent steps of the review, and thus are important to REA planning considerations and policy evaluations in the PA, as well as to judgments of the Administrator regarding the protection provided by the NAAQS.

Table 4-1. The five types of causality determinations that may be made in the science assessment of health and welfare effects.

Descriptor	Meaning
Causal relationship	Evidence is sufficient to conclude that there is a causal relationship *{of health or welfare effect}* with relevant pollutant exposures.
Likely to be a causal relationship	Evidence is sufficient to conclude that a causal relationship is likely to exist *{for health or welfare effect}* with relevant pollutant exposures.
Suggestive of, but not sufficient to infer, a causal relationship	Evidence is suggestive of, but not sufficient to infer, a causal relationship *{of health or welfare effect}* with relevant pollutant exposures; chance, confounding, and bias cannot be ruled out with confidence.
Inadequate to infer a causal relationship	Evidence is inadequate to determine that a causal relationship exists *{of health or welfare effect}* with relevant pollutant exposures.
Not likely to be a causal relationship	Evidence indicates there is no causal relationship *{of health or welfare effect}* with relevant pollutant exposures.

In the context of welfare effects, the causality determinations that address the first question also address the second question, *What is affected?,* through identification of the affected ecological receptor. For example, the 2024 Pb ISA identified terrestrial plants as an affected entity with regard to Pb by concluding there to be a causal relationship between Pb and terrestrial plant growth. Causality determinations reached on the welfare effects evidence include additional dimensions, compared to those for health effects evidence, in light of the multiple flora and fauna and organizational units (e.g., species, communities and ecosystems).

With regard to health effects, the ISA addresses the second question*, Who is affected?,* by reaching conclusions on characteristics that may result in populations or lifestages being at higher risk of air pollutant-related health effects than the general population. In its identification of potential risk factors and populations/lifestages at

Oxides Review Panel comments on Appendix A of oxides of nitrogen IRP, Volume 2, were then reflected in the Appendix of Volume 2 of the IRP for ozone and related photochemical oxidants (U.S. EPA, 2024c).

increased risk (i.e., at-risk populations and lifestages), the ISA characterizes the strength of the evidence for such identification (e.g., adequate, suggestive or inadequate) based on a structured framework as described in detail in the Preamble. This identification informs REA planning considerations, policy evaluations in the PA, and the Administrator's decisions on adequacy of protection provided by primary standards, which are intended to protect public health, including the health of at-risk populations. For example, to the extent there is support for such analysis, the REA may focus on characterizing risk to an at-risk population, as has been the case for the O_3 health REAs that have characterized risks for children with asthma.

In its comprehensive characterization of the current evidence, the ISA also provides information important to the third question, *Under what exposure conditions?*. This information, which includes identification of limitations and associated uncertainties, is essential to exposure/risk analyses, policy evaluations and the associated judgments of the Administrator in each review. For example, in the case of human respiratory effects for SO_2, the strong evidence base for respiratory effects, as characterized in the ISA, identified people with asthma (an important at-risk population for SO_2) as particularly sensitive to very short exposures, with studies of 5-minute exposures providing the basis for identifying health-based benchmark concentrations for use in the REA. Thus, the ISA characterization of the evidence regarding exposure conditions eliciting effects was a critical foundation for risk characterization in the REA, which has been important to the Administrator's judgments in establishing and retaining the current primary NAAQS for SO_X.[36] For welfare effects, this question can relate to air quality conditions. An example is visibility impairment associated with PM, for which the evidence base indicates visibility can vary with humidity and PM composition. Analyses based on this information have been included in the REA and have informed the Administrator's judgments regarding the current 24-hour secondary $PM_{2.5}$ standard.[37]

[36] The most recent decision on this standard is described in 84 FR 9866, March 18, 2019.

[37] The most recent decision on this standard is described in 89 FR 16202, March 6, 2024.

In its review of a draft ISA, areas in which the CASAC usually provides advice to the EPA include the causality determinations for health effects and conclusions on at-risk populations/ lifestages, as well as the causality determinations for welfare effects, including associated ecosystem components. The CASAC may also identify additional studies that it believes meet the ISA's scoping and study quality criteria and should be considered for inclusion in the ISA. The CASAC also generally advises the EPA when the document is (or will be, following revisions) adequate for the EPA's purposes in the review. The EPA carefully considers advice received from the CASAC and comments from the public in developing the final ISA. The final ISA is posted on the EPA website, with its public availability announced in the *Federal Register*.

4.2 RISK AND EXPOSURE ASSESSMENT

In NAAQS reviews, quantitative exposure/risk information generally provides a basis for considering the potential for health or welfare effects of concern to occur under air quality conditions that meet the existing standards, or potential alternative standards contemplated, and associated estimates of the magnitude of risk of such effects. This information may come from REAs newly developed in a review or, when a new REA is not conducted in a review, from previously available information. The PA considers the REA and its results, together with the ISA, as part of the evidence that may support a range of policy options for consideration by the Administrator in reaching decisions, as required under section 109 of the CAA, on what standards are requisite.

The REAs are generally designed to assess human exposure and health risk, as well as ecological exposure and welfare risk, for air quality conditions associated with the existing standards and potential alternative standards. For example, a policy-relevant question posed of a health or welfare-based REA is:

- *What are the nature and magnitude of exposures and associated health/welfare risks for air quality conditions just meeting the current standard?*

A related question concerns the strengths and limitations of the analyses conducted:

- *What are the important uncertainties associated with these risk and exposure estimates?*

The types of analyses that comprise each REA are based on the nature and strength of the scientific evidence available in the review, as well as the available

assessment and modeling tools and associated data. In identifying health and welfare effects or endpoints for quantitative assessment (at the planning stage, as summarized in section 3.2.3), the EPA focuses on considering endpoints for which there is the strongest support in the scientific evidence, as presented in the ISA. Generally, such endpoints are those for which the ISA has determined pollutant exposures to be causally or likely to be causally related to occurrence of the health or welfare endpoint. For analysis in the REA, the extent of support for quantitative assessment, including strong evidence describing a relationship between exposures and the health or welfare endpoint of interest, is then also considered. Identification of the exposure metric or the surrogate metric for the assessment depends on the extent to which the evidence provides support for a quantitative relationship between the endpoint and a given metric.

With regard to health REAs, the evidence bases for the different criteria pollutants provide support for quantitative health risk assessment of varying levels of refinement, with the exposure metric used ranging from a surrogate for personal exposure (e.g., PM) to exposure concentrations (e.g., O_3) to internal dose metrics (e.g., CO and Pb), as illustrated in Figure 4-1 below. In identifying the assessment approach for a particular criteria pollutant, the EPA evaluates the extent of support in the scientific evidence for relationships between exposure metrics and health effects of interest. This approach results in development of an assessment based on the relationships most well founded in the biological evidence base for each pollutant.

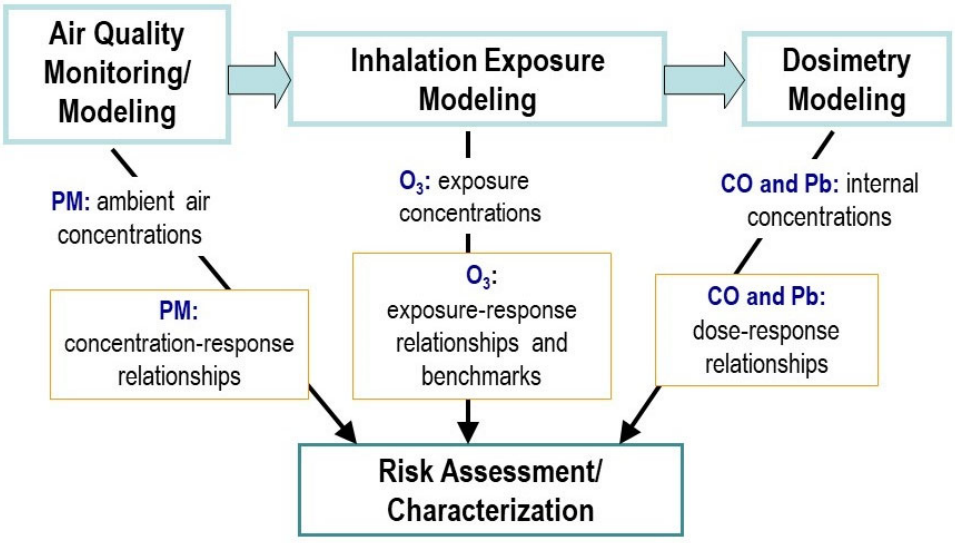

Figure 4-1. Array of concentration/exposure/dose metrics used in health REAs.

Based on the type of evidence available for a particular pollutant, any of a variety of quantitative human exposure and health risk analyses may be conducted, as illustrated by the array of examples in Table 4-2 below. As one example, in recent O_3 REAs, the evidence from controlled human exposure studies has supported the derivation of exposure-response (E-R) models for relating exposures to lung function response and the identification of health-based benchmark concentrations for risk characterization across an array of respiratory effects (U.S. EPA, 2020a, Appendix 3D). More detail presentations of analysis approaches employed in O_3 and Pb REAs are provided in Appendix B.

Table 4-2. Examples of quantitative health risk assessments performed for past NAAQS reviews, and the models and datasets on which they rely.

Pollutant: Analysis	Key Elements of Approach	Modeling, Tools, Datasets
O_3: Characterization of potential risk to children with asthma of experiencing days with O_3 exposures above health-based benchmark concentrations for an array of respiratory effects, and of experiencing lung function decrements.	Estimated spatial and temporal pattern of study area O_3 concentrations for conditions meeting existing and potential alternative standards	Ambient air monitoring data with application of spatial interpolation technique; air quality modeling (CMAQ) to derive air quality scenario adjustment; emissions estimates, meteorological data
	Estimates of human exposure concentrations at elevated exertion	Population exposure modeling (APEX); U.S. Census, National Health Interview Survey data on disease status, human activity data (CHAD); other inputs
	Health-based exposure concentration benchmarks	Controlled human exposure studies, at exertion, for 6.6-hour average exposure concentrations eliciting array of respiratory effects
	O_3-related lung function risk function	Database of controlled human exposure study lung function decrements at varying exertion and duration
PM: Quantification of premature mortality risk associated with $PM_{2.5}$ concentrations in ambient air	Estimated spatial pattern of annual average $PM_{2.5}$ concentrations for conditions meeting existing standard and potential alternatives	Spatial fields of $PM_{2.5}$ concentrations in each study area based on photochemical grid model (e.g. CMAQ) estimates combined with measured $PM_{2.5}$ concentrations; emissions estimates, meteorological data, $PM_{2.5}$ monitoring data
	PM-related premature mortality risk function and premature mortality risk estimates	BenMAP; concentration-response relationships from U.S. multicity studies of PM and mortality; National Center for Health Statistics mortality data; U.S. Census demographic information
CO: Characterization of potential risk to adults with coronary heart disease of experiencing days with internal COHB levels above health-based benchmark concentrations for angina-related response.	Estimated spatial and temporal pattern of CO concentrations across study area for conditions meeting existing and potential alternative standards	Ambient air quality monitoring data; studies of indoor and outdoor CO concentrations Proportional adjustment used for different air quality scenarios; microenvironmental proximity factors to derive concentrations for indoor locations
	Estimates of human exposure concentrations	Population exposure modeling (APEX); U.S. Census data; human activity data (CHAD); NHIS data on disease status
	Estimates of internal COHB levels	Physiological model (Coburn-Forester-Kane equation) for COHB
	Health-based COHB benchmarks	Controlled human exposure studies of COHB and reduced time to chest pain while exercising
Pb: Assessment of IQ decrement risk to young children associated with multi-pathway, multi-route exposure to air-related Pb	Estimates of ambient air, indoor air and dust Pb concentrations	Ambient air quality monitoring data; micro-environmental/indoor factor; regressions and hybrid (mechanistic compartmental-2-stage regression) models
	Estimates of blood Pb concentrations	IEUBK model; national data for soil, drinking water and dietary Pb concentrations; other inputs; U.S. Census data
	Blood Pb concentration-IQ response functions	Epidemiological studies of young children blood Pb associations with IQ decrements

Abbreviations: APEX = Air Pollutants Exposure Model; BenMAP = Benefits Mapping and Analysis Program; CHAD = Comprehensive Human Activity Database; CMAQ = Community Multiscale Air Quality model; COHB = carboxyhemoglobin; IEUBK = Integrated Exposure Uptake Biokinetic Model NHIS = National Health Interview Survey
References: O_3 REA - U.S. EPA, 2020a (section 3.4 and Appendices 3C and 3D); PM REA - U.S. EPA, 2020b (section 3.3, Appendix C); CO REA - U.S. EPA, 2010; Pb REA - U.S. EPA, 2007a,b,c.

Given the broad array of effects included in the definition of welfare effects, the air quality, exposure, and risk analysis approaches commonly employed for welfare REAs vary widely. The types of information that might support different assessments may include databases of ecosystem pollutant loading that have been associated with different levels of specific acidification metrics, as in the case of the assessment of deposition-related acidification effects of sulfur oxides, or E-R functions derived from controlled exposure studies of plants of interest, as in the case of E-R functions that relate O_3 exposures to tree seedling growth. The type of evidence available will influence what quantitative analyses are developed for the REA. Table 4-3 presents examples of quantitative welfare effects analyses developed in past NAAQS reviews.

Table 4-3. Examples of quantitative assessments performed for past reviews of secondary standards, and the models and datasets on which they rely.

Pollutant: Analysis	Key Elements of Approach	Modeling, Tools and Datasets
PM: Potential for visibility-related effects	Light extinction coefficient-based visibility metric	Three derivation approaches relying on: $PM_{2.5}$ and PM_{10} monitoring data, $PM_{2.5}$ and PM_{10} composition data; meteorological data (relative humidity)
	Potential visibility protection targets	Human preference study findings
SO_X: Characterization of aquatic acidification risk in acid-sensitive ecoregions	Estimates of annual sulfur and nitrogen deposition during five time periods in U.S. waterbodies	TDep (i.e., Spatial fields of total sulfur and nitrogen annual deposition based on CMAQ estimates of wet and dry deposition combined with NADP wet deposition measurements), SO_X emissions, meteorological data, $PM_{2.5}$ monitoring data
	Deposition estimates for achieving three acid neutralizing capacity targets in individual waterbodies	Critical loads database (NCLD), water chemistry models (e.g., MAGIC)
	Characterization of ecoregion risk from waterbody-specific results	Ecoregion-specific summarization of portion of waterbodies achieving ANC targets for ecoregion deposition at/below values and for different time periods
O_3: Tree seedling growth-related risk and effects on carbon sequestration	Estimated spatial pattern of W126 index across tree species' ranges for multiple air quality scenarios	Ambient air monitoring data with spatial interpolation technique; air quality modeling (CMAQ) for air quality adjustment; emissions estimates, meteorological data,
	Species-specific exposure-tree growth response functions	Controlled tree seedling exposure studies of annual growth; W126 cumulative exposure index function
	Estimates of carbon storage in multi-species tree and crop communities	Forest- and agriculture-related carbon sequestration model (FASOMGHG), urban tree-related carbon sequestration model (iTREE)

Abbreviations: CMAQ = Community Multiscale Air Quality model; MAGIC = Model of Acidification of Groundwater In Catchments; NADP = National Atmospheric Deposition Program; NCLD = National Critical Load Database; TDep = estimates developed by NADP, TDep Science Committee (https://nadp.slh.wisc.edu/committees/tdep/)
References: PM REA - U.S. EPA, 2020b (section 3.3, Appendix C); SO_X REA – U.S. EPA, 2024d (section 5.1, Appendix 5A); O_3 REA – U.S. EPA, 2014a,b (section 6.2, Appendices 4A, 6A, 6B, 6F)

As noted above, the air quality conditions evaluated in each REA generally include those associated with meeting the existing standard(s), as well as air quality conditions that might be associated with potential alternative standards. Depending on the pollutant and type of assessment (e.g., air pathway only or multimedia), the air quality conditions may be characterized using ambient air measurements from fixed site monitors, satellite measurements, air quality modeling, or a combination of these or other approaches. Determining the best approach for using available air quality information to generate air quality scenarios that simulate just meeting the current or alternative standards may depend on the chemistry and transport of the pollutant, the spatial resolution needed, and the exposure time frame of interest.

In the exposure assessment step, as noted above, depending on the scientific evidence for a pollutant (e.g., support for internal dose-, personal exposure-, or ambient air concentration-response relationships in a health risk assessment), the ambient air concentration estimates may sometimes be used as surrogates for exposure. In deriving human exposure and also dose estimates, however, the EPA generally utilizes exposure and internal dosimetry modeling.[38] In addition to influencing whether the exposure metric used in the assessment is personal (or population) exposure, an internal dose metric, or an ambient air concentration estimate, the scientific evidence base also influences the type of mathematical metric used. For example, the health REA focus could be on 5-minute exposure concentrations or the frequency of 5-minute exposure concentrations above specific benchmarks, or the focus could be on annual average

[38] For example, the established Air Pollutant Exposure (APEX) and Integrated Exposure, Uptake and Biokinetic (IEUBK) models are routinely used in human exposure modeling for O_3 and Pb reviews, respectively.

ambient air concentrations.[39] As noted above (e.g., Figure 4-1), the metrics used in a welfare effects assessment also reflect the underlying evidence base.[40]

The REAs for NAAQS reviews generally utilize a case-study design such that exposure and risk estimates are derived for one or more case studies. The set of case studies employed are intended to illustrate differences in the variables that influence risk and that may occur across the U.S., particularly in areas where ambient air concentrations are near the existing NAAQS. While the same conceptual air quality scenarios are simulated in all study areas (e.g., conditions that just meet an existing or potential alternative standard), variability in factors such as pollutant or precursor emissions patterns, meteorological conditions, and population characteristics in the study areas contribute to variability in the estimated magnitude of exposure and associated risk across study areas. The case studies illustrate a variety of exposure patterns that may be associated with air quality conditions occurring under an existing or potential alternative standards.

In the most recent NAAQS reviews, the complete REA is published in association with the PA and discussed within the body of the PA.[41] In addition to providing a time-saving efficiency in a review, this approach helps to explicitly convey the role of the REA in informing policy-relevant considerations in NAAQS reviews. The quantitative

[39] For example, for an assessment focused on risk associated with short-term exposure (e.g., lung function decrements following inhalation of SO_2), the analyses may generate hourly air quality concentrations across an urban case study area. In other situations, an annual average may be more appropriate for assessment of a longer-term exposure health endpoint (e.g., mortality risk from $PM_{2.5}$). Additionally, other air quality approaches may be used in ecological assessments that focus on air quality information linking the transformation and deposition of the criteria pollutant.

[40] While the averaging time and form of a pollutant standard may be established based on some similar considerations as the exposure metric for the REA, there are a number of additional considerations in specifying the elements of a standard. Accordingly, the exposure metric for an REA may have some similarity to the averaging time and form of the pollutant standard (e.g., short-term or long-term in nature); but it generally differs in any of a number of ways. For example, in the health REA for recent reviews of the primary NAAQS for SO_X, the exposure metric was a 5-minute average SO_2 exposure concentration, and the standard is the 3-year average of 99th percentile annual 1-hour ambient air concentrations.

[41] With this approach, the details of the REA (e.g., design, methods, results, uncertainty characterization) are presented in one or more appendices to the PA. There may also be situations where the REA is presented in a separate volume accompanying the PA.

estimates from the REA are considered in the policy evaluations of the PA along with the health and/or welfare effects evidence from the ISA. Together, these evaluations inform the Administrator's decision-making on the public health and/or welfare protection provided by the current or potential alternative standards.

The draft REA (e.g., in association with the draft PA) is made available to the public and transmitted to the CASAC for its review, along with a set of charge questions (as noted in section 2.2). The charge questions are intended to elicit review of the soundness of the quantitative analyses for their purpose in informing an understanding of exposure and risk associated with the existing standards and potential alternatives, as well as an understanding of their limitations and associated uncertainties. The EPA carefully considers the comments from the CASAC and the public in developing final analyses. The final REA generally includes a summary of changes made to analyses and their presentation in response to the CASAC review and public comments. The final REA is posted on the EPA website, with its public availability announced in the *Federal Register*.

4.3 POLICY ASSESSMENT

The PA presents analyses and staff conclusions regarding a range of policy options supported by the current scientific information and exposure/risk information. It considers the policy implications of the key scientific and technical information, along with its limitations and associated uncertainties. The PA integrates and interprets the current scientific evidence from the ISA and the analyses from the REA to address a set of policy-relevant questions. The PA focuses on information that is most pertinent to evaluating each standard (i.e., is "policy-relevant"). This includes both evidence-based (i.e., drawn from the ISA and the studies contained therein) and exposure/risk-based (i.e., drawn from REA analyses) considerations. In focusing on the policy implications of the current information, the PA is intended to "bridge the gap" between the Agency's scientific and quantitative risk and exposure assessments (in the ISA and REA) and the judgments required of the Administrator in determining whether it is appropriate to retain or revise the NAAQS.

In addition to the evaluations of policy implications of the current information, the PA includes background material that informs the evaluations. The background material includes an overview of the legislative requirements for the NAAQS and a history of past NAAQS reviews for the pollutant, as well as the progress and future steps in the current review. The air quality information presented generally includes recent information on pollutant or precursor emissions and ambient air concentrations, as well as a summary of the NAAQS sampling and monitoring network regulations, and data handling conventions for comparisons to the NAAQS. For some pollutants (e.g., O_3), a characterization of concentrations associated with background sources may also be presented.[42] The PA also summarizes the general approach for the review, including fundamental aspects of NAAQS reviews (summarized in section 2.4). As a point of reference for the policy evaluations, the PA also includes a summary of the current NAAQS and key aspects of their basis, including important judgments made by the Administrator in the last review.

As part of the evaluation, the PA summarizes the policy-relevant aspects of the current evidence and quantitative exposure/risk information. This includes an overview of key conclusions from the ISA, including identification of the health and welfare effects associated with the pollutant (e.g., causal determinations), at-risk populations (for primary standard reviews), as well as discussion regarding public health and welfare implications and uncertainties associated with the evidence. In summarizing this information, the PA addresses questions such as the following: *Does the currently available scientific evidence alter conclusions from the last review regarding the health/welfare effects attributable to the criteria pollutant in ambient air and at-risk populations? What are important limitations of the evidence and associated uncertainties?* The PA also describes the quantitative analyses for the review, including the risk and exposure assessments, and summarizes and discusses the key results and associated uncertainties and limitations. The PA evaluates policy implications of the exposure/risk estimates, including by addressing the question: *Are these exposures and risks of*

[42] The air quality information presented in the PA includes analyses and information relevant to the policy assessment.

sufficient magnitude such that the health or welfare effects might reasonably be judged to be important from a public health or public welfare perspective? Further, the PA addresses the question: *What are the important uncertainties associated with these risk and exposure estimates?*

The evaluation in the PA considers aspects of the scientific evidence and exposure/risk information that are particularly relevant in the context of the NAAQS. The basic elements of a standard – indicator, averaging time, form, and level – that together serve to define each standard, are considered collectively in evaluating the public health and public welfare protection the standard affords. The PA describes the support in the evidence and quantitative information for an array of policy options, as appropriate, and identifies limitations of the information and associated uncertainties. The CASAC, in fulfilling its responsibility under section 109 of the CAA, reviews the preliminary conclusions of the draft PA and provides its advice on the standards. Together, the staff conclusions in the final PA, along with the evidence- and exposure/risk-based considerations and the CASAC advice, are summarized for consideration by the Administrator.

In presenting its conclusions, the PA recognizes that the decisions on the NAAQS are, as noted in section 2.4.4 above, decisions made by the Administrator. It further recognizes that such decisions are based on public health and public welfare policy judgments necessary to reach conclusions as to what standards are requisite to protect public health or public welfare and are neither more nor less stringent than necessary for this purpose. In this context, the PA, in its evaluation of the health and/or welfare effects evidence from the ISA and exposure/risk information from the REA, provides the Administrator with information needed to make decisions, as required under section 109 of the CAA, on standards that are requisite.

The draft PA is made available to the public and transmitted to the CASAC for its review. As noted in section 2.2, in transmitting the draft PA, the EPA also provides a series of charge questions. While there may also be pollutant- or NAAQS-specific charge questions, there is also a commonality to these questions across reviews (e.g., Table 4-4). The CASAC conveys its comments on the PA and advice regarding the standards, in accordance with its responsibility under the CAA, in a letter to the Administrator. The

EPA carefully considers the comments from the CASAC and the public in developing final PA and its conclusions. The final PA incorporates appropriate changes and includes a section summarizing the CASAC advice on the standards. The final PA is posted on the EPA website, with its public availability announced in the *Federal Register*.

Table 4-4. Examples of generic charge questions for the CASAC in its review of a draft PA.

- Is the information presented in the draft PA technically sound, clearly communicated and appropriately characterized? Are key aspects of the available scientific evidence and quantitative analyses, along with the uncertainties associated with each, accurately presented?
- What are the CASAC's views on the preliminary conclusions presented in the draft PA regarding the range of policy options identified as appropriate for the Administrator to consider based on the available scientific evidence and quantitative information, along with associated uncertainties?
- Does the draft PA identify the key uncertainties and areas for additional research and data collection? Are there additional areas that should be highlighted?

5 REGULATORY DECISION-MAKING

The regulatory decision-making process in a NAAQS review conforms to the procedures for such regulatory actions in the federal government and those specified by the CAA.[43] This includes establishment and maintenance of dockets for information considered in the decision making and publication of proposed and final decisions in the *Federal Register*, with opportunity provided for public comment on the proposed decisions. These aspects are further described below.

At the initiation of a NAAQS review, the EPA establishes two dockets, one for the review of the air quality criteria (the ISA docket) and one for the review of the NAAQS (the regulatory docket).[44] The ISA docket generally receives the public comments from the Call for Information and also public comments submitted on the draft ISA. The EPA also places into the ISA docket any additional information supporting development of the ISA, including draft ISAs, letters transmitting CASAC advice on draft ISAs and communications (e.g., emails) with authors of individual scientific studies regarding salient details of studies. The regulatory docket receives all *Federal Register* notices for the review of the NAAQS (e.g., announcements of document availability, public comment periods, and public hearings; notices of proposed and final rulemakings) and all public comments in response to these notices. Additionally, the EPA places into the regulatory docket all documents considered in the decision-making for a review, including the IRP volumes, and draft and final REA and PA, with associated materials (e.g., quantitative analyses, scientific studies, datasets), and other relevant documents (e.g., technical memoranda).

In reaching decisions in the review, the Administrator considers the currently available information, including the scientific conclusions of the ISA, quantitative air quality/exposure/risk information, policy evaluations in the PA, public comment, and

[43] The administrative process that the EPA follows in NAAQS reviews, including for public participation and judicial review, adheres to the CAA section 307(d) requirements for administrative proceedings and judicial review, as well as any additional requirements of the Administrative Procedure Act, which describes aspects of the process for federal agencies in general to develop and issue regulations.

[44] Both dockets are publicly accessible at *www.regulations.gov*.

CASAC advice. As summarized in section 2.4.4, the Administrator is required to exercise his judgment to set standards that are requisite to protect public health (with an adequate margin of safety) or public welfare and are neither more nor less stringent than necessary for this purpose. All of the information supporting the proposed and final decisions is made available in the docket with those decisions.

In accordance with CAA and other requirements, the Administrator's proposed decisions in each review are published in the *Federal Register* with opportunity for public comment. After consideration of public comments and any related additional analyses, the final decisions are also published in the *Federal Register*. The sections below summarize the process for developing and issuing the notices of proposed and final decisions in NAAQS reviews.

5.1 PROPOSED DECISION

Following the issuance of the final PA, the Agency develops a notice of proposed decision based on the available scientific evidence and quantitative information, as well as the conclusions presented within the final PA, and taking into consideration advice from the CASAC and public comments received up to that point in the review. This notice describes the basis for and the Administrator's rationale for the proposed decision, reached after considering the analyses and conclusions in the documents developed in the review (e.g., as described in the preceding sections), public comment and advice from the CASAC.

As appropriate, the draft notice of the proposed decision is submitted to the Office of Management and Budget (OMB)'s Office of Information and Regulatory Affairs (OIRA) for its review and for its coordination of review by other federal agencies.[45] The interagency review period generally lasts 90 days. The EPA considers the comments received from the OIRA and other agencies during this step, making revisions as appropriate.[46]

[45] Executive Order 12866 describes OIRA's role in the rulemaking process.

[46] In accordance with Executive Order 12866 disclosure provisions, the OMB makes available on *www.RegInfo.gov* a list of all rules undergoing EO 12866 regulatory review. Consistent with the CAA and other requirements, the EPA includes in the regulatory docket notice of any changes to the draft notice made at this stage.

After completing the interagency review, the notice of proposed action is published in the *Federal Register*.[47] At the time of publication, all materials on which the proposed decisions are based are made available in the public docket for the review. Publication of the proposal notice is followed by a public comment period, generally lasting 45 to 90 days, during which the public is invited to submit comments on the proposal to the docket. The EPA also offers the opportunity for one or more public hearings for the public and stakeholders to provide comments orally. The EPA also offers the opportunity for consultation with federally recognized Tribal governments to ensure meaningful and timely input by Tribal officials prior to taking actions or implementing decisions that may affect Tribes.[48]

5.2 FINAL DECISION

After consideration of comments received on the proposed decision, the Agency develops a notice of final action, which communicates the Administrator's final decision(s) in the NAAQS review. The final decision notice describes the basis for and the Administrator's rationale for the decision, including consideration of the scientific and quantitative information, limitations and associated uncertainties, advice from the CASAC, and comments from the public. The EPA also responds to all significant comments on the proposal; this may be done wholly within the final decision notice or, depending on the volume of significant comments received, the notice may be augmented by a separate response-to-comments document.

In reviewing and considering public comments, the EPA also provisionally considers any "new" scientific studies cited by public commenters to enable the EPA to consider them in the context of the associated comments as they relate to the rationale

[47] Where implementation of the proposed decision would have an annual effect on the economy of $100 million or more, e.g., by necessitating the implementation of emissions controls, the EPA develops and releases a draft regulatory impact analysis (RIA) concurrent with the notice of proposed rulemaking. This activity is conducted under Executive Order 12866 and is completely independent of, and by statute is not considered in, decisions regarding the review of the NAAQS.

[48] The EPA Policy on Consultation with Indian Tribes provides more information on the policy and process for Tribal consultations in the regulatory decision-making phase (*https://www.epa.gov/system/files/documents/2023-12/epa-policy-on-consultation-with-indian-tribes-2023.pdf*).

and decisions in the review. As the EPA's provisional consideration of studies at this stage of the review cannot provide the same kind of in-depth critical review of the scientific evidence as in the assessment phase, this consideration focuses on determining whether the "new" studies warrant reopening the air quality criteria.[49] Based on this provisional consideration, if the EPA concludes that the studies would not materially change the scientific conclusions of the ISA in the review, the air quality criteria are not reopened and the studies are considered in the context of addressing the comments on the proposed decision.[50]

The draft notice of final action also generally undergoes OMB-coordinated interagency review by the process described in section 5.1. When complete, the Administrator signs the notice and it is published in the *Federal Register*, completing the review process.[51]

[49] The EPA's NAAQS decisions are based on studies and related information included in the ISA, REA, and PA, which have undergone CASAC and public review. The studies assessed in the ISA and the integration of the scientific evidence in that document have undergone extensive critical review by the EPA, CASAC, and the public during ISA development. The rigor of that review makes these studies, and their integrative assessment, the most reliable source of scientific information on which to base NAAQS decisions. Decisions on the NAAQS can have profound impacts on public health and welfare and should be based on studies that have been rigorously assessed in an integrative manner not only by the EPA but also by the statutorily-mandated independent advisory committee, CASAC, and have also been subject to the public review that accompanies this process. Provisional assessments do not provide that kind of in-depth critical review.

[50] Where the air quality criteria are not reopened, studies provisionally considered in this way are considered for inclusion in the ISA for the next review (as noted in section 3.1).

[51] The notice of final decision specifies the date on which the decision, and any associated regulatory changes, are effective.

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APPENDIX A

LEGISLATIVE REQUIREMENTS

The Clean Air Act (CAA) is the comprehensive federal law that regulates air emissions from stationary and mobile sources. Sections 108 and 109 of the CAA govern the establishment, review, and revision, as appropriate, of the NAAQS for each criteria air pollutant. These sections of the CAA are discussed more below, along with key caselaw (Figure A-1).

Section 108 (42 U.S.C. 7408) describes the air quality criteria, which are the basis for reviewing NAAQS.[52] Air quality criteria are intended to "accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of [a] pollutant in the ambient air…." (42 U.S.C. § 7408(a)(2)).

The EPA sets NAAQS for six criteria air pollutants: carbon monoxide, lead, oxides of nitrogen, ozone and other photochemical oxidants, particulate matter, and sulfur oxides.

Section 109 (42 U.S.C. 7409) directs the Administrator to propose and promulgate "primary" and "secondary" NAAQS for pollutants for which air quality criteria are issued (42 U.S.C. § 7409(a)). Section 109(b)(1) defines primary standards as ones "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."[53] Under section 109(b)(2), a secondary standard must "specify a level of air quality the attainment and maintenance of which, in the judgment of the Administrator, based on such criteria, is requisite to protect the public welfare from any

[52] The CAA describes criteria pollutants as those pollutants "emissions of which, in [the Administrator's] judgment, cause or contribute to air pollution which may reasonably be anticipated to endanger public health or welfare"; "the presence of which in the ambient air results from numerous or diverse mobile or stationary sources"; and for which the Administrator "plans to issue air quality criteria…." (42 U.S.C. § 7408(a)(1)).

[53] 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); see also *Coalition of Battery Recyclers Ass'n v. EPA*, 604 F.3d 613, 618 (D.C. Cir. 2010), *Am. Lung Ass'n v. EPA,* 134 F.3d 388, 389 (D.C. Cir. 1998).

known or anticipated adverse effects associated with the presence of [the] pollutant in the ambient air."[54]

In setting primary and secondary standards that are "requisite" to protect public health and welfare, as provided in section 109(b), the EPA's task is to establish standards that are neither more nor less stringent than necessary. In so doing, the EPA may not consider the costs of implementing the standards. See, *Whitman v. American Trucking Ass'ns*, 531 U.S. 457, 465–472, 475–76 (2001). Likewise, "[a]ttainability and technological feasibility are not relevant considerations in the promulgation of national ambient air quality standards." See *American Petroleum Institute v. Costle*, 665 F.2d 1176, 1185 (D.C. Cir. 1981); accord *Murray Energy Corp. v. EPA*, 936 F.3d 597, 623–24 (D.C. Cir. 2019).[55]

The requirement that primary standards protect the public health with 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 still needs to identify. See *Lead Industries Ass'n v. EPA*, 647 F.2d 1130, 1154 (D.C. Cir. 1980); *American Petroleum Institute v. Costle*, 665 F.2d at 1186; *Coalition of Battery Recyclers Ass'n v. EPA*, 604 F.3d 613, 617–18 (D.C. Cir. 2010); *Mississippi v. EPA*, 744 F.3d 1334, 1353 (D.C. Cir. 2013). Both uncertainties are components of the risk associated with pollution at levels below those at which human health effects can 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. The CAA does not require the

[54] Under CAA section 302(h) (42 U.S.C. § 7602(h)), effects on welfare include, but are not limited to, "effects on soils, water, crops, vegetation, manmade 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."

[55] At the same time, courts have clarified that the EPA may consider "relative proximity to peak background … concentrations" as a factor in deciding how to revise the NAAQS in the context of considering standard levels within the range of reasonable values supported by the air quality criteria and judgments of the Administrator. See *American Trucking Ass'ns, v. EPA*, 283 F.3d 355, 379 (D.C. Cir. 2002).

Administrator to establish a primary NAAQS at a zero-risk level or at background concentration levels (see *Lead Industries Ass'n v. EPA*, 647 F.2d at 1156 n.51, *Mississippi v. EPA*, 744 F.3d at 1351), but rather at a level that reduces risk sufficiently to protect public health with an adequate margin of safety.

In addressing the requirement to protect the public health with an adequate margin of safety, the EPA considers such factors as the nature and severity of the health effects involved, the size of the sensitive population(s), and the kind and degree of uncertainties. Selecting any particular approach to providing an adequate margin of safety is a policy choice left specifically to the Administrator's judgment. See *Lead Industries Ass'n v. EPA*, 647 F.2d at 1161–62; *Mississippi v. EPA*, 744 F.3d at 1353. In addressing the requirement to protect the public welfare from known or anticipated adverse effect, the EPA considers which effects are "adverse" to the public welfare. Such determinations require policy judgments about the societal impacts of the various welfare effects (e.g., effects on soils, water, crops, vegetation), and the kind and degree of associated uncertainties.

Section 109(d)(1) of the Act requires periodic review and, if appropriate, revision of existing air quality criteria to reflect advances in scientific knowledge concerning the effects of the pollutant on public health and welfare. Under the same provision, the EPA is also to review periodically and, if appropriate, revise the NAAQS based on the revised air quality criteria.[56]

[56] This section of the Act requires the Administrator to complete these reviews and make any revisions that may be appropriate "at five-year intervals." It further authorizes the Administrator to review and revise criteria or standards "earlier or more frequently."

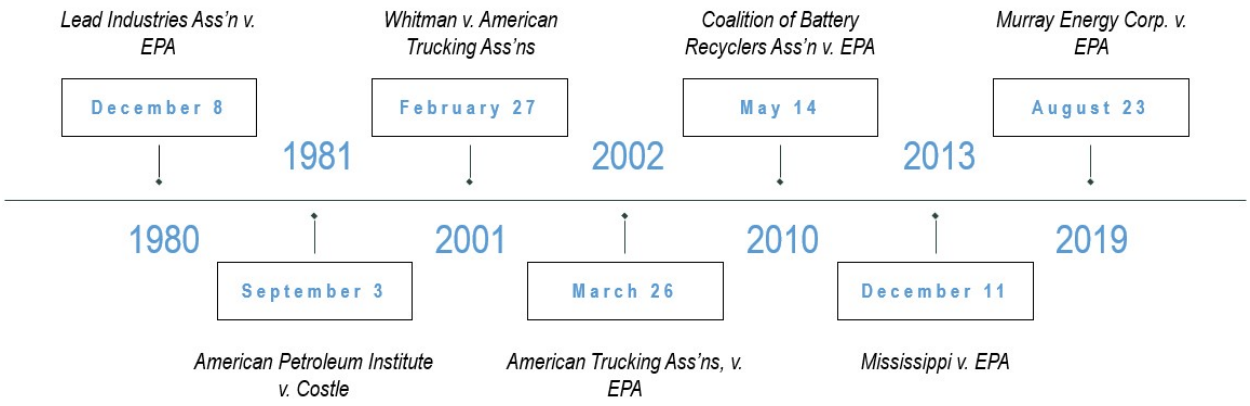

Figure A-1. Timeline depicting key caselaw.

Section 109(d)(2) addresses the appointment and advisory functions of an independent scientific review committee. Section 109(d)(2)(A) requires the Administrator to appoint this committee, which is to be composed of "seven members including at least one member of the National Academy of Sciences, one physician, and one person representing State air pollution control agencies." Section 109(d)(2)(B) provides that the 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 1980s, this independent review function has been performed by the Clean Air Scientific Advisory Committee (CASAC) of the EPA's Science Advisory Board (SAB).[57] In each review, the seven-member CASAC is typically assisted by a pollutant-specific panel of experts that are nationally and internationally recognized for their expertise and research in the field of air pollution related to the criteria pollutant under review. The nomination process and appointment of the CASAC and pollutant specific panels is managed through the EPA's SAB Staff Office.

Several other advisory functions are also identified for the committee by section 109(d)(2)(C), which reads:

> Such committee shall also (i) advise the Administrator of areas in which additional knowledge is required to appraise the adequacy and basis of

[57] The CASAC charter (publicly available on the "About the CASAC" webpage at: www.epa.gov/casac) provides more information on the objectives and scope of the CASAC's activities, a description of duties, as well as other administrative guidance. The CASAC charter is renewed in accordance with the provisions of the Federal Advisory Committee Act (FACA) every two years.

> existing, new, or revised national ambient air quality standards, (ii) describe the research efforts necessary to provide the required information, (iii) advise the Administrator on the relative contribution to air pollution concentrations of natural as well as anthropogenic activity, and (iv) advise the Administrator of any adverse public health, welfare, social, economic, or energy effects which may result from various strategies for attainment and maintenance of such national ambient air quality standards.

As previously noted, the Supreme Court has held that section 109(b) "unambiguously bars cost considerations from the NAAQS-setting process" in *Whitman v. American Trucking Ass'ns*, 531 U.S. 457, 471 (2001). Accordingly, while some of the issues listed in section 109(d)(2)(C), such as those on which Congress has directed the CASAC to advise the Administrator, are relevant to the standard-setting process, others are not. Issues that are not relevant to standard setting may be relevant to implementing the NAAQS once they are established.

APPENDIX B

EXAMPLES OF SOME ANALYTICAL APPROACHES

USED IN

NAAQS RISK AND EXPOSURE ASSESSMENTS

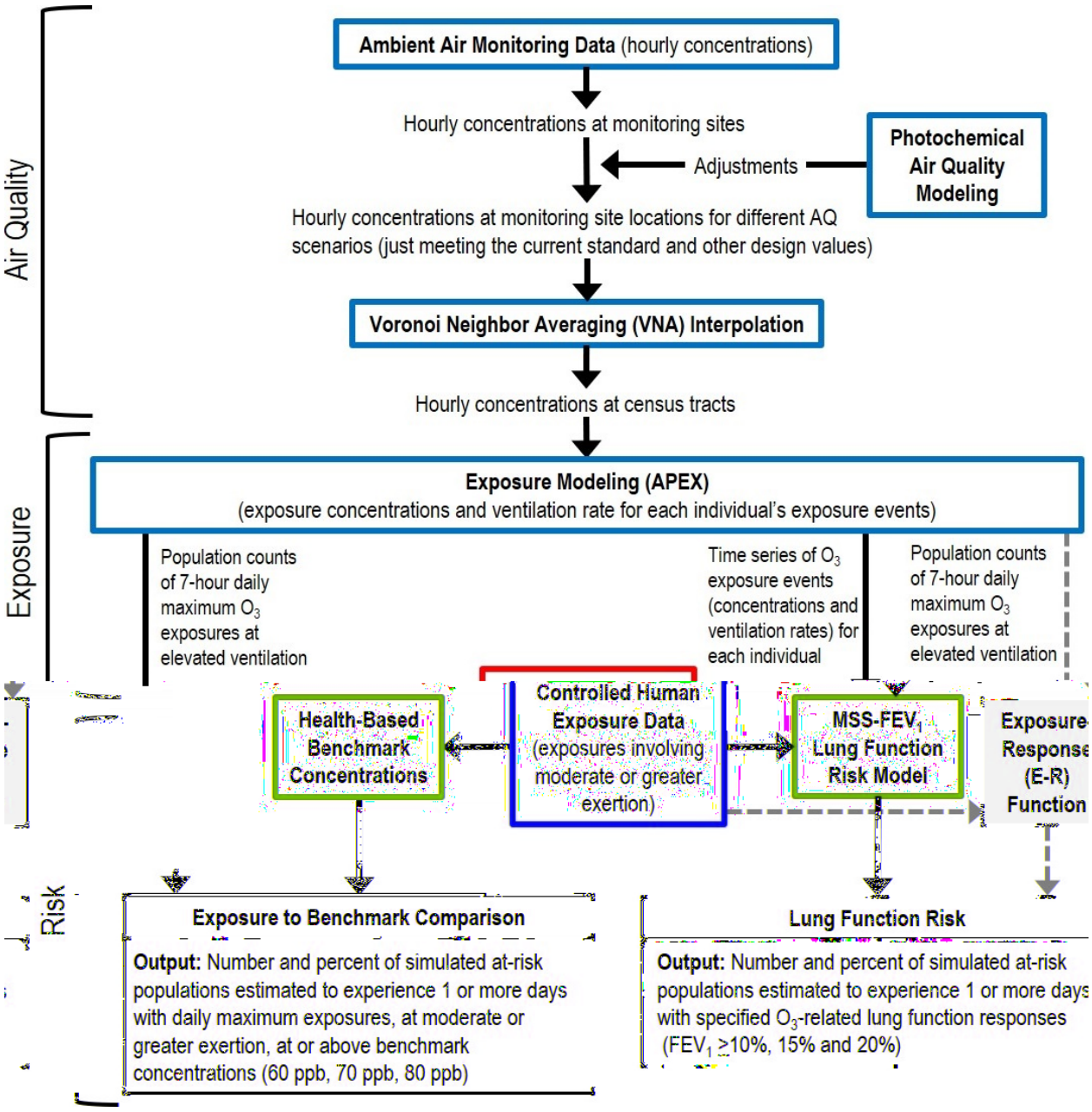

Figure B-1. General analytical approach employed in an ozone NAAQS REA (U.S. EPA, 2020a).

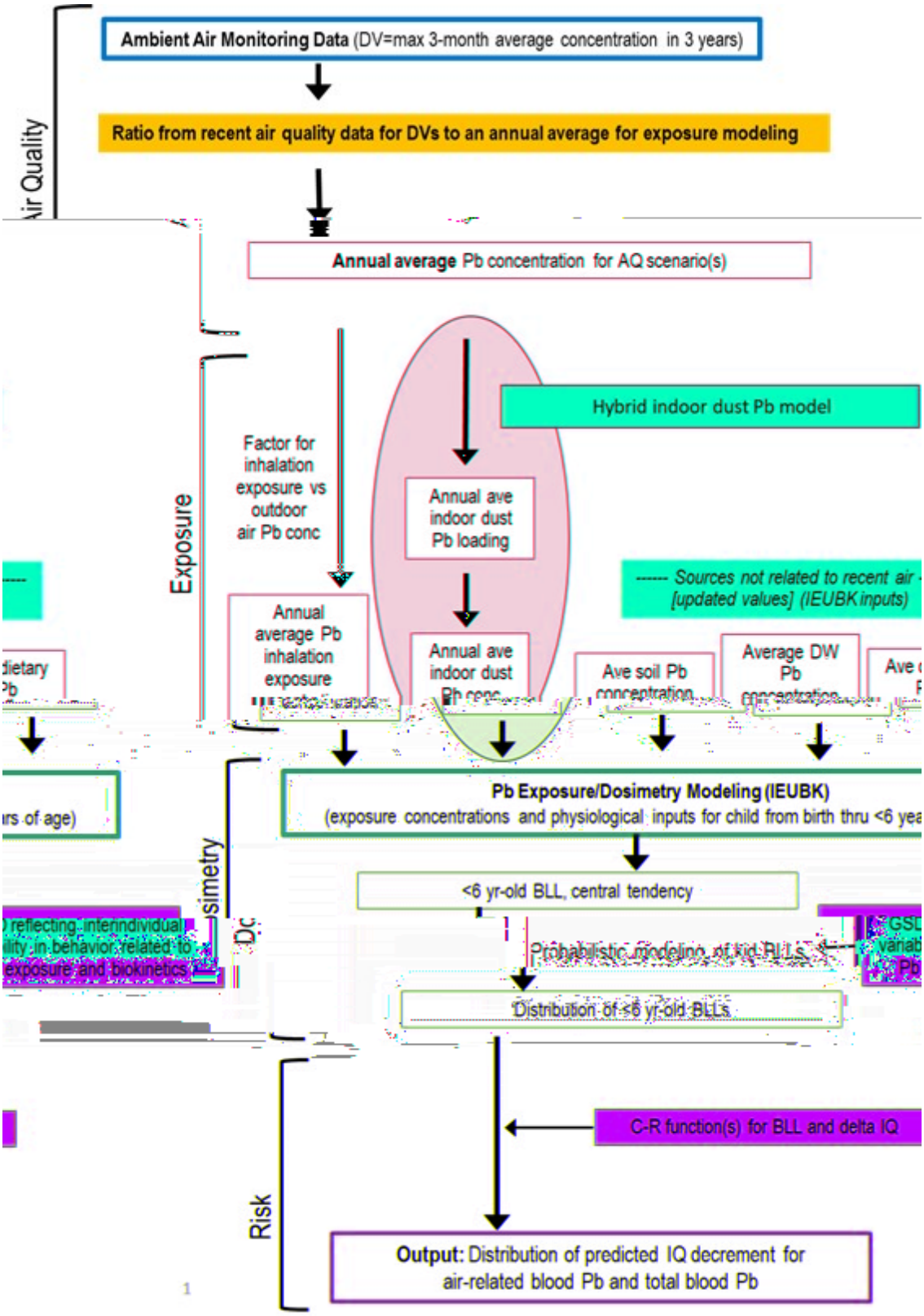

Figure B-2. General analytical approach developed in planning for a Pb NAAQS REA (U.S. EPA, 2023).

United States
Environmental Protection
Agency

Office of Air Quality Planning and Standards
Health and Environmental Impacts Division
Research Triangle Park, NC

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