

## **Overview of the Role of the Clean Air Scientific Advisory Committee in the Review of the NAAQS**

This document addresses the following three topics related to describing the role of the Clean Air Scientific Advisory Committee (CASAC) in EPA's periodic reviews of the national ambient air quality standards (NAAQS) as laid out in the Clean Air Act (CAA):

- Statutory role assigned to CASAC
- Statutory framework for the NAAQS
- Constraints on decision making by the EPA Administrator

This document is intended to serve as background information for the members of CASAC and the CASAC Review Panels formed for each NAAQS review to assist in carrying out their responsibilities in the review of the NAAQS.

### **Statutory role assigned to CASAC**

The CAA calls for EPA to appoint an “independent scientific review committee” that is 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). CASAC is this review committee. CASAC, augmented by subject-matter-experts, forms the CASAC Review Panel for a specific NAAQS.

The review committee is charged with two separate obligations (CAA section 109(d)(2)(B))<sup>1</sup>:

- Review the “air quality criteria” (AQC) issued by EPA, and recommend revisions that may be appropriate
- Review the primary and secondary NAAQS, and recommend revisions to the NAAQS and any new NAAQS that may be appropriate.

The CAA (section 108(a)(2)) defines “air quality criteria” as follows:

*“Air quality criteria for an air pollutant shall 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 such pollutant in the ambient air, in varying quantities. The criteria for an air pollutant, to the extent practicable, shall include information on—*

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<sup>1</sup> CASAC also has a third role, providing advice on a variety of related matters such as advising on areas where research is needed, and the research efforts necessary to meet these needs. CAA section 109(d)(2)(C).

*(A) those variable factors (including atmospheric conditions) which of themselves or in combination with other factors may alter the effects on public health or welfare of such air pollutant;*

*(B) the types of air pollutants which, when present in the atmosphere, may interact with such pollutant to produce an adverse effect on public health or welfare; and*

*(C) any known or anticipated adverse effects on welfare.”*

CASAC’s role in reviewing and recommending appropriate revisions to the AQC calls upon CASAC to advise the Administrator on the relevant scientific information that is to serve as the basis for the NAAQS. In addition, CASAC’s role is to review the NAAQS and recommend any appropriate revisions or new NAAQS, in light of the available scientific and other information.

The CAA does not specify how CASAC is to perform its advisory role.<sup>2</sup> EPA’s and CASAC’s practice has been for CASAC to review and provide advice on various draft or final documents prepared by EPA or its staff as part of EPA’s review of the AQC and NAAQS. CASAC has also chosen in certain instances to comment on EPA’s proposed NAAQS rulemakings, including most recently on advance notices of proposed rulemaking.

## **Statutory Framework for the NAAQS**

CASAC’s obligation to review the NAAQS and provide recommendations to the Administrator on appropriate revisions calls for an understanding of the statutory criteria that the Administrator must apply when establishing, retaining, or revising a NAAQS. The CAA (section 109(b)) defines the health-based primary NAAQS and the welfare-based secondary NAAQS as follows:

*Primary NAAQS: “National primary ambient air quality standards ... shall be ambient air quality standards 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.”*

*Secondary NAAQS: “Any national secondary ambient air quality standard ... shall specify a level of air quality the attainment and maintenance of which in the judgment of the Administrator, based on such criteria, is requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of such air pollutant in the ambient air.”*

Key terms in the definitions of the NAAQS are discussed below.

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<sup>2</sup> CASAC’s procedures are subject to other statutory provisions, such as the Federal Advisory Committee Act.

- **Requisite to protect:** The Supreme Court accepted EPA’s definition of what “requisite” means: “sufficient, but not more than necessary.” This “require[s] the EPA to make judgments of degree.” In setting standards that are requisite to protect public health and welfare, EPA’s task is to establish standards that are neither more nor less stringent than necessary for these purposes.<sup>3</sup>
  - > This required judgment of degree is particularly difficult where there are no clear discernable population thresholds, as is often the case for NAAQS pollutants. EPA has repeatedly rejected claims that the lack of a clear discernable threshold requires the Administrator to set zero-risk standards. Further, the CAA does not require the Administrator to establish a primary NAAQS at a zero-risk level or at background concentration levels,<sup>4</sup> but rather at a level that reduces risk sufficiently so as to protect public health with an adequate margin of safety.
  - > EPA has long recognized that this calls for exercising informed judgment concerning the degree of certainty or uncertainty of a risk and the seriousness of the effects at issue. As EPA said in its 1979 final Ozone decision, “the decision as to what standard protects public health with an adequate margin of safety is based on the uncertainty that any given level is low enough to prevent health effects and on the relative acceptability of various degrees of uncertainty, given the seriousness of the effects.” (44 FR 8213, Feb. 8, 1979)
  - > The “requisite to protect” criteria applies to the entire standard – for the primary standard, protection with an adequate margin of safety. Thus the Administrator is determining what primary standard is sufficient to protect with an adequate margin of safety, but not more than what is necessary to provide such protection.
- **Public health:** The primary standards are to protect the health of the public, not the health of every individual. Legislative history and court decisions indicate that NAAQS must be set to protect sensitive, at-risk population groups, but not the most sensitive or maximally exposed individual.<sup>5</sup>
  - > The primary standards are not intended to protect against all identifiable health effects, only those judged to be “adverse.” EPA has consistently recognized that judgments are required about which effects and what degree of physiological responses should be considered “adverse” health effects for which the NAAQS should provide protection. For example, in revising the ozone NAAQS in 1979, EPA stated “It is EPA’s best judgment that physiological responses probably occur in extremely sensitive persons at very low levels. At what point these responses become an adverse health effect and at what level they most likely

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<sup>3</sup> *Whitman v. American Trucking Associations*, 531 U.S. 457, 473, 475-6.

<sup>4</sup> *Lead Industries Association v. EPA*, 647 F.2d 1130, 1156 n.51 (D.C. Cir 1980), *cert. denied*, 449 U.S. 1042 (1980). 73 FR 66964, 66966 (November 12, 2008) (Lead NAAQS).

<sup>5</sup> S. Rep. No. 91-1196, 91st Cong., 2d Sess. 10 (1970); *American Lung Ass’n v. EPA*, 134 F.3d 388, 389 (D.C. Cir. 1998); *Lead Industries Association v. EPA*, 647 F.2d at 1153. 73 FR at 66965.

occur in sensitive persons must necessarily be an informed judgment.” (44 FR 8215, Feb. 8, 1979)

- > This can require difficult public health judgments, for example where there is no discernible threshold. In its 1978 ozone NAAQS proposal, EPA noted that the criteria document “confirms that no clear threshold can be identified for health effects due to ozone. Rather there is a continuum consisting of ozone levels at which health effects are certain, through levels at which scientists can generally agree that health effects are less certain and harder to identify.” (43 FR 26965, June 22, 1978).
- > Because the primary NAAQS were intended to be precautionary and preventive, the Administrator is not free to define as adverse only those effects which are clearly harmful or for which there is medical consensus about the degree of harm. Rather, the Administrator evaluates reasonable medical judgments and theories in deciding which effects are significant enough to be considered adverse.<sup>6</sup>
- ***Adequate margin of safety***: The requirement of an adequate margin of safety for the primary standards was intended to address uncertainties associated with inconclusive scientific and technical information available at the time of standard setting. It was also intended to provide a reasonable degree of protection against hazards that research has not yet identified.<sup>7</sup>
  - > Both kinds of uncertainties are components of the risk associated with pollution at levels below those at which human health effects can be said to occur with reasonable scientific certainty. Thus, in selecting primary standards that include an adequate margin of safety, the Administrator is seeking not only to prevent pollutant 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.<sup>8</sup>
  - > EPA often approaches the requirement of providing an adequate margin of safety by recognizing the need for informed judgment by the Administrator based on several important considerations. EPA has recognized and applied criteria that include the nature of the effects, size of the populations at risk and degree of exposure, and the degree of scientific certainty that such effects will occur upon attaining alternative standards under consideration. “For example, if a suspected but uncertain health effect is severe and the size of the population at risk is large, a more cautious approach will be appropriate than would be if the effect were less troubling or the exposed population smaller.” (52 FR 24641, July 1, 1987) (PM NAAQS)

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<sup>6</sup> *Lead Industries Association v. EPA*, 647 F.2d at 1154.

<sup>7</sup> *Lead Industries Association v. EPA*, 647 F.2d at 1154.; *American Petroleum Institute v. Costle*, 665 F.2d 1176, 1186 (D.C. Cir. 1981), *cert. denied*, 455 U.S. 1034 (1982).

<sup>8</sup> 73 FR at 66964, 66966.

- > The selection of any particular approach to providing an adequate margin of safety is a policy choice left specifically to the Administrator's judgment.<sup>9</sup> "Adding the margin of safety at the end of the analysis is one approach, but it is not the only possible method. Indeed, the Administrator considered this approach but decided against it because of complications raised by multiple sources of lead exposure: The choice between these possible approaches is a policy choice of the type that Congress specifically left to the Administrator's judgment. This court must allow him the discretion to determine which approach will best fulfill the goals of the Act."<sup>10</sup>
- > The Administrator's past practice has been to take margin of safety considerations into account in making decisions about setting the primary standard, including in determining its level, averaging time, form and indicator.
- **Public welfare:** Public welfare is not defined in the Act. "Effects on welfare" is defined to "include, but [is] 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 section 302(h).
- > As with public health, EPA is called on to make judgments concerning the adversity of effects on the public welfare.

### **Constraints on decision making by the Administrator**

Within this statutory framework, the Administrator must employ *reasoned decision making* in setting a NAAQS.

- In its most recent opinion on the NAAQS, the D.C. Circuit stated: "Petitioners misread *American Lung Ass'n*, however, if they think it requires EPA, prior to setting primary NAAQS, to identify perfectly safe levels of pollutants, to rely on specific risk estimates, or to specify threshold amounts of scientific information. Although we recognize that the Clean Air Act and circuit precedent require EPA qualitatively to describe the standard governing its selection of particular NAAQS, we have expressly rejected the notion that the Agency must 'establish a measure of the risk to safety it considers adequate to protect public health every time it establishes a [NAAQS].'"<sup>11</sup>
- The Court also stated that "[t]he Act requires EPA to promulgate protective primary NAAQS even where, as here, the pollutant's risks cannot be quantified or 'precisely identified as to nature or degree,' ... For its part, *American Lung Ass'n*. requires only

<sup>9</sup> *Lead Industries Association v. EPA*, 647 F.2d at 1161–62.

<sup>10</sup> *Lead Industries Association v. EPA*, 647 F.2d at 1154.

<sup>11</sup> *American Trucking Assoc. v. EPA*, 283 F.2d 355, 369 (D.C. Cir. 2002)

that EPA ‘engage in reasoned decision-making,’ 134 F.3d at 392, not that it definitively identify pollutant levels below which risks to public health are negligible.”<sup>12</sup>

- The CAA provides that EPA must consider relevant factors, apply relevant facts, respond to criticisms, and adequately explain its rationale. CAA section 307(d) (2) - (6). Courts may overturn EPA’s decision if it is “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.” CAA section 307(d)(9)(A)

***With respect to the advice provided by CASAC***, in the proposed rule EPA is specifically required to “set forth or summarize and provide a reference to any pertinent findings, recommendations, and comments by the Scientific Review Committee [CASAC] and, if the proposal differs in any important respect from any of these recommendations, an explanation of the reasons for such differences.” This also applies to the final rule. CAA section 307(d)(3), (6)(A).

- In those situations where the proposed or final rule differs from the recommendations of CASAC, the Administrator’s explanation of the reasons for the difference has focused on: (i) describing CASAC’s recommendation, (ii) identifying whether the difference in views is a difference in interpretation of the science or a difference in public health or welfare judgments, and (iii) describing the extent to which the interpretation of the scientific evidence or the reasoning and judgments relied upon by the Administrator differ from CASAC.
- For example, in the 2006 decision on the annual average standard for PM<sub>2.5</sub>, EPA discussed in detail CASAC’s comments and advice on the proposed rule (71 FR 61144, 61174, October 17, 2006), and explained the reasons why EPA’s decision differed from CASAC’s recommendation on the level of the annual average (71 FR at 61174-75, 61176 fn 49).

The NAAQS must be “***based on the air quality criteria.***” This arises as an issue when EPA is asked to consider recent scientific studies that were published too late for inclusion in EPA’s and CASAC’s review of the air quality criteria.

- In the recent review of the Lead NAAQS, EPA explained “that NAAQS decisions are to be based on scientific studies and related information that have been assessed as a part of the pertinent air quality criteria .... This longstanding interpretation was strengthened by new legislative requirements enacted in 1977, which added section 109(d)(2) of the Act concerning CASAC review of air quality criteria. *See* 71 FR 61144, 61148 (October 17, 2006) (final decision on review of PM NAAQS) for a detailed discussion of this issue and EPA’s past practice. As discussed in EPA’s 1993 decision not to revise the NAAQS for ozone, “new” studies may sometimes be of such significance that it is appropriate to delay a decision on revision of a NAAQS and to supplement the pertinent air quality criteria so the studies can be taken into

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<sup>12</sup> *American Trucking Assoc. v. EPA*, 283 F.2d at 369-70.

account (58 FR at 13013–13014, March 9, 1993).” (73 FR 66964, 66968, November 12, 2008).

- EPA explained the important policy considerations behind this interpretation -- the studies included in the review of the air quality criteria “have undergone extensive critical review by EPA, CASAC, and the public. The rigor of that review makes these studies, and their integrative assessment, the most reliable source of scientific information on which to base decisions on the NAAQS, decisions that all parties recognize as of great import. NAAQS decisions can have profound impacts on public health and welfare, and NAAQS decisions should be based on studies that have been rigorously assessed in an integrative manner not only by EPA but also by the statutorily mandated independent advisory committee, as well as the public review that accompanies this process.” (73 FR at 66968)

EPA is *precluded from taking into consideration the costs of implementation* of a NAAQS. EPA cannot consider possible impacts on public health that could occur as a result of the costs to come into compliance, or otherwise take into consideration costs of compliance. This applies to both the primary and the secondary NAAQS.<sup>13</sup>

- In determining whether air pollution is adverse to public welfare, EPA may consider the impact of the air pollution itself on economic values, such as the impact of a pollutant on commercial crops, based on the definition of effects on welfare. However, EPA may not consider the cost of measures to attain and maintain compliance with a NAAQS.
- EPA may consider whether a NAAQS promotes safety overall, and so may consider factors such as whether the form of the standard will promote the standard’s stable implementation.<sup>14</sup>

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<sup>13</sup> *Whitman v. American Trucking Associations*, 531 U.S. at 464-472.

<sup>14</sup> *American Trucking Assoc. v. EPA*, 283 F. 3d at 374-75, with reference to *Whitman*, 531 U.S. at 495 (Breyer, J., concurring).

**ATTACHMENT**  
**Excerpts from the Clean Air Act**

***CAA Section 108:***

42 USC § 7408. Air quality criteria and control techniques

(a) Air pollutant list; publication and revision by Administrator; issuance of air quality criteria for air pollutants.

(1) For the purpose of establishing national primary and secondary ambient air quality standards, the Administrator shall within 30 days after the date of enactment of the Clean Air Amendments of 1970 [enacted Dec. 31, 1970] publish, and shall from time to time thereafter revise, a list which includes each air pollutant--

(A) emissions of which, in his judgment, cause or contribute to air pollution which may reasonably be anticipated to endanger public health or welfare;

(B) the presence of which in the ambient air results from numerous or diverse mobile or stationary sources; and

(C) for which air quality criteria had not been issued before the date of enactment of the Clean Air Amendments of 1970 [enacted Dec. 31, 1970], but for which he plans to issue air quality criteria under this section.

(2) The Administrator shall issue air quality criteria for an air pollutant within 12 months after he has included such pollutant in a list under paragraph (1). Air quality criteria for an air pollutant shall 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 such pollutant in the ambient air, in varying quantities. The criteria for an air pollutant, to the extent practicable, shall include information on--

(A) those variable factors (including atmospheric conditions) which of themselves or in combination with other factors may alter the effects on public health or welfare of such air pollutant:

(B) the types of air pollutants which, when present in the atmosphere, may interact with such pollutant to produce an adverse effect on public health or welfare; and

(C) any known or anticipated adverse effects on welfare.

***CAA Section 109:***

42 USC § 7409. National primary and secondary ambient air quality standards

(a) Promulgation.

(1) The Administrator--

(A) within 30 days after the date of enactment of the Clean Air Amendments of 1970 [enacted Dec. 31, 1970], shall publish proposed regulations prescribing a national

primary ambient air quality standard and a national secondary ambient air quality standard for each air pollutant for which air quality criteria have been issued prior to such date of enactment; and

(B) after a reasonable time for interested persons to submit written comments thereon (but no later than 90 days after the initial publication of such proposed standards) shall by regulation promulgate such proposed national primary and secondary ambient air quality standards with such modifications as he deems appropriate.

(2) With respect to any air pollutant for which air quality criteria are issued after the date of enactment of the Clean Air Amendments of 1970 [enacted Dec. 31, 1970], the Administrator shall publish, simultaneously with the issuance of such criteria and information, proposed national primary and secondary ambient air quality standards for any such pollutant. The procedure provided for in paragraph (1)(B) of this subsection shall apply to the promulgation of such standards.

(b) Protection of public health and welfare.

(1) National primary ambient air quality standards, prescribed under subsection (a) shall be ambient air quality standards 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. Such primary standards may be revised in the same manner as promulgated.

(2) Any national secondary ambient air quality standard prescribed under subsection (a) shall specify a level of air quality the attainment and maintenance of which in the judgment of the Administrator, based on such criteria, is requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of such air pollutant in the ambient air. Such secondary standards may be revised in the same manner as promulgated.

(c) National primary ambient air quality standard for nitrogen dioxide. The Administrator shall, not later than one year after the date of the enactment of the Clean Air Act Amendments of 1977 [enacted Aug. 7, 1977], promulgate a national primary ambient air quality standard for NO<sub>2</sub> concentrations over a period of not more than 3 hours unless, based on the criteria issued under section 108(c) [42 USC § 7408(c)], he finds that there is no significant evidence that such a standard for such a period is requisite to protect public health.

(d) Review and revision of criteria and standards; independent scientific review committee; appointment; advisory functions.

(1) Not later than December 31, 1980, and at five-year intervals thereafter, the Administrator shall complete a thorough review of the criteria published under section 108 [42 USC § 7408] and the national ambient air quality standards promulgated under this section and shall make such revisions in such criteria and standards and promulgate such new standards as may be appropriate in accordance with section 108 [42 USC § 7408] and subsection (b) of this section. The Administrator may review and revise criteria or promulgate new standards earlier or more frequently than required under this paragraph.

(2) (A) The Administrator shall appoint an independent scientific review committee 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.

(B) Not later than January 1, 1980, and at five-year intervals thereafter, the committee referred to in subparagraph (A) shall complete a review of the criteria published under section 108 [42 USCS § 7408] and the national primary and secondary ambient air quality standards promulgated under this section and shall recommend to the Administrator any new national ambient air quality standards and revisions of existing criteria and standards as may be appropriate under section 108 [42 USCS § 7408] and subsection (b) of this section.

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

### **CAA Section 307:**

42 USC § 7607. Administrative proceedings and judicial review

(d) Rulemaking.

(1) This subsection applies to--

(A) the promulgation or revision of any national ambient air quality standard under section 109 [42 USCS § 7409],

(2) Not later than the date of proposal of any action to which this subsection applies, the Administrator shall establish a rulemaking docket for such action (hereinafter in this subsection referred to as a "rule"). Whenever a rule applies only within a particular State, a second (identical) docket shall be simultaneously established in the appropriate regional office of the Environmental Protection Agency.

(3) In the case of any rule to which this subsection applies, notice of proposed rulemaking shall be published in the Federal Register, as provided under *section 553(b) of title 5, United States Code*, shall be accompanied by a statement of its basis and purpose and shall specify the period available for public comment (hereinafter referred to as the "comment period"). The notice of proposed rulemaking shall also state the docket number, the location or locations of the docket, and the times it will be open to public inspection. The statement of basis and purpose shall include a summary of--

(A) the factual data on which the proposed rule is based;

(B) the methodology used in obtaining the data and in analyzing the data; and

(C) the major legal interpretations and policy considerations underlying the proposed rule.

The statement shall also set forth or summarize and provide a reference to any pertinent findings, recommendations, and comments by the Scientific Review Committee established under section 109(d) [42 USC § 7409(d)] and the National Academy of Sciences, and, if the proposal differs in any important respect from any of these recommendations, an explanation of the reasons for such differences. All data, information, and documents referred to in this paragraph on which the proposed rule relies shall be included in the docket on the date of publication of the proposed rule.

(4) (A) The rulemaking docket required under paragraph (2) shall be open for inspection by the public at reasonable times specified in the notice of proposed rulemaking. Any person may copy documents contained in the docket. The Administrator shall provide copying facilities which may be used at the expense of the person seeking copies, but the Administrator may waive or reduce such expenses in such instances as the public interest requires. Any person may request copies by mail if the person pays the expenses, including personnel costs to do the copying.

(B) (i) Promptly upon receipt by the agency, all written comments and documentary information on the proposed rule received from any person for inclusion in the docket during the comment period shall be placed in the docket. The transcript of public hearings, if any, on the proposed rule shall also be included in the docket promptly upon receipt from the person who transcribed such hearings. All documents which become available after the proposed rule has been published and which the Administrator determines are of central relevance to the rulemaking shall be placed in the docket as soon as possible after their availability.

(ii) The drafts of proposed rules submitted by the Administrator to the Office of Management and Budget for any interagency review process prior to proposal of any such rule, all documents accompanying such drafts, and all written comments thereon by other agencies and all written responses to such written comments by the Administrator shall be placed in the docket no later than the date of proposal of the rule. The drafts of the final rule submitted for such review process prior to promulgation and all such written comments thereon, all documents accompanying such drafts, and written responses thereto shall be placed in the docket no later than the date of promulgation.

(5) In promulgating a rule to which this subsection applies (i) the Administrator shall allow any person to submit written comments, data, or documentary information; (ii) the Administrator shall give interested persons an opportunity for the oral presentation of data, views, or arguments, in addition to an opportunity to make written submissions; (iii) a transcript shall be kept of any oral presentation; and (iv) the Administrator shall keep the record of such proceeding open for thirty days after completion of the proceeding to provide an opportunity for submission of rebuttal and supplementary information.

(6) (A) The promulgated rule shall be accompanied by (i) a statement of basis and purpose like that referred to in paragraph (3) with respect to a proposed rule and (ii) an explanation of the reasons for any major changes in the promulgated rule from the proposed rule.

(B) The promulgated rule shall also be accompanied by a response to each of the significant comments, criticisms, and new data submitted in written or oral presentations during the comment period.

(C) The promulgated rule may not be based (in part or whole) on any information or data which has not been placed in the docket as of the date of such promulgation.

(9) In the case of review of any action of the Administrator to which this subsection applies, the court may reverse any such action found to be--

(A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;

(B) contrary to constitutional right, power, privilege, or immunity;

(C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right; or

(D) without observance of procedure required by law, if (i) such failure to observe such procedure is arbitrary or capricious, (ii) the requirement of paragraph (7)(B) has been met, and (iii) the condition of the last sentence of paragraph (8) is met.