

**Clean Air Scientific Advisory Committee (CASAC) Draft Report (3/19/24) to Assist Meeting Deliberations  
-Do Not Cite or Quote-**

This draft CASAC report is a work in progress, does not reflect consensus advice or recommendations, has not been reviewed or approved by the Chartered CASAC, and does not represent EPA policy.

DATE

EPA-CASAC-24-XXX

The Honorable Michael S. Regan  
Administrator  
U.S. Environmental Protection Agency  
1200 Pennsylvania Avenue, N.W.  
Washington, D.C. 20460

Subject: CASAC Advice on the National Ambient Air Quality Standards (NAAQS) Review Process

Dear Administrator Regan:

In order to optimize the role of the Clean Air Scientific Advisory Committee (CASAC) in providing advice regarding the National Ambient Air Quality Standards (NAAQS), the CASAC wishes to recommend process modifications for future NAAQS reviews, including reconsideration reviews. Recent CASAC deliberations on the NAAQS reviews for particulate matter (PM), ozone, and the secondary NAAQS for nitrogen oxides/sulfur oxides/PM have been characterized by conflicting perspectives and lack of consensus, which has diminished the usefulness of the CASAC's advice. Thus, the CASAC recommends several changes to the NAAQS review process, including reconsideration reviews, in an effort to enhance consensus among the CASAC and strengthen its advice. Specifically, the CASAC recommends:

1. The agency provide the CASAC and the Administrator with a sufficient set of alternative standards to review, even in cases where the agency staff recommend that the current standard should be retained. Specifically,
  - a. Risk and/or exposure assessment analyses should include the more protective levels as well as the indicators, averaging times, and forms that were recommended by the CASAC prior to and/or during the current review.
  - b. The agency should revamp its decision process and flow chart followed in the policy assessments (PAs).
2. The agency provide a second draft PA whenever the CASAC advises that it is needed. This is most important in reviews where the staff recommendations and the CASAC advice on the standards do not align.
3. At the initiation of any reconsideration review, the CASAC requests a briefing from the agency about the process. The CASAC notes that for regular NAAQS reviews, the Integrated Review Plan (IRP) consultations provide this mechanism.

Further elaboration on these points is provided in the enclosed consensus comments.

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The CASAC appreciates the opportunity to provide you with this advice and looks forward to the Agency's response.

Sincerely,

Dr. Elizabeth A. (Lianne) Sheppard, Chair  
Clean Air Scientific Advisory Committee

Enclosures

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**NOTICE**

The Clean Air Scientific Advisory Committee (CASAC) is a chartered federal advisory committee, operating under the Federal Advisory Committee Act (FACA; 5 U.S.C. § 10). The committee provides advice to the Administrator of the U.S. Environmental Protection Agency on the scientific and technical bases of the National Ambient Air Quality Standards. The findings and recommendations of the committee do not represent the views of the Agency, and this document does not represent information approved or disseminated by EPA. The CASAC reports are posted on the EPA website at: <https://casac.epa.gov>.

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**U.S. Environmental Protection Agency  
Clean Air Scientific Advisory Committee**

**CHAIR**

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**Consensus Comments on the NAAQS Review Process**

**Recommendation 1**

*The agency should provide the CASAC and the Administrator with a sufficient set of alternative standards to review, even in cases where the agency staff recommend that the current standard should be retained. Specifically:*

- a. Risk and/or exposure assessment analyses should include the more protective levels as well as the indicators, averaging times, and forms that were recommended by the CASAC prior to and/or during the current review.*
- b. The agency should revamp its decision process and flow chart followed in the policy assessments (PAs).*

The CASAC recommends that the agency include consideration of potential alternative standards in most PA first drafts. The CASAC finds that this broader consideration of potential alternative standards is particularly important when previous CASAC advice or public comment has recommended consideration of alternative standards.

To support this argument, the CASAC provides a summary of the past ~20 years of ozone reviews and standard setting decisions for the primary standard. Figure 1 shows the levels of the primary ozone standard over time, along with the EPA staff recommendations and CASAC's advice. The dates that the standard was upheld or revised are given along the x axis. The dates of the CASAC's comments, typically after the PA/Staff Paper review, are given in the figure, along with the range recommended by the agency staff (brown) and the CASAC (blue). The ranges ending with square brackets indicate that the recommendations include the value at the end; the ranges ending with curved brackets exclude that value. In several recent reviews either the agency and/or the CASAC did not provide a recommended range; these are indicated by a dot on the figure. The supporting information for this figure is provided in the Appendix Table.

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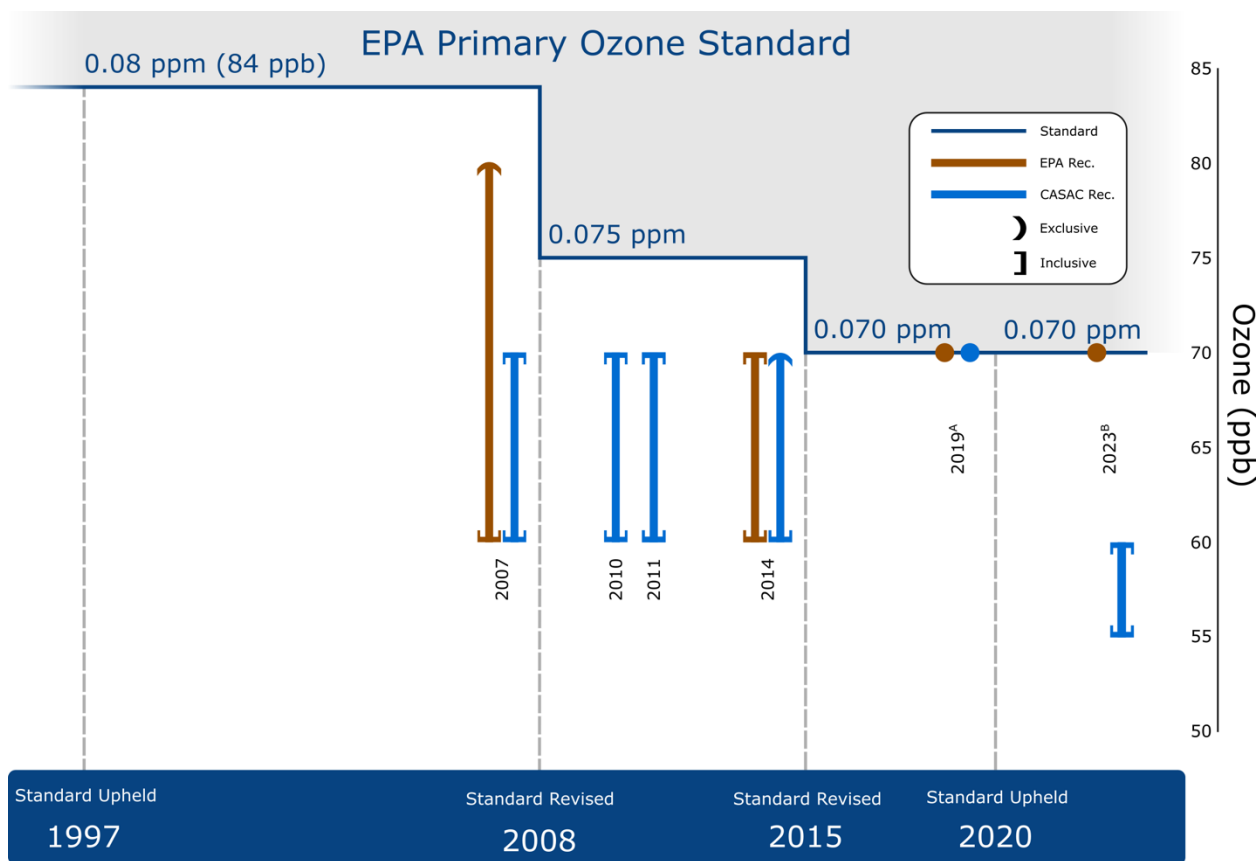


Figure 1: History of the Primary O3 NAAQS from 1997 to the present.

Footnotes:

- A. For the 2019 review: The minority opinion recommended the same range that the CASAC recommended in 2014
- B. For the 2023 review: One CASAC member recommended that the current standard be retained due to lack of supporting risk and exposure assessment analyses for alternative standards

Note that between 2007 and 2014 the CASAC consistently recommended that the Agency consider standards that were well below the current standard at that time and with a range that extended down to 60 ppb. Even so, the agency staff included limited risk or exposure analyses for alternative standards in both the 2019 review and the 2022-2023 reconsideration. In the 2022-2023 reconsideration, the rationale in 2023 for one CASAC members' recommendation to retain the current standard was based on the lack of any risk or exposure analyses for alternative standards. It is possible that the CASAC could have reached consensus had the PA included a comprehensive set of risk and exposure analyses in the reconsideration PA.

Recommendation 1a states that the risk and exposure analyses should include the more protective levels as well as the indicators, averaging times, and forms that were recommended by the CASAC prior to and/or during the current review. In many cases, public comments also suggest that more protective levels be considered, or that there be consideration of different averaging times and forms. For example, regarding the secondary ozone standard, the CASAC has recommended since 2007 that the Agency consider an additional metric and that the W126 form be adopted as it is the most appropriate metric to

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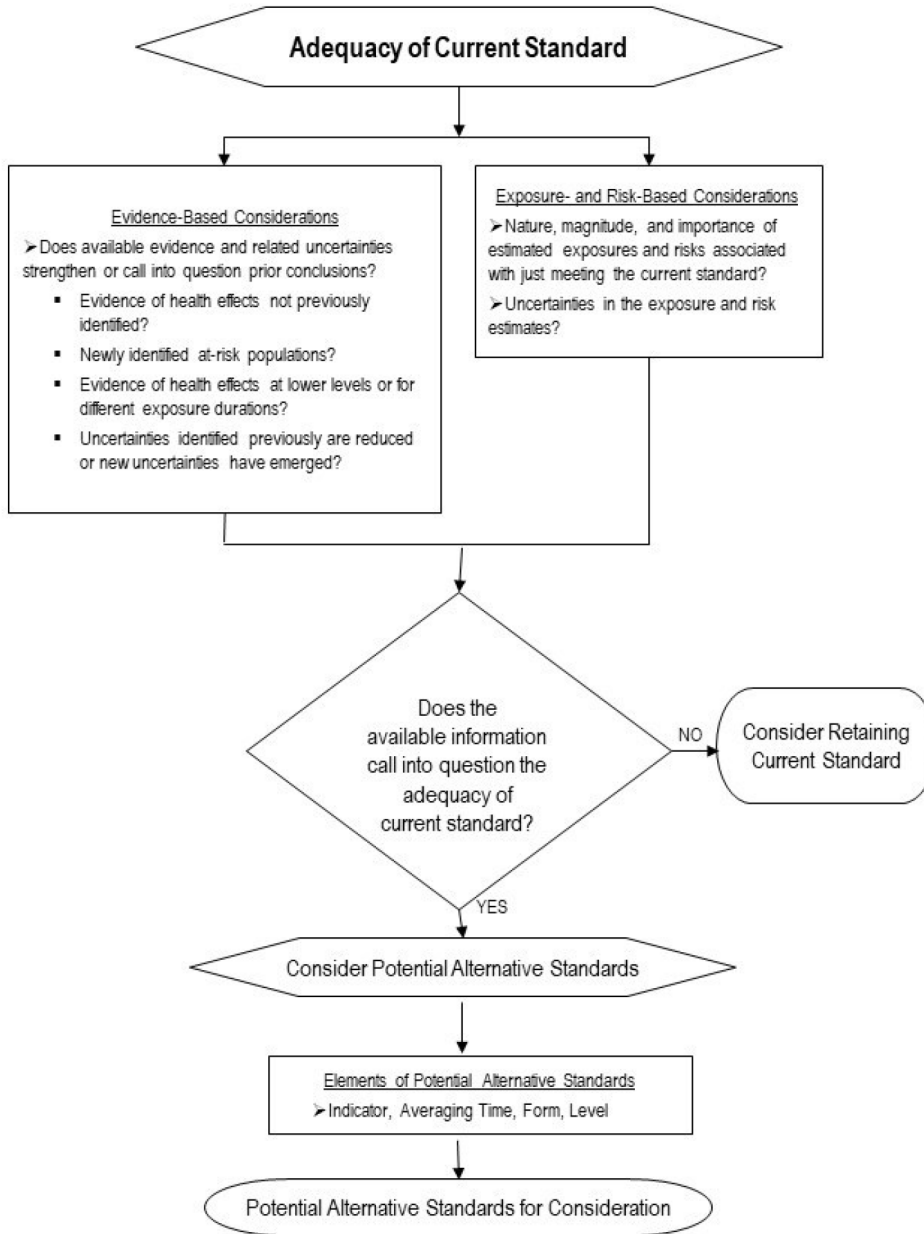
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1 protect public welfare. Specifically, in March 2007, the CASAC unanimously recommended that a  
2 secondary ozone NAAQS “that is substantially different from the primary ozone standard in averaging  
3 time, level and form” is required to protect “managed agricultural crops and natural terrestrial  
4 ecosystems.” The CASAC recommended the W126 metric with a range of 7.5 to no higher than 15 ppm-  
5 hrs. In June 2014, the CASAC recommended the same form and range of levels. In June 2023, all but  
6 one member of the CASAC yet again recommended the W126 form, with levels ranging between 7 and  
7 9 ppm-hrs in order “to control the effects of peak concentrations on plant growth and to protect against  
8 reduced growth in sensitive species and annual plants.” In objecting to the CASAC’s recommendations,  
9 the dissenting member noted that the CASAC’s recommendations were “not supported by a welfare risk  
10 and exposure assessment (WREA)” and “recommending an alternative secondary standard without the  
11 support of a WREA is inappropriate and should be viewed with extreme skepticism.” Given that the  
12 CASAC has recommended the W126 metric since 2007 with the lowest level at 7.5, it is concerning that  
13 no WREA analyses were presented to address this recommendation. The CASAC recommends that the  
14 next ozone review include WREA analyses that follow its 2023 advice. Specifically, the CASAC  
15 recommends that the Agency consider the highest value of the W126 metric accumulated over a rolling  
16 92-day window and that these WREA analyses use its recommended form, which is a single-year  
17 highest cumulative W126 index that is not to be exceeded more than two years out of any 5-year interval  
18 to control for interannual variability.  
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1 To address Recommendation 1b, the CASAC notes that the agency decision process has been  
2 summarized in the flow chart shown in the figure below.  
3



4 **Figure 3-1. Overview of general approach for the primary O<sub>3</sub> standard.**

5 U.S. EPA, 2023. Policy Assessment for the Reconsideration of the Ozone National Ambient Standards, External Review Draft  
6 Volume 2, p. 3-19.

7 This approach dates to the August 2012 First External Review Draft Ozone PA (Figure 4-1) or earlier.  
8 The flow chart begins with consideration of the adequacy of the current standard in terms of evidence-  
9 based and exposure- and risk-based considerations. These two boxes flow into a binary decision box:  
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1 Does the available information call into question the adequacy of the current standard? When the agency  
2 staff conclude that the current standard is adequate, subsequent focus is on retaining the current  
3 standard. Thus, the remaining PA review does not address consideration of potential alternative  
4 standards in any depth. This focus does not provide the CASAC and other reviewers of the document  
5 with sufficient risk- and exposure-based considerations of potential alternative standards and it limits the  
6 options provided to the Administrator. Thus, should the CASAC or the Administrator not concur with  
7 the agency staff's conclusion regarding this question, they must rely heavily or exclusively on evidence-  
8 based justifications in their recommendations regarding potential alternative standards. And with only a  
9 single draft of the PA, the Administrator may be faced with conflicting advice from the agency staff and  
10 the CASAC. Thus, the CASAC concludes that the current agency approach is too restrictive and does  
11 not present the Administrator with a sufficient range of possible options. The CASAC recommends that  
12 the agency revise its decision process and flow chart. In future reviews, the CASAC recommends that  
13 the agency provide the CASAC and the Administrator with a sufficient set of alternative standards to  
14 review, even in cases where the agency staff conclude that the current standard should be retained.  
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17 **Recommendation 2**

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19 *The agency should provide a second draft PA whenever the CASAC advises that it is needed. This is*  
20 *most important in reviews where the staff recommendations and the CASAC advice on the standards do*  
21 *not align.*  
22

23 The CASAC recommends that the agency return to its practice of planning for more than one draft of the  
24 PA, with the final decision about the need for this draft based on a comprehensive consideration of the  
25 preliminary staff conclusions, the CASAC advice from the current review, and public comment. The  
26 CASAC recognizes that judiciary-mandated deadlines may compress the timeline; so, adjustment may  
27 need to be made early in the review timeline to allow for the possibility of a second draft PA. As noted  
28 in the 2014 final Lead PA, footnote 4 on page 1-2, "Typically a second draft PA has been prepared in  
29 cases where the available information calls into question the adequacy of the current standard and  
30 analyses of potential alternative standards are developed taking into consideration CASAC advice and  
31 public comment."  
32

33 Since approximately 2019, the agency has refrained from providing the CASAC with a second draft PA  
34 and by that date the agency also was routinely combining the REA analyses into the PA rather than  
35 producing a standalone REA. Further, the agency staff have stated in recent CASAC public meetings  
36 that their intent is to only produce single drafts of documents. The combined effect of these decisions is  
37 that there has been less comprehensive information included in the PA to allow the CASAC to assess a  
38 full range of alternative standards, particularly when the agency staff recommendations differ from the  
39 CASAC's views. This includes sufficient breadth and depth of REA analyses. The 2022-2023 ozone  
40 reconsideration and the NOx/SOx/PM secondary NAAQS review are recent examples. This approach 1)  
41 limits the quality of the advice that the CASAC is able to provide, 2) makes it more challenging for the  
42 CASAC to reach consensus, 3) challenges the ability of the agency and the CASAC opinions to  
43 converge, and 4) limits the options available for the Administrator's consideration in proposing a new  
44 standard.  
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1 **Recommendation 3**

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3 *At the initiation of any reconsideration review, the CASAC requests a briefing from the agency about the*  
4 *process. The CASAC notes that for regular NAAQS reviews, the Integrated Review Plan (IRP)*  
5 *consultations provide this mechanism.*

6

7 The 2022-2023 ozone reconsideration process was challenging for the CASAC to navigate. The CASAC  
8 was not briefed on the reconsideration review process prior to the External Review Draft (Version 1)  
9 Ozone Reconsideration PA being delivered. This was unlike the process for routine NAAQS reviews  
10 where the CASAC first comments on an IRP. Further, the CASAC was asked to review the Ozone  
11 Reconsideration PA without the benefit of having considered the underlying scientific information. As  
12 was noted in the CASAC's June 15, 2022 letter, the CASAC concluded that it was not prepared to  
13 review the agency's Ozone Reconsideration Policy Assessment without first having a fuller discussion  
14 of the science. An advance briefing would have allowed the CASAC to ask questions and provide input  
15 on the reconsideration process at its inception, potentially avoiding subsequent delays. Thus, the  
16 CASAC recommends that in future reconsideration reviews, the CASAC receive a briefing from the  
17 agency about the process before commencing the review. Finally, in both drafts of the ozone  
18 reconsideration PA, there was very limited opportunity for the CASAC to consider alternative standards  
19 given the presentation in these draft documents. A briefing on the plans for the reconsideration PA also  
20 may have avoided this challenge.

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**Appendix A**

**Ozone Standards History and CASAC Advice on the Ozone NAAQS**

The Appendix Table summarizes the history of the primary ozone standards from 1997 to the present, as well as agency staff recommendations and CASAC advice on the ozone NAAQS since the 1997 rule. Note that between 2007 and 2015, and again in 2023, the CASAC has recommended a range for the primary standard that is well below the current standard. Regarding the secondary standard, the CASAC has advised repeatedly since 2006 ([EPA-CASAC-07-001](#)) that the agency adopt a secondary ozone standard based on a seasonal averaging time, such as the W126 metric. These CASAC reviews were conducted by three distinct ozone review panels made up of 53 different experts, and under the leadership of four different CASAC Chairs.

*Appendix Table. History of ozone primary NAAQS levels beginning with the 1997 rule. The table lists the final rule, EPA staff recommendations, and CASAC advice on the level of the primary standard*

<b>Review information</b>	<b>Final rule</b>	<b>Agency staff recommendation</b>	<b>CASAC advice</b>
<a href="#">Final rule</a> , July 18, 1997	0.08 ppm, two decimal places		
Final Draft Ozone Staff Paper, January 2007 ( <a href="#">Final Staff Paper July 2007</a> )		Below 0.80 ppm to 0.060 ppm	
<a href="#">EPA-CASAC-07-002</a> , Henderson, March 26, 2007			0.060 to 0.070 ppm; specify the NAAQS to the 3rd decimal place
<a href="#">Final rule</a> , March 27, 2008	0.075 ppm, abandoned the use of two decimal places		
<a href="#">EPA-CASAC-08-009</a> , Henderson, April 7, 2008			New primary O3 standard is not sufficiently protective of public health; re-stated range of 0.060-0.070 ppm
<a href="#">EPA-CASAC-10-007</a> , Samet, February 19, 2010			Range of 0.060-0.070 ppm
<a href="#">EPA-CASAC-11-004</a> , Samet, March 30, 2011			Range of 0.060-0.070 ppm

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<b>Review information</b>	<b>Final rule</b>	<b>Agency staff recommendation</b>	<b>CASAC advice</b>
Policy Assessment, <a href="#">2<sup>nd</sup> External Review Draft</a> , January 2014 ( <a href="#">Final PA August 2014</a> )		Range of 0.060-0.070 ppm	
<a href="#">EPA-CASAC-14-004</a> , Frey, June 26, 2014			Range of 0.060 to 0.070 ppm, with “policy advice” lower than .070 ppm
<a href="#">Final rule</a> , October 26, 2015	0.070 ppm		
Policy Assessment <a href="#">External Review Draft</a> , October 2019		Retain the current standard of 0.070 ppm; no potential alternative standards were identified for consideration (p. 3-87)	
<a href="#">EPA-CASAC-20-003</a> , Cox, February 19, 2020			Some recommend retaining the current standard of 0.070 ppm, others agree with the CASAC’s 2014 advice
<a href="#">Final rule</a> , December 31, 2020	0.070 ppm		
Policy Assessment for the Reconsideration, <a href="#">External Review Draft Version 2</a> , March 2023		Retain the current standard of 0.070 ppm; no potential alternative standards were identified for consideration. However, standard levels in the range from 70 to 60 ppb may be appropriate to consider (p. 3-115)	
<a href="#">EPA-CASAC-23-002</a> , Sheppard, June 9, 2023			Range of 55-60 ppb (all but one), one recommends retaining the primary standard due to lack of REA analysis.

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Table notes:

- Form and averaging time for all O3 NAAQS is MDA8, 4<sup>th</sup> highest averaged over 3-years. The indicator is O3.

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- Not included in the table is any CASAC review of a policy assessment (or staff paper) where the level of the standard was not discussed
  - CASAC recommendations were taken from the linked CASAC documents
  - Useful links: [Ozone NAAQS timeline](#); Consolidated links to [O3 air quality standards and related review documents](#); [Table of CASAC advisory reports](#)