

**UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT**

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STATE OF NEW YORK, <i>et al.</i> ,)	
)	
Petitioners,)	
)	No. 21-1028
v.)	(and consolidated cases)
)	
U.S. ENVIRONMENTAL)	
PROTECTION AGENCY, <i>et al.</i> ,)	
)	
Respondents.)	
_____)	

**UNOPPOSED MOTION FOR VOLUNTARY REMAND WITHOUT
VACATUR**

Respondents United States Environmental Protection Agency and Administrator Michael Regan (collectively, “EPA” or “the Agency”), respectfully move for an order remanding without vacating EPA’s final action titled “Review of the Ozone National Ambient Air Quality Standards,” 85 Fed. Reg. 87,256 (Dec. 31, 2020) (“2020 Ozone NAAQS Decision”), which is under review in these consolidated petitions. EPA also requests a stay of the January 5, 2024 deadline for the parties to submit proposed schedules for merits briefing, pending the Court’s action on EPA’s request for remand of the case. Counsel for EPA has conferred with counsel for Petitioners and Intervenors in these consolidated cases and is authorized to state that no party opposes the relief requested in this motion.

BACKGROUND

The Clean Air Act, 42 U.S.C. §§ 7401-7671q, establishes a comprehensive program to protect and enhance the Nation's air quality through a system of shared federal and state responsibility. *Id.* § 7401(b)(1). Central to this program are the national ambient air quality standards ("NAAQS"), which EPA sets to limit the concentration of certain air pollutants in the ambient air to protect against the pollutants' effects on public health and welfare. *Id.* §§ 7408–09. EPA has established NAAQS for six common air pollutants, including ozone and related photochemical oxidants ("Ozone NAAQS"). 40 C.F.R. pt. 50. EPA is required to periodically review both the standards and the air quality criteria (the scientific information on which the standards are based) and, if appropriate, make revisions. 42 U.S.C. § 7409(d). The Act also requires that EPA appoint an independent scientific review committee, the Clean Air Scientific Advisory Committee ("Advisory Committee"), which must advise EPA on the agency's review of the air quality criteria and on appropriate revisions to the NAAQS. *Id.* § 7409(d)(2).

When EPA conducts this periodic review, it reviews current scientific literature on known and anticipated effects on public health and welfare associated with the particular pollutant in the ambient air. *See* attached Declaration of Joseph ("Goffman Decl."), ¶ 12. As part of the review of the science, EPA's practice is to develop a document called an Integrated Science Assessment. *Id.* Based on

information in the Integrated Science Assessment, as well as other relevant information, EPA may also prepare quantitative analyses of exposure and risk to public health and environment, as appropriate, from various ambient levels of the pollutant. Goffman Decl. ¶ 13. And EPA's practice is to develop a Policy Assessment in which it evaluates the scientific evidence and technical information described in the Integrated Scientific Assessment and related exposure and risk analyses to inform the Administrator's policy judgments in the review, including consideration of whether to revise or retain a NAAQS. Goffman Decl. ¶ 14. Before these documents are finalized, EPA's practice is to provide drafts of the Integrated Science Assessment, the Policy Assessment, and any quantitative risk/exposure analyses for review by the Advisory Committee, as well as an opportunity for public comment. Goffman Decl. ¶ 12.

To assist the Advisory Committee in its review, EPA has historically established pollutant-specific expert review panels. Goffman Decl. ¶ 15. EPA does so both because it frequently seeks the Advisory Committee's advice on multiple NAAQS reviews simultaneously, and because each NAAQS review covers a broad array of scientific issues. *Id.*

EPA most recently revised the Ozone NAAQS in 2015. 80 Fed. Reg. 65,292 (Oct. 26, 2015). In the 2020 Ozone NAAQS Decision challenged here, EPA decided to retain the 2015 Ozone NAAQS. In the assessment preceding that

decision, EPA prepared an Integrated Science Assessment (“2020 Science Assessment”), quantitative analyses of the risks to public health and the environment from exposure to ozone, and a Policy Assessment (“2020 Policy Assessment”). EPA presented those documents to the Advisory Committee for review. Rather than forming a traditional ozone-specific review panel, EPA provided the Advisory Committee with a pool of expert consultants to respond to written questions. Comparing the process in that review cycle to the traditional review process, the Advisory Committee recommended that EPA “consider restoring a traditional interactive discussion process in which the [Advisory Committee] can interact directly with external expert panels,” and further stated: “interactive discussion between the [Advisory Committee] and a pollutant-specific review panel, enables significantly more discussion and deliberation among experts with differing backgrounds and opinions, potentially resulting in a more comprehensive examination of some controversial topics.” Letter from Louis Anthony Cox, Jr., Chair, Clean Air Scientific Advisory Committee, to Administrator Andrew R. Wheeler, Re: CASAC Review of the EPA’s Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards (External Review Draft – October 2019), Consensus Responses to Charge Questions at 1 (February 19, 2020), available at <https://casac.epa.gov/ords/sab/f?p=>

[113:0:5537166072354:APPLICATION_PROCESS=REPORT_DOC:::REPORT_ID:1075.](#)

On January 20, 2021, President Biden issued an “Executive Order on Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis,” which directed review of certain agency actions taken from January 20, 2017, until January 20, 2021. Exec. Order No. 13990, 86 Fed. Reg. 7037 (Jan. 25, 2021). After reviewing the 2020 Ozone NAAQS Decision, on October 29, 2021, EPA announced its decision to initiate proceedings to reconsider that action. Goffman Decl. ¶ 19. At EPA’s request, on December 21, 2021, the Court held these cases in abeyance. Doc. 1927582.

As part of its reconsideration proceeding, EPA convened an 18-member ozone-specific review panel (“Review Panel”) to assist the seven-member Advisory Committee. Goffman Decl. ¶ 21. EPA also developed an updated draft Policy Assessment (“2022 Draft Policy Assessment”), which it provided to the Advisory Committee and Review Panel and on which it sought public comment. Goffman Decl. ¶ 22. As noted in that document, EPA planned to reconsider the 2020 Ozone NAAQS Decision “based on the existing scientific record and in a manner that adheres to rigorous standards of scientific integrity and provides ample opportunities for public input and engagement.” 2022 Draft Policy Assessment at

1–13, available at https://www.epa.gov/system/files/documents/2022-04/o3_reconsideration_draft_pa-v_final-compressedfinal.pdf.

Following several public meetings of the Review Panel and briefings from EPA staff, the Advisory Committee provided EPA with comments and advice reflecting its “evaluation of the scientific issues in the [2020 Science Assessment] to inform its future review of the [2022 Draft Policy Assessment].” *See* Letter from Dr. Elizabeth A. Sheppard, Re: CASAC Review of the EPA’s Integrated Science Assessment (ISA) for Ozone and Related Photochemical Oxidants (Final Report - April 2020) (Nov. 22, 2022) (EPA-CASAC-23-001), at 1, available at <https://casac.epa.gov/ords/sab/f?p=113:12:362646059624:::12>.

Responding to comments in the Advisory Committee’s November 2022 letter, EPA created a revised draft Policy Assessment (“2023 Draft Policy Assessment”), which it presented to the Review Panel and Advisory Committee.¹ Goffman Decl. ¶ 25. The Advisory Committee and Review Panel then held additional public meetings, and on June 9, 2023, the Advisory Committee issued its final report on the 2023 Draft Policy Assessment (“2023 Advisory Committee

¹ While the Advisory Committee’s November 2022 letter focused on the 2020 Integrated Science Assessment, it also included comments that referenced the Policy Assessment, and consideration of those comments led to development of the 2023 Draft Policy Assessment. *See* 2023 Draft Policy Assessment, at 1–16, available at https://www.epa.gov/system/files/documents/2023-03/O3_Recon_v2_Draft_PA_Mar1-2023_ERDcmp_0.pdf

Report”), available at <https://casac.epa.gov/ords/sab/f?p=113:12:362646059624:::12>. This report stated the Advisory Committee’s view that the 2023 Draft Policy Assessment was missing important analyses and information. *See* Goffman Decl. ¶¶ 29–32 (summarizing report). Among other things, in the June 9 report, the Advisory Committee: opined that the 2023 Draft Policy Assessment did “not provide sufficient information to adequately consider alternative form and level combinations,” 2023 Advisory Committee Report at 9; recommended that EPA “incorporate the information available from epidemiological studies” in risk assessments supporting the 2023 Draft Policy Assessment, *id.* at 4; and referenced several new studies that were published recently and were not included in the 2020 Science Assessment, Cover letter from Dr. Elizabeth Shepherd (June 9, 2023) at 4. Relying in part on those new studies, the June 9 report conveys the recommendation of all but one member of the Advisory Committee that the primary and secondary Ozone NAAQS be revised. *Id.* at 4–5.

The EPA Administrator responded by noting that the Advisory Committee had “identified several issues arising in the reconsideration that warrant additional evaluation and review . . . including newly available information that has not yet been integrated into the air quality criteria and the value of developing additional analyses to inform further evaluation of the current standards.” Letter from EPA Administrator Regan (Aug. 18, 2023), at 1–2, available at <https://casac.epa.gov/>

[ords/sab/f?p=113:12:362646059624:::12](#). “Given the scope of those issues,” and EPA’s obligation to periodically review the NAAQS and the air quality criteria, the Administrator “decided that the best path forward is to initiate a new statutory review of the ozone NAAQS and the underlying air quality criteria and to wrap the EPA’s reconsideration process of the 2020 ozone NAAQS decision into that review.” *Id.*

STANDARD OF DECISION

This Court will “generally grant an agency’s motion to remand so long as the agency intends to take further action with respect to the original agency decision on review.” *Util. Solid Waste Activities Grp. v. EPA*, 901 F.3d 414, 436 (D.C. Cir. 2018) (internal quotation marks omitted). “An agency may obtain a remand without confessing error, so long as it genuinely intends to reconsider, re-review or modify its original decision.” *Cadillac of Naperville, Inc. v. NLRB*, 14 F.4th 703, 719 (D.C. Cir. 2021) (internal quotation marks omitted). In deciding a motion to remand, the Court will “consider whether the agency has provided a reasoned explanation for a remand, whether its motion is frivolous or made in bad faith, and whether granting the motion would unduly prejudice the non-moving party.” *Id.* (internal citations and quotation marks omitted).

ARGUMENT

The Court should grant EPA’s motion for a voluntary remand of the 2020 Ozone NAAQS Decision. As explained in the attached declaration of Joseph Goffman, EPA has initiated a full NAAQS review, and incorporated its reconsideration of the 2020 Ozone NAAQS Decision into that review, to support its work addressing “significant issues” that the Advisory Committee and Review Panel recently identified. Goffman Decl. ¶¶ 33–34. EPA’s decision to reconsider its prior action, particularly based on new information, is well-recognized as a basis for voluntary remand. *Util. Solid Waste Activities Grp.*, 901 F.3d at 436; *see also SKF USA Inc. v. United States*, 254 F.3d 1022, 1027–30 (Fed. Cir. 2001) (discussing bases for voluntary remand). In seeking remand, EPA does not, and need not, confess error. Goffman Decl. ¶ 34. But the Agency is committed to conducting a transparent, scientifically rigorous review that provides opportunities for public input and engagement. *See* Goffman Decl. ¶¶ 39–42 (discussing steps in EPA’s review). EPA will complete review “as expeditiously as possible,” Goffman Decl. ¶ 38, and, indeed, has already commenced it, Goffman Decl. ¶ 39. Thus, EPA’s motion is supported by a reasoned basis and is neither frivolous nor made in bad faith.

Remanding this case would avoid “wasting the courts’ and the parties’ resources.” *Ethyl Corp. v. Browner*, 989 F.2d 522, 524 (D.C. Cir. 1993).

“Administrative reconsideration is a more expeditious and efficient means of achieving adjustment of agency policy than is resort to the federal courts.” *B.J. Alan Co. v. ICC*, 897 F.2d 561, 562 n.1 (D.C. Cir. 1990) (quoting *Commonwealth of Pennsylvania v. ICC*, 590 F.2d 1187, 1194 (D.C. Cir. 1978)). That is particularly true where, as here, no party has yet filed merits briefs supporting or opposing the action under administrative reconsideration.

Finally, granting EPA’s motion for remand of these cases would not prejudice a non-moving party as no party opposes EPA’s requested relief.

CONCLUSION

For the foregoing reasons, the Court should remand without vacating the 2020 Ozone NAAQS Decision. EPA further requests that the Court stay the parties’ deadline to propose a schedule for merits briefing in these cases until it acts on EPA’s motion for voluntary remand. This motion is unopposed.

January 3, 2024

Respectfully submitted,

/s/ Andrew S. Coghlan

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CERTIFICATE OF COMPLIANCE

Pursuant to Federal Rule of Appellate Procedure 27(d), I hereby certify that the foregoing complies with the type-volume limitation because it contains 1,964 words, according to the count of Microsoft Word.

/s/ Andrew S. Coghlan

ANDREW S. COGHLAN

CERTIFICATE OF SERVICE

I hereby certify, pursuant to Fed. R. App. P. 25(c), that the foregoing was electronically filed with the Clerk of the Court using the CM/ECF system, which will send a notification to the attorneys of record in this matter, who are registered with the Court's CM/ECF system.

/s/ Andrew S. Coghlan

ANDREW S. COGHLAN

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DECLARATION OF JOSEPH GOFFMAN

I, Joseph Goffman, under penalty of perjury, affirm and declare that the following statements are true and correct to the best of my knowledge and belief, and are based on my own personal knowledge or on information contained in the records of the United States Environmental Protection Agency (EPA or the Agency) or supplied to me by EPA employees under my supervision.

1. I am Principal Deputy Assistant Administrator performing delegated duties of Assistant Administrator for the United States Environmental Protection Agency

Office of Air and Radiation (OAR), which is located at 1200 Pennsylvania Avenue, NW, Washington, D.C. 20460.

2. OAR is the EPA headquarters-based unit with primary responsibility for administration of the Clean Air Act (CAA). As the Principal Deputy Assistant Administrator performing delegated duties of Assistant Administrator for OAR, I serve as the principal advisor to the Administrator of the EPA on matters pertaining to air and radiation programs, and I am responsible for managing these programs, including: program policy development and evaluation; development of emissions standards; program policy guidance and overview; and technical support and evaluation of regional air and radiation program activities.

3. As part of my duties as Principal Deputy Assistant Administrator performing delegated duties of Assistant Administrator of OAR, I oversee the development and implementation of actions, regulations, policy, and guidance associated with the review and establishment of National Ambient Air Quality Standards (NAAQS) under sections 108 and 109 of the CAA, 42 U.S.C. §§ 7408 and 7409.

4. This declaration is filed in support of the EPA's motion for voluntary remand in *State of New York et al. v. EPA*, No. 21-1028 (D.C. Cir.) and consolidated cases.

5. Under sections 108 and 109 of the of the CAA, the EPA has established, and must periodically review, NAAQS for six common air pollutants. This includes the NAAQS for ozone and related photochemical oxidants (Ozone NAAQS).

6. Section 108 of the CAA directs the Administrator to identify and list certain air pollutants and then to issue air quality criteria for those pollutants. 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....”

7. Section 109 of the CAA directs the Administrator to propose and promulgate “primary” and “secondary” NAAQS for pollutants for which air quality criteria are issued. 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.” Under section 109(b)(2), a secondary 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 [the] pollutant in the ambient air.”

8. Section 109(d)(1) further directs the Administrator, in five-year intervals, to review both the air quality criteria published under section 108, and the NAAQS

promulgated under section 109, and make such revisions as may be appropriate in accordance with section 108 and section 109(b). This section further provides that the Administrator may review and revise the air quality criteria or promulgate new standards earlier or more frequently than required under section 109(d).

9. Section 109(d)(2) requires that the EPA appoint an independent scientific review committee and further requires that committee to advise the EPA on its review of the air quality criteria and on appropriate revisions to the NAAQS. The Clean Air Scientific Advisory Committee (Advisory Committee or CASAC) of the EPA's Science Advisory Board was accordingly established pursuant to section 109(d) to provide independent scientific advice on NAAQS matters.

10. NAAQS reviews generally begin with a Call for Information for the Agency to consider in the review, which is published in the *Federal Register*, and initiates the planning phase of the review. The planning phase also typically includes development of an integrated review plan which is made available for public comment and provided to the Advisory Committee for consultation.

11. NAAQS reviews typically also include an assessment phase which precedes and informs the decision-making phase of a review.

12. To help facilitate the Advisory Committee's advisory role during the assessment phase, the EPA has developed a practice of providing drafts of various scientific and technical documents to the Advisory Committee for its review, in

addition to making such documents available for public comment. In the assessment phase, the EPA prepares a scientific assessment, a policy assessment, and, as appropriate, assessments of exposure and risk. The science assessment, the Integrated Science Assessment, provides a comprehensive assessment of the current scientific literature pertaining to known and anticipated effects on public health and welfare associated with the pollutant in the ambient air and forms the scientific foundation for each NAAQS review.

13. The EPA may also prepare analyses to assess exposure and risk to public health and to the environment, as appropriate, from various ambient levels of the pollutant. These analyses use the science from the Integrated Science Assessment, along with information about exposure of sensitive human population groups or, in some cases, sensitive plant or animal species to different ambient levels of the pollutant, to provide a quantified analysis of risks to public health and welfare at various levels of ambient air quality.

14. The documents prepared during the assessment phase in recent NAAQS reviews have also included Policy Assessments, which use the information from the scientific assessment and exposure/risk analyses and weigh the strengths and limitations of the scientific and technical information, as well as the quantitative estimates of exposure and risks. The Policy Assessment frames this information in a manner that informs policy judgments to be made in the review concerning the

adequacy of the current standards and identifies various options, as appropriate, in terms of possible alternative standards for consideration.

15. A NAAQS review may cover a wide range of scientific issues, and the EPA is frequently conducting a number of NAAQS reviews simultaneously, and thus is obtaining the Advisory Committee's advice on different pollutants in the same timeframe. In light of the breadth of scientific issues covered by each review and the potential for multiple simultaneous reviews, the EPA has historically had a practice of establishing pollutant-specific review panels to assist the Advisory Committee in fulfilling its review and advisory functions for a particular pollutant.

16. Based on the science, exposure/risk, and policy assessment documents, advice of the Advisory Committee, and public comments, the Administrator then decides whether it is appropriate to propose a revision to the NAAQS in question. Such a proposal is governed by special rulemaking procedures set forth in section 307(d) of the CAA, 42 U.S.C. § 7607(d), and would go through a notice-and-comment process consistent with the requirements of section 307(d).

17. In 2015, the EPA completed a review of the Ozone NAAQS and finalized revisions to the standards through an action titled "National Ambient Air Quality Standards for Ozone," 80 Fed. Reg. 65,292 (Oct. 26, 2015). In this action, the EPA revised the levels of both the primary and the secondary Ozone NAAQS to 0.070 parts per million, while retaining the other elements (indicator, form, and

averaging time) of the standards. *Id.* The EPA completed its last statutory periodic review of the Ozone NAAQS in 2020. Based on its review of the air quality criteria and current standards, it decided to retain the 2015 standards without revision and published notice of that decision in an action titled “Review of the Ozone National Ambient Air Quality Standards,” 85 Fed. Reg. 87,256 (Dec. 31, 2020) (2020 Ozone NAAQS Decision).

18. President Biden issued an “Executive Order on Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis” (Executive Order), which directed review of certain agency actions taken from January 20, 2017, until January 20, 2021.¹ An accompanying fact sheet provided a non-exclusive list of agency actions that agency heads were to review in accordance with that order, including the 2020 Ozone NAAQS Decision.²

19. The EPA reviewed the 2020 Ozone NAAQS Decision, consistent with the direction in the Executive Order. On October 29, 2021, the Agency announced its decision to reconsider the 2020 Ozone NAAQS final action.³

¹ <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-protecting-public-health-and-environment-and-restoring-science-to-tackle-climate-crisis/>

² <https://www.whitehouse.gov/briefing-room/statements-releases/2021/01/20/fact-sheet-list-of-agency-actions-for-review/>

³ This announcement is available at <https://www.epa.gov/ground-level-ozone-pollution/epa-reconsider-previous-administrations-decision-retain-2015-ozone>.

20. In initiating the reconsideration, the EPA described its intent to proceed in a manner that reflects its commitment to a robust NAAQS review process, adheres to rigorous standards of scientific integrity, and provides ample opportunities for public input and engagement.⁴

21. In late February 2022, to advance its reconsideration of the 2020 Ozone NAAQS Decision, the EPA established an eighteen-member Clean Air Scientific Advisory Committee Ozone Review Panel (Review Panel) to provide advice through the seven-member chartered Advisory Committee.

<https://perma.cc/Q8KY-J3DX>; *see also* 86 Fed. Reg. 63,024 (Nov. 15, 2021) (request for nomination of candidates for the Review Panel).

22. In late April of 2022, the EPA made a draft document, titled *Policy Assessment for the Reconsideration of the Ozone National Ambient Air Quality Standards, External Review Draft* (2022 Draft Policy Assessment), available for review by the Review Panel and the Advisory Committee, as well as providing an opportunity for public comment. 87 Fed. Reg. 25,485 (April 29, 2022).

23. During 2022, the Review Panel held several public meetings to discuss providing advice on the EPA's reconsideration of the 2020 Ozone NAAQS Decision and to discuss scientific issues related to the 2020 Ozone Integrated

⁴ *See id.*

Science Assessment. These meetings included opportunities for members of the public to submit comments.

24. On November 22, 2022, the Advisory Committee sent a letter to the EPA Administrator conveying comments and advice reflecting its “evaluation of the scientific issues in the [2020 Ozone Integrated Science Assessment] to inform its future review of the [Policy Assessment].”⁵

25. This letter included comments that referenced the Policy Assessment and consideration of those comments led to development of a second version of the draft Policy Assessment for the reconsideration. In March of 2023 EPA made this document, titled *Policy Assessment for the Reconsideration of the Ozone National Ambient Air Quality Standards, External Review Draft Version 2 (2023 Draft Policy Assessment)*, available for review by the Review Panel and the Advisory Committee, as well as providing an opportunity for public comment. 88 Fed. Reg. 15940 (Mar. 15, 2023).

26. The Review Panel and the Advisory Committee held public meetings in March and in May of 2023 to discuss the draft report on the 2023 Draft Policy Assessment. These meetings included opportunities for members of the public to submit comments. The Advisory Committee provided its final report on the 2023

⁵ Letter from Dr. Elizabeth A. Sheppard to Administrator Regan, Re: CASAC Review of the EPA’s *Integrated Science Assessment (ISA) for Ozone and Related Photochemical Oxidants (Final Report - April 2020)* (Nov. 22, 2022) (EPA-CASAC-23-001), at 1.

Draft Policy Assessment via a letter to the EPA Administrator dated June 9, 2023 (2023 Advisory Committee Report).⁶

27. On August 18, 2023, the EPA Administrator sent a letter in response to the 2023 Advisory Committee Report.⁷ This letter explains that after careful consideration of the Advisory Committee advice in this report, and in light of the EPA's obligation under the Clean Air Act to conduct periodic five-year reviews of the air quality criteria and the NAAQS, the EPA decided to initiate a new, full statutory review of the Ozone NAAQS and the underlying air quality criteria, and to incorporate the EPA's ongoing reconsideration of the 2020 Ozone NAAQS Decision into that new review. Acknowledging the scope of the issues that the Advisory Committee had raised in the reconsideration, the Administrator's letter explains that this was the best path forward, given the continuing commitment to upholding the integrity and rigor of the NAAQS review process and to addressing the issues the Advisory Committee had raised.

28. The Administrator's August 18, 2023 letter further observes that the Advisory Committee's review had identified several issues arising in the reconsideration that warrant additional evaluation and review both by the EPA and

⁶ Letter from Dr. Elizabeth A. Sheppard to Administrator Regan, Re: CASAC Review of the EPA's *Policy Assessment (PA) for the Reconsideration of the Ozone National Ambient Air Quality Standards (External Review Draft Version 2)* (June 9, 2023) (EPA-CASAC-23-002).

⁷ Letter from Administrator Regan to Dr. Elizabeth A. Sheppard (August 18, 2023).

the Advisory Committee. Among those issues are the Advisory Committee's advice that the draft Policy Assessment is missing important analyses and information, and its advice on the importance of new studies not evaluated in the Integrated Science Assessment for the 2020 Ozone NAAQS Decision.

29. For example, the 2023 Advisory Committee Report includes several recommendations related to the EPA's consideration of epidemiological evidence. It states, for instance, the Advisory Committee's views that the draft Policy Assessment "fails to adequately consider and incorporate findings from epidemiological and panel studies of short-term respiratory effects in the exposure and risk analysis" (Response to Charge Questions, p. 5) and advises that the EPA "incorporate the information available from the epidemiological studies in the risk assessment." Response to Charge Questions, p. 4.

30. As another example, the 2023 Advisory Committee Report identified issues relating to the EPA's consideration of the controlled human exposure studies with respect to the draft Policy Assessment, stating their views that the "exclusive reliance on [controlled human exposure] studies for the risk analysis is inappropriate, and underestimates the public health impacts for children, people with underlying lung disease including asthma, and other groups at increased risk." Response to Charge Questions, p. 7. It also states that all Advisory Committee

members except one “are concerned about the overreliance on [controlled human exposure] studies.” Letter p. 4.

31. Additionally, the 2023 Advisory Committee Report indicates that the draft Policy Assessment “does not provide sufficient information to adequately consider alternative form and level combinations.” Response to Charge Questions, p. 9.

32. The Advisory Committee advice also highlights a number of new studies that were recently published and not included in the Integrated Science Assessment for the 2020 Ozone NAAQS Decision. The 2023 Advisory Committee Report states that “[n]ew literature that is not included in the [draft Policy Assessment] questions some key assumptions presented” and describes concerns of CASAC members regarding both the primary and secondary standards. Letter, pp. 4-5. The Administrator’s August 18, 2023 letter notes the Advisory Committee’s reliance on this new literature in recommending revisions to the standards.

33. These issues are among the significant issues raised by the Advisory Committee that warrant additional evaluation to inform the Agency’s consideration of the current Ozone NAAQS and its reconsideration of the 2020 Ozone NAAQS Decision. As the reconsideration has been incorporated into the new review, the EPA intends to examine these issues in the context of a full and systematic review of both the air quality criteria and the standards and anticipates that its evaluation

will benefit from the resources and processes that are employed in such a new review.

34. The EPA recognizes that addressing the Advisory Committee's advice on these issues will involve additional work, and it has incorporated the reconsideration into the new review to best position the Agency to fully consider the new information and advice that the Advisory Committee provided. Similarly, the EPA is seeking a voluntary remand to support its additional work to address the Advisory Committee advice and further evaluate these issues. Thus, the EPA is not confessing any error with respect to the 2020 Ozone NAAQS Decision in seeking voluntary remand in the above-captioned matter. Rather, a voluntary remand would allow the Agency to focus the resources available to the Ozone NAAQS on this full and systematic review, rather than dividing those resources between defending the 2020 Ozone NAAQS Decision in litigation while also working to address the issues raised by the Advisory Committee in the reconsideration of that decision in the context of a new, full review.

35. While the EPA cannot prejudge the decisions that would be made through this process, those decisions would be based on the record available in the new review. The EPA anticipates that this record would necessarily be augmented, compared to the record for the 2020 review, as it would include information and the Advisory Committee advice from the reconsideration of the 2020 Ozone

NAAQS Decision, as well as any additional information that is newly available and considered in the new review, such as new studies identified, updated analyses developed, and the Advisory Committee advice provided in the new review.

36. The EPA acknowledges that consultation under Section 7 of the Endangered Species Act is an issue that was raised in public comments on the proposal for the 2020 Ozone NAAQS Decision, and the Agency intends to consider whether and to what extent such consultation is applicable, for example whether an effects determination should be made, as part of the new review.

37. The EPA recognizes that it cited a 2018 Memorandum entitled “Back-to-Basics Process for Reviewing National Ambient Air Quality Standards” in describing certain aspects of the 2020 Ozone NAAQS Decision.⁸ The EPA is reviewing this Memorandum and is considering issuing a new or revised document that would reflect any changes or updates in the policies described in the 2018 Memorandum. Accordingly, the EPA does not anticipate using the 2018 Memorandum as guidance for the new review.

38. Consistent with the direction in the Administrator’s August 18, 2023 letter to the Advisory Committee, EPA intends to complete the new review as expeditiously as possible, while also upholding the scientific integrity and rigor of

⁸ Memorandum from E. Scott Pruitt, Administrator, U.S. EPA to Assistant Administrators. Back-to-Basics Process for Reviewing National Ambient Air Quality Standards. Office of the Administrator U.S. EPA HQ, Washington DC (May 9, 2018).

the NAAQS review process and providing opportunities for public input and engagement.

39. The EPA has already published a Call for Information in the *Federal Register* to initiate the new review. 88 Fed. Reg. 58264 (Aug. 25, 2023). The EPA is currently working to convene a public workshop to gather input from the scientific community and the public on science and policy-relevant issues important in this review, including specific areas of science that warrant particular focus and analytic enhancements. In conducting a robust NAAQS review process for the new review, the EPA expects that the process would also include development of an Integrated Review Plan; an Integrated Science Assessment; and a Policy Assessment, supported, as appropriate, by analyses of air quality, exposure and risk; and a notice-and-comment process to reach a final decision.

40. The EPA intends to provide multiple opportunities for public and the Advisory Committee engagement in the new review. In addition to the notice-and-comment process for the final decision, the EPA anticipates making the Integrated Review Plan available for public comment and providing it to the Advisory Committee for consultation. The EPA also intends to make drafts of the Integrated Science Assessment and the Policy Assessment, including any accompanying analyses of air quality, exposure and risk, available for Advisory Committee review and public comment. Further, the Call for Information published in August

2023 also provided an opportunity for public input by inviting submissions of research studies and data that have been published or accepted for publication since January 1, 2018, to the assist EPA in developing and refining the scientific information base for the review of the Ozone NAAQS.

41. The EPA intends to convene a pollutant-specific Review Panel to assist the Advisory Committee in the new review. The EPA notes that the review of the Ozone NAAQS culminating in the 2020 Ozone NAAQS Decision was completed without the benefit of an ozone-specific panel to support the Advisory Committee, and that the Advisory Committee itself recommended that “the EPA consider restoring a traditional interactive discussion process in which the [Advisory Committee] can interact directly with external expert panels.”⁹ The 2023 Advisory Committee Report similarly supported the practice of convening a panel of additional experts to assist the Advisory Committee in NAAQS reviews. *See* Letter, p. 5.

42. The EPA anticipates that the Administrator’s final decision in the new review would be based on consideration of the science assessment and policy assessment documents; analyses of air quality, exposure and risk; the advice of the

⁹ Letter from Dr. Louis Anthony Cox, Jr., to Administrator Wheeler, Re: CASAC Review of the EPA’s *Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards (External Review Draft – October 2019)*, Letter, p. 2, (February 19, 2020) (EPA-CASAC-20-003).

Advisory Committee; and public comments. As the new review incorporates the agency's reconsideration of the 2020 Ozone NAAQS Decision, the EPA's intent is for that final decision to also address the reconsideration and include consideration of the Advisory Committee's advice on the 2020 Ozone NAAQS Decision and the reconsideration of that decision.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this 20th day of December 2023.



Joseph Goffman
Principal Deputy Assistant Administrator
performing delegated duties of
Assistant Administrator
Office of Air and Radiation
United States Environmental Protection Agency