May 16, 2023

Dr. Elizabeth A. Sheppard
Clean Air Scientific Advisory Committee
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, DC 20460

Submitted via email to: yeow.aaron@epa.gov

Re: Technical Comments of Clean Air Task Force on Environmental Protection Agency's Policy Assessment for the Reconsideration of the Ozone National Ambient Air Quality Standards

Clean Air Task Force ("CATF") appreciates the opportunity to submit the following technical comments on the Environmental Protection Agency's ("EPA") *Policy Assessment (PA) for the Reconsideration of the Ozone National Ambient Air Quality Standards (External Review Draft Version 2)*, hereafter referred to as the "PA." CATF is a global nonprofit working to protect public health and the environment from the impacts of harmful air pollution and climate change by catalyzing the development and deployment of pollution control technologies, and by encouraging cleaner and more efficient energy production through research, analysis, and public advocacy.

EPA must select a National Ambient Air Quality Standard ("NAAQS") for ozone that is based on air quality criteria reflecting "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."[1] Primary NAAQS must be set at a level "requisite to protect the public health" with "an adequate margin of safety."[2] The D.C. Circuit has characterized the NAAQS as "preventative in nature."[3] The Clean Air Act's ("CAA") mandate requires that in considering uncertainty EPA "must err on the side of caution" in terms of protecting human health and welfare.[4] EPA's review of the NAAQS must "accurately reflect the latest scientific knowledge,"[5] and the review must be "thorough."[6] Additionally, EPA's NAAQS determination must not run "counter to the evidence before the agency."[7] Given the magnitude of risk and health concerns associated with ozone exposure, EPA must prioritize determining this NAAQS efficiently. CATF urges EPA to finalize this reconsideration action by April 2024.

---

[1] 42 U.S.C. § 7408(a)(2).
[2] *Id.* § 7409(b)(1).
[3] *E.g.,* Ethyl Corp. v. EPA, 541 F.2d at 15; *see also* H. Rep. No. 95-294, at 49–51 (explaining amendments designed inter alia "[t]o emphasize the preventive or precautionary nature of the act, i.e., to assure that regulatory action can effectively prevent harm before it occurs").
[4] *E.g.,* Am. Trucking Ass'n v. EPA, 283 F.3d 355, 369, 378 (D.C. Cir. 2002) ("The Act requires EPA to promulgate protective primary NAAQS even where … the pollutant's risks cannot be quantified or 'precisely identified as to nature or degree.'").
[5] 42 U.S.C. § 7408(a)(2).
[6] *Id.* § 7409(d)(1).
[7] Motor Vehicles Manufacturers Ass'n v. State Farm, 463 U.S. 29, 43 (1983).

CATF disagrees with EPA's conclusion in the draft PA that the available evidence and quantitative information, including uncertainties, do not call into question the adequacy of protection provided by the current standard, and provide support for retaining the current primary standard. In its determination, EPA relies heavily on controlled human exposure ("CHE") studies, which generally assess exposure to young, healthy individuals. The Agency downplays the importance of epidemiological studies that better represent the population, including children and asthmatics. These epidemiological studies show adverse effects at lower exposure concentrations than the CHE and may reflect more complete ambient exposures to oxidants beyond the ozone indicator.

As highlighted in 2022 Duffney Memo,[8] the Hernandez (2021) study[9] provides recent evidence that statistically significant FEV1 reduction occurs to individuals at rest at 70 parts per billion ("ppb"), although the magnitude of reduction was somewhat less than that observed in previous studies focused on exercising individuals. That evidence suggests that the exposure assessment in the PA, which is focused on exposures of highly active children and adults, likely underestimates the frequency of harmful exposures.

The prior 1-hour ("[duration]-hr") ozone standard clearly emphasized the importance and harmful nature of multiple exposures with its form, not to be exceeded more than once per year. The exposure assessment also recognizes the importance of limiting frequent exposures by reporting statistics for one, and greater than one high exposure occurrence. The current 8-hr standard, with its form of a three-year average of the 4th high, permits multiple days above the level of the standard with a design value of 70 ppb.

Analyses of recent air quality data from 2019 to 2021 demonstrate that meeting the current standard inadequately protects health for all individuals with an adequate margin of safety. The Agency must reduce the level of the standard in order to minimize harmful exposures, especially to children and those with existing disease.

Exposure averaging time.

In its presentation to CASAC[10], [EPA Presentation - Policy Assessment for the Reconsideration of the 2020 Decision on the Ozone National Ambient Air Quality Standards - External Review Draft, Version 2] and repeatedly in the PA, EPA suggests that an 8-hr average of 70 ppb is below

[8] Parker F. Duffney et al, EPA, *Memorandum: Provisional Evaluation of Newly Identified Controlled Human Exposure Studies in the context of the 2020 Integrated Science Assessment for Ozone and Related Photochemical Oxidants* (2022), https://casac.epa.gov/ords/sab/f?p=113:0:10863468969247:APPLICATION_PROCESS=MEETING_FILE:::MM_ID:6170

[9] Michelle Hernandez et al., *Respiratory Effects of Sedentary Ozone Exposure at the 70-ppb National Ambient Air Quality Standard: A Randomized Clinical Trial*, 203 Am. J. Respiratory & Critical Care Med. 910 (2021), http://dx.doi.org/10.1164/rccm.202006-2597LE.

[10] Office of Air Quality Planning and Standards, EPA, *Policy Assessment for the Reconsideration of the 2020 Decision on the Ozone National Ambient Air Quality Standards* (2023), https://casac.epa.gov/ords/sab/f?p=113:0:10162145748940:APPLICATION_PROCESS=MEETING_FILE:::MM_ID:6171.

the level of exposure harm of 6.6 hrs of 73 ppb from Schelegle (2009). In fact, the PA notes that "…the Administrator in 2015 judged that a standard with a level of 70 ppb would incorporate a margin of safety against the adverse O3-induced effects shown to occur in the controlled human exposure studies following exposures (while at moderate or greater exertion) to a concentration somewhat higher than 70 ppb…" [PA 3-10] These claims are unsupported.

CATF had commented previously and provided analysis to demonstrate that 70 ppb 8-hr average is not protective of 6.5-hr exposures above 72 ppb.[11] This fact has not changed based on a limited analysis of days in recent years with a maximum 8-hr average of 70 ppb. One can easily determine the peak 6.5-hr average internal to an 8-hr peak. Generally, for 8-hr peaks of 68 to 72, 90 percent of the associated 6.5-hr peaks are 1 to 5 ppb greater. CATF reviewed three years of data from 30 monitors for the years 2019 through 2021. There were 63 days whose peak 8-hr average was 70 ppb and on 23 of those days the 6.5-hr peak was 73 or higher. In other words, 70 ppb 8-hr average fails to provide any margin of safety, even allowing harmful levels of ozone over one-third of the time. Based on the limited data reviewed, an 8-hr average of 68 ppb would likely prevent 6.6s-hr exposures of 73 or greater, though would allow frequent averages of 72 or 71 ppb, or not much of a margin.

Comparisons between the 8-hr peak daily average and corresponding 6.5-hr average daily peak are tabulated (Table 1). On average, the 6.5-hr peak is 2.3 ppb greater than the 8-hr peak and the maximum 6.5-hr peak averages 5.4 ppb greater. The table helps to map 6.6-hr exposure levels to corresponding 8-hr averages.

8-Hour Average	# of days	Average 6.5-hr peak	Max 6.5-hour peak
65	23	68.8	72
66	54	68.6	72
67	69	69.1	74
68	64	70.0	72
69	51	70.7	73
70	63	72.1	75
71	49	73.3	78
72	38	74.1	76
73	28	74.8	78
74	30	76.4	79

Table 1 Summary of relationship between the 8-hour peak daily average and the corresponding 6.5-hr peak within that 8-hour period.

Exposure frequency exceeding the level of the standard, based on the current form.

[11] Comments of Clean Air Task Force on Proposed Rule, National Ambient Air Quality Standards for Ozone (Mar. 17, 2015), https://www.regulations.gov/comment/EPA-HQ-OAR-2008-0699-3061. 6.5-hr averages are calculated using the midpoint from the data submitted by states to AQS.

CATF reviewed ozone data for monitoring locations operating in the US between 2019 and 2021. Based on EPA's Design Value Spreadsheets for ozone,[12] 1173 sites collected valid data for at least one year, 1080 of those had valid design values, and 199 locations failed to meet the current NAAQS of 70 ppb. The number of days over the current standard are graphed against corresponding design values in Figure 1 covering the preponderance of ozone levels; 948 sites have design values in this range. The chart shows that 37 locations that just met the standard (DV70) averaged nearly four days per year over the standard, with the worst location exceeding the standard more than 6 days per year during the 2019 to 2021 period. The frequency of those high levels suggests a high likelihood of harmful exposures on multiple days each year for people living nearby. There is a steady decline as the DV decreases, such that one exceedance of 70 ppb per year could be realized for locations with design values of 64 to 65 ppb. Functionally, the current form of the standard requires the level to be set 5 to 6 ppb below the identified level of harm to healthy individuals to achieve the level of protection afforded under the prior 1-hr standard which allowed one exceedance annually.

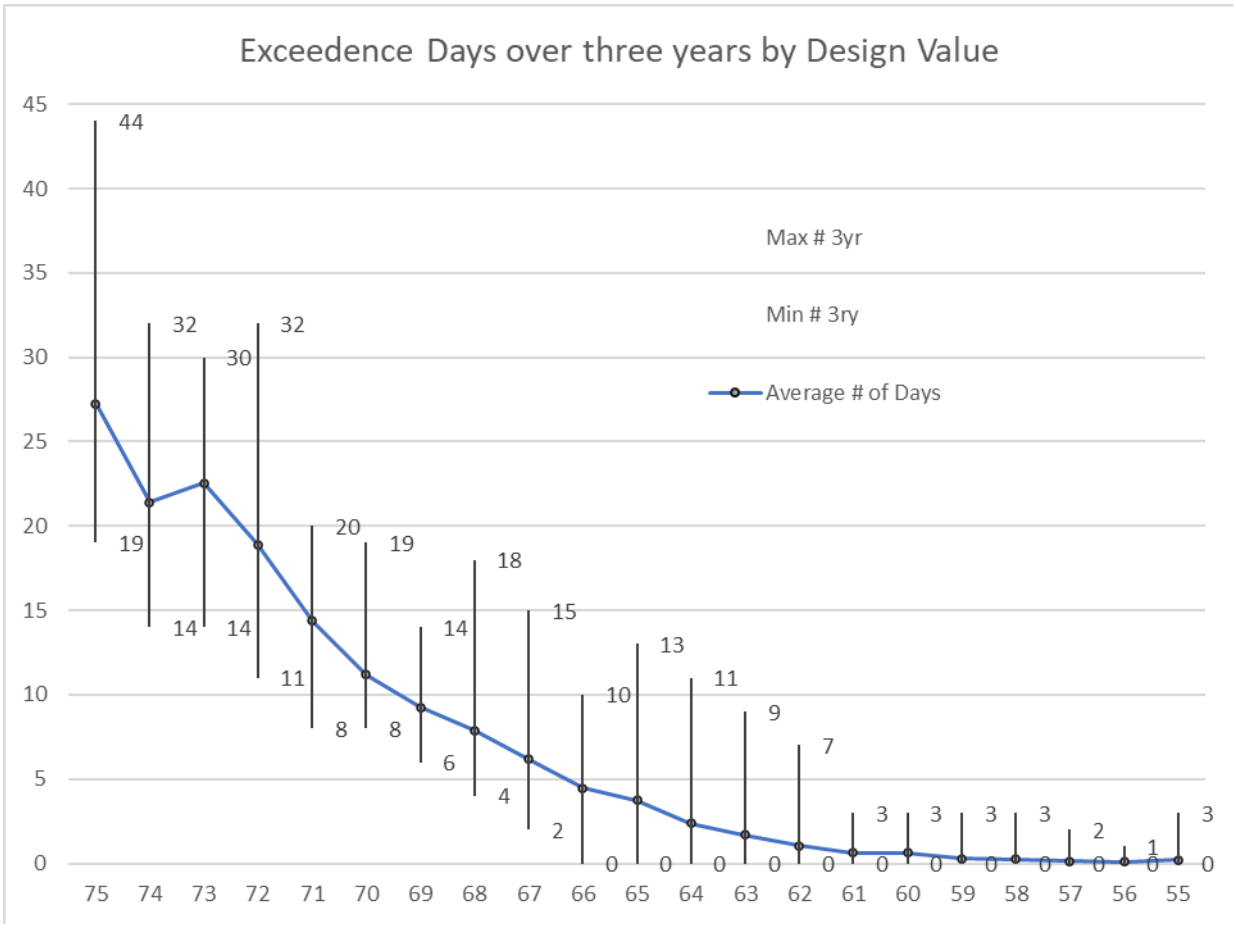

Figure 1 Y-axis shows the number of days over 70 ppb as a function of Design Value (sum days over three years). The trend line shows the average for monitors at each DV level, with the max

[12] Spreadsheet of Design Values for the Ozone NAAQS, EPA, https://www.epa.gov/system/files/documents/2022-05/O3_DesignValues_2019_2021_FINAL_05_25_22.xlsx (last visited May 15, 2023).

and minimum number of days is indicated by the vertical line. The average number of monitoring sites per DV bin is 45, ranging from 17 (DV 75) to 80 (DV 64) locations.

Another way to investigate the relationship between the annual 4th high 8-hr average is to consider individual years. The table demonstrates the frequency of days with 8-hr max average over 70 ppb, for monitoring locations with a valid 4th high during years 2019, 2020 and 2021. Just over one-fourth of the valid monitors had a 4th high value under 60 ppb, and those locations rarely had more than one day in the year with an 8-hr peak over 70 ppb. Over a third of the sites had a 4th high value in the range of 60 to 65, with a quarter of the monitors having at least one day exceeding 70 ppb. Nearly one in five monitors had a 4th high value in the 66 to 70 ppb range, with just over half having more than one day exceeding 70 during the year, and about another 30 percent of the locations having one high ozone day. Locations with a 4th high over 70 obviously have multiple exceedance days each year. Overall, more than 44 percent of the monitors had at least one day over the level of the standard, with nearly one third of the current monitors exceeding multiple times. Like the chart of design values, the table highlights how the standard form permits multiple days above the standard, and the number of those days decreases as the 4th high drops further below the standard.

	Annual 4th high 8-hour ozone (ppb)					
	<60	60-65	66-70	over std	meet std	All Monitors
# with one day>70	27	251	203	0	481	481
# with 2 or more	5	72	379	677	456	1133
total # of days>70	37	407	1138	11493	1582	13075
% one day	2.8%	19.5%	28.7%	0.0%	16.3%	13.2%
% with 2+ days	0.5%	5.6%	53.5%	100.0%	15.4%	31.2%
# of monitors	957	1290	708	677	2955	3632
% of monitors	26.3%	35.5%	19.5%	18.6%		

Table 2 Annual Ozone statistics from 2019-21 data. The first four columns are binned by 4th high ozone value for one year. The meet std column is the sum of the first three columns. The All Monitors column is the sum of the first four columns.

Frequency of harmful ambient levels of 6.6-hr average ozone.

Since the 8-hr average of 70 does not protect against all harmful exposures, CATF reviewed a subset of monitors whose design values are 70 and 65 to assess the number of days over three years that locations with those pollution levels had 6.5-hr daily max values of 73 or greater, or 63 or greater. These values are the two lowest exposure tiers evaluated in Schlegle (2009).

The 2019-21 data had many monitors at these pollution levels, and CATF reviewed data from 15 locations to assess the number of high exposure days permitted at each monitor. Monitors at both DV levels were selected to represent conditions across the entire country. Locations just meeting the current standard averaged 11.9 days with 6.5-hr levels of at least 73, ranging from 7 to 18 days over the three-year period. This compares favorably to the data in Figure 1, indicating the differences in averaging time for the standard and CHE studies does not strongly affect conclusions about the frequency of high ambient ozone levels. There are nearly 58 days with

peak 6.5-hr levels at or above 63 ppb at locations just meeting the current standard, with a range of 43 to 82 days. This means there are nearly three weeks a year of moderate peak ozone levels that may be harmful for children and people with asthma.

Locations with a DV of 65 show substantially lower frequencies of high and moderately high 6.5-hr peak ozone. These sites have just over one day per year with a harmful level of ozone at or above 73 ppb, and under ten days per year of at least 63 ppb. In other words, reducing the current 8-hr average standard by 5 ppb to 65 ppb would reduce high exposure days by a factor of 4 while cutting days above 63 (6.5-hr average) in half.

Limitations of the exposure assessment.

The joint comments from environmental groups submitted in 2020 contain a detailed discussion of some of the uncertainties and limitations of the APEX model and its representation of behaviors to determine exposure levels to ozone.[13] With recent evidence that adverse effects occur due to ozone exposure while not exercising, the assessment of exposures provided seem even less likely to fairly characterize the true extent of community exposures. EPA should revisit the analysis and provide exposure statistics regardless of activity level. The current results seem overly restrictive when considering the ambient pollution levels present in metropolitan areas that just meet the current standard.

Based on recent data, there are three metropolitan areas that just meet the current standard of 70: Cincinnati, Detroit and Washington, D.C. These airsheds have eight, ten and sixteen ozone monitors distributed across the counties. Based on the locations, which span upwind, downwind, and densely populated urban areas, it seems reasonable to assume the monitored data fairly represents the span of ozone levels experienced by people living in these cities.

CATF reviewed the data from all of the monitors in these cities covering 2019 through 2021, counting the number of days with 8-hr peaks above 60, 65 and 70. Results are summarized in Figure 2. An inspection of the results can provide a common-sense assessment of the likelihood individuals in these cities experience exposures to these three ambient levels. On average, there is at least one day per year over 70 and as many as 15 days per year over 60. At the worst locations, there are 4 to 5 days over 70 and nearly three weeks above 60 ppb. Based on this, it seems entirely reasonable to expect a large fraction of people are exposed to one day per year over 70 and everyone would experience multiple exposures over 60 every year. This compares to EPA's risk assessment for exposures in metropolitan areas that 'just meet' the current standard where they estimate 0.4 percent of active children would be exposed to levels above 70 once per year, 5 percent would be exposed to levels above 60 once per year, and only 1 percent of children exposed to levels over 60 more than once. The contrast between the actual number of days over these metrics and the estimated exposures is stark and calls into question the ability of the exposure modeling to reasonably determine the number of exposures at various pollution levels. Even in Washington, where the average number of days over 60 ppb is 8, it seems

[13] Comments of Appalachian Mountain Club et al. on EPA's Review of the National Ambient Air Quality Standards for Ozone (Oct. 1, 2020), https://www.regulations.gov/comment/EPA-HQ-OAR-2018-0279-0444.

implausible that only one in 20 children would be outside on just one of these afternoons, even if we restrict that to being active.

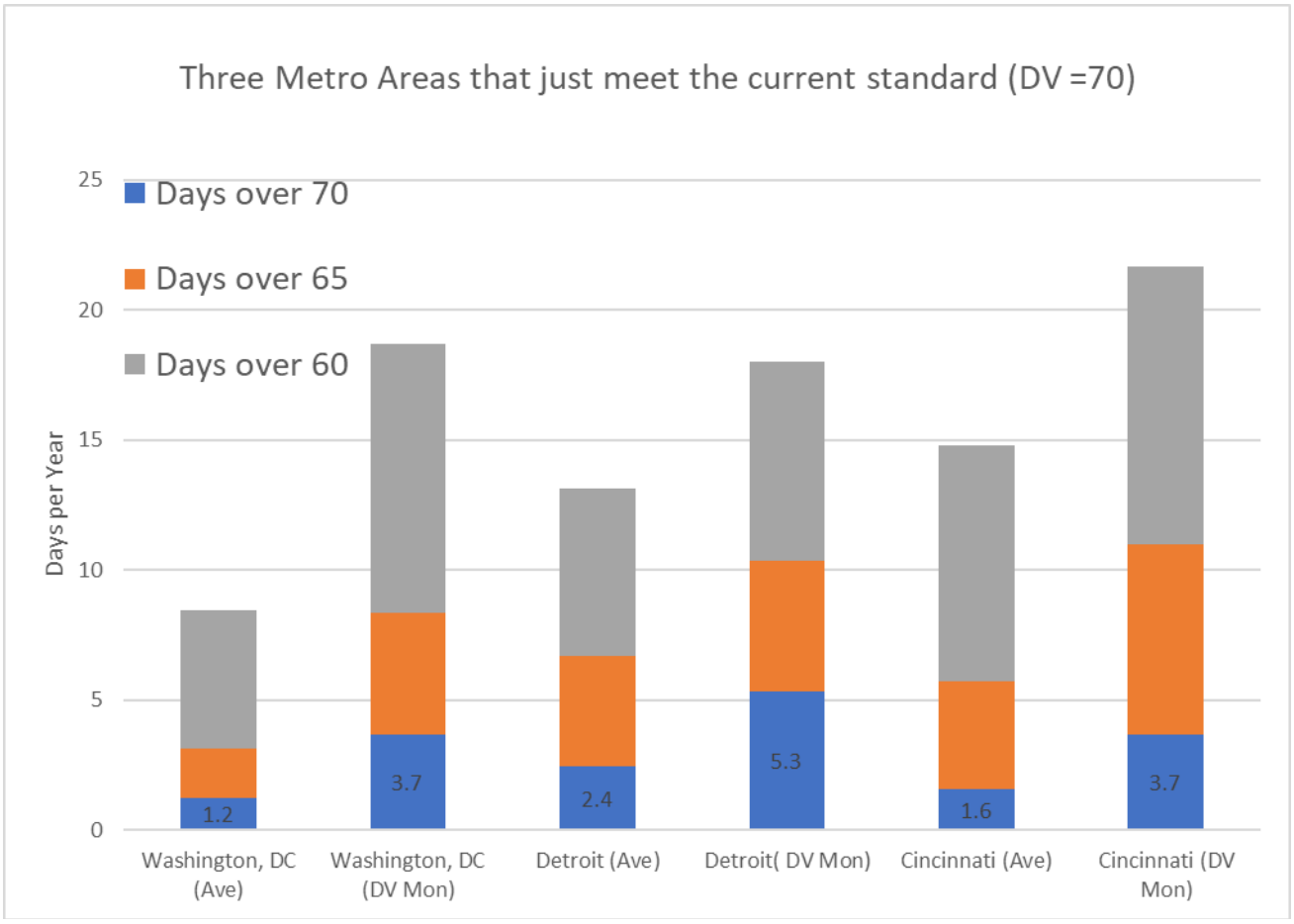

Figure 2 Summary of days per year over 60/65/70 daily peak 8-hour average. The left bar of each city is the average of all monitors and the right bar is for the location with the DV monitor (DV = 70)

Conclusion

The current standard level and its existing form are insufficient to adequately protect the health of all people with an adequate margin of safety. As CASAC considers the evidence to determine the level, or range of levels, likely to cause harm to people exposed to ozone, it must also evaluate the impact of the form of the standard. By relying on the 4th highest value and averaging across three years, attainment of the standard allows a significant number of days to occur above the level of the standard. To sufficiently reduce exposure occurrences at harmful levels, the actual level of the standard must be set below, or at the lower end of, the level determined to be harmful. The analysis presented in these comments suggests that the level of the standard should be set at about 5 ppb lower than the level of harm, if the intent is to limit harmful exposures to

once per year, assuming the form is retained. Specifically, CATF recommends the primary standard be set at a level no higher than 60 ppb.

Respectfully submitted,

Clean Air Task Force