Administrator Michael S. Regan
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

March 28, 2023

Re: Docket No. EPA–HQ–OAR–2015–0072–1543
COMMENTS: Reconsideration of the National Ambient Air Quality Standards for Particulate Matter (Jan 27, 2023)

To the Administrator:

The North American Chapter of the International Society for Environmental Epidemiology (NAC ISEE) has previously provided both oral and written comments as part of the current review process for the National Ambient Air Quality Standards (NAAQS) for particulate matter.[1] Based on our review of the available evidence in the Integrated Science Assessment (ISA), ISA Supplement, and Policy Assessment documents, we have consistently advocated for a revision of the $PM_{2.5}$ annual and 24-hour standard to 8 $\mu g/m^3$ and 25 $\mu g/m^3$, respectively.

Here we provide additional comments and recommendations on the following issues:

- Interpretation of epidemiological evidence in support of a revised annual standard;
- Need for revised 24-hour standard to address exposure and health inequalities; and,
- Comments on the Air Quality Index (AQI) breakpoints including a request for follow-up rulemaking more broadly addressing the AQI.

Interpretation of Epidemiological Evidence in Support of a Revised Annual Standard

The NAC ISEE is just one of numerous health and medical professional societies that have independently concluded that the current annual standard for $PM_{2.5}$ is inadequate to protect public health, and that the scientific evidence supports a revision of the annual standard to 8 $\mu g/m^3$. Given our previous comments during the current review that highlighted key health studies, and recognizing the large number of responses anticipated to be received that articulate the need for a more stringent annual standard, we limit ourselves here to specific issues related to the interpretation of environmental epidemiology studies in support of a revised annual standard.

The EPA has taken great care in the proposed rule, and throughout the review process, to align itself with the approaches used in previous reviews. This is particularly true in adopting a decision framework in which "there is significantly greater confidence in the magnitude and significance of observed associations...*in each study*...at or around the mean concentration" (emphasis added). As such, the EPA has gone to admirable lengths to attempt to reconcile the diverse approaches used in reporting mean exposures in individual studies to a corresponding NAAQS-relevant average concentration (see section II.B.3.a). However, this adopted framework was established when there were only a few epidemiology studies available that

[1] EPA-HQ-ORD-2014-0859-0087. (Submitted Nov 29, 2021)

assessed the adverse health impacts of long-term $PM_{2.5}$ exposures; this is no longer the case and as such a slight modification to this framework is warranted.

Rather than relying on the mean exposure of each study to provide insight into the level at which adverse health effects are occurring, we instead focus on how each study helps inform our understanding of the underlying relationship between ambient $PM_{2.5}$ exposures and the adverse health outcome of interest. In other words, we are less concerned with the precise magnitude of association reported in an individual study, and the potential confidence we have in that one specific association (which may be greatest around the study mean as concluded by the adopted framework used by the EPA), and instead seek to understand what each study adds to our understanding of the overall shape and structure of the underlying concentration-response relationship.

In applying this approach to the same set of studies considered by the EPA as contained in the ISA and ISA supplement, we fully concur with the conclusion of CASAC that "the evidence remains clear and consistent in supporting a no-threshold relationship, and in supporting a linear relationship for $PM_{2.5}$ concentrations >8 $\mu g/m^3$" for both mortality and morbidity impacts as observed in U.S. populations.

By the same token, we strongly disagree with the frequent use of language by the Administrator in the proposed rule that the strength of evidence for adverse health impacts (particularly mortality associated with long-term $PM_{2.5}$ exposures) is somehow different at concentrations above this level. In particular, we specifically find no quantitative or qualitative difference in the strength of evidence for mortality risk for long-term exposures between the proposed range of 9-10 $\mu g/m^3$.

It is our conclusion that increased risks of adverse health events have already been observed to occur for individuals in the U.S. with long-term exposures above 8 $\mu g/m^3$ as compared to individuals with exposures below 8 $\mu g/m^3$. Even though it is anticipated that adverse health impacts may continue to occur at concentrations below this level (as already evidenced by studies based in Canada),[2] we are supportive of a sustainable approach to regular NAAQS reviews that allows for ongoing revision as new scientific evidence based on lower ambient concentrations in the U.S. becomes available.

Need for a Revised 24-hour Standard to Address Exposure and Health Inequalities

Health burdens of ambient $PM_{2.5}$ air pollution are not evenly distributed across demographic groups. It has been well documented that people of color and people of low socioeconomic status are often exposed to higher-than-average levels of ambient $PM_{2.5}$.[3] Similarly, improvements in ambient $PM_{2.5}$ concentrations do not occur uniformly; even as ambient $PM_{2.5}$ concentrations

[2] Weichenthal, S., Pinault, L., Christidis, T., Burnett, R.T., Brook, J.R., Chu, Y., Crouse, D.L., Erickson, A.C., Hystad, P., Li, C. and Martin, R.V., 2022. How low can you go? Air pollution affects mortality at very low levels. *Science Advances*, *8*(39), p.eabo3381

[3] J. Liu, L. P. Clark, M. J. Bechle, A. Hajat, S.-Y. Kim, A. L. Robinson, L. Sheppard, A. A. Szpiro, J. D. Marshall, Disparities in air pollution exposure in the United States by race/ethnicity and income, 1990–2010. *Environ. Health Perspect.* 129, 127005 (2021); A. Jbaily, X. Zhou, J. Liu, T.-H. Lee, L. Kamareddine, S. Verguet, F. Dominici, Air pollution exposure disparities across US population and income groups. *Nature*. 601, 228–233 (2022).

have improved across the U.S. over the last 15 years, exposure inequality has persisted: the absolute exposure and health risks within groups have decreased while relative disparities have not.[4]

The NAC ISEE finds that the current inequalities in exposure and health risk that are present in the U.S., which are not fully reflected by the current stationary monitoring network, cannot be remedied through revising the annual standard alone. High-resolution modeling studies have indicated that revision of the annual standard, even down to hypothetical levels as low as 5 $\mu g/m^3$, will not result in a reduction of current disparities in exposure and health risk.[5] A 2022 study by Wang et. al., used a reduced-form air quality model (InMAP) to estimate the changes of annual-averaged $PM_{2.5}$ concentrations and racial-ethnic exposure inequalities. InMAP simulates the fate and transport of anthropogenic emissions and predicts both primary and secondary $PM_{2.5}$ concentrations. The study simulates successive, proportional emission reductions in each CBSA violating the hypothetical NAAQS. The results showed that both national, and within-urban, inequalities are not eliminated with various hypothetical standards from 5 to 10 $\mu g/m^3$.

Addressing health inequalities is a priority for NAC ISEE and a revised annual standard alone is not sufficient to address existing environmental justice disparities. This is because it regulates on the "average" rather than the spatial and temporal "distributions" within each metropolitan area or county. If the EPA is serious about addressing environmental justice issues related to unequal $PM_{2.5}$ exposures and health risks, it will require a much more rigorous consideration of a revision of the 24-hour standard. Based on our review of the evidence, these disparities would be best addressed through a revision of the 24-hour standard to 25 $\mu g/m^3$ in addition to efforts to site additional permanent regulatory monitors in identified hot-spot pollution locations.

The current regulatory air quality monitoring sites within metropolitan areas or counties are sparsely located,[6] especially in low-income and non-White communities,[7] which are also tend to be overburdened with $PM_{2.5}$ air pollution. Low-cost $PM_{2.5}$ sensors have made it feasible for denser monitoring networks, yet they are far less accessible for disadvantaged communities and are insufficient to serve as regulatory tools to trigger required mitigation actions.[8] Similarly, advances in satellite and modeling capabilities make identifying peak exposures that are not well represented by existing stationary monitors increasingly more accessible, but these newer technologies cannot replace the established accountability that accompanies a permanent regulatory monitor. We support the EPA for proposing to add a network design requirement to specifically locate monitors in at-risk communities, which is a good first step to help provide

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[4] J. Colmer, I. Hardman, J. Shimshack, J. Voorheis, Disparities in $PM_{2.5}$ air pollution in the United States. *Science*. 369, 575–578 (2020); C. W. Tessum, J. S. Apte, A. L. Goodkind, N. Z. Muller, K. A. Mullins, D. A. Paolella, S. Polasky, N. P. Springer, S. K. Thakrar, J. D. Marshall, J. D. Hill, Inequity in consumption of goods and services adds to racial–ethnic disparities in air pollution exposure. *Proc. Natl. Acad. Sci.* 116, 6001–6006 (2019).

[5] Y. Wang, J. S. Apte, J. D. Hill, C. E. Ivey, R. F. Patterson, A. L. Robinson, C. W. Tessum, J. D. Marshall, Location-specific strategies for eliminating US national racial-ethnic PM2.5 exposure inequality. *Proc. Natl. Acad. Sci.* 119, e2205548119 (2022).

[6] D. Sullivan, A. Krupnick, "Using satellite data to fill the gaps in the US air pollution monitoring network", Working paper RFF WP 18-21, Resources for the Future, Washington, DC, September 2018.

[7] C. Grainger & A. Schreiber, Discrimination in ambient air pollution monitoring? *AEA Pap. Proc.* 109, 277–282 (2019).

[8] P. deSouza, P. L. Kinney, On the distribution of low-cost PM2.5 sensors in the US: demographic and air quality associations. *J. Expo. Sci. Environ. Epidemiol*. 31, 514–524 (2021).

more protection to the disadvantaged communities and in the long term may help address exposure inequalities.

Request for Follow-up Rulemaking More Broadly Addressing the AQI

The AQI is a highly useful tool for public health communication during pollution events that has been widely adopted by both the scientific community and the public. We thank EPA for the development and continued revision of this tool for clear, accurate communication on the health risks of outdoor air pollution.

The proposed rule requests comments on a few specific aspects of the AQI which we have addressed in part below. However, we would specifically request that the EPA initiate a separate rulemaking process that allows for a more rigorous consideration of the various aspects of the AQI including: breakpoints for each pollutant, health messaging, consideration of the additive impacts of multiple pollutants, adjustments based on different averaging times, etc. This process should also include thorough consideration of implementation issues which are largely absent from the NAAQS setting process.

The NAC ISEE would gladly support and participate in such an effort. While the AQI has been widely utilized, and exported to many locations around the world, we believe that careful consideration of the details of the AQI has been insufficiently prioritized by scientific, medical, and regulatory communities. A separate rulemaking process focused on the AQI has the potential to reconsider how improvements could best support efforts to protect public health.

Comments on Upper AQI Breakpoints

The NAC ISEE supports the EPA's decision to consider improvements to the upper breakpoints for the >200 AQI levels for $PM_{2.5}$ based on the most current epidemiological evidence for short-term and wildfire-sourced $PM_{2.5}$ exposures. We similarly support EPA's decision to consider studies of wildfire smoke exposure in the setting of these levels.

Steady reductions in anthropogenic pollution emissions, combined with increases in wild fire-sourced $PM_{2.5}$, has resulted in a dramatic increase in total $PM_{2.5}$ attributable to wildland fires.[9] In particular, days with population exposure greater than 100 $\mu g/m^3$ of smoke-sourced $PM_{2.5}$ increased by 27 times from 2006 to 2020.[10] Wildfire-sourced $PM_{2.5}$ has a different composition

[9] Malm, William C., Bret A. Schichtel, Jenny L. Hand, and Jeffrey L. Collett. 2017. "Concurrent Temporal and Spatial Trends in Sulfate and Organic Mass Concentrations Measured in the IMPROVE Monitoring Program." *Journal of Geophysical Research: Atmospheres* 122 (19): 2017JD026865; Ridley, D. A., C. L. Heald, K. J. Ridley, and J. H. Kroll. 2018. "Causes and Consequences of Decreasing Atmospheric Organic Aerosol in the United States." *Proceedings of the National Academy of Sciences* 115 (2): 290–95; O'Dell, Katelyn, Bonne Ford, Emily V. Fischer, and Jeffrey R. Pierce. 2019. "Contribution of Wildland-Fire Smoke to US PM2.5 and Its Influence on Recent Trends." *Environmental Science & Technology* 53 (4): 1797–1804; McClure, Crystal D., and Daniel A. Jaffe. 2018. "US Particulate Matter Air Quality Improves except in Wildfire-Prone Areas." *Proceedings of the National Academy of Sciences*, July, 201804353.

[10] Childs, Marissa L., Jessica Li, Jeffrey Wen, Sam Heft-Neal, Anne Driscoll, Sherrie Wang, Carlos F. Gould, Minghao Qiu, Jennifer Burney, and Marshall Burke. 2022. "Daily Local-Level Estimates of Ambient Wildfire Smoke PM2.5 for the Contiguous US." *Environmental Science & Technology* 56 (19): 13607–21.

than anthropogenically sourced $PM_{2.5}$ which may lead to different effects on human health.[11] The careful consideration of these issues support EPA's decision to revise the $PM_{2.5}$ breakpoints for AQI values > 200.

If the revised breakpoints are adopted, it will be important to consider messaging surrounding the AQI values greater than 500 and implications of repeated short-term exposures. With the revised, breakpoints for AQI values > 200, there will be more instances of AQI values that are "off the charts" (> 500). In addition, days which exceed this threshold are often due to smoke from large western wildfires, which are expected to increase in both frequency and intensity over the coming century.[12] The occurrence of daily-mean wildfire-sourced $PM_{2.5}$ events > 200 $\mu g/m^3$ has already increased by over 1,000x over the past decade.[13] Therefore, public health guidance for these days should be made clear.

In the absence of accompanying proposed changes in health messaging that accompanies specific breakpoints for upper AQI values, it is difficult to provide detailed recommendations in regards to the utility of the revised breakpoints vs. a newly modified linear approach. However, we find a great deal of utility in a non-linear relationship between $PM_{2.5}$ concentrations and AQI values from 0-200 that strongly reflect evidence for effects that correspond to the intent of the "Moderate", "Unhealthy for Sensitive Groups", and "Unhealthy" categories. While we would again repeat our request for a separate rulemaking process to wrestle with these issues in a much more substantive manner, we would recommend that for purposes of this rulemaking that these values correspond to breakpoints of 25 $\mu g/m^3$ (100 value); 55 $\mu g/m^3$ (150 value); and 115 $\mu g/m^3$ (200 value).

We additionally find value in a linear association for upper AQI values > 200 due to the allowing the public to more easily make sense of relative $PM_{2.5}$ concentrations that occur between different wildland fire or other extreme pollution events. This linear association should begin at the 200 value, and not the 150 value, in order to more closely align with the evidence that was well presented in the proposed rule, particularly as it relates to the 500 value of the index. Using the proposed change to the 200 value of the index of 125 $\mu g/m^3$, this would result in concentrations of 187.5 $\mu g/m^3$ (300 value) and 312.5 $\mu g/m^3$ (500 value).

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[11] Verma, Vishal, Andrea Polidori, James J. Schauer, Martin M. Shafer, Flemming R. Cassee, and Constantinos Sioutas. 2009. "Physicochemical and Toxicological Profiles of Particulate Matter in Los Angeles during the October 2007 Southern California Wildfires." *Environmental Science & Technology* 43 (3): 954–60; Aguilera, Rosana, Thomas Corringham, Alexander Gershunov, and Tarik Benmarhnia. 2021. "Wildfire Smoke Impacts Respiratory Health More than Fine Particles from Other Sources: Observational Evidence from Southern California." *Nature Communications* 12 (1): 1493; DeFlorio-Barker, S., J. L. Crooks, J. Reyes, and A. G. Rappold. 2019. "Cardiopulmonary Effects of Fine Particulate Matter Exposure among Older Adults, during Wildfire and Non-Wildfire Periods, in the United States 2008-2010." *Environmental Health Perspectives* 127 (3): 037006.

[12] Abatzoglou, John T., David S. Battisti, A. Park Williams, Winslow D. Hansen, Brian J. Harvey, and Crystal A. Kolden. 2021. "Projected Increases in Western US Forest Fire despite Growing Fuel Constraints." *Communications Earth & Environment* 2 (1): 1–8.

[13] Childs, Marissa L., Jessica Li, Jeffrey Wen, Sam Heft-Neal, Anne Driscoll, Sherrie Wang, Carlos F. Gould, Minghao Qiu, Jennifer Burney, and Marshall Burke. 2022. "Daily Local-Level Estimates of Ambient Wildfire Smoke PM2.5 for the Contiguous US." *Environmental Science & Technology* 56 (19): 13607–21.

Protecting Public Health through Revision of the 100 value of the AQI

Even in the absence of a revised 24-hour standard for $PM_{2.5}$, it is critical that the 100 value of the AQI sub-index for $PM_{2.5}$ is adjusted to reflect the health risks of short-term exposures that have been demonstrated to occur in US populations below the current level of 35 $\mu g/m^3$.

The AQI has been appropriated by clinicians and patient populations, with encouragement by EPA training documents, to understand health-related air quality information for general and sensitive populations in the U.S. This is evident in studies that have demonstrated avoidance behaviors in susceptible patient populations and the general public in response to air quality alerts and clinical communication strategies based on the U.S. AQI.[14] The breakpoint that is used almost exclusively by clinicians and patients in making individual modification decisions is the 100 value of the index, and as such is critical that this breakpoint adequately reflects the health and clinical evidence of the adverse health risks of short-term pollution exposures.

The historical approach to setting an AQI value of 100 is to set it at the same level as the primary 24-hour $PM_{2.5}$ standard. The EPA "sees no basis to deviate from this approach" since the "primary 24-hour standard is set to provide protection to the public, including at-risk populations." This approach potentially falls short, however, if the annual standard and 24-hour standard are considered together as a suite of standards to address both long-term and short-term exposures as is being used in this proposed rule.

The Administrator has proposed retaining the 24-hour standard for $PM_{2.5}$, in part, due to the results from the risk assessment showing that "for most of the U.S., the annual standard is the controlling standard and that revision to the standard has the most potential to reduce $PM_{2.5}$ exposure related risk." The proposed rule continues to explain that "[i]n considering how to revise the suite of standards to provide the requisite degree of protection, the Administrator recognizes that the current annual standard and 24-hour standard, *together* (emphasis added), are intended to provide public health protection against the full distribution of short- and long-term $PM_{2.5}$ exposures." The Administrator notes that "a more stringent annual standard is expected to reduce both average (annual) concentrations and peak (daily) concentrations...[and] proposes to conclude that the 24-hour standard should be retained, particularly when considered in conjunction with the protection provided by the suite of standards and the proposed decision to revise the annual standard to a level of 9.0 to 10.0 $\mu g/m^3$.

While we disagree with the proposed conclusion that the 24-hour standard does not need to be revised to adequately protect public health (in part due to there being specific locations in which attaining the proposed revised annual standard may not adequately constrain peak concentrations; and more broadly due to the inability of the revised annual standard to adequately address exposure inequalities that occur within a metropolitan region or county), we do concur with the reasoning that annual and 24-hour standards can be considered in tandem in order to accomplish the desired levels of protection from both long- and short-term exposures. However, this rationale for addressing the distribution of exposures through the attainment of the

[14] Wen XJ, Balluz L, Mokdad A. Association between media alerts of air quality index and change of outdoor activity among adult asthma in six states, BRFSS, 2005. J Community Health. 2009 Feb;34(1):40-6; Reyes-Angel J, Han YY, Forno E, Celedón JC, Rosser FJ. Parental knowledge and usage of air quality in childhood asthma management. Front Pediatr. 2022 Oct 26;10:966372.

standards taken together, does not extend to the determination of AQI breakpoints that are needed to inform the public regarding levels are air pollution that may adversely impact their individual health. In other words, while attainment of a revised annual standard may provide adequate public health protection against peak (daily) exposures in the judgment of the Administrator, it does nothing the communicate the health risks of these peak exposures to the public through the AQI.

It is long overdue that the determination of the 100 value of the AQI is operationally distinct from the myriad of considerations that go into determining the level of the 24-hour standard. While decisions regarding potential revisions of the level of the $PM_{2.5}$ standards include evidence-based considerations, risk-based considerations, and what has long been termed "other" considerations, the decision in establishing AQI breakpoints should be made solely on clinical and health evidence. Doing so will ensure that the AQI 100 value effectively communicates health risks and promotes healthy behaviors that mitigate the adverse effects of daily $PM_{2.5}$ exposure, independent of potential revisions to the 24-hour standard.

The NAC ISEE recommends revising the 100 value for the $PM_{2.5}$ sub-index to 25 $\mu g/m^3$. This recommendation is supported by current U.S.-based evidence, which clearly demonstrates various health risks after restricting analyses to days with $PM_{2.5}$ exposure at or above 25 $\mu g/m^3$. Examined health risks include increases in all-cause mortality, increased infection rates, and cardiovascular, respiratory, neurologic, and psychiatric morbidity and mortality.[15] This evidence is further supported by epigenetic research that has demonstrated positive associations between short term $PM_{2.5}$ exposure at or above 25 $\mu g/m^3$ and pathologic markers of inflammation and oxidative stress.[16]

In addition to published studies as contained in the ISA, it is appropriate to also take into account the complimentary information from the individual experiences of patients in how they manage symptoms due to asthma, COPD, atrial fibrillation,[17] or any number of other chronic conditions

[15] Di Q, Dai L, Wang Y, Zanobetti A, Choirat C, Schwartz JD, Dominici F. Association of Short- term Exposure to Air Pollution With Mortality in Older Adults. *JAMA*. 2017 Dec 26;318(24):2446-2456; Xu L, Taylor JE, Kaiser J. Short-term air pollution exposure and COVID-19 infection in the United States. *Environ Pollut*. 2022 Jan 1;292(Pt B):118369; deSouza P, Braun D, Parks RM, Schwartz J, Dominici F, Kioumourtzoglou MA. Nationwide Study of Short-term Exposure to Fine Particulate Matter and Cardiovascular Hospitalizations Among Medicaid Enrollees. *Epidemiology*. 2021 Jan;32(1):6-13; Chen C, Warrington JA, Dominici F, Peng RD, Esty DC, Bobb JF, Bell ML. Temporal variation in association between short-term exposure to fine particulate matter and hospitalizations in older adults in the USA: a long-term time-series analysis of the US Medicare dataset. *Lancet Planet Health*. 2021 Aug;5(8):e534-e541. doi: 10.1016/S2542-5196(21)00168-6; Liu RA, Wei Y, Qiu X, Kosheleva A, Schwartz JD. Short term exposure to air pollution and mortality in the US: a double negative control analysis. *Environ Health*. 2022 Sep 6;21(1):81; Cromar KR, Gladson LA, Hicks EA, Marsh B, Ewart G. Excess Morbidity and Mortality Associated with Air Pollution above American Thoracic Society Recommended Standards, 2017-2019. *Ann Am Thorac Soc*. 2022 Apr;19(4):603-613; Qiu X, Danesh-Yazdi M, Wei Y, Di Q, Just A, Zanobetti A, Weisskopf M, Dominici F, Schwartz J. Associations of short-term exposure to air pollution and increased ambient temperature with psychiatric hospital admissions in older adults in the USA: a case-crossover study. *Lancet Planet Health*. 2022 Apr;6(4):e331-e341.

[16] Danesh Yazdi M, Nassan FL, Kosheleva A, Wang C, Xu Z, Di Q, Requia WJ, Comfort NT, Wu H, Laurent LC, DeHoff P, Vokonas P, Baccarelli AA, Schwartz JD. Short-term air pollution and temperature exposure and changes in the extracellular microRNA profile of Normative Aging Study (NAS) participants. *Environ Int*. 2023 Jan;171:107735.

[17] Chen M, Zhao J, Zhuo C, Zheng L. The Association Between Ambient Air Pollution and Atrial Fibrillation. Int Heart J. 2021 Mar 30;62(2):290-297.

that are impacted by outdoor air pollution. During the EPA's February 2023 public hearings for the Reconsideration of the National Ambient Air Quality Standards, numerous patient advocacy organizations and individual, high-risk patients shared how risk communication related to the AQI 100-level was essential to their health and well-being. To revisit just one of many testimonies provided, a lung transplant recipient and representative from the Respiratory Health Association in Illinois clearly stated, "Air pollution directly impacts my life. I have one lung, and pollution above 25$\mu g/m^3$ makes it much harder for me to breathe. The science is showing that people like me are still getting sick and dying at levels that today might only reach the EPA's yellow air quality level, which means I am putting myself in danger even on days where it does not reach orange."

We thank the EPA for their ongoing efforts to improve the AQI to reflect the current health risks related to ambient air pollution exposure in the U.S. and hope to engage more fully in a future rulemaking to more rigorously evaluate this important tool.

Comments prepared on behalf of the North American Chapter of the International Society for Environmental Epidemiology by:

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