

May 29, 2018

Written Statement for the Public Meeting of the EPA Chartered Science Advisory Board, Re: 5/31 SAB Discussions about EPA Planned Actions and their Supporting Science

The Environmental Protection Network (EPN) appreciates the opportunity to provide written and oral comments to the EPA Science Advisory Board for consideration in its discussion of EPA planned actions and supporting science. EPN is a volunteer organization of former EPA employees and others concerned about current efforts to undermine protection of public health and the environment.

Overview

EPN agrees with the Chartered SAB work group rationale and recommendations that the SAB review the following actions:

- Reconsideration of Final Determination: Mid Term Evaluation of Greenhouse Gas Emissions Standards for Model Year 2022-2025 Light Duty Vehicles
- Repeal of Emission Requirements for Glider Vehicles, Glider Engines, and Glider Kits
- Review of the 2016 Oil and Gas New Source Performance Standards for New, Reconstructed, and Modified Sources
- Review of the Clean Power Plan
- Review of the Standards of Performance for Greenhouse Gas Emissions from New, Modified, and Reconstructed Stationary Sources: Electric Generating Units
- Proposed Rule: Strengthening Transparency in Regulatory Science

In addition, EPN also recommends that the SAB and the Clean Air Scientific Advisory Committee (CASAC) review and comment on how the proposed regulatory science rule, in concert with a May 9 EPA memorandum,¹ would work together to undermine the ability of EPA to produce, and CASAC to appropriately review, the full array of relevant scientific information, as well as the subsequent risk and policy assessments that up until now have been based on a peer reviewed scientific assessment. SAB and/or CASAC should examine these and other science and workload issues in the National Ambient Air Quality Standards (NAAQS) review process memorandum before the process is adopted in ongoing reviews.

¹ Pruitt, E.S. 2018. Memorandum: Back-to-Basics Process for Reviewing National Ambient Air Quality Standards, May 9. Online at <https://www.epa.gov/sites/production/files/2018-05/documents/image2018-05-09-173219.pdf>, Accessed May 18, 2018.

EPA's Transparency Proposal is a Solution in Search of a Problem

The proposal asserts that it is dealing with a “replication crisis”, 83 FR 18770. Setting aside the confusion introduced by using “replication” when the references cited in the supporting footnote are focused on “reproducibility,” and “reanalysis,” EPA offers no support for there being either a replication or reproducibility “crisis” in studies that have been used to support major decisions for EPA programs.² The proposal does not cite a single instance where a study used by EPA for any type of regulatory action (including ‘pivotal regulatory science’ used for major rules) was shown to be flawed due to a lack of access to the underlying data.

EPN supports the goal of increasing transparency in ongoing scientific research, as well as the practice of providing as much access to information from existing and older studies as possible, consistent with privacy issues and available resources. The core science/policy problem with EPA’s proposal is that it elevates what it calls “transparency” above all other attributes of a published study as a criterion for assessing its value. Thus, a study that has been replicated many times may be excluded from consideration, while one that uses an inferior data base that is publicly available would be considered. This preemption not only excludes existing studies with potentially important scientific and policy relevant insights, but would eliminate additional prospective studies that otherwise might continue to exploit some of the largest and/or most useful data sets that cannot be made fully public.

Defenders of this proposal point to a clause in the proposed rule that would allow the Administrator to grant exemptions to the general prohibition. The exemption as proposed seems to us as a fig leaf, trying to cover the fundamental flaw in the proposed rule. Nowhere in the proposal is an explanation of how the exemption provision would be administered. While the provision is permissive, providing that the Administrator “may” grant exemptions when compliance is impracticable, it provides no standards for identifying cases where EPA will or will not grant an exemption. This lack of standards for picking and choosing among cases where compliance is impracticable creates the potential for arbitrary application and is particularly troublesome in the context of a politically charged context. Critical decisions like these must be made on the basis of science, not politics. Otherwise highly relevant studies for which data cannot be publicly shared, even if published in the best peer reviewed journals, are judged to

² EPA ignores the fact that the two studies most often cited as a cause for concern about transparency (Dockery et al, 1993; Pope et al. 1995) were successfully *reanalyzed* and *reproduced* by an independent team of investigators (Krewski, D., Burnett, R.T., Goldberg, M. Hoover, K., Siemiatycki, J., Jerrett, M., Abrahamowicz, M. and White, W. H. 2000. “Investigators' report”. In *Reanalysis of the Harvard Six Cities Study and the American Cancer Society Study of particulate air pollution and mortality. Special report*, 7–244. Cambridge, MA: Health Effects Institute.).

Moreover, at last count the literature contains dozens of additional studies using different data sets and different investigators that *replicate* the essential findings of these two studies, (see e.g. Burnett. 2018; *Particulate Matter Reproducibility and Air Pollution Epidemiology*. Presentation to Health Effects Institute 2018 Annual Conference, Chicago, IL. April 30, 2018).

<https://www.healtheffects.org/cdn/farfuture/prvBPJ1viddR3LQlwQGszgOOZfSQnlK4WANcnfSePGQ/mtime:1525981635/sites/default/files/burnett-reproducibility-hei-2018.pdf>

be inherently untrustworthy – whether the reasons are privacy issues, agreements with subjects, or loss of data for older studies.

The entire process is wholly inconsistent with scientific practice and EPA’s use of science in regulatory decisions over the last four decades. Where studies with novel results appear, scientific assessments can note the lack of replication as a limitation, and in a number of cases EPA has made arrangements for reanalyses.³ EPA’s science, risk, and policy assessments are themselves peer reviewed by SAB panels and CASAC, to further ensure the evaluation of studies take place in context of the relevant scientific literature. It is particularly troubling here that EPA has not done any analyses of the potential impacts of the proposal on existing regulations or how widely it might affect key studies that support IRIS risk assessments, many of which are decades old, that are used to support regulations for multiple statutes. If anything, adopting this approach has the potential to create chaos and serve to decrease public confidence in the objectivity and credibility of EPA’s assessments of scientific information, as well as for decisions on future regulations and cost-benefit assessments.

It is therefore not surprising that many scientists and scientific publications, who otherwise may strongly support the benefits of increased data sharing for new scientific research, have rejected the proposal’s preemption of existing studies based on availability of raw data. Ioannidis, who EPA cites as supporting transparency, reacted strongly to the proposal in a PLOS editorial,⁴ noting that “If the proposed rule is approved, science will be practically eliminated from all decision-making processes. Regulation would then depend uniquely on opinion and whim.” Editors of several science journals whose policies and articles on data sharing were cited in the proposal issued a joint statement of the proposal stating that “It does not strengthen policies based on scientific evidence to limit the scientific evidence that can inform them; rather, it is paramount that the full suite of relevant science vetted through peer review, which includes ever more rigorous features, inform the landscape of decision making. Excluding relevant studies simply because they do not meet rigid transparency standards will adversely affect decision-making processes.⁵” And the Chartered SAB Workgroup has already correctly identified multiple specific scientific issues with the proposal that should be examined.

The leadership of the Agency was in such a rush to judgement that it did not provide a role for its own career scientific and science/policy experts in crafting the proposal or in

³ See D.S. Greenbaum, Bachmann, J.D., Krewski, D., Samet, J.M., White, R. and R.E. Wyzga, Particulate Air Pollution Standards and Morbidity and Mortality: Case Study. *American Journal of Epidemiology*, Volume 154, Issue 12, 15 December 2001, Pages S78–S90, <https://doi.org/10.1093/aje/154.12.S78>

⁴ Ioannidis JPA (2018). All science should inform policy and regulation. *PLoS Med* 15(5): e1002576. <https://doi.org/10.1371/journal.pmed.1002576>

⁵ Berg et. al (2108) Joint statement on EPA proposed rule and public availability of data. *Science* 04 May 2018: Vol. 360, Issue 6388, eaau0116DOI: 10.1126/science.aau0116. *Science, Nature, PLOS One, and Proceedings of the National Academy of Sciences.*

assessing its potential impacts, never included the rule in its regulatory agenda, did not notify or consult with the SAB, much less request a review of the draft proposal as required by law, did not solicit the advice of the National Academy of Sciences on provisions that would change dose-response models used in risk assessment from those previously recommended by the NAS, and did not ask for an interagency review to solicit the views of other Agencies that conduct research and/or use health effects science in developing policies and regulations.⁶ Finally, the Agency originally allowed only a 30 day comment period on this remarkable proposed departure from decades of past practice in the assessment and use of science, a period that would have closed one day before this long-scheduled meeting of the full SAB. This rushed and largely secret process illustrates a complete disinterest in transparency in the formulation of public policy, much less in science.⁷

The New Back to Basic NAAQS Process should go back to the drawing board

Both the process of developing the NAAQS process memorandum and some of its poorly considered prescriptions provide further evidence that the Agency is in a hurry to get results, regardless of the untoward consequences of mixing science and policy, as well as placing unreasonable burdens - some of which have nothing to do with establishing standards - on CASAC as well as EPA staff. In this case, the Administrator has set specific dates that may provide a clue to the reason for moving quickly on the transparency rule and the NAAQS. The memo targets the completion of reviews of the ozone and particulate matter (PM) standards as October and December of 2020, respectively.⁸

⁶ According to the revised dates on OMB's Reginfo.gov site, OMB received the draft proposal on Thursday April 19th and cleared it just four days later, on Monday April 23rd. Given the intervening weekend, there was no time for interagency discussion.

⁷ It is useful to contrast this process with the one EPA followed for a less far-reaching change in science/policy assessment that took place largely in 2006. The deputy Administrator requested a top to bottom review of the process of reviewing scientific criteria supporting the review and setting NAAQS and to make recommendations that would strengthen the process. It began with a workgroup that included experienced staff from both the research and air offices. They first consulted with CASAC and some other stakeholder and within three months wrote a report with conclusions and recommendations and an analysis of how the process could be completed in the mandated five years. This was followed by a public workshop involving stakeholders and public comments. EPA management made final decisions based on staff recommendations and CASAC and public comment and announced a revised process in December 2006. Some smaller changes were made based on EPA and CASAC experience with executing the process and issued in 2009.

EPA. Historical Information on the NAAQS Review Process <https://www.epa.gov/naaqs/historical-information-naaqs-review-process>

⁸ The memo's first principle for these reviews is meeting the statutory deadlines (every 5 years). While EPA has completed some reviews in 5 years, it has never met this requirement for all six criteria pollutants. That said, execution of this principle would require work to begin on the current carbon monoxide (2011) standard before ozone (2015), and lead (2016) after, as CO was last revised in 2011. Reviews for all other pollutants (PM, NOx, SOx) were either completed more recently, or are already in progress. Moving ozone and PM ahead of CO is an appropriate policy decision, but also an admission that the first principle cannot be met for all pollutants, even with the ill-advised streamlining procedures suggested in the memo.

The approach followed to make such substantial changes to the NAAQS Process mirrors that followed in the transparency proposal, and accordingly is also in stark contrast to the far more transparent and inclusive process that led to most recent, and largely successful NAAQS Review process we have today.⁶ The changes imposed or recommended in the Pruitt memo were developed without meaningful involvement by those EPA staff experienced in developing integrated scientific assessments, risk and exposure analyses, and policy assessment documents. This is evidenced both in the major recommendations, and in details in drafting specific portions. The memo announces that the entire process will be managed by the Office of Air, including the science assessment formerly managed by the Office of Research and Development. No draft of the approach was presented to the full CASAC committee for review. While it is good that the drafters did search for and cite selected pieces from past CASAC communications, this is no substitute for showing the revised process to the committee itself, before it was made final. In fact some of the points cited from these past letters were written regarding the 2006 -2009 process, and concerned issues that were addressed by the current process.⁹

The two most problematic aspects of the revised process both present issues with respect to 1) the Administrator's fourth principle, separating science and policy considerations in the review and 2) creating unreasonable expectations for EPA staff and relevant CASAC panels. The first of these flows from the major departures from the current process that are intended to streamline the production and review of key documents (Figure 1 in the memo). The statements specifying the need to sharpen the focus of the Integrated Science Assessment (ISA), Risk and Exposure Assessments (REA), and Policy Assessments (PA) are not different in scope and tone from the intent of the 2006 process review and recommendations. The major problems with streamlining the process flows from the specific prescriptions regarding the steps in producing and reviewing these documents.

The memo requires EPA to "consider combining its integrated science, risk and exposure, and policy assessment into a single review" (page 3). From a science and policy perspective, this is an astonishingly bad idea, one that is inconsistent with EPA staff or strongly CASAC comments on the matter¹⁰ made during the 2006 process. These documents are

⁹ An example is the quote from Dr. Henderson's May 12, 2006 letter to the administrator [https://yosemite.epa.gov/sab/sabproduct.nsf/WebCASAC/CASAC-05-12-06/\\$File/CASAC-05-12-06.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/WebCASAC/CASAC-05-12-06/$File/CASAC-05-12-06.pdf) (footnote 30 in the memo) regarding the need to exclude certain older studies that are not relevant to standard setting. In fact this issue was directly addressed in developing the 2006-2009 revised process that transformed the "compendium" approach used for criteria document to an Integrated Science Assessment that placed greatest focus on reviewing studies that had been published since the end of the previous review. Most importantly, beyond the novel approach used in developing a multipollutant ISA that combines Nitrogen and Sulfur Oxide welfare affects, the memo provides no evidence that supports its claim that, under the 2006-2009 process, "CASAC has frequently identified reducing the length and complexity of the ISA as a key process improvement for streamlining NAAQS reviews." In fact, such concerns *were* often raised about the older Criteria Documents.

¹⁰ The May 12 Henderson letter above states "the 'doubling-up' of the scientific subject matter to be covered at certain CASAC meetings (e.g., reviews of the draft Science Assessment and Risk Assessment documents at the same meeting and, at a subsequent meeting, the Risk Assessment and Policy Assessment documents) may even increase the number of CASAC meetings." The letter from former CASAC chair Roger McClellan on the process

intended to be logically sequential, each building on the one before. Producing them concurrently risks conflict with principle four, the separation of science and policy. It also would require an unreasonable effort by EPA staff produce these three documents simultaneously, and somehow create initial drafts independently of each other, coordinate them quickly, and be of such quality that they would require only a signal CASAC review for each. The CASAC panelists and interested members of the public would be required to review all three at the same time. This would place a significant burden on all panel members both before as well as during an extended public meeting. A concurrent preparation and review process for these documents would jeopardize the memo's goal of having only a single CASAC and public review for each document (page 9). For example, if CASAC found problems with the science or risk and exposure assessment, this might well require redrafting and review of the policy assessment, which depends upon both.

Without the kind of detailed timeline provided in figure 5 (see attachment A) of the 2006 EPA staff workgroup report,¹¹ it is difficult to assess the time the process illustrated in Figure 1 of the memo would provide for developing the three documents, as well as the time allotted for review. To insure higher quality for a single review, authors would need additional time, staff and contract resources, especially because the schedule planned for PM and ozone will contain significant overlaps, and in the early stages, the process to complete the ongoing reviews for other pollutants will continue. Is EPA budgeting for that time and resources?

EPA staff should now be developing schedules for following the new requirements. Before it goes too far down the path towards concurrent production of documents, EPA and CASAC should consider the kind of sequential process illustrated in Attachment A. As the Integrated Science Assessment is developed, staff could prepare a draft plan for conducting the Risk and Exposure Assessment, and if the first document is reviewed favorably, staff would be prepared to produce the first draft of the Risk assessment. A similar staggered approach would apply to the Policy Assessment Document, which depends on both. This would ensure each document could be produced with the certainty that the preceding one had undergone at least one peer review by CASAC. This would be more likely to provide better quality and appropriate separation of science and policy statements. The chance of meeting 5 year NAAQS schedule and obtaining CASAC conditional approval after a single review varies by pollutant. The growth of relevant research for ozone and PM over the past decade has been significant, as compared to that for some other pollutants. This increases the difficulty in identifying and assessing the recent literature for these two pollutants, as compared to pollutants such as sulfur dioxide,

(cited in footnote 38 of the memo as Attachment 3B) is even stronger, stating "A draft Staff Paper should never be released to CASAC and the public prior to the Criteria Document being finalized" and later, "draft Staff Papers should not be released until after the Criteria Document is finalized and the risk assessment is available." NAAQS Process Report, Attachment 3-B (March 2006) available at:

https://www3.epa.gov/ttn/naaqs/pdfs/naaqs_process_report_march2006_attachments.pdf

¹¹ EPA, 2006. Review of the Process for Setting National Ambient Air Quality Standards.

https://www3.epa.gov/ttn/naaqs/pdfs/naaqs_process_report_march2006.pdf

with fewer new health effects studies. A one size fits all process is unlikely to produce similar results in terms of the time required for each review.

Accordingly, CASAC should request that EPA provide detailed schedules for the process it intends to follow for ozone and PM, and the committee should review them as well as the process recommended in the memo, consider the inherent structural and workload issues, and provide the Administrator with more up-to-date comments and advice before the revised process is put into practice.

The second major problem area, requiring CASAC to provide to advice on background concentrations and the effects of implementing standards also raises issues of the appropriate separation of science and policy and placing additional burdens on staff and CASAC. Advice on natural and anthropogenic background is more straightforward, because the ISA needs to assess the relevant new science in this area, to support the risk and exposure assessment. This at least gives CASAC a summary of the scientific information needed to make statements regarding background. In fact, one of the CASAC letters cited by the memo has already provided unsolicited science and policy advice on ozone background¹² that EPA might well consider in deciding on regulation of methane emissions from the oil and gas industry, as well as continuing discussions with international partners in addressing long-range transport of air pollution.

Asking CASAC to respond to Section 109(d)(2)(C) requirements to evaluate adverse effects on health, welfare, social, economic, or energy effects of implementing standards is a more challenging undertaking. Doing a good job of evaluating the scientific information on these topics and their implications for improving implementation would require far more effort than has been traditionally required of either CASAC or the SAB. EPA has always believed scientific assessments of these issues is important, but EPA and Congress have traditionally looked to the National Academy of Sciences and interagency groups such as NARSTO to produce assessments that are relevant for improving air quality management. Some examples of such NAS reports include *Acid Deposition: Atmospheric processes in Eastern North America* (1983), *Rethinking the Ozone Problem in Urban and Regional Air Pollution* (1993), *Estimating the Public Health benefits of Proposed Air Pollution Regulations* (2002), *New Source Review for Stationary Sources of Air Pollution* (2006), and the landmark *Air Quality Management in the United States* (2004). These and other documents have provided important benchmarks for policies that range from new provisions in the 1990 Clean Air Act Amendments to EPA and

¹² The letter states: “Zhang et al. [2011] estimated that during spring-summer 2006-2008 the mean enhancement from intercontinental pollution and anthropogenic methane is 9 ppb at low-altitude sites and 13 ppb at high-altitude sites (>1,500 m elevation), both roughly one third of the North American background ozone in the respective areas.” (CASAC Review of EPA’s Second Draft Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards, EPA-CASAC-14-004 (June 2014). The letter goes on: “Given the significant portion of ozone coming from anthropogenic sources outside North America, the CASAC recommends that EPA seek opportunities for international cooperation to reduce long-range transport of ozone.”

states adoption of science-based multistate regional NO_x and SO_x programs, which have produced marked reductions in both ozone and fine particles, enabling more cost-effective implementation of these standards.

Producing this level of detailed assessment and analysis is beyond the capacity of traditional CASAC and SAB actions, which provide important guidance and insights through the process of reviewing documents provided by EPA, but do not provide extensive original assessments. Unless EPA intends to provide more comprehensive assessments than have been produced for past NAAQS Regulatory Impact Analysis (RIA), CASAC or SAB could not comply with all of the requirements regarding advice on such adverse impacts. EPA and CASAC should carefully consider the costs and benefits of the effort it would take to meet these requirements fully.

Even assuming that evaluating RIAs and/or implementation guidance documents would begin to meet some of these requirements, EPA needs to consider how better to structure any such reviews. The first issue is again separating CASAC review and recommendations on the NAAQS from reviews of RIAs and guidance that present information that should not be considered in deciding upon the standards. The memo takes a first step in this direction by requiring these reviews take place only after the NAAQS review and recommendations are completed. This is not enough. The Agency should have considered the recommendation in the June 2014 letter from CASAC cited in footnote 13, which stated: "In response to such a request, the SAB Staff Office would form an *ad hoc* CASAC panel to obtain the full expertise necessary to conduct such a review."

An *ad hoc* panel, whether housed in CASAC or the SAB, such as the former Advisory Council on Clean Air Compliance Analysis, which reviewed EPA cost benefit assessments of the Clean Air Act, would appropriately separate the individuals selected for their ability to review the relevant science and policy assessments and making recommendations the NAAQS from those with the expertise to assess either RIAs or EPA guidance documents for implementing standards. CASAC members who make recommendations on the standards should not play a role in the implementation review. Such an approach would also spread the burden for the additional steps involved in completing the review of the NAAQS and those subsequent reviews of analyses and guidance that cannot be used in setting the NAAQS.

A standing panel of experts that could serve needed reviews for implementation and related effects issues for all NAAQS reviews would provide an opportunity to broaden the use of available scientific insights. Over the past two decades, improved scientific information has made more-cost effective strategies possible. Policy makers at all levels now recognize the multipollutant nature of the criteria pollutants, with significant overlaps in terms of sources affected by sequential requirements for ozone, PM, CO, NO₂, and SO₂ as well as many hazardous pollutants. The memo cites an example of this recognition in footnote 22. This group could help guide policies that take better advantage of the multi-pollutant opportunities and tradeoffs. EPA might also consider a requesting a follow up to the NAS report on air quality management focused on these specific concerns.

EPA, CASAC, and SAB must go well beyond the level of detail provided in the NAAQS process memo in terms of how best to produce necessary documents and structure the SAB/CASAC to review them. Again, it is critical that CASAC take a strong role in reviewing the memo requirements, and how best to respond.

Beyond these two major issues, the idea of “one size fits all” charge questions seems at odds with the CASAC recommendations for focused charge questions referred to in footnote 24. While it is possible to start with some fundamental questions, CASAC is suggesting a greater focus, which almost certainly would require questions that pertain to issues that may be unique to a particular pollutant. An example of curious wording that staff might have corrected is the first question/bullet on page 6, regarding what new evidence suggests as to whether “NAAQS need to be revised or if an alternative level or form of these standards is needed...” This is not an either or question, as both alternatives are revisions. As an example, a more focused question might apply more a single pollutant than to all. For example, does the recent scientific information suggest the need for a new indicator and standard for ultrafine particles? This of course would depend on the first look at the available evidence. The more generic question provided in the list with respect to naming all of the key NAAQS values, including indicators, would cover that, but again, this does not provide the kind of focus that would help guide CASACS review. Beyond that, whether the last ‘generic’ question regarding adverse effects is asked at the same time and to the same group as the others bears some consideration in terms of separating the NAAQS review from the parts of the adverse effects related issues noted above.

Finally, EPA should carefully consider the practical difficulties in issuing implementation regulations and guidance simultaneously with promulgating revised NAAQS, given that the first step requires designations of nonattainment areas, a process that includes interactions with the states. The level of effort for and number of areas needing new designations can vary significantly for a range of standards under consideration, and EPA recently has shown difficulties in meeting the current statutory timelines for the 2015 ozone standards. This could present a significant problem for simultaneous release of designations and guidance, especially if EPA decides to develop such materials and enlist a CASAC panel to review them before the revisions are promulgated.

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Attachment A – Figure 5 from 2006 NAAQS Process Review Report – see next page.

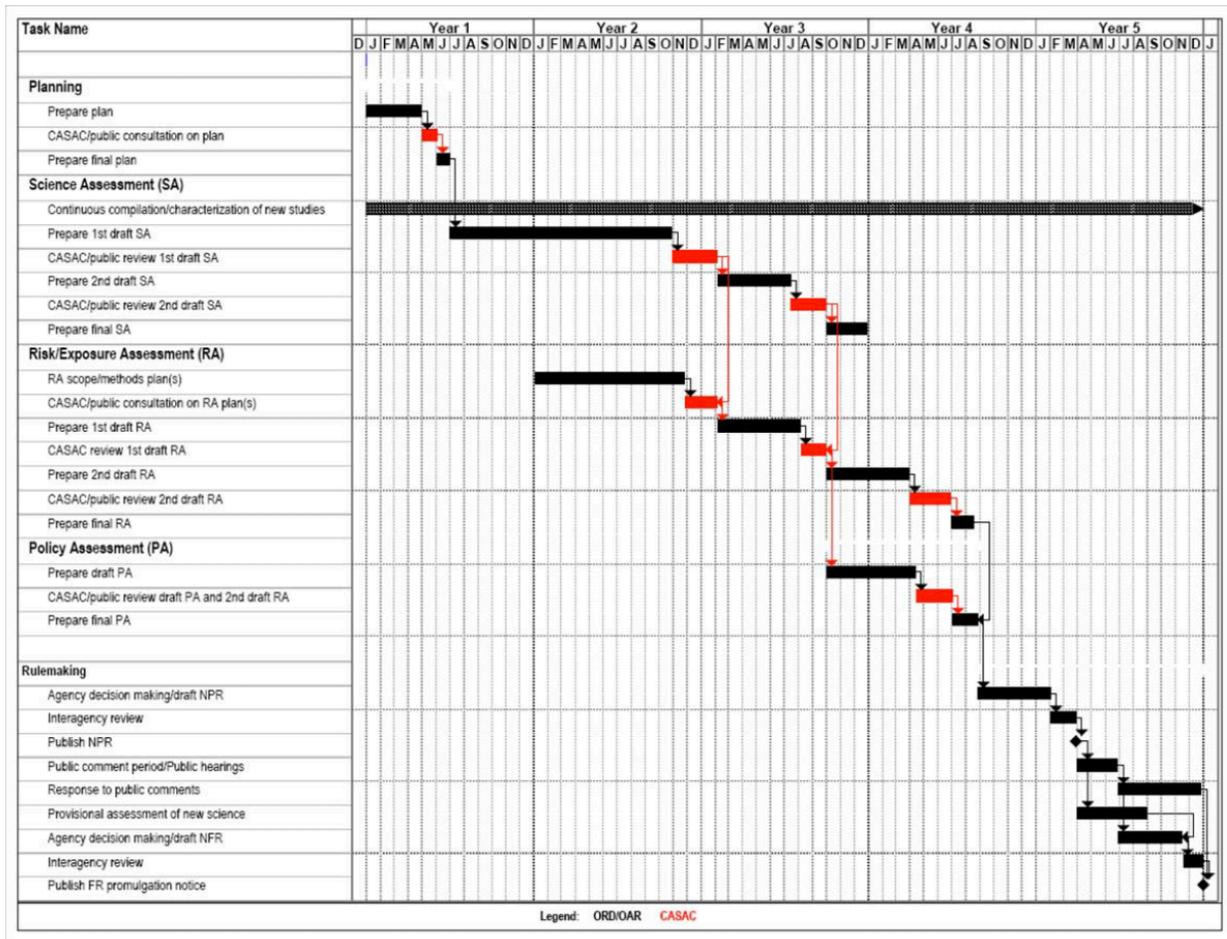


Figure 5. Timeline for Alternative NAAQS Review Framework

