



ENVIRONMENTAL PROTECTION AGENCY

[ORD-2022-0831; FRL-10465-01-ORD]

Call for Information on the Integrated Science Assessment for Oxides of Nitrogen—

Health Criteria

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice; call for information.

SUMMARY: The Environmental Protection Agency (EPA) is preparing an Integrated Science Assessment (ISA) as part of the review of the primary (health-based) National Ambient Air Quality Standards (NAAQS) for oxides of nitrogen. For gaseous oxides of nitrogen (i.e., oxidized nitrogen compounds), which also include nitric oxide (NO) and gases produced from reactions involving NO and NO₂, the primary NAAQS are specified in terms of nitrogen dioxide (NO₂). The ISA will be developed by EPA's Center for Public Health and Environmental Assessment (CPHEA) within the Office of Research and Development. When final, this ISA is intended to update the previous Integrated Science Assessment for Oxides of Nitrogen – Health Criteria (EPA/600/R-15/068, 2016), published on January 28, 2016 (2016 ISA). Interested parties are invited to assist EPA in developing and refining the scientific information base for the review of the primary NO₂ NAAQS by submitting research studies and data that have been published in the peer-reviewed scientific literature, accepted for publication, or presented at a public scientific meeting since May 15, 2015.

DATES: All communications and information should be received by EPA [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATON IN THE FEDERAL REGISTER].

ADDRESSES: Information may be submitted electronically, by mail, by facsimile, or by hand delivery/courier. Please follow the detailed instructions as provided in the section of this notice entitled **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: For information on the period of submission, contact the Office of Research and Development (ORD) Docket; telephone: 202-566-1752; facsimile: 202-566-1753; or email ORD.Docket@epa.gov. For technical information, contact Christine Alvarez; phone: 919-541-3881; fax: 919-541-5078 or email: Alvarez.christine@epa.gov, or Stephanie DeFlorio-Barker; phone 919-541-4621; fax: 919-541-5078 or email: DeFlorio-Barker.Stephanie@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Information About the Document

Section 108(a) of the Clean Air Act directs the Administrator to identify certain air pollutants which, among other things, “cause or contribute to air pollution which may reasonably be anticipated to endanger public health or welfare”;¹ and to issue air quality criteria for them. These air quality criteria are 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....”. Under section 109 of the Act, EPA is then to establish NAAQS for each pollutant for which EPA has issued criteria. Section 109(d)(1) of the Act subsequently requires periodic review and, if appropriate, revision of existing air quality criteria to reflect advances in scientific knowledge on the effects of the pollutant on public health or welfare. EPA is also required to review and, if appropriate, revise the NAAQS, based on the revised air quality criteria (for more information on the NAAQS review process, see <https://www.epa.gov/naaqs>).

EPA has established NAAQS for six criteria pollutants including oxides of nitrogen. Periodically, EPA reviews the scientific basis for these standards by preparing an ISA. In conjunction with additional technical and policy assessments conducted by EPA’s Office of Air

¹ Under Clean Air Act section 302(h), welfare effects include, but are not limited to, “effects on soils, water, crops, vegetation, manmade materials, animals, wildlife, weather, visibility, and climate, damage to and deterioration of property, and hazards to transportation, as well as effects on economic values and on personal comfort and well-being.”

Quality Planning and Standards (OAQPS), the ISA provides the scientific and technical basis for EPA decisions on the adequacy of the current NAAQS and the appropriateness of possible alternative standards.

Early steps in this process include announcing the beginning of this periodic NAAQS review and the development of the ISA, and EPA requesting that the public submit scientific literature that they want to bring to the attention of the Agency for consideration as it begins this review process. The Clean Air Scientific Advisory Committee (CASAC), whose review and advisory functions are mandated by section 109(d)(2) of the Clean Air Act, is charged (among other things) with independent scientific review of the Agency's air quality criteria. In conjunction with the CASAC review, the public will have an opportunity to review and comment on the draft ISA. These opportunities will be announced in the *Federal Register*.

The next ISA for Oxides of Nitrogen - Health Criteria will build on the 2016 ISA used in the previous review,² focusing on assessing newly available information. The public is encouraged to assist in identifying relevant scientific information for the review by submitting research studies that were not part of the prior review and have been published or accepted for publication in a peer-reviewed journal May 15, 2015. The Agency is interested in obtaining information from new and emerging toxicological studies examining the effects of controlled exposures to oxides of nitrogen in laboratory animals, humans and in-vitro systems, as well as epidemiologic (observational) studies examining associations between health effects and exposures to ambient oxides of nitrogen in human populations. In addition to studies that provide information on health outcomes, EPA also seeks recent information in other areas of research relevant to oxides of nitrogen such as sources and emissions, analytical methods, transport and transformation in the environment, and ambient concentrations. This and other

² The scientific assessment for the last review is documented in the Integrated Science Assessment for Oxides of Nitrogen – Health Criteria (Final Report EPA/600/R-15/068, 81 FR 4910, January 28, 2016).

literature relevant to a review of the primary (health-based) NO₂ NAAQS will be considered for inclusion in the assessment in the forthcoming ISA.

The Agency seeks information regarding the design and scope of the review of the air quality criteria to ensure that the ISA addresses key policy-relevant issues and considers the new science that is relevant to informing our understanding of these issues. The Agency also seeks new scientific information that may address key uncertainties identified in the last review of the primary NO₂ NAAQS, which are provided in the Policy Assessment (EPA-452/R-17-003, April 2017).³ Additional opportunities for submission of new peer-reviewed, published (or in-press) papers will be possible as part of public comment on the draft ISA that will be reviewed by the CASAC.

II. *How to Submit Technical Comments to the Docket at www.regulations.gov*

We encourage the public to submit comments to Docket ID No. ORD-2022-0831 by one of the following methods:

- The web at <https://www.regulations.gov>: Follow the on-line instructions for submitting comments.
- E-mail: Docket_ORD@epa.gov.
- Fax: 202-566-9744.
- Mail: EPA Docket Center, ORD Docket (Mail Code: 28221T), U.S. Environmental Protection Agency, 1200 Pennsylvania Ave., N.W., Washington, DC 20460. The phone number is 202-566-1752. Due to COVID-19, there may be a delay in processing comments submitted by mail.
- Hand Delivery or Courier (by scheduled appointment only): EPA Docket Center, WJC West Building, Room 3334, 1301 Constitution Avenue NW, Washington, DC 20004. The Docket Center's hours of operations are 8:30 a.m.–4:30 p.m., Monday–Friday (except

³ The 2014 Policy Assessment is available at:
https://www3.epa.gov/ttn/naaqs/standards/NO2/data/140501_pa_NO2_fin.pdf

Federal holidays).

Instructions: Direct your comments to Docket ID No. ORD-2022-0831. Please ensure that your comments are submitted within the specified comment period, so that EPA has adequate time to consider them. Comments received after the closing date will be marked “late,” and may not be considered if time does not permit. It is EPA's policy to include all materials it receives in the public docket without change and to make the materials available online at www.regulations.gov, including any personal information provided, unless materials include information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through www.regulations.gov or e-mail. The www.regulations.gov website is an “anonymous access” system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail directly to EPA without going through www.regulations.gov, your e-mail address will be automatically captured and included as part of the materials that are placed in the public docket and made available on the Internet. If you submit electronic materials, EPA recommends that you include your name and other contact information in the body of your materials and with any disk or CD-ROM you submit. CD-ROM and disks can only be accepted via UPS/FedEx/hand delivery and not through regular mail. If EPA cannot read your materials due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider the materials you submit. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA’s public docket visit EPA’s Docket Center homepage at www.epa.gov/epahome/dockets.htm.

Docket: Documents in the docket are listed in the www.regulations.gov index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other materials, such as copyrighted material, are publicly available only in hard copy. Publicly available docket materials are available either

electronically in www.regulations.gov or at EPA's Docket Center.

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