



Summary of Public Comments and Responses for EPA Guidance; Administrative Procedures for Issuance and Public Petitions

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List of Acronyms and Abbreviations

APA	Administrative Procedures Act
CFR	Code of Federal Regulations
CSV	Comma separated values
CWA	Clean Water Act
D.C.	District of Columbia
E.O.	Executive Order
EPA	U.S. Environmental Protection Agency
FCC	Federal Communications Commission
FDA	U.S. Food and Drug Administration
FOIA	Freedom of Information Act
FR	Federal Register
IRIS	Integrated Risk Information System
NESHAP	National Emission Standards for Hazardous Air Pollutants
OECA	Office of Enforcement and Compliance Assurance
OIRA	Office of Information and Regulatory Affairs
OMB	Office of Management and Budget
RCRA	Resource Conservation and Recovery Act
RFS	Renewable Fuel Standard
RTC	Response to comments
TRI	Toxics Release Inventory
U.S.	United States
U.S.C.	United States Code

1 General

The United States (U.S.) Environmental Protection Agency (EPA) received 64 comment letters to the docket on the proposed rule. Some significant comments and EPA's responses appear in the preamble to the final rule. This document contains summaries of all the public comments that the EPA received on the proposed rule and EPA's responses. In certain responses to comments summarized in this document, we note that our response is expounded in the preamble to the final rule. Copies of all comments submitted are available at EPA docket Center Public Reading Room. Comment letters are also available electronically through <http://www.regulations.gov> by searching Docket ID No. EPA-HQ-OA-2020-0128.

1.1 Support

Comment: Many commenters stated general support for the proposed rule, noting that the proposed rule will increase transparency and improve the way in which guidance documents are developed, issued, revised, and maintained by creating a standardized approach.

Commenters also stated support of a framework for issuance of guidance documents and significant guidance documents that promotes public participation.

Commenters stated that they believe these proposed changes will create an improved process for the EPA to gather the necessary public input from impacted stakeholders and help ensure a more equitable and beneficial guidance document that promotes compliance with existing regulations.

Several commenters supported EPA's proposed improvements to the guidance process that ensure the agency's guidance is considered non-binding. Commenters stated that while guidance documents are not binding, they can have significant impact on industry, and this proposed rule provides necessary clarity and transparency in line with Executive Order (E.O.) 13891.

Some commenters noted that the proposed rule adheres to the regulatory due process of the Administrative Procedure Act (APA). A few commenters noted that in previous administrations, guidance was used as a policymaking tool in order to avoid the requirements of APA regulatory due process which this will help avoid.

Several commenters that stated support for the proposed rule also offered specific suggestions for improvements to the rule, provided in comments in other sections of this document.

EPA Response: The EPA acknowledges the commenters' support for the proposed rulemaking. The EPA agrees that this rule will increase transparency and improve the process for issuing, modifying, and rescinding guidance documents. Specific suggestions for improvements are addressed in the relevant sections of this Response to Comments (RTC) document.

1.2 Oppose

Comment: Several commenters stated that they oppose the proposed rule.

A couple commenters stated that it will not promote transparency as the rule text suggests. One commenter stated that EPA should rescind the proposed rule and instead promulgate a rule that truly promotes transparency through public involvement in the development and assessment of guidance documents, in accordance with statutory grants of authority made to EPA.

One commenter stated that while many aspects of this proposal are conceptually sound, they do not require issuing a rule.

One commenter stated that the proposed rule could impede the ability to receive direction on statutory, regulatory, and technical matters.

A couple commenters stated that the proposed rule helps those who choose to destroy natural resources to make a profit and it limits the ability of citizens to complain, it puts an emphasis on rulings based on cost rather than the public good, and it seems to purposefully undercut the public benefit and fact-based science of the Agency.

Several commenters that stated opposition for the proposed rule also offered specific suggestions for improvements to the rule to establish procedures that are transparent and accountable, provided in comments in other outline headings.

EPA Response: The EPA disagrees with these comments. The EPA believes that this rule will increase transparency and improve the process for issuing, modifying, and rescinding guidance documents. Specific comments are addressed in the relevant sections of this RTC document.

2 Legal and Rulemaking Process Issues

2.1 EPA's Authority

Comment: Several commenters expressed their concerns regarding the EPA citing the Federal Housekeeping Statute as the legal authority for the proposed rulemaking. Some of their comments include:

- Federal Housekeeping authority cannot be applied to substantive rulemaking.
- Given the real-world impacts of the proposed rule, EPA has no power to promulgate it under the Federal Housekeeping statute.
- EPA has failed to provide how exactly the Federal Housekeeping Statute authorizes promulgation of the proposed rulemaking. EPA stated that the proposed rule is intended to “improve the internal management of the EPA.” Perhaps EPA is implying that because these regulations govern how EPA internally treats active guidance documents, the Federal Housekeeping statute is an additional source of authority. If this is the case, the agency is far off the mark.
- EPA would be mistaken in suggesting that this rule is simply a matter of “internal management” with no substantive effect. The proposed rule certainly has real-world substantive effects because it will determine which guidance documents remain active as well as their substance. Further, opening the guidance document assessment and promulgation processes to the public contradicts any claim that the proposed rule is merely a description of “internal management” with no substantive effect.
- The Federal Housekeeping Statute does not confer any authority on EPA to promulgate regulations because EPA is not an “executive department” within the meaning of the statute. Even if the Housekeeping Statute did confer authority on EPA, these rules exceed those authorities. The Housekeeping Statute authorizes limited “day-to-day office housekeeping in the Government departments,” not substantive regulations that create public rights and agency obligations.
- A typical housekeeping rule would govern purely internal agency procedures and practices. That is not what EPA is doing with this regulation, which establishes requirements that govern the development, use, and disclosure of guidance documents, and expressly requires that they be made available to the public and specifies how this must be done. It is explicitly intended for the benefit of external parties and not just to organize EPA’s internal activities.
- The rule establishes norms and imposes legal requirements concerning the development, availability, use, and modification of guidance documents affecting the public, and specifies what types of actions or practices can or cannot be announced through such guidance documents. It also spells out what guidance documents have or do not have any “legal effect.” On its face, it is clearly intended to affect the public. That is something that cannot be done using a housekeeping rule.

EPA Response: For the EPA’s response, see section I.C of the preamble to the final rule. The EPA disagrees with the assertion that some benefit to or effect on the public, such as transparency or predictability, turns this non-substantive rule into a substantive one. The EPA also disagrees that this rule exceeds its housekeeping authority. See *American Hosp. Ass’n v. Bowen*, 834 F.2d 1037, 1051 (D.C.

Cir. 1987) (“[A]gency rules that impose ‘derivative,’ ‘incidental,’ or ‘mechanical’ burdens upon regulated individuals are considered procedural, rather than substantive.”). The EPA believes this rule reasonably manages its internal affairs and does not conflict with its existing obligations.

This rule merely details methods for submitting certain petitions regarding guidance documents. See *JEM Broad. Co. v. F.C.C.*, 22 F.3d 320, 326 (D.C. Cir. 1994) (“the ‘critical feature’ of the procedural exception ‘that it covers agency actions that do not themselves alter the rights or interests of parties, although it may alter the manner in which the parties present themselves or their viewpoints to the agency.’”) (citation omitted); *James V. Hurson Assocs., Inc. v. Glickman*, 229 F.3d 277, 281 (D.C. Cir. 2000) (“[A]n otherwise-procedural rule does not become a substantive one, for notice-and-comment purposes, simply because it imposes a burden on regulated parties.”). Outside of the petition process, any additional procedures set forth by this rule are purely internal, such as content of guidance documents and delegated authority to issue significant guidance documents.

Comment: One commenter mentioned that the proposed rulemaking cites a hodgepodge of statutory authority, none of which is valid to allow EPA to fundamentally alter its process for determining which guidance documents remain active. The commenter noted that EPA incorrectly relied upon various statutory provisions stating the powers of the Attorney General of the U.S. (Freedom of Information Act (FOIA), Privacy Act of 1974, APA, 28 U.S. Code (U.S.C.) 509, 28 U.S.C. 510, 28 U.S.C. 534, 31 U.S.C. 3717) as support for the proposed rulemaking when said provisions clearly fail to authorize or proscribe any actions by EPA.

EPA Response: The EPA disagrees with the commenter’s assertions. The commenter references a summary of authorities that is relevant to the whole of 40 CFR. Part 2, which is a standard construction in the *Code of Federal Regulations* (CFR). This action, as proposed, would principally “Add subpart D[.]” The EPA clarifies that it does not assert that all of the authorities listed under Part 2’s “Authority” heading apply to Subpart D.

Comment: A few commenters noted that the proposed rulemaking illegally alleges that the proposed regulation will continue in effect if E.O. 13891 is revoked. Proposed §2.502(e) of the regulations states that this subpart remains in force if E.O. 13891, or any provision thereof, is rescinded or superseded. The commenters stated that this appears to be an improper attempt to tie the hands of future presidents who may wish to supersede provisions of this regulation so as to provide, for example, a broader definition of guidance document or provide greater public access to “former” guidance documents that have not been included in the EPA Guidance Portal.

EPA Response: EPA disagrees with this comment. EPA is promulgating this rule under its housekeeping authority, and this authority is not contingent on E.O. 13891. If E.O. 13891 is modified or revoked in the future, the Agency retains the discretion to amend or rescind this regulation.

Comment: One commenter stated that the proposed rulemaking would codify several E.O.s into a rule mandating that all guidance documents comply therewith. The commenter pointed out that EPA cited

no authority or rationale for doing this in the proposed rulemaking. The commenter also stated that the proposed rulemaking arbitrarily applies only E.O.s designed to elevate consideration of cost and the reduction of regulation over those focusing on protection of health, environmental justice, and environmental quality.

EPA Response: EPA disagrees with this comment. The regulation requires that significant guidance documents comply with E.O.s 12866, 13563, 13609, and 13891. EPA believes that compliance with these E.O.s—which direct the Agency to assess issues such as the potential impacts of significant guidance documents and the incentives of regulated parties—would benefit the public generally and improve the EPA’s process for implementing significant guidance documents. Such compliance would provide consistency with significant rulemakings, for which the EPA also makes such assessments. Further, as stated in the proposal, “[t]he EPA has not historically issued economically significant guidance documents (i.e., those that lead to an annual effect on the economy of \$100 million or more).”

Comment: One commenter noted that E.O. 13891 is deeply flawed and presents legally incorrect information and baseless accusations. Specifically, the commenter states that the E.O. suggests that agency rulemaking authority is legally suspect, that any “implicit threats of enforcement” are from the underlying regulation because guidance documents are not legally binding, that the APA does not require a public comment period for guidance documents, and that guidance documents do not set forth policy but rather explain the policy and encourage compliance.

EPA Response: The EPA agrees with the commenter’s observation that guidance documents are not legally binding. The EPA, however, disagrees that guidance documents never establish new policy. The interpretations of regulatory provisions included in EPA guidance documents can set forth new policies. Although the APA does not require notice and comment for guidance documents, the EPA has historically provided notice and the opportunity for public comment on guidance documents that may substantially impact stakeholders and that would benefit from public input.

2.2 Deviation from Procedures

Several commenters expressed concerns regarding §2.502(f), which states that “[t]he Agency may deviate from the procedures in this subpart, if necessary, at the written direction of the Administrator. The decision to deviate from the procedures in this subpart is in the Administrator’s sole and unreviewable discretion.” Some of their concerns include:

- This provision turns the regulation into a sham, such that the Administrator can choose to rely on guidance which has not been placed in the EPA Guidance Portal, or equally to ignore guidance which has been placed in the EPA Guidance Portal.
- This absolute discretion to avoid the regulations, coupled with the proposed rule’s disclaimer that it does not create any private right or benefit, mean that there appears to be no consequence for the Agency’s failure to follow the procedures. The proposed authority to disregard the guidance procedures without threat of challenge could provide some benefit, in that EPA would be able to issue or modify significant guidance documents in an expedited fashion when circumstances require such swift action.
- The notion that EPA could ignore its own regulation without explanation runs counter to the fundamental principle of administrative law. EPA should include in the final rule a requirement that the Agency at least explain a decision to deviate from the rule’s procedures.
- The benefits of the proposed rule—transparency and certainty—would be greatly diminished by the Administrator’s sole discretion to “deviate” from the guidance procedures.
- The proposal painstakingly outlines the process, requirements and procedures for creating, sharing and petitioning for the modification or withdrawal of guidance documents, yet provides the Administrator with sole discretion to deviate from the procedures. The commenter finds this troubling, as it undermines the very purpose of the rule in the first place – to increase the transparency of EPA’s guidance practices and improve the process used to manage EPA guidance documents.
- §2.502(f) negates the entire purpose of the proposed rulemaking and is arbitrary and capricious. Issuing a rule but allowing the EPA Administrator to “deviate” from it at his or her whim renders it fatuous.

Another commenter suggested that adhering to a defined process provides a higher likelihood of consistency through this and future administrations.

EPA Response: For the EPA’s response, see section III.F of the preamble to the final rule and section 2.6 of this response to comment document.

2.4 Procedural Rulemaking

Comment: One commenter supported the Agency's decision to voluntarily seek input, even though this is a rulemaking regarding agency procedure and thus exempt from notice and comment under 5 U.S.C. §553(b)(3)(A).

Another commenter questioned whether the proposed rule is indeed "a rule of agency organization, procedure, or practice that lacks the force and effect of law" that is therefore exempt from the notice-and-comment requirements under the APA, 5 U.S.C. §553(b), (c). The commenter stated that the proposed rule would have substantive effects and urged EPA to treat the proposed rule as subject to the APA's notice-and-comment requirements and to take the comments into account when crafting the final procedures.

EPA Response: EPA agrees that it is valuable to seek public input, even though it is not required under the APA for procedural rules. For the EPA's response, see section I.C of the preamble to the final rule and section 2.1 in this response to comment document.

2.5 Rulemaking Process

Comment: One commenter stated that EPA should finalize the rule expeditiously, as it will provide regulated entities with EPA's interpretations of regulatory requirements to which they are subject, consistent with the principles of due process and fair notice.

A couple commenters stated that more discussion is warranted between EPA and the regulated community on this important rule, with one commenter stating that EPA should engage with states in advance of the final rule.

One commenter requested that EPA re-propose a document that would address commenters' issues before moving forward with this initiative.

EPA Response: The EPA disagrees that the final rulemaking should be delayed. Implementation of this final rule will promote transparency and consistency in the issuance, modification, and rescission of EPA guidance documents. Additionally, E.O. 13891 directs agencies to finalize regulations setting forth processes and procedures for issuing guidance documents within 300 days of the date on which the Office of Management and Budget (OMB) issued their memorandum implementing the E.O., which corresponds to the date of August 28, 2020. To the extent that commenters recommend additional public notification or public comment opportunities, the EPA retains discretion to exceed the minimum procedures required in this regulation for guidance documents on a case-by-case basis, where deemed appropriate.

2.6 Scope

Comment: One commenter suggested that it is important for EPA to include a clear general duty statement or clause in §2.502 “Scope” that the objective of these procedures in EPA’s development and management of guidance documents is to provide non-binding clarifications to existing obligations. The commenter stated that not doing so would create the risk of misinterpretation that EPA is allowed to create new and enforceable requirements through guidance, which would lead to consequential outcomes adverse to the central policy of E.O. 13891. The commenter recommended adding “All guidance documents managed by EPA under the procedures herein are provided as non-binding clarifications to existing obligations and do not create enforceable requirements” to the end of §2.502(d) and adding “Within the scope of Executive Order 13891” to the beginning of §2.502(f).

EPA Response: The EPA disagrees that it is necessary to include a general duty clause in these procedures. The procedures already require that each guidance document include a disclaimer that the guidance document is non-binding (except in situation where binding guidance is authorized by law or because the guidance is incorporated into a contract). Further, the EPA notes that this rule, absent Agency action, would remain in force even if E.O. 13891 were rescinded or modified. See also EPA’s response in section 2.1 of this response to comment document and section III.F of the preamble to the final rule.

Comment: One commenter noted that the proposed rulemaking would limit the applicability of the guidance procedures to “to all active guidance documents as defined in this subpart, issued by all components of the EPA after [date of issuance for the final rule].” The commenter stated that limiting the scope of the regulations is both necessary and reasonable, but the regulatory text as proposed is problematic.

EPA Response: For the EPA’s response, see section III.E of the preamble to the final rule.

Comment: One commenter requested that the EPA clarify §2.502(a) . This provision is unclear because it provides a cross reference to the E.O. rather than actually listing the documents excluded by the E.O. The commenter stated that §2.502(a) should be revised to state that the relevant exclusions are listed in the §2.503 definition of “guidance document.”

EPA Response: The EPA agrees that proposed §2.502(a) was unclear and has revised that provision accordingly. In the revision, the provision explicitly cites to the definition of guidance document in this regulation. However, the EPA disagrees that it is inappropriate to provide any cross reference to E.O. 13891, as the cross reference provides additional useful information regarding the exemptions.

3 Definitions

3.1 Guidance Document

Comment: Several commenters provided strong support for EPA’s definition of “guidance document.”

One commenter noted that the proposed definition of “guidance document” is consistent with the targeted approach under E.O. 13891, which is to include only guidance that is “intended to have future effect on the behavior of regulated parties.”

A couple of commenters expressed their concerns that the definition of “guidance” does not provide complete clarity as to what guidance is and which documents EPA considers guidance. One commenter requested that EPA fully specify which existing documents, such as letters used to implement broad policy changes, are considered “guidance.” They stated that this would enhance stakeholder certainty and confidence in the Agency’s processes.

EPA Response: For the EPA’s response, see section III.A of the preamble to the final rule.

Comment: One commenter noted that the definition of “guidance document” could be interpreted to only apply to guidance that applies to regulated parties, not States. The commenter requested that EPA revise the definition to say “an Agency statement of general applicability, intended to have future effect on the behavior of regulated parties or the States or Tribes, that sets forth a policy on a statutory, regulatory, or technical issue, or an interpretation of a statute or regulation.”

Another commenter requested that EPA clarify that a guidance document intends to provide a guide, or suggestions, on how regulated parties should comply with a legal requirement.

EPA Response: For the EPA’s response, see section III.A of the preamble to the final rule.

Comment:

A few commenters recommended that EPA revise the proposed §2.503 to create three or more categories of EPA guidance documents, such as:

1. Significant Guidance, which already has a proposed definition,
2. Important Guidance that Does not Meet the OMB Office of Information and Regulatory Affairs (OIRA) definition of “significant impact” that EPA intends to place on the EPA Guidance Portal; and
3. Other technical program guidance, such as case-by-case applicability determinations, flow charts, and implementation tools that are produced by EPA’s program offices.

EPA Response: For the EPA’s response, see section III.A of the preamble to the final rule.

Comment: One commenter noted the importance that all guidance documents be subject to the proposed rulemaking. The commenter added that EPA Offices should not be given an incentive to avoid procedures by labelling guidance in some other way.

EPA Response: For the EPA's response, see section III.A of the preamble to the final rule. The EPA agrees in the importance of properly labeling guidance documents. As noted in the proposal preamble, the EPA issues non-binding guidance using a variety of methods and formats. Any document that satisfies the definition of "guidance document" in this regulation would qualify, regardless of name or format.

Comment: One commenter asked if EPA were to establish separate policies for the issuance of pre-enforcement documents, how would these documents be defined? Several commenters stated that EPA has not indicated whether they are considering separate policies for the issuance of pre-enforcement rulings, agency statements of specific applicability, or other documents that are excluded from the EPA Guidance Portal. The commenters stated that they are concerned that the absence of such documents will reopen existing requirements contemplated under permits, corrective actions, and other matters of environmental compliance and create substantial uncertainty. One commenter requested clarification on how EPA will make a distinction between guidance documents and pre-enforcement documents. The commenter stated that this needed to prevent confusion among stakeholders.

EPA Response: The EPA is not establishing separate policies for specific types of guidance documents in this regulation. To the extent that any particular document (regardless of what it is termed as or called) satisfies the definition of "guidance document" in this regulation, the document would be subject to these procedures. This regulation does not modify the procedures for documents that do not meet this definition. For the EPA's final definitions, see section III.A of the preamble to the final rule and §2.503 in the regulatory text.

3.1.1 Exclusions from Definition of Guidance

Comment: Many commenters asked EPA for further clarification on the §2.503 subsection 7 exemption included in the proposed “guidance document” definition, which exempts agency statements of circumstance-specific applicability that are directed to particular companies. Specific comments include:

- EPA should be able to provide responses of specific applicability posed by regulated parties. This agency correspondence, though exempt from being guidance, should not create new obligations that are inconsistent with the underlying applicable law and regulatory record.
- In issuing situation-specific guidance, the Agency must define the applicable general principles of law, regulation, or policy that are applied in the fact-specific situation. Therefore, situation-specific guidance can be as much a source of generally applicable guidance as a “general” guidance document.
- States would like clarification on whether guidance on interactions between states and EPA like the memo, Enhancing Effective Partnerships Between the EPA and the States in Civil Enforcement and Compliance Assurance Work, would be excluded from the proposed rulemaking.

One commenter stated their support for the 11 categorical exceptions in the proposed definition of “guidance documents.” The commenter noted that EPA appropriately recognized that documents reflecting individualized determinations are not “guidance” and should not be subject to notice-and-comment requirements.

Another commenter noted that proposed §2.503(5) which excludes guidance “directed to...other agencies that is not intended to have substantial future effects on the behavior of regulated parties” from the definition of “guidance document” is insensitive to the needs of implementing agencies and is arbitrary.

One commenter recommended that guidance documents issued along with a legislative rulemaking should be excluded from the definition of “guidance document.”

EPA Response: Although the final rule provides some minor clarifications regarding the exclusions from the definition, the EPA disagrees that further clarifications are needed regarding specific applicability. This regulation does not modify the procedures for documents that do not meet the definition of guidance document in this regulation, and the EPA will continue to use the same process that it currently uses for notifying regulated entities of responses of specific applicability. To determine the status of a guidance document excluded from the EPA Guidance Portal, the public is encouraged to contact the EPA program office or regional office that issued the guidance document. In addition, if a member of the public believes that a guidance document (as defined in this regulation) was improperly rescinded, these procedures allow them to petition the EPA to reinstate it.

3.1.2 Science Documents

Comment: One commenter recommended that the definition of “guidance document” should not exclude scientific or technical determinations.

One commenter recommended that EPA should state that scientific guidance documents are not covered by this rule or include on the EPA Guidance Portal all scientific guidance that the agency has relied on to develop rules, standards, permits or other guidance documents since 2008, and allow the public to review such list.

EPA Response: For the EPA’s response, see section III.A of the preamble to the final rule.

Comment: One commenter suggested that EPA direct the Office of Research and Development to consider Integrated Risk Information System (IRIS) values as guidance covered by this Proposed rulemaking.

One commenter stated that IRIS values would meet the proposed definition of “significant guidance.”

Another commenter noted that in the EPA Guidance Portal, EPA’s Office of Research and Development listed 12 guidance documents. The commenter stated that this number seems low, seeing as how there are 568 individual chemical assessments in the EPA IRIS. The commenter requested that this omission be corrected. They also recommended that references to specific IRIS values in the EPA Guidance Portal contain disclaimer language required in §2.505.

EPA Response: For the EPA’s response, see section III.A of the preamble to the final rule.

Comment: One commenter agreed with EPA that health advisories are appropriately considered guidance with regards to the proposed rulemaking.

One commenter specifically requested that EPA address Clean Water Act (CWA) Section 304(a) water quality criteria document as part of this proposed rulemaking. The commenter stated that it is unclear if they would qualify as “significant guidance” or even “guidance” under the proposed rulemaking. The commenter noted that these criteria often have significant ramifications for the clean water community and effectively function as the type of “guidance” addressed by the proposed rulemaking.

EPA Response: For the EPA’s response, see section III.A of the preamble to the final rule.

3.2 Significant Guidance Document

Comment: Many commenters expressed their support of the definitions of “significant guidance document.”

A few commenters recommended clarification on how EPA will identify a guidance document is or is not significant. One commenter suggested that EPA include a provision to explain their process for determining a guidance document is “significant.” Another commenter asked for clarity on the definition by using the preamble to cite examples of existing guidance that meets the criteria of “adversely affect in a material way the economy...”

A handful of commenters recommended that EPA allow the Administrator the discretion to decide unilaterally that a guidance document is significant and deserving of public notice, comment, and agency response. One commenter mentioned that EPA should be able to identify guidance as significant even if it may not meet the dollar threshold.

EPA Response: The EPA disagrees that revisions are necessary to the definition of significant guidance document. As noted in the preambles to the proposed and final rules, the EPA will seek significance determinations from OIRA for guidance documents pursuant to E.O. 12866, as appropriate. See also EPA’s response at section III.C of the preamble to the final rule.

Comment: Several commenters suggested that EPA explain in the final rulemaking how a guidance document may “lead to” a significant economic impact.

EPA Response: The definition of significant guidance document referenced in the proposed rule’s preamble is consistent with the one used in E.O. 13891, which, in turn, is closely related to the definition used in OMB’s 2007 “Final Bulletin for Agency Good Guidance Practice.” (72 FR 3432, at 3434; January 25, 2007.) OMB notes that the definition in the Bulletin closely tracks E.O. 12866’s general definition but is better suited for the non-binding nature of guidance. As such, the prefatory language in E.O. 13891 makes clear that the impacts of guidance often will be more indirect and attenuated than binding legislative rules. Although a guidance document itself may be non-binding, it could indirectly lead to actions voluntarily taken by the private sector or cause a change in behavior, which could have an economically significant impact.

3.2.1 Significance Criteria and Interagency Review

Comment: A couple of commenters recommended that, with regards to the “significant guidance documents” definition, the regulatory text should list the criteria for a guidance document to be labeled “significant” rather than incorporating the definitions in E.O.s 13891 and 12866 by reference. The commenter stated that this change would make the regulations clearer and more readily understandable to the public.

One commenter requested that EPA expand the definition to include guidance that ““may reasonably be anticipated to” “(v) have a substantial impact, including but not limited to: (I) setting forth initial interpretations of statutory or regulatory requirements, (II) setting forth changes in interpretation or policy that are of more than a minor nature, (III) including complex scientific or technical issues, or (IV) covering highly controversial issues.”

Another commenter noted that EPA should provide clarification on how a guidance document would qualify as “significant,” since the E.O. definitions are broad and vague. The commenter stated that, for example, the definition of “significant guidance document” would include guidance that “adversely affect[s] in a material way the economy,... the environment, [or] public health or safety.” The commenter stated that this language is vague due to no additional clarification or explanation of what constitutes a “material” or “adverse” effect, since environmental policies inherently implicate the economy, the environment, and public health.

A couple of commenters requested clarification on what “material” mean in the context of the definition. One commenter questioned how EPA would determine a “material” effect and recommended that EPA define “material” broadly to allow the agency to solicit public comment on any guidance document that would benefit from stakeholder review and input. The same commenter also questioned what it means for a guidance to “adversely” affect each element of the definition.

One commenter recommended that EPA should adopt the U.S. Food and Drug Administration (FDA)’s triggers for notice and comment on draft guidance, rather than the “significance” criteria in E.O. 12866, because the FDA’s criteria are more specifically oriented toward the circumstances when guidance documents can create problems.

EPA Response: Regarding expanding the criteria for significance, the EPA disagrees that the criteria should be revised in the regulatory text, as the regulation is clear that OMB makes the determination pursuant to E.O. 12866 and its criteria. Further, referencing E.O.s 12866 and 13891 in the definition of significant guidance document allows for consistency and efficiency of inter-government practices and procedures. Regarding adopting expanded criteria for notice and comment, the EPA further disagrees that EPA should adopt FDA’s criteria triggers for public notice and comment. The criteria are sufficiently similar to the criteria in E.O. 12866 in terms of which EPA guidance documents are likely to be deemed significant. Notwithstanding the requirement for notice and comment for significant guidance, EPA would have the authority to seek comment on any document that the Agency determines would benefit from public input and would do so when appropriate. See also EPA’s response at section III.C of the preamble to the final rule.

Comment: A few commenters stated their support of the OIRA review of guidance. The commenters stated that this will contribute to more consistency across EPA and other agencies ultimately benefiting the regulated community who often comply with requirements from multiple regulatory agencies.

One commenter recommended that EPA should make publicly available the criteria that will be used to determine which documents will be subject to OIRA review. The commenter stated that EPA should also clarify whether EPA or OIRA's determination as to significance will determine whether notice and comment will be offered. The commenter also requested that EPA make any correspondence with OIRA publicly available.

EPA Response: The EPA agrees that the criteria used to determine significance should be publicly available and consistent, which is why the final rule continues to cite to E.O. 12866. Further, the final rule is clear that all significant guidance documents are required to provide public notice and comment opportunities, unless it meets one of the "good cause" exemptions, which are expected to be rare. Finally, section 6(a)(3)(E) of E.O. 12866 directs agencies to identify for the public, in a complete, clear, and simple manner, the substantive changes between the draft submitted to OIRA for review and the action subsequently announced and to identify for the public those changes that were made at the suggestion or recommendation of OIRA.

3.3 Active Guidance Document

Comment: The commenter stated that, first, the term “active guidance document” is undefined and inconsistent with the language of E.O. 13891.

EPA Response: For the EPA’s response, see section III.A of the preamble to the final rule.

3.4 Rescinded Guidance Document

Comment: One commenter stated that EPA should clarify what it means for a guidance document to be “rescinded” or “in effect,” as neither term is expressly defined in the proposed rule or explained in the preamble and clarifying would ensure that the public understands which guidance documents have legal effect. The commenter stated that EPA should clarify that a “rescinded” guidance document is a guidance document that is not included on the EPA Guidance Portal, and means that EPA cannot “cite, use, or rely on” it as explaining regulatory requirement, but may rely on such documents to be cited as establishing historical facts. The commenter stated that EPA should clarify that a guidance document “in effect” is one that meets the proposal’s definition of “guidance document” and is included in the EPA Guidance Portal, and thus means that EPA may cite it.

EPA Response: For the EPA’s response, see section III.A of the preamble to the final rule.

4 Identification of EPA's Active Guidance Documents

4.1 EPA Guidance Portal

Comment: Many commenters stated that they support the Agency's decision to maintain a consolidated online portal for all active and effective guidance. Commenters appreciated the EPA Guidance Portal and stated that placing all active EPA guidance documents into a single online repository is a constructive step toward clarifying Agency policies and will promote regulatory compliance. One commenter stated that the EPA Guidance Portal will be especially helpful for smaller businesses with limited resources and personnel for regulatory compliance.

One commenter stated that because the EPA Guidance Portal is public, it affects how the agency provides notice to the public of documents it will use or rely on in actions affecting the public. One commenter noted that publishing guidance documents in a centralized location will ensure stakeholders have full view of Agency guidance and will support transparency, as those seeking to understand how EPA interprets or applies a complex requirement will be able to easily find relevant guidance documents.

Many commenters provided suggestions for EPA to improve the EPA Guidance Portal.

- Several commenters stated that EPA should break the guidance documents into issue, statute, regulation, or program areas as well as EPA offices, and provide a link to the relevant program pages.
- Several commenters stated that the EPA Guidance Portal should improve the search function, such as making it searchable by document name, original issuance date, topic, key terms, and by specific regulatory provisions. One commenter suggested EPA create a more complete set of indices (not just the current "topic" attribute), which are needed to allow users to find the most current and relevant guidance.
- Several commenters stated that EPA should highlight linkages to statutory authority, regulatory text, and companion guidance and should cross reference all guidance documents to the regulations and programs they impact.
- A couple commenters suggested that once the EPA Guidance Portal has been brought up to date and the rule is finalized, EPA should issue an additional notice through the Federal Register (FR) for stakeholders to review the EPA Guidance Portal for functionality improvements and to identify guidance documents that may be missing. One commenter stated that EPA should include a transition period for applying the EPA Guidance Portal requirements.
- One commenter suggested that EPA offer a downloadable Excel file that can be used to view and organize all the guidance documents within an EPA Program Office, as some of the older comma separated values (CSV) files are in inconsistent data formats.
- One commenter stated that the EPA Guidance Portal should be searchable without having to download a CSV file.
- One commenter suggested linking from the EPA Guidance Portal to specific websites housing guidance documents as a temporary measure to ensure guidance is not inadvertently rescinded via exclusion.

- One commenter said that EPA should eliminate the separate web listing of “significant guidance documents,” which was required by OMB’s 2007 Final Bulletin for Agency Good Guidance Practices, as all of these documents should be included in the EPA Guidance Portal.
- One commenter stated that the current chronological order hierarchy based on date of issuance is inadequate, and a better hierarchy of guidance needs to be in place to identify related documents.
- One commenter suggested EPA keep a record of inactive guidance documents.
- One commenter suggested that EPA consolidate all guidance documents into a single platform. One commenter stated that EPA should add flags to the guidance documents if they are “new” or “changed/updated.”
- One commenter stated that the agency should not update the summary of the guidance it proposes to include for each guidance document to explain the document’s status, but to post a link to an ongoing proceeding concerning the document.
- One commenter stated that EPA should identify a contact person on the EPA Guidance Portal who might be able to provide more information for the public after review of a guidance document.
- One commenter stated that the rule should require specific improvements to EPA’s existing database of guidance documents to ensure ongoing access to those materials for the regulated community.
- One commenter stated that the lack of clarity about what documents the rule would apply to could be a serious problem in implementing the EPA Guidance Portal.

EPA Response: For the EPA’s response, see section III.B of the preamble to the final rule.

4.1.1 Miscellaneous Comments on Active Guidance and EPA Guidance Portal

Comment: One commenter requested that EPA confirm in the final rulemaking the applicability of E.O. 13891, which states an agency may not cite a document presenting the Agency's interpretation of a rule unless it (1) is designed to guide the conduct of the broader public, and (2) appears on the web portal.

One commenter stated that EPA should confirm in the final rule that, pursuant to the E.O., an agency may not cite a document presenting the Agency's interpretation of a rule unless it is designed to guide the conduct of the broader public and appears on the web portal.

EPA Response: The EPA agrees with the importance of providing clear definitions in the final rule. Thus, the EPA is clarifying some of the proposed definitions and adding definitions of "active guidance document" and "rescinded guidance document." Additionally, the preamble to the rule is clear that the Agency may not cite, use, or rely on any guidance document as defined in this rule, that is not posted on the EPA Guidance Portal, except to establish historical facts.

Comment: One commenter stated that they oppose making the EPA Guidance Portal the only source of "guidance" on its website (rather than through program specific websites).

EPA Response: For the EPA's response, see section III.B of the preamble to the final rule.

Comment: One commenter stated that if the Guidance Portal and the procedures within this rule are used to revoke guidance that has not been formally replaced, it could end up creating more confusion for regulated entities and stakeholders rather than helping to resolve it.

EPA Response: For the EPA's response, see section III.C of the preamble to the final rule.

4.2 Guidance Not on the EPA Guidance Portal

Comment: One commenter stated that they support the prohibition on EPA's ability to "cite, use, or rely on" guidance documents not included on the EPA Guidance Portal.

One commenter requested that EPA clarify the statement on the guidance website that, "[t]he agency may not cite, use, or rely on any guidance that is not posted on this web area, except to establish historical facts," only applies prospectively and is non-binding. The commenter further states that the intent of this rule is not to invalidate previous EPA decisions because guidance used in reaching those decisions is not on the EPA Guidance Portal.

EPA Response: For the EPA's response, see section III.B of the preamble to the final rule.

Comment: One commenter stated that they believe EPA creates significant legal risk by purporting to categorically rescind all existing guidance documents that are not included on the EPA Guidance Portal. The commenter added that it is well established that an administrative agency may not revise or rescind an existing rule (including an "interpretive rule," such as the guidance covered by the proposed rule) without providing a "reasoned explanation" for its action (citing *FCC v. Fox*, 566 U.S. 502 (2009)). The commenter stated that categorical rescission of any guidance document not included on the EPA Guidance Portal would be arbitrary and capricious. The commenter recommended that EPA revise the final rule to provide that existing guidance documents cannot be categorically rescinded and that any decision to rescind an existing guidance document must be based on findings specific to that document.

EPA Response: This rule does not categorically rescind existing guidance documents or require any document to be rescinded. Established in conformance with E.O. 13891, which directs federal agencies to make active guidance documents available via an online guidance document portal, the EPA Guidance Portal first became available to the public on February 28, 2020. This rule sets forth the procedures for posting active guidance documents and notes that guidance documents, as defined in this rule, not posted on the EPA Guidance Portal would be deemed rescinded. This rule does not make determinations, categorical or otherwise, regarding the rescission of any guidance document. This final rule requires all future active guidance documents to be placed on the EPA Guidance Portal, which will increase transparency regarding the future issuance, modification, and rescission of guidance documents and benefit regulated entities and stakeholders by clarifying which guidance documents are active and in effect. Nothing in this rulemaking would change the EPA's discretion to evaluate whether any specific guidance document should continue to be considered active or should be superseded or rescinded, consistent with historical practice.

Comment: One commenter stated that EPA should clarify the legal significance of documents of various types that are included on the EPA Guidance Portal and that are not.

One commenter stated that they are concerned that EPA failed to include many important guidance documents in its initial listing of "active" guidance documents and believe EPA should be over-inclusive in its initial listing so that no essential guidance gets accidentally rescinded. One commenter stated that the EPA Guidance Portal appears to contain guidance documents that seems to no longer be relevant (e.g., "Guidance for [Renewable Fuel Standard] RFS 2011 Annual Compliance Reporting"), creating confusion as to what is considered "active" guidance.

EPA Response: For the EPA’s response, see section III.B of the preamble to the final rule.

Comment: Commenters stated that E.O. 13891 limits agency use of guidance documents unless they are posted to the EPA Guidance Portal, but the use of guidance documents by non-agency parties is not limited in the same way. The commenters stated that EPA should clarify when and the manner in which the regulated community may continue to rely on documents providing the Agency’s views on a matter even if they do not fit the definition of “guidance document” and are not included in the EPA Guidance Portal. Commenters stated that since any guidance document excluded from the EPA Guidance Portal will not represent final guidance of the Agency and have “no effect,” it affects the Agency’s ability to cite, use, or rely on the documents in public actions.

EPA Response: For the EPA’s response, see section III.A of the preamble to the final rule and section 4.1.1 of this response to comment document.

Comment: One commenter requested that EPA extend the June 27 deadline by which existing guidance will be rescinded, allowing at least enough time to see if guidance that was submitted to EPA in the spring is included in the updated database.

One commenter stated that EPA should allow the regulated community to continue to suggest adding or removing guidance documents up until this rule is final and published in the FR.

EPA Response: The EPA agrees that additional time beyond the initial deadline in E.O. 13891 was warranted to ensure that the EPA Guidance Portal contained all active guidance documents. The EPA fully populated the EPA Guidance Portal on July 31, 2020.

4.2.1 List of Rescinded Guidance

Comment: A couple commenters urged EPA to address rescission of guidance documents in a transparent manner and clearly explain the process to “rescind” guidance. Commenters stated that they are concerned with potential confusion over the impact of being listed (or not listed) in the EPA Guidance Portal and that EPA must clarify what is being included on its list of “active” guidance.

Commenters stated that EPA should include two new sections on the EPA Guidance Portal for documents that EPA has determined not to be a “guidance document” and for guidance documents that are rescinded. One commenter stated that it will be difficult for an interested party to ascertain the status of a document because the proposed rule provides no mechanism for determining the status of an unlisted document. One commenter stated that such listings would significantly improve the usefulness of the EPA Guidance Portal when determining if a document had been rescinded. One commenter suggested that it could be a list of select documents to streamline the process (e.g., those that EPA knows have broad interest or in response to a request from an interested party), while another stated that a list would be helpful even if not comprehensive.

EPA Response: For the EPA’s response, see section III.B of the preamble to the final rule.

Comment: One commenter stated that previously released guidance should not be excluded from the database without formal documentation identifying why it was rescinded.

EPA Response: The EPA disagrees that formal documentation is necessary to identify why any particular guidance document was rescinded. Such a requirement would go beyond E.O. 13891 and EPA believes that this rule already provides greater transparency regarding active guidance documents. These procedures do, however, provide that the EPA would provide the opportunity for public review and comment if the Agency proposes to withdraw a significant guidance document, including via publication in the FR. See also the EPA’s response at section III.B. of the preamble to the final rule and section 4.4.1 of this response to comment document.

4.2.2 List of Documents Not Meeting Definition of Guidance Document

Comment: One commenter stated that EPA should include two new sections on the EPA Guidance Portal for documents that EPA has determined not to be a “guidance document” and for guidance documents that are rescinded. The commenter noted that a document that appears to many interested parties to be a guidance document may not be included on the EPA Guidance Portal because EPA has decided that it is not a guidance document. The commenter stated that in such cases, it will be difficult for an interested party to ascertain the status of the document because the proposed rule provides no mechanism for easily determining the status of an unlisted document. The commenter stated that a list of documents determined to not meet the guidance document definition, even if not comprehensive, would be helpful.

One commenter also provided example categories of exclusion for a guidance document from the database: Rescinded guidance (i.e., it conflicts with other active guidance), Inactive guidance (i.e., the regulation or issue is no longer germane), Does not meet the definition of guidance document, Not applicable/Review not required.

One commenter stated that EPA needs to provide information on how it will treat documents that are excluded from the definition of “guidance document,” as well as how a user will be able to identify if a guidance document has been intentionally excluded or just not entered into the EPA Guidance Portal yet. The commenter stated that if EPA excludes guidance, such as EPA’s New Source Review Reactivation Policy which is not on the EPA Guidance Portal, it must make clear whether it still intends to rely on such documents. The commenter added that if EPA plans to rely on documents not included on the EPA Guidance Portal, they must create and publicize a way for the public to learn about these documents that are intended to guide EPA and implementing agencies’ decisions.

One commenter requested that EPA clarify whether guidance that has been noticed in the FR is exempt from Database listing or not. The commenter stated that if they are not, all the documents in those tabulations should be added to the Database.

One commenter recommended clarifying that supporting rule information, such as Background Information Documents, which are excluded from the definition of “guidance document” are still active but excluded from the EPA Guidance Portal.

One commenter stated that based on the definition of “guidance document,” scientific guidance would not be included. The commenter stated that if EPA intends to treat all scientific documents not posted on its EPA Guidance Portal as rescinded, EPA must provide notice of any such scientific guidance documents that it believes are covered by the proposed definition, and a justification for why they are rescinding them without discussion.

EPA Response: For the EPA’s response, see section III.B of the preamble to the final rule.

4.2.3 Specific Document(s) not on EPA Guidance Portal

Comment: Several commenters noted that EPA had not included all guidance documents that should be in the EPA Guidance Portal, with some noting specific documents excluded. A couple commenters stated that many guidance documents associated with technical issues were excluded. Commenters asked that EPA take time to find and add the missing guidance documents or clarify why they were not included. One commenter noted that the absence of some documents in the EPA Guidance Portal creates uncertainty about the status of documents on which industry has previously relied. Several commenters noted that their internal reviews found that some guidance documents from a program were included while others were not, without clear reasoning. One commenter stated that they had submitted guidance documents to be posted to the EPA Guidance Portal, but they had not yet been posted. One commenter urged EPA to consider whether notices of violation and other such notices related to specific facilities could be posted on the EPA Guidance Portal.

Several commenters noted that as the rule is written, it would void any guidance document omitted from the EPA Guidance Portal, even if done so unintentionally. The commenters stated that since there is not a list of documents excluded from the EPA Guidance Portal, EPA should establish a mechanism by which the public can identify any missing guidance documents so EPA can determine if they were accidentally omitted or create a petition process for the agency to reconsider their exclusion of a document.

One commenter stated that it is unclear if EPA's existing databases of guidance documents for the Resource Conservation and Recovery Act (RCRA) and Toxic Release Inventory (TRI) will remain as standalone resources or be folded into the new database. One commenter stated that EPA should maintain and continue to update EPA programmatic websites for the policy and technical assistance to regulated entities and other members of the public.

31 **EPA Response:** For the EPA's response, see section III.B of the preamble to the final rule.

4.3 Public Notification for Guidance Added or Removed from the EPA Guidance Portal

Comment: A couple commenters supported EPA's proposed process for using notifications on the EPA Guidance Portal or other Agency website to inform the public that a new guidance document has been issued, an active guidance document has been modified, or an active guidance document has been withdrawn.

Many commenters expressed support for public notification in the event an active guidance document is modified or withdrawn. The commenters requested that notices be provided to the public via the EPA Guidance Portal. Another commenter mentioned that EPA could use a "flag" in the EPA Guidance Portal when a document has been updated or withdrawn, which would allow stakeholders readily note a "change" in a document.

EPA Response: For the EPA's response, see section III.B of the preamble to the final rule.

Comment: A couple commenters suggested that the Agency create and operate a federal listserv for electronic notifications regarding the addition and removal of guidance documents to and from the EPA Guidance Portal. The commenters stated that this would provide members of the public with the most up-to-date information about the status of EPA guidance documents. Another commenter recommended that EPA use the FR in conjunction with the listserv to notify the public when new guidance documents have been added, modified or withdrawn. The commenter stated that EPA should have flexibility to use the notification mechanism that is appropriate to the agency action on guidance documents, such as using the FR for the issuance of a new guidance document, but a modification could be noticed at the EPA Guidance Portal or related list serve.

One commenter stated that EPA should consider designing the database to allow the public to register for future notifications when specific guidance documents are modified or withdrawn.

One commenter stated that they already rely on the Office of Enforcement & Compliance Assurance's (OECA) quarterly Applicability Determination Index postings of new National Emission Standards for Hazardous Air Pollutants' (NESHAP) applicability determinations in the FR. They added that, depending on the volume of notices the Agency anticipates, it may be sufficient for EPA to simply to place a "notice" that a new guidance has been added, revised, or withdrawn with a link rather than be "batched" like the OECA notices. The commenter also suggested the Agency create an index with links for recently published determinations in the last six months on their website.

EPA Response: For the EPA's response, see section III.B of the preamble to the final rule.

Comment: One commenter recommended that EPA put in place a formal process to manage obsolete and superseded guidance documents, similar to the existing EPA process for RCRA Online documents. The commenter stated that when a stakeholder searches for a particular RCRA document, a summary page shows up indicating whether the document has been superseded. The commenter stated that establishing a clearer process for managing guidance documents would help to eliminate confusion for stakeholders and the general public, especially for guidance documents automatically deemed withdrawn even if the guidance was omitted by oversight.

Another commenter recommended EPA maintain a historical record of the prior versions of modified, replaced, or withdrawn guidance. Historical records would be useful in explaining why past decisions were made.

EPA Response: The EPA disagrees with these comments because such additional processes would be duplicative and cumbersome.

Comment: Several commenters recommended that state regulatory programs should be directly notified through EPA Headquarters program offices or EPA Region staff when the agency is considering developing, modifying, or revoking guidance.

Several commenters suggested that EPA utilize email notifications to alert users of any additions or changes to guidance documents on the EPA Guidance Portal. Commenters suggested that the EPA Guidance Portal could allow email alert triggers on certain guidance documents or EPA could establish an e-mail distribution or listserv, so that interested parties could be notified when their followed documents are updated or withdrawn. One commenter stated that this could be done on a document-by-document basis in batches on a periodic basis.

Several commenters recommended public notices should be made via a FR notice. One commenter suggested a simple FR notice with a link to EPA's webpage. Another commenter noted that guidance documents not deemed significant should be announced through a FR notice on a periodic basis.

EPA Response: For the EPA's response, see section III.B of the preamble to the final rule.

4.4 Procedures for Determining Active Guidance

Comment: One commenter stated that the preamble caused confusion regarding procedures for significant guidance versus “other” guidance documents and recommended that EPA denominate the two categories of guidance that will appear on the EPA Guidance Portal early on in the rule.

One commenter stated that EPA should provide the opportunity for public comment on the withdrawals, citing EPA’s Proposed Guidance Procedures Rule as an example.

One commenter stated that EPA has no authority to repeal guidance documents without notice and comment.

EPA Response: For the EPA’s response, see section III.B of the preamble to the final rule.

Comment One commenter inquired whether EPA would have a concurrence process, similar to that for a significant guidance document receiving concurrence from the corresponding Presidentially-approved EPA official, before making the decision to exclude documents from the EPA Guidance Portal.

One commenter stated that EPA should add an internal agency process to assure that any final guidance placed on the EPA Guidance Portal is an interpretative rule and not a legislative rule and describe how they will endeavor to not place legislative rules on the EPA Guidance Portal.

EPA Response: The EPA disagrees that the additional processes suggested by the commenters would be appropriate as they go beyond the requirements of E.O. 13891 or that it would be necessary or appropriate to establish such a process through regulation. Further, all guidance documents (as defined in this regulation) will be required to have a disclaimer regarding its non-binding nature.

5 Requirements for Guidance Documents

5.1 Elements Included in Guidance Documents

Comment: Several commenters stated that all proposed criteria to include in guidance documents are appropriate and should be finalized. The commenters stated that the requirements are clearly identifiable to the public and supports E.O. 12891's goal of providing regulatory transparency.

One commenter stated that the inclusion of standard elements for both types of guidance documents will improve the ability to both read and understand the information provided.

Many commenters agreed that guidance documents as defined by E.O. 13891 should be nonbinding and the guidance document should include a disclaimer up front in the document. The commenters added that the disclaimer should state that the contents of the guidance document are non-binding and "do not have the force and effect of law and that the guidance does not bind the public in any way." One commenter suggested that the disclaimer may not be sufficient enough and EPA may need an internal forcing mechanism well-beyond a disclaimer to help ensure that a rulemaking is not "masquerading as guidance."

Several commenters agreed that agencies should refrain from using mandatory language, such as "shall," "must," "required," or "requirement," in guidance documents to formulate policy changes and should instead reserve such language for notice and comment rulemakings.

A few commenters stated that all forms of guidance should only be used to clarify existing obligations.

One commenter stated that there should be a section (or sections) in a guidance document that provides reference to and citations for any statute, regulation, or court decisions on which guidance document relies.

EPA Response: For the EPA's response, see section III.C of the preamble to the final rule.

Comment: One commenter recommended that the guidance document identify a responsible EPA official for each guidance, including a name, email address, and telephone number. The commenter also suggested that EPA provide a short summary at the end of each guidance document with a list of the modification dates of the guidance and a list of the changes made at each modification.

One commenter recommended that when identifying the office issuing the document, the name of other EPA offices that collaborated and provided input on the Guidance document should be included.

Another commenter recommended EPA to adhere to the Plain Writing Act of 2010, which calls for federal government departments and agencies to exercise writing that is clear, concise, and well-organized.

EPA Response: For the EPA's response, see section III.C of the preamble to the final rule.

5.2 Concurrence on Guidance Issued by EPA Regional Offices

Comment: Many commenters noted that the proposed criteria that all guidance documents issued by a Regional Office receive concurrence from the corresponding Presidentially-appointed EPA official at EPA headquarters is appropriate. The commenters stated that this would promote consistent application and interpretation of EPA regulations nationwide by ensuring that headquarters officials have an opportunity to vet and approve regional guidance. One commenter mentioned that that regional offices seem to be unduly independent of EPA Headquarters so this approach would minimize unnecessary divergence among Regions.

Several commenters requested that §2.505(b) of the proposed rule should be changed to provide that all guidance documents must receive a signature by a “...relevant Assistant Administrator or an official who is serving in the acting capacity) at EPA headquarters who is responsible for administering the national program to which the guidance document pertains.” The commenters stated that the extra signature would provide assurance that Regional administrators could not be adopting separate guidelines that are not in line with the policy of the Agency.

One commenter recommended that the final rulemaking should specify that the Assistant Administrator may delegate approval authority to other relevant officials in his or her office.

Another commenter opposed this proposed requirement because it facilitates political influence over policies that should be based on statutory obligations and principles of good governance, and not influenced by political judgments. The commenter stated that this top-down approach could prove to be damaging by limiting the authority of those with the best understanding of a given region’s needs.

One commenter noted that having to go through senior management at EPA Headquarters prior to issuing regional guidance would add an unnecessary delay in addressing pressing matters affecting human health and the environment.

EPA Response: For the EPA’s response, see section III.C of the preamble to the final rule.

5.3 Public Comment for Non-significant Guidance

Comment: Several commenters stated that EPA should provide an opportunity for public comment on all guidance documents, not just those defined as “significant,” as they can contain complex, technical, and detailed information as well. Commenters stated that EPA should make clear in the final rule that agency management has discretion to allow public comment on non-significant guidance if warranted. The commenters also noted that the vast majority of guidance documents would be posted on the EPA Guidance Portal without the opportunity for public notice, as many are not defined as “significant.”

One commenter stated that additional transparency, stakeholder and scientific review and discourse, and public input in the criteria development process is needed for guidance documents that are not deemed “significant.”

One commenter stated that limiting public participation to only significant documents places many small businesses at a disadvantage. The commenter added that providing the public an opportunity to provide input on all guidance that is not clearly instructional or clarifying in nature could ensure the guidance that EPA develops and relies on does not blur the lines between general interpretation and mandatory requirement.

EPA Response: For the EPA’s response, see section III.C of the preamble to the final rule.

5.4 State Engagement and Federalism

Comment: One commenter requested that EPA meet with states in the spirit of cooperative federalism to discuss in greater detail the scope and intent of this rulemaking, and EPA should consider the unique and distinct role that states play in implementing guidance in authorized and delegated programs.

One commenter noted that when EPA partners and collaborates with states, better regulations are drafted, superior policy is created, duplication is curtailed, national consistency is improved, necessary flexibility is incorporated, unintended consequences are avoided, greater certainty is realized, legal challenges are minimized, and the public is much better served.

One commenter noted that state environmental agencies are co-regulators with EPA and requested that states have the opportunity for early, meaningful, and substantial involvement in developing the content of relevant guidance documents.

EPA Response: For the EPA's response, see section III.A of the preamble to the final rule.

Comment: One commenter stated that they urge EPA to revise the proposed rule to expressly distinguish states and state officials from the general public and to provide states with opportunities to engage with EPA officials, on a government-to-government basis, beyond the public comment process.

EPA Response: For the EPA's response, see section III.C of the preamble to the final rule.

Comment: One commenter stated that the rule should also expressly require EPA officials to engage in proper state consultation as part of the development, modification, and rescission of agency guidance documents.

EPA Response: The EPA agrees that proper state consultation is important. The EPA will continue to satisfy all its federalism requirements per E.O. 13132 for future guidance documents, as it has done historically.

Comment: One commenter disagreed that this regulation does not have federalism implications. The commenter stated that it is incorrect that the rule "will not have substantial direct effects on the states," because guidance documents frequently contain instructions as to how state and local agencies are to interpret statutes and regulations. The commenter added that determining which guidance documents are "valid" and in effect will impact states and local agencies in how they do their work.

EPA Response: The EPA disagrees that this regulation has federalism implications, as defined in E.O. 13132. This is a rule of agency procedure and practice, which governs the activities of EPA staff only. As such, it does not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Further, it does not impose substantial direct compliance costs or preempt state or local law. However, the EPA acknowledges the dual role of States, which can be either regulated entities or co-regulators.

Comment: A couple commenters recommended that EPA should discuss whether states with delegated authority will be afforded flexibility to make their own determinations regarding the future effect of documents excluded from the EPA Guidance Portal.

One commenter asked if states with delegated authority will have to abide by EPA's definitions and processes on guidance documents. The commenter asked if states could be "more stringent" under RCRA by adhering to guidance documents that EPA has rescinded.

EPA Response: For the EPA's response, see section III.A of the preamble to the final rule.

5.5 Other Comments on Guidance Procedures

Comment: Another commenter expressed concerns that the proposed rulemaking, as currently designed, could have the effect of discouraging the use of guidance. The commenter noted that guidance provides important benefits, including:

- It helps to ensure that the Agency acts consistently from case to case and across regions.
- It helps to ensure that program staff use the best scientific information currently available.
- It allows the Agency to address regulatory issues at a far greater level of detail than would be possible in rules, and without being overly prescriptive because of the greater flexibility inherent in guidance or policy.

This commenter also expressed concerns that this proposed rulemaking will have the effect of making the process of issuing guidance as time-consuming and burdensome as rulemaking. The commenter explained that the rulemaking would largely undermine the value of guidance and its advantages in allowing the agency to act more quickly than the rulemaking allows.

EPA Response: Although the EPA agrees with the important role of guidance documents, the Agency disagrees with the commenter that the procedures in this regulation would discourage the development and use of guidance documents. The intent of this regulation is not to discourage guidance but rather to ensure that they have increased transparency and consistency.

Comment: One commenter requested that EPA clarify what is meant by “appropriate review” when the proposed rulemaking states that the purpose is to ensure EPA’s guidance documents are developed with appropriate review.

EPA Response: Appropriate review, as used in the background section of the preamble to the proposed rule, refers to the new procedures provided in this regulation.

Comment: A couple of commenters recommended that EPA should develop guidance documents for new rules as close to finalization of the rule as possible. The commenters stated that this would minimize misunderstandings about implementation and compliance.

One commenter suggested that EPA commit to either finalize or retract every proposed guidance document within a year, so that draft guidance documents do not persist indefinitely.

EPA Response: The EPA disagrees with this comment. As there is substantial variability in the types and complexity of the thousands of EPA guidance documents, it is neither feasible nor reasonable to require a specific timeline for the finalization of every guidance document issued by the Agency. However, the EPA works to finalize all guidance documents as expeditiously as practicable.

Comment: Another commenter recommended that proposed rulemaking be revised to require a transparent and accountable process for EPA officials to determine whether a particular agency policy or

decision may be properly communicated through a guidance document, or whether such action is subject to more formal procedural requirements under the APA.

EPA Response: The EPA disagrees that additional process is necessary to ensure that the Agency uses guidance documents appropriately. The process suggested by the commenter would be duplicative and cumbersome to implement.

6 Requirements for Significant Guidance Documents

6.1 Notice and Public Comment requirement

Comment: Several commenters stated that they support EPA’s proposal to provide public notice and comment opportunities for significant guidance. Commenters stated that the public comment procedures are reasonable and would allow for stakeholders, including regulated entities, to offer insight to EPA on the most impactful guidance documents before they are issue, modified, or withdrawn. One commenter stated that EPA should make comments on guidance documents publicly available. Another commenter stated that the public comment provisions do not unduly burden EPA and can potentially speed up EPA’s policy-making process by clarifying issues rather than waiting for the final document to be challenged.

One commenter added that the proposed procedures for issuing significant guidance, including clear public notice and an opportunity for comment, would add a level of transparency and public inclusion that have been missing in the past when EPA issued significant guidance.

One commenter stated that EPA could use the comments from the public comment process to identify potential shortcomings before significant guidance is finalized.

One commenter stated that a change to or rescission of an existing significant guidance document should not be treated differently from a public notice standpoint than issuance of a new significant guidance document, since both can have substantive impacts.

Another commenter stated that EPA should make clear that while new significant guidance documents will be proposed through a notice and comment process, the new guidance will not create binding legal obligations on regulated entities.

One commenter stated that EPA should keep in mind that any significant guidance that goes through notice-and-comment moving forward must only clarify existing obligations and cannot confer any new obligations on regulated entities.

One commenter stated that EPA should not establish “new” policy or make a “change” in policy that could have nationwide impacts without obtaining public input.

EPA Response: For the EPA’s response, see section III.D of the preamble to the final rule.

Comment: One commenter stated that if “significant” is defined too broadly, the Agency could be deterred from providing any guidance at all to avoid the resources it must commit to public notice, internal Administrator approval, and responding to comments. The commenter added that an impracticably broad application of the notice-and-comment procedures can generate regulatory confusion by blurring the lines between guidance and rulemaking and can be counterproductive by imposing all the requirements of a rulemaking without the benefit of its legal certainty. The commenter stated that certain guidance documents may benefit from swift issuance, and waiting for public feedback, and developing the required response, would be unreasonable.

EPA Response: For the EPA’s response, see sections II.C and III.D of the preamble to the final rule.

Comment: One commenter stated that EPA should limit their response to comments on draft guidance documents to the “major concerns” specified in E.O. 13891.

A couple commenters stated that the proposed rule states that EPA is required to respond to “major” public concerns and comments when finalizing significant guidance document but does not define what constitutes as “major.” The commenters stated that EPA should define “major” in the rule, or at least address it in the preamble.

One commenter stated that EPA’s response to public input should be focused on key issues, not a detailed administrative record of the kind created for rulemaking. The commenter stated that the public comment process should be designed to maximize the value of input, without creating a highly formalized process similar to rulemaking.

EPA Response: For the EPA’s response, see section III.D of the preamble to the final rule.

Comment: One commenter stated that in addition to noticing draft significant guidance documents in the FR, the proposed regulation should require EPA to directly notify State environmental protection agencies, either by email or mail, of any draft significant guidance documents.

EPA Response: For the EPA’s response, see section III.D of the preamble to the final rule.

6.1.1 Announcement in Federal Register

Comment: Several commenters stated that they support the proposed process for a public review and comment opportunity for all significant guidance documents, whether that document is new or a modification or withdrawal of an active guidance document, through the FR. The commenters noted that this formal process aids in transparency. One commenter stated that the distribution mechanisms for FR notices are robust and not replicable in another system.

One commenter stated that providing notice of draft and final significant guidance document issuance, modification, or withdrawal via the EPA Guidance Portal would ultimately support a more streamlined and effective approach to giving notice of guidance. The commenter added that providing notice *via* the EPA Guidance Portal would be consistent with E.O. 13891 and the OMB Implementing Memorandum.

EPA Response: For the EPA's response, see section III.D of the preamble to the final rule.

6.1.2 30-day Comment Period

Comment: Some commenters stated that they supported a comment period of at least 30 days given the potential impact the guidance document could have on regulated industries.

Several other commenters stated that EPA should not limit the length of the comment period to just 30 days, as it would be insufficient to ensure adequate stakeholder involvement.

Some commenters suggested changing the minimum comment period to 60 days, while others suggested changing the comment period length based on the guidance document topic.

EPA Response: For the EPA's response, see section III.D of the preamble to the final rule.

6.2 Exceptions from Notice and Comment Requirement

Comment: Several commenters recognized there are instances when it is essential for EPA to be able to issue regulatory guidance quickly and that they support the public health, safety, environmental, or other emergency exception proposed.

One commenter stated that they are concerned the proposed emergency exception to the public comment process is too vague and would allow the agency to declare an emergency to address long-term policy goals. The commenter suggested revising the proposed exemption from public notice requirements to clarify it applies only to guidance issued for emergency purposes and must be timely, targeted, and temporary.

Several commenters stated that the exemption for significant guidance of “good cause” exemption should not be in the final rule as it is separate from an emergency, not defined, and decreases transparency. The commenters are concerned that it would allow the Administrator to suspend public input for an open-ended “good cause” and too many significant guidance documents may be created under “good cause.”

One commenter stated that what constitutes public health, safety, environmental, or other emergencies requiring immediate issuance of guidance documents should be defined, thus allowing the agency flexibility to respond to emergencies while curtailing abuse of the exception to implement long-term policy changes through guidance.

One commenter stated that EPA must ensure that these exceptions are exercised transparently so that the public is aware if a guidance document has been deemed “significant,” but will not be subject to the process EPA has set up for significant guidance documents.

One commenter stated that EPA should be required to post the guidance that was subject to the exemption to the EPA Guidance Portal with an explanation for why they suspended notice and comment response procedures. The commenter added that EPA should then retroactively allow for notice and comment and respond to all public comments.

EPA Response: For the EPA’s response, see section III.D of the preamble to the final rule.

6.3 Approval of Significant Guidance

Comment: One commenter stated that they think it is important for the EPA Administrator or other Presidentially-appointed EPA official, or an official who is serving in an acting capacity of either of the foregoing, be required to approve each significant guidance document before it is issued and posted on the EPA Guidance Portal as this promotes more accountability within the agency. Another commenter stated that requiring a high-level official's approval prior to new guidance taking effect promotes accountability.

A couple of commenters questioned the need for the EPA Administrator "or other Presidentially-appointed EPA official" to weigh in on guidance documents. The commenters suggested that EPA clarify that companies can continue to seek guidance from EPA staff on regulatory and compliance questions without having it potentially politicized.

A couple commenters opposed the requirement that a guidance document be pre-approved by a political official. The commenters stated that the requirements would reduce the flexibility of the Regions, increase the time it takes to implement guidance, and would create a top-down approach and reduce the control of regional officers. One commenter stated it would facilitate political influence over policies that should be based on statutory obligations and principles of good governance.

EPA Response: The EPA agrees that it is important that significant guidance documents be approved by the EPA Administrator or other Presidentially-appointed EPA official, as directed by E.O. 13891, and has clarified in this rule that this approval shall occur on a non-delegable basis.

7 Procedures for Public to Petition

7.1 Petition Process for Withdrawal or Modification of Guidance Documents

Comment: Several commenters supported the process of being able to petition the agency to modify or withdraw an active guidance document. One commenter noted that petitions can help the agency be made aware of existing guidance that is of concern to impacted stakeholders.

One commenter suggested that the section on the procedures for the public to petition for modification or withdrawal should be removed from the rulemaking. The commenter noted that petitions would provide too much authority and influence to corporate and industry lobbyists to further capture the regulatory and enforcement processes.

One commenter stated that the petition process could be abused or overwhelmed by duplicative petitions submitted as part of mass petitioning efforts. The commenter suggested that EPA should develop an automated process to identify unique requests and treat mass petition efforts as a single request.

One commenter recommended that EPA include periodic review requirements in the final rulemaking that would require the Administrator to periodically evaluate the effectiveness of the petition process.

One commenter suggested that EPA should consider limiting petitions on a guidance document to only those parties that are directly affected by the guidance document. Allowing anyone to petition a guidance document could tie up EPA resources and make it harder to publish new or modified guidance that are meaningful and necessary or withdraw existing guidance that is no longer applicable.

Another commenter recommended that EPA should consider the resource implications regarding responding to many petitions.

One commenter requested clarification or confirmations that the petition process will be applied both to new guidance documents issued after EPA finalizes this rulemaking and existing guidance documents in use right now.

One commenter stated that limiting applicability of the regulations to guidance “issued after” the proposed rulemaking is finalized creates inconsistency with respect to applicability of procedures for the modification and withdrawal of guidance.

EPA Response: For the EPA’s response, see section III.E of the preamble to the final rule.

Comment: One commenter noted that the proposed rule could call into question the failure of EPA to provide for judicial review of significant guidance documents, but the proposed petition process to withdraw or revise guidance undercuts such arguments. The commenter recommended that EPA include a discussion in the final rulemaking acknowledging this issue and the public’s ability to petition for withdrawal or modification of guidance at any time (not temporally limited).

EPA Response: The EPA agrees that the petition process to modify or withdraw guidance document provides an added opportunity for the public to seek revisions of significant guidance documents. The

EPA disagrees that additional discussion is needed on this issue. The scope of judicial review set forth in the APA is not modified by this procedural rule.

Comment: One commenter recommended that EPA should prioritize petitions or requests made by states, since states are co-regulators with EPA and implement EPA's regulations.

EPA Response: The EPA disagrees that petitions from certain entities should be prioritized over other petitions. The purpose of the new petition procedures is to ensure that all petitions are handled transparently and consistently, which would be undercut by the commenter's recommendation. Additionally, creating priority tiers for petitions would be cumbersome to implement, especially where multiple petitions are received for the same guidance document.

Comment: One commenter noted that there is no provision that has been proposed that addresses whether the EPA's decision regarding withdrawal or revision of current guidance is "final agency action."

Another commenter noted that if EPA was to choose to ignore a petition, there is no legal right to enforce transparency in this process.

EPA Response: The EPA disagrees that the petition procedures should specify whether withdrawal or revision of guidance documents is "final agency action." Guidance documents are generally non-binding, do not have legal consequences, and do not conclusively determine rights or obligations. Further, the EPA is adding a requirement to make information about petitions received publicly available to provide increased transparency. Finally, the rule specifies that the EPA should respond to a petition in a timely manner, no longer than 90 days unless an extension of 90 days is asserted.

7.1.1 EPA Decisionmaking regarding Petitions

Comment: One commenter recommended that the petition process include the following:

- A process for how EPA will respond to petitions.
- A process for how EPA will consider the petition, evaluate the claims and evidence/information submitted by the petitioner, and criteria for determining whether the guidance document should be modified/withdrawn.
- The evidentiary standard for modifying or withdrawing a guidance document should include:
 - (a) a presumption that the document is accurate, correct and should not be withdrawn.
 - (b) The burden of proof should be on the petitioner.
 - (c) The petitioner should have to show by "clear and convincing evidence" (e.g. more than "substantial evidence") that the guidance document should be withdrawn.
- Guidance Documents should only be withdrawn as a result of patently false information or statements.

One commenter noted that EPA needs to outline how they will evaluate public petitions and who within the Agency will make decisions to take actions in response to a petition request.

One commenter mentioned that EPA did not provide any details on how the agency would assess the merits of a petition.

Another commenter suggested that with regards to denied petitions, EPA needs to provide a reasoned response that gives an explanation for the grounds of denial, including, if applicable, responses to major issues raised in the petition.

EPA Response: The EPA disagrees that additional steps are necessary for the petition procedures at this time. The diversity of guidance documents, and the corresponding possibility of the diversity in petitions received, would make such requirements cumbersome to implement and would be unlikely to provide consistent and timely responses to petitions.

Comment: One commenter recommended that EPA develop a more formal dispute resolution process. The commenter believes that if a portion or entire guidance document needs revision, a petitioner should have a process to elevate those issues beyond the initial response contemplated by EPA.

EPA Response: The EPA disagrees that a formal dispute resolution process is necessary for the petition procedures. There is nothing in these procedures that would prohibit a member of the public from submitting an additional petition if they disagree with the disposition of an initial petition.

7.1.2 Format and Content Elements for Public Petitions

Comment: Many commenters noted that they had no suggestions for additional information to be included in petitions to modify or withdraw an active guidance document.

One commenter suggested that EPA consider requiring disclosure of certain affiliations of the petitioner, so that corporate or other influence can be readily understood by the agency and the public.

Another commenter noted that EPA should only consider petitions from those that follow all instructions and filed the petition correctly. The commenter stated that it would be unnecessary for EPA staff to devote resources to locate incorrectly filed petitions.

Another commenter complimented EPA on the agency's willingness to accept and respond to petitions that do not contain all of the enumerated elements.

One commenter recommended that EPA include an additional content element for economic impact. They stated that this would include a brief explanation of the estimated economic impact that the guidance document has on the petitioner, the method of calculation by the petitioner for that estimated economic impact, and the estimated economic impact/benefit of the proposed modification or withdrawal of the guidance document on the petitioner.

EPA Response: The EPA acknowledges the supportive comments regarding the proposed petition procedures. At this time, the EPA does not agree that additional petition content or disclosures are necessary.

7.1.3 Public Notification regarding Petitions

Comment: Several commenters noted that for transparency purposes, EPA should make petitions publicly available.

Several commenters supported that petitions and EPA's response to petitions should be made public, and appropriately noted on the EPA Guidance Portal.

One commenter suggest that EPA maintain a publicly-available list of petitions received to modify or withdraw an active guidance document, with hyperlinks to the petitions. The commenter stated that the most appropriate place to identify the petitions is on the EPA Guidance Portal.

One commenter suggested that EPA publicize and provide a comment period to allow stakeholders and members of the public to comment on such a petition.

EPA Response: For the EPA's response, see section III.E of the preamble to the final rule.

Comment: One commenter stated that EPA did not indicate how EPA would notify the public of subsequent actions pursuant to the petition.

EPA Response: For the EPA's response, see section III.E of the preamble to the final rule.

7.1.4 Petition Response Deadlines

Comment: Many commenters provided suggestions regarding EPA's petition response deadlines.

- One commenter mentioned that responding to petitioners in a timely manner will ensure that EPA is responding to legitimate concerns by public stakeholders.
- One commenter recommended that EPA not include the mandatory agency response deadlines of 90 days with the ability to extend and additional 90 days. The commenter noted that EPA should strive to provide prompt responses to petitioners.
- One commenter requested that EPA clarify that the time periods are targets, not enforceable deadlines.
- One commenter stated that EPA should have the option to extend the time for reply by up to an additional 180 days if deemed necessary. Without more flexibility, EPA may be forced to reject otherwise meritorious petitions.
- One commenter stated that during the 90-day timeline, EPA should work with stakeholders to develop guidance documents that ensure clarity.

EPA Response: The EPA disagrees with the suggested revisions to the petition process deadlines. As noted by some commenters, a timely response to petitions received is imperative and the procedures allow flexibility if the EPA needs additional time to respond to a complex petition.

7.3 Petition Procedures for Rulemakings

Comment: Many commenters noted that there is no need for EPA to invent additional procedures for rulemakings beyond those which are already provided by statute. Commenters stated that creating additional petition procedures outside of those provided by statute creates the opportunity for inconsistency and confusion for the public as to what requirements to apply. One commenter mentioned that the current public petition right established in APA section 553(e) is sufficient.

One commenter stated their strong support of a unified petition process for EPA rulemakings and would be pleased to engage with EPA through comments to create a unified petition process.

EPA Response: At this time, the EPA declines to establish procedures for petitions regarding substantive rules. The EPA acknowledges commenters' desires to have a fuller discussion of establishing a petition process for substantive rules. The United States Court of Appeals for the District of Columbia (D.C.) Circuit has held that "agencies have great discretion to treat a problem partially." *City of Las Vegas v. Lujan*, 891 F.2d 927 (D.C. Cir. 1989) ("we [sh]ould not strike down [a regulation] if it [is] a first step toward a complete solution.").

7.4 Other Petitions

Comment: A few commenters noted that proposed §2.507 does not contain procedures for the public to petition EPA to “add” guidance to the EPA Guidance Portal. The commenters request that the proposed rule should be amended to add a specific procedure by which any party can petition for the inclusion of an existing guidance document in the EPA Guidance Portal.

One commenter stated that if EPA declines to add a document to the EPA Guidance Portal, then EPA should be required to explain the basis for their decision.

EPA Response: For the EPA’s response, see section III.E of the preamble to the final rule.

Comment: A couple of commenters recommended that EPA consider adding a procedure for the review of final agency decisions on petitions by EPA’s Administrative Appeals Board.

EPA Response: For the EPA’s response, see section III.E of the preamble to the final rule.

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8 Other Comments

8.1 Requests to Extend the Comment Period

Comment: Several commenters stated that EPA should extend the comment period, with extensions ranging from 60-90 additional days.

Commenters stated that their organizations and companies represent a number of companies or facilities that are subject to EPA guidance, and would need additional time to ensure that they all had adequate time to review, deliberate, and prepare a meaningful response. One commenter stated that given the sheer number of guidance documents used in their industry, they need additional time to review the documents included on the EPA Guidance Portal.

A couple commenters stated that as a result of COVID-19, the public and many of their members, who have been focused on continuing operations and addressing issues that have arisen in maintaining service, have had limited time to collaborate on this proposed rule as readily as under normal circumstances.

One commenter stated that EPA failing to provide a comment deadline extension on this proposed rule will violate the core notice-and-comment, and meaningful public participation requirements of the Clean Air Act, the APA, and other statutes EPA administers that cover guidance EPA has issued.

EPA Response: As stated in the proposal preamble, the EPA voluntarily sought comment from the public on the proposed rule as a matter of good government, even though this is a rule of agency organization, procedure, or practice, and providing notice and an opportunity for public comment is not required. EPA believes that the 30-day comment period was sufficient for the public to review the proposed rulemaking and provide comments. Regarding the commenter's concern with individual documents in the EPA Guidance Portal, that is beyond the scope of this rulemaking and the commenter will continue to have opportunities to engage with the Agency about specific documents, including through the new petition process.

8.2 Beyond the Scope

Comment: Several commenters raised issues that were beyond of the scope of this rulemaking or were non-substantive.

One commenter expressed their support for E.O. 13777 “Enhancing the Regulatory Reform Agenda”, which established a federal policy “to alleviate unnecessary regulatory burdens” on the American people. The commenter understands that the EPA is interested in reviewing regulations consistent with the E.O.

One commenter recommended changes to the EPA’s handling of small refinery exemptions in the RFS program, which the commenter asserts is contrary to the goals of E.O. 13891. The commenter states that these exemptions meet the criteria to be significant guidance documents and urges greater transparency in the process for determining exemptions, including opportunities for notice and public comment. The commenter suggested that EPA impose deadlines on responding to petitions for reconsideration/rulemaking with respect to the RFS program.

One commenter alleges that EPA disregarded scientific data that the commenter submitted and published misinformation in a guidance document that resulted in ambiguity and confusion in the regulated community. The document (“Strategies to Achieve Full Lead Service Line Replacement” supporting the proposed National Primary Drinking Water Regulations: Lead and Copper Rule Revisions (EPA-HQ-OW-2017-0300)) did not include the word “guidance”, and there was no formal procedure for the public to petition for modifications at the time.

EPA Response: The EPA disagrees that these comments are relevant to this rulemaking.

9 List of Commenters

Below is the list of public comments posted in the docket for this regulation. Some of these comments are non-substantive and/or beyond the scope of this rulemaking.

Commenter	Comment ID
Anonymous public comment	ID EPA-HQ-OA-2020-0128-0005
Anonymous public comment	ID EPA-HQ-OA-2020-0128-0006
Anonymous public comment	ID EPA-HQ-OA-2020-0128-0007
Anonymous public comment	ID EPA-HQ-OA-2020-0128-0008
Anonymous public comment	ID EPA-HQ-OA-2020-0128-0009
Darrell K. Smith, President and Chief Executive Officer, National Waste & Recycling Association (NWRA)	ID EPA-HQ-OA-2020-0128-0010
David Owen, President, National Association of Small Trucking Companies (NASTC)	ID EPA-HQ-OA-2020-0128-0011
S. Lasswell	ID EPA-HQ-OA-2020-0128-0012
Anonymous public comment	ID EPA-HQ-OA-2020-0128-0013
Anonymous public comment	ID EPA-HQ-OA-2020-0128-0014
Anonymous public comment	ID EPA-HQ-OA-2020-0128-0015
Keith Jones, Executive Director, Biological Products Industry Alliance (BPIA) and David Beaudreau, Executive Director, U.S. Biostimulant Coalition	ID EPA-HQ-OA-2020-0128-0016
Anonymous public comment	ID EPA-HQ-OA-2020-0128-0018
Anonymous public comment	ID EPA-HQ-OA-2020-0128-0019
Anonymous public comment	ID EPA-HQ-OA-2020-0128-0020
Marcia Y. Kinter, Vice President, Government and Regulatory Affairs, Printing United Alliance (PrUA)	ID EPA-HQ-OA-2020-0128-0022
Doug Burgum, Governor of North Dakota, Chair and Kate Brown, Governor of Oregon, Vice Chair, Western Governors' Association (WGA)	ID EPA-HQ-OA-2020-0128-0023
Donald S. Welsh, Executive Director, Environmental Council of the States (ECOS)	ID EPA-HQ-OA-2020-0128-0024
John W. Bode, President and CEO, Corn Refiners Association (CRA)	ID EPA-HQ-OA-2020-0128-0025
J. Alan Roberson, Executive Director, Association of State Drinking Water Administrators (ASDWA)	ID EPA-HQ-OA-2020-0128-0026
Michelle Roos, Environmental Protection Network (EPN)	ID EPA-HQ-OA-2020-0128-0027
John Wagner, Managing Counsel, American Petroleum Institute (API)	ID EPA-HQ-OA-2020-0128-0028
Melanie Davenport, President, Water Permitting Division Director, Virginia Department of Environmental Quality, Association of Clean Water Administrators (ACWA)	ID EPA-HQ-OA-2020-0128-0030
Andrew T. O'Hare, Vice President, Public Policy, The Fertilizer Institute (TFI)	ID EPA-HQ-OA-2020-0128-0031
Todd Parfitt, Director, Wyoming Department of Environmental Quality (WDEQ)	ID EPA-HQ-OA-2020-0128-0032
Ben Côté, President, Sanexen Water, Inc. and Jeff Tanner, President, Flow-Liner Systems, Ltd.	ID EPA-HQ-OA-2020-0128-0034
Caitlyn Cook, Center for Biological Diversity	ID EPA-HQ-OA-2020-0128-0037
Howard L. Ground, Director of Regulatory Affairs, The Petroleum Alliance of Oklahoma	ID EPA-HQ-OA-2020-0128-0038
Darrell K. Smith, President and CEO, National Waste & Recycling Association (NWRA)	ID EPA-HQ-OA-2020-0128-0039

Debra J. Jezouit, Baker Botts L.L.P. on behalf of Class of '85 Regulatory Response Group	ID EPA-HQ-OA-2020-0128-0040
Selin Hoboy, Vice President, Government Affairs and Compliance, Stericycle, Inc.	ID EPA-HQ-OA-2020-0128-0041
Charles Franklin, Vice President and Counsel, Government Affairs, Portland Cement Association (PCA)	ID EPA-HQ-OA-2020-0128-0042
Sandra P. Franco, Franco Environmental Law LLC on behalf of Producers of Renewables United for Integrity Truth and Transparency	ID EPA-HQ-OA-2020-0128-0043
David Cox, General Counsel, The Coalition for Renewable Natural Gas	ID EPA-HQ-OA-2020-0128-0044
Chuck Knauss et al., Hunton Andrews Kurth LLP on behalf of American Forest & Paper Association (AF&PA)	ID EPA-HQ-OA-2020-0128-0045
James W. Conrad, Jr., Conrad Law & Policy Counsel	ID EPA-HQ-OA-2020-0128-0046
Jane Williams, Executive Director, California Communities Against Toxics, and Emma Cheuse and David Baron, Attorneys, Earthjustice	ID EPA-HQ-OA-2020-0128-0047
American Public Gas Association et al.	ID EPA-HQ-OA-2020-0128-0048
Kevin H. Bell, Staff Counsel, Public Employees for Environmental Responsibility (PEER)	ID EPA-HQ-OA-2020-0128-0049
Alice Henderson, Environmental Defense Fund (EDF)	ID EPA-HQ-OA-2020-0128-0050
Leslie Sue Ritts, National Environmental Development Associations' Clean Air Project (NEDA/CAP)	ID EPA-HQ-OA-2020-0128-0051
Howard L. Ground, President, Environmental Federation of Oklahoma (EFO)	ID EPA-HQ-OA-2020-0128-0053
Richard D. Gupton, Senior Vice President, Public Policy & Counsel, Agricultural Retailers Association (ARA)	ID EPA-HQ-OA-2020-0128-0054
Daryll Joyner, Administrator, Water Quality Standards Program, Florida Department of Environmental Protection	ID EPA-HQ-OA-2020-0128-0055
David Bauer, President & CEO, American Road and Transportation Builders Association (ARTBA)	ID EPA-HQ-OA-2020-0128-0056
Ram Singhal, Vice President Technology & Environmental Strategy, Flexible Packaging Association (FPA)	ID EPA-HQ-OA-2020-0128-0057
Michael P. Walls, Vice President, Regulatory & Technical Affairs, American Chemistry Council (ACC)	ID EPA-HQ-OA-2020-0128-0058
James A. Williams, II, Vice President of Government Affairs and David R. Case, Executive Director, Environmental Technology Council (ETC)	ID EPA-HQ-OA-2020-0128-0059
J. Roger Kelley, Regulatory Chairman, Domestic Energy Producers Alliance (DEPA)	ID EPA-HQ-OA-2020-0128-0060
Matthew Hite, Vice President of Government Affairs, GPA Midstream Association	ID EPA-HQ-OA-2020-0128-0061
Susan Asmus, Senior Vice President, National Association of Home Builders (NAHB)	ID EPA-HQ-OA-2020-0128-0062
Megan J. Provost, President, Responsible Industry for a Sound Environment (RISE)	ID EPA-HQ-OA-2020-0128-0063
Ray S. McAllister, Senior Director, Regulatory Policy, CropLife America (CLA)	ID EPA-HQ-OA-2020-0128-0064
Jennifer Gibson, Vice President, Regulatory Affairs, National Association of Chemical Distributors (NACD)	ID EPA-HQ-OA-2020-0128-0065
David Friedman, Vice President, Regulatory Affairs, American Fuel & Petrochemical Manufacturers (AFPM)	ID EPA-HQ-OA-2020-0128-0066
Misael Cabrera, Director, Arizona Department of Environmental Quality (ADEQ)	ID EPA-HQ-OA-2020-0128-0067
Jerry D. Worsham, II, Attorney, The Cavanagh Law Firm	ID EPA-HQ-OA-2020-0128-0068