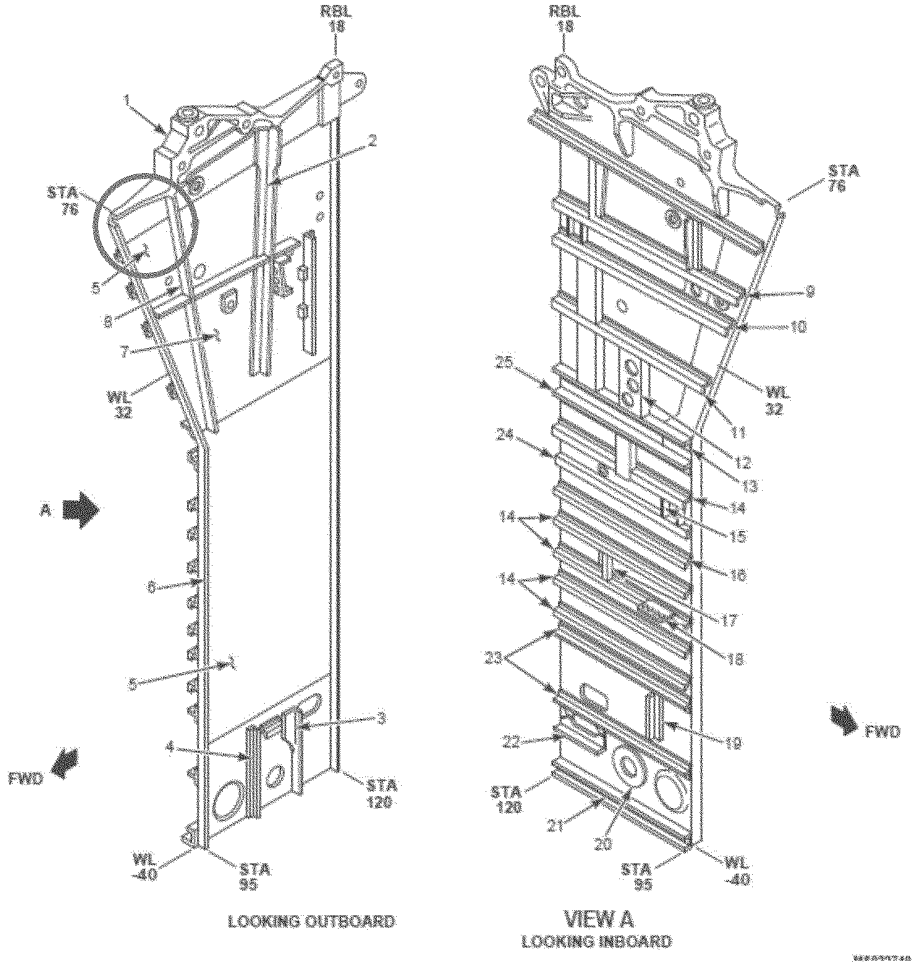

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(2) For repairs accomplished before the effective date of this AD, within 30 days after the effective date of this AD, submit the information specified in paragraphs (g)(2)(i) through (v) of this AD to the person identified in paragraph (j) of this AD.

(i) Aircraft serial number, registration number, and TIS when fitting was repaired.

(ii) Design data used to accomplish repair (drawings, engineering orders, etc.).

(iii) Substantiation data used to approve repair.

(iv) Copy of FAA Form 337 ''Major Repair or Alteration'' or other approval of return to service. If repair was performed by the U.S. military, provide a copy of Form 2408–15 (or equivalent) documenting major repair.

(v) Alternative methods of compliance for previously approved repairs.

(3) For fittings that have been replaced before the effective date of this AD, within 30 days after the effective date of this AD, submit the information specified in paragraphs (g)(3)(i) and (ii) of this AD to the person identified in paragraph (j) of this AD.

(i) If the replacement fitting was new production (under 14 CFR 21.9 or exemption): where the part was sourced from, when the part was produced, and the manufacturer of the part.

(ii) If the replacement fitting was used: where the part was sourced from (aircraft registration and serial number or manufacturer), TIS of the used part prior to installation, and TIS after installation.

(h) Special Flight Permits

Special flight permits are prohibited.

(i) Alternative Methods of Compliance (AMOCs)

(1) The Manager, West Certification Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the West Certification Branch, send it to the attention of the person identified in paragraph (j) of this AD and email to: *AMOC@faa.gov*.

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(j) Additional Information

For more information about this AD, contact Sarah Illg, Aviation Safety Engineer, FAA, 3960 Paramount Boulevard, Lakewood, CA 90712; phone: (206) 231–3517; email: *sarah.a.illg@faa.gov.*

(k) Material Incorporated by Reference

None.

Issued on December 17, 2025.

Steven W. Thompson,

Acting Deputy Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2025–23613 Filed 12–19–25; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[EPA–HQ–OAR–2024–0392; FRL–7688–03–OAR]

RIN 2060–AU75

Petition To Delist Hazardous Air Pollutant: 2-Butoxyethyl Benzoate (2-BEB)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The U.S. Environmental Protection Agency (EPA or Agency) is proposing to grant a petition to remove

2-Butoxyethyl benzoate (2-BEB) (Chemical Abstract Service (CAS) No. 5451–76–3) from the glycol ethers category in the list of hazardous air pollutants (HAP) in Clean Air Act (CAA). The EPA proposes to find that there are adequate data on the health or environmental effects of 2-BEB to support the request for removal. This action also details a streamlined approach to the review process of future petitions.

DATES: Comments must be received on or before February 20, 2026.

Public hearing: If anyone contacts us requesting a public hearing on or before Saturday, December 27, 2025, we will hold a virtual public hearing. See **SUPPLEMENTARY INFORMATION** for information on requesting and registering for a public hearing.

ADDRESSES: You may send comments, identified by Docket ID No. EPA–HQ–OAR–2024–0392, by any of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov* (our preferred method). Follow the online instructions for submitting comments.
- *Email: a-and-r-docket@epa.gov.* Include Docket ID No. EPA–HQ–OAR–2024–0392 in the subject line of the message.
- *Fax:* (202) 566–9744. Attention Docket ID No. EPA–HQ–OAR–2024–0392.
- *Mail:* U.S. Environmental Protection Agency, EPA Docket Center, Docket ID No. EPA–HQ–OAR–2024–0392, Mail Code 28221T, 1200 Pennsylvania Avenue NW, Washington, DC 20460.
- *Hand Delivery or Courier:* EPA Docket Center, WJC West Building, Room 3334, 1301 Constitution Avenue NW, Washington, DC 20004. The Docket Center's hours of operations are 8:30 a.m.–4:30 p.m., Monday–Friday (except Federal holidays).

Instructions: All submissions received must include the Docket ID No. for this rulemaking. Comments received may be posted without change to *https://www.regulations.gov,* including any personal information provided. For detailed instructions on sending comments and additional information on the rulemaking process, see the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: For information about this proposed action, contact Marisa Pfohl, Impacts and Ambient Standards Division (C539–02), Office of Clean Air Programs, U.S. Environmental Protection Agency, 109 T.W. Alexander Drive, P.O. Box 12055 RTP, North Carolina 27711; telephone number: (919) 541–7607; email address: *pfohl.marisa@epa.gov.* For additional information, see *https://www.epa.gov/haps/deletion-2-butoxyethyl-benzoate-2-beb-glycol-ethers-category-clean-air-act-list-hazardous-air.*

SUPPLEMENTARY INFORMATION:

Participation in virtual public hearing. To request a virtual public hearing, contact the public hearing team at (888) 372–8699 or by email at *SPPDpublichearing@epa.gov.* If requested, the virtual hearing will be held on January 12, 2026. The EPA will announce further details at *https://www.epa.gov/haps/deletion-2-butoxyethyl-benzoate-2-beb-glycol-ethers-category-clean-air-act-list-hazardous-air.* We note that if a hearing is requested, the planned schedule for the hearing will be provided on this website, but the EPA may close a session 15 minutes after the last pre-registered speaker has testified if there are no additional speakers.

If a public hearing is requested, the EPA will begin pre-registering speakers for the hearing no later than one business day after a request has been received. To register to speak at the virtual hearing, please use the online registration form available at *https://www.epa.gov/haps/deletion-2-butoxyethyl-benzoate-2-beb-glycol-ethers-category-clean-air-act-list-hazardous-air* or contact the public hearing team at (888) 372–8699 or by email at *SPPDpublichearing@epa.gov.* The last day to pre-register to speak at the hearing will be Saturday, January 3, 2026. Prior to the hearing, the EPA will post a general agenda that will list pre-registered speakers at: *https://www.epa.gov/haps/deletion-2-butoxyethyl-benzoate-2-beb-glycol-ethers-category-clean-air-act-list-hazardous-air.*

The EPA will make every effort to follow the schedule as closely as possible on the day of the hearing; however, please plan for the hearings to run either ahead of schedule or behind schedule.

Each commenter will have four minutes to provide oral testimony. The EPA encourages commenters to submit a copy of their oral testimony as written comments to the rulemaking docket. The EPA may ask clarifying questions during the oral presentations but will not respond to the presentations at that time. Written statements and supporting information submitted during the comment period will be considered with the same weight as oral testimony and supporting information presented at the public hearing.

Please note that any updates made to any aspect of the hearing will be posted online at *https://www.epa.gov/haps/deletion-2-butoxyethyl-benzoate-2-beb-glycol-ethers-category-clean-air-act-list-hazardous-air.* While the EPA expects the hearing to go forward as described in this section, please monitor our website or contact the public hearing team at (888) 372–8699 or by email at *SPPDpublichearing@epa.gov* to determine if there are any updates. The EPA does not intend to publish a document in the **Federal Register** announcing updates.

If you require special accommodation such as audio description, please pre-register for the hearing with the public hearing team and describe your needs by Monday, December 29, 2025. The EPA may not be able to arrange accommodations without advanced notice.

Docket. The EPA has established a docket for this rulemaking under Docket ID No. EPA–HQ–OAR–2024–0392. All documents in the docket are listed at *https://www.regulations.gov.* Although listed, some information is not publicly available, *e.g.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The EPA does not place certain other material, such as copyrighted material, on the internet; this material is publicly available only as pdf versions accessible only on EPA computers in the docket office reading room. The public cannot download certain data bases and physical items from the docket but may request these items by contacting the docket office at 202–566–1744. The docket office has 10 business days to respond to such requests. With the exception of such material, publicly available docket materials are available electronically at *regulations.gov.*

Written Comments. Submit your comments, identified by Docket ID No. EPA–HQ–OAR–2024–0392, at *https://www.regulations.gov* (our preferred method), or the other methods identified in the **ADDRESSES** section. Once submitted, comments cannot be edited or removed from the docket. The EPA may publish any comment received to its public docket. Do not submit to EPA's docket at *https://www.regulations.gov* any information you consider to be CBI or other information for which disclosure is restricted by statute. This type of information should be submitted as discussed in the *Submitting CBI* section of this document.

Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will

generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.*

The *https://www.regulations.gov* website allows you to submit your comment anonymously, which means the EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to the EPA without going through *https://www.regulations.gov,* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the internet. If you submit an electronic comment, the EPA recommends that you include your name and other contact information in the body of your comment and with any digital storage media you submit. If the EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, the EPA may not be able to consider your comment. Electronic files should not include special characters or any form of encryption and be free of any defects or viruses. For additional information about the EPA's public docket, visit the EPA Docket Center homepage at *https://www.epa.gov/dockets.*

Submitting CBI. Do not submit information containing CBI to the EPA through *https://www.regulations.gov.* Clearly mark the part, or all, of the information that you claim to be CBI. For CBI information on any digital storage media that you mail to the EPA, note the docket ID, mark the outside of the digital storage media as CBI, and identify electronically within the digital storage media the specific information that is claimed as CBI. In addition to one complete version of the comments that includes information claimed as CBI, you must submit a copy of the comments that does not contain the information claimed as CBI directly to the public docket through the procedures outlined in the *Written Comments* section of this document. If you submit any digital storage media that does not contain CBI, mark the outside of the digital storage media clearly that it does not contain CBI and note the docket ID. Information not marked as CBI will be included in the public docket and the EPA's electronic public docket without prior notice. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

Our preferred method to receive CBI is transmitted electronically using email attachments, File Transfer Protocol (FTP), or other online file sharing services (*e.g.,* Dropbox, OneDrive, Google Drive). Electronic submissions must be transmitted directly to the OAQPS CBI Office at the email address *oaqps_cbi@epa.gov* and, as described above, should include clear CBI markings and note the docket ID. If assistance is needed with submitting large electronic files that exceed the file size limit for email attachments, and if you do not have your own file sharing service, please email *oaqps_cbi@epa.gov* to request a file transfer link. If sending CBI information through the postal service, please send it to the following address: OAQPS Document Control Officer (C404–02), OAQPS, U.S. Environmental Protection Agency, 109 T.W. Alexander Drive, P.O. Box 12055 RTP, North Carolina 27711, Attention Docket ID No. EPA–HQ–OAR–2024–0392. The mailed CBI material should be double wrapped and clearly marked. Any CBI markings should not show through the outer envelope.

Preamble acronyms and abbreviations. Throughout this document, the use of ''Agency,'' ''we,'' ''us,'' or ''our'' refers to the EPA. We use multiple acronyms and terms in this preamble. While this list may not be exhaustive, to ease the reading of this preamble and for reference purposes, the EPA defines the following terms and acronyms here:

2-BEB 2-Butoxyethyl benzoate
AERMOD American Meteorological Society/EPA Regulatory Model
BAA Butoxyacetic acid
CAA Clean Air Act
CBI Confidential Business Information
CFR Code of Federal Regulations
EFAST Exposure and Fate Assessment Screening Tool
EPA Environmental Protection Agency
FDA Food and Drug Administration
GLP Good Laboratory Practice
HAP hazardous air pollutant(s)
HED human equivalent dose
HEM human exposure model
HQ hazard quotient
IRIS Integrated Risk Information System
ISC3 Industrial Source Complex 3
kg/yr kilograms per year
lbs/yr pounds per year
LOAEL lowest-observed-adverse-effect level
mg/kg milligram per kilogram
NOAEL no-observed-adverse-effect level
NESHAP national emission standards for hazardous air pollutants
OMB Office of Management and Budget
OPPT Office of Pollution Prevention and Toxics
PNEC predicted no-effect concentration
ppm parts per million
PRA Paperwork Reduction Act
REL California Reference Exposure Level
RfC Reference Concentration
RfD oral reference dose
tpy tons per year
UMRA Unfunded Mandates Reform Act
VOC volatile organic compound

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I. Background

A. Where can I get a copy of this document and other related information?

In addition to being available in the docket, an electronic copy of this action is available on the internet. Following signature by the EPA Administrator, the EPA will post a copy of this proposed action at *https://www.epa.gov/haps/deletion-2-butoxyethyl-benzoate-2-beb-glycol-ethers-category-clean-air-act-list-*

hazardous-air. Following publication in the **Federal Register,** the EPA will post the **Federal Register** version of the proposal and key technical documents at this same website. In accordance with 5 U.S.C. 553(b)(4), a brief summary of this rule may be found at *https://www.regulations.gov,* Docket ID No. EPA–HQ–OAR–2024–0392.

A memorandum showing the edits that would be necessary to incorporate the changes to 40 CFR part 63, subpart C proposed in this action is available in the docket (Docket ID No. EPA–HQ–OAR–2024–0392). The EPA also will post a copy of this document to *https://www.epa.gov/haps/deletion-2-butoxyethyl-benzoate-2-beb-glycol-ethers-category-clean-air-act-list-hazardous-air.*

B. What is the HAP list?

In this section, the EPA provides a brief overview of the list of HAP subject to regulation under CAA section 112 (''the HAP list''), the Agency's process for considering petitions to modify the HAP list by adding or deleting a substance, and information about 2-BEB, CAS No. 5451–76–3.

The HAP list is a list of organic and inorganic substances that have been identified as HAP to be regulated under CAA section 112. The initial HAP list, which can be found in CAA section 112(b)(1), was established by Congress in the 1990 amendments to the CAA. The substances listed as HAP have been associated with a wide variety of adverse health effects, including cancer, neurological effects, reproductive effects, and developmental effects. The health effects associated with various HAP differ depending on the toxicity of the specific HAP and the circumstances of exposure, such as the amount of the substance present, the length of time a person is exposed, and the stage of life at which the person is exposed. CAA section 112(c) directs the EPA to first identify and list source categories that emit HAP, then set emission standards for those listed source categories under CAA section 112(d). Standards promulgated under CAA section 112(d) are commonly referred to as National Emission Standards for Hazardous Air Pollutants (NESHAP).

C. What is the authority to modify the HAP list?

CAA section 112(b)(3)(A) specifies that any person may petition the Administrator to modify the HAP list by adding or deleting a substance.[1] The Administrator must grant or deny a petition to delete a HAP within 18 months. CAA section 112(b)(3)(C) and (D) sets out the substantive criteria for granting a petition to delete a HAP from the HAP list.[2] Petitions should include sufficient information to support the requested deletion of a HAP.

To grant a petition to delete a substance from the HAP list, CAA section 112(b)(3)(C) provides that the Administrator must determine that ''there is adequate data on the health and environmental effects of the substance to determine that emissions, ambient concentrations, bioaccumulation, or deposition of the substance may not reasonably be anticipated to cause any adverse effects to the human health or adverse environmental effects.'' [3] CAA section 112(a)(7) defines an ''adverse environmental effect'' as ''[a]ny significant and widespread adverse effect, which may reasonably be anticipated, to wildlife, aquatic life, or other natural resources, including adverse impacts on populations of endangered or threatened species or significant degradation of environmental quality over broad areas.'' [4]

The EPA has long explained that CAA section 112(b)(3)(C) does not require absolute certainty that a pollutant will not cause adverse effects on human health or the environment before it may be deleted from the list.[5] The use of the terms ''adequate'' and ''reasonably'' in CAA section 112(b)(3)(C) indicate that the EPA must weigh the potential uncertainties and likely significance of any projections, assessments, and estimations. Uncertainties concerning the risks of adverse health or environmental effects may be mitigated if it is shown that projected exposures are sufficiently low in relation to levels where adverse effects may occur, thus providing reasonable assurance that such adverse effects will not occur. Similarly, uncertainties concerning the magnitude of projected exposures may be mitigated if it is demonstrated that the levels that might cause adverse health or environmental effects are sufficiently high to provide reasonable assurance that exposures will not reach harmful levels.

The EPA further posited that questions as to whether HAP emissions present adverse health and environmental effects, and questions regarding the kinds of effects that can come from exposure to those emissions, may, in certain instances, border on the frontiers of scientific knowledge and involve limited or inconsistent data. For example, there could be limited scientific knowledge of the effects of pollutant exposure on human health or the environment. There could also be limited emissions data from the relevant source category. Further, some pollutants have no known safe level of exposure. CAA section 112(b)(3)(C) does not require the Administrator to base his determination to grant a delisting petition solely on a single parameter or measure; therefore, the EPA's historical view has been that the Administrator has the discretion to weigh various factors or data differently.[6] The Administrator's decision to delist (or to deny a petition to delist) a HAP is made on a case-by-case basis and involves a thorough and comprehensive review of factual issues, scientific evidence, and data provided in support of a delisting petition. The EPA has also long explained that CAA section 112(b)(3)(C) allows the Administrator to balance the likelihood of adverse health effects against the limits of available scientific data and to exercise informed judgement in making decisions considering uncertainties in scientific data. Any projections, assessments, and estimations by a petitioner must thus be reasonable and not based on conjecture. In sum, the CAA does not call for certitude of harm but rather accords the Administrator discretion and flexibility in taking action that is protective of public health and the environment, including by considering and balancing factors and relevant policy concerns.

If the Administrator decides to deny a petition, the EPA publishes a written explanation of the basis for denial in the **Federal Register**. A decision to deny a petition is a final Agency action subject to judicial review in the U.S. Court of Appeals for the District of Columbia Circuit under CAA section 307(b). If the Administrator decides to grant a petition, the EPA publishes a written explanation of the decision in a proposed rule to delete the substance from the HAP list codified in 40 CFR part 63, subpart C as we are doing here.

[1] 42 U.S.C. 7412(b)(3)(A).

[2] 42 U.S.C. 7412(b)(3)(C)–(D).

[3] 42 U.S.C. 7412(b)(3)(C).

[4] 42 U.S.C. 7412(a)(7).

[5] 70 FR 75047, 75048, Dec. 19, 2005 (final rule delisting methyl ethyl ketone as a HAP); 69 FR 69320, 69321, Nov. 29, 2004 (final rule delisting ethylene glycol monobutyl ether as a HAP).

[6] *Nat'l Lime Ass'n* v. *EPA,* 627 F.2d 416, 454 n.143 (D.C. Cir. 1980) (''Where a statute is precautionary in nature, the evidence difficult to come by, uncertain, or conflicting because it is on the frontiers of scientific knowledge, the regulations designed to protect the public health, and the decision that of an expert administrator, we will not demand rigorous step-by-step proof of cause and effect. Such proof may be impossible to obtain if the precautionary purpose of the statute is to be served.'') (citing *Ethyl Corp.* v. *EPA,* 541 F.2d 1, 28–29 (D.C. Cir. 1976)); *See also Baltimore Gas & Elec. Co.* v. *NRDC,* 462 U.S. 87, 103 (1983).

D. What is the process for delisting a HAP?

In this section, the EPA describes the Agency's historical process for considering petitions to delist a HAP from the HAP list and what process the EPA is following for the petition to delist 2-BEB.

A petition to delist a HAP is a formal request to the EPA from an individual or group to remove a substance from the HAP list. Removal from the HAP list means the substance is no longer subject to the regulatory provisions of CAA section 112 and related statutory provisions governing HAP. CAA section 112(b)(3)(A) requires the Administrator to either grant or deny a petition by publishing a written explanation of the reasons for the Administrator's decision. CAA section 112(b)(3)(A) does not specifically require a formal rulemaking process to either grant or deny a petition to delist a HAP from the HAP list. Although the delisting action for a listed HAP is not subject to the rulemaking procedures of CAA section 307(d), for all previous delisting actions the EPA has published and solicited public comment on relevant aspects of the Agency's consideration of such a complete petition in the **Federal Register**.[7] Once the EPA grants a petition to delist a HAP, such deletion is codified into 40 CFR part 63, subpart C.

The EPA's petition review process proceeds in two phases: a completeness determination and a technical review. During the completeness determination, the EPA conducts a broad review of the petition to determine whether all the necessary subject areas are addressed and whether reasonable information and analyses are presented for each of these subject areas. During the technical review, the EPA conducts a thorough scientific review of the complete petition to determine whether the data, analyses, interpretations, and conclusions in the petition are appropriate and technically sound. During the technical review, the EPA also determines whether the petition satisfies the necessary requirements of CAA section 112(b)(3)(B) or (C) and adequately supports a decision to either list or delist the HAP.

Under prior EPA practice, once a petition was determined to be complete, the Agency placed a notice of receipt of a complete petition in the **Federal Register**. The **Federal Register** notice announced a public comment period on the complete petition and started the technical review phase of our decision-making process.[8] Then, during the technical review of the petition, the EPA considered all comments and data submitted during the public comment period for the notice of receipt of a complete petition. Subsequently, the EPA would publish a document in the **Federal Register** containing a written explanation of the basis for the decision to either grant or deny the petition. If the EPA intended to grant the delisting petition, the Agency would also propose the addition of regulatory text to 40 CFR part 63, subpart C to codify the deletion. After consideration of public comments, the EPA would publish the final decision on the petition in the **Federal Register**. If the EPA granted a delisting petition, in a final action the Agency would amend 40 CFR part 63, subpart C, List of Hazardous Air Pollutants, Petitions Process, Lesser Quantity Designations, Source Category List, to codify the deletion of the substance from the HAP list. Thus, the EPA's prior practice encompassed at least three publications in the **Federal Register**.

In this action, the EPA is announcing a streamlined approach to petitions under section CAA 112(b)(3)(B) effective with this petition to delist 2-BEB. Rather than issuing a **Federal Register** document announcing the receipt of a complete petition, the EPA will now inform the petitioner by letter once a preliminary evaluation determines that the petition is complete according to Agency criteria.[9] Subsequently, once the EPA's technical review is complete, the Agency will publish a **Federal Register** document with a written explanation of the basis for the proposed decision to grant or deny the petition and, if appropriate, propose the addition of regulatory text to 40 CFR part 63, subpart C to codify the deletion. After the opportunity for comment and review of the comments, the EPA will publish in the **Federal Register** the final action either granting or denying the petition. If the petition to delist is granted, 40 CFR part 63, subpart C will be modified to incorporate the change.

Additionally, the EPA intends to reorganize 40 CFR part 63, subpart C to provide clarity and allow space for future amendments. See section IV. of this preamble for more information on this reorganization.

E. What is the history of the 2-BEB delisting process?

In this section, the EPA provides an overview and information about the Agency's technical review of the petition to delist 2-BEB.

On September 30, 2019, the Dow Chemical Company (the ''Petitioner'') submitted a petition to delete 2-BEB (CAS No. 5451–76–3) from the glycol ethers category of the HAP list (the ''Petition''). 2-BEB is a colorless liquid with low odor, a high boiling point (292 °C at 760 millimeters of mercury (mmHg)), and low vapor pressure (2.09E–04 mmHg at 20 °C). It is miscible in water with moderate water solubility (106 mg/L at 20 °C). 2-BEB has utility as a coalescing solvent for water-based, low volatility organic compound (VOC) coatings. It can also be used as a replacement for phthalate-based plasticizers in caulking compounds and in some polyvinyl chloride (PVC) formulations.

Following receipt of the Petition, the EPA conducted a preliminary evaluation to determine whether the Petition was complete according to Agency criteria. To be deemed complete, the EPA requires that a petition consider available data on health and environmental effects of the substance to be deleted. A petition should also provide comprehensive emissions data, including peak and annual average emissions for each known source or for an appropriately selected subset of sources, and must estimate the resulting exposures to people living in the vicinity of the sources. In addition, a petition must discuss the environmental impacts associated with emissions of the substance to the ambient air and impacts associated with the subsequent cross-media transport of those emissions.[10] The EPA determined the Petition to be incomplete and requested additional information from the Petitioner. After receiving additional

[7] *Am. Forest & Paper Ass'n.* v. *EPA,* 294 F.3d 113, 117 n.3 (D.C. Cir. 2002) (''Section 112(b) does not contemplate a formal rulemaking and is not among the sections enumerated in section 307(d)(1) (although other subsections of section 112 are included there.)'') (Petition to delist methanol as a HAP).

[8] *See, e.g.,* 70 FR 30407, May 26, 2005 (notice of receipt of a complete petition to delist 4,4'-methylene diphenyl diisocyanate as a HAP); 64 FR 42125, Aug. 3, 1999 (notice of receipt of a complete petition to delist ethylene glycol monobutyl ether as a HAP); 64 FR 38668, July 19, 1999 (notice of receipt of a complete petition to delist methanol as a HAP); 64 FR 33453, June 23, 1999 (notice of receipt of a complete petition to delist Methyl Ethyl Ketone as a HAP).

[9] For the petition to delist 2-BEB, we informed the petitioner of the determination that the petition was complete on Nov. 24, 2021.

[10] *E.g.,* 70 FR 30407, May 26, 2005 (notice of receipt of a complete petition to delist 44-methylene diphenyl diisocyanate as a HAP); 64 FR 42125, Aug. 3, 1999 (notice of receipt of a complete petition to delist ethylene glycol monobutyl ether as a HAP); 64 FR 38668, July 19, 1999 (notice of receipt of a complete petition to delist methanol as a HAP); 64 FR 33453, June 23, 1999 (notice of receipt of a complete petition to delist Methyl Ethyl Ketone as a HAP).

submittals from the Petitioner through August 13, 2021, the EPA determined the Petition to be complete.[11] The EPA notified the Petitioner by electronic mail of this determination on November 24, 2021.[12]

Following the completeness determination, the EPA conducted a preliminary technical review of the Petition. Based on the preliminary assessment, the EPA had follow-up conversations with the Petitioner in June 2022 to further clarify certain aspects of the Petition. After these discussions, the Petitioner submitted additional information in September 2022.[13] The Petition and all supplements to the Petition are available for review in the docket.[14] The EPA has fully considered all of the Petitioners' submissions in the technical review and the determination to propose granting the Petition to delist 2-BEB from the glycol ethers category in the HAP list.

II. Summary of the Petition

In this section, the EPA presents the details of the Petition that includes the exposure assessment, the human health effects assessment, the Petitioners' risk assessment and methodology and ecological assessment and conclusions.

A. Overview

The Petition is presented in the form of a risk assessment that considers multiple routes of exposure and evaluates the likelihood and severity of adverse effects to human health and the environment arising from exposures to ambient levels of 2-BEB. Existing literature on the toxicity and health effects of 2-BEB is sparse. To address this gap, the Petitioner performed oral, dermal, and inhalation toxicity testing according to the Organisation for Economic Co-operation and Development (OECD) guidelines.[15] The Petitioner also relied on the EPA's 2010 Integrated Risk Information System (IRIS) assessment for ethylene glycol monobutyl ether (EGBE) as the basis for the human health effects evaluation of 2-BEB.[16] The Petitioner further provided a worst-case inhalation toxicity analysis that used ethylene glycol monomethyl ether (EGME), which is the most potent chemical with a reference concentration (RfC) available from the EPA's IRIS assessment program for the glycol ethers category.[17] In sum, the Petition characterizes the sources and releases of 2-BEB, estimates exposures, identifies the potential hazard and the dose-response relationship of 2-BEB, characterizes environmental risk, and characterizes the human health risk from a reasonable worst-case lifetime exposure to 2-BEB and a reasonable worst-case short-term (24-hour) exposure to 2-BEB.

B. Inhalation Exposure Assessment

1. Air Emissions Estimate

The Petitioner estimated 2-BEB emissions based on nationwide projected production volume and modeled emissions estimates. In the Petition, the Petitioner states that, as of September 30, 2019, all 2-BEB produced domestically has been for export and use outside of the United States. The Petitioner estimated that about 200,000 pounds (lbs) (91,000 kilograms (kg)) of 2-BEB were produced in the United States from 2016 to mid-2019, an average of about 57,000 lbs/yr (26,000 kg/yr). The Petitioner further stated that 2-BEB is being explored as a substitute for current components of water-based coatings but is not currently used or sold in the United States. Additionally, there are no emissions or monitoring data available that are pertinent to the domestic manufacture, use, and release of 2-BEB in the United States.

To address the absence of available domestic emissions or monitoring data for 2-BEB, the Petitioner estimated 2-BEB emissions based on their projected production volume. To estimate the projected maximum production volume of 2-BEB, the Petitioner assumed that the production time would be 48–50 hours per batch and that 2-BEB would be manufactured in 10 batches. Thus, the approximate production time for the entire quantity of 2-BEB would range from 480–500 hours. For processing, it was assumed that 2-BEB would be incorporated into a water-based paint product and that 265,000 kg/yr would be available for processing (275,000 kg/yr minus 10,000 kg/yr lost to emissions in manufacturing). The Petitioner estimated that the projected maximum production volume of 2-BEB would be about 275,000 kg/yr.

The Petitioner then used the Chemical Screening Tool for Exposure and Environmental Releases (ChemSTEER) to generate screening-level emissions estimates for potential releases of 2-BEB into the air and water from manufacturing and processing. ChemSTEER is a computer-based software program developed by the EPA's Office of Pollution Prevention and Toxics (OPPT). ChemSTEER combines multiple mathematical models (*e.g.,* EPA/OPPT penetration model) and emissions estimation methods (*e.g.,* AP–42) into one tool that can be used to generate ''screening-level estimates for environmental releases of and worker exposures to a chemical manufactured and used in industrial and commercial operations (*i.e.,* workplaces).'' [18] ChemSTEER results are considered screening level because many of the models in ChemSTEER are characterized by the EPA to be screening-level models. As such, the screening-level results from ChemSTEER ''are intended to be conservative in that predicted results are likely to be higher, or at least higher than average, as compared to actual releases and exposures occurring in the real-world setting.'' [19]

To generate screening-level emissions estimates for potential releases of 2-BEB into the air from manufacturing and processing, the Petitioner used the following emission points. For manufacturing, emissions points for 2-BEB included:

- Aqueous wash of organic mass.
- Distillation column bottoms disposal.
- Sampling of liquid product.
- Loading of liquid product into drums.
- Equipment cleaning losses of liquids from multiple vessels.

For processing, emissions points for 2-BEB included:

- Unloading liquid raw material from drums.
- Vapor release from open liquid surfaces.
- Sampling liquid product.
- Loading liquid product into drums.
- Equipment cleaning of liquids from multiple vessels.
- Cleaning liquid residuals from drums used to transport raw material.

[11] The complete Petition can be found in the docket, EPA–HQ–OAR–2024–0392–0003 through EPA–HQ–OAR–2024–0392–0018.

[12] The email notification can be found in the docket, EPA–HQ–OAR–2024–0392–0033.

[13] A summary of this correspondence can be found in the risk assessment in the docket, EPA–HQ–OAR–2024–0392–0038.

[14] Docket ID No. EPA–HQ–OAR–2024–0392.

[15] OECD Guidelines for the Testing of Chemicals, section 4. Health Effects: *https://doi.org/10.1787/20745788*.

[16] U.S. Environmental Protection Agency. (2010). IRIS Toxicological Review of Ethylene Glycol Mono Butyl Ether (EGBE) (Final Report), EPA/635/R–08/006F.

[17] U.S. Environmental Protection Agency. (1991). Integrated risk information system (IRIS) assessment for 2-Methoxyethanol. Prepared by the National Center for Environmental Assessment.

[18] ChemSTEER Users Guide, May 2015. Available at *https://www.epa.gov/sites/default/files/2015-05/documents/user_guide.pdf.*

[19] ChemSTEER Users Guide, May 2015. Available at *https://www.epa.gov/sites/default/files/2015-05/documents/user_guide.pdf.*

The Petitioner then used the Equilibrium Criterion model to estimate emissions of 2-BEB from wastewater into the air.[20] Table 1 summarizes the Petitioner's estimated air emissions of 2-BEB from manufacturing, processing, and wastewater.

TABLE 1—AIR EMISSIONS OF 2-BEB

Source	Air emissions (kg/yr)	Air emissions (tpy)
Manufacturing	2.74E–3	3E–6
Processing	7.65E–1	8E–4
Wastewater	9.73E1	1.07E–1
Total	9.8E1	1.1E–1

2. Modeling of 2-BEB Air Concentrations and Calculation of Noncancer Hazard Quotient

The Petitioner used the EPA's Exposure and Fate Assessment Screening Tool (EFAST) to estimate ambient air concentrations of 2-BEB emitted from manufacturing, processing, and wastewater.[21] The EFAST tool uses SCREEN3, a single-source Gaussian plume model that provides maximum ground-level concentrations for point, area, flare, and volume sources. The SCREEN3 model is the screening version of the Industrial Source Complex 3 (ISC3) model.[22] The SCREEN3 model is listed by the EPA as an appropriate screening model. As a screening tool, EFAST/SCREEN3 ''modeled estimates of concentrations and doses are designed to reasonably overestimate exposures, for use in an exposure assessment in the absence of or with reliable monitoring data.'' [23]

The Petitioner conducted air concentration modeling using the air emissions of 2-BEB that are presented in table 1 and assumed that the mass of 2-BEB is released as fugitive emissions (using the following fugitive release parameters for manufacturing/processing—a 3 meter (m) release height from the ground and a release area that is 10 m in length and 10 m in width; using the following fugitive release parameters for wastewater—a 3 m release height from the ground and a release area that is 10,000 m in length and 10,000 m in width) with no emission control technologies in operation. Table 2 presents the maximum 24-hour and annual average 2-BEB inhalation exposure concentrations in milligram per cubic meter (mg/m^3) that resulted from the Petitioner's analysis.

TABLE 2—PETITIONER'S MODELED INHALATION EXPOSURE CONCENTRATIONS FOR 2-BEB BY SOURCE

Source	Max 24 hour air concentration (mg/m^3)	Max annual air concentration (mg/m^3)
Manufacturing	1.82E–5	7.98E–8
Processing	3.98E–4	2.18E–5
Wastewater	2.61E–6	2.08E–7

C. Human Health Effects Assessment

The Petitioner claimed that 2-BEB is rapidly metabolized in vivo to form EGBE (CAS No. 111–76–2) and benzoic acid (CAS No. 65–85–0) in both animals and humans. The EPA has previously modified the HAP list by removing EGBE from the glycol ethers category.[24] To address the sparse literature on the toxicity and health effects of 2-BEB, the Petitioner performed oral, dermal, and inhalation toxicity testing according to OECD guidelines. The Petitioner used subchronic oral toxicity data for 2-BEB consistent with OECD Guideline 408 (1998) [25] and the 2010 IRIS assessment for EGBE [26] as the basis for their human health effects evaluation of 2-BEB. The Petitioner also provided a worst-case inhalation toxicity analysis using EGME, which is the most potent chemical with a RfC available for the glycol ethers category.[27]

To evaluate the potential for acute inhalation toxicity, the Petitioner provided inhalation studies that were performed using aerosolized 2-BEB. Male and female F344/DuCrl rats were exposed via a nose-only exposure system for four hours to chamber concentrations of 3.71 or 5.39 mg 2-BEB per liter (L) (these exposure concentrations were significantly higher than the estimated ambient concentrations in table 2). The rats were observed for 14 days post-exposure. Clinical observations of soiling on various parts of the body were made; however, this effect was resolved by day seven. All treated groups had mean body weight losses on day two, with recovery to pre-exposure levels by day eight. There were no gross pathological abnormalities detected at necropsy.

[20] EQC, v 1.0, *https://www.trentu.ca/cemc/resources-and-models/eqc-equilibrium-criterion-model.*

[21] U.S. Environmental Protection Agency. (2014). E-FAST-Exposure and Fate Assessment Screening Tool Version 2014: *https://www.epa.gov/tsca-screening-tools/e-fast-exposure-and-fate-assessment-screening-tool-version-2014.*

[22] *See* U.S. Environmental Protection Agency. Air Quality Dispersion Modeling—Screening Models: *https://www.epa.gov/scram/air-quality-dispersion-modeling-screening-models#screen3.*

[23] U.S. Environmental Protection Agency. (2014). E-FAST-Exposure and Fate Assessment Screening Tool Version 2014: *https://www.epa.gov/tsca-screening-tools/e-fast-exposure-and-fate-assessment-screening-tool-version-2014.*

[24] 69 FR 69320, Nov. 29, 2004.

[25] OECD. (2018). Test No. 408: Repeated Dose 90-Day Oral Toxicity Study in Rodents, OECD Guidelines for the Testing of Chemicals, section 4, *OECD Publishing: https://doi.org/10.1787/9789264070707-en.*

[26] U.S. Environmental Protection Agency. (2010). IRIS Toxicological Review of Ethylene Glycol Mono Butyl Ether (EGBE) (Final Report), EPA/635/R–08/006F, 2010. Available at *https://www.epa.gov/iris* and in the docket for this action.

[27] U.S. Environmental Protection Agency. (1991). Integrated risk information system (IRIS) assessment for 2-Methoxyethanol. Prepared by the National Center for Environmental Assessment. Available at *https://www.epa.gov/iris* and in the docket for this action.

To compensate for the lack of 2-BEB vapor inhalation data, the Petitioner relied on the chronic inhalation data for EGBE to estimate the chronic risk of 2-BEB exposure to human health. EGBE is one of the two rapidly generated metabolites for 2-BEB, which the EPA has previously delisted from the glycol ethers category,[28] The Petitioner also provided a route-to-route extrapolation based on 2-BEB oral toxicity data for comparison. To address the uncertainty associated with estimates that are either not chemical or route specific, the Petitioner also performed a worst-case toxicity analysis for EGME, the most potent chemical for the glycol ethers category with a RfC.

The Petitioner conducted acute and subchronic oral toxicity studies according to OECD guidelines. These studies served to help characterize the hazards from oral exposure to 2-BEB and to estimate a screening oral reference dose (RfD) value for 2-BEB exposure. Additionally, the Petitioner conducted an acute dermal exposure study. The study details and results can be found in Attachment A–1 and Attachments 1–12 of the Petition and are available in the docket for this action.

In the acute oral study, the Petitioner estimated the median lethal dose (LD50) value to be 940 mg/kg in female Wistar rats. In mice dosed with 2000 mg/kg, adverse effects or abnormal findings were observed in the kidney, urinary bladder, stomach glandular mucosa, and liver. Mice dosed at 550 mg/kg showed no abnormal clinical signs. In the dermal study, female and male Wistar rats were exposed at 2000 mg/kg with no clinical signs of toxicity, skin reactions, or mortality under the 14-day observation period.

The Petitioner submitted a 28-day study on the reproductive toxicity of 2-BEB via oral exposure. The study, published by Johnson et al., 2016 was conducted in groups of 12 male and 12 female Crl:CD(SD) rats fed either 0, 500, 1,500, or 5,000 parts per million (ppm) of 2-BEB.[29] For both female and male rats, dosing began two weeks before breeding. For females, dosing continued until postpartum day four and for male rats until test day 36. Over the course of the study, dams (pregnant rats) were monitored for clinical observations, body weight gain, and feed consumption. At necropsy, dams were evaluated for gross pathologic lesions, organ weights (liver, kidney, spleen, uterine), hematological effects, number of corpora lutea, uterine implantations, resorptions, and live/dead fetuses. The fetuses were weighed, sexed, and evaluated for external alterations or skeletal abnormalities. No treatment-related effects on reproductive function or pre-natal/early neonatal growth and survival in the offspring were observed at any dose level. At 5,000 ppm, decreased feed consumption and body weight, increased spleen weight, and regenerative anemia were observed in female rats. Females given 5,000 ppm also had a treatment-related higher platelet count, which may occur in association with reticulocytosis. Higher mean urea nitrogen, triglyceride, creatinine, and phosphorus concentrations were found in female rats in the 5,000-ppm treatment group. No adverse effects were observed in the females given 500 or 1,500 ppm or in males at any dose level.

The Petitioner also submitted a subchronic oral toxicity study.[30] The study was performed in compliance with Good Laboratory Practice (GLP) and OECD guidelines. The dose selections were informed by a previously conducted range-finding study published by Johnson et al., 2015.[31] Ten male and ten female rats per treatment group consumed food containing 0, 500, 1,500, or 5,000 ppm of 2-BEB for at least 90 days. These diets resulted in time-weighted average doses of 0, 28.9, 88.1, or 285 mg/kg/day for males and 0, 32.6, 94.9, or 310 mg/kg/day for females, respectively. The Petitioner reported daily cage-side observations, weekly detailed clinical observations, ophthalmic examinations, body weights/body weight gains, feed consumption, hematology, prothrombin time, clinical chemistry, urinalysis, selected organ weights, and gross and histopathologic examinations. No 2-BEB-related effects on clinical signs, ophthalmic, hematology, prothrombin time, urinalysis parameters, organ weight, or gross or histopathologic observations were observed. At the highest dose (5,000 ppm), female rats showed a decrease in body weight gain and feed consumption. At the same dose, male rats demonstrated a statistically significant reduction in serum sodium levels. No effects were observed at the doses below 5,000 ppm. The Petitioner selected a no-observed-adverse-effect level (NOAEL) of 1,500 ppm based on decreases in body weight gain and feed consumption in females.

The NOAEL was identified as 1,500 ppm because this was the highest dose administered to rats that did not result in any measurable adverse effects. In the 90-day oral toxicity study, the 5,000-ppm dose reduced body weight and food consumption in female rats. The Petitioner estimated the NOAEL to be equivalent to roughly 100 mg/kg/day in rats. The Petitioner chose not to convert the rat dose to a human equivalent dose (HED), citing species differences in the rate of formation of, and sensitivity to, the butoxyacetic acid (BAA) metabolite of EGBE, which is linked to hemolytic toxicity. The Petitioner applied a cumulative uncertainty factor (UF) of 90 to account for extrapolation from the subchronic to a chronic exposure duration ($UF_S = 1$), extrapolation from a lowest-observed-adverse-effect level (LOAEL) to a NOAEL ($UF_L = 1$), variation in sensitivity within the human population ($UF_H = 10$), variation in sensitivity from animals to humans ($UF_A = 3$), and gaps in the database ($UF_D = 3$). The Petitioner's selection of uncertainty factors assumed that 2-BEB toxicity is driven solely by the EGBE/BAA metabolites, resulting in an estimated RfD of 1.1 mg/kg/day based on 2-BEB oral toxicity data.

The Petitioner selected the UF_H of 10 to match the UF_H used in the EGBE RfD determination and account for the potential for some individuals to have altered metabolism, excretion, or susceptibility to hemolytic toxicity of the BAA metabolite. The Petitioner selected the UF_A of 3 for toxicokinetics due to the absence of a physiologically based pharmacokinetic (PBPK) model for 2-BEB to account for species differences between the rats and humans. A value of 1 was selected by the Petitioner for the toxicodynamic portion citing several studies that have been performed indicating that humans are significantly less susceptible than rats to the hemolytic effects of BAA.[32] [33] [34] [35] The Petitioner also

[28] 69 FR 69320, Nov. 29, 2004.

[29] Johnson, K.J. et al. (2016). 2-Butoxyethyl Benzoate: A Combined Dietary Toxicity Study with the Reproduction/Developmental Toxicity Screening Test in Crl:CD(SD) Rats. *Report of Toxicology and Environmental Research And Consulting, The Dow Chemical Company.*

[30] 2-Butoxyethyl Benzoate: 90-Day Dietary Toxicity Study in Crl:CD(SD) Rats, which is available in the docket for this action in the document Attachment A–1.

[31] Johnson, K.J. et al. (2015). 2-Butoxyethyl Benzoate: Dietary Range-Finding Study in Crl:CD(SD) Rats. *Report of Toxicology and Environmental Research And Consulting, The Dow Chemical Company.*

[32] Carpenter CP, Pozzani MS, Weil CS, Nair JH, Keck GA, Smyth HF (1956). The toxicity of butyl CELLOSOLVE™ solvent. Arch Ind Hlth, 14, –114–31.

[33] Ghanayem BI and Sullivan CA (1993). Assessment of the haemolitic activity of 2-butoxyethanol and its major metabolite, butoxyacetic acid, in various mammals including humans. Human & Exp. Toxicol., 12, 305–311.

[34] Udden MM (2000). Rat erythrocyte morphological changes after gavage dosing with 2-butoxyethanol: a comparison with the in vitro

selected the UF_D of 3 because 2-BEB lacks a chronic study and subchronic studies in a second species. The Petitioner did not select the UF_D of 10 because of the available data on the 2-BEB metabolites, EGBE and benzoic acid. The Petitioner determined that the UF_S of 1 is sufficient because the effect used as the basis of their RfD, hemolysis, does not increase with longer exposure. The Petitioner also determined that the UF_L of 1 is sufficient because the RfD was derived using a NOAEL.

The Petitioner provided the following reports on the methods and results of three key in vitro GLP-studies to assess 2-BEB's potential for genotoxicity: a Bacterial Reverse Mutation Assay (OECD Guideline 471), an In Vitro Mammalian Cell Gene Mutation Test (OECD Guideline 476), and an In Vitro Mammalian Chromosome Aberration Test (OECD Guideline 473). In addition, the Petitioner provided the results of a Mammalian Erythrocyte Micronucleus Test (OECD Guideline 474).[36] For genotoxicity, 2-BEB tested negative both with and without metabolic activation for all three in vitro genotoxicity assays and likewise tested negative in the in vivo micronucleus test assay.

D. Risk Characterization and Conclusions Regarding Risks to Human Health

There is currently no RfC for 2-BEB. Therefore, to calculate a conservative noncancer hazard quotient (HQ) for inhalation exposure to 2-BEB, the Petitioner used the most conservative RfC value associated with a member of the glycol ethers category as a surrogate, namely, EGME.[37] According to the IRIS, the RfC for EGME is 0.02 mg/m^3. The Petitioner divided the concentrations in table 2 of this preamble by the RfC for EGME to calculate a conservative noncancer HQ for 2-BEB. Table 3 presents the resulting HQs by emissions source.

TABLE 3—NONCANCER HAZARD QUOTIENTS USING 2-BEB EXPOSURES AND EGME RfC

Source	Max 24 hour HQ	Max annual HQ
Manufacturing	9.1E–4	3.99E–6
Processing	1.99E–2	1.09E–3
Wastewater	1.31E–4	1.04E–5
Total	2E–2	1.1E–3

The Petitioner concluded that despite the conservative assumptions and large production volumes, all HQs are substantially below 1, indicating low to minimal risk for human inhalation exposures. For ingestion and dermal exposures, the Petitioner summarized various HQs estimated in table 17 of the Petition, which is available in the docket for this action.

E. Ecological Assessment and Conclusions

The Petitioner conducted an aquatic and terrestrial ecological risk assessment to evalute the potential for adverse environmental effects from 2-BEB. The Petitioner estimated a water-concentration benchmark that should be protective of aquatic life as a predicted no-effect concentration (PNEC) value considering invertebrates, fish, and algae. For terrestrial PNECs, the Petitioner evaluated earthworms and plants. Sediments were excluded from the Petitioner's analysis because the fugacity modeling predicted minor partitioning to sediments.

The Petitioner conducted ecotoxicity tests for aquatic biota using the the appropriate OPPT guideline.[38] The Petitioner also conducted acute and chronic fish and invertebrat, toxicity tests along with algal tests for 2-BEB in surface water using appropriate EPA/OECD guidelines. The Petitioner further conducted earthworm and seedling emergence tests on 2-BEB in soils using appropriate guidelines. Based on those tests, which also fulfill the EPA OPPT minimum data set requirement, the Petitioner calculated an aquatic PNEC of 0.00659 mg/L water and a soil PNEC of 2.5 mg/kg dry weight (dw) soil. To estimate environmental risks, the Petitioner used the HQ approach, as described in section II.D. of this preamble. In this case, the HQ compares the estimated exposure level in the environment to the calculated PNEC.

III. EPA Analysis of the Petition

In this section, the EPA provides an overview of the Agency's substantive and technical review of the Petition. In section III.A., the EPA presents the details of the Agency's review of 2-BEB. In section III.B., the EPA presents the Agency's review of the inhalation exposure assessment for 2-BEB, which includes the Petitioner's estimate of emissions of 2-BEB, modeling of 2-BEB air concentrations, and calculation of noncancer HQs. In section III.C., the EPA discusses the Agency's review of oral and dermal exposure of 2-BEB. In section III.D., the EPA discusses the Agency's review of human health effects of 2-BEB. In section III.E., the EPA presents the review of human health risk characterization for 2-BEB and relevant conclusions. In section III.F., the EPA presents the review of ecological risk characterization for 2-BEB.

The EPA's substantive review of the Petition described in this section indicates that the Petitioner has provided sufficient information to support the requested deletion of 2-BEB under the substantive criteria set forth in CAA section 112(b)(3)(C) and (D). Therefore, the EPA is determining that there are adequate data on the potential health and environmental effects of 2-BEB and further determining that emissions, ambient concentrations, bioaccumulation, or deposition of 2-BEB may not reasonably be anticipated to cause any adverse human health or environmental effects.

A. Overview

2-BEB falls within the CAA section 112(b)(1) definition of the glycol ether category, which is a listed HAP as

effects of butoxyacetic acid on rat and human erythrocytes. J. Appl. Toxicol., 20, 381–387.

[35] Udden MM and Patton CS (1994). Hemolysis and deformability of erythrocytes exposed to butoxyacetic acid, a metabolite of 2-butoxyethanol: sensitivity in rats and resistance in normal humans. J. Applied Toxicol., 14(2), 91–96.

[36] The detailed methods and results are available in the docket for this action in the document Attachments 1–12.

[37] See documents ''EGME_Worst-case-toxicity-9-8-22'' and ''Revised_Tables11and12'' in the docket for details.

[38] Summarized in table 2, p. 9, of Attachment 2 of the Petition.

redefined by 40 CFR part 63, subpart C. It is a colorless liquid with low odor, a high boiling point (292 °C at 760 mmHg), and low vapor pressure (2.09E–04 mmHg at 20 °C). It is miscible in water with moderate water solubility (106 mg/L at 20 °C). Additionally, 2-BEB has utility as a coalescing solvent for water-based, low VOC coatings. It can also be used as a replacement for phthalate-based plasticizers in caulking compounds and in some PVC formulations.

The Petition states that 2-BEB released to the air has a degradation half-life of 11.8 hours with an overall environmental persistence of 21.6 hours. The EPA evaluated the predicted half-life of 2-BEB in air and found these values to be reasonable.

Based on the EPA's review of the available information on 2-BEB, the Agency has concluded that inhalation and ingestion are the important routes of nonoccupational exposures that would result from 2-BEB emissions, and we have considered these two routes of exposure as well as some dermal exposures in evaluating the Petition.

B. Inhalation Exposure Assessment

1. Air Emissions Estimate

As a first step in evaluating the Petitioner's inhalation risk assessment, the EPA reviewed the Petitioner's estimate of emissions of 2-BEB upon which the Petitioner based the exposure modeling. Upon review, the EPA determined the Petitioner appropriately identified the potential sources of 2-BEB air emissions from manufacturing, processing, and wastewater. The quantities of 2-BEB that the Petitioner assumed to be manufactured and processed, which are presented in section II.B.1. of this preamble, were reasonable maximum values that provided conservatively high emissions estimates. Specifically, the Petitioner indicated that, on average, 57,000 lbs/yr (26,000 kg/yr) of 2-BEB were produced from 2016 to mid-2019. The Petitioner estimated that their maximum production would be 600,000 lbs/yr (275,000 kg/yr), which is more than 10 times current production. The EPA welcomes comment on this production assumption to ensure that it is reasonable and conservative. The Petitioner indicated in its June 29, 2021, letter that ''based on its current understanding of production potential, the petitioner adhered to the 275,000 kg/year figure for projected future growth and/or new product applications related to future delisting.'' [39] In the same letter, the Petitioner clarified that a previously mentioned production estimate of 5,000,000 lbs/yr (2.286,000 kg/yr), which was presented as a ''high-end wishful thinking estimate,'' was deemed to be ''unrealistic'' given the Petitioner's current knowledge of the potential customer base. The EPA also finds that the model inputs, assumptions, analysis, and methods used by the Petitioner to estimate 2-BEB air emissions are appropriate and provide reasonably conservative screening-level estimates of 2-BEB emissions and exposure estimates.[40]

2. Modeling of 2-BEB Air Concentrations and Calculation of Noncancer Hazard Quotient

The Petitioner performed the inhalation exposure assessment using the screening models discussed in section II.B. of this preamble. The Petitioner stated that a high level of conservatism was built into deriving 2-BEB exposure estimates. The conservative assumptions built into the analysis include:

- Assumed open-top mixing and processing of 2-BEB during incorporation into water-based paints. Traditionally, this is a closed-unit operation, but for this worst-case assumption, the process is assumed to be an open process.
- Assumed any release of 2-BEB into water does not undergo any treatment at Publicly Owned Treatment Works (POTWs).
- Assumed all emissions during both manufacturing and processing are uncontrolled, such as when a thermal oxidizer is utilized.
- Assumed emissions to be fugitive emissions and not point or stack sources. Stack or point emissions usually result in lower ambient ground-level concentrations compared with fugitive emissions modeling.
- Assumed that a person exposed to 2-BEB lives in the vicinity where the chemical is both manufactured and processed.
- Used theoretical maximum production values of 2-BEB for emissions calculations and modeling. (Performed the screen using both the ''Maximum'' estimate of 275,000 kg/yr and the ''High End—Unrealistic'' estimate of 2,300,000 kg/yr).

The EPA has determined that the Petitioner performed the dispersion modeling analysis following appropriate modeling guidance for a screening assessment. To verify the Petitioner's results, the EPA conducted a screening assessment of the Petitioner's 2-BEB emissions estimates using a Human Exposure Model (HEM) screening tool that uses data from American Meteorological Society/EPA Regulatory Model (AERMOD).[41] These assumptions included:

- Assumption of fugitive/ground level emissions (1 m release height, 10 m length, 10 m width).
- 100 m to the nearest residence.
- 100 m to the fenceline.
- 10x acute factor for releases directly to air, 1x acute factor for releases from water.

Using the ''maximum'' production volume estimate of 275,000 kg/yr, the EPA's screening assessment shows that the highest predicted maximum annual average off-site (*i.e.,* beyond the fenceline, which was assumed to be 100 m from the emissions source) concentration of 2-BEB would be 7E–4 mg/m^3. This concentration is approximately one order of magnitude higher than the highest concentration estimated by the Petitioner of 2.2E–5 mg/m^3. The primary reason the EPA's screen resulted in a higher concentration is that the Agency used much more conservative fugitive release parameters, particularly for the fugitive release from water. The chronic noncancer HQ for 2-BEB, which was calculated by dividing the maximum annual concentration of 2-BEB from the EPA's conservative screening analysis by the RfC for EGME (chronic noncancer HQ = 7E–4 mg/m^3 divided by 0.02 mg/m^3) is 3.6E–2. This is approximately one order of magnitude higher than the HQ estimated by the Petitioner of 1.1E–3. The primary reason the EPA's screen resulted in a higher concentration is that the Agency used much more conservative fugitive release parameters. Regardless, both the Petitioner's and the EPA's assessments result in an HQ value for 2-BEB that is well below 1, which indicates that chronic noncancer risk is below levels of concern. Even using the ''high end—unrealistic'' production volume estimate of 2,300,000 kg/yr in the screening assessment, the EPA finds that the chronic noncancer HQ for 2-BEB is below levels of concern at 1.6E–1.

The EPA's screening assessment also evaluated potential acute exposure

[39] This letter can be found in the docket, EPA–HQ–OAR–2024–0392–0038.

[40] Note, as described in section III.B.2. of this preamble, the EPA conducted the chronic noncancer inhalation risk screening analysis using both the ''maximum'' production volume estimate of 275,000 kg/yr and the ''high end—unrealistic'' production volume estimate of 2,300,000 kg/yr, which is over 8 times higher than the ''maximum'' value. In the EPA's screening analysis, the acute noncancer risks were below levels of concern using either production value.

[41] U.S. Environmental Protection Agency. AERMOD Modeling System Development: *https://www.epa.gov/scram/aermod-modeling-system-development.*

levels. As indicated above, a 10x acute factor was applied to emissions from manufacturing and processing to account for surges in emissions from the batch manufacturing and processing emissions points.[42] Assuming that 2-BEB slowly partitions into the air from wastewater throughout the year, a factor of 1x was used for acute air emissions from wastewater. Based on the EPA's screening assessment of potential acute exposure levels, the Agency determined the maximum 1-hour concentrations to be 2.5E–4 mg/m^3 from manufacturing and processing and 3.2E–2 mg/m^3 from wastewater. The acute noncancer HQ for manufacturing and processing from the EPA's screening analysis is 2.7E–2 and was calculated by dividing the acute concentration of 2-BEB from manufacturing and processing by the California Reference Exposure Level (REL) for EGME and then multiplying by an acute factor of 10 (acute noncancer HQ = 2.5E–4 mg/m^3 divided by 0.093 mg/m^3 times 10). The acute noncancer HQ for wastewater from the EPA's screening analysis is 3.43E–1 and was calculated by dividing the acute concentration of 2-BEB from wastewater by the California REL for EGME (acute noncancer HQ = 3.2E–2 mg/m^3 divided by 0.093 mg/m^3). The total acute HQ is 3.7E–1 and was calculated as the sum of the HQ for manufacturing and processing and wastewater (total HQ = 2.7E–2 + 3.43E–1). Even with conservative screening assumptions, the acute HQ (REL) for 2-BEB is below 1 and, therefore, indicates that acute noncancer risk is below levels of concern. Based on the results of the acute inhalation study in rats (which showed no acute effects even at very high concentrations, discussed in section II.C. of this preamble), the Petitioner concluded that 2-BEB was not likely to cause acute effects. Thus, the Petitioner did not perform an evaluation of the acute inhalation risks. This largely agrees with the acute inhalation risk analysis that the EPA performed out of an abundance of caution.

C. Oral and Dermal Exposure

For oral and dermal exposures, the Petitioner estimated possible exposures of adults (18+ years), children (6–12 years), and young children (1–5 years). Regarding workplace exposures and acute events resulting from workplace accidents, it is the EPA's longstanding view that these kinds of exposures are beyond the scope of consideration for HAP delisting actions because CAA section 112(b)(3)(C) only references ''emissions, ambient concentrations, bioaccumulation, or deposition of the substance.[43] For all other scenarios, the Petitioner assumed its modeled ambient water concentration of 3.84E–11 mg/L.

For the analysis, the EPA derived dermal and ingestion values for the exposure factors from the EPA's Exposure Factors Handbook.[44] Although uptake via the oral and dermal routes likely have different absorption efficiencies, an oral exposure results in a first pass of the chemical substance through the liver while dermal exposure does not. The EPA's estimates of uptake of 2-BEB for dermal and ingestion exposures are provided in table 4. For this evaluation, the EPA used the water concentration of 3.84E–11 mg/L, which is the same concentration assumed by the Petitioner. In the EPA's evaluation, the possible uptakes via both routes were added to estimate a total possible internal dose. As a result of the findings of the acute oral study submitted by the Petitioner, the EPA believes that it is reasonable that an oral screening value would be protective against any potential acute dermal effects.[45]

TABLE 4—UPTAKE VIA INGESTION AND DERMAL EXPOSURES TO 2-BEB IN WATER

Dermal and ingestion uptake	Adult	Child 6 to <11 yr	Child 1 to <6 yr
Exposure Factor Values:			
Skin surface area (cm^2), upper 95th percentile	25,000	14,800	8,320
Body weight (kg), mean	80	31.8	13.5
Skin permeability coefficient (cm/hr)	0.012	0.012	0.012
Drinking water ingestion (L/day), upper 95th percentile	2.938	1.258	0.8134
Absorption via dermal or oral routes, assumed	100%	100%	100%
Incidental ingestion rate while swimming (mL/hr),			
upper 95th percentile	92	96	96
Swimming (min/year), upper 95th percentile	2172	2172	2172
Bathing (hr/day), upper 95th percentile	0.500	0.767	0.857
Estimated 2-BEB Uptake from Water:			
Ingestion via drinking water (mg/kg/day)	1.34E–12	1.31E–12	1.80E–12
Dermal uptake when showering (mg/kg/day)	7.20E–14	1.64E–13	2.43E–13
Incidental ingestion when swimming (mg/kg/day)	4.38E–15	1.15E–14	2.71E–14
Dermal uptake during swimming (mg/kg/day)	1.43E–14	2.13E–14	2.82E–14
Total uptake (mg/kg/day)	1.43E–12	1.51E–12	2.10E–12

D. Human Health Effects of 2-BEB

The EPA is unaware of any verified chronic or subchronic inhalation studies on 2-BEB. Due to the lack of health benchmarks or speciated exposure data for 2-BEB and other HAP in the glycol ethers category, the EPA used the EGME health benchmark to conduct an initial risk screen for human health effects that

[42] Note that, since the acute screen already includes a 10x factor for emissions, the acute analysis was performed using the ''maximum'' production volume estimate only.

[43] *See, e.g.,* 70 FR 75055, Dec. 15, 2005 (explaining that the ''EPA cannot consider the health effects of emissions within facility boundaries. That is the purview of the Occupational Safety and Health Administration.''(final rule delisting methyl ethyl ketone as a HAP)); 61 FR 30816, 30821, June 18, 1996 (explaining that ''it would be illogical to assume that worker exposures should be considered in deciding whether to delist [a HAP] when continued listing would not itself lead to any requirement that occupational exposures be controlled.'' (final rule delisting caprolactam as a HAP.)).

[44] U.S. Environmental Protection Agency (EPA). (2011). Exposure Factors Handbook: 2011 Edition (EPA/600/R–09/052F). National Center for Environmental Assessment, Washington, DC. Available at: *https://www.epa.gov/expobox/about-exposure-factors-handbook.*

[45] For additional information on the EPA's analysis, see the memo titled ''ICF Review of the Dow Chemical Company petition to the U.S. Environmental Protection Agency under the Clean Air Act, section 112(b)(3) to Remove 2-Butoxyethyl Benzoate (2-BEB, CAS RN 5451–76–3) from the Glycol Ethers Category in the List of Hazardous Air Pollutants dated September 30, 2019,'' which is available in the docket for this action.

was based on total glycol ethers exposure.[46] The EPA assumes that there is no relevant potential for risk from exposure to the glycol ethers category if no risk is found when assuming that 100% of the glycol ethers exposure is to EGME. Therefore, the EPA finds the use of the RfC for EGME to be a conservative approach for assessing the potential for chronic risk from 2-BEB exposure. To also inform the EPA's evaluation of the Petition, the Agency considered the worst-case toxicity scenario using EGME and the chemical substance specific data but did not rely on the route-to-route or EGBE-based approaches provided by the Petitioner. The EPA determined that the worst-case inhalation toxicity data for EGME and the submitted data concerning the potential for health effects from oral exposure to 2-BEB are sufficient data for deciding whether to delist 2-BEB.

The Petitioner stated that it was unable to perform either chronic or subchronic inhalation studies due to the low volatility of 2-BEB (vapor pressure of 0.00029 mmHg at 20 °C). The boiling point of 2-BEB at 760 mm Hg (ambient pressure) is 282 °C. Based on this low vapor pressure and substantially high boiling point, and given that the manufacturing and conditions of use for water-based paints occur at ambient temperatures, the Petitioner concluded that it is unlikely that sufficient vapor of 2-BEB can be generated under conditions that represent those scenarios. The theoretical maximum saturated vapor concentration was calculated by the Petitioner to be 3.5 mg/m^3.

As discussed in section II.C. of this preamble, the Petitioner relied on the inhalation data for EGBE to estimate the chronic risk of 2-BEB exposure to human health and, for comparison, provided a route-to-route extrapolation based on 2-BEB oral toxicity data. To address the uncertainty associated with estimates that are neither chemical nor route specific, the Petitioner also performed a worst-case toxicity analysis relying on the RfC for EGME, the most potent chemical with a RfC available from the EPA's IRIS assessment program for the glycol ethers category.

The results of the oral toxicity studies lead EPA to conclude that 2-BEB is not reasonably anticipated to cause developmental or reproductive toxicity at the doses tested (up to 5,000 ppm in diet), based on the lack of fetal loss or observed abnormalities. The RfC for EGME is based on reproductive effects. Adverse testicular effects from exposure to EGME were observed in rabbits and rats, with the LOAEL identified as 311 mg/m^3 or 100 ppm. Based on the lack of any adverse effects observed at doses up to 1,500 ppm of 2-BEB, the EPA concludes that the use of the EGME toxicity value is sufficiently conservative to account for the potential for adverse reproductive, developmental, or other noncancer effects from exposure to 2-BEB.

Further, the RfC for EGME of 0.02 mg/m^3 is expected to sufficiently account for any adverse inhalation noncancer effects from potential exposure to 2-BEB's metabolite EGBE.[47] The EPA considers using the RfC for EGME as more conservative than using the available chronic RfC for EGBE of 0.1 mg/m3. Further, the RfC for EGME is expected to account for acute inhalation effects from EGBE as supported by available acute inhalation values for EGBE that include the acute inhalation Minimal Risk Level (MRL) of 6 ppm (28.8 mg/m^3),[48] the acute inhalation REL of 4.7 mg/m3, and the 8-hr inhalation REL of 0.164 mg/m3.[49]

As part of the three oral dietary repeat-dose studies (acute, 28-day, and 90-day), the Petitioner performed a toxicokinetic evaluation to measure the parent chemical, 2-BEB, and two of its expected metabolites, EGBE and BAA, in the blood of the non-fasted animals using liquid chromatography with tandem mass spectrometry detection (LC/MS–MS). BAA has been identified as the metabolite responsible for the hemolytic toxicity of EGBE. While the data provided suggest the BAA metabolite may be responsible for observations of hemolytic toxicity at the high dose exposure to 2-BEB, the data do not demonstrate that the BAA metabolite is solely responsible for the full range of adverse effects observed at doses of 5000 ppm.

In the 90-day study, the parent chemical (2-BEB) and two expected metabolites (EGBE and BAA) were also measured in urine using both LC/MS–MS and gas chromatography with tandem mass spectrometry detection (GC/MS–MS). 2-BEB was not detected in any of the treated blood samples. However, 2-BEB was detected in most of the treated urine samples, with one sample in the low-dose group and all samples in the higher-dose groups showing quantifiable levels. The levels of 2-BEB in 24-hr urine samples from male and female rats accounted for up to 0.294% and 0.599%, respectively, of the administered dose (the daily intake of 2-BEB) from all treatment groups. The Petitioner hypothesized that the positive results in urine may be attributed to contamination of urine samples with 2-BEB test diet. In all urine samples from treated rats, 2-BEB, EGBE, and BAA were all quantifiable. Toxicokinetic evaluations in blood showed the concentrations of BAA and EGBE were linear across dose levels in both male and female rats. While BAA showed a linear relationship across dose levels in female rats, non-detects in treated females prevented a toxicokinetic analysis for EGBE. However, the toxicokinetic evaluations in urine showed that the measured concentrations of 2-BEB, EGBE, and BAA were linear across dose levels in both male and female rats.

The EPA performed a separate evaluation of the submitted data and the Petitioner's estimate of an RfD based on 2-BEB toxicity data. Based on this evaluation, the EPA has determined that the worst-case inhalation toxicity data for EGME and the submitted data concerning the potential for health effects from oral exposure to 2-BEB are sufficient data for deciding whether to delist 2-BEB.

Using the rat point of departure of 100 mg/kg/day, the EPA calculated the HED based on the available information and the recommendations provided in EPA guidance.[50] The resulting HED was estimated to be 24 mg/kg/day. The EPA also applied differing UFs to this HED. However, the EPA agreed with the Petitioner's selection of the NOAEL based on the limited data available for 2-BEB.[51] Additionally, the EPA agreed

[46] A similar surrogate approach was applied to support the removal of the surfactant alcohol ethoxylates and their derivatives (SAED) from the glycol ethers category in the HAP list. In this case the subchronic RfC for 2-methoxy-1-propanol (MP) was used as a surrogate for SAED compounds (65 FR 47342, Aug. 2, 2000).

[47] U.S. Environmental Protection Agency. (2010). IRIS Toxicological Review of Ethylene Glycol Mono Butyl Ether (EGBE) (Final Report), EPA/635/R–08/006F, 2010.

[48] Agency for Toxic Substances and Disease Registry (ATSDR). (1998). Toxicological profile for 2-butoxyethanol and 2-butoxyethanol acetate. *U.S. Department of Health and Human Services, Public Health Service.*

[49] California Office of Environmental Health Hazard Assessment. Ethylene Glycol Monobutyl Ether: *https://oehha.ca.gov/air/chemicals/ethylene-glycol-monobutyl-ether.*

[50] U.S. Environmental Protection Agency. (2011). Recommended use of body weight ¾ as the default method in derivation of the oral reference dose [EPA Report]. (EPA/100/R11/0001).

[51] The EPA notes the Petitioner's choice not to calculate an HED from the rat data citing species differences in the rate of formation of, and sensitivity to, the BAA metabolite, which is linked to hemolytic toxicity. The EPA additionally notes that the UF of 3 is representative of half an order of magnitude (*i.e.,* the square root of 10) and multiplying two factors of 3 should lead to a product of 10. In a risk assessment done by the EPA using these factors, the total UF applied based on the Petitioner's choices should have been 100, not 90. Further, the EPA notes some of the choices the Petitioner made in the application of UFs. For

with the Petitioner's recommended UF_H of 10 based on the absence of human data available for 2-BEB, the potential for interindividual differences in metabolism and excretion of the BAA metabolite, and the potential for interindividual susceptibility to the benzoic acid metabolite, the metabolite of 2-BEB formed in addition to EGBE. The EPA adjusted the UF_A from 3 to 1 based on the Agency's application of default dosimetry methods to calculate the HED and evidence that animals may be more sensitive than humans to 2-BEB's benzoic acid, EGBE, and BAA metabolites that may drive the observed oral toxicity of 2-BEB. This is consistent with the application of the UF_A in the IRIS assessments available for EGBE and benzoic acid. Finally, the EPA adjusted the UF_D from 3 to 10 to address the uncertainty attributable to the very limited database available on the toxicity of 2-BEB.

In summary, to screen for the potential for oral risk from 2-BEB, the EPA used the Petitioner's data and applied more conservative values. Specifically, the EPA used the HED of 24 mg/kg/day and applied a cumulative UF of 1,000 (UF_S = 10, UF_H = 10, UF_A = 1, and UF_D = 10). This resulted in an oral screening value of 0.024 mg/kg/day. This screening value is expected to be protective of effects from 2-BEB's metabolites. Benzoic acid has an available chronic RfD of 4 mg/kg/day, whereas EGBE has an available intermediate MRL of 0.07 mg/kg/day. The 2-BEB chronic oral screening value is expected to also be protective of acute oral risk from EGBE, based on the availability of an acute oral MRL from the Agency of Toxic Substances and Disease Registry (ATSDR) for EGBE of 0.4 mg/kg/day.

The EPA evaluated the available information on 2-BEB genotoxicity and relied on this information to evaluate the evidence regarding the potential for 2-BEB to cause cancer in humans. Currently, the EPA is not aware of any available two-year carcinogenicity study for 2-BEB. However, due to consistent evidence of non-genotoxicity in vitro, lack of genotoxicity or lesions observed in repeated dose studies in vivo, and supplemental evidence regarding a lack of carcinogenicity for 2-BEB's metabolites, the EPA has concluded that the available evidence suggests that 2-BEB is unlikely to be a carcinogen at doses below the derived RfC and RfD.

E. Human Health Risk Characterization and Conclusions

To characterize the noncancer risk associated with exposure to 2-BEB or EGME, we calculated a HQ. For EGME, the inhalation HQ was developed by comparing the modeled level of exposure to the RfC for EGME. For 2-BEB, the HQ was calculated by comparing the modeled level of exposure to the EPA-estimated RfD for 2-BEB. If the HQ is less than 1, the reference level is not exceeded, and adverse noncancer health effects are unlikely.

The EPA has determined that the use of the RfC for EGME is health conservative. The Petitioner points out that the critical effect used to derive the RfC for EGME is a potential effect on the testes, but that no effect on the testes has been observed with 2-BEB. Similarly, the EPA finds that there is no data to support that 2-BEB would be expected to be equal to or greater in toxicity than EGME. In addition, the EGME RfC criterion includes margins of safety built into the IRIS RfC (*i.e.,* any needed UFs to address sensitive subpopulations and other factors) and, therefore, accounts for sensitive subpopulations.

The EPA also finds that the Petitioner performed the dispersion modeling analysis following appropriate modeling guidance for a screening assessment. To verify the Petitioner's results, the EPA conducted a screening assessment using the Petitioner's 2-BEB emissions estimates, a HEM screening tool that uses data from AERMOD, and conservative assumptions, including the use of the RfC for EGME.[52]

Using the ''maximum'' production volume estimate of 275,000 kg/yr, the HQ for 2-BEB based on the EPA's conservative screening analysis, $3.6E-2$, is approximately one order of magnitude higher than the HQ estimated by the Petitioner of $1.1E-3$. The primary reason the EPA's screen resulted in a higher concentration is that the Agency used much more conservative fugitive release parameters. Regardless, both screens result in an HQ value for 2-BEB that is well below 1 and, therefore, indicate that chronic noncancer risk is below the presumed level of concern. In addition, the EPA performed the chronic noncancer screen using the ''high end—unrealistic'' production volume estimate of 2,300,000 kg/yr and the HQ for 2-BEB based on the same conservative screening values was still below 1 at $1.6E-1$.

The EPA's screen also included an estimate of the acute noncancer risk using the REL for EGME of 0.093 mg/m^3. As indicated above, a 10x acute factor was applied to emissions from manufacturing and processing to account for surges in emissions from the batch manufacturing and processing emissions points (note that, since the acute screen already includes a 10x factor for emissions, the acute analysis was performed using the ''maximum'' production volume estimate only). Since the EPA assumes that 2-BEB slowly partitions into the air from the water throughout the year, a factor of 1x was used for acute air emissions from water. Table 5 shows the calculations of the acute HQs based on the REL from the EPA's screen:

example, the Petitioner's selection of UF_S of 1 does not consider the non-BAA mediated or hemolytic adverse outcomes observed in the 90-day toxicity study.

[52] U.S. Environmental Protection Agency. AERMOD Modeling System Development: *https://www.epa.gov/scram/aermod-modeling-system-development.*

TABLE 5—ACUTE HQ (REL) FOR 2-BEB BASED ON THE EPA'S SCREEN

Source	Max 1-hour concentration (mg/m^3)	Acute factor	Acute HQ (REL)
Manufacturing and Processing	2.5E–4	10	2.71E–2
Wastewater	3.2E–2	1	3.43E–1
Total			3.7E–1

Even with conservative screening assumptions, the acute HQ (REL) for 2-BEB is well below 1 and, therefore, indicates that acute noncancer risk is below levels of concern.

In summary, the Petitioner's modeling analysis demonstrated that, using conservative assumptions, the maximum noncancer HQ is well below 1 and therefore below levels of concern. This finding was confirmed by the EPA's own screening analysis. In addition, the EPA's screening analysis indicated that the acute HQ, based on the maximum 1-hour concentration and the application of acute factors, was also below 1 and therefore below levels of concern. Therefore, the EPA does not anticipate inhalation exposure to 2-BEB to occur at levels of concern for human health.

Regarding ingestion and dermal exposures, the Petitioner summarizes various HQs it estimated for ingestion and dermal exposures in table 17 of the Petition. None exceed 1.29E − 11 (youngest age group, ingestion exposure). The Petitioner used an RfD of 0.19 based on 2-BEB's molar equivalent of EGBE. The EPA also performed a seperate risk screening analysis for oral and dermal expsoure to 2-BEB. As shown in the last row of table 6, the total HQs for dermal and ingestion exposures are well below 1 and therefore below levels of concern. The screening level the EPA used to determine 2-BEB's ingestion HQ is the EPA's screening oral value based on the Petitioner's 2-BEB toxicity data of 0.024 mg/kg/day. Based on the EPA's analysis, the Agency expects that maximum exposures to 2-BEB via ingestion of water contaminated with 2-BEB from air releases are unlikely to exceed 0.024 mg/kg/day. The resulting HQs for adults and children are well below 1, ranging from 5.96E − 11 to 8.75E − 11. Therefore, the EPA's analysis of dermal and ingestion exposures confirms the Petitioner's findings.[53]

TABLE 6—HAZARD QUOTIENTS FOR DERMAL AND INGESTION

Dermal and ingestion	Adult	Child 6 to <11 yr	Child 1 to <6 yr
Total uptake (mg/kg/day)	1.43E–12	1.51E–12	2.10E–12
Hazard Quotient (total uptake/0.024 mg/kg/day)	5.96E–11	6.29E–11	8.75E–11

Therefore, based on the EPA's evaluation of information presented in the Petition, data made available after the submission of the Petition, and the Agency's own analyses, we have made an initial determination that emissions, ambient concentrations, bioaccumulation, or deposition of 2-BEB may not reasonably be anticipated to cause any adverse effects to human health.

F. Ecological Risk Characterization and Conclusions

2-BEB has moderate solubility in water (106 mg/L) and low vapor pressure. These properties lead to the potential for 2-BEB air emissions to deposit into water systems, which can result in ecological exposure. Considering the mammalian data on metabolism and the predicted fish biotransformation, the EPA expects that 2-BEB would be quickly metabolized in fish and, therefore, agrees with the Petitioner's finding that 2-BEB would be unlikely to bioaccumulate in aquatic food chains. In addition, based on the EQC multimedia fugacity modeling conducted by the Petitioner, the EPA agrees that 2-BEB is expected to readily degrade (hydrolyze) after release to air and deposition to soils and surface waters.

The exposure estimates for the environment were based on concentrations predicted by the Equilibrium Partitioning (EQP) model worst-case projected emissions to air only. The EPA has summarized the Petitioner's data from appendix 2, tables 3 and 4 in table 7, below. The HQ values for water and soil in the last row of table 7 are 10 orders of magnitude below the HQ of 1. Even though the EPA considers the Petitioner's exposure estimates to be uncertain, it is unlikely that environmental concentrations were underestimated by 10 orders of magnitude. Thus, the very low HQs indicate that the potential for adverse environmental effects is too low to be of concern.[54]

TABLE 7—POTENTIAL FOR ADVERSE AND WIDESPREAD EFFECTS OF 2-BEB IN THE ENVIRONMENT IS LOW

Parameter	Air (mg/m^3) [a]	Water (mg/L) [b]	Soil (mg/kg dw) [b]	Sediment (mg/kg dw) [a]
EQP-Estimated Concentration	5.4E–11	2.02E–12	1.19E–10	2.31E–11

[53] For additional information on the EPA's analysis, see the memo titled ''ICF Review of the Dow Chemical Company petition to the U.S. Environmental Protection Agency under the Clean Air Act, section 112(b)(3) to Remove 2-Butoxyethyl Benzoate (2-BEB, CAS RN 5451–76–3) from the Glycol Ethers Category in the List of Hazardous Air Pollutants dated September 30, 2019'' in the docket for this rulemaking.

[54] For additional information on the EPA's analysis, see the memo titled ''ICF Review of the Dow Chemical Company petition to the U.S. Environmental Protection Agency under the Clean Air Act, section 112(b)(3) to Remove 2-Butoxyethyl Benzoate (2-BEB, CAS RN 5451–76–3) from the Glycol Ethers Category in the List of Hazardous Air Pollutants dated September 30, 2019,'' which is available in the docket for this action.

TABLE 7—POTENTIAL FOR ADVERSE AND WIDESPREAD EFFECTS OF 2-BEB IN THE ENVIRONMENT IS LOW—Continued

Parameter	Air (mg/m^3) [a]	Water (mg/L) [b]	Soil (mg/kg dw) [b]	Sediment (mg/kg dw) [a]
PNEC	NR	6.59E–3	2.5	NC
Hazard Quotient (HQ)	NR	3.07E–10	4.75E–11	NC

2-BEB = 2-butoxyethyl benzoate; EQP = Equilibrium Partitioning modeling based on the Equilibrium Criterion (EQC) multimedia fugacity model; PNEC = predicted no-effect concentration; dw = dry weight; NR = not relevant; NC = not calculated.
[a] From table 3 of Attachment 2 to the petition.
[b] From table 4 of Attachment 2 to the petition.

G. Conclusions

The proposal to grant the Petition is based on the EPA's evaluation of the Petition and available information concerning the potential hazards and projected exposures to 2-BEB.[55] The EPA made an initial determination that there are adequate data on the health and environmental effects of 2-BEB to determine that emissions, ambient concentrations, bioaccumulation, or deposition of 2-BEB may not reasonably be anticipated to cause adverse human health or environmental effects. This action therefore includes the EPA's detailed rationale for proposing to grant the Petition to delete 2-BEB from the glycol ethers category of HAP under CAA section 112(b)(1). If, after opportunity for public comment and review of those comments, the EPA makes the final determination to grant the Petition, the deletion of 2-BEB will be codified in 40 CFR part 63, subpart C.

In section III.D., the EPA also discussed uncertainty with respect to available evidence of the risk of 2-BEB. Uncertainty is an inherent part of risk assessment that requires the integration of multiple factors and predictions of risk that are not directly observable. For decisions that are based largely on risk assessments, some degree of uncertainty is acceptable and unavoidable.

To this end, the risk assessment applies conservative toxicity and exposure assumptions to bias potential error toward overstating human and ecological health effects. Thus, the EPA is confident that even when we consider the uncertainties in the Petition's initial assessment and in the additional analyses by the EPA and the Petitioner, the results are more likely to overestimate rather than underestimate true exposures and risks.[56] The EPA long maintained that CAA section 112(b)(3)(C) does not require absolute certainty that a pollutant will not cause adverse effects on human health or the environment before it may be deleted from the HAP list. For example, the EPA has previously explained that the terms ''adequate'' and ''reasonably'' in CAA section 112(b)(3)(C) indicate that the Agency must weigh the potential uncertainties and the likely significance of any projections, assessments, and estimations.[57]

Uncertainty arises for several reasons in the risk assessment for 2-BEB, including that the physicochemical properties of 2-BEB make it difficult to directly assess the inhalation toxicity. Further, the use of a worst-case toxicity IRIS value for EGME as the source of the human health effects decision criteria, while considered a conservative approach, is imperfect and leads to uncertainty in characterizing the risk of inhalation exposure to 2-BEB. Additionally, there are gaps in the database of toxicity information available for 2-BEB with little to no scientific data available outside of what the Petitioner provided. No chronic oral exposure study is available for 2-BEB. While the potential for oral or dermal risk was estimated to be very low based on the data available, this represents an area of uncertainty addressed in part by the application of the 10-fold subchronic UF_S. Further, the adverse health outcomes observed in the 90-day oral toxicity study mirror those observed in animals for 2-BEB's metabolite, benzoic acid. In the IRIS assessment of benzoic acid,[58] animals were considered to be a poor predictor of human toxicity levels based on the observation of effects in chronic animal studies at levels generally recognized as safe for humans by the Food and Drug Administration (FDA). However, the RfD for benzoic acid was set in 1988 based on a study conducted by the FDA in 1973 and is likely out of date. The EPA also recognizes that uncertainty exists in the EQC multimedia fugacity model used to predict the fate and transport of 2-BEB in the environment. These models are simplifications of reality, and some variables are excluded. For example, in the EQC model, the characteristics of the environment are fixed to facilitate chemical-to-chemical comparison.[59] The EPA believes these uncertainties are largely addressed by using the reference value for the more toxic EGME (which incorporates UFs) and the conservative assumptions used in the emissions and exposure assessments. Taken together, these assumptions bias any potential error towards overstating the human health effects, even considering the uncertainties described above.

Regarding carcinogenicity, the information available to the EPA currently indicates a lack of genotoxicity for 2-BEB and no evidence suggests carcinogenicity at levels below the oral noncancer screening level of 0.024 mg/kg/day and the EGME RfC of 0.02 mg/m^3. If additional information on 2-BEB is provided to the EPA between the proposal and the final action on this delisting decision, the Agency expects to evaluate and peer-review such information.

Additionally, regarding environmental effects, the HQ values for water and soil are 10 orders of magnitude below the HQ of 1. Even though the EPA considers the Petitioner's exposure estimates to be uncertain, it is unlikely that

[55] See *e.g.,* 70 FR 75056 (final rule delisting methyl ethyl ketone as a HAP); 69 FR 69322 (final rule delisting ethylene glycol monobutyl ether as a HAP); 61 FR 30822 (final rule delisting caprolactam as a HAP).

[56] For example, the EPA has also long acknowledged that the maximum individual lifetime cancer risk, under CAA section 112(f)(2), ''does not necessarily reflect the true risk, but [rather] displays a conservative risk level which is an upper-bound that is unlikely to be exceeded.'' National Emissions Standards for Hazardous Air Pollutants: Benzene Emissions from Maleic Anhydride Plants, Ethylbenzene/Styrene Plants, Benzene Storage Vessels, Benzene Equipment Leaks, and Coke By-Product Recovery Plants (Benzene NESHAP) (54 FR 38044, 38045 (Sep. 14, 1989).

[57] See *e.g.,* 70 FR 75047, 75048 (Dec. 19, 2005) (final rule delisting methyl ethyl ketone as a HAP). The final decision involves the consideration and balancing of factors that are uniquely within the Administrator's expertise, including policy choices, and predictions on ''the frontiers of scientific knowledge.'' *Nat'l Lime Ass'n* v. *EPA,* 627 F.2d 416, 454 (D.C. Cir. 1980); *See also Baltimore Gas & Elec. Co.* v. *NRDC,* 462 U.S. 87, 103 (1983).

[58] U.S. Environmental Protection Agency. (1988). IRIS Chemical Assessment Summary of Benzoic Acid. Available at: *https://iris.epa.gov/static/pdfs/0355_summary.pdf.*

[59] Trent University. EQC (EQuilibrium Criterion) Model: *https://www.trentu.ca/cemc/resources-and-models/eqc-equilibrium-criterion-model.*

environmental concentrations of 2-BEB were underestimated by 10 orders of magnitude. Thus, the EPA reasonably expects that the potential for adverse environmental effects posed by emissions of 2-BEB would be low.

In conclusion, upon the showing made by the Petitioner, the EPA has made an initial determination that there are adequate data on the potential health and environmental effects of 2-BEB. Based on this data, the EPA has determined that emissions, ambient concentrations, bioaccumulation, or deposition of 2-BEB may not reasonably be anticipated to cause any adverse effects to the human health or adverse environmental effects. Therefore, the EPA proposes to grant the Petition and delete 2-BEB from the glycol ethers category of the HAP list.

IV. Proposed Amendments to 40 CFR Part 63, Subpart C

The EPA is proposing to amend 40 CFR part 63, subpart C to codify the deletion of 2-BEB from the glycol ethers category in the HAP list established by 42 U.S.C. 7412(b)(1). Additionally, the EPA intends to reorganize 40 CFR part 63, subpart C to provide clarity and allow space for future amendments. The EPA is not, however, reopening for comment any of the previous decisions currently codified in 40 CFR part 63, subpart C. The EPA is making a ministerial, administrative revision to better reorganize the subpart and is not reexamining either the broader regulatory framework or specified earlier delisting decisions.

Specifically, the EPA intends to reorganize subpart C to dedicate 40 CFR 63.61 to deletions from the HAP list and 40 CFR 63.62 to additions to the HAP list. Under 40 CFR 63.61, the EPA intends to begin each paragraph with a paragraph heading that states the delisted HAP. Under 40 CFR 63.62, the EPA intends to begin each paragraph with a heading that states the listed HAP.

Additionally, the EPA intends to revise the entry for EGBE to state: ''deleted from the glycol ethers category in the list of hazardous air pollutants established by 42 U.S.C. 7412(b)(1)'' instead of ''deleted from the list of hazardous air pollutants established by 42 U.S.C. 7412(b)(1).'' The EPA is not, however, reopening for comment the previous delisting decision for EGBE.

A memorandum showing the rule edits that would be necessary to incorporate the changes to 40 CFR part 63, subpart C is available in the docket for this rulemaking (Docket ID No. EPA–HQ–OAR–2024–0392).

V. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is not a significant regulatory action and was therefore not submitted to the Office of Management and Budget (OMB) for review.

B. Executive Order 14192: Unleashing Prosperity Through Deregulation

This action is expected to be an Executive Order 14192 deregulatory action. This proposed rule is expected to provide burden reduction by removing a compound from the HAP list, therefore decreasing the regulatory burden of any facility that uses or plans to use the compound.

C. Paperwork Reduction Act (PRA)

This action does not impose an information collection burden under the PRA. The final action will remove 2-BEB from the CAA section 112(b)(1) HAP list and, therefore, eliminate the need for information collection under the CAA.

D. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. In making this determination, the EPA concludes that the impact of concern for this rule is any significant adverse economic impact on small entities and that the Agency is certifying that this rule will not have a significant economic impact on a substantial number of small entities because the rule relieves regulatory burden on the small entities subject to the rule. The acceptance of this proposal would delist a HAP currently listed under CAA section 112(b)(1); therefore, the regulatory burden would decrease. The EPA has therefore concluded that this action would relieve regulatory burden for all directly regulated small entities.

E. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local or Tribal governments or the private sector.

F. Executive Order 13132: Federalism

This action does not have federalism implications. It will 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.

G. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have Tribal implications as specified in Executive Order 13175. It will not have substantial direct effects on Tribal governments, on the relationship between the Federal government and Indian Tribes, or on the distribution of power and responsibilities between the Federal government and Indian Tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this action.

H. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

Executive Order 13045 directs Federal agencies to include an evaluation of the health and safety effects of the planned regulation on children and explain why the regulation is preferable to potentially effective and reasonably feasible alternatives. This action is not subject to Executive Order 13045 because it is not a significant regulatory action under section 3(f)(1) of Executive Order 12866, and because the EPA does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children. This determination is based on the fact that the RfC is determined to be protective of sensitive sub-populations, including children.

EPA's *Policy on Children's Health* applies to this action. Section III.E. of this preamble describes the analyses conducted to determine the human health impacts of 2-BEB for all populations, including children. We have made an initial determination that 2-BEB may not reasonably be anticipated to cause any adverse effects to human health, including children.

I. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This action is not subject to Executive Order 13211, because it is not a significant regulatory action under Executive Order 12866.

J. National Technology Transfer and Advancement Act (NTTAA)

This rulemaking does not involve technical standards.

Lee Zeldin,

Administrator.

[FR Doc. 2025–23566 Filed 12–19–25; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 25

[IB Docket Nos. 17–95 and 18–315; DA 25–1045; FR ID 322435]

Space Bureau Seeks To Refresh the Record on Proposed Rules To Permit the Use of Additional Frequency Bands for NGSO Satellites To Communicate With Earth Stations in Motion

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: In this document, the Space Bureau seeks to refresh the record on proposed rules to permit the use of additional frequency bands for non-geostationary orbit (''NGSO'') Fixed Satellite Service (''FSS'') satellites to communicate with Earth Stations in Motion (''ESIMs'').

DATES: Comments are due January 21, 2026.

Reply Comments are due February 5, 2026.

ADDRESSES: You may submit comments, identified by IB Docket Nos. 17–95 and 18–315, by any of by any of the following methods:

Federal Communications Commission's Website: https://apps.fcc.gov/ecfs/. Follow the instructions for submitting comments. the following methods:

People with Disabilities. Contact the FCC to request reasonable accommodations (accessible format documents, sign language interpreters, CART, etc.) by email: *fcc504@fcc.gov* or phone: 202–418–0530 (voice) or TTY: 202–418–0432.

For detailed instructions for submitting comments and additional information on the rulemaking process, see the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Gregory Coutros, (202) 418–2351, *Gregory.Coutros@fcc.gov* or Carolyn Roddy, (202) 418–0960, *Carolyn.Roddy@fcc.gov.*

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Public Notice, DA 25–1045, released December 10, 2025 by the Commission's Space Bureau. The document is available for public inspection online at *https://docs.fcc.gov/public/attachments/DA-25-1045A1.pdf.*

Filing Requirements

Interested parties may file comments and reply comments on or before the dates indicated in the **DATES** section above.

☐ *Electronic Filers.* Comments may be filed electronically using the internet by accessing the Commission's Electronic Comment Filing System (ECFS): *http://apps.fcc.gov/*ecfs.

☐ *Paper Filers.* Parties who file by paper must include an original and one copy of each filing.

○ Filings can be sent by hand or messenger delivery, by commercial courier, or by the U.S. Postal Service. All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission.

○ Hand-delivered or messenger-delivered paper filings for the Commission's Secretary are accepted between 8:00 a.m. and 4:00 p.m. by the FCC's mailing contractor at 9050 Junction Drive, Annapolis Junction, MD 20701. All hand deliveries must be held together with rubber bands or fasteners. Any envelopes and boxes must be disposed of before entering the building.

○ Commercial courier deliveries (any deliveries not by the U.S. Postal Service) must be sent to 9050 Junction Drive, Annapolis Junction, MD 20701.

○ Filings sent by U.S. Postal Service First-Class Mail, Priority Mail, and Priority Mail Express, must be sent to 45 L Street NE, Washington, DC 20554.

• *People with Disabilities.* To request materials in accessible formats for people with disabilities (Braille, large print, electronic files, audio format), send an email to *fcc504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at 202–418–0530.

Ex Parte Presentations

This proceeding shall be treated as a ''permit-but-disclose'' proceeding in accordance with the Commission's *ex parte* rules. Persons making *ex parte* presentations must file a copy of any written presentation or a memorandum summarizing any oral presentation within two business days after the presentation (unless a different deadline applicable to the Sunshine period applies). Persons making oral *ex parte* presentations are reminded that memoranda summarizing the presentation must (1) list all persons attending or otherwise participating in the meeting at which the *ex parte* presentation was made, and (2) summarize all data presented and arguments made during the presentation. If the presentation consisted in whole or in part of the presentation of data or arguments already reflected in the presenter's written comments, memoranda or other filings in the proceeding, the presenter may provide citations to such data or arguments in his or her prior comments, memoranda, or other filings (specifying the relevant page and/or paragraph numbers where such data or arguments can be found) in lieu of summarizing them in the memorandum. Documents shown or given to Commission staff during *ex parte* meetings are deemed to be written *ex parte* presentations and must be filed consistent with 47 CFR 1.1206(b). In proceedings governed by 47 CFR 1.49(f) or for which the Commission has made available a method of electronic filing, written *ex parte* presentations and memoranda summarizing oral *ex parte* presentations, and all attachments thereto, must be filed through the electronic comment filing system available for that proceeding, and must be filed in their native format (*e.g.,* .doc, .xml, .ppt, searchable .pdf). Participants in this proceeding should familiarize themselves with the Commission's *ex parte* rules.

Regulatory Flexibility Analysis

The *NGSO ESIM FNPRM* included an Initial Regulatory Flexibility Analysis (''IRFA'') pursuant to 5 U.S.C. 603, exploring the potential impact on small entities of the Commission's proposals. We invite parties to file comments on the IRFA in light of this request to refresh the record.

Providing Accountability Through Transparency Act

Consistent with the Providing Accountability Through Transparency Act, Public Law 118–9, a summary of this document will be available on *https://www.fcc.gov/proposed-rulemakings.*

Synopsis

In the document, the Space Bureau seeks to refresh the record on proposed rules to permit the use of additional frequency bands for non-geostationary orbit (''NGSO'') Fixed Satellite Service (''FSS'') satellites to communicate with Earth Stations in Motion (''ESIMs''). The Commission sought comment in 2020 on proposals that would allow NGSO FSS systems to communicate with ESIMs in the 28.35–28.6 GHz band. The comment period closed over five years