



**ENVIRONMENTAL PROTECTION AGENCY**

**[EPA-HQ-OAR-2014-0471; FRL-10010-36-OAR]**

**RIN 2060-AS26**

**Granting Petitions to Add 1-bromopropane (also known as 1-BP) to the List of Hazardous Air Pollutants**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** The U.S. Environmental Protection Agency (EPA) is granting petitions to add n-propyl bromide (nPB) (Chemical Abstract Service (CAS) No. 106-94-5) to the list of hazardous air pollutants (HAP) contained in the Clean Air Act (CAA). The EPA is taking final action to grant these petitions based on the petitioners having met the requirements contained in CAA section 112(b)(3), which allows any person to petition the Administrator to add a substance to the list of HAP. The term 1-bromopropane (1-BP), which is used throughout this document, is the common name for nPB. This is the first occasion on which the EPA is granting petitions to add a substance to the list of HAP that Congress created in 1990. Following this action, the EPA will take a separate regulatory action to add 1-BP to the list of HAP under CAA section 112(b)(1).

**DATES:** The petitions are granted as of **[INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

**ADDRESSES:** The EPA has established a docket for this document under Docket ID No. EPA-HQ-OAR-2014-0471. All documents in the docket are listed on the <https://www.regulations.gov/> website. Although listed, some information is not publicly available, *e.g.*, Confidential Business

Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available electronically through <https://www.regulations.gov/>. Out of an abundance of caution for members of the public and our staff, the EPA Docket Center and Reading Room was closed to public visitors on March 31, 2020, to reduce the risk of transmitting COVID-19. Our Docket Center staff will continue to provide remote customer service via email, phone, and webform. There is a temporary suspension of mail delivery to the EPA, and no hand deliveries are currently accepted. For further information and updates on EPA Docket Center services and the current status, please visit us online at <https://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** For questions about this final action, contact Mr. John Schaefer, Sector Policies and Programs Division, Policies and Strategies Group (D205-02), Office of Air Quality Planning and Standards, Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541-0296; fax number: (919)-541-4991; and email address: [schaefer.john@epa.gov](mailto:schaefer.john@epa.gov).

**SUPPLEMENTARY INFORMATION:**

*Acronyms and abbreviations.* We use multiple acronyms and terms in this document.

While this list may not be exhaustive, to ease the reading of this document and for reference purposes, the EPA defines the following terms and acronyms here:

1-BP	1-bromopropane (also known as n-propyl bromide (nPB))
CAA	Clean Air Act
CAS	Chemical Abstract Service
EPA	Environmental Protection Agency
HAP	hazardous air pollutant(s)
HSIA	Halogenated Solvents Industry Alliance
ICL	Israel Chemicals Ltd.
MOA	mode of action

NESHAP	national emission standards for hazardous air pollutants
NTP	National Toxicology Program
NYSDEC	New York State Department of Environmental Conservation
OMB	Office of Management and Budget
PERC	perchloroethylene
TRI	Toxics Release Inventory

*Organization of this document.* The information in this document is organized as follows:

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#### **I. Background**

*A. How do I obtain a copy of this document and other related information?*

The docket number for this final action is Docket ID No. EPA-HQ-OAR-2014-0471. In addition to being available in the docket, an electronic copy of this document will also be available on the Internet. The EPA will post a copy of this final action at

<https://www3.epa.gov/ttn/atw/pollutants/atwsmo.html> following official Agency signature.

Following publication in the **Federal Register**, the EPA will post the **Federal Register** version and key technical documents on this same website.

*B. CAA Authority: Petitions to Modify the List of HAP*

The CAA section 112(b)(3)(A) specifies that any person may petition the Administrator to modify the list of HAP contained in CAA section 112(b)(1) by adding or deleting a substance.

CAA section 112(b)(3)(B) sets out the substantive criteria for granting a petition. It calls for the Administrator to add a substance to the CAA section 112(b)(1) list, otherwise known as the HAP list, “upon a showing by the petitioner or on the Administrator’s own determination that the substance is an air pollutant and that emissions, ambient concentrations, bioaccumulation or deposition of the substance are known to cause or may reasonably be anticipated to cause adverse effects to human health or adverse environmental effects.” The Administrator is required under the CAA section 112(b)(3)(A) to either grant or deny a petition within 18 months of the receipt of a complete petition by publishing a written explanation of the reasons for the Administrator’s decision. The Administrator may not deny a petition based solely on inadequate resources or time for review.

Finally, under the CAA section 112(e)(4), the Administrator’s decision to add a pollutant to the CAA section 112(b)(1) HAP list is not a final Agency action subject to judicial review, except that any such action may be reviewed when the Administrator promulgates emission standards for the pollutant. Accordingly, this decision to grant petitions to add 1-BP to the HAP list is not subject to judicial review until the Administrator promulgates applicable the CAA section 112(d) standards addressing emissions of 1-BP. Under the CAA section 112(d) the EPA has a “clear statutory obligation to set emissions standards for each listed HAP.” *National Lime Association v. EPA*, 233 F. 3d 625, 634 (D.C. Cir. 2000). Additionally, under CAA section 112(c)(5), the EPA is required to promulgate emission standards under the CAA sections 112(d)(2) and (3) within two years of adding a new source category to the CAA section 112(c)(1) source category list.

This is the first occasion on which the EPA is granting a petition to add a substance to the list of HAP that Congress created in 1990. Since 1990, the EPA has amended the CAA section

112(b)(1) HAP list by removing four listed HAPs. They are caprolactam (61 FR 30816 (June 18, 1996)); ethylene glycol monobutyl ether (69 FR 69320 (August 2, 2000)); surfactant alcohol ethoxylates and their derivatives (these are compounds that were considered to be included in glycol ethers, which is a listed HAP; (65 FR 47342 (August 2, 2000)); and methyl ethyl ketone (MEK) (70 FR 75047 (December 19, 2005)). For more information, see <https://www.epa.gov/haps/initial-list-hazardous-air-pollutants-modifications#mods>. The EPA has also denied a petition to remove methanol from the CAA section 112(b)(1) HAP list. 66 FR 21929 (May 2, 2001).

### *C. Petitions Submitted to the EPA*

Halogenated Solvents Industry Alliance (HSIA) and New York State Department of Environmental Conservation (NYSDEC) submitted petitions to add 1-BP to the CAA section 112(b)(1) HAP list on October 28, 2010, and November 24, 2011, respectively. Both HSIA and NYSDEC petitions referred to the chemical as nPB and 1-BP. In an action published on November 23, 2015, the EPA added the chemical by the name 1-BP to the Community Right-to-Know Toxic Chemical Release Reporting requirements. In addition, the chemical is listed in the EPA's Substance Registry Services, the EPA's authoritative resource for basic information about chemicals, as 1-BP. Finally, the chemical is currently undergoing an EPA Toxic Substances Control Act risk evaluation, under Docket ID No. EPA-HQ-OPPT-2015-0084 as 1-BP. Therefore, for this action and for future regulations under the CAA, the EPA will refer to the chemical identified by CAS No. 106-94-5 as 1-bromopropane or 1-BP.

On November 28, 2012, in response to the EPA's requests for additional data, HSIA supplemented its petition. Following the receipt of the petitions, the EPA conducted a review to determine whether the petitions were complete according to Agency criteria for the CAA section

112(b) actions, which we explained in the February 6, 2015, document (80 FR 6676).

Specifically, after reviewing these petitions and supplemental information, the EPA determined that the petitions addressed all the necessary subject areas for the Agency to assess whether emissions, ambient concentrations, bioaccumulation, or deposition of 1-BP are known to cause or may reasonably be anticipated to cause adverse human health effects or adverse environmental effects. The EPA determined these petitions to add 1-BP to the HAP list to be complete and published a notification of receipt of a complete petition in the **Federal Register** on February 6, 2015 (80 FR 6676), and invited the public to comment on the technical merits of these petitions and to submit any information relevant to the technical review of the petitions. On March 11, 2015 (80 FR 12794), the EPA agreed to extend the comment period for the notification of receipt of complete petitions to May 7, 2015.

On January 9, 2017, the EPA published a draft document in the **Federal Register** containing the Agency's intended rationale for granting the petitions to add 1-BP to the CAA section 112(b)(1) HAP list (82 FR 2354). In the draft document, the EPA determined that these petitions met criteria specified in the CAA section 112(b): *i.e.*, 1-BP is an air pollutant and its emissions and ambient concentrations "may reasonably be anticipated to cause adverse effects to human health." Subsequently, on June 6, 2017, the EPA published an action granting the request by Albemarle Corporation, a U.S.-based manufacturer of 1-BP, to extend the comment period until October 1, 2017, to provide an opportunity for prospective commenters to review the 2017 Toxics Release Inventory (TRI), which included newly required emission reporting of 1-BP (82 FR 26091). This current action is the final step in granting the petitioners' request to add 1-BP to the CAA section 112(b)(1) HAP list. Even following the granting of this petition to add 1-BP to the list, sources will remain under no regulatory or statutory obligation to reduce emissions of 1-

BP until a separate regulatory action is taken. In section IV of this document, we explain the future additional regulatory actions that the EPA intends to consider either simultaneously with the addition of 1-BP to the CAA section 112(b)(1) HAP list or soon thereafter.

## **II. What comments were received on the draft document to grant the petitions to add 1-BP to the CAA section 112(b)(1) HAP list?**

The EPA received 12 comments on the draft document to add 1-BP to the CAA section 112(b)(1) list of HAP. Two commenters opposed adding 1-BP to the CAA section 112(b)(1) HAP list, while 10 commenters supported the action. All comments are in the docket for this action. A summary of the major comments and our responses are presented in this section.

### *A. Comments Regarding Estimated 1-BP Emissions*

*Comment:* Albemarle Corporation requested that the EPA extend the comment period to October 1, 2017, to ensure that data from the TRI database for 1-BP would inform the final document. Albemarle Corporation stated the extension would provide the public with an opportunity to review the TRI dataset for 1-BP usage, sources, and emissions and also to use those data to prepare meaningful comments on the draft document.

*Response:* The EPA also agreed that it would be useful to review reported TRI emissions releases for 1-BP prior to finalizing the document. Since January 2017, when the draft document was published, two years of emissions data had been submitted to the EPA's TRI. Specifically, one commenter provided TRI data for 1-BP for calendar year 2016 during the extended comment period. Further, according to the EPA's TRI, in 2016, 55 facilities (in 27 states) reported emissions totaling 626,659 pounds (more than 313 tons) of 1-BP into the air, with multiple sources reporting emissions in excess of 20,000 pounds (10 tons per year). Total 1-BP air emissions reported to TRI in 2017 were 746,562 pounds (more than 373 tons).

Finally, the emissions data provided supported the risk analysis submitted by HSIA. The primary risk driver for the analysis was a degreasing operation in Collegeville, Pennsylvania, where the maximum individual lifetime risk was estimated at 38-in-1 million. The emissions reported by the facility to the TRI database showed approximately 70 tons per year of 1-BP emissions, which supports the petitioner's emissions estimates and the assertion that 1-BP may present a risk to human health.

*Comment:* Albemarle Corporation also commented that the emission estimates used by petitioners to estimate the fence-line ambient concentration of 1-BP lacked accuracy and were "wholly inadequate to support the petition." They requested an extension of the comment period to October 1, 2017, in order to resolve the significant differences between the estimates provided by the petitioner, HSIA, and the commenter's estimated emissions.

*Response:* The EPA agreed that resolving any differences between the commenter's emission estimates and the petitioner's estimates was an important issue that needed to be resolved prior to deciding on the petitions. Therefore, the EPA extended the comment period until October 1, 2017 (82 FR 26091, June 6, 2017). The commenter, however, did not provide additional information during the comment period extension. The EPA evaluated HSIA's emission estimates and modeling assumptions and found them to be reasonable and found their risk assessment methodology consistent with the best practices for estimating carcinogenic risk for an air pathway analysis. Given that no evidence was provided to change the EPA's previous review of the petitioner's risk assessment, the petitioner's original emission estimates used for the air pathway risk modeling were found to be acceptable and to provide the basis for a reasonable analysis of the risks associated with inhalation of 1-BP.

#### *B. Comments on 1-BP Cancer Risk Factors*

*Comment:* Israel Chemicals Ltd. (ICL) requested that the EPA reconsider its initial decision to add 1-BP to the HAP list. ICL made this request based on a September 2016 study titled *In Vivo Mutation Assay of n-Propyl Bromide at the cII Locus in Big Blue® Transgenic B6C3F1 Mice Exposed via Whole-Body Inhalation*.<sup>1</sup> Based on this study, ICL argued for removing cancer as a potential hazard from 1-BP exposure, which, in their view, would eliminate the basis for listing 1-BP as a HAP.

*Response:* The EPA rejects the premise that the results of a single assay for mutagenicity in a single gene locus in a transgenic (Big Blue®) mouse strain can be used to make general statements on potential mutagenicity or carcinogenicity. The EPA finds adequate support from submitted evidence and comments that 1-BP presents a potential cancer hazard and, therefore, is granting these petitions to list 1-BP as a HAP for purposes of regulatory actions based on the following considerations:

First, not all carcinogens operate via a mutagenic mode of action (MOA). In fact, many of the National Toxicology Program (NTP) substances categorized as “Known to be a human carcinogen” are carcinogenic via non-mutagenic mechanisms. There is mixed evidence of mutations in bacterial and mammalian cells and limited data on DNA damage in 1-BP-exposed workers. However, there is clear evidence for the carcinogenicity of 1-BP in multiple tissues in two rodent species from a 2-year cancer bioassay<sup>2</sup> by the NTP. The NTP’s *Report on Carcinogens, 14<sup>th</sup> Edition*<sup>3</sup> finds 1-BP is “reasonably anticipated to be a human carcinogen” based on sufficient evidence of carcinogenicity from studies in experimental animals.

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<sup>1</sup><https://www.regulations.gov/>, Docket ID Item No. EPA-HQ-OAR-2014-0471-0067.

<sup>2</sup> <https://ntp.niehs.nih.gov/testing/status/agents/ts-m000017.html>.

<sup>3</sup> <https://ntp.niehs.nih.gov/ntp/roc/content/profiles/bromopropane.pdf>.

Second, regarding the ICL claim that if 1-BP is not a mutagen, any cancer potential will be a threshold effect. The 2005 EPA Cancer Guidelines<sup>4</sup> provide the latitude to apply a non-linear model when data positively establish the MOA to be non-linear. However, it is not automatically assumed that a non-linear MOA is operational if a chemical is not a mutagen.

Third, as explained in greater detail in the draft document, there is significant evidence that 1-BP poses a negative health impact for noncancer effects including reproductive toxicity and neurotoxicity in both controlled and uncontrolled environments; the evidence for these noncancer effects provides sufficient justification to list 1-BP as a HAP, regardless of the potential for a cancer effect (82 FR 2354, 2360-61, January 9, 2017).

Finally, as also explained in the draft document, the EPA “interpret[s] the CAA section 112(b)(3)(B) as invoking the Administrator’s expertise in considering information/data that addresses the potential or likelihood of harm rather than concrete proof of actual harm,” and that the Administrator is authorized to “act in the face of uncertainty as to the proven health effects of a substance” and to “draw inferences from the data” before him. (82 FR 2357, January 9, 2017); see generally *Id.* at 2356-58, 2361-62.

### *C. Comments Requesting the Addition of 1-BP to the CAA Section 112(b)(1) HAP List*

*Comment:* Ten commenters supported the EPA’s initial decision to grant petitions to add 1-BP to the CAA section 112(b)(1) HAP list and encouraged the EPA to issue a final action granting the petitions. They also stated that petitioners had provided substantial evidence to support the conclusion that 1-BP either is known to cause or can reasonably be anticipated to cause cancer and noncancer health effects in humans. Their comments generally discussed this evidence.

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<sup>4</sup> [https://www.epa.gov/sites/production/files/2013-09/documents/cancer\\_guidelines\\_final\\_3-25-05.pdf](https://www.epa.gov/sites/production/files/2013-09/documents/cancer_guidelines_final_3-25-05.pdf).

One commenter stated that the decision to list 1-BP as a HAP under the CAA depends only on showing potential adverse effects from a chemical, not whether exposure is at levels that cause those effects. The commenter also noted that exposures of concern for 1-BP are already occurring. The commenter likewise disagreed with the negative mutagenesis assay findings submitted by ICL, stating that results of a single assay for mutagenicity cannot be used to apply across-the-board statements on potential mutagenicity.

*Response:* The EPA acknowledges commenters' statements. The EPA also agrees with the comments on the availability of substantial evidence to support the addition of 1-BP to the CAA section 112(b)(1) HAP list.

### **III. The EPA's Decision to Grant the Petitions**

Consistent with the draft document, petitioners have provided sufficient information demonstrating the adverse health effects of 1-BP that supports the EPA's determination that 1-BP is an air pollutant as defined under the CAA section 302(g) and that "emissions, ambient concentrations, bioaccumulation or deposition of the substance are known to cause or may reasonably be anticipated to cause adverse effects to human health or adverse environmental effects" as specified under CAA section 112(b)(3)(B). The documented known or anticipated adverse health effects of 1-BP, which are based on established sound scientific principles, include carcinogenicity, reproductive toxicity, and neurotoxicity. The EPA also concludes that petitioners' assessments regarding estimates of potential ambient concentrations of 1-BP that are likely to result at a facility's fence line, process emissions related information, and chemical usage information that are representative of normal operating conditions are reasonable. The EPA is, therefore, granting petitions to add 1-BP to the CAA section 112(b)(1) list of HAP. This action concludes the petition process under the CAA section 112(b)(3). As previously explained,

the EPA's granting of the petitions by itself, as accomplished by this document, does not impose any regulatory or statutory obligations on sources of 1-BP emissions. Following this action, the EPA will take a separate regulatory action to add 1-BP to the list of HAP under the CAA section 112(b)(1). At that time, the EPA will publish a **Federal Register** document that formally proposes the addition of 1-BP to the CAA section 112(b)(1) HAP list and assess the impacts of adding 1-BP to the HAP list on potentially affected sources.

#### **IV. Reducing Emissions from Sources of 1-BP**

The first step in this process is to grant the petitions requesting that 1-BP be listed as a HAP, which we are completing with this action. As a general matter, granting a petition to add an air pollutant to the CAA section 112(b)(1) HAP list initiates the process of bringing the air pollutant into consideration in the national emission standards for hazardous air pollutants (NESHAP) program, under the CAA section 112(d). (The CAA section 112(d) imposes a "clear statutory obligation to set emissions standards for each listed HAP." *National Lime Association v. EPA*, 233 F. 3d 625, 634 (D.C. Cir. 2000)). As previously explained, by itself, granting the petitions will not create new regulatory or statutory obligations for sources that emit 1-BP, until further actions are taken by the Agency. During the period from when this document is published and until the next step of adding 1-BP to the CAA section 112(b)(1) HAP list is taken, sources emitting 1-BP will have no regulatory obligations related to approval of the petitions.

The second step is to publish a **Federal Register** document that formally announces the addition of 1-BP to the CAA section 112(b)(1) HAP list. In granting the petitions to list 1-BP as a HAP, the EPA has learned that most source categories emitting 1-BP will not become subject to emission standards until the EPA amends or promulgates new maximum achievable control technology standards for specific source categories. The single largest user of 1-BP is the

Halogenated Solvent Cleaning source category. However, the current Halogenated Solvent Cleaning NESHAP (40 CFR part 63, subpart T) does not regulate 1-BP emissions because only emissions of methylene chloride, perchloroethylene (PERC), and trichloroethylene (TCE) are subject to the rule. Therefore, the use of 1-BP as a solvent degreaser will not be subject to regulation until such time as the EPA revises 40 CFR part 63, subpart T, issues new standards, or takes other actions to reduce 1-BP emissions from the Halogenated Solvent Cleaning source category.

Further, the EPA may need to take additional regulatory action to address 1-BP emissions from certain dry cleaning operations. The PERC Dry Cleaning source category, which sets out requirements for these operations, covers only PERC emissions. PERC is a solvent used in dry cleaning and has been identified as a probable human carcinogen. 40 CFR 63.322(o)(5)(i) requires that the existing co-residential dry cleaning subcategory phase out the use of PERC by December 21, 2020. The EPA has learned that 1-BP is currently used as a replacement solvent in this subcategory. Considering the public health effects discussed earlier in this document and the information before us, the EPA is concerned about the use of 1-BP as a substitute for PERC in the co-residential dry cleaning subcategory. Further, these public health effects may call for the need for adequate controls for 1-BP emissions from other dry cleaning subcategories other than the dry cleaning co-residential subcategory. The EPA is, therefore, planning in a future action to modify the CAA section 112(c)(1) source category list to add a new source category that would cover 1-BP emissions from all dry cleaning operations. Under the CAA section 112(c)(5), the EPA may add additional source categories to the CAA section 112(c)(1) source category list.

Beyond the Halogenated Solvent Cleaning source category and 1-BP dry cleaning operations, the EPA does not believe that other source categories need to be added to the source

category list or otherwise modified to reduce emissions of 1-BP. After adding a new source category to regulate 1-BP emissions from dry cleaning operations, the EPA would be required under CAA section 112(c)(5), to promulgate emission standards under the CAA section 112(d) within two years.

Additionally, some sources could become immediately subject to existing standards once 1-BP is placed on the CAA section 112(b)(1) list given that these sources may become major sources of HAP emissions (greater than 10 tons per year of a single HAP or 25 tons per year of total HAP). For these sources, 40 CFR 63.6(c)(5) allows three years to comply after 1-BP is added to the HAP list unless the underlying rule specifies another schedule.

These future actions that the EPA intends to consider for purposes of addressing 1-BP emissions reduction, such as the listing of new source categories under the CAA section 112(c)(1), can occur either simultaneously with listing 1-BP on the HAP list or shortly thereafter. In sum, as a result of granting these petitions, the EPA intends to consider taking additional regulatory actions as a result of adding 1-BP to the CAA section 112(b)(1) HAP list.

## **V. Statutory and Executive Order Review**

Additional information about this Executive Order can be found at <https://www.epa.gov/laws-regulations/laws-and-executive-orders>.

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

This action is a significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review because it raises novel legal or policy issues. Any changes made in response to OMB recommendations have been documented in the docket.

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**Andrew Wheeler,**

*Administrator.*

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