



**ENVIRONMENTAL PROTECTION AGENCY**

**[EPA-HQ-OAR-2014-0471; FRL-9958-00-OAR]**

**RIN 2060-AS26**

**Granting Petitions to Add n-Propyl Bromide to the List of Hazardous Air Pollutants**

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

**ACTION:** Notice; request for public comment.

**SUMMARY:** The Environmental Protection Agency (EPA) is publishing a draft notice of the rationale for granting petitions to add n-propyl bromide (nPB), also known as 1-bromopropane (1-BP), (Chemical Abstract Service No. 106-94-5) to the list of hazardous air pollutants (HAP) contained in section 112(b)(1) of the Clean Air Act (CAA). The Halogenated Solvents Industry Alliance (HSIA) and New York State Department of Environmental Conservation (NYSDEC) submitted petitions requesting that nPB be added to the list of HAP. In response to the EPA requests for additional data, HSIA subsequently supplemented its petition. Petitions to add a substance to the list of HAP are permitted under the CAA section 112(b)(3).

Based on the EPA's evaluation of the petitioners' showing concerning potential hazards, emissions, and atmospheric dispersion modeling that provided estimates of ambient concentrations of nPB, the EPA has determined that there is

adequate evidence to support a determination that emissions and ambient concentrations of nPB may reasonably be anticipated to cause adverse health effects.

**DATES:** Comments must be received on or before **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

**ADDRESSES:** Comments. Submit your comments, identified by Docket ID No. EPA-HQ-OAR-2014-0471, at <http://www.regulations.gov>.

Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from Regulations.gov. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

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 <http://www2.epa.gov/dockets/commenting-epa-dockets>.

**FOR FURTHER INFORMATION CONTACT:** For questions about this proposed action, contact Ms. Elineth Torres, 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) 541-4347; email address: [torres.elineth@epa.gov](mailto:torres.elineth@epa.gov).

**SUPPLEMENTARY INFORMATION:**

Docket: The EPA has established a docket for this action under Docket ID No. EPA-HQ-OAR-2014-0471. All documents in the docket are listed in the <http://www.regulations.gov> index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy form. Publicly available docket materials are available either electronically at: <http://www.regulations.gov>, or in hard copy at the EPA Docket Center, EPA WJC West Building, Room 3334, 1301 Constitution Ave., NW, Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the EPA Docket Center is (202) 566-1742.

Instructions: All submissions must include agency name and docket number or Regulatory Information Number (RIN) for this rulemaking. Direct your comments to Docket ID No. EPA-HQ-OAR-2014-0471. The EPA's policy is that all comments received will be included in the public docket and may be made available online at: <http://www.regulations.gov>, including any personal information provided, unless the comment includes information claimed to be CBI, or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI, or otherwise protected through <http://www.regulations.gov> or email. The <http://www.regulations.gov> Web site is an "anonymous access" system, 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 <http://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 disk or CD-ROM 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 avoid the use of special characters, 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 <http://www.epa.gov/dockets>.

Acronyms. A number of acronyms are used in this document. To ease the reading of the document and for reference purposes, the following acronyms are defined as follows:

1-BP	1-Bromopropane (also known as n-propyl bromide, nPB)
ATSDR	Agency for Toxic Substances and Disease Registry
CAA	Clean Air Act
CBI	Confidential Business Information
EPA	U.S. Environmental Protection Agency
EPCRA	Emergency Planning and Community Right-to-Know Act
ETI	Enviro Tech International
HAP	Hazardous Air Pollutants
HSIA	Halogenated Solvents Industry Alliance
IRIS	Integrated Risk Information System
nPB	n-Propyl Bromide (also known as 1-bromopropane, 1-BP)
NESHAP	National Emissions Standards for Hazardous Air Pollutants
NTP	National Toxicology Program
NYSDEC	New York State Department of Environmental Conservation
OMB	Office of Management and Budget
PPA	Pollution Prevention Act
PERC	Perchloroethylene
SNAP	Significant New Alternatives Policy
TCE	Trichloroethylene
TRI	Toxics Release Inventory

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**I. General Information**

A. What should I consider as I prepare my comments for the EPA?

Submitting CBI. Do not submit information that you consider to be CBI electronically through <http://www.regulations.gov> or email. Send or deliver information identified as CBI to only the following address: OAQPS Document Control Officer (Room C404-02), Environmental Protection Agency, Research Triangle Park, North Carolina 27711; Attn: Docket ID No. EPA-HQ-OAR-2014-0471.

Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to the EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the

information claimed as CBI must be submitted for inclusion in the public docket. If you submit a CD-ROM or disk that does not contain CBI, mark the outside of the disk or CD-ROM clearly that it does not contain CBI. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 Code of Federal Regulations part 2.

If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this document.

B. Where can I get a copy of this document?

In addition to being available in the docket, the electronic copy of this document will be available on the World Wide Web. Following signature, a copy of this document will be posted on at the following address:

<https://www.epa.gov/haps/initial-list-hazardous-air-pollutants-modifications>.

**II. Background Information**

A. What is the list of HAP?

The list of HAP, which can be found in CAA section 112(b)(1), is a list of a wide variety of organic and inorganic substances that Congress identified as hazardous air pollutants in the 1990 CAA Amendments. These 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 upon the toxicity of the individual HAP and the particular circumstances of exposure, such as the amount of chemical present, the length of time a person is exposed, and the stage of life at which the person is exposed. The CAA directs the EPA to first identify and list source categories that emit HAP and then to set emission standards for those listed source categories. Standards promulgated under CAA section 112(d) are commonly referred to as National Emission Standards for Hazardous Air Pollutants (NESHAP).

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

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 "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 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 solely on the basis of inadequate resources or time for review.

CAA section 112(b)(2) gives the Administrator authority to add to the CAA section 112(b)(1) list "pollutants which present, or may present through inhalation or other routes of exposure, a threat of adverse human health effects (including, but not limited to, substances, which are known to be, or may reasonably be anticipated to be, carcinogenic, mutagenic, teratogenic, neurotoxic, which cause reproductive dysfunction or which are acutely or chronically toxic) or adverse environmental effects whether through ambient concentrations, bioaccumulation, deposition or otherwise." CAA section 302(k) defines an air pollutant as "any air pollution agent or combination of such agents, including any physical, chemical, biological, radioactive . . . substance or matter which is emitted into or otherwise enters the ambient air." CAA section 112(a)(7) specifically defines the term "adverse environmental effect" as "any 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."

The EPA reviews petitions to add substances to the HAP list in two phases: (1) a completeness determination and (2) a substantive technical review. During the completeness determination, we conduct a broad review of the petition to determine whether the necessary subject areas have been addressed and whether reasonable information and analyses are present for each of the subject areas. Once we determine the petition complete, we publish a notice of receipt of a complete petition in the **Federal Register** and request public comment and/or additional data.

During the technical review, we conduct an evaluation of both the petition and the information received from the public in response to the **Federal Register** notice of complete petition to determine whether the data, analyses, interpretations, and conclusions in the petition are adequate. Based on this review, we decide whether the petition satisfies the requirements of CAA section 112(b)(3)(B) and adequately supports a decision to grant the petition. Upon conclusion of this review, we publish a draft notice in the **Federal Register** with the written explanation of the Administrator's decision to grant the petition. After considering the comments received on the draft document, we publish a final notice in the **Federal Register**. A final notice granting a petition to add a pollutant to the HAP list in CAA section 112(b)(1) brings sources emitting that HAP into

consideration in the EPA's program to promulgate NESHAP.

Finally, under CAA section 112(e)(4), the Administrator's action 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 applicable CAA section 112(d) standards for the pollutant. Thus, any final decision to grant petitions to add nPB to the HAP list would not be subject to review until the Administrator promulgates applicable CAA section 112(d) standards addressing emissions of nPB.

### C. Criteria for Listing

As previously explained, CAA section 112(b)(3)(A) allows any person to petition the EPA to modify the CAA section 112(b)(1) list of HAP by adding or deleting a substance. A petitioner must make "a showing . . . that there is adequate data on the health or environmental effects of the pollutant or other evidence adequate to support the petition." CAA section 112(b)(3)(A). Thus, this section places the burden on a petitioner to demonstrate that the data sufficiently support an affirmative determination that the substantive criteria contained in CAA section 112(b)(3)(B) have been met. In other words, a petitioner bears the burden of showing that emissions, ambient concentrations, bioaccumulation or deposition of a substance are known to cause or may reasonably be anticipated to

result in adverse human health or environmental effects. "The statutory language unambiguously places on a [ ]listing petitioner the burden to make a 'showing' that 'there is adequate data' about a substance to determine exposure to it 'may ... reasonably be anticipated to cause' adverse effects." Am. Forest & Paper Ass'n v. EPA, 294 F.3d 113, 119 (D.C. Cir. 2002) (emphasis in original). The statute does not further define what constitutes adequate data and we believe that by employing the term "adequate," the statute acknowledges the limitations of data on human health and environment and gives the Administrator discretion to determine what constitutes sufficient or adequate information for purposes of a listing petition. We also note that CAA section 112(b)(4) allows the Administrator to "acquire" information "when she determines that information on the health or environmental effects of a substance is not sufficient to make a determination," under CAA section 112(b)(3). Moreover, Congress could have provided, but did not provide, specific criteria to guide the Administrator's exercise of her discretion in deciding whether the data presented are sufficient under CAA section 112(b)(3)(A).<sup>1</sup> Thus,

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<sup>1</sup> This is in contrast to various provisions in the CAA that specify listing criteria for pollutants (See for example, CAA section 108(a)(2), which states that within 12 months of the listing of a pollutant under CAA section 108(a), the Administrator must issue "air quality criteria" that "accurately

we interpret the statutory silence in CAA section 112(b)(3)(A) as allowing the Administrator to apply her expertise when reviewing data/information provided by the petitioner to make the demonstration required by CAA section 112(b)(3)(B), as well as to consider limitations and difficulties inherent in information on public health, welfare, and/or the environment.

As previously noted, CAA section 112(b)(3)(B) calls for the Administrator to add to the CAA section 112(b)(1) list of HAP a substance that is shown to be "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." CAA section 112(b)(2) provides additional guidance on how the Administrator's decision is to be formed by identifying carcinogenicity, mutagenicity, teratogenicity, neurotoxicity, reproductive dysfunction, and acute or chronic toxicity as types of adverse health effects. Further, the language used in CAA section 112(b)(3)(B) does not call for either complete substantiation or require absolute certainty that a substance will cause adverse effects to human health or the environment. In fact, it calls for listing a

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reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of such pollutant in the ambient air, in varying quantities.").

substance that "may reasonably be anticipated to cause" certain impacts. The EPA interprets this language as recognizing the limitations and difficulties associated with information on public health and environment. Typically, questions as to whether a substance presents adverse health and welfare effects and the types of effects border on the frontiers of scientific knowledge and are given to uncertainty because there is either insufficient or inconsistent data. For example, there might be limited scientific knowledge of exposure effects on human health and the environment. Some substances have no known safe level. There might also be limited emissions data on a substance that is considered for addition to the list given that it would be largely unregulated.

Moreover, the CAA is a protective or preventive statute. One of its stated purposes is "to protect and enhance the quality of the Nation's air resources so as to promote the public health and welfare." CAA section 101(b)(1). Relevant legislative history also provides support for this stated purpose. (The CAA is "to assure that regulatory action can effectively prevent harm before it occurs; to emphasize the predominant value of protection of public health." H.R. Rep. No. 95-294, 95th Cong., 1st Sess. 49 (1977)). Such statutes do not call for certainty of harm, but rather accord a decision maker flexibility in taking regulatory action that is protective of

public health and the environment. They allow a decision maker to exercise discretion when forming her judgement, which would likely involve balancing of factors that are uniquely within her expertise and policy choices, and predictions on the frontiers of scientific knowledge. (“[A]n agency [has] latitude to exercise its discretion in accordance with the remedial purposes of the controlling statute where relevant facts cannot be ascertained or are on the frontiers of scientific inquiry.” Nat’l Lime Ass’n v. EPA, 627 F.2d 416, 454 (D.C. Cir. 1980)).

Further, requiring data/information that provides absolute certainty of the adverse health effects of a substance would likely result in making listing decisions similar to the risk- and health-based approach employed prior to the 1990 CAA Amendments. See S. Rep. No. 101-228 at 3, 128 (1989); see also H.R. Rep. No. 101-490, pt. 1, at 322 (1990). Up until then, the EPA was required to list HAP for regulation based on a conclusion that they could “cause or contribute to, an increase in mortality, an increase in serious irreversible, or incapacitating reversible illness.” Section 112(a)(1), CAA, Pub. L. No. 91-604, 84 Stat. 1676, 1685 (1970).<sup>2</sup> In doing so, the EPA

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<sup>2</sup> Additionally, until 1990, a HAP was defined as an “air pollutant...which in the judgment of the Administrator cause, or contribute to, air pollution which may reasonably be anticipated to result in an increase in mortality or an increase in serious

would consider emissions levels at which health effects have previously been observed and factor in an ample margin of safety to protect public health. This approach proved unsatisfactory in achieving the goal of improved public health and in the 1990 CAA Amendments, Congress dispensed with this provision, listed 189 HAP in CAA section 112(b)(1) for regulation, and provided for modifications of the HAP list either by petition or on the Administrator's determination in CAA sections 112(b)(3)(A) and (B). Thus, we interpret 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. We also believe that CAA section 112(b)(3)(B) would allow the Administrator to act in the face of uncertainty as to the proven health effects of a substance, draw inferences from the data before her, as well as err on the side of caution in determining whether the data are sufficient to support listing a substance. This determination would likely take into account the risks associated with not taking an action as compared to taking action and granting the petition to add a substance to the CAA section 112(b)(1) HAP list.

We note that the Administrator's discretion is neither unbounded nor limitless, but rather constrained by the EPA's

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irreversible, or incapacitating reversible, illness." Section 112(a)(1), CAA, Pub. L. No. 91-604, 84 Stat. 1676, 1685 (1970).

duty to protect human health and welfare. See Massachusetts v. EPA, 127 S. Ct. 1438, 1462. (The goal of the CAA is "to protect and enhance the quality of the Nation's air resources so as to promote the public health and welfare and the productive capacity of its population." CAA section 101(b)(1)). Therefore, we believe that CAA section 112(b)(3) would allow the Administrator to make a comparative assessment of adverse health or environment effects of a substance, projections, or predictions of future possibilities of harm, consideration of uncertainties, and extrapolation of limited and even imperfect scientific data. We also believe that it would allow the Administrator to balance the likelihood of adverse health effects against limited scientific data and to err on the side of caution in making her decision in light of uncertainties in scientific data. Any projections, assessments, and estimations, however, must be reasonable and not based on conjecture. She must also make any necessary policy choices and considerations. Therefore, we do not read CAA section 112(b)(3)(B) as requiring a bright-line test on how a CAA section 112(b)(1) listing decision should be made. The Administrator will neither require nor base her determination solely on a single parameter or measure, i.e., in arriving at her decision, no one set of data will outweigh the other. Rather, the Administrator's decision to list a HAP would be made on a case-by-case basis and involve a

thorough and comprehensive review of factual issues, scientific evidence, and data provided in support of a petition to add a substance to the CAA section 112(b)(1) HAP list.

In summary, we read CAA section 112(b)(3)(B) as allowing the Administrator to exercise her expertise to decide, based on all relevant considerations, whether the data presented in a petition are adequate to support a decision to add a substance to the CAA section 112(b)(1) list of HAP. In other words, to determine whether a petitioner has shown that emissions of a substance cause or may reasonably be anticipated to cause adverse effects to human health or the environment. The Administrator would also likely assess potential or probable public health and environmental risks rather than proof of actual harm and consider necessary policy issues. The burden, however, remains on a petitioner to provide data sufficient to support an affirmative determination that emissions of a substance may cause or may reasonably be anticipated to cause adverse human health or environmental effects. Thus, a petitioner must provide a detailed assessment of the available data concerning the substance's potential adverse human health and environmental effects and, where appropriate, characterize the potential for human and environmental exposures resulting from emissions of the substance. We expect that such data would most likely demonstrate that emissions, ambient concentrations,

bioaccumulation, or deposition of the substance may reasonably be anticipated to cause adverse effects to human health or the environment. We believe this is a reasonable and proper manner of giving effect to the Administrator's duty to address public health and environmental effects under CAA section 112(b)(3).

### **III. Summary of Petitions**

#### A. Background

HSIA and NYSDEC submitted petitions to add nPB, also known as 1-BP, to the CAA section 112(b)(1) list of HAP on October 28, 2010, and November 24, 2011, respectively. On November 28, 2012, in response to the EPA's requests for additional data, HSIA supplemented its petition. The petitions to add nPB to the list of HAP presented the following information:

- Background data on nPB, including chemical properties, physical properties, production data, and use data;
- Toxicological evidence describing the human health effects of nPB;
- Estimation of an inhalation unit risk;
- nPB emissions estimates and atmospheric dispersion modeling estimating potential ambient concentrations of nPB adjacent to facilities that emit it; and
- Characterization of potential risks to human health due to potential exposure to ambient air concentrations of nPB.

We discuss in detail the information presented in the petitions in section IV of this document, titled EPA's Technical Review of the Petitions.

Following the receipt of the petitions, the EPA conducted a review to determine whether the petitions were complete according to the agency criteria. After reviewing these petitions and supplemental information, the EPA determined that the petitions addressed all of the necessary subject areas for the agency to assess whether emissions, ambient concentrations, bioaccumulation, or deposition of nPB are known to cause or may reasonably be anticipated to cause adverse human health effects or adverse environmental effects. The EPA determined the petitions to add nPB to the list of HAP to be complete and published a notice of receipt of a complete petition in the **Federal Register** on February 6, 2015, 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.

B. Public Comments Received on EPA's Notice of Complete Petition

We received 17 submissions in response to the request for comments and additional information. The submissions are in the docket. Almost all the submissions agreed with the EPA's completeness determination of the petitions to add nPB to the CAA section 112(b)(1) HAP list. The majority of commenters

referenced the National Toxicology Program (NTP) Report on Carcinogens (RoC), 13th Edition, 2014 (NTP, 2014) in which the NTP classified nPB, identified as 1-BP, as being reasonably anticipated to be a human carcinogen.

Both petitioners, HSIA and NYSDEC, provided comments and additional information on occupational hazards and toxicity of nPB to support their petitions. Albemarle Corporation and Enviro Tech International (ETI), a manufacturer and a supplier of nPB respectively, disagreed with the EPA's completeness determination and provided their own evaluation of the emissions estimates, nPB carcinogenicity, as well as the exposure and cancer risk assessment included in the HSIA petition. Both Albemarle and ETI did not support the granting of petitions to add nPB to the HAP list based on their risk assessment. Submissions from various states, the city of Philadelphia, and groups representing state air pollution control agencies supported the EPA's completeness determination, presented state-specific information regarding the uses of nPB in dry cleaning and as a solvent in adhesives and degreaser operations, provided information on nPB state-specific studies and regulations, and supported the granting of the petitions to add nPB to the HAP list.

Submissions from national environmental organizations and other members of the public provided the EPA with additional

references to studies on nPB's carcinogenic potential and neurotoxicity as well as information relevant to the NTP's peer-reviewed report on the carcinogenicity of nPB, and to the occupational exposure limits for nPB. These commenters also referenced the EPA's addition of nPB to the list of toxic chemicals subject to reporting requirements under section 313 of the Emergency Planning and Community Right-to-Know Act (EPCRA) and section 6607 of the Pollution Prevention Act (PPA). We considered all comments in our technical review.

#### **IV. EPA's Technical Review of the Petitions**

In this section, we present the EPA's evaluation of the evidence provided by the petitioners and information submitted by commenters beyond what was provided in the petitions relevant to our technical review. The purpose of this evaluation is to determine whether the data, analyses, interpretations, and conclusions in the petitions are adequate and whether they support a determination under CAA section 112(b)(3) 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 EPA's technical review focuses on the evidence provided by petitioners and commenters regarding emissions, ambient

concentrations, and health effects of nPB. We are seeking comments on the EPA's technical review of the HSIA and NYSDEC petitions, on whether the criteria for listing have been met, and the agency's rationale for the decision to grant these petitions.

A. Chemical Characteristics, Uses, Sources, and Emissions of nPB

nPB, also known as 1-BP or 1-propyl bromide (CAS # 106-94-5), is a brominated organic colorless liquid that is insoluble in water, but soluble in ethanol and ether. Both petitioners and public commenters provided background information regarding nPB's chemical properties, physical properties, production, and usage. nPB is used as an intermediate chemical in the manufacture of pharmaceuticals and agricultural products, as well as a carrier solvent in aerosols and adhesives. The petitioners presented information on specific applications of nPB, including its use in aerosol solvents, adhesives, dry cleaning, and for open vapor degreasing applications in electronic, metal, and precision cleaning operations. Many commenters raised concerns with the use of nPB as a replacement of perchloroethylene (PERC), a HAP, in the dry cleaning industry and as replacement for HAP chlorinated solvents, like trichloroethylene (TCE), in solvent cleaning operations. Commenters pointed out that nPB's vapor pressure (146 millimeters of mercury (mm Hg) at 20°C) is higher than the vapor

pressure for PERC (14 mm Hg at 20°C) and TCE (58 mm Hg at 20°C) and that indoor and outdoor air emissions associated with nPB use are likely to be higher than those caused by similar use of other solvents with lower vapor pressure.

The petitioners expressed the difficulty in obtaining data on production, uses, and emissions of nPB due to the lack of publically available data. HSIA estimated the global production of nPB in 2007 was 20,000-30,000 metric tons and projected the use of nPB as a solvent in the U.S. to be growing at a rate of 15-20 percent per year (5,000 metric tons or 5,511 short tons). ETI commented on the HSIA's estimates and presented its own data on the use of nPB in the U.S. in the precision cleaning industry sector, dry cleaning industry, and the adhesive, coatings, and inks sectors. Per ETI, in 2014 the U.S. used a total of 4,080 short tons of nPB within these three sectors.

The EPA agrees with the petitioners that since nPB has not been a regulated pollutant under CAA section 112 and reporting data under the Toxics Release Inventory (TRI) Program will not be available until July 2017,<sup>3</sup> it is difficult to ascertain public data on usage, sources, and emissions. Nevertheless, in

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<sup>3</sup> The final rule adding 1-BP to the list of toxic chemicals subject to reporting under section 313 of the EPCRA and section 6607 of the PPA, 80 FR 72906, November 23, 2015, became effective on November 30, 2015. The reporting year began on January 1, 2016, with reports due on July 1, 2017.

evaluating the information included in the petitions regarding uses and sources of nPB, the EPA compared the information with previous assessments of nPB performed by the EPA for the Significant New Alternatives Policy (SNAP) program and TRI. Based on this review, the EPA finds that the petitioner's showing of information regarding nPB uses and sources is reasonable.

To assess nPB air emissions, HSIA estimated nPB emissions for five facilities: a narrow tube manufacturing/degreasing operation, two dry cleaners, and two furniture manufacturing/spray adhesive facilities. HSIA's emission estimates are based on the internal concentration of nPB as measured by industrial hygiene studies or based on permit files and assuming that nPB is emitted in quantities similar to what would be expected for volatile organic compounds, TCE, or PERC. HSIA acknowledged in their petition that since the emission estimates have been made without access to the facilities, specific nPB use data provided by the facilities, or stack testing data, actual nPB emissions for these facilities could be different from the emission estimates. In their comments, Albemarle presented their own nPB emissions estimates for the same facilities included in the HSIA petition. The EPA believes the emissions estimates provided by HSIA and Albemarle represent a reasonable range of potential nPB emissions, with HSIA

providing more conservative (higher) emissions estimates. The EPA finds that HSIA has presented adequate evidence to support the determination that nPB is an air pollutant as defined by CAA section 302(k).

#### B. nPB Health Effects

To support their request for listing nPB as a HAP, the petitioners provided citations for peer-reviewed published papers and reports describing health effects of nPB. The summary from HSIA's original petition focused on reproductive effects, carcinogenicity, and neurotoxicity. When the EPA requested additional information, HSIA supplemented the information with additional scientific literature on these primary health outcomes. The NYSDEC's petition addressed these same health effects. The petitioners submitted summaries of 2-year bioassays in rats and mice, along with recommendations of the NTP Technical Reports Review Subcommittee, as evidence of carcinogenic activity (NTP, 2011). Claims of neurotoxicity are supported by the laboratory animal studies, as well as occupational studies and case reports of altered peripheral nerve function in workers exposed to concentrations of nPB as low as 1-3 parts per million (ppm). Developmental and reproductive effects, which were described by the EPA SNAP rule (72 FR 30142, May 30, 2007), were referenced by the petitioners. The petitioners claimed that the data are sufficient to conclude

that nPB can and does produce adverse human health outcomes. Public comments mostly concurred with this description of health effects. In particular, Dr. Adam Finkel (a subject-matter expert on chemical toxicology) provided comments expanding upon the submitted evidence to lend more support and explanations of nPB toxicity. Regarding these health effects, Albemarle provided comments and summaries of additional studies to refute conclusions of carcinogenicity and to discount methods used in one human occupational study.

#### 1. Cancer Effects

The petitions included a draft report of the NTP Technical Reports Review Subcommittee, followed by the final NTP report summarizing the carcinogenicity bioassays in rats and mice (NTP, 2011).<sup>4</sup> This NTP report concluded "clear evidence of carcinogenicity" of nPB based on increased incidences of alveolar/bronchiolar neoplasms in female mice and intestinal adenomas in female rats and "some evidence of carcinogenicity" based on skin neoplasms and intestinal adenomas in male rats. There were also increased incidences of non-neoplastic lesions in both rats and mice. More recently the NTP has synthesized information from the existing animal and mechanistic studies, public comments, and peer review and concluded that nPB is

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<sup>4</sup> References used in the evaluation of nPB health effects are available in the docket of this action.

“reasonably anticipated to be a human carcinogen” in the NTP’s 13<sup>th</sup> RoC (NTP, 2014). The EPA has reviewed that assessment to assure its consistency with the EPA Guidelines for Carcinogen Risk Assessment and agreed with the conclusions and classification by the NTP (U.S. EPA Office of Environmental Information, 2014); the details of the EPA’s review of these data were presented in the proposed (80 FR 20189, April 15, 2015) and final (80 FR 72906, November 23, 2015) documents to add nPB to the TRI list.

Comments submitted by Albemarle regarding these HAP listing petitions are the same as those submitted on the EPA’s proposed TRI action (80 FR 20189, April 15, 2015). Detailed responses by the EPA to these comments are described therein. Albemarle disputed the use of the alveolar/bronchiolar adenomas in the cancer assessment, suggesting a lack of human relevance of these mouse tumors. While this topic has been debated in the scientific literature and was the topic of a technical workshop convened by the EPA (U.S. EPA, 2014),<sup>5</sup> there is no cross-chemical consensus on the human relevance of mouse lung tumors; each

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<sup>5</sup> U.S. EPA. Summary Report: State-of-the-Science Workshop on Chemically-Induced Mouse Lung Tumors: Applications to Human Health Assessments. U.S. Environmental Protection Agency, Washington, DC, EPA/600/R-14/002, 2014. Available at <https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=291094&CFID=67867665&CFTOKEN=37343828>.

chemical will need to be judged separately regarding relevance. Furthermore, the NTP conclusions, supported by the EPA, do not rely solely on the lung tumor data, but rather on the totality of the available information. The commenter also claimed that the EPA has not considered potential uncertainties in the mutagenicity, genotoxicity, and carcinogenicity data for nPB. The NTP review, however, assessed available mutagenicity data in its review. This took into account reports of mutations in bacterial and mammalian cells and limited data on DNA damage in nPB-exposed workers. Furthermore, it is noted that metabolic pathways are similar in humans and experimental animals, and several metabolites of nPB have been identified as mutagens and are known to cause DNA damage. Results from some of these in vitro assays are mixed, and confounding factors may include the volatility of nPB or active metabolites. Finally, the commenter provided a summary of an unpublished study they commissioned showing negative results in the Ames assay; however, the EPA is not persuaded, and these results do not change the conclusion regarding the mutagenicity of nPB and its metabolites. Another commenter (Dr. Adam Finkel) provided counter-arguments to each of Albemarle's points and strongly encouraged the EPA to grant the petitions and to add nPB to the CAA 112(b)(1) list of hazardous pollutants. Considering the available information, including that presented in the petitions and in public

comments, the EPA continues to agree with NTP's conclusion that nPB is "reasonably anticipated to be a human carcinogen."

## 2. Non-Cancer Effects

### a. Developmental/reproductive toxicity

In a previous SNAP ruling (72 FR 30142, May 30, 2007), the EPA reviewed a two-generation study (WIL Research, 2001) and concluded that reproductive toxicity, specifically changes in sperm motility and estrus cycles, was the most sensitive effect of nPB. The petition repeated this information, added references to literature studies that replicated these changes, and suggested that a metabolite may be responsible for the spermatotoxicity (Liu et al., 2009; Banu et al., 2007; Garner et al., 2007; Yamada et al., 2003). These effects are reported at inhalation exposures  $\geq 200$  ppm in rats and  $\geq 50$  ppm in mice. The petition also summarized the deliberations of the NTP Center for the Evaluation of Risks of Human Reproduction (NTP-CERHR), an expert panel that evaluated the available scientific literature on the potential for nPB to adversely affect human reproduction or development (NTP-CERHR, 2003). That monograph summarized nPB effects, including alterations in sperm count and motility, estrus cyclicity, follicular count, and reproductive organ weights. The impact of these changes is evident in the two-generation study that reported decreased fertility, increased post-implantation loss, and decreased number of litters, and

live litter size. Decreased fetal weight and skeletal abnormalities, as well as depressed postnatal weight gain have also been reported in the literature. Using a weight-of-evidence approach, the panel concluded that there is clear evidence of adverse developmental/reproductive toxicity in laboratory animals and serious concern for adverse effects in humans at levels of occupational exposures.

The EPA has previously reviewed the reproductive and developmental data and agreed with the NTP panel's conclusions. In its SNAP ruling (72 FR 30142, May 30, 2007), the descriptions and evaluations of these data were provided in considerable detail. At that time the data on sperm counts and estrus cyclicity were used for derivations of acceptable exposure levels. In a recent draft report (81 FR 12099, March 8, 2016), the EPA again described nPB-induced reproductive and developmental toxicity, supplemented with studies made available after the 2003 NTP report (NTP-CERHR, 2003). These studies confirm and extend the findings of spermatotoxicity, alterations in estrous cycles, and decreased reproductive organ weights. In this recent report, the EPA considered decreased live litter size (WIL Research, 2001) to be among the most sensitive endpoints for dose-response modeling. Public comments received on the **Federal Register** notice of complete petition (80 FR 6676, February 6, 2015) supported and reiterated concern for this

health outcome and noted that nPB is listed as a developmental/reproductive toxicant under Proposition 65 in California.

Given the available information in the petitions, and as described by the EPA in other agency actions on nPB,<sup>6</sup> the EPA concludes that there is clear evidence that nPB produces adverse developmental and reproductive effects.<sup>7</sup>

b. Neurotoxicity

The petitions presented data from published studies in humans and laboratory animals that demonstrate that both the peripheral and central nervous systems are sensitive targets of nPB exposure. The petitions described case reports of severe neurotoxicity requiring hospitalization and potentially irreversible effects (Perrone et al., 2008; Majersik et al., 2007; Sclar, 1999). There are also epidemiological studies that describe concentration-related neurological impacts at relatively low levels; these findings were initially reported in small worker populations while later studies expanded testing to

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<sup>6</sup> See 72 FR 30142, May 30, 2007; 80 FR 20189, April 15, 2015; 80 FR 72906, November 23, 2015; and 81 FR 12098, March 8, 2016.

<sup>7</sup> In January, 2016, the Agency for Toxic Substances and Disease Registry published a Draft Toxicological Profile for nPB that includes an analysis of the available data on the toxicity of nPB that provides further support for the evidence presented in this notice on the adverse health effects of nPB. The document can be found at <https://www.atsdr.cdc.gov/ToxProfiles/tp209.pdf>.

larger groups from several Chinese production facilities (Li et al., 2010; Ichihara et al., 2004; Ichihara et al., 2002). Measurements used in these occupational studies included tuning fork vibration sensitivity and neurophysiological measures of conduction velocity and latency in motor and sensory nerves. Li et al. (2010) allocated exposure levels (measured by passive sampling) into tertiles with medians of 1.28 to 22.58 ppm for female workers and conducted the analyses using time-weighted averages and cumulative exposures. Vibration sensitivity, the most sensitive endpoint, significantly decreased in all exposure groups, and tibial motor distal latency and sural nerve conduction velocity were altered in the middle and/or high exposure groups. Hematological and hormonal changes were also reported in some or all groups.

The petitions also referenced a number of animal studies showing hind limb weakness, altered neurophysiological measures, and ataxic gait from nPB exposure, which are qualitatively similar to the reported human neurological outcomes. Behavioral measures of neuromuscular function are sensitive measures of nPB neurotoxicity (Banu et al., 2007; Honma et al., 2003; Ichihara et al., 2000). Significant changes were documented at exposures as low as 50 ppm for 21 days (Honma et al., 2003) and changes may be slow or not reversible (Banu et al., 2007). Motor nerve conduction velocity and latency measured in the rat tail nerve

were altered at higher concentrations with progressive changes from 4 to 12 weeks of exposure (Yu et al., 2001; Ichihara et al., 2000). Studies of very high exposures report severely altered gait, weakness or loss of hind limb control, convulsions, and death (Banu et al., 2007; Yu et al., 2001; Ichihara et al., 2000; Ohnishi et al., 1999), as well as peripheral nerve degeneration, myelin sheath abnormalities, and spinal cord axonal swelling (Wang et al., 2002; Yu et al., 2001; Ichihara et al., 2000). The petitions included studies of potential mechanisms including neurotransmitter dysregulation (Suda et al., 2008; Wang et al., 2002) and disinhibition in paired-pulse stimulation of hippocampal slices (Fueta et al., 2007).

Some of these neurotoxic effects were described in the EPA's SNAP ruling (72 FR 30142, May 30, 2007), and the conclusions of that review are in agreement with the claims of the petitioners. Since then, the EPA has reviewed the larger literature on the neurotoxicity of nPB and has described the physiological, behavioral, and biochemical measures that characterize and develop exposure-response data for neurological effects (81 FR 12098, March 8, 2016). The EPA has concluded that the concordance of outcomes across humans and laboratory rodents provides striking evidence of neurotoxic effects.

One commenter (Albemarle) expressed concerns regarding the

validity and conduct of the tuning fork test of peripheral neuropathy (Li et al., 2010) for risk assessment purposes. The EPA is not persuaded by these objections given that electrophysiological measures of peripheral nerve function were also altered in that and other studies, and, furthermore, considerations regarding hazard do not rely solely on that endpoint. The conclusion of nPB neurotoxicity is supported by the EPA's review of numerous human reports and the preponderance of studies in laboratory animals.

### 3. Inhalation Unit Risk

HSIA and Albemarle each submitted separate quantitative estimates of cancer unit risk. In addition, the 2010 HSIA petition recommended a non-cancer reference value based on a larger composite uncertainty factor than was used in the SNAP rule's acceptable exposure level. When using quantitative reference values for determining risk from chronic cancer and non-cancer effects, for CAA section 112 actions, the EPA uses only final values that have undergone a rigorous development and review process,<sup>8</sup> i.e., the EPA Integrated Risk Information System (IRIS), the Agency for Toxic Substances and Disease Registry

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<sup>8</sup> <https://www.epa.gov/fera/dose-response-assessment-assessing-health-risks-associated-exposure-hazardous-air-pollutants>.

(ATSDR)<sup>9</sup> and the California Office of Environmental Health Hazards Assessment. At this time, there are no final dose-response values for chronic cancer and non-cancer effects for nPB from these sources. Notwithstanding, the EPA acknowledges that the petitioners have shown that adequate information exists to develop such values and that this provides additional support for the potential cancer and non-cancer hazards from exposure to nPB.

### C. Potential Human Exposure and Cancer Risk

The petition submitted by HSIA, including supplemental information and analyses submitted through February 2016, contains an exposure assessment and estimates of lifetime potential cancer risks for populations downwind of the five facilities discussed in section IV.A of this document. The petitioner's assessment used the latest version of the EPA's Human Exposure Model (HEM)<sup>10</sup> to model estimated facility emissions and account for the effects on plume dispersion from building downwash and whether the facility was located in an urban or rural area. Census block centroids from the 2010 Census are used as model receptors in HEM and are surrogates for

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<sup>9</sup> In January 2016 ATSDR published a draft toxicological profile for nPB. The document can be found at the effects of nPB. The document can be found at <https://www.atsdr.cdc.gov/ToxProfiles/tp209.pdf>.

<sup>10</sup> <https://www.epa.gov/fera/risk-assessment-and-modeling-human-exposure-model-hem>.

locations of human exposure. The petitioner supplemented these default receptor locations with the locations of actual residences near the facilities. The petitioner applied its derived cancer unit risk estimate to the modeled ambient concentrations to estimate potential lifetime individual cancer risks and population risks. The petitioner's estimates of potential risk range from 5-in-1 million to 40-in-1 million, with about 9,000 people estimated to have cancer risk greater than 1-in-1 million.

A commenter (Albemarle) noted issues with several aspects of the estimation of ambient concentration and potential cancer risks originally submitted by the petitioner, including the use of an outdated model, which used old census and meteorological data, failure to consider the urban heat island effect, incorrect source release parameters, and failure to diurnally vary source emissions. Most of the concerns raised by this commenter have been addressed by the petitioner's use of the latest model version in its most recently submitted assessment, which used current census data, recent meteorological data from a larger library of meteorological stations, and specified urban or rural dispersion for each facility. Although the petitioner did not make any revisions to source release parameters nor temporalize source emissions, the EPA concludes that the petitioner's assessment is to be viewed less as a refined

assessment of these specific facilities, but rather as an indication that it is reasonable that nPB emissions and ambient concentrations have the potential to cause elevated risks. It is important to note that the commenter's own assessment of the facilities modeled by the petitioner indicate cancer risk estimates as high as 10-in-1 million.

Moreover, as explained earlier in section II.C of this document, CAA section 112(b)(3)(B) does not specifically require an exposure assessment as a criterion for listing a substance. Rather it requires the EPA to consider whether "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." In contrast, EPCRA section 313(d)(2)(A) mandates that the EPA consider whether "a chemical is known to cause or can reasonably be anticipated to cause significant adverse acute human health effects at concentration levels that are reasonably likely to exist beyond facility site boundaries." The contrast demonstrates that when Congress intends to specifically require a risk assessment, it does so. It decided not to do so in CAA section 112(b)(3). The CAA is silent on the issue of noncancer hazards and quantitative cancer risk evaluation and does not explicitly prohibit the EPA from considering it when making a determination under CAA section 112(b)(3)(B). As previously

explained in section II.C, the EPA also believes that in meeting its obligation under CAA section 112(b)(3)(B), the Administrator has discretion in forming her decision to either grant or deny a petition to add a substance to the CAA section 112(b)(1) HAP list. We believe this discretion would allow her, where appropriate, to consider risk evaluation of a substance in order to make the requisite determination as to whether a substance is "known to cause or may reasonably be anticipated to cause adverse effects to human health or adverse environmental effects," under CAA section 112(b)(3)(B).

Thus, the EPA concludes that the petitioners have met the CAA section 112(b)(3)(A) requisite showing of adequate data by estimating nPB emissions and ambient concentrations that are likely to result beyond a facility's fence line and providing adequate evidence of adverse health effects of nPB. Because the EPA is granting the petition for reasons stated above, the agency does not find it necessary to make determinations regarding other elements of the petition, such as a petitioner's noncancer hazards and quantitative cancer risk evaluation, or whether nPB presents adverse environmental effects.

#### **V. EPA's Decision to Grant the Petitions**

Based on the EPA's evaluation of the petitions submitted by HSIA and NYSDEC, we conclude that the petitioners have provided sufficient information demonstrating the adverse health effects

of nPB. The documented adverse health effects of nPB, which are based on established sound scientific principles, include carcinogenicity, reproductive toxicity, and neurotoxicity. The EPA also concludes that the petitioner's assessment regarding estimates of potential ambient concentrations of nPB that are likely to result at a facility's fence line and process emissions related information and chemical usage information representative of normal operating conditions are reasonable. The EPA concludes that there is adequate evidence to support a determination that nPB is an air pollutant and that emissions and ambient concentrations of nPB may reasonably be anticipated to cause adverse effects to human health. As mentioned above, we are seeking comments on all aspects of this notice, including EPA's technical review of the HSIA and NYSDEC petitions, whether the criteria for listing have been met, and the agency's rationale for the decision to grant these petitions.

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

Additional information about this Executive Order can be found at <http://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.

Accordingly, the EPA is issuing this draft notice announcing the decision to grant petitions to add nPB to the CAA section 112(b)(1) HAP list.

Dated: December 28, 2016.

Gina McCarthy,  
Administrator.

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