

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 82

[EPA-HQ-OAR-2002-0064; FRL-xxxx-x]

RIN 2060-AK26

**Protection of Stratospheric Ozone: Listing of Substitutes for Ozone-Depleting
Substances—n-Propyl Bromide**

AGENCY: Environmental Protection Agency.

ACTION: Notice of Proposed Rulemaking

SUMMARY: Pursuant to the U.S. Environmental Protection Agency’s (EPA or “we”) Significant New Alternatives Policy (SNAP) program, this action proposes to list n-propyl bromide (nPB) as an unacceptable substitute for methyl chloroform, chlorofluorocarbon (CFC)-113, and hydrochlorofluorocarbon (HCFC)-141b when used in adhesives or in aerosol solvents because nPB in these end uses poses unacceptable risks to human health when compared with other substitutes that are available. This action also proposes to list nPB as acceptable, subject to use conditions, as a substitute for methyl chloroform, CFC-113, and hydrochlorofluorocarbon (HCFC)-141b in the coatings end use. This proposal supersedes EPA’s proposal of June 3, 2003 on the acceptability of nPB as a substitute for ozone-depleting substances for aerosols and adhesives.

DATES: Comments must be received in writing by **[Insert date 60 days after Federal Register publication date]**. Under the Paperwork Reduction Act, comments on the information collection provisions must be received by OMB on or before *[insert date [thirty] days after date of publication in the Federal Register]*. Any person interested in requesting a public hearing,

must submit such request on or before [insert 30 days from date of publication in the Federal Register]. If a public hearing is requested, a separate notice will be published announcing the date and time of the public hearing and the comment period will be extended until 30 days after the public hearing to allow rebuttal and supplementary information regarding any material presented at the public hearing. Inquires regarding a public hearing should be directed to the contact person listed below.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-HQ-OAR-2002-0064, by one of the following methods:

- <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.
- E-mail: A-And-R-Docket@epa.gov
- Mail: Air and Radiation Docket, Environmental Protection Agency, Mailcode 6102T, 1200 Pennsylvania Ave., NW, Washington, DC, 20460, Attention Docket ID No. EPA-HQ-OAR-2002-0064. In addition, please mail a copy of your comments on the information collection provisions to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attn: Desk Officer for EPA, 725 17th St. NW., Washington, DC 20503.
- Hand Delivery: EPA Docket Center, (EPA/DC) EPA West, Room 3334, 1301 Constitution Ave., NW, Washington, D.C., Attention Docket ID No. EPA-HQ-OAR-2002-0064. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA-HQ-OAR-2002-0064. EPA's policy is that all comments received will be included in the public docket without change and

may be made available online at www.regulations.gov, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through www.regulations.gov or e-mail. The www.regulations.gov website is an “anonymous access” system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through www.regulations.gov, your e-mail 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, 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 EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, 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 instructions on submitting comments, go to Section I.B. of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: All documents in the docket are listed in the www.regulations.gov index. Although listed in the index, some information is not publicly available, i.e., CBI 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 either electronically in www.regulations.gov or in hard copy at the Air and Radiation Docket, EPA/DC, EPA West, Room B102, 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 Air and Radiation Docket is (202) 566-1742.

FOR FURTHER INFORMATION CONTACT: Margaret Sheppard, Stratospheric Protection Division, Office of Atmospheric Programs, Mail Code 6205J, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number (202) 343-9163; fax number (202) 343-2362 e-mail address: sheppard.margaret@epa.gov. Notices and rulemakings under the SNAP program are available on EPA's Stratospheric Ozone World Wide Web site at www.epa.gov/ozone/snap/regs.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. General Information

- A. Does this action apply to me?
- B. What should I consider as I prepare my comments for EPA?
- C. What acronyms and abbreviations are used in the preamble?

II. How does the Significant New Alternatives Policy (SNAP) program work?

- A. What are the statutory requirements and authority for the SNAP program?
- B. How do the regulations for the SNAP program work?
- C. Where can I get additional information about the SNAP program?

- III. What is EPA proposing today?
 - A. What is n-propyl bromide?
 - B. What industrial end uses are included in our proposed decision?
 - C. What is the proposed text for EPA's listing decisions?
 - D. What does an unacceptability determination on adhesives and aerosols mean?
 - E. What is the scope of the proposed determination for coatings?
- IV. What criteria did EPA consider in preparing this proposal?
 - A. Availability
 - B. Impacts on the atmosphere and local air quality
 - C. Ecosystem and other environmental impacts
 - D. Flammability and fire safety
 - E. Health effects and exposure
- V. How did EPA assess impacts on human health?
 - A. Newly available exposure data
 - B. Newly available data on health effects
 - C. Evaluation of acceptable exposure levels for the workplace
 - D. Other analyses of nPB toxicity
 - E. Community exposure guideline
- VI. What listing is EPA proposing for each end use, and why?

- A. Aerosol solvents
- B. Adhesives
- C. Coatings

VII. What other regulatory options did EPA consider?

- A. Alternative option for comment: acceptable with use conditions requiring exposure limit and monitoring
- B. Regulatory options where nPB would be acceptable with use conditions requiring ventilation equipment

VIII. What are the anticipated costs of this regulation to the regulated community?

IX. How do the decisions for EPA's June 2003 proposal compare to those for this proposal?

X. How can I use nPB as safely as possible?

XI. Statutory and Executive Order Reviews

- A. Executive Order 12866: Regulatory Planning and Review
- B. Paperwork Reduction Act
- C. Regulatory Flexibility Act
- D. Unfunded Mandates Reform Act

- E. Executive Order 13132: Federalism
- F. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments
- G. Executive Order 13045: Protection of Children from Environmental Health and Safety Risks
- H. Executive Order 13211: Actions that Significantly Affect Energy Supply, Distribution, or Use
- I. National Technology Transfer and Advancement Act

XII. References

I. General Information

- A. Does this action apply to me?

This proposed rule would regulate the use of n-propyl bromide as an aerosol solvent and as a carrier solvent in adhesives and coatings. Businesses in these end uses that currently might be using nPB, or might want to use it in the future, include:

- Businesses that manufacture electronics or computer equipment.
- Businesses that require a high level of cleanliness in removing oil, grease, or wax, such as for aerospace applications or for manufacture of optical equipment.
- Foam fabricators that glue pieces of polyurethane foam together or foam cushion manufacturers that glue fabric around a cushion.

- Furniture manufacturers that use adhesive to attach wood parts to floors, tables and counter tops.
- A company that manufactures ammunition for the U.S. Department of Defense.

Regulated entities may include:

Table 1–Potentially Regulated Entities, by North American Industrial Classification System (NAICS) Code or Subsector

Category	NAICS code or subsector	Description of regulated entities
Industry	331	Primary Metal Manufacturing
Industry	332	Fabricated Metal Product Manufacturing
Industry/Military	332992	Small Arms Ammunition Manufacturing
Industry	333	Machinery Manufacturing
Industry	334	Computer and Electronic Product Manufacturing
Industry	335	Equipment Appliance, and Component Manufacturing
Industry	336	Transportation Equipment Manufacturing
Industry	337	Furniture and Related Product Manufacturing
Industry	339	Miscellaneous Manufacturing
Industry	326150	Urethane and Other Foam Product (except Polystyrene) Manufacturing

This table is not intended to be exhaustive, but rather a guide regarding entities likely to be regulated by this action. If you have any questions about whether this action applies to a particular entity, consult the person listed in the preceding section, “FOR FURTHER INFORMATION CONTACT.”

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

1. *Submitting Confidential Business Information (CBI).* Do not submit this information to EPA through www.regulations.gov or e-mail. 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 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. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for Preparing Your Comments.* When submitting comments, remember to:

- Identify the rulemaking by docket number and other identifying information (subject heading, Federal Register date and page number).
- Follow directions - The agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.
- Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.
- Describe any assumptions and provide any technical information and/or data that you used.
- If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

- Provide specific examples to illustrate your concerns, and suggest alternatives.
 - Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
 - Make sure to submit your comments by the comment period deadline identified.
- C. What acronyms and abbreviations are used in the preamble?

Below is a list of acronyms and abbreviations used in this document.

8-hr—eight hour

ACGIH—American Conference of Governmental Industrial Hygienists

AEI—acceptable exposure limit

ASTM—American Society for Testing and Materials

BMD—benchmark dose

BMDL—benchmark dose lowerbound, the lower 95%-confidence level bound on the dose/exposure associated with the benchmark response

BSOC—Brominated Solvents Consortium

CAA—Clean Air Act

CAS Reg. No.—Chemical Abstracts Service Registry Identification Number

CBI—Confidential Business Information

CEG—community exposure guideline

CERHR—Center for the Evaluation of Risks to Human Reproduction

CFC-113—the ozone-depleting chemical 1,1,2-trifluoro-1,2,2-trichloroethane, C₂Cl₃F₃, CAS Reg. No. 76-13-1

CFC—chlorofluorocarbon

cfm—cubic feet per minute

CFR—Code of Federal Regulations

CNS—central nervous system

DNA—deoxyribonucleic acid

EDSTAC--The Endocrine Disruptor Screening and Testing Advisory Committee

EPA—the United States Environmental Protection Agency

FR—Federal Register

GWP—global warming potential

HCFC-123—the ozone-depleting chemical 1,2-dichloro-1,1,2-trifluoroethane, CAS Reg. No. 306-83-2

HCFC-141b—the ozone-depleting chemical 1,1-dichloro-1-fluoroethane, CAS Reg. No. 1717-00-6

HCFC-225ca/cb—the commercial mixture of the two ozone-depleting chemicals 3,3-dichloro-1,1,1,2,2-pentafluoropropane, CAS Reg. No. 422-56-0 and 1,3-dichloro-1,1,2,2,3-pentafluoropropane, CAS Reg. No. 507-55-1

HCFC—hydrochlorofluorocarbon

HEC—human equivalent concentration

HFC-245fa—the chemical 1,1,3,3,3-pentafluoropropane, CAS Reg. No. 460-73-1

HFC-365mfc—the chemical 1,1,1,3,3-pentafluorobutane, CAS Reg. No. 405-58-6

HFC-4310mee —the chemical 1,1,1,2,3,4,4,5,5,5-decafluoropentane, CAS Reg. No. 138495-42-8

HFC—hydrofluorocarbon

HFE—hydrofluoroether

HHE—health hazard evaluation

ICF—ICF Consulting

ICR—Information Collection Request

iPB—isopropyl bromide, C₃H₇Br, CAS Reg. No. 75-26-3, an isomer of n-propyl bromide; also called 2-bromopropane or 2-BP

K_{oc}—organic carbon partition coefficient, for determining the tendency of a chemical to bind to organic carbon in soil

LC₅₀—the concentration at which 50% of test animals die

LOAEL—Lowest Observed Adverse Effect Level

Log K_{ow}—logarithm of the octanol-water partition coefficient, for determining the tendency of a chemical to accumulate in lipids or fats instead of remaining dissolved in water

mg/l—milligrams per liter

MSDS—Material Safety Data Sheet

NAICS—North American Industrial Classification System

NESHAP—National Emission Standard for Hazardous Air Pollutants

NIOSH—National Institute for Occupational Safety and Health

NOAEL—No Observed Adverse Effect Level

NOEL—No Observed Effect Level

nPB—n-propyl bromide, C₃H₇Br, CAS Reg. No. 106-94-5; also called 1-bromopropane or 1-BP

NPRM—Notice of Proposed Rulemaking

NTP—National Toxicology Program

NTTAA—National Technology Transfer and Advancement Act

ODP—ozone depletion potential

ODS—ozone-depleting substance

OEHHA—Office of Environmental Health Hazard Assessment of the California Environmental Protection Agency

OMB—U.S. Office of Management and Budget

OSHA—the United States Occupational Safety and Health Administration

PCBTF—parachlorobenzotrifluoride, CAS Reg. No. 98-56-6

PEL—Permissible Exposure Limit

ppm—parts per million

RCRA—Resource Conservation and Recovery Act

RFA—Regulatory Flexibility Act

RfC—reference concentration

SIP—state implementation plan

SNAP—Significant New Alternatives Policy

TCA—the ozone-depleting chemical 1,1,1-trichloroethane, CAS Reg. No. 71-55-6; also called methyl chloroform, MCF, or 1,1,1

TCE—the chemical 1,1,2-trichloroethene, CAS Reg. No. 79-01-6, C₂Cl₃H; also call trichloroethylene

TERA—Toxicological Excellence for Risk Assessment

TLV—Threshold Limit Value™

TSCA—Toxic Substances Control Act

TWA—time-weighted average

UF–uncertainty factor

UMRA–Unfunded Mandates Reform Act

U.S.C.–United States Code

VMSs–volatile methyl siloxanes

VOC–volatile organic compound

WEL–workplace exposure limit

II. How does the Significant New Alternatives Policy (SNAP) program work?

A. What are the statutory requirements and authority for the SNAP program?

Section 612 of the Clean Air Act (CAA) authorizes EPA to develop a program for evaluating alternatives to ozone-depleting substances, referred to as the Significant New Alternatives Policy (SNAP) program. The major provisions of section 612 are:

- Rulemaking–Section 612(c) requires EPA to promulgate rules making it unlawful to replace any class I (chlorofluorocarbon, halon, carbon tetrachloride, methyl chloroform, and hydrobromofluorocarbon) or class II (hydrochlorofluorocarbon) substance with any substitute that the Administrator determines may present adverse effects to human health or the environment where the Administrator has identified an alternative that (1) reduces the overall risk to human health and the environment, and (2) is currently or potentially available.

- Listing of Unacceptable/Acceptable Substitutes--Section 612(c) also requires EPA to publish a list of the substitutes unacceptable for specific uses. We must publish a corresponding list of acceptable alternatives for specific uses.
- Petition Process--Section 612(d) grants the right to any person to petition EPA to add a substitute to or delete a substitute from the lists published in accordance with section 612(c). EPA has 90 days to grant or deny a petition. Where the Agency grants the petition, we must publish the revised lists within an additional six months.
- 90-day Notification--Section 612(e) requires EPA to require any person who produces a chemical substitute for a class I substance to notify the Agency not less than 90 days before new or existing chemicals are introduced into interstate commerce for significant new uses as substitutes for a class I substance. The producer must also provide the Agency with the producer's health and safety studies on such substitutes.
- Outreach--Section 612(b)(1) states that the Administrator shall seek to maximize the use of federal research facilities and resources to assist users of class I and II substances in identifying and developing alternatives to the use of such substances in key commercial applications.
- Clearinghouse--Section 612(b)(4) requires the Agency to set up a public clearinghouse of alternative chemicals, product substitutes, and alternative manufacturing processes that

are available for products and manufacturing processes which use class I and II substances.

B. How do the regulations for the SNAP program work?

On March 18, 1994, EPA published the original rulemaking (59 FR 13044) that described the process for administering the SNAP program and issued the first acceptability lists for substitutes in the major industrial use sectors. These sectors include: refrigeration and air conditioning; foam blowing; solvents cleaning; fire suppression and explosion protection; sterilants; aerosols; adhesives, coatings and inks; and tobacco expansion. These sectors comprise the principal industrial sectors that historically consumed large volumes of ozone-depleting substances.

Anyone who plans to market or produce a substitute for an ozone-depleting substance (ODS) in one of the eight major industrial use sectors must provide the Agency with health and safety studies on the substitute at least 90 days before introducing it into interstate commerce for significant new use as an alternative. This requirement applies to the person planning to introduce the substitute into interstate commerce, typically chemical manufacturers, but may also include importers, formulators or end-users when they are responsible for introducing a substitute into commerce.

The Agency has identified four possible decision categories for substitutes: acceptable; acceptable subject to use conditions; acceptable subject to narrowed use limits; and unacceptable. Use conditions and narrowed use limits are both considered “use restrictions” and are explained below. Substitutes that are deemed acceptable with no use restrictions (no use conditions or narrowed use limits) can be used for all applications within the relevant sector end-

use. Substitutes that are acceptable subject to use restrictions may be used only in accordance with those restrictions. It is illegal to replace an ODS with a substitute listed as unacceptable.

After reviewing a substitute, the Agency may make a determination that a substitute is acceptable only if certain conditions of use are met to minimize risks to human health and the environment. We describe such substitutes as "acceptable subject to use conditions." If you use these substitutes without meeting the associated use conditions, you use these substitutes in an unacceptable manner and you could be subject to enforcement for violation of section 612 of the Clean Air Act.

For some substitutes, the Agency may permit a narrowed range of use within a sector. For example, we may limit the use of a substitute to certain end-uses or specific applications within an industry sector or may require a user to demonstrate that no other acceptable end uses are available for their specific application. We describe these substitutes as "acceptable subject to narrowed use limits." If you use a substitute that is acceptable subject to narrowed use limits, but use it in applications and end-uses which are not consistent with the narrowed use limit, you are using these substitutes in an unacceptable manner and you could be subject to enforcement for violation of section 612 of the Clean Air Act.

The Agency publishes its SNAP program decisions in the Federal Register. For those substitutes that are deemed acceptable subject to use restrictions (use conditions and/or narrowed use limits), or for substitutes deemed unacceptable, we first publish these decisions as proposals to allow the public opportunity to comment, and we publish final decisions as final rulemakings. In contrast, we publish substitutes that are deemed acceptable with no restrictions in "notices of acceptability," rather than as proposed and final rules. As described in the rule implementing the

SNAP program (59 FR 13044), we do not believe that rulemaking procedures are necessary to list alternatives that are acceptable without restrictions because such listings neither impose any sanction nor prevent anyone from using a substitute.

Many SNAP listings include “comments” or “further information.” These statements provide additional information on substitutes that we determine are unacceptable, acceptable subject to narrowed use limits, or acceptable subject to use conditions. Since this additional information is not part of the regulatory decision, these statements are not binding for use of the substitute under the SNAP program. However, regulatory requirements listed in this column are binding under other programs. The further information does not necessarily include all other legal obligations pertaining to the use of the substitute. However, we encourage users of substitutes to apply all statements in the “Further Information” column in their use of these substitutes. In many instances, the information simply refers to sound operating practices that have already been identified in existing industry and/or building-code standards. Thus, many of the comments, if adopted, would not require the affected industry to make significant changes in existing operating practices.

C. Where can I get additional information about the SNAP program?

For copies of the comprehensive SNAP lists of substitutes or additional information on SNAP, look at EPA’s Ozone Depletion World Wide Web site at <http://www.epa.gov/ozone/snap/lists/index.html>. For more information on the Agency's process for administering the SNAP program or criteria for evaluation of substitutes, refer to the SNAP final rulemaking published in the Federal Register on March 18, 1994 (59 FR 13044), codified at Code of Federal Regulations at 40 CFR part 82, subpart G. You can find a complete chronology

of SNAP decisions and the appropriate Federal Register citations at

<http://www.epa.gov/ozone/snap/chron.html>.

III. What is EPA proposing today?

In this action, EPA proposes to list n-propyl bromide (nPB) as (1) unacceptable for use as a substitute for CFC-113¹, methyl chloroform² and HCFC-141b³ in the adhesive and aerosol solvent end uses; and (2) acceptable subject to use conditions (limited to coatings at facilities that have provided EPA with information as of [INSERT DATE OF PUBLICATION] demonstrating their ability to meet the recommended workplace exposure limit) as a substitute for methyl chloroform, CFC-113, and HCFC-141b in the coatings end use. This Notice of Proposed Rulemaking (NPRM) supersedes the NPRM published on June 3, 2003 (68 FR 33284) for aerosol solvents and adhesives.

A. What is n-propyl bromide?

n-propyl bromide (nPB), also called 1-bromopropane, is a non-flammable organic solvent with a strong odor. Its chemical formula is C₃H₇Br. Its identification number in Chemical Abstracts Service's registry (CAS Reg. No.) is 106-94-5. nPB is used to remove wax, oil, and grease from electronics, metal, and other materials. It also is used as a carrier solvent in adhesives. Some brand names of products using nPB are: Abzol®, EnSolv®, and Solvon® cleaners; Pow-R-Wash® NR Contact Cleaner, Superkleen Flux Remover 2311 and LPS NoFlash NU Electro Contact Cleaner aerosols; and Whisper Spray and Fire Retardant Soft Seam 6460 adhesives.

¹ CFC-113 is also referred to as Freon-113, or 1,1,2-trifluoro-1,2,2-trichloroethane. Its CAS Reg. No. is 76-13-1.

² Methyl chloroform is also referred to as 1,1,1-trichloroethane, TCA, MCF, or 1,1,1. Its CAS Reg. No. is 71-55-6.

³ HCFC-141b is also referred to as 1,1-dichloro-1-fluoroethane. Its CAS Reg. No. is 1717-00-6.

B. What industrial end uses are included in our proposed decision?

This proposal addresses the use of n-propyl bromide in the aerosol solvent end use of the aerosol sector and the adhesives and coatings end uses in the adhesives, coatings, and inks sector as discussed below. EPA is issuing a decision on the use of nPB in metals, electronics, and precision cleaning in a separate final rule. EPA has insufficient information for ruling on other end uses or sectors where nPB might be used (e.g., inks, foam blowing, fire suppression).

1. Aerosol Solvents

We understand that nPB is being used as an aerosol solvent in:

- Lubricants, coatings, or cleaning fluids for electrical or electronic equipment;
- Lubricants, coatings, or cleaning fluids for aircraft maintenance; or
- Spinnerette lubricants and cleaning sprays used in the production of synthetic fibers.

2. Adhesives

Types of adhesives covered under the SNAP program are those that formerly used methyl chloroform, specifically, adhesives for laminates, flexible foam, hardwood floors, tire patches, and metal to rubber adhesives. Of these applications, nPB-based adhesives have been used most widely in spray adhesives used in manufacture of foam cushions, and to a lesser degree in laminate adhesives.

3. Coatings

The SNAP program regulates the use of carrier solvents in durable coatings, including paints, varnishes, and aerospace coatings (59 FR 13118). The SNAP program currently does not regulate carrier solvents in lubricant coatings, such as silicone coatings used on medical equipment (59 FR 13119). Methyl chloroform has been used as a carrier solvent in coatings, and

to a much lesser degree, HCFC-141b also has been a carrier solvent. This rule responds to a submission from a facility that is substituting methyl chloroform with nPB in an ammunition coating (sealant).

C. What is the proposed text for EPA’s listing decisions?

In the proposed regulatory text at the end of this document, you will find our proposed decisions for those end uses for which we have proposed nPB as unacceptable or acceptable subject to use conditions. The proposed conditions listed in the “Use Conditions” column would be enforceable while information contained in the “Further Information” column of those tables provides additional recommendations on the safe use of nPB. Our proposed decisions for each end use are summarized below in tables 2 through 4.

PROPOSED LISTINGS

Table 2. AEROSOLS
PROPOSED UNACCEPTABLE SUBSTITUTES

End Use	Substitute	Decision	Further Information
Aerosol solvents	n-propyl bromide (nPB) as a substitute for CFC-113, HCFC-141b, and methyl chloroform	Unacceptable	EPA finds unacceptable risks to human health in this compared to other available alternatives. nPB, also known as 1-bromopropane, is Number 106-94-5 in the CAS Registry.

Table 3. ADHESIVES, COATINGS, AND INKS
PROPOSED UNACCEPTABLE SUBSTITUTES

End Use	Substitute	Decision	Further Information
Adhesives	n-propyl bromide (nPB) as a substitute for CFC-113, HCFC-141b, and methyl chloroform	Unacceptable	EPA finds unacceptable risks to human health in this end use compared to other available alternatives. nPB, also known as 1-bromopropane, is Number 106-94-5 in the CAS Registry.

Table 4. ADHESIVES, COATINGS, AND INKS
SUBSTITUTES THAT ARE PROPOSED ACCEPTABLE SUBJECT TO USE CONDITIONS

End Use	Substitute	Decision	Use Conditions	Further Information
Coatings	n-propyl bromide (nPB) as a substitute for methyl chloroform, CFC-113, and HCFC-141b	Acceptable subject to use conditions	Use is limited to coatings at facilities that have provided EPA information demonstrating their ability to maintain workplace exposure levels at or below the range that the Agency considers acceptable as of [INSERT DATE OF PUBLICATION OF PROPOSAL].	EPA recommends the use of personal protective equipment, including chemical goggles, flexible laminate protective gloves and chemical-resistant clothing. EPA expects that all users of nPB will continue to maintain workplace exposure levels within the range of those data that have been submitted to the Agency. EPA will continue to monitor data that have been submitted to the Agency and will comply with any final Permissible Exposure Limit (PEL) issued by the Occupational Safety and Health Administration (OSHA) in the future under 42 U.S.C. 7610(a). nPB, also known as 1-bromopropane, is Number 74-84-5 in the CAS Registry.

Note: As of [INSERT DATE OF PUBLICATION], the Lake City Army Ammunition Plant is the only facility that has provided information to EPA demonstrating the facility's ability to maintain exposure levels at or below the range that the Agency considers acceptable when using nPB in coatings.

D. What does an unacceptability determination on adhesives and aerosols mean?

In this action, EPA is proposing to find nPB unacceptable as a substitute for methyl chloroform, CFC-113, and HCFC-141b for use as a carrier solvent in adhesives and as an aerosol solvent. If this proposal were to become final, it would be illegal to use nPB or blends of nPB and other solvents in adhesives or in aerosol solvent formulations as a substitute for ozone-depleting substances.

E. What is the scope of the proposed determination for coatings?

We propose to list nPB as an acceptable substitute, subject to use conditions, for methyl chloroform, CFC-113, and HCFC-141b in coatings for facilities that, as of [INSERT DATE OF PUBLICATION], have provided EPA information demonstrating their ability to maintain exposure at or below levels that the Agency considers acceptable (in a range from 18 to 30 ppm to protect against male reproductive effects [e.g., reduced sperm motility], in the range of 17 to 22 ppm to protect against female reproductive effects [e.g., number and length of estrous cycles], and at approximately 20 ppm for effects related to reproductive success [live litter size]). EPA has received a petition to allow use of nPB for the ammunition coating application at Lake City Army Ammunition Plant. This is the only coatings application or facility for which EPA has exposure and usage data demonstrating an ability to maintain workplace exposure levels at or below the range described above that EPA considers acceptable (i.e., 17-30 ppm) when using nPB in coatings. If other facilities are interested in using nPB as a substitute for methyl chloroform, CFC-113, or HCFC-141b in their coatings application, or if a person wishes to market nPB for such use, then the interested party would need to make a submission under the SNAP program.

IV. What criteria did EPA consider in preparing this proposal?

In the original rule implementing the SNAP program (March 18, 1994; 59 FR 13044, at 40 CFR 82.180(a)(7)), the Agency identified the criteria we use in determining whether a substitute is acceptable or unacceptable as a replacement for class I or II compounds:

- (i) Atmospheric effects and related health and environmental impacts;
[e.g., ozone depletion potential]

- (ii) General population risks from ambient exposure to compounds with direct toxicity and to increased ground-level ozone;
- (iii) Ecosystem risks [e.g., bioaccumulation, impacts on surface and groundwater];
- (iv) Occupational risks;
- (v) Consumer risks;
- (vi) Flammability; and
- (vii) Cost and availability of the substitute.

In this review, EPA considered all the criteria above except for consumer risks. n-propyl bromide is used in industrial applications such as electronics cleaning or spray adhesives used in foam fabrication. In those consumer products made using nPB, such as a piece of furniture or a computer, the nPB would have evaporated long before a consumer would purchase the item. Therefore, we believe there is no consumer exposure risk to evaluate in the end uses we evaluated for this rule. The Agency has determined that the Clean Air Act does not authorize EPA to regulate for global climate change purposes (Fabricant, 2003). The Agency has not yet concluded how this determination would affect its consideration of the global warming potential (GWP) of substitutes under the SNAP program. Regardless, the global warming potential of nPB is not a determinative factor in EPA's proposed determination. The GWP for nPB is comparable to or below that of previously approved substitutes in these end uses (ICF, 2006a).

Section 612(c) of the Clean Air Act directs EPA to publish a list of replacement substances (“substitutes”) for class I and class II ozone depleting substances based on whether the Administrator determines they are safe (when compared with other currently or potentially

available substitutes) for specific uses or are to be prohibited for specific uses. EPA must compare the risks to human health and the environment of a substitute to the risks associated with other substitutes that are currently or potentially available. In addition, EPA also considers whether the substitute for class I and class II ODSs “reduces the overall risk to human health and the environment” compared to the ODSs being replaced. Our evaluation is based on the end use; for example, we compared nPB as a carrier solvent in adhesives to other available or potentially available adhesive alternatives.

Although EPA does not judge the effectiveness of an alternative for purposes of determining whether it is acceptable, we consider effectiveness when determining whether alternatives that pose less risk are available in a particular application within an end use. There are a wide variety of acceptable alternatives listed for aerosol solvents, but not all may be appropriate for a specific application because of differences in materials compatibility, flammability, degree of cleanliness required, local environmental requirements, and other factors.

EPA evaluated each of the criteria separately and then considered overall risk to human health and the environment in comparison to other available or potentially available alternatives. We concluded that overall, environmental risks were not sufficient to find nPB unacceptable in any of the evaluated end uses. However, the overall risks to human health, and particularly the risks to worker health, are sufficiently high in the adhesive and aerosol solvent end uses to warrant our proposal to find nPB unacceptable.

A. Availability

Other alternatives are available in each end use considered in this proposal. Examples of other available alternatives for aerosol solvents that have already been found acceptable or acceptable subject to use conditions under the SNAP program include water-based formulations, alcohols, ketones, esters, ethers, terpenes, HCFC-141b, HCFC-225ca/cb, hydrofluoroethers (HFEs), hydrofluorocarbon (HFC)-4310mee, HFC-365mfc, HFC-245fa, hydrocarbons, trans-1,2-dichloroethylene, methylene chloride, trichloroethylene⁴ (TCE), perchloroethylene⁵, and parachlorobenzotrifluoride (PCBTF). Of these, hydrocarbons, alcohols, blends of trans-1,2-dichloroethylene and HFEs or HFCs, and HCFC-225ca/cb are most likely to be used in the same applications as nPB. nPB is already commercially available in aerosols. Its use is primarily for electrical contact cleaning, with some use for benchtop cleaning applications (Williams, 2005).

Many alternatives are also available for use in adhesives, coatings, and inks: water-based formulations, high solid formulations, alcohols, ketones, esters, ethers, terpenes, HFEs, hydrocarbons, trans-1,2-dichloroethylene, chlorinated solvents, PCBTF, and a number of alternative technologies (e.g., powder, hot melt, thermoplastic plasma spray, radiation-cured, moisture-cured, chemical-cured, and reactive liquid). Of these, the alternative adhesives most likely to be used in the same applications as nPB are water-based formulations, adhesives with methylene chloride, and flammable adhesives with acetone (IRTA, 2000). nPB is already used in adhesives, and particularly in foam fabrication and in constructing seating for aircraft (IRTA, 2000; Seilheimer, 2001).

To our knowledge, nPB is potentially available as a carrier solvent in coatings, but has not yet been commercialized, except for use by one facility, the Lake City Army Ammunition

⁴ Also called trichlorethene or TCE, C₂Cl₃H, CAS Reg. No. 79-01-6.

⁵ Also called PERC, tetrachloroethylene, or tetrachloroethene, C₂Cl₄, CAS Reg. No. 127-18-4.

Plant. The Lake City Army Ammunition Plant evaluated twenty-nine carrier solvent alternatives to methyl chloroform and determined that nPB is the only satisfactory alternative for their application given the current process at that facility (Harper, 2005).

B. Impacts on the atmosphere and local air quality

As discussed in the June, 2003 proposal, nPB emissions from the continental United States are estimated to have an ozone depletion potential (ODP) of approximately 0.013-0.018, (Wuebbles, 2002)⁶, lower than that of the ozone depletion potential of the substances that nPB would replace -- CFC-113 (ODP=1.0), and methyl chloroform and HCFC-141b (ODPs = 0.12) (WMO, 2002). Some other acceptable alternatives for these ODSs also have low ODPs. For example, HCFC-225ca/cb has an ODP of 0.02-0.03 (WMO, 2002) and is acceptable as an aerosol solvent. There are other acceptable solvents for aerosols, adhesives, and coatings that essentially have no ODP--aqueous cleaners, HFEs, HFC-4310mee, HFC-365mfc, HFC-245fa, hydrocarbons, VMSs, methylene chloride, TCE, perchloroethylene, and PCBTF. Based on this information, we do not believe the use of nPB within the U.S., and within the end-uses reviewed in this rulemaking, poses a significantly greater risk to the ozone layer than other available substitutes.

Comments on the June 2003 NPRM expressed concern that other countries, particularly those in equatorial regions, might assume that nPB does not pose a danger to the stratospheric ozone layer if the U.S. EPA's SNAP program finds nPB acceptable (Linnell, 2003; Steminiski, 2003). Because the ODP for nPB is higher when used in the tropics (see footnote 9), we

⁶ nPB emissions in the tropics have an ODP of 0.071 to 0.100; the portions of the U.S. outside the continental U.S., such as Alaska, Hawaii, Guam, and the U.S. Virgin Islands, contain less than 1 percent of the U.S.'s businesses in industries that could use nPB. Thus, their potential impact on the ozone layer must be significantly less than that of the already low impact from nPB emissions in the continental U.S. (U.S. Economic Census, 2002a through f)

recognize the concerns raised by these commenters. However, EPA is regulating use in the U.S. and cannot dictate actions taken by other countries. We believe the more appropriate forum to address this concern is through the Parties to the Montreal Protocol. At the most recent Meeting of the Parties, the Parties made the following decision with regard to n-propyl bromide, in order to “allow Parties to consider further steps regarding n-propyl bromide, in the light of available alternatives” (Decision XVIII/11):

1. To request the Scientific Assessment Panel to update existing information on the ozone depletion potential of n-propyl bromide, including ozone depleting potential depending on the location of the emissions and the season in the hemisphere at that location;
2. To request the Technology and Economic Assessment Panel to continue its assessment of global emissions of n-propyl bromide, ...paying particular attention to:
 - (a) Obtaining more complete data on production and uses of n-propyl bromide as well as emissions of n-propyl bromide from those sources;
 - (b) Providing further information on the technological and economical availability of alternatives for the different use categories of n-propyl bromide and information on the toxicity of and regulations on the substitutes for n-propyl bromide;
 - (c) Presenting information on the ozone depletion potential of the substances for which n-propyl bromide is used as a replacement;
3. To request that the Technology and Economic Assessment Panel prepare a report on the assessment referred to in paragraph 1 in time for the twenty-seventh meeting of the

Open-ended Working Group for the consideration of the Nineteenth Meeting of the Parties. (MOP 18, 2006)

Use of nPB may be controlled as a volatile organic compound (VOC) under state implementation plans (SIPs) developed to attain the National Ambient Air Quality Standards for ground-level ozone, which is a respiratory irritant. Users located in ozone non-attainment areas may need to consider using a substitute for cleaning that is not a VOC or if they choose to use a substitute that is a VOC, they may need to control emissions in accordance with the SIP. Companies have petitioned EPA, requesting that we exempt nPB from regulation as a VOC. However, unless and until EPA issues a final rulemaking exempting a compound from the definition of VOC and states change their SIPs to exclude such a compound from regulation, that compound is still regulated as a VOC. Other acceptable ODS-substitute solvents that are VOCs for state air quality planning purposes include most oxygenated solvents such as alcohols, ketones, esters, and ethers; hydrocarbons and terpenes; trichloroethylene; trans-1,2-dichloroethylene; monochlorotoluenes; and benzotrifluoride. Some VOC-exempt solvents that are acceptable ODS substitutes include HFC-245fa, HCFC-225ca/cb, HFC-365mfc and HFC-4310mee for aerosol solvents, and methylene chloride, perchloroethylene, HFE-7100, HFE-7200, PCBTF, acetone, and methyl acetate for aerosol solvents, adhesives, and coatings.

C. Ecosystem and other environmental impacts

EPA considered the possible impacts of nPB if it were to pollute soil or water as a waste and compared these impacts to screening criteria developed by the Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC, 1998) (see Table 5). Available data on the organic carbon partition coefficient (K_{oc}), the breakdown processes in water and hydrolysis

half-life, and the volatilization half-life indicate that nPB is less persistent in the environment than many solvents and would be of low to moderate concern for movement in soil. Based on the LC₅₀, the acute concentration at which 50% of tested animals die, nPB's toxicity to aquatic life is moderate, being less than that for some acceptable cleaners (for example, trichloroethylene, hexane, *d*-limonene, and possibly some aqueous cleaners) and greater than that for some others (methylene chloride, acetone, isopropyl alcohol, and some other aqueous cleaners). The LC₅₀ for nPB is 67 mg/l, which is greater than 10 mg/l. Based on EPA's criteria for listing under the Toxics Release Inventory (US EPA, 1992), we believe that nPB would not be sufficiently toxic to aquatic life to warrant listing under the Toxics Release Inventory. Based on its relatively low bioconcentration factor and log K_{ow} value, nPB is not prone to bioaccumulation. Table 5 summarizes information on environmental impacts of nPB; trans-1,2-dichloroethylene, a commonly-used solvent in blends for aerosol solvents, precision cleaning, and electronics cleaning; acetone, a commonly-used carrier solvent in adhesives; trichloroethylene, a solvent used for metals, electronics, and precision cleaning that could potentially be used in aerosol or adhesive end-uses; and methyl chloroform, an ODS that nPB would replace.

Table 5. Ecosystem and Other Environmental Properties of nPB and Other Solvents

Property	Description of environmental property	Value for nPB	Value for trans-1,2-dichloroethylene	Value for acetone	Value for trichloroethylene	Value for methyl chloroform
K _{oc} , organic-carbon partition coefficient	Degree to which a substance tends to stick to soil or move in soil. Lower values (< 300)* indicate great soil mobility; values of 300 to 500 indicate moderate mobility in soil.	330 (Source: ICF, 2004a)	32 to 49 (Source: ATSDR, 1996)	5.4 (Source: ATSDR, 1994)	106 to 460 (Source: ATSDR, 1997)	152 (Source: US EPA, 1994b)
Break down in water	Mechanism and speed with which a compound breaks down in the environment. (Hydrolysis half-life values > 25 weeks* are of concern.)	Hydrolysis is significant. Hydrolysis half-life of 26 days (Source: ICF, 2004a)	Photolytic decomposition, dechlorination and biodegradation are significant; hydrolysis not significant (Source: ATSDR, 1996)	Biodegradation is most significant form of breakdown (Source: ATSDR, 1994)	Volatilization and biodegradation most significant, with hydrolysis relatively insignificant. Hydrolysis half-life of 10.7 to 30 months (Source: ATSDR, 1997)	Volatilization most significant; biodegradation and hydrolysis also occur (Source: ATSDR, 2004)
Volatilization half-life from surface waters	Tendency to volatilize and pass from water into the air.	3.4 hours-4.4 days (Source: ICF, 2004a)	3 to 6.2 hours (Source: ATSDR, 1996)	7.8 to 18 hours (Source: ATSDR, 1994)	3.4 hours to 18 days (Source: ATSDR, 1997)	hours to weeks (Source: US EPA, 1994b)

Property	Description of environmental property	Value for nPB	Value for trans-1,2-dichloroethylene	Value for acetone	Value for trichloroethylene	Value for methyl chloroform
LC ₅₀ (96 hours) for fathead minnows	Concentration at which 50% of animals die from toxicity after exposure for 4 days.	67 mg/L (Source: Geiger, 1988)	108 mg/L (Source: US EPA, 1980)	7280 to 8120 mg/L (Source: Fisher Scientific, 2001)	40.7 to 66.8 mg/L (Source: NPS, 1997)	52.8 to 105 mg/L (Source: US EPA, 1994b)
log K _{ow}	Logarithm of the octanol/water partition coefficient, a measure of tendency to accumulate in fat. Log K _{ow} values >3* indicate high tendency to accumulate.	2.10 (Source: ICF, 2004a)	-0.48 (Source: LaGrega et al., 2001, p. 1119)	-0.24 (Source: LaGrega et al., 2001, p. 1117)	2.38 (Source: LaGrega et al., 2001, p. 1127)	2.50 (Source: LaGrega et al., 2001, p. 1127)
Bioconcentration factor	High factors (>1000)* indicate strong tendency for fish to absorb the chemical from water into body tissues.	23 (Source: HSDB, 2004)	5 to 23 (Source: ATSDR, 1996)	<1 (Source: ATSDR, 1994)	10 to 100 (Source: ATSDR, 1997)	<9 (Source: US EPA, 1994b)

* Criteria from EDSTAC, 1998.

nPB is not currently regulated as a hazardous air pollutant and is not listed as a hazardous waste under the Resource Conservation and Recovery Act (RCRA). nPB is not required to be reported as part of the Toxic Release Inventory under Title III of the Superfund Amendments and Reauthorization Act. Despite this, large amounts of nPB might be harmful if disposed of in water. We recommend that users dispose of nPB as they would dispose of any spent halogenated solvent (F001 waste under RCRA). Users should not dump nPB into water, and should dispose of it by incineration. We conclude that nPB does not pose a significantly greater risk to the environment than other available alternatives, and that the use of nPB within the U.S. should not be prohibited under the SNAP program on the basis of its environmental impacts.

D. Flammability and fire safety

A number of commenters on the June 2003 proposal provided additional information on the flammability of nPB using standard test methods for determining flash point, such as the American Society for Testing and Materials (ASTM) D 92 open cup, ASTM D56 Tag closed cup, and ASTM D93 Pensky-Martens closed cup methods (BSOC, 2000; Miller, 2003; Morford, 2003a and 2000b; Shubkin, 2003; Weiss Cohen, 2003). We agree with the commenters that by these standard test methods, nPB displayed no flash point. Thus under standard test conditions, nPB is not flammable, and it should not be flammable under normal use conditions. With its low potential for flammability, nPB is comparable to chlorinated solvents, HCFCs, HFEs, HFC-245fa, HFC-4310mee, and aqueous cleaners, and is less flammable than many acceptable substitutes, such as ketones, alcohols, terpenes, and hydrocarbons. nPB exhibits lower and upper flammability limits of approximately 3% to 8% (BSOC, 2000). A number of other solvents that are typically considered to be non-flammable also have flammability limits (for example,

methylene chloride, HCFC-141b, and methyl chloroform). If the concentration of vapor of such a solvent falls between the upper and lower flammability limits, it could catch fire in presence of a flame. Such a situation is unusual, but users should take appropriate precautions in cases where the concentration of vapor could fall between the flammability limits.

E. Health impacts and exposure

In evaluating potential human health impacts of nPB used as a substitute for ozone-depleting substances, EPA considered impacts on both exposed workers and on the general population. Using the same approach commented on and then finalized in the original SNAP rulemaking, EPA evaluated the available toxicity data using EPA guidelines to develop health-based criteria to characterize human health risks (US EPA, 1994a. RfC Guidelines; US EPA, 1991. Guidelines for Developmental Toxicity Risk Assessment; US EPA, 1995b. Benchmark Dose guidelines; US EPA, 1996. Guidelines for Reproductive Toxicity Risk Assessment).

To assess human health risks, EPA followed the four basic steps of risk assessment outlined by the National Academy of Sciences: hazard identification, dose-response relationship, exposure assessment, and risk characterization (NAS, 1983). First, EPA examined available studies on nPB's effects. Second, EPA considered the acceptable exposure levels for evaluating worker exposure and a community exposure guideline (CEG) for evaluating exposure to the general population based upon inhalation exposure. Third, EPA compared the acceptable exposure levels and CEG to available exposure data and projections of exposure levels to assess exposure, including new exposure data available since publication of the June 2003 NPRM. Finally, EPA decided whether there was sufficient evidence indicating that nPB could be used as safely as other alternatives available in a particular end use.

Authority to set an acceptable exposure limit

Two commenters on the June 2003 NPRM said that EPA has no jurisdiction to develop any acceptable exposure limit (AEL) designed to be applicable to a workplace environment and that only OSHA has that authority (Stelljes, 2003 (23); Morford, 2003x (49?)). In contrast, another commenter said that EPA has the authority to set an AEL for nPB under section 612 of the Clean Air Act, has done so in the past for other chemicals (e.g., HFC-4310mee, HCFC-225ca/cb), and should require the AEL as a use condition (Risotto, 2003 (50)).

EPA believes that we have the authority to calculate exposure limits for the workplace under section 612. Section 612(c) specifically states that “the Administrator shall issue regulations:

providing that it shall be unlawful to replace any class I or class II substance with any substitute substance which the Administrator determines may present adverse effects to human health or the environment, where the Administrator has identified an alternative to such replacement that--

- (1) reduces the overall risk to human health and the environment; and
- (2) is currently or potentially available.”

Thus, we must compare the risks to human health and the environment of a substitute to the risks associated with other substitutes that are currently or potentially available, as required by the Clean Air Act. In order to compare risks to human health, EPA performs quantitative risk assessments on different chemicals comparing exposure data and exposure limits, following the process described above by the National Academies of Science (NAS, 1983) and as described in

the preamble to the original final SNAP rule (March 18, 1994; 59 FR 13044). Because most of the humans who are exposed to nPB are exposed in the workplace, the appropriate exposure data and exposure limits to protect human health must include workplace exposure data and acceptable exposure limits for the workplace. Because there is wide disparity in acceptable exposure limits for nPB developed by industry, ranging from 5 ppm to 100 ppm (Albemarle, 2003; Chemtura, 2006; Docket A-2001-07, item II-D-19; Enviro Tech International, 2006; Farr, 2003; Great Lakes Chemical Company, 2001), and because there is not a Permissible Exposure Limit for nPB set by the Occupational Safety and Health Administration, EPA believes it is appropriate to independently evaluate the human health risks associated with use of nPB in the workplace. Similarly, EPA has developed a community exposure guideline to assess the human health effects of nPB exposure to the general public.

Skin Notation

Several commenters on the June 2003 proposal stated that a skin notation for nPB is appropriate, while another commenter agreed with EPA's proposal that no skin notation was necessary (Smith, 2003 (0024); HESIS, 2003 (0039); Werner, 2003 (0058), Weiss Cohen, 2003 (0038)). Rat studies indicate that dermal exposure to nPB results in neither appreciable absorption through the skin (RTI, 2005) nor systemic toxicity (Elf Atochem, 1995). Unlike methyl chloride and dichlorvos, which are absorbed through the skin and could contribute to systemic toxicity (ACGIH, 1991), EPA is not proposing to include a skin notation for nPB in the information provided to users associated with this rulemaking because of the relatively low level of absorption. The ACGIH provides no skin notation in its TLV documentation for several solvents, including nPB (ACGIH, 2005), methylene chloride, and perchloroethylene, and there is

no evidence that absorption through the skin is greater for nPB than for the other halogenated compounds. Further, including the statement, “EPA lists nPB with a skin notation” in the “Further Information” column of listings is likely to be more informative to workers than a skin notation.

Given the possibility that some nPB can be absorbed through the skin in humans, and that the solvent can irritate the skin, EPA encourages users to wear protective clothing and flexible laminate gloves when using nPB and encourages vendors to include such precautions in their Material Safety Data Sheets (MSDSs). EPA requests comment on whether it would be useful, in lieu of a skin notation to add the following statement in the “further information” column of each end use where we find nPB acceptable with restrictions: “EPA recommends the use of personal protective equipment, including chemical goggles, flexible laminate protective gloves and chemical-resistant clothing, when using nPB.”

EPA also considered the potential health effects of contamination of nPB formulations with isopropyl bromide (iPB).⁷ In the June 2003 proposed rule, we proposed as a use condition that nPB formulations contain no more than 0.05% iPB by weight. One commenter opposed the implementation of that proposed use condition, stating that it places an undue legal burden on end users, rather than the manufacturers of raw materials, that it would not benefit worker safety, and that the nPB industry has worked to reduce iPB content below 0.05% (Morford, 2003x (42)). We agree that industry has met this contamination limit for several years without regulation. Furthermore, EPA agrees that if users are exposed to nPB concentrations at acceptable exposure levels (i.e., at or below the range of 17 to 30 ppm), a worker’s exposure to iPB will be sufficiently

⁷ iPB is also referred to as 2-bromopropane, 2-propyl bromide, or 2-BP. Its CAS registry number is 75-26-3.

low to avoid adverse effects. Therefore, this proposed rule does not include a use condition limiting iPB content in nPB formulations.

1. Workplace Risks

In the June 2003 NPRM, EPA proposed that an exposure limit of 25 ppm would be protective of a range of effects observed in animal and human studies, including reproductive and developmental toxicity, neurotoxicity, and hepatotoxicity. Reduction of sperm motility in rats, noted across multiple studies at relatively low exposures, was determined to be the most sensitive effect. The Agency derived an exposure limit of 18 ppm from a dose response relationship in male rat offspring (“F1 generation”) whose parents were exposed to nPB from prior to mating through birth and weaning of the litters (WIL Research Laboratories, 2001). We then proposed to adjust this value upwards to 25 ppm based on principles of risk management, consistent with one of the original “Guiding Principles” of the SNAP program (59 FR 13046, March 18, 1994). As we discussed in the June 2003 NPRM, EPA noted that adhesives users should be able to achieve an AEL of 25 ppm and that 25 ppm was between the level based on the most sensitive endpoint (sperm motility in the F1 offspring generation at 18 ppm) and the second most sensitive endpoint (sperm motility in the F0 parental generation at 30 ppm). Following SNAP program principles, we noted that “a slight adjustment of the AEL may be warranted after applying judgment based on the available data and after considering alternative derivations”(69 FR 33295) Because the animals were exposed to nPB for some time periods that would not occur during actual occupational exposure, we stated further that “18 ppm is a reasonable but possibly conservative starting point, and that exposure to 25 ppm would not pose substantially greater risks, while still falling below an upper bound on the occupation[al] exposure limit.”

Since the 2003 proposal, the Agency has reviewed both information available at the time of the 2003 NPRM related to the health risks associated with nPB use, as well as more recent case studies of nPB exposures and effects in the workplace, newly published toxicological studies, comments to the June 2003 NPRM, including new risk assessments on nPB, and a new threshold limit value (TLV) issued by the American Council of Government and Industrial Hygienists (ACGIH).

OSHA has not developed a permissible exposure limit (PEL) for nPB that EPA could use to evaluate toxicity risks from workplace exposure. The American Conference of Governmental Industrial Hygienists (ACGIH), an independent organization with expertise in industrial hygiene and toxicology, has developed a final workplace exposure limit of 10 ppm (ACGIH, 2005); however, as discussed below, EPA has concerns about the documentation and basis of ACGIH's derivation.

The Agency reconsidered which exposure levels are likely to protect against various health effects, based on review of all available information. We summarize benchmark dose data for a number of endpoints found in these analyses in Table 6 below. We examined these data to assess the acceptability of nPB use in the aerosol solvent, adhesive and coatings end uses reviewed in this proposed rule. These data indicate that, once uncertainty factors are applied consistent with EPA guidelines, the lowest levels for acceptable exposures would be derived for reproductive effects⁸. The data indicate that a level sufficient to protect against male

⁸ By EPA guidelines, we would apply an uncertainty factor of $\sqrt{10}$, or approximately 3, for differences between species for all health effects. We would also apply an uncertainty factor of $\sqrt{10}$ (3) for variability within the working population for reproductive and developmental effects, because, among other reasons, these conditions would not necessarily screen out an individual from being able to work, unlike for liver or nervous system effects. Therefore, for reproductive and developmental effects, we use a composite uncertainty factor of 10. See further discussion of uncertainty factors in section V.C. below.

reproductive effects (e.g., reduced sperm motility) would be in a range from 18 to 30 ppm⁹, in the range of 17 to 22 ppm to protect against female reproductive effects (e.g., number and length of estrous cycles), and at approximately 20 ppm for effects related to reproductive success (live litter size).

**Table 6: Summary of endpoints
using benchmark response modeling**

Endpoint^a	Study	BMDL^b (ppm)	Human Equivalent Concentration (HEC)^c (ppm)
<i>Liver Effects^d</i>			
Liver vacuolation in males (F₁ offspring generation)	WIL, 2001 as analyzed in ICF, 2002	110	116
Liver vacuolation in males (F₀ parent generation)	WIL, 2001 as analyzed in ICF, 2002	143	150
Liver vacuolation	ClinTrials, 1997b as analyzed in ICF, 2002 and Stelljes & Wood, 2004	226	170
<i>Reproductive Effects—Male</i>			
Sperm motility (F₁ offspring generation)	WIL, 2001 as analyzed in ICF, 2002	169	177
	WIL, 2001 as analyzed in Stelljes & Wood, 2004	156	164
Sperm motility (F₀ parent generation)	WIL, 2001 as analyzed in ICF, 2002	282	296
	WIL, 2001 as analyzed in Stelljes & Wood, 2004	263	276
Prostate weight (F₀ parent generation)	WIL, 2001 as analyzed in TERA, 2004	190	200
Sperm count	Ichihara et al., 2000b as analyzed in Stelljes & Wood, 2004	232	325
Sperm deformities (F₀ parent generation)	WIL, 2001 as analyzed in Stelljes & Wood, 2004	296	311
<i>Reproductive Effects—Female</i>			

⁹ Based on WIL, 2001, as analyzed in ICF, 2002. The equivalent values based upon Stelljes and Wood's (2004) analysis of WIL, 2001 would be slightly lower, from 16 to 28 ppm.

Number of estrus cycles during a 3 week period (F₀ parent generation)	WIL, 2001 as analyzed in ICF, 2006	162	170
	WIL, 2001 as analyzed in ICF, 2006	208	218
Estrous cycle length (F₁ offspring generation)^d	WIL, 2001 as analyzed in TERA, 2004	400	420
Estrous cycle length (F₀ parent generation)^e	WIL, 2001 as analyzed in TERA, 2004	210	220
No estrous cycle incidence (F₁ offspring generation)	WIL, 2001 as analyzed in TERA, 2004	180	189
No estrous cycle incidence (F₀ parent generation)	WIL, 2001 as analyzed in TERA, 2004	480	504
<i>Reproductive Effects—Reproductive Success</i>			
Decreased live litter size (F₁ offspring generation)	WIL, 2001 as analyzed in TERA, 2004	190	200
Decreased live litter size (F₂ offspring generation)	WIL, 2001 as analyzed in TERA, 2004	170	179
Pup weight gain, post-natal days 21 to 28 (F₁ offspring generation)	WIL, 2001 as analyzed in TERA, 2004	180	189
<i>Developmental Effects</i>			
Fetal body weight	WIL, 2001 as analyzed in TERA, 2004	310	326
Fetal body weight	WIL, 2001 as analyzed in CERHR, 2002a	305	320
<i>Nervous System Effects</i>			
Hindlimb strength	Ichihara et al, 2000a as analyzed in Stelljes and Wood, 2004	214	300

^a Unless explicitly stated, data are from a parental generation. Of the studies analyzed, only the WIL, 2001 study has multiple generations to be analyzed.

^b The benchmark response value represents a specified level of excess risk above a control response.

^c When considering workplace exposures, the human equivalent concentration is the BMDL, adjusted to apply to a 40-hour work week in which workers are exposed for 8 hours a day for five days per week. Animals in the WIL, 2001 study were exposed for 6 hours a day, 7 days a week. Animals in the Ichihara, 2000a and 2000b studies were exposed for 8 hours a day, 7 days a week. Animals in the ClinTrials, 1997b study were exposed for 6 hours a day, 5 days a week.

^d After applying an uncertainty factor of 3 for animal to human extrapolation, acceptable levels of exposure to protect against liver effects would be in the range of 39 to 57 ppm.

^e Omits data from those animals that have stopped estrous cycling altogether (TERA, 2004).

2. General population risks

EPA used a community exposure guideline of 1 ppm to assess potential risks to the general population living near a facility using nPB (see section V.E below). Of the end uses covered in this rule, use of nPB-based adhesives would result in the highest exposure levels, and so, we first examined general population exposure from adhesives. ICF Consulting modeled inhalation exposure to nPB to people living near a plant using nPB-based adhesives in several scenarios using the Agency's SCREEN3 model. Based on this modeling, EPA found that the exposure to individuals in the general population was below the community exposure guideline. The analysis indicates that nPB is no greater a hazard to the general population than other acceptable solvents under the SNAP program. For further discussion, see the risk screen for nPB (ICF, 2006a).

Representatives from a state environmental agency and from a potential user of nPB have asked EPA whether we had developed a reference concentration (RfC). We clarify that the community exposure guideline is a value developed by the SNAP program for our risk assessment of nPB following EPA's RfC Guidelines. However, it is not a formal RfC developed by EPA's National Center for Environmental Assessment and is not in IRIS. At this time, EPA does not have plans to issue an official RfC for nPB.

V. How did EPA assess impacts on human health?

A. Newly available exposure data

Since publication of the June 2003 NPRM, EPA has received additional information on exposure levels in each end use discussed in this proposal.

In the adhesives end use, we considered new exposure modeling based on information from site visits to facilities using spray adhesives (ICF, 2006a). These data predicted that:

- At average rates of ventilation and adhesive application, average workplace exposures would be approximately 60 ppm.
- Average adhesive application rates and poor ventilation rates resulted in average exposures of approximately 250 ppm.
- High (90th percentile) adhesive application rates and average ventilation rates resulted in average exposures of approximately 600 ppm.
- In the worst case scenario with high adhesive application rates and poor ventilation, average workplace exposures would be as high as 2530 ppm.

We compared the modeled data in the four exposure scenarios to measured exposure data in three NIOSH health hazard evaluations (NIOSH 2002a, 2002b, 2003). Our understanding is that North Carolina OSHA received complaints from workers and requested that NIOSH evaluate health hazards at these three facilities. NIOSH found average exposure levels of 68 ppm, 116 ppm, 127 ppm, and 195 ppm for sprayers actively using the adhesive prior to installation of state-of-the-art ventilation systems (NIOSH 2002a, 2002b, 2003). The plant with an average exposure level of 68 ppm for sprayers (9 samples) had an average exposure level comparable to the average concentration of 60 ppm in the modeling scenario with average adhesive rates and average ventilation levels. The other plants with average exposure levels of 116 to 127 ppm (20 samples), and of 195 ppm (36 samples) for sprayers had exposure levels between the average modeled exposure for a facility with average adhesive application rates and average ventilation (60 ppm) and the average modeled exposure for a facility with average adhesive application rates and poor ventilation (250 ppm). Based on this comparison, EPA

believes the modeled exposure levels are a reasonable predictor of actual exposure based on current industry practice in the adhesive end use.

In the aerosol solvent end use, we received a study on workplace exposure levels of nPB-based aerosols from a commenter (Linnell, 2003). Personal breathing zone samples taken from the collars of workers showed 8-hour time-weighted average (TWA) exposures of 5.5, 13, and 32 ppm for workers using 310 g of nPB from a spray can¹⁰ (Linnell, 2003). The two higher exposure levels occurred in the absence of any local or regional ventilation; the use of both local and regional ventilation equipment with ventilation levels around 1900 ft³/min was associated with the lowest exposure level. Short-term exposures taken from a room with regional ventilation at 640 cfm, when averaged over an 8-hour period, resulted in exposures of 6, 12, 34, and 66 ppm (Linnell, 2003). EPA considers the highest of these values, 66 ppm, not to be representative of worker exposure from inhalation because the measurement was taken from the worker's wrist, rather than from his breathing zone. Similar measurements were made in another study we considered in developing the June 2003 NPRM: 8-hr TWA exposures of 11.3, 15.1, 17.0, and 30.2 ppm with regional ventilation of 300 cubic feet per minute from a fan for the entire room (Confidential submission, 1998).

Another commenter submitted information on aerosol exposures for a number of other available alternative aerosols (Werner, 2003). While these data do not include nPB, based on the properties of aerosol solvents, we believe it is reasonable to compare concentrations of these different chemicals to potential nPB exposures. The study compared concentrations of eight

¹⁰ Unlike samples measured directly in the breathing zone, area samples measured in the study are not considered representative of actual exposure and are not discussed here. Short-term measurements taken over 15 minutes from personal samplers, although in some cases extremely high, are not discussed in detail here because available toxicity information does not indicate need for a short-term exposure limit for nPB in addition to the 8-hr TWA limit (ACGIH, 2005; ERG, 2004). Additional information on these other samples is in the occupational exposure assessment for aerosols in the risk screen for nPB (ICF, 2006a).

different chemicals that are acceptable under the SNAP program in aerosol formulations: HFE-7100, HFE-7200, trans-1,2-dichloroethylene, HCFC-225ca and -225cb, acetone, pentane, and HFC-134a. In this study, with ventilation of only 48 cfm, 8-hr TWA exposure from the different chemicals varied from 35.5 ppm to 194.0 ppm, below the recommended exposure levels for these particular chemicals (ICF, 2006a) but above the range of exposure levels that EPA would consider acceptable for nPB.

In addition, we considered new information from modeling of nPB exposures (ICF, 2006a). The modeling examined exposure levels that would be expected at ventilation levels of 450 cfm, 625 cfm, and 1350 ppm, considering the molecular weight of the compound and the composition of different aerosol blends. EPA's SNAP program has previously used these same levels to calculate potential aerosol exposures, based upon exposure levels expected during benchtop cleaning. In a space with an air exchange rate of 450 ft³/minute or less¹¹, EPA's modeling predicts 8-hour average exposure of approximately 16 to 17 ppm if a user sprays 450 g of pure nPB (approximately 1 lb)¹², and corresponding higher exposure values at higher spray rates (e.g., 33 ppm if the amount of nPB sprayed is 900 g) (ICF, 2006a). Exposure values were predicted to be lower at higher ventilation rates.

Since the June 2003 NPRM, EPA received a new submission for nPB in coatings (Lake City Army Ammunition Plant, 2003). The Lake City Army Ammunition Plant provided data on workplace exposure to nPB (Lake City Army Ammunition Plant, 2004). The mean exposure at this facility was 3.7 ppm. Out of 31 samples taken, 25 (approximately 80%) were below 5 ppm.

¹¹ This corresponds roughly to a regional or room fan at low levels or natural air currents in an open area. Confined areas would have even lower air exchange rates with higher exposure levels.

¹² We consider use of 1000 g/day to be the high end of typical use, based on the setup of one of the exposure studies (Confidential Submission, 1998). The typical aerosol solvent user in the electronics industry uses a can per day (Williams, 2005). This is comparable to or slightly less than the spray rate assumed in the modeling.

Only one of 31 samples had an exposure level above 10 ppm, and that exposure value was approximately 21 ppm.

. B. Newly available data on health effects

Since publication of the June 2003 NPRM, EPA has examined additional occupational (Table 7) and animal (Table 8) studies that have become available:

Table 7. Recent Studies on nPB Occupational Exposure

Case Study	Sample Size/Population	Exposure Data	Observations	Remarks
Beck and Caravati, 2003	6 foam cushion factory workers (gluers)	Exposure during 30-40 hr/wk for a 3-month period. Exposure measured in one day was a mean of 130 ppm (range, 91-176 ppm).	Lower leg weakness accompanied by pain and difficulty with standing and walking, numbness of legs and feet, hyperreflexia and hypertonicity of lower extremities, dizziness and shortness of breath, and peripheral neurotoxicity. Measured serum bromide levels were elevated, range 44-170 mg/dL.	Small sample size studied. Possible interference or synergistic effects from other adhesive ingredients (1,2-epoxybutane and styrene-butadiene).
Majersik et al., 2004; Majersik et al., 2005 *	6 foam cushion factory workers (gluers)	5-8 hr/day for at least 2 years with mean air concentration of 130 ppm on last day of study. Measurements taken over 9 hours (equivalent to 92-127 ppm with mean of 108 ppm for an 8-hour TWA).	Subacute onset of lower extremity pain, difficulty walking, and high serum bromide levels in blood. Neurotoxic symptoms persisted for at least 2 years after exposure ended.	Follow-up to Beck and Caravati (2003). Chronic nPB exposure associated with incapacitating neurotoxic syndrome. Initial report from Utah OSHA indicated erroneously that workers were not spraying while measurements were taken. In fact, adhesives were being sprayed and fans were being used only for portions of the day that measurements were taken, making measurements likely to be representative of conditions during the past several months at the plant.
Ichihara et al., 2004a	37 chemical plant workers (24 males and 13 females)	12 hour shifts over 2-day period, mean concentration of 82 ppm (range, 0-170 ppm)	Mucosal irritation (nose, throat), headache, dizziness, constipation, intoxication, and feeling light-headed or heavy-headed. Four female workers complained of disruption or cessation of menstruation. No severe chronic symptoms of neurological damage at less than 170 ppm. Several workers had hemoglobin and hematocrit values outside of the normal range and were diagnosed with mild anemia; most of these cases also showed signs of iron deficiency.	Inadequate exposure characterization and exposure to other potential toxicants, small sample size, and no appropriate control group. Healthy worker effect possible, where more sensitive workers left the factory between 1996 and 1999.

Case Study	Sample Size/Population	Exposure Data	Observations	Remarks
Ichihara et al., 2004b	27 female chemical plant workers (23 age matched with 23 females from a beer factory control group)	1-day exposure period, range of exposure, 0.34-49 ppm	Responses indicated anxiety, fatigue, confusion, tension, and depression. Changes in menstrual status but not statistically significant. Effects on peripheral and central nervous system — diminished vibration sensation of the foot; significantly longer distal latency in the tibial nerve; decreased values in sensory nerve conduction velocity in the sural nerve; and lower scores on memory and perceptual tests. No comparable effects seen in control group.	No long-term exposure measurements, small sample size; lack of controls for age, height, and body-weight. Low B vitamin levels in normal range in some workers but researchers concluded this did not cause observed neurological effects. Additionally, the study did not indicate any significant differences in the prevalence of menstrual cycle abnormalities.
Nemhauser, 2005 *	Foam cushion factory workers (gluers) in North Carolina	In 1999 study, 16 workers exposed to mean air concentration of 116 ppm, and 12 sprayers exposed to mean concentration of 108 ppm with range of 58 to 254 ppm. In 2001 study, 13 workers exposed to nPB mean air concentration of 46 ppm and 12 sprayers were exposed to mean concentration of 101 ppm, with range of 38 to 281 ppm.	Higher exposure to nPB and dose-dependent relationship among those who reported anxiety, headache, and ataxia. No reproductive abnormalities reported in medical survey for men or women. Semen analysis found no differences between exposed and unexposed workers.	Small sample sizes studied with moderate worker participation. Healthy worker effect likely occurred: those that had most significant health effects had already removed themselves from workplace by the time of the study. No arsenic found at the plant. Neurotoxic effects caused by nPB. See related Health Hazard Evaluation (HHE): NIOSH, 2003a.
NIOSH, 2003a	16 workers in 1999 evaluation; 13 workers in 2001 follow-up evaluation.	1999 Initial Site Visit: geometric mean nPB concentration (from personal samples), 81.2 (range, 18-254 ppm); 2001 follow-up: geometric mean, 81.2 ppm (range, 7-281 ppm)	Most workers exposed to >25 ppm nPB levels. Exposure concentrations lower in 2001 than 1999, but difference not statistically significant. Headache, anxiety, feeling drunk associated with nPB exposure. Hematological endpoints unaffected in exposed group. No correlation of nPB exposure with sperm or semen indices or with neurological abnormalities.	Arsenic was not attributed to occupational exposure. The National Institute for Occupational Safety and Health (NIOSH) stated that neurological symptoms may have been related to excess exposure to nPB, but that no other effects could conclusively be related to nPB exposure.

Case Study	Sample Size/Population	Exposure Data	Observations	Remarks
Raymond and Ford, 2005*	4 foam cushion factory workers (gluers) in North Carolina	Exposure study conducted 9 months after index patient became ill indicated workers exposed to mean nPB air concentration of 116 ppm. 4 workers exposed for 2-3 weeks before initial symptoms detected.	Dizziness, numbness, ocular symptoms, lower extremity weakness and unsteady gait, weakness, hypesthesia, and ataxic gait in all four workers. Symptoms decreased over time but after six years, at least one worker re-exposed twice at other furniture plants; one or more still suffer from ataxia.	Small sample size, possible confounding effect from arsenic.
Toraason et al., 2006	41 and 22 foam cushion factory workers (gluers) at 2 facilities	1-3 days up to 8 hrs per day, with concentrations of 0.2 – 271 ppm at facility A, 4 - 27 ppm at facility B.	No statistically significant differences in DNA damage with worker's nPB exposure. In vitro results showed nPB increased DNA damage.	Authors find limited evidence that nPB poses a "small risk" for DNA damage.

*Presentation at North American Congress of Clinical Toxicology on September 14, 2005.

Citation	Population/ sample size	Exposure	Observations	Comments
		<p>Offspring in control groups C and D were exchanged, but not exposed.</p>	<p>chemistry endpoints at any measured timepoint. Analyses of reported findings of liver histopathology in 800-ppm males and females were apparently not subjected to statistical analyses, so no firm conclusions could be drawn. No comments were made regarding liver histopathology of 100- and 400-ppm offspring of either sex, which also precludes drawing firm conclusions regarding the changes in liver enzymes observed at these concentrations.</p> <p>2) Second experiment: (Significant number of dead offspring of the dams exposed at 800 ppm.) Body weights and pregnancy endpoints did not differ between exposed (800 ppm) and unexposed (0 ppm) dams. Live offspring at day 0 (day of birth) were significantly decreased and number of dead offspring and ratio of dead/live offspring were significantly increased in 800-ppm groups compared to controls. Survival rates of offspring exposed either during gestation or nursing (groups A & B) were significantly decreased compared to unexposed offspring (groups C & D) throughout nursing, but were not different from each other. The offspring nursing from the exposed dams (group A) had the lowest body weights, followed by the offspring of the exposed dams that nursed from non-exposed dams (group B), with the control animals having the highest body weights (groups C and D). Group A had significantly more dead offspring in the F2 generation than the other groups.</p>	<p>behavior, changes in milk production, exposure in utero, changes in the intrauterine environment). Many of these endpoints (e.g., nPB metabolites in milk, normal pup rearing behavior) could have been analyzed in this study, but were not.</p>

Citation	Population/ sample size	Exposure	Observations	Comments
Honma et al., 2003	Fisher 344 male rats	8 hr/day, 7day/wk for three weeks exposed to 0, 10, 50, 200 or 1000 ppm (5 rats/dosage and 5 different tests)	3 week exposure to greater than 50 ppm temporarily increased locomotor activity and ambulatory and rearing behaviors in male rats.	Neurological effects shown to be transient and reversible at ≥ 200 ppm (Ichihara et al., 2000) or absent after 28 days of exposure at concentrations ≥ 400 ppm (ClinTrials, 1997a) or after 90 days of exposure at concentrations up to 600 ppm (ClinTrials, 1997b) in other studies. Human studies are limited by co-exposures and poor estimates of exposure concentrations. Thus, EPA is not using this endpoint as the basis of an AEL.
Ishidao et al., 2002	30 male Wistar rats	6 hr/day, 5 day/wk with test groups (10/dose) exposed to 700 ppm for 4 and 12 weeks and 1500 ppm for 3 and 4 weeks	nPB is metabolized rapidly in the rat following exposures to nPB at concentrations ≥ 700 ppm for at least 3 weeks.	Exposure levels are higher than in some other studies and are much higher than concentrations seen in the workplace. nPB metabolism appears to be different following multiple exposures as compared to acute exposures (see RTI, 2005; ICF, 2006b).
NTP, 2003	Female and male B6C3F1 mice and Fischer 344 rats	0, 62.5, 125, 250, 500 (rats and mice), 1000 (rats) ppm for 90 days	Early mortality in mice at 500 ppm accompanied by liver and lung cell degeneration and cytoplasmic vacuolization. Cytoplasmic vacuolization also in rat liver cells ≥ 250 ppm (males) and ≥ 500 ppm (females), with increased severity at higher doses. No adverse central nervous system (CNS) effects or histopathology reported.	Unpublished study. Conclusions drawn from a review of raw data from the National Toxicology Program (NTP) web site. In general, the severity of effects (in non-reproductive organs) is slightly higher at lower concentrations in male rats than in females.
RTI, 2005/Garner et al., 2006	Female and male B6C3F1 mice and Fisher 344N rats, four to six animals in each test trial	Exposure via several injection routes (intraperitoneal, intravenous, cannulization), inhalation, and dermal. Injection conducted via bolus dosing at 5, 20, or 100 mg/kg body weight. Inhalation concentrations of 70, 240, 800, and 2700 ppm administered in a single	nPB cleared by mice after 48 hours as follows: 45% as volatiles in the breath, 28% as CO ₂ in the breath, 26% in urine, <3% in feces, and 2% retained in the body. Distribution was similar in male rats, although amounts in urine and volatiles in breath were higher in mice. At higher doses, the amount of nPB excreted in urine and as CO ₂ decreased, with a much greater change in rats compared to mice.	The study authors concluded that: <ul style="list-style-type: none"> nPB administered via intraperitoneal injection or inhalation is eliminated mostly through the breath, with urine as a secondary path. Metabolism of nPB appears to be primarily through cytochrome P450 enzymes (CYP2E1), particularly in mice; glutathione conjugation still plays an important role in rats. At high concentrations, female rats may have a decreased capacity to metabolize nPB compared to

Citation	Population/ sample size	Exposure	Observations	Comments
		acute exposure. A dose of 96 mg/kg was applied to a shaved area on the backs of six male rats with a non-occlusive charcoal filter covering (that is, one that does not prevent evaporation).	<ul style="list-style-type: none"> • After pretreatment with a cytochrome P450 inhibitor, a decrease in nPB cleared as CO₂ (80%) and urine (40%); pretreatment with a glutathione inhibitor reduced nPB cleared as CO₂ by 10% and urine by 4%. • The V_{max}, a measure of the maximum initial rate of an enzyme-catalysed reaction, is 0.227 for male rats, 0.143 for female rats, 0.329 for male mice and 0.234 for female mice. Half-lives were comparable between males and females at ≤ 800 ppm. • For rats exposed to nPB through skin, 37% of the dose was excreted in volatiles, 1.2 % in urine, 1.7% as CO₂, and 35.7% was on the applicators or in the skin washes. Only 0.32% remained in tissues. Airborne concentrations of nPB in the chamber were 4 to 10 ppm after dosing. 	<p>male rats.</p> <ul style="list-style-type: none"> • nPB decreases glutathione levels in the liver after a one-time exposure to nPB at concentrations as low as 70 ppm. • nPB is not appreciably absorbed (~3-27%) in rats following dermal application. <p>EPA agrees with these points, except we found that gender differences were only apparent in rats at very high concentrations (2700 ppm and greater). We also note that:</p> <ul style="list-style-type: none"> • Inhalation tests were only one-time exposures at very high concentrations (240 to 2700 ppm), and thus, are not comparable to long-term dosing at the lower levels expected in the workplace. • Results of dermal testing are not conclusive because of potential for inhalation exposure.
Sohn et al., 2002	40 male and 40 female Sprague-Dawley rats	6 hr/day, 5 day/wk for 13 weeks, test groups (10/sex/dose) were exposed to 0, 200, 500 or 1250 ppm	No effects on mortality, activity, weight gain, food consumption, urinalysis, or histological effects in the brains and spinal cords.	The differences between the various studies may be due to variability in exposure methodology and achieved concentrations of nPB.
Stump, 2005*	125 female/125 male rats in first generation and 100 female/100 male rats in offspring	Both test groups of 25 male rats/ 25 female rats exposed to 0, 100, 200, 250, 500 and 750 ppm nPB for 10 weeks	Decreased litter size at 250 and 500 ppm in both generations. Decreased fertility at 100 and 250 ppm in offspring generation. Complete infertility at 750 ppm.	Reproductive effects seen in both rat sexes which is a strong signal of reproductive toxicity potential in humans. The author considers 100 ppm to be a lowest observed adverse effect level (LOAEL). This is a presentation of data from WIL, 2001.

Citation	Population/ sample size	Exposure	Observations	Comments
	generation			
Wang et al., 2003	36 male Wistar rats	8 hr/day, 5 day/wk for 12 weeks, test groups (9 rats) were exposed to 0, 200, 400 or 800 ppm	Decrease in creatine kinase in the spinal cord (17% at ≥ 200 ppm) and brain (15-28% at ≥ 400 ppm) at 200, 400, and 800 ppm. No physical or behavioral changes observed.	Small study size. No behavioral changes or physical symptoms were observed in the animals, so the toxicological relevance of the decrease in creatine kinase is questionable.
Yamada et al., 2003	40 female Wistar rats	8 hr/day, 7 day/wk with test groups (9/dose) exposed to 0, 200, 400, or 800 ppm for 12 weeks	All rats at 800 ppm became seriously ill after 7 weeks of exposure. Significant decrease in antral follicles at ≥ 200 ppm, and a decrease in the number of female rats exhibiting regular estrous cycles in 400-ppm females during 7-9 weeks of exposure and at 2-3 weeks at the 800-ppm dose.	Data suggest that nPB is affecting the maturation of ovarian follicles. A no observed adverse effect level (NOAEL) of 200 ppm is identified with a LOAEL of 400 ppm for the changes in estrus cycles.

*Presentation at North American Congress of Clinical Toxicology on September 14, 2005

- In general, the recent animal studies collectively show a range of effects associated with nPB exposure that are qualitatively consistent with previously published findings. (Exceptions to this are the negative results regarding central nervous system toxicity in the NTP (2003) study and the Sohn (2002) study on rats.) Some general conclusions we draw from the new studies include:
 - Case reports of nPB exposure in the workplace indicate that severe, possibly irreversible, neurological effects may occur at sustained concentrations of approximately 100 ppm or greater (Beck and Caravati, 2003; Majersik et al, 2004; Majersik et al., 2005; Ichihara et al., 2002a; Miller, 2005; Raymond and Ford, 2005). In other cases, similar or higher concentrations up to 170 ppm caused less severe nervous system effects (Nemhauser, 2005; NIOSH, 2003a; Ichihara, 2004a). Some neurological effects occurred in workers at levels of less than 50 ppm (Ichihara et al., 2004b). Because of design and methodological limitations, such as small numbers of subjects and limited exposure information, these studies do not provide a sufficient quantitative basis to derive an acceptable exposure limit.
 - Data on female rats indicate that nPB affects the maturation of ovarian follicles and the ovarian cycle (Yamada et al., 2003), consistent with previously reviewed data (WIL , 2001; Sekiguchi et al., 2002).
 - Some data on occupation exposure suggest that workers exposed to nPB may have experienced menstrual disorders (Ichihara et al., 2002; Ichihara et al., 2004b). However, the data are not statistically significant and are not sufficient to conclude that nPB exposure caused these female reproductive effects.

- Data on DNA damage in workers exposed to nPB was not statistically significant (Toraason et al., 2006).
- Metabolic data on mice and rats indicate some species differences. Metabolism of nPB appears to be primarily through cytochrome P450 enzymes, particularly in mice; glutathione conjugation also plays a role, and a bigger role for rats than for mice (RTI, 2005).
- New data from toxicological studies on nervous system effects remain inconsistent and equivocal concerning the level at which nervous system effects occur (Fueta et al., 2002; Fueta et al., 2004; Honma et al., 2003; Ishidao et al., 2002, NTP, 2003; Sohn et al. 2002, Wang et al., 2003).

A number of commenters on the June 2003 NPRM suggested that EPA should consider neurotoxicity as the endpoint in deriving an AEL for nPB (Linnell, 2003; Werner, 2003; Bernhard and Rusch, 2003 (0059), Rusch, 2003b (0073?)). In particular, they requested that EPA consider the study conducted by Wang (2003) and epidemiological data on neurotoxic effects of nPB. As discussed above, the data on neurotoxic effects of nPB on workers is limited and are not sufficient to determine acceptable levels of exposure. In the study on rats by Wang et. al (2003), measurements found a decrease in enzymes in the spinal cord and brain at 200, 400, and 800 ppm, but the animals displayed no physical or behavioral changes. Because of the lack of physical symptoms or behavioral changes, EPA does not believe that the decrease in enzyme levels in the central nervous system are toxicologically relevant. Other studies examining neurological effects of nPB showed those effects to be transient and reversible at and above 200 ppm (Ichihara et al., 2000). Exposures of 200 ppm and above for three weeks had no effect on memory, learning function, or coordination of limbs (Honma, 2003); the effect of spontaneous

locomotor activity seen in this study at 50 ppm and above was not considered adverse by the authors. In other studies, neurological effects were absent after extended periods of exposure—after 28 days of exposure at concentrations > 400 ppm (ClinTrials, 1997a) and after 90 days of exposure at concentrations up to 600 ppm (ClinTrials, 1997b). Thus, although neurological effects have been associated with nPB exposure, the data are currently insufficient to quantify and determine acceptable exposure levels based on this endpoint.

One commenter on the June 2003 NPRM requested that EPA evaluate a study by Yamada et al (2003), a study published just prior to the June 2003 NPRM. In response to the comment, EPA reexamined Yamada et al., 2003 and re-evaluated the literature (Ichihara et al., 1999, 2002, 2004a,b; Sekiguchi, 2002, Yamada et al., 2003; WIL, 2001) to assess potential reproductive toxicity in females (ICF, 2006a, Att. A). A peer review of these effects is in the public docket (ICF, 2004b). Multiple benchmark analyses found a statistically significant decrease in the number of estrous cycles and increase in estrous cycle length associated with nPB exposure, consistent with other reproductive endpoints, namely reductions in sperm motility, decreased live litter size, and change in prostate weight (ICF, 2002a; ICF, 2006a; Stelljes and Wood, 2004; TERA, 2004).

Reproductive effects are seen in males, females, and offspring, and in different generations of the two-generation study (WIL, 2000). They also are consistent with results seen in one-generation reproductive studies, such as Ichihara et al. (2000) and Yamada (2003). See Table 6 above in section IV.E.1. for a more complete list of the different health effects. EPA believes that the preponderance of the data indicate that exposure levels sufficient to protect against male reproductive effects (e.g., reduced sperm motility) would be in a range from 18 to

30 ppm, in the range of 17 to 22 ppm to protect against female reproductive effects (e.g., number and length of estrous cycles), and at approximately 20 ppm for effects related to reproductive success (live litter size). The Agency is assessing the acceptability of nPB in various end-uses by considering the likelihood that exposures in those end-uses would fall within this range of acceptable exposure levels.

In the June 2003 NPRM, EPA used a BMDL of 169 ppm as a point of departure for developing an AEL. Some commenters stated that data from the F1 generation is inappropriate for calculating occupational exposure, citing statements from toxicologists, such as, “occupational exposure involves adults only.” They also stated that EPA has not required this for other chemicals and that the resulting value is more conservative than what is normal and appropriate for industrial toxicology (Morford, 2003x--exhibits, Ruckriegel, 2003). Others stated that sperm motility effects on the F1 generation are appropriate to consider (Risotto, 2003; Farr, 2003), particularly because of the potential for *in utero* effects and because of the consistent presence of these reproductive effects in both generations and at multiple levels. EPA acknowledges that using data from the F1 offspring generation may be conservative because the pups in the F1 generation were exposed to nPB between weaning and sexual maturity (WIL, 2001). During occupational exposure, this period of exposure would not occur because children under age 16 are not allowed to work in industrial settings. However, EPA believes that because of the potential for *in utero* effects that would only be seen in the offspring generation, looking only at the F0 parental generation could underestimate the adverse health impacts of a chemical. Therefore, we believe it is appropriate to consider effects seen in both the F0 parental generation and the F1 offspring generation. Further, effects on sperm motility in the parental and offspring

generations are seen at levels generally consistent with multiple reproductive effects seen in both generations and both sexes exposed to nPB, such as estrous cycle length, lack of estrous cycling, the number of estrous cycles in a given period of time, fertility indices, and the number of live pup births (TERA, 2004; ICF, 2006a; Stelljes, 2001). Therefore, we believe that the available data indicate that in order to protect against adverse reproductive effects, exposure levels at or below the range of 17 to 30 ppm would be acceptable. We would reach the same proposed decisions of unacceptability based upon data from the F0 generation.

B. Evaluation of acceptable exposure levels for the workplace

To calculate acceptable exposure levels for nPB, EPA uses standard risk assessment methods delineated in Agency guidance (US EPA, 1994a) in evaluating data, choosing a benchmark dose level or a NOAEL, and making the adjustments and uncertainty factors prescribed to account for differences in the duration of exposure and in sensitivity between and within species.

Adjustment for Occupational Exposure Pattern

To account for differences between the exposure pattern used in the WIL study (6 hours per day for 7 days per week) when compared to a typical workweek of 8 hours per day and 5 days a week, a “human equivalent concentration” (HEC) is first calculated by adjusting the benchmark dose level:

$$(BMDL \text{ in ppm} \times 6 \text{ hours}/8 \text{ hours}) \times 7 \text{ days}/5 \text{ days} = HEC \text{ (ppm)}$$

HECs for the major health endpoints are shown in Table 6 above in section IV.E.1.

Uncertainty Factors

According to EPA risk assessment guidance for reference concentrations (RfC) (EPA 1994a), uncertainty factors of up to 10 may be applied to the HEC for each of the following conditions:

- (1) Data from animal studies are used to estimate effects on humans;
- (2) Data on healthy people or animals are adjusted to account for variations in sensitivity among members of the human population (inter-individual variability);
- (3) Data from subchronic studies are used to provide estimates for chronic exposure;
- (4) Studies that only provide a LOAEL rather than a NOAEL or benchmark dose; or
- (5) An incomplete database of toxicity information exists for the chemical.

EPA believes that two uncertainty factors are appropriate for this database to account for (1) physiological differences between humans and rats; and (2) variability within the working population. The rationale for the use of these two uncertainty factors is described below.

EPA RfC guidelines state that an uncertainty factor of 10 may be used for potential differences between study animals and humans. This factor of 10 consists in turn of two uncertainty factors of 3 – the first to account for differences in pharmacodynamics¹³ and the second to account for differences in pharmacokinetics¹⁴ between the study animal and humans. (The value of three is the square root of 10 rounded to one digit, with 10 representing an order of magnitude (EPA, 1994a). In practice, EPA uses the square root of 10 when there are two or four uncertainty factors of 3, yielding a total uncertainty factor of 10 or 100, and we use a value of 3 when multiplying by an uncertainty factor of 10). By EPA RfC guidelines (EPA, 1994a), no

¹³ Pharmacodynamics refers to the biochemical and physiological effects of chemicals in the body and the mechanism of their actions.

¹⁴ Pharmacokinetics refers to the activity or fate of chemicals in the body, including the processes of absorption, distribution, localization in tissues, biotransformation, and excretion.

adjustment for differences in pharmacokinetics is necessary in this instance because the blood/air partition coefficient¹⁵ for nPB in the human (7.1) is less than in the rat (11.7), indicating that the delivered dose of nPB into the bloodstream in rats is slightly higher than in humans. Consistent with Appendix J of EPA's RfC guidelines for an inhaled compound that exerts its effects through the bloodstream, EPA applies an uncertainty factor of 1 for pharmacokinetics.

However, EPA recognizes that the lack of an uncertainty adjustment for pharmacokinetic differences between animals and humans rests on a default approach applied to category 3 gases described in Appendix J of its guidelines for deriving an inhalation RfC. This default approach assumes that nPB's toxicokinetics follow a model in which: (1) the toxicity is directly related to the inhaled parent compound in the arterial blood, and (2) the critical metabolic pathways scale across species, with respect to body weight, in the same way as the ventilation rate. Given the hypothesized metabolic pathways for nPB (ICF, 2002a; CERHR, 2002a), it is plausible that toxicity in rats may be related to a reactive metabolite in the target tissue rather than the blood level of the parent compound. EPA is not aware of any quantitative data on nPB metabolism in humans, or evidence implicating the biologically active agent or mode of action. Some commenters on the June 2003 NPRM stated that EPA should use an uncertainty factor of 1 or 2 to extrapolate from animals to humans (Weiss Cohen, 2003 (38), while others suggested uncertainty factors of 2 or 3 for pharmacokinetics, or an overall uncertainty factor of 10 for rat to human extrapolation because of a lack of information on the metabolism and mode of action of nPB and because the rat is an insensitive model for effects on male reproduction in humans (Werner, 2003; Rusch, 2003a). Commenters provided no data to indicate that (1) the toxicity is

¹⁵ The blood/air partition coefficient is the ratio of a chemical's concentration between blood and air when at equilibrium.

not directly related to the inhaled parent compound in the arterial blood, or (2) the critical metabolic pathways do not scale across species, with respect to body weight, in the same way as the ventilation rate. Recent studies provide additional data regarding metabolism of nPB in rats and mice (RTI, 2005), but data on human metabolism are still lacking.

One analysis of these metabolic data suggested that mice are less sensitive to the effects of nPB than rats and hypothesized that humans would also be less sensitive than rats (Stelljes, 2005). However, this analysis makes numerous assumptions about toxic nPB metabolites and metabolic activation pathways that have not been confirmed by experimental data. A review of this analysis is available in the public docket (ICF, 2006c). Despite the difference in metabolic pathways for nPB in mice and rats (RTI, 2005), EPA finds no significant species-specific differences in toxicity exist between rats and mice at inhaled concentrations <500 ppm for 13 weeks (NTP, 2003; ICF, 2006b). These metabolic and subchronic inhalation studies conducted under the National Toxicology Program did not specifically examine for reproductive toxicity or nPB metabolism in target organs that control reproductive function. In summary, there are little available data about the metabolic activation or reactive metabolites responsible for reproductive toxicity in rodents. Similarly, for nPB, there is little information available about differences and similarities between rodents and humans. Given this circumstance, EPA assumes, in the absence of evidence to the contrary, that nPB toxicity is directly related to the inhaled parent compound in the arterial blood and that the critical metabolic pathways scale across species in a manner similar to the ventilation rate. Therefore, the Agency is proposing to apply an uncertainty factor of 1 to account for interspecies differences in pharmacokinetics.

EPA requests additional data and comment from the public on the pharmacokinetics, metabolism, and mode of action of nPB that will help determine whether an interspecies uncertainty factor greater than the default value of 1 is warranted to account for pharmacokinetics. If data become available indicating that nPB does not conform to the constraints assumed by the default pharmacokinetic model in the RfC guidelines, we would revise our risk assessment for nPB as necessary, and apply an uncertainty factor for pharmacokinetics consistent with the RfC guidelines in extrapolating from animal to humans. Depending on the resulting difference in the acceptable exposure levels, we would also revise our acceptability determinations accordingly. Given the available data on the blood/air partition coefficient and EPA RfC guidance in the absence of other information, EPA is applying the same rationale used for other compounds reviewed under EPA's SNAP program with a comparable amount of data where an uncertainty factor of 1 for pharmacokinetics was applied. To account for uncertainty in pharmacodynamics of nPB, EPA is applying the default uncertainty factor (UF) of 3. This follows the procedures in EPA's RfC guidelines for situations where there are no data to compare pharmacodynamics in rats versus humans (EPA, 1994a). Recently published data on humans and rodents do not decrease the uncertainty regarding the pharmacodynamics of nPB; therefore, modification of the UF of 3 for differences between species is not justified.

One commenter stated that EPA did not cite any data that describes the size, condition, or very existence of a subpopulation of men especially sensitive to the effects of nPB. In addition, this commenter asserted that sensitive populations are not traditionally considered when deriving an occupational exposure limit, and that EPA has never mentioned a concern with sensitive subpopulations in previous SNAP reviews.

EPA disagrees with the comments. There are preexisting reproductive conditions as well as significant variability in fertility among otherwise healthy adults in the workplace. Women over age 35 and men over age 40 have fertility rates up to three times lower than those of people in their twenties, with effects on the ovarian cycle and on sperm motility as major factors changing with increasing age for women and men, respectively (Dunson et al., 2002). Adding damage from other factors, such as smoking or occupation exposure to chemicals such as nPB, therefore, can potentially harm an individual's ability to reproduce further (Dunson, et al. 2002). In addition, we note that EPA has used uncertainty factors in the past to protect sensitive subpopulations on other chemicals reviewed under the SNAP program (e.g., trifluoriodomethane). For deriving AELs from health endpoints such as liver effects and neurotoxicity, the SNAP program typically has assigned an uncertainty factor of 1 for sensitive subpopulations because we assume that individuals who are especially susceptible to these effects will have greater difficulty working than most people. However, there is no connection between the ability to reproduce and the ability to work in the industrial sectors discussed in this rule. Thus, we find it appropriate to apply an uncertainty factor greater than 1 for reproductive effects.

Some commenters on the June 2003 NPRM said that an uncertainty factor of 1 is appropriate for variability within the working population because sensitive subpopulations will not be present in the working population (Stelljes, 2003, Morford, 2003 (47)). Other commenters stated that there will be very little difference in variability between the worker population and the general population and that it is unclear why EPA selected an uncertainty factor of 3 instead of 10 (Werner, 2003). Commenters suggested uncertainty factors for

variability in the working population of 1, 2, and 5 (Stelljes, 2003, Weiss Cohen, 2003, Werner, 2003).

EPA disagrees with the commenters. EPA's RfC guidelines recommend an uncertainty factor of 10 to account for intraspecies variability within the general population. However, in deriving an acceptable exposure limit, EPA's focus is on worker exposure, which excludes some particularly vulnerable populations, such as children, most adolescents, and the elderly. Thus, we believe that a full uncertainty factor of 10, as for the general population, may be higher than necessary to protect workers. However, because of variability in reproductive function due to factors present among workers, such as aging, smoking, and sexually transmitted disease, and because there is no screening of workers that would make workers more likely to have healthy reproductive systems than non-workers of the same age, we believe that an uncertainty factor of 1 is not sufficiently protective. Under EPA guidelines, 3 is a default value for an uncertainty factor where there is indication that a value less than an order of magnitude (10) but greater than one is appropriate, and where the available data are not sufficiently quantified to select a specific value. Therefore, EPA is again proposing to assign an uncertainty factor of 3 to account for difference between individuals in the working population.

The uncertainty factors of 3 for animal-human extrapolation and 3 for variability within the human working population (each representing the square root of ten, half an order of magnitude) yield a composite uncertainty factor of 10. This factor was applied to all HECs derived from reproductive studies summarized in Table 6 in section IV.E.1 above. The resultant values are higher than the value that would have been obtained had EPA used the TLV of 10

ppm developed by the ACGIH. EPA believes that the benchmark dose approach more accurately characterizes the observed effects and provides a more robust utilization of the data.

D. Other analyses of nPB toxicity

Analyses reviewed during preparation of June 2003 NPRM

One commenter on the June 2003 NPRM stated that documents by Drs. Doull, Rozman, Stelljes, Murray, Rodricks, and the KS Crump Group were not acknowledged (Morford, 2003 (2,47)). EPA specifically mentioned and responded to the occupational exposure limit recommendations from Drs. Rozman, Doull, and Stelljes in the preamble to the June 2003 NPRM at 68 FR 33298-33299. In addition, EPA included more detailed written responses to these derivations and the evaluation by Dr. Rodricks in the online docket prior to proposal (EPA-HQ-OAR-2002-0064-0017, -0018, and -0019). We considered these documents in preparation of the June 2003 proposal as well as this proposal. EPA is discussing our response to the other documents in a separate final rule addressing the solvent cleaning sector. In general, we disagree that the neurotoxicity endpoint selected by Drs. Rozman and Doull is the most appropriate endpoint for setting an AEL and we agree with Dr. Stelljes that sperm motility in the F1 offspring generation of the WIL, 2001 2-generation study is an appropriate endpoint. We agree with a number of these documents that data from the F1 generation may be conservative because workplace exposure would not include exposure to the F1 animals during the four-week period from weaning to sexual maturity. However, EPA believes that because of the potential for *in utero* effects that would only be seen in the offspring generation, looking only at the F0 parental generation could underestimate the adverse health impacts of a chemical. Therefore, it was appropriate for us to consider effects seen in both the F0 parental generation and the F1 offspring

generation. Further, effects on sperm motility in the parental and offspring generations are seen at levels generally consistent with multiple reproductive effects seen in both generations and both sexes exposed to nPB, such as estrous cycle length, lack of estrous cycling, the number of estrous cycles in a 3-week period, and the number of live pup births (TERA, 2004; ICF, 2006a; Stelljes, 2001; Stelljes and Wood, 2004). We believe that the document from the K. S. Crump group, a survey of the ratio of points of departure to TLVs set by the ACGIH, is not relevant now that the ACGIH has issued a TLV specifically for nPB. ACGIH appears to set an AEL for nPB that is a factor of 10 lower than the endpoint cited as lowest (100 ppm for effects on pup weight) (ACGIH, 2005). Thus, ACGIH has used an approach for nPB consistent with the total uncertainty factor of 10 assigned by EPA. In general, we find that these documents submitted by the commenter assigned uncertainty factors in a manner inconsistent with EPA guidance. This would result in a higher AEL than we would determine following the approach EPA has used on other chemicals, as well as an AEL that in our view would not sufficiently protect human health from nPB's effects because of multiple sources of uncertainty in available data (e.g., variability within the working population, differences between animals and humans in how nPB affects the reproductive system).

Since the 2003 NPRM, a number of reviews of nPB toxicity have been issued, several of which include recommendations for occupational exposure limits. CERHR, 2003a and 2004a are similar to CERHR, 2002a, the expert panel report for nPB for the Center for the Evaluation of Risks to Human Reproduction (CERHR). CERHR, 2003b and 2004b are similar to CERHR, 2002b, the CERHR expert panel's report for iPB. These documents discuss the usefulness of data in available studies for assessing nPB's health impacts and establish No Observed Adverse

Concentration levels of 100 ppm for both male and female reproductive effects in animals, but do not derive an AEL. Rozman and Doull, 2005 derived an AEL of 25 ppm for nPB based on neurotoxicity, using more recent information than Rozman and Doull, 2002.

The Stelljes and Wood (2004) analysis is similar in its results to SLR International (2001), a study by the same authors. EPA previously reviewed SLR International, 2001 in developing the June 2003 NPRM. Both studies by Stelljes and Wood concluded with a recommended AEL of 156 ppm, based on male reproductive effects and uncertainty factors of 1 in driving the AEL. Stelljes (2005) reviews RTI's 2005 study on metabolism of nPB in mice and rats and other literature and speculates that humans should be less sensitive to nPB than either mice or rats based on differences in metabolite production. Stelljes (2005) recommends that no uncertainty factor is required to extrapolate from animals to humans and that an uncertainty factor of no more than 2 is appropriate to account for differences within the working population. All of these documents assigned uncertainty factors in a manner that is not sufficiently supported by the available data and that is inconsistent with EPA's guidance. For example, Stelljes (2005) discusses metabolic data in rats and mice from RTI, 2005 and concludes that on this basis, the uncertainty factor for extrapolation from animals to humans should be 1. However, the metabolic data relate to pharmacokinetics--the activity of chemicals in the body--and do not address EPA's proposed uncertainty factor of 3 related to pharmacodynamics (the biochemical and physiological effects of chemicals in the body and the mechanism of their actions). Using the AEL from one of these documents would result in a higher, less protective AEL than we would determine following the approach EPA has used for other chemicals under the SNAP program and would not consider multiple sources of uncertainty in health effects (i.e., variability

within the working population and differences between animals and humans in how nPB affects the reproductive system). Thus, we are concerned that the AELs based on these documents would not be sufficiently protective and would result in an inappropriate acceptability decision. Detailed reviews of these documents are available in the public docket.

TERA, 2004 reviews other AEL derivations for nPB, performs a benchmark dose (BMD) analysis, and recommends an AEL of 20 ppm based on live litter size. This analysis is consistent with EPA guidance for BMD modeling and for assigning uncertainty factors. A review of this document is available in the public docket (ICF, 200x).

ICF (2004a, 2006b) derived an AEL for nPB based upon female reproductive effects. ICF (2004a, 2006b) discussed the relevant literature (Ichihara et al, 1999, 2002, 2004a, 2004b; Sekiguchi, 2002; Yamada et al., 2003; WIL, 2001) and calculated mean estrous cycle length and the mean number of estrous cycles occurring during a three-week period at different exposure levels in the WIL, 2001 2-generation study. ICF (2004a, 2006a) found statistically significant reductions in the number of estrous cycles in a three-week period, both including and excluding females that had stopped their estrous cycles, at 250, 500, and 750 ppm in the F0 parental generation and at 500 and 750 ppm in the F1 generation. ICF (2004a, 2006a) conducted BMD modeling and calculated BMDL values of the number of estrous cycles in a three-week period that varied from 102 to 208 ppm, depending upon the model used and the benchmark criteria selected. All data were calculated based on the mean reductions in estrous cycle number calculated from the WIL, 2001 study. Values were calculated for the F0 generation; the number of data for the F1 generation was too small for statistical analysis. The BMDLs that ICF calculated for the number of estrous cycles in a three-week period were 162 ppm and 208 ppm,

depending on the benchmark response criteria (10% change in response vs. one standard deviation) and using a linear-heterogeneous model.

The California Environmental Protection Agency's Office of Environmental Exposure and Hazard Assessment (OEHHA) listed both nPB and iPB as reproductive toxins on the basis of developmental, male reproductive, and female reproductive toxicity under the State's Safe Drinking Water and Toxic Enforcement Act of 1986, also known as Proposition 65 (OEHHA, 2006). Under this law, California is required to list chemicals known to be carcinogenic or to be reproductive toxins and to update that list at least annually.

The American Conference of Government Industrial Hygienists (ACGIH) issued a recommended Threshold Limit Value™ (TLV) of 10 ppm (time-weighted average) for nPB (ACGIH, 2005). ACGIH summarized numerous studies showing different effects of nPB and identified no observed effect levels (NOELs) of 200 ppm for hepatotoxicity (ClinTrials, 1997b) and less than 100 ppm for developmental toxicity, as evidenced by decreased fetal weight (Huntingdon Life Sciences, 2001).

OSHA has not developed a permissible exposure limit (PEL) for nPB that EPA could use to evaluate toxicity risks¹⁶ from workplace exposure. In prior SNAP reviews, EPA has used ACGIH TLVs where available in assessing a chemical's risks and determining its acceptability if OSHA has not set a PEL. ACGIH is recognized as an independent, scientifically knowledgeable organization with expertise in issues of toxicity and industrial hygiene. However, in this case, EPA believes that ACGIH's TLV for nPB of 10 ppm has significant limitations as a reliable

¹⁶ Vendors of nPB-based products have recommended a wide range of exposure limits, from 5 ppm to 100 ppm (Albemarle, 2003; Chemtura, 2006; Docket A-2001-07, item II-D-19; Enviro Tech International, 2006; Farr, 2003; Great Lakes Chemical Company, 2001).

basis for an acceptable exposure limit, especially given the availability of other, more comprehensive analyses described in this proposal. First, according to the authors of the Huntingdon Life Sciences study, the decrease in fetal weight was an artifact of sampling procedure that biased the data (test animals were only sacrificed at the end of the day rather than at random). The CERHR expert panel excluded “aberrantly low” fetal weights from one litter in this study and calculated a BMDL greater than 300 ppm for this endpoint after removing those outlier data (CERHR, 2002a, 2003a, and 2004a). TERA calculated a similar BMDL when analyzing the same data set (TERA, 2004). Further, the reference list in the documentation on the TLV indicates that ACGIH did not review and evaluate all the studies available prior to the development of the recommended exposure limit. For example, key supporting articles that reported disruption of estrous cycles (Yamada et al., 2003 and Sekiguchi et al., 2002) were not discussed in the TLV documentation. Further, ACGIH did not provide sufficient reasoning for the selection of the chosen endpoint over others (e.g., reproductive toxicity and/or neurotoxicity). The lack of discussion of applied uncertainty factors also prevents a determination of how ACGIH arrived at a TLV of 10 ppm. In summary, EPA is not basing its proposed acceptability determination for nPB on the ACGIH TLV because: (1) other scientists evaluating the database for nPB did not find the reduced pup weight to be the most sensitive endpoint; (2) benchmark dose (BMD) analysis of the reduced pup weight data (CERHR, 2002a; TERA, 2004) results in a higher BMDL (roughly 300 ppm) than those for reproductive effects; and (3) ACGIH may not have reviewed the complete body of literature as several studies discussing neurotoxicity and female reproductive effects were omitted from the list of references. A number of reviews of this document are available in the public docket (ICF, 2004x; Albemarle, 2004).

We note that, even if EPA had selected the ACGIH TLV as our basis for assessing the risks of nPB, we would have proposed the same acceptability determinations. In the specific coatings application that we propose to find acceptable subject to use conditions at the Lake City Army Ammunition Plant, exposure data showed an ability to meet an exposure level of 10 ppm, with the vast majority of measurements below that value. Thirty-four of 35 samples had concentrations below 10 ppm, and the mean concentration for the plant was less than 4 ppm (Lake City Army Ammunition Plant, 2004). For the aerosol and adhesive end uses, it would be even more difficult to achieve an exposure level of 10 ppm than to achieve levels in the range of 18 to 30 ppm to protect against male reproductive effects [e.g., reduced sperm motility], in the range of 17 to 22 ppm to protect against female reproductive effects [e.g., number and length of estrous cycles], and at approximately 20 ppm for effects related to reproductive success [live litter size]). Thus, we would have proposed the same decisions for nPB of acceptable, subject to use conditions for coatings and unacceptable for aerosols and adhesives using the ACGIH's TLV of 10 ppm to assess health risks. Despite some flaws in its derivation, the TLV of 10 ppm is less than two-fold lower than the low end of the range of acceptable exposure levels based on the most sensitive reproductive endpoints. This small difference is well within the uncertainty required to extrapolate a benchmark dose from an experimental study in rats to an occupational exposure limit in humans.

E. Community exposure guideline

In this proposal, EPA is using a community exposure guideline (CEG) of 1 ppm to evaluate potential health risks among populations living near facilities using nPB. This community exposure guideline is an estimate of a continuous inhalation exposure (averaged over

24 hours per day, 7 days per week) to the general public (including sensitive subgroups) that is likely to be without an appreciable risk of adverse health effects during a lifetime.

Based on EPA risk assessment guidelines (EPA, 1994a), the CEG was derived using the lowest BMDL from effects listed in Table 6 as the point of departure (110 ppm for vacuolation in the liver of animals in the F1 generation of WIL, 2001). The HEC was calculated as follows:

$$110 \text{ ppm} \times (6 \text{ hours exposure in study} / 24 \text{ hours avg time}) \times (7 \text{ days} / 7 \text{ days}) = 28 \text{ ppm}$$

EPA used an uncertainty factor of 3 for extrapolation from animals to humans, as discussed above in section VI.A, and an uncertainty factor of 10 for variability within the general population, consistent with EPA's RfC guidelines. Dividing the HEC of 28 ppm by 30 yields a community exposure guideline of approximately 1 ppm. If we had used sperm motility (HEC of 42 ppm based on a BMDL of 169 ppm) or number of estrous cycles (HEC of 40 ppm based on a BMDL of 162 ppm) as starting points, we would calculate the same approximate CEG value. We note that, following RfC guidelines, EPA's community exposure guideline includes a number of conservative assumptions, including exposure adjustments to protect an individual exposed for up to 24 hours a day for 70 years (US EPA, 1994a, p. 1-5).

EPA evaluated general population exposure using EPA's SCREEN3 (US EPA, 1995a) air dispersion model to assess the likely maximum concentration of nPB from single sources¹⁷.

EPA used data collected from actual facilities (Swanson, 2002) to characterize two scenarios:

¹⁷ We performed the modeling for a facility using nPB-based adhesives because the nPB emissions from this type of facility were expected to be higher than those from facilities using nPB for other end uses. Thus, if a facility using adhesives would not result in emissions exceeding the CEG, facilities using nPB in aerosols or in metals, electronics, or precision cleaning also would not result in emissions exceeding the CEG.

(1) a typical large, high-use adhesive application facility where the closest resident is 100 meters away; and (2) a smaller facility with average-use adhesive application in an urban area, where the nearest resident is only 3 meters away. The results indicated that modeled exposures in either scenario did not exceed the CEG of 1 ppm. The highest exposure modeled was 0.24 ppm at a distance of 3 meters away from the source in the urban scenario, while most other exposures were at least an order of magnitude lower (ICF, 2003; ICF, 2006a). Because the community exposure guideline was not exceeded for any of the exposure scenarios in this conservative screening approach, EPA has concluded that nPB exposure to populations living close to facilities using nPB is not a concern for purposes of determining the acceptability of nPB under the SNAP program.

VI. What listing is EPA proposing for each end use, and why?

In this rule, EPA is proposing to find nPB unacceptable in adhesive and aerosol solvent end uses, and acceptable subject to use conditions in the coatings end use. The proposed listings, summarized in Table 9, are intended to allow the use of nPB where it does not pose a human health risk significantly greater than other substitutes (i.e., where users can reliably maintain exposures below the range of acceptable exposure levels, 17 to 30 ppm) and prohibit nPB’s use where nPB exposure cannot be maintained, or is unlikely to be maintained, at these levels. We also are taking comment on an alternate approach of finding nPB acceptable subject to use conditions in all of the above end uses (see Section VII.A).

Table 9. Proposed Decisions by End Use and Sector

For nPB in this sector and end use:	Our proposal is to list nPB as:	And our proposed alternate approach is:
<i>Aerosols</i>		

Aerosol solvents	Unacceptable	Acceptable, subject to use conditions ²
<i>Adhesives, Coatings, and Inks</i>		
Coatings	Acceptable, subject to use conditions ¹	Acceptable, subject to use conditions ²
Adhesives	Unacceptable	Acceptable, subject to use conditions ²

¹ Use of nPB in this end use is limited to coatings at facilities that have provided EPA information demonstrating their ability to maintain exposure levels at or below the range the Agency finds acceptable, as of [INSERT DATE OF PUBLICATION] (i.e., the Lake City Army Ammunition Plant).

² Use conditions would include proposed requirements that users must (1) meet an exposure limit of 20 ppm on an eight-hour time-weighted average, (2) monitor workers' exposure to nPB using a personal breathing zone sampler on an eight-hour time-weighted average initially and periodically (every 6 months or longer, depending on the concentration during initial monitoring), and (3) keep records of the worker exposure data on site at the facility for at least three years from the date of the measurement.

Aerosol Solvents

In this rule, EPA proposes to find nPB unacceptable in the aerosol solvent end use. There are a number of aerosol solvent alternatives that do not pose any risk for ozone depletion or for ground level smog formation¹⁸. EPA's greatest concern with nPB-based aerosols is that users of nPB as an aerosol solvent cannot reliably maintain exposures at or below the range that EPA considers acceptable (i.e., 17 to 30 ppm), unlike other available alternatives. This finding is based on measured exposure data and model estimations indicating the likelihood of elevated concentrations associated with nPB-based aerosols given typical ventilation conditions.

Ventilation conditions are an important consideration in evaluating potential risks within this end-use category. "Benchtop cleaning" of individual parts, which is feasible under exhaust hoods or in spray booths with adequate ventilation, comprises 25% or less of the market involving ODS substitutes (ICF, 2004). According to industry information and several

¹⁸ Smog, also known as ground-level ozone, is produced from emissions of volatile organic compounds that react under certain conditions of temperature and light.

commenters, the majority of the market for nPB-based aerosols involves in-place applications requiring a portable aerosol, such as cleaning energized electrical contacts and switches, maintenance in underground mines, or cleaning active elevator motors (CSMA, 1999; ICF, 2004; Williams, 2005). These applications often occur in tightly confined spaces where it is not feasible to install ventilation equipment or remove parts to ventilated areas (CSMA, 1999; Linnell; 2003; Werner, 2003). Other acceptable substitutes, such as blends of HFEs or HFCs and trans-dichloroethylene, are available in these end uses. One commenter also pointed out that a user of an nPB-based aerosol will assume that they are being provided with a product that offers similar margins of safety as the product being replaced (i.e., HCFC-141b) and therefore can be used under the same conditions (Werner, 2003).

The likelihood that nPB aerosol solvents would be used in poorly ventilated spaces is of particular concern given the likelihood of elevated exposure levels. Limited data from aerosol solvent use for cleaning electronics and automotive brakes with seven samples ranging from 5.5 to 32 ppm had three of seven 8-hour TWA values taken from the breathing zone that equaled or exceeded 17 ppm, and two were above 30 ppm (Anonymous, 1998; Linnell, 2003). The distribution of exposure levels corresponded to the range of ventilation rates reported in these facilities--0, 300, 472, 640, and 1900 cfm—with the highest ventilation rates resulting in the lowest exposure levels and the lower ventilation levels resulting in the three values at or above 17 ppm. Short-term exposures taken from workers' collars in a room with regional ventilation at 640 cfm, when averaged over an 8-hour period, resulted in exposure levels of 6, 12, and 34 ppm. In modeling nPB exposure from aerosol solvent use at a low ventilation rate of 450 cfm that might be expected during benchtop cleaning, 8-hour average concentrations of 16.5 to 33 ppm

are predicted (ICF, 2006a). Exposure levels for confined spaces with even lower ventilation rates, as we would expect for in-place cleaning, would be even higher. These data sets have a small sample size and do not provide EPA with convincing data that nPB can be used safely, at exposure levels at or below the range we consider acceptable (i.e., 17 to 30 ppm to protect against reproductive effects).

EPA is concerned that many, and perhaps most, uses of nPB aerosol solvents result in a high probability of exposures at or above the range that the Agency would consider acceptable. EPA is aware of no data on ventilation levels demonstrating that most users of aerosol solvents, or of nPB in particular, would use aerosols in locations with sufficiently high ventilation levels to protect human health (e.g., 640 cfm or greater). We request data on exposure levels, typical ventilation rates, and patterns for usage of nPB-based aerosols, considering both benchtop and in-place use.

EPA has found numerous other aerosol solvents acceptable. These aerosol solvents can be used safely in a manner consistent with their respective acceptable exposure limits. This is highlighted in a study comparing concentrations of eight different chemicals that are acceptable under the SNAP program in aerosol formulations: HFE-7100, HFE-7200, trans-1,2-dichloroethylene, HCFC-225ca and -225cb, acetone, pentane, and HFC-134a. In this study, with ventilation of only 48 cfm, 8-hr TWA exposure from the different chemicals varied from 35.5 ppm to 194.0 ppm, and all chemicals met their respective recommended exposure levels (ICF, 2006a). Given the properties of aerosols, it is reasonable to expect that nPB concentrations would be within a comparable range (i.e., 35 to 194 ppm), which is clearly above levels the Agency would consider acceptable. Based on these considerations, the Agency believes that

nPB used as an aerosol solvent would impose significantly more risk to human health than other alternatives available for this end use.

B. Adhesives

EPA proposes to find nPB unacceptable in the adhesive end use. As for aerosol solvents, we found that some alternative adhesive formulations could reduce particular environmental risks more than nPB, such as generation of ground level “smog” or ozone depletion potential. However, we find the greatest concern in this end use is with nPB’s human health effects. We propose to find nPB unacceptable in adhesives because it increases overall impacts on human health and the environment significantly more than other available alternatives in this end use.

In the June 2003 NPRM, we initially proposed to find nPB acceptable in adhesives based on the SNAP program principle that “EPA does not intend to restrict a substitute if it poses only marginally greater risk than another substitute....The Agency also does not want to intercede in the market’s choice of available substitutes, unless a substitute has been proposed or is being used that is clearly more harmful to human health and the environment than other alternatives.” (68 FR 33294, citing the original March 18, 1994 SNAP rule at 59 FR 13046). At the time of the proposal, we considered data from NIOSH monitoring and health hazard evaluations for three facilities using nPB-based adhesives. At two of the three facilities, NIOSH worked together with the companies to install state-of-the-art ventilation equipment. Looking at exposure data from all workers after ventilation improvements, we believed it would be possible for facilities to achieve an AEL of 25 ppm (68 FR 33294).

One public commenter suggested that EPA should reconsider whether industrial exposures consistently occur and /or can be controlled at 25 ppm (Werner, 2003). We reevaluated the exposure data for the two plants that had improved their ventilation, focusing on exposure to the workers that receive the highest exposures because they directly spray the nPB-based adhesive. We found that, even in the best case, a substantial number of workers spraying nPB-based adhesives would be exposed above the range of acceptable exposures (i.e., the range from 18 to 30 ppm to protect against male reproductive effects [e.g., sperm motility], in the range of 17 to 22 ppm to protect against female reproductive effects [e.g., estrous cycle numbers and length], and at approximately 20 ppm for effects related to reproductive success [live litter size]).

- NIOSH investigators initially reported that mean exposures to nPB ranged from 60 to 381 ppm (8-hour time weighted averages) at three different foam-fabrication facilities using nPB-based adhesives (NIOSH, 2000a, 2000b, 2001, 2002a, 2002b, 2003a). In one facility, average (mean) nPB exposures were reduced from 169 ppm to 19 ppm, following installation of ventilation equipment (NIOSH, 2000b). Although use of spray booths at this facility reduced the average exposure level to 19.4 ppm for all workers, the majority of the sprayers directly using nPB-based adhesives still would be exposed at unacceptably high levels. Out of fourteen sprayers at the Custom Products facility:
 - Six, or 43% of sprayers, would be exposed to more than 30 ppm.
 - Nine, or 64% of sprayers, would be exposed to more than 25 ppm.
 - Ten, or 71% of sprayers, would be exposed to more than 20 ppm.
 - Eleven, or 79% of sprayers, would be exposed to more than 15 ppm.
 - Thirteen, or 93% of sprayers, would be exposed to more than 10 ppm.

At another facility using nPB-based adhesives, the average exposure was reduced from 58 ppm to 19 ppm after the company installed ventilation recommended by NIOSH (NIOSH, 2001). Data on exposure for sprayers found fewer individuals receiving high exposures than at the facility monitored in NIOSH (2000b), but 65% (22 of 34) of exposure samples for sprayers were higher than 15 ppm, 33% (11 of 34) were higher than 20 ppm and 15% (5 of 34) were higher than 25 ppm after improving ventilation.

Overall, 42% of sprayers in these two facilities using nPB-based adhesives were exposed to concentrations of nPB greater than 20 ppm (21 of 48 workers) and 23% (14 of 48 workers) were exposed to more than 25 ppm, even after installing state-of-the-art ventilation with assistance from NIOSH. Sprayers had significantly higher individual exposures than workers who did not work directly with the nPB-based adhesive.

In response to public comment and additional information available to EPA since the June 2003 NPRM, we now conclude that use of nPB-based adhesives results poses significantly higher risks to human health than other available adhesives. Since the June 2003 NPRM, there have been a number of reports of workers working with nPB-based adhesives that have suffered adverse, persistent neurological effects that resulted in hospitalization (Beck and Caravati, 2003, and Majersik et al., 2004, 2005; Calhoun County, 2005; Miller, 2005; Raymond and Ford, 2005). Based on data from actual facilities using adhesives, it is estimated that a facility using nPB with average adhesive application rates and average ventilation rates would have exposure levels of approximately 60 ppm (ICF, 2006a). Modeling of exposures at high adhesive application rates and average or lower ventilation rates resulted in exposures of approximately 250 to 2530 ppm (ICF, 2006). We believe these modeling results show that most adhesive users would exceed

acceptable exposure levels by significant margins and that it is unlikely that adhesive users would be able to use nPB safely.

Considering the exposure data for nPB-based adhesives, we believe it is unlikely that, even with ventilation, adhesive users could reduce exposures to acceptable levels on a consistent basis. Given the information above, we are concerned that nPB-based adhesives cannot be reliably used in a manner that protects human health. We request comment and further data on whether it is feasible to use nPB-based adhesives with worker exposure levels consistently at or below the range of exposure levels that EPA proposes to find acceptable (i.e., the range from 18 to 30 ppm to protect against male reproductive effects [e.g., sperm motility], in the range of 17 to 22 ppm to protect against female reproductive effects [e.g., estrous cycle numbers and length], and at approximately 20 ppm for effects related to reproductive success [live litter size]).

The available information indicates that all acceptable carrier solvents in adhesives other than nPB have projected or actual exposure less than the appropriate workplace exposure limit set by OSHA, the ACGIH, the American Industrial Hygiene Association, or recommended by EPA. Examples of other carrier solvents currently used in adhesives and acceptable under the SNAP Program include hydrocarbon solvents, acetone, methylene chloride, and water. EPA finds that there are other available alternatives that pose significantly less risk to human health and the environment compared to nPB in the adhesives end use.

During the public comment period on the June 2003 NPRM, one commenter representing the adhesives industry stated that there are some small but critical applications that require nonflammability and high solvency (Collatz, 2003). The commenter did not specify what those applications are, and whether there was information showing that other types of adhesives, such

as those using water, flammable solvents, or methylene chloride, are technically infeasible in these applications. We request comment and data on whether there are any unique applications of nPB in the adhesives end use for which there are no other technically feasible alternatives, and thus, for which nPB should be allowed. If so, we would consider finding nPB acceptable subject to narrowed use limits, with requirements for each end user to perform a demonstration that there are no other technically feasible alternatives for their particular site, to install local exhaust ventilation equipment designed to reduce exposure levels to acceptable exposure levels (i.e., at or below the range from 17 to 30 ppm to protect against reproductive effects) and to perform worker exposure monitoring. Alternatively, if there was sufficient information provided during the public comment period showing that there are applications in which only nPB can be used, we would consider finding nPB acceptable in adhesives, subject to use conditions requiring installation of local exhaust ventilation and worker exposure monitoring, and subject to a narrowed use limit for those specific applications where other alternatives are not technically feasible, without requiring a site-specific demonstration that nPB is the only feasible alternative. This would allow for safer use of nPB in any applications where nPB is the only alternative, if any such applications exist.

C. Coatings

We are proposing to find nPB acceptable, subject to use conditions, for facilities that have provided EPA information demonstrating their ability to meet levels at or below the range that EPA would consider acceptable (i.e., 17 to 30 ppm to protect against reproductive effects), as of [INSERT DATE OF PUBLICATION]. The SNAP submission with information on coatings was made for a single facility and EPA is unaware of anyone else interested in using

nPB in this end use. Therefore, there are currently no analyses indicating whether nPB would pose significantly greater risks in any coating applications other than this facility. Workplace exposure levels to nPB from ammunition sealant at Lake City Army Ammunition Plant ranged from less than 1 ppm up to 21 ppm on an eight-hour time-weighted average. Thirty-four of 35 samples had concentrations below 10 ppm, and the mean concentration for the plant was less than 4 ppm (Lake City Army Ammunition Plant, 2004). The vast majority of measurements show worker exposure well below the range of exposures that EPA considers acceptable. Thus, we believe that nPB can be used as safely as other acceptable solvents used at their acceptable exposure limits under the conditions at this facility.

Other acceptable substitutes for ozone-depleting substances in coatings, in general, include oxygenated solvents, hydrocarbon solvents, terpenes, hydrofluoroethers 7100 and 7200, benzotrifluorides (include parachlorobenzotrifluoride), monochlorotoluenes, trans-1,2-dichloroethylene, chlorinated solvents, water-based formulations, and high-solids formulations. In the particular application for ammunition coatings, the submitter evaluated a large number of alternatives and found that n-propyl bromide was the only one of 29 solvents tested that could meet performance specifications at this facility (Harper, 2005). Thus, it is not clear that there are other substitutes available for this specific application, and exposure data show that in this specific application, nPB can be used in a way that does not pose significantly greater risks to human health compared to other acceptable substitutes in the coatings end use.

VII. What other regulatory options did EPA consider?

EPA considered several different options, but we prefer the approach proposed in this rule. We also take comment on the options discussed below.

A. Alternate option for comment: acceptable with use conditions requiring exposure limit and monitoring

We also take comment on a proposed alternate approach in which nPB would be acceptable subject to use conditions in all the end uses addressed in this action. Under this alternate approach, users would meet an exposure limit, monitor exposure of workers using nPB, and keep records to demonstrate compliance with these requirements. For purposes of this alternative proposal, we selected 20 ppm to use as an exposure level above which use would be unacceptable, and 10 ppm as an action level that allows reduced exposure monitoring. The following requirements would apply at each facility where nPB is used:

Exposure Limit

The owner or operator would be required to ensure that workers using nPB achieve 20 ppm on an 8-hour time-weighted average. The exposure limit could be met through engineering controls (e.g., ventilation equipment), work practices, or reduced use of nPB.

Initial Worker Exposure Monitoring

For each facility where nPB is used, the owner or operator of the facility would be required to ensure that personal breathing zone air samples of each nPB user's exposure would be collected on an eight-hour, time-weighted average initially within 90 days after a final rule becomes effective. Monitoring measurements may be taken with an organic chemical monitoring badge on the collar or a tube filled with charcoal on the collar.

Periodic Exposure Monitoring

- 1) The owner or operator of the facility would be required to ensure that personal breathing zone air samples of user exposure are collected periodically on an eight-hour, time-

weighted average depending on the results of the most recent set of exposure data. A monitoring program could be instituted by the company or by the nPB supplier for that facility. Periodic sampling requirements would be based on the most recent monitoring results, as follows:

Table 10. Alternative Approach Exposure Levels and Periodic Exposure Monitoring

<i>If exposure measurements for nPB are at this level:</i>	<i>Then the owner or operator:</i>
all measurements at or below 10 ppm	is not required to perform periodic exposure monitoring.
all measurements at or below 20 ppm, with some measurements above 10 ppm	must take personal breathing zone samples again at least once in the next six months.
at least one measurement above 20 ppm	must stop using nPB in the application exceeding the exposure limit until exposure data show that 20 ppm can be met.
unknown, in cases of new workplace conditions increasing exposure or new applications of nPB	must take personal breathing zone samples as a test before using nPB in new industrial applications or conditions, or within 7 days of an emergency caused by a leak, rupture or breakdown, and use this value to determine the next time monitoring is required.

- 2) For periodic monitoring, the owner or operator would be allowed either to monitor each nPB user's exposure, or to monitor exposure of a representative nPB user in each job classification in a work area during every work shift, where the monitored nPB user is expected to have the highest exposure.
- 3) The owner or operator would be allowed to discontinue the periodic 8-hour TWA monitoring for nPB users at the facility where at least two consecutive sets of measurements taken at least seven days apart are below 10 ppm.

Monitoring for new conditions or applications

Whenever there is a change in workplace conditions that may increase exposure or whenever a new application of nPB is introduced, the owner or operator would be required to take personal breathing zone samples accounting for all nPB users as a test before using nPB in manufacturing or repair. These could be either samples for each nPB user or samples representing each job classification in a work area during a work shift, so long as the samples are based on the user with the likely highest exposure. Examples of changes in workplace conditions that may increase exposure include changes in production, process control equipment, or work practices, or a leak, rupture, or other breakdown¹⁹. Examples of introduction of a new application of nPB include aerosol contact cleaning in a location with regional ventilation or natural ventilation, where previous measurements were carried out on workers in a location with local ventilation. If the change occurs because of an unpredictable emergency, then the owner or operator would need to ensure exposure monitoring takes place within 7 days of the change.

Sampling methods and accuracy

Exposure samples would be required to be analyzed either by NIOSH method 1003 for halogenated hydrocarbons or method 1025 for 1-bromopropane and 2-bromopropane or by another method that is accurate to $\pm 25\%$ at the 95 percent confidence level.

Recordkeeping requirements

The owner or operator of the facility would be required to keep records of the monitored exposure data at the facility for at least three years from the date the measurements were taken for purposes of this rule. These records would be required to be made available in the

¹⁹ See 29 CFR 1910.1052(d)(4)(i).

event of a facility inspection or a request for the data by EPA. Note that the employer would still need to meet OSHA's standard on access to employee exposure and medical records, which requires retaining any exposure records for at least 30 years (29 CFR 1910.1020(d)(ii)).

The regulatory listings by end-use under this alternate approach that the Agency requests comment on would be as follows:

Table 11. *Alternate Approach: AEROSOLS*
SUBSTITUTES THAT ARE ACCEPTABLE SUBJECT TO USE CONDITIONS

End Use	Substitute	Decision	Use Conditions	Further Information
Aerosol solvents	n-propyl bromide (nPB) as a substitute for CFC-113, HCFC-141b, and methyl chloroform	Acceptable subject to use conditions	<ol style="list-style-type: none"> 1) The owner or operator of a facility must ensure that users of nPB achieve an exposure limit of 20 ppm on an 8-hour time-weighted average. 2) The owner or operator of a facility must ensure that workers using nPB are monitored for their exposure to nPB using personal breathing zone samples on an eight-hour, time-weighted average (8-hr TWA) no later than 90 days after the effective date of this rule. 3) If the most recent data from exposure monitoring shows all personal breathing exposures to be at or below 10 ppm, no periodic exposure monitoring is required. If the most recent data from exposure monitoring shows all exposures to be at or below 20 ppm, but some above 10 ppm, the owner or operator must take personal breathing zone samples for nPB users at least once during the next six months. 4) The owner or operator may discontinue the periodic 8-hour TWA monitoring for nPB users at the facility where at least two consecutive sets of measurements taken at least seven days apart are below 10 ppm. 5) The owner or operator must determine the exposure of each nPB user by either taking personal breathing zone air samples of each user's exposure or samples that are representative of each user's exposure. The samples are representative where the owner or operator has taken one or more personal breathing zone air samples for at least one nPB user in each job classification in a work area during every work shift, and the nPB user sampled is expected to have the highest exposure to nPB. 6) The owner or operator also must perform exposure monitoring when a change in workplace conditions indicates that employee exposure may have increased or whenever new applications of nPB are introduced. Perform exposure monitoring before making planned changes, and perform monitoring no later than 7 days after an emergency change in conditions. 7) All personal breathing zone samples must be analyzed either by NIOSH method 1003 or 1025 or by another method that is accurate to $\pm 25\%$ at a 95 percent confidence level. 8) The owner or operator must keep records of nPB worker exposure data at the facility for at least three years from the date the measurements were taken. 	<p>EPA recommends the use of personal protective equipment, including chemical goggles, flexible laminate protective gloves and chemical-resistant clothing.</p> <p>Note that the Occupational Safety and Health Administration (OSHA) may establish a final Permissible Exposure Limit (PEL) standard in the workplace at 29 CFR part 1910 under 42 U.S.C. 7610(a).</p> <p>OSHA's standard on access to employee exposure and medical records requires retaining exposure records for at least 30 years (29 CFR 1910.1020(d)(ii)).</p>

Note: In accordance with the limitations provided in Section 310(a) of the Clean Air Act (42 U.S.C. 7610(a)), nothing in this table shall affect the Occupational Safety and Health Administrations' authority to promulgate and enforce standards and other requirements under the Occupational Safety and Health Act of 1970 (29 U.S.C. 651 et seq.)

Table 12. *Alternate Approach: ADHESIVES, COATINGS, AND INKS
SUBSTITUTES THAT ARE
ACCEPTABLE SUBJECT TO USE CONDITIONS*

End Use	Substitute	Decision	Use Conditions	Further Information
Adhesives and coatings	n-propyl bromide (nPB) as a substitute for CFC-113, HCFC-141b, and methyl chloroform	Acceptable subject to use conditions	<ol style="list-style-type: none"> 1) The owner or operator of a facility must ensure that users of nPB achieve an exposure limit of 20 ppm on an 8-hour time-weighted average. 2) The owner or operator of a facility must ensure that workers using nPB are monitored for their exposure to nPB using personal breathing zone samples on an eight-hour, time-weighted average (8-hr TWA) no later than 90 days after the effective date of this rule. 3) If the most recent data from exposure monitoring shows all personal breathing exposures to be at or below 10 ppm, no periodic exposure monitoring is required. If the most recent data from exposure monitoring shows all exposures to be at or below 20 ppm, but some above 10 ppm, the owner or operator must take personal breathing zone samples for nPB users at least once during the next six months. 4) The owner or operator may discontinue the periodic 8-hour TWA monitoring for nPB users at the facility where at least two consecutive sets of measurements taken at least seven days apart are below 10 ppm. 5) The owner or operator must determine the exposure of each nPB user by either taking personal breathing zone air samples of each user's exposure or samples that are representative of each user's exposure. The samples are representative where the owner or operator has taken one or more personal breathing zone air samples for at least one nPB user in each job classification in a work area during every work shift, and the nPB user sampled is expected to have the highest exposure to nPB. 6) The owner or operator also must perform exposure monitoring when a change in workplace conditions indicates that employee exposure may have increased or whenever new applications of nPB are introduced. Perform exposure monitoring before making planned changes, and perform monitoring no later than 7 days after an emergency change in conditions. 7) All personal breathing zone samples must be analyzed either by NIOSH method 1003 or 1025 or by another method that is accurate to $\pm 25\%$ at a 95 percent confidence level. 8) The owner or operator must keep records of nPB worker exposure data at the facility for at least three years from the date the measurements were taken. 	<p>EPA recommends the use of personal protective equipment, including chemical goggles, flexible laminate protective gloves and chemical-resistant clothing. nPB, also known as 1-bromopropane, is Number 106-94-5 in the CAS Registry.</p> <p>Note that the Occupational Safety and Health Administration (OSHA) may establish a final Permissible Exposure Limit (PEL) standard in the workplace at 29 CFR part 1910 under 42 U.S.C. 7610(a).</p> <p>OSHA's standard on access to employee exposure and medical records requires retaining exposure records for at least 30 years (29 CFR 1910.1020(d)(ii)).</p>

Note: In accordance with the limitations provided in Section 310(a) of the Clean Air Act (42 U.S.C. 7610(a)), nothing in this table shall affect the Occupational Safety and Health Administrations' authority to promulgate and enforce standards and other requirements under the Occupational Safety and Health Act of 1970 (29 U.S.C. 651 et seq.)

1. Use Conditions and Their Rationale

The major provisions of the use conditions and the related issues that EPA considered in developing the alternate approach that we are taking comment on are as follows:

Exposure limit. A requirement to meet a workplace exposure limit would be an interim measure to ensure that nPB will be used safely until OSHA issues a final permissible exposure limit (PEL) under the Occupational Safety and Health Act. In the event that OSHA issues a final PEL, it would supersede EPA's exposure limit. EPA is specifically deferring to OSHA, and has no intention to assume responsibility to displace OSHA's authority under Public Law 91-596. EPA's exposure limit would not pre-empt the authority of OSHA to take regulatory or enforcement action with respect to exposure to this substance. This is made clear by the Clean Air Act under which EPA would promulgate this regulation (Subchapter VI – Stratospheric Ozone Protection), which provides at 42 U.S.C. 7610 in pertinent part: "...this chapter [Chapter 85 – Air Pollution Prevention] shall not be construed as superseding or limiting the authorities, under any other provision of law, of the Administrator or any other Federal officer, department, or agency." By issuing an exposure limit for nPB, EPA's intention would be to fill existing regulatory gaps during the interim period of substitution away from ozone-depleting compounds and provide the needed margin of protection for human health and the environment until OSHA develops other regulatory controls or standards under appropriate authorities.

As discussed above in section IV.E.1, EPA considers 17 to 30 ppm to be an appropriate range to protect against nPB's adverse health effects. For purposes of having a clear compliance target under this alternative approach for public comment, we are proposing 20 ppm as the exposure level above which use would be unacceptable. We chose this value because we expect

it to be protective against the reproductive and developmental effects identified previously (live litter size, sperm motility, estrous cycles).

Worker exposure monitoring. The worker exposure monitoring requirements under the use conditions in the alternate approach were modeled after OSHA's requirements for monitoring for methylene chloride. 29 CFR 1910.1052(d). We expect that the regulated community would be familiar with this approach and there might be fewer changes for regulated businesses if OSHA later were to establish a workplace standard for nPB. Because the exposure limit would be an 8-hr TWA value that is derived from studies that measured exposure via inhalation, the proposed use conditions require the owner or operator to monitor 8-hr TWA values that measure workers' exposure in the breathing zone (e.g., samples from a worker's collar). We are not proposing to monitor short-term exposures because acute, short-term exposures of nPB are not of significant health concern, so long as long-term exposures are below the 8-hour TWA limit or acceptable exposure levels (ERG, 2004).

Option for monitoring representative set of workers. Personal breath zone samples could be taken either from each worker using nPB or from a representative²⁰ set of exposed workers expected to have the highest exposure. Allowing exposure monitoring from representative workers using nPB, rather than requiring separate monitoring for each individual using nPB, would reduce overall compliance burden, while still detecting any exposure levels in excess of the exposure limit and avoiding underestimates of exposure.

²⁰ In its methylene chloride standard, OSHA defined representative sampling as follows: "The employer has taken one or more personal breathing zone air samples for at least one employee in each job classification in a work area during every work shift, and the employee sampled is expected to have the highest...exposure." (29 CFR 1910.1052(d)(1)(ii)(A)).

Initial monitoring. Users already using nPB would need to undergo exposure monitoring no later than 90 days after the date the final rule becomes effective. A user that has never used nPB before would need to perform initial monitoring before beginning to use nPB in the facility's industrial applications.

Periodic monitoring. Monitoring would have to be performed periodically on a schedule based on the results of the most recent set of exposure monitoring data. Monitoring from workers' personal breathing zone would be required during the next six months if an initial measurement finds exposure levels between the action level²¹ and the 8-hour TWA exposure limit. No periodic monitoring would be required if initial measurements are below the action level. We would use a value of 10 ppm, half the exposure limit of 20 ppm, as the action level. OSHA standards also set an action level of half the PEL.

Under the alternate approach, monitoring would no longer be required where the most recent exposure monitoring data found all worker exposures at or below 10 ppm. OSHA rules also reduce monitoring requirements for exposures below the action level because if measured values are that low, it is unlikely that any measurement will exceed the PEL unless a major change to the process occurs.

Monitoring for changes in workplace conditions or nPB use. New monitoring would be required if an event occurs that would make the most recent set of monitoring data no longer representative. EPA would expect that the owner or operator would plan new applications of nPB or changes to control equipment or work practices and would perform a test for worker exposure levels before using nPB on a regular basis in that application. In the case of an

²¹ The action level is the exposure level that is half the 8-hour TWA exposure limit. In this case, the action level would be 10 ppm.

emergency, such as a breakdown of ventilation equipment or a leak, we would expect exposure monitoring to be performed as soon as possible, and no later than 7 days after the change in workplace conditions. This period is intended to give an owner or operator time to locate and purchase exposure monitoring equipment in an emergency where the equipment may not already be available at the facility.

Monitoring method and accuracy. We take comment on the use of NIOSH methods 1003 and 1025 (NIOSH, 2003b and c) for analyzing nPB exposure under the proposed alternate approach. Several of the studies that supplied EPA with exposure data used this method and they are standardized methods prepared by NIOSH, a recognized authority on industrial hygiene. In addition, we would allow other methods that are accurate to $\pm 25\%$ at the 95 percent confidence level. Based on the accuracy of available methods, most OSHA standards require exposure monitoring accurate to 25% at the 95 percent confidence level, as in the methylene chloride standard (29 CFR 1910.1052(d)(1)(iii)(A)) and other OSHA standards.

Recordkeeping requirements. We would require that users keep records of the worker exposure data for three years from the date the measurement is taken²². This would provide information allowing EPA to determine if facilities are complying with the exposure limit and if workers exposed to nPB are sufficiently protected.

Responsibility for meeting requirements. Under the alternate approach, the owner or operator of a facility using nPB would be responsible for meeting the rule's use conditions.

²² OSHA's standard on access to employee exposure and medical records requires retaining exposure records for at least 30 years (29 CFR 1910.1020(d)(ii)), and these requirements would not be affected by this regulation.

2. Advantages and disadvantages of the alternate approach

Setting use conditions that require users to meet an exposure limit and to monitor and keep records to demonstrate achieving the limit would protect the health of nPB users while giving industry more flexibility and more options for ODS substitutes, compared to finding nPB unacceptable. This could be especially useful for users of HCFC-141b as an aerosol solvent that are seeking an effective ODS substitute. If there were any situations in which other available alternatives did not provide as good performance, nPB would still be available as an option, provided the use conditions could be met. The monitoring requirements would encourage good industrial hygiene and safe use of nPB.

Considering the list of use conditions above, we believe that setting use conditions requiring an exposure limit, worker exposure monitoring, and recordkeeping would be complex and potentially confusing. Requiring users to meet the exposure limit, although providing greater potential flexibility, also would provide less certainty about how to comply. A user could spend considerable time and expense trying to meet the exposure limit, only to find that it is not achievable.

Given the limited circumstances under which we expect aerosol and adhesive users could meet an acceptable exposure limit and given the availability of other, less toxic alternatives in both of these end uses, EPA's preferred option is to find nPB unacceptable in aerosols and adhesives. Further, considering that the users of nPB at the Lake City Army Ammunition Plant have been operating with exposure levels at or below the range EPA considers acceptable (i.e., the range from 17 to 30 ppm) without regulatory requirements (Lake City Army Ammunition Plant, 2004), it appears unnecessary to require an exposure limit in that application.

B. Regulatory options where nPB would be acceptable with use conditions requiring ventilation equipment

We considered use conditions for the adhesive and aerosol solvent end uses that would reduce the human health risks of using nPB by reducing exposure levels with requirements for installation and use of ventilation equipment.

1. Aerosols

For the aerosol solvent end use, EPA considered proposing a requirement for installation of ventilation equipment. Such a use condition would need to specify and define which kinds of ventilation equipment would be necessary. For example, because one study on exposure levels found that exposure fell to a level within the range that EPA would consider acceptable (i.e., 17 to 30 ppm) reliably only where both local exhaust ventilation and regional ventilation equipment were used, a possible requirement would be for installation of both local exhaust ventilation and regional ventilation. We would define local exhaust ventilation as ventilation that removes vapors from a specific work location using ducts and fans. We would define regional ventilation as ventilation that moves air around in a large working area, such as one or more fans used for an entire room. A problem with requiring the type of ventilation equipment that all facilities must use is that it still might not provide enough ventilation in some situations and in other situations may be unnecessary to meet an exposure limit.

Another approach for aerosols we considered was to require a specific level of ventilation. Possible criteria for the level of ventilation would be the air flow rate, in cubic feet per minute (cfm) or cubic meters per second, or the face velocity at the location where a user would work, in feet per minute (fpm) or meters per second face velocity. Based on both

modeling and exposure data from one study (ICF, 2006a; Linnel, 2003), an appropriate air flow rate for nPB-based aerosols would be greater than 1900 cfm and an appropriate face velocity would be 170 fpm. Alternatively, we considered requiring that facilities meet the guidelines for face velocity in spray booths from the ACGIH Ventilation Manual, in the range of 100 to 150 fpm, depending on the specific type of booth.

These options would appear to provide greater flexibility for industry compared to finding nPB unacceptable in aerosol solvents. However, our understanding is that in most aerosol applications, it might not be feasible to install adequate ventilation, and thus, to reduce human health risks. In the case of benchtop cleaning or degreasing, such as during rework of individual parts that are not yet sufficiently clean, it is possible to transport the part to a hood or spray booth to provide sufficient ventilation. However, for applications that require in-place cleaning such as cleaning energized electrical contacts and switches, maintenance in underground mines, or cleaning hot elevator motors, it is not feasible to install ventilation equipment in place or to remove the parts for cleaning in ventilation equipment (CSMA, 1999; Linnel, 2003). Information available to EPA shows that benchtop cleaning is perhaps 25% or less of the market for the ODS being replaced in aerosols (ICF, 2004) and that electrical contact cleaning makes up the vast majority of the market for nPB-based aerosols (Williams, 2005); thus, we expect that necessary ventilation cannot be installed in most aerosol applications for nPB. It would be difficult to explain and potentially confusing for users that an aerosol product may be used for cleaning in one location in a facility, but not in another, particularly when the ODS being substituted for could be used in all locations without excessive worker exposure. Further, it would be difficult for EPA to enforce use conditions on ventilation equipment,

because aerosols are portable and can easily be used outside of the ventilation equipment. Other acceptable substitutes, such as blends of HFEs or HFCs and trans-dichloroethylene, are available in these end uses.

2. Adhesives

EPA also considered use conditions for ventilation equipment or for specific ventilation levels for use of nPB-based adhesives. However, to date, we have found no study that demonstrates a ventilation option that could achieve levels that EPA would consider acceptable (i.e., in a range from 17 to 30 ppm to protect against reproductive effects) when using spray adhesives. Even with state-of-the-art ventilation equipment installed with the expert assistance of NIOSH, adhesives users were not able to lower exposure limits sufficient to protect the vast majority of their workers. Modeling of different levels of adhesive usage and ventilation, based on conditions at different facilities indicates that air flow rates would need to be more than 100,000 cfm. Even this high air flow rate might not be sufficient, since an air flow rate of 28,500 cfm resulted in exposure levels of 3.5 to 35 times an acceptable exposure level, depending on the amount of adhesive used (ICF, 2006a, Att. D). Less toxic substitutes such as water-based adhesives and acetone-based adhesives are available in this end use.

VIII. What are the anticipated costs of this regulation to the regulated community?

As part of our rulemaking process, EPA estimated potential economic impacts of this proposed regulation. In our analysis, we assumed that capital costs are annualized over 15 years or less using a discount rate for determining net present value of 7.0%. Because the use condition for coatings still permits nPB's use in the only known coatings application using nPB, we find no additional cost to the user community from this regulatory provision. We found that

if this proposed rule were to become final, the cost to the user community of the unacceptability determinations, which are regulatory prohibitions on the use of nPB in adhesives and aerosols, would be in the range of \$2.3 to \$6.7 million per year for adhesive users and \$36.3 to 39.7 million per year for aerosol users.

EPA also estimated the cost to the user community of the use conditions in the proposed alternate approach for aerosols, adhesives, and coatings. The requirements for users to meet an acceptable exposure limit and to perform exposure monitoring would be in the range of \$ 42.3 to 67.5 million per year. The upper end of the range of estimated impacts assumes laboratory grade ventilation for aerosols, which we expect to be significantly more expensive than standard industrial fume hoods or spray booths (approximately \$10,000 compared to \$1,000 for each hood). For coatings, use of nPB is limited to a single facility that already performs workplace exposure monitoring, and thus, no new costs would be incurred. For aerosols and adhesives, we assumed the installation of fume hoods or spray booths, the use of personal protective equipment, and monitoring for 1.9 to 2.0 times per year on average. Using these assumptions, we calculated the cost of the use conditions in the proposed alternate approach at \$18.0 to 24.0 million for adhesive users, and \$24.3 to 43.5 million for aerosol users. The estimated cost of the use conditions does not consider that some users could choose to switch to other alternatives at a lower cost.

Estimated costs of the proposed regulation and proposed alternate approach are summarized in Table 13. For more detailed information, see section XIII.C. below and EPA's analysis in the docket (US EPA, 2006).

Table 13. Estimated Costs of Regulatory Options EPA is Providing for Comment

Sector or End Use	Requirements under Proposed Rule	Annual Cost of Proposed Rule	Requirements under Alternate Approach	Annual Cost of Alternate Approach
Aerosol Solvents	Cease use of nPB and switch to a different ODS substitute.	\$ 36.3 to 39.7 million	Achieve 20 ppm; exposure monitoring one or two times per year; Recordkeeping	\$24.3 to 43.5 million
Coatings	Decision applies to use nPB in coatings at facilities that have provided EPA information demonstrating their ability to meet exposure levels that protect human health as of [INSERT DATE OF PUBLICATION].	None	Achieve 20 ppm; exposure monitoring, one or two times per year; recordkeeping.	None
Adhesives	Cease use of nPB and switch to a different ODS substitute.	\$ 2.3 to 6.7 million	Achieve 20 ppm; exposure monitoring, one or two times per year; recordkeeping	\$ 18.0 to 24.0 million
Total		\$38.6 to 46.4 million		\$ 42.3 to 67.5 million

IX. How do the decisions for EPA’s June 2003 proposal compare to that for this proposal?

Table 14 compares the acceptability determination and evidence cited in the June 2003 proposal and this proposal.

Table 14: n-Propyl Bromide Acceptability Decision

Proposed Decision	2003 Proposed Rule	Current Proposed Rule—Preferred Proposal
Industrial End Use #1: Aerosol Solvents	Acceptable, Subject to a Use Condition (Limiting use to nPB formulations containing no more than 0.05% by weight isopropyl bromide; AEL of 25 ppm ¹ on 8-hr TWA recommended)	Unacceptable
Industrial End Use #2: Adhesives	Acceptable, Subject to a Use Condition (Limiting use to nPB formulations containing no more than 0.05% by weight isopropyl bromide; AEL of 25 ppm ¹ on 8-hr TWA recommended)	Unacceptable
Industrial End Use #3: Coatings	Not addressed	Acceptable, Subject to Use Conditions (Decision limited to coatings at facilities that have provided EPA information demonstrating their ability to meet exposure levels that protect human health as of [INSERT DATE OF PUBLICATION]); (protective exposure levels are in a range from 18 to 30 ppm to protect against male reproductive effects (e.g., reduced sperm motility), in the range of 17 to 22 ppm to protect against female reproductive effects (e.g., number and length of estrous cycles), and at approximately 20 ppm for effects related to reproductive success (live litter size))

¹ Proposed acceptable exposure limit of 25 ppm adjust upward from value of 18 ppm based upon nPB's effect on sperm motility from evaluation of the WIL 2001 Study "An Inhalation Two-Generation Reproductive Toxicity Study of 1-Bromopropane in Rats."

- a) ICF, 2001. "Brief Discussion of the BMD Approach: Overview of its Purpose, Methods, Advantages, and Disadvantages." Prepared for U.S. EPA.
- b) ICF, 2002a. "Risk Screen for Use of N Propyl Bromide." Prepared for U.S. EPA, May, 2002.
- c) ICF, 2002b. Comments on the NTP- Center for the Evaluation of Risks to Human Reproduction, Final Report on 1- Bromopropane. Cover Letter Dated 5/9/02.

Also, evaluation of documents by CERHR (2002a, b), Doull and Rozman (2001), Rodricks (2002), Rozman and Doull (2002), SLR International (2001), and others.

² Protective exposure levels based upon nPB's effects on estrous cycle length at 17 to 22 ppm, live litter size at 20 ppm, and sperm motility at 18 to 30 ppm from evaluation of the WIL 2001 Study "An Inhalation Two-Generation Reproductive Toxicity Study of 1-Bromopropane in Rats" and confirmed by comparison with other studies. Also, considers evaluation of documents by Stelljes and Wood (2004); TERA (2004); ICF, 2006a; ACGIH (2005); Rozman and Doull (2005); Stelljes (2005); and others.

X. How can I use nPB as safely as possible?

Below are actions that will help nPB users meet the recommended acceptable exposure limit in this proposal:

All end uses

- All users of nPB should wear appropriate personal protective equipment, including chemical goggles, flexible laminate protective gloves (e.g., Viton, Silvershield) and chemical-resistant clothing. Special care should be taken to avoid contact with the skin since nPB, like many halogenated solvents, can be absorbed through the skin. Refer to OSHA's standard for the selection and use of Personal Protective Equipment, 29 CFR 1910.132.
- Limit worker exposure to solvents to minimize any potential adverse health effects. Workers should avoid staying for long periods of time in areas near where they have been using the solvent. Where possible, shorten the period during each day when a worker is exposed. Where respiratory protection is necessary to limit worker exposures, respirators must be selected and used in accordance with OSHA's Respiratory Protection standard, 29 CFR 1910.134.
- Use less solvent, or use a different solvent, either alone or in a mixture with nPB.
- Follow all recommended safety precautions specified in the manufacturer's MSDS.

- Workers should receive safety training and education that includes potential health effects of exposure to nPB, covering information included on the appropriate MSDSs, as required by OSHA's Hazard Communication Standard (29 CFR 1910.1200).
- Request a confidential consultation from your State government on all aspects of occupational safety and health. You can contact the appropriate state agency that participates in OSHA's consultation program. These contacts are on OSHA's web site at <http://www.osha.gov/oshdir/consult.html>. For further information on OSHA's confidential consultancy program, visit OSHA's web page at <http://www.osha.gov/html/consultation.html>.
- Use the employee exposure monitoring programs and product stewardship programs where offered by manufacturers and formulators of nPB-based products.
- If the manufacturer or formulator of your nPB-based product does not have an exposure monitoring program, we recommend that you start your own exposure monitoring program, and/or request a confidential consultation from your State government. A medical monitoring program should be established for the early detection and prevention of acute and chronic effects of exposure to nPB. The workers' physician(s) should be given information about the adverse health effects of exposure to nPB and the workers' potential for exposure.

Spray applications

- For spray applications (e.g., aerosols), use sufficient ventilation to meet the range of levels that would be at or below the range that the Agency considers acceptable (i.e., in a range from 17 to 30 ppm to protect against reproductive effects).

- For ventilation, we recommend that you follow the design guidelines for ventilation in ACGIH's *Industrial Ventilation: A Manual of Recommended Practice* (ACGIH, 2002). In particular, the guidelines in Chapter 10.75 are appropriate for spray booths, and the guidelines in Chapter 10.35 are appropriate for laboratory hoods.
- The ACGIH Ventilation Manual recommends a minimum flow rate of 150 cubic feet per minute (cfm) for each sq-ft of opening for a small booth with at least 4 sq-ft of open face area. This equates to an average face velocity of 150 ft/min. For a large booth, the recommended face velocity is 100 ft/min for walk-in booths and 100 to 150 ft/min for a large spray booth where the operator works outside. In general, the opening should be kept as small as possible to accommodate the work-pieces, generally 12 inches wider and taller than the largest piece of work. If all spraying is not directed towards the back of the booth or the booth is too shallow for the size of the pieces being sprayed or if disruptive air currents are present at the face of the booth, a greater flow of air will be needed.

We note that these steps are useful for reducing exposure to any industrial solvent, and not just nPB.

XI. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review

Under Executive Order (EO) 12866 (58 FR 51735, October 4, 1993), this action is a "significant regulatory action." It raises novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

Accordingly, EPA submitted this action to the Office of Management and Budget (OMB) for

review under EO 12866 and any changes made in response to OMB recommendations have been documented in the docket for this action.

In addition, EPA prepared an analysis of the potential costs and benefits associated with this action. This analysis is contained in the document “Analysis of Economic Impacts of nPB Rulemaking.” A copy of the analysis is available in the docket for this action (Ref. EPA-HQ-OAR-2002-0064) and the analysis is briefly summarized here. EPA estimates the total costs of the proposed rule to be between \$37 and 44.4 million per year, with the health benefits being as high as \$111 million per year.

B. Paperwork Reduction Act

The information collection requirements in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB) under the Paperwork Reduction Act, 44 U.S.C. 3501 et seq. An Information Collection Request (ICR) document has been prepared by EPA (ICR No. 2224.01) and a copy may be obtained from Susan Auby by mail at Collection Strategies Division; U.S. Environmental Protection Agency (2822T); 1200 Pennsylvania Ave., NW, Washington, DC 20460, by email at auby.susan@epamail.epa.gov, or by calling (202) 566-1672. A copy may also be downloaded off the internet at www.regulations.gov in Docket EPA-HQ-OAR-2002-0064.

If the provisions of this proposed rule become final, there would be no new information collection burden. This proposed rule contains no new requirements for reporting or recordkeeping. OMB has previously approved the information collection requirements contained in the existing regulations in subpart G of 40 CFR part 82 under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 et seq. and has assigned OMB control number 2060-

0226 (EPA ICR No. 1596.05). This ICR included five types of respondent reporting and record-keeping activities pursuant to SNAP regulations: submission of a SNAP petition, filing a SNAP//Toxic Substance Control Act (TSCA) Addendum, notification for test marketing activity, record-keeping for substitutes acceptable subject to use restrictions, and record-keeping for small volume uses.

However, if EPA were to finalize the proposed alternate approach, users of nPB would have an information collection burden from exposure monitoring and recordkeeping. Under the proposed alternate approach, users of nPB would be required to monitor worker exposure initially and periodically (usually every 6 months) and keep records of these exposure data at the facility for at least three years from the date the samples were taken. This data is necessary to ensure that users of nPB are meeting the regulatory use conditions. If the data indicates that the use condition is not being met, it could be used by EPA or citizens in an enforcement action against the facility. These data would be considered available to the public and would not be considered confidential.

The estimated burden of recordkeeping for the entire regulated community under the proposed alternate approach is as much as \$ 7.0 million and 13,170 hours per year. The estimated recordkeeping burden for a typical user is \$96 and 0.18 hours per worker per monitoring event. We estimate approximately 1.9 monitoring events per year per worker, assuming that roughly 90% of exposed workers must be monitored every six months and 10% must be monitored once annually. We estimate that up to 35,000 workers would be monitored for exposure to nPB. Costs include the annual cost of purchasing passive organic exposure

monitoring badges, the annual cost of services for analyzing the resulting exposure, and the annual cost of reviewing and filing the data up to 2 times per year.

Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR Part 9 and 48 CFR Chapter 15.

We request comments on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques. Send comments on the ICR to the Director, Collection Strategies Division; U.S. Environmental Protection Agency (2822T); 1200 Pennsylvania Ave., NW, Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th St., N.W., Washington, DC 20503, marked "Attention: Desk Officer for EPA." Include the ICR number in any correspondence. Since OMB is required to make a decision concerning the ICR between 30 and 60 days after [Insert date of publication in the FEDERAL REGISTER], a comment to OMB is

best assured of having its full effect if OMB receives it by [Insert date 30 days after publication in the FEDERAL REGISTER]. The final rule will respond to any OMB or public comments on the information collection requirements contained in this proposal.

C. *Regulatory Flexibility Act (RFA)*

The Regulatory Flexibility Act (RFA) generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions. The RFA provides default definitions for each type of small entity. Small entities are defined as: (1) a small business as defined by the Small Business Administration's (SBA) regulations at 13 CFR 121.201; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field. However, the RFA also authorizes an agency to use alternate definitions for each category of small entity, "which are appropriate to the activities of the agency" after proposing the alternate definition(s) in the *Federal Register* and taking comment. 5 USC 601(3) - (5). In addition, to establish an alternate small business definition, agencies must consult with SBA's Chief Counsel for Advocacy.

For purposes of assessing the impacts of the proposed rule on small entities, EPA is proposing to define "small business" as a small business with less than 500 employees, rather than use the individual SBA size standards for the numerous NAICS subsectors and codes. We

believe that no small governments or small organizations are affected by this rule. EPA chose to use the alternate definition to simplify the economic analysis. This approach slightly reduced the number of small businesses subject to inclusion in our analysis but slightly increased the percentages of small business significantly impacted in the analysis. Furthermore, this size standard was set by the Small Business Administration for all NAICS codes for businesses using nPB-based adhesives, one of the end uses that would be affected by this rule. We solicited comments on the choice of this alternate definition for this analysis on the June 2003 NPRM, and received no public comments. We again request comment on this alternate definition of “small business.”

EPA consulted with the Small Business Administration Office of Advocacy on the alternate small business definition of 500 employees for the June 2003 proposal. The Office of Advocacy concurred with EPA’s approach. The number and types of small businesses that would be regulated have not changed significantly in this NPRM from the June 2003 proposal, and EPA is proposing the same definition.

After considering the economic impacts of this proposed rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. EPA estimates that up to 3380 small industrial end users currently use nPB in the end uses addressed by this rule and thus could be subject to the regulatory impacts of this rule. This number includes approximately 3100 users of nPB-based aerosol solvents, and 280 users of nPB-based adhesives. Considering the regulatory impacts on adhesive and aerosol users that must switch to other alternatives, we found that up to 258 (8%) small businesses would experience impacts of 1% or greater of annual sales and no small businesses would experience impacts of

3% or greater of annual sales. Based on the relatively small number and percentage of small businesses that would experience significant impacts, EPA concludes that this rule would not have a significant economic impact on a substantial number of small entities.

In the case of coatings uses, our understanding is that only a single facility, the Lake City Army Ammunition Plant, is currently using coatings with nPB as the carrier solvent, and this facility could continue to use nPB following its current practices. Therefore, we consider there to be no economic impact of this rule on coatings users and have not done further analysis for this end use.

Types of businesses that would be subject to this proposed rule include:

- Manufacturers of computers and electronic equipment that clean with nPB cleaning solvents (NAICS subsector 334).
- Manufacturers of appliances, electrical equipment, and components that require oil, grease, and solder flux to be cleaned off (NAICS subsection 335).
- Manufacturers of transportation equipment, such as aerospace equipment that requires cleaning either in a tank or with aerosols, or aircraft seating, which is assembled using adhesives containing nPB as a carrier solvent; and ship or boat builders applying adhesives with nPB (NAICS subsector 336).
- Manufacturers of furniture, including various kinds of furniture with cushions and countertops assembled using adhesives containing nPB as a carrier solvent (NAICS subsector 337).
- Foam fabricators, who assemble foam cushions or sponges using adhesives containing nPB as a carrier solvent (NAICS code 326150).

In order to consider the resources that affected small businesses have available to operate and to respond to the proposed regulatory requirements, EPA compared the cost of meeting the proposed regulatory requirements to small businesses' annual sales. In our analysis for this proposed rule, we used the average value of shipments for the products manufactured by the end user as a proxy for sales or revenues, since these data are readily available from the U.S. Department of Commerce. The following tables display the average value of shipments for different sizes of business and different NAICS subsectors or codes in the affected industrial sectors. EPA then used data from these sources to determine the potential economic impacts of this proposed rule on small businesses.

Table 15. Average Value of Shipments in NAICS Subsectors Using Aerosol Solvents, by Number of Employees at Business

Number of Employees at Business	Average Value of Shipments per Business (\$) by NAICS Subsector Code		
	334, Computer and Electronic Products	335, Electrical Equipment, Appliance, and Component Mfg	336, Transportation Equipment
1 to 4 employees	345,007	315,772	412,460
5 to 9 employees	1,317,238	1,243,065	1,414,384
10 to 19 employees	2,566,913	2,483,327	2,573,352
20 to 49 employees	5,672,245	5,389,945	5,738,739
50 to 99 employees	12,951,836	12,650,236	12,735,583
100 to 249 employees	31,258,875	31,290,638	34,256,544
250 to 499 employees	84,270,454	77,279,974	86,911,454
Avg Value Ship Small Businesses in Sub-sector	8,261,788	9,539,205	11,029,561
Avg Value Ship ALL Businesses in Subsector	20,810,094	13,417,905	45,029,773
Avg Value Shipments Subset Small Businesses using nPB	11,246,045	12,066,562	13,422,547

**Table 16. Average Value of Shipments in NAICS Categories
Using nPB as a Carrier Solvent in Adhesives, by Number of Employees at Business**

Number of Employees at Business	Average Value of Shipments per Small Business (\$) by NAICS Sub Sector				
	337121, Upholstered household furniture	337110, Wood kitchen cabinet and counter tops	326150, Urethane and other foam products (except polystyrene)	336360, Motor vehicle seating and interior trim	337124, Metal household furniture
1 to 4 employees	234,345	156,833	496,318	425,863	187,950
5 to 9 employees	963,021	622,744	1,305,183	1,728,132	903,393
10 to 19 employees	1,771,416	1,141,119	3,152,283	3,082,486	1,431,480
20 to 49 employees	3,653,623	2,619,197	6,615,331	5,508,370	3,538,684
50 to 99 employees	8,089,968	7,386,365	13,281,000	14,088,500	7,547,536
100 to 249 employees	17,502,175	17,151,091	31,524,872	44,310,286	19,821,719
250 to 499 employees	40,250,813	55,982,674	64,119,800	123,803,610	D(1)
Avg Small Businesses in Sub sector	3,588,297	1,150,768	10,472,992	12,542,725	3,141,720
Avg ALL Businesses in Sub sector	5,490,101	1,475,602	11,110,822	44,808,573	5,239,747
Avg Subset Small Businesses using nPB	11,519,540	5,999,622	18,950,068	12,019,847	20,401,301

⁽¹⁾“d” designates “Data withheld to avoid disclosing data of individual companies; data are included in higher level totals.” The average value of shipments for businesses estimates those values marked with “d,” and thus may be overestimated or underestimated.

This proposed rule would require that nPB be unacceptable for use in adhesives and aerosols. The available alternatives identified include adhesive formulations based on water, methylene chloride, or flammable solvents such as acetone and aerosol formulations of flammable solvents, combustible solvents, blends of trans-dichloroethylene and HFEs or HFCs, and HCFC-225ca/cb. We considered various aspects of the cost of switching to other alternatives, including the cost of meeting OSHA requirements and the cost of the alternative adhesive. We specifically request public comment on the assumptions and costs used in EPA's analysis (US EPA, 2007b).

We estimate that up to 9 small businesses using nPB-based adhesives, or roughly 3% of the 280 or so small businesses that use nPB-based adhesives, would experience a cost increase (i.e., an impact) of greater than 1.0% of annual sales, and no small businesses would experience an impact of greater than 3% of annual sales if this proposed rule became final. For small businesses using nPB-based aerosols, we estimate that approximately 249 would experience a cost increase of greater than 1.0% of annual sales. This equates to roughly 8% of the 3100 or so small businesses currently using nPB-based aerosol solvents. No small businesses using aerosols would experience an impact of greater than 3% of annual sales. Approximately eight percent of all 3380 or so small businesses choosing to use nPB in these end uses would experience an impact of greater than 1.0% of annual sales and no small businesses would experience an impact of greater than 3.0% of annual sales. Because of the small total number and small percentage of affected businesses that would experience an impact of greater than either 1.0% or 3.0% of annual sales, EPA does not consider this proposed rule to have a significant impact on a substantial number of small businesses.

We also analyzed the potential small business impacts of the proposed alternate approach. Under the proposed alternate approach, users would have to: (1) meet an exposure level of 20 ppm on an eight-hour time-weighted average, (2) monitor workers' exposure to nPB using a personal breathing zone sampler on an eight-hour time-weighted average initially and periodically (every 6 months or longer, depending on the concentration during initial monitoring), and (3) keep records of the worker exposure data on site at the facility for at least three years from the date of the measurement. We assume that the cost of following the proposed alternate approach is the cost of installing ventilation for aerosols and adhesives or emission controls for solvent cleaning, the cost of using personal protective equipment, and the cost of monitoring worker exposure. Approximately 67 to 387 aerosol solvent users (2 to 13 percent), 25 to 54 adhesive users (9 to 19 percent), and 2.6 to 12.6 percent of all 3380 or so small businesses would experience impacts of greater than 1% of annual sales if they chose to use nPB subject to the proposed use conditions rather than switching to another ODS substitute. Four to nine users of nPB-based adhesives, or less than 1% of all small businesses affected by this proposal, would experience impacts of 3% or greater of annual sales under the proposed alternate approach. Based on this analysis, the proposed alternate approach would not create a significant adverse impact on a significant number of small entities.

Although this proposed rule would not have a significant economic impact on a substantial number of small entities if it became final, EPA nonetheless has tried to reduce the impact of this rule on small entities. Before selecting preferred the regulatory option in this proposed rule, we considered a number of regulatory options, such as:

- Placing a narrowed use limit on the use of nPB in adhesives and aerosols that would allow its use only in those cases where alternatives are technically infeasible due to performance or safety issues. This would have required testing, recordkeeping, and some installation of capital equipment.
- Requiring that when nPB is used in adhesives or aerosols, it must be used with local ventilation equipment and personal protective equipment. This would have required further installation of capital equipment, without necessarily protecting workers as thoroughly as a required acceptable exposure limit or requiring a switch to another alternative.
- Prohibiting the use of nPB in all end uses.
- Retaining the previously proposed requirement for a limit on iPB content in nPB formulations.

The costs of a number of these options are included in EPA's analysis (US EPA, 2006; US EPA, 2007b).

In developing our regulatory options, we considered information we learned from contacting small businesses using or selling nPB. EPA staff visited the site of a small business using nPB for cleaning electronics. We contacted several fabricators of foam cushions that have used adhesives containing nPB. We participated in meetings with a number of adhesive manufacturers and users of adhesives in furniture construction. We developed a fact sheet and updated our program web site to inform small businesses about the proposed rule and to request their comments.

We continue to be interested in the potential impacts of the proposed rule on small entities and welcome comments on issues related to such impacts.

D. *Unfunded Mandates Reform Act*

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104-4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. Under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with "Federal mandates" that may result in expenditures to State, local, and tribal governments, in the aggregate, or to the private sector, of \$100 million or more in any one year. Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective or least burdensome alternative if the Administrator publishes with the final rule an explanation why that alternative was not adopted. Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, it must have developed under section 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on

compliance with the regulatory requirements. EPA has determined that this rule does not contain a Federal mandate that may result in expenditures of \$100 million or more for State, local, and tribal governments, in the aggregate, or the private sector in any one year. This proposed rule does not affect State, local, or tribal governments. The enforceable requirements of the rule for the private sector affect a number of end users in manufacturing. The estimated cost of the proposed requirements for the private sector is approximately \$38.6 to 46.4 million per year, and the proposed alternate approach would cost the private sector approximately \$ 42.3 to 67.5 million per year. Therefore, the impact of this rule on the private sector is less than \$100 million per year. Thus, this rule is not subject to the requirements of sections 202 and 205 of the UMRA. EPA has determined that this rule contains no regulatory requirements that might significantly or uniquely affect small governments. This regulation applies directly to facilities that use these substances and not to governmental entities.

E. *Executive Order 13132: Federalism*

Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure “meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.” “Policies that have federalism implications” is defined in the Executive Order to include regulations that 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.”

This proposed rule 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, as specified in Executive Order 13132. This regulation applies directly to facilities that use these substances and not to governmental entities. Thus, Executive Order 13132 does not apply to this rule.

F. *Executive Order 13175: Consultation and Coordination with Indian Tribal Governments*

Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 6, 2000), requires EPA to develop an accountable process to ensure “meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.” “Policies that have tribal implications” is defined in the Executive Order to include regulations that have “substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.”

This proposed rule does not have tribal implications. 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.

This proposed rule would not significantly or uniquely affect the communities of Indian tribal governments, because this regulation applies directly to facilities that use these substances and not to governmental entities. Thus, Executive Order 13175 does not apply to this proposed rule.

G. *Executive Order 13045: Protection of Children from Environmental Health and Safety Risks*

Executive Order 13045: “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997) applies to any rule that: (1) is determined to be "economically significant" as defined under Executive Order 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

This proposed rule is not subject to the Executive Order because it is not economically significant as defined in Executive Order 12866, and because the Agency does not have reason to believe the environmental health or safety risks addressed by this action present a disproportionate risk to children. The exposure limits and acceptability listings in this proposed rule apply to the workplace. These are areas where we expect adults are more likely to be present than children, and thus, the agents do not put children at risk disproportionately. Further, this proposed rule provides both regulatory restrictions and recommended exposure guidelines based upon toxicological studies in order to reduce risk of exposure to a reproductive toxin, nPB. This proposed rule is not subject to Executive Order 13045 because it is not economically significant as defined in Executive Order 12866 and because the Agency does not have reason to believe the environmental health or safety risks addressed by this action present a disproportionate risk to children.

The public is invited to submit or identify peer-reviewed studies and data, of which the agency may not be aware, that assessed results of early life exposure to nPB.

H. *Executive Order 13211: Actions that Significantly Affect Energy Supply, Distribution, or Use*

This rule is not a “significant energy action” as defined in Executive Order 13211, “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355 (May 22, 2001)) because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. This action would impact manufacturing of various metal, electronic, medical, and optical products cleaned with solvents containing nPB and products made with adhesives containing nPB. Further, we have concluded that this rule is not likely to have any adverse energy effects.

I. *National Technology Transfer and Advancement Act*

As noted in the proposed rule, Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (“NTTAA”), Pub L. No. 104-113, § 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

This action does not involved technical standards. Therefore, EPA did not consider the use of any voluntary consensus standards. We note that the American Conference of Governmental

Industrial Hygienists (ACGIH), although it sets voluntary standards, is not a voluntary consensus standards body. Therefore, use of an acceptable exposure limit from the ACGIH is not subject to the NTTAA.

XII. References

The documents below are referenced in the preamble. All documents are located in the Air Docket at the address listed in section I.B.1 at the beginning of this document. Unless specified otherwise, all documents are available electronically through the Federal Docket Management System, Docket # EPA-HQ-OAR-2002-0064. Some specific items are available only in hard copy in dockets A-2001-07 or A-92-42 (legacy docket numbers for SNAP nPB rule and for SNAP program and submissions). Numbers listed after the reference indicate the docket and item numbers.

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Statutory and Executive Order Reviews

List of Subjects in 40 CFR Part 82

Environmental protection, Administrative practice and procedure, Air pollution control,

Reporting and recordkeeping requirements.

Protection of Stratospheric Ozone: Listing of Substitutes for Ozone-Depleting

Substances—n-Propyl Bromide

Notice of Proposed Rulemaking

Page 143 of 145 pages

Dated: _____

Stephen L. Johnson, Administrator

For the reasons set out in the preamble, 40 CFR part 82 is proposed to be amended as follows:

PART 82 - PROTECTION OF STRATOSPHERIC OZONE

1. The authority citation for Part 82 continues to read as follows:

Authority: 42 U.S.C. 7414, 7601, 7671 - 7671q.

2. Subpart G is amended by adding Appendix Q to read as follows:

Subpart G - Significant New Alternatives Policy Program

Appendix Q to Subpart G - Substitutes Subject to Use Restrictions and Unacceptable Substitutes

Listed in the [**publication date of final rule**] final rule.

AEROSOLS

UNACCEPTABLE SUBSTITUTES

End Use	Substitute	Decision	Further Information
Aerosol solvents	n-propyl bromide (nPB) as a substitute for CFC-113, HCFC-141b, and methyl chloroform	Unacceptable	EPA finds unacceptable risks to human health in this end use compared to other available alternatives. nPB, also known as 1-bromopropane, is Number 106-94-5 in the CAS Registry.

ADHESIVES, COATINGS, AND INKS

SUBSTITUTES THAT ARE ACCEPTABLE SUBJECT TO USE CONDITIONS

End Use	Substitute	Decision	Use Conditions	Further Information
Coatings	n-propyl bromide (nPB) as a substitute for methyl chloroform, CFC-113, and HCFC-141b	Acceptable subject to use conditions	Use is limited to coatings at facilities that have provided EPA information demonstrating workplace exposure levels at or below the range that the Agency considers acceptable as of [INSERT DATE OF PUBLICATION].	EPA recommends the use of personal protective equipment, including chemical goggles, flexible laminate protective gloves and chemical-resistant clothing. EPA expects that users of nPB in this end use will continue to meet workplace exposure levels within the range of values in data that have been submitted to the Agency and would comply with any final Permissible Exposure Limit that the Occupational Safety and Health Administration issues in the future under 42 U.S.C. 7610(a). nPB, also known as 1-bromopropane, is Number 106-94-5 in the CAS Registry.

Note: As of [INSERT DATE OF PUBLICATION], the Lake City Army Ammunition Plant is the only facility that has provided information to EPA demonstrating the facility's ability to maintain exposure levels at or below the range that the Agency considers acceptable when using nPB in coatings.

ADHESIVES, COATINGS, AND INKS

UNACCEPTABLE SUBSTITUTES

End Use	Substitute	Decision	Further Information
Adhesives	n-propyl bromide (nPB) as a substitute for CFC-113, HCFC-141b, and methyl chloroform	Unacceptable	EPA finds unacceptable risks to human health in this end use compared to other available alternatives. nPB, also known as 1-bromopropane, is Number 106-94-5 in the CAS Registry.

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