ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 82

[FRL–7504–3]

RIN 2060–AK28

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

AGENCY: Environmental Protection Agency.

ACTION: Notice of proposed rulemaking.

SUMMARY: This action proposes to list n-propyl bromide (nPB) as an acceptable substitute for ozone-depleting substances (ODSs), subject to use conditions, in the solvent cleaning sector and aerosol solvents and adhesive end uses under the U.S. Environmental Protection Agency's (EPA or ''we'') Significant New Alternatives Policy (SNAP) program. The SNAP program implements section 612 of the amended Clean Air Act of 1990 (CAA), which requires EPA to evaluate substitutes for ODSs in order to reduce overall risk to human health and the environment.

While we find that nPB has a short atmospheric lifetime and low ozone depletion potential when emitted from locations in the continental U.S., the Agency cautions that significant use of nPB closer to the equator poses significant risks to the stratospheric ozone layer. Further, if workplace exposure to nPB is poorly controlled, it may increase health risks to workers. In the interim, until the Occupational Safety and Health Administration (OSHA) develops a mandatory workplace exposure limit under Section 6 of the Occupational Safety and Health Act, the Agency recommends that users of nPB adhere to an acceptable exposure limit of 25 parts per million (ppm) over an eight-hour time-weighted average.

In today's action, EPA proposes that the use of nPB is acceptable subject to a use condition, in a limited number of specific applications where emissions can be tightly controlled for both environmental and exposure concerns. The proposal only allows the use of nPB as a solvent in metals, precision, and electronics cleaning, and in aerosol solvent and adhesive end-uses. EPA is proposing to list nPB as an acceptable substitute for chlorofluorocarbon (CFC)-113, hydrochlorofluorocarbon (HCFC)-141b, and methyl chloroform when used in aerosol solvent and adhesive end uses, subject to the condition that nPB used in these end uses not contain more than 0.05% isopropyl bromide by weight before adding stabilizers or other chemicals. We are also proposing to list nPB as an acceptable substitute for CFC–113 and methyl chloroform in general metals cleaning, electronics cleaning, and precision cleaning, subject to the condition that nPB used in these end uses not contain more than 0.05% isopropyl bromide by weight before adding stabilizers or other chemicals.

DATES: Comments must be received in writing by August 4, 2003.

ADDRESSES: Comments may be submitted by mail to: Air and Radiation Docket, Environmental Protection Agency, Mailcode 6102T, 1200 Pennsylvania Ave., NW., Washington, DC 20460, Attention Docket ID No. OAR–2002–0064. Comments may also be submitted electronically, by facsimile, or through hand delivery/courier. Follow the detailed instructions as provided at the beginning of the ''supplementary information'' section.

FOR FURTHER INFORMATION CONTACT: For further information about this proposed rule, contact Margaret Sheppard by telephone at (202) 564–9163, or by e-mail at *sheppard.margaret@epa.gov.* Notices and rulemakings under the SNAP program are available on EPA's Stratospheric Ozone World Wide Web site at *http://www.epa.gov/ozone/snap/regs.*

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I. General Information

A. Regulated Entities

Today's proposal would regulate the use of n-propyl bromide as a solvent used in industrial equipment for metals cleaning, electronics cleaning, or precision cleaning, and as an aerosol solvent and a carrier solvent in adhesives. Businesses that currently might be using nPB, or might want to use it in the future, include:

- Businesses that clean metal parts, such as automotive manufacturers, machine shops, machinery manufacturers, and electroplaters.
- 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.

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	333	Machinery manufacturing
Industry	334	Computer and electronic product manufacturing
Industry	336	Transportation equipment manufacturing
Industry	337	Furniture and related product 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. How Can I Get Copies of Related Information?

1. Docket

EPA has established an official public docket for this action under Docket ID No. OAR–2002–0064 (continuation of Docket A–2001–07). The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Hard copies of documents from prior to the public comment period are found under Docket ID No. A–2001–07. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Air and Radiation Docket in the EPA Docket Center, (EPA/DC) EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC. The EPA Docket Center 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 Reading Room is (202) 566–1742, and the telephone number for the Air and Radiation Docket is (202) 566–1742.

2. Electronic Access

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once in the system, select ''search,'' then key in the appropriate docket identification number.

Certain types of information will not be placed in the EPA Dockets.Information claimed as CBI and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in section I.B.1. above.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA's electronic public docket. Public comments that are mailed or delivered to the Docket will be scanned and placed in EPA's electronic public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff.

C. How and to Whom Do I Submit Comments?

You may submit comments electronically, by mail, by facsimile, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket identification number in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked ''late.'' EPA is not required to consider these late comments. If you wish to submit CBI or information that is otherwise protected by statute, please follow the instructions in section I.D. Do not use EPA Dockets or e-mail to submit CBI or information protected by statute.

1. *Electronically.* If you submit an electronic comment as prescribed below, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also include this contact information on the outside of any disk or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. 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.

Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at *http://www.epa.gov/edocket,* and follow the online instructions for submitting comments. To access EPA's electronic public docket from the EPA Internet Home Page, select ''Information Sources,'' ''Dockets,'' and ''EPA Dockets.'' Once in the system, select ''search,'' and then key in Docket ID No. OAR–2002–0064. The system is an ''anonymous access'' system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

Comments may be sent by electronic mail (e-mail) to *A-And-R-*

Docket@epa.gov, Attention Docket ID No. OAR–2002–0064. In contrast to EPA's electronic public docket, EPA's e-mail system is not an ''anonymous access'' system. If you send an e-mail comment directly to the Docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

You may submit comments on a disk or CD ROM that you mail to the mailing address identified in section I.B.1. These electronic submissions will be accepted in WordPerfect or ASCII file format. Avoid the use of special characters and any form of encryption.

2. *By Mail.* Send two copies of your comments to: Air and Radiation Docket, Environmental Protection Agency, Mailcode: 6102T, 1200 Pennsylvania Ave., NW., Washington DC, 20460, Attention: Docket ID No. OAR–2002–0064.

3. *By Hand Delivery or Courier.* Deliver your comments to: EPA Docket Center, (EPA/DC) EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC, Attention Docket ID No. OAR–2002–0064. Such deliveries are only accepted during the Docket's normal hours of operation as identified in section I.B.1.

4. *By Facsimile.* Fax your comments to: 202–566–1741, Attention: Docket ID No. OAR–2002–0064.

D. How Should I Submit CBI to the Agency?

Do not submit information that you consider to be CBI electronically through EPA's electronic public docket or by e-mail. Send or deliver information identified as CBI only to the following address: Margaret Sheppard, U.S. EPA, 4th floor, 501 3rd Street NW., Washington DC 20001, via delivery service. You may claim information that you submit to EPA as CBI by marking any part or all of that information as CBI (if you submit CBI on disk or CD ROM, 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 CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

In addition to one complete version of the comment that includes any 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 and EPA's electronic public docket. If you submit the copy that does not contain CBI on disk or CD ROM, mark the outside of the disk or CD ROM clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and EPA's electronic public docket without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified in the **FOR FURTHER INFORMATION CONTACT** section.

E. Acronyms and Abbreviations Used in the Preamble

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

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

1–BP—the chemical 1-bromopropane, C_3H_7Br, CAS Reg. No. 106–94–5; also called n-propyl bromide or nPB

2–BP—the chemical 2-bromopropane, C_3H_7Br, CAS Reg. No. 75–26–3; also called isopropyl bromide or iPB

2–D—two-dimensional

3–D—three dimensional

ACGIH—American Congress of Governmental Industrial Hygienists

AEL—acceptable exposure limit

AFEAS—Alternative Flurocarbon Environmental Acceptability Study

AIC—Akaike Information Criterion

AIHA—American Industrial Hygienists Association

ANPRM—Advance Notice of Proposed Rulemaking

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

BMR—benchmark response

BSOC—Brominated Solvents Consortium

CAA—Clean Air Act

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

CBI—Confidential Business Information

CERHR—Center for the Evaluation of Risks to Human Reproduction

CFC–113—the ozone-depleting chemical trifluorotrichloroethane, $C_2Cl_3F_3$, CAS Reg. No. 76–13–1

CFCs—chlorofluorocarbons

CFR—Code of Federal Regulations

CNS—Central nervous system

EPA—the United States Environmental Protection Agency

FR—**Federal Register**

GLP—Good Laboratory Practice

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 1,1,1-trichloro-2-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-pentafluoro-propane, CAS Reg. No. 422–56–0 and 3,3-dichloro-1,1,2,2,3-pentafluoropropane, CAS Reg. No. 507–55–1

HCFCs—hydrochlorofluorocarbons

HEC—human equivalent concentration

HESIS—Hazard Evaluation System and Information Service of the California Department of Health Services

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

HFC–365mfc—the chemical 1,1,3,3,3-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

HFCs—hydrofluorocarbons

HFEs—hydrofluoroethers

HHE—health hazard evaluation

HSIA—Halogenated Solvents Industry Alliance

IARC—International Agency for Research on Cancer

ICF—ICF Consulting

ICR—Information Collection Request

iPB—isopropyl bromide, C_3H_7Br, CAS Reg. No. 75–26–3, an isomer of n-propyl bromide; also called 2-bromopropane or 2-BP

IPCC—International Panel on Climate Change

IRTA—Institute for Research and Technical Assistance

LOAEL—Lowest Observed Adverse Effect Level

MF—modifying factor

MSDS—Material Safety Data Sheet

NAICS—North American Industrial Classification System

NESHAP—National Emission Standards for Hazardous Air Pollutants

NIEHS—National Institute of Environmental Health Services

NIOSH—National Institute for Occupational Safety and Health

NOAEL—No Observed Adverse Effect Level

NOEL—No Observed Effect Level

nPB—n-propyl bromide, C_3H_7Br, 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

OMB—U.S. Office of Management and Budget

OSHA—U.S. Occupational Safety and Health Administration
PCBTF—parachlorobenzotrifluoride, CAS Reg. No. 98–56–6
PEL—Permissible Exposure Limit
PERC—perchloroethylene, also called tetrachloroethylene; C_2Cl_4, CAS Reg. No. 127–18–4
POD—point of departure
ppm—parts per million
RCRA—Resource Conservation and Recovery Act
RFA—Regulatory Flexibility Act
RfC—reference concentration
RfD—reference dose
SBREFA—Small Business Regulatory Enforcement Fairness Act
SNAP—Significant New Alternatives Policy
STEL—short term exposure limit
TCA—the ozone-depleting chemical 1,1,1-trichloroethane, CAS Reg. No. 71–55–6; also called 1,1,1, methyl chloroform, or MCF
TCE—trichloroethylene, C_2Cl_3H, CAS Reg. No. 79–01–6
TEAP—Technical and Economic Assessment Panel of the United Nations Environmental Programme
TSCA—Toxic Substances Control Act
TWA—time-weighted average
UF—uncertainty factor
UMRA—Unfunded Mandates Reform Act
UNEP—United Nations Environmental Programme
VMSs—volatile methyl siloxanes
VOC—volatile organic compound

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 our 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 produces a substitute for an ODS 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 chemical manufacturers, but may 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 (that is, we may limit the use of a substitute to certain end-uses or specific applications within an industry sector), to allow alternatives to be used in specific uses that would otherwise be deemed unacceptable. 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 specified as acceptable in 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 either unacceptable, acceptable subject to narrowed use limits, or acceptable subject to use conditions. Since this additional information is not part of the regulatory decision, you are not required to follow these statements to use a substitute unless they specifically reference regulatory requirements. 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 application of these substitutes, regardless of any regulatory requirements. 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. Is EPA Listing n-Propyl Bromide as an Acceptable Substitute for Ozone-Depleting Substances?

A. What Is EPA Proposing Today?

EPA is proposing today to list n-propyl bromide (nPB) acceptable, subject to use conditions, for use as a substitute for CFC–113 and methyl chloroform [1] in metals, precision and electronics cleaning, and acceptable, subject to use conditions, for use as a substitute for CFC–113, methyl chloroform and HCFC–141b in adhesives and aerosol solvent end uses. The use conditions for each end use provide that nPB not contain more than 0.05% isopropyl bromide (iPB)[2] by weight before adding stabilizers or other chemicals. By this, we mean the chemical n-propyl bromide that is produced by the manufacturer or reclaimed by a recycler before other substances are added, such as stabilizers, other solvents, or adhesive solids. End users would need to keep documentation for two years from the date on the documentation to show that the nPB-based product that they are using contains no more than 0.05% iPB in the nPB. EPA's decision is based upon comparing environmental and health risks associated with the use of nPB in specific applications in the United States, compared to other available alternatives. Based on our review, the impact of using nPB in the U.S. does not warrant listing the chemical as an unacceptable substitute under the SNAP program.

We recommend, but do not require, that users in all industrial sectors adhere to EPA's recommended guideline for worker exposure of 25 parts per million (ppm) over an eight-hour time-weighted average. While we believe it is possible to achieve the recommended exposure limit of 25 ppm in the kinds of applications listed above, we are concerned about potentially high emissions and exposure levels of nPB in adhesive applications in particular. Consequently, EPA intends to work with the National Institute for Occupational Safety and Health (NIOSH) to develop information for employers and workers at facilities that use, or could use, nPB. NIOSH and state occupational safety and health agencies will provide technical assistance to help ensure a safe workplace environment if owners or workers request it.

EPA strongly recommends that users follow responsible use practices suggested by the manufacturer when using nPB. You can also reduce risk in the workplace by monitoring workers' levels of exposure to nPB. These practices will reduce the risk of toxic effects to workers, as well as reducing the impact of emissions on the environment.

[1] Methyl chloroform is also referred to as 1,1,1-trichloroethane, TCA, or 1,1,1.

[2] iPB is also referred to as 2-bromopropane, 2-propyl bromide, or 2-BP. Its CAS registration number is 75–26–3.

B. 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 C_3H_7Br. 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, and Whisper Spray and Fire Retardant Soft Seam 6460 adhesives.

C. What Industrial Sectors Are Included in Our Proposed Decision?

EPA has received petitions under CAA Section 612(d) to add nPB to the list of acceptable alternatives for CFC–113, methyl chloroform, and HCFC–141b in the solvent cleaning sector for general metals, precision, and electronics cleaning, as well as in aerosol solvent and adhesive applications.[3] Today's proposal does not list nPB as a substitute for HCFC–141b for the solvent cleaning sector, but does list nPB as an acceptable substitute for HCFC–141b, subject to use conditions, for aerosol solvents. This is because EPA previously listed HCFC–141b as unacceptable for use in non-aerosol solvent cleaning applications because of the availability of safer alternatives (59 FR 13090; March 18, 1994), and listed HCFC–141b as acceptable for use in aerosol solvents. No one may legally use HCFC–141b for non-aerosol solvent cleaning and, therefore, no one would substitute for its use.

The proposal for aerosol solvents only applies to a limited number of aerosol solvent applications because of the Nonessential Products Ban promulgated under Section 610 of the Act which prohibits the sale, distribution, or offer for sale or distribution in interstate commence of many products containing CFCs and HCFCs. All aerosol products, pressurized dispensers and foam products containing or manufactured with CFCs and HCFCs—except those specifically exempted by the regulations at 40 CFR part 82, subpart C, and those that are listed as essential medical devices by the Food and Drug Administration at 21 CFR 2.125(e)—are banned from sale and distribution in the

[3] EPA also received petitions for using nPB in the foam blowing and fire suppression sectors. Because the information in these petitions about the use of nPB is incomplete, EPA was unable to consider them. Therefore, today's action does not address nPB's use in the foam blowing and fire suppression sectors.

United States. Users of aerosol solvents can purchase them only for those applications that are exempted from the Non-Essential Products Ban. The SNAP program applies to the use of substitutes for ODSs, and thus, applies only to those applications where ODSs may be used. Therefore, today's proposed listing only applies to those specific aerosol solvent applications where ODSs are allowed to be sold. This list of permissible uses is subject to change. Of the allowable applications for aerosol solvents, it is most likely that nPB would be used as a solvent in:

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

In addition, no one has specifically stated that they use, or intend to use, nPB in coatings or inks. Thus, our proposed ruling only addresses nPB use in the adhesives end use, in the adhesives, coatings, and inks sector. We would require a separate SNAP submission and additional information on nPB use and exposure data in coatings and inks to consider its acceptability in those applications.

EPA notes that the SNAP program currently does not cover some uses of solvents, such as manual cleaning, carriers for flame retardants, dry cleaning, or paint stripping. Ozone-depleting solvents were never used in significant quantities in these applications, compared to applications that are covered by the SNAP program, such as vapor degreasing or cold batch cleaning. For further discussion, see the original SNAP rule (March 18, 1994; 59 FR 13089–13090 and 59 FR 13117–13120).

We summarize our proposed actions by sector and end use in Table 2 below.

TABLE 2.—SUMMARY OF PROPOSED ACTIONS BY SECTOR AND END USE

For this industrial sector...	in this end use...	we propose to list nPB as follows...	as a substitute for these ozone depleting substances:		
			CFC–113	methyl chloroform	HCFC–141b
Solvents Cleaning	Metals Cleaning	Acceptable, subject to use conditions[1]	X	X	
	Electronics Cleaning	Acceptable, subject to use conditions[1]	X	X	
	Precision Cleaning	Acceptable, subject to use conditions[1]	X	X	
Aerosols	Aerosol Solvents	Acceptable, subject to use conditions[1]	X	X	X
Adhesives, Coatings, and Inks.	Adhesives	Acceptable, subject to use conditions[1]	X	X	X

[1] In order to use nPB, the nPB would have to contain no more than 0.05% iPB by weight before adding stabilizers or other chemicals.

At the end of today's action, you will find language that we are proposing to add as Appendix L to subpart G of 40 CFR part 82 to summarize our proposed listing decisions. Information contained in the ''Further Information'' column of those tables provides additional information on nPB. Although EPA expects nPB users to conform to all information shown in Appendix L, the ''further information'' is not part of the regulatory decision, and, therefore, is not mandatory. Also, there may be other legal obligations pertaining to the manufacture, use, handling, disposal of nPB that are not included in the comments listed in Appendix L.

IV. What Did EPA Consider for Today's Acceptability Decision?

To assess the acceptability of any substitute, including nPB, EPA reviews the environmental and health risks potentially posed by the substitute, including ozone depletion potential, global warming potential, flammability, and toxicity. Today's action on nPB follows the publication of an Advanced Notice of Proposed Rulemaking (ANPRM) published in the **Federal Register** on February 18, 1999, at 64 FR 8043. The ANPRM provided the public an opportunity to review the information available to the Agency at that time, and requested additional information and comment to assist in the development of regulatory options. In particular, the ANPRM asked for information on those key parameters where information was limited—that is, the toxicity, ozone depletion potential, and market potential of nPB. The Agency also issued a notice on December 18, 2000 which provided the public with an update on the information EPA had received regarding nPB's ODP and toxicity, and provided a summary of anticipated next steps in developing regulations under SNAP for nPB (65 FR 78977).

Based on all information now available, EPA is proposing to find nPB acceptable subject to use conditions. The Agency is concerned that excessive exposure to nPB can pose risks of adverse health effects and is recommending a workplace exposure guideline that we believe will protect workers who are exposed to this chemical. EPA is basing this recommendation on several factors, including a review of the toxicological literature and a subsequent risk evaluation conducted according to EPA guidelines (adjusted to represent workplace exposure), and consideration of risk management principles. EPA finds that it is possible to reduce workplace exposure to nPB to acceptable levels with commonly available control equipment or ventilation equipment. Thus, the Agency has concluded that it is appropriate to list nPB as acceptable because there is evidence that it can be used in a way that does not present greater risk than other substitutes.

Based on these data, the Agency is proposing to list nPB as acceptable, subject to a use condition, for the non-aerosol solvents cleaning sector, aerosol solvents end use, and adhesives end use because we believe it is feasible to meet the recommended AEL of 25 ppm in the solvents cleaning sector, the aerosol solvents end use, and the adhesives end use. However, EPA expects users to defer to any permissible exposure limit ultimately established by OSHA. We note that section 6 of the Occupational Safety and Health Act requires OSHA to make specific legal findings to support a standard. Specifically, under the case law OSHA can set a standard only where there is ''substantial evidence'' that the particular standard will provide

''significant'' risk reduction of a ''material'' adverse health effect to workers. Because OSHA operates under a different statute, employs different methodology, and will presumably have additional data at some point in the future, OSHA's derivation of a permissible exposure limit (PEL) may result in a different number than the AEL we set using EPA's own methodology and the data available today.

Today's proposed decision to find nPB acceptable under the SNAP program is based in part on its relatively low ozone depletion potential when emitted within the continental United States. However, the ODP of nPB varies with latitude; therefore, this decision should not guide decisions of other countries. For example, nPB emitted closer to the equator has a significantly higher ozone depleting potential than nPB emitted from the middle and northern latitudes, which include the continental United States (for a further discussion, see section IV.B. below on Ozone Depletion Potential). EPA recommends that any decisions on the use of nPB outside the U.S. should be based on latitude-specific ODPs and volumes of the chemical projected to be used in those regions.

A. Toxicity

A primary concern regarding nPB use in the United States is its potential adverse health effects to exposed workers. Since EPA recommended a preliminary exposure guideline in 1999, additional studies have been conducted on the toxicity of nPB and its isomer, iPB. EPA has reviewed available toxicity data in order to develop a contamination limit for iPB and an Acceptable Exposure Limit (AEL)[4] for occupational exposure to nPB that are protective of human health. EPA has also reviewed workplace exposure measurements from several facilities where nPB has been used.

1. What Acceptable Exposure Limit Is EPA Recommending for n-Propyl Bromide, and Why?

Today, EPA is recommending an AEL for nPB of 25 ppm as an eight-hour time-weighted average. Based upon currently available data, EPA believes that workers can be exposed to an average nPB concentration of 25 ppm without appreciable risk of adverse health effects. In addition, like many halogenated solvents, nPB has the potential to be absorbed through the skin, so we recommend avoiding skin exposure to nPB by wearing protective clothing and flexible laminated gloves. The discussion below describes the derivation of the recommended AEL of 25 ppm for workplace exposure.

a. Summary of toxicity studies. EPA reviewed all the studies listed in docket numbers A–2001–07 and A–91–42 and the studies cited as references in Section XI at the end of this preamble. The epidemiological data on nPB are limited. An anecdotal report by Sclar described neurotoxic effects seen in one patient who used an nPB-based solvent (Sclar, 1999). Another recently published paper describes three women exhibiting signs of peripheral and central nervous system toxicity, such as stumbling, numbness, urinary incontinence, diarrhea, nausea, difficulty in concentrating, dizziness, and headaches which was attributed to nPB exposure (Ichihara, 2002a). Because detailed exposure data are not available in either of these papers, it is difficult to use this information in a risk assessment. Vibration sense deficits, decreased nerve conduction, and reduced scores on neurological functional tests were reported in female workers in China exposed to nPB between <1 ppm and 49 ppm (Ichihara *et al.*, 2002b). The study authors concluded that their findings suggest that exposure to nPB at levels below or around 50 ppm may affect peripheral and central nervous system function. However, because only an abstract of the study was available to EPA, it was not possible to determine if the exposures and effects were well-characterized or if the sample was large enough to draw reliable conclusions. As discussed below in section IV.A.1.e, ''Feasibility of meeting the AEL for nPB in each industrial sector,'' NIOSH has performed a number of health hazard evaluations with measured workplace exposures to nPB. However, only one of these studies attempted to assess health effects (NIOSH, 2002). In this study, NIOSH conducted a voluntary medical survey and performed a complete blood count on those workers who chose to participate (43 out of 70 workers participated). The medical survey included questions on whether workers had headaches at least once per week, and whether workers had difficulty having children. No exposure-response relationship could be identified from these data. The survey was not designed to fully characterize effects on the reproductive system, nor did the study employ a control group (a group of workers who were not exposed to nPB), further limiting the utility of this data for risk assessment.

The acute toxicity of nPB has been studied in Sprague-Dawley rats for inhalation (Elf Atochem, 1997), oral (Elf Atochem, 1993), and dermal (Elf Atochem, 1995b) routes of exposure. The 4-hour LC50 (lethal concentration for 50% of the test animals) for inhalation of nPB was 35,000 mg/m3 (Elf Atochem, 1997), with death resulting from pulmonary edema. The LD50 (lethal dose for 50% of the test animals) for gavage dosing of nPB was greater than 2,000 mg/kg (Elf Atochem, 1993).

Animals receiving 2,000 mg/kg nPB dermally (with occlusion of the exposure area) showed no cutaneous reactions and no evidence of toxicity (Elf Atochem, 1995b). A skin sensitization test in Guinea pigs was also negative (Elf Atochem, 1995c).

Key chronic and subchronic toxicological studies on nPB include a 28-day inhalation study (ClinTrials, 1997a), a 90-day inhalation study (ClinTrials, 1997b), a two-generation reproductive toxicity study (WIL, 2001), and various papers and abstracts published in peer-reviewed scientific journals (Ichihara, 1998, 1999, 2000a, 2000b; Kim, 1999; Wang, 1999; Yu, 2001; Ichihara 2002a, 2002b). The results of these studies consistently show that sensitive health endpoints[5] (*i.e.*, the biological effects occurring at the lowest levels of nPB exposure) include effects on the liver (centrilobular vacuolation—cellular changes in the central area of the liver) and on the male reproductive system (decreases in absolute and relative seminal vesicle weights, and reduced sperm count, motility and maturation, and effects on sperm shape).

The ClinTrials 90-day inhalation study showed liver effects at exposures of 400 ppm and above, which is consistent with the effects seen by Kim *et al.* (1999). Effects of nPB on the central and peripheral nervous system have also been reported, including peripheral nerve degeneration and axonal swelling in the spinal cord at 1000 ppm (Yu, 2001), degeneration of the myelin of peripheral nerves at 800 ppm (Ichihara, 1999), and significantly decreased hind limb grip strength (a measure of motor nerve function) at 400 ppm (Ichihara, 2000b).

Concerns over potential reproductive toxicity associated with nPB were initially raised because exposure to iPB,

[4] An AEL is the SNAP program's generic term for an eight-hour time-weighted average occupational exposure limit.

[5] An endpoint is an observable or measurable biological event or chemical concentration (*e.g.*, metabolite concentration in a target tissue) used as an index of an effect of a chemical exposure.

a structural analog of nPB, was associated with significant reproductive effects in both male and female workers (Kim, 1996; Park, 1997; Ichihara, 1997). In animal studies, iPB has been shown to induce estrous cycle alterations, decreases in accessory sex gland weights (*e.g*, seminal vesicle, prostate), reductions in sperm counts and sperm motility, and changes in sperm morphology (Yu, 1997; Ichihara, 1997; Kamijima, 1997). Results presented by Ichihara and colleagues indicated that nPB exerts some level of reproductive toxicity in rats (Ichihara *et al.*, 1998, 1999; Wang, 1999).

More recently, two studies have reported effects of nPB on the female reproductive system in rats. In the first study, female rats were dosed at 0, 200, 400, and 800 ppm for eight hours a day for 7 weeks. Tests of vaginal smears showed a significant increase in the number of irregular estrous cycles with extended diestrus [6] in the 400 and 800 ppm dose groups, and dose dependent reduction of the number of normal antral follicles in the 400 ppm group (Yamada, 2003). In the second study, female rats were exposed to 1000 ppm nPB for 7 days per week for three weeks. The ratio of the number of estrous cycles of 6 days or longer to the total number of estrous cycles was calculated for the 1000 ppm exposure group and the control group. This ratio was two times higher in the exposed animals than controls, however, this difference was not statistically significant (Sekiguchi, 2002).

In 1999, the Brominated Solvents Consortium (BSOC), a group of several nPB manufacturers, initiated a two-generation study (WIL, 2001) designed to investigate thoroughly the reproductive toxicity of nPB, as well as to provide additional information on other toxic endpoints of concern, including liver effects, and effects on the central nervous system (CNS). In this study, groups of 25 male and female rats were exposed to nPB via whole-body inhalation. The F0, or first generation, animals were exposed to target air concentrations of 0, 100, 250, 500, or 750 parts per million (ppm) of nPB for 6 hours/day, 7 days/week for at least 70 days prior to mating. The F1, or second generation, animals were exposed to 0, 100, 250, or 500 ppm nPB (infertility in the F0 750 ppm group precluded having an F1 750 ppm group). Exposure of male animals in both generations continued throughout mating to the day prior to study termination. Exposure for female animals in both generations continued throughout mating and gestation through gestation day 20. After birth of the pups, the females' exposure continued on lactation day 5 through the day prior to study termination.

In this study, fertility was compromised significantly at 500 ppm, and no live offspring were produced at 750 ppm. There was strong evidence of dose-response in both the parent (F0) and offspring (F1) generations for a constellation of reproductive effects in both males and females, including decreases in sperm motility and changes in sperm morphology, reduced numbers of implantation sites and changes in estrous cycles, and reduced litter size. There were slight decreases (only some of which were statistically significant) at 250 ppm, and even 100 ppm for some reproductive endpoints. Statistically significant effects were observed at 250 ppm for reduced prostate weight in F0 males and increased estrous cycle length F1 females. Sperm motility in the 250 ppm group of F1 males was slightly reduced (84.8%) compared to the control group (88.9%). The difference was statistically significant ($p<0.05$). The study authors noted, however, that the sperm motility percentage for F1 males was slightly higher than the mean value in the WIL Research Laboratories historical control data (83.2%). Therefore, the authors did not attribute the reduction in sperm motility to exposure to nPB at 250 ppm. Male reproductive effects were consistent with those identified in the Japanese studies previously cited (Ichihara *et al.*, 1998, 1999, 2000a; Wang, 1999).

Liver effects similar to those reported in the ClinTrials (1997b) 90-day inhalation study were observed in males and females in both generations. Increases in liver weights occurred in both sexes following exposure to 500 ppm; corresponding increases in the incidence of minimal to mild hepatocellular vacuolation were observed at 250 ppm in males and 500 ppm in females. The adverse effects on the central and peripheral nervous system reported by Yu (2001) and Ichihara (1999, 2000b) occurred at higher doses than those associated with reproductive and liver effects in the two-generation study.

Carcinogenicity/Mutagenicity. Limited *in vitro* screening assays testing for mutagenicity and potential carcinogenicity have been conducted on nPB. Two studies have been performed investigating the potential mutagenicity of nPB in bacterial strains. Barber *et al.* (1981) exposed five *S. typhimurium* strains (TA98, TA100, TA1535, TA1537 and TA1538) to five different vapor concentrations of nPB ranging from 1.1 to 20.3 μmol/plate (135–2497 μg/plate). Exposures were performed in a closed incubation system in the presence and absence of liver S9 fraction (from Arochlor-induced rats). Increases in revertants were observed in only strains TA100 and TA1535 in both the absence and presence of S9; increases were not reported in the other strains. Elf Atochem (1994) exposed the same bacterial strains to nPB concentrations of 100 to 100,000 μg/plate in both the absence and presence of liver S9 (from male Sprague-Dawley rats induced with Arochlor 1254). This protocol also used a closed system (closed stainless-steel vessels). The highest concentration was slightly cytotoxic; however, this assay did test up to the limit dose (5,000 μg/plate) recommended for bacterial reversion assays. Appropriate positive and negative controls were used to determine spontaneous background revertant frequency. No increases in revertants were reported in any strain or condition. Given these conflicting studies, the current data regarding mutagenicity of nPB in bacterial strains are equivocal. Unpublished studies of in vivo micronucleus formation (Elf Atochem 1995a) indicate that nPB is not clastogenic, and a published dominant lethal assay with NPB was negative (Saito-Suzuki *et al.* 1982).

In a cell death bioassay using cultured human liver cells (HepG2 hepatoma), the cytotoxicity of nPB was evaluated at concentrations ≤500 ppm (SLR 2001a). Results of the bioassay indicated that nPB was cytotoxic (measured as decreased cell viability) at the highest concentration tested (500 ppm). There were no positive responses reported at any concentration for tests that evaluated enzyme function, DNA damage, or DNA damage and repair when tested at concentrations up to 500 ppm. A closely related compound, ethyl bromide, is weakly carcinogenic in rodents (Haseman and Lockhart 1994), and iPB has been shown to induce reverse mutations in bacteria (Maeng and Yu 1997). Results from these screening assays for short-term genotoxicity do not suggest significant concerns regarding nPB's potential carcinogenicity, although more data are needed.

The National Institute of Environmental Health Sciences' National Toxicology Program (NTP) is planning to conduct carcinogenicity studies in both sexes of rats and mice, which will allow for more definitive conclusions. To date, the NTP has not initiated new experimental studies on nPB, and the data will not be available for several years.

[6] Diestrus is a period of sexual inactivity during the estrous cycle.

b. Derivation of an AEL for nPB.

Benchmark Dose Modeling Background. EPA considered two methods to derive a recommended acceptable exposure level for workplace exposure: (1) The use of the no-observed-adverse-effect level (NOAEL) to define the starting point of departure (POD) for the computation of a reference value, and (2) the use of benchmark dose-response (BMD) modeling to define the POD. Both methods are essentially a two-step process, the first step defining a POD, and then the second extrapolating from the POD to a lower, environmentally relevant exposure level. EPA's in-depth analysis uses the BMD modeling approach, for reasons explained below; however, under either approach, one arrives at a similar value.

The traditional approach to derive safe exposure limits for numerous chemicals regulated in a variety of programs, including the SNAP program, has been to first determine the NOAEL (or LOAEL if a NOAEL cannot be identified), use the NOAEL as the POD, and then apply uncertainty factors based on EPA's guidelines to determine an appropriate reference value. Using the NOAEL to determine a reference value has long been recognized as having limitations in that it: (1) Is limited to one of the doses in the study; (2) does not account for variability in the estimate of the dose-response, which is due to the characteristics of the study design; (3) does not account for the slope of the dose-response curve; and (4) cannot be applied when there is no NOAEL, except through the application of an additional uncertainty factor (Crump, 1984; Kimmel and Gaylor, 1988).

A newer analytic approach is to use benchmark dose modeling to define a point of departure for deriving a reference value or slope factor that is more independent of study design. For risk assessment of nPB, EPA followed the BMD guidelines to develop an AEL. The EPA Risk Assessment Forum has written guidelines for the use of the BMD approach in the assessment of non-cancer health risk (USEPA, 1995b), and the EPA Benchmark Dose Workgroup is in the process of drafting technical guidance for the application of the BMD approach in cancer and non-cancer dose-response assessments. Use of BMD methods involve fitting mathematical models to dose-response data and using the results to select a BMD that is associated with a predetermined benchmark response (BMR) at the low end of the observed range in the studies used, such as a 10% increase in the incidence of a particular lesion or a 10% decrease in body weight gain. The BMD derived from mathematical modeling is the central estimate of the dose/exposure associated with the BMR. The point of departure derived from BMD modeling, however, is the Benchmark Dose Lowerbound (BMDL), or the lower 95% bound on the dose/exposure associated with the BMR. Using the lower bound accounts for the uncertainty inherent in a given study (*e.g.*, small sample size), and assures (with 95% statistical confidence) that the desired BMR is not exceeded.

The advantage of the benchmark dose approach is that it considers response data across all exposure groups. For example, a benchmark dose can be calculated even in studies where a NOAEL could not be identified, *i.e.*, in studies where responses even in the lowest exposure group tested were considered adverse. Unlike the NOAEL/LOAEL, the benchmark dose does not have to be one of the exposure levels (dose groups) chosen in the experimental design. In a hypothetical experiment where groups of rats are exposed to a chemical at 0 ppm, 100 ppm, 500 ppm and 1,000 ppm, the NOAEL or LOAEL must be either 100 ppm, 500 ppm, or 1,000 ppm simply because those were the only levels tested in the experiment. However, the benchmark dose derived from the data in the same experiment could be 200 ppm, 750 ppm, or even 997 ppm depending on the shape of the dose response curve described by the data. EPA uses the BMD approach whenever possible because it provides a more quantitative alternative to identification of a point of departure than the traditional NOAEL/LOAEL approach (US EPA 1995b).

Dosimetric adjustments and application of uncertainty factors. Under either approach—NOAEL/LOAEL or BMD modeling—an adjustment to the point of departure for the calculation of a reference value may be necessary to calculate a ''human equivalent concentration'' (HEC) if there are differences between the exposure regime used in the toxicity studies and a typical workweek of 8 hours per day and 5 days per week. Once a POD and the corresponding HEC is identified, uncertainty factors (UFs) are applied to account for extrapolation uncertainties that could underestimate the chemical's toxicity potential for exposed humans (in this case, workers using nPB). According to standard risk assessment methods as delineated in Agency guidance (US EPA, 1994), UFs of up to 10 may be applied 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 (*e.g.*, interindividual variability);

(3) Data from subchronic studies are used to provide estimates for chronic exposure;

(4) Studies that only provide a lowest observed adverse effect level (LOAEL) rather than a no observed adverse effect level (NOAEL) or benchmark dose; or

(5) An incomplete data base of toxicity information exists for the chemical (US EPA, 1995b).

Finally, a modifying factor (MF), which is an additional uncertainty factor that is greater than zero and less than or equal to 10, may be used. The magnitude of the MF depends upon the professional assessment of scientific uncertainties of the study and data base not explicitly treated above, *e.g.*, the completeness of the overall data base and the number of species tested. The default value for the MF is 1.

It is important to note that EPA does not have specific guidelines for occupational studies. As such, EPA is applying its general risk assessment principles and adapting its methodologies, as appropriate to consider risk in an occupational setting. For example, as mentioned above, EPA is adjusting its exposure scenario to derive a human equivalent concentration (HEC) that is representative of workplace exposure, rather than continuous lifetime exposure.

Selection of Endpoints for Benchmark Dose Modeling. Based on EPA guidance, endpoints were selected for BMD analysis and for potential use as a point of departure using the following principles:

- Toxicological significance of the endpoint
- Relevance to humans
- Quality of study and dose-response data
- Reproducibility of effects across multiple studies.

EPA selected reduced sperm motility and increased liver vacuolation for BMD analysis because they met the above criteria, and because these effects were seen consistently throughout the toxicological database at low exposures. EPA guidance states that endpoints selected as appropriate for risk assessment should be modeled if their LOAEL is up to 10-fold above the lowest LOAEL. This ensures that no endpoints with the potential to have the lowest BMDL are excluded from the analysis. The selection of the most appropriate

BMDs to use for determining the point of departure must be made by the risk assessor using scientific judgement and principles of risk assessment, as well as the results of the modeling process.

Toxicological Evaluation for AEL Derivation. Benchmark dose modeling was conducted following EPA guidelines. EPA modeled six data sets for liver vacuolation and reduced sperm motility based on results from two studies to identify the lowest BMDL as a point of departure (POD).[7] EPA selected these endpoints for BMD analysis because they were consistently found to be the most sensitive effect across the many studies that were conducted on the compound. Further, these particular studies provided robust data on these endpoints so that BMD analysis could be conducted. Based on this analysis, sperm motility in the F1 males from the WIL (2001) study was selected as the POD as it would be protective for all effects of nPB. SLR conducted a BMD analysis using data sets for numerous endpoints from 5 studies, including the WIL (2000) and ClinTrials (1997b) studies used by EPA (SLR International Corp., 2001b).[8] SLR also identified sperm motility in F1 males from the WIL (2001) study as the lowest BMDL. The SLR BMD analysis is discussed further in section IV.A.1.d. The methods used in development of the AEL based on sperm motility are described below. It is important to note that the animals in the 2-generation study were dosed every day for six hours. As such, the dosing scenario used for the testing procedure does not exactly mirror the human exposure scenario in the workplace of 8 hours per day 5 days per week. However, it is still appropriate to consider the data because they address the most sensitive health endpoints, and because the BMDL is adjusted by deriving a HEC to account for workplace exposures. A more complete discussion of EPA's adjustment of the BMDL is contained in ICF, 2002a.

EPA did not use neurotoxic effects as endpoints for deriving an AEL value since we did not consider this to be one of the most sensitive endpoints. No neurotoxic effects were reported in the 2-generation reproductive toxicity assay (WIL, 2001), and no adverse effects were observed in the functional observational battery analysis, either in an abbreviated form in the 28-day study at exposure concentrations of 400 and 1,000 ppm (ClinTrials, 1997a), nor in the 90-day study at concentrations of 400 and 600 ppm (ClinTrials, 1997b). Although the NIOSH voluntary medical survey performed in 1999 attempted to assess symptoms of neurotoxic effects, no exposure-response trend for headache or other neurological effects could be identified from the data.

The vacuolation of the white brain matter that was observed in the 28-day study at all exposure concentrations was not observed in the 90-day study, indicating that this effect may be a transient response and not adverse. Further, the vacuolation was not dose-dependent and did not correlate with other gross CNS effects observed at 1,600 ppm in the 28-day study. In the 2-generation study, clinical signs were monitored and CNS effects were not observed at any exposure concentration (0, 100, 250, 500, and 750 ppm) in the F0 or F1 animals, nor were histopathologic lesions observed in the brain, spinal cord or peripheral (sciatic) nerve of rats in the 750-ppm group of the F0 generation in the 2-generation study or in the F1 population.

EPA's Benchmark Dose Software (BMDS) was used for model fitting and BMD and BMDL estimation. To derive a BMD and BMDL for reduced sperm motility in the F0 and F1 males from WIL (2001), the data were modeled as continuous effects. Following EPA's Benchmark Dose guidelines, BMDs and BMDLs were defined based on benchmark responses (BMRs) of 10% extra risk—that is, the level at which 10% of the animals would show adverse effects for a particular endpoint. BMDLs were defined as the 95% lower confidence bound on the corresponding BMD estimates. Confidence bounds were calculated by BMDS using a likelihood profile method. The data sets for the reduced sperm motility endpoint were quantitatively summarized by group means and measures of variability (standard errors or standard deviations). The models used to represent the dose-response behavior of these continuous endpoints are those implemented in EPA's Benchmark Dose Software which are the Power model, the Hill model, and the polynomial model. Goodness-of-fit for each model for a given data set was determined based on a likelihood ratio statistic. In particular, maximized log-likelihoods associated with the modeling were sequentially compared.

Based on the criteria below, the most appropriate mathematical model and its corresponding BMDL was chosen as the best fit for each of the data sets modeled:

1. Models with an unacceptable fit (including consideration of local fit in the low-dose region) were excluded. Visual fit, particularly in the low-dose region, was assessed for models that had acceptable global goodness-of-fit.

2. If the BMDL values for the remaining models for a given endpoint were within a factor of 3, no model dependence was assumed, and the models were considered indistinguishable in the context of the precision of the methods. The models were then ranked according to the Akaike Information Criterion (AIC), which is reported by the BMDS software to aid in comparing the fit of different models. The model with the lowest AIC (within the family of models) was chosen as the basis for the BMDL.

3. If the BMDL values were not within a factor of 3, some model dependence was assumed, and the lowest BMDL was selected as a reasonable conservative estimate, unless it was an outlier compared to the results from all of the other models. Note that when outliers are removed, the remaining BMDLs may then be within a factor of 3, and so the criteria given in item 2 would be applied.

BMDs for reduced sperm motility in F1 and F0 males were 276 ppm and 362 ppm respectively, and BMDLs were 169 ppm and 282 ppm. Consistent with EPA risk assessment guidance, the BMDL of 169 ppm for reduced sperm motility in F1 males (WIL, 2001) was selected as the POD. EPA considered whether a BMDL derived from the F1 generation should be used to determine a workplace exposure limit, particularly in relation to the potential mechanisms by which nPB exerts its effects on the reproductive system. While some mechanistic data are available on this subject, they are inconclusive and limited. The available data do not rule out the possibility that the effects on the F1 generation occurred as a result of effects on parental germ cells (sperm or ova) or effects mediated by changes to the endocrine system. Because of the lack of mechanistic data on developmental and potential transgenerational effects, it is most appropriate and protective, as well as consistent with EPA risk assessment

[7] Data sets that were modeled from the WIL study include sperm motility and liver vacuolation in the F0 and F1 generations. Data sets modeled from ClinTrials (1997b) were liver vacuolation in both males and females.

[8] SLR International Corp. (2001b) conducted BMD modeling on the following studies: ClinTrials (1997a), ClinTrials (1997b), Ichihara, *et al.* (2000a and b), and WIL (2001). Reproductive endpoints modeled included sperm count, retained sperm in seminiferous tubules, sperm deformities, sperm motility, epididymal sperm count, fertility index, litter viability, and plasma glucose levels. Other toxicological endpoints modeled included forelimb strength, hind limb strength, motor conduction velocity, distal latency time, plasma creatinine phosphokinase levels, brain cell vacuolation, liver vacuolation in males, and analysis in various parameters associated with effects on blood formation.

guidelines, to use the endpoint observed at the lowest effect level to derive the AEL. In this case, that endpoint is decreased sperm motility in the F1 generation.

The BMDL was multiplied by 6/8 and 7/5 in order to derive the HEC, which accounts for temporal differences between the exposure duration used in the study (6 hours per day, 7 days per week) and an 8-hour per day, 5-day work week. This results in a HEC for spermatic effects of 177 ppm. Uncertainty factors were then applied to the HEC, taking into account the following considerations listed below.

(1) An uncertainty factor is needed to account for physiological differences between humans and rats. EPA reference concentration (RfC) guidelines describe the factors that must be considered and state that an uncertainty factor 10 may be used for potential differences between study animals and humans. This factor of 10 is often thought to consist of two uncertainty factors of 3—the first to account for differences in pharmacokinetics [9] and another uncertainty factor to account for differences in pharmacodynamics [10] between the study animal and humans. (The value of 3 is the closest whole number to the square root of 10.) According to EPA RfC guidelines, no adjustment for differences in pharmacokinetics is necessary in this case since the blood/air partition coefficient [11] 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.

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 the pharmacokinetics of nPB conform to a model that requires several assumptions, in particular: (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 (*e.g.*, $BW^{3/4}$). 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. EPA requests additional data and comment from the public on nPB pharmacokinetics, metabolism, and mode of action that will help determine whether an interspecies uncertainty factor greater than 1 is appropriate 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, EPA would refine its risk assessment for nPB as necessary, and apply an uncertainty factor for pharmacokinetics in extrapolating from animal to humans. We would also revise our acceptability determinations accordingly.

With regard to the UF for pharmacodynamics, no data exist to compare the effect of nPB on human spermatocytes and rat spermatocytes. EPA does not have data suggesting that the default of 3 for pharmacodynamics should not be used. Thus, the full uncertainty factor of 3 for differences in pharmacodynamics was applied. EPA also requests comments and data on this uncertainty factor.

(2) Although workers employed in the types of industrial sectors that are part of this SNAP review likely represent a generally healthy population, pre-existing reproductive conditions as well as general variability in fertility would not impact a worker's overt health or employment status, and would be largely unobserved. It is estimated that 6% of adult males are infertile (Purves, 1992), and that 40%–90% of these cases are due to deficient sperm production of unidentifiable origin (Griffin, 1994). Given this information, EPA concludes that a significant portion of the male population has pre-existing reproductive deficits. EPA's risk guidelines for deriving community-based reference concentrations recommend a factor of 10 in accounting for intraspecies variability. EPA believes that in the case of nPB, a lower uncertainty factor is appropriate to account for variability within the worker population. This UF is intended to protect for potential ''unobserved'' reproductive medical conditions (*e.g.*, decreased sperm motility, aberrant sperm formation) that are known to exist among otherwise healthy males of working age. Because we are concerned about exposures in the workplace, not exposures to the full population, and because exposures would not be continuous, such as would be expected when developing an RfC, we employed an UF of three as an upper bound instead of the full uncertainty factor of 10 for intrahuman variability.

The following equation describes how EPA derives 18 ppm as a starting point in the development of a recommended AEL using a UF of 3 for variations in the human population, and 3 for pharmacodynamics:

$$169 \text{ ppm} * 6/8 * 7/5 * 1/3 * 1/3) = 18 \text{ ppm}$$

This derivation rests on assumptions that some may consider conservative, including the use of the F1 generation as the point of departure for workplace exposure, and the fact that reduced sperm motility may be a particularly sensitive endpoint for male reproductive effects. For a further discussion, see the next section below, ''AEL adjustment based on risk management principles.''

AEL adjustment based on risk management principles. Risk management uses risk characterization, along with directives of the enabling regulatory legislation and other factors, to decide whether to control exposure to the suspected agent and the level of control. Risk management decisions also consider socioeconomic, technical, and political factors (EPA Reproductive Risk Assessment Guidelines, 1996). Unlike many other chemicals being reviewed by SNAP, nPB is already in use. Therefore, a decision on the AEL that incorporates risk management considerations may be appropriate. Doing so is consistent with one of the original ''Guiding Principles'' of the SNAP program (59 FR 13046, March 18, 1994):

> EPA does not intend to restrict a substitute if it poses only marginally greater risk than another substitute. Drawing fine distinctions concerning the acceptability of substitutes would be extremely difficult given the variability in how each substitute can be used within a specific application and the resulting uncertainties surrounding potential health and environmental effects. 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.

If EPA adopted 18 ppm as the AEL, we would likely propose that use of nPB be listed as unacceptable in adhesives applications, based on data indicating that exposure to nPB in such uses regularly exceed 18 ppm on average. However, EPA has determined that adhesive operations can meet an AEL of 25 ppm with proper ventilation and

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

[10] Pharmacodynamics refers to the biochemical and physiological effects of chemicals in the body and the mechanisms of their actions.

[11] A ratio of a chemical's concentration between blood and air when at equilibrium.

controls (see Section IV.A.1.e., ''Feasibility of meeting the AEL for nPB in each industrial sector''). The AEL of 18 ppm was derived using assumptions that some may consider conservative. Following the SNAP principle referenced above, some slight adjustment of the AEL may be warranted after applying judgment based on the available data, and after considering alternative derivations.

To assess how much of an adjustment may be appropriate that would still be protective of human health, EPA considered potential sources of conservatism in the AEL derivation—specifically, the use of the BMDL in the F1 generation as a point of departure. To assess the magnitude of this conservatism, we derived an AEL based on the BMDL for reduced sperm motility in the F0 generation (282 ppm), the second most sensitive endpoint found in the 2-generation study. Deriving an HEC (296 ppm), and applying the same uncertainty factors as applied to the F1 generation (3 for intraspecies variability and 3 for differences in pharmacodynamics), would result in an occupational exposure limit of approximately 30 ppm. A derivation based on F0 data could be considered as a reasonable and protective upper bound for the occupational exposure limit. EPA requests comment on whether it appropriate to interpret 30 ppm as an upper bound for an occupational exposure limit.

EPA has determined 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 exposure limit. An AEL of 25 ppm would reduce overall risk to worker health while adhering to EPA's SNAP guiding principle of not finding a substitute unacceptable unless the proposed substitute is clearly more harmful than other alternatives. EPA specifically requests comment on this approach.

Dermal Exposure. EPA believes that workers should use good workplace practices and proper handling procedures to avoid unnecessary dermal exposure to all industrial solvents, including nPB. Similar to other halogenated solvents, nPB may defat the skin and may cause local irritation due to this characteristic. A skin notation is applied to those chemicals where ''dermal absorption contributes substantially to the overall systemic toxicity'' (skin notation documentation for methyl chloride; ACGIH, 1991). As described previously, the available acute dermal toxicity study in rats (Elf Atochem, 1995) indicates that acute dermal exposure to nPB does not result in systemic toxicity. Because significant dermal absorption of nPB was not demonstrated in this study, EPA is not including a skin notation for nPB along with our recommended AEL in the comments section of the regulatory text. The database regarding dermal toxicity for nPB is not as conclusive as the data for chemicals that have a skin notation, (*e.g.*, methyl chloride, dichlorvos). To apply a skin notation to nPB would imply that the dermal toxicity of this compound is similar to that of these other compounds. It is also noteworthy that there is no skin notation for other halogenated solvents such as methylene chloride or perchloroethylene, and there is no evidence that absorption through the skin is greater for nPB than for the other halogenated compounds. Thus, in EPA's judgement the database currently does not support the need for a skin notation for nPB.

However, we note that the acute dermal study did not provide information regarding chronic dermal absorption. Further, NIOSH evaluated the potential of nPB to permeate skin and promote chronic, systemic toxicity using a mathematical model and the log octanol::water coefficient for nPB, which is approximately 2. This evaluation found that nPB dermal exposure may be an additional source of exposure to workers if the unprotected skin of both hands is exposed (NIOSH, 2003). Given the above information, EPA specifically requests comment on whether to add a skin notation to our recommended AEL in the final rule if there are data that support this change.

c. Overview of the Evaluation of Risks to Human Reproduction (CERHR) Expert Panel Report on nPB. In December 1999, NIOSH submitted an assessment nomination to the National Toxicology Program's (NTP) Center for the Evaluation of Risks to Human Reproduction (CERHR) for both nPB and iPB. The NTP and the National Institute of Environmental Health Sciences (NIEHS) established CERHR in June 1998. CERHR's purpose is to provide timely, unbiased, scientifically sound evaluations of human and experimental evidence for adverse effects on reproduction, including development, caused by agents to which humans may be exposed.

nPB (1-Bromopropane) was nominated by NIOSH and selected for evaluation by the CERHR based primarily on documented evidence of worker exposures and published evidence of reproductive and developmental toxicity in rodents (this evidence is reviewed above in section IV.A.1.a). The evaluation of nPB was a four-month effort by a ten-member Expert Panel of academic, private and government scientists that culminated in a public meeting in December 2001. At that meeting, the Expert Panel reviewed the scientific evidence on nPB and reached conclusions regarding its potential effects on human reproduction and development. The Expert Panel Report on nPB was issued in March 2002 (CERHR, 2002a). An Expert Panel Report on iPB was issued at the same time and is discussed in section IV.A.4. of this preamble (CERHR, 2002b).

The Expert Panel Report on nPB is intended to: (1) Interpret the strength of scientific evidence that a given exposure or exposure circumstance may pose a hazard to reproduction and the health and welfare of children; (2) provide objective and scientifically thorough assessments of the scientific evidence that adverse reproductive/developmental health effects are associated with exposure to specific chemicals or classes of chemicals, including descriptions of any uncertainties that would diminish confidence in assessment of risks; and (3) identify knowledge gaps to help establish research and testing priorities.

NTP–CERHR sought public comment on the Expert Panel Report through a Federal Register notice on March 8, 2002 (67 FR 10734). The NTP has issued a final report, and has published all the public comments that were received on that report. These documents may be accessed through the CERHR Web site at *http://cerhr.niehs.nih.gov/news/bromo/index.html.*

The conclusions of the March 2002 Expert Panel Report on nPB were as follows:

- Available human data are insufficient to draw conclusions on the potential for reproductive or developmental toxicity.
- Available toxicological data were sufficient to conclude that nPB exposure can induce developmental and reproductive toxicity in rats. In evaluating the potential effects on human reproduction, the rat data are assumed to be relevant for humans.
- The mechanisms that lead to reproductive or developmental toxicity are unknown.
- There are no relevant kinetic or metabolism data for nPB to compare human and animal exposure levels.

The Expert Panel identified LOAELs from the body of animal data as follows:

- A LOAEL for male reproductive effects of 200 ppm based on decreases in absolute and relative seminal vesicle weight reported in Ichihara (2000b). A

NOAEL of 100 ppm was identified based on decreases in prostate weight observed at 250 ppm in WIL (2001).

- A LOAEL of 250 ppm, and a NOAEL of 100 ppm for female reproduction based on increased estrous cycle length in WIL (2001).
- A LOAEL of 250 ppm and a NOAEL of 100 ppm for mineralization of the kidney pelvis in both F0 and F1 generations, based on WIL (2001).

EPA agrees with the panel's conclusions that the available human data are insufficient to draw conclusions on the reproductive or developmental toxicity of nPB and that the mechanisms that lead to reproductive or developmental toxicity are unknown. EPA also agrees with the panel that a NOAEL for reproductive effects (male) would be considered to be 100 ppm under a traditional risk assessment analysis. However, based on the criteria described previously for selecting endpoints for BMDL analysis, we believe the CERHR endpoints are not appropriate for developing the AEL for nPB, as explained below.

Reduced seminal vesicle weight. EPA did not conduct BMD analysis for reduced seminal vesicle weight observed in the Ichihara (2000b) study because there is no consistency of effect across available studies for this endpoint. Reduced seminal vesicle weight was not found to be a sensitive endpoint in WIL (2001). In fact, a statistically significant reduction in seminal vesicle weight was only seen in the 750 ppm group in the F0 generation, and there were no statistically significant effects on seminal vesicle weight in the F1 generation. Because there were other endpoints that were more sensitive in the WIL study, we regard those endpoints to be of greater toxicological importance. Further, EPA believes that because the Ichihara study was not performed according to GLP guidelines, and there were conflicting reports regarding the exposure regime and the number of animals used, it is not appropriate to use this study in quantitative risk assessment.

Reduced absolute prostate weight. Based on the WIL study, the CERHR Expert Panel identified a NOAEL of 100 (with a LOAEL of 250) for reduced absolute prostate weight in the F0 males. The toxicological relevance of absolute prostate weight reduction is questionable since this endpoint may be associated with reduction in overall weight gain. To assess the significance of this particular endpoint, EPA calculated the mean relative prostate weights for exposed dose groups from the WIL (2001) study. Relative prostate weights (organ weight/body weight) in F0 males were 0.0040, 0.0039, 0.0036, 0.0035, and 0.0035 at 0, 100, 250, 500, and 750 ppm respectively, revealing that relative prostate weight at exposures greater than or equal to 250 ppm decreased only 10% relative to controls. Because the dose-response relationship in other endpoints was more pronounced, EPA did not conduct BMD modeling on this endpoint.

Increased estrous cycle length. The Expert Panel identified 250 ppm as a LOAEL for females based on increased estrous cycle length in the F1 generation of the WIL (2001) study. EPA agrees that the slight increase in estrous cycle length may be a result of nPB exposure. However, because the estrous cycle length of 4.9 days at 250 ppm is within the range of historical controls, the effect cannot be conclusively attributed to exposure without statistical analysis. The study report also notes lack of cycling in some females, which may have caused difficulty in accurately determining the average estrous cycle length for each affected group. Because these data are lacking, this endpoint should not be used for developing the AEL.

Mineralization of the kidney pelvis. The Expert Panel concluded that mineralization of the pelvis of the kidneys at 250 ppm was an adverse effect. EPA notes that mineralization of the kidney was not consistently associated with nPB exposure across different studies, and that in WIL (2001) the severity of mineralization did not increase above a category of minimal except at 750 ppm where it was mild. Therefore, EPA did not consider using this endpoint as useful for developing the AEL.

Sperm Motility. The Expert Panel identified 500 ppm as the LOAEL for reduced sperm motility. The Panel agreed with the WIL (2001) study authors that the slight but statistically significant reduction in the percentage of motile sperm in the F1 males at 250 ppm (85% vs. 89% in concurrent control animals) could not be attributed to nPB exposure since the percentage of motile sperm in this dose group slightly exceeded that of historic controls (83%). The data indicate that the small changes observed at 250 ppm are consistent with larger changes in sperm motility observed at 500 and 750 ppm. Thus, results for sperm motility in F0 and F1 males exhibited dose-related trends, and conformed to other principles for the selection of endpoints for BMD analysis (See earlier discussion in section IV.A.1.b.). Thus, regardless of whether a LOAEL of 500 ppm or 250 ppm is assigned to this particular endpoint, the Agency determined that reduction in the percentage of motile sperm in the F1 males is a good candidate for BMD analysis. In addition, it is important to note that the Panel did not have access to either the ICF or SLR International benchmark dose analyses. As discussed in section IV.A.1.b, benchmark dose modeling overcomes the issue of drawing a ''bright line'' in the form of a LOAEL or NOAEL and instead uses the full set of data across all exposure levels (ICF, Inc., 2002a; SLR International, 2001b). Using the results of benchmark dose modeling, it becomes clear that sperm motility is a sensitive effect, and is an appropriate effect upon which to base an AEL.

d. AELs suggested by other reviewers and outside parties. In the draft final nPB risk screen conducted for EPA in preparation for today's proposal, ICF Consulting states that ''Given the strength of the data base and the extrapolation of the data to occupational exposures, a range of uncertainty factors to account for variability in the human population of 2 to 3 is considered appropriate.'' (ICF, 2002a). EPA recognizes that the choice of UF relates to a wide range of considerations including the strength of the data base. Applying a range of UFs between 2 and 3 to account for intrahuman variability would yield a range of occupational exposure limits between 18 and 30 ppm. ICF suggested that the midpoint of this range, 25 ppm, was an appropriate occupational limit value for the purposes of the risk screen for nPB. EPA requests comment on this recommended approach in deriving an occupational exposure limit, including the application of uncertainty factors.

EPA's Office of Atmospheric Programs solicited comments regarding ICF Consulting's analysis and derivation of a recommended AEL from EPA's Office of Research and Development (ORD), external toxicologist William Brock, external toxicologist Darol Dodd, and the State of California, Department of Health Services, Hazard Evaluation System & Information Service (HESIS). The comments are available in docket A–2001–07.

ORD's comments focused on the WIL Research Laboratories two-generation study and its use in identifying sensitive endpoints. ORD noted that the study's results indicated dose-related trends, that a number of endpoints were significantly affected at 500 ppm in both generations, and there were slight—though in most cases not statistically significant—decreases at 250 ppm and even 100 ppm for some endpoints. They also stated that ''[i]n the absence of evidence of dominant lethality or trans-generational effects typical of endocrine

disrupting chemicals, it is reasonable to conclude that the effects of [nPB] are elicited in both sexes via their exposure as adults.'' They also noted that ''the modest degree of change in the 250 ppm F1 sperm motility endpoint (and lack of significance in the F0 at this dose) compared to the collective more robust changes at 500 ppm, in both the F0 and F1, indicates that 250 ppm could reasonably be considered a NOAEL for nPB, with 500 ppm being a LOAEL.'' Finally, ORD noted that ''even if the F1 data may not be directly applicable for occupational exposures in males, it certainly is applicable to occupational exposures of pregnant women.'' They conclude with suggestions for further research (Klinefelter and Darney, 2002).

EPA asked William Brock to review the draft AEL report from a general toxicological point of view. Dr. Brock is currently a senior manager with Environ Corporation. In his review, Dr. Brock noted that several subchronic studies in rats have been conducted with nPB with concentrations ranging from approximately 100 ppm to 1800 ppm. Biological effects have been on liver, male reproductive tissue, and, to some extent, hematological parameters. Although some of the studies have not been conducted according to GLP, this fact does not necessarily limit the usefulness of the studies to recommend an exposure limit. Overall, the sperm effect observed at 400 ppm and the effects on fertility at 500 ppm with hepatic vacuolation at 250 represent the PODs for setting exposure limits for nPB. The NOAEL for these effects would be 200 ppm. Dr. Brock notes that ''exposure limits that have historically been established are generally, but no[t] always, an order of magnitude below the NOAEL. Taking this approach would result in an occupational limit of 20 ppm (200/10). Although the ICF report could be improved by being more specific on effects and concentrations, the logic provided in the report and the end result, *i.e.*, a 25 ppm exposure limit, is certainly justified'' (Brock, 2002).

EPA asked Darol Dodd to review and comment on the draft AEL report (ICF, 2000a). Dr. Dodd is currently the Laboratory Director for ManTech Environmental Technology, Inc. In his comments, Dr. Dodd stated that the ICF report provided logical and consistent explanations for selection of the BMDL and uncertainty factors. He noted that several of the studies show LOAEL or NOAEL values at 200 ppm to 250 ppm. In his opinion, ''a recommended AEL value that is about one order of magnitude lower than LOAELs/NOAELs in a number of laboratory rodent studies does not appear to be overly protective'' (Dodd, 2002).

HESIS provided comments on the AEL derivation for nPB that focused on the available studies useful for low-dose risk assessment, identifying the LOAELs and NOAELs from these studies, and identifying their disagreements with the ICF evaluation. Overall, HESIS took issue with the approach used by ICF to derive an AEL: ''ICF repeatedly ignores or discounts effects seen with low-level exposures. At most points where a decision based on professional judgment must be made, ICF makes the choice that leads to the highest possible AEL.'' HESIS states that, contrary to the ICF approach, an appropriate risk assessment methodology would take a NOAEL, LOAEL or appropriate BMDL, and apply uncertainty factors of 10 for each of the following conditions: (1) Interspecies variation, (2) intraspecies variation, (3) reliance on a LOAEL rather than a NOAEL where necessary, and (4) extrapolation from acute or subchronic exposure to chronic exposure. The total uncertainty factor would be between 1,000 and 10,000. HESIS stated that appropriate endpoints and points of departure would be reduced pup weight seen in the Huntingdon (2001) study at 103 ppm, the neurotoxicity seen in Ichihara (2000a) at 200 ppm, reduced seminal vesicle weight and increase in tailless sperm seen at 200 ppm in Ichihara (2001a), reduced sperm motility at 200 ppm in Wang (1999), CNS pathology (vacuolation of white matter) at 400 ppm seen in ClinTrials (1997a), and from the WIL (2001) study, reduced fertility observed at 100 ppm and other adverse reproductive and kidney effects observed at 250 ppm or the lowest BMDL calculated from all studies. Using any of these points of departure, HESIS suggests that a reasonable AEL could range from less than 0.05 ppm to less than 5 ppm, and recommends an AEL of 1 ppm.

HESIS stated that, in deriving the AEL for the liver vacuolation, ICF used no uncertainty factor for interspecies pharmacokinetic variation, assuming ''without any basis, that gas exchange within the lung constitutes the entire pharmacokinetic variation between the species, simply because the blood-air partition coefficient is lower in humans than in rats.'' HESIS also disagreed with the use of no uncertainty factor for intraspecies variation for liver vacuolation. With regard to ICF's derivation of an AEL for sperm motility, HESIS disagreed with ICF's use of no uncertainty factor for interspecies pharmacokinetic variation for the same reason given for liver vacuolation. HESIS also stated that there ''is no data base at all on which to determine the likelihood and degree of interhuman variability in sensitivity to the spermatotoxic effect of [nPB] * * * .'' Finally, HESIS stated that nPB ''is an organic solvent that is probably well absorbed through the skin and should be listed with a skin notation * * * .''

A response from ICF Consultants to HESIS's comments is included in the docket (ICF 2002c). EPA concluded that the issues HESIS raises are, in fact, questioning EPA's risk assessment guidelines that were the basis for the AEL report, rather than comments unique to the AEL for nPB. For example, EPA's risk assessment guidelines allow use of a default uncertainty factor of 1 instead of 3 for pharmacokinetics for nPB and other inhaled gases where the toxicity is from the parent compound, rather than metabolites. As discussed above in section IV.A.1.b, we request comment and data that would confirm or refute the appropriateness of the assumptions in Appendix J of EPA's risk assessment guidelines. In addition, EPA disagrees that the uncertainty factor for variability in the worker population should be the same as that for variability in the general population (10). Because the working population does not include children or the elderly, as is the case for the general population, we do not believe that a full UF of 10 for sensitive subpopulations is necessary. Further, workers are only potentially exposed during a 40-hour workweek and not continuously, as would be expected for the general population. Finally, because of the length of the WIL Laboratories study, we do not believe that it is necessary to add an uncertainty factor to extrapolate from subchronic to chronic exposures.

Various chemical manufacturers and solvent formulators have derived their own recommended industrial exposure limits. Albemarle Corporation and Dead Sea Bromine Group, both of whom continue to produce nPB, recommend an AEL of 25 ppm in their Material Data Safety Sheets. Great Lakes Chemical and Atofina recommended AELs of 10 ppm and 5 ppm respectively, although neither of these companies currently sells nPB. Petroferm produces nPB formulations and recommends an exposure limit of 25 ppm. Finally, Enviro Tech International, Poly Systems International, TULSTAR Products, and Amity International, all of whom produce nPB formulations, recommend an exposure limit of 100 ppm.

In a November 6, 2000, meeting with EPA, Albemarle explained that its derivation of a workplace exposure guideline of 25 ppm is based upon raw

data from the two-generation reproductive study (WIL, 2001). In the fall of 2000, Albemarle analyzed preliminary data from the two highest exposure groups in two-generation study, 750 ppm and 500 ppm, and found evidence of reproductive effects. As a proactive measure while completing analysis of the data, Albemarle started with an exposure level of 250 ppm and divided by a safety factor of 10, yielding an exposure guideline of 25 ppm. EPA has not seen the derivation of Great Lakes Chemical Corporation's workplace exposure guideline of 10 ppm or Atofina's guideline of 5 ppm.

The AEL recommended by Enviro Tech International is based on two separate analyses. In the first analysis, Rozman and Doull (2001) recommend an AEL of 60–90 ppm based on the results obtained from a health questionnaire administered as a part of a NIOSH Health Hazard Evaluation at a site where nPB is used as an adhesive (NIOSH, 1999). This AEL derivation was subsequently published in *Applied Occupational Environmental Hygiene,* the ACGIH's journal, in 2002 (Rozman and Doull, 2002).

In their analysis, Rozman and Doull identified the most sensitive endpoint for nPB toxicity as peripheral/central neurotoxicity followed by reproductive toxicity and then liver toxicity. This ranking was based on a subchronic inhalation study by Ichihara (2000b) in which decreased hind limb strength in mice was observed following 4 weeks of exposure at 200 ppm. Rozman and Doull concluded that rats are more sensitive to reproductive effects of nPB than humans based on the NIOSH health survey (NIOSH 2002b), which did not identify any statistically significant reproductive effects in humans exposed to nPB. Based on the NIOSH health survey data, conducted at a facility where nPB was used as an adhesive solvent, Rozman and Doull identified 170 ppm as a no observed effect level (NOEL) in workers who reported having a headache more than once per week. They then applied a safety of 2 to protect nearly all workers, and a safety factor of 3 to provide a larger margin of safety from this adverse effect. This approach resulted in a recommended industrial exposure guideline for nPB of 60–90 ppm.

EPA does not agree with Rozman and Doull's AEL recommendation. First, their ranking of neurotoxicity as the most sensitive toxicological endpoint fails to take into account that in the Ichihara study, rats were dosed 8 hours per day for 12 weeks, while in the two-generation study, animals were exposed to nPB for 6 hours per day. Therefore, the exposure levels in the Ichihara study must be adjusted by a factor of 0.75 in order to directly compare doses to the 2 generation study. If this adjustment is made, the LOAEL for the Ichihara study becomes 266 ppm, higher than the LOAEL of 250 ppm for reproductive and liver effects identified in the two-generation study. Further, the results of the Ichihara study conflict with the results of the 90-day inhalation study (ClinTrials, 1997b), in which decreases in grip strength were not observed in rats exposed to levels up to 600 ppm nPB for 6 hours/day for 5 days/week. In fact, in the ClinTrials study, there were no consistent treatment-related changes reported in the rats following 4, 8, or 13 weeks of exposure in any parameter evaluated in a full functional observational battery (a suite of tests designed to assess a full spectrum of neurotoxic effects). Because the LOAEL for neurotoxic effects in Ichihara *et al.* (2000b) is actually higher than the LOAEL identified in the two-generation study, and because the findings on neurotoxicity from the Ichihara study conflict with the results of the 90-day ClinTrials (1997b) study, it is erroneous to conclude that neurotoxicity is the most sensitive endpoint for nPB exposure.

Second, the NIOSH medical survey used by Rozman and Doull is not a suitable basis for deriving an AEL. Use of epidemiological data for a quantitative risk assessment requires that the exposures be well-characterized, that the sample size be large enough to allow for the detection of subtle effects in a statistically significant way, and that comparisons to an unexposed control group be made. The data provided in the NIOSH evaluation do not fit these criteria: (1) The sample size in this study was relatively small (46 participants); (2) the health survey was not given to an unexposed control population for comparison; (3) no obvious exposure-response trend for headache was seen, since the low and medium exposure groups had similar prevalence of headache. For each of the neurological symptoms evaluated in the NIOSH health survey, air concentrations of nPB were not statistically different between those employees reporting the symptom compared to those not reporting the symptom (NIOSH 2002).

Finally, EPA disagrees with Rozman and Doull's conclusion that reproductive toxicity did not occur in workers exposed to up to 190 ppm of nPB, which is the basis for their assertion that humans are less sensitive to reproductive health effects of nPB compared to rats (Rozman and Doull, 2001). The NIOSH report states that 3 workers (2 male and 1 female) who had been exposed to between 110 and 157 ppm of nPB reported difficulty in having a child. However, as noted by the authors of the NIOSH report, due to the small sample size and the personal nature of the questions, there were significant limitations in the ability of the NIOSH medical survey to detect reproductive or fertility problems. The data from the NIOSH medical survey should not be used to conclude that rats are more sensitive than humans to reproductive effects of nPB, or to draw any general conclusions regarding the potential reproductive toxicity of nPB in humans.

In the second analysis submitted by Enviro Tech, SLR International Corporation derived an AEL for nPB of 156 ppm (SLR International, 2001b). We understand that this derivation is currently undergoing peer review for potential publication in a scientific journal. This analysis used benchmark dose-response modeling using data sets for several effects taken from the various animal toxicity tests that have been conducted with nPB. SLR derived a BMDL at a 10% response level of 156 ppm, based on reduced sperm motility in F1 males from the WIL (2001) study. This BMDL is similar to EPA's BMDL for sperm motility of 169 ppm. SLR stated that ''Due to the relative completeness of the toxicological database on nPB, including data on human *in vitro* bioassays, use of a UF is likely not considered necessary for this chemical.'' Thus, SLR's recommended AEL is equivalent to their BMDL. EPA maintains that an uncertainty factor is necessary for protection of sensitive individuals since low sperm count is a condition that can occur in otherwise healthy workers. There are no data indicating that human sperm are less sensitive than rat sperm. In fact, sperm production is less efficient in humans, suggesting that human males are likely to be more susceptible than rats to nPB (Amann, 1986). Further, based on EPA's RfC guidelines, an uncertainty factor of 3 is necessary to account for interspecies differences in pharmacodynamics between rats and humans. Had SLR applied what EPA considers appropriate uncertainty factors, their recommended AEL would have been 17 ppm.

In a memorandum submitted to Poly Systems International, Joel Charm, a certified industrial hygienist, supported the analyses by both SLR and Rozman and Doull. Mr. Charm suggested that establishing an occupational exposure level of 100 ppm as a ceiling value (i.e.,

a level not to be exceeded during any part of the working day), coupled with an effective Product Stewardship program, would help companies maintain exposure to their workers as low as reasonably achievable. He suggests that a Product Stewardship program focused on: (1) Training material on how nPB can be handled and used safely; (2) conducting industrial hygiene evaluations as a service to customers, to develop actual exposure level information for a variety of end uses under varying circumstances; and (3) monitoring the health (including reproductive parameters) of workers would, over time, aid in assessing the validity of the occupational exposure limit selected. He also states that through the Product Stewardship program and the regulatory reporting requirements of the Toxic Substances Control Act (TSCA), Section 8, corrective actions could be taken if necessary.

While we do not agree with the AELs derived by Rozman and Doull or by SLR, EPA agrees that producers and formulators of nPB should engage in responsible Product Stewardship programs. Albermarle Corporation has been conducting an extensive stewardship program for nPB involving air sampling and workplace practice evaluation for customers to help ensure exposures below 25 ppm. We also note that, in order to verify if exposure levels are below a ceiling value, it would be necessary to monitor workplace exposure continuously. Periodic evaluations of exposure levels would be sufficient for determining long-term exposure to workers. EPA recommends that workplace exposures should be controlled to levels at or below the AEL in order to avoid risk of adverse health effects.

e. Feasibility of meeting the AEL for nPB in each industrial sector. Each of the three sectors EPA is considering in today's proposal could potentially expose workers to nPB in different ways. Therefore, we considered separately whether it is feasible to meet the AEL in each of the three sectors. If EPA becomes aware of further information showing that nPB use is likely to pose unacceptable risks to human health in particular applications or end uses, we will find nPB unacceptable in those applications or end uses.

Solvents cleaning. When using industrial cleaning equipment, workers are likely to be exposed to solvent vapors continually over the course of a workday. However, users can control nPB emissions from vapor degreasers by changes to the equipment, as well as changes in operating practice. For example, a user can install an additional set of condensation coils to prevent vapor from leaving the vapor degreaser or defluxer. An operator can tilt pieces to be cleaned to allow the solvent to drain off inside the vapor degreaser instead of evaporating outside of the degreaser where workers will breathe the vapors.

Exposure data on nPB used in vapor degreasers indicate that it is possible to maintain exposure levels from 2 to 24 ppm over an 8-hour average, as measured using personal samplers (Albemarle, 1997). In 1998, Albemarle Corporation also collected workplace monitoring data from metal cleaning operations. Many, although not all, of the samples collected showed concentrations that, extrapolated to an 8-hour period, would remain under 25 ppm. In addition, another manufacturer and distributor of nPB-based solvents stated that, ''For a properly designed, installed, operated, and maintained traditional open-top vapor degreaser, experience has shown that eight-hour time weighted operator exposure levels will be < 20 ppm. For enclosed and automated degreasers, lower exposures can be achieved'' (Amity UK Ltd, 2001).

EPA has only one set of direct exposure data for equipment that cleans using nPB below its boiling point (''cold cleaning''). These data are from a NIOSH Health Hazard Evaluation for a company that produces instrumentation and components for radio and microwave frequency communications. In this study, NIOSH measured exposures to nPB from a cold batch cleaner that was in a special enclosed room with a local exhaust ventilation system. The highest exposure level was 8.4 ppm (NIOSH, 2000b). However, the type of enclosure and ventilation used at this site is not typical of most facilities using cold cleaning equipment.

In general, it is expected that it will be more difficult to control emissions from cold cleaning equipment than from vapor degreasers. The design of vapor degreasers reduces emissions from the equipment by boiling the solvent and then causing it to condense, rather than allowing solvent vapors to be emitted. Because cold cleaning equipment may expose workers to high levels of nPB, we recommend that nPB not be used in cold cleaning equipment unless additional engineering controls are instituted to keep worker exposure to levels below the recommended AEL of 25 ppm.

The limited data available on manual cleaning indicate that it may be difficult to attain exposures less than 50 ppm when wiping with nPB by hand (Albemarle, 2001). The SNAP program currently does not regulate manual cleaning with solvents. However, we recommend that nPB not be used for manual cleaning because of the likelihood of high exposures.

Aerosol Solvents. Only limited data are available on exposure levels to nPB from aerosol solvent usage. Four measurements on a single user showed exposures to nPB that ranged from 5 to 14 ppm over an 8-hour time-weighted average (Albemarle, 2001). Since the user was cleaning brakes on public works equipment, it is possible that the mechanic was working outdoors, or in an area that was only partially enclosed. EPA expects that these data are not representative of the diverse conditions under which aerosol solvents are used. Confidential data from another facility revealed that exposures vary greatly and in some instances can be higher than 200 ppm. In contrast to vapor degreasers, aerosol solvents tend to be used intermittently for short periods of 1–2 minutes. In some cases, aerosols containing nPB are used in confined spaces without ventilation ducts and fans where workers could be exposed to high levels over a short time. Emissions from aerosols are typically not controlled with equipment that captures the nPB vapor, although aerosol users can improve ventilation and reduce exposure levels through a variety of approaches (e.g., fume hoods). Given this information, EPA requests further workplace exposure data on nPB's use as an aerosol solvent. In addition, we request comment on whether nPB should be acceptable for use as an aerosol solvent, or if its use should be limited in this end use (e.g., use limit restricting nPB only to applications with ventilation equipment).

EPA believes that users should adhere to a short-term exposure limit (time weighted average over 15 minutes) of three times the AEL. We recommend this short-term exposure limit, which would equal 75 ppm over 15 minutes, in addition to the 8-hour time weighted average of 25 ppm. We believe that limiting short-term exposure to 75 ppm in a 15 minute period of exposure is feasible with proper ventilation and/or low use volumes. We also recommend only using aerosols containing nPB in open or well-ventilated areas. This procedure is recommended for use of any aerosol solvent, compared to use in enclosed, unventilated areas.

Adhesives. In adhesives applications, exposures are expected to vary depending upon the particular kind of application. For example, in the foam-fabrication industry, workers generally are exposed to evaporating solvents on

a long-term basis. When adhering tops on counters or tables, workers are more likely to have breaks between exposure, with short-term exposure being of greater concern (HSIA, 2001).

EPA is aware that it may be difficult to meet the recommended 25 ppm AEL in adhesive applications that are highly emissive. Exposure data from nPB used in adhesives in the foam-fabrication industry show high nPB concentrations within the workplace. At three different foam-fabrication facilities, NIOSH investigators reported that mean exposures to nPB ranged from 60 to 381 ppm (8-hour time weighted averages) (NIOSH, 1999, 2000a, 2000c, 2001). In one facility, average nPB exposures were reduced from 169 ppm to 19 ppm, following installation of ventilation equipment recommended by NIOSH (NIOSH, 2000c). Although use of spray booths at this facility had a dramatic effect of reducing average exposures to nPB, a significant percentage of workers whose jobs required direct use of spray adhesive containing nPB continued to have exposures in excess of 25 ppm. Among sprayers and assemblers working in the Assembly area, 2 of 10 (20%) full-shift samples exceeded 25 ppm, and among sprayers working in the Covers department, 9 of 11 (81%) of samples exceeded 25 ppm, with a maximum of 58 ppm (time-weighted average, TWA). These findings indicate that it may be necessary for employees to wear appropriate respiratory protection where engineering controls do not reduce exposures to or below the AEL. Where respirators are used to protect workers against nPB, employers should be aware that OSHA's Respiratory Protection standard (29 CFR 1910.134) would apply.

Because there is evidence that workplace exposures to nPB can be reduced to levels close to or below the recommended AEL, the Agency has concluded that it is appropriate to find the use of nPB acceptable in adhesive applications. Nevertheless, EPA expects that businesses using nPB in adhesive applications may have difficulty meeting the recommended exposure limit without some form of engineering controls such as confining operations to spray booths with ducts and a fan providing ventilation. Further, although use of spray booths at this facility had a dramatic effect of reducing exposures to nPB, as discussed above, some workers whose jobs required direct use of spray adhesive containing nPB continued to be exposed to nPB in excess of 25 ppm. Given this information, EPA requests comment on whether nPB should be acceptable for use in adhesives.

EPA conducted a detailed risk screen for nPB use in adhesives applications in the foam fabrication industry (ICF, 2001a , Attachment C) since this represents the most emissive use, and the use where workers and the general population have the highest exposures. Because this highly emissive use passed our risk screen, we did not conduct a formal risk screen for the solvents cleaning sector and aerosol solvents sectors end use, because emissions and worker exposures in these uses are expected to be lower than the adhesives end use.

2. Are There Other Entities That May Set or Recommend Workplace Standards?

Under the National Technology Transfer and Advancement Act of 1995, Section 12(d), Public. Law. 104–113, Federal agencies are required to consider using technical standards that are developed or adopted by voluntary consensus standards bodies, using such technical standards as a means to carry out policy objectives or activities. No such standards for occupational exposure to nPB currently exist. In comparison, the American Conference of Governmental Industrial Hygienists (ACGIH) has established threshold limit values (TLVs) for the primary chlorinated solvents used in the same applications as nPB. The most current TLVs for these solvents—25 ppm for perchloroethylene, and 50 ppm for trichloroethylene and methylene chloride—are identical or moderately higher than our proposed recommended guideline for nPB. It is possible that the American Industrial Hygiene Association (AIHA) or the ACGIH will review the toxicity of nPB in the future and set a voluntary standard. AIHA may develop a Workplace Environmental Exposure Limit (WEEL) for nPB. Further, in 2002, the ACGIH listed 1-Bromopropane and 2-Bromopropane (nPB and iPB, respectively) in its list of ''Chemical substances and other issues under study.'' If either of these standard-setting bodies recommends an exposure limit on nPB, we would make that information available to the public for comment.

In the future, OSHA may develop a mandatory exposure limit for nPB use in the workplace. The result of OSHA's review could result in a permissible exposure limit (PEL) different from EPA's recommended exposure limit of 25 ppm. Unlike nPB, the chlorinated solvents are regulated by OSHA and have been regularly re-evaluated by OSHA, NIOSH, and EPA (*e.g.*, as a National Emission Standard for Hazardous Air Pollutants). The most current permissible exposure limits for these solvents established by OSHA are 25 ppm for methylene chloride and 100 ppm for perchloroethylene and trichloroethylene. The OSHA permissible exposure levels for perchlorethylene and trichloroethylene of 100 ppm were originally issued on 1971 based on the 1968 threshold limit values established by the ACGIH. Since then, ACGIH has issued TLVs of 25 ppm for perchloroethylene and 50 ppm for trichloroethylene and OSHA has issued a PEL of 25 ppm for methylene chloride; as such, the Agency does not believe that a 25 ppm recommended AEL for nPB would result in a significant competitive advantage for any of these solvents. As stated earlier in this preamble, EPA defers to OSHA in regulating workplace safety. The recommended AEL in today's proposal is an interim measure in the absence of an OSHA PEL. Thus, any PEL that OSHA sets would supersede EPA's recommended AEL.

3. Is the General Population Exposed To Too Much nPB?

As a part of the SNAP review process for alternative chemicals, EPA also considers exposure to the general population. Near facilities that use nPB in non-emissive applications such as vapor degreasing, exposure is expected to be insignificant. For emissive applications of nPB, such as an adhesive solvent in foam fabrication, we conducted a more detailed assessment of potential exposure to people living in the immediate vicinity of a facility. We first estimated a community exposure guideline, using EPA's Methods for Derivation of Reference Concentration Guidelines (1994) as a risk index to compare against potential community exposure. 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. Community exposure guidelines can be derived from a NOAEL, LOAEL, or benchmark concentration, with uncertainty factors generally applied to reflect limitations of the data used. Average daily exposures of people living close to facilities where nPB is used in an emissive application were then estimated and compared to the community exposure guideline to determine whether nPB exposure presents an appreciable risk to the general population.

EPA derived the community exposure guideline for nPB using the same critical

studies and BMDLs for spermatic effects and liver effects that were used in developing the AEL. Adjustments were made to account for continuous lifetime exposure and sensitive subpopulations. The lowest BMDL of 110 ppm was based on the incidence of liver effects (centrilobular vacuolation) in the two-generation reproductive study (WIL, 2001). Using EPA's dosimetry guidelines for a category 3 gas (US EPA, 1994), and making adjustments to account for continuous exposure, the human equivalent concentration (HEC) is 110 ppm * (6 hours/24 hours) = 27.5 ppm. No adjustment for differences in pharmacokinetics was necessary based on EPA's RfC guidelines. EPA applied an UF of 3 for extrapolation from rat to human pharmacodynamics. An additional factor of 10 was applied for intrahuman variability including the protection of sensitive subpopulations (*e.g.*, individuals with liver disease, children, or the elderly). Therefore, the total uncertainty factor was 30 (3 for differences in pharmacodynamics, 10 for sensitive subpopulations). The application of the uncertainty factor of 30 to the HEC of 27.5 ppm results in a community exposure guideline of approximately 1 ppm. EPA requests comment on the appropriate use of uncertainty factors for the community exposure guideline.

The next lowest BMDL (169 ppm) was for the effects on sperm motility in the second generation of male rats in the two generation study. In the derivation of a community exposure guideline RfC for this endpoint, EPA adjusted the BMDL to account for continuous exposure averaged over 24 hours a day, resulting in an HEC of 42 ppm. An uncertainty factor of up to 10 may be applied for animals to human extrapolation in consideration of potential differences in pharmacokinetics and pharmacodynamics. However, for the reasons listed earlier, we did not consider an uncertainty factor necessary to account for differences in pharmacokinetics. The results of the in vitro studies conducted with liver cells do not allow us to draw any conclusions regarding the relative sensitivity of the human and rat spermatocyte to nPB. Consequently, EPA applied a factor of 3 for differences in pharmacodynamics. Finally, an uncertainty factor of 10 was applied for intrahuman variability including the protection of sensitive individuals in the general population (*e.g.,* children whose sex organs are in development, pregnant women, and individuals with low fertility). An overall uncertainty factor of 30 results (3 for differences in pharmacodynamics, and 10 for the protection of sensitive individuals). The application of the overall uncertainty factor (30) to the HEC (42 ppm) results in a community exposure guideline an RfC of approximately 1 ppm. The estimated community exposure guideline values are identical for both liver and reproductive effects. Consequently, EPA estimated that a RfC community exposure guideline of 1 ppm would be protective for all health endpoints—that is, someone exposed to an average of 1 ppm of nPB, 24 hours of every day during a lifetime, would not be at appreciable risk for adverse health effects during their lifetime.

The next step was to determine whether people living close to sites where nPB is used in emissive applications could potentially be exposed to levels above the estimated RfC community exposure guideline of 1 ppm. Data collected from actual facilities (CCPCT, 2001) used to characterize two scenarios: (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.

EPA's SCREEN3 (US EPA, 1995a) air dispersion model was used to assess the likely maximum-potential concentration of nPB from single sources. This technique is typically used to evaluate air quality impacts of sources pursuant to the requirements of the Clean Air Act, such as New Source Review and air toxic regulations. The approach applied here was the initial-phase approach used to determine if either: (1) The source clearly poses no air quality problem or (2) the potential for an air quality problem exists. If a potential problem exists, then a more refined analysis is necessary.

The results from our screen indicated that modeled exposures in either scenario did not exceed the RfC of 1 ppm. The urban scenario where a facility uses fans to ventilate nPB horizontally (through windows or other openings in the walls as opposed to openings in the roof), modeled exposures of 0.24 ppm at a distance of 3 meters away from the source, 0.19 ppm at 5 meters from the source, and 0.13 ppm at 10 meters from the source. These levels were by far the highest concentrations of nPB exposures modeled. The majority of modeled exposures were at least an order of magnitude lower, and ranged from 0 ppm to 0.08 ppm. 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 adhesive application sites is not a major concern. A memo describing the risk screen in detail may be found in the public docket (ICF, 2002a).

4. What Limit Is EPA Proposing on Isopropyl Bromide Contamination of nPB as a Condition of Acceptability, and Why?

Isopropyl bromide (iPB or 2-bromopropane), an isomer of nPB (1-bromopropane), is a contaminant that is created to different degrees in the manufacture of some nPB formulations. In reviewing the toxicological risks of iPB, EPA initially was concerned that its molecular structure was similar to chemicals that are potent reproductive toxins and carcinogens. This concern focused on the position of the halogen atom within the compound. There are toxicological data that indicate that when the halogen atom is located on the second carbon, there may be increased potential for the compound to cause cancer when compared to the compound with the halogen atom on carbon number 1. One example of this is the differential toxicity of 1-nitropropane and 2-nitropropane. Inhalation exposure to 2-nitropropane has been linked to liver toxicity in humans and has resulted in liver, and to a lesser extent, lung toxicity in male and female Sprague-Dawley rats (US EPA, 1991); it has also been shown to induce liver cancer in both Sprague-Dawley (IARC, 1992) and Fischer rats (Fiala, 1995). 1-Nitropropane has shown no carcinogenic potential to date.

Direct data on the carcinogenic potential of iPB are limited, although it has been shown to induce reverse mutations in bacteria (Maeng and Yu, 1997). Further, iPB was shown to be more cytotoxic and genotoxic to human liver cells than nPB and other toxins, including methylene chloride and trichloroethylene (SLR, 2001a). The combination of the position of the bromine atom in iPB (and its relationship to the carcinogenic potential of the compound) and the genotoxicity of the compound in bacterial and human cells indicate that caution is necessary when recommending an acceptable exposure concentration for iPB.

In the limited animal testing data available, iPB has been shown to be inherently more toxic than nPB on reproductive and hematopoietic endpoints. In two separate studies, significant disruptions in the estrous cycles and abnormal growth in uterine cells were reported in female rats

exposed to iPB daily for 9 weeks (Kamijima, 1997a, 1997b; Yu, 2001). Daily exposure of male rats to iPB at 300, 1000, and 3000 ppm was associated with effects ranging from reduced body and organ (e.g., kidneys, liver, testis) weight, reduced sperm counts and sperm motility, abnormal sperm, reduced red blood cell and platelet counts, and hemoglobin volume (Ichihara, 1997). A recent study has been published (Sekiguchi, 2002) in which the effects of iPB exposure on the reproductive physiology of female F344 rats were investigated. The rats were exposed to air (in the control group, the number of animals, n, is 7) or 50 (n=6), 200 (n=7), or 1000 (n=9) ppm of iPB via whole-body inhalation for 8 hours/day for 21–24 days (exact number of days not specified in the article). A larger number of females at the high concentration exhibited an estrous cycle of >6 days (7 of 9 animals) than those at the control, low- and mid-concentration (4, 2, and 3, respectively) which corresponded to the greater number of estrous cycles lasting >6 days (9 of 34 animals) in the high-concentration group as compared to the other groups (4 of 31, 4 of 30, 3 of 30). A dose-dependent increase in the number of days/cycle was observed in rats at 200 and 1000 ppm. These increases did not reach statistical significance, however. A smaller number of females per group was analyzed for uterine and ovary weights because only rats showing the estrous stage upon vaginal smear test were chosen for autopsy (5, 5, 5, and 7, respectively in the low-, mid-, and high-concentration groups). No changes were noted in the weights of ovaries or uterus, or in the number of ovulated ova among any of the female groups (exposed or controls). Although this study indicates that iPB was not a strong reproductive toxin in the female rat, the small number of animals exposed is a significant limitation to the study. The dose dependent increase in estrous cycles observed at 200 and 1000 ppm suggest the potential for reproductive failure from exposure to this compound. These results also indicate the need for additional studies using greater numbers of exposed animals.

Both male and female workers occupationally exposed to iPB have been found to exhibit some of the same effects reported in animal toxicological studies. Ichihara (1999) reported low sperm motility, low semen volume, abnormal sperm cells, and decreased blood cell count, hemoglobin and hematocrit in otherwise healthy Chinese male workers exposed to a wide range of iPB concentrations (2.5–111 ppm). Abnormal or an absence of menstruation was associated with iPB exposure in several female workers, as well as reduced blood cell count, hemoglobin, and hematocrit. Employees of an electronics factory in South Korea showed similar effects following exposure to iPB (Kim, 1996). In female workers, disrupted or absent menstruation, abnormal hormone levels, hot flashes, and abnormal bone marrow were found, while male workers exhibited significantly reduced sperm counts and sperm motility.

CERHR convened an Expert Panel to consider existing toxicological studies on effects of both nPB and iPB. (See section IV.A.1.c. for a discussion of CERHR review process and the Expert Panel Report.) The CERHR Expert Panel came to the following conclusions on the existing studies on iPB (CERHR, 2002b, p. 44):

- Available human and animal data are insufficient to draw conclusions on the potential for developmental toxicity due to iPB.
- There is sufficient evidence that iPB is a reproductive hazard in men and women, particularly based upon the epidemiological data from Korea.
- At low levels (less than 0.004 ppm), there is minimal concern for human reproduction. At higher levels up to 1.35 ppm, there is some concern.
- For reproductive data from male rats, the panel identified a NOAEL of 100 ppm.

The toxicological studies on male reproductive endpoints for iPB have limitations which (*e.g.*, small number of dose groups) make them inappropriate for use in quantitative risk assessment. Although the occupational exposure studies also are limited, given the mutagenicity of the compound and that human exposures have resulted in significant health effects consistent with those reported in the available animal studies, the Agency considers it appropriate to limit the amount of iPB exposure resulting from nPB use to the maximum extent feasible.

Today's action proposes to limit SNAP acceptability of nPB to those formulations of nPB that contain concentrations less than 0.05% iPB by weight before adding stabilizers or other chemicals. The current American Society for Testing and Materials (ASTM) standard for vapor degreasing grade and general grade nPB specifies that unstabilized nPB must have less than 0.1% of iPB as a contaminant. EPA believes that this level should be reduced to 0.05% given the toxicity of iPB, and the fact that achieving a level of 0.05% is technologically feasible and would not cause significant economic impacts (US EPA, 2003). The Agency also requests comment on the appropriateness of alternative concentration limits for iPB in nPB, including 0.1%. If this provision is finalized, the iPB concentration limit would be a condition that all users in the U.S. must observe in all sectors and end uses where nPB is listed as acceptable.

In order to show compliance with the use condition, end users would need to keep records to demonstrate that the nPB used in the product contains no more than 0.05% iPB by weight before adding stabilizers or other chemicals. Documentation could involve, for example, keeping a certificate of analysis or purity provided by the manufacturer or formulator for two years from the date of creation of that record. Such records are customary business information that chemical companies provide to their customers, so we do not expect that this requirement will impose an additional paperwork burden.

B. Ozone Depletion Potential

The ozone depletion potential (ODP) of a chemical compound provides a measure of its impact on stratospheric ozone levels relative to the impact of an equal mass emission of CFC–11. The Parties to the Montreal Protocol have used the ODP benchmark index as a means of characterizing the relative risks associated with the various ozone-depleting compounds subject to the requirements of the Protocol and to calculate the total allowable production and consumption of different classes of ozone depleting substances. Every four years the World Meteorological Organization publishes the *Scientific Assessment of Ozone Depletion*. These assessments are authored by leading experts in the fields of atmospheric science and atmospheric chemistry, and include the most current research findings relevant to the science of ozone depletion. These assessments, along with other studies in the field of atmospheric chemistry, have traditionally focused on compounds with relatively long atmospheric lifetimes (in excess of 3 months).

Two-dimensional (2–D) models that base calculations on latitude and altitude are sufficient for calculating the ODP of long-lived chemicals. However, 2–D models cannot simulate the complex atmospheric transport pathways that are necessary to determine the ODP of short-lived compounds like nPB (Wuebbles, 2000). nPB is estimated to remain in the atmosphere for only 11 to 20 days after

emission.[12] The short lifetime of nPB complicates the calculation of its ODP because it is not valid to make the standard simplifying assumption that concentrations are ''well mixed'' in the troposphere. Thus, a meaningful comparison can be made between the ODP of nPB and the longer-lived compounds already controlled under the Montreal Protocol only by using the results from a 3–D model that bases calculations on longitude, latitude, and altitude to augment the ODP calculation using a 2–D model.

Generally, a compound emitted in the troposphere travels toward the equator and into the tropics before rising convectively into the stratosphere. As a result, a compound emitted at high latitudes, such as the northern United States or the southern tip of Brazil, will take longer to reach the stratosphere than one emitted in the tropics. For a long-lived chemical, this difference in travel time is insignificant. But for a short-lived compound such as nPB, which is subject to degradation in the troposphere, the latitude of emission can have a significant impact on the amount of ozone-destroying bromine that is delivered to the stratosphere.

Using a combination of 2–D and 3–D models, Wuebbles *et al.* (2001) estimated the ODP to be between 0.016 and 0.019 for nPB emissions over the United States. In the tropical latitudes, over India, Southeast Asia and Indonesia, nPB emissions have a larger ODP of 0.087 to 0.105. A more recent paper by Wuebbles found that the ODP of nPB emissions from the United States would be closer to 0.013–0.018, while nPB emissions in the tropics would have an ODP of 0.071 to 0.100 (Wuebbles, 2002).

In proposing to list nPB as an acceptable substitute for CFC–113, methyl chloroform and HCFC–141b, EPA has considered that the ODP for nPB at the latitude of the continental U.S. is substantially less than the ODPs for the chemicals it would replace (0.8 for CFC–113, 0.1 for methyl chloroform, and 0.11 for HCFC–141b). Given that fact, we do not believe that nPB's ODP is a compelling reason to list it as an unacceptable substitute for CFC–113, methyl chloroform, and HCFC–141b for use in the U.S.

While advances in modeling are producing more specific methods to better estimate nPB's ODP, the value will never be pinpointed to a single number that may be applied to all latitudes. EPA notes that if the ODP were as high in the U.S. as it is in the tropics (0.071 to 0.100), we would have found it unacceptable as a substitute. When making regulatory determinations, governments or users in other latitudes should consider the ODP at their latitude as well as the toxicity of other solvents available for use. For example, users in other counties may find nPB preferable to carbon tetrachloride, which has a high ODP (1.1) and is highly toxic. On the other hand, users in the tropics should realize that nPB at their latitude has an ODP comparable to substances controlled by the Montreal Protocol (methyl chloroform or HCFC–141b). EPA also recommends that any decisions on the use of nPB outside the U.S. should be based on latitude-specific ODPs and volumes of the chemical projected to be used in those regions.

Few commenters on the ANPRM discussed the ODP of nPB. However, the Agency agrees with two commenters who stated that nPB's low ODP should be balanced against the much longer atmospheric lifetime of other choices.

We have attempted to gather and assess all available information from the full range of experts on nPB's ODP. EPA continues to be interested in receiving from the public any other information pertaining to the atmospheric effects and ODP of short-lived atmospheric chemicals, especially nPB. In the event that data become available after final rulemaking that are contrary to the current scientific understanding, section 612 of the CAA allows the Agency to reconsider our decision under the SNAP program.

C. Global Warming Potential

The global warming potential (GWP) index is a means of quantifying the potential integrated climate forcing of various greenhouse gases relative to carbon dioxide. Thus, the GWP of carbon dioxide is, by definition, equal to one. Since GWP is a measure of the climate forcing integrated over time, the value of the index depends on the choice of time horizon. The standard GWP used for making climate-related policy decisions is based on a 100-year time horizon (called the 100yr GWP).[13]

The 100yr GWP of nPB is 0.31 (Atmospheric and Environmental Research, Inc., 1995). This is a relatively low GWP, representing a climate forcing approximately one third that of carbon dioxide, by weight. Estimations of the net climate impact must take into consideration the amount of the compound expected to be emitted. As will be discussed in section V.B. below, nPB will most likely be emitted in small enough quantities worldwide that there should not be a concern about its causing climate change. Additionally, the GWP of nPB is considerably lower than that of the chemicals it potentially replaces. (100yr GWP values are 6000 for CFC–113, 140 for methyl chloroform and 700 for HCFC–141b.)[14] Therefore, we conclude that the use of nPB as a substitute for CFC–113, HCFC–141b, or methyl chloroform should not be restricted based on its GWP.

D. Flammability

nPB forms flammable mixtures in air within only a narrow range. All estimates that EPA reviewed fall somewhere within the range of 3.5%–9%. Most, but not all, of the material safety data sheets we reviewed state that nPB has no flashpoint. The 1998 Report of the United Nations Environment Programme's Solvents, Coatings and Adhesives Technical Option Committee stated that ''under certain test conditions, using standard flash point testing apparatus, pure nPB has demonstrated a flash point at −10°C * * * [O]ther ASTM test methods have resulted in no observed flash point'' (UNEP, 1999). In response to information requests in the nPB ANPRM, various commenters asserted that nPB has a flashpoint of 10°C, 14°C, and 21°C–25°C, 70°F (21°C), and 70°C. These data are inconclusive about the flashpoint of nPB and whether nPB is likely to be flammable under normal use conditions.

In addition, we are aware that many manufacturers of foam cushions use adhesives containing nPB because it is essentially non-flammable compared to many other solvents used in adhesives, such as acetone or heptane. Also, one company has submitted a fire suppressant containing nPB as the active ingredient for review by the SNAP program. (We are not addressing this incomplete submission in today's proposed rule.) It is not surprising that nPB would have little or no flammability, given that many organic compounds containing bromine have little or no flammability, such as halons or hydrobromofluorocarbons.

Based on the full range of available information, we do not currently believe that the use of nPB as a substitute for CFC–113, methyl chloroform, or HCFC–141b should be restricted because of flammability. EPA, however, invites

[12] Wuebbles *et al.*, 1998; Wuebbles *et al.*, 2000.

[13] The 100yr GWP is the index recommended by the Intergovernmental Panel on Climate Change (IPCC) for comparing the climate impacts of various global warming gases. The United States employs the standard 100yr GWP index for making climate policy decisions and reporting of greenhouse gases.

[14] All GWPs (other than that of nPB) discussed in this NPRM are taken from the *Scientific Assessment of Ozone Depletion: 1998* (WMO, 1999).

commenters to submit more specific information concerning the flashpoint of pure nPB. We are aware that nPB blends may have flashpoint characteristics different from that of pure nPB, depending on the nature of the additives or stabilizers. In this rulemaking, EPA is evaluating only pure nPB as a substitute for CFC–113 and methyl chloroform. We therefore are not interested in receiving information concerning the flashpoints of blends that contain nPB. Commenters providing information on nPB's flashpoint should refer to the specific test methodology and apparatus used to determine the flashpoint, such as ISO 1523, American Society of Testing Materials (ASTM) E–681, D92, D93–85—Pensky-Martens closed cup, or D56–96—Tag closed cup. EPA also invites readers to submit information concerning any potential fire or explosion hazards that may result from the use in solvent cleaning of compounds that have flashpoints within the range of normal atmospheric pressures and temperatures.

E. Other Environmental Concerns

Because nPB breaks down in the atmosphere within 21 days, and is not particularly soluble in water, it is unlikely that ''rain out'' from nPB released into the atmosphere could cause contamination of water supplies. However, as with all chemicals, significant contamination of soil and water can result when directly introduced into water or onto the ground. Thus, EPA expects that users will dispose of nPB in accordance with relevant regulations under the Resource Conservation and Recovery Act, and with applicable state and local regulations. Compliance with these regulations will mitigate the possibility that nPB might enter water supplies or top soil.

nPB is a volatile organic compound (VOC). VOCs are associated with the formation of ground-level ozone, a respiratory irritant. Therefore, nPB use currently is controlled under state and local regulations implementing Federal clean air requirements at 40 CFR part 51. These regulations are intended to bring areas into compliance with the National Ambient Air Quality Standards for ground-level ozone. Users located in ozone non-attainment areas may need to consider using other alternatives for cleaning that are not VOCs or control emissions.

F. Comparison of nPB to Other Solvents

Section 612 of the Clean Air Act directs EPA to determine the acceptability of a replacement substance (''substitutes'') for class I and class II ozone depleting substances based on whether such substitute creates an overall greater risk to human health and the environment than other substitutes that are available. 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, 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, consistent with the safe alternatives policy of § 612.

In our evaluation, we considered the substitutes available within a given end use. In other words, we compared nPB as a metal cleaning solvent against other metal cleaning alternatives, and we compared nPB as a carrier solvent in adhesives to other adhesive alternatives. Because of the large amount of overlap in the alternatives available in the different end uses, the discussion below will mention alternatives from multiple end uses where nPB is used.

Although EPA does not judge the effectiveness of alternatives, this factor is an additional one that we consider when determining what alternatives are available in a particular application within an end use. For example, aqueous cleaners are the substitute of choice for many in the metal cleaning end use and many electronics applications now use the ''no clean'' technology. However, some types of soils are especially difficult to remove and some applications require a high degree of cleanliness; thus, in some applications, particularly in precision cleaning, there may still be a need for organic solvents for cleaning. Depending on the particular application, it may be necessary to use an aggressive cleaning solvent such as nPB.

nPB has an ODP of 0.013 to 0.018 at the latitudes of the continental U.S. Thus, nPB reduces risk compared to CFC–113, methyl chloroform, and HCFC–141b, the ODSs it replaces, which have ODPs of 0.8, 0.1, and 0.11, respectively. HCFC–225ca/cb has an ODP of approximately 0.03. HCFC–225ca/cb is acceptable in metals cleaning and aerosol solvents, and acceptable subject to use conditions in precision cleaning and electronics cleaning. Although HCFC–141b has been phased out of production in the U.S., its use is currently acceptable in aerosol solvents; HCFC–141b has a higher ODP than nPB. HCFC–123 has an ODP of 0.0124, which is comparable to that of nPB. HCFC–123 is acceptable in precision cleaning. There are other acceptable cleaners that essentially have no ODP (aqueous cleaners, hydrofluoroethers (HFEs), hydrofluorocarbon (HFC)-4310mee, HFC–365mfc, HFC–245fa, hydrocarbons, volatile methyl siloxanes (VMSs), methylene chloride, trichloroethylene (TCE), perchloroethylene (PERC), and parachlorobenzotrifluoride (PCBTF).

nPB has a GWP of only 0.31, which is lower than or comparable to that of the lowest GWP solvents. Acceptable HCFC, HFC and HFE solvents all have GWPs that are two to four orders of magnitude higher than that of nPB (55 to 1700 on a 100 year time horizon compared to CO_2).

nPB is a volatile organic compound for purposes of EPA regulations, although there are petitions with EPA requesting its exemption. Thus, nPB currently is subject to regulations for ground-level ozone and local air quality. nPB is not currently regulated as a hazardous air pollutant and is not listed as a hazardous waste under RCRA.

nPB is less flammable than many acceptable substitutes, such as ketones, alcohols, terpenes, and hydrocarbons. nPB is comparable in its low flammability to chlorinated solvents, HCFCs, HFEs, HFC–245fa, HFC–4310mee, and aqueous cleaners.

EPA used an acceptable exposure limit of 25 ppm as the basis for comparison with measured exposure levels in the workplace to determine whether nPB could be used safely, and thus, to determine the acceptability of nPB. EPA found that nPB could be used as safely at 25 ppm as other acceptable solvents when they are used at their AELs or other relevant occupational exposure limits, such as OSHA PELs or ACGIH TLVs.[15] Based on the

[15] The recommended AEL for nPB is lower than that for many acceptable solvents (HFEs, ketones, HFCs, HCFC–225ca/cb, hydrocarbons), but is higher or comparable to the AEL for some acceptable solvents (d-limonene, VMSs, dichlorobenzotrifluoride, HCFC–123, methylene chloride, PCBTF). However, a direct comparison between two compounds with different AELs does not necessarily mean that using a compound with a higher AEL is more risky. Actual exposure levels will vary based upon factors other than the AEL,

assumption that most users will attain exposure levels at or below the AEL of 25 ppm, EPA finds nPB acceptable in terms of its human health risks. As discussed in section IV.A.4, ''What limit is EPA proposing on isopropyl bromide contamination of nPB as a condition of acceptability, and why?'' iPB is a contaminant in nPB formulations that is considerably more toxic than nPB. Therefore, in order for nPB formulations to ''reduce overall risk to human health and the environment,'' EPA finds it necessary for users to use nPB formulations that have minimal levels of iPB. Hence, the Agency's proposed decision of acceptability depends on the condition that users use nPB formulations that limit the amount of iPB. EPA's proposes that this limit be 0.05% before other chemicals are added.

Balancing these different factors, it is not clear that nPB poses greater risks than other substitutes in the same end uses, so long as nPB is used consistent with the use condition and recommended AEL. Further, it appears that nPB reduces overall risk compared to the ozone depleting substances being replaced. Thus, EPA proposes to find that nPB is acceptable, subject to a use condition.

V. What Other Factors Did EPA Consider That Are Unique to nPB?

A. Review of nPB by Other Federal and International Programs

In proposing to find nPB acceptable in solvents cleaning, and as a solvent in adhesive and aerosol applications, we have sought to avoid overlap with other existing regulatory authorities. EPA's mandate under the CAA is to list agents that ''reduce overall risk to human health and the environment'' for ''specific uses.'' In light of this authorization, EPA is recommending an occupational exposure limit which, if adhered to, would result in the safe use of nPB in the workplace. This is an interim measure until OSHA issues a PEL for nPB. EPA defers to OSHA on workplace safety standards, and is not in any way assuming that agency's responsibility for regulating workplace safety.

As stated in a footnote in today's proposed rule language at the end of this document, ''In accordance with the limitations provided in section 310(a) of the Clean Air Act (42 U.S.C. 7610(a)), nothing in this [rule] shall affect the Occupational Safety and Health Administration's authority to enforce standards and other requirements under the Occupational Safety and Health Act of 1970 (29 U.S.C. 651 *et seq.*).'' EPA's recommended workplace exposure guidelines, which are not regulatory, and use requirements, which are not expressly related to use in the workplace, will not bar OSHA from regulating under authority of the Occupational Safety and Health Act.

As mentioned above in section IV.E, nPB is a VOC. Two companies have petitioned EPA to exempt nPB from VOC regulations. To date, EPA has not received sufficient information on photochemical reactivity of nPB and thus, has no plans to exempt it. In contrast to other solvents, nPB is not controlled as a hazardous air pollutant under the CAA and generates wastes that are not considered hazardous under regulations implementing the Resource, Conservation and Recovery Act (RCRA). Several commenters on the ANPRM argued that because no U.S. environmental authorities regulate nPB use, EPA's SNAP program has all the more obligation to establish an acceptable exposure limit for the workplace, even if it is recommended rather than mandated (IRTA, 1999). With today's proposed rule, EPA is recommending a workplace exposure limit to protect workers exposed to nPB in the absence of OSHA regulations.

While the Montreal Protocol currently does not control the production and distribution of nPB worldwide, nPB may be controlled by the Protocol in the future. At the Thirteenth Meeting of the Parties to the Montreal Protocol in Colombo, Sri Lanka, the Parties made a decision regarding nPB. Decision XIII/7 states:

> Noting the Technology and Economic Assessment Panel's report that n-propyl bromide (nPB) is being marketed aggressively and that nPB use and emissions in 2010 currently projected to be around 40,000 metric tonnes,
>
> A. To request Parties to inform industry and users about the concerns surrounding the use and emissions of nPB and the potential threat that these might pose to the ozone layer;
>
> B. To request Parties to urge industry and users to consider limiting the use of nPB to applications where more economically feasible and environmentally friendly alternatives are not available, and to urge them also to take care to minimize exposure and emissions during use and disposal;
>
> C. To request the Technology and Economic Assessment Panel to report annually on nPB use and emissions.

B. Potential Market for nPB

There are varying estimates of the total market for nPB. The Brominated Solvents Consortium, which consists of producers of nPB, estimated in 2001 that approximately 9.2 million pounds of nPB were sold worldwide in 2000, with that number expected to rise to 15 million pounds in 2002 (Biles, 2001). In contrast, the Technology and Economic Assessment Panel (TEAP) of the United Nations Environment Programme (UNEP) estimated that the ''most likely'' amount of nPB use in 2010 would be between 44 million and 132 million pounds worldwide, pending the result of toxicity testing and price trends of various solvents (UNEP, 2001). EPA believes that the actual market size in 2010 may be lower than the 44–132 million pounds cited by the TEAP report. Further, since the TEAP report was published, some manufacturers and blenders of nPB have withdrawn their products from the market.

EPA notes that the TEAP report based its estimates of how much nPB would be used by assuming that nPB will displace significant amounts of chlorinated solvents and HCFCs in the marketplace. The report states, ''If occupational exposure limits for nPB were 2–4 times higher than exposure limits of methylene chloride, nPB would replace a substantial portion of methylene chloride solvent use even if nPB had a significantly higher price. High rates of market penetration will require U.S. EPA SNAP listing, a favorable AEL, and market confidence'' (UNEP, 2001). Given that today's proposal recommends an AEL equivalent to that for methylene chloride (OSHA PEL) and perchloroethylene (ACGIH TLV) and slightly lower than that for trichloroethylene (ACGIH TLV = 50 ppm, 8 hour TWA), it is likely that the TEAP's estimates for market penetration of nPB are too high.

In addition, we note that producers of HCFC–141b, a solvent with slightly lower cost and similar solvency to nPB, never sold more than 36 million pounds per year as a solvent, even at the height of its usage (AFEAS, 2002). HCFC–141b has recently been phased out of production in the U.S. and the Agency expects nPB to be only one of several alternative solvents that will substitute for it. Further, experience with the growth of the market for HCFC–141b suggests that the growth in the market for nPB is unlikely to continue at its current pace for more than a few years. The most recent information from suppliers of nPB indicates that in 2001, sales were approximately 9 million pounds, similar to the level in 2000 (Biles, 2002).

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such as emission controls in place, work practices, ventilation, rate of spraying, and vapor pressure of the solvent.

C. Estimated Economic Impacts on Businesses

As part of our rulemaking process, EPA estimated potential economic impacts of today's proposed regulation. In our analysis, we assumed that capital costs are annualized over 10 years and that the discount rate for determining net present value is 7.0%. We found the following impacts from the regulatory use condition on the iPB content in nPB formulations:

• In general, users in the solvent cleaning sector and aerosol solvent end use are already using nPB formulations containing less than 0.05% iPB by weight, and will experience little or no rise in prices. Most of the costs of compliance would fall upon adhesives users, since some of them currently use nPB formulations containing as much as 1% iPB.

• If today's proposed rule were to become final, the cost of the regulatory condition to the user community would be in the range of $2 to $3 million per year.

EPA also considered potential costs end users could incur if they implemented the recommended acceptable exposure limit. Qualitatively, EPA found that those users using nPB-based solvents in a vapor degreaser would save money by reducing solvent losses, and that the savings would recover the costs of emissions controls (*e.g.*, secondary cooling coils, automated lifts or hoists) within a year of installation. Based on evidence from solvent suppliers, EPA believes that some of those users would have chosen to use nPB in order to avoid meeting requirements of the national emission standard for halogenated solvents cleaning and that they would only become aware of the potential savings due to reduced solvent usage as a result of today's proposal (Ultronix, 2001; Albemarle, 2003). Based on the experience of companies that assist their customers in meeting an exposure limit of 25 ppm for nPB, we assumed that 75% to 90% of nPB users in the non-aerosol solvent cleaning sector already have exposure levels of 25 ppm or less. Of those nPB users with exposure levels above 25 ppm, we examined the cost associated with reducing emissions by 50% to 75%. EPA also found:

• Balancing the savings due to reduced solvent loss and the cost of emission controls on vapor degreaser, the range of costs for solvent cleaning ranged from a net savings of $83,900 to a cost of $2000 per user.

• Installing ventilation equipment was a minor expense for aerosol solvent users ($124 to $1230 annualized cost per user).

• The more extensive ventilation equipment necessary for adhesive users was more expensive ($24,000 to $39,000 annualized cost per user).

• EPA estimated that full implementation of the recommended workplace exposure guideline across all nPB users in all three industrial sectors would range in cost from a potential net savings up to $1.9 million to a cost of $5.5 million dollars per year. The value will depend on the number of users that attempt to meet the recommended exposure guideline, the initial exposure level of cleaning solvent users, the price of nPB, and the amount of emission control equipment or ventilation equipment installed. The high end of the range likely would be an overestimate of actual impacts because, among other things, it does not consider that some users may choose to switch to other alternatives.

• When the potential costs of compliance with the regulatory use condition and implementation of the recommended acceptable exposure limit are considered together, EPA found the total cost to range from a savings of $0.1 million to a cost of $8.1 million.

For purposes of comparison with these costs numbers, average values of shipments as a proxy for revenues for different types of businesses are as follows:

TABLE 3.—EXAMPLES OF nPB USERS BY NAICS CODE OR SUBSECTOR AND AVERAGE ANNUAL VALUE OF SHIPMENTS

NAICS code for subsector code	NAICS description	Example Uses of nPB	Average annual value of shipments by each company in subsector (million)
326150	Urethane and other foam product (except polystyrene) manufacturing.	Carrier solvent in adhesivs to stick together foam pieces in foam fabrication.	10.1
332	Fabricated Metal Product Manufacturing.	Metals cleaning to remove oil, grease, and wax from metal parts.	3.9
333	Machinery Manufacturing	Metals cleaning to remove oil, grease, and wax from metal parts.	8.9
334	Computer and Electronic Product Manufacturing.	Electronics cleaning, and aerosol solvent use to remove solder flux from circuit boards.	25.2
336	Transportation Equipment Manufacturing.	Aerosol solvent use for cleaning aerospace equipment; carrier solvent in adhesives for aircraft seating.	44.6
337	Furniture and Related Product Manufacturing.	Carrier solvent in adhesives for cushions or kitchen countertops; metals cleaning to remove grease from metal furniture parts.	3.1

For more detailed information, see section X.C. below and EPA's analysis in the docket (US EPA, 2003).

VI. How is EPA Responding to Comments on the Advance Notice of Proposed Rulemaking (ANPRM) and December 18, 2000 Notice of Data Availability?

EPA received 66 comments on the February 18, 1999, Advance Notice of Proposed Rulemaking (64 FR 8043) from 61 commenters. Forty-eight commenters advocated listing nPB as an acceptable substitute for CFC–113 and methyl chloroform under SNAP; ten commenters opposed listing nPB as acceptable; and three commenters responded to the information requests contained in the ANPRM without taking a position on the acceptability of nPB. Close to one-third of the commenters were manufacturers of products that require solvent cleaning. Other commenters included chemical manufacturers, solvent and lubricant distributors, consultants, academicians, adhesive manufacturers, product repair companies, vapor degreaser manufacturers, an aerosol manufacturer, an adhesive distributor, a machinery distributor, the U.S. Army, the U.S. Department of Energy, a solvent

blender, a printed circuit board repair facility, and a labor union. Almost all of the comments focused on the use of nPB in solvent cleaning, although the Agency did receive a few comments on the use of nPB in adhesives and aerosols applications. No commenter suggested using nPB in coatings or inks.

Many of the commenters described the complex task of searching for an optimal substitute for CFC–113 or methyl chloroform. Factors they have considered include maintaining superior performance, minimizing contamination, maintaining cost-effective and efficient processes, complying with local and other national regulatory requirements, assuring employee safety, and meeting exacting customer standards. These commenters often described their specific experiences using nPB, and compared nPB with other solvents and with other cleaning processes such as aqueous cleaning. Proponents of nPB listed as its chief advantages its lower cost compared to some alternatives (*e.g.*, HFCs, HFEs), lack of corrosiveness, potency as a solvent, low conductivity, minimal residues, and quick drying time. They also noted its ODP, short atmospheric lifetime and low GWP.

One commenter stated that because of its expense, users may use nPB more efficiently than they would use other, less expensive solvents. The commenter, a manufacturer of precision electromagnetic relays, formerly used about 5,000 pounds of methyl chloroform each year, and now uses about 1,500 pounds of nPB. Another commenter noted that nPB's bad odor provides users with an incentive to minimize evaporative losses. Commenters who oppose listing nPB as an acceptable substitute cited its instability, reactivity, and toxicity. Several commenters argued that nPB should not be used in solvent cleaning because it is largely uncontrolled and relatively little is known about its health effects.

In response to the Agency's December 18, 2000, SNAP notice and update on nPB (65 FR 78977), one commenter expressed concern about the use of nPB in cleaning and adhesive applications because of data showing that nPB is a reproductive toxin. The commenter also noted that the chemical sold as nPB contains fairly high quantities of iPB, a potent reproductive toxin. In addition, the commenter expressed concern that one manufacturer of nPB had recently left the market, and asked EPA to seek input on setting the proper exposure level from NIOSH, OSHA, and toxicologists who are not from industry or EPA.

Our proposal today reflects the Agency's agreement with those commenters who stated that there are some cleaning operations for which only nPB (and presumably, the CFC–113 or methyl chloroform that it replaced) meets all of the criteria necessary for the success of those operations. However, we also agree that some, but not all, cleaning operations that formerly relied on CFC–113 or methyl chloroform can use alternative cleaning agents, or alternative processes such as aqueous or semi-aqueous cleaning. EPA has discussed the results of the 2-generation reproductive study (WIL, 2001) and the recommended exposure limit with NIOSH as well as outside toxicologists not involved with the solvent industry or EPA, as one commenter suggested. We agree that the quantity of iPB in nPB is of concern. In response, we are proposing today to limit the iPB content in nPB to 0.05% by weight. We also are recommending an acceptable exposure limit for nPB of 25 ppm as an eight-hour time-weighted average, and recommending that users employ controls to minimize worker exposure to nPB to the lowest levels reasonably possible. The Agency believes that today's proposed rule takes into account environmental and workplace safety concerns associated with nPB, and that adhering to the recommended AEL of 25 ppm will protect against adverse health effects.

VII. What Should I Include in My Comments on EPA's Proposal?

In your comments, please explain what you think EPA should do in this rulemaking and why you think your suggested approach is appropriate. You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at your estimate.
5. Provide specific examples to illustrate your concerns.
6. Offer alternatives.
7. Make sure to submit your comments by the comment period deadline identified.
8. To ensure proper receipt by EPA, identify the appropriate docket identification number, OAR–2002–0064 in the subject line on the first page of your response. It would also be helpful if you provided the name, date, and **Federal Register** citation related to your comments.

EPA invites comment on all aspects of today's proposed rule. A number of specific issues are raised throughout the **SUPPLEMENTARY INFORMATION** section of today's preamble. We request your comments on the following issues in particular:

(1) Is it appropriate for EPA to find nPB acceptable for use in the solvents metals, electronics and precision cleaning, aerosol solvents, and adhesives, coatings, and inks sectors? Why or why not? Should EPA have different decisions for different sectors or end uses? In particular, given that the CERHR Expert Panel expressed concern about ''poorly controlled spray adhesive applications,'' should EPA find nPB acceptable, subject to use conditions, for use in spray adhesives? Should the Agency find nPB acceptable, subject to use conditions, for use in aerosol solvents, or should nPB's use be limited to certain applications in this end use? (See section III of today's notice and CERHR, 2002a, p. 50.)

(2) What is an appropriate and achievable limit on the content of isopropyl bromide (iPB) in unstabilized nPB? Should this impurity limit be 0.1%, 0.05%, or 0.025% iPB by weight? Why? How much does each of these purity levels add to the cost of cleaning solvents or adhesives made using nPB, in terms of $/drum and as a percentage of the current cost? (See section IV.A.4. of today's notice.)

(3) What is an appropriate acceptable exposure limit for EPA to recommend, and why? If you disagree with the proposed recommended exposure limit of 25 ppm, why do you disagree? Should EPA consider risk management principles in developing a recommended AEL? Please cite specific points of concern (*e.g.*, studies considered, endpoints considered in BMD analysis, uncertainty factors applied). (*See* sections IV.A.1.a through d. of today's notice.)

(4) Should nPB be listed acceptable with a skin notation? (*See* section IV.A.1.b of today's notice.)

EPA also invites commenters to submit any new, relevant data pertaining to nPB and iPB beyond what is discussed in today's notice. Under EPA guidelines, there is a preference for peer reviewed data because of the potential to improve the quality and credibility of the product. Peer-reviewed data are studies/analyses that have been reviewed by qualified individuals (or organizations) who are independent of those who performed the work, but who are collectively equivalent in technical expertise (*i.e.*, peers) to those who

performed the original work. A peer review is an in-depth assessment of the assumptions, calculations, extrapolations, alternate interpretations, methodology, acceptance criteria, and conclusions pertaining to the specific major scientific and/or technical work products and of the documentation that supports them (US EPA, 2000b).

To ensure that we have time to consider your comments, please submit them to EPA's Air Docket by the date in the **DATES** section at the beginning of this document. You may submit them via e-mail to *A-And-R-Docket@epa.gov.* Comments may be submitted electronically, by mail, by facsimile, or through hand delivery/courier. Follow the detailed instructions provided in sections I.B through I.D. To give us more time to consider your comments, please also send a copy via e-mail to our staff directly at *sheppard.margaret@epa.gov*. EPA's responses to comments, whether the comments are written or electronic, will be in a final rule published in the **Federal Register** or in a response-to-comments document placed in the rulemaking docket. We will not reply to respondents electronically other than to seek clarification of electronic comments that may be disrupted in transmission or during conversion to paper form.

VIII. What Is the Federal Government Doing To Help Businesses Use nPB Safely?

EPA is concerned that careless use of nPB will place those exposed at risk of serious adverse health effects. We are also concerned that some users perceive nPB as a ''path of less resistance'' because it has similar properties to methyl chloroform, but, unlike methyl chloroform, OSHA has not issued a permissible exposure limit (PEL) for nPB. In particular, the adhesives industry widely used methyl chloroform and then methylene chloride as carrier solvents. Since the introduction of OSHA workplace regulations for methylene chloride, some companies appear to prefer nPB-based adhesives because nPB is not yet regulated, and because nPB is not flammable under normal conditions. Because of these concerns, EPA is working with NIOSH to develop outreach materials to share with facilities that use, or could use, nPB to inform them of good workplace practices.

Further, EPA recommends that users contact OSHA's consultation service. OSHA funds confidential consultation services to users through state government staff. Employers can find out about potential hazards at their worksites, improve their occupational safety and health management systems, and even qualify for a one-year exemption from routine OSHA inspections. The consultation service is separate from inspections and enforcement. To request a consultation, telephone or write to the appropriate state consultation service, listed on the web at *http://www.osha.gov/oshdir/consult.html*. For example, if you have a facility in North Carolina, call the North Carolina Department of Labor at (919) 807–2899. See OSHA's web site at *http://www.osha.gov/html/consultation.html* for further information on consultation services.

IX. How Can I Use nPB as Safely as Possible?

As discussed above in section IV.A.1.e, EPA believes that the AEL of 25 ppm can be met in all the industrial sectors being reviewed today, including solvent cleaning applications, adhesives applications, and aerosol solvents applications, as long as appropriate controls are put in place. However, EPA also realizes that this exposure guideline is relatively low and that in many cases, users will have to implement additional emissions control measures to reach this level. Below are actions that will help nPB users meet the exposure guideline recommended in today's proposed rule:

- All users of nPB should wear appropriate personal protective equipment, including chemical goggles, flexible laminate protective gloves 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.
- Follow guidelines in the National Emission Standard for Hazardous Air Pollutants (NESHAP) for halogenated solvents cleaning if you are using nPB for non-aerosol solvent cleaning. The equipment and procedural changes described in the halogenated solvents NESHAP can reduce emissions, reduce solvent losses and lower the cost of cleaning with organic solvents. For more information on the halogenated solvents NESHAP, visit *http://www.epa.gov/ttn/atw/eparules.html* and *http://www.epa.gov/ttn/atw/degrea/halopg.html.*
- Use the employee exposure monitoring programs and product stewardship programs where offered by manufacturers and formulators of nPB-based solvents and adhesives.
- Follow all recommended safety precautions specified in the manufacturer's Material Safety Data Sheets (MSDSs).
- Use sufficient ventilation and emissions controls to meet the 25 ppm AEL in adhesives or aerosol applications (or, once developed, the applicable OSHA PEL). Examples of ventilation equipment for aerosol uses include ventilation hoods and fans. Adhesive appliers can use spray booths, ventilation hoods or ducts, and fans to reduce exposure.
- Request a confidential consultation from your State government. 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.*
- 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.
- Workers should receive safety training and education that includes potential health effects of exposure to nPB, covering information included on the appropriate material data safety sheets, as required by OSHA's Hazard Communication Standard (29 CFR 1910.1200).

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

X. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review

Under Executive Order 12866, (58 FR 51735; October 4, 1993) the Agency must determine whether the regulatory action is ''significant'' and therefore subject to the Office of Management and Budget (OMB) review and the requirements of the Executive Order. The Order defines ''significant regulatory action'' as one that is likely to result in a rule that may: (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal

governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlement, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

Pursuant to the terms of Executive Order 12866, OMB notified EPA that it considers this action a ''significant regulatory action'' within the meaning of the Executive Order, and EPA submitted this action to OMB for review. Changes made in response to OMB suggestions or recommendations have been documented in the public record.

B. Paperwork Reduction Act

This action does not impose any new information collection burden. Today's proposal is an Agency determination. It contains no new requirements for reporting. The only new recordkeeping requirement involves customary business practice. The Office of Management and Budget (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 numbers 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/TSCA Addendum, notification for test marketing activity, record-keeping for substitutes acceptable subject to use restrictions, and record-keeping for small volume uses. Today's proposed rule, if finalized, would require minimal record-keeping for two years from the date of creation of the record to demonstrate that the nPB contains no more than 0.05% iPB. Because it is customary business practice that chemical companies provide certificates of analysis to their customers, we believe this requirement will not impose an additional paperwork burden.

Copies of the ICR document(s) may be obtained from Sandy Farmer, by mail at the Office of Environmental Information, Collection Strategies Division; U.S. Environmental Protection Agency (2822); 1200 Pennsylvania Ave., NW., Washington, DC 20460, by e-mail at *farmer.sandy@epa.gov,* or by calling (202) 566–1676. A copy may also be downloaded off the Internet at *http://www.epa.gov/icr.* Include the ICR and/or OMB number in any correspondence.

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.

C. Regulatory Flexibility Act (RFA)

The 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. For purposes of assessing the impacts of today's rule on small entities, small entity is defined as: (1) A small business that has fewer than 500 employees; (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. EPA has consulted with the Small Business Administration's Office of Advocacy on the alternate small business definition of 500 employees. For today's rule, we chose to use 500 employees, rather than use the individual size standards for the numerous NAICS subsectors and codes to simplify the economic analysis. Furthermore, this size standard was set by SBA for all NAICS codes for businesses using nPB-based adhesives, which is the end use that could experience the greatest cost impacts under today's rule. We solicit comments on the choice of this alternate definition for this analysis.

After considering the economic impacts of today's proposed rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities.

Types of businesses that would be subject to today's proposed rule, if it became final, would include:

- Manufacturers of computers and electronic equipment that clean with nPB cleaning solvents (NAICS subsector 334).
- Manufacturers of fabricated metal parts, including plating, ball and roller bearings, machined parts, and other metal parts that require oil and grease to be cleaned off (NAICS subsectors 332 and 333).
- Manufacturers of transportation equipment, such as aerospace equipment that requires cleaning either in a tank or with aerosols, and aircraft seating, which is assembled using adhesives containing nPB as a carrier solvent (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 using adhesives containing nPB as a carrier solvent (NAICS code 326150).

EPA estimates that up to 7330 small industrial end users currently use nPB and thus could be subject to this rule. This number includes approximately 500 to 2300 users of nPB industrial cleaning solvents (*e.g.*, cleaning with vapor degreasers), 900 to 4750 users of nPB-based aerosol solvents, and 40 to 280 users of nPB-based adhesives.

In order to consider the resources that affected small businesses have available to operate and to respond to regulatory requirements, EPA compared the cost of meeting regulatory requirements to small businesses' annual sales. In our analysis for today's proposal, 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 on small businesses of today's proposed rule.

TABLE 4.—AVERAGE VALUE OF SHIPMENTS IN NAICS SUBSECTORS PERFORMING SOLVENT CLEANING [1], BY NUMBER OF EMPLOYEES AT BUSINESS

Number of employees at business	Average value of shipments per company ($) by NAICS subsector code				
	332, Fabricated metal products	333, Machinery	334, Computer and electronic products	336, Transportation equipment	337, Furniture and related products
1–4	174,832	230,806	279,683	d [2]	141,654
5–9	d [2]	766,045	903,756	d [2]	501,193
10–19	1,393,019	d [2]	1,925,077	1,897,347	1,102,104
20–49	3,596,222	d [2]	4,270,554	4,190,678	2,744,633
50–99	9,283,654	10,429,360	10,440,847	10,140,871	6,908,332
100–249	24,566,631	25,781,244	d [2]	27,861,502	17,898,851
250–499	55,392,738	64,822,617	d [2]	69,529,351	d [2]
Average—All Small Businesses in Subsector	3.2 million	4.2 million	2.4 million	8.9 million	1.7 million
Average—All Businesses in Subsector	3.9 million	8.9 million	25.2 million	44.6 million	3.1 million

[1] Aerosol solvents are used in NAICS subsectors 334 and 336. Non-aerosol solvents are used in all five NAICS subsectors.
[2] ''d'' designates ''Data withheld to avoid disclosing data of individual companies; data are included in higher level totals.'' The average value of shipments for small businesses does not include those values marked with ''d,'' and thus may be overestimated or underestimated.

TABLE 5.—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 Company ($) by NAICS Code				
	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
1–4	135,545	135,046	287,744	174,500	170,820
5–9	428,646	457,310	1,211,200	532,875	582,725
10–19	913,225	1,015,967	2,537,028	2,490,455	1,299,671
20–49	2,582,340	2,326,857	5,892,653	3,901,979	3,730,479
50–99	5,680,148	5,655,585	11,608,984	8,981,786	7,522,129
100–249	14,832,151	16,139,988	26,480,552	44,153,730	16,911,474
250–499	d	47,943,433	59,104,111	100,579,000	33,330,714
Average—All Small Businesses in NAICS Code	3.3 million	0.9 million	9.4 million	18.3 million	4.1 million
Average—All Businesses in NAICS Code	4.9 million	1.1 million	10.1 million	29.1 million	6.0 million

Today's proposed rule would require that users use nPB that contains no more than 0.05% iPB by weight. Most chemical manufacturers and solvent formulators already make products that meet this requirement. Some users of adhesives containing nPB use formulations that do not meet the proposed limit on iPB content. These users may need to purchase a more expensive grade of nPB-based adhesives that contains less iPB. Many users of adhesives containing nPB are small businesses that fabricate foam to be used in cushions for furniture.

If the requirements of today's proposed rule were to be finalized, we estimate that between 0 and 13 small businesses using nPB-based adhesives, or less than 5% 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. Because solvent and aerosol solvent formulations of nPB already contain less than 0.05% iPB by weight, there were no impacts on end users in the non-aerosol solvent cleaning sector and aerosol solvents end use; only the 0 to 13 adhesive end users experienced a significant impact. An even smaller percentage of all 7330 or so small businesses choosing to use nPB would experience an impact of greater than 1.0% of annual sales. In addition, we estimate that no small businesses would experience an impact of greater than 3.0% of annual sales. We conclude that no small business subject to today's rule would go out of business as a result of the rule's requirements, if they were to become final. 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 rule to have a significant impact on a substantial number of small businesses.

The recommended acceptable exposure limit is only a recommendation and not an enforceable requirement of today's rule, and thus, EPA is not required to analyze the cost associated with implementing the recommended exposure limit. Nevertheless, the Agency did analyze the cost impacts of the combination of implementing the exposure limit and complying with the regulatory use condition in order to provide additional information about potential effects on small businesses. We found that, when the costs to comply with the regulatory use condition and to implement the recommended acceptable exposure limit are considered together, at most 47 small businesses choosing to use nPB would experience an impact of greater

than 1.0% of annual sales, and none would experience an impact of greater than 3.0% of annual sales. All of the small businesses that would experience significant impacts are users of nPB-based adhesives. Thus, slightly less than 17% of the 280 or so small businesses choosing to use nPB-based adhesives would experience significant impacts, and less than 1% of all 7330 or so small businesses choosing to use nPB would experience significant impacts. Based on the relatively small number and percentage of small businesses that would experience significant impacts, EPA concludes that even if costs of implementing the recommended exposure limit were considered together with costs of complying with the regulatory use condition, today's rule would not have a significant impact on a substantial number of small entities.

Although this proposed rule will not have a significant economic impact on a substantial number of small entities, EPA nonetheless has tried to reduce the impact of this rule on small entities. Before selecting the regulatory options proposed today, we considered a number of regulatory options that would have had greater impacts on small businesses, such as:

- Finding nPB unacceptable for use in adhesives. This approach would require hundreds of small businesses to use other types of adhesives, with no option to improve ventilation to reduce worker exposure. Although small businesses could potentially save money by using a less expensive adhesive, such as a flammable adhesive, the capital costs of fire-proofing currently discourage small businesses from using inexpensive flammable adhesives. In addition, requirements of the Federal Aviation Administration for aircraft seating cushions effectively require either using nPB-based or methylene chloride-based adhesive or receiving a special waiver from the Administration. Recent regulations for hazardous air pollutants disallow use of methylene chloride in foam fabrication facilities. Thus, it is useful for adhesive users to have the option of nPB-based adhesives.
- Placing a narrowed use limit on the use of nPB in adhesives that would allow its use only in those cases where alternatives are technically infeasible due to performance or safety issues.
- Requiring that users clean metal, electronics, or other parts with nPB in vapor degreasing equipment that meets the requirements of the national emission standards for halogenated solvent cleaning.

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 have developed a fact sheet and have updated our program web site to inform small businesses about this proposed rule and to request their comments. We continue to be interested in the potential impacts of the proposed rule on small entities and request 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. Today's proposed rule does not affect State, local, or tribal governments. The enforceable requirements of the rule for the private sector affect only a small number of manufacturers and importers of nPB in the United States, and most of them already claim to meet the proposed standard prior to regulation. Therefore, the impact of this rule on the private sector is less than $100 million per year. Thus, today's 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.

Today's proposed rule does 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, today's proposed rule provides both regulatory restrictions and recommended exposure guidelines based upon toxicological studies in order to reduce risk of exposure to reproductive toxins, both iPB and nPB. This 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 or iPB.

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

This proposed 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

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (''NTTAA''), Public Law 104–113, Section 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in 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 proposed rulemaking involves technical standards since EPA is proposing to limit the amount of iPB as a contaminant of nPB formulations to 0.05%, which is lower than the 0.1% limit set by the ASTM standard for vapor degreasing grade and general grade nPB. Based on the relatively potent toxicity of iPB (see discussion in section IV.A.4 of the preamble), EPA believes it is prudent to reduce the level of iPB to 0.05% to protect worker health. EPA has consulted with producers and formulators of nPB products, and all have stated that an iPB limit of 0.05% is achievable. EPA requests comment on this aspect of the proposed rulemaking and, specifically, invites the public to comment on the level of iPB contamination that EPA should set, and to explain why such limits should be set in this regulation.

XI. 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 in hard copy in docket number A–2001–07 (legacy docket number for Docket ID No. OAR–2002–0064). Numbers listed after the reference indicate the item number within the docket.

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List of Subjects in 40 CFR Part 82

Environmental protection, Administrative practice and procedure, Air pollution control, Reporting and recordkeeping requirements.

Dated: May 21, 2003.

Christine Todd Whitman,

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 the following appendix M to read as follows:

Subpart G—Significant New Alternatives Policy Program

* * * * *

Appendix M to Subpart G—Substitutes Subject to Use Restrictions and Unacceptable Substitutes Listed in the [publication date of final rule] final rule

SOLVENT CLEANING SUBSTITUTES THAT ARE ACCEPTABLE SUBJECT TO USE CONDITIONS

End use	Substitute	Decision	Use condition	Further information
Metals cleaning	n-propyl bromide (nPB) as a substitute for CFC–113 and methyl chloroform.	Acceptable subject to use conditions.	nPB in this end use shall not contain more than 0.05% isopropyl bromide by weight before adding stabilizers or other chemicals. End users must keep records documenting compliance with this condition for up to two years from the date on the documentation.	EPA expects that all users of nPB will adhere to a voluntary acceptable exposure limit of 25 ppm on an 8-hour time-weighted average. nPB is Number 106–94–5 in the CAS Registry.
Electronics cleaning.	nPB as a substitute for CFC–113 and methyl chloroform.	Acceptable subject to use conditions	nPB in this end use shall not contain more than 0.05% isopropyl bromide by weight before adding stabilizers or other chemicals. End users must keep records documenting compliance with this condition for up to two years from the date on the documentation.	EPA expects that all users of nPB will adhere to a voluntary acceptable exposure limit of 25 ppm on an 8-hour time-weighted average. nPB is Number 106–94–5 in the CAS Registry.
Precision cleaning	nPB as a substitute for CFC–113 and methyl chloroform.	Acceptable subject to use conditions.	nPB in this end use shall not contain more than 0.05% isopropyl bromide by weight before adding stabilizers or other chemicals. End users must keep records documenting compliance with this condition for up to two years from the date on the documentation.	EPA expects that all users of nPB will adhere to a voluntary acceptable exposure limit of 25 ppm on an 8-hour time-weighted average. nPB is Number 106–94–5 in the CAS Registry.

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 appendix shall affect the Occupational Safety and Health Administration's authority to enforce standards and other requirements under the Occupational Safety and Health Act of 1970 (29 U.S.C. 651 *et seq.*)

AEROSOLS SUBSTITUTES THAT ARE ACCEPTABLE SUBJECT TO USE CONDITIONS

End use	Substitute	Decision	Use condition	Further information
Aerosol solvents ...	n-propyl bromide (nPB) as a substitute for CFC–113, HCFC–141b, and methyl chloroform.	Acceptable subject to use conditions.	nPB in this end shall not contain more than 0.05% isopropyl bromide by weight before adding stabilizers or other chemicals. End users must keep records documenting compliance with this condition for up to two years from the date on the documentation.	EPA expects that all users of nPB will adhere to a voluntary acceptable exposure limit of 25 ppm on an 8-hour time-weighted average. nPB is Number 106–94–5 in the CAS Registry.

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 appendix shall affect the Occupational Safety and Health Administration's authority to enforce standards and other requirements under the Occupational Safety and Health Act of 1970 (29 U.S.C. 651 *et seq.*)

ADHESIVES, COATINGS, AND INKS SUBSTITUTES THAT ARE ACCEPTABLE SUBJECT TO USE CONDITIONS

End use	Substitute	Decision	Use Condition	Further information
Adhesives	n-propyl bromide (nPB) as a substitute for CFC–113, HCFC–141b, and methyl chloroform.	Acceptable subject to use conditions.	nPB in this end use shall not contain more than 0.05% isopropyl bromide by weight before adding stabilizers or other chemicals. End users must keep records documenting compliance with this condition for up to two years from the date on the documentation.	EPA expects that all users of nPB will adhere to a voluntary acceptable exposure limit of 25 ppm on an 8-hour time-weighted average. nPB is Number 106–94–5 in the CAS Registry.

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 appendix shall affect the Occupational Safety and Health Administration's authority to enforce standards and other requirements under the Occupational Safety and Health Act of 1970 (29 U.S.C. 651 *et seq.*)

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