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Protection of Stratospheric Ozone: Listing of Substitutes for Ozone-Depleting Substances-n-Propyl Bromide in Solvent Cleaning; Protection of Stratospheric Ozone: Listing of Substitutes for Ozone-DepletingSubstances-n-Propyl Bromide in Adhesives, Coatings, and Aerosols; Final Rule and Proposed Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 82

[EPA–HQ–OAR–2002–0064; FRL–8316–8]

RIN 2060–AO10

Protection of Stratospheric Ozone: Listing of Substitutes for Ozone-Depleting Substances-n-Propyl Bromide in Solvent Cleaning

AGENCY: Environmental Protection Agency.

ACTION: Final Rule.

SUMMARY: The Environmental Protection Agency (EPA) determines that n-propyl bromide (nPB) is an acceptable substitute for methyl chloroform and chlorofluorocarbon (CFC)–113 in the solvent cleaning sector under the Significant New Alternatives Policy (SNAP) program under section 612 of the Clean Air Act. The SNAP program reviews alternatives to Class I and Class II ozone depleting substances and approves use of alternatives which do not present a substantially greater risk to public health and the environment than the substance they replace or than other available substitutes.

DATES: This final rule is effective on July 30, 2007.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA–HQ–OAR–2002–0064. All documents in the docket are listed on the *http://www.regulations.gov* Web site. Although listed in the index, some information is not publicly available, *i.e.*, Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in *http://www.regulations.gov* or in hard copy at the Air and Radiation Docket, EPA/DC, EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC. This docket facility is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the Air and Radiation Docket is (202) 566–1742.

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

SUPPLEMENTARY INFORMATION: Table of Contents: This action is divided into eight sections:

I. General Information

A. Does this action apply to me?

This final rule lists n-propyl bromide (nPB) as an acceptable substitute when used as a solvent in industrial equipment for metals cleaning, electronics cleaning, or precision cleaning. General metals, precision, and electronics cleaning includes cleaning with industrial cleaning equipment such as vapor degreasers, in-line cleaning systems, or automated equipment used for cleaning below the boiling point. We understand that nPB is used primarily for cleaning in vapor degreasers. Manual cleaning, such as pail-and-brush, hand wipe, recirculating over-spray (''sink-on-a-drum'') parts washers, immersion cleaning into dip tanks with manual parts handling, and use of squirt bottles, is not currently regulated under the SNAP program. EPA also does not regulate the use of solvents as carriers for flame retardants, dry cleaning, or paint stripping under the SNAP program.

This final action does not address the use of n-propyl bromide as an aerosol solvent or as a carrier solvent in adhesives or coatings. We are issuing a proposed rule addressing these end uses in a separate **Federal Register** action. Neither this final nor the proposed rule issue a decision on other end uses in which nPB was submitted as an ozone-depleting substance (ODS) substitute, such as fire suppression or foam blowing, because of insufficient information.

Affected users under this final rule could 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.

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	335	Equipment Appliance, and Component Manufacturing.
Industry	336	Transportation Equipment Manufacturing.
Industry	337	Furniture and Related Product Manufacturing.
Industry	339	Miscellaneous Manufacturing.

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

B. What 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; Pow-R-Wash® NR Contact Cleaner, Superkleen Flux Remover 2311 and LPS NoFlash NU Electro Contact Cleaner aerosols; and Whisper Spray and Fire Retardant Soft Seam 6460 adhesives.

C. What acronyms and abbreviations are used in the preamble?

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

8-hr—eight hour
ACGIH—American Conference of Governmental Industrial Hygienists
AEL—acceptable exposure limit
ASTM—American Society for Testing and Materials
BMD—benchmark dose
BMDL—benchmark dose lowerbound, the lower 95%-confidence level bound on the dose/exposure associated with the benchmark response
BSOC—Brominated Solvents Consortium
CAA—Clean Air Act
CAS Reg. No.—Chemical Abstracts Service Registry Identification Number
CBI—Confidential Business Information
CEG—community exposure guideline
CERHR—Center for the Evaluation of Risks to Human Reproduction
CFC-113—the ozone-depleting chemical 1,1,2-trifluoro-1,2,2-trichloroethane, $C_2Cl_3F_3$, CAS Reg. No. 76–13–1
CFC—chlorofluorocarbon
cfm—cubic feet per minute
CFR—Code of Federal Regulations
CNS—central nervous system
DNA—deoxyribonucleic acid
EDSTAC—The Endocrine Disruptor Screening and Testing Advisory Committee
EPA—the United States Environmental Protection Agency
FR—**Federal Register**
GWP—global warming potential
HCFC-123—the ozone-depleting chemical 1,2-dichloro-1,1,2-trifluoroethane, CAS Reg. No. 306–83–2
HCFC-141b—the ozone-depleting chemical 1,1-dichloro-1-fluoroethane, CAS Reg. No. 1717–00–6
HCFC-225ca/cb—the commercial mixture of the two ozone-depleting chemicals 3,3-dichloro-1,1,1,2,2-pentafluoropropane, CAS Reg. No. 422–56–0 and 1,3-dichloro-1,1,2,2,3-pentafluoropropane, CAS Reg. No. 507–55–1
HCFC—hydrochlorofluorocarbon
HEC—human equivalent concentration
HFC-245fa—the chemical 1,1,3,3,3-pentafluoropropane, CAS Reg. No. 460–73–1
HFC-365mfc—the chemical 1,1,1,3,3-pentafluorobutane, CAS Reg. No. 405–58–6
HFC-4310mee—the chemical 1,1,1,2,3,4,4,5,5,5-decafluoropentane, CAS Reg. No. 138495–42–8
HFC—hydrofluorocarbon
HFE—hydrofluoroether
HHE—health hazard evaluation
ICF—ICF Consulting
ICR—Information Collection Request
iPB—isopropyl bromide, C_3H_7Br, CAS Reg. No. 75–26–3, an isomer of n-propyl bromide; also called 2-bromopropane or 2-BP
K_{oc}—organic carbon partition coefficient, for determining the tendency of a chemical to bind to organic carbon in soil
LC_{50}—the concentration at which 50% of test animals die
LOAEL—Lowest Observed Adverse Effect Level
Log K_{ow}—logarithm of the octanol-water partition coefficient, for determining the tendency of a chemical to accumulate in lipids or fats instead of remaining dissolved in water
mg/l—milligrams per liter
MSDS—Material Safety Data Sheet
NAICS—North American Industrial Classification System
NESHAP—National Emission Standard for Hazardous Air Pollutants
NIOSH—National Institute for Occupational Safety and Health
NOAEL—No Observed Adverse Effect Level
NOEL—No Observed Effect Level
nPB-n-propyl bromide, 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
OEHHA—Office of Environmental Health Hazard Assessment of the California Environmental Protection Agency
OMB—U.S. Office of Management and Budget
OSHA—the United States Occupational Safety and Health Administration
PCBTF—parachlorobenzotrifluoride, CAS Reg. No. 98–56–6
PEL—Permissible Exposure Limit
ppm—parts per million
RCRA—Resource Conservation and Recovery Act
RFA—Regulatory Flexibility Act
RfC—reference concentration
SIP—state implementation plan
SNAP—Significant New Alternatives Policy
STEL—Short term exposure limit
TCA—the ozone-depleting chemical 1,1,1-trichloroethane, CAS Reg. No. 71–55–6; also called methyl chloroform, MCF, or 1,1,1
TCE—the chemical 1,1,2-trichloroethene, CAS Reg. No. 79–01–6, C_2Cl_3H; also call trichloroethylene
TERA—Toxicological Excellence for Risk Assessment
TLV—Threshold Limit Value™
TSCA—Toxic Substances Control Act
TWA—time-weighted average
UMRA—Unfunded Mandates Reform Act
U.S.C.—United States Code
VMSs—volatile methyl siloxanes
VOC—volatile organic compound
WEL—workplace exposure limit

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

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

Section 612 of the Clean Air Act (CAA) authorizes EPA to develop a

program for evaluating alternatives to ozone-depleting substances, referred to as the Significant New Alternatives Policy (SNAP) program. The major provisions of section 612 are:

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

• *Listing of Unacceptable/Acceptable Substitutes*—Section 612(c) also requires EPA to publish a list of the substitutes unacceptable for specific uses. We must publish a corresponding list of acceptable alternatives for specific uses.

• *Petition Process*—Section 612(d) grants the right to any person to petition EPA to add a substitute to or delete a substitute from the lists published in accordance with section 612(c). EPA has 90 days to grant or deny a petition. Where the Agency grants the petition, we must publish the revised lists within an additional six months.

• *90-day Notification*—Section 612(e) requires EPA to require any person who produces a chemical substitute for a class I substance to notify the Agency not less than 90 days before new or existing chemicals are introduced into interstate commerce for significant new uses as substitutes for a class I substance. The producer must also provide the Agency with the producer's health and safety studies on such substitutes.

• *Outreach*—Section 612(b)(1) states that the Administrator shall seek to maximize the use of federal research facilities and resources to assist users of class I and II substances in identifying and developing alternatives to the use of such substances in key commercial applications.

• *Clearinghouse*—Section 612(b)(4) requires the Agency to set up a public clearinghouse of alternative chemicals, product substitutes, and alternative manufacturing processes that are available for products and manufacturing processes which use class I and II substances.

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

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

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

C. How does the SNAP program list our decisions?

The Agency has identified four possible decision categories for substitutes: Acceptable; acceptable subject to use conditions; acceptable subject to narrowed use limits; and unacceptable. Use conditions and narrowed use limits are both considered ''use restrictions'' and are explained below. Substitutes that are deemed acceptable with no use restrictions (no use conditions or narrowed use limits) can be used for all applications within the relevant sector end-use. Substitutes that are acceptable subject to use restrictions may be used only in accordance with those restrictions. It is illegal to replace an ODS with a substitute listed as unacceptable.

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

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

The Agency publishes its SNAP program decisions in the **Federal Register**. For those substitutes that are deemed acceptable subject to use restrictions (use conditions and/or narrowed use limits), or for substitutes deemed unacceptable, we first publish these decisions as proposals to allow the public opportunity to comment, and we publish final decisions as final rulemakings. In contrast, we publish substitutes that are deemed acceptable with no restrictions in ''notices of acceptability,'' rather than as proposed and final rules. As described in the rule implementing the SNAP program (59 FR 13044), we do not believe that rulemaking procedures are necessary to list alternatives that are acceptable without restrictions because such listings neither impose any sanction nor prevent anyone from using a substitute.

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

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

For copies of the comprehensive SNAP lists of substitutes or additional information on SNAP, look at EPA's

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

III. What is EPA's final listing decision on nPB in solvent cleaning?

The Agency is listing nPB as an acceptable substitute in metals, precision and electronics cleaning end uses. Based on the available information, we find that nPB can be used with no substantial increase in overall risks to human health and the environment, compared to other available or potentially available substitutes for ozone-depleting substances in these end uses.

EPA is issuing today's listing in the form of a final rule, rather than in a notice of acceptability, in order to respond to the public comments received on a Notice of Proposed Rulemaking (NPRM) that we issued on June 3, 2003 (68 FR 33284). In that rule, we proposed listing n-propyl bromide (nPB) as an acceptable substitute for use in metals, precision, and electronics cleaning, and in aerosols and adhesives end-uses, subject to the use condition that nPB used in these applications contains no more than 0.05% by weight of isopropyl bromide. In addition, in that proposed rule, EPA indicated that we also would recommend that users adhere to a voluntary acceptable exposure limit (AEL) of 25 parts per million averaged over an eight-hour time-weighted average (TWA). Based on new information received after the close of the comment period on the June 2003 NPRM relevant to our proposed determinations for adhesive and aerosol solvent end uses in that same proposal, the Agency is issuing a new proposal for those end uses in a separate **Federal Register** action. The Agency is not including a recommended AEL in this final rule.

Table 2 contains the text pertaining to nPB use in solvent cleaning end-uses that will be added to EPA's list of acceptable substitutes located on the SNAP Web site at *http://www.epa.gov/ozone/snap/lists/index.html*. This and other listings for substitutes that are acceptable without restriction are not included in the Code of Federal Regulations because they are not regulatory requirements. The information contained in the ''Further Information'' column of those tables are non-binding recommendations on the safe use of substitutes.

TABLE 2.—SOLVENT CLEANING ACCEPTABLE SUBSTITUTE

End use	Substitute	Decision	Further information
Metals cleaning, electronics cleaning, and precision cleaning.	n-propyl bromide (nPB) as a substitute for CFC–113 and methyl chloroform.	Acceptable	EPA recommends the use of personal protective equipment, including chemical goggles, flexible laminate protective gloves and chemical-resistant clothing. EPA expects that all users of nPB would comply with any final Permissible Exposure Limit that the Occupational Safety and Health Administration issues in the future under 42 U.S.C. 7610(a). nPB, also known as 1-bromopropane, is Number 106–94–5 in the Chemical Abstracts Service (CAS) Registry.

IV. What criteria did EPA consider in making this final determination?

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

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

(ii) General population risks from ambient exposure to compounds with direct toxicity and to increased ground-level ozone;

(iii) Ecosystem risks [e.g., bioaccumulation, impacts on surface and groundwater];

(iv) Occupational risks;

(v) Consumer risks;

(vi) Flammability; and

(vii) Cost and availability of the substitute.

In this review, EPA considered all the criteria above. However, n-propyl bromide is used in industrial applications such as electronics cleaning. In those consumer products made using nPB, such as a computer, the nPB would have evaporated long before a consumer would purchase the item. Therefore, we believe there is no consumer exposure risk in the end uses we evaluated for this rule.

Section 612(c) of the Clean Air Act directs EPA to publish a list of replacement substances (''substitutes'') for class I and class II ozone depleting substances based on whether the Administrator determines they are safe (when compared with other currently or potentially available substitutes) for specific uses or are to be prohibited for specific uses. EPA must compare the risks to human health and the environment of a substitute to the risks associated with other substitutes that are currently or potentially available. In addition, EPA also considers whether the substitute for class I and class II ODSs ''reduces the overall risk to human health and the environment'' compared to the ODSs being replaced. Our evaluation is based on the end use; for example, we compared nPB as a metal cleaning solvent against other available or potentially available metal cleaning alternatives.

Although EPA does not judge the effectiveness of an alternative for purposes of determining whether it is acceptable, we consider effectiveness when determining whether alternatives that pose less risk are available in a particular application within an end use. There are a wide variety of acceptable alternatives listed for solvent cleaning, but not all are appropriate for a specific application because of differences in soils, materials compatibility, degree of cleanliness required, local environmental requirements, and other factors. For example, aqueous cleaners are effective cleaners in many situations and are the substitute of choice for many in the metal cleaning end use. However, in some specific precision cleaning applications that require a high degree of cleanliness and that have narrow

spaces that may trap water used in rinsing, aqueous cleaners may not be appropriate and thus are not available in those specific applications.

EPA evaluated each of the criteria separately and then considered overall risk to human health and the environment in comparison to other available or potentially available alternatives. We concluded that overall, while there are a number of alternatives that reduce the risks from ozone depletion or from smog production [1] slightly more than nPB when used in industrial solvent cleaning equipment, we found no single alternative that could work in all applications that clearly would reduce overall risks to human health and the environment in metals cleaning, electronics cleaning, and precision cleaning. Balancing the different criteria discussed below, nPB used in solvent cleaning end-uses does not pose a significantly greater risk than other substitutes or than the ODS it is replacing in these end uses. Thus, we are listing nPB as acceptable in metals cleaning, electronics cleaning, and precision cleaning.

A. Availability of Alternatives to Ozone-Depleting Substances

Other alternatives to methyl chloroform and CFC–113 are available for metals, electronics, and precision cleaning that have already been found acceptable or acceptable subject to use conditions under the SNAP program including: Aqueous cleaners, semi-aqueous cleaners, alcohols, ketones, esters, ethers, terpenes, HCFC–225ca/cb, hydrofluoroethers (HFEs), hydrofluorocarbon (HFC)–4310mee, HFC–365mfc, heptafluorocyclopentane, hydrocarbons, volatile methyl siloxanes (VMSs), trans-1,2-dichloroethylene, methylene chloride, trichloroethylene [2] (TCE), perchloroethylene,[3] parachlorobenzotrifluoride (PCBTF), and alternative technologies like supercritical fluids, plasma cleaning, and ultraviolet/ozone cleaning. Some alternatives are unlikely to be used in particular end uses because of constraints such as cleaning performance, materials compatibility, cost, workplace exposure requirements, or flammability. For example, no-clean technology is used in electronics cleaning and not in precision cleaning because of the need for a high degree of cleanliness in precision cleaning. Of the available substitutes, aqueous cleaners or solvents for vapor degreasing such as TCE, blends of alcohols or trans-1,2-dichloroethylene and HFCs or HFEs, and HCFC–225ca/cb are most likely to be used in the same applications as nPB. nPB is already commercially available in solvent cleaning, and is used mostly for vapor degreasing in the electronics and precision cleaning end uses (IBSA, 2002).

B. Impacts on the Atmosphere and Local Air Quality

As discussed in the June 2003 proposal, nPB emissions from the continental United States are estimated to have an ozone depletion potential (ODP) of approximately 0.013–0.018, (Wuebbles, 2002) [4], lower than that of the ozone depletion potential of the substances that nPB would replace—CFC–113 (ODP=1.0), and methyl chloroform and HCFC–141b (ODPs = 0.12) (WMO, 2002). Some other acceptable alternatives for these ODSs also have low ODPs. For example, HCFC–225ca/cb has an ODP of 0.02–0.03 (WMO, 2002) and is acceptable in metals cleaning and aerosol solvents, and acceptable subject to use conditions in precision cleaning and electronics cleaning. HCFC–123 has an ODP of 0.02 (WMO, 2002), and is an acceptable substitute in precision cleaning. There are other acceptable cleaners that essentially have no ODP—aqueous cleaners, HFEs, HFC–4310mee, HFC–365mfc, HFC–245fa, hydrocarbons, VMSs, methylene chloride, TCE, perchloroethylene, and PCBTF.

The global warming potential (GWP) index is a means of quantifying the potential integrated climate forcing of various greenhouse gases relative to carbon dioxide. Earlier data found a direct 100-year integrated GWP (100yr GWP) for nPB of 0.31 (Atmospheric and Environmental Research, Inc., 1995). More recent analysis that considers both the direct and the indirect GWP of nPB found a 100-yr GWP of 1.57 (ICF, 2003a; ICF, 2006a). In either case, the GWP for nPB is comparable to or below that of previously approved substitutes in these end uses.

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

C. Ecosystem and Other Environmental Impacts

EPA considered the possible impacts of nPB if it were to pollute soil or water as a waste and compared these impacts to screening criteria developed by the Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC, 1998) (see Table 3). Available data on the organic carbon partition coefficient (K_{oc}), the breakdown processes in water and hydrolysis half-life, and the volatilization half-life indicate that nPB is less persistent in the environment than many solvents and would be of low to moderate concern for movement in soil. Based on the LC_{50}, the acute concentration at which 50% of tested animals die, nPB's toxicity to aquatic life is moderate, being less than that for some acceptable cleaners (for example, trichloroethylene, hexane, *d*-limonene, and possibly some aqueous cleaners) and greater than that for some others (methylene chloride, acetone, isopropyl alcohol, and some other aqueous cleaners). The LC_{50} for nPB is 67 mg/l, which is greater than 10 mg/l. Based on EPA's criteria for listing under the Toxics Release Inventory (U.S. EPA,

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

[2] Also called trichlorethene or TCE, C_2Cl_3H, CAS Reg. No. 79–01–6.

[3] Also called PERC, tetrachloroethylene, or tetrachloroethene, C_2Cl_4, CAS Reg. No. 172–18–4.

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

1992), we believe that nPB would not be sufficiently toxic to aquatic life to warrant listing under the Toxics Release Inventory. Based on its relatively low bioconcentration factor and log K_{ow} value, nPB is not prone to bioaccumulation. Table 3 summarizes information on environmental impacts of nPB; trans-1,2-dichloroethylene, a commonly-used solvent in blends for aerosol solvents, precision cleaning, and electronics cleaning; trichloroethylene, a solvent used for metals, electronics, and precision cleaning; and methyl chloroform, an ODS that nPB would replace.

TABLE 3.—ECOSYSTEM AND OTHER ENVIRONMENTAL PROPERTIES OF nPB AND OTHER SOLVENTS

Property	Description of environmental property	Value for nPB	Value for trans-1,2-dichloro-ethylene	Value for trichloro-ethylene	Value for methyl chloroform
K_{oc}, organic-carbon partition coefficient.	Degree to which a substance tends to stick to soil or move in soil. Lower values (< 300)* indicate great soil mobility; values of 300 to 500 indicate moderate mobility in soil.	330 (Source: ICF, 2004a).	32 to 49 (Source: ATSDR, 1996).	106 to 460 (Source: ATSDR, 1997).	152 (Source: U.S. EPA, 1994a).
Break down in water.	Mechanism and speed with which a compound breaks down in the environment. (Hydrolysis half-life values > 25 weeks* are of concern.)	Hydrolysis is significant. Hydrolysis half-life of 26 days (Source: ICF, 2004a).	Photolytic decomposition, dechlorination and biodegradation are significant; hydrolysis not significant (Source: ATSDR, 1996).	Volatilization and biodegradation most significant, with hydrolysis relatively insignificant. Hydrolysis half-life of 10.7 to 30 months (Source: ATSDR, 1997).	Volatilization most significant; biodegradation and hydrolysis also occur (Source: ATSDR, 2004).
Volatilization half-life from surface waters.	Tendency to volatilize and pass from water into the air.	3.4 hours-4.4 days (Source: ICF, 2004a).	3 to 6.2 hours (Source: ATSDR, 1996).	3.4 hours to 18 days (Source: ATSDR, 1997).	Hours to weeks (Source: U.S. EPA, 1994a).
LC_{50} (96 hours) for fathead minnows.	Concentration at which 50% of animals die from toxicity after exposure for 4 days.	67 mg/L (Source: Geiger, 1988).	108 mg/L (Source: U.S. EPA, 1980).	40.7 to 66.8 mg/L (Source: NPS, 1997).	52.8 to 105 mg/L (Source: U.S. EPA, 1994a).
log K_{ow}	Logarithm of the octanol/water partition coefficient, a measure of tendency to accumulate in fat. Log K_{ow} values >3* indicate high tendency to accumulate.	2.10 (Source: ICF, 2004a).	−0.48 (Source: LaGrega *et al.*, 2001, p. 1119).	2.38 (Source: LaGrega *et al.*, 2001, p. 1127).	2.50 (Source: LaGrega *et al.*, 2001, p. 1127).
Bioconcentration factor.	High factors (>1000)* indicate strong tendency for fish to absorb the chemical from water into body tissues.	23 (Source: HSDB, 2004).	5 to 23 (Source: ATSDR, 1996).	10 to 100 (Source: ATSDR, 1997).	<9 (Source: U.S. EPA, 1994a).

*Criteria from EDSTAC, 1998.

nPB is not currently regulated as a hazardous air pollutant and is not listed as a hazardous waste under the Resource Conservation and Recovery Act (RCRA). nPB is not required to be reported as part of the Toxic Release Inventory under Title III of the Superfund Amendments and Reauthorization Act. Despite this, large amounts of nPB might be harmful if disposed of in water. We recommend that users dispose of nPB as they would dispose of any spent halogenated solvent (F001 waste under RCRA). Users should not dump nPB into water, and should dispose of it by incineration.

D. Flammability and Fire Safety

A number of commenters on the June 2003 proposal provided additional information on the flammability of nPB using standard test methods for determining flash point, such as the American Society for Testing and Materials (ASTM) D 92 open cup, ASTM D56 Tag closed cup, and ASTM D93 Pensky-Martens closed cup methods (BSOC, 2000; Miller, 2003; Morford, 2003a, b and c; Shubkin, 2003; Weiss Cohen, 2003). We agree with the commenters that by these standard test methods, nPB displayed no flash point. Thus under standard test conditions, nPB is not flammable, and it should not be flammable under normal use conditions. With its low potential for flammability, nPB is comparable to chlorinated solvents, HCFCs, HFEs, HFC–245fa, HFC–4310mee, and aqueous cleaners, and is less flammable than many acceptable substitutes, such as ketones, alcohols, terpenes, and hydrocarbons. nPB exhibits lower and upper flammability limits of approximately 3% to 8% (BSOC, 2000). A number of other solvents that are typically considered to be non-flammable also have flammability limits (for example, methylene chloride, HCFC–141b, and methyl chloroform). If the concentration of vapor of such a solvent falls between the upper and lower flammability limits, it could catch fire in presence of a flame. Such a situation is unusual, but users should take appropriate precautions in cases where the concentration of vapor could fall between the flammability limits.

E. Impact on Human Health

In evaluating potential human health impacts of nPB, EPA considered impacts on both exposed workers and on the general population because we identified these groups of people as the ones likely to be exposed to nPB when it is used as a substitute for ozone-depleting substances. EPA evaluated the available toxicity data using EPA guidelines to develop health-based criteria to characterize human health risks (U.S. EPA, 1994b. RfC Guidelines; U.S. EPA, 1991. Guidelines for Developmental Toxicity Risk Assessment; U.S. EPA, 1995b. Benchmark Dose guidelines; U.S. EPA, 1996. Guidelines for Reproductive Toxicity Risk Assessment).

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

As part of this final rulemaking, the Agency has reviewed both information available at the time of the 2003 NPRM related to the health risks associated with nPB use, as well as more recent case studies of nPB exposures and effects in the workplace, newly published toxicological studies, comments to the NPRM, new risk assessments on nPB, and a new threshold limit value (TLV) issued by the American Council of Government and Industrial Hygienists (ACGIH). The new information is reviewed in greater detail in EPA's proposal specific to the use of nPB in aerosol solvents, adhesives, and coatings.

Some general conclusions we draw from the new studies include:

- New data from toxicological studies on nervous system effects remain inconsistent and equivocal concerning the level at which nervous system effects occur (Fueta *et al.*, 2002; Fueta *et al.*, 2004; Honma *et al.*, 2003; Ishidao *et al.*, 2002, NTP, 2003; Sohn *et al.* 2002, Wang *et al.*, 2003).
- Case reports of nPB exposure in the workplace indicate that severe, possibly irreversible, neurological effects may occur at sustained concentrations of approximately 100 ppm or greater (Beck and Caravati, 2003; Majersik *et al.*, 2004; Majersik *et al.*, 2005; Ichihara *et al.*, 2002; Miller, 2005; Raymond and Ford, 2005). In other cases, similar or higher concentrations up to 170 ppm caused less severe nervous system effects (Nemhauser, 2005; NIOSH, 2003a; Ichihara, 2004a). Some neurological effects occurred in workers at levels of less than 50 ppm (Ichihara *et al.*, 2004b). Because of design and methodological limitations, such as small numbers of subjects and limited exposure information, these studies do not provide a sufficient quantitative basis to derive an acceptable exposure limit.
- Data on female rats indicate that nPB affects the maturation of ovarian follicles and the ovarian cycle (Yamada *et al.*, 2003), consistent with previously reviewed data (WIL, 2001; Sekiguchi *et al.*, 2002).
- Some data on occupation exposure suggest that workers exposed to nPB may have experienced menstrual disorders (Ichihara *et al.*, 2002; Ichihara *et al.*, 2004b). However, the data are not statistically significant and are not sufficient to conclude that nPB exposure caused these female reproductive effects.
- Data on DNA damage in workers exposed to nPB was not statistically significant (Toraason *et al.*, 2006).
- Metabolic data on mice and rats indicate some species differences. Metabolism of nPB appears to be primarily through cytochrome P450 enzymes, particularly in mice; glutathione conjugation also plays a role, and a bigger role for rats than for mice (RTI, 2005).

These more recent studies do not cause us to change our acceptability determination for solvent cleaning.

In addition, we considered new evaluations of the toxicity of nPB from Stelljes and Wood (2004), Toxicological Excellence in Risk Assessment (TERA, 2004), ICF (2004a, 2006a), and the TLV documentation from the ACGIH (ACGIH, 2005).

- Stelljes and Wood (2004) is similar in its results to SLR International (2001), a study by the same authors. EPA previously reviewed SLR International, 2001 in developing the June 2003 NPRM. Both these studies concluded with a recommended AEL of 156 ppm, based on male reproductive effects and uncertainty factors of 1 in driving the AEL. These documents assigned uncertainty factors in a manner inconsistent with EPA's guidance. This would result in a higher AEL than we would determine following the approach EPA has used on other chemicals, as well as an AEL that in our view would not sufficiently protect human health from nPB's effects because of multiple sources of uncertainty in available data (*i.e.*, variability within the working population and differences between animals and humans in how nPB affects the reproductive system).
- TERA (2004) reviews other AEL derivations for nPB, performs a benchmark dose (BMD) analysis, and recommends an AEL of 20 ppm based on live litter size. This document is consistent with EPA guidance for BMD modeling and for assigning uncertainty factors. A review of this document is available in the public docket (ICF, 2004b).
- ICF (2004c, 2006b) derived an AEL for nPB based upon female reproductive effects. ICF (2004c, 2006b) discussed the relevant literature (Ichihara *et al.*, 1999, 2002, 2004a, 2004b; Sekiguchi, 2002; Yamada *et al.*, 2003; WIL, 2001) and calculated mean estrous cycle length and the mean number of estrous cycles occurring during a three-week period at different exposure levels in the WIL, 2001 2-generation study. ICF (2004c, 2006a) found statistically significant reductions in the number of estrous cycles in a three-week period, both including and excluding females that had stopped their estrous cycles, at 250, 500, and 750 ppm in the F0 parental generation and at 500 and 750 ppm in the F1 generation. ICF (2004c, 2006a) conducted BMD modeling and calculated benchmark dose lowerbound (BMDL) values of the number of estrous cycles in a three-week period that varied from 102 to 208 ppm, depending upon the model used and the benchmark criteria selected. All data were calculated based on the mean reductions in estrous cycle number calculated from the WIL, 2001 study. Values were calculated for the F0 generation; the number of data for the F1 generation was too small for statistical analysis. The BMDLs that ICF calculated for the number of estrous cycles in a three-week period were 162 ppm and 208 ppm, depending on the benchmark response criteria (10% change in response vs. one standard deviation) and using a linear-heterogeneous model.
- The ACGIH issued a recommended TLV of 10 ppm (time-weighted average) for nPB (ACGIH, 2005). ACGIH summarized numerous studies showing

different effects of nPB and identified no observed effect levels (NOELs) of 200 ppm for hepatotoxicity (ClinTrials, 1997b) and less than 100 ppm for developmental toxicity, as evidenced by decreased fetal weight (Huntingdon Life Sciences, 2001).

The Occupational Safety and Health Administration (OSHA) has not developed a permissible exposure limit (PEL) for nPB that EPA could use to evaluate toxicity risks [5] from workplace exposure. In prior SNAP reviews, EPA has used ACGIH TLVs where available in assessing a chemical's risks and determining its acceptability if OSHA has not set a PEL. ACGIH is recognized as an independent, scientifically knowledgeable organization with expertise in issues of toxicity and industrial hygiene. However, in this case, EPA believes that ACGIH's TLV for nPB of 10 ppm has significant limitations as a reliable basis for an acceptable exposure limit, especially given the availability of other, more comprehensive analyses described in this preamble. First, according to the authors of the Huntingdon Life Sciences study, the decrease in fetal weight was an artifact of sampling procedure that biased the data (test animals were only sacrificed at the end of the day rather than at random). The Center for the Evaluation of Risks to Human Reproduction (CERHR) expert panel excluded ''aberrantly low'' fetal weights from one litter in this study and calculated a BMDL greater than 300 ppm for this endpoint after removing those outlier data (CERHR, 2002a, 2003a, and 2004a). TERA calculated a BMDL similar to that of the CERHR expert panel when analyzing the same data set (TERA, 2004). Further, the reference list in the documentation on the TLV indicates that ACGIH did not review and evaluate all the studies available prior to the development of the recommended exposure limit. For example, key supporting articles that reported disruption of estrous cycles (Yamada *et al.,* 2003 and Sekiguchi *et al.*, 2002) were not discussed in the TLV documentation. Further, ACGIH did not provide sufficient reasoning for the selection of the chosen endpoint over others (e.g., reproductive toxicity and/or neurotoxicity). The lack of discussion of applied uncertainty factors also prevents a determination of how ACGIH arrived at a TLV of 10 ppm. In summary, EPA is not basing its proposed acceptability determination for nPB on the ACGIH TLV because: (1) Other scientists evaluating the database for nPB did not find the reduced pup weight to be the most sensitive endpoint; (2) BMD analysis of the reduced pup weight data (CERHR, 2002a; TERA, 2004) results in a higher BMDL (roughly 300 ppm) than those for sperm effects and estrous cycle changes; and (3) ACGIH may not have reviewed the complete body of literature as several studies discussing neurotoxicity and female reproductive effects were omitted from the list of references. A number of reviews of this document are available in the public docket (ICF, 2004d; O'Malley, 2004). Despite some flaws in its derivation, the TLV of 10 ppm is less than two-fold lower than the low end of the range of acceptable exposure levels based on the most sensitive reproductive endpoints (see below). This small difference is well within the uncertainty we see when extrapolating a benchmark dose from an experimental study in rats to an occupational exposure limit in humans.

We summarize the data for a number of end points found in these analyses in Table 4 below. We examined these data to assess the acceptability of nPB use in the metals, electronics, and precision cleaning end uses reviewed in this final rule. These data indicate that, once uncertainty factors are applied consistent with EPA guidelines, the lowest levels for acceptable exposures would be derived for reproductive effects.[6] The data also indicate that a level sufficient to protect against male reproductive effects (e.g., reduced sperm motility) would be in a range from 18 to 30 ppm, in the range of 17 to 22 ppm to protect against female reproductive effects (e.g., estrous cycle length), and at approximately 20 ppm for effects related to reproductive success (live litter size).

TABLE 4.—SUMMARY OF ENDPOINTS USING BENCHMARK RESPONSE MODELING

Endpoint [a]	Study	BMDL[b] (ppm)	Human equivalent concentration (HEC)[c] (ppm)
Liver Effects [d]			
Liver vacuolation in males (F_1 offspring generation).	WIL, 2001 as analyzed in ICF, 2002	110	116
Liver vacuolation in males (F_0 parent generation).	WIL, 2001 as analyzed in ICF, 2002	143	150
Liver vacuolation	ClinTrials, 1997b as analyzed in ICF, 2002 and Stelljes & Wood, 2004	226	170
Reproductive Effects—Male			
Sperm motility (F_1 offspring generation).	WIL, 2001 as analyzed in ICF, 2002	169	177
	WIL, 2001 as analyzed in Stelljes & Wood, 2004	156	164
Sperm motility (F_0 parent generation)	WIL, 2001 as analyzed in ICF, 2002	282	296
	WIL, 2001 as analyzed in Stelljes & Wood, 2004	263	276
Prostate weight (F_0 parent generation).	WIL, 2001 as analyzed in TERA, 2004	190	200
Sperm count	Ichihara *et al.*, 2000b as analyzed in Stelljes & Wood, 2004	232	325

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

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

TABLE 4.—SUMMARY OF ENDPOINTS USING BENCHMARK RESPONSE MODELING—Continued

Endpoint [a]	Study	BMDL[b] (ppm)	Human equivalent concentration (HEC)[c] (ppm)
Sperm deformities (F_0 parent generation).	WIL, 2001 as analyzed in Stelljes & Wood, 2004	296	311
Reproductive Effects—Female			
Number of estrus cycles during a 3 week period (F_0 parent generation).	WIL, 2001 as analyzed in ICF, 2006a	162	170
	WIL, 2001 as analyzed in ICF, 2006a	208	218
Estrous cycle length (F_1 offspring generation) [d].	WIL, 2001 as analyzed in TERA, 2004	400	420
Estrous cycle length (F_0 parent generation) [e].	WIL, 2001 as analyzed in TERA, 2004	210	220
No estrous cycle incidence (F_1 offspring generation).	WIL, 2001 as analyzed in TERA, 2004	180	189
No estrous cycle incidence (F_0 parent generation).	WIL, 2001 as analyzed in TERA, 2004	480	504
Reproductive Effects—Reproductive Success			
Decreased live litter size (F_1 offspring generation).	WIL, 2001 as analyzed in TERA, 2004	190	200
Decreased live litter size (F_2 offspring generation).	WIL, 2001 as analyzed in TERA, 2004	170	179
Pup weight gain, post-natal days 21 to 28 (F_1 offspring generation).	WIL, 2001 as analyzed in TERA, 2004	180	189
Developmental Effects			
Fetal body weight	WIL, 2001 as analyzed in TERA, 2004	310	326
Fetal body weight	WIL, 2001 as analyzed in CERHR, 2002a	305	320
Nervous System Effects			
Hindlimb strength	Ichihara *et. al.*, 2000a as analyzed in Stelljes and Wood, 2004	214	300

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

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

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

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

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

These more recent evaluations do not change EPA's acceptability determination for solvent cleaning. As discussed below, users of solvent cleaning equipment are reliably able to achieve exposure levels well below our proposed AEL of 25 ppm in the June 2003 NPRM and therefore we expect nPB users in the metals, electronics, and precision cleaning end uses to be able to achieve acceptable exposure levels. Concentrations of nPB emitted from industrial solvent cleaning equipment were found to be below 25 ppm in roughly 88% of 500 samples on an 8-hr time-weighted average, below 18 ppm in 81% of these samples, and below 10 ppm in roughly 70% of these samples (U.S. EPA, 2003).

Based on review of the previously available information and information submitted in comments to the NPRM, the Agency believes that its derivation of 18 ppm as a starting point in the development of a recommended acceptable exposure level is still valid. For purposes of assessing the acceptability of nPB use in solvent cleaning applications, the Agency evaluated whether exposure levels expected to result from solvent cleaning would approach either the 2003 proposed recommended AEL of 25 ppm, or the more conservative starting point of 18 ppm which was derived from the Agency's original risk analysis. We also evaluated any potential risks to the general population associated with nPB use as a solvent.

1. Workplace Risks

EPA believes that the great majority of users of nPB in metals cleaning, electronics cleaning, and precision cleaning have been able to attain exposure levels of well below 25 ppm, the proposed AEL in the 2003 NPRM, with their existing equipment. Recently measured exposure levels for nPB are much lower than historic exposure data from the 1970s and 1980s for metals cleaning and electronics cleaning (ICF, 2006a); this reflects both improvements in industrial hygiene practices and improvements in cleaning equipment since 1994 spurred by the National Emission Standard for Hazardous Air Pollutants for Halogenated Solvent Cleaning (59 FR 61801). Concentrations

of nPB emitted from industrial solvent cleaning equipment were found to be below 25 ppm in roughly 88% of 500 samples on an 8-hr time-weighted average, below 18 ppm in 81% of these samples, and below 10 ppm in roughly 70% of these samples (U.S. EPA, 2003).

One nPB supplier provided evidence that on the few occasions when nPB concentrations from vapor degreasers were higher than the company's recommended AEL of 25 ppm, users were able to reduce exposure easily and inexpensively by changing work practices, such as reducing drafts near the cleaning equipment (Kassem, 2003). The ability to meet the workplace exposure limit depends on: (1) The features of the cleaning equipment used, such as the presence of secondary cooling coils; and (2) the work practices, such as avoiding drafts near cleaning equipment and lifting cleaned pieces out slowly from the cleaning equipment. Workplace controls could include, but are not limited to, the use of the following: Covers on cold-cleaning and vapor degreasing equipment when not in use; devices to limit air movement over the degreaser; and/or a lip-vent exhaust system to capture vapors and vent them out of the room. Training workers in industrial hygiene practices and in the proper use of cold cleaning and vapor degreasing equipment, as well as warning workers of the symptoms that may occur from over-exposure to nPB, will also help reduce exposure. Therefore, we expect that users of nPB in the solvent cleaning sector following typical industry practices and using typical equipment for vapor degreasing will continue to meet acceptable exposure levels and to use nPB safely without regulatory requirements. This is the approach the SNAP program has taken with many other solvents where users are readily able to meet workplace exposure limit that will protect human health and there is no enforceable OSHA PEL (*e.g.*, HFC–365mfc, HFC–245fa, heptafluorocyclopentane, ketones, alcohols, esters, hydrocarbons, etc.). Based on the available exposure data and current industry practices, EPA believes that users of nPB as an industrial solvent for metals cleaning, electronics cleaning, and precision cleaning are likely to be exposed to concentrations of nPB well below the proposed AEL of 25 ppm from the 2003 NPRM.

2. General Population Risks

In the 2003 NPRM, the Agency provided analyses demonstrating that people living in the immediate vicinity of a facility using nPB in spray adhesives would have exposures below the community exposure guideline of 1 ppm (68 FR 33300–33301). The community exposure guideline was derived considering both sperm motility and liver effects in the WIL (2001) 2-generation study using EPA's reference concentrations (RfC) guidelines (U.S. EPA, 1994b). Since the general population would not be exposed in excess of the community exposure guideline from a highly emissive application, the less emissive uses such as metals, electronics, and precision cleaning would create insignificant exposures (well below 1 ppm). Thus, we believe that proper use of nPB in solvent cleaning would not pose measurable risks to the general population.

V. How is EPA responding to comments on the June 2003 NPRM?

In this section, EPA responds to comments on the major issues in the June 2003 NPRM. A complete response to comments is in docket EPA–HQ–OAR–2002–0064.

A. EPA's Acceptability Decision

There was no consensus among commenters about whether EPA should find nPB acceptable, acceptable subject to use conditions, or unacceptable in the various end uses listed in the proposal. Some commenters raised concerns about specific end uses, particularly aerosols and adhesives. Others supported finding nPB acceptable in solvents cleaning and in adhesives. We are not taking final action in this rule with respect to nPB as a substitute in aerosols or adhesives. We will respond to any comments regarding those end uses at the time we take final action for aerosols and adhesives.

Comment: Several commenters supported EPA's proposed approval of nPB under the SNAP program in various end uses. In contrast, two commenters opposed EPA's proposed acceptability determination in all end uses, including solvent cleaning, citing concerns about exposure and the toxicity of nPB. Another commenter stated that applications cited in the proposal (e.g., electronics and metals cleaning, label removal and spray cleaning) are not suitable for use of nPB. This commenter reasoned that if nPB provides unique performance characteristics, its uses should be limited to non-emissive and low-volume applications. A commenter from a company that markets nPB as a chemical intermediate but not as a solvent, noted that his company recognizes the health concerns associated with nPB, and thus his company continues to prohibit the sale of nPB to customers with dispersive uses. Another commenter stated that nPB is dangerous to the ozone layer and workers and urged EPA to find a safe substitute.

Response: EPA believes nPB may be found acceptable under the SNAP program only in those end uses where it has been shown to be used safely, as compared with other substitutes that are currently or potentially available. We find this to be the case for metals cleaning, electronics cleaning, and precision cleaning.

Comment: Several commenters agreed with EPA's proposed approval for nPB in metal cleaning, electronics cleaning, and precision cleaning end uses. One specifically reported that his company's industrial hygiene program for nPB-based solvents in metal and electronics cleaning has conducted extensive air sampling, and that the majority of the samples have shown values well below 25 ppm. This commenter also noted that, in those few workplaces where higher levels were found, adoption of recommended workplace ventilation and handling practices produced acceptable subsequent sample values. Thus, this commenter believes that exposures can be controlled to protective levels.

One commenter expressed concerns over the approval of nPB as acceptable for use in solvent cleaning, maintaining that toxicity data is insufficient to be convincing that long-term effects will not be a concern. Two other commenters did not support EPA's proposal to find nPB acceptable. One of the commenters concurred with EPA that exposures from manual wipe cleaning will not be acceptable and that nPB should not be used in such operations. Another commenter opposed EPA's proposed acceptability determination for solvent cleaning, stating that use of nPB in applications such as electronics and metals cleaning, label removal, and spray cleaning is not appropriate.

Response: EPA agrees with those commenters who said nPB should be acceptable for use in metal cleaning, electronics cleaning, and precision cleaning. By our definition of the solvent cleaning sector, such users are cleaning using industrial cleaning equipment. For an organic solvent, this means a vapor degreaser or an automated cold cleaning machine. Emissions from vapor degreasers can be controlled both through improving equipment (increasing the freeboard, adding cooling coils, or adding a lift that raises cleaned pieces slowly) and through improved work practices (leaving the vicinity of the vapor degreaser when done with work, tipping

work-pieces so they do not catch solvent, or lifting cleaned pieces out slowly).

In solvent cleaning equipment, exposure data show that nPB can meet an exposure level well below 25 ppm, even at levels of 5 ppm or less, the majority of the time (U.S. EPA 2003; ICF, 2006a). Concentrations of nPB emitted from industrial solvent cleaning equipment were measure to be below 25 ppm in roughly 88% of more than 500 samples, below 18 ppm in 81% of these samples, and at or below 5 ppm in 56% of these samples (U.S. EPA, 2003). In cases where exposure levels are higher, there are simple, cost-effective changes that can be made to reduce emissions (Kassem, 2003). We agree that manual cleaning using nPB is inappropriate, because of the difficulty of controlling emissions, but manual cleaning is currently beyond the scope of the SNAP Program. EPA plans to address spray cleaning using aerosols in a new proposal.

B. Toxicity

1. Health Endpoints

Comment: A number of commenters on the June 2003 NPRM suggested that EPA should consider neurotoxicity as the endpoint in deriving the AEL for nPB (Linnell, 2003; Werner, 2003; Rusch and Bernhard, 2003; Rusch, 2003). In particular, they requested that EPA consider the study conducted by Wang (2003) and epidemiological data on neurotoxic effects of nPB.

Response: Recent data collected from occupational settings indicate that severe, possibly irreversible, neurological effects may occur at sustained concentrations of approximately 100 ppm or greater (Beck and Caravati, 2003; Majersik, 2004; Majersik, 2005), with variability in effects observed in different studies, although in most cases exposures may have been much higher. Other studies with human data are discussed above in section IV.E. Because of design and methodological limitations, such as small numbers of subjects and limited exposure information, none of the recent studies individually provides a sufficient quantitative basis to derive an AEL.

In the study on rats by Wang *et al.* (2003), measurements found a decrease in enzymes in the spinal cord and brain at 200, 400, and 800 ppm, but the animals displayed no physical or behavioral changes. Because of the lack of physical symptoms or behavioral changes, EPA does not believe that the decrease in enzyme levels in the central nervous system are toxicologically relevant. Other studies examining neurological effects of nPB showed those effects to be transient and reversible at and above 200 ppm (Ichihara *et al.*, 2000a). Exposures of 200 ppm and above for three weeks had no effect on memory, learning function, or coordination of limbs (Honma, 2003); the effect of spontaneous locomotor activity seen in this study at 50 ppm and above was not considered adverse by the authors. In other studies, neurological effects were absent after extended periods of exposure—after 28 days of exposure at concentrations > 400 ppm (ClinTrials, 1997a) and after 90 days of exposure at concentrations up to 600 ppm (ClinTrials, 1997b). Thus, although neurological effects have been associated with nPB exposure, the data are currently insufficient to quantify and set an AEL based on this endpoint. More recent data does not change EPA's acceptability determination for solvent cleaning.

Comment: One commenter on the June 2003 NPRM requested that EPA evaluate a study by Yamada et al (2003), a study published just prior to the June 2003 NPRM.

Response: EPA reexamined Yamada *et al.*, 2003 and re-evaluated the literature (Ichihara *et al.*, 1999, 2002, 2004a,b; Sekiguchi, 2002, Yamada *et al.*, 2003; WIL, 2001). Multiple benchmark analyses found a statistically significant decrease in the number of estrous cycles and increase in estrous cycle length associated with nPB exposure, consistent with other reproductive endpoints, namely reductions in sperm motility, decreased live litter size, and change in prostate weight (ICF, 2002a; ICF, 2006a; Stelljes and Wood, 2004; TERA, 2004). These more recent evaluations, which could lead to an HEC of 170 ppm and an AEL of 17 ppm, do not change EPA's acceptability determination for solvent cleaning, since the evidence supports the ability of users in this end use to consistently meet such a level.

Comment: Some commenters stated that data from the F1 generation is inappropriate for calculating occupational exposure, citing statements from some toxicologists that use of effects on adult F1 generation animals is inappropriate. They also stated that EPA has not required this for other chemicals and that the resulting value is more conservative than what is normal and appropriate for industrial toxicology (Morford, 2003d and e; Ruckriegel, 2003). One commenter claims that because EPA's review of nPB differed from EPA's review of other SNAP alternatives, the process violates equal protection (Morford, 2003d and e). Others stated that sperm motility effects on the F1 generation are appropriate to consider (Risotto, 2003; Farr, 2003), particularly because of the potential for *in utero* effects and because of the consistent presence of these reproductive effects in both generations and at multiple levels.

Response: EPA is not finalizing a specific AEL for the purposes of this final rule. EPA acknowledges that using data from the F1 offspring generation may be conservative because the pups in the F1generation were exposed to nPB between weaning and sexual maturity (WIL, 2001). During occupational exposure, this period of exposure would not occur because children under age 16 are not allowed to work in industrial settings. However, EPA believes that because of the potential for *in utero* effects that would only be seen in the offspring generation, looking only at the F0 parental generation could underestimate the adverse health impacts of a chemical. Therefore, it was appropriate for us to consider effects seen in both the F0 parental generation and the F1 offspring generation. Further, effects on sperm motility in the parental and offspring generations are seen at levels generally consistent with multiple reproductive effects seen in both generations and both sexes exposed to nPB, such as estrous cycle length, lack of estrous cycling, the number of estrous cycles in a given period of time, fertility indices, and the number of live pup births (TERA, 2004; ICF, 2006a; SLR International, 2001).

We also note that different substances have different toxicological effects and those effects must be considered based on the best scientific information and methodologies available. It is incorrect to claim that such reviews, which focus on the effects of different substances, resulted in disparate treatment of nPB [7].

2. Adjustments to Acceptable Exposure Level Based on Risk Management Principles

In the 2003 NPRM, EPA derived 18 ppm as the starting point for an acceptable exposure level based on reduced sperm motility in the offspring generation of animals exposed to nPB (WIL, 2001). Following a SNAP program principle that alternatives should be restricted only where it is ''clearly more harmful to human health and the

[7] We interpret the commenter's use of the term ''equal protection'' to mean that the commenter beleives that EPA has performend a harsher review of nPB than it has for other substitutes and not a claim that EPA has violated the 14th Amendment of the Constitution, which applies only to the states and not the Federal Government.

environment than other alternatives,'' we noted that ''a slight adjustment of the AEL may be warranted after applying judgment based on the available data and after considering alternative derivations''(69 FR 33294, 33295). The Agency proposed an upward adjustment of the AEL to 25 ppm based on principles of risk management, and based, among other things, on a determination that 25 ppm was between the level based on the most sensitive endpoint (sperm motility in the F1 offspring generation) and the second most sensitive endpoint (sperm motility in the F0 parental generation). We stated further that ''18 ppm is a reasonable but possibly conservative starting point, and that exposure to 25 ppm would not pose substantially greater risks, while still falling below an upper bound on the occupation[al] exposure limit.''

Comment: Commenters responded that: (1) The SNAP program does not create a presumption in favor of substances that are already available on the market, especially where other alternatives exist (Linnell, 2003; Werner, 2003); (2) EPA's AEL derivation of 18 ppm is not conservative enough (Werner, 2003; Risotto, 2003) and further adjustment upward further reduces protection; (3) the data do not support adjusting the AEL upward (EPA–HQ–OAR–2002–0064–0003); (4) EPA should first use the same methodology in establishing an AEL as for other chemicals to ensure that the program's guiding principle in comparing risks is not compromised (Werner, 2003); and (5) EPA should reconsider whether industrial exposures consistently occur or can be controlled at 25 ppm (Werner, 2003). No commenters specifically supported adjusting the AEL upward.

Response: EPA is not finalizing a specific AEL for the purposes of this final rule. In a separate proposed rulemaking for the aerosol, adhesive and coatings end uses, we will be providing the public an opportunity to comment on a range of exposure level values that are comparable to the levels discussed in the June 2003 proposal (69 FR 33295) that the Agency would consider to be acceptable. Because we have concluded that end users in the solvent sector are routinely able to meet even the lowest exposure level we considered recommending (U.S. EPA, 2003), we do not need to make a final determination as to the appropriate level for purposes of this rulemaking.

3. Uncertainty Factors

According to EPA risk assessment guidance for RfC (EPA 1994a), uncertainty factors of up to 10 may be applied to the ''human equivalent concentrations (which accounts for worker exposure patterns of 8 hours per day for 5 days a week), for each of the following conditions:

(1) Data from animal studies are used to estimate effects on humans;

(2) Data on healthy people or animals are adjusted to account for variations in sensitivity among members of the human population (inter-individual variability);

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

(4) Studies that only provide a LOAEL rather than a NOAEL or BMD; or

(5) An incomplete database of toxicity information exists for the chemical.

Comment: Some commenters on the June 2003 NPRM stated that EPA should use an uncertainty factor of 1 or 2 to extrapolate from animals to humans (Weiss Cohen, 2003), while others suggested uncertainty factors of 2 or 3 for pharmacokinetics, or an overall uncertainty factor of 10 for rat to human extrapolation because of a lack of information on the metabolism and mode of action of nPB and because the rat is an insensitive model for effects on male reproduction in humans (Werner, 2003; Rusch and Bernhardt, 2003).

Response: EPA believes that two uncertainty factors are appropriate for this database to account for (1) physiological differences between humans and rats; and (2) variability within the working population. EPA RfC guidelines state that an uncertainty factor of 10 may be used for potential differences between study animals and humans. This factor of 10 consists in turn of two uncertainty factors of 3—the first to account for differences in pharmacodynamics[8] and the second to account for differences in pharmacokinetics[9] between the study animal and humans. (The value of three is the square root of 10 rounded to one digit, with 10 representing an order of magnitude [EPA,1994a, pp. 1–6, 4–73]. In practice, EPA uses the square root of 10 when there are two or four uncertainty factors of 3, yielding a total uncertainty factor of 10 or 100, and we use a value of 3 when multiplying by other uncertainty factors.) In general, EPA's RfC guidelines state that for the uncertainty factor extrapolating from animal to human data, ''Use of a 3 is recommended with default dosimetric adjustments.'' (U.S. EPA, 1994b, p. 4–73). By EPA RfC guidelines (US EPA, 1994b), no adjustment for differences in pharmacokinetics is necessary in this instance because the blood/air partition coefficient[10] 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. EPA has seen no data to indicate that (1) the toxicity is not directly related to the inhaled parent compound in the arterial blood, or that (2) the critical metabolic pathways do not scale across species, with respect to body weight, in the same way as the ventilation rate. Consistent with Appendix J of EPA's RfC guidelines for an inhaled compound that exerts its effects through the bloodstream, EPA applies an uncertainty factor of 1 for pharmacokinetics and an uncertainty factor of 3 for differences between animals and humans.

Recent studies provide additional data regarding metabolism of nPB in rats and mice (RTI, 2005), but data on human metabolism are still lacking. One analysis of these metabolic data suggested that mice are less sensitive to the effects of nPB than rats and hypothesized that humans would also be less sensitive than rats (Stelljes, 2005). This analysis makes numerous assumptions about toxic nPB metabolites and metabolic activation pathways that have not been confirmed by experimental data. A review of this analysis is available in the public docket (ICF, 2006c). Despite the difference in metabolic pathways for nPB in mice and rats (RTI, 2005), EPA finds no significant species-specific differences in toxicity exist between rats and mice at inhaled concentrations <500 ppm for 13 weeks (NTP, 2003; ICF, 2006c). However, these metabolic and subchronic inhalation studies conducted under the National Toxicology Program did not specifically examine for reproductive toxicity or nPB metabolism in target organs that control reproductive function. In summary, there is little available data about the metabolic activation or reactive metabolites responsible for reproductive toxicity in rodents. Similarly, for nPB, there is little information available about differences and similarities between rodents and humans. Given this circumstance, EPA assumes, in the absence of evidence to the contrary, that nPB toxicity is directly related to the inhaled parent

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

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

compound in the arterial blood and that the critical metabolic pathways scale across species in a manner similar to the ventilation rate (U.S. EPA, 1994b). Therefore, the Agency applied an uncertainty factor of 1 to account for interspecies differences in pharmacokinetics.

Given the available data on the blood/air partition coefficient and EPA RfC guidance in the absence of other information, EPA is applying the same rationale used for other compounds reviewed under EPA's SNAP program with a comparable amount of data where an uncertainty factor of 1 for pharmacokinetics was applied. To account for uncertainty in pharmacodynamics of nPB, EPA is applying the default uncertainty factor of 3. This follows the procedures in EPA's RfC guidelines for situations where there are no data to compare pharmacodynamics in rats versus humans (U.S. EPA, 1994b). Recently published data on humans and rodents do not decrease the uncertainty regarding the pharmacodynamics of nPB; therefore, modification of the uncertainty factor of 3 for differences between species was not justified.

Comment: One commenter stated that EPA did not cite any data that describes the size, condition, or existence of a subpopulation of men especially sensitive to the effects of nPB. In addition, this commenter asserted that sensitive populations are not traditionally considered when deriving an OEL, and that EPA has never mentioned a concern with sensitive subpopulations in previous SNAP reviews. Another commenter said that there is no evidence to support the assertion that nPB exposure below a 100 ppm average will further reduce sperm count or that the removal of nPB exposure will improve sperm count.

Response: EPA disagrees with the comments. There are preexisting reproductive conditions as well as significant variability in fertility among otherwise healthy adults in the workplace. Both male and female reproduction have been shown to be adversely affected by aging, with effects on the ovarian cycle and on sperm motility as major factors changing with increasing age for women and men, respectively (Dunson *et al.*, 2002). Adding damage from other factors, such as smoking or occupational exposure to chemicals such as nPB, therefore, can potentially harm an individual's ability to reproduce further (Dunson, *et al.* 2002). EPA did not issue a proposal based on sperm count, so that comment is not relevant to this rule. In addition, we note that EPA has used uncertainty factors in the past to protect sensitive subpopulations on other chemicals reviewed under the SNAP program (*e.g.*, trifluoroiodomethane at 60 FR 31092, 61 FR 25585 and IoGas™ Sterilant Blends at 69 FR 58903). For deriving AELs from health endpoints such as liver effects and neurotoxicity, the SNAP program typically has assigned an uncertainty factor of 1 for sensitive subpopulations because we assume that individuals who are especially susceptible to these effects will have greater difficulty working than most people. However, there is no connection between the ability to reproduce and the ability to work in the industrial sectors discussed in this rule. Thus, we find it appropriate to require an uncertainty factor greater than 1 for reproductive effects for variability within the working population.

Comment: Some commenters said that an uncertainty factor of 1 is appropriate for variability within the working population because sensitive subpopulations will not be present in the working population (Stelljes, 2003, Morford, 2003e). Other commenters stated that there will be very little difference in variability between the worker population and the general population and that it is unclear why EPA selected an uncertainty factor of 3 instead of 10 (Werner, 2003). Commenters suggested uncertainty factors for variability in the working population of 1, 2, and 5 (Stelljes, 2003, Weiss Cohen, 2003, Werner, 2003).

Response: EPA disagrees with the commenters. EPA's RfC guidelines recommend an uncertainty factor of 10 to account for intraspecies variability within the general population. However, in developing an AEL, EPA's focus is on worker exposure, which excludes some particularly vulnerable populations, such as children, most adolescents, and the elderly. Thus, we believe that a full uncertainty factor of 10, as for the general population, may be higher than necessary to protect workers. Certain individuals in the general population but not in the working population that might be particularly vulnerable would include children and adolescents under age 16 and individuals with immune deficiency disorders. However, because of variability in reproductive function due to factors present among workers, such as aging, smoking, and sexually transmitted disease (Dunson *et al.*, 2002), and because there is no screening of workers that would make workers more likely to have healthy reproductive systems than non-workers of the same age, we believe than an uncertainty factor of 1 is not sufficiently protective. Under EPA guidelines, 3 is a default value for an uncertainty factor where there is indication that a value less than an order of magnitude (10) but greater than one is appropriate, and where the available data are not sufficiently quantified to select a specific value.

4. Other Analyses of nPB's Toxicity

Comment: One commenter stated that documents by Drs. Doull, Rozman, Stelljes, Murray, Rodricks, and the KS Crump Group were not acknowledged (Morford, 2003d,e, and f). Another commenter requested that EPA take into account the scientific presentations presented by Drs. Doull, Rozman and Stelljes and mentions a review by Dr. Rodricks (Weiss Cohen, 2003).

Response: EPA specifically mentioned and responded to the occupational exposure limit recommendations from Drs. Rozman, Doull, and Stelljes in the preamble to the June 2003 NPRM at 68 FR 33298–33299. In addition, EPA included more detailed written responses to these derivations and the evaluation by Dr. Rodricks in the online docket prior to proposal (EPA–HQ–OAR–2002–0064–0017, –0018, and –0019). Here are abbreviated responses to the various documents cited by the commenter:

- Drs. Doull and Rozman's letter dated August 24, 2001, stating that a two-generational reproductive study is not appropriate (Docket A–2001–07, item II–D–26)—Drs. Doull and Rozman do not provide a rationale for their statement. Their statement is in conflict with their AEL derivation, in which they consider use of the F1 generation of the WIL Laboratories two-generation study. As discussed above in section V.B.1, EPA believes that data from a two-generation reproductive study are appropriate in developing a guideline for the workplace in order to assure that workers and their children are protected from any adverse health effects of workplace exposure, including exposure *in utero.* We acknowledge that this value may be more conservative than considering data only from the parental generation.
- Drs. Doull and Rozman's critique of ICF's AEL derivation (II-D–41b)—Drs. Doull and Rozman's primary stated reason for rejecting ICF Consulting's evaluation is that it does not reflect their own AEL derivation. They reiterate that they find neurotoxicity to be the appropriate basis for an AEL without addressing the reasons that ICF's derivation provides for finding reproductive toxicity to be of greater concern than neurotoxicity. We disagree with Doull and Rozman's conclusion that neurotoxicity is the more

appropriate endpoint for several reasons: (1) The human data are insufficient to draw conclusions because of a small number of subjects, limited exposure information, and lack of statistical significance; (2) the animal data on neurotoxicity are inconsistent and equivocal concerning the level at which nervous system effects occur, and they indicate that neurotoxic effects may be reversible; and (3) neurotoxicity is a less sensitive endpoint than reproductive effects. However, if we had used neurotoxicity as the endpoint for an AEL, we would have reached the same acceptability determination for solvent cleaning.

The basis of EPA's June 2003 NPRM is different from either one of these documents because it uses a different endpoint from Doull and Rozman's derivation (2001) and an uncertainty factor of 3 instead of 2 to 3 for variability within the working population (Doull and Rozman, 2001; ICF, 2002a). According to EPA guidance on establishing uncertainty factors, if a uncertainty factor is between 1 and 10 and the data are not sufficient to quantify the uncertainty between those values, the default uncertainty factor to be used is 3 (U.S. EPA, 1994b).

• Drs. Rozman and Doull's derivation of an AEL (II–D–63)—EPA discussed our evaluation of this document at length in the preamble of the June 2003 NPRM at 68 FR 33298. In particular, we disagree with Rozman and Doull's selection of the most sensitive endpoint. Rozman and Doull concluded that reproductive toxicity should not be considered the most sensitive endpoint, stating that a National Institute for Occupational Safety and Health (NIOSH) evaluation found that no human beings at a facility using nPB-based adhesives experienced reproductive health effects from the nPB. However, the NIOSH study in fact concluded that the survey questions would not be sufficient to determine if there were reproductive health effects, which is significantly different from saying that there was no health effect. The expert panel for the CERHR looked at the NIOSH report and a wide range of human and animal studies on nPB; in contrast to Rozman and Doull, the expert panel concluded that there was insufficient information on reproductive effects of nPB on humans and that the results of tests on animals were considered appropriate for evaluating potential reproductive health effects on humans.

Further, EPA disagrees with the specific AEL value of 60 to 90 ppm that Rozman and Doull derived. They used data on headaches from a draft NIOSH survey, selecting an endpoint of 190 ppm. However, the data in the final survey were not sufficient to detect any dose-response with any statistical significance (Custom Products HHE, II–A–49). Further, more recent studies on human exposure to nPB have found neurotoxic effects occurring at levels at least as low as 86 ppm, and possibly lower than 60 ppm (Ichihara 2004a, Beck and Caravati 2003). These data would indicate that an AEL of 60 to 90 ppm is not sufficiently protective against neurotoxic effects. Drs. Rozman and Doull themselves now suggest that an AEL of 25 ppm may be more appropriate for protecting against neurotoxic effects (Rozman and Doull, 2005).

• Dr. Rodricks' AEL derivation and comments on ICF's derivation (II–D–65)—EPA reviewed Rodricks (2002) in developing its June 2003 NPRM, although the study was not explicitly mentioned in that preamble. Rodricks (2002) suggests an AEL of 60 to 88 ppm for nPB, based on male reproductive effects. Dr. Rodricks says that the most sensitive endpoint that is relevant for occupational exposure is data from the parent generation of the two-generation reproductive study. Dr. Rodricks suggests that an uncertainty factor of only 1 to 2 is necessary for animal to human extrapolation because one should consider animals and workers of average sensitivity; although such an argument presumably could be made for any chemical used in the workplace, EPA has not seen other AEL derivations that use this approach. Dr. Rodricks appears to agree with ICF that an uncertainty factor for variability in reproductive function in the human population is reasonable, although he suggests a factor of 2 instead of the range of 2 to 3 in ICF's derivation. Dr. Rodricks and colleagues previously recommended an AEL for nPB of less than 10 ppm, and at that time suggested an uncertainty factor of 10 for variability in reproductive function in the human population (A–91–42, X–B–53). We discussed above the use of data from both the F0 and F1 generations and the use of an uncertainty factor of 3 for variability within the working population.

• Dr. Stelljes's critique of ICF's AEL derivation (II–D–41a)—Dr. Stelljes states that ICF should have used data from the parent generation rather than from the offspring generation because ''data from F1 animals is not directly applicable to a workplace exposure setting because both parents would not be exposed to nPB on a daily basis over the reproductive cycle, and also have their offspring exposed daily from weaning.'' EPA disagrees in part with Dr. Stelljes's reasoning. Data from F0 animals may not be sufficiently protective because effects on the F0 animals will not reflect effects of *in utero* exposure. However, we agree that exposure during weaning is not reflective of workplace exposure, and thus, data from F1 animals may be conservative. EPA proposed 25 ppm instead of 18 ppm in part to take this conservatism into account.

• Dr. Stelljes's (SLR International's) AEL derivation (II–D–13)—EPA discussed this AEL derivation at length in the preamble to the proposed rule at 68 FR 33298. We agreed with Dr. Stelljes's BMD modeling and his selection of reduced sperm motility in the F1 offspring generation of the WIL Laboratories study as the most sensitive endpoint. However, we disagree with Dr. Stelljes's selection of uncertainty factors. There is no information showing that human sex cells are less sensitive to nPB than rat sex cells, and there is considerable evidence that human males have less reproductive capacity than male rats (U.S. EPA, 1996). Therefore, it is appropriate to add an uncertainty factor of at least 3 to account for differences between rats and humans. Further, Stelljes dismisses the use of an uncertainty factor for differences within the human population. Although we agree that children and the elderly would not be present in the workplace as sensitive subpopulations, there certainly is variability in the reproductive abilities of different working-age people that would have no impact on the individual's ability to be hired or to work; therefore, EPA expects there is some variability in the susceptibility of working individuals to the effects of reproductive toxicants. EPA believes that male reproductive capacity is very susceptible to chemical insult (U.S. EPA, 1996).

• Dr. Murray's opinion on parent and offspring generations (II–D–58)—Dr. Murray says that because the offspring generation will not yet have developed sperm while *in utero,* it is more appropriate to use data from the parent generation of the two-generation study. However, Dr. Murray does not address the possibility that nPB exposure during pregnancy could influence the production of hormones that eventually would result in sperm production. Further, Dr. Murray's response does not address potential effects on ova, which would be present while a fetus is still in its mother's womb.

• Report on uncertainty factors used by ACGIH from K.S. Crump Group (IV–D–26/OAR–2002–0064–0047 and –48)—This report concluded that EPA's

approach to selecting uncertainty factors for use in risk assessment was more transparent, with justification for each value selected, and was more consistent than the values apparently used by the ACGIH in deriving TLVs. EPA agrees with these conclusions.

Comment: A commenter states that ''an uncertainty factor of 10 is NOT 'generally' used to derive occupational exposure limits and that in fact, uncertainty factors of 3 or less or more commonly used,'' citing the K. S. Crump Group's report.

Response: In the case of the TLV that ACGIH established for nPB, ACGIH appears to set an AEL that is a factor of 10 lower than the endpoint cited as lowest (100 ppm for effects on pup weight) (ACGIH, 2005). Thus, ACGIH has used an approach for nPB consistent with the total uncertainty factor of 10 assigned by EPA.

5. Overall Stringency of the Acceptable Exposure Limit

Comment: Some commenters supported the proposed AEL of 25 ppm, stating that it was derived using appropriate conservative and cautious scientific processes. Other commenters said that the proposed AEL of 25 ppm was too high, citing uncertainties in the data, the inappropriateness of adjusting the AEL upward from 18 ppm, reports of health effects on humans, and a need for higher uncertainty factors. Other commenters said that the proposed AEL of 25 ppm was too low, citing higher AELs derived by Drs. Stelljes, Doull, Rozman, and Rodricks, NIOSH studies, and a need for lower uncertainty factors. Commenters suggested alternate AEL values ranging from 1 ppm to 156 ppm.

Response: In this final rule, EPA is not recommending an acceptable exposure limit. We have based our determination of acceptability by comparing measured exposure levels from workers using nPB in solvent cleaning to exposure levels discussed by EPA in the proposal (see section IV.E). At the levels discussed in the NRPM or higher, we find nPB acceptable for solvent cleaning. After considering the available scientific studies on toxicity, exposure data, and alternative derivations of the acceptable exposure limit, we find that the exposure levels discussed in 2003 provide sufficient protection for human health and are consistent with EPA's derivations of AELs for other chemicals reviewed under the SNAP program and EPA guidance for risk assessment.

6. Skin Absorption

In the June 2003 NPRM, EPA discussed listing nPB with a skin notation, and proposed that this was not necessary (68 FR 33295).

Comment: Several commenters on the June 2003 proposal stated that a skin notation for nPB is appropriate, while another commenter agreed with EPA's proposal that no skin notation was necessary (Smith, 2003; HESIS, 2003; Werner, 2003, Weiss Cohen, 2003). One commenter said that EPA should require manufacturers, distributors, and marketers of nPB-containing products to communicate such information on the Material Safety Data Sheets (MSDS) and the product label.

Response: We agree with the commenter that said a skin notation is not necessary. However, today's decision includes a recommendation for users to wear protective clothing and flexible laminate gloves when using nPB to address the concerns about dermal exposure.

Rat studies indicate that dermal exposure to nPB results in neither appreciable absorption through the skin (RTI, 2005) nor systemic toxicity (Elf Atochem, 1995). Unlike methyl chloride and dichlorvos, which are absorbed through the skin and could contribute to systemic toxicity (ACGIH, 1991), EPA is not including a skin notation for nPB in the information provided to users associated with this rulemaking because of the relatively low level of absorption. The ACGIH provides no skin notation in its TLV documentation for several solvents, including nPB (ACGIH, 2005), methylene chloride, and perchloroethylene, and there is no evidence that absorption through the skin is greater for nPB than for the other halogenated compounds. The TLV documentation for nPB states, ''There is no basis for a skin notation because the dermal LD50 of 1-BP was >2 g/kg.'' Further, including a statement giving advice about how to reduce skin exposure in the ''Further Information'' column of listings is likely to be more informative to workers than a skin notation.

Given the possibility that some nPB can be absorbed through the skin in humans, and that the solvent can irritate the skin, EPA encourages users to wear protective clothing and flexible laminate gloves when using nPB and encourages manufacturers, distributors, and marketers of nPB-containing products to include such precautions in their MSDSs. EPA believes that our regulatory authority for the SNAP program is over the substitution (use) of ozone-depleting substances, and thus, we do not believe we have sufficient authority to regulate the manufacturers, distributors and marketers of nPB.

7. Iso-Propyl Bromide Limit

In the June 2003 proposed rule, we proposed as a use condition that nPB formulations contain no more than 0.05% isopropyl bromide (iPB) [11] by weight because of potential health effects associated with this isomer (68 FR 33301–33302).

Comment: Two commenters said that 0.05% iPB is an appropriate and achievable limit. (Smith, 2003; Weiss Cohen, 2003). One of these commenters stated that industry test studies showed that lower limits were neither toxicologically justified nor economical. Another commenter opposed the implementation of the proposed use restriction, stating that it places an undue legal burden on end users, rather than the manufacturers of raw materials, and would not benefit worker safety. This commenter also stated that this is the only instance that SNAP has regulated residual contaminants. This commenter also suggested that EPA defer to an AEL of 1 ppm for iPB established by the government of Korea and the Japan Society for Occupational Health. Moreover, this commenter said that the difference between the acceptable iPB exposure determined by EPA and that determined by ASTM–D6368–00 is very small and, thus, EPA's proposed regulation does not add any value to existing standards. Finally, this commenter noted that epidemiological data found no adverse effect on human workers exposed to 110 ppm of iPB (Ichihara, specific study not identified by the commenter). (Morford, 2003g and h).

Response: We agree that industry has achieved this contamination limit for several years without regulation. We also agree that the concentration of iPB likely to be breathed in by workers would be below 1 ppm even if workers were exposed to concentrations of nPB at 100 ppm or more, provided that the iPB content meets the ASTM–D6368–00 standard for nPB used in vapor degreasing. Further, even if iPB were present in nPB formulations in concentrations as high as 1%, if industry meets the AEL for nPB proposed in 2003 of 25 ppm, or lower, exposures still would be at most 0.25 ppm. This is below the level of 1 ppm established by the Korean government and by the Japan Society for Occupational Health (Morford, 2003h). Therefore, we are not adopting a use condition for iPB for the solvent cleaning end uses.

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

8. Short-Term Exposure Limit (STEL)

In the June 2003 NPRM, EPA recommended a short-term exposure limit of 75 ppm (three times the AEL).

Comment: One commenter noted that there was no indication in the various applications as to how the exposures from those operations compared to the EPA recommendation for a STEL at 75 ppm. This commenter asserted that the potential for exceeding the STEL in solvent cleaning applications appears high and should, therefore, be investigated by EPA. This commenter also stated that, depending on the results of this investigation, EPA may choose to find nPB unacceptable in metals cleaning or restrict its use to where ventilation is employed and/or personal protective equipment is worn.

Response: EPA disagrees that it is necessary to use a short-term exposure limit in determining the acceptability of nPB in solvent cleaning. Acute, short-term exposures of nPB are not of significant health concern, so long as long-term exposures are below the 8-hour TWA limit (ERG, 2004). EPA provided the STEL recommendation in the June 2003 proposal to give guidance to the user community, consistent with the following recommendation of the American Conference of Governmental Industrial Hygienists (ACGIH): ''Excursions in worker exposure levels may exceed 3 times the [threshold limit value] TLV–TWA for no more than a total of 30 minutes during a workday'' (ACGIH 1999). We note that when the ACGIH developed a TLV for nPB, they said there were no data to support a short-term exposure limit (ACGIH, 2005).

C. Ozone Depletion Potential

We proposed that, since the ODP of nPB in the continental U.S. is only 0.013 to 0.018 relative to an ODP of 0.8 for CFC-113, 0.1 for methyl chloroform, and 0.1 for HCFC-141b, nPB should not be found unacceptable because of its ODP (68 FR 33303). The Agency recognized that nPB's ODP could be much higher in tropical regions, as high as 0.071 to 0.100, but since EPA is regulating nPB used in the U.S., we made our decision based on the ODP in the continental U.S.

Comment: One commenter on the June 2003 NPRM provided information (Wuebbles, 2002) and stated that ''even if the entire amount of nPB produced in 2002 was emitted across North American, European and Asian latitudes, the resulting effects on ozone depletion would be too small to measure.'' The same commenter said that the effects on ozone would only be larger if all emissions were to occur in the equatorial region. (Morford, 2003f).

Response: EPA agrees that, based on the current usage of nPB and its ODP in the U.S., there is not a significant impact on the ozone layer.

Comment: Comments on the June 2003 NPRM expressed concern that other countries, particularly those in equatorial regions, might assume that nPB does not pose a danger to the stratospheric ozone layer if the U.S. EPA's SNAP program finds nPB acceptable (Linnell, 2003; Steminiski, 2003).

Response: Because the ODP for nPB is higher when used in the tropics (see footnote 3 above in section IV.2), we recognize the concerns raised by these commenters. However, EPA is regulating use in the U.S. and cannot dictate actions taken by other countries. For example, other countries could choose to continue to use nPB even if EPA were to find it unacceptable in the U.S. We believe the more appropriate forum to address this concern is through the Parties to the Montreal Protocol.

At the most recent Meeting of the Parties to the Montreal Protocol, the Parties made the following decision with regard to n-propyl bromide, in order to ''allow Parties to consider further steps regarding n-propyl bromide, in the light of available alternatives'' (Decision XVIII/11):

1. To request the Scientific Assessment Panel to update existing information on the ozone depletion potential of n-propyl bromide, including ozone depleting potential depending on the location of the emissions and the season in the hemisphere at that location;

2. To request the Technology and Economic Assessment Panel to continue its assessment of global emissions of n-propyl bromide, * * * paying particular attention to:

(a) Obtaining more complete data on production and uses of n-propyl bromide as well as emissions of n-propyl bromide from those sources;

(b) Providing further information on the technological and economical availability of alternatives for the different use categories of n-propyl bromide and information on the toxicity of and regulations on the substitutes for n-propyl bromide;

(c) Presenting information on the ozone depletion potential of the substances for which n-propyl bromide is used as a replacement;

3. To request that the Technology and Economic Assessment Panel prepare a report on the assessment referred to in paragraph 1 in time for the twenty-seventh meeting of the Open-ended Working Group for the consideration of the Nineteenth Meeting of the Parties. (MOP 18, 2006)

D. Other Environmental Impacts

With respect to environmental effects other than ozone depletion potential, we stated in the June 2003 NPRM that users should observe existing Federal, state, and local regulations such as those under the Resource Conservation and Recovery Act or those for compliance with the National Ambient Air Quality Standards (68 FR 33304).

Comment: Commenters stated that, until the safety of nPB has been demonstrated conclusively, more stringent controls are necessary to protect the public and the environment. In particular, these commenters said that the potential for cross-media impacts was not given adequate consideration in the proposed rule. They also stated that EPA did not address the potential for nPB to bioaccumulate in the environment or its impact on sensitive species. One commenter said that he thought it was appropriate to ensure that nPB be kept out of wastewater, and an independent contractor also mentioned concerns about water pollution. Another commenter said that nPB hydrolyzes more quickly than the chlorinated solvents, and so would have less impact on water quality. Currently, the representative's company recommends that spent solvents be incinerated, and offers free pickup and disposal of spent solvent to its customers.

Response: EPA agrees that it should not be standard practice to dispose of spent nPB in water, and that nPB should be kept out of wastewater to the extent possible. This may be achieved by recycling or through incineration. These also are good practices with other spent halogenated solvents, whether or not they are specifically listed as hazardous wastes.

EPA's PBT (persistence/bioaccumulation/toxicity) profiler tool suggested that, based on its structure, nPB would not be considered persistent in water or soil and that nPB would have a low tendency to bioaccumulate (8.3, where 1000 is considered bioaccumulative and greater than 5000 is considered very bioaccumulative). Further, the calculated bioconcentration factor for nPB is only in the range of 18 to 23 (HSDB, 2004; ICF, 2004a). Under EPA's criteria for listing chemicals on the Toxics Release Inventory, this would not be a level of concern (ICF 2004a, EPA 1992). Therefore, we conclude further testing for bioaccumulation of this chemical is not needed before rendering a decision for

use of nPB in the solvent cleaning sector.

Currently, the estimated amount of nPB used in the U.S. in SNAP sectors is on the order of 10 to 12 million pounds per year, which corresponds to roughly 1% of the organic solvent cleaning market, a relatively small amount. It is unlikely that very large amounts of nPB will enter and remain in the nation's water supply, because:

- nPB tends to evaporate quickly, with a calculated half-life of 3.4 hours in a river or 4.4 days in a lake due to volatilization.
- nPB hydrolyzes readily, with a measured hydrolysis half-life of 26 days at 25° C and pH 7.
- If released to the atmosphere, nPB will exist solely in the vapor phase based on its vapor pressure of 110.8 mm Hg. Thus, it is unlikely to be redeposited in rainwater in significant amounts. (PBT Profiler, 2007; ICF, 2004a)

Further, because nPB is short-lived compared to ODS and many ODS substitutes, it is unlikely that nPB will create a substantially greater impact than other acceptable cleaning solvents and than the ODS it replaces. EPA is required by the Clean Air Act to consider whether a replacement for an ODS is more harmful, overall, to human health and the environment than other available or potentially available substitutes. The available information shows that nPB will not be more hazardous than other available, acceptable solvents if it pollutes water or soil.

E. Flammability

In the June 2003 NPRM, we proposed that nPB should not be restricted or found unacceptable because of flammability (68 FR 33303). EPA specifically requested data concerning the flashpoint of pure nPB, including the test method used to provide the data.

Comment: Several manufacturers of nPB and nPB-based solvents and an independent contractor stated that nPB has no flash point under a number of accepted consensus standards for flash point. In support of these statements, the manufacturers of nPB and nPB-based solvents provided flash point test data from a number of different test methods (ASTM D 92 open cup, ASTM D56 Tag closed cup, and ASTM D93 Pensky-Martens closed cup).

Response: EPA agrees. The test results provided by the commenters indicates that nPB has no flash point using a number of standard test methods, including ASTM D 92 open cup, ASTM D56 Tag closed cup, and ASTM D93 Pensky-Martens closed cup. Based on these data, we find that nPB is not flammable under standard test conditions. EPA concludes that nPB should not be considered unacceptable on the basis of flammability risks.

F. Legal Authority to Set Exposure Limits

Comment: Two commenters stated that EPA has no jurisdiction to develop any AEL designed to be applicable to a workplace environment, and that this right belongs to OSHA.

Response: As an initial matter, EPA notes that it has not established an AEL applicable to the workplace in this rule. Rather, EPA reviewed the available information to determine what a safe workplace exposure might be in order to determine whether use of nPB in the solvent cleaning sector poses substantially more risk than use of other available substitutes. The analysis performed by EPA imposes no binding obligation on anyone, particularly in this case where EPA determined that nPB is acceptable for use in the solvent cleaning sector.

Although the Occupational Safety and Health Act (OSH Act) gives the Occupational Safety and Health Administration (OSHA) authority to issue a rule setting or revising an occupational safety or health standard (29 U.S.C. 655(b)), it does not prohibit other Federal agencies from reviewing the safe level of exposure under other statutes that require consideration of the human health and environmental effects of a substance. Conversely, although section 4(b)(1) of the OSH Act prohibits OSHA from regulating a working condition addressed by another federal agency's regulations affecting occupational safety or health, this provision is overridden with respect to EPA's exercise of authority under the Clean Air Act by 42 U.S.C. 7610. That provision states: ''(a) Except as provided in subsection (b) of this section, this chapter shall not be construed as superseding or limiting the authorities and responsibilities, under any other provision of law, of the Administrator or any other Federal officer, department, or agency.''

Section 612 of the Clean Air Act expressly recognizes that some substitutes for ODS may pose more risk to human health and the environment than others and expressly requires EPA to prohibit use of substitutes that pose more risk than other substitutes that are currently or potentially available. Thus, in evaluating whether a substitute should be found acceptable, we must compare the risks to human health and the environment of that substitute to the risks associated with other substitutes that are currently or potentially available.

Our long-standing interpretation is that worker safety is a factor we consider in determining whether a substitute poses significantly greater risk than other available substitutes. In the original SNAP rule, we promulgated the criteria we would review for purposes of determining whether a substitute posed more risk than other available substitutes. Specifically, 40 CFR 82.178(a) specifies the information we require as part of a SNAP application and 40 CFR 82.180(a)(7) identifies the criteria for review. Notably, we require submitters to provide information regarding the exposure data (40 CFR 82.178(a)(10)) and we identify ''occupational risks'' as one of the criteria for review (40 CFR 82.180(a)(7)(iv)). In the preamble of the original SNAP rule, we said that we would use any available OSHA PELs, EPA inhalation reference concentrations, or EPA cancer slope factor data for a substitute together with exposure data to explore possible concerns with toxicity (March 18, 1994; 59 FR 13066). We have reviewed substitutes based on existing OSHA PELs, where available, and, where not available, based on our own assessment of what level is safe for workers. (See e.g., March 18, 1994, 59 FR 13044; Sept. 5, 1996, 61 FR 47012; June 8, 1999, 64 FR 30410; June 19, 2000, 65 FR 37900; December 18, 2000, 65 FR 78977; March 22, 2002, 67 FR 13272; August 21, 2003, 68 FR 50533). In making our own assessment, we review any existing recommended exposure guidelines and available scientific studies and use EPA's risk assessment guidelines (e.g., U.S. EPA, 1994b).

In the case of EPA's evaluation of nPB, there is no final OSHA PEL for EPA to use in evaluating workplace exposure risks. There is a wide variability in the workplace exposure guidelines recommended by manufacturers of nPB-based products, ranging from 5 ppm to 100 ppm, thus providing no definitive value for evaluating the human health risks of workplace exposure. The ACGIH has recently established a TLV for nPB of 10 ppm; however, as discussed above in section IV.E, EPA has concerns about the scientific basis for this TLV. As provided in the original SNAP rule, in the absence of a definitive workplace exposure limit set by OSHA, we evaluated the available information to establish our own health-based criteria for evaluating nPB's human health risks to workers.

Comment: A commenter said that EPA's authority for the SNAP program is under section 615 of the Clean Air Act and that the SNAP program only has authority to take action based on effects on the stratosphere. Specifically, the commenter claims section 615 of the CAA limits EPA's authority under title VI to regulating for purposes of protecting the stratospheric ozone layer. Citing section 618, the commenter also contends that section 618 identified SNAP requirements as ''requirements for the control and abatement of air pollution'' and cites the CAA and EPA policy documents as identifying ambient air as air external to buildings. The commenter also notes that title VI was intended to implement the Montreal Protocol and that it replaced former Part B. The commenter cites legislative history from the enactment of Part B that indicated EPA's authority under Part B was not intended to pre-empt authority of other agencies to take action with respect to hazards in their areas of jurisdiction and that EPA's authority under Part B was only to fill regulatory gaps and not to supersede existing authority of other agencies. With respect to the legislative history of the 1990 Amendments, the commenter argues that there is no suggestion that ''EPA has authority to set workplace worker-exposure standards.'' The commenter also cites legislative history from the Toxic Substances Control Act in which Congress indicated EPA's authority under that statute does not extend to setting workplace standards.

Response: While many provisions in title VI address the regulation of substances that deplete the stratospheric ozone layer, section 612 which governs the SNAP program is broader. The purpose of Section 612 is to review substitutes for ODS and Section 612 of the Clean Air Act clearly requires EPA to consider both the environmental effects as well as *human health,* which includes both the health of the general population and workers. EPA believes there is no doubt that the statutory language requires EPA to consider effects beyond those on the stratospheric ozone layer. In addition, the legislative history makes clear that this language is to be interpreted broadly. Specifically, the report of House Debate on the Clean Air Act Amendments provides ''the Administrator shall base risk estimates on the total environmental risk (toxicity, flammability, atmospheric, etc.) that is perceived to exist, not just the risk as it relates to ozone depletion.'' House Debate on the Clean Air Act Amendments of 1990 Conference Report, S–Prt 103–38 at 1337. The legislative history cited by the commenter is not pertinent. The legislative history for Part B of Title I of the Act is not relevant because that section was repealed in 1990. Public Law 101–549, section 601. Nor is the legislative history for other statutes, such as TSCA, relevant for determining what authority Congress granted to EPA under the CAA.

The commenter incorrectly states that sections 615 and 618 of the CAA place limits on EPA's authority under section 612 of the Act. These provisions expand, rather than restrict, the Administrator's authority. Section 615 is a separate provision of the statute and provides general authority for the Administrator to regulate for purposes of addressing adverse effects to the stratosphere. This provision does not explicitly or implicitly purport to limit the Administrator's authority under other provisions of the Act. Rather, it is a general provision authorizing the Administrator to regulate for protecting against adverse effects to the stratospheric ozone layer.

With respect to section 618, we first note that the commenter appears to equate the stratospheric ozone layer with ''ambient air.'' In fact, they are two different things. Ambient air is defined as ''that portion of the atmosphere, external to buildings, to which the general public has access.'' 40 CFR 50.1(e). The stratospheric level generally extends from 10 to 50 kilometers above the earth and is not considered air to which the public has access. [See *http://www.epa.gov/ozone/defns.html*]. The definition of ''air pollutant'' under the CAA is defined in terms of substances emitted to the ''ambient air.'' The purpose of section 618 is to make clear that for purposes of sections 116 (retention of state authority) and 118 (control of pollution from federal facilities), the provisions in Title VI governing protection of the stratospheric ozone layer shall be treated the same as if they were for the purpose of controlling and abating ''air pollution'' (i.e., pollution to the ambient air). Again, this is not for the purpose of restricting the Administrator's authority under any provision of the Act. Rather, it is for the purpose of extending the protections of Title VI to programs that otherwise only address air pollution (i.e., ambient air, which does not include the stratospheric ozone layer).

Comment: A commenter stated that EPA's claim to authority conflicts with the Department of Labor's administrative ''whistleblower'' case law. These cases hold that a whistleblower action may proceed under the CAA only when the complaint concerned substances emitted to the ambient air. Claims regarding air quality within the workplace are brought under the whistleblower provisions of the OSH Act.

Response: The commenter overstates the import of the decisions issued by the Administrative Review Board. In each of the cited decisions, the Board examined the specific circumstances before it to determine which statutory whistleblower provision provided the basis for the claimed action. While making general pronouncements that the CAA regulates ambient air and OSHA regulates air within the workplace, none of these opinions specifically addressed the scope of EPA's authority under section 612, the SNAP provisions of the Act.

Comment: A commenter stated that even if ventilation or other measures could reduce exposures to below 25 ppm, there is nothing to ensure that companies will take such measures. This commenter also stated that he is aware of nPB formulators that have already announced they will not adhere to this voluntary standard. Three commenters, all representing local environmental regulators, stated that a recommendation that worker exposure be limited to 25 ppm will not carry the enforcement powers of an OSHA standard, and that this lack of control will encourage the use of nPB in applications beyond those envisioned by EPA. Another commenter asserted that the proposed exposure limits (both the AEL and the STEL) should be established as use conditions, citing Section 612 as the basis for EPA's authority to do so. This commenter stated that a precedent has already been set for EPA to accept an alternative chemical subject to use conditions—including that observance of workplace concentration limits—in the adhesives, aerosols, and solvent cleaning sectors (e.g., HCFC–225 ca/cb, HFC–4310mee, monochlorotoluenes, benzotrifluorides; 40 CFR part 82, subpart G, appendices A, B, and D).

Response: EPA agrees that a recommended AEL from EPA does not provide the same level of protection as an enforceable standard from OSHA. We also agree that EPA has the authority under section 612 to require use conditions in those circumstances where use of a potentially promising substitute would otherwise be unacceptable unless those use conditions are met and there are significant concerns about the ability of industry to meet a safe level for use. In the preamble to the original SNAP rule,

we recognized that there may be cases where OSHA has not regulated worker exposure to a substitute. We went on to say that ''EPA anticipates applying use conditions only in the rare instances where clear regulatory gaps exist, and where an unreasonable risk would exist in the absence of any conditions.'' For the solvent cleaning end use, we do not believe that there is an unreasonable risk in the absence of a use condition. Available exposure data show that roughly 88% of samples from nPB users in solvent cleaning met an exposure level of 25 ppm, 81% met an exposure level of 18 ppm, and 70% met an exposure level of 10 ppm (U.S. EPA, 2003). One nPB supplier provided evidence that on the few occasions when nPB concentrations from vapor degreasers were higher than the company's recommended AEL of 25 ppm, users were able to reduce exposure easily and inexpensively by changing work practices, such as reducing drafts near the cleaning equipment (Kassem, 2003). Therefore, we expect that users of nPB in the solvent cleaning sector following typical industry practices and using typical equipment for vapor degreasing will continue to use nPB at levels considered safe for workers. As noted above, this is the approach we indicated we would follow at the time of the original SNAP rule and we have taken this same approach for many other solvents where users are readily able to meet a workplace exposure limit that will protect human health and there is no enforceable OSHA PEL (e.g., HFC–365mfc and heptafluorocyclopentane at 65 FR 78977, ketones, alcohols, esters, and hydrocarbons at 59 FR 13044).

Comment: One commenter claims that section 6 of the Occupational Safety and Health Act requires OSHA to make certain legal findings before promulgating a standard and that therefore EPA has no authority to develop any AEL applicable to a workplace environment. Furthermore, since OSHA is the only agency that can make standards applicable in the workplace, any level developed by EPA is misleading. The same commenter said that EPA offers no reasoning as to why a different methodology for setting an AEL (from that of OSHA) is necessary or advisable. Therefore, this commenter believes that the Agency's process violates equal protection unless EPA is publishing a new standard for chemical review under SNAP.

Response: In this rulemaking, EPA has not developed an AEL that is applicable in any workplace. Rather, EPA looked at a range of possible AELs for purposes of determining whether nPB will pose significantly greater risk than other substitutes that are available in the same end use. The range of levels EPA used for its analysis is not binding. Moreover, as explained above in section V.B.2, EPA has concluded that for purposes of finding nPB acceptable in the solvent cleaning end use, it is not necessary to provide a non-binding recommended workplace exposure limit because these users in the solvent cleaning sector are regularly able to comply with even the lowest level EPA considered in performing its evaluation.

For standards covering hazardous chemicals in the workplace, the OSH Act requires OSHA to set standards that, to the extent feasible, ensure that workers do not suffer material impairments of health. Standards established by OSHA under their statute have not typically prohibited the use of the chemical in any particular application, but instead establish performance goals for the use and handling of hazardous chemicals that reduce such risks to the extent feasible. The available information on health effects of nPB on workers is not sufficiently well-characterized to develop a standard based on avoiding material impairments of health in workers. Most manufacturers and organizations that set workplace exposure limits such as ACGIH and the American Industrial Hygiene Association use an approach similar to EPA's and do not base exposure limits on avoiding material impairments of health in workers. Because of the need for large amounts of well-characterized data from the workplace on exposures and associated health effects to prepare an AEL to prevent material impairment, if EPA were to develop AELs for nPB and other chemicals based on the approach required by section 6 of the OSH Act, EPA would effectively be unable to assess the human health effects of ODS alternatives in time to assist industry in transitioning away from ODS. In order to provide for a more timely assessment of human health effects, as well as one that is consistent with federal guidelines of the National Academies of Science (NAS, 1983), we have considered exposure levels following EPA guidance (U.S. EPA, 1994b). Different substances have different toxicological effects and those effects must be considered based on the best scientific information and methodologies available. It is incorrect to claim that such reviews, which focus on the effects of different substances, resulted in disparate treatment of nPB.

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

Below are actions that will help nPB users minimize exposure levels:

All End Uses

- All users of nPB should wear appropriate personal protective equipment, including chemical goggles, flexible laminate protective gloves (e.g., Viton, Silvershield) and chemical-resistant clothing. Special care should be taken to avoid contact with the skin since nPB, like many halogenated solvents, can be absorbed through the skin. Refer to OSHA's standard for the selection and use of Personal Protective Equipment, 29 CFR 1910.132.
- Limit worker exposure to solvents to minimize any potential adverse health effects. Workers should avoid staying for long periods of time in areas near where they have been using the solvent. Where possible, shorten the period during each day when a worker is exposed. Where respiratory protection is necessary to limit worker exposures, respirators must be selected and used in accordance with OSHA's Respiratory Protection standard, 29 CFR 1910.134.
- Use less solvent, or use a different solvent, either alone or in a mixture with nPB.
- Follow all recommended safety precautions specified in the manufacturer's MSDS.
- Workers should receive safety training and education that includes potential health effects of exposure to nPB, covering information included on the appropriate MSDSs, as required by OSHA's Hazard Communication Standard (29 CFR 1910.1200).
- Request a confidential consultation from your State government on all aspects of occupational safety and health. You can contact the appropriate state agency that participates in OSHA's consultation program. These contacts are on OSHA's Web site at *http://www.osha.gov/oshdir/consult.html.* For further information on OSHA's confidential consultancy program, visit OSHA's web page at *http://www.osha.gov/html/consultation.html.*
- Use the employee exposure monitoring programs and product stewardship programs where offered by manufacturers and formulators of nPB-based products.
- If the manufacturer or formulator of your nPB-based product does not have an exposure monitoring program, we recommend that you start your own exposure monitoring program, and/or request a confidential consultation from your State government. A medical monitoring program should be

established for the early detection and prevention of acute and chronic effects of exposure to nPB. The workers' physician(s) should be given information about the adverse health effects of exposure to nPB and the workers' potential for exposure.

• For non-aerosol solvent cleaning, follow guidelines in the National Emissions Standards for Hazardous Air Pollutant (NESHAP) for halogenated solvents cleaning if you are using nPB. 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.* We note that these steps are useful for reducing exposure to any industrial solvent, and not just nPB.

VII. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review

Under Executive Order (EO) 12866 (58 FR 51735, October 4, 1993), this action is a ''significant regulatory action.'' It raises novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. Accordingly, EPA submitted this action to the Office of Management and Budget (OMB) for review under EO 12866 and any changes made in response to OMB recommendations have been documented in the docket for this action.

In addition, EPA prepared an analysis of the potential costs and benefits associated with this action. This analysis is contained in the document ''Analysis of Economic Impacts of nPB Rulemaking.'' A copy of the analysis is available in the docket for this action (Ref. EPA–HQ–OAR–2002–0064) and the analysis is briefly summarized here.

In our analysis, we assumed that capital costs are annualized over 15 years or less using a discount rate for determining net present value of 7.0%. The acceptability determination for solvents cleaning imposes no requirements and thus creates no additional cost to users.

EPA also considered potential costs end users could incur to meet acceptable exposure levels if they are not already achieving it. 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 this proposal (Ultronix, 2001; Kassem, 2003; Tattersall, 2004). Based on available exposure data for each sector, we assumed that 81% of nPB users in the non-aerosol solvent cleaning sector already achieve exposure levels at the lowest level that we considered, i.e., 18 ppm (U.S. EPA, 2003). Of those nPB solvent users with exposure levels above that, we examined the cost associated with reducing emissions on average by 60%.

If all nPB users in solvent cleaning reduced exposures to 18 ppm, EPA estimates that users would save up to $2 million dollars per year, overall (U.S. EPA, 2007). The value will depend on the number of users that attempt to meet an acceptable exposure level which is already being achieved with existing equipment, the initial exposure level of cleaning solvent users, the price of nPB, and the amount of emission control equipment installed.

B. Paperwork Reduction Act

There are no new requirements for reporting or recordkeeping or information collection associated with this final rule. The final rule merely allows the use of substitutes for ozone-depleting substances, without requiring the collection, keeping, or reporting of information. OMB has previously approved the information collection requirements contained in the existing regulations in subpart G of 40 CFR part 82 under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* and has assigned OMB control number 2060–0226 (EPA ICR No. 1596.06). This ICR included five types of respondent reporting and record-keeping activities pursuant to SNAP regulations: submission of a SNAP petition, filing a SNAP//Toxic Substance Control Act (TSCA) Addendum, notification for test marketing activity, record-keeping for substitutes acceptable subject to use restrictions, and record-keeping for small volume uses. A copy of the OMB approved Information Collection Request (ICR) may be obtained from Susan Auby, Collection Strategies Division; U.S. Environmental Protection Agency (2822T); 1200 Pennsylvania Ave., NW., Washington, DC 20460 or by calling (202) 566–1672.

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 in 40 CFR are listed in 40 CFR part 9.

C. Regulatory Flexibility Act

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

For purposes of assessing the impacts of EPA's June 2003 proposed rule on

small entities, EPA proposed to define ''small business'' as a small business with less than 500 employees, rather than use the individual SBA size standards for the numerous NAICS subsectors and codes to simplify the economic analysis. We solicited comments on the use of this alternate definition for this analysis in the June 2003 NPRM and received no public comments. EPA also consulted with the SBA's Office of Advocacy on the use of an alternate small business definition of 500 employees. The Office of Advocacy concurred with EPA's use of this alternate definition to analysis the economic impacts on small businesses from the use of n-propyl bromide as an acceptable substitute for use in metals, precision, and electronics cleaning, and in aerosols and adhesives end-uses. Therefore, EPA used this alternate definition for this final rule. We believe that no small governments or small organizations are affected by this rule. This approach slightly reduced the number of small businesses included in our analysis and slightly increased the percentage of small businesses for whom the analysis indicated the use of nPB in metals, precision, and electronics cleaning may have an economically significant impact. The number and types of small businesses that are subject to this rule have not changed significantly since the June 2003 proposal. EPA intends to use this alternate definition of ''small business'' for regulatory flexibility analyses under the RFA for any other rule related to the use of nPB as a chemical alternative to ozone-depleting substances (ODS) for the same end uses in the June 2003 NPRM (e.g., adhesives and aerosol solvents).

After considering the economic impacts of this rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. EPA estimates that approximately 1470 users of nPB industrial cleaning solvents (e.g., cleaning with vapor degreasers) would be subject to this rule. This rule lists nPB as an acceptable substitute for ODS. This rule itself does not impose any binding requirements on users of nPB, and therefore will not have a significant economic impact on a substantial number of small entities. EPA did however analyze the potential economic impacts on small businesses that use nPB for cleaning solvents for metals cleaning, electronics cleaning, or precision cleaning. The details of EPA's analysis are described in the supporting materials for this rulemaking (U.S. EPA, 2007). Based on its analysis, EPA believes businesses using nPB-based cleaning solvents for metals cleaning, electronics cleaning, or precision cleaning would experience significant cost benefits by reducing spending on solvent.

D. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. Under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with ''Federal mandates'' that may result in expenditures to State, local, and tribal governments, in the aggregate, or to the private sector, of $100 million or more in any one year. Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective or least burdensome alternative if the Administrator publishes with the final rule an explanation why that alternative was not adopted. Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, it must have developed under section 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements. EPA has determined that this rule does not contain a Federal mandate that may result in expenditures of $100 million or more for State, local, and tribal governments, in the aggregate, or the private sector in any one year. This final rule does not affect State, local, or tribal governments. This rule contains no enforceable requirements. The impact of users meeting the AEL range discussed in the preamble is from a savings of $2 million per year to a cost of $0 million per year. Therefore, the impact of this rule on the private sector is less than $100 million per year. Thus, this rule is not subject to the requirements of sections 202 and 205 of the UMRA. EPA has determined that this rule contains no regulatory requirements that might significantly or uniquely affect small governments. This regulation applies directly to facilities that use these substances and not to governmental entities.

E. Executive Order 13132: Federalism

Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.''

This final 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 final rule does not have tribal implications. It will not have substantial direct effects on tribal governments, on the relationship between the Federal government and Indian tribes, or on the

distribution of power and responsibilities between the Federal government and Indian tribes, as specified in Executive Order 13175.

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

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

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

I. National Technology Transfer and Advancement Act

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 its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

This action does not involve technical standards. Therefore, EPA did not consider the use of any voluntary consensus standards.

J. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq*., as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2). This rule will be effective July 30, 2007.

VIII. References

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

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List of Subjects in 40 CFR Part 82

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

Dated: May 15, 2007.

Stephen L. Johnson,

Administrator.

Appendix A: Summary of Decision

SOLVENT CLEANING ACCEPTABLE SUBSTITUTE

End uses	Substitute	Decision	Further information
Metals cleaning, electronics cleaning, and precision cleaning.	n-propyl bromide (nPB) as a substitute for CFC–113 and methyl chloroform.	Acceptable	EPA recommends the use of personal protective equipment, including chemical goggles, flexible laminate protective gloves and chemical-resistant clothing. EPA expects that all users of nPB would comply with any final Permissible Exposure Limit that the Occupational Safety and Health Administration issues in the future under 42 U.S.C. 7610(a). nPB, also known as 1-bromopropane, is Number 106–94–5 in the Chemical Abstracts Service (CAS) Registry.

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