ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 721

[OPPT–2004–0111; FRL–7692–8]

RIN 2070–AJ12

2-ethoxyethanol, 2-ethoxyethanol acetate, 2-methoxyethanol, and 2-methoxyethanol acetate; Proposed Significant New Use Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing a significant new use rule (SNUR) under section 5(a)(2) of the Toxic Substances Control Act (TSCA) which would require persons to notify EPA at least 90 days before commencing the manufacture, import, or processing of 2-ethoxyethanol (CAS No. 110–80–5) (2-EE), 2-ethoxyethanol acetate (CAS No. 111–15–9) (2-EEA), 2-methoxyethanol (CAS No. 109–86–4) (2-ME), or 2-methoxyethanol acetate (CAS No. 110–49–6) (2-MEA) for domestic use in a consumer product or the manufacture or import of 2-MEA at levels greater than 10,000 pounds per year. EPA believes that this action is necessary because these chemicals may be hazardous to human health and their use in a consumer product may result in human exposure. The required notice would provide EPA with the opportunity to evaluate intended new uses and associated activities, and if necessary, prohibit or limit those uses and activities before they occur.

DATES: Comments, identified by docket identification (ID) number OPPT–2004–0111, must be received on or before May 2, 2005.

ADDRESSES: Submit your comments, identified by docket ID number OPPT–2004–0111, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov/.* Follow the on-line instructions for submitting comments.
- *Agency Website: http://www.epa.gov/edocket/.* EDOCKET, EPA's electronic public docket and comment system, is EPA's preferred method for receiving comments. Follow the on-line instructions for submitting comments.
- *E-mail: oppt.ncic@epa.gov.*
- *Mail:* Document Control Office (DCO) (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Hand Delivery:* OPPT Document Control Office, EPA East Bldg., Rm. 6428, 1201 Constitution Ave., NW., Washington, DC. Attention: Docket ID number OPPT–2004–0111. The DCO is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the DCO is (202) 564–8930. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to docket ID number OPPT–2004–0111. EPA's policy is that all comments received will be included in the public docket without change and may be made available on-line at *http://www.epa.gov/edocket/*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through EDOCKET, regulations.gov, or e-mail. The EPA EDOCKET and the regulations.gov websites are ''anonymous access'' systems, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through EDOCKET or regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket, visit EDOCKET on-line or see the **Federal Register** of May 31, 2002 (67 FR 38102) (FRL–7181–7).

Docket: All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket/*. Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the OPPT Docket, EPA Docket Center, EPA West, Rm. B102, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The EPA Docket Center Reading Room telephone number is (202) 566–1744, and the telephone number for the OPPT Docket, which is located in the EPA Docket Center, is (202) 566–0280.

FOR FURTHER INFORMATION CONTACT: *For general information contact:* Colby Lintner, Regulatory Coordinator, Environmental Assistance Division (7408M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (202) 554–1404; e-mail address: *TSCA-Hotline@epa.gov*.

For technical information contact: Amy Breedlove, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (202) 564–9823; e-mail address: *breedlove.amy@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you manufacture, import, or process 2-EE (CAS No. 110–80–5), 2-EEA (CAS No. 111–15–9), 2-ME (CAS No. 109–86–4), or 2-MEA (CAS No. 110–49–6) for use in consumer products or manufacture or import 2-MEA (CAS No. 110–49–6) at levels greater than 10,000 pounds per year.

Persons who intend to import any chemical substance governed by a final SNUR are subject to the TSCA section 13 (15 U.S.C. 2612) import certification requirements, and to the regulations codified at 19 CFR 12.118 through 12.127 and 127.28. Those persons must certify that they are in compliance with the SNUR requirements (see TSCA section 13 (15 U.S.C. 2612) and 19 CFR 12.118 through 12.127 and 127.28). The EPA policy in support of import certification appears at 40 CFR part 707, subpart B. In addition, any persons who export or intend to export a chemical substance that is the subject of this proposed rule on or after March 31, 2005 are subject to the export notification provisions of TSCA section 12(b) (15 U.S.C. 2611(b)) (see 40 CFR 721.20), and must comply with the

export notification requirements in 40 CFR part 707, subpart D. Potentially affected entities may include, but are not limited to:

- Manufacturers (defined by statute to include importers) and processors of 2-EE, 2-EEA, 2-ME, and 2-MEA (NAICS 325 and 324110), e.g., chemical manufacturing and petroleum refineries.

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions in 40 CFR 721.5 for SNUR-related obligations. If you have any questions regarding the applicability of this action to a particular entity, consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Access Electronic Copies of this Document and Other Related Information?

In addition to using EDOCKET (*http://www.epa.gov/edocket*), you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 721 is available on E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr/*.

C. What Should I Consider as I Prepare My Comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through EDOCKET, regulations.gov, or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD ROM that you mail to EPA, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:

i. Identify the rulemaking by docket ID number and other identifying information (subject heading, **Federal Register** date, and page number).

ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns, and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

II. Background

A. What Action is the Agency Taking?

EPA is proposing to designate the manufacture, import, or processing of 2-EE (CAS No. 110–80–5), 2-EEA (CAS No. 111–15–9), 2-ME (CAS No. 109–86–4), and 2-MEA (CAS No. 110–49–6) for domestic use in consumer products as a significant new use, as well as the manufacture or import of 2-MEA (CAS No. 110–49–6) at levels greater than 10,000 pounds per year. ''Consumer product'' is defined at 40 CFR 721.3 as ''a chemical substance that is directly, or as part of a mixture, sold or made available to consumers for their use in or around a permanent or temporary household or residence, in or around a school, or in recreation.'' This proposed rule would require persons intending to manufacture or import 2-MEA at levels greater than 10,000 pounds per year as well as those intending to manufacture, import, or process 2-EE, 2-EEA, 2-ME, or 2-MEA for domestic use in a consumer product to submit a Significant New Use Notice (SNUN) to EPA at least 90 days before such manufacture, import, or processing.

B. What is the Agency's Authority for Taking this Action?

Section 5(a)(2) of TSCA (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a ''significant new use.'' EPA must make this determination by rule after considering all relevant factors, including those listed in TSCA section 5(a)(2). Once EPA determines that a use of a chemical substance is a significant new use, and promulgates a SNUR, section 5(a)(1)(B) of TSCA requires persons to submit a SNUN to EPA at least 90 days before commencement of manufacture, import, or processing of the chemical substance for that use.

C. What is the Applicability of the General Regulatory Provisions?

General regulatory provisions for SNURs appear under subpart A of 40 CFR part 721. These provisions describe persons subject to the rule, recordkeeping requirements, and exemptions to reporting requirements. Provisions relating to user fees appear at 40 CFR part 700. Persons subject to the rule, when finalized, would be required to comply with the same notice requirements and EPA regulatory procedures as submitters of premanufacture notices (PMNs) under section 5(a)(1)(A) of TSCA. In particular, these requirements include the information submission requirements of TSCA section 5(b) and 5(d)(1), the exemptions authorized by TSCA section 5(h)(1), (2), (3), and (5), and the regulations at 40 CFR part 720. Receipt of a SNUN by EPA may trigger regulatory action under TSCA sections 5(e), 5(f), 6, or 7, if appropriate, to control the activities on which it has received the SNUN. If EPA does not take action, EPA is required under TSCA section 5(g) to explain in the **Federal Register** its reasons for not taking action.

Persons who intend to export a substance identified in a proposed or final SNUR are subject to the export notification provisions of TSCA section 12(b). The regulations that interpret TSCA section 12(b) appear at 40 CFR part 707, subpart D. Persons who intend to import a chemical substance identified in a final SNUR are subject to the TSCA section 13 import certification requirements, which are codified at 19 CFR sections 12.118 through 12.127 and section 127.28. Such persons must certify that they are in compliance with TSCA requirements. The EPA policy relating to import certification appears at 40 CFR part 707, subpart B.

III. Summary of this Proposed Rule

A. Why is EPA Taking this Action?

1. *Background.* On January 24, 1984, EPA published an Advance Notice of Proposed Rulemaking (ANPRM) (49 FR 2921) which stated that EPA determined, based on animal studies, that adverse reproductive and developmental effects are associated with the subject glycol ethers, i.e., 2-EE,

2-EEA, 2-ME, and 2-MEA, at concentrations to which humans may be exposed. (Ref. 1). EPA was considering the regulatory options available under TSCA section 6 to control any unreasonable risks from these chemicals. It solicited comments on the appropriateness of imposing a partial or total ban on these chemicals. EPA had also consulted with the Occupational Safety and Health Administration (OSHA) and the Consumer Product Safety Commission (CPSC) on possible actions under their legal authorities. Later, in October 1984, the Agency concluded that these chemicals may pose a significant hazard to humans (Ref. 2). However, by 1986, EPA's investigation of risks to consumers had led the Agency to conclude that the current information would not support an unreasonable risk finding for consumer use. This conclusion was based on the fact that because of wholesale switching to substitute solvents, EPA had not been able to identify manufacturers who were currently using these glycol ethers in their consumer products. EPA stated that it would continue to consult with the CPSC pursuant to section 9(d) of TSCA to resolve outstanding issues, particularly to clarify whether these glycol ethers were being used in consumer products (Ref. 3). Additionally, EPA stated it was satisfied that any risks from the substitutes were less than those presented by 2-EE, 2-EEA, 2-ME, or 2-MEA, and that use of substitutes would reduce overall risks to humans (Ref. 4).

On May 20, 1986 (51 FR 18488), EPA issued a report to OSHA, under section 9(a) of TSCA, stating that EPA had a reasonable basis to conclude that the risk of injury to worker health from exposure to 2-EE, 2-EEA, 2-ME, and 2-MEA during their manufacturing, processing, and use is unreasonable and that this risk may be prevented or reduced sufficiently by OSHA regulatory action (Ref. 3).

2. *Initial regulatory response by OSHA*. OSHA published its response on December 11, 1986 (51 FR 44699), stating that it had preliminarily concluded that occupational exposures to 2-EE, 2-EEA, 2-ME, and 2-MEA at the current OSHA permissible exposure limits (PELs) may present significant risks to the health of workers (Ref. 5). On April 2, 1987 (52 FR 10586), OSHA published an ANPRM under section 6(b) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 654), announcing its intention to proceed to rulemaking to reduce occupational exposure to 2-EE, 2-EEA, 2-ME, and 2-MEA (Ref. 6). On March 23, 1993 (58 FR 15526), OSHA published a proposed rule that would reduce the chemicals' PELs and provide other protective measures for the approximately 46,000 workers exposed to the substances (Ref. 7). After publishing the 1993 proposal, OSHA held informal public hearings on the proposal, and the record closed in March 1994 (Ref. 8).

3. *EPA regulatory activities in the 1990's*. In the period immediately after OSHA published its proposed rule, EPA, on July 27, 1993 (58 FR 40262) (Ref. 9), promulgated a TSCA section 4 test rule to require neurotoxicity testing of 2-EE (among other chemical substances). The required testing was based on suggestive evidence of neurotoxicity involving the alteration of motor performance and avoidance conditioning in the offspring of rats exposed to 100 and 200 parts per million (ppm) (Refs. 10 and 11), as well as substantial occupational and consumer exposure, and substantial environmental release (Ref. 12). After publication of that rule, however, the producers of 2-EE told EPA that there were no consumer uses of 2-EE (Ref. 13). Given this information, and because OSHA was continuing to work toward revising the PELs for glycol ethers, EPA believed that exposure to 2-EE was not substantial and revoked the TSCA section 4 testing requirements for 2-EE in a settlement agreement with producers in 1994 (Ref. 13). The settlement agreement required that the Chemical Manufacturers Association (now the American Chemistry Council (ACC)) and the manufacturers and processors of these chemicals perform certain neurotoxicity and pharmacokinetics testing on 7 of the 10 chemicals subject to the final neurotoxicity test rule (Ref. 14). This revocation was also reflected in the January 23, 1995 **Federal Register** (60 FR 4514) (FRL–4924–7) (Ref. 15). At the time that EPA was considering revoking the testing requirements in the section 4 rule, the Agency also believed it would be prudent to provide some mechanism to monitor the possible re-emergence of the consumer use of 2-EE. Therefore, in the same notice in which it proposed to revoke the testing requirements of 2-EE (59 FR 33187, June 27, 1994) (Ref. 14), EPA announced its intention to propose and promulgate a SNUR. The parties to the settlement agreement supported such a SNUR (Ref. 13).

4. *Final OSHA regulatory actions*. OSHA reopened the record on August 8, 2002 seeking comment on how the substances were being used in the workplace, including their level of production, and the industries and processes in which they were used (Ref. 16). Based on the information submitted during this comment period, OSHA determined that a major decline in the production of the substances was apparent and that their use in several key industry sectors has been eliminated or is in the process of being phased out. Additionally, OSHA determined that where these substances were still being manufactured, their production was virtually limited to ''closed systems'' and average exposures already were at or below the proposed PEL (Ref. 8). OSHA concluded that the proposed rule was no longer necessary and withdrew its proposed Glycol Ethers rule on December 31, 2003 (Ref. 8).

B. What are the Uses and Production Levels of these Chemicals?

The chemical substances 2-EE, 2-EEA, 2-ME, and 2-MEA, are considered members of a broad class of chemicals known as ethylene glycol ethers. As with other glycol ethers, 2-EE, 2-EEA, 2-ME, and 2-MEA are colorless, flammable liquids which are compatible with a broad range of resins and can be mixed with both organic solvents and water. They have relatively low vapor pressures, high boiling points, low evaporation rates and high flash points. Due to these physical characteristics, 2-EE, 2-EEA, 2-ME, and 2-MEA are potentially useful in a wide variety of applications, particularly as solvents (Ref. 7). They have been used in many industrial and consumer products, but concerns for their health effects have caused these uses to be severely curtailed in recent years.

U.S. production of 2-EE peaked at 200.7 million pounds in 1980 and had decreased to 118 million pounds by 1999. U.S. consumption of 2-EE (including consumption to manufacture 2-EEA) was 175 million pounds in 1980, and down to 53 million pounds in 1999, of which, 52 of the 53 million pounds was used to manufacture 2-EEA. U.S. consumption of 2-EE for uses other than acetate production was less than 1 million pounds. Production and/or imports of 2-EE were below 100 million pounds based on data collected for the 2002 TSCA section 8(a) Inventory Update Rule (IUR) (see 40 CFR part 710) (Ref. 17).

U.S. production of 2-EEA dropped from 136.7 million pounds in 1984 to 72 million pounds in 1999. In 1999, all but one million of those pounds were exported. Data collected for the 2002 IUR show production and/or import levels of less than 100 million pounds (Ref. 17).

U.S. production of 2-ME, which peaked at 97.3 million pounds in 1980, was down to 55 million pounds by 1999 (at which time most 2-ME produced was exported). U.S. consumption, still 50 to 53 million pounds in the early 1990's, had declined to approximately 3 million pounds in 1999. 2002 IUR data show that production and/or import was less than 50 million pounds (Ref. 17).

U.S. production of 2-MEA in 1991 was estimated to be 0.5 million pounds. There were no reports of 2-MEA production or import under the IUR in 1994, 1998, and 2002 (Ref. 17). Therefore, EPA is proposing that persons intending to manufacture or import 2-MEA at levels greater than 10,000 pounds per year as well as persons intending to manufacture, import, or process 2-EE, 2-EEA, 2-ME, or 2-MEA for domestic use in a consumer product to submit a SNUN to EPA at least 90 days before such manufacture, import, or processing.

Production of the E-series glycol ethers, i.e., ethanol based glycol ethers and their acetates, had been declining or has ceased and EPA believes there is no ongoing use of these chemicals in consumer products in the U.S. In response to a proposed TSCA section 4 test rule, manufacturers of 2-EE told EPA that there was no consumer use of 2-EE (Ref. 13). In 2004, a representative for the Ethylene Glycol Ethers Panel of the ACC confirmed that concerns over the toxicity of E-series glycol ethers has subsequently resulted in the elimination of E-series glycol ethers from all consumer products in the 1980's and the development of alternatives to 2-ME, 2-EE, and 2-EEA (Ref. 18).

C. What are the Potential Routes of Exposure?

Despite the diminished potential for human exposure due to the decline in production and use in industrial products and the termination of the chemicals' use in consumer products as discussed in Unit III.B., EPA believes there may still be some potential for human exposure to 2-EE, 2-EEA, 2-ME, and 2-MEA. Their physical characteristics discussed in Unit III.B. make them useful in a variety of applications, particularly as solvents. ''A major route of exposure is the skin. The ubiquity of solvents and the casual approach [of consumers] to their use almost assure skin contact with liquid solvents.'' (Ref. 19). Also, as members of the ethylene series (''E-series'' used in Unit III.B.) of glycol ethers, 2-EE, 2-EEA, 2-ME, and 2-MEA are well absorbed from the skin. They are so readily absorbed through the skin that the dermal to oral 50% lethal dose (LD_{50}) ratio is approximately one (Ref 19).

Although 2-EE, 2-EEA, 2-ME, and 2-MEA are not highly volatile, high vapor concentrations can be generated under the conditions of solvent use. When glycol ether vapors enter the lungs they can readily diffuse across respiratory membranes and enter the bloodstream (Ref. 19).

D. What are the Potential Sources of Exposure?

EPA believes that 2-EE, 2-ME, 2-MEA, and 2-EEA are currently used only in industrial products. EPA also believes that the documented decline in production volumes of 2-EE, 2-EEA, 2-ME, and 2-MEA discussed in Unit III.B. has probably already reduced the potential for occupational exposure. OSHA reported in late 2003 that production, use, and exposure to these glycol ethers has ceased or is virtually limited to closed system production where there is little opportunity for worker exposure. Exposure levels in those operations already are at or below the proposed PELs. In addition, use of these glycol ethers has largely been replaced by less-toxic substitutes, such as E-series butyl glycol ethers, other ethylene glycol ethers, propylene glycol ethers, and other types of solvents (Ref. 8). A decline in environmental release of 2-EE is reflected in Toxics Release Inventory (TRI) data from the years 1987 through 1996 which indicates a steady decline from 2,770,113 pounds in 1987 to 192,468 pounds in 1996 (Ref. 20) to 103,513 pounds in 2001 (Ref. 17).

EPA has found evidence which suggests that 2-EE, as well as 2-ME, 2-MEA, and 2-EEA, are not currently used in consumer products (Ref. 17), and the manufacturers of 2-EE which were parties to the 1994 settlement agreement told EPA that, to the best of their knowledge, there were, at that time, no consumer uses of 2-EE (Refs. 9 and 13).

The ACC also reported in 2001, citing the SRI Chemical Economics Handbook as its source, that the remaining domestic consumption of 2-EE is in non-consumer solvents for paints, coatings, and other industrial uses; the only remaining domestic use of 2-EEA is in machinery and equipment paints and coatings; and the only remaining use of 2-ME, other than as a chemical intermediate, is as a jet fuel deicer. No information on current uses of 2-MEA was identified (Ref. 17).

E. What are the Health Effects of these Chemicals?

Toxicity studies in rats, rabbits, mice, and monkeys via inhalation, dermal, and oral exposure, have shown clearly and consistently that 2-EE and 2-ME can cause adverse hematologic, reproductive, and developmental effects. These effects include decreased white and red blood cell counts, decreased hemoglobin, decreased fertility, decreased sperm count, decreased testes size and weight, increased resorptions, increased fetal malformations, and behavioral and neurochemical alterations in the neonate (Refs. 7 and 2).

Although data on workers is often compromised by confounding exposure to other solvents, studies of workers exposed to 2-ME and 2-EE have documented adverse effects on the hematologic and male reproductive systems. Blood effects observed among the exposed workers include bone marrow injury, reduced red and white blood cell counts, and anemia, while the major reproductive effect observed is reduced sperm count (Ref. 7). Thus, although the human data have their limitations, there is evidence of certain adverse effects in humans exposed to 2-EE and 2-ME and this evidence is consistent with a strong body of evidence of the same or similar effects in experimental animals.

Animal studies with 2-EEA and 2-MEA have shown that these acetates induce adverse reproductive, developmental, and hematological effects similar to those ascribed to their parent glycol ethers, 2-EE and 2-ME. These studies confirm the findings of metabolic studies which indicate that 2-ME, 2-EE, and their acetates follow similar metabolic pathways, producing the same metabolites, which are the active agents most likely responsible for the observed effects (Ref. 7).

IV. Determining a Significant New Use

Section 5(a)(2) of TSCA provides that EPA's determination that a use of a chemical substance is a significant new use must be made after consideration of all relevant factors including:

- The projected volume of manufacturing and processing of a chemical substance.
- The extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance.
- The extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance.
- The reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

EPA construes the statute to allow consideration of any other relevant factors, in addition to those enumerated

in section 5(a)(2)(A) through (D) of TSCA.

To determine what would constitute a significant new use of 2-EE, 2-EEA, 2-ME, and 2-MEA, EPA considered relevant information about the toxicity of the substances, likely exposures/releases associated with possible uses, and the four factors listed in section 5(a)(2) of TSCA.

The latest information available to EPA indicates that there is no ongoing domestic use of 2-EE, 2-EEA, 2-ME, or 2-MEA in consumer products. EPA believes that the renewed use of 2-EE, 2-EEA, 2-ME, or 2-MEA in a consumer product would increase the magnitude and duration of exposure. Considering the health concerns for 2-EE, 2-EEA, 2-ME, and 2-MEA, EPA believes that individuals could suffer adverse effects from their use in consumer products. Thus, EPA is proposing to designate ''domestic use in a consumer product'' as well as the manufacture or import of 2-MEA at levels greater than 10,000 pounds per year as a significant new use of 2-EE, 2-EEA, 2-ME, and 2-MEA.

Based on these considerations, EPA is pursuing the following objectives with regard to the use of 2-EE, 2-EEA, 2-ME, and 2-MEA in consumer products:

- EPA wants to ensure that it would receive notice of any person's intent to manufacture or import 2-MEA at levels greater than 10,000 pounds per year or intending to manufacture, import, or process 2-EE, 2-EEA, 2-ME, and 2-MEA for domestic use in a consumer product before that activity begins.
- EPA wants to ensure that it would have the opportunity to review and evaluate data submitted in a SNUN before the notice submitter begins manufacturing, importing, or processing 2-EE, 2-EEA, 2-ME, and 2-MEA for domestic use in a consumer product or manufacturing or importing 2-MEA at levels greater than 10,000 pounds per year.
- EPA wants to ensure that it would be able to regulate prospective manufacturers, importers, or processors of 2-EE, 2-EEA, 2-ME, and 2-MEA before use of any of these chemicals in a consumer product occurs, provided that the degree of potential risk is sufficient to warrant such regulation.

As noted in Unit III.B., the production of the chemicals included in this SNUR have declined significantly over time. EPA is not aware of current domestic consumer uses for the chemicals, and substitutes are available. The Agency will use information submitted pursuant to the Inventory Update Rule (40 CFR part 710) to track the production volumes and uses of these chemicals. If needed, EPA may pursue additional regulatory actions as appropriate under TSCA sections 4, 5, 6, or 8.

V. Test Data and Other Information

EPA recognizes that section 5 of TSCA does not require the development of any particular test data before submission of a SNUN. Persons are required only to submit test data in their possession or control and to describe any other data known to or reasonably ascertainable by them (15 U.S.C. 2604(d); 40 CFR 721.25).

However, SNUN submitters should be aware that EPA will be better able to evaluate SNUNs which provide detailed information on:

- Human exposure and environmental releases that may result from the significant new use of the chemical substances.
- Potential benefits of the chemical substances.
- Information on risks posed by the chemical substances relative to risks posed by potential substitutes.

Submitters should consider including with a SNUN any other available studies on the chemical substances or studies on analogous substances which may demonstrate that the significant new uses being reported are unlikely to present an unreasonable risk.

In view of the potential risks posed by these chemicals, EPA would recommend that potential SNUN submitters include data that would permit a reasoned evaluation of risks posed by these chemicals. EPA encourages persons to consult with the Agency before submitting a SNUN for these substances. As part of this optional pre-notice consultation, EPA would discuss specific data it believes are necessary to evaluate a significant new use. A SNUN submitted without sufficient data to reasonably evaluate risks posed by a significant new use of 2-EE, 2-EEA, 2-ME, and/or 2-MEA may increase the likelihood that EPA will take action under TSCA section 5(e) to prohibit or limit activities associated with these chemicals. EPA recommends that potential SNUN submitters contact the Agency early enough that they will be able to conduct any appropriate tests.

VI. Recordkeeping Requirements

In addition to the recordkeeping requirements of 40 CFR 721.40 which require persons subject to a SNUR to retain documentation of information contained in a SNUN, EPA is proposing to require the recordkeeping requirements in 40 CFR 721.125 (a), (b), and (c) in this SNUR. Section 721.125(a) requires records documenting manufacture and importation volume and dates; § 721.125(b) documents volumes purchased in the U.S. by processors, the names and addresses of suppliers, and the dates of purchase; and § 721.125(c) requires records documenting the names and addresses (including shipment destination address, if different) of all persons outside the site of manufacture, importation, or processing to whom the manufacturer, importer, or processor directly sells or transfers the substance, the date, and the quantity of each sale or transfer. EPA is also proposing to require the maintenance of records documenting the compliance with the significant new use of domestic use in a consumer product or the manufacture or import of 2-MEA at levels greater than 10,000 pounds per year. For the significant new use of 2-MEA manufacture or import at levels greater than 10,000 pounds per year, records required by § 721.125(a) would be sufficient. For the significant new use of domestic use in a consumer product, required documentation must demonstrate compliance with the significant new use, i.e.,: 1) That 2-EE, 2-EEA, 2-ME or 2-MEA were not manufactured, imported, or processed for use in a consumer product; and, 2) that, where no significant new use notice is filed, any recipients of these chemicals either (a) were notified of the SNUR and its provisions by the manufacturer, importer, or processor, (b) knew of the SNUR independently, or (c) cannot undertake the significant new use. See 40 CFR 720.5(a)(2). These records will enable EPA to determine compliance with the SNUR.

VII. SNUN Submissions

SNUNs should be mailed to the Environmental Protection Agency, OPPT Document Control Office (7407M), 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. Information must be submitted in the form and manner set forth in EPA Form No. 7710–25. This form is available from the Environmental Assistance Division (7408M), OPPT, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001 (see 40 CFR 721.25(a) and 720.40(a)(2)(i)).

VIII. Alternatives

Before proposing this SNUR, EPA considered promulgating a TSCA section 8(a) reporting rule for 2-EE, 2-EEA, 2-ME, and 2-MEA. Under such a rule, EPA could generally require any person to report information to the Agency when they intend to manufacture, import, or process 2-EE, 2-EEA, 2-ME, or 2-MEA. However, in the case of these particular substances, the

use of TSCA section 8(a) rather than SNUR authority would have several drawbacks. First, EPA would not be able to take immediate follow-up regulatory action under TSCA sections 5(e) or 5(f) to prohibit or limit the activity before it begins. In addition, EPA may not receive important information from small businesses, because such firms generally are exempt from TSCA section 8(a) reporting requirements. In view of the level of health concerns for 2-EE, 2-EEA, 2-ME, and 2-MEA, EPA believes that a TSCA section 8(a) rule for these substances would not meet EPA's regulatory objectives.

Currently 2-EE, 2-EEA, 2-ME, and 2-MEA are not subject to any other Federal regulation which would notify the Federal Government of activities that might result in adverse exposures associated with the proposed significant new uses, or provide a mechanism that could protect against potentially adverse exposures associated with those uses before they occur.

IX. Applicability of Rule to Uses Occurring Before Effective Date of the Final Rule

As discussed in the **Federal Register** of April 24, 1990 (55 FR 17376), EPA believes that the intent of TSCA section 5(a)(1)(B) is best served by designating a use as a significant new use as of the date of publication of the proposed SNUR rather than as of the effective date of the final rule. If uses begun after publication of the proposed SNUR were considered to be ongoing rather than new, it would be difficult for EPA to establish SNUR notice requirements, because any person could defeat the SNUR by initiating the proposed significant new use before the rule became final.

Any person who, after publication of this proposed SNUR, begins to manufacture, import, or process 2-EE, 2-EEA, 2-ME, or 2-MEA for a proposed significant new use must stop such activity before the effective date of the final rule. Persons who cease those activities will have to meet all SNUR notice requirements and wait until the end of the notice review period, including all extensions, before engaging in any activities designated as significant new uses. If, however, persons who begin to manufacture, import, or process any of these chemicals between the proposal and the effective date of the final SNUR meet the conditions of advance compliance as codified at 40 CFR 721.45(h), those persons would be considered to have met the requirements of the final SNUR for those activities.

X. Economic Analysis

EPA has evaluated the potential costs of establishing SNUR reporting requirements for potential manufacturers, importers, and processors of the chemical substances included in this proposed rule. While there is no precise way to calculate the total annual cost of compliance with the final rule, given the uncertainties related to predicting the number of SNUN's that would be submitted as a result of this SNUR, EPA estimates that the cost for preparing and submitting a SNUN is $7,174, including a $2,500 user fee required by 40 CFR part 700.45(b)(2)(iii) (Ref. 18). Small businesses with annual sales of less than $40 million when combined with those of the parent company (if any) are subject to a reduced user fee of $100 (40 CFR part 700.45(b)(1)). Based on past experience with SNURs and the low number of SNUNs which are submitted on an annual basis, EPA believes that there will be few, if any, SNUNs submitted as a result of this SNUR. The costs of submission of SNUNs will not be incurred by any company unless a company decides to pursue a significant new use as defined in this SNUR. Furthermore, while the expense of a notice and the uncertainty of possible EPA regulation may discourage certain innovations, that impact would be limited because such factors are unlikely to discourage an innovation that has high potential value. EPA's complete economic analysis is available in the public docket for this proposed rule (Ref. 18).

Under section 12(b) of TSCA, exporters must notify EPA if they export or intend to export a chemical substance or mixture for which a rule has been proposed or promulgated under section 5 or 6. Notice must be provided for the first export or intended export to a particular country in a calendar year. In an economic analysis of an amendment to the rules implementing TSCA section 12(b), EPA estimated that the one-time cost of preparing and submitting an export notification was $62.60 in 1992, or $93.02 when inflated to 2003 dollars by a factor of approximately 1.5, from the Employment Cost Index for White Collar Occupations. The total costs of export notification will vary per chemical, depending on the number of required notifications (i.e., number of countries to which the chemical is exported). EPA is unable to make any estimate of the likely number of export notifications for chemicals covered in this SNUR (Ref. 17).

XI. References

The public docket for this action, OPPT–2004–0111, currently includes the following documents:

1. USEPA. ''2-Methoxyethanol and 2-Ethoxyethanol and their Acetates; Initiation of Regulatory Investigation, Advance Notice of Proposed Rulemaking.'' 49 FR 2921. (January 24, 1984).

2. USEPA. ''Glycol Ethers Health Effects Assessment.'' Intra-agency memorandum from M.S. Ottley to Harry Teitelbaum, Existing Chemicals Assessment Division. (October 31, 1984).

3. U.S. Environmental Protection Agency (USEPA). ''Toxic and Hazardous Substances Control; 2-Methoxyethanol, 2-Ethoxyethanol and their Acetates; Referral For Additional Action.'' TSCA section 9 referral to OSHA. 51 FR 18488. (May 20, 1986).

4. USEPA. ''Substitutes for 2-Ethoxyethanol (2-EE), 2-Methoxyethanol (2-ME) and their Acetates.'' Intra-agency memorandum from Harry Teitelbaum, Risk Management Branch to Joseph Merenda, Existing Chemicals Assessment Division. (March 15, 1984).

5. OSHA. ''Occupational Exposure to 2-Methoxyethanol, 2-Ethoxyethanol and Their Acetates; Response to the Environmental Protection Agency under section 9(a) of the Toxic Substances Control Act.'' 51 FR 44699. (December 11, 1986).

6. OSHA. ''Occupational Exposure to 2-Methoxyethanol, 2-Ethoxyethanol and Their Acetates; Advance Notice of Proposed Rulemaking.'' 52 FR 10586. (April 2, 1987).

7. Occupational Health and Safety Administration (OSHA). ''Occupational Exposure to 2-Methoxyethanol, 2-Ethoxyethanol and their Acetates (Glycol Ethers); Proposed Rule.'' 58 FR 15526 (March 23, 1993).

8. OSHA. ''Occupational Exposure to 2-Methoxyethanol, 2-Ethoxyethanol and Their Acetates (Glycol Ethers); Withdrawal of Proposed Rule.'' 68:75475–75476. (December 31, 2003).

9. USEPA. ''Multi-substance Rule for the Testing of Neurotoxicity; Final Rule.'' 58 FR 40262. (July 27, 1993).

10. Nelson, B.K., Brightwell, W.S., Setzer, J.V., Taylor, B.J., Hornung, R.W. and O'Donohue, T.L. ''Ethoxyethanol Behavioral Teratology in Rats.'' Neurotoxicology. 2:231–249. (1981).

11. Nelson, B.K., Brightwell, W.S. and Setzer, J.V. ''Prenatal Interaction Between Ethanol and the Industrial Solvent 2-Ethoxyethanol in Rats; Maternal and Behavioral Teratogenic Effects.'' Neurobehavioral Toxicology and Teratology. 4:387–394. (1982).

12. USEPA. ''Multi-substance Rule for the Testing of Neurotoxicity; Proposed Rule.'' 56 FR 9105. (March 4, 1991).

13. United States Court of Appeals for the Fifth Circuit. Settlement Agreement between Environmental Protection Agency and petitioners (Chemical Manufacturers Association et al.), No. 93–5381. (April 28, 1994).

14. USEPA. ''Proposed Revocation of Final Multi-substance Rule for the Testing of Neurotoxicity; Proposed Rule.'' 59 FR 33187 (June 27, 1994).

15. USEPA. ''Revocation of Final Multi-substance Rule for the Testing of Neurotoxicity.'' 60 FR 4514. (January 23, 1995).

16. OSHA. ''Occupational Exposure to 2-Methoxyethanol, 2-Ethoxyethanol and Their Acetates (Glycol Ethers).'' 67 FR 51524. (August 8, 2002).

17. USEPA, 2004. ''Economic Analysis of Expedited Significant New Use Rules for Four Glycol Ethers.'' Washington, DC: U.S. EPA/OPPT/EETD/EPAB, October 27, 2004.

18. ACC, 2004. Personal Communication Between American Chemistry Council, Ethylene Glycol Ethers Panel representative and Jason Sacks, Abt Associates Inc. May 10, 2004.

19. Casarett and Doull's Toxicology. Editors: Klaassen, C.D., Amdur, M.O., and Doull J. Chapter 20: Toxic Effects of Solvents and Vapors. Pages 636–638 and 656–658, 3rd Edition. (1986).

20. USEPA. Toxic Release Inventory (TRI). Total annual environmental releases of 2-ethoxyethanol for the years 1987 through 1996. TRI printouts. (April 26, 1994, May 6, 1994, May 19, 1998, and May 28, 1998).

XII. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review

Under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993), the Office of Management and Budget (OMB) has determined that proposed or final SNURs are not a ''significant regulatory action'' subject to review by OMB, because they do not meet the criteria in section 3(f) of the Executive Order.

B. Paperwork Reduction Act

According to the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, an Agency may not conduct or sponsor, and a person is not required to respond to a collection of information that requires OMB approval under the PRA, unless it has been approved by OMB and displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the **Federal Register**, are listed in 40 CFR part 9, and included on the related collection instrument or form, if applicable.

The information collection requirements related to this action have already been approved by OMB pursuant to the PRA under OMB control number 2070–0038 (EPA ICR No. 1188). This action would not impose any burden requiring additional OMB approval. If an entity were to submit a SNUN to the Agency, the annual burden is estimated to average 105 hours per submission. This burden estimate includes the time needed to review instructions, search existing data sources, gather and maintain the data needed, and complete, review, and submit the required SNUN.

Send any comments about the accuracy of the burden estimate, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques, to the Director, Collection Strategies Division, Office of Environmental Information (2822T), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. Please remember to include the OMB control number in any correspondence, but do not submit any completed forms to this address.

C. Regulatory Flexibility Act

Pursuant to section 605(b) of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), the Agency hereby certifies that promulgation of this SNUR would not have a significant adverse economic impact on a substantial number of small entities. The rationale supporting this conclusion is as follows. A SNUR applies to any person (including small or large entities) who intends to engage in any activity described in the rule as a ''significant new use.'' By definition of the word ''new,'' and based on all information currently available to EPA, it appears that no small or large entities presently engage in such activity. Since a SNUR only requires that any person who intends to engage in such activity in the future must first notify EPA by submitting a SNUN, no economic impact would even occur until someone decides to engage in those activities. Although some small entities may decide to conduct such activities in the future, EPA cannot presently determine how many, if any, there may be. However, EPA's experience to date is that, in response to the promulgation of over 1,000 SNURs, the Agency receives on average only 10 notices per year. Of those SNUNs submitted, none appear to be from small entities in response to any SNUR. In addition, the estimated reporting cost for submission of a SNUN (see Unit X.), are minimal regardless of the size of the firm. Therefore, EPA believes that the potential economic impact of complying with this SNUR is not expected to be significant or adversely impact a substantial number of small entities. In a SNUR that published on June 2, 1997 (62 FR 29684) (FRL–5597–1), the Agency presented its general determination that proposed and final SNURs are not expected to have a significant economic impact on a substantial number of small entities, which was provided to the Chief Counsel for Advocacy of the Small Business Administration.

D. Unfunded Mandates Reform Act

Based on EPA's experience with proposing and finalizing SNURs, State, local, and Tribal governments have not been impacted by these rulemakings, and EPA does not have any reasons to believe that any State, local, or Tribal government would be impacted by this rulemaking. As such, EPA has determined that this regulatory action would not impose any enforceable duty, contain any unfunded mandate, or otherwise have any affect on small governments subject to the requirements of sections 202, 203, 204, or 205 of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4).

E. Executive Order 13132: Federalism

This action would not have a substantial direct effect on 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, entitled *Federalism* (64 FR 43255, August 10, 1999).

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

This proposed rule would not have Tribal implications because it is not expected to have substantial direct effects on Indian Tribes. This proposed rule would not significantly or uniquely affect the communities of Indian Tribal governments, nor would it involve or impose any requirements that affect Indian Tribes. Accordingly, the requirements of Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000), do not apply to this proposed rule.

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

This action is not subject to Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997), because this is not an economically significant regulatory action as defined by Executive Order 12866, and this action does not address environmental health or safety risks disproportionately affecting children.

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

This proposed rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001), because this action is not expected to affect energy supply, distribution, or use.

I. National Technology Transfer Advancement Act

In addition, since this action does not involve any technical standards, 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), does not apply to this action.

J. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations

This action does not entail special considerations of environmental justice related issues as delineated by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

K. Executive Order 12988: Civil Justice Reform

In issuing this proposed rule, EPA has taken the necessary steps to eliminate drafting errors and ambiguity, minimize potential litigation, and provide a clear legal standard for affected conduct, as required by section 3 of Executive Order 12988, entitled *Civil Justice Reform* (61 FR 4729, February 7, 1996).

List of Subjects in 40 CFR Part 721

Environmental protection, Chemicals, Hazardous substances, Reporting and recordkeeping requirements.

Dated: February 16, 2005.

Charles M. Auer,

Director, Office of Pollution Prevention and Toxics.

Therefore, it is proposed that 40 CFR part 721 be amended as follows:

PART 721—[AMENDED]

1. The authority citation for part 721 would continue to read as follows:

Authority: 15 U.S.C. 2604, 2607, and 2625(c).

2. Add new § 721.10001 to subpart E to read as follows:

§ 721.10001 2-Ethoxyethanol, 2-ethoxyethanol acetate, 2-methoxyethanol, and 2-methoxyethanol acetate.

(a) *Chemical substances and significant new uses subject to reporting.* (1) The chemical substances identified as 2-ethoxyethanol (CAS No. 110–80–5), 2-ethoxyethanol acetate (CAS No. 111–15–9), 2-methoxyethanol (CAS No. 109–86–4), and 2-methoxyethanol acetate (CAS No. 110–49–6) are subject to reporting under this section for the significant new use described in paragraph (a)(2) of this section.

(2) The significant new use is domestic use in a consumer product or the manufacture or import of 2-methoxyethanol acetate at levels greater than 10,000 pounds per year.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), and (c) apply to the significant new use specified in § 721.10001. In addition, records documenting compliance with the significant new use of domestic use in a consumer product or the manufacture or import of 2-methoxyethanol acetate at levels greater than 10,000 pounds per year must be maintained.

(2) [Reserved]

[FR Doc. 05–3911 Filed 2–28–05; 8:45 am]

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