

and responsibilities established in the Clean Air Act. This rule also is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because it is not economically significant.

In reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. In this context, in the absence of a prior existing requirement for the State to use voluntary consensus standards (VCS), EPA has no authority to disapprove a SIP submission for failure to use VCS. It would thus be inconsistent with applicable law for EPA, when it reviews a SIP submission, to use VCS in place of a SIP submission that otherwise satisfies the provisions of the Clean Air Act. Thus, the requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. As required by Section 3 of Executive Order 12988 (61 FR 4729, February 7, 1996), in issuing this 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. EPA has complied with Executive Order 12630 (53 FR 8859, March 15, 1988) by examining the takings implications of the rule in accordance with the "Attorney General's Supplemental Guidelines for the Evaluation of Risk and Avoidance of Unanticipated Takings" issued under the executive order.

This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

B. Submission to Congress and the Comptroller General

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. Section 804 exempts from Section 801 the following types of rules: (1) Rules of particular applicability; (2) rules relating to agency management or personnel; and (3) rules of agency organization, procedure, or practice that do not substantially affect the rights or obligations of non-agency parties. 5 U.S.C. 804(3). EPA is not required to submit a rule report regarding today's action under Section 801 because this is a rule of particular applicability.

C. Petitions for Judicial Review

Under Section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action approving a revision to the Marshall County, West Virginia, SO₂ SIP, must be filed in the United States Court of Appeals for the appropriate circuit by October 2, 2000. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See Section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Reporting and record keeping requirements, Sulfur oxides.

Dated: June 23, 2000.

Bradley M. Campbell,
Regional Administrator, Region III.

40 CFR Part 52 is amended as follows:

PART 52—[AMENDED]

1. The authority citation for Part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart 2520—West Virginia

2. Section 52.2520 is amended by adding paragraphs (c)(44) to read as follows:

§ 52.2520 Identification of plan.

* * * * *

(c) * * *

(44) Revisions to the West Virginia Regulations to attain and maintain the sulfur dioxide national ambient air quality standards in Marshall County submitted on February 17, 2000, by the Director, West Virginia Division of Environmental Protection:

(i) Incorporation by reference.

(A) Letter of February 17, 2000, from the Division of Environmental Protection transmitting a revision to the State Implementation Plan (SIP) for Attainment and Maintenance of Sulfur Dioxide National Ambient Air Quality Standards.

(B) Consent Orders entered between the West Virginia Office of Air Quality and:

(1) CO-SIP-2000-1, PPG Industries, Inc., Dated January 25, 2000.

(2) CO-SIP-2000-2, Bayer Corporation, Dated January 26, 2000.

(3) CO-SIP-2000-3, Columbian Chemicals Company, Dated January 31, 2000.

(ii) Additional Material.—Remainder of February 17, 2000 SIP revision submittal.

[FR Doc. 00-19371 Filed 8-1-00; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 63 and 302

[FRL-6843-3]

RIN 2060-A108

Redefinition of the Glycol Ethers Category Under Section 112(b)(1) of the Clean Air Act and Section 101 of the Comprehensive Environmental Response, Compensation, and Liability Act

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rules.

SUMMARY: This action deletes each individual compound in a group called the surfactant alcohol ethoxylates and their derivatives (SAED) from the glycol ethers category in the list of hazardous air pollutants (HAP) established by section 112(b)(1) of the Clean Air Act (CAA). Under section 112(b)(3)(D) of the CAA, EPA may delete specific substances from certain listed categories, including glycol ethers. To implement this action, EPA is revising the definition of glycol ethers to exclude the deleted compounds. This action is also making conforming changes with respect to designation of hazardous substances under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). These final rules are being issued by EPA in response to an analysis of potential exposure and hazards of SAED that was prepared by the Soap and Detergent Association (SDA) and submitted to EPA. Based on this information, EPA has made a final determination that there are adequate data on the health and environmental effects of these substances to determine that emissions, ambient concentrations, bioaccumulation, or deposition of these substances may not reasonably be anticipated to cause adverse human health or environmental effects.

EFFECTIVE DATE: August 2, 2000.

ADDRESSES: The docket is available for public inspection and copying between 8 a.m. and 5:30 p.m., Monday through Friday, at EPA's Air and Radiation Docket and Information Docket, Room

M1500, U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460.

FOR FURTHER INFORMATION CONTACT: For information concerning this final rule, contact Dr. Roy L. Smith, Risk and Exposure Assessment Group, Office of Air Quality Planning and Standards, U.S. EPA, Research Triangle Park, North Carolina 27711, telephone number (919) 541-5362, facsimile number (919) 541-0840, electronic mail address smith.roy@epa.gov.

SUPPLEMENTARY INFORMATION:

Docket

Docket number A-98-39 contains the supporting information for this promulgated rule, including SDA's report on SAED and EPA's analysis of that report. The docket also includes public comments on the proposed rule for this action, published on January 12, 1999 (64 FR 1780). The docket is an organized and complete file of all the information considered by the EPA in the development of this rulemaking. The docket is a dynamic file because material is added throughout the rulemaking process. The docketing system is intended to allow members of the public and industries involved to readily identify and locate documents so that they can effectively participate in the rulemaking process. Along with the proposed and promulgated standards and their preambles, the contents of the docket will serve as the record in the case of judicial review. (See section 307(d)(7)(A) of the CAA.) An index for each docket, as well as individual items contained within the dockets, may be obtained by calling (202) 260-7548 or (202) 260-7549. Alternatively, docket indexes are available by facsimile, as described on the Office of Air and Radiation, Docket and Information Center Website at <http://www.epa.gov/oar/docket>. A reasonable fee may be charged for copying docket materials.

Worldwide Web (WWW)

In addition to being available in the docket, an electronic copy of this final rule will be available on the WWW through the Technology Transfer Network (TTN). Following signature, a copy of the rule will be posted on the TTN's policy and guidance page for newly proposed or promulgated rules <http://www.epa.gov/ttn/oarpg>. The TTN provides information and technology exchange in various areas of air pollution control. If more information regarding the TTN is needed, call the TTN HELP line at (919) 541-5384.

Effective Dates

These rules will take effect on August 2, 2000. Although section 553(d) of the Administrative Procedure Act, 5 U.S.C. 553(d), provides that substantive rules must be published at least 30 days prior to their effective date, this requirement does not apply to these rules. First, the rule deleting specified substances from the glycol ethers category in the CAA section 112(b)(1) HAP list was promulgated pursuant to CAA section 307(d), and that provision expressly states that the provisions of section 553 do not apply to this action. Second, even under section 553, the requirement that a rule be published 30 days prior to its effective date does not apply to a rule "which grants or recognizes an exemption or relieves a restriction," and both rules incorporated herein fit that criterion.

Judicial Review

The final rule deleting specified substances from the glycol ethers category in the CAA section 112(b)(1) HAP list is based on a determination of nationwide scope and effect. A petition for judicial review of this final rule may be filed solely in the United States Court of Appeals for the District of Columbia. Any such petition for judicial review of this rule must be filed no later than October 2, 2000, except for judicial review challenging solely the amendment to the CERCLA regulations in 40 CFR part 302, which must be filed no later than October 31, 2000. In any resulting action, no objection can be made which was not raised with reasonable specificity during the period for public comment.

Outline

The information presented in this preamble is organized as follows:

- I. What is the background for this rule?
- II. What was our analysis of the information SDA submitted?
- III. What is the basis for our final decision to delete SAED compounds from the glycol ethers category under the CAA?
- IV. What is the basis for the revised designation of glycol ethers as hazardous substances under CERCLA?
- V. How have we involved stakeholders in this rulemaking?
- VI. What are the administrative requirements for these final rules?
 - A. Executive Order 12866
 - B. Paperwork Reduction Act
 - C. Regulatory Flexibility Act (RFA), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), (5 U.S.C. 601, *et seq.*)
 - D. Unfunded Mandates Reform Act
 - E. Executive Order 13045
 - F. Executive Order 13084
 - G. National Technology Transfer and Advancement Act

- H. The Congressional Review Act
- I. Executive Order 13132

I. What Is the Background for This Rule?

Section 112 of the CAA contains a mandate for EPA to evaluate and control emissions of HAP. Section 112(b)(1) includes an initial list of HAP that is composed of specific chemical compounds and groups of compounds. This list is used to identify source categories for which we will subsequently promulgate emissions standards.

Section 112(b)(2) requires EPA to conduct periodic reviews of the initial list of HAP set forth in section 112(b)(1) and outlines criteria to be applied in deciding whether to add or delete particular substances. Section 112(b)(2) identifies pollutants that should be added to the list as:

* * * pollutants which present, or may present, through inhalation or other routes of exposure, a threat of adverse human health effects (including, but not limited to, substances which are known to be, or may reasonably be anticipated to be, carcinogenic, mutagenic, teratogenic, neurotoxic, which cause reproductive dysfunction, or which are acutely or chronically toxic) or adverse environmental effects whether through ambient concentrations, bioaccumulation, deposition, or otherwise, * * *.

Section 112(b)(3) establishes general requirements for petitioning the Agency to modify the HAP list by adding or deleting a substance. In general, the burden is on a petitioner to include sufficient information to support the requested addition or deletion under the substantive criteria set forth in section 112(b)(3)(B) and (C). The Administrator must either grant or deny a petition within 18 months of receipt. If the Administrator decides to grant a petition, we publish a written explanation of the Administrator's decision, along with a proposed rule to add or delete the substance. The proposed rule is open to public comment and public hearing and any additional information received is considered prior to issuance of a final rule. If the Administrator decides to deny the petition, we publish a written explanation of the basis for denial. A decision to deny a petition and/or the issuance of a final rule granting a petition is final Agency action subject to review in the D.C. Circuit Court of Appeals under section 307(b).

To promulgate a final rule deleting a substance from the HAP list, section 112(b)(3)(C) provides that the Administrator must determine that:

* * * there is adequate data on the health and environmental effects of the substance to

determine that emissions, ambient concentrations, bioaccumulation, or deposition of the substance may not reasonably be anticipated to cause any adverse effects to the human health or adverse environmental effects.

We will grant a petition to delete a substance and publish a proposed rule to delete that substance if we make an initial determination that this criterion has been met. After affording an opportunity for comment and for a hearing, we will make a final determination whether the criterion has been met.

The Administrator may also act to add or delete a substance on her own initiative. In this instance, we have been engaged in a substantive dialogue with the SDA, a national trade association representing manufacturers of cleaning products and ingredients, concerning the toxicity of and exposure to SAED, a group of compounds that is within the definition of the glycol ethers category as listed in section 112(b)(1). The SDA initiated this dialogue by requesting that we revise the definition of glycol ethers to exclude SAED. We asked the SDA to support its request by compiling information to satisfy the statutory criteria for delisting this class of compounds under section 112(b)(3). The SDA submitted this information in a report to us. Although SDA elected not to formally petition us to delete SAED compounds from the HAP list, we chose to evaluate the SDA report against the standards by which substances may be removed from the list of HAP. We made an initial determination that the statutory criteria for delisting SAED were satisfied and published a notice of proposed rulemaking (64 FR 1780, January 12, 1999).

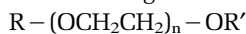
We do not interpret section 112(b)(3)(C) to require absolute certainty that a pollutant will not cause adverse effects to human health or the environment before it may be deleted from the list. The use of the terms "adequate" and "reasonably" indicate that we should weigh the potential uncertainties and their likely significance. Uncertainties concerning the risk of adverse health or environmental effects may be mitigated if we can determine that projected exposures are sufficiently low to provide reasonable assurance that such adverse effects will not occur. Similarly, uncertainties concerning the magnitude of projected exposures may be mitigated if we can determine that the levels that might cause adverse health or environmental effects are sufficiently high to provide reasonable assurance that exposures will not reach harmful levels.

II. What Was Our Analysis of the Information SDA Submitted?

The SDA contended that the present definition of glycol ethers adopted by Congress in section 112(b)(1) was incorporated verbatim from the definition of glycol ethers utilized in section 313 of the Emergency Planning and Community Right-to-Know Act (EPCRA), 42 U.S.C. 11023. The SDA noted that we subsequently modified the definition of glycol ethers under EPCRA to exclude SAED compounds (59 FR 34386, July 5, 1994) and the SDA requested that we make a conforming change in the CAA list. We responded that the substantive criteria for deleting chemicals under EPCRA section 313(d) are materially different than the criteria for deleting a hazardous pollutant under section 112(b)(3). It is our view that whatever the origins of the glycol ethers definition in section 112(b)(1), we cannot redefine the glycol ethers category to exclude particular compounds without making a substantive determination that such compounds meet the applicable criteria for HAP delisting. Under section 112(b)(3)(D), we may delete specific substances included in certain listed categories without a Chemical Abstract Service number, including the glycol ethers category.

Although the SDA does not necessarily agree with us that deletion of individual compounds is the only manner in which we may adopt the requested redefinition of the glycol ethers category, the SDA agreed to assist us in this effort by collecting information concerning SAED compounds that would enable us to make a substantive assessment of potential risks under section 112(b)(3). On April 25, 1997, the SDA submitted a report entitled "Exposure Assessment Undertaken to Support the Evaluation of the HAP Definition of 'Glycol Ethers'."

Surfactant alcohol ethoxylates and their derivatives comprise a group of compounds that, individually, satisfy the following definition:



Where:

n = 1, 2, or 3;

R = alkyl C8 or greater

R' = any group.

Rather than asking the SDA to compile an exhaustive list of each specified SAED compound, we requested that the SDA undertake a generic analysis of the potential toxicity of, and potential exposure to, SAED compounds as a group. We requested that the analysis be based, to the extent possible, on worst-case assumptions

that could be deemed to be conservative with respect to each and every individual compound in the SAED group. Such an approach to delisting would normally be impracticable due to the likelihood that use of such extreme assumptions would greatly exaggerate the magnitude of potential risks. In this instance, such an approach was considered practical only because of assertions by the SDA that SAED compounds present both very low potential toxicity and very limited exposure potential.

The report submitted by the SDA presented estimates of both the potential exposure to, and potential toxicity of, SAED compounds. The principal emissions estimate in the report was based on a hypothetical facility either manufacturing SAED or formulating products from an SAED precursor. The facility was assumed to use 600 million pounds per year of SAED, the total annual domestic production of Shell Chemical Company, the largest SAED manufacturer. The report developed conservative emissions estimates for this facility associated with the storage and transfer, processing, and fugitive releases of SAED compounds.

Emissions of SAED from raw materials during storage and transfer were estimated by assuming emissions of a volume of air, fully saturated with SAED, equal to the total volume of 600 million pounds of displaced SAED liquid per year. The estimated SAED concentration in this air was based on the vapor pressure of the lowest molecular weight compound in the SAED category, although typical SAED compounds have greater molecular weight and substantially lower volatility.

Additional SAED emissions from manufacture of SAED compounds and formulation of other products containing SAED were estimated by a process factor derived from industry experience. The process factor incorporated assumptions on the effect on emissions of higher temperatures and air contact rates that are characteristic of SAED processing. Potential SAED emissions during processing were estimated to be three times greater than during storage and transfer.

Finally, fugitive emissions were estimated by applying a proportionality factor of 41 percent to the sum of raw material and process emissions. This factor was derived from reported emissions for all glycol ethers in the EPA Toxics Release Inventory database, although it is likely that the proportion of total emissions attributable to fugitive releases would be much less for SAED

compounds than for the lower molecular weight glycol ethers.

This analysis estimated a total emissions rate for the hypothetical facility of 105 pounds of SAED per year from raw materials storage and transfer, manufacturing processes, and fugitive emissions combined.

Exposures at the fence line for the hypothetical facility were then estimated using the SCREEN3 dispersion model, the calculated total emissions rate, and a variety of assumptions concerning terrain, stack height and configuration, and distance to the fence line. The predicted annual average SAED concentration associated with an emissions rate of 105 pounds per year was 0.03 micrograms of SAED per cubic meter of air for a "representative" facility and 97.3 micrograms per cubic meter for a "hypothetical worst-case" facility.

The SDA submission also summarized the available toxicity data on SAED compounds. There have been few acute and no subchronic or chronic inhalation studies utilizing SAED compounds. Available animal study data do not indicate any adverse effects at air concentrations up to those produced by full saturation with SAED vapors. Acute toxicity has been demonstrated only when animals inhaled undiluted SAED in the form of a respirable aerosol. In one 10-day repeated inhalation study, test animals exhibited local respiratory irritation. Long-term animal studies of SAED administered by the oral or dermal routes have not reported any significant effects such as skin sensitization, reproductive or developmental toxicity, genetic mutations, or cancer. Evidence on the toxic potential of glycol ethers as a group strongly suggests that toxic potency decreases as molecular weight increases. Therefore, SAED (which have high molecular weights) are likely to be substantially less toxic than lighter glycol ether compounds for which more complete toxicity data are available.

There is no verified or proposed reference concentration (RfC) for any SAED compound. The SDA developed a proposed "key exposure index" for chronic exposure to SAED compounds based on the subchronic RfC for 2-methoxy-1-propanol (MP), a structurally similar compound which also has no demonstrated systemic toxicity by inhalation. 2-Methoxy-1-propanol has a lower molecular weight (90 grams per mole) than the lightest SAED compound (ethylene glycol octyl ether, 174 grams per mole). Therefore, MP is expected to be more toxic than any SAED compound, and its use as a surrogate should be conservative.

The SDA's analysis began with the subchronic RfC for MP, then reduced it by a factor of 10 to account for the differences between subchronic effects and chronic effects, and by an additional factor of between 1 and 10 to account for the use of data for a structurally related compound. This resulted in a proposed concentration range of 0.2 to 2.0 milligrams per cubic meter (mg/m^3) at which no adverse effects would be expected in human populations, including sensitive individuals. The SDA's proposed concentration range is approximately 1,000 to 10,000 times lower than the acutely toxic level for inhalation in rats. It is also approximately 1,000 to 10,000 times greater than the exposure estimated by the SDA for a "representative" facility and 2 to 20 times greater than the estimated exposure for a "hypothetical worst-case" facility.

The proposed chronic no-effect concentration range for SAED of 0.2 to 2.0 mg/m^3 is also consistent with chronic RfCs available from EPA's Integrated Risk Information System (IRIS) for lower-molecular weight, non-SAED glycol ethers (*i.e.*, 0.02 mg/m^3 for 2-methoxyethanol, 0.2 mg/m^3 for 2-ethoxyethanol, and 13 mg/m^3 for ethylene glycol monobutyl ether). The SDA's analysis has, therefore, treated SAED as if they were as toxic as much lighter glycol ether compounds, which EPA considers to be unlikely and conservative.

Although the SDA document does not include a discussion of levels of SAED that would be protective of non-human species, the toxicity data used to support the health impact assessment were obtained from animal studies. The derivation of human no-effect levels from these animal data, appropriately adjusted for uncertainty, should be protective of non-human animal species as well. Overall, there is no evidence to suggest that any species or any ecosystem would be harmed by any exposure below the SAED no-effect level proposed for humans.

III. What Is the Basis for Our Final Decision To Delete SAED Compounds From the Glycol Ethers Category Under the CAA?

Based on the SDA submission as a whole, we believe that the available data on potential exposure to, and toxicity of, SAED compounds are considerably more limited than would normally be necessary to support the findings required by section 112(b)(3) before we may delete a substance from the HAP list. However, there is a sufficiently large discrepancy between the

maximum predicted exposure level for these compounds based on plausible worst-case assumptions and the lowest concentration likely to present any potential risk of adverse effects to compensate for the paucity of the data. The conservative techniques used by the SDA in its submission, which tend to overestimate both exposure to and toxicity of SAED, are appropriate in the context of the limited data that are available on SAED compounds.

We cannot construe the process by which Congress adopted the current definition of glycol ethers in section 112(b)(1) as relieving us of the obligation to apply the statutory criteria before deleting any substance included in the present definition. Nevertheless, it is important to observe that there is no evidence suggesting that the current broader definition of glycol ethers was adopted because of any actual concerns regarding the potential hazards of SAED compounds. We believe that the absence of any discernable affirmative rationale for the initial inclusion of SAED compounds in the statutory HAP list, while not dispositive in itself, lends additional support to our conclusion that the available evidence supports deletion of these compounds.

Based on the available information, we have made a final determination, with respect to each and every individual substance that satisfies the definition of SAED compounds set forth above, that there are adequate data on the health and environmental effects of those substances to determine that emissions, ambient concentrations, bioaccumulation or deposition of the substances may not reasonably be anticipated to cause adverse human health or environmental effects. Based on that determination, we have decided to delete from the glycol ethers category in the HAP list established by CAA section 112(b)(1) each and every SAED compound. The EPA will implement this action to delete all SAED compounds by adopting a revised definition of the entire glycol ethers category that excludes each of the deleted substances.

IV. What Is the Basis for the Revised Designation of Glycol Ethers as Hazardous Substances Under CERCLA?

When a HAP is listed under section 112 of the CAA, it is also defined as a hazardous substance under section 101(14) of CERCLA, 42 U.S.C. 9601(14). In an April 4, 1985 final rule, under our authority in section 102(a) of CERCLA, we designated and listed, in the table at 40 CFR 302.4, all the elements and compounds and hazardous wastes incorporated as hazardous substances

by reference to other environmental statutes under section 101(14)(50 FR 13456). In a June 12, 1995 final rule, we revised Table 302.4 to add, among other HAP newly listed by the 1990 CAA Amendments, the broad generic category of glycol ethers (60 FR 30926). We designated the broad generic category of glycol ethers as hazardous under CERCLA based solely on its inclusion in the CAA HAP list. We have no independent basis upon which to retain the current definition of the glycol ethers category in order to include the SAED compounds as CERCLA hazardous substances. Therefore, in addition to revising the definition of glycol ethers in the HAP list in the CAA, we are also making a corresponding change to the list of CERCLA hazardous substances at 40 CFR part 302, Table 302.4.

V. How Have We Involved Stakeholders in This Rulemaking?

The SDA has worked with us for several years to compile evidence supporting this action. This evidence, submitted in April 1997 as a technical report, is summarized above and can be obtained in complete form from the docket. The proposed rules were signed on December 30, 1998 and published in the **Federal Register** on January 12, 1999 (64 FR 1780). We solicited public comments on the proposal for a 2-month period ending on March 15, 1999, and received letters conveying comments from the Chemical Manufacturers Association, the Chemical Specialties Manufacturers Association, the Illinois Environmental Protection Agency, and the SDA.

All commenters expressed full approval of the proposed action, its likely effects, and the rationale on which it is based. We received no negative comments.

VI. What Are the Administrative Requirements for These Final Rules?

A. Executive Order 12866

Under Executive Order 12866 (58 FR 51735, October 4, 1993), EPA must determine whether a regulatory action is "significant" and therefore subject to Office of Management and Budget (OMB) review and the requirements of the Executive Order 12866. The Executive Order defines "significant regulatory action" as one that is likely to result in a rule that may:

(1) Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or

State, local, or tribal governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

Although EPA is not aware of any effects associated with the present inclusion of SAED compounds on the CAA HAP and the CERCLA hazardous substance lists, the effect of the final rules will be to reduce potential regulatory obligations. Neither of the final rules included in this action appear to meet any of the criteria enumerated above, and EPA, therefore, has determined that neither of these actions constitute a "significant regulatory action" under the terms of Executive Order 12866.

B. Paperwork Reduction Act

As required by the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, OMB must clear any reporting and recordkeeping requirements that qualify as an "information collection request" under the PRA. Neither of the final rules in this notice contain any new information collection requirements.

C. Regulatory Flexibility Act (RFA), as Amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), (5 U.S.C. 601, *et seq.*)

The RFA generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small business, small organizations, and small governmental jurisdictions. For the purposes of assessing the impacts of today's proposed rule on small entities, small entity is defined as: (1) A small business that meets the definitions for small business based on the Small Business Association (SBA) size standards which, for this proposed action, can include manufacturing (SIC 20 and SIC 30) and air transportation (SIC 45) operations that employ less than 1,000 people and engineering services (SIC 87) operations that earn less than \$20 million annually; (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.

After considering the economic impact of today's proposed rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. In determining whether a rule has significant economic impact on a substantial number of small entities, the impact of concern is any significant adverse economic impact on small entities, since the primary purpose of the regulatory flexibility analysis is to identify and address regulatory alternatives "which minimize any significant economic impact of the proposed rule on small entities." (5 U.S.C. sections 603 and 604). Thus, an agency may certify that a rule will not have a significant economic impact on a substantial number of small entities if the rule relieves regulatory burden, or otherwise has a positive economic effect on all of the small entities subject to the rule. The final rules will eliminate the burden of additional controls necessary to reduce SAED emissions and the associated operating, monitoring and reporting requirements. We have therefore concluded that today's final rules will relieve regulatory burden for all small entities.

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 1 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 requirement 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.

The EPA has determined that today's action does not include a Federal mandate that may result in estimated costs of \$100 million or more to either State, local, or tribal governments in the aggregate, or to the private sector, in any 1 year. Therefore, the requirements of sections 202 and 205 of the UMRA do not apply to this action. The EPA has likewise determined that today's action does not include regulatory requirements that would significantly or uniquely affect small governments. Thus, today's action is not subject to the requirements of section 203 of the UMRA.

E. Executive Order 13045

The Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997), applies to any rule that EPA determines (1) is economically significant as defined under Executive Order 12866, and (2) for which the environmental health or safety risk addressed by the rule may have a disproportionate effect on children. If the regulatory action meets both criteria, EPA 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 EPA.

Today's action is not subject to Executive Order 13045 because it is not an economically significant regulatory action as defined by Executive Order 12866, and it does not address an environmental health or safety risk that would have a disproportionate effect on children. Nevertheless, the estimated human no-effect levels on which this action is based were derived in a manner designed to protect children and other sensitive members of human populations. The EPA, therefore,

anticipates that the action will impose no disproportionate risks upon children.

F. Executive Order 13084

Under Executive Order 13084, EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments, or EPA consults with those governments. If EPA complies by consulting, Executive Order 13084 requires EPA to provide to OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments "to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities." Today's rules do not significantly or uniquely affect the communities of Indian tribal governments because they will result in no increase either in air pollution or reporting requirements. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to these rules.

G. 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 rulemaking does not involve technical standards. Therefore, EPA is not considering the use of any voluntary consensus standards, and the

requirements of the NTTAA do not apply.

H. The 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. The EPA will submit a report containing these rules 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 rules 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). These rules will be effective August 2, 2000.

I. Executive Order 13132

The 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." Under section 6 of Executive Order 13132, EPA may not issue a regulation that has federalism implications, that imposes substantial direct compliance costs, and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by State and local governments, or EPA consults with State and local officials early in the process of developing the regulation. The EPA also may not issue a regulation that has federalism implications and that preempts State law unless the Agency consults with State and local officials early in the process of developing the regulation.

These rules do not have federalism implications. They 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. Thus, the requirements of section 6 of Executive Order 13084 do not apply to these amendments.

List of Subjects

40 CFR Part 63

Environmental protection, Administrative practice and procedure, Air pollution control, Chemicals, Glycol ethers, Hazardous substances, Reporting and recordkeeping requirements.

40 CFR Part 302

Air pollution control, Chemicals, Glycol ethers, Hazardous substances, Intergovernmental relations, Reporting and recordkeeping requirements, Superfund.

Dated: July 24, 2000.

Carol M. Browner,
Administrator.

For the reasons set out in the preamble, title 40, chapter I, parts 63

and 302 of the Code of Federal Regulations are amended as follows:

PART 63—NATIONAL EMISSION STANDARDS FOR HAZARDOUS AIR POLLUTANTS FOR SOURCE CATEGORIES

1. The authority citation for part 63 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart C—[Amended]

2. Subpart C is amended by adding § 63.62 to read as follows:

§ 63.62 Redefinition of glycol ethers listed as hazardous air pollutants.

The following definition of the glycol ethers category of hazardous air pollutants applies instead of the definition set forth in 42 U.S.C. 7412(b)(1), footnote 2: Glycol ethers include mono- and di-ethers of ethylene

glycol, diethylene glycol, and triethylene glycol R-(OCH₂CH₂)_n-OR'.

Where:

- n = 1, 2, or 3;
- R = alkyl C7 or less; or
- R = phenyl or alkyl substituted phenyl;
- R' = H or alkyl C7 or less; or
- OR' consisting of carboxylic acid ester, sulfate, phosphate, nitrate, or sulfonate.

PART 302—DESIGNATION, REPORTABLE QUANTITIES, AND NOTIFICATION

1. The authority citation for part 302 continues to read as follows:

Authority: 42 U.S.C. 9602, 9603, and 9604; 33 U.S.C. 1321 and 1361.

2. In § 302.4, footnote d to Table 302.4 is revised to read as follows:

§ 302.4 Designation of hazardous substances.

* * * * *

TABLE 302.4.—LIST OF HAZARDOUS SUBSTANCES AND REPORTABLE QUANTITIES

*	*	*	*	*	*	*	*
<p>^d Includes mono- and di-ethers of ethylene glycol, diethylene glycol, and triethylene glycol R-(OCH₂CH₂)_n-OR'. Where: n = 1, 2, or 3; R = alkyl C7 or less; or R = phenyl or alkyl substituted phenyl; R' = H or alkyl C7 or less; or OR' consisting of carboxylic acid ester, sulfate, phosphate, nitrate, or sulfonate.</p>							
*	*	*	*	*	*	*	*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 130

RIN 0906-AA56

Ricky Ray Hemophilia Relief Fund Program

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Interim final rule; status of comments and confirmation of effective date.

SUMMARY: This document is to inform potential petitioners that the Department has received several comments on the Ricky Ray Hemophilia Relief Fund Program's interim final rule, published on May 31, 2000. The Department has reviewed all of these comments carefully and continues to consider the suggestions made in these comments. However, none of the comments received by the Department

leads us to change the substance of the regulation, the petition form, or the confidential physician or nurse practitioner affidavit appended to the interim final rule at this time. In addition, these comments do not change the effective date of the interim final rule or the fact that July 31, 2000, will be the first date that petitions for payment may be postmarked or accompanied by a receipt from a commercial carrier or the U.S. Postal Service.

DATES: The interim final rule published on May 31, 2000, remains effective on July 31, 2000.

FOR FURTHER INFORMATION CONTACT: Paul T. Clark, Program Manager, Ricky Ray Program Office, Bureau of Health Professions, Health Resources and Services Administration, Room 8A-54, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857; (301) 443-2330.

SUPPLEMENTARY INFORMATION: The Ricky Ray Hemophilia Relief Fund Act of 1998 established the Ricky Ray Hemophilia Relief Fund Program, which is designed to provide compassionate payments to

certain individuals with blood-clotting disorders, such as hemophilia, who contracted HIV through the use of antihemophilic factor administered between July 1, 1982, and December 31, 1987. The Act also provides for compassionate payments for certain persons who contracted HIV from the foregoing individuals for certain survivors of these individuals.

On May 31, 2000 (65 FR 34860), the Department published an interim final rule to establish procedures and requirements for documentation of eligibility and to establish a mechanism for providing compassionate payments to individuals who are eligible for payment under the Act. Attached to the rule was a confidential physician or nurse practitioner affidavit, a petition form, and petition instructions, which included a documentation checklist.

The May 31, 2000, document solicited public comments on the interim final rule and indicated that June 30, 2000, was the deadline for the submission of all such comments. The regulation further indicated that the interim final rule would become effective on July 31, 2000, and that petitions could be