List of Subjects in 29 CFR Part 1625

Advertising, Aged, Employee benefit plans, Equal employment opportunity, Retirement.

Substantive Rules

PART 1625—[AMENDED]

Therefore, it is proposed that 29 CFR Part 1625 is amended as follows:

1. The authority citation for Part 1625 continues to read as follows:

Authority: 81 Stat. 602; 29 U.S.C. 621, 5 U.S.C. 301, Secretary's Order No. 10-68; Secretary's Order No. 11-68, and sec. 2; Reorg. Plan No. 1 of 1978, 43 FR 19807.

2. Section 1625.21 is added to Subpart B to read as follows:

§ 1625.21 Benefits under retirement and pension plans—Application of section 4(f)(2) of the Act.

(a) *Effective date.* [Reserved]

(b) *Benefits.* (1) A defined contribution plan shall not permit the cessation or reduction of employer contributions on the basis of the age of a participant, whether or not the participant has attained the plan's normal retirement age. For purposes of this subsection, a target benefit plan shall not be treated as a defined contribution plan.

(2) In defined contribution plans and target benefit plans in which investment gains and losses and (where appropriate) forfeitures are allocated to individual accounts, such allocations shall be made no less favorably on the basis of age to older employees, including those who continue to work past normal retirement age, than to younger employees.

(3) A defined benefit plan or target benefit plan shall not cease the accrual of benefits based on the age of a participant, whether or not the participant has attained the plan's normal retirement age. With respect to all employees, the plan must credit:

(i) Years of service (up to the maximum number of years specified in the plan);

(ii) Benefit improvements under the plan; and

(iii) Salary increases

(4) Nothing contained in this section shall compel the payment or accrual of benefits or the making of contributions in excess of the limitations provided in Internal Revenue Code section 415.

Dated: March 27, 1987.

Clarence Thomas,

Chairman, Equal Employment Opportunity Commission.

[FR Doc. 87-7210 Filed 4-1-87; 8:45 am]

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DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1910

[Docket No. H-044]

Health and Safety Standards; Occupational Exposure to 2-Methoxyethanol, 2-Ethoxyethanol and Their Acetates

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Advance Notice of Proposed Rulemaking (ANPR).

SUMMARY: This notice announces the initiation of action by OSHA with respect to reducing occupational exposure to 2-Methoxyethanol, 2-Ethoxyethanol, 2-Methoxyethanol Acetate and 2-Ethoxyethanol Acetate (2-ME, 2-EE, 2-MEA, and 2-EEA, respectively) under section 6(b) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 655(b)). This regulatory action follows: (a) OSHA's review of scientific studies indicating that 2-ME, 2-EE and their acetates cause adverse reproductive, developmental and hematologic effects in several animal species, and (b) OSHA's acceptance of the Environmental Protection Agency's (EPA's) referral (50 FR 41393) of these chemicals under the authority of section 9(a) of the Toxic Substances Control Act (TSCA) (15 U.S.C. 2608).

This notice summarizes information currently available to OSHA concerning production and use of 2-ME, 2-EE and their acetates, health effects, estimates of employee exposure and risk assessments. This notice invites interested parties to submit comments, recommendations, data, and information on several important issues. Based on the information expected to be gathered as a result of this notice, OSHA will decide upon the appropriate action.

DATE: Comments in response to this Advance Notice should be submitted by July 31, 1987.

ADDRESS: Comments should be submitted in quadruplicate to the Docket Officer, Occupational Safety and Health Administration, Docket No. H-044, Room N-3670, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210.

FOR FURTHER INFORMATION CONTACT: James F. Foster, Occupational Safety and Health Administration, U.S. Department of Labor, Office of Information, Room N-3649, Washington, DC 20210. Telephone (202) 523-8151.

SUPPLEMENTARY INFORMATION:

I. Background

1. Chemical Identification and Properties

The chemicals, 2-Methoxyethanol (2-ME), 2-Methoxyethanol acetate (2-MEA), 2-Ethoxyethanol (2-EE), and 2-Ethoxyethanol acetate (2-EEA) are members of a class of chemicals known as ethylene glycol ethers which are, in turn, members of a broader class of chemicals known as glycol ethers. In this document the term ethylene glycol ethers will refer to 2-ME, 2-MEA, 2-EE and 2-EEA. The term glycol ethers will refer to these as well as other glycol ethers. The respective Chemical Abstracts Service (CAS) Registry numbers for the subject ethylene glycol ethers are 109-86-4, 110-49-6, 110-80-5, and 111-15-9. All four compounds are completely miscible with water and many organic solvents. At room temperature and atmospheric pressure, these compounds are colorless liquids that are highly reactive in the presence of strong oxidizers: 2-MEA and 2-EEA are also highly reactive in the presence of nitrates and strong acids. Decomposition products during combustion or fire include toxic gases and vapors such as carbon monoxide.

2-ME, chemical formula $CH_3OCH_2CH_2OH$, has a molecular weight of 76.1, a boiling point at 760mm Hg of 124 °C, a vapor pressure at 20 °C of 6mm Hg, a flash point of 42 °C and possesses a mild non-residual odor with odor threshold warning properties around 60 ppm. 2-MEA, chemical formula $CH_3COOCH_2OCH_3$, has a molecular weight of 118, a boiling point of 145 °C, a vapor pressure of 2mm Hg, a flash point of 44 °C and possesses a mild ether-like odor with an odor threshold at approximately 50 ppm. 2-EE, chemical formula $C_2H_5OCH_2CH_2OH$, has a molecular weight of 90.1, a boiling point of 135 °C, a vapor pressure of 4mm Hg, a flash point of 49 °C and possesses a sweetish odor that is slight at low concentrations and strong at high concentrations. 2-EEA has a chemical formula $C_2H_5OCH_2CH_2OCOCH_3$, a molecular weight of 132, a boiling point of 156 °C, a vapor pressure of 2mm Hg, a flash point of 47 °C and possesses a mild non-residual odor with odor threshold warning properties at approximately 100 ppm.

2. Production and Use

Ethylene glycol ethers are produced by the reaction of ethylene oxide and an alcohol. The type of ethylene glycol ether is determined by the type of alcohol employed. Methyl alcohol produces ethylene glycol monomethyl

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ether (2-ME) and ethyl alcohol produces ethylene glycol monoethyl ether (2-EE). The corresponding acetates, 2-MEA and 2-EEA, are produced by reacting 2-ME and 2-EE with acetic acid.

Over 420 million pounds of the four substances were produced in the U.S. in 1981, with domestic consumption accounting for approximately 80%. Approximate 1981 consumption in the United States for each substance was: 90 million pounds of 2-ME, 170 million pounds of 2-EE, three million pounds of 2-MEA, and 100 million pounds of 2-EEA.

Domestic consumption of these chemicals falls into five major categories: chemical intermediates, industrial coatings, industrial solvents, solvents and coatings used in trade industries, and jet fuel additives: The major chemical intermediate use is in the production of the glycol ether acetates, 2-MEA and 2-EEA. Another chemical intermediate application is in the production of plasticizers. Industrial coating use includes finishes for cars, trucks, heavy equipment, appliances, metal furniture, steel sheet and metal cans. Electric circuit board manufacture, semiconductor manufacture, photographic applications, textile dyeing and various industrial cleaning solvents are among the many industrial solvent application. The major trade industry uses are in commercial printing as solvents and as components of inks, and in auto refinishing and maintenance painting. Glycol ethers are used in jet fuels to prevent freezing. Military uses dominate this category. However, small private planes represent a small portion of the total use.

3. History of the Standard

OSHA's current Permissible Exposure Limits (PELs) for 2-ME, 2-MEA, 2-EE and 2-EEA are 25 ppm, 25 ppm, 200 ppm, and 100 ppm, respectively. All are time weighted averages (TWAs) for an 8-hour workshift (29 CFR 1910.1000 Table Z-1). In the Z-1 Table, 2-ME, 2-MEA, 2-EE and 2-EEA are listed under the names Methyl Cellosolve, Methyl Cellosolve Acetate, 2-Ethoxyethanol and 2-Ethoxyethyl Acetate, respectively. The OSHA standards bear a skin notation, indicating the potential contribution to the overall exposure by the cutaneous route, including mucous membranes and eye, either by airborne or more particularly, by direct contact with the substance.

The current standards were adopted in 1971 pursuant to section 6(a) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 655). The source of these standards was the American Conference of Governmental Hygienists (ACGIH) and they are based primarily on blood, kidney, liver and central nervous system toxicity.

Private firms, under section 8(e) of TSCA, submitted the results of animal studies to EPA indicating that inhalation and dermal exposure to low levels of 2-ME and 2-EE may pose a serious risk of fetotoxic affects and a risk of adverse reproductive effects in males. As a result of the testicular effects observed in animal studies, the ACGIH, in its notice of Intended Changes (for 1982), proposed TWAs of 5 ppm for 2-ME, 2-EE and their acetates which were subsequently adopted in 1984. Likewise, NIOSH published, on May 2, 1983, a Current Intelligence Bulletin recommending that 2-ME and 2-EE be regarded in the workplace as having the potential to cause adverse reproductive effects in male and female Workers (Ex. 5-001).

On January 24, 1984, EPA published an Advance Notice of Proposed Rulemaking (ANPR) (49 FR 2921) in which it determined that adverse reproductive and developmental effects are associated with these glycol ethers at concentrations to which humans may be exposed. As a result of information received in response to the ANPR and other information developed by EPA, EPA determined that the risks associated with exposure to 2-ME, 2-EE and their acetates may be reduced to a sufficient extent by action taken under the OSH Act. Following these findings, EPA, in accordance with section 9(a) of TSCA, on May 20, 1986, referred 2-ME, 2-EE, and their acetates to OSHA to give this Agency an opportunity to regulate the chemicals under the OSH Act (51 FR 18488). EPA requested OSHA to determine whether the risks described in the EPA report may be prevented or reduced to a sufficient extent by action taken under the OSH Act. If such a determination was made, then OSHA was requested to issue an order declaring whether the manufacture and use described in the EPA report present the risk therein described. EPA requested OSHA to respond within 180 days.

On December 11, 1986, OSHA published a notice (51 FR 42257) responding to the EPA referral report by making a preliminary determination that a revised OSHA standard limiting occupational exposure to 2-ME, 2-EE and their acetates could prevent or reduce the risks due to exposure to a sufficient extent and that such a risk had been accurately described by EPA in the report.

With this notice, OSHA is initiating action within the meaning of section 9(a) of TSCA.

II. Health Effects

The effects of exposure to the ethylene glycol ethers on the reproductive system and on fetal development have been studied in several animal species. The results uniformly show developmental toxicity, including increases in the incidences of fetal malformations and resorptions, and testicular damage. Studies have also shown adverse hematologic effects and adverse behavioral effects in offspring. Data are limited on mutagenicity and potential carcinogenicity. A summary of OSHA's preliminary review of the experimental studies is presented below.

A. Absorption and Metabolism

Ethylene glycol ethers are readily absorbed following oral, dermal or inhalation exposure. Measurements made on excised human skin show an extremely rapid absorption of 2-ME, 2-EE and 2-EEA (Ex. 4-115). After 2-ME and 2-EE are taken into the body, they are metabolized to methoxyacetic acid and ethoxyacetic acid, respectively, by alcohol and acetaldehyde dehydrogenases. The acetate esters, 2-MEA and 2-EEA, are also metabolized to the same alkoacetic acids as their parent compounds. Current evidence suggests that the acid metabolites of these glycol ethers may be the actual toxicants (Exs. 4-102, 4-133, and 4-192).

B. Reproductive and Developmental Effects

Studies of inhalation exposures to 2-ME and 2-EE have shown that these exposures produce adverse reproductive and developmental effects in several animal species. A reproductive effect refers to alterations in the reproductive or sexual functioning of the adult from sexual maturation through adulthood (e.g., impotence or infertility). Developmental effects refer to adverse effects on the developing organism that may result from toxic exposures to either parent prior to conception, during prenatal development, or postnatally to the time of sexual maturation (e.g., death, structural abnormality, or functional deficiency of the developing organism). The effects observed from exposure to 2-ME and 2-EE include testicular damage, reduced fertility, maternal toxicity and developmental abnormalities of the fetus.

Available data show that 2-ME is developmentally toxic in rabbits and rats exposed by inhalation (Ex. 4-042a). Fetotoxic effects (embryo/fetal death or resorptions) were observed after exposures of 10 ppm in rabbits and 50 ppm in rats. The No Observed Effect

Levels (NOELs) were 3 ppm and 10 ppm, respectively. Other fetal effects such as skeletal and soft tissue abnormalities occurred at higher doses of 50 ppm and above in rats and rabbits. In addition, fetotoxic effects were observed in mice after inhalation exposure to 2-ME at 50 ppm (Ex. 4-106). The NOEL was 10 ppm. In a one-dose behavioral study, neurochemical imbalances and behavioral changes in rat offspring were observed after maternal *or* paternal exposures of 25 ppm 2-ME (Ex. 4-136).

Testicular damage was observed in rats and rabbits after inhalation exposures to 2-ME (Ex. 4-045). At 100 ppm, degenerative changes occurred in the germinal epithelium of rabbit testicles. The NOEL was 30 ppm. In the rat, decreased testicular weight and testicular epithelial degeneration were observed at 300 ppm, and the NOEL was 100 ppm. Testicular damage was also observed in a study in rabbits exposed orally to 100 mg/kg/day (Ex. 4-110). In particular in this study, a one-time exposure of 250 mg/kg resulted in testicular damage. These results are verified by the findings of a cross-sectional study of men engaged in the production of 2-ME, where workers with the highest potential exposures exhibited decreases in testicular size, when compared to unexposed controls (Ex. 5-002).

2-EE has been shown to be developmentally toxic in laboratory animals after inhalation exposure. In rabbits (Ex. 4-039), fetal skeletal abnormalities were observed at 175 ppm. In rats (Ex. 4-038) exposed at 250 ppm, the fetal effects included decreased mean live weight, increased resorptions and increased external and skeletal effects. The NOEL in both species was 50 ppm. In addition, 2-EE has also been shown to be developmentally toxic after dermal exposure in the rat (Ex. 4-121): doses totaling 1 ml/day caused resorptions and visceral and skeletal abnormalities. In behavioral testing of offspring, separate maternal and paternal exposures to 2-EE both resulted in neurotoxic effects, including impaired neuromuscular ability and neurochemical imbalances in the brain (Ex. 4-138).

Testicular damage was observed in rabbits after inhalation of 2-EE (Ex. 4-108) at exposures of 400 ppm; decreases in testicular weight and degeneration of seminiferous tubules were observed. The NOEL was 100 ppm. Rats similarly exposed did not exhibit any adverse reproductive effects (Ex. 4-109). Thus, in rats in this study, the NOEL was measured at 400 ppm. A recent human study has evaluated the semen quality of men exposed to 2-EE during the preparation of ceramic shells in metal casting (Ex. 5-003). Workers exposed by inhalation to 2-EE at airborne levels ranging from non detectable to 33.8 ppm exhibited a decrease in average sperm count compared to the counts of in-plant controls.

2-MEA and 2-EEA are expected to show developmental and reproductive toxicity similar to their parent compounds 2-ME and 2-EE. This is based on the fact that each glycol ether and its acetate are metabolized to the same acid metabolite (methoxyacetic acid and ethoxyacetic acid, respectively) and the fact that the metabolite is believed to be toxic. For example, data suggest that 2-ME, through its metabolite methoxyacetic acid, has an adverse effect on the testis (Ex. 4-133). Intraperitoneal injections of methoxyacetic acid have induced developmental toxicity, lending support to the idea that methoxyacetic acid is the active agent (Ex. 4-102). Because 2-EE is metabolized in a manner similar to which 2-ME is metabolized. 2-EE's metabolite, ethoxyacetic acid, is also believed to be a toxic agent.

C. Hematologic Effects

Data from laboratory animals have demonstrated that exposure to 2-ME may result in a variety of hematologic effects including hemolysis, bone marrow depression, and immunosuppression. (Exs. 4-017, 4-042a and 4-077). The effects observed have resulted from exposures similar to those producing reproductive or developmental effects. Limited data from mouse studies suggest that 2-EE, 2-EEA and 2-MEA may also produce adverse effects on the peripheral blood. (Ex. 4-135).

Adverse hematologic effects including anemia, lowered white blood cell counts and bone marrow depression have also been observed in humans exposed to 2-ME, and possibly 2-EE. After dermal exposure to an undetermined quantity of 2-ME, workers in an electroplating facility exhibited bone marrow injury and pancytopenia as well as encephalopathy (Ex. 4-139). Air concentrations during the use of 2-ME averaged 8 ppm. 2-ME had been substituted temporarily for acetone due to a shortage. Clinical recovery followed cessation of exposure to 2-ME. One death from aplastic anemia, three cases of bone marrow injury, and four cases with non-specific bone marrow changes were observed in lithographers exposed dermally and by inhalation to multiple solvents including 2-EE and dipropylene glycol monomethyl ether (DPME) (Ex. 5-004). However, this study is difficult to interpret because the exposure situations, 2-EE concentrations and concentrations of other chemicals were not well characterized. Exposure measurements were made for DPME only, as the authors considered this the most likely etiologic agent. Thus it is uncertain whether 2-EE could be implicated.

III. Risk Assessment

The EPA has prepared a risk assessment (Ex. 4-004) for 2-ME, 2-MEA, 2-EE and 2-EEA. This assessment estimated human risk on the basis of the most sensitive end point(s) observed in the animal studies. To estimate this risk, EPA calculated the margins of safety. The margin of safety is defined as the No Observed Effect Level (NOEL), in the most sensitive species studied, divided by the estimated human exposure level.

The NOELs for testicular toxicity utilized by the EPA in calculating margins of safety were 30 ppm for 2-ME and 100 ppm for 2-EE. For developmental toxicity, the NOELs were 3 ppm for 2-ME and 50 ppm for 2-EE. Because the acetates are thought to rapidly hydrolyze to acetate and glycol ether in the body, the effects of 2-MEA and 2-EEA were assumed to be the same as those of 2-ME and 2-EE, respectively. Therefore, the NOEL for each acetate was assumed to be the same as that for the respective glycol ether.

Exposure data for various segments of industry where glycol ethers are produced or used were obtained and used to calculate margins of safety for worker exposures in each segment. An exposure level with a 100-fold margin of safety is considered unlikely to produce adverse effects in humans. However, for many uses of these glycol ethers, the occupational exposure levels were so high that only a small or non-existent margin of safety would be provided to workers. The EPA estimated that between 206,000 and 350,000 workers are exposed to these four glycol ethers at air concentrations that provide less than a 100-fold margin of safety, while approximately 46,000 workers are exposed with less than a 10-fold margin of safety. The EPA risk assessment (Ex. 4-004) considered only inhalation exposures; a risk assessment that accounted for absorption through the skin of exposed workers could considerably increase the assessed risks of exposure and the population at risk.

From the testicular effects observed in experimental studies, it was possible to further estimate the risks of human exposure. EPA estimated that a six to seven percent reduction in fertility could

occur among males exposed to 2-ME at levels between 1 and 5 ppm. Furthermore, EPA observed that, because hematologic effects have been found at exposure levels producing developmental effects, controlling the risks of developmental toxicity will also reduce the risks of hematologic effects.

In its risk assessment, EPA has relied primarily on a qualitative method, the use of a margin of safety approach, to estimate the risk of reproductive hazards. Although the use of margins of safety is a generally accepted methodology, OSHA has often relied on a more quantitative approach to risk assessment in order to establish significant risks. To date, only a few attempts have been made to develop methodology to quantitatively assess the risks associated with reproductive and developmental hazards. Therefore, OSHA is currently searching for methods to quantify these risks and the Agency welcomes any information with respect to this issue.

IV. Occupational Control Measures

Currently, the primary source of occupational exposure data is the Pedco Environmental, Inc. (PEI) report prepared for EPA (Ex. 4-007). PEI based estimates of occupational exposure on data from OSHA and NIOSH. The exposure data show that in most large industries (manufacturing, formulation and industrial solvent uses), the majority of exposures are below 0.03 ppm for 2-ME and below 1 ppm for 2-EE. However, the trade industries involved in the application of surface coatings and inks are characterized by higher exposures (exposures above 3 ppm for 2-ME and above 10 ppm for 3-EE).

The exposure data collected by PEI were obtained from published reports, unpublished data maintained by OSHA and NIOSH, and several industry trade groups. Most of these data represent exposures occurring in the late 1970's and early 1980's. In addition, these data sources contained little information on current industry practices with regard to the use of engineering and work practice controls and personal protective equipment. OSHA is currently gathering additional data to broaden and update its data base on airborne exposure levels and current industry practices.

The exposure data in the PEI report are based solely on inhalation exposure to glycol ethers. Dermal absorption can be a major contributor to the total exposure. OSHA is currently gathering additional exposure information, including data on the contribution of dermal exposure, which will permit the Agency to develop a more accurate profile of the current exposure situation.

OSHA's preliminary evaluation of available information indicates that exposures can be controlled by instituting engineering controls, improving work practices or requiring employees to use personal protective equipment wherever engineering controls fail to reduce the exposure to the desired level. The use of engineering controls, such as enclosing the operation and using local exhaust ventilation, would contribute to the reduction of exposure levels in the workplace. Using personal protective equipment such as goggles, gloves, aprons and respirators (where necessary) and substituting for the chemical (if feasible) could also further decrease worker exposure.

V. Technological Feasibility and Economic Analysis

Industrial Economics, Incorporated (IEc) prepared a draft regulatory impact analysis for EPA (Ex. 4-008) that has assessed the cost of installing engineering equipment to control glycol ether exposures. They estimate that if all workplaces, industrial and trade, installed engineering controls and used personal protective equipment, the capital costs to attain a 0.1 or 0.5 ppm exposure level, would be $86.6 million and $42.8 million, respectively, and the operating costs would be about $1.25 billion for either exposure level. EPA suggests that many firms, due to high costs, will opt for substitution. Therefore, assuming a move by firms to substitutions, EPA estimated that the annualized cost of revising the current PELs for all workers would be $83 million.

OSHA's preliminary evaluation of the available information suggests that it would be technologically and economically feasible to implement engineering controls and other protective measures which may be necessary in order to reduce the current PEL. OSHA intends to develop a more detailed regulatory assessment on the feasibility of reducing the PELs.

VI. Scope of Regulation

In the past OSHA has typically regulated chemicals under the 6(b) rulemaking process by developing health standards for one substance at a time. However EPA, under section 9(a) of TSCA, has referred, as a group, four ethylene glycol ethers to OSHA. These four substances have been treated as a group by EPA, NIOSH and the ACGIH because of their industrial, significance (volume of production and length of use), their similar chemical properties and uses, and because of the available toxicity data for 2-ME and 2-EE. Thus, in its response to EPA's referral and in this notice, OSHA is considering these four ethylene glycol ethers for a single rulemaking.

However OSHA is considering whether it may be best to treat 2-E, 2-EE and their acetates as a group or to treat each substance separately. There are data which suggest that different PELs would be appropriate. For example toxicity data have established that 2-ME is a more potent reproductive toxin than 2-EE. Thus there is a potential risk differential between 2-ME and 2-EE and similar differences between their respective acetates.

OSHA is also considering the possibility of expanding the scope of its rulemaking to cover other glycol ethers. The glycol ethers family, of which the ethylene glycol ethers 2-ME, 2-EE and their acetates are a subset, contains hundreds of compounds, many of which have not been tested. It is reasonable to assume that, based on structural similarities and similar metabolic pathways, that the adverse effect of at least some of these compounds may be similar to those already tested. Some preliminary studies being conducted by NIOSH suggest that exposure to some higher order glycol ethers may present reproductive risks similar to those for ethylene glycol ethers. The industrial and trade users who employ substitutes for 2-ME, 2-EE and their acetates to reduce employee risk from exposure to ethylene glycol ethers, may choose other glycol ethers which are potentially as toxic as these four. Therefore, it may be appropriate to include other glycol ethers within the scope of a possible standard.

Adopting a more generic approach to regulating glycol ethers might also lead to more efficient rulemaking. In the past regulating chemicals on a substance by substance basis has involved major commitments of the Agency's time to one substance. Including more than one substance in a single rulemaking, where those substances show many similarities in their chemical properties and uses, would enable OSHA to make a more efficient use of its resources, saving both time and effort which could be utilized on standards for other toxic substances.

OSHA solicits information and comments with respect to this issue. Specifically, is a generic approach feasible or appropriate for glycol ethers, or should OSHA continue to regulate substance by substance? Also if a generic approach is feasible how might such an approach be implemented, given the fact that the observed adverse effects for different substances may occur at different exposure levels?

References Cited

4–004 USEPA, OPTS, ECAD. *Risk Assessment of Glycol Ethers 2-Methoxyethanol, 2-Ethoxyethonol and Their Acetates.* Draft Report. (December 12, 1984):60pp

4–007 USEPA, OPTS, ETD. *Control of Occupational Exposure to Two Glycol Ethers and Their Acetates.* (April 25, 1984):142pp. prepared under Contract #68–02–3935 by PEDCo.

4–008 USEPA, OPTS, ETD. *Draft Regulatory Impact Analysis of Proposed Regulation of Glycol Ethers.* (June 1985):229pp. Prepared by Industrial Economics, Inc.

4–038 Tinston, DJ et al. *Ethylene Glycol Monoethyl Ether (EE): Teratogenicity Study in Rats.* (April 14, 1983):54pp. prepared under Contract to ICI, Center Toxicology Lab Report. #CTL/P/761.

4–039 Tinston, DJ et al. *Ethylene Glycol Monoethyl Ether (EE): Inhalation Teratogenicity Study in Rabbits.* (April 21, 1983):54PP. Prepared under Contract to ICI, Center Toxicology Lab Report. #CTL/P/776

4–042a Hanley, TR et al. *Ethylene Glycol Monomethyl Ether: Inhalation Teratology Study in Rats and Rabbits. (September 20, 1982.)*:91pp. Prepared under contract # G–2–0–Ter–Ihl–Dow. Dow Chemical.

4–045 Miller, RR et al. Ethylene Glycol Monomethyl Ether: 13 Week Vapor Inhalation Study in Rats and Rabbits. (January 19, 1982) Follow-up. 8(e) Submission to EPA by Dow Chemical Co.

4–077 USEPA, OPTS, HERD. Memo from JJ Murphy to H Teitelbaum. Subject: Review of Hematologic Effects of 2-Methoxyethanol (12/28/84):9pp

4–102 Brown, NA et al."Teratogenicity of Methoxyacetic Acid in the Rat." *Toxicology Letters* 22. (1984):93–100.

4–106 Hanley, TR et al. *Ethylene Glycol Monomethyl Ether: Inhalation Teratology Probe Study in Mice.* (April 22, 1982):18pp. Toxicology Res Lab, Dow Chemical, Midland, MI.

4–107 Hanley, TR et al. *Ethylene Glycol Monomethyl Ether: Inhalation Teratology Probe Study in Rats and Rabbits.* (January 29, 1982):33pp. Toxicology Res. Lab, Dow Chemical, Midland, MI.

4–108 Terrill, JB. Biodynamics Inc. *13-Week Inhalation Toxicity Study of Ethylene Glycol Monoethyl Ether in the Rabbit.* Project No. 82.7589. (10/24/83):116pp.

4–109 Ackerman, LJ. Biodynamics Inc. 13-Week Inhalation Toxicity Study of Ethylene Glycol Monoethlyl Ether in the Rat. Final Report Vol 1. Project No. 82–7588. (October 21, 1983):122pp.

4–110 Creasy, DM and PMD Foster."Morphological Development of Glycol Ether-Induced Testicular Atrophy in the Rat." *Experimental & Molecular Pathology* 40(1984):169.176.

4–115 Dugard, PH et al."Absorption of Some Glycol Ethers Through Human Skin in Virto." *Environmental Health Perspectives* 57 (1984):193–197.

4–121 Hardin, BD et al."Teratogenicity of 2-Ethoxyethanol by Dermal Application." *Drug and Chemical Toxicology* 5:3 (1982):277 294.

4–133 Miller, RR et al."Toxicity of Methoxyacetic Acid in Rats." *Fund and Appl Toxicol* 2(1982):158 160.

4–135 Nagano, K et al."Mouse Testicular Atrophy Induced by Ethylene Glycol Monoalkyl Ethers. *Jap. J. Ind. Health 20:1* (1979):29–35.

4–136 Nelson, BK et al."Behavioral and Neurochemical Alterations in the Offspring of Inhalations Exposure to the Industrial Solvent 2-Methoxethanol." *Pharmacol Biochem and Behav* 20 (1984):269–279.

4–138 Nelson, BK."Ethoxyethanol Behavioral Teratology in Rats." *Neurotoxicology* 2:2(1981):231 247.

4–139 Ohi, G and DH Wegman."Transcutaneous Ethylene Glycol Monomethyl Ether Poisoning in the Work Setting." *J Occup Med* 20:10 (October 1978):675–676.

4–192 Yonemoto, J. et al."Effects of Dimethoxyethyl Phthalate, Monomethoxy-Ethyl Phthalate, 2-Methoxyethanol and Methoxyacetic Acid on Post Implantation Rat Embryos in Culture." *Toxicology Letters* 21(1984):97–102.

5–001 NIOSH. Current Intelligence Bulletin 39. Glycol Ethers; 2-Methoxyethanol and 2-Ethoxyethanol. (May 2, 1983).

5–002 Cook, R.R. et al. "A Cross-Sectional Study of Ethylene Glycol Monomethyl Ether Process Employees." *Arch. Envr. Health* (1982) 37(6):346–51.

5–003 NIOSH. Ratcliffe, J et al. Health hazard evaluation determination Report no. 84–415–1668, Precision Castparts Corporation, Portland, Oregon (1986). Cincinnati: U.S. Dept. of Health and Human Services.

5–004 Cullen, Mark R. et al."Bone Marrow Injury in Lithographers Exposed to Glycol Ethers and Organic Solvents Used in Multicolor Offset and Ultraviolet Curing Printing Processes." *Arch. Envr. Health* (1983) 38(6):347–54.

5–005 OSHA Analytical Laboratory. Organic Methods Evaluation Branch, Salt Lake City Utah. Analytical Methods for Monitoring 2-Methoxyethanol, 2-Methoxyethyl Acetate, 2-Ethoxyethanol, and 2-Ethoxyethyl Acetate.

Request for Comments

OSHA solicits information and comments relevant to the effects and controls of exposure to 2–ME, 2–EE and their acetates. OSHA is also considering whether to broaden the scope of the rulemaking to include glycol ethers other than those referred by EPA. Thus, OSHA is also interested in information on other glycol ethers. Interested parties are invited to express opinions as to what provisions, including those which set the permissible exposure limit(s), should be included in a revised standard for these ethylene glycol ethers. OSHA is specifically interested in methods, costs, and effectiveness of control strategies that have already been employed to reduce exposure to 2–ME, 2–EE, and 2–MEA and 2–EEA. The questions below will provide specific guidance on OSHA's request for information. Please provide the rationale that supports your submissions.

Information on glycol ethers that has already been submitted to EPA (Docket No. OPTS–62030) is part of the OSHA record (Docket No. H–044) and need not be resubmitted. Comments and data previously submitted to OSHA remain part of this record and likewise need not be resubmitted.

Comments should be sent in quadruplicate to the Docket Officer, at the address noted above, where they will be available for inspection and copying. The data received will be carefully reviewed by OSHA to determine appropriate action.

A. *Health Effects.*

(1) What studies should OSHA consider to assess potential health risks, especially the reproductive and developmental effects, of 2–ME, 2–EE, 2–MEA, and 2–EEA?

(a) What available data, such as medical records or unpublished studies not now in the record, should be included in OSHA's decision making?

(b) In light of the reproductive, developmental, and hematotoxic effects shown by the animal studies, what human data show such effects?

(c) What recent animal toxicity data for glycol ethers other than 2–ME, 2–EE and their acetates exist?

(2) What dermal absorption studies are available and what is the extent of potential adverse health effects resulting from such dermal exposure?

(3) What studies and other evidence are available indicating the combined effects of inhalation and dermal exposures?

(4) How should OSHA estimate the significance of risk at the current exposure levels for the 4 subject glycol ethers?

Specifically:

(a) What mathematical models are most appropriate to quantify the risk of reproductive and developmental effects or other adverse health effects from exposure to glycol ethers?

(b) What approaches, other than quantitative risk assessment, are available for assessing reproductive or developmental risks?

(c) Is EPA's use of margins of safety an appropriate method? Why? What are its advantages and/or disadvantages?

(d) Which studies should be used for a quantitative risk assessment for glycol ethers.

(e) Which health effects in which animal species, by which route(s) of administration and at which dose level(s), should be selected for use?

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(f) How should dose levels in experimental animal studies be converted to equivalent doses for occupationally exposed persons? How should the dose levels be expressed?

(g) What exposure duration other than working lifetime, i.e., gestation period, first trimester, etc., should be incorporated into a risk assessment model?

(h) Should corrections be made for species to species extrapolation and for combined routes of exposure (i.e., dermal and inhalation)? How should these extrapolations be done?

(i) Are there data available to indicate a "dose response" effect for glycol ether exposure?

(j) What is the relationship between frequency and duration of exposure to glycol ethers and risk of reproductive developmental effects?

(k) What quantitative methods are available for estimating risks other than reproductive or developmental risks that are associated with glycol ether exposures (e.g., hematological effects, neurological effects)?

(l) What methods are available to measure the health risks from dermal contact with the glycol ethers?

B. *Permissible exposure limits.*

2-ME and 2-MEA have been found to be more toxic than 2-EE and 2-EEA. Therefore, it may be necessary to set four permissible exposure limits within one standard. The development of four separate standards may not be as efficient as one standard for the group because of the similarities in the adverse effects observed, because it may be necessary to consider their combined effects, and because exposure data indicate that in many workplaces more than one of them are in use simultaneously.

(1) Should OSHA set 4 separate PELs within one standard or set one PEL for all 4 substances?

(2) Would compliance with limits for these four chemicals be facilitated by the promulgation of a single limit for all four chemicals, based on the hazards associated with the most toxic chemical (i.e., 2-ME)?

(3) Should the glycol ethers 2-ME, 2-MEA, 2-EE, and 2-EEA be treated separately or as a group in terms of rulemaking?

(4) Should OSHA take a generic approach to the regulation of the family of glycol ethers and include other gylcol ethers in the scope of its rulemaking?

(5) Should a revised standard for 2-ME, 2-EE and their acetates include an 8-hour time weighted average, a short term exposure limit (STEL), a ceiling level, and an action level or some combination of these limits?

(6) What permissible exposure limits should be proposed and what health evidence is available to support these limits?

(7) What are the limits of detection and accuracy of the available methods of monitoring for each of the four glycol ethers under consideration?

(8) What data support the technological feasibility of achieving the permissible limits under consideration for the various job categories?

C. *Production and Control Systems.*

(1) What current production processes and their associated engineering controls are utilized.

(2) What data are there indicating the efficiency of the currently employed control techniques?

(3) Is there any industrial process or trade use for which engineering controls are not adequate to control workers' exposure to levels at or below the current limits?

(4) What are the potential modifications in process or production technologies that are available or can be implemented for reducing workers exposures?

(5) What level of exposure reduction can be expected from employing specific process modifications or installing specific engineering controls?

D. *Substitution Availability.*

(1) What substitutes are there for 2-ME, 2-EE and their acetates and what are their limitations?

(2) For any available substitute are there studies available documenting potential adverse health effects?

(3) Are there unique situations, industrial operations or trade uses where substitutes have been determined to be either unavailable or infeasible to use for controlling worker exposures?

(4) Where are there industrial uses where substitutes can replace only a part of 2-ME, 2-EE, 2-MEA or 2-EEA in a mixture?

(5) What is the extent and the impact of such partial substitution?

(6) How efficient are substitutes as compared to 2-ME, 2-EE and their acetates in specific industrial uses?

(7) What non-chemical substitutes are there for uses that now employ glycol ethers?

(8) What costs are involved in reformulating products or redesigning processes so that substitutes can be used.

(9) Are there improvements in productivity or other economic advantages to be gained from substituting other chemicals for glycol ethers?

E. *Protective Equipment and Respirators.*

(1) What types of respirators are currently being supplied by employers for protection against glycol ethers? In what processes?

(2) What are the costs associated with the use of respiratory protection? In particular, if chemical cartridges are being used, how often are they replaced?

(3) What data are available for the glycol ethers on breakthrough times of organic vapor-cartridges?

(4) What other types of protective equipment, such as gloves and aprons, are currently being supplied by employers?

(5) OSHA is aware that butyl rubber may provide the best 8-hour protection against dermal contact with 2-ME, 2-EE and their acetates and that nitrile rubber is effective in splash (short term) situations.

(a) Have any other materials been tested and been found to be equally protective?

(b) In what processes or job categories is it current practice to use protective gloves? aprons?

(c) How often must these gloves be replaced to ensure that there is no dermal contact with glycol ethers?

(d) Are there processes that have the potential for dermal contact where it is not desirable to wear protective gloves because their use will interfere with productivity or product quality?

(e) What are the costs of these gloves per employee per year?

(6) What is the durability or resistivity of this protective equipment?

(7) Under what conditions (e.g. exposure level, type of operation, duration of exposure) do employers presently provide protective equipment and respirators to their exposed employees?

F. *Exposure and Monitoring.*

(1) What proportion of the workforce in each of the following sectors is exposed to 2-ME, 2-EE and/or their acetates? At what levels?

(a) Chemical production and intermediates?

(b) Industrial coatings and formulation?

(c) Ink formulation?

(d) Electronics manufacture?

(e) Metal fabrication?

(f) Coatings application (e.g. for appliances, automobiles machinery and equipment)?

(g) Commercial printing?

(h) Maintenance painting?

(2) In what other industry sectors are workers exposed to glycol ethers? At what levels?

(3) What are the job categories in each of the affected sectors in which

workers are potentially exposed to glycol ethers? For each job category, please provide a brief description of the operation.

(4) What is the distribution, by age and sex, of the exposed populations in each of the affected sectors?

(5) How many workers are exposed or have the potential for exposure to glycol ethers in each job category?

(6) What are the frequency, duration and levels of exposures to glycol ethers for each job category? Please include the analytical method and type of samples used for determining exposure levels.

(7) What engineering controls and types of protective equipment are available or in use for each job category.

(8) What is the extent to which occupational exposure in formulation or trade uses is "mixed" i.e., involves exposure to more than one glycol ether or acetate, either concurrently or serially? Are employees involved in the following processes exposed to one or more chemicals in the glycol ethers family?

(a) Coatings application.
(b) Automobile refinishing.
(c) Maintenance painting.
(d) Print shops.
(e) Metal fabrication.
(f) Coatings application formulation.
(g) Ink formulation.

(9) OSHA s current method for monitoring glycol ethers and their acetates is based on the use of charcoal tubes and gas chromatographic analysis. The limits of detection for 2-ME, 2-MEA, 2-EE, and 2-EEA are 0.1, 0.01, 0.02, and 0.01 ppm, respectively. Recently, silica gel and passive dosimeters have been tested and found to be adequate for monitoring under some circumstances.

(a) What other methods are available to monitor for 2-ME, 2-EE and their acetates which have lower limits of detection than current analytical methods?

(b) What are the limitations that apply to the use of these methods? Please provide details on the accuracy and precision of the sampling method, the range and limits of detection, and the method of validation of sampling and analyses.

(c) What methods can be used to monitor short-term exposures to 2-ME, 2-EE and their acetates?

(d) Can passive dosimeters or charcoal tubes distinguish among the glycol ethers and their acetates in situation where there is mixed exposure?

(10) OSHA has evidence that suggests that exposure to glycol ethers may not be insignificant among airline and refinery employees.

(a) Under what circumstances might airline employees be exposed to glycol ether vapors.?

(b) What are the points of employee exposure in the blending of glycol ether de-icing additives into jet fuel?

(c) What are the job categories, number of employees, and frequency and duration of exposure among employees involved in the blending process?

G. *Worker Training.*

(1) Describe the training that workers currently receive for the purpose of reducing the risk associated with glycol ethers exposure (e.g. length of course, topics covered, frequency, and availability of audio visual aids, and written operating instructions).

(2) Is there any evidence documenting the effectiveness of the training being received by the employee (e.g. decreased absenteeism, decreased medical/insurance costs, a decrease in accident/illness rates/severity, an increase in productivity?

(3) What are the basic elements which should be considered in developing or revising the training given to workers exposed to glycol ethers in the various industry sectors?

(4) OSHA's Hazard Communication standard requires that manufacturers label their products to provide information on hazardous material contained in these products.

(a) At what volume percent do labels on products containing glycol ethers currently identify glycol ethers as an ingredient.

(b) What products are currently labeled as containing glycol ethers?

H. *Medical Surveillance.*

(1) What illnesses or conditions attributable to glycol ethers have been observed?

(2) What elements are appropriate for inclusion in medical and clinical examinations performed to identify overexposed workers and/or to indicate the status of workers health?

(3) Are semen analyses included in medical surveillance programs for male workers exposed to glycol ethers.

(4) Is it current practice for reproductive history to be given special emphasis in the medical surveillance of glycol ethers exposed employees?

(5) Do employers currently provide specific tests or procedures as part of medical surveillance for glycol ether exposed employees? What is the basis for selecting or choosing these tests or procedures? At what frequency are these tests performed?

(6) What are the exposure levels encountered by workers (including their job categories and/or job classifications) who are covered by medical surveillance programs?

(7) What evidence is available indicating risk reduction due to implementation of medical surveillance programs?

I. *Costs of Control Measures.*

(1) What are the costs of implementing engineering controls or modifications to production and process equipment (either currently in place or planned to be installed for reducing workers' exposures)? How much reduction in employee exposure can be achieved by each particular control measure? What are the service life and maintenance costs for this equipment?

(2) In what sectors is it current practice to remove pregnant workers from jobs involving exposure to glycol ethers?

(3) What is the cost of the personal protective equipment currently in use or projected for future use? Which employees or job descriptions would be required to wear what type of equipment? (Please indicate the type of protective equipment as well as process descriptions).

(4) What is the cost of the currently employed and/or projected medical surveillance program?

(5) What is the cost of the currently instituted and/or projected training program?

(6) What is the cost of the currently employed and/or projected personnel exposure monitoring and sampling analyses?

(7) What values can be determined for benefits of reduced glycol ether exposure, such as projected reductions in medical treatment, insurance premiums, and workers compensation payments, decreased absenteeism and employment turnover, and increased productivity?

J. *Environmental Effects.*

The National Environmental Policy Act (NEPA) of 1969 (42 U.S.C. 4321, *et seq.*), the Council on Environmental Quality (CEQ) regulations (49 CFR part 1500, 43 FR 55978, November 29, 1978), and the Department of Labor (DOL) NEPA Compliance Regulations (29 CFR Part 11); (45 FR 51187 *et seq.*, August 1, 1980) require that Federal agencies give appropriate consideration to environmental issues and impacts of proposed actions significantly affecting the quality of the human environment. OSHA is currently collecting written information and data on possible environmental impacts that may occur outside of the workplace as a direct or indirect result of promulgation of a revised standard for occupational exposure to glycol ethers. Such

information should include any negative or positive environmental effects that could be expected to result from a revised regulation. Specifically, OSHA requests comments and information on the following:

(1) How might a revised regulation for glycol ether exposure affect the environment?

(2) What is the potential direct or indirect impact on water and air pollution, energy usage, solid waste disposal and land use.

(3) How would glycol ether substitutes (if available) alter the ambient air quality, water quality, solid waste disposal and land use?

K. *Impact on Small Business Entities.*

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), agencies are required to assess the impact of proposed and final rules on small entities. In that regard, OSHA solicits the following information:

(1) How many and what kind of small businesses or other small entities would be affected by revising the standard for 2-ME, 2-EE and their acetates.

(2) Could difficulties be encountered by small business entities when attempting to comply with specific provisions of a glycol other regulation covering such areas as exposure monitoring, exposure limits, methods of compliance, medical surveillance, respirators, protective clothing, hygiene facilities, recordkeeping, housekeeping information and training and labels and signs?

(3) Could such provisions be modified for small business entities which would assure equivalent protection of the health of their employees?

L. *Duplication/Overlapping/ Conflicting Rules.*

(1) Are there other federal regulations which may duplicate, overlap or conflict with an OSHA regulation concerning glycol ethers?

(2) Are there critical federal programs (defense, energy,) which may be impacted by an OSHA regulation concerning glycol ethers?

M. *Financial and Economic Profile.*

(1) For the producers of glycol ethers, what are the total annual volumes and dollar values (for the last 5 years) of production, shipments, inventories, imports and exports of 2-ME, 2-EE and their acetates? Are these expected to increase or decrease in future years? How much glycol ether is manufactured by companies for their own use as a raw material or product?

(2) For companies engaged in glycol ether production, distribution and/or use, what are the total annual investments categorized as replacement, expansion, modernization and health and safety protection programs.

(3) For the last 5 years. What are total assets, stockholders equity, net worth, depreciation charges, debt-equity ratios and rate of return on assets and equity for companies engaged in glycol ether production, distribution and/or use?

(4) For each glycol ethers production facility, what was the date it began operation and how much longer is it expected to remain in operation?

(5) How would the balance of trade in products produced with glycol ethers be affected by a more stringent U.S. occupational regulation or health standard for glycol ethers?

(6) What were the annual labor turnover rates over the last five years for each of the affected industry sectors?

(7) Are there any unique characteristics in any of the affected industry sectors (e.g., rental of capital equipment, unique employee skills) that could affect the ability to achieve compliance with a glycol ether standard? What are these unique characteristics?

(8) What is the degree of market concentration (including the role of small business) and the approximate number of firms in each of the affected industry sectors?

(9) What are the availability, price and serviceability of substitutes for products containing 2 ME, 2-EE and their acetates?

(10) Assuming no change in regulation, what are the projected trends in the use of 2-ME, 2-EE and their acetates?

(11) If the market price of 2-ME, 2-EE and their acetates were to increase by 1%, 5%, or 10% as a result of regulation, what would be the magnitude of the impact on the production and consumption of these glycol ethers?

(12) How profitable are the production processes which either produce or consume glycol ethers? What are the most profitable processes in production?

(13) What is the gross annual consumption of 2-ME, 2/EE and their acetates? What is the approximate annual consumption of these glycol ethers per plant?

(14) Do companies in each of the affected industry sectors purchase glycol ethers from one or several suppliers of the product? What is the geographic distribution of the industry and its customers? Where are these suppliers located geographically with respect to the facilities that use or process it?

(15) For products in which glycol ethers are used, what portion of the cost could be accounted for by the use of glycol ethers?

(16) For a firm using glycol ethers, what other chemicals covered by OSHA standards are currently used in the plant? How would engineering controls or process modification for glycol ethers affect exposure to these other chemicals?

Statutory Authority

This Advance Notice of Proposed Rulemaking was prepared under the direction of John A. Pendergrass, Assistant Secretary of Labor for Occupational Safety and Health, 200 Constitution Avenue, NW., Washington, DC 20210. It is issued pursuant to section 6(b) of the Occupational Safety and Health Act (84 Stat. 1593; 29 U.S.C. 655).

List of Subjects in 29 CFR Part 1910

Chemicals, 2-Ethoxyethanol, 2-Ethoxyethanol acetate, Glycol ethers, 2-Methoxyethanol, 2-Methoxyethanol acetate, Occupational safety and health, Reproductive and developmental toxicity.

Signed at Washington, DC, this 25th day of March 1987.

John A. Pendergrass,

Assistant Secretary of Labor.

[FR Doc. 87-7028 Filed 4-1-87; 8:45 am]

BILLING CODE 4510-26-M

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 100

[CGD3 87-09]

Regatta; Barnegat Bay Classic, Toms River, NJ

AGENCY: Coast Guard, DOT.

ACTION: Notice of proposed rule making.

SUMMARY: The Coast Guard is proposing to amend the Special Local Regulations governing the annual Barnegat Bay Classic power boat race. The location of the regulated area and effective period of the regulations are being changed along with correction of the event name. This regulation is needed to provide for the safety of participants and spectators on navigable waters during the event.

DATE: Comments must be received on or before May 4, 1987.

ADDRESSES: Comments should be mailed to Commander (b), Third Coast Guard District, Governors Island New York, NY 10004-5098. The comments and any other materials referenced in this notice will be available for inspection and copying at the Boating