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V. Authority and Signature

This document was prepared under the direction of David Michaels, PhD, MPH, Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, pursuant to sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657), 29 CFR part 1911, and Secretary's Order 5-2007 (72 FR 31160).

Signed at Washington, DC, on April 26, 2010.

David Michaels,

Assistant Secretary of Labor for Occupational Safety and Health.

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DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1910

Docket No. OSHA-2007-0024]

RIN 1218-AC23

Notice of Availability of the Regulatory Flexibility Act Review of the Methylene Chloride Standard

AGENCY: Occupational Safety and Health Administration, Labor.

ACTION: Availability of completed regulatory review.

SUMMARY: The Occupational Safety and Health Administration (OSHA) has completed a review of the Methylene Chloride (MC) Standard (29 CFR 1910.1052) pursuant to section 610 of the Regulatory Flexibility Act and section 5 of Executive Order 12866 on Regulatory Planning and Review. The purpose of this review was to determine whether the MC Standard has functioned as intended, whether it could be simplified or improved to reduce the regulatory burden on small businesses, or whether it is no longer needed and should be rescinded.

DATES: As of May 5, 2010 the report is available to the public, (*see ADDRESSES* section to obtain copies).

ADDRESSES: Copies of the entire report may be obtained from the OSHA Publications Office, Room N-3101, 200 Constitution Avenue, NW., Washington, DC 20210; telephone (202) 693-1888; fax (202) 693-2498. All documents and comments received relevant to the review and documents discussed in this report are available at the OSHA Docket Office, Docket No. OSHA-2007-0024, Technical Data Center, Room N-2625, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210, Telephone (202) 693-2350. The main text of the report, this **Federal Register** Notice and any news releases will become available at the OSHA Webpage at <http://www.OSHA.gov>. Electronic copies of this **Federal Register** Document, the full text of the report, comments and referenced documents are or will become available at <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT:

General information: Joanna Dizikes Friedrich, OSHA Directorate of Evaluation and Analysis, Room N-3641, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC, 20210; telephone (202) 693-1939.

SUPPLEMENTARY INFORMATION:

Background

MC (also known as methylene dichloride or dichloromethane [DCM or MC]) is a common industrial solvent used in a number of different applications, including paint stripping, metal cleaning and the manufacture of plastics and adhesives. Without proper ventilation or respiratory protection, short-term exposure to large amounts of MC can cause respiratory or central nervous system failure. In 1985, the U.S. Environmental Protection Agency (EPA) determined that MC was a probable human carcinogen and posed a long term danger to human health.¹ EPA

promulgated rules governing the use of MC in several industries during 1994-1995. On January 10, 1997, OSHA published its final MC Standard to protect workers from occupational exposure to MC.² It reduced the permissible exposure limit from an 8-hour-time-weighted-average (TWA) of 500 parts per million (ppm) to 25 ppm.³

Regulatory Review

The purpose of this lookback study was to review the current MC Standard, in accordance with section 610 of the Regulatory Flexibility Act and Section 5 of Executive Order 12866, to determine whether the rule has functioned as intended, whether it could be simplified or improved, or whether it is no longer needed and should be rescinded. The purpose of a review under section 610 of the Regulatory Flexibility Act is:

“to determine whether such rule should be continued without change, or should be rescinded, or amended consistent with the stated objectives of applicable statutes to minimize any significant impact of the rules on a substantial number of small entities.”

In conducting a section 610 review, the Agency must consider the following factors:

- (1) The continued need for the rule;
- (2) The nature of complaints or comments received concerning the rule from the public;
- (3) The complexity of the rule;
- (4) The extent to which the rule overlaps, duplicates or conflicts with other Federal rules, and, to the extent feasible, with State and local governmental rules; and
- (5) The length of time since the rule has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the rule.”

The review requirements of section 5 of EO 12866 require agencies:

“To reduce the regulatory burden on the American people, their families, their communities, their State, local, and tribal governments, and their industries; to determine whether regulations promulgated by the [Agency] have become unjustified or unnecessary as a result of changed circumstances; to confirm that regulations are both compatible with each other and not duplicative or inappropriately burdensome in the aggregate; to ensure that all regulations are consistent with the President's priorities and the principles set forth in this Executive Order, within applicable law; and to otherwise improve the effectiveness of existing regulations.”

To carry out its lookback review of the MC Standard under these provisions, OSHA requested public comment, on July 10, 2007, on: the impacts of the rule

² 62 FR 1494.

³ Regulatory Impact Analysis (Methylene Chloride) ES-2, January 7, 1996.

¹ 62 FR 1497, January 10, 1997.

on small businesses; the benefits and utility of the rule in its current form and, if amended, in its amended form; the continued need for the rule; the complexity of the rule; and whether, and to what extent, the rule overlaps, duplicates, or conflicts with other Federal, State, and local government rules. OSHA also asked for comments on new developments in technology, economic conditions, or other factors affecting the ability of covered firms to comply with the standard. Furthermore, OSHA asked for comments on alternatives to the rule that would minimize significant impacts on small businesses while achieving the objectives of the Occupational Safety and Health Act.

Conclusions and Recommendations

OSHA's Section 610 review of the MC Standard finds the following:

- There is a continued need for the Standard.
- The Standard does not impose an unnecessary or disproportionate burden on small businesses or on industry in general.
- Although the Standard does impose costs, these costs are essential to protecting worker health.
- This lookback review did not identify any industries in which the Standard diminished the industries' viability.
- There is no indication that employers are unable to comply due to the complexity of the Standard.
- The Standard does not overlap, duplicate, or conflict with other state or federal rules.
- Economic and technological trends have not reduced the need for the Standard.
- No public commenter felt the MC Standard should be rescinded. Several of the comments underscored the hazards associated with exposure to MC and that it is feasible to comply with the Standard. Other comments contained specific suggestions for how compliance with the Standard could be improved through compliance assistance, and how worker health could be improved through information on the toxicity of substitutes for MC use.

OSHA's review of the MC Standard under EO 12866 finds the following:

- The Standard remains justified and necessary in light of ongoing hazards and fatalities.
- In general, the Standard is compatible and not duplicative with other state or federal rules.
- The Standard remains consistent with E.O. 12866 because it has produced the intended benefits (i.e.,

protecting workers' health), and has not been unduly burdensome.

OSHA concludes that the MC Standard has protected workers from adverse health effects resulting from exposure to MC in the workplace. In terms of economic impacts, the MC Standard does not impose an unnecessary or disproportionate burden on small businesses or on industry in general. Although the Standard does impose costs, these costs are essential to protecting worker health. This lookback review did not identify any industries in which the MC Standard diminished the industries' viability.

OSHA recommends the following:

- The MC Standard should continue without change.
- According to public comments, lack of information and training are the most common barriers in the construction industry for compliance with the MC Standard. Therefore, OSHA recommends reviewing its compliance assistance materials to determine the need for updates. OSHA also recommends reviewing the adequacy of how these materials are disseminated and additional means for reaching affected populations.
- The use of substitutes for MC has increased in certain industries. These substitutes may pose their own health hazards. Therefore, based on public comments, OSHA will consider putting out guidance recommending that, before a substitute for MC is used, the toxicity of that substitute should be checked on the EPA and NIOSH Web sites (<http://www.epa.gov> and <http://www.niosh.gov>, respectively).

Authority: This document was prepared under the direction of David Michaels, PhD, MPH, Assistant Secretary of Labor for Occupational Safety and Health, 200 Constitution Avenue, NW., Washington, DC 20210. It is issued under Section 610 of the Regulatory Flexibility Act (5 U.S.C. 610) and Section 5 of Executive Order 12866 (58 FR 51735, October 4, 1993).

Signed at Washington, DC, on April 26, 2010.

David Michaels,

Assistant Secretary of Labor for Occupational Safety and Health.

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DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 1

RIN 2900-AN42

Drug and Drug-Related Supply Promotion by Pharmaceutical Company Sales Representatives at VA Facilities

AGENCY: Department of Veterans Affairs.

ACTION: Proposed rule.

SUMMARY: The Department of Veterans Affairs (VA) proposes to amend its regulations regarding access to VA facilities to control the promotion of drugs and drug-related supplies at VA facilities and the business relationships between VA staff and sales representatives promoting drugs and drug-related supplies. The purposes of the proposed rule are to reduce or eliminate any potential for disruption in the patient care environment, manage activities and promotions at VA facilities, and provide sales representatives with a consistent standard of permissible business practice at VA facilities. It would also facilitate mutually beneficial relationships between VA and such sales representatives.

DATES: Comments must be received by VA on or before July 6, 2010.

FOR FURTHER INFORMATION CONTACT: Louis E. Cobuzzi, PBM Services (119), Veterans Health Administration, Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420; (202) 461-7362. (This is not a toll-free number).

SUPPLEMENTARY INFORMATION: Under 38 U.S.C. 303, the Secretary of Veterans Affairs is responsible for "the proper execution and administration of all laws administered by the Department and for the control, direction, and management of the Department." The Secretary has authority to prescribe all rules necessary to carry out the laws administered by the Department, such as section 303 regarding control and management of the Department. See 38 U.S.C. 501(a). VA has implemented this authority, as it pertains to management of VA facilities, in 38 CFR part 1.

VA proposes to amend 38 CFR part 1 to regulate access to VA medical facilities by sales representatives (including account managers and clinical liaisons) promoting drugs and drug-related supplies. Currently, many policies regarding access to VA facilities are established and maintained at the local level, either by Veterans Integrated Service Network (VISN) leaders or by