Regulatory Review of 29 CFR 1910.1052:

Methylene Chloride

Pursuant to
Section 610 of the Regulatory Flexibility Act
and Section 5 of Executive Order 12866

Occupational Safety and Health Administration
Directorate of Evaluation and Analysis
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Table of Contents

Executive Summary **2**

1. Introduction and Background **4**

1.1 NATURE OF THE REVIEW 4
1.2 USES OF METHYLENE CHLORIDE IN THE WORKPLACE 5
1.3 REGULATORY HISTORY 6
1.4 SUMMARY OF THE STANDARD 9
1.5 ANALYTICAL CHALLENGES 11

2. Industry Usage and Trends **13**

2.1 ENTITIES AFFECTED BY THE STANDARD 13
2.2 TECHNOLOGICAL ADVANCES AND FEASIBILITY 15
2.3 ECONOMIC TRENDS 19
2.4 CONCLUSIONS 22

3. Compliance With The Standard **23**

3.1 FATALITIES 23
3.2 COMPLIANCE WITH THE STANDARD 25
3.3 COMPLIANCE WITH SPECIFIC RULE PROVISIONS 30

4. Health Risk And Benefits **32**

4.1 HEALTH BASIS OF CURRENT METHYLENE CHLORIDE STANDARD 33
4.2 HEALTH RISKS AND BENEFITS OF CURRENT STANDARD 39
4.3 NEW HEALTH AND SAFETY DATA 41
4.4 OTHER HEALTH-BASED ADVANCES 43
4.5 SUMMARY AND DISCUSSION 44

5. Public Comments **45**

6. The MC Standard And Small Businesses **59**

6.1 ESTIMATION OF THE NUMBER OF SMALL BUSINESSES 59
6.2 DISTRIBUTION OF FIRMS BY NUMBER OF EMPLOYEES 61
6.3 IMPACTS ON SMALL BUSINESSES 66

7. Section 610 Review **67**

Nature of Comments Received 69

8. Executive Order 12866 Review Of The Standard **70**

9. Conclusions and Recommendations **72**

APPENDIX I: REGULATORY FLEXIBILITY ACT, SECTION 610 ..... **73**

APPENDIX II: INTRODUCTION AND SECTION 5 OF EXECUTIVE ORDER 12866 ..... **74**

EXECUTIVE SUMMARY

Methylene chloride (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, the Occupational Safety and Health Administration (OSHA) published its final MC Standard. It reduced the permissible exposure limit from an 8-hour-time-weighted-average (TWA) of 500 parts per million (ppm) to 25 ppm.[2]

The purpose of this lookback study is 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 applicable requirements of Section 610 of the Regulatory Flexibility Act and Section 5 of Executive Order 12866 are given in Appendices I and II, respectively.

Conclusions and Recommendations

This regulatory review of the MC Standard meets the requirements of both Section 610 of the Regulatory Flexibility Act and Section 5 of EO 12866. Under Section 610, this review examines whether the Standard should be continued without change, rescinded, or amended to minimize any significant impact on a substantial number of small entities considering the continued need for the rule, comments and complaints received, complexity of the rule, whether the rule is duplicative, and the degree to which technology and economic conditions have changed since its issuance. Under Section 5 of EO 12866, this review examines whether the Standard has become unjustified or unnecessary as a result of changed circumstances, and whether the Standard is compatible with other regulations or is duplicative or inappropriately burdensome in the aggregate. This review also ensures that the regulation is consistent with the priorities and the principles set forth in EO 12866 within applicable law, and examines whether the effectiveness of the Standard can be improved. To assist OSHA in this review, OSHA requested public comments on these issues.

The Section 610 review of the Standard finds the following:

[1] 62 FR 1497, January 10, 1997.
[2] Regulatory Impact Analysis (Methylene Chloride) ES-2, January 7, 1996.

- There is a continued need for the Standard.

- 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.

- 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.

- Public 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.

Based on the findings of this review, OSHA finds that the MC Standard should be continued unchanged. OSHA also believes that further improvements in worker health might be achieved through increased outreach and training and 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.

1. Introduction and Background

This lookback review evaluates the industries that use MC, examines available literature and data on exposures and compliance issues, assesses trends, and considers issues raised by the public with respect to the Standard. The remainder of this first chapter provides background information that is helpful in understanding the issues and analyses presented in this lookback review. Section 1.1 discusses the nature of the review. Section 1.2 introduces and summarizes the uses and health effects of MC. Section 1.3 provides an overview of the regulatory history of MC. Section 1.4 summarizes the provisions in the current standard. Section 1.5 discusses some of the analytical challenges that arose in completing this lookback review.

1.1 Nature of the Review

OSHA conducts its review of the MC Standard under Section 610 of the Regulatory Flexibility Act[3] and Section 5 of EO 12866 on Regulatory Planning and Review.[4]

The purpose of a review under Section 610 of the Regulatory Flexibility Act:

> "(S)hall be 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."
>
> "The Agency shall 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:

[3] 63 FR 34139 (June 23, 1998). For complete text of the Regulatory Flexibility Act, Section 610, 5 U.S.C. 601 *et seq.,* see Appendix 1.
[4] For the relevant text of EO 12866, see Appendix II.

> "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 these reviews, on July 10, 2007, OSHA requested public comment on all issues raised by these provisions (72 FR 37501). Specifically, OSHA requested comments on: the impacts of the rule 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.

The 90-day comment period ended on October 9, 2007. However, in response to a request from the public for additional time, OSHA reopened the comment period for an additional 60 days. OSHA did this to allow stakeholders time to provide more thorough comments on the lookback review, which, in turn, would also give OSHA a more complete record. This reopened comment period ended March 10, 2008.

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, N.W., Washington, DC 20210, Telephone (202) 693-2350.

1.2 Uses of Methylene Chloride in the Workplace

MC is primarily used in the metal cleaning and paint stripping industries and is less commonly used in the manufacture of products such as semiconductors, pharmaceuticals and adhesives. It is also used in shipyards and on construction sites. While it is used in many different industries, there are some similarities in its application. Whether cleaning furniture, metal parts or semiconductors, MC acts as an effective solvent. It is used in the furniture stripping industry because it causes no damage to wood when removing paint, and it is not flammable. MC is used in the metal fabrication industry because it effectively removes excess lubricants used during production. Also, it is used

to formulate adhesives and produce injection-molded plastics. Another primary use is the removal of ink from printing presses.[5]

Without appropriate precautions, MC is hazardous to worker health. In the short term, high levels of MC act as an anesthetic. With continued exposure, it can cause mental confusion, headaches and nausea, and death. Acute, negative effects of MC are normally caused by inhalation, but dermal absorption of high concentrations can have similar effects.[6] Contact with unprotected skin and eyes causes irritation and burns. Studies performed on laboratory animals have indicated that chronic exposure to MC can lead to cancer. (See Section 4.3 for a detailed discussion of health effects.)

While MC can be hazardous to worker health, relatively simple control measures can be used to reduce these risks. These measures include: rescheduling work shifts so operations requiring use of MC are performed when few employees are present; sealing containers of MC when not in use; and prohibiting employees from eating, drinking and smoking within the work area.[7] In some cases, more expensive engineering controls are used to reduce the risk to workers. These controls include exhaust ventilation systems and special enclosures to isolate workers using MC. Some industries and establishments supplement these controls with personal respirators for employees working directly with MC.

1.3 Regulatory History

The initial Methylene Chloride Standard was adopted by OSHA in 1971 pursuant to section 6(a) of the OSH Act, 29 U.S.C. 655, from an existing Walsh-Healey Federal Standard. The standard was intended to protect workers from injury to the neurological system, including loss of awareness and functional deficits linked to anesthetic and irritating properties of MC, which had been observed from excessive acute or chronic exposures to MC in humans and experimental animals. The MC Standard required employers to ensure that employee exposure does not exceed 500 ppm as an 8-hour TWA, 1000 ppm as a ceiling concentration, and 2000 ppm as a maximum peak for a period not to exceed five minutes in any two hours (29 CFR 1910.1000, Table Z-2).

In 1946, the American Conference of Governmental Industrial Hygienists (ACGIH) recommended a Threshold Limit Value (TLV) of 500 ppm for MC. In 1975, the ACGIH lowered the recommended TLV to 100 ppm. In March 1976, the National Institute for Occupational Safety and Health (NIOSH) published "Criteria for a Recommended Standard for Methylene Chloride," which recommended a reduction of occupational exposures to MC to 75 ppm as an 8-hour TWA, and a lower peak exposure not to exceed 500 ppm. ACGIH further lowered the TLV to 50 ppm in 1988 (56 FR 57036, 57039 Nov. 7, 1991).

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[5] Methylene Chloride Final Economic and Regulatory Flexibility Analysis, Table ES-1, January 7 1996.
[6] 62 FR 1501, January 10, 1997
[7] Methylene Chloride informational booklet, OSHA 3144, p. 10.

In February 1985, the National Toxicology Program (NTP), U.S. Department of Health and Human Services, reported the final results of animal studies. NTP classified MC as "reasonably anticipated to be a human carcinogen" based on sufficient evidence of carcinogenicity in experimental animals. This action triggered several regulatory actions: 1) The U.S. Environmental Protection Agency (EPA) conducted a risk assessment to determine whether MC presents an unreasonable risk to human health or the environment and to determine if regulatory actions are needed to eliminate or reduce exposures. In May 1985, EPA announced its determination that MC was a probable human carcinogen and announced the initiation of a 180-day priority review under section 4(f) of the Toxic Substances Control Act (TSCA). 2) The U.S. Consumer Product Safety Commission (CPSC) released its risk assessment findings for MC and began to consider a regulatory action to ban products containing MC and to develop a voluntary hazard communication program for consumers. 3) The U.S. Food and Drug Administration (FDA) published a proposal to ban the use of MC as an ingredient in aerosol cosmetic products.

In July 1985, the International Union, United Automobile, Aerospace and Agricultural Implement Workers of America (UAW) petitioned OSHA to act expeditiously on reducing workers' exposure to MC. Six labor unions joined UAW in petitioning OSHA to revise the standard. On November 24, 1986, OSHA issued an Advance Notice of Proposed Rulemaking (ANPR) (51 FR 42257) for the MC Standard. On November 7, 1991, OSHA issued a Notice of Proposed Rulemaking (NPRM)(56 FR 57036), which proposed reducing the occupational exposure to MC and instituting ancillary measures, such as employee training and medical surveillance, to further protect MC-exposed workers. OSHA subsequently scheduled informal public hearings in connection with the proposal (57 FR 24438 (June 9, 1992)).

In May 1992, OSHA presented the MC proposal to the Advisory Committee on Construction Safety and Health (ACCSH) for consultation. ACCSH established an MC work group to generate information and recommendations regarding MC use and exposure in the construction industry. Based on the input from the ACCSH and its work group, OSHA issued a supplemental hearing notice (57 FR 36964, August 17, 1992) which raised MC use, exposure and control issues specific to the construction industry. OSHA convened informal public hearings in Washington, D.C. on September 16-24, 1992 and in San Francisco on October 14-16, 1992.

On March 11, 1994, OSHA reopened the rulemaking record for 45 days (59 FR 11567) to receive public comment on reports related to engineering controls for MC exposure in the furniture refinishing industry, MC carcinogenicity, and the availability of water-based substitutes for MC-based adhesives in the manufacture of flexible foam products. On October 25, 1995, OSHA again reopened the rulemaking record to obtain input regarding studies submitted by the Halogenated Solvents Industry Alliance (HSIA) addressing the use of animal data to estimate human cancer risk from MC exposure. Small businesses, particularly in the furniture refinishing and polyurethane foam blowing industries, expressed concern that the proposed rule would impose excessive compliance burdens on

their operations. The Agency promulgated the final MC rule on January 10, 1997 (62 FR 1494).

On December 18, 1997, in response to a petition from the UAW and other labor unions, HSIA, and others, OSHA delayed until August 31, 1998, the requirement to use respiratory protection to achieve the 8-hour TWA PEL, and to December 10, 1998, the requirement to achieve the 8-hour TWA PEL and the short-term exposure limit (STEL) through engineering controls (62 FR 66275). On May 4, 1998, OSHA published for comment proposed amendments to the standard (63 FR 24501). Based on the rulemaking record and the comments received, OSHA amended the standard by adding a provision for temporary medical removal protection benefits for employees who are removed or transferred to another job because of a medical determination that exposure to MC may aggravate or contribute to the employee's existing skin, heart, liver, or neurological disease (63 FR 50712 (Sept. 22, 1998)). Also, OSHA amended the startup dates by which employers in certain identified application groups must achieve the PEL and the dates by which they must achieve the STEL by means of engineering controls (63 FR 50712 (Sept. 22, 1998)). The final rule became effective on October 22, 1998, except that the revision regarding start-up dates became effective September 22, 1998 (63 FR 50712 (Sept. 22, 1998)).

In other regulatory actions affecting MC usage, Title VI of the Clean Air Act Amendments (CAAA) of 1990 required the phase-out of ozone-depleting chemicals by the year 2000 and required EPA to determine which alternatives to ozone-depleting chemicals are safe for use. MC was among the potential substitutes studied by the EPA. In addition, section 112 of the CAAA required the EPA to address the residual risks of MC and other specified Hazardous Air Pollutants (HAPs) by establishing Maximum Achievable Control Technology (MACT) standards. In particular, section 112(d) required EPA to promulgate National Emission Standards for Hazardous Air Pollutants (NESHAP) over a 10-year period.

In February 1992, then-President Bush announced an accelerated phase-out schedule for ozone depleting substances and ordered the EPA to accelerate its review of substitutes (such as MC) whose use would reduce damage to the ozone layer. A year later, pursuant to section 112 of the CAAA, the EPA issued a notice requesting information on the anticipated impacts of a NESHAP for the halogenated solvent cleaning-vapor degreasing source category. This notice characterized MC as the third most commonly used halogenated solvent, based on 1991 data. On November 29, 1993, EPA issued a NPRM describing MACT rules for the use of MC and other HAPs in halogenated solvent cleaning-vapor degreasing operations (58 FR 62566).

On March 18, 1994, EPA issued a final rule that addressed the use of MC as a substitute for ozone-depleting chemicals being phased out under the CAAA (59 FR 13044). EPA found the use of MC to be acceptable in the production of flexible polyurethane foam; polyurethane integral skin foams; metal cleaning; electronics cleaning; precision cleaning; and adhesives, coatings and inks (59 FR 13044). However, EPA expressed

concern regarding MC toxicity, stating "methylene chloride use will be subject to future controls for hazardous air pollutants under Title III section 112 of the CAA. In addition, use of the compound must conform to all relevant workplace safety standards… Use is also subject to waste disposal requirements under RCRA (59 FR at 13088)."

EPA subsequently finalized NESHAP rulemakings covering halogenated solvent cleaning, aerospace manufacture, rework facilities and wood furniture manufacturing, and also engaged in MC-related NESHAP proceedings addressing several other industries, including pharmaceuticals, flexible polyurethane foam, polycarbonates and nylon 6. For example, EPA imposed effluent limitation guidelines for the pharmaceutical industry. EPA also characterized MC as one of the most significant priority pollutants to be addressed under the Clean Water Act (CWA) and addressed the use of stream stripping and distillation technology to recover MC from wastewater for reuse or sale for use in other industries.

The FDA banned the use of MC in cosmetic products in June 1989. In April 1994, the Department of Housing and Urban Development (HUD) announced that it had funds available for the removal of lead-based paint, but that the funds could not be used for paint removal activities using products containing MC.

Finally, since promulgation of the MC Standard, the World Health Organization's (WHO's), International Agency for Research on Cancer (IARC) has classified MC as possibly carcinogenic to humans. This classification is based on sufficient evidence from studies in animals and limited evidence of carcinogenicity from studies in humans.[8]

In addition, on January 14, 2009, the European Parliament announced that it was banning MC for certain consumer and professional uses.[9] This ban was based on the toxicity of MC and the availability of substitutes.

1.4 Summary of the Standard

OSHA's standard covers all occupational exposures to MC in all workplaces in general industry, shipyard employment, and construction. The action level for a concentration of airborne MC is 12.5 ppm, calculated as an 8-hour time weighted average (TWA). Reaching or exceeding the action level signals that the employer must begin compliance activities (e.g., exposure monitoring and medical surveillance, as discussed below).[10]

[8] IARC, 2004, Overall Evaluations of Carcinogenicity to Humans, last accessed April 10, 2006 at http://monographs.iarc.fr/monoeval/crthgr02b.html.

[9] http://www.europarl.europa.eu/oeil/FindByProcnum.do?lang=en&procnum=COD/2008/0033

[10] This summary does not contain all the requirements of the MC Standard; for a full listing of all the requirements in the Standard, please consult the Standard, 29 CFR 1910.1052.

Permissible Exposure Limit (PEL) and Short-Term Exposure Limit (STEL). The employer must ensure that no employee is exposed to an airborne concentration of MC in excess of 25 ppm as an 8-hour TWA or short-term exposure limit (STEL) in excess of 125 ppm during a sampling period of 15 minutes. 29 C.F.R. § 1910.1052(c).

Exposure Monitoring. Where an employer has determined that exposure meets or exceeds the action level, the employer must begin to conduct periodic monitoring of worker exposure to MC. Consult the standard for the rate at which periodic monitoring must be performed.

Regulated Areas. The employer must establish a regulated area wherever exposure to airborne concentrations of MC exceed or can be expected to exceed either the PEL or STEL. Only authorized employees may enter a regulated area. Authorized employees entering a regulated area, must be supplied appropriate respirators (as specified in the standard). While employees are in regulated areas, they may not engage in non-work activities that may increase any type of exposure to MC. 29 C.F.R. § 1910.1025(e).

Engineering and Work Practice Controls. The employer must control MC exposure to or below the PEL using engineering controls and work practices (but not including worker rotation) as the primary methods, unless the employer can demonstrate that these controls are infeasible. If engineering and work practices are not sufficient to reduce employee exposure to or below the PEL or STEL, the employer shall use them to reduce employee exposure to the lowest levels achievable by these controls and shall supplement them by the use of appropriate respirators (as specified in the standard). The employer may not implement a schedule of employee rotation to comply with the PELs. Employers must implement procedures to detect leaks of MC in the workplace, and must make provisions to contain any spills and safely dispose of contaminated waste materials. Employees must be properly trained before attending to leaks and spills, and must use appropriate personal protective equipment. 29 C.F.R § 1910.1052(f).

Respiratory Protection. Appropriate respirators (as specified in the standard) must be used in the following situations: periods when an employee's exposure to MC exceeds the 8-hour TWA, PEL, or STEL (for example, when an employee is using MC in a regulated area); periods necessary to install or implement feasible engineering and work-practice controls; a few work operations, such as some maintenance operations and repair activities, for which the employer demonstrates that engineering and work-practice controls are infeasible; work operations for which feasible engineering and work-practice controls are not sufficient to reduce employee exposures to or below the PELs; and emergencies. 29 C.F.R. § 1910.1052(g).

Protective Work Clothing and Equipment. The Standard requires employers to provide appropriate protective work clothing and equipment where needed to prevent MC-induced skin or eye irritation. Employers must clean, launder, and repair, and replace this clothing and equipment as needed, to ensure that it will effectively protect workers, and

must be responsible for the safe disposal of the clothing and equipment. 29 C.F.R § 1910.1052(h).

Hygiene Facilities. The employer must provide conveniently located washing facilities capable of removing MC if there is a potential for skin contact with solution containing as little as 0.1 percent MC. If there is the potential of eye contact with solutions of 0.1 percent of MC or greater, employers must provide appropriate emergency eyewash facilities within the immediate work area for emergency use. Employers must ensure that employees use hygiene facilities as needed. 29 C.F.R. § 1910.1052(i).

Medical Surveillance. Employers must implement and make medical surveillance available for employees under certain circumstances, including, among other things, exposure to a concentration of MC at or above the action level for 30 or more days of the year or above the PEL or STEL for 10 or more days a year. The standard provides specific requirements for elements of the examination and exam periodicity depending, among other things, on the nature of the exposure, age, and health status of the employee. If a medical professional determines that exposure to MC may aggravate or contribute to an employee's existing skin, heart, liver, or neurological disease, the standard provides for temporary medical removal and protection of benefits during removal. 29 C.F.R. § 1910.1052(j).

Employee Information and Training. Employers must provide information and training to all employees potentially exposed to MC, prior to initial assignment and periodically thereafter, (as specified in the standard). This training must consist of, among other things, the risks of MC, the requirements of the standard and the specific operations that could cause employee exposure. The employer must inform each employee that is exposed (or could potentially be exposed) to concentrations above the action level, of, among other things, the amounts, location and proper use of MC in the workplace. 29 C.F.R. § 1910.1052(k), (1).

Recordkeeping. Employers must retain employee exposure and medical surveillance records for at least 30 years in accordance with the Access to Employee Exposure and Medical Records Standard (29 CFR 1910.1020). These records must be made available, as specified in the standard, 29 C.F.R. § 1910.1052(m).

1.5 Analytical Challenges

This lookback review faced two analytical challenges. First, the initial gathering of data, less than 10 years after the MC Standard was finalized, necessarily limited the amount of post-Standard data. With respect to economic data, for example, there is typically a lag of several years before the Bureau of the Census can collect and compile a given year's data. This made it a little difficult to draw meaningful conclusions. Similarly, there has been a relatively brief period of time for studies and articles to be prepared by third-party researchers in academia and industry. Second, it is difficult to identify affected industries because: 1) the use of MC is rarely central to the "value added" by a given industry; and

2) between 1997 and 1998 a change occurred from the use of "Standard Industrial Classification" (SIC) codes to "North American Industrial Classification System" (NAICS) codes as a means for categorizing economic activities. In many cases, there is not a one-to-one correspondence between SIC codes and NAIC codes.

2. Industry Usage and Trends

2.1 Entities Affected by the Standard

OSHA's Standard covers all occupational exposures to Methylene Chloride (MC) in all workplaces in general industry, shipyard employment, and construction. OSHA's Regulatory Impact Analysis (RIA) for the MC Standard estimated users and usage within 28 "application groups," i.e., groups of firms that use MC to perform a particular function. These application groups and related estimates of users and usage are reported in Exhibit 2-1.

Exhibit 2-1
Industry Groups Affected by 1997 OSHA Methylene Chloride Standard

Application Group Category	Application Group	Estimated Number of MC-Using Establishments	Estimated Total Employment	Estimated Number of Exposed Workers	Estimated MC Handled (Millions of Pounds)
	Methylene Chloride Manufacturing	4	1,664	84	469.20
	Distribution/Formulation of Solvents	320	84,004	1,701	189.65
Metal Cleaning	Cold Degreasing and Other Cold Cleaning	23717	901,232	94.537	32.56
	Open-Top Vapor Degreasing	278	27,105	608	14.87
	Conveyorized Vapor Degreasing	45	2,920	75	1.13
	Semiconductors	239	217,960	1,392	0.40
	Printed Circuit Boards	141	77,795	298	13.98
	Aerosol Packaging	52	4,142	520	25.21
	Paint Remover Manufacturing	80	6,134	200	136.85
	Paint Manufacturing	49	8,909	229	3.54
Paint Stripping	Aircraft Stripping	300	266,826	2,470	13.17
	Furniture Stripping	6,152	23,592	7,872	23.26
	Other Industrial Paint Stripping	35,041	2,312,721	46,605	59.36
	Flexible Polyurethane Foam Manufacturing	100	9,800	600	50.32
Plastics and Adhesives Manufacturing and Use	Total of Application Group	3,487	1,186,040	10,481	41.90
	Adhesive Production	165	56,254	497	-
	Adhesive Use	1,753	596,291	5,269	-
	Injection Molding	80	27,211	240	-
	Lamination	1,323	450,031	4,070	-
	Mold Release	165	56,254	497	-
Ink Use	Ink and Ink Solvent Manufacturing	15	2,010	58	3.68
	Ink Solvent Use in Printing	11,869	197,619	39,481	3.68
	Pesticide Manufacturing and Formulation	60	1,440	120	9.58
	Pharmaceutical Manufacturing	108	70,223	1,431	39.53
	Solvent Recovery	34	932	137	32.10
	Film Base Manufacturing	1	45,000	500	8.90
	Polycarbonate Manufacturing	4	1,898	67	6.70
	Construction	9,504	63,115	24,896	2.44
	Shipyards	25	85,212	3,040	0.47
	TOTAL, ALL APPLICATION GROUPS	**91,624**	**5,598,293**	**237,496**	*

Source: Final Economic and Regulatory Flexibility Analysis For OSHA's Standard for Occupational Exposure to Methylene Chloride, Table ES-1, 1996.

*Total not provided in RIA.

In developing these estimates and other findings, the RIA also identified more than 40 industry sectors by "Standard Industrial Classification" (SIC) code. These sectors are reported in Exhibit 2-2.

Exhibit 2-2
Industries Affected by 1997 OSHA Methylene Chloride Standard

SIC Code	SIC Title
15	Building Restoration Contractors
1721	Painting Contractors
1721	Building Restoration Contractors
1742	Insulations
1751	Cabinet Refinishers (at Installation Shop)
1752	Floor Refinishers
1799	Special Trade Contractors, NEC (includes, Miscellaneous Trade Contractors, Industrial Seating Refinishers, Building Restoration Contractors and Church Pew Refinishers)
2399	Fabricated Textile Products
24	Wood Products Industries
25	Wood Products Industries
2675	Die-Cut Paper and Board
2689	Manufacturers of Industrial Organic Chemicals, NEC
2711	Newspapers
275	Commercial Printers
2759	Commercial Printing, NEC
283	Drugs
2851	Paints, Varnishes, Lacquers, Enamels, and Allied Products
2879	Pesticides and Agricultural Chemicals, NEC
2893	Printing and Ink Manufacturing
34	Metal Fabrication Industries
35	Metal Fabrication Industries
36	Metal Fabrication Industries
37	Transportation Equipment Industries
3731	Shipyards
3728	Aircraft Parts and Auxiliary Equipment, NEC
3732	Boat Builders and Repairers
38	Metal Fabrication Industries
4011	Railroads, Line-Haul Operating
4581	Aircraft Stripping
5058	Industrial Supply Companies
5085	Industrial Supply Companies
5169	Chemical and Allied Products, NEC
5199	Nondurable Goods, NEC
5712	Cabinet Refinishing Shops (In Shop)
5932	Used Furniture Dealers
7389	Business Services, NEC (includes Sign Maintenance and Repair)
7532	Automotive Paint Shops, Truck Body Builders and Repair
7641	Reupholstery and Furniture Repair
7699	Miscellaneous Repair Shops and Related Services NEC (includes Piano and Organ Repair and Refinishers, Farm Equipment and Tractor Repairers, Mirror Resilvering, Tank Truck Cleaning Services and Archaeological/Museum/Art Restorers)
8410	Archaeological/Museum/Art Restorers
8412	Museums and Art Galleries
8999	Services NEC
9223	Correctional Institution Furniture Refinishers
9621	State Departments of Transportation
9631	City Public Works Department

Source: Final Economic and Regulatory Flexibility Analysis For OSHA's Standard for Occupational Exposure to Methylene Chloride, Chapter II: Industry Profile, 1996. The RIA also noted additional industries that were expected to be affected by the MC Standard but that were not identified by SIC code because it was not necessary given the RIA's methodology.

Since the time the MC Standard was phased in (i.e., between 1997 and 2000), substitution of other products for MC has occurred to a significant degree, as discussed in Section 2.2. As discussed in Chapter 1, workplaces that continued to use MC after this time have been required to institute a variety of requirements, including engineering controls.

2.2 Technological Advances and Feasibility

Substitution

The primary area of technological advancement relevant to the MC Standard has been the identification and development of products that can substitute for MC in particular applications. Substitutes for MC vary for different purposes and industries, a fact that is indicative of MC's versatility. Some substitutes are replacement chemicals, while in other cases new techniques and equipment are used to replicate the functions of MC. For example, carbon dioxide is now used instead of MC by many foam blowers. Carbon dioxide is less dangerous to worker health and can create foam that is soft enough to be used for furniture cushions. Acetone also is used in some foam blowing applications. MC is still used to create extra-soft foam, but this accounts for only a small share of the foam blowing market. Printing facilities (such as newspaper production facilities), which previously used MC to remove ink from printing presses, shifted from MC to 1,1,1-trichlorethane during the 1980s. The growing use of soy-based inks in recent years has allowed presses to use soy-based solvents for ink removal.

N-methyl pyrrolidone (NMP) is a viable substitute to MC for metal paint stripping and electronic circuit board cleaning applications. The US Military's *Joint Service Pollution Prevention Opportunity Handbook* compared the two chemicals and found that while it is more expensive than MC, 30-40 percent less solvent is required when using NMP.[11] NMP takes longer to strip paint, but it can remove multiple layers of paint with one application. NMP-based solvents typically have lower vapor pressure than MC, which reduces the potential for inhalation. However, a multi-generational study initiated in 1999 on male and female rats indicated that NMP significantly affected the reproduction of the second-generation populations.[12]

Substitution to alternative products also has occurred in the aircraft stripping industry. Large airlines, which typically paint their airplanes using thin layers, now primarily use benzol alcohol for stripping. However, general aviators who own small, private airplanes still generally use MC to remove paint because private airplanes tend to be painted with thicker layers, and for these airplanes, MC remains the most effective chemical for paint removal. Aqueous cleaners, which combine water-based solutions with heat and rubbing and brushing, also have become popular for general solvent and cleaning needs.[13,14]

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[11] The *Joint Service Pollution Prevention Opportunity Handbook* is available at http://p2library.nfesc.navy.mil/P2_Opportunity_Handbook/.

[12] "N-methyl Pyrrolidone Based Cleaners and Strippers." *Joint Service Pollution Prevention Opportunity Handbook*, August 2003. Available at http://p2library.nfesc.navy.mil/P2_Opportunity_Handbook/5_10.html.

[13] ICF telephone conversation with Steve Risotto, Halogenated Solvents Industry Alliance, March 3, 2006.

MC was commonly used prior to the standard in car assembly plants to clean paint guns. MC also was used to clean foam molding guns (used for car seats) on the assembly line. Most factories now use one of multiple substitutes, and a significant number of factories have switched to n-propyl-bromide, an organic solvent used to clean metal.[15]

Continued Use

Despite the significant shift towards the use of substitutes for numerous purposes, it remains true that MC is still widely used for a variety of other purposes. In fact, MC remains the product of choice across a wide range of applications. The Chemical Marketing Reporter's Methylene Chloride Industry Profile estimates the 2004 usage of MC as spanning the following application groups:

- Paint Removal – 30 percent
- Adhesives – 22 percent
- Pharmaceuticals – 11 percent
- Metal Cleaning – 8 percent
- Aerosols – 8 percent
- Chemical Processing – 8 percent
- Flexible Polyurethane Foam – 5 percent
- Miscellaneous – 8 percent

The Halogenated Solvents Industry Alliance (HSIA) attributes MC's popularity in these applications to the following list of key properties:[16]

- As a paint remover, it is aggressively solvent and does not harm wood.
- It is an effective carrier and extraction solvent.
- It has no flash point under normal use conditions and can be used to reduce the flammability of other substances.
- It does not contribute significantly to smog, depletion of the stratospheric ozone layer, or global warming.

Feasibility

Existing worker protection controls for MC include the following:

- Engineering controls, such as local exhaust ventilation, general ventilation systems, and special enclosures and isolation devices.

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[14] "Results of the Massachusetts Methylene Chloride End-Users Survey," Roelofs, Cora and Ellenbecker, Michael. Applied Occupational and Environmental Hygiene, Volume 18(2), 132-137, 2003.
[15] Telephone conversation with Frank Mirer, United Auto Workers, March 3, 2006.
[16] "Methylene Chloride White Paper," Halogenated Solvents Industry Alliance, January 2003.

- Work practices, such as keeping containers closed, maintaining and servicing equipment as recommended by the manufacturer, training, and undertaking immediate and appropriate spill cleanup measures.

- Administrative controls, such as scheduling certain operations during off-hours; and

- Leak and spill detection.

The cost of engineering controls and other controls is frequently dependent on site-specific factors. When these controls do not sufficiently reduce MC levels, employers are required to provide respiratory protections to individual employees.

Engineering controls are more effective than respirators to protect workers from exposure to MC. Ventilation systems do not require the worker to take any specific action, such as wearing a respirator. A properly designed, built, and maintained ventilation system will remove MC from the work area automatically.

After the MC Standard was implemented, numerous researchers and MC users investigated the effectiveness of ventilation systems. One study found that ventilation systems can effectively protect workers using MC if the equipment is maintained and cleaned occasionally, and if work practice controls are implemented. Some of the recommended maintenance includes greasing fan motor bearings and cleaning debris from slots and air vents.[17]

Another study found that the OSHA PEL of 25 ppm could be met through a combination of factors:[18]

> *"There were many factors that acted together to reduce exposures to these levels, the most important being the local ventilation systems at both the stripping and rinsing areas. The installation of adequate ventilation alone will reduce exposures to about 50 ppm. However, other factors need to be controlled to meet the challenging 25 ppm level; adequate make-up air needs to be supplied, paraffin wax needs to be added to the stripping solution, the stripping tank needs to be filled to a high level, and workers need to be trained in good work practices… Installation of these engineering controls are projected to cost furniture stripping facilities $8,900."*

Prices of ventilation systems, however, prevent many furniture stripping facilities from using them. (Furniture strippers use MC almost exclusively as it is far more effective than any substitute.) In many cases, these businesses are small and may not have sufficient capital to purchase a full ventilation system. OSHA's Regulatory Impact

[17] Estill, Cheryl F., et. al., "The Impact of Maintenance and Design for Ventilation Systems." *Applied Occupational and Environmental Hygiene*. Volume 17(5). May 2002. pp 344 – 351.
[18] Estill, Cheryl F., et. al., "Engineering Controls for Furniture Strippers to Meet the OSHA Methylene Chloride PEL." *AIHA Journal*. May/June 2002. pp. 326 – 333.

Analysis (RIA) for the MC Standard estimated the cost of furniture stripping engineering control equipment at $3,067 in 1994 dollars (or $3,810 in 2005 dollars), which does not include the cost of a make-up air system.[19] Make-up air systems can cost an additional $4,000 and are necessary for a ventilation system to function properly.[20] Make-up air systems are more difficult to use in colder climates during the winter months because make-up air should be heated before it is blown into the work area. This increases energy costs for businesses.

Large facilities using MC have somewhat less trouble implementing effective engineering controls, partially because recommended engineering controls make up a smaller portion of operating expenses for large factories. Kodak recently noted that its single facility using MC is equipped with five monitoring stations, and the average air concentration measures about seven parts per billion, or .007 parts per million (the 8-hour time-weighted average action level in the MC Standard is 12.5 ppm).[21] In this report Kodak also noted the importance of MC in its film base manufacturing process:

> *"Methylene chloride is vital to the manufacture of film, having been the primary solvent used to manufacture plastic film base since the mid-1940s. While the company uses millions of pounds of the chemical each year, more than 99 percent is reused over and over again through one of the world's largest closed-loop recycling systems."*

There are two types of respirators that can be used to prevent worker exposure to MC: filtered air respirators and supplied air respirators. Filtered air systems do not provide protection to workers exposed to MC for prolonged periods of time. After about 20 minutes, MC breaks through the filter and reaches the worker.[22] Supplied air respirators, when correctly used and properly maintained, can adequately protect workers from exposure to MC.

The RIA estimated the cost of a supplied air respirator (including a two-person air compressor to supply fresh air) at between $600 and $700 in 1994 dollars. NIOSH-certified one-person supplied air systems (including respirator and air compressor) currently are listed at various supply stores for as little as $500. Supplied air systems, which require an uninterruptible line to supply air from the compressor to the worker, are not always viable in larger facilities where workers' movements can be restricted by the air line. It also can be difficult to ensure that exposed workers use the supplied air systems appropriately.

Summary

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[19] Figures adjusted to 2005 dollars using implicit price deflators for gross domestic product, as reported in the March 2006 Survey of Current Business, published by the Bureau of Economic Analysis.

[20] Hall, Ronald and Estill, Cheryl. Report of Health Hazard Evaluation in Chattanooga, Tennessee on September 3, 1999. National Institute of Occupational Safety and Health, November 22, 1999.

[21] Kodak Environmental Information, *Kodak's Record of Environmental Responsibility*, undated. Available at http://www.kodak.com/US/plugins/acrobat/en/corp/HSE/issuesandchallenges.pdf.

[22] ICF telephone conversation with Cherie Estill, National Institute of Occupational Safety and Health, CDC, March 17, 2006.

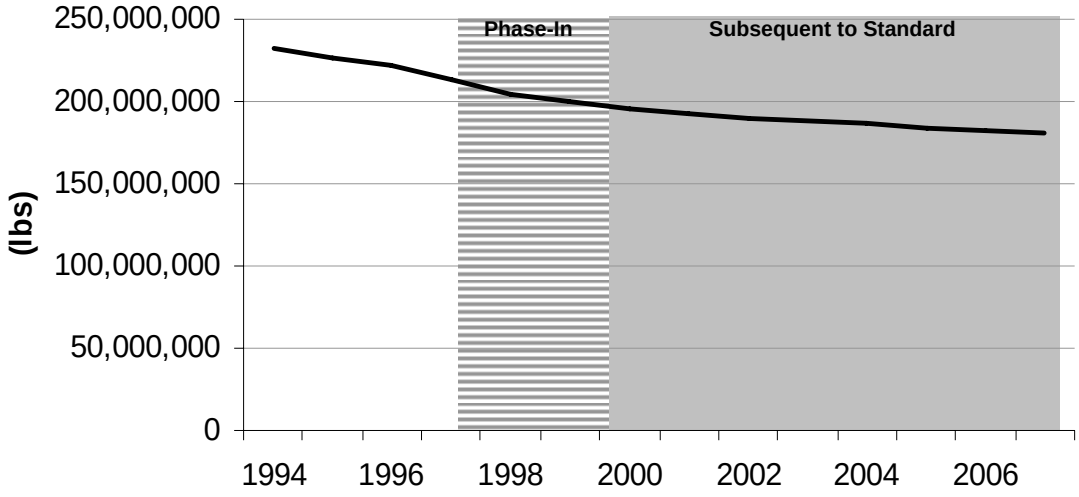
Substitution has occurred for applications where appropriate substitutes could be found, as well as in cases where MC's use is sufficiently infrequent that the MC Standard's compliance costs cannot be justified in light of the benefits. This suggests that the costs of government regulations addressing MC (including OSHA's MC Standard, regulations issued by the U.S. Environmental Protection Agency, and others, as discussed in Chapter 7) have reduced the set of applications for which MC usage remains viable. However, MC remains widely-used for applications that take advantage of its unique properties. This lookback has not identified any significant change in the engineering control costs that would be likely to change incentives for employers.

2.3 Economic Trends

Production and Demand

It is reasonable to expect that MC demand would be reduced as a result of the MC Standard and other governmental regulations. This appears to be the case. U.S. demand for MC has fallen from approximately 232 million pounds in 1994 to approximately 188 million pounds in 2003, as shown in Exhibit 2-3.

Exhibit 2-3
MC Demand in the US (1994-2007)



Source: ICF analysis of data from the Chemical Marketing Reporter, Methylene Chloride Profiles 1995, 1997, 2000, 2004.

According to the Chemical Marketing Reporter's Methylene Chloride Industry Profile from October 2000,

> *"As of April 2000, all compliance deadlines were to have been satisfied. Those facilities which could not justify investment in vapor control equipment ceased consuming [MC]. Assuming no new restrictions are imposed, the demand should stabilize around 200 million pounds this year and continue at that level for the next several years. Although demand in those industries still served*

will continue to grow, the negative position of the EPA toward chlorinated materials in general will encourage further product substitutions."

This suggests that, barring the discovery of new uses or substitutes for MC, the demand for MC is likely to increase only in proportion to the growth of the general economy.

Economic Impacts on Businesses

This section considers the relative growth of the industrial sectors using MC. As an analytical convenience, the analysis focuses on five sectors, believed to use MC to a considerable degree. The sectors evaluated, and their associated North American Industrial Classification System (NAICS) code, include the following:[23]

- 326130: Laminated Plastics Plate, Sheet (except Packaging), and Shape Manufacturing
- 326150: Urethane and Other Foam Product (except Polystyrene) Manufacturing
- 336612: Boat Building
- 337110: Wood Kitchen Cabinet and Countertop Manufacturing[24]
- 811420: Reupholstery and Furniture Repair

Exhibit 2-4 displays the change in the number of firms for three of the industries that use MC: boat building, urethane and other foam manufacturers; and laminated plastics/plate/sheet/shape manufacturing. (The other two industries are displayed in Exhibit 2-5 due to differences in scale). The number of firms in the Boat Building industry remained stable during the Standard's phase-in period and the first years it was effective. The number of firms in the Urethane and Other Foam Manufacturing industry increased from 1998 to 1999, and then remained stable through 2003. The number of firms in the laminated plastics industry has fluctuated.

[23] The NAICS has replaced the Standard Industrial Classification (SIC) system for categorizing economic activities. The SIC system was in use when the RIA for the MC Standard was prepared in 1996. Although the SIC system is used less frequently with the passage of time, it remains relevant for certain historical datasets. This study references SIC codes or NAIC codes as appropriate given the classification system used by the relevant source datasets.

[24] This sector corresponds to a SIC code that contained wood cabinet refinishers, and which were cited by OSHA for more than 100 MC violations.

Exhibit 2-4
Change in Number of Firms (All Firm Sizes) for Selected MC Industries, 1998-2003

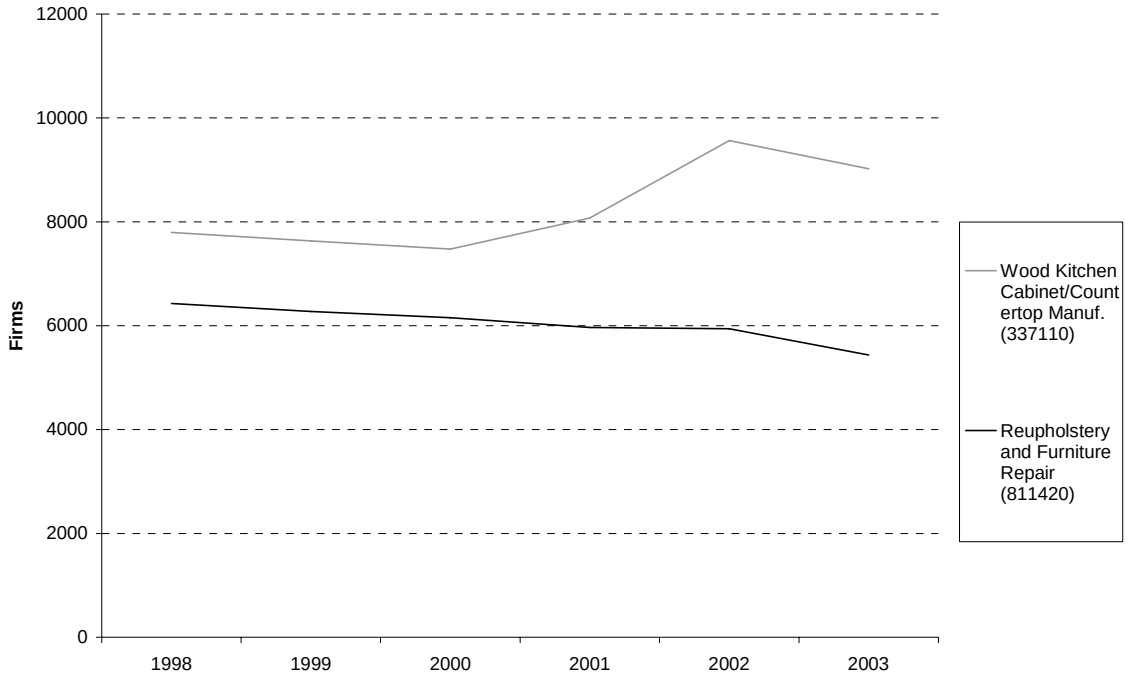
Source: ICF Analysis of data from SBA. "All industries by NAICS codes, Classified by employment size of firm," U.S. Small Business Administration (SBA) Office of Advocacy. http://www.sba.gov/advo/research/data.html#us.

Exhibit 2-5 shows the change in the number of firms for Wood Kitchen Cabinet and Countertop Manufacturing and Reupholstery and Furniture Repair. The number of firms in the Cabinet and Countertop Manufacturing industry initially decreased during the MC Standard's phase in period (1998-2000), but recovered in 2001 and 2002.

The Reupholstery and Furniture Repair industry experienced a slight decline in the number of firms from 1998 to 2003. However, there are numerous factors besides government regulation which could have caused this contraction. For example, the growth of less expensive, imported furniture has reduced overall demand to repair and refinish older furniture.[25]

[25] Telephone conversation with Bob Flexner, former editor of *Professional Refinishing* magazine, March 20, 2006.

Exhibit 2-5
Change in Number of Firms (All Firms Sizes) for Selected MC Industries, 1998-2003



Source: ICF Analysis of data from SBA. "All industries by NAICS codes, Classified by employment size of firm," U.S. Small Business Administration (SBA) Office of Advocacy. http://www.sba.gov/advo/research/data.html#us.

2.4 Conclusions

The health and environmental risks of MC, along with the resulting governmental regulations (including OSHA's MC Standard, among others), have led to the substitution of other products for MC in many uses, applications, and products. Consequently, MC is used in fewer workplaces than at the time OSHA issued the MC Standard. Nevertheless, because of certain unique properties, MC remains the product of choice for numerous other users, even after accounting for the costs of regulatory compliance. Absent the discovery or development of additional uses or substitutes for MC, the demand for MC – and therefore the use of MC in the workplace – is likely to remain fairly constant in relative terms (i.e., it should grow only in proportion to the general economy). This lookback review was unable to identify any industries in which the MC Standard diminished the industries' viability.

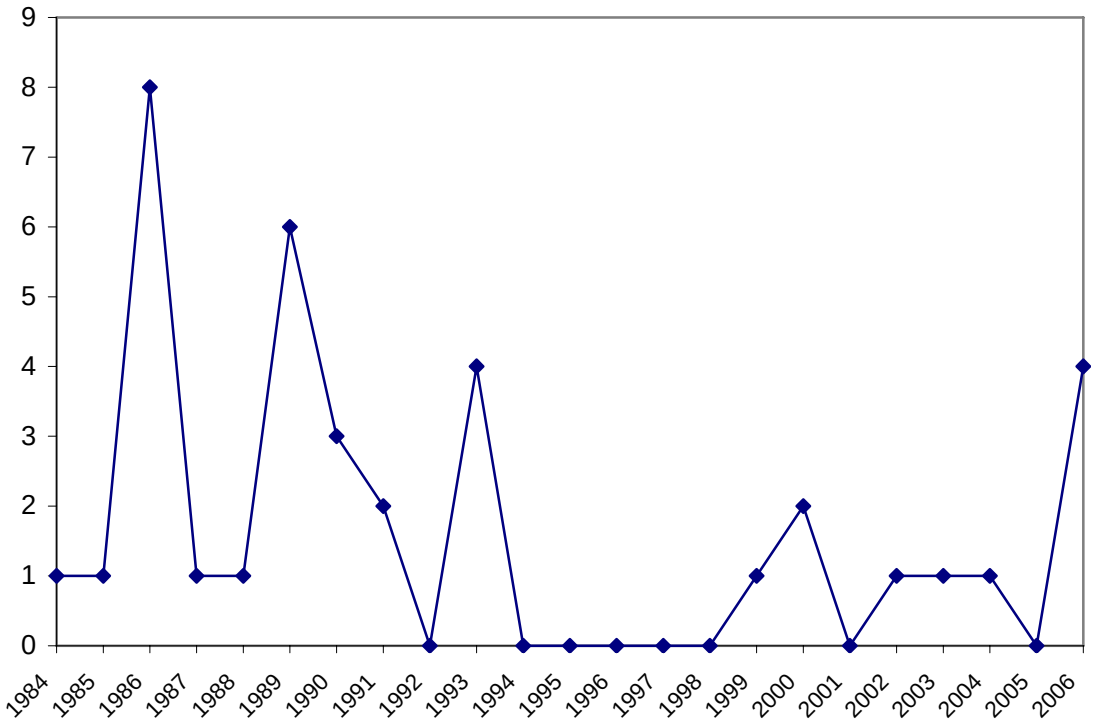
3. Compliance with the Standard

This chapter considers several issues related to industry compliance with the MC Standard at 29 CFR 1910.1052, including the incidence of fatalities among workers, the industries cited for violations of the Standard and the incidence of violations in these industries, and the specific rule provisions being cited in violations. The analysis draws primarily on compliance data contained in OSHA's Integrated Management Information System (IMIS) database.[26]

3.1 Fatalities

At least nine fatalities have occurred between when the MC Standard became fully effective in 2000, through 2006. Exhibit 3-1 tallies these nine fatalities by year, along with an additional 28 MC-related fatalities in the 16-year period prior to 2000 (i.e., 1984-1999). Exhibit 3-2 presents these 37 fatalities by year, SIC code, number of fatalities, and description of the event.

Exhibit 3-1
Number of MC-related Fatalities by Year, 1984-2006



[26] Integrated Management Information System (IMIS), U.S. Department of Labor, Occupational Safety and Health Administration, as of March 2006.

Exhibit 3-2
Methylene Chloride Fatalities by Year, 01/01/1984 – 12/31/2006

Year	SIC Codes	Number of Fatalities	Event
1984	3625	1	Asphyxia of MC vapor in a confined space.
1985	7641	1	Inhalation MC solvent vapor (≥ 1,500 ppm) in breathing zone
1986	1629, 1721, 1731, 2899, 4119, 4213, 4953, 7641	8	1 Inhalation of MC vapors (51 µg/mL in blood and 18 µg/mL); 2 inhalation of MC vapors in confined space); 1 inhalation of MC vapors on the floor of basement; 1 electrician overcome by paint stripper MC fumes; 2 poisoned by MC in tank; 1 killed after inhaling MC vapors.
1987	2869	1	1 inhalation of MC in tank
1988	4212	1	1 inhalation of MC in tank
1989	7349, 7699, 5085, 2851, 7641	6	2 asphyxiated by MC vapors; 1 inhalation of MC vapors; 1 systemic poisoning of MC while cleaning tank; 1 inhalation of MC vapors; 1 overcome by MC vapors
1990	9223, 3479, 3724	3	3 inhalation of MC vapors
1991	2869, 7641	2	1 dies of burns from reactor explosion; 1 dies of overexposure to MC
1992	-	-	-
1993	1752, 3764, 2891	4	2 die of overexposure to MC; 1 dies in chemical explosion; 1 dies from exposure to MC.
1999	7641	1	1 drowns when overcome by chemical after falling into the stripping tank
2000	1793, 7641	2	1 inhalation of MC vapors; 1 face down in MC tank.
2001	-	-	-
2002	1799	1	1 killed from breathing in MC fumes
2003	7641	1	1 experienced massive heart attach and died after using MC stripping solution
2004	1799	1	1 died of MC exposure after using MC based stripping solution
2005	-	-	-
2006	1799, 3732,	4	1 inhalation of MC vapors; 1 MC poisoning after refinishing operation using MC; 1 asphyxia carpet installer and overcome by MC vapor from carpet glue; 1 inhalation of MC during fiberglass stripping
Total		37	

Source: IMIS Database.

For each industry sector that suffered at least one fatality during this time, Exhibit 3-3 compares the number of fatalities that occurred before and after the Standard became fully effective, by SIC code. The only industry that suffered fatalities during both time periods is *Reupholstery and Furniture Repair* (SIC 7641), which also was the single most cited industry for violations of the MC Standard, as discussed later in this chapter.

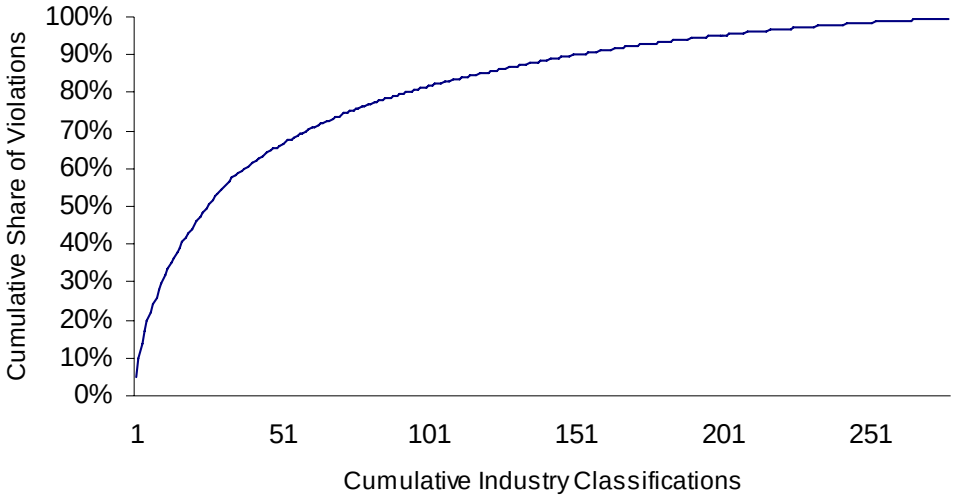
Exhibit 3-3
Methylene Chloride Fatalities by SIC Codes between 01/01/1984 – 12/31/2006

SIC Codes	Number of Fatalities		Event
	Prior to standard 1984-1999	Subsequent to standard 2000-2006	
1629: Heavy Construction, Nec	1		Inhaled MC vapors
1721: Painting and Paper Hanging	1		Exposed to MC in a confined space
1731: Electrical Work	1		Asphyxiated due to MC paint stripper fume
1752: Floor Laying and Floor Work, Nec	2		Exposed to MC vapors
1793: Glass and Glazing Work	0	1	Inhaled MC vapors
1799: Special Trade Contractors, Nec	0	5	Exposed to MC fumes
2851: Paints and Allied Products	1		Inhaled MC vapors
2869: Industrial Organic Chemicals, Nec	1		Died of burns from reactor explosion
2891: Adhesives and Sealants	1		Died from exposure to MC vapors
2899: Chemical Preparations, Nec	1		Exposed to MC in a confined space
3479: Metal Coating and Allied Services	1		Inhaled MC vapors
3625: Relays and Industrial Controls	1		Inhaled MC in a confined space
3724 Aircraft Engines and Engine Parts	1		Inhaled MC vapors.
3732: Boat Building and Repairing	0	1	Inhaled MC vapors from carpet glue
3764: Space Propulsion Units	1		Died from chemical explosion containing MC
4119: Local Passenger Transportation, Nec	1		Exposed to MC in a confined space
4212: Local Trucking Without Storage	1		Inhaled MC in tank
4213: Trucking, Except Local	1		Poisoned by MC in tanker compartment
4953: Refuse Systems	2		Exposed to MC in a confined space
5085: Industrial Supplies	1		Killed while cleaning tank with paint remover containing MC
7349: Building Maintenance Services, Nec	2		Asphyxiated by MC
7641: Reupholstery and Furniture Repair	5	2	Inhaled toxic solvent MC vapors
7699: Repair Services, Nec	1		Inhaled MC vapors
9223: Correctional Institutions	1		Died of MC overexposure
Total	28	9	

3.2 Compliance with the Standard

Since 2000, OSHA has recorded 7,220 total violations cited during 1,046 inspections in almost 300 different industries.[27] The top 50 industries accounted for 66 percent of all firms cited and the top 100 accounted for 82 percent. Exhibit 3-4 shows the cumulative distribution of violations across these different industries.

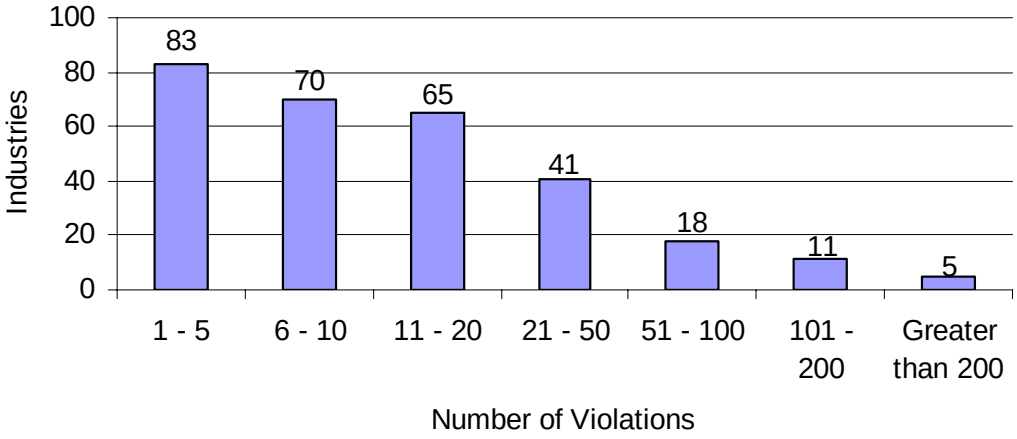
Exhibit 3-4
Cumulative Share of Violations by Number of Industries, 2000-2004



Source: ICF analysis of data from IMIS Database.

Most firms cited for MC-related violations did not commonly violate the standard. Of the 297 industries cited for MC-violations in the 2000-2004 period, 153 were cited for 10 or fewer violations. Exhibit 3-5 reports on the number of firms cited by OSHA for multiple violations of the MC Standard.

Exhibit 3-5
Industries by Number of Violations, 2000-2004

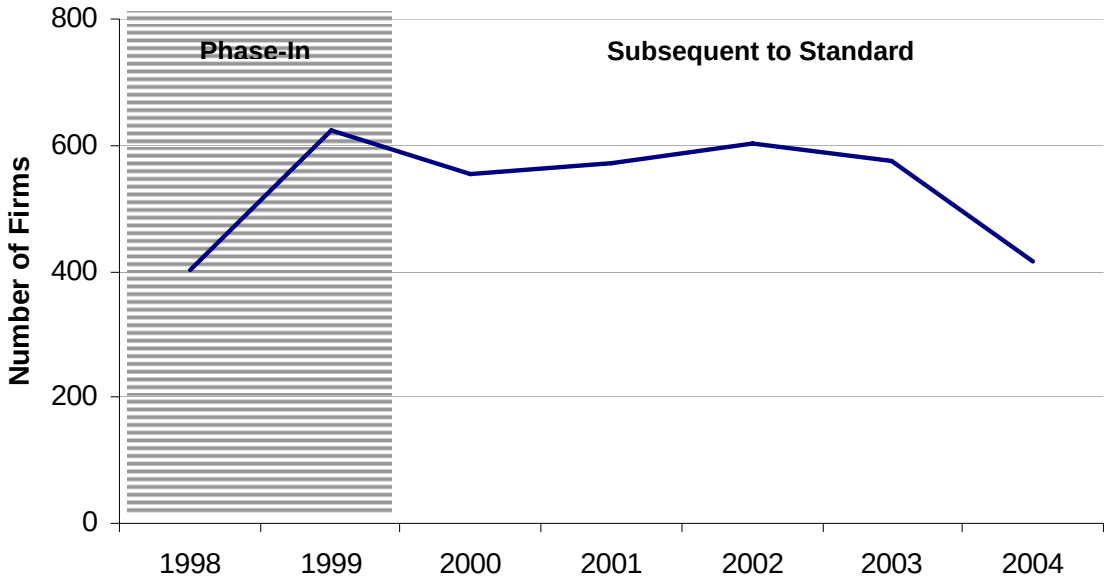


Source: ICF analysis of data from IMIS Database.

[27] For the purposes of this analysis, "industry" refers to a four-digit SIC code (e.g., 9223: Correctional Institutions) and "major group" refers to the two-digit SIC code (e.g., 28: Chemicals and Allied Products). Two-digit SIC codes are compiled into "divisions" (e.g., SICs 20 through 39 are considered part of "Division D: Manufacturing").

Exhibit 3-6 portrays the number of firms cited for violations, by year, since the standard became effective in 2000. The number of firms cited increased in 1998 as the Standard began to take effect but has since stabilized. Given that data for 2004 may not be complete, it does not appear that compliance has improved.

Exhibit 3-6
Number of Firms with Violations (1998 – 2004)



Source: ICF analysis of data from IMIS database.

The *Reupholstery and Furniture Repair* industry (SIC 7641) received the most violations, accounting for 5 percent of the total. This single industry was cited for over 350 violations from 2000 to 2004. The industry that received the second-most violations of the MC Standard was *Top, Body, and Upholstery Repair Shops and Paint Shops* (SIC 7532) with 4.6 percent. *Plastics Products, Not Elsewhere Classified* (SIC 3089) accounted for 3.9 percent of all violations, *Signs and Advertising Specialties* (SIC 3993) accounted for 3.3 percent and *Commercial Printing, Lithographic* (SIC 2752) accounted for 3 percent. No other industry accrued more than 3 percent of total violations between 2000 and 2004.

The 50 industries that accounted for the most violations from 2000 to 2004, ordered by number of violations, are reported in Exhibit 3-7.

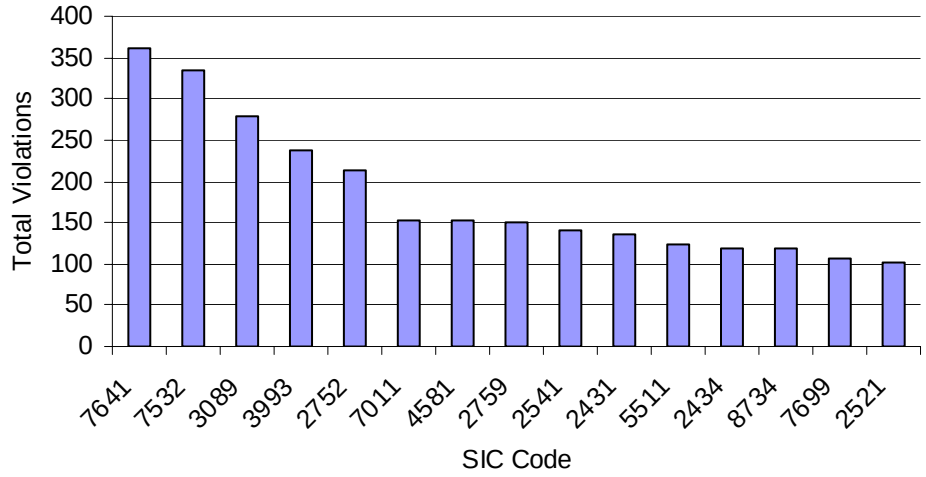
Exhibit 3-7
Violations for Top 50 Industries, 2000-2004

SIC Code	SIC Title	Number of Violations	Percent Share	Cumulative Total
7641	Reupholstery and Furniture Repair	361	5.0%	5.0%
7532	Top, Body, and Upholstery Repair Shops and Paint Shops	335	4.6%	9.6%
3089	Plastics Products, NEC (plastics sausage casings)	280	3.9%	13.5%
3993	Signs and Advertising Specialties (screen printing purchased advertising specialties)	238	3.3%	16.8%
2752	Commercial Printing, Lithographic (except quick printing)	214	3.0%	19.8%
7011	Hotels and Motels (hotels, except casino hotels, and motels)	153	2.1%	21.9%
4581	Airports, Flying Fields, and Airport Terminal Services (private air traffic control)	152	2.1%	24.0%
2759	Commercial Printing, NEC (flexographic printing)	150	2.1%	26.1%
2541	Wood Office and Store Fixtures, Partitions, Shelving, and Lockers (counter tops)	141	2.0%	28.0%
2431	Millwork (wood windows and doors)	136	1.9%	29.9%
5511	Motor Vehicle Dealers (New and Used)	123	1.7%	31.6%
2434	Wood Kitchen Cabinets	120	1.7%	33.3%
8734	Testing Laboratories (except veterinary testing laboratories)	119	1.6%	34.9%
7699	Repair Shops and Related Services, NEC (farriers)	107	1.5%	36.4%
2521	Wood Office Furniture	103	1.4%	37.8%
3086	Plastics Foam Products (polystyrene foam products)	102	1.4%	39.3%
3471	Electroplating, Plating, Polishing, Anodizing, and Coloring	99	1.4%	40.6%
2511	Wood Household Furniture, Except Upholstered (except wood box spring frames)	98	1.4%	42.0%
3714	Motor Vehicle Parts and Accessories (dump truck lifting mechanisms and fifth wheels)	81	1.1%	43.1%
2396	Automotive Trimmings, Apparel Findings, and Related Products (textile products except automotive and apparel trimmings and findings, printing or embossing on apparel, and contractors)	80	1.1%	44.2%
2261	Finishers of Broadwoven Fabrics of Cotton	79	1.1%	45.3%
3999	Manufacturing Industries, NEC (fur dressing and finishing)	79	1.1%	46.4%
2515	Mattresses, Foundations, and Convertible Beds (convertible beds)	76	1.1%	47.5%
2542	Office and Store Fixtures, Partitions, Shelving, and Lockers, Except Wood (lunchroom tables and chairs)	76	1.1%	48.5%
3599	Industrial and Commercial Machinery and Equipment, NEC (machine shops)	75	1.0%	49.5%
2499	Wood Products, NEC (wood containers, such as noncoopered vats and reed or straw baskets)	73	1.0%	50.6%
3732	Boat Building and Repairing (boat building)	73	1.0%	51.6%
3442	Metal Doors, Sash, Frames, Molding, and Trim	72	1.0%	52.6%
2821	Plastics Materials, Synthetic and Resins, and Nonvulcanizable Elastomers	63	0.9%	53.4%
3728	Aircraft Parts and Auxiliary Equipment, NEC (fluid power aircraft subassemblies)	62	0.9%	54.3%
3499	Fabricated Metal Products, NEC (powder metallurgy)	60	0.8%	55.1%
1799	Special Trade Contractors, NEC (indoor swimming pool construction contractors)	58	0.8%	55.9%
3443	Fabricated Plate Work (Boiler Shops) (fabricated plate work and metal weldments)	55	0.8%	56.7%
3444	Sheet Metal Work (stamped metal skylights)	55	0.8%	57.5%
1721	Painting and Paper Hanging (traffic lane painting)	50	0.7%	58.1%
7389	Business Services, NEC (tobacco sheeting service)	49	0.7%	58.8%
7539	Automotive Repair Shops, NEC (except automotive air-conditioning repair)	43	0.6%	59.4%
3281	Cut Stone and Stone Products	42	0.6%	60.0%
3585	Air-Conditioning and Warm Air Heating Equipment and Commercial and Industrial Refrigeration Equipment (except motor vehicle air-conditioning)	42	0.6%	60.6%
7538	General Automotive Repair Shops	40	0.6%	61.1%
2893	Printing Ink	39	0.5%	61.7%
3339	Primary Smelting and Refining of Nonferrous Metals, Except Copper and Aluminum	38	0.5%	62.2%
4953	Refuse Systems (hazardous waste treatment and disposal)	37	0.5%	62.7%
2732	Book Printing	36	0.5%	63.2%
3441	Fabricated Structural Metal	35	0.5%	63.7%
6513	Operators of Apartment Buildings	35	0.5%	64.2%
2891	Adhesives and Sealants	34	0.5%	64.7%
3088	Plastics Plumbing Fixtures	34	0.5%	65.1%
1752	Floor Laying and Other Floor Work, NEC	33	0.5%	65.6%
3354	Aluminum Extruded Products	32	0.4%	66.0%
TOTAL		***4767***	***66.0%***	

Source: ICF Analysis of data from IMIS Database.

Exhibit 3-8 identifies the 15 industries that accounted for the firms receiving the most violations. This exhibit reports that *Reupholstery and Furniture Repair* (SIC 7641) and *Top, Body, and Upholstery Repair Shops and Paint Shops* (SIC 7532) were the two industries that received the most violations.

Exhibit 3-8
Top 15 Industries by Number of Violations (2000-2004)



See Exhibit 3-6 for further description of these SIC Codes

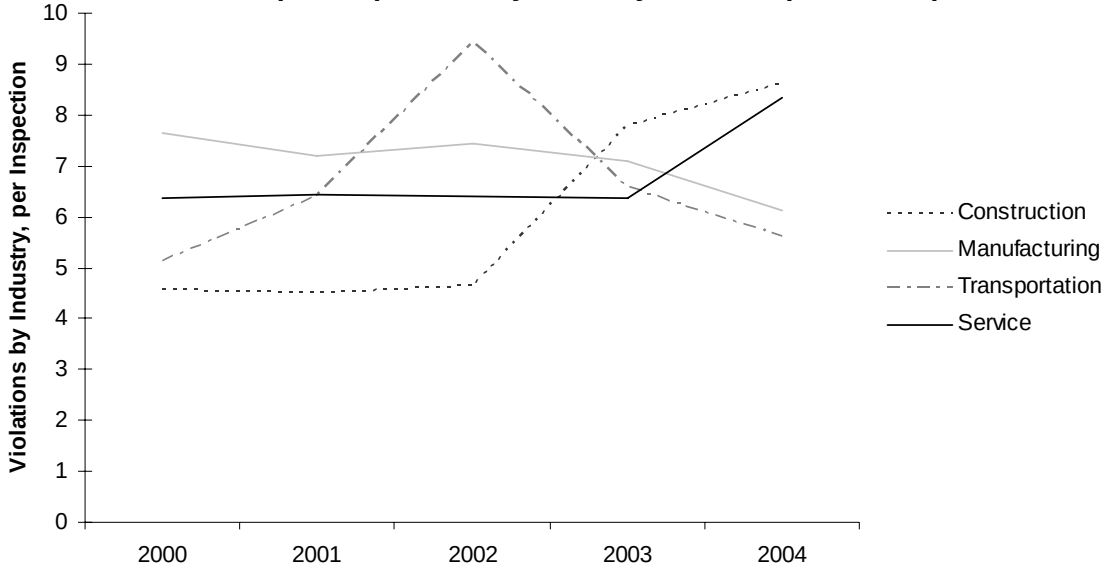
Source: ICF analysis of data from IMIS database.

More generally, manufacturing firms accounted for 63 percent of all violations, with the "Furniture and Fixtures" industry group (SIC Major Group 25) accounting for 8 percent of violations by itself, and the "Rubber and Miscellaneous Plastics Products" industry group (SIC Major Group 30) accounting for almost 7 percent.

Exhibit 3-9 shows the relative change in compliance over time for the four SIC "divisions" that received the most violations. These four divisions accounted for 93 percent of all firms cited for violations of the MC Standard. The rate of cited firms per inspection generally posted a modest increase in the Manufacturing, Services and Transportation divisions, although there were some substantial year-to-year fluctuations. The rate of cited firms per inspection in the Construction division fluctuated more substantially throughout the period and reported a 47 percent gain from 2000 to 2004.[28] Again, the data do not suggest that compliance with the MC Standard has improved.

[28] The spike in 2000 can be traced to three specific industries. Painting and Paper Hanging (traffic lane painting) (SIC 1721), Floor Laying and Other Floor Work, NEC (SIC 1752) and Glass and Glazing Work (SIC 1793) all received 72 percent of their total violations in 2000. Yet, only four of the 10 total inspections of these industries took place in 2000. Two inspections were due to referrals (both in SIC 1721), one occurred after an accident (SIC 1793) and the other inspection was due to a complaint (SIC 1752). Additionally, one of the four MC-related fatalities between 1998 and 2003 occurred in SIC 1793 in 2000. The two inspections of SIC 1721 were the first since the standard became effective. In 2001 and 2002, OSHA performed three additional referral inspections in SIC 1721.

Exhibit 3-9
Violations per Inspection, by Industry Division (2000-2004)[29]



Source: ICF analysis of data from IMIS Database.

3.3 Compliance with Specific Rule Provisions

The analysis also examined OSHA data on the specific subsections of the MC Standard being violated. The most-violated subsection, Section 1052(d)(2)(i), requires employers to perform initial monitoring in order to determine employee exposure to MC. The second most-violated subsection requires all employers to notify employees and potential employees of the dangers of working with MC and to properly train employees that use MC [29 CFR § 1910.1052 (l)(1)]. Employers also were commonly cited for not providing protective clothing and equipment for employees who work with MC [29 CFR § 1910.1052 (h)(1)].

Approximately 70 percent of all the MC-related violations referred to only ten subsections and approximately 89 percent of all violations were cited to 20 subsections. Exhibit 3-10 identifies the ten most-cited subsections of the Standard, and Exhibit 3-11 identifies the ten subsections with the highest associated average penalty amounts.

[29] "Transportation" division includes Communications, Electric, Gas, and Sanitary Services (SIC Division E)

Exhibit 3-10
Top 10 Provisions Cited in Violations by Standard Subsection (2000 – 2004)

Standard Subsection	Number of Violations	Percent of Total
1910.1052 (d)(2)(i): Initial determination. Each employer whose employees are exposed to MC shall perform initial exposure monitoring to determine each affected employee's exposure, except under the following conditions: w*here objective data demonstrate that MC cannot be released in the workplace in airborne concentrations at or above the action level or above the STEL. The objective data shall represent the highest MC exposures likely to occur under reasonably foreseeable conditions of processing, use, or handling. The employer shall document the objective data exemption as specified in paragraph (m) of this section.*	486	15.8%
1910.1052 (l)(1): The employer shall provide information and training for each affected employee prior to or at the time of initial assignment to a job involving potential exposure to MC.	426	13.8%
1910.1052 (h)(1): Where needed to prevent MC-induced skin or eye irritation, the employer shall provide clean protective clothing and equipment which is resistant to MC, at no cost to the employee, and shall ensure that each affected employee uses it. Eye and face protection shall meet the requirements of 29 CFR 1910.133 or 29 CFR 1915.153, as applicable.	219	7.1%
1910.1052 (l)(3)(i): The employer shall inform each affected employee of the requirements of this section and information available in its appendices, as well as how to access or obtain a copy of it in the workplace;	207	6.7%
1910.1052 (d)(1)(i): Where MC is present in the workplace, the employer shall determine each employee's exposure by either: *taking a personal breathing zone air sample of each employee's exposure or taking personal breathing zone air samples that are representative of each employee's exposure.*	204	6.6%
1910.1052 (i)(2): If it is reasonably foreseeable that an employee's eyes may contact solutions containing 0.1 percent or greater MC (for example through splashes, spills or improper work practices), the employer shall provide appropriate eyewash facilities within the immediate work area for emergency use, and shall ensure that affected employees use those facilities when necessary.	193	6.3%
1910.1052 (f)(1): Engineering and work practice controls. The employer shall institute and maintain the effectiveness of engineering controls and work practices to reduce employee exposure to or below the PELs except to the extent that the employer can demonstrate that such controls are not feasible. Wherever the feasible engineering controls and work practices which can be instituted are not sufficient to reduce employee exposure to or below the 8-TWA PEL or STEL, the employer shall use them to reduce employee exposure to the lowest levels achievable by these controls and shall supplement them by the use of respiratory protection that complies with the requirements of paragraph (g) of this section.	113	3.7%
1910.1052 (k): Hazard communication. The employer shall communicate the following hazards associated with MC on labels and in material safety data sheets in accordance with the requirements of the Hazard Communication Standard, 29 CFR 1910.1200, 29 CFR 1915.1200, or 29 CFR 1926.59, as appropriate: cancer, cardiac effects (including elevation of carboxyhemoglobin), central nervous system effects, liver effects, and skin and eye irritation.	109	3.5%
1910.1052 (j)(1)(i): Affected employees. The employer shall make medical surveillance available for employees who are or may be exposed to MC as follows*: at or above the action level on 30 or more days per year, or above the 8-hour TWA PEL or the STEL on 10 or more days per year*;	103	3.3%
1910.1052 (e)(1): The employer shall establish a regulated area wherever an employee's exposure to airborne concentrations of MC exceeds or can reasonably be expected to exceed either the 8-hour TWA PEL or the STEL.	99	3.2%

Source: ICF Analysis of data from IMIS Database.

Exhibit 3-11
Top 10 Provisions Resulting in Highest Penalties (1998 – 2003)

Standard Subsection	Average Penalty
1910.1052 (l)(1): The employer shall provide information and training for each affected employee prior to or at the time of initial assignment to a job involving potential exposure to MC.	$2,700
1910.1052 (g)(1): General. For employees who use respirators required by this section, the employer must provide respirators that comply with the requirements of this paragraph.	$2,500
1910.1052 (g)(3): Respirator selection. The employer must select appropriate atmosphere-supplying respirators from Table 2 of this section. *(table of requirements for respiratory protection included)*[30]	$2,250
1910.1052 (d)(4)(i): The employer shall perform exposure monitoring when a change in workplace conditions indicates that employee exposure may have increased. Examples of situations that may require additional monitoring include changes in production, process, control equipment, or work practices, or a leak, rupture, or other breakdown.	$1,978
1910.1052 (g)(1)(v): General. For employees who use respirators required by this section, the employer must provide respirators that comply with the requirements of this paragraph. Respirators must be used during: emergencies.	$1,500
1910.1052 (h)(3): The employer shall be responsible for the safe disposal of such clothing and equipment. (i.e., protective clothing and equipment required by this paragraph)	$1,500
1910.1052 (j)(8): Information provided to the physician or other licensed health care professional. The employer shall provide [specified] information to a physician or other licensed health care professional who is involved in the diagnosis of MC-induced health effects.	$1,500
1910.1052 (c)(1): Eight-hour time-weighted average (TWA) PEL. The employer shall ensure that no employee is exposed to an airborne concentration of MC in excess of twenty-five parts of MC per million parts of air (25 ppm) as an 8-hour TWA.	$1,210
1910.1052 (d)(3): Periodic monitoring. Where the initial determination shows employee exposures at or above the action level or above the STEL, the employer shall establish an exposure monitoring program for periodic monitoring of employee exposure to MC in accordance with Table 1. (table of initial determination exposure scenarios)	$868
1910.1052 (g)(1)(ii): General. For employees who use respirators required by this section, the employer must provide respirators that comply with the requirements of this paragraph. Respirators must be used during: Periods necessary to install or implement feasible engineering and work-practice controls.	$833

Source: ICF Analysis of data from IMIS Database.

4. Health Risk and Benefits

[30] OSHA amended the respirator selection requirements in its 2006 final rule on assigned protection factors for respiratory protection. *See* 71 Fed. Reg. 50122, 50190 (Aug. 24, 2006). The standard now requires that employers must "[s]elect, and provide to employees, the appropriate atmosphere-supplying respirator specified in paragraph (d)(3)(i)(A) of 29 CFR § 1910.134," that "employers must not select or use half masks of any type because MC may cause eye irritation or damage," and that employers must "[f]or emergency escape, provide employees with one of the following respirator options: A self-contained breathing apparatus operated in the continuous-flow or pressure-demand mode; or a gas mask with an organic vapor canister." 29 C.F.R. § **1910.1052 (g)(3).**

4.1 Health Basis of Current Methylene Chloride Standard

This section is a summary of the health basis for the current MC Standard and the health benefits of the rule. MC's routes of exposure, metabolism, carcinogenicity, and other health effects data are summarized. The physiologically-based pharmacokinetic (PBPK) modeling used to develop the MC Standard also is summarized. A more detailed description of the health basis of the MC Standard and of the PBPK modeling is found in Sections V and VI of the preamble to the rule.[31]

Routes of Exposure

Inhalation is the most significant route of exposure for MC in occupational settings.[32] The quantity of MC taken into the body through inhalation depends on the concentration of MC in inspired air, the breathing rate, the duration of exposure to MC, and the solubility of MC in blood and tissues. Because MC is highly volatile, inhalation exposures to MC can be quite high, especially in poorly ventilated spaces.

Dermal absorption of MC is a slow process relative to inhalation. Nevertheless, given sufficient exposure and time, dermal absorption can conceivably exceed inhalation exposure (e.g., exposure to liquid MC without protective clothing), and even exceed that experienced by workers exposed to MC through inhalation of 25 ppm for 8 hours.[33] For this reason, the MC Standard requires that employers provide personal protective clothing and equipment appropriate to the hazard. For example, if an employee will be at risk of hand contact with liquid MC, impermeable gloves must be provided.

Metabolism

Once MC is absorbed into the body, it is widely distributed in the body fluids and in various tissues. The uptake and elimination of MC has been well described in human and animal studies. The carcinogenic mechanism of action for MC has not been clearly established. However, new studies submitted during the final rulemaking process increased the level of concern regarding the carcinogenicity of MC because these studies made it clearer that MC is likely to act by a genotoxic (damaging to DNA) mechanism; animal studies are most relevant to humans when clear genotoxic agents are involved.[34] Therefore, current evidence indicates that MC is a genotoxic carcinogen. Genotoxic carcinogens typically are reactive compounds or metabolized to reactive compounds. MC is unreactive in the body until it is metabolized. As will be explained, many investigators believe that one or more of the metabolites of MC, and not MC itself, is the ultimate carcinogen.

[31] OSHA, 1997 (January 10), Occupational Exposure to Methylene Chloride; Final Rule, *Federal Register*, Vol. 62, No. 7, page 1491-1543.
[32] Ibid.
[33] Ibid.
[34] Ibid.

Thus, the metabolism of MC in test animals and humans is a central component of the OSHA MC risk assessment and Standard. As seen in Figure 4-1, OSHA considered MC to be metabolized via two basic pathways in mammals:

1. The mixed function oxidase (MFO) system and
2. The glutathione *S*-transferases (GST) pathway.[35]

The MFO pathway (pathway 1 in Figure 4-1) produces formyl chloride, which in turn decomposes to give chloride ion and the toxic compound carbon monoxide (CO), which leads to MC's carboxyhemoglobinemic effects. It has been postulated that if the MFO pathway contributes to the carcinogenicity of MC, it is through the production of formyl chloride, which is a reactive compound. It has also been postulated that the increased CO levels from metabolism of MC levels contributes to MC's central nervous system effects.

The GST pathway (pathway 2 in Figure 4-1) metabolizes MC to formaldehyde and chloride ions. Formaldehyde, a compound known to react with protein, RNA, and DNA, is further metabolized to carbon dioxide in mammalian systems. Some evidence at the time indicated that another reactive metabolite is generated. OSHA concluded in the final rule that MC carcinogenicity is most probably caused primarily by reactive metabolites formed via the GST pathway and that this information can be used to estimate risk in humans. This approach represented a case-specific departure from the default assumption that the administered dose of the parent compound is the relevant metric for exposure.

An important concept of the PBPK modeling used for MC is that animal data indicated that the MFO pathway has a low capacity for metabolizing MC and becomes "saturated" (basically becomes overwhelmed or used up) at relatively low concentrations, while the GST pathway has a large capacity and remains linear throughout the exposure levels examined. Because these pathways are so important to the PBPK modeling and hence risk estimate for MC, as part of the rulemaking process, OSHA solicited and received a significant amount of data on them during the rulemaking period (see Section 1.3, Regulatory History, ***supra***). OSHA and most commenters agreed that these data showed a quantitative (and quantifiable) difference between mice and humans with regard to the metabolism of MC, but not an infinite, qualitative difference; that is, there was substantial evidence that humans and mice metabolize MC similarly, only at different rates.[36]

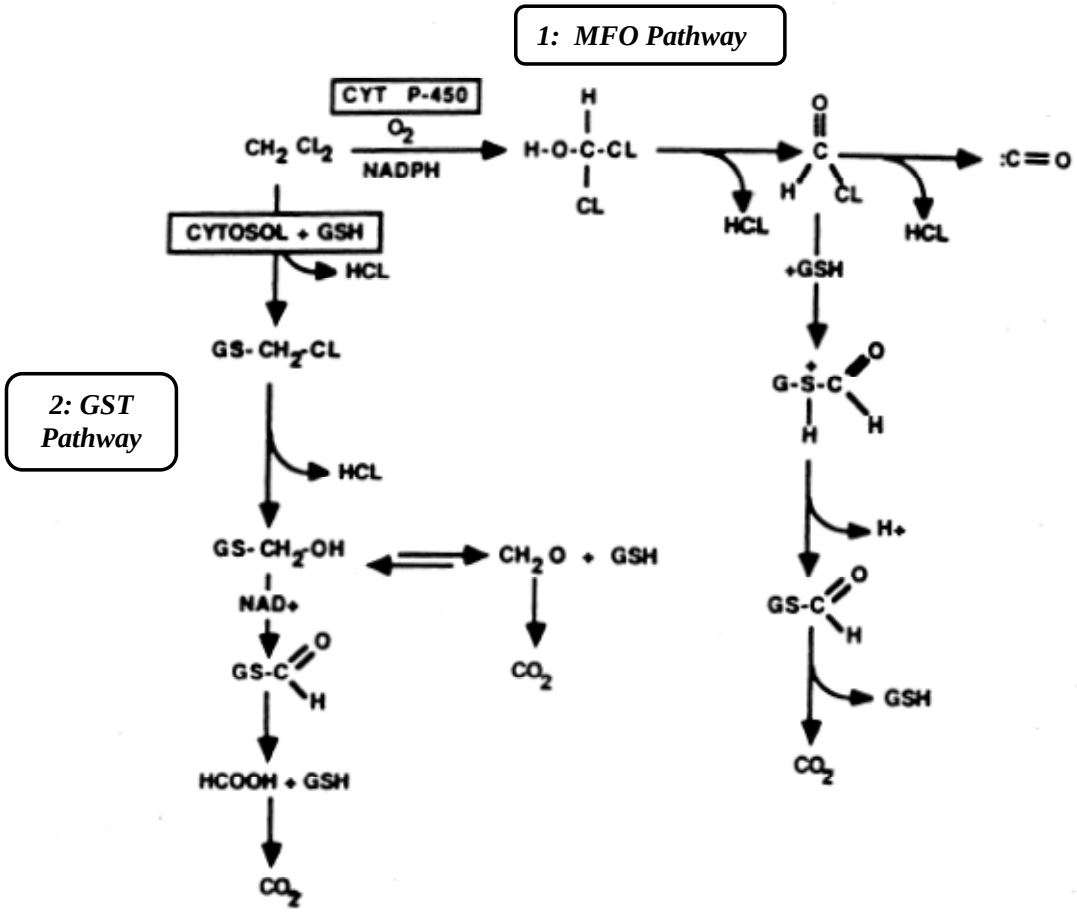
Carcinogenicity

OSHA determined for the final rulemaking that MC is a potential occupational carcinogen.[37] OSHA concluded in its final rulemaking that "MC is a multi-species, multi-site carcinogen in various rodent species, and is likely to be so in humans, and that it most probably acts via one or more genotoxic metabolite(s)."[38] OSHA found that the "evidence for this conclusion is quite strong: there exist several positive bioassays with

[35] Ibid.
[36] Ibid
[37] Ibid.
[38] Ibid

low background incidence and dose-related increases; there is an unusually large amount of mechanistic information; and there are several positive epidemiological studies and no negative epidemiological studies of sufficient power to rule out the animal-based potency estimates."[39] While the evidence for the carcinogenicity of MC was derived from mutagenicity studies, animal bioassays, and human epidemiological studies, OSHA's determination of carcinogenicity was based primarily on the positive findings of chronic inhalation bioassays in rodents.

Figure 4-1
Proposed Metabolism of Methylene Chloride[a]



[a]Modified from 62 FR 1497, January 10, 1997.

The differing results in the mutagenicity studies suggested that the exact mechanism of MC mutagenicity, even in bacterial cells, had not been determined with certainty. However, OSHA concluded that the evidence that MC is genotoxic is compelling, which is important because animal tests are most relevant to humans when clear genotoxic agents are involved.

[39] Ibid

MC was described in the final rulemaking preamble as carcinogenic to mice of both sexes, producing lung and liver neoplasms. In rats, MC produced dose-related increases in mammary tumors and increases in the number of tumors per tumor-bearing rat. These National Toxicology Program (NTP) studies showed the clearest evidence of a carcinogenic effect of MC. OSHA used these studies as the basis of its risk assessment for the following reasons: (1) the studies were well conducted and underwent extensive peer review; (2) the inhalation route of exposure was used, which is the most appropriate route for extrapolation to occupational exposures; and (3) dose-related, statistically significant increases in tumor incidence were observed in both sexes in mice and in female rats. OSHA concluded from these studies that MC causes cancer in two species of test animals by the inhalation route, and that a clear dose-response has been demonstrated.

The evidence in rodents was supported by epidemiologic findings from workers producing cellulose triacetate fiber and a case-control study of individuals with astrocytic brain cancer. The study of fiber production workers suggested an association between liver and biliary cancer and long term (greater than 10 years) exposure to MC. The case-control study indicated an association between risk of astrocytic brain cancer and occupational exposure to MC. Considered as a whole, however, the available epidemiologic evidence did not demonstrate a strong, statistically significant cancer risk associated with occupational exposures to MC. Nevertheless, the data were considered suggestive of an association between MC exposure and cancer risk. In addition, the non-positive epidemiological studies summarized were not of sufficient power to rule out the positive results from the animal studies.

Other Health Effects

MC acts on the central nervous system (CNS) as a CNS depressant. CNS depression has been described in humans exposed to MC concentrations as low as 175 ppm (8-hour TWA). This depression in CNS activity was manifested as increased tiredness, decreased alertness and decreased vigilance. These effects could compromise worker safety by leading to an increased likelihood of accidents following MC exposure. OSHA concluded that there were clearly sufficient data to determine that a 125 ppm 15-minute STEL was needed to reduce the significant risk of material impairment to the CNS.

OSHA also examined and expressed concern for the potential cardiac, hepatic, and reproductive toxicity from MC and metabolites, in particular from CO following the metabolism of MC via the MFO pathway (pathway 1 in Figure 4-1). However, the Agency decided to set the exposure limits based on cancer and CNS effects and to continue to gather information and revisit these issues if warranted.

Dose Extrapolation and PBPK Modeling

One of the central issues in the MC rulemaking was estimating carcinogenic and other risks for purposes of standard-setting. Exposure levels used for analysis (e.g., the doses given to test animals) typically are much higher than the concentrations to which humans

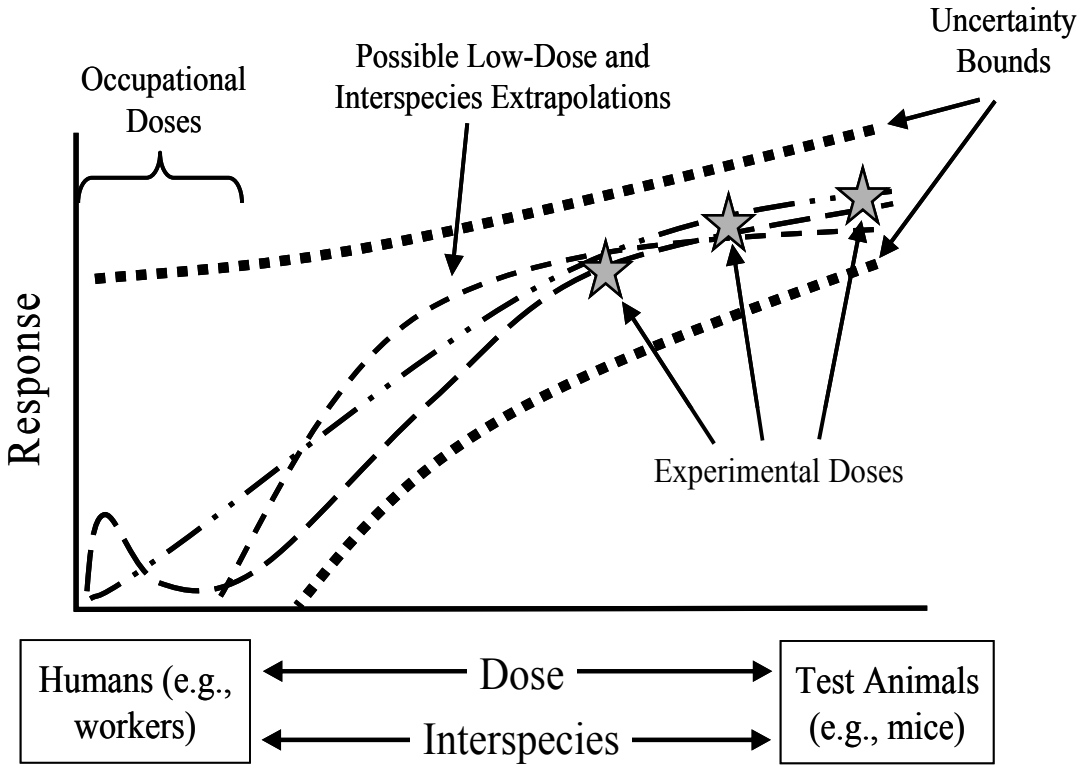
typically are exposed. These higher levels usually are necessary for statistical power and, furthermore, typically are obtained from test animals or unique human populations by extrapolating the animal and other data to lower exposure levels and to different species or populations. (Additional factors, such as the frequency and length of exposure, also must be considered.) Also, as described in more detail in the MC preamble[40] and elsewhere,[41] several approaches have been used to conduct these extrapolations and estimate cancer risk from exposure to toxic agents. A standard approach uses mathematical models to describe the relationship between dose (e.g., airborne concentration or target tissue dose) and response (cancer). Generally, mathematical functions are fit to the data points observed at different exposure levels and these functions are used to estimate the risk that would occur at exposure levels below those observed. The shapes of these curves vary, ranging from linear extrapolations from the observed points through the origin (zero exposure and zero risk) to curves which may deviate far from linearity at the very highest or lowest doses. Figure 4-2 provides a simple illustration of these concepts.

The most commonly used technique for low-dose extrapolation is the "multistage model" (not to be confused with PBPK modeling) of carcinogenesis. This model, which is used by OSHA and most other regulatory agencies, is based on the biological assumption that cancer is induced by carcinogens through a series of independent stages. The multistage model is generally considered to be a conservative model because it is approximately linear at low doses and because it assumes no threshold for carcinogenesis, although there are other plausible models of carcinogenesis which are more conservative at low doses. ("No threshold" means that any incremental amount of exposure to a carcinogen is associated with some amount of increased risk. "Approximately linear at low doses" means that one unit of change in dose will result in one unit of change in risk at low doses.)

Pharmacokinetic models in general characterize the routes of exposure, absorption, distribution, metabolism, and elimination of toxicants in organisms. These tools help relate the internal concentration of a toxicant at its target sites (e.g., the liver) with the administered dose. As described in more detail elsewhere,[42] PBPK modeling involves the development of compartments that represent groupings of tissues with physiologically relevant volumes, blood flows, and pathways for metabolism. Figure 4-3 provides a simple schematic of the PBPK model used for MC. Each compartment and arrow represents a series of algorithms designed to estimate the fate of the toxicant and its metabolites.

[40] Ibid.
[41] For example, see Reddy, M., Yang, R.S., Andersen, M.E., and Clewell, III, H.J., 2005, Physiologically Based Pharmacokinetic Modeling: Science and Applications, John Wiley & Sons, Inc.
[42] Ibid.

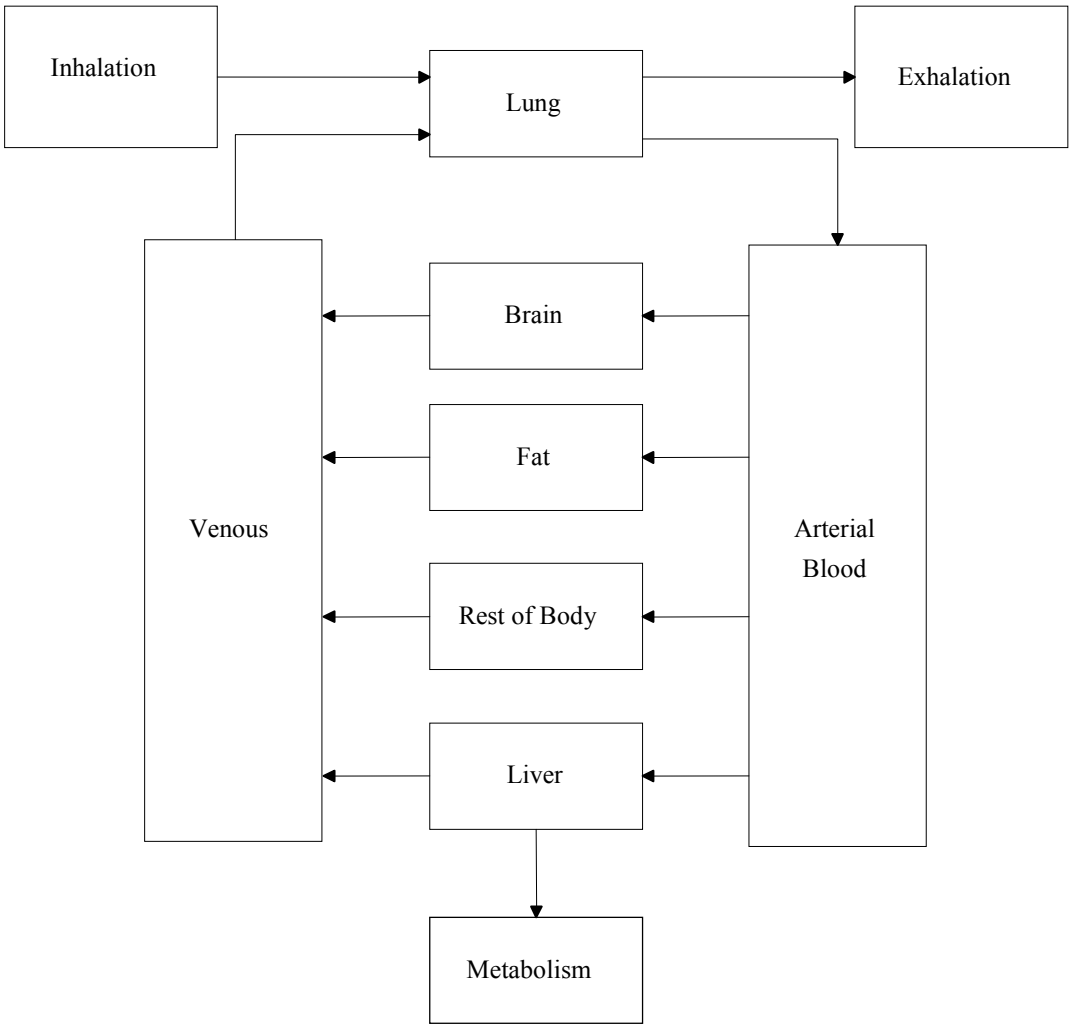
Figure 4-2
Uncertainties of MC Dose Extrapolation



[a]Modified from Connolly, R.B., 2005, "Biologically-motivated approaches to extrapolation from high to low doses and the advent of systems biology: The road to toxicological safety assessment," Center for Computational Systems Biology & Human Health Assessment, CIIT Centers for Health Research; presented to the EPA Board of Scientific Counselors Risk Assessment Workshop, National Academy of Sciences Auditorium, Washington, DC, February 2-3, 2005. Last accessed February 16, 2006 at http://epa.gov/osp/bosc/ra_work.htm.

For the MC Standard, OSHA reviewed the various models and decided to conduct a quantitative risk assessment based on the highest-quality animal tumor data available and constructing a state-of-the-art pharmacokinetic (PBPK) model that incorporated rodent and human metabolic information; this resulted in the PEL for MC of 25 ppm.

Figure 4-3
Simplified MC PBPK Model Schematic[a]



[a]Modified from Boyes, WK, Eklund, C, and Simmons, JE, 2001, "Use of Pharmacokinetic Models as an Alternative to Haber's-based Adjustments," presented to the Research Triangle Chapter of the Society for Risk Analysis; last accessed on February 14, 2006 at http://www.rtc-sra.org/Seminars/.

The specific use of PBPK modeling within the context of the MC rule – specifically health risks and benefits – is described in more detail below.

4.2 Health Risks and Benefits of Current Standard

Given the strong evidence for carcinogenicity and the large database on the metabolic pathways and mode of action of MC, OSHA decided to use a PBPK model to estimate risks rather than use a purely non-PBPK approach. OSHA analyzed numerous models from the literature and from submissions to the Agency and selected an approach developed by Harvey Clewell of ICF Kaiser International as the most comprehensive

approach available.[43] OSHA modified Dr. Clewell's model to accommodate a number of advances that had occurred prior to the rulemaking. These modifications also allowed incorporation of additional biochemical and physiological data that had been added to the rulemaking record.

The PBPK model used by OSHA contained the following types of parameters, as discussed more in the rulemaking:[44] body weight, breathing rate, cardiac output, blood flows to tissue compartments (as a fraction of the cardiac output), volumes of tissue compartments (as a fraction of body weight), partition coefficients, the metabolic parameters, and the ratio of the pathway-specific metabolic capacity between the major metabolic sites (lung and liver). Several aspects of this modeling are central to the accuracy and precision of the risk assessment used to develop the MC Standard and assess the risks and benefits. Briefly, these include:

- Selection of the model modifications (e.g., which tissue compartments does the model include? how are the compartments related mathematically? what parameters do they use, have the modifications been peer reviewed?);

- Selection of the parameter values (e.g., how relevant are the values? how recent are they? have they been peer reviewed?).

See the MC preamble for a detailed discussion of the specific modifications and values used.[45]

Based on the selected PBPK model, OSHA's final estimate of risk was 3.62 deaths per 1000 workers who are occupationally exposed to 25 ppm of MC for a working lifetime.[46] The estimated average risks at exposure levels prior to the MC rulemaking were estimated to be 7.6 deaths per 1000 workers to 126 deaths per 1000 workers; (the PEL for MC prior to the 1997 final rule was 500 ppm, but most exposures were believed to be lower than 500 ppm.) Furthermore, according the OSHA's Regulatory Impact Analysis for the 1997 MC final Standard, the Standard would save an average of 31 cancer deaths per year.[47]

In addition to cancer deaths, the Standard is estimated to prevent 3 deaths per year from MC's acute central nervous system and carboxyhemoglobinemic effects.[48] In addition, MC exposures above the level at which the final rule's STEL is set – 125 ppm – are also associated with acute CNS effects, such as dizziness, staggered gait, and diminished alertness, all effects that can lead to workplace accidents. OSHA estimates that as many as 30,000 to 54,000 workers will be protected by the final rule's STEL from experiencing CNS effects and episodes of carboxyhemoglobinemia every year. Moreover, exposure to

[43] OSHA, op. cit.
[44] Ibid.
[45] Ibid.
[46] OSHA, 1997 (January 10), Occupational Exposure to Methylene Chloride; Final Rule, *Federal Register*, Vol. 62, No. 7, page 1491-1543.
[47] Ibid.
[48] Ibid.

the liquid or vapor forms of MC can lead to eye, skin, and mucous membrane irritation, and these material impairments will also be averted by compliance with the final rule. Finally, contact of the skin with MC can lead to percutaneous absorption and systemic toxicity and thus lead to additional cases of cancer that have not been taken into account in the benefits assessment presented in the preamble to the final rule.

Together, the rule's provisions were designed to substantially reduce significant risk to occupational exposure to MC to the extent feasible. The final Standard was estimated to prevent an approximately 31 cancer deaths per year, 3 deaths per year from acute central nervous system (CNS) and carboxyhemoglobinemic effects, and will also reduce cardiovascular disease and material impairment of the CNS in as many as 30,000 to 54,000 workers every year.

4.3 New Health and Safety Data

Carcinogenicity

Since promulgation of the MC Standard, the International Agency for Research on Cancer (IARC) has classified MC in Group 2B (possibly carcinogenic to humans) based on sufficient evidence from studies in animals and limited evidence of carcinogenicity from studies in humans.[49] Furthermore, in 2000, the Agency for Toxic Substances and Disease Registry (ATSDR) published an updated toxicological profile for MC that includes post-1997 data.[50] Finally, the U.S. Environmental Protection Agency (EPA), which previously determined that MC is a probable human carcinogen based on sufficient evidence from studies in animals and inadequate evidence in humans, is examining new pharmacokinetic studies, published since the promulgation of the MC Standard, as part of its new qualitative assessment of the health effects from MC and new quantitative estimates of reference values for non-cancer and cancer health effects from MC.

Other Health Effects

Cardiovascular Effects. OSHA stated in the final rule that MC is metabolized to CO and CO_2 and causes cardiovascular stress. CO successfully competes with oxygen and blocks the oxygen binding site on hemoglobin, producing carboxyhemoglobin (COHb) and reducing delivery of oxygen to the tissues. This reduces the oxygen supply to the heart itself, which can result in myocardial infarction (heart attack). Although OSHA set the exposure limits based on cancer and CNS effects only, OSHA continues to be concerned about the potential CO effects from metabolism of MC and will continue to monitor the scientific literature on this topic.

Neurological Effects. ATSDR confirmed OSHA's conclusions with respect to: MC's neurobehavioral effects, including tiredness, decreased alertness, dizziness, intoxication,

[49] IARC, 2004, Overall Evaluations of Carcinogenicity to Humans, last accessed April 10, 2006 at http://monographs.iarc.fr/monoeval/crthgr02b.html.
[50] ATSDR. 2000. Toxicological Profile for Methylene Chloride. http://www.atsdr.cdc.gov/toxprofiles/tp14.pdf.

incoordination, headache, and paresthesia, as observed in MC exposed workers; ATDSR also confirmed that worker blood COHb was reported to be higher (5%) than the normal value (1%) as observed in human and some animal studies.[51] Finally, ATSDR also noted that MC has been shown to decrease visual and auditory functions in workers with MC in the range of 200-300 ppm. These effects could compromise worker safety by leading to an increased likelihood of accidents following MC exposure.

As a result of its findings, ATSDR calculated a new acute inhalation Minimal Risk Level (MRL) of 0.6 ppm in 2000.[52] The previous MRL was 3 ppm. This reduction was based on an acute study in humans that examined CNS effects. ATSDR also calculated a new acute oral MRL of 0.2 mg/kg/day, which was also based on neurological effects. This MRL supersedes the previous acute oral MRL of 0.5 mg/kg/day published in the 1998 draft for public comment version of the ATSDR profile.

Systemic Effects. ATSDR also confirmed OSHA reports that there is evidence of systemic effects including respiratory, gastrointestinal, and hematological effects based on limited studies from humans and animals.[53] A few reports of pulmonary congestion in humans were reported, although the exposure concentration was unknown. Nausea and vomiting have been noted in workers with acute inhalation exposure of MC, although again the concentration was unknown. Exposure to high amounts of MC vapor in the range of 500 ppm results in stress polycythemia, especially cigarette smokers, and increases red cell count, hemoglobin, and hematocrit in women.

As a result of its findings, ATSDR calculated a new chronic oral MRL of 0.06 mg/kg/day, which was based on liver effects in animals. This MRL supercedes the previous chronic oral MRL of 0.2 mg/kg/day published in the 1998 draft for public comment version of the ATSDR profile.

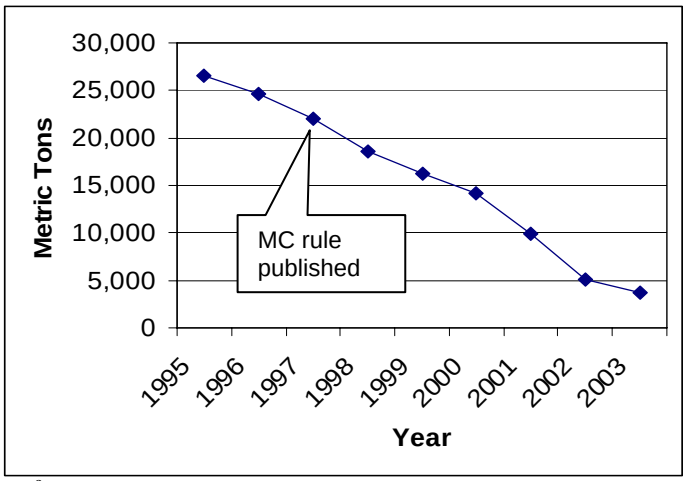
Reproductive Effects. ATSDR reported that some studies of humans occupationally or environmentally exposed to MC have observed associations between high levels of MC in blood and abortion in women and genital pain and decreased sperm count in men.[54] OSHA reported in the 1997 Standard that, since MC is metabolized to CO, there was concern for the adverse reproductive effects of CO as a metabolite of MC.[55] OSHA continues to be concerned about the potential for reproductive health effects of carbon monoxide as a result of MC metabolism and will continue to gather information about this topic.

[51] ATSDR, op. cit.
[52] Ibid.
[53] Ibid.
[54] Ibid.
[55] OSHA, op. cit.

Exposure

As described in Chapter 2, significant reductions in the production and use of MC have occurred since promulgation of the MC OSHA standard. Nevertheless, significant production and use still exist, and thus significant occupational exposure likely still exists. In contrast, however, total MC air releases in the U.S. were examined as a (very rough) surrogate for worker exposure trends (Figure 4-4). The data reveal a significant continual decline in reported MC releases and thus possibly MC exposure.

Figure 4-4. Total MC Air Releases Reported to EPA[a]



[a]EPA. 2006. TRI Explorer. Last accessed February 2, 2006 at http://www.epa.gov/triexplorer/.

To further examine this issue, some of the compliance data shown in Chapter 3 were reviewed. These data show that at least six fatalities that appear to be attributable to MC have occurred since the MC Standard became fully effective in 2000. In most of these cases, improper ventilation and/or lack of personal protective equipment (i.e. respirators) contributed to the fatality. The case reports do not generally provide specific information on exposure. However, one of the case reports discusses air sampling conducted by OSHA subsequent to a fatality in which workers at a facility performing wood stripping operations were exposed to concentrations of 46 ppm as an 8 hour time weighted average and to 159 ppm as a short term exposure at the time of his death. These levels are above the respective PEL of 25 ppm and STEL of 125 ppm.

In an article by Estill et al.,[56] ventilation systems reduced exposures below the 1997 PEL (geometric mean 5.6 ppm, 95% upper confidence limit 8.3 ppm) with local exhaust ventilation used at stripping tank and rinsing area (exhausted together 138 m^3/min). Additional controls used included adequate make-up air, adding paraffin wax to stripping solution, raising the level of stripping solution in tank, and discussing good work practices with employees. Thus, while exposures above the PEL and STEL do appear to be occurring – and likely would occur in the absence of the MC Standard – the Standard can be met using readily available controls.

4.4 Other Health-based Advances

Several new guidance documents, literature reviews, and other sources of information have emerged in recent years related in PBPK modeling and risk assessment in general, including:

[56] Estill CF, Watkins DS, Shulman SA, Kurimo RW, Kovein RJ. 2002. Engineering controls for furniture strippers to meet the OSHA methylene chloride PEL. AIHA J 63(3):326-33.

- Recent risk assessment workshops, such as a 2005 workshop by EPA's Board of Scientific Counselors;[57]

- EPA's new *Guidelines for Carcinogen Risk Assessment* (EPA, 2005b);[58]

- Recent textbooks, such as *Physiologically Based Pharmacokinetic Modeling: Science and Applications*[59] and *Recent Advances in Quantitative Methods in Cancer and Human Health Risk Assessment*;[60] and

- Recent reviews on scientific advances, such as "Toxicogenomics: the new frontier in risk analysis"[61] and "A consistent approach for the application of pharmacokinetic modeling in cancer and noncancer risk assessment".[62]

4.5 Summary and Discussion

When it promulgated the MC Standard in 1997, OSHA completed an assessment of the resulting health risks and benefits of the MC rule. This assessment included a critical examination and analysis of the available toxicity and exposure data. OSHA concluded that the Standard would prevent approximately 31 cancer deaths per year and 3 deaths per year from acute central nervous system (CNS) and carboxyhemoglobinemic effects. Furthermore, OSHA estimated that as many as 30,000 to 54,000 workers would be protected by the final rule's STEL from experiencing CNS effects and episodes of carboxyhemoglobinemia every year. For cancer risk, OSHA constructed and used a PBPK model.

For CNS and carboxyhemoglobinemic effects, concerns by NIOSH and others about effects below the 125 ppm STEL prompted OSHA to state during the rulemaking that it would carefully monitor and follow up on data to determine if this level eliminates significant risk. OSHA also expressed concern about potential cardiac, hepatic, and reproductive toxicity from MC, but due to lack of data decided to continue to gather information on these topics. More recent data have not alleviated OSHA's concerns and OSHA will continue to collect information on these topics.

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[57] EPA. 2005a (February). EPA Chemical Risk Assessment Principles and Practices. A workshop on February 2-3, 2005 in response to a white paper on "Risk Assessment Principles and Practices," recently issued by EPA's Office of the Science Advisor. Last accessed February 15, 2006 at http://epa.gov/osp/bosc/ra_work.htm.

[58] EPA. 2005b (March). Guidelines for Carcinogen Risk Assessment. Last accessed February 15, 2006 at http://cfpub.epa.gov/ncea/raf/recordisplay.cfm?deid=116283.

[59] Reddy, M., Yang, R.S., Andersen, M.E., and Clewell, III, H.J. 2005. Physiologically Based Pharmacokinetic Modeling: Science and Applications. John Wiley & Sons, Inc.

[60] Edler, L. and Kitsos, C. 2005 (May). Recent Advances in Quantitative Methods in Cancer and Human Health Risk Assessment. John Wiley & Sons, Inc.

[61] Simmons, P.T. and Portier, C.J. 2002 (June). Toxicogenomics: the new frontier in risk analysis. Carcinogenesis. Vol. 23, No. 6, 903-905.

[62] Clewell, III, H.J., Andersen, M.E., and Barton, H.A. 2002 (January). A consistent approach for the application of pharmacokinetic modeling in cancer and noncancer risk assessment. Environmental Health Perspectives. Vol. 110, No. 1. Last accessed February 16, 2006 at http://ehp.niehs.nih.gov/members/2002/110p85-93clewell/EHP110p85PDF.PDF.

5. Public Comments

A critical part of this lookback review involves the gathering and analysis of information from affected persons about their experience with the MC Standard and any material changes in circumstances since issuance of the MC Standard. On July 10, 2007, OSHA issued a Federal Register Notice that provided background information about this lookback review of the MC Standard, raised questions of special concern to the Agency regarding this lookback review, and requested public comments (72 FR 37501). The 90-day comment period ended on October 9, 2007. However, in response to a request from the public for additional time, OSHA reopened the comment period for an additional 60 days. OSHA did this to allow stakeholders time to provide more thorough comments on the lookback review. This reopened comment period ended March 10, 2008.

There are fourteen numbered entries on the docket for the MC lookback review; these entries can be found at www.regulations.gov, Docket Number OSHA-2007-0024. Of these fourteen entries, there are eight commenters. One commenter is from industry; one commenter is from labor; two commenters are from the Federal government; one commenter is from state government; one commenter is from academia; two commenters are private citizens. Entries from three of the commenters included extensive attachments and/or research studies. The following are summaries of the entries from these eight commenters and OSHA's responses.

1. A former worker at a Government Owned Contractor Operated (GOCO) facility, the U.S. Department of Energy (DOE) Pinellas Plant, stated in his comment that MC was used in processes associated with weapons component manufacturing and that MC was one of the main constituents of groundwater contamination (OSHA Docket Number: OSHA-2007-0024-0002). He commented: a) that the Standard should be amended to make it consistent with the Cadmium standard, which regulates previously exposed employees; and b) that the Standard should clarify whether responsibility for compliance belongs to DOE, which owns the facility, or to the management and operating contractors which employs the facility's workers. He also inquired about the time periods of OSHA's jurisdiction over GOCO facilities like the Pinellas plant.

OSHA Response: a) The Cadmium standard 29 C.F.R. § 1910.1027(l), requires medical surveillance for certain veteran employees who were exposed to Cadmium prior to the effective date of the standard. The MC Standard does not contain a similar requirement. *See* 29 C.F.R. § 1910.1052(j). However, the two standards have different purposes. *Compare* 62 Fed. Reg. 1494, 1589 (Jan. 10, 1997) (one of the main purposes of MC Standard's medical surveillance provisions is to "benefit workers with cardiovascular disease, central nervous system effects, and dermal irritation") *with* 57 Fed. Reg. 42101, 42351 (September 14, 1992) (Cadmium standard requires medical surveillance for previous exposure to prevent or minimize cadmium-induced kidney disease).

b) Pursuant to Section 19 of the OSH Act, 29 U.S.C. § 688, Executive Order 12196 (Feb. 26, 1980), and OSHA regulations contained at 29 C.F.R. Pt. 1960, DOE has responsibility to protect its own employees by establishing and maintaining an effective

and comprehensive occupational safety and health program that is consistent with the standards promulgated under section 6 of the OSH Act. OSHA is authorized to advise and make recommendations to DOE and, under certain circumstances, may make announced and unannounced inspections and evaluate or investigate complaints arising from or relating to Federal employees at DOE facilities. OSHA may also issue reports describing the nature of any violations found during an inspection, but may not assess penalties.

The above provisions do not apply with respect to employees of private contractors working at GOCO facilities. However, DOE has exercised statutory authority to regulate the occupational safety and health of private contractor employees working in GOCO facilities that are subject to the Atomic Energy Act (AEA). As such, section 4(b)(1) of the OSH Act, 29 U.S.C. § 653(b)(l), renders the OSH Act inapplicable, as a matter of law, to working conditions of these private contractor employees. *See* Aug. 28, 1992 Memorandum of Understanding between DOL and DOE.

OSHA retains jurisdiction over the occupational safety and health of private contractor employees working at non-AEA GOCO facilities. 71 Fed. Reg. 36988 (June 29, 2006). OSHA may cite private contractors for violations arising from the exposure of these employees to hazardous conditions.

Questions about DOE's health and safety program, as well as its responsibilities and relationships with respect to individual private contractors, should be directed to DOE.

2. The Halogenated Solvents Industry Alliance, Inc. (HSIA) submitted comments and studies to the docket (OSHA-2007-0024-0005 to OSHA-2007-0024-0005.6). HSIA's comments focused on health effects information and the medical surveillance provisions in Appendix B of the MC Standard. HSIA stated that it "is not aware of any new technologies or medical tests that could improve the current medical surveillance provisions in the Methylene Chloride Standard" (OSHA-2007-0024-0005.1, p.1). The following are summaries of HSIA's comments and OSHA's responses.

---HSIA questioned the MC Standard's medical surveillance provisions, 29 C.F.R. § 1910.1052(j), compared to the medical surveillance provisions of other standards, such as the Vinyl Chloride standard, 29 C.F.R. § 1910.1017(k), on which it places particular emphasis. HSIA states that complete uniformity is not desirable. However, it appears to feel that the MC Standard's provisions are unnecessarily strict.

OSHA Response: The MC Standard's medical surveillance provisions are not materially different from those contained in other standards. For instance, HSIA comments about the specificity of the standard's Appendix B, Section IV.A, "Medical and Occupational History," which contains a questionnaire "broken down according to general, respiratory, cardiovascular, hepatobiliary and pancreas, central nervous system, and hematology." The questionnaire simply tracks the standard's requirements with respect to medical history. 29 C.F.R. § 1910.1052(J)(5)(i). The vinyl chloride standard

is similar to the MC Standard, as it also contains a list of requirements with respect to medical history. 29 C.F.R. § 1910.1017(k)(l)(ii).

--- HSIA suggested deleting the following paragraphs from Sections III ("Medical Signs and Symptoms of Acute Exposure") and IV ("Surveillance and Preventive Considerations") of Appendix B to the MC Standard.

> "Low levels and short duration exposures do not seem to produce permanent disability, but chronic exposures to MC have been demonstrated to produce liver toxicity in animals, and therefore, the evidence is suggestive for liver toxicity in humans after chronic exposure.
>
> "Chronic exposure to MC may also cause cancer."
>
> "As discussed above, MC is classified as a suspect or potential human carcinogen. It is a central nervous system (CNS) depressant and a skin, eye and respiratory tract irritant. At extremely high concentrations, MC has caused liver damage in animals."
>
> "Based on the animal evidence and three epidemiologic studies previously mentioned, OSHA concludes that MC is a suspected human carcinogen. The medical surveillance program is designed to observe exposed workers on a regular basis. While the medical surveillance program cannot detect MC induced cancer at a preneoplastic stage, OSHA anticipates that, as in the past, early detection and treatments of cancers leading to enhanced survival rates will continue to evolve."

OSHA Response: OSHA does not agree with this comment. Scientific articles indicate that MC has sufficiently demonstrated animal carcinogenicity with the liver and lung as target organs. Several studies have investigated the adverse health effects of chronic exposure to MC. The findings of recent studies have suggested that chronic exposure to MC may cause headache, mental confusion, depression, liver damage, kidney damage, bronchitis, loss of appetite, nausea, lack of balance, and visual disturbance, and that exposure to MC may also cause cancer in humans.[63,64,65] LaDou stated the MC was not teratogenic to rats and mice exposed to 1225 ppm, although it was fetotoxic, causing delayed skeletal development typically seen with exposures that stress the maternal animal.[66]

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[63] Ruder A. Potential health effects of occupational chlorinated solvent exposure. *N.Y. Acad Sci* 1076:207-227; 2006.

[64] Lynge et al. Organic solvents and cancer. *Cancer Causes and Control.* 1997; 8: 406-419.

[65] Environmental Health & Safety (EHS). Methylene Chloride: Material Safety Data Sheet (MSDS) # M4420; 2005. Online: http://www.jtbaker.com/msds/englishhtml/M4420.htm

[66] LaDou J. Current Occupational & Environmental Medicine, 4 th edition. McGraw Hill Medical, 2007, p 510.

Furthermore, studies have found excess risk of liver and biliary tract cancers with MC exposure.[67] There is epidemiological evidence for breast, brain, rectal, non-Hodgkin's lymphoma (NHL), and multiple myeloma.[68] Studies indicate that MC is a CNS depressant and a skin, eye, and respiratory tract irritant, as well as a potential human carcinogen that has caused liver damage in animals.[69, 70] Furthermore, studies indicate that MC is a suspected human carcinogen.[71] Additionally, OSHA reviewed the scientific literature regarding the carcinogenicity of MC, and no study indicated that MC is not carcinogenic.[72,73,74,75,76,77,78,79,80] The National Toxicology Program (NTP) in the U.S. Department of Health and Human Services has classified MC as reasonably anticipated to be a human carcinogen based on sufficient evidence of carcinogenicity in experimental animals. The International Agency for Research on Cancer (IARC) of the World Health Organization (WHO) has classified MC as possibly carcinogenic to humans (Group 2B) based on the evidence of carcinogenicity in experimental animals. OSHA's conclusion is consistent with the findings from other researchers such as the National Institute for Occupational Safety and Health (NIOSH), NTP, and IARC.

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[67] Lynge et al. Organic solvents and cancer. *Cancer Causes and Control.* 1997; 8: 406-419.

[68] Ruder, A. Potential Health Effects of Occupational Chlorinated Solvent Exposure. *N.Y.Acad.Sci.* 2006;1076:207-227

[69] Olsen KR. *Poisoning & Drug Overdose.* 4th. McGraw-Hill Co., 2004, p 265-266.

[70] NIOSH Pocket Guide to Chemical Hazards. DHHS.CDC. NIOSH. September 2007. Publication No. 2005-149.

[71] Ruder, A. Potential Health Effects of Occupational Chlorinated Solvent Exposure. *N.Y.Acad.Sci*. 2006;1076:207-227.

[72] Dumas S, Parent ME, Siemiatycki J, Brisson J. Rectal cancer and occupational risk factors: A hypothesis-generating, exposure-based case-control study. Int J Cancer [Internet]. 2000 Sep 15;87(6):874-9.

[73] Cantor KP, Stewart PA, Brinton LA, Dosemeci M. Occupational exposures and female breast cancer mortality in the united states. J Occup Environ Med [Internet]. 1995 Mar;37(3):336-48.

[74] Goldberg MS, Theriault G. Retrospective cohort study of workers of a synthetic textiles plant in Quebec: I. general mortality. Am J Ind Med [Internet]. 1994 Jun;25(6):889-907.

[75] Heineman EF, Cocco P, Gomez MR, Dosemeci M, Stewart PA, Hayes RB, Zahm SH, Thomas TL, Blair A. Occupational exposure to chlorinated aliphatic hydrocarbons and risk of astrocytic brain cancer. Am J Ind Med [Internet]. 1994 Aug;26(2):155-69.

[76] Blair A, Hartge P, Stewart PA, McAdams M, Lubin J. Mortality and cancer incidence of aircraft maintenance workers exposed to trichloroethylene and other organic solvents and chemicals: Extended follow up. Occup Environ Med [Internet]. 1998 Mar;55(3):161-71.

[77] Gibbs GW, Amsel J, Soden K. A cohort mortality study of cellulose triacetate-fiber workers exposed to methylene chloride. J Occup Environ Med [Internet]. 1996 Jul;38(7):693-7.

[78] Goldberg MS, Theriault G. Retrospective cohort study of workers of a synthetic textiles plant in Quebec: II. colorectal cancer mortality and incidence. Am J Ind Med [Internet]. 1994 Jun;25(6):909-22.

[79] Lanes SF, Rothman KJ, Dreyer NA, Soden KJ. Mortality update of cellulose fiber production workers. Scand J Work Environ Health [Internet]. 1993 Dec;19(6):426-8.

[80] Hearne FT, Pifer JW. Mortality study of two overlapping cohorts of photographic film base manufacturing employees exposed to methylene chloride. J Occup Environ Med [Internet]. 1999 Dec;41(12):1154-69.

--- HSIA suggested deleting several other provisions from Appendix B to the MC Standard based on the belief that there is an "enormous disparity" in the amount of guidance among OSHA's standards and that, because of this disparity, Appendix B contains "unnecessary and potentially confusing discussion" that will lead to inconsistency in the elements of medical programs for different standards. Among other provisions HSIA wants deleted are: an example of a work and medical history questionnaire that would satisfy the requirements of the standard; paragraphs addressing the assessment of pulmonary function; and parts of a summary of elements of a physical examination that would fulfill the MC Standard's requirements.

OSHA Response: OSHA does not agree with these comments. Employers have a duty to comply with OSHA's standards. As explained in a prior response, the MC Standard's medical surveillance provisions are not materially different from those contained in other standards. The information contained in the MC Standard's appendices does not, by itself, create any additional obligations not otherwise imposed or detract from any existing obligation. 29 C.F.R. § 1910.1017(k)(1)(ii). That Appendix B might contain more detail than similar appendices contained in other standards does not render the appendix unnecessary or confusing, or render the MC Standard inconsistent with the other standards. To the contrary, the appendix contains useful guidance to help the regulated community comply with the medical surveillance provisions of the standard. Comments from the AFL-CIO indicate that guidance of this sort fosters compliance with the standard (Docket Number OSHA-2007-0024-0012.1).

--- HSIA submitted four peer reviewed studies for OSHA's consideration.[81,82,83,84] The first, Warbrick, et al. found that inhalation exposure did not demonstrate immunotoxicity in rats. The three others, which are summarized below, are pharmacokinetic (PBPK) studies that were published after the promulgation of the MC Standard.

> Sweeney, et al. used a modification of an older pharmacokinetic (PBPK) model to predict the percent of MC metabolized by the P450 pathway, as opposed to the glutathione transferase pathway.[85] The study concluded that a comparison of the observed variation in maximum velocity values to other estimates of variability in the rate of oxidative metabolism and human CYP2E1 activity suggested a relatively narrow range in human hepatic activity toward DCM. The study used human volunteers in order to draw its conclusions, but noted that ethical concerns hinder the generation of new data from human PBPK studies.

[81] Warbrick EV et al, Inhalation exposure to methylene chloride does not induce systemic immunotoxicity in rats. J Toxicol Environ health A. 2003 Jul 11;66 (13):1207-19.
[82] Sweeney LM et al. Estimation of interindividual variation in oxidative metabolism of dichloromethane in human volunteers. Toxicol Lett. 2004 Dec 30;154(3):201-16.
[83] Marino DJ et al. Revised assessment of cancer risk to dichloromethane: Part I. Bayesian PBPK and dose-response modeling in mice. Regul Toxicol Pharm. 2006:45(1):44-54.
[84] David RM et al. Revised assessment of cancer risk to dichloromethane II. Application of probabilistic methods to cancer risk determinations. Regul Toxicol Pharmacol. 2006 Jun;45(1):55-65. Epub.
[85] Sweeney LM et al. Estimation of interindividual variation in oxidative metabolism of dichloromethane in human volunteers. Toxicol Lett. 2004 Dec 30;154(3):201-16.

Marino, et al. identified the hierarchical Bayesian PBPK model as an improved cancer risk assessment of MC than the deterministic mouse PBPK model.[86] The authors discussed whether the later PBPK model would give better estimates and a different internal dose for mice, than the earlier model.

David, et al. drew conclusions about MC cancer risk based on probabilistic methodology. They note that validity of their lower risk estimate may need comparison to epidemiological data for exposed populations.[87]

OSHA Response: Possible immunotoxity from exposure to MC is one area where there have been data gaps. ATSDR has stated that because of lack of direct information on exposure to MC and quantitative response measurements, the immunological effects of MC in humans after inhalation exposure to MC have not been studied very well.[88] More data are needed to establish immunotoxicity effects of MC.[89]

HSIA asserts that the three pharmacokinetic studies show that OSHA's PEL "is much more health protective than indicated in the preamble to the Methylene Chloride Standard." However, HSIA does not state that there is no significant cancer risk below the PEL and does not ask OSHA to amend the Standard. Moreover, EPA is developing its new qualitative assessment and quantitative estimates of cancer risk, which will take into account the submitted studies. OSHA will examine the EPA assessment to determine whether it has any relevance.

3. The National Institute for Occupational Safety and Health (NIOSH) submitted comments and research articles to the Docket (OSHA-2007-0024-0006, OSHA-2007-0024-0006.1, OSHA-2007-0024-0006.2, OSHA-2007-0024-0007, OSHA-2007-0024-0008). NIOSH provided the following answers to questions posed in the Federal Register notice soliciting public comments (72 FR 37501):

OSHA asked: Have better respirator filters been developed for MC? Are there actions OSHA or NIOSH could take to encourage the development of better filters?

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[86] Marino DJ et al. Revised assessment of cancer risk to dichloromethane: Part I. Bayesian PBPK and dose-response modeling in mice. Regul Toxicol Pharm. 2006:45(1):44-54.

[87] David RM et al. Revised assessment of cancer risk to dichloromethane II. Application of probabilistic methods to cancer risk determinations. Regul Toxicol Pharmacol. 2006 Jun;45(1):55-65. Epub.

[88] Agency for Toxic Substances & Disease Registry (ATSDR). Toxicological Profile for Methylene Chloride. Centers for Disease Control and Prevention (CDC), U.S. Department of Health and Human Services (DHHS): Atlanta, GA; 2001. http://www.atsdr.cdc.gov/tfacts14.html. Last updated on September 11, 2007.

[89] Veraldi A, et al. Immunotoxic effects of chemicals: A matrix for occupational and environmental epidemiological studies. Am J Ind Med. 49: 1046-1055; 2006.

NIOSH responded that it is not aware of published data on new respirator filtration or adsorption technology for protection against MC but did cite to a study, Dharmarajan V, Cummings B and Lingg RD, "Evaluation or organic-vapor respirator cartridge efficiency for toluene diisocyanate vapor in the presence of MC or acetone solvents," Applied Occupational and Environmental Hygiene, 18:620-628 (2003). This study discusses the use of typical commercial organic vapor cartridges in polyurethane foam operations. NIOSH also commented on the work it is doing to advance the development of better filters.

OSHA Response: NIOSH's comment supports the conclusion that it is feasible to use respirators to reduce occupational exposure to MC and that better respirator filters for MC are being developed.

OSHA asked: Have small furniture refinishers implemented the low cost engineering controls developed by NIOSH?

NIOSH responded that it is not aware of industry-wide adoption of engineering controls, but that it is aware of some specific studies addressing engineering controls using different ventilation systems and stripping solutions. Some of these studies found that specific engineering controls used at specific work sites reduced MC exposure to or below the 25 ppm PEL, while others did not. The relevant studies include:

- NIOSH [2004]. In-depth survey report. Assisting furniture strippers in reducing the risk from methylene chloride stripping formulations at The Strip Joint, Inc., Cincinnati, OH: Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, Report No. 170–23a.

- NIOSH [2002]. In-depth survey report. Assisting furniture strippers in reducing the risk from methylene chloride stripping formulations at Sunset Strip, Inc., Cincinnati, OH: Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, Report No. 170–22a.

- Estill C, Watkins D, Shulman S, Kurimo R, Kovein R [2002]. Engineering controls for furniture strippers to meet the OSHA methylene chloride PEL. AIHAJ 63:326–333.

- NIOSH [2000]. In-depth survey report. Control of methylene chloride during furniture stripping at Tri-County Furniture Stripping, Cincinnati, OH: Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, Report No. 170–13c.

- NIOSH [1999]. In-depth survey report. Assisting furniture strippers in reducing the risk from methylene chloride stripping formulations at Los Angeles Stripping and Refinishing Center, Cincinnati, OH: Department of Health and Human

Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, Report No. 170–20a.

- Hall R, Martinez K, Jensen P [1995]. Control of methylene chloride – furniture stripping dip tank. Appl Occup Environ Hyg 10(3):188–195.

OSHA Response: NIOSH's comments support the conclusion that it is feasible to use engineering controls to reduce occupational exposure to MC.

OSHA asked: Have new studies been completed since 1996 on the health effects of MC? NIOSH submitted copies of MC health effects and toxicity studies completed since 1996. These submitted studies can be grouped into three general topic areas, as follows:

1.) Pharmacokinetics/Metabolism/Risk Assessment

Jonsson F, Bois F, Johanson G [2001]. Physiologically based pharmacokinetic modeling of inhalation exposure of humans to dihchloromethane during moderate to heavy exercise. Toxicol Sci 59(2):209-218.

Preston RJ, Williams GM [2005]. DNA-reactive carcinogens: mode of action and human cancer hazard. Crit Rev Toxicology 35:673-683.

Slikker W Jr., Andersen ME, Bogdanffy MS, Bus JS, Cohen SD, Conolly RB, David RM, Doerrer NG, Dorman DC, Gaylor DW, Hattis D, Rogers JM, Setzer RW, Swenberg JA, Wallace K[2004]. Dose-dependent transitions in mechanisms of toxicity. Toxicol Appl Pharmacol 201:203-225.

Slikker W Jr., Andersen ME, Bogdanffy MS, Bus JS, Cohen SD, Conolly RB, David RM, Doerrer NG, Dorman DC, Gaylor DW, Hattis D, Rogers JM, Setzer RW, Swenberg JA, Wallace K[2004]. Dose-dependent transitions in mechanisms of toxicity: case studies Toxicol Appl Pharmacol 201:226-294.

Watanabe K, Guengerich FP [2006]. Limited reactivity of formyl chloride with glutathione and relevance to metabolism and toxicity of dichloromethane. Chem Res Toxicology 19:1091-1096.

Slikker W, Andersen ME, Bogdanffy MS, Bus JS, Cohen SD, Conolly RB, David RM, Doerrer NG, Dorman DC, Gaylor DW, Hattis D, Rogers JM, Setzer RW, Swenberg JA and Wallace K. Dose-dependent transitions in mechanisms of toxicity: case studies. Toxicol. and Appl. Pharmacol. 201: 226-294; 2004.

Slikker W, Andersen ME, Bogdanffy MS, Bus JS, Cohen SD, Conolly RB, David RM, Doerrer NG, Dorman DC, Gaylor DW, Hattis D, Rogers JM, Setzer RW, Swenberg JA and Wallace K. Dose-dependent transitions in mechanisms of toxicity. Toxicol. and Appl. Pharmacol. 201: 203-225; 2004.

Bos PMJ, Zeilmaker MJ, and van Eijkeren JCH. Application of physiologically based pharmacokinetic modeling in setting acute exposure guideline levels for methylene chloride. Toxicological Sciences 91(2):576-585; 2006.

David RM, Clewell HJ, Gentry PR, Covington TR, Morgott DA, and Marino DJ. Revised assessment of cancer risk to dichloromethane II. Application of probabilistic methods to cancer risk determinations. Regulatory and Toxicology and Pharmacology 45:55-65; 2006.

Green T. Methylene chloride induced mouse liver and lung tumours: An overview of the role of mechanistic studies in human safety assessment. Human and Experimental Toxicology 16:3-13; 1997.

Inoue K, Higashino H, Yoshikado H, Nakanishi J. Estimation of aggregate population cancer risk from dichloromethane for Japanese using atmospheric dispersion model. Environmental Sciences 13(1):59-74; 2006.

Jonsson F, Bois F, and Johanson G. Physiologically based pharmacokinetic modeling of inhalation exposure of humans to dichloromethane during moderate to heavy exercise. Toxicological Sciences 59:209-218; 2001.

Liteplo RG, Long GW and Meek ME. Relevance of carcinogenicity bioassays in mice in assessing potential health risks associated with exposure to methylene chloride. Human & Experimental Toxicology 17:84-87; 1998.

Preston RJ, Williams GM. DNA-reactive carcinogens: mode of action and human cancer hazard. Critical Reviews in Toxicology 35:673-683; 2005.

Starr TB, Matanoski G, Anders MW, Andersen ME. Workshop overview: reassessment of the cancer risk of dichloromethane in humans. Toxicological Sciences 91(1):20-28; 2006

2.) Health Effects

Heightman AJ; [2006]; Bizarre crash produces unexpected hazard. JEMS; 31:S3.

Ruder AM. Potential health effects of occupational chlorinated solvent exposure. Ann. N.Y. Acad. Sci. 1076:207-227; 2006.

Liss GM, House RA, and Wills MC. Cranial neuropathy associated with chlorinated solvents. RE: Facial nerve palsy after acute exposure to dichloromethane. American Journal of Industrial Medicine 49:310; 2006.

Jacubovich RM, Landau D, Dayan YB, Zilberberg M and Goldstein L. Facial nerve palsy after acute exposure to dichloromethane. American Journal of Industrial Medicine 48:389-392; 2005.

Brown-Woodman PDC, Hayes LC, Huq F, Herlihy C, Picker K, and Webster WS. In vitro assessment of the effect of halogenated hydrocarobons:chloroform. Dichloromethane, and dibromoethane on embryonic development of the rat. Tetratology 57: 321-333; 1998.

Alguacil J, Porta M, Malats N, Kaupppinen T, Kogevinas M, Benavides FG, Partanen T, and Carrato A. Occupational exposure to organic solvents and K-ras mutations in exocrine pancreatic cancer. Carcinogenesis 23(1):101-106; 2002.

Warbrick EV, Kilgour JD, Dearman RJ, Kimber I and Dugard PH. Inhalation exposure to methylene chloride does not induce systemic immunotoxicity in rats. Journal of Toxicology and Environmental Health 66:1207-1219; 2003.

Mahmud M and Kales SN. Methylene Chloride Poisoning in a Cabinet Worker. Environ Health Perspect 107:769-772.

Socko R, Kupcewska-Dobecka M. Is dichloromethane an occupational carcinogen? Med Pr. 2007; 58(2):143-53.

3.) Engineering Controls

Estill CF, Watkins DS, Shulman SA, Kurimo RW, and Kovein RJ. Engineering controls for furniture strippers to meet the OSHA methylene chloride PEL. AIHA Journal 63:326-333; 2002.

Dharmarajan V, Cummings B and Lingg RD. Evaluation of organic-vapor respirator cartridge efficiency for toluene diisocyanate vapor in the presence of methylene chloride or acetone solvents. Applied Occupational and Environmental Hygiene 18:620-628; 2003.

Hall RM, Martinez KF, and Jensen PA. Control of methylene chloride: chloride-furniture stripping dip tank. Appl. Occup. Environ. Hyg 10(3):188-195; 1995.

Estill CF, Kovein RJ, Jones JH, Morton A. In-Depth Survey Report: Assisting Furniture Strippers in Reducing the Risk from Methylene Chloride Stripping Formulations at Los Angeles Stripping and Refinishing Center. U.S. Department of Health and Human Services, National Institute for Occupational Safety and Health (NIOSH)/CDC, Report No. 170-20a; March 1999, NIOSH; Cincinnati, OH.

Estill CF, Watkins DS, Shulman SA, Kurimo RW, and Kovein RJ. In-Depth Survey Report: Control of Methylene Chloride during Furniture Stripping at Tri-County Furniture Stripping. U.S. Department of Health and Human Services, National Institute for Occupational Safety and Health (NIOSH)/CDC, Report No. 170-13C; April 2000, NIOSH; Cincinnati, OH.

Jones JH, Estill CF, Kurimo RW, Kovein RJ, Watkins DS, and Shaw PB. In-Depth Survey Report: Assisting Furniture Strippers in Reducing the Risk from Methylene Chloride Stripping Formulations at Sunset Strip, Inc. U.S. Department of Health and Human Services, National Institute for Occupational Safety and Health (NIOSH)/CDC, Report No. 170-22a; May 2002, NIOSH; Cincinnati, OH.

Estill CF, Jones JH, and Kovein. In-Depth Survey Report: Assisting Furniture Strippers in Reducing the Risk from Methylene Chloride Stripping Formulations at the Strip Joint, Inc. U.S. Department of Health and Human Services, National Institute for Occupational Safety and Health (NIOSH)/CDC, Report No. 170-23a; November 2004, NIOSH; Cincinnati, OH.

Estill CF, Watkins DS, Shulman SA, Kurimo RW, Kovein RJ [2002]. Engineering controls for furniture strippers to meet the OSHA Methylene Chloride PEL. AIHA J 63:326-333.

OSHA Response: OSHA has examined the pharmacokinetics/metabolism/risk assessment studies submitted by NIOSH. OSHA will also examine EPA's new qualitative assessment and quantitative estimates of cancer risk to determine whether it has any relevance. The studies addressing health effects are, for the most part, additional evidence of the detrimental health effects associated with MC exposure. The studies addressing engineering controls generally support the conclusion that it is feasible to reduce exposure to MC.

4.) A commenter from academia submitted two research articles (OSHA-2007-0024-10). The first research article involved a survey conducted of 17 Massachusetts manufacturing companies that reported using over 10,000 lbs/yr of MC between 1995 and 1999; this survey was designed to assess the use of MC by these companies in 2000. At the time of the survey in 2000, 10 of the 17 manufacturing companies had eliminated their use of MC, and five of the 17 companies had reduced their use of MC to below 10,000 lbs/yr. Many of the surveyed companies switched to aqueous cleaning from MC degreasing. The most frequent reason given for eliminating or reducing MC use was environmental concerns. However, worker safety and health concerns, especially compliance with the OSHA MC Standard, were also given as motivation to eliminate or reduce MC use. This study stated that, "In general, companies associated many benefits and few problems with eliminating or reducing use of methylene chloride. Exposure reduction strategies based on toxics use reduction techniques appear to be feasible for many manufacturing companies. However, research should be conducted to assess the introduction of new hazards as a result of tightened regulations on methylene chloride."[90]

[90] Roelofs, Cora R, et al. "Results of the Massachusetts Methylene Chloride End-User Survey." Applied Occupational and Environmental Hygiene. 2003: 18(2): 132-137.

A second research article submitted by this commenter discussed "source reduction" as a method for prevention of MC hazards.[91] "Source reduction, also called pollution prevention, includes chemical substitution, process modification, and substitute technologies that intervene in the industrial process itself to eliminate or reduce hazards."[92] This study investigated source reduction at four companies that had used MC for cleaning and adhesive thinning and found that all were able to reduce their use of MC through source reduction.

OSHA Response: These articles support other evidence indicating that MC use is decreasing for some applications, most likely because of environmental and worker health concerns. Also, one article underscores that new hazards may be posed by substitutes for MC use. OSHA will continue to assess any new information it receives as to any new hazards that might be posed by substitutes for MC use.

5.) A mother submitted a Special Report regarding her 18 year old son who collapsed and died while working with MC at a poorly ventilated furniture stripping facility (OSHA-2007-0024-0011). She asked OSHA to help prevent anyone else from going through what she has been through.

OSHA Response: OSHA recognizes the grave dangers MC exposure can pose to worker health and will maintain a Standard that protects workers from these dangers.

6.) The Building and Construction Trades Department of the AFL-CIO submitted comments to the Docket (OSHA-2007-0024-0012). These comments stated that lack of information and training are the most common barriers in the construction industry for compliance with the MC Standard. The comments state that compliance with the Standard could be improved if OSHA worked through labor and industry representatives to develop training programs and information pamphlets on MC hazards and the MC Standard. Also, the comments urge OSHA to maintain the protections in the MC Standard.

OSHA Response: OSHA will review its compliance assistance materials to determine the need for updates. OSHA also will review the adequacy of how these materials are disseminated and additional means for reaching affected populations.

7.) An industrial hygienist with the Navy and Marine Corps Public Health Center provided the following comments regarding the MC Standard (OSHA-2007-0024-0013):

> Paragraph 1910.1052(g)(3) discusses respirator selection, stating that employers must provide "the appropriate atmosphere-supplying respirator specified in paragraph (d)(3)(i)(A) of 29 CFR 1910.134. Paragraph 1910.1052(g)(3)(ii) addresses emergency escape respirators, i.e., "A self-contained breathing

[91] Roelofs, Cora R, et al. "Source reduction for prevention of methylene chloride hazards: cases from four inductrial sectors." Environmental Health: A Global Access Science Source. 2003: July 2:9.

[92] Ibid

apparatus operated in the continuous-flow or pressure-demand mode; or a gas mask with an organic vapor canister." However, the following paragraph, 1910.1052(g)(4), seems to imply that medical evaluations are only needed for two types of respirators:

(g)(4) Medical Evaluation. Before having an employee use a supplied-air respirator in the negative-pressure mode, or a gas mask with an organic-vapor canister for emergency escape, the employer must:

(g)(4)(i) Have a physician or other licensed health-care professional (PLHCP) evaluate the employee's ability to use such respiratory protection.

Recommend changing paragraph 1910.1052(g)(4) to read simply:

(g)(4) Before having an employee use respiratory protection, the employer must:

Justification: Even though paragraph 1910.1052(g)(2)(i) states that "The employer must implement a respiratory protection program in accordance with 29 CFR 1910.134 (b) through (m)," the text in (g)(4) suggests that medical evaluation for wearing respirators is only required for supplied air respirators in the negative pressure mode or gas masks with organic vapor cartridges. Changing the statement in (g)(4) makes it clear that medical evaluations are required for all employees who must wear respirators to control methylene chloride exposure - not just for those who wear negative pressure respirators.

OSHA Response: The recommended technical change could be considered for future OSHA standard improvement projects.

8.) An industrial hygienist with the OSHA Consultation Program in Massachusetts provided the following three recommendations (OSHA-2007-0024-0014):

- Regarding Section 1910.1052 (d) (3), air monitoring every three months should be required only when workers might be unprotected due to lack of testing.
- Regarding Section 1910.1052 (j), the MC Standard should require blood lead and ZPP (zinc protoporphyrin) testing for furniture stripping workers and workers who use MC for paint removal.
- Because some substitutes for MC are as toxic or more toxic than MC, acceptable substitution products and unacceptable substitution products should be discussed on the OSHA website and NIOSH guide for furniture strippers.

OSHA Response: OSHA disagrees with the first recommendation. During the MC rulemaking, several commenters stated that the standard would require unnecessarily frequent monitoring. 62 Fed. Reg. 1494, 1579 (Jan. 10, 1997). OSHA decided that reducing the frequency of monitoring could result in inadequate employee protection because MC exposure is highly variable due to the substance's volatility. *Ibid.* Monitoring at the rate set by the standard is also "similar to that in other OSHA

standards, such as Ethylene Oxide (29 CFR 1910.1047)," and is important to evaluating "the effectiveness of exposure control strategies." *Ibid.* The second recommendation, blood lead and ZPP testing for furniture strippers and workers who use MC, pertains to lead exposure and could be considered with regard to review of OSHA's Lead Standard (29 CFR 1910.1025). With respect to the third recommendation, OSHA will consider putting out guidance recommending that before a substitute for MC is used, the toxicity of the substitute should be checked on the U.S. Environmental Protection Agency and NIOSH websites (www.epa.gov and www.niosh.gov, respectively).

6. The MC Standard and Small Businesses

This chapter of the review focuses on small businesses affected by the MC Standard. Section 6.1 begins by characterizing the number of small businesses affected by the standard. Next, Section 6.2 provides a further breakdown of affected firms by considering various ranges in the number of employees. Section 6.3 relates fatalities to firm size by, first, estimating the distribution of fatalities and the fatality rates for firms in different employment ranges and, second, by estimating the distribution of fatalities by the number of employees at the site. Section 6.4 describes the economic impacts of the standard on small businesses.

6.1 Estimation of the Number of Small Businesses

This study estimates the number and proportion of small businesses based on size standards established by the Small Business Administration (SBA). As an analytical convenience, the analysis focuses on five sectors that are believed to use MC to a considerable degree. The sectors evaluated, and their associated North American Industrial Classification System (NAICS) code, include the following:

- 326130: Laminated Plastics Plate, Sheet (except Packaging), and Shape Manufacturing
- 326150: Urethane and Other Foam Product (except Polystyrene) Manufacturing
- 336612: Boat Building
- 337110: Wood Kitchen Cabinet and Countertop Manufacturing[93]
- 811420: Reupholstery and Furniture Repair

Analysis of other sectors where MC usage is more tangentially related to economic performance may be less relevant.[94] The SBA size thresholds for the five sectors are stated in terms of employees or annual revenue and are presented in Exhibit 6.1. This study evaluates all sectors based on employment of 500 or fewer for reasons of data availability.

To estimate the impact of this rule on small businesses, this section analyzes the growth in the number of firms with fewer than 500 employees between 1989 and 1998.

[93] This sector corresponds to a SIC code that contained wood cabinet refinishers, and which were cited by OSHA for more than 100 MC violations.

[94] For example, even if MC is used by a shipyard to strip paint from ships, this is a very small fraction of the economic activity occurring at the shipyard. A more in-depth analysis of such industry sectors might yield insights, but is infeasible given the number of sectors of interest.

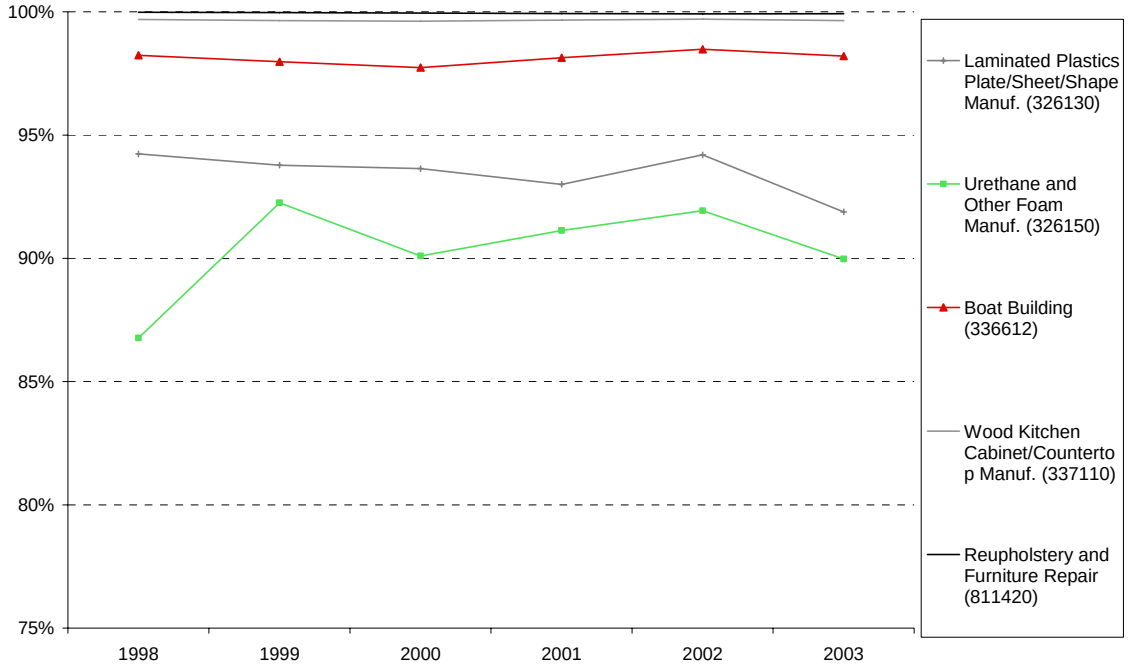
Exhibit 6-1
2006 SBA Size Standards for Relevant NAICS Codes

NAICS Code	Description	Size Standard (Number of Employees)	Size Standard (In Millions)
326130	Laminated Plastics Plate, Sheet (except Packaging), and Shape Manufacturing	500	-
326150	Urethane and Other Foam Product (except Polystyrene) Manufacturing	500	-
336612	Boat Building	500	-
337110	Wood Kitchen Cabinet and Countertop Manufacturing	500	-
811420	Reupholstery and Furniture Repair	-	$6.5

Source: "Small Business Size Standards matched to North American Industry Classification System, Effective January 5, 2006." Small Business Administration.
http://www.sba.gov/size/sizetable2002.html

Analysis of data for each of the five NAIC codes shows that the Standard has not adversely impacted small businesses. Specifically, as shown in Exhibit 6-2 and Exhibit 6-3, there has not been any systematic fluctuation of the proportion of all businesses that qualify as small based on the implementation schedule (1997-2000) for the Standard.

Exhibit 6-2
Percentage of Small Business Firms for Selected MC Industries, 1998-2003



Source: ICF analysis of data from SBA. "All industries by NAICS codes, Classified by employment size of firm," U.S. Small Business Administration (SBA) Office of Advocacy. http://www.sba.gov/advo/research/data.html#us.

Exhibit 6-3
Percentage of Small Business Firms for Selected MC Industries, 1998-2003

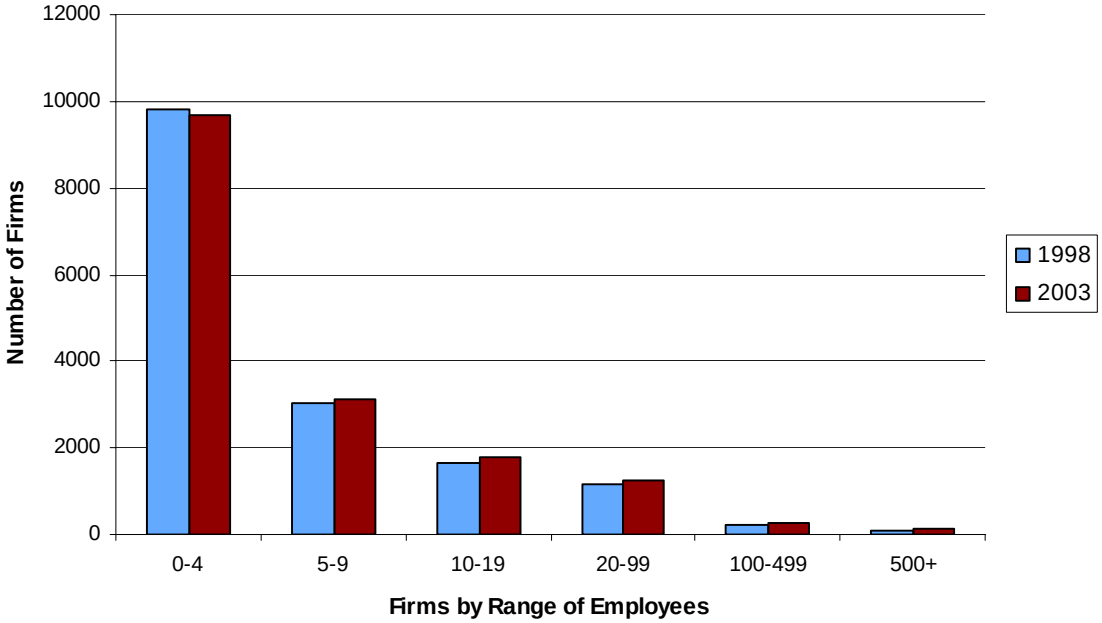
NAICS	1998	1999	2000	2001	2002	2003
Laminated Plastics Plate, Sheet (except Packaging), and Shape Manufacturing (326130)	94%	94%	94%	93%	94%	92%
Polystyrene Foam Product Manufacturing (326140)	92%	91%	90%	91%	91%	91%
Urethane and Other Foam Product (except Polystyrene) Manufacturing (326150)	87%	92%	90%	91%	92%	90%
Boat Building (336612)	98%	98%	98%	98%	98%	98%
Wood Kitchen Cabinet and Countertop Manufacturing (337110)	100%	100%	100%	100%	100%	100%
Reupholstery and Furniture Repair (811420)	100%	100%	100%	100%	100%	100%

Source: ICF analysis of data from SBA. "All industries by NAICS codes, Classified by employment size of firm," U.S. Small Business Administration (SBA) Office of Advocacy. http://www.sba.gov/advo/research/data.html#us.

6.2 Distribution of Firms by Number of Employees

Analysis of the distribution of firms by number of employees shows that there has been little change in the number (see Exhibit 6-4) or percent (see Exhibit 6-5) of firms in various employment-size categories in the collective group of five individual NAIC codes described above.

Exhibit 6-4
Number of Firms by Employee Size Categories for Selected MC industries, 1998 and 2003



Source: ICF analysis of data from SBA. "All industries by NAICS codes, Classified by employment size of firm," U.S. Small Business Administration (SBA) Office of Advocacy. http://www.sba.gov/advo/research/data.html#us.

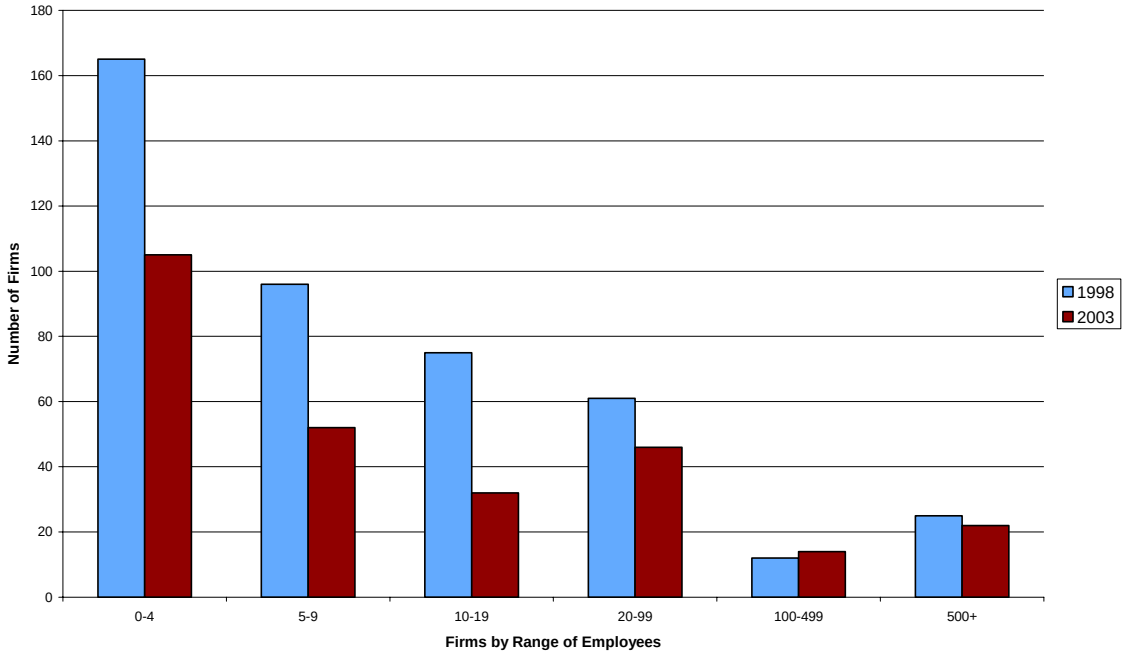
Exhibit 6-5
Percentage Change in the Number of Firms by Employee Size Categories for Selected MC Industries Between 1998 and 2003

NAICS	0-4	5-9	10-19	20-99	100-499	500+
Laminated Plastics Plate, Sheet (except Packaging), and Shape Manufacturing (326130)	-36%	-46%	-57%	-25%	17%	-12%
Urethane and Other Foam Product (except Polystyrene) Manufacturing (326150)	118%	315%	120%	23%	-6%	18%
Boat Building (336612)	7%	-11%	-10%	-14%	23%	0%
Wood Kitchen Cabinet and Countertop Manufacturing (337110)	17%	13%	15%	13%	15%	33%
Reupholstery and Furniture Repair (811420)	-16%	-13%	-7%	-30%	33%	300%
TOTAL	**-1%**	**3%**	**8%**	**4%**	**13%**	**14%**

Source: ICF analysis of data from SBA. "All industries by NAICS codes, Classified by employment size of firm," U.S. Small Business Administration (SBA) Office of Advocacy. http://www.sba.gov/advo/research/data.html#us.

Exhibits 6-6 through 6-10 consider each of the five industries individually. Although there are changes in each range for each industry, the data are consistent with economic trends other than the implementation of the MC Standard. For example, the growth of less expensive, imported furniture has reduced overall demand to repair and refinish older furniture.[95]

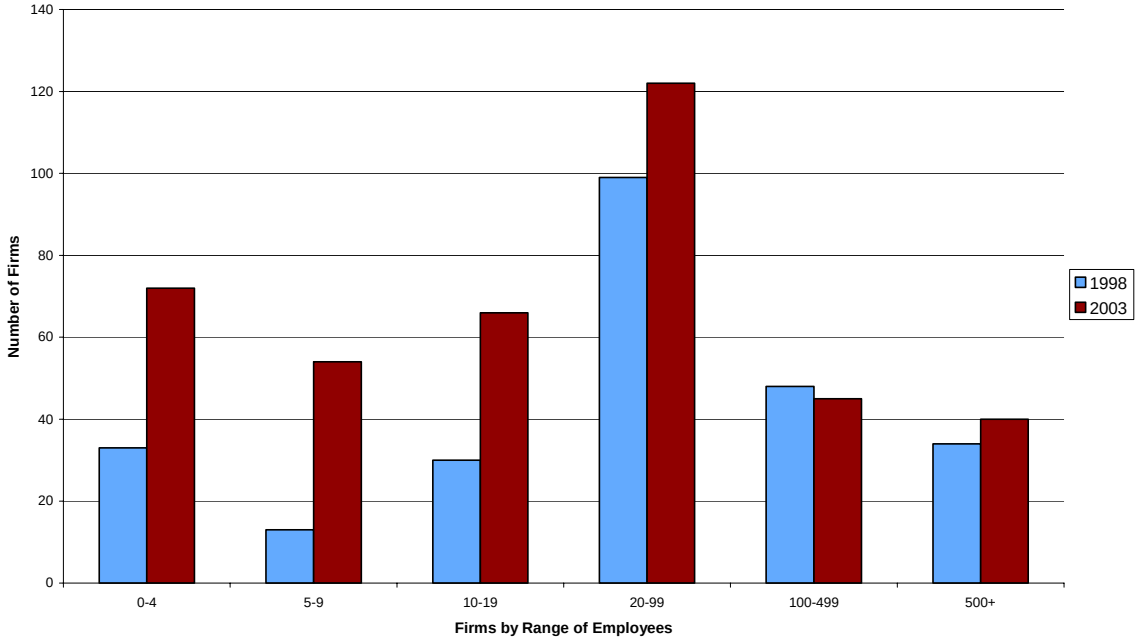
Exhibit 6-6
Number of Firms by Employee Size Categories for Laminated Plastics Plate, Sheet (except Packaging), and Shape Manufacturing (326130), 1998 and 2003



Source: ICF analysis of data from SBA. "All industries by NAICS codes, Classified by employment size of firm," U.S. Small Business Administration (SBA) Office of Advocacy. http://www.sba.gov/advo/research/data.html#us.

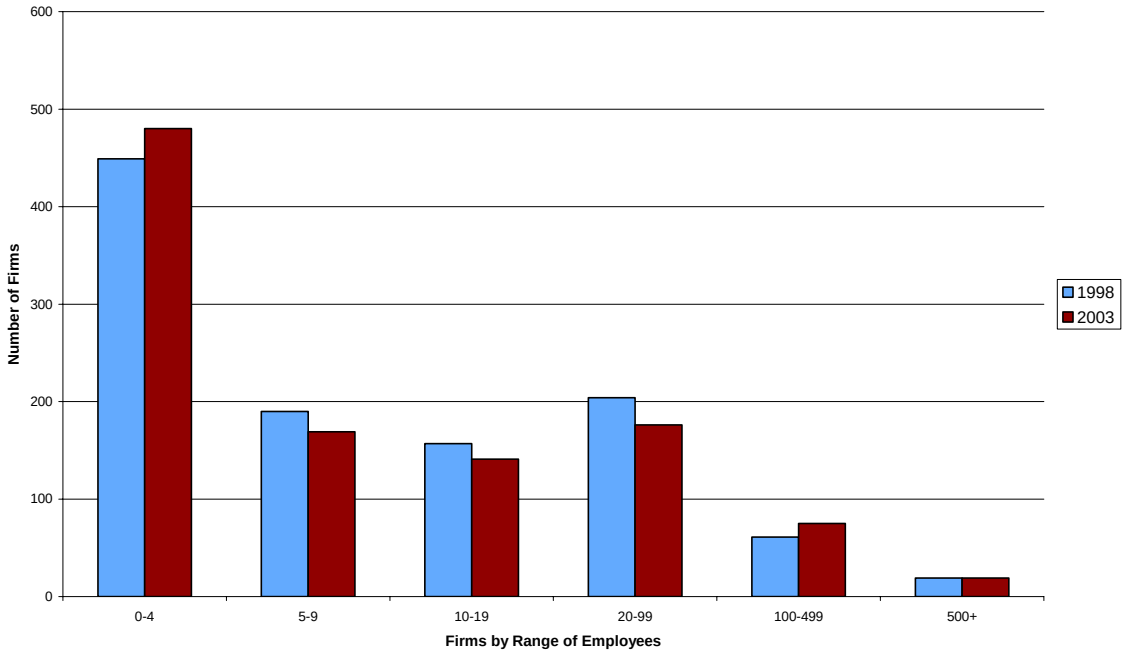
[95] Telephone conversation with Bob Flexner, former editor of *Professional Refinishing* magazine, March 20, 2006.

Exhibit 6-7
Number of Firms by Employee Size Categories for Urethane and Other Foam Product (except Polystyrene) Manufacturing (326150), 1998 and 2003



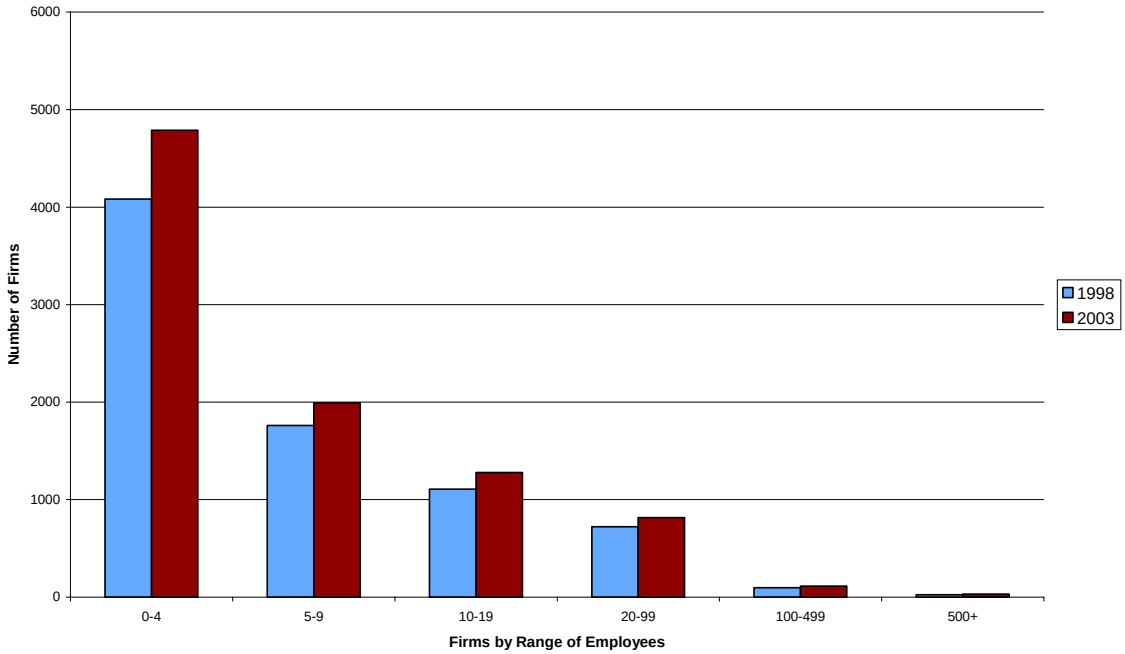
Source: ICF Analysis of data from SBA. "All industries by NAICS codes, Classified by employment size of firm," U.S. Small Business Administration (SBA) Office of Advocacy. http://www.sba.gov/advo/research/data.html#us.

Exhibit 6-8
Number of Firms by Employee Size Categories for Boat Building (336612), 1998 and 2003



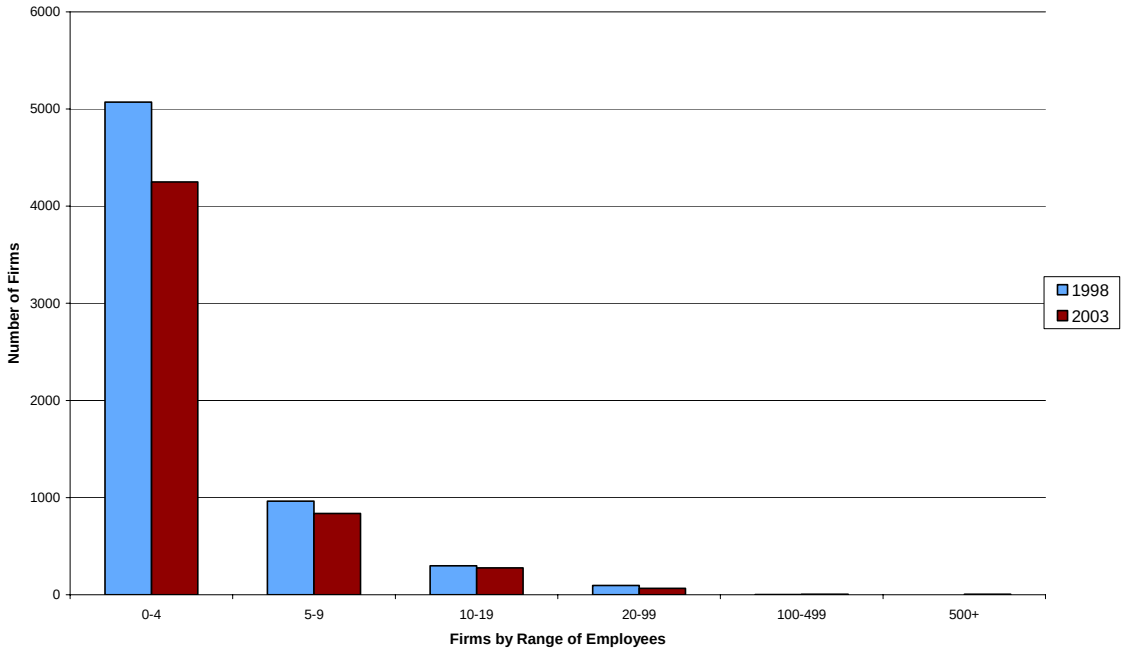
Source: ICF Analysis of data from SBA. "All industries by NAICS codes, Classified by employment size of firm," U.S. Small Business Administration (SBA) Office of Advocacy. http://www.sba.gov/advo/research/data.html#us.

Exhibit 6-9
Number of Firms by Employee Size Categories for Wood Kitchen Cabinet and Countertop Manufacturing (337110), 1998 and 2003



Source: ICF Analysis of data from SBA. "All industries by NAICS codes, Classified by employment size of firm," U.S. Small Business Administration (SBA) Office of Advocacy. http://www.sba.gov/advo/research/data.html#us.

Exhibit 6-10
Number of Firms by Employee Size Categories for Reupholstery and Furniture Repair (NAICS 811420), 1998 and 2003



Source: ICF Analysis of data from SBA. "All industries by NAICS codes, Classified by employment size of firm," U.S. Small Business Administration (SBA) Office of Advocacy. http://www.sba.gov/advo/research/data.html#us.

6.3 Impacts on Small Businesses

This lookback review examined economic impacts on small businesses in several ways.

- First, it considered the relative growth in the number of small businesses between 1997 and 2003, as well as the change in the percentage of small firms relative to large firms in individual industry sectors. This analysis, which is discussed in Section 6.1, finds that the percentage of small businesses does not appear to have changed significantly as a result of the Standard.

- The second approach, discussed in Section 6.2, considered different subsets of small businesses (i.e., across several ranges of number of employees). The results of this analysis were inconclusive.

- Third, the lookback review evaluated the feasibility of compliance with the MC Standard. As discussed in Chapter 2, it appears that cost may be a factor for small firms trying to comply with the Standard, particularly in the reupholstery and furniture repair industry. However, the economic effects observed in that industry may have been caused by factors unrelated to the standard. Thus, the standard's impact on that industry remains unclear.

- Finally, the lookback review considered the public comments submitted to OSHA. Public comments indicate that some industries have easily and effectively adopted substitutes for MC use.

Based on all of these findings, OSHA concludes that 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.

7. Section 610 Review

Section 610 of the Regulatory Flexibility Act directs agencies to review impacts of regulations on small businesses. Section 610 also provides that agencies should specifically consider five areas in reviewing the impact of a regulation on small businesses. This section discusses the impact of the MC Standard in these five areas, which are as follows:[96]

1. The continued need for the Standard.
2. The concerns about the complexity of the rule.
3. 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.
4. The degree to which technology, economic conditions, and other factors have changed to affect the Standard.
5. The nature of complaints and comments received by OSHA about the Standard.

Continued Need for the Rule

MC poses significant health risks from acute or chronic exposures. Therefore, there is a continued need for the rule.

OSHA's original MC Standard was adopted by OSHA in 1971 (from an existing Walsh-Healey Federal Standard) to address the potential for injury to the neurological system, including loss of awareness and functional deficits linked to anesthetic and irritating properties of MC; these effects had been observed from excessive, acute or large chronic exposures to MC in humans and experimental animals. In 1997, OSHA promulgated a revised MC Standard to better address acute risks, including carboxyhemoglobonic effects,[97] and to address longer-term cancer risks associated with lower exposures to MC that had not been addressed by the previous standard. OSHA evaluated cancer risks based on the best data and physiologically-based pharmacokinetic (PBPK) modeling then available.

Complexity of the Rule

No public comments indicate that employers are unable to comply due to the complexity of the Standard. HSIA commented that small businesses do not have the resources to comply with the standard's medical surveillance provisions due to the disparity in the amount of detail and guidance between the MC Standard and other OSHA Standards (OSHA-2007-0024-0005.1). However, as explained in Chapter 5, there is no material disparity between OSHA's standards, and guidance on the MC Standard helps employers to comply with the standard.

[96] Regulatory Flexibility Act §610(b)(1).
[97] MC is metabolized to carbon monoxide and therefore causes health impairment similar to that caused by direct exposure to carbon monoxide.

The Building and Construction Trades Department of the AFL-CIO stated that lack of information and training are the most common barriers in the construction industry for compliance with the MC Standard (OSHA-2007-0024-0012.1). The commenter stated that compliance with the Standard could be improved if OSHA worked through labor and industry representatives to develop training program and information pamphlets on MC hazards and the MC Standard. As stated in Chapter 5, OSHA will review its compliance assistance materials to determine the need for updates. OSHA also will review the adequacy of how these materials are disseminated and additional means for reaching affected populations.

Extent to which the Rule Overlaps, Duplicates, or Conflicts with other Rules
No public commenters indicate that the MC Standard overlaps, duplicates, or conflicts with other rules. MC is regulated by numerous agencies in addition to OSHA, including the following:

- The Environmental Protection Agency (EPA) regulates MC under at least five separate statutes:

  - Clean Air Act (CAA). EPA's maximum achievable control technology (MACT) standards and National Emission Standards for Hazardous Air Pollutants (NESHAPs) affect the halogenated solvent industry, aircraft depainting, pharmaceutical manufacture, wood furniture manufacturing, polyurethane foam fabrication, polyurethane foam blowing, and paint stripping industries.

  - Safe Drinking Water Act (SDWA). The EPA also regulates MC as a drinking water contaminant with a National Primary Drinking Water Regulation (NPDWR).

  - Resource Conservation and Recover Act (RCRA) and the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). Under RCRA and CERCLA, EPA regulates the storage, transportation, disposal, and release of MC as a hazardous waste

  - Toxic Substances Control Act (TSCA). Certain entities that release MC are subject to TSCA reporting requirements.

- The Department of Transportation (DOT) regulates transporters of hazardous materials, including MC.

- The Food and Drug Administrations (FDA) restricts the use of MC in cosmetic products and as a decaffeinating agent.

- The Consumer Product Safety Commission (CPSC), under the Federal Hazardous Substances Act, has established labeling guidance for household products containing MC.

The MC Standard does not duplicate or conflict with these other federal rules because each addresses issues other than worker safety. Even the CPSC's labeling guidance, which does address personal safety, is targeted at consumers rather than employers.

Changes in Technology, Economic Conditions, and Other Factors

Since the time the MC Standard was phased in (i.e., between 1997 and 2000), substitution of other products for MC has occurred to a significant degree for applications where appropriate substitutes can be found. Nevertheless, MC remains widely-used for applications that take advantage of its unique properties.

Research conducted for this lookback review did not identify any significant change in the engineering control costs that would be likely to change incentives for employers. Absent the discovery or development of additional uses or substitutes for MC, the demand for MC - and therefore the use of MC in the workplace - is likely to remain fairly constant in relative terms (i.e., it should grow only in proportion to the general economy).

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.

In combination with other factors, such as the growth of imports of foreign, inexpensive furniture and the impact of other environmental regulations, the MC Standard may have contributed to economic impacts in the Reupholstery and Furniture Repair industry, which remains dependent on MC for certain key operations. However, given the other factors, the impact of the standard on this industry remains unclear.

Nature of Comments Received

The public comments are addressed in detail in Chapter 5. No public commenter felt the MC Standard should be rescinded. As described in detail in Chapter 5, OSHA does not agree with suggestions made by HSIA to amend the medical surveillance provisions or Appendix B to the standard. Other commenters suggested amendments that could be considered in a future standard improvement project. Also, commenters suggested additional compliance assistance, especially to help small businesses comply with the Standard and also suggested that information be presented on the toxicity of alternatives to MC use.

8. Executive Order 12866 Review of the Standard

EO 12866 on Regulatory Planning and Review states that agencies of the Federal government must review their existing significant rules "to determine whether any such regulations should be modified or eliminated so as to make the Agency's regulatory program more effective in achieving the regulatory objectives, less burdensome, or in greater alignment with the President's priorities and principles set forth in this Executive Order." This review focuses on four major points:

1. Whether the standard has become unjustified or unnecessary as a result of changed circumstances;
2. Whether standards are compatible with each other and not duplicative or inappropriately burdensome in the aggregate;
3. Whether the standard is consistent with the President's priorities;
4. Whether the effectiveness of the standard can be improved.

This review of the MC Standard, consistent with EO 12866, finds that the Standard serves an important purpose in protecting workers from the effects of acute and chronic exposures to MC.

Whether the MC Standard Has Become Unjustified or Unnecessary as a Result of Changed Circumstances

The MC Standard remains necessary. MC poses significant health risks from acute or chronic exposures.

Whether the Standard is Compatible with Other Regulations and Not Duplicative or Inappropriately Burdensome in the Aggregate

As explained previously, the Standard is compatible and not duplicative with other state or federal rules.

Whether the Standard is Consistent With the President's Priorities

The Standard remains consistent with the President's priorities. In 1970, concerned about the high rates of deaths, injuries, disabilities, and diseases associated with the workplace, Congress passed the Occupational Safety and Health Act (OSH Act). The OSH Act was passed by a bipartisan Congress "to assure so far as possible every working man and woman safe and healthful working conditions and to preserve our natural resources." OSHA was created to develop mandatory job safety and health standards and enforce them effectively.

The objective of EO 12866 is to reform and make more efficient the regulatory process. The regulatory process must be consistent with the President's priorities to enhance planning and coordination with respect to both new and existing regulations; to restore

the integrity and legitimacy of regulatory review and oversight; and to make the process more accessible and open to the public.

The MC Standard is consistent with these priorities because it has produced the intended benefits, a reduction in acute and non-acute health effects associated with MC use in the workplace and has not been overly burdensome.

Whether the Effectiveness of the Standard Can Be Improved

The MC Standard has been effective in protecting workers from adverse health effects resulting from exposure to MC in the workplace. 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 will review its compliance assistance materials to determine the need for updates. OSHA also will review the adequacy of how these materials are disseminated and additional means for reaching affected populations. As explained in Chapter 5, several commenters made certain recommendations to amend the Standard. To the extent OSHA has not disagreed with these suggestions, OSHA may consider these issues in future standards improvement projects. Finally, as stated in Chapter 5, OSHA will examine EPA's new qualitative assessment and quantitative estimates of cancer risk to determine whether it has any relevance.

9. Conclusion and Recommendations

OSHA has concluded 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 websites (www.epa.gov and www.niosh.gov, respectively).

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APPENDIX I: REGULATORY FLEXIBILITY ACT, SECTION 610

§ 610. Periodic Review of Rules

(a) Within one hundred and eighty days after the effective date of this chapter, each agency shall publish in the Federal Register a plan for the periodic review of the rules issued by the agency which have or will have a significant economic impact upon a substantial number of small entities. Such plan may be amended by the agency at any time by publishing the revision in the Federal Register. The purpose of the review shall be to determine whether such rules should be continued without change, or should be amended or rescinded, consistent with the stated objectives of applicable statutes, to minimize any significant economic impact of the rules upon a substantial number of such small entities. The plan shall provide for the review of all such agency rules existing on the effective date of this chapter within ten years of that date and for the review of such rules adopted after the effective date of this chapter within ten years of the publication of such rules as the final rule. If the head of the agency determines that completion of the review of existing rules is not feasible by the established date, he shall so certify in a statement published in the Federal Register and may extend the completion date by one year at a time for a total of not more than five years.

(b) In reviewing rules to minimize any significant economic impact of the rule on a substantial number of small entities in a manner consistent with the stated objectives of applicable statutes, the agency shall 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.

(c) Each year, each agency shall publish in the Federal Register a list of the rules which have a significant economic impact on a substantial number of small entities, which are to be reviewed pursuant to this section during the succeeding twelve months. The list shall include a brief description of each rule and the need for and legal basis of such rule and shall invite public comment upon the rule

APPENDIX II: INTRODUCTION AND SECTION 5 OF EXECUTIVE ORDER 12866

REGULATORY PLANNING AND REVIEW

The American people deserve a regulatory system that works for them, not against them: a regulatory system that protects and improves their health, safety, environment, and well-being and improves the performance of the economy without imposing unacceptable or unreasonable costs on society; regulatory policies that recognize that the private sector and private markets are the best engine for economic growth; regulatory approaches that respect the role of State, local, and tribal governments; and regulations that are effective, consistent, sensible, and understandable. We do not have such a regulatory system today.

With this Executive order, the Federal Government begins a program to reform and make more efficient the regulatory process. The objectives of this Executive order are to enhance planning and coordination with respect to both new and existing regulations; to reaffirm the primacy of Federal agencies in the regulatory decision-making process; to restore the integrity and legitimacy of regulatory review and oversight; and to make the process more accessible and open to the public. In pursuing these objectives, the regulatory process shall be conducted so as to meet applicable statutory requirements and with due regard to the discretion that has been entrusted to the Federal agencies.

Accordingly, by the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

Section 1. Statement of Regulatory Philosophy and Principles.

(a) The Regulatory Philosophy. Federal agencies should promulgate only such regulations as are required by law, are necessary to interpret the law, or are made necessary by compelling public need, such as material failures of private markets to protect or improve the health and safety of the public, the environment, or the well-being of the American people. In deciding whether and how to regulate, agencies should assess all costs and benefits of available regulatory alternatives, including the alternative of not regulating. Costs and benefits shall be understood to include both quantifiable measures (to the fullest extent that these can be usefully estimated) and qualitative measures of costs and benefits that are difficult to quantify, but nevertheless essential to consider. Further, in choosing among alternative regulatory approaches, agencies should select those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity), unless a statute requires another regulatory approach.

(b) The Principles of Regulation. To ensure that the agencies' regulatory programs are consistent with the philosophy set forth above, agencies should adhere to the following principles, to the extent permitted by law and where applicable:

(1) Each agency shall identify the problem that it intends to address (including, where applicable, the failures of private markets or public institutions that warrant new agency action) as well as assess the significance of that problem.

(2) Each agency shall examine whether existing regulations (or other law) have created, or contributed to, the problem that a new regulation is intended to correct and whether those regulations (or other law) should be modified to achieve the intended goal of regulation more effectively.

(3) Each agency shall identify and assess available alternatives to direct regulation, including providing economic incentives to encourage the desired behavior, such as user fees or marketable permits, or providing information upon which choices can be made by the public.

(4) In setting regulatory priorities, each agency shall consider, to the extent reasonable, the degree and nature of the risks posed by various substances or activities within its jurisdiction.

(5) When an agency determines that a regulation is the best available method of achieving the regulatory objective, it shall design its regulations in the most cost-effective manner to achieve the regulatory objective. In doing so, each agency shall consider incentives for innovation, consistency, predictability, the costs of enforcement and compliance (to the government, regulated entities, and the public), flexibility, distributive impacts, and equity.

(6) Each agency shall assess both the costs and the benefits of the intended regulation and, recognizing that some costs and benefits are difficult to quantify, propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs.

(7) Each agency shall base its decisions on the best reasonably obtainable scientific, technical, economic, and other information concerning the need for, and consequences of, the intended regulation.

(8) Each agency shall identify and assess alternative forms of regulation and shall, to the extent feasible, specify performance objectives, rather than specifying the behavior or manner of compliance that regulated entities must adopt.

(9) Wherever feasible, agencies shall seek views of appropriate State, local, and tribal officials before imposing regulatory requirements that might significantly or uniquely affect those governmental entities. Each agency shall assess the effects of Federal regulations on State, local, and tribal governments, including specifically the availability of resources to carry out those mandates, and seek to minimize those burdens that uniquely or significantly affect such governmental entities, consistent with achieving regulatory objectives. In addition, as appropriate, agencies shall seek to harmonize

Federal regulatory actions with related State, local, and tribal regulatory and other governmental functions.

(10) Each agency shall avoid regulations that are inconsistent, incompatible, or duplicative with its other regulations or those of other Federal agencies.

(11) Each agency shall tailor its regulations to impose the least burden on society, including individuals, businesses of differing sizes, and other entities (including small communities and governmental entities), consistent with obtaining the regulatory objectives, taking into account, among other things, and to the extent practicable, the costs of cumulative regulations.

(12) Each agency shall draft its regulations to be simple and easy to understand, with the goal of minimizing the potential for uncertainty and litigation arising from such uncertainty.

Sec. 5. Existing Regulations.

In order 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 executive branch of the Federal Government 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:

(a) Within 90 days of the date of this Executive order, each agency shall submit to OIRA a program, consistent with its resources and regulatory priorities, under which the agency will periodically review its existing significant regulations to determine whether any such regulations should be modified or eliminated so as to make the agency's regulatory program more effective in achieving the regulatory objectives, less burdensome, or in greater alignment with the President's priorities and the principles set forth in this Executive order. Any significant regulations selected for review shall be included in the agency's annual Plan. The agency shall also identify any legislative mandates that require the agency to promulgate or continue to impose regulations that the agency believes are unnecessary or outdated by reason of changed circumstances.

(b) The Administrator of OIRA shall work with the Regulatory Working Group and other interested entities to pursue the objectives of this section. State, local, and tribal governments are specifically encouraged to assist in the identification of regulations that impose significant or unique burdens on those governmental entities and that appear to have outlived their justification or be otherwise inconsistent with the public interest.

(c) The Vice President, in consultation with the Advisors, may identify for review by the appropriate agency or agencies other existing regulations of an agency or groups of regulations of more than one agency that affect a particular group, industry, or sector of

the economy, or may identify legislative mandates that may be appropriate for reconsideration by the Congress.