NIOSH Testimony to DOL

TESTIMONY OF THE NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH ON THE OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION'S PROPOSED RULE ON OCCUPATIONAL EXPOSURE TO 4,4'-METHYLENEDIANILINE (MDA)

29 CFR Parts 1910 and 1926
Docket No. H-040

Presented at the OSHA Informal Public Hearing
March 20, 1990
Washington, D.C.

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50272-101

REPORT DOCUMENTATION PAGE	1. REPORT NO.	2.	3. PB91-169607
4. Title and Subtitle NIOSH Testimony on Occupational Exposure to 4,4'-Methylenedianiline, (MDA) by R. W. Niemeier, March 20, 1990			5. Report Date 1990/03/20 6.
7. Author(s) NIOSH			8. Performing Organization Rept. No.
9. Performing Organization Name and Address NIOSH			10. Project/Task/Work Unit No. 11. Contract (C) or Grant(G) No. (C) (G)
12. Sponsoring Organization Name and Address			13. Type of Report & Period Covered 14.

15. Supplementary Notes

16. Abstract (Limit: 200 words) This testimony concerns the support of NIOSH for the proposed rule on occupational exposure to 4,4'-methylenedianiline (101779) (MDA) put forth by OSHA. Specific issues addressed include biological monitoring, exposure limits, medical surveillance, respiratory protection, chemical protective clothing (laundering, permeability rates of aprons and other clothing including footwear, signs and labels, visual examination), and the sampling and analytical method. Specific comments were offered on a de minimum exclusion for mixtures of MDA less than 0.1% MDA, the appropriateness of establishing dermal disposition limits and using these limits to define the likelihood of dermal exposure, the establishment of regulated areas, a method for determining that lunch areas are free of MDA contamination, the use material safety data sheets for mixtures containing MDA rather than furnishing employees with such information for MDA only, requirements for medical examinations of workers at specific time intervals, questions concerning the multiple physician review, medical removal benefits with regard to workers' compensation, exemptions for cured composites, visual monitoring of the skin for MDA exposure, rotation of employees, voluntary use of respirators, and the need for a plain language appendix to facilitate explanation of the standard to workers and nontechnical managers.

17. Document Analysis a. Descriptors

b. Identifiers/Open-Ended Terms NIOSH-Publication, NIOSH-Author, NIOSH-Testimony, Niemeier-R-W, Safety-practices, Chemical-industry-workers, Personal-protective-equipment, Anilines, Carcinogens, Skin-exposure, Plastics-industry

c. COSATI Field/Group

18. Availability Statement	19. Security Class (This Report)	21. No. of Pages 16
	22. Security Class (This Page)	22. Price

Introduction

I am Richard W. Niemeier, Director of the Division of Standards Development and Technology Transfer (DSDTT) of the National Institute for Occupational Safety and Health (NIOSH). With me today are senior staff from NIOSH. NIOSH is pleased to have this opportunity to testify in support of the Occupational Safety and Health Administration (OSHA) proposed rule on Occupational Exposure to 4,4'-Methylenedianiline (MDA). NIOSH endorsed and participated, as a technical advisor, in the MDA Mediated Rulemaking, Advisory Committee [52 FR 26776] which was the basis for the proposed rule.

NIOSH has previously submitted written comments to this docket and continues to endorse the positions stated in these comments [NIOSH 1989]. Our testimony today is intended to offer additional data in support of our written comments, and to make ourselves available for questions from interested parties.

In July of 1986, NIOSH published a Current Intelligence Bulletin on 4,4'-Methylenedianiline (MDA) [NIOSH 1986a] in which it was concluded that MDA should be regarded as a potential occupational carcinogen. A NIOSH Health Hazard Evaluation [NIOSH 1982] implicated MDA as a suspected bladder carcinogen. In this proportional cancer mortality ratio analysis, only the excess of bladder cancer remained significantly elevated. The National Toxicology Program (NTP) bioassay [NTP 1983] confirms MDA as an animal carcinogen; therefore, it meets the OSHA definition of a potential occupational carcinogen. MDA is also regarded as a hepatotoxin, exhibiting acute and chronic effects in both animals and humans. Exposure to MDA can be through dermal absorption and/or inhalation. Studies show that because of the low vapor pressure of MDA (on the order of 10^{-7} mm Hg), the primary route of exposure would be dermal absorption [McGill et al. 1974; Williams et al. 1974; Dunn et al. 1980].

We would like to specifically address the issues of biological monitoring, exposure limits, medical surveillance, respiratory protection, chemical protective clothing, and the sampling and analytical method. We will also present some specific comments on the issues raised by OSHA in the Federal Register notice for these hearings [55 FR 2101].

Exposure Level

NIOSH supports OSHA in developing a proposed rule for MDA that establishes a permissible exposure level (PEL) for air of 10 parts per billion (ppb) and a short-term exposure limit (STEL) of 100 ppb. However, because NIOSH has stated that MDA is a potential occupational carcinogen, NIOSH continues to recommend that occupational exposures be

reduced below the PEL to the lowest feasible level [NIOSH 1986a]. The Environmental Protection Agency (EPA) also concluded that MDA presented an unreasonable risk of cancer to exposed humans [Federal Register 1985].

Because MDA is a high molecular weight compound with a melting point of 92°C and a vapor pressure of approximately 10^{-7} mm Hg at 25°C, any airborne exposure at room temperature will most likely be airborne particulate. NIOSH requests that OSHA consider describing the PEL in both ppb and milligrams per cubic meter (mg/m^3). It should be noted that heating MDA may produce significant airborne concentration that may be inhaled or deposited upon surfaces.

Biological Monitoring

NIOSH recommends biological monitoring to assess the degree of protection offered by the use of recommended protective equipment, and to assess the effectiveness of other controls such as work practices. In the proposed rule, whenever OSHA states there is a "likelihood of dermal exposure," NIOSH recommends that biological monitoring of MDA in the urine of workers be utilized to assess the degree of exposure. It may be noted that biological monitoring assesses exposure by all routes (i.e., dermal, inhalation, ingestion). The primary route of exposure is dermal in most cases due to the low vapor pressure of MDA and the ease by which MDA is absorbed through the skin. A study of 111 workers at five factories [Cocker et al. 1986], assessed the presence of MDA in the urine of workers exposed to MDA. Workers were involved in the (1) preparation of epoxy hardeners; (2) impregnation of carbon fiber mats (composite materials); and (3) use of silk screening of seals and gaskets. In this study, all of the factories used MDA in a solution with other chemical components so that exposure by inhalation of dust and vapor was minimal. Therefore, the source of the MDA in urine was primarily attributed to dermal contact (even though protective equipment was used by workers).

Air sampling and visual checks of skin contact inherently are very limited in addressing exposure by skin absorption. Urine monitoring for the presence of MDA is an indirect method of detecting dermal absorption, as well as exposure occurring from all other routes. Urine monitoring is no more expensive than air sampling, and as a complement to air and surface wipe sampling, can offer significant additional information--namely, the extent of personal uptake of MDA from the external environment. Presently, a lack of information on the rate of excretion of MDA in workers prevents knowing a dose-excretion relationship. A lack of dose-response epidemiological information concerning the role of MDA as a human carcinogen, further precludes the possibility of establishing a index value for biological excretion. Nevertheless, urine monitoring can be used for checking work practices and assessing performance of personal protective equipment afforded the

workers [Boeniger et al. (unpublished)]. MDA in urine samples, collected after potential dermal exposure, can be analyzed for MDA or N-acetyl MDA by several variations of methods which involve either gas chromatography (GC), or high-performance liquid chromatography (HPLC) [Cocker et al. 1986; Vaudaine et al. 1982; Brown 1990].

Each of the referenced methods above have been reported to perform similarly. The limits of detection vary somewhat, ranging from 1 to 20 parts per billion.

Contact Dermatitis

Skin contact with MDA is associated with contact dermatitis [Emmett 1976]. Skin contact with MDA also has been associated with yellow staining of the skin [Cohen 1985]. However, the author of this study has subsequently questioned whether MDA was the cause of yellow staining [Cohen 1988]. Nonetheless, NIOSH suggests that periodic screening for skin changes is useful and appropriate, particularly when it is done in conjunction with biological monitoring. Such screening for skin changes may be done by (1) taking a medical history (perhaps by questionnaire), and (2) examination of the skin. Such screening is not invasive and there are no apparent risks to workers.

Medical Surveillance

NIOSH supports OSHA in requiring medical surveillance of workers exposed to MDA. OSHA and the committee have identified bladder cancer, liver toxicity, and contact dermatitis as potential health effects of such exposure.

NIOSH is currently cooperating with OSHA to develop standardized recommendations for medical screening. While such recommendations are directed primarily at substances for which OSHA has not established specific screening requirements, the same considerations for selecting screening tests for specific health effects apply. The final document is not available for reference here, but a draft of this document will be peer reviewed in Cincinnati, Ohio, on April 11 and 12, 1990.

As previously stated, biological monitoring should also be an important part of the surveillance program. Although at the present time NIOSH is not aware of data correlating urine levels with risk for liver disease or cancer, biological monitoring is an important tool in determining exposure to MDA and documenting the effectiveness of changes in engineering controls, work practices, or personal protective equipment.

Liver Toxicity

NIOSH supports OSHA in requiring medical screening for liver toxicity. NIOSH suggests that screening is indicated in the following situations:

1) if there is evidence of sufficient exposure to MDA based on knowledge of dermal exposure and/or biological monitoring results;

2) if a sentinel health event occurs (e.g., toxic hepatitis is documented in an exposed worker);

3) if airborne concentrations exceed an ambient action level.

Regarding the latter situation, OSHA has, based upon carcinogenicity, appropriately selected a low ambient concentration (5 ppb) for the MDA action level. Although NIOSH is not aware of data indicating that workers exposed at this airborne concentration would have abnormalities in liver function tests, NIOSH supports OSHA in the action level/trigger concept.

Bladder Cancer

Generally, for an occupational disease to be a good candidate for medical screening, a test of known and acceptably high sensitivity and specificity must be available to detect the disease of interest in its preclinical phase. The predictive value of a positive test should be sufficiently high to make screening beneficial to the individual; intervention in the disease process should be more effective in the preclinical phase than after symptoms develop [Hulka 1986]. For occupational cancers, NIOSH recommends screening when there is evidence that such screening meets these criteria; direct evidence of such benefit is most clearly established by comparing the mortality and morbidity of a group screened with a group which is not screened.

Since, however, such direct evidence is not usually available to evaluate the utility of screening tests, NIOSH also recommends that cancer screening be offered to workers (with appropriate counseling) when screening tests are widely available which are safe, adequately effective, and either:

-- limited evidence suggests that screening may be beneficial, at least in high-risk groups, or

-- state-of-the-art treatment may improve survival (many individuals underestimate the effectiveness of cancer treatment and do not know how to secure state-of-the-art treatment once they are diagnosed) [NCI 1986].

With regard to bladder cancer:

1) effective screening tests are available (urine cytology and microhematuria) [Mariani et al. 1989; Koss et al. 1985; Parry and Hemstreet 1988; West et al. 1987]

2) some researchers consider these screening tests to be predictive of future development of bladder cancer [Ellwein and Farrow 1987; Cartwright 1988]

3) and state-of-the-art treatment may improve survival.

Therefore, NIOSH recommends that workers exposed to MDA at the proposed action level (5 ppb) be offered medical screening with appropriate counseling. Such counseling should include:

1) a discussion of the evidence suggesting that such screening may be of benefit; in the case of bladder cancer, the worker should be told that while some researchers feel that such screening is beneficial to the individual, others do not agree;

2) the action to be taken if the screening test is positive should be clearly explained to the worker (e.g., referral for further workup, which may include cystoscopy).

Respiratory Protection

The respiratory recommendations are based upon MDA being considered a potential occupational carcinogen. NIOSH recommends the following respiratory protection for MDA:

1) Self-contained breathing apparatus (SCBA) with a full-facepiece and operated in the pressure-demand or other positive-pressure mode;

2) Supplied-air respirator equipped with a full-facepiece and operated in a pressure-demand or other positive-pressure mode in combination with an auxiliary positive-pressure SCBA [NIOSH 1987a].

The proposed rule allows the use of high-efficiency particulate respirators when MDA is in solid form, or organic vapor/high-efficiency respirator cartridge when it is liquid. MDA has poor warning properties (PEL = 0.01 ppm, irritation level = 0.5 - 1.0 ppm) [ACGIH 1986]. The NIOSH/MSHA approval for cartridges is limited to organic vapors with adequate warning properties. Thus, only atmosphere-supplying respirators should be allowed for protection against MDA. OSHA should require mandatory use of full-facepiece

respirators to reduce skin exposures for all spraying operations involving exposure to MDA [Chalk 1989]. Requiring a full-facepiece respirator at all concentrations would provide additional skin protection for the facial area.

Chemical Protective Clothing

NIOSH agrees with OSHA that the use of chemical protective clothing is important to reduce exposure resulting from skin contact. The Advisory Committee recommends that polyvinyl chloride (PVC), natural latex and polyethylene are currently the best candidates for protection against methanolic solutions containing MDA. Based on permeation data, NIOSH agrees with OSHA that PVC will provide adequate dermal protection [Forsberg and Keith 1988]. NIOSH recommends that the employer be responsible for providing, maintaining, and assuring the proper use of chemical protective clothing in accordance with the manufacturer of the clothing.

NIOSH has the following concerns in regard to chemical protective clothing:

1. Laundering:

   The proposed rule endorses the laundering and reuse of protective clothing. The few studies that are available on this subject have shown that regular laundering does not adequately decontaminate clothing, and that for volatile chemicals, thermal decontamination is more effective [Vahdat and Delaney 1989; Perkins et al. 1987; Forsberg and Olsson 1988]. A non-volatile chemical such as MDA, that is transported into and through the clothing by a smaller molecule and more penetrating chemical such as methanol, poses a difficult decontamination problem, which, to NIOSH's knowledge, has not been studied. The proposed rule gives the impression that laundering is an effective means to decontaminate the clothing. In light of the uncertainty concerning the effectiveness of laundering decontaminated clothing, and considering the dermal problems associated with MDA, the employer should select a decontamination process that is proven to be effective. However, NIOSH is unaware of any proven method or current research on methods for effectively decontaminating clothing contaminated with MDA. It may be necessary to dispose of contaminated clothing until a proven method is available.

2. Permeability Rates of Aprons, Overalls, and Footwear

   Because MDA is readily absorbed through the skin, protective clothing must provide sufficient resistance to chemical flow (low permeation rate) in order to protect the worker from dermal

exposure until the clothing is removed. In the preamble (page 20695), it is stated that liquid MDA (presumably in a methanolic mixture) spilled on aprons, coveralls, or footgear can be effectively wiped off within minutes. This statement may be misleading in that if the protective clothing has very little chemical resistance (e.g., most coveralls and boots), the clothing will act as a sponge, trapping MDA within the material and act as a reservoir for subsequent dermal exposure. Wiping will not be effective to remove the spilled MDA from the surface of non-chemically resistant protective clothing.

3. Signs and Labels

It is recommended that due to MDA's carcinogenic and dermal properties, signs and/or labels should be required containing the information that MDA is a potential occupational carcinogen, it is absorbed by the skin, and specific protective clothing is required.

4. Visual Examination

NIOSH supports OSHA in the request for periodic visual examination of protective clothing. However, it should be noted that visual examinations are not effective in determining small holes and tears. The visual examination process is not acceptable to ensure integrity of new or decontaminated protective clothing. As previously stated, biological monitoring is recommended as a tool to monitor the effectiveness of the protective clothing program.

Sampling and Analytical Method

NIOSH provided in its previously submitted comments a draft method for sampling and analyzing MDA in air. This method is presently under review, and when completed, the final method will be available in the NIOSH Manual of Analytical Methods. This method should be considered the draft of record.

SPECIFIC COMMENTS ON ITEMS

Issue 1
OSHA proposes to include a de minimus exclusion for mixtures of MDA less than 0.1% MDA.

Response
Under the de minimus exclusions, NIOSH knows of no basis for excluding any occupational environments with any exposure to MDA. This would include occupational environments which involve the use of products

having less than 0.1 percent MDA from coverage under this proposed rule [NIOSH 1986b]. If OSHA has data that demonstrate such a product does not result in an occupational exposure to MDA, then these data should be explicitly presented. Otherwise, such occupational environments should be covered by the provisions of the final rule.

Certain mixtures may increase the initiator-promoter potential of MDA. It should be noted that Hiasa reported in 1984 [Hiasa 1984] that MDA acted as a carcinogenic promoter when in a mixture with 2,2'-dihydroxy-N-nitroso-propylamine as an initiator [NIOSH 1986a].

Issue 2
OSHA seeks testimony on the appropriateness of establishing dermal disposition limits and using these established limits to define the phrase "likelihood of dermal exposure." Also OSHA invites testimony on the necessity of requiring some effectiveness testing (e.g., biological monitoring). In addition, testimony on the feasibility of dermal monitoring techniques, biological monitoring, and visual monitoring techniques for occupational exposure to MDA.

Response
For initial screening, wipe samples on surfaces may be a useful tool for defining "potential" for skin contamination and subsequent absorption, and a check on housekeeping and clean-up of spills. After detection of MDA by wipe samples, biological monitoring would be the recommended approach to differentiate "potential" exposure from that caused by the breach of engineering controls, work practices or protective devices. NIOSH has developed a method for wipe sampling [Neumeister and Geraci 1987] which has a limit of detection (LOD) of 0.07 micrograms per gauze pad and a limit of quantification (LOQ) of 0.23 micrograms/gauze.

Issue 3
Method for establishing "regulated areas."

Response
NIOSH recommends that "regulated areas" could be defined as: areas where the potential for airborne exposure or surface/dermal exposure to MDA exists. "Potential for airborne exposure" may be defined as areas where analyzed airborne samples show detectable levels of MDA. "Potential for surface/dermal exposure," may be defined as areas where wipe samples detect MDA.

Issue 4
Quantifiable method for determining "free of MDA" for lunch areas.

Response
For lunch areas, NIOSH suggests that "free of MDA" means that wipe samples and air samples should not reveal detectable levels of MDA [Neumeister and Geraci 1987].

Issue 5
Allowing employers to use material safety data sheets (MSDS) for mixtures containing MDA rather than furnishing the employee with an MSDS for MDA only.

Response
NIOSH has no comment on this issue.

Issue 6
Requirement for medical examination at specific time intervals.

Response
OSHA and the committee have properly identified bladder cancer, liver toxicity, and contact dermatitis as potential health effects of exposure to MDA. NIOSH recommends the following periodicity of screening (for contact dermatitis, liver toxicity, and bladder cancer) for workers who have sufficient potential for exposure to MDA:

1) Baseline medical screening is recommended when employment begins or when the worker begins potential exposure to MDA (whether as a result of a job change, work practice change, or work process change).

2) Repeat medical screening is recommended periodically (at yearly intervals) as long as there is sufficient potential for exposure. In addition, screening for contact dermatitis and liver toxicity is indicated following substantial, non-routine exposures (e.g., large spills).

3) Repeat medical screening is also recommended when potential exposure ends (whether as a result of job change, work practice change, or work process change) or when employment ends.

Issue 7
Clarification of paragraph concerning multiple physician review.

Response
The section in question, (m)(6)(i), is ambiguous with regard to the designation of "he." The "he" in this section could refer to the "employee," "employer," or "examining physician." The "he" should be clarified. Also, the term "mutually acceptable" should be clarified as to whether it is referring to employee, employer, and/or perhaps, first physician.

Issue 8
Restricting application of multiple physician review mechanics to include only those employers who have been adversely affected as a result of occupational exposure to MDA.

Response
OSHA has asked if temporary removal and multiple physician review was appropriate for employees whose liver function abnormalities are not a result of MDA exposure, but which may be exacerbated by such exposure. Liver functions may be abnormal secondary to many different exposures (e.g., work-related toxins, alcohol, drugs, or viral infections) [Wright et al. 1988]. Since the liver injury resulting from such exposures is additive, the level of exposure to MDA is an important consideration in determining whether workers with liver abnormalities (resulting from nonoccupational etiologies) can continue to work in a job with MDA exposure. NIOSH agrees that the option of temporary medical removal and multiple physician review should be available to deal with these issues.

Issue 9
Medical removal benefits with regard to workers' compensation.

Response
NIOSH has no comment on this issue.

Issue 10
Should cured composites such as PMR-15 be exempt from requirements of the regulation?

Response
In order to be exempt from the regulation, the manufacturer should be responsible for demonstrating by established monitoring techniques that the material is free of available MDA in all stages of its use at the workplace.

Issue 11
Change in terminology for emergency plan from "possibility" to "probability."

Response
NIOSH has no comment on this issue.

Issue 12
Requirement for conducting visual monitoring of the skin for MDA exposure.

Response
Visual observation of changes in skin [e.g., dermatitis and yellow staining] and biological monitoring should be included in the medical screening section. NIOSH supports visual observation and the implementation of a biological monitoring program. NIOSH recognizes

that workers will be primarily aware of changes in skin condition. Therefore, the worker should be instructed and trained to routinely monitor for yellow staining and dermatitis as part of the safety and health program proposed and enforced by the employer.

Issue 13
Employee rotation to achieve compliance with MDA PEL.

Response
Worker rotation should not be allowed to replace engineering controls and/or safe work procedures to achieve compliance [NIOSH 1987b]. NIOSH further suggests that if OSHA allow worker rotation to achieve compliance OSHA should still require medical screening. NIOSH agrees the OSHA provision is appropriate for the removal of workers showing abnormalities in liver function test is.

Issue 14
Voluntary use of respirators.

Response
NIOSH recommends that OSHA should allow the voluntary use of respirators by workers when exposures are less that the PEL. However, OSHA should reinforce that the voluntary use of respirators should not be in lieu of the use of engineering controls and work practices as the primary means of controlling exposures to MDA. Whenever respirators are worn, including the voluntary use of such respirators, OSHA should require the implementation of a complete respirator protection program as outlined in the proposed rule under paragraphs (i)(1) through (i)(5) and under 29 CFR 1910.134 [NIOSH 1987a].

Issue 15
Should change room requirements be written using specification or performance language?

Response
NIOSH has no comment on this issue.

Issue 16
Removal of MDA deposited in the skin from "ambient" sources.

Response
MDA deposited in skin from any source—airborne, containers, spill, surface, etc.—should be removed as soon as possible. OSHA makes the statement that workers handling liquid mixtures of MDA for whom exposure would result from material being spilled on the skin need not shower at the end of the shift, while workers exposed to dust, fumes, and mists containing MDA should shower at the end of the shift. NIOSH recommends that all workers who are subjected to "potential dermal exposure" areas be required to shower at the end of the shift.

Issue 17
The need for a "plain language" appendix to facilitate explanation of the standard to workers and non-technical managers.

Response
NIOSH supports the inclusion of an appendix to explain the provisions of the rule in plain language. With the large diversity of individuals and the process involving MDA, it is unrealistic to apply a "generic" safety policy to all situations. However, certain elements must be achieved such as regular safety inspections, disposal procedures, formal and regular safety programs that ensure training, and regular monitoring.

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Enclosures and/or attachments that are not included are available free of charge from the NIOSH Docket Office (513/533-8450).