94-342

CHEMICAL MANUFACTURERS ASSOCIATION

M.L. Mullins
Vice President-Regulatory Affairs

July 22, 1994

NIOSH Docket Officer
NIOSH Docket Office
Robert A. Taft Laboratories
Mail Stop C34
4676 Columbia Parkway
Cincinnati, Ohio 45266

Re: Comments on the NIOSH's Proposed Rule Modifying Certification Requirements For Respiratory Protective Devices

Dear Sir or Madam:

The Chemical Manufacturers Association (CMA) is pleased to submit these comments on the National Institute for Occupational Safety and Health's (NIOSH) proposed rule, *(59 Federal Register 26850, May 24, 1994)*, modifying certification requirements for respiratory protective devices. CMA is a non-profit trade association whose member companies represent over 90 percent of the productive capacity for basic industrial chemicals in the United States. CMA is interested in this proposed rule, because CMA members use respiratory protective devices that are tested and certified by NIOSH and subject to this rulemaking.

In general, CMA supports the development of updated standards for testing and certification of respiratory protective devices to reflect advances in respiratory protection technology and modern analytical testing methods. CMA has reviewed comments submitted to NIOSH by the American Industrial Hygiene Association's Respiratory Protection Committee (AIHA). CMA generally supports AIHA's comments, and offers the following specific points for your consideration.

- NIOSH should consider the effect that the proposed changes in particulate air filter efficiency and testing will have on overall respiratory protection.

- NIOSH should strive to minimize confusion associated with new terminology for classifying particulate respiratory filter efficiency.

- NIOSH should use the American National Standards Institute's (ANSI) definition of loose-fitting face-piece in the proposed rule.

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CMA Comments on NIOSH Respirator Certification
July 22, 1994

I. The Proposed Changes In Particulate Air Filter Efficiency May Reduce Overall Respiratory Protection.

In the preamble to the proposed rule, NIOSH states that the proposed change in filter tests and filter efficiency criteria will produce a significant improvement in the level of protection provided to the wearers of respiratory protection. This assertion is not supported by the facts. In the case of high efficiency particulate air (HEPA) filters, NIOSH has proposed no changes in filter efficiency. However, for Dust/Mist (DM) and Dust/Fume/Mist (DFM) filters, NIOSH has proposed raising the filter efficiency requirements, but has not shown that these changes will have a material impact on health.

To date, NIOSH has not provided adequate data to show that current respirators and filters are insufficient to protect respirator users. NIOSH previously considered lowering its assigned protection factors based on a draft report, "A Performance Evaluation of DM and DFM Filter Respirators Certified for Protection Against Toxic Dusts, Fumes and Mists" which concluded that current filters were inadequate. However, based on an external peer review panel's recommendations, revision of the APF was determined not to be necessary.

Although the current DM and DFM filters would not pass the proposed filter efficiency criteria, they have been shown to provide adequate protection in the workplace. For example, Stevens and Moyer have presented data on a number of respirator filters.[1] For dust and mist filters, the estimated minimum filter efficiency at a flow rate of 85 lpm ranged from 67-74% when testing sodium chloride aerosol. Although this filter efficiency would fall below the efficiency levels proposed in this rule, in a number of workplace protection factor studies, these same types of filters had an average workplace protection factor of 200 or a penetration of 0.005.[2] This is equivalent to a 99.5% percent efficiency. Based on this analysis, use of current respirator filters can provide sufficient levels of protection.

NIOSH must also consider the potential for reduced overall respirator protection due to "pressure drop" which may occur when using filters designed to capture smaller particles. NIOSH should consider the effect that use of the new filters will have on overall respiratory protection. D.L. Campbell predicts that increasing "pressure drop" across a filter will cause a decrease in the amount of protection. [3] Another effect likely to be seen with the proposed

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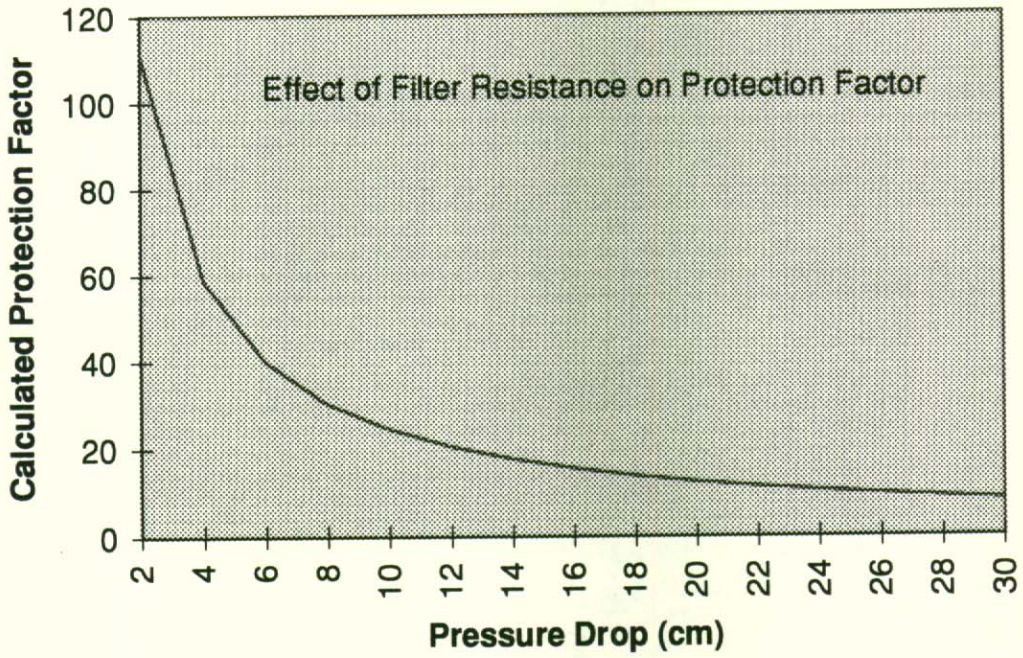
[1] Stevens G. A. and E. S. Moyer: "Worst Case" Aerosol Testing Parameters: 1. Sodium Chloride and Dioctyl Phthalate Aerosol Filter Efficiency as a Function of Particle Size and Flow Rate *Am. Ind. Hyg. Assoc. J.* 50(5):257-264 (1989).

[2] Nelson, T. J. : The Assigned Protection Factor of Ten For Half-Mask Respirators. Presented at the *American Industrial Hygiene Conference and Exposition,* May 1994 in Anaheim, California.

[3] Campbell D. L.: The Theoretical Effect of Filter Resistance and Filter Penetration on Respiratory Protection Factors. J. Int. Soc. Respir. Prot. 2(4):198-204(1984).

changes in filter efficiency is an increase in the rate at which pressure drop increases due to loading. Loading will also decrease the average protection attained, according to Campbell's model.

For example, consider a respirator that has a protection factor of 200, an inhalation pressure of one (1) cm and a filter penetration of 0.001. This is comparable to many of the disposable dust/mist respirators on the market today. Using Campbell's model, the respirator protection factor decreases as filter resistance is increased:



To avoid increased leakage which may result from increasing pressure drop, NIOSH could lower the required filter efficiency for the Type C filter from 95 to 90%, and Type B respirators from 99% to 95%. This reduction in filter efficiency would actually improve the overall protection factor for the respirator by reducing the amount of "pressure drop" associated with its use.

II. NIOSH Should Strive To Minimize Confusion Associated With New Terminology For Classifying Particulate Respiratory Filter Efficiency.

NIOSH should strive to minimize potential confusion associated with using new terminology for classifying particulate respiratory filter efficiency. NIOSH is proposing to reclassify particulate air filters as type A, B or C, with an S or S&L designation to indicate solid or solid/liquid. This new designation scheme could be confusing for workers, and for those who must select and distribute filters. Instead, NIOSH could use the actual filter efficiency to designate filter penetration instead of the letters A, B, or C, and NIOSH could spell out solid or solid/liquid, for example, "99.97% solid/liquid." Use of this plain language should help avoid any confusion about the capabilities of specific filters.

III. NIOSH Should Use The American National Standards Institute's (ANSI) Definition Of Loose-Fitting Face-Piece In The Proposed Rule.

In this rulemaking, NIOSH inappropriately recognizes only two types of PAPRs; tight-fitting and loose-fitting. NIOSH should use the American National Standards Institute's (ANSI) definition of loose-fitting face-piece in the proposed rule. OSHA, in some of its substance-specific standards, and ANSI, in its Z-88.2 standard (1992) on respiratory protection, have recognized four types of PAPRs: half mask, full facepiece, loose-fitting facepiece and helmets/hoods. A visual examination of the types of respirator inlet coverings supports a four-part delineation. Workplace protection factor studies have also found differing levels of protection for these types of PAPRs. As a result, NIOSH's recognition of four distinct types of PAPRs could help to achieve greater consistency with OSHA and ANSI.

Finally, this rule will increase the cost of respirators. NIOSH must evaluate this increase against the potential for improved respiratory protection. Because this proposal may actually reduce overall respiratory protection, it should be reconsidered. In addition, because this proposal is the first module in a five-part rulemaking, NIOSH should evaluate the aggregate cost of the modules to ensure conformance with Executive Order 12866.

CMA welcomes the opportunity to discuss these comments in greater detail with the Institute. If you have any questions regarding this matter, please contact Karen M. Cragg of my staff at (202) 887-1384.

Sincerely,

M.L. Mullins
Vice President-Regulatory Affairs