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June 19, 1996

Ms. Diane Manning  
Education and Information Division  
NIOSH  
4676 Columbia Parkway  
Mail Stop C-34  
Cincinnati, OH 45226-1998

Regarding: Metalworking Fluids

Dear Ms. Manning:

The American Petroleum Institute (API) appreciates the opportunity to review NIOSH's draft *Criteria for a Recommended Standard: Occupational Exposures to Metalworking Fluids*. It is obvious that a great deal of labor has been dedicated to the preparation of this draft. API commends NIOSH on their efforts to incorporate the large amount of recent information that has become available on this complex issue. However, API disagrees with several aspects of this document, including:

- The recommended 0.5 mg/m<sup>3</sup> REL.
- Carcinogenicity analysis.
- Proposed limit on PAH content.
- Inadequate sampling and analytical methods to support the proposed REL.

API does not feel that the scientific evidence for nonmalignant respiratory effects is strong enough to support the proposed recommended exposure limit (REL). The precise basis for the REL is not completely clear (and should be clarified in the final document), but it appears to be based largely on cross-shift studies showing acute changes in lung function that are very small and similar in magnitude to normal variations. NIOSH suggests that these cross-shift changes may ultimately lead to irreversible lung function impairment. While this is a plausible hypothesis, we feel that there are inadequate scientific data to support this conclusion. Several studies of workers with long term exposures indicate that lung function is at or near expected levels (Armeille et al., 1995; Jarvholm et al., 1982; Kennedy et al., 1989). Our conclusion that the current data do not justify the 0.5 mg/m<sup>3</sup> REL was widely supported at *The Industrial Metalworking Environment: Assessment and Control Symposium* sponsored by the American Automobile Manufacturers Association in November 1995 (proceedings are available).

In reviewing the draft Criteria Document, it is our view that NIOSH's conclusions from the cancer epidemiological studies selectively apply and oversimplify the results. From the numerous studies published, NIOSH has selected those data that support a positive association between metalworking fluid exposures and cancers at various sites, rather than objectively evaluating the overall coherence of the findings. NIOSH concludes that there is "substantial" evidence that

exposure to metalworking fluids is associated with cancers of the stomach, pancreas, larynx, rectum, skin and bladder. In fact, most of the referenced studies did not exhibit statistically significant associations at these sites. For several of these sites, NIOSH's conclusions were largely based on results of proportional mortality ratio studies (PMR). PMR studies are not appropriate for assessing causality. The only evidence suggestive of causal association comes from the earlier exposures (pre-1950s) with unrefined oils where skin cancers were observed, and the more recent large studies by Eisen, et al. (1992) and Tolbert et al. (1992) where laryngeal cancers were associated with base oil exposures. Since the 1950s, the production of oils has changed such that the current refining processes greatly reduces the components thought to be potentially carcinogenic. Therefore, results from these studies are largely irrelevant to regulating today's materials. We remind NIOSH that in these latter two large studies, exposures to metalworking fluids were not associated with significant increases in cancer of the stomach, pancreas, rectum, bladder, esophagus, lung, prostate, brain, colon, or hematopoietic system. NIOSH also failed to integrate into its analysis two important studies by Zheng et al. (1992)<sup>1</sup> and Tola et al. (1988)<sup>2</sup> which did not show a positive association for mineral oils and laryngeal cancers. Overall, the inconsistent nature of the cancer findings does not support the NIOSH conclusions.

In addition, we note that on page 151, the draft Criteria Document refers to the recent ACGIH "Notice of Intended Changes" for oil mists. The 1996-97 Notice of Intended Change no longer includes a TLV-TWA of 0.2 ug/m<sup>3</sup>, but rather recommends a TLV-TWA of 5 ug/m<sup>3</sup> for the sum of 15 specific PAHs. We are currently working with ACGIH to develop an alternative proposed oil mist exposure limit.

On page 199, NIOSH recommends that if mineral oils are used in metalworking fluids they should have less than 1% PAH content. NIOSH does not describe how PAH content is to be calculated. Depending on the method used and the material involved, a 1% PAH content cut-off could be either overly stringent or conceivably under-protective. A simple measure of total PAHs will not reflect the relative potency of individual PAHs in any particular material. PAHs are a broad class of chemicals, some of which have carcinogenic activity, but many of which are non-carcinogenic. We strongly urge that NIOSH recommend using only mineral oils that are classified as non-carcinogenic for use in metalworking fluids, without establishing a limit on PAH content. Again, we are working with ACGIH on these same issues. We recommend that NIOSH not finalize this draft document until more research is available for review.

Regarding sampling and analysis of metalworking fluid mists, the methods specified by NIOSH (Nos. 0500 and 5026) are inadequate to accurately isolate metalworking fluid mists from other components in the air. NIOSH Method No. 0500 is a nonspecific gravimetric procedure designed to monitor total dust concentrations. NIOSH Method No. 5026 is a non-specific infrared method used to measure oil mists, as well as other long-chained hydrocarbons. Due to the non-specific nature of both methods, there is a great potential for measuring extraneous

<sup>1</sup>Zheng, W, Blot WJ, Shu X-O, Gao Y-T, Ji B-T, et al. (1992). Diet and other risk factors for laryngeal cancer in Shanghai, China. *Am J Epidemiol* 136: 178-191.

<sup>2</sup>Tola S, Kallimaki P-L, Pukkala E, Asp S, Korkala M-L (1988). Incidence of cancer among welders, platers, machinists, and pipe fitters in shipyards and machine shops, *Br J Ind Med* 45:209-218.

components, which could result in inaccurate exposure values for metalworking fluid mists. We realize that currently there is not an alternative method that will measure only metalworking fluid mists, however, the proposed REL appears to have been established by incorporating a broad safety factor that is redundant because of the propensity to over-estimate exposures to metalworking fluids by the proposed methods. We question the practical feasibility of the proposed REL, given that the metalworking fluid mist component cannot be isolated when taking air samples.

We can provide more detailed comments to support our views if it would be helpful. However, many of our specific comments have been communicated to NIOSH in prior documents and meetings between NIOSH and industry stakeholders. Again, thank you for the opportunity to review and comment on this document. Please contact Diana Giammarco of my staff at (202) 682-8478 if you have any questions.

Sincerely,



Paul Bailey