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Dear Mr. Gettelfinger:

On December 9, 1993, the UAW petitioned OSHA to initiate rulemaking proceedings to protect workers from the health effects of occupational exposure to metalworking fluids (MWFs). In the following years, OSHA made significant efforts to resolve the complex scientific and policy issues involved in regulating MWFs, including establishing, in 1997, a Metalworking Fluids Standards Advisory Committee to help in developing an appropriate response. However, OSHA never formally responded to the UAW petition.

In the last few months, OSHA has again reviewed the available evidence to determine whether initiation of rulemaking proceedings on MWFs would be appropriate. As part of this review, the agency considered newly published scientific evidence and the impact of a MWFs rulemaking on other current regulatory priorities. For the reasons set forth below, OSHA is denying your petition insofar as it requests rulemaking under section 6(b) of the Act. OSHA will, however, use other methods to reduce employee exposure to MWFs.

There are two main reasons why rulemaking on MWFs is not appropriate now or in the foreseeable future. First, it is not clear that regulating MWFs is appropriate. The term MWFs covers a wide range of materials that can have different effects depending upon their composition. The composition of MWFs has changed over the years in response to the available health information, and studies involving older formulations do not reflect the risks to which workers are currently exposed in the workplace.

The health effects evidence available at this time is not compelling. The evidence linking current formulations of MWFs to cancer is equivocal at best. MWFs aerosols are associated primarily with respiratory conditions of widely varying levels of severity, and the risks MWFs pose for such conditions are unclear. There is substantial uncertainty about the basic nature and composition of MWFs in the work environment, the mechanisms by which MWFs may cause health impairments, the nature and risk of the health effects involved and other issues. OSHA believes that a flexible approach, incorporating "best practices" guidelines, coupled with outreach and education efforts, is

the most appropriate response to the available information and will effectively reduce the hazards exposed workers may face.

Second, OSHA is currently preparing to propose standards for three toxic substances that pose more serious health risks than MWFs do. These substances are hexavalent chromium, crystalline silica and beryllium. The limited agency resources available for toxic substance rulemakings cannot be diverted to MWFs without compromising the progress of these higher priority projects.

The material below is organized in two parts. The background section addresses the actions OSHA has taken on MWFs since receipt of the UAW petition. The discussion section demonstrates in detail that the evidence on MWFs does not compel regulatory action at this time.

I. Background

The UAW petition requested that OSHA initiate rulemaking proceedings by issuing a proposed standard under section 6(b) of the OSH Act containing a “provisional exposure limit” of 0.5mg/ M³ with medical surveillance and medical removal protection provisions, and that the Agency consider whether an Emergency Temporary Standard (ETS) under section 6(c)(1) of the Act would be appropriate. The petition also asked OSHA to consider several non-regulatory options, including publishing a hazard alert for MWFs and requiring that hazard warnings and training under the Hazard Communication Standard (HCS) be updated to include new information.

In response to the petition, OSHA included MWFs among eighteen health and safety hazards it was considering as possible candidates for future regulatory action. See Occupational Safety Health Priorities for the Nation, December 1995 at 5. After receiving input from labor, industry, professional and academic organizations, OSHA selected five of these hazards for development of regulatory “action plans:” Noise/Hearing Conservation in Construction, New or Revised Permissible Exposure Limits for general industry, Electric Power Transmission and Distribution in Construction, Metalworking/Machining Fluids, and Crystalline Silica. Id. at 5-6. OSHA also emphasized that policy decisions about whether and when to regulate any of these hazards would be reviewed periodically as new information became available. Id. at 5. The Priority Planning document stated that the new priorities “supplement rather than replace OSHA’s ongoing activities” and would “be added to [the] regulatory calendar as other standards are completed and resources become available.” Id. at 6. Any future rulemaking on the five new priorities would be initiated only after existing regulatory items were completed and resources could be allocated.

OSHA established a Metalworking Fluids Standards Advisory Committee to assist it in assessing the hazards of occupational exposure to MWFs and developing an appropriate response to them. See Advisory Committee Charter, Standards Advisory Committee on Metalworking Fluids, September 8, 1997. The committee was asked to evaluate the health risks of MWFs, and the possible hazard abatement strategies, and to make

recommendations on possible agency approaches, including non-regulatory as well as regulatory alternatives. Ibid. See also letter from Charles Jeffress to Senator Rick Santorum, dated April 7, 1999.

The Committee delivered its report on July 15, 1999. The majority of committee members who expressed opinions on the evidence believed that there was either no evidence or only equivocal evidence that current formulations of MWFs may cause cancer.¹ The committee majority found that current MWFs formulations are associated with dermatitis and acute and chronic respiratory effects, including asthma, bronchitis and hypersensitivity pneumonitis (HP). The committee did not evaluate the quantitative relationship between exposure and response for any health effect.

The majority recommended that OSHA develop a section 6(b) standard to address the non-malignant respiratory effects associated with MWFs, to include a permissible exposure limit (PEL), as well as systems management criteria and medical surveillance provisions. Four members argued that systems management guidelines would be a more effective response than a standard, in light of the complexity of the issues.

Given the other regulatory priorities and the complexity of the MWFs issue, the previous administration began working on a systems management guideline for MWFs. OSHA published a best practices guide in 2001. Metalworking Fluids: Safety and Health Best Practices Manual, Directorate of Technical Support (2001). The manual covers major topics such as a systems approach, exposure assessment, medical surveillance and training. It explains how to establish a MWF management program to control exposure and minimize employee contact with the fluid.

II. Discussion

I recently directed OSHA to review the evidence on MWFs again. As a result of that review, I have determined that rulemaking is not appropriate at this time, but that other actions should be taken that, together with the comprehensive guidance already available, constitute an effective response to the hazards machinists and others exposed to MWFs may face. The reasons for this decision are as follows.

¹ The committee evaluated the issue of skin cancer separately from the issue of cancer at other sites. As to skin cancer, five members believed that there was no evidence of carcinogenicity for current formulations, three members believed the evidence was equivocal, three members believed that there was known evidence for new formulations and one member believed that it was reasonably anticipated that there was evidence for current formulations. Two members did not think they had adequate information to make a decision. As to cancer at other sites, three members believed that there was no evidence of carcinogenicity for current formulations, four members believed that the evidence was equivocal and four members viewed the evidence as reasonably anticipating cancer associated with current fluids. Three members noted that prudence dictates that current formulations be considered carcinogenic and one member had no opinion. Committee Report at 52-53.

In determining whether to initiate regulatory action on MWFs I must consider both the evidence relating to the hazards posed by these fluids, and the effect that an MWFs rulemaking would have on regulatory projects of equal or greater priority. OSHA's current priorities include developing proposed standards on three substances, hexavalent chromium, crystalline silica and beryllium, for which there is strong evidence of significant risks of cancer and other fatal and disabling diseases.

I believe the risk of cancer and other debilitating health effects from exposure to the other toxic substances far outweigh those associated with MWFs. After extensively reviewing the evidence, the majority of the advisory committee members were not persuaded that cancer is associated with current formulations of MWFs. The committee majority found that MWFs are associated with dermatitis and non-malignant respiratory effects, including asthma and HP. The most serious of these are occupational asthma and HP. The effects of asthma range from occasional mild symptoms to more serious episodes requiring medical treatment. Similarly, HP symptoms, including cough, shortness of breath, fever and pulmonary function changes, resolve more quickly in some cases, than in others. Even in their more severe forms, asthma and HP are rarely fatal.

There are questions as to whether several of the non-malignant health effects associated with MWFs, such as HP and the pulmonary function effects and respiratory symptoms described in the scientific literature, are appropriate for regulation. The risk of HP appears low, especially in comparison to risks being addressed by our current projects. The data provided by Reeve, derived from his study of Ford plants between 1994 and 1996, indicated an incidence rate of between 3 and 5 cases per 10,000 exposed workers. Committee Report at 35. This points to the need for further scientific study to determine the strength of any causal connection between MWFs and HP.

It is questionable whether other respiratory effects addressed by the committee, such as cross-shift declines in pulmonary function, bronchial hyperresponsiveness (BHR), and pulmonary symptom prevalence are material health impairments. Cross-shift declines in pulmonary function, which may or may not be clinically significant, are generally recognized as transient conditions. Although there is concern that repeated transient declines in pulmonary function may lead to more serious respiratory illness, it is unclear whether and to what extent this progression occurs. Similarly, BHR is primarily relevant as an indicator of lung sensitization to a substance. Repeated exposure to the substance may or may not result in asthma or other lung disease. Whether and to what extent the prevalence of bronchial symptoms is indicative of underlying disease is also unclear.

By contrast, strong evidence exists that chromium, silica and beryllium cause fatal and disabling diseases. Several well-conducted studies have implicated chromium compounds as the likely cause of lung cancer to workers in a variety of industries. OSHA has preliminarily estimated that between 9 and 34 percent of workers exposed to chromium at the current permissible limit will develop lung cancer as a result of this exposure. Studies have also linked chromium to ulceration of the nasal passages,

including perforation of the septum in severe cases, and to respiratory and dermal effects as well.

The available evidence indicates that occupational exposure to crystalline silica causes chronic and acute silicosis and lung cancer, increases the risk of developing various autoimmune diseases and is associated with serious kidney diseases. The agency believes that a substantial number of excess deaths could be prevented by compliance with its draft silica standard.

Exposure to beryllium and beryllium compounds causes sensitization in some workers, which can lead to chronic beryllium disease (CBD). CBD produces a variety of symptoms, including chest pain, fatigue, progressive shortness of breath and, in some cases, heart failure and death. Estimates of the prevalence of CBD range from 2% to 15% of workers involved in machining operations in the manufacture of beryllium products. 67 Fed. Reg. 70708. Beryllium has also been shown to cause lung cancer in animals and has been linked to excess lung cancer deaths among exposed workers in recent epidemiological studies.

At this time, OSHA's highest regulatory priorities for toxic substance rulemakings are the proposed standards for chromium, silica and beryllium. Each of these health standards projects has a team of health scientists, statisticians, economists and others who are primarily responsible for the analyses necessary to support the rule. This work requires individuals with specialized knowledge in interpreting human and animal studies, and in performing complex quantitative risk and regulatory flexibility analyses. In addition, each team requires an experienced team leader capable of coordinating and reviewing the work. Reassigning key personnel to a fourth major toxic substance project would result in substantial delay in completing one or more of these higher priority rules.

OSHA is also working on several major safety standards projects, including a proposed rule to update the electrical safety standards, a proposed rule to protect workers who build electric power transmission and distribution facilities, and a rule to protect employees from fall hazards on elevated surfaces and to establish requirements for personal fall protection systems. These projects will also require work by agency economists and statisticians. They will have to be carefully reviewed by officials within the Department and by OMB.

In addition, risk assessments are subject to peer review by outside experts, while proposed regulatory flexibility analyses for rules affecting small businesses are subject to review under the Small Business Regulatory Enforcement Fairness Act (SBREFA). These detailed and lengthy review steps can be performed by only a relatively few individuals, regardless of the number of rulemakings OSHA schedules. Any time allocated to internal and external review of matters related to MWFs would leave less time for review on other rules, resulting in delays across the board.

OSHA sees no compelling justification for reordering its regulatory priorities at this time. Under this administration, OSHA is committed to focusing its limited health standards

resources on a realistic number of projects so that these projects can be completed within a reasonable time. Department officials have noted that OSHA's past regulatory agendas have included many more items than could realistically have been completed. See, e.g., BNA Daily Labor Report April 22, 2002 (remarks of Deputy Secretary of Labor Cameron Findlay). These earlier agendas may have supported unrealistic perceptions by the public about OSHA's ability to develop a large number of complex rules simultaneously.

A rulemaking on MWFs would require an enormous resource commitment. There are serious gaps in the evidence on a number of issues related to rulemaking. First, the MWFs environment is extremely complex, consisting of the virgin fluids themselves, the additives and contaminants introduced over time, the machines and machine tooling, and the workplace types and configurations. All of these variables have been linked in some way to health effects associated with MWFs; however, the causative agent or agents has not been identified. The evidence suggests that contaminants such as bacterial particulates or endotoxins may be responsible for some of the effects.

The evidence also strongly suggests that all classes of fluids are not equally hazardous. When OSHA regulates a group of substances that pose varying levels of risk, it needs to consider whether to assess the hazards of each separately and devise control measures accordingly. See, e.g., Color Pigments Mfrs. Ass'n v. OSHA, 16 F.3d 1157, 1161 (OSHA presented sufficient evidence of toxicity of cadmium pigments to include them in PEL applicable to all cadmium compounds). Given the number of combinations and mixtures of fluid types in use, it is doubtful that OSHA could regulate all of them in an omnibus proceeding. Plainly, such a proceeding would be complex and lengthy.

There are other concerns. In order to regulate a substance, OSHA must first find that it presents a "significant risk" of material harm at current levels, and that the new standard will substantially reduce that risk. Industrial Union Department, AFL-CIO v. American Petroleum Inst., 448 U.S.607 (1980). The advisory committee did not quantify the risks associated with MWFs. In testimony before the committee, OSHA health scientists identified weaknesses in the data and explained the kinds of additional analyses necessary to credibly quantify the risk of MWFs. For example, Dr. Steven Bayard, who headed OSHA's Office of Risk Assessment, explained that further evaluation was necessary to determine the degree of statistical uncertainty in the data, and the degree of uncertainty in the exposure estimates for members of the study cohorts. Bayard testimony at 42-43. He indicated that OSHA would need to reanalyze the studies before it could be confident in any risk estimates. Ibid.

OSHA must also find that the standard is technologically feasible, in that compliance can be achieved with control measures that already exist or can reasonably be developed, and is economically feasible in that industry can absorb or pass on the cost of compliance without threatening its long term profitability or competitive structure. American Textile Mfrs. Inst., Inc. v. Donovan, 452 U.S. 490, 513, 530, n.55 (1980). The advisory committee report indicates that there are approximately 3.1 million machines requiring MWFs, of which about 1.3 million are used in the smallest businesses (1-19 employees).

Committee Report at 69. Although OSHA has some data on the feasibility of various control methods, it has not analyzed how widely they could be used or their costs. The committee recommended four different sampling methods that could be used to measure MWFs. There were broad differences in view among the committee members on which of these measurements was the most appropriate metric or indicator for the respiratory health effects associated with MWFs. Id. at 131-132. There is substantial controversy on whether specific agents contained in MWF mixtures believed to be related to cancer, asthma or HP should be independently monitored, or whether the measurement of MWF particulate is sufficient.

Under these circumstances, I believe that non-regulatory measures, such as dissemination of OSHA's comprehensive best practices manual is the most appropriate way to address hazards workers exposed to MWFs may face. The manual outlines safe procedures for handling and using MWFs that will minimize exposure and contamination. Another concern highlighted in the UAW petition is whether the Material Safety Data Sheets (MSDSs) on MWFs accurately describe the hazards associated with these chemicals and mixtures. OSHA will notify its field staff of the type of information that should appear on MSDSs for metalworking fluids to ensure appropriate reviews. OSHA is also participating in an alliance with the Independent Lubricant Manufacturers Association to help in further identifying hazards and ways of addressing them, developing additional education and outreach materials. I believe all of these tools will enable workers and employers to control exposures to MWF hazards effectively .

Sincerely,

John Henshaw
Assistant Secretary