



INDEPENDENT LUBRICANT MANUFACTURERS ASSOCIATION

June 23, 2004

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Research Triangle Park, North Carolina 27709

Re: Public Comments Submission *Re NTP Nomination of Metalworking Fluids to 12th Report on Carcinogens*

Dear Dr. Shane:

The Independent Lubricant Manufacturers Association (ILMA) wishes to make the following statement regarding the nomination of metalworking fluids (MWFs) in the *Report on Carcinogens, Twelfth Edition* (RoC) at the June 29, 2004 meeting of the National Toxicology Program's (NTP) Board of Scientific Counselors. Dr. Richard Kraska, Manager of Special Toxicology and Regulatory Projects for Lubrizol Corporation, will present ILMA's statement at this meeting. Dr. Kraska chairs the Association's Safety, Health, Environmental and Regulatory Affairs Committee.

ILMA is a national trade association of 145 North American manufacturing member companies, consisting largely of small businesses. As a group, ILMA's members manufacture approximately 80% of the MWFs used in North America. ILMA members developed and operate LubeCare®, the product stewardship program for the lubricants industry. The Association recently entered into an alliance with the Occupational Safety and Health Administration (OSHA) to promote the safe use of lubricants and to provide MWF users with educational and outreach information. Accordingly, ILMA and its members have a direct interest in the nomination of MWFs for listing in the RoC, which was published in the *May 19, 2004 Federal Register*. ILMA will be submitting detailed comments to NTP by the July 19, 2004 deadline.

As recognized by NTP in its May 19 notice, MWFs are diverse, complex products designed for a multitude of specific applications in the machining environment. MWFs are highly-developed and engineered products used for the removal of metal, metal forming, metal protecting and treating, and metal cooling. However, MWF formulations have evolved and have changed significantly over time both to enhance the fluid for its intended application and to address suspicions of adverse health effects from exposure to former MWF components, such as poorly-refined base oils and nitrites. These MWF formulation changes have been recognized by other Federal agencies and by the courts.

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ILMA and its member companies are still developing extensive comments for submission by the July 19 deadline. However, the Association would like to go on the record now with the following points that we believe are fundamental to NTP's listing criteria:

- MWFs are both complex and dynamic mixtures. While four classes of MWFs (straight, soluble, synthetic, and semi-synthetic) are generally recognized, there are thousands of formulations within each of these classes. Moreover, a MWF may include as many as 20 different components, and many of these components themselves can be complex mixtures.
- It is estimated that more than 700 unique Chemical Abstract Services Numbers may be representative of the components intentionally added and used in MWFs, also leading to their complexity. None of these raw materials are classified as known or listed carcinogens. Because MWFs comprise such a wide variability of composition, it is scientifically incorrect to view all MWFs as one group for purposes of the RoC review. Moreover, each chemical that is used in a MWF composition is assessed for its suitability for use under OSHA's Hazard Communication Standard and product stewardship principles. Further, some MWF components, such as anti-microbials, are highly regulated and tens of millions of dollars have been spent on risk assessments for these components.
- Fluids used for metal removal operations undergo dynamic changes in active distribution systems. The fluids are subject to contamination from "tramp oils," such as hydraulic oil or gear lubricant, bacteria and fungi, dirt particles and dissolved metals, and metal oxides and abrasives. Also, formulated chemicals are depleted over time. Therefore, the actual fluid in use may be different than that supplied by the formulator. As such, generalizations about MWFs are difficult and, in some cases, irresponsible.
- MWFs underwent substantial reformulation as the result of the 1985 implementation of OSHA's Hazard Communication Standard. For example, over these past two decades, the use of certain suspicious chemicals in formulations have been eliminated or severely reduced:
 - Alkali metal nitrite salts that can form nitrosamines (in combination with secondary amines) have been eliminated from use.
 - The polynuclear aromatic (PNA) content of mineral oils has been reduced since the industry switched to more highly-refined oils based on the 1984 IARC mineral oil classification.
 - The use of short-chain chlorinated paraffins has sharply diminished.
 - More recently, there has been significant reduction in the fluids which contain diethanolamine.
- Most scientists agree that associations found in epidemiological studies between cancer rates and MWF exposures are weak at best. (An U.S. appeals court found these studies "equivocal" in a decision earlier this year.) Data from these studies were inconsistent regarding the site of the cancer formation. There also can be non-MWF sources which can explain cancer risks, including welding fumes, tow motor exhaust, mists from parts washers and heat-treat operations. It is difficult to conclude that the association of cancer to currently marketed MWFs is valid when there are so many variables to consider.

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- ILMA will comment on the studies that were cited in the NTP executive summary entitled, Metalworking Fluids, Summary of Nomination for Review: NTP 12th Report on Carcinogens (Submitted by Report on Carcinogens Group NIEHS)(Summary). The key point to understand here is that, because MWF composition changes have been profound and documented over the past 20 years, the validity of applying results of earlier epidemiologic studies to current risk assessment or a decision to include MWFs in the RoC is very problematic. While the studies themselves may be valid, the application of the findings by NTP to current products and work settings is inappropriate.
- Relevant laboratory animal studies are few and far between. Six studies were published between 1955 and 1990. Based on the time intervals, the fluids in these studies were likely all different and some were not even chemically characterized. The fluids in the earlier studies likely do not even remotely resemble fluids in use today.
- The diverse compositions of MWFs utilized by industries today are significantly different from the composition of the fluids used when the epidemiologic and animal toxicology studies cited in the Summary were done. Therefore, the association between MWFs exposures is weak and the cited studies do not support any of NTP's criteria to justify a blanket listing of current MWFs as human carcinogens or reasonable anticipated human carcinogens.

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ILMA appreciates the opportunity for Dr. Kraska to make these brief remarks at the June 29 meeting. We look forward to working with NTP and its review committees on this important matter.

Sincerely,



Celeste M. Powers, CAE
Executive Director

cc: ILMA Board of Directors
SHERA Committee
Dr. Richard Kraska
Jeffrey L. Leiter, Esq.
Dr. C.W. Jameson, NIEHS