



INDEPENDENT LUBRICANT MANUFACTURERS ASSOCIATION

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November 29, 2004

By Email & U.S. Mail

Dr. Barbara Shane
Executive Secretary
NTP Liaison and Scientific Office
National Institute of Environmental Health Sciences
P.O. Box 12233 – MD A3-01
111 T.W. Alexander Drive
Research Triangle Park, North Carolina 27709

***Re: NTP Board of Scientific Counselors
June 29, 2004 Meeting Follow-up***

Dear Dr. Shane:

The Independent Lubricant Manufacturers Association (ILMA) submits the following information to supplement the presentation of Dr. Richard Kraska at the June 29, 2004 meeting of the National Toxicology Program's (NTP) Board of Scientific Counselors (Board). ILMA requests that this letter be shared with the Board members.

Dr. Kraska, in his presentation which was summarized in my June 21, 2004 letter to you, highlighted ILMA's comments which subsequently were submitted to NTP on the nomination of metalworking fluids (MWFs) in the *Report on Carcinogens, Twelfth Edition (RoC)*. A comment was made to Dr. Kraska during the question-and-answer period that followed his presentation that implied that NTP should give less weight to ILMA's RoC comments on MWFs because the Association did not "cooperate" with the Agency during the process more than three years ago to conduct chronic inhalation studies on MWFs. As you can understand, ILMA is very concerned about such an implication that ILMA ignored NTP at that time.

ILMA engaged in ongoing discussions with NTP during the nomination process in 2001 for the toxicology testing of MWFs. The Agency's specific request to the Association at the time was for ILMA to assist in identifying the "Coca Cola" of MWFs that would serve as an appropriate surrogate for testing from which the results could easily be extrapolated across all MWFs. NTP's preference at the time was for a commercially-available MWF, if the Association could identify the appropriate formulation.

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ILMA's response to NTP at the time was straight forward and in no way should or could be interpreted as ignoring the Agency's request. ILMA made the following points to NTP:

- There is no generic or "Coca Cola" MWF that would be representative of all MWFs.
- It would be possible to develop a representative or generic fluid formulation for each of the four major classes of MWFs (*i.e.*, straight oil, soluble oil, semi-synthetic fluid, and synthetic fluid); however, each such formulation would raise the issue of applicability of any test results to commercial fluid formulations.
- There are literally thousands of formulations within each of the four major classes of MWFs. Moreover, MWFs are complex mixtures whose compositions vary widely between manufacturers and even by a single manufacturer.
- MWFs used in metal removal operations undergo dynamic changes (including both chemical and microbial contamination) in active distribution systems, so it would be difficult to make generalizations from "virgin" to "in use" fluids.

Thus, rather than ignoring the Agency's request in 2001, ILMA went to great lengths to explain that the validity of applying the test results from one or even four generic MWF formulations to all commercially-available products was problematic. Stated differently, the Association said at the time that, while the chronic inhalation studies themselves might be valid, the application of the results to all MWFs and work settings is inappropriate. In addition to ILMA's discussions with NTP on this issue, the Association addressed its views to the Agency in letters, dated January 31 and September 19, 2001. Further, several ILMA member companies that formulate MWFs met with NTP staff at the time to discuss the likely compositions of generic test fluids.

ILMA hopes that the above clarifies what took place between the Association and the Agency during 2001. ILMA acted in a responsible fashion at that time to assist the Agency with sound and factual information, even if such information may have frustrated the study design.

The Association appreciates this opportunity to supplement Dr. Kraska's June 29, 2004 presentation.

Sincerely,



Celeste M. Powers, CAE
Executive Director

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