

**AMERICAN CHEMISTRY COUNCIL
ANTIMICROBIAL EXPOSURE ASSESSMENT TASK FORCE II (AEATF II)**

BACKGROUND ON EXPOSURE MONITORING STUDIES

January 22, 2005

The AEATF II has requested help from ILMA members to find a volunteer machining site in which human exposure monitoring for biocides can be conducted.

The AEATF II consists of 40 companies that have agreed with EPA and other regulatory agencies to generate generic exposure data on a broad range of use pattern/application method combinations and post application exposures to support registration and reregistration of such uses for most antimicrobial active ingredients. Regulatory agencies now conduct risk assessments for antimicrobial uses employing the stringent risk assessment criteria evolved from implementing the Food Quality Protection Act of 1996 (FQPA), and when empirical exposure data are not available, they use highly conservative estimates of exposures to assess antimicrobial risks. The most cost-effective and efficient way to generate an array of exposure data is to design studies that collect generic data on the widest possible range of use scenarios and active ingredients. When empirical exposure data are available, regulatory agencies do not rely on highly conservative assumptions that can severely overestimate exposures. Numerous antimicrobial active ingredients will be reregistered in the next four to six years and risk assessments will be conducted for many of the registered uses. EPA officials have said that in instances where there are no significant toxicity concerns, they will wait for confirmatory data for covered uses from these generic studies before taking final action, but only if assured that the work is underway on a registrant's behalf.

The planned studies cover most scenarios that regulatory agencies have outlined for antimicrobials and study results could be used generically by both the AEATF II and regulatory agencies for registration and reregistration purposes. During preliminary discussions on the conduct of antimicrobial exposure assessment studies with EPA, the Agency provided the Task Force with an antimicrobial exposure matrix composed of 19 application methods and 12 use site patterns.

Experienced laboratories will conduct these studies. Some studies will be done by simulation in a laboratory setting. EPA did request that AEATF II strive to conduct some of these settings in actual workplaces. The AEATF II is targeting the study for metalworking fluids to be conducted in an industrial machine shop. In this study, actual dermal and inhalation biocide exposure of workers will be measured over an eight-hour work shift. The study team will use the federal guidelines for human subjects to assure safety of the workers at the site who volunteer for the study.

The AEATF II has discussed this effort with the ILMA SHERA committee and was advised that ILMA members may be willing to help find a fluid customer that would be willing to volunteer. AEATF II would like as many volunteers as possible so that EPA can be given the opportunity to pick the most representative site for the conduct of this study.

The AEATF II work group for the metalworking study would be willing to work with an ILMA member company to develop a list of incentives for the volunteer machine shop. The project

team would certainly work with machinists and other employees of the volunteer company to explain the purpose of the project. Free training sessions on the purpose and safe handling of biocides could be given. The data collected at the site would also be shared with site management. Data collected on biocide levels in the fluid may be useful to a site that is having a particular microbe problem. Other incentives are possible and negotiable.

The AEATF II needs these data to assure that useful biocides can maintain their EPA registrations for use in metalworking fluids. Further information on this study is available at www.ilma.org. If any member is interested they should contact Has Shah (703-741-5637; has.shah@americanchemistry.com) of the American Chemistry Council or Richard Kraska (216-470-7280; kraskaconsultants@comcast.net) who leads the work group for the metalworking study.