American Chemistry Council

Antimicrobials Exposure Assessment Task Force II (AEATF II)

Background and Scoping Summary

November 28, 2006

On November 1, 2004, the American Chemistry Council Biocides Panel established an Antimicrobial Exposure Assessment Task Force II (AEATF II or Task Force) to conduct occupational exposure monitoring studies involving the mixing, loading and application of products containing antimicrobials or biocides in industrial, institutional and other occupational settings.[1] The Task Force also plans to develop methodologies to assess post-application exposure to applied products containing biocides, and will work with EPA to determine the most useful approach. The Task Force aims to design study protocols that would make study results broadly acceptable to both North American and European regulatory authorities. The Task Force currently consists of 43 companies.

The AEATF II will generate generic exposure data on a broad range of use pattern/application methods to support the Registration, Reregistration and Registration Review of most antimicrobial active ingredients. Regulatory agencies now conduct most risk assessments for antimicrobial uses employing the stringent risk assessment criteria evolved from implementing the Food Quality Protection Act of 1996 (FQPA). There is a very limited amount of empirical exposure data for antimicrobial uses and EPA and other regulators routinely have used highly conservative estimates of exposures to assess antimicrobial risks. The Task Force has been formed to generate an array of generic exposure data in the most cost-effective and efficient way possible. To this end, studies are being designed to collect generic data on the widest possible range of use scenarios.

During preliminary discussions on the conduct of antimicrobial exposure assessment studies with EPA, a range of application methods were identified as appropriate for covering 12 broad antimicrobial use patterns. The Use Patterns adopted by EPA, along with pertinent application methods that cover the vast majority of antimicrobial uses follow. Because of the overlap of application methods among exposure scenarios, generic exposure data developed under the AEATF research program will be applicable to the vast majority of antimicrobial uses.

[1] The general terms “antimicrobials and “biocides” are used interchangeably.

USE PATTERN	APPLICATION METHODS
Agricultural Premises and Equipment	pump, pour liquid, aerosol spray, spray, mop, wipe, fog, soak/immerse
Food Handling/Storage Establishments mop, wipe, fog, Premises and Equipment	pump, pour liquid, aerosol spray, spray, soak/immerse
Commercial, Institutional & Industrial mop, wipe, fog, Premises and Equipment	pump, pour liquid, aerosol spray, spray, soak/immerse
Residential and Public Access Premises	pump, pour liquid, aerosol spray, spray, mop, wipe, fog, soak/immerse
Medical Premises and Equipment	aerosol spray, spray, mop, wipe, fog, soak/immerse
Human Drinking Water Systems	pump
Industrial Process Water Systems	pump, pour liquid
Material Preservatives	pump, pour liquid, pour solid, place solid, spray, soak/immersion, airless spray, brush/roll
Antifoulant Coatings	airless spray, brush/roll
Wood Preservatives	pressure treatment, soak/immersion, brush/roll, spray
Swimming Pools	pump, pour liquid, pour solid, place solid
Aquatic Areas	pump, pour liquid, pour solid, place solid

For handlers of active ingredients, the nature of exposure is governed more by the method of application and usually quantity of chemical used (which provides a unit of exposure [mg exposure per pound of active ingredient applied][2]), rather than by where or to what the chemical is applied. For example, a disinfectant may be applied by wipe or mop, but under these two application scenarios, the handler is much closer to the source with a wipe than a mop, and the unit of exposure is expected to be greater for wipe, although more material may be applied by mop. The unit of exposure is unlikely to differ

[2] Alternative normalization methods for dermal and inhalation unit exposure metrics, e.g., mg exposure per unit time, task frequency, etc., may be used by different government jurisdictions.

whether the surface being wiped is a counter top in a restaurant or a residential kitchen counter.

However, the setting where a use occurs may impact overall exposure because of the duration of exposure. Generally, duration of exposure is proportional to the amount of product used. Typically a worker in a restaurant during an 8-hour workday will spend more time wiping countertops than will a person in a home kitchen over the same period of time. Duration of use and therefore exposure is expected to be higher for a restaurant worker than for a person in a home kitchen.

AEATF plans to collect key ancillary, pertinent data for each study including duration of specified activities, amount of active ingredient used for a specified activity, clothing configurations, viscosity and concentration of the solution used, and surface area covered, etc. These ancillary data will be stored in a custom-designed database and can be used in conjunction with other data for risk assessment. They also may be useful in evaluating alternate means of data normalization. They also will be available to elucidate any trends identified among the data points and to provide future opportunities for data evaluation.

AEATF understands that unique physico-chemical properties of antimicrobial active ingredients may confound interpretation of generic data. This appears to be particularly true of antimicrobials, since many of them are reactive and may produce volatile and/or transient reaction products that are associated with the actual biocidal activity. In continuing dialogue with regulators, AEATF is working to gain concurrence on how generic data can be used to characterize exposure to different antimicrobial active ingredients. Therefore, the Task Force will place a high priority on resolving this particular technical challenge with regulators.

The AEATF II had planned to conduct two studies to address potential post-application dermal exposure to residues on hard and non-hard surfaces. Other post-application exposures can be covered by existing methods e.g., the SWIMODEL for persons contacting recreational water. The purpose of conducting the new studies would be to produce generic transfer coefficients for general use in estimating potential dermal exposures to surface residues. This work also would include the development of a standardized protocol for measurements of chemical-specific transferable residues (TRs). The protocol would be made available to AEATF members and used in conjunction with the generic transfer coefficients to estimate potential post application exposure. Because TRs are chemical-specific and may also be matrix-specific, it is not possible to generate a generic TR number. The development of these values would be the responsibility of each individual registrant. However, in preliminary discussions with North American regulators, it has become apparent that they are highly uncertain about how they want to approach post-application data collection and risk assessment. The Task Force will continue to work with the regulators to design a post-application research program that will be of maximum utility to its members.

All Task Force studies will be conducted according to current EPA's Office of Pesticide Programs Harmonized Test Guidelines – Series 875 Occupational and Residential Exposure Test Guidelines (Series 875 A and B for handler and reentry, respectively) and conducted under EPA's FIFRA GLP standards at 40 CFR Part 160. To the extent

possible, protocols will be designed to make study results broadly applicable to a variety of use pattern/application method scenarios in both North America and Europe.

The data from the Task Force study will enable EPA to conduct more realistic risk assessments for biocides and subsequently enable the Agency to make sound regulatory decisions. The AEATF research program is being conducted in consultation with the U.S. EPA, California Department of Pesticide Regulation (CDPR), Canada Pest Management Regulatory Authority (PMRA), OECD Task Force on Biocides and European Commission Competent Authorities. Therefore, results from the AEATF sponsored studies are anticipated to be widely acceptable.

List of AEATF Planned Studies

A. MIXER/LOADER/APPLICATOR EXPOSURE STUDIES

Mop Study
Wipe Study
Pour Solid Study
Pour Liquid Study
Aerosol Spray Study
Metal Working Fluid Study
Brush/Roller Study
Pump Liquid Study
High Pressure and Low Pressure Spray Studies (4 studies)
Airless Spray Study
Immersion/Dip/Soak Study
Pressure Treatment Study
Place Solid Study
Fogging Study

B. POST-APPLICATION EXPOSURE RESEARCH

To be determined

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