UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

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MEMORANDUM

SUBJECT: Science Review of the AEATF II Mop Human Exposure Monitoring Study.
MRID Numbers 48210201, 48231201, and 48231901

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This memorandum presents the EPA/OPP Antimicrobials Division (AD) science review of the human exposure mop study submitted by the Antimicrobial Exposure Assessment Task Force II (AEATF II). The dermal and inhalation exposure data as represented in this review are acceptable and, subject to the considerations described below, are recommended for use for pesticide handler exposure assessments.

EXECUTIVE SUMMARY

This document represents the USEPA, Office of Pesticides Program, Antimicrobials Division (AD) review of the Antimicrobial Exposure Assessment Task Force II (AEATF II) mop study. The mop study investigators monitored inhalation and dermal exposures to 18 workers mopping floors using a mop and bucket. EPA confirms that the data meet the study design objective outlined in the AEATF II Governing Document and are considered the most reliable data for assessing exposures from mopping floors. The reader is referred to Section 3.0 for a discussion on the data limitations and generalizability.

EPA intends to use this AEATF II mop dataset instead of the Chemical Manufacturers Association (CMA) dataset to assess exposure for persons using an antimicrobial product while mopping floors. The exposure data in the AEATF II mop scenario represent mopping only. The scenario does not cover the pouring of the concentrate into the mop bucket; open pouring of the concentrate will be measured in a future study. If pesticide products are used with open pouring of concentrates (rather than as ready-to-use mops or with automatic dispensers), estimates of dermal and inhalation exposures from the future pour study will be combined with mop exposures from this study when assessing exposures and risks from pesticide products applied by mopping.

Select summary statistics for the "unit exposures" normalized to pounds active ingredient handled are presented in Table 1 for inhalation exposure as well as for 3 clothing configurations. Each worker wore both inner and outer whole body dosimeters (WBD) that were sectioned and analyzed separately for each body part (e.g., lower leg, upper leg, lower arm, upper arm, etc). Therefore, the analyses of residues on the dosimeters worn by each individual worker allow for the estimation of exposure for the following 3 clothing configurations:

(1) long pants, long-sleeved shirt, shoes/socks, and no gloves;

(2) long pants, short-sleeved shirt, shoes/socks, and no gloves; and

(3) short pants, short-sleeved shirt, shoes/socks, and no gloves.

For comparison, results from the earlier CMA study for mopping are also presented. The summary statistics reported in Table 1 for the AEATF II data are estimated using the lognormal mixed model while the CMA results are empirical estimates.

Table 1. Unit Exposures: Mopping Scenario				
Exposure Route	**Clothing**	**CMA[a]**	**AEATF II[b, c] (n=18)**	
		Arithmetic Mean	**Arithmetic Mean[d]**	**95th Percentile[e]**
Dermal (mg/lb ai)	Long pants/long-sleeves, shoes/socks, no gloves	71.6 ± 129 (n=6) (workers short-sleeves and long-sleeves)	23.2 (17.4, 31.4)	50.8 (33.3, 77.3)
	Long pants/short-sleeves, shoes/socks, no gloves		26.3 (20.3, 34.6)	54.7 (37.2, 80.3)
	Short pants/short-sleeves, shoes/socks, no gloves	Not available	82.1 (55.1, 125.5)	215 (124, 373)
Inhalation ($\mu g/m^3$/lb ai)	Breathing zone	75.6 ± 87.4 (n=8) (all non-detects)	52.4 (27.0, 105.7)	130 (54.8, 318)

[a] CMA data: Mean ± std. Inhalation LOQ varied among samples. Task of mixing of product, mopping, and dumping mop bucket; janitors as subjects; observations of incidental contact (splash & contact with mop); and sites included hospital, university building, and office building.
[b] Dermal unit exposures reflect method removal efficiencies of 90.3% for hands and 58.8% for face/neck measurements. The percent of dermal exposure representing the hands is 93% for the long pants scenario and 38% for the short pants scenario.
[c] Lower and upper 95% confidence intervals reported in "( )"; statistics are estimated using a variance component model accounting for correlation between measurements conducted within the same field study (i.e., measurements collected during the same time and at the same location). Additional model estimates (e.g., empirical and simple random sample assumptions) are described in Appendix A.
[d] Arithmetic Mean (AM) = GM * $\exp\{0.5*(\ln GSD)^2\}$
[e] 95th percentile = GM * $GSD^{1.645}$

The following important points with respect to these data are noted:

- The AEATF II data and associated unit exposures are considered superior to the existing mop dataset (i.e., CMA data). AEATF II efforts represented a well-designed, concerted process to collect reliable exposure data in a way that takes advantage of and incorporates a more robust statistical design, better analytical methods, and improved data handling techniques.

- The report containing dermal and inhalation exposure results is considered scientifically complete. No additional monitoring data are required at this time.

- The data are applicable for assessment of exposure to non-volatile pesticides. The cutoff for volatility is reviewed on a case-by-case basis (generally <1E-4 mmHg @ 20° C is considered non-volatile).

- Statistical analysis provides support for proportionality between dermal exposure and pounds of active ingredient (ai) handled as described in Section 2.4 below. However, the statistical analysis suggests that the inhalation exposure is independent of the amount of pesticide usage.

To assess the risks resulting from mopping exposures, EPA will combine appropriate unit exposure (UE) values with chemical-specific inputs (maximum labeled application rates, dermal absorption rates, and toxicological endpoints of concern) and default inputs (high end area treated or volume applied) in the standard pesticide handler exposure algorithm (i.e., potential

exposure = UE (mg/lb ai or µg/m^3/lb ai) x absorption (%) if applicable x maximum label rate (lb ai/gallon) x volume (gallons)).

1.0 Background

The AEATF II is developing a database representing inhalation and dermal exposure during a number of antimicrobial handler scenarios. A scenario is defined as a pesticide handling task based on activity (e.g., application) and equipment type (e.g., mop & bucket, ready-to-use wipes, pressure treatment of wood facilities, painting). The AEATF II is monitoring both inner and outer dosimeters which will allow the EPA to estimate exposures to various clothing configurations (e.g., long pants, long-sleeved shirt or long pants, short-sleeved shirt or short pants, short-sleeved shirts, plus shoes, socks, and no gloves).

1.1 Mop Scenario Defined

The "scenario" in this study is defined as mopping floors and emptying each mop bucket while wearing long-sleeved shirts, long pants, shoes, socks, and no gloves. The conditions under which the study participants handle the pesticide as they are monitored are referred to as the scenario. Both inner and outer dosimeters were worn by the monitored study participants, and both inner and outer dosimeters were analyzed for residues. This scenario is defined to exclude pouring the antimicrobial product into the mop bucket. Antimicrobial products may be added to mop buckets in various ways, including open pouring from no-glug containers, open pouring from typical glug containers, or automated dispensers; some mop systems are ready-to-use and require no pouring of the concentrated product. Open pouring a pesticide concentrate will be monitored in a future AEATF II study.

1.2 Study Objective

The study objective is to monitor inhalation and dermal exposures to be used as inputs in exposure algorithms to predict future exposures to persons mopping floors. Dermal and inhalation exposure monitoring was conducted while study participants mopped floors and emptied the mop buckets; results are expressed, for use in exposure assessments, as "unit exposures".

"Unit exposure" (UE) is defined as the expected external chemical exposure an individual may receive (i.e., "to-the-skin" or "in the breathing zone") per weight-unit of chemical handled and is the default data format used in pesticide handler exposure assessments. Mathematically, unit exposures are expressed as "handler" exposure normalized by the amount active ingredient handled by participants in scenario-specific exposure studies (e.g., mg exposure/lb ai handled). EPA uses these UEs generically to estimate exposure for other chemicals having the same or different application rates.

Criteria for determining when a scenario is considered complete and operative have been developed (Myrta 2007). Outlined in the AEATF II Governing Document, the criteria can be briefly summarized as follows:

- The primary objective of the study design is to be 95% confident that key statistics of normalized dermal exposure are accurate within 3-fold. Specifically, the upper and lower 95% confidence limits should be no more than 3-fold (K=3) higher or lower than the estimates for each the geometric mean, arithmetic mean, and 95th percentile dermal unit exposures. To meet this primary objective AEATF II proposed an experimental design with a 3 cluster by 6 monitoring events (MEs).

- A secondary objective is to evaluate the presumption of proportionality between exposure and amount of active ingredient handled. To meet this secondary objective, AD used the same statistical tests as that being proposed by the AHETF and HED. They proposed a log-log regression test to distinguish complete proportionality (slope = 1) from complete independence (slope = 0), with 80% statistical power, achieved when the width of the 95th confidence interval of the regression slope is 1.4 or less (Sarkar 2010).

1.3 Protocol Modifications, Amendments, and Deviations

1.3.1 Protocol Modifications Subsequent to EPA/HSRB Review

EPA required two science-based modifications to the protocol (EPA 2008). EPA indicated that the scope of the monitoring event (ME) needed to be revised to include the monitoring of the workers disposing of the spent mop bucket solution. The AEATF II responded by including the typical disposal events as part of the ME (i.e., pouring the spent solution from the bucket into a sink as the worker would normally do). EPA also required a residue removal efficiency study to address the efficiency of the hand wash and face/neck wipes. The AEATF II responded by purchasing an existing study conducted to assess the removal efficiency (Boatwright 2007, MRID 47214801).

The HSRB provided written discussion on a number of concerns including:

- ***Sampling size and replication of ME*** – The HSRB questioned whether or not the sampling size of 3 clusters by 6 MEs per cluster would provide an accuracy goal of k=3. Based on EPA's statistical review provided in Section 2.4 below, the sampling size as designed is sufficient to meet the accuracy goal. The HSRB also discussed the need for repeat measurements or in lieu of repeat measurements the need for a discussion on the limitations of the study design. EPA acknowledges that ideally, the sample design would benefit from a large sample size that includes multiple replicates from each worker. However, EPA also recognizes that the repeat measures is as a trade-off for overall sample size (resource issue). Sampling the same worker twice (or 3X, 4X....) would have provided information on the within-worker variability (e.g., do some workers consistently experience high or low exposures day-after-day while others are highly variable?). Such information would be useful, especially because worker assessments generally represent longitudinal (multi-day) exposures. But any gain in characterization of within-worker variability information would result in a loss in characterization of between-worker variability and, given a fixed sample size, in accuracy (the fold relative accuracy or "K" factor as discussed in the AEATF II Governing Document). With respect to the K-factor, because of the inherent correlation, sampling workers multiple times reduces "effective"

sample size - which, due to the relationship between sample size, variability, and accuracy -- would have made the K-factor unacceptably larger. Thus, if EPA wanted both within-worker variability information and a K=3, the AEATF II would need to increase the total number of workers monitored not only in this study but for the other planned scenarios as well. Thus, the trade-off becomes the number of pesticide exposure scenarios that could be monitored by the AEATF II.

Alternatively, EPA could have accepted a larger K-factor if within-worker variability was more desirable. Instead, because assumptions can be made for within-worker variability in order to model longitudinal exposures from the collected 1-day exposures, EPA elects to continue to utilize the 3-fold K factor as its accuracy benchmark In summary, given the fixed sample size, EPA has chosen the larger "effective" sample size/smaller K-factor and between-worker variability, while sacrificing more concrete information on within-worker variability.

- ***ME duration*** – The HSRB noted that the durations of the MEs should be longer. The AEATF II responded with the following, which was discussed and accepted by the JRC: "*…information from the following sources: 1) the American Hospital Association (http://www.aha.org/aha_app/index.jsp), the American Society for Health Care Environmental Services (http://www.ashes.org/ashes_app/index.jsp), and the U.S. EPA's Environmental Best Practices for Health Care Facilities (JCAHO Environment of Care Standards 1.3,2.3,4.0, November 2005) indicates that a single individual at a hospital would typically clean from 15 to 20 hospital patient rooms per day during a standard 6.5 hour shift. In addition to hospitals, application of antimicrobials by mopping is also likely at medical and dental offices and specialty lodging facilities. In these settings JohnsonDiversey Inc. feels that the lower typical range could be less than 15 rooms per day. Consequently, depending on the degree of conservatism desired, 20-25 rooms/day would appear to be a reasonable upper bound for these professional applicators. Thus, using the above estimate of 3.3 minutes/room, the total amount of mopping time required for these 20-25 rooms would be about 66-83 minutes per workday. This result is also consistent with the maximum duration of 66 minutes found by Popendorf et al. (1992). Rounding the upper value of 83 minutes to the nearest half-hour suggests that about 90 minutes of mopping per workday is a reasonable maximum duration to use in the AEATF II mopping study.*"

- ***Amount active ingredient handled (AaiH)*** – The HSRB noted that the AaiH instead of exposure duration should be used to differentiate among MEs. Other protocols (e.g., aerosol can spraying) have been modified to use the amount handled instead of exposure duration to differentiate among MEs. However, for the mop study, the information above on mopping duration was determined by the JRC to be the best information available on the task of mopping. Individual workers were given the ability to choose to use the appropriate amount of mop diluted treatment solution and mop as they would normally do.

- ***Proportionality between exposure and AaiH*** – The HSRB indicated in their written protocol review comments that they wanted to see a discussion of proportionality and

regressions with the completed data. EPA reviewed the data and presents the analysis of proportionality in Section 2.4 below and Appendix A. In brief, the statistical analysis compared pounds of active ingredient as the normalization variable. *[Note: To be thorough, alternative analyses were also performed using other normalization variables of exposure duration and number of mop buckets used and these results are also presented in Appendix A but are not summarized within this review.]* Results indicate that the preferred normalization method is by pounds active ingredient for the dermal exposure and that these exposures can be assumed to be proportional to pounds active ingredient. Inhalation exposure cannot be assumed to be proportional to the pounds active ingredient.

- ***Monitoring equipment*** – The HSRB indicated that they wanted to see better descriptions of the equipment used to measure light levels, air temperature, and relative humidity. Better descriptions of these monitoring devices within the protocol are not apparent. However, the environmental conditions (e.g., temperature & humidity) do not appear to have been a factor that would have hampered the workers in their performance of their mopping activities.

1.3.2 Protocol Amendments

The study report (page 92) lists 7 protocol amendments. The amendments range from changing the building selection criteria to improving efficiency of the conduct of the study. The building selection criteria were updated based on EPA requirement of including the dumping of spent mop solution. A criterion was added to include that the building must have *"…janitorial sinks or floor drains suitable for disposing of used mopping solutions…"* (page 378 of study report).

1.3.3 Protocol Deviations

The majority of the deviations were due to the air sampling. For a detailed description of the protocol deviations the reader is referred to pages 92 to 94 in the study report. These deviations did not adversely affect the outcome of the study.

1.4 Material & Methods

The following is a summary of the field aspects of the study:

- ***Study Location:*** The mop study was conducted in Fresno County, CA. Pictures and floor plans of clusters 1, 2, and 3 are provided in Appendix H, I, and J on study report pages 257, 260, and 263, respectively. Each cluster is a different building. The buildings are an office building, a Rite Aid, and a retired teacher's memorial building.

- ***Pesticide Tested:*** The test substance monitored was didecyl dimethyl ammonium chloride (DDAC), CAS number 7173-51-5. DDAC was formulated in a product known as Buckeye Sanicare Lemon Quat (EPA Reg No. 47371-131-559). This product also contained another Quat, ADBAC. DDAC and ADBAC are in Lemon Quat at 2.54% and 1.69%, respectively.

- ***Test System:*** The mop and bucket configuration used in the study and presented in Figure 1 is a string mop and open bucket with a wringer to wring the mop. The mop bucket is a 35 Quart Splash Guard Down-Press Combo Pack (product No. 335-37YW) manufactured by Continental Manufacturing Company and the mop head is a Bulldog Blend Loop, Narrow Band, Large string mop (product Nos. A05013 by Wilen and 151032 by Buckeye).

Figure 1: Mop and Bucket Equipment Used in Study.

- ***Sequence of Events:*** A table listing the chronological order of key events for the study (e.g., test site selection, IIRB approval, subject recruitment, start of each monitoring events, etc) is reported on page 100 of the study report. A second listing of the sequence of events is provided on pages 161 - 162 of the supplemental #1 report. Each list reports different set of details such that both need to be reviewed for a full accounting of the sequence.

- ***Sample Size:*** The study consisted of 3 clusters and 6 MEs per cluster for a total of 18 MEs.

- ***Tank Mix Solution:*** The diluted treatment solution of Lemon Quat was prepared by the researchers in a 50 gallon tank. The preparation of the treatment solution was not part of the monitoring events. The 2.54% DDAC in concentrated solution was diluted 1:64 (0.0397% DDAC) in cluster 1 and 1:63 (0.0403% DDAC) in clusters 2 and 3.

- ***Duration & AaiH:*** For each of the 3 clusters, the MEs were randomly assigned to 1 of the 6 purposively selected mopping times. The pre-determined mopping times were:

    - 30 to <40 minutes
    - 40 to <50 minutes
    - 50 to <60 minutes
    - 60 to <70 minutes
    - 70 to <80 minutes
    - 80 to <90 minutes

    Actual mopping duration for each ME is reported in Table 2 below. The amount of DDAC handled by the 18 MEs ranged from 0.00308 to 0.0183 lbs ai with a mean of 0.00634 ± 0.00328 lb ai. The 18 MEs used varying numbers of mop bucket refills/dumps ranging from 2 to 6 buckets per ME. The amount ai per ME is the amount actually mopped onto the floor, determined by weighing the bucket before and after mopping. These data are also reported in Table 2 below. Because the workers were instructed to work as they normally would do, the number of buckets and amount of active ingredient handled did not correlate to the monitoring duration. Some workers used more buckets of mop solution than others. For example, in cluster 1 subject number ID M6 mopped for 45 minutes and used 6 buckets (0.00669 lb ai) while M27 worked for 85 minutes yet only used 2 buckets (0.00419 lb ai).

- ***Mopping procedures***: Appendix K on page 266 of the study report records the observation notes taken during each ME. The workers were instructed to mop "*as they would normally do*". Typical mopping procedures/observations were that the workers mopped either in a side-to-side motion or figure 8 and walked backwards as they mopped. Mop heads were wrung at varying times as the study participant would normally do.

- ***Environmental Conditions*:** Environmental conditions (humidity and temperature) are reported for the MEs on pages 105 to 107 of the study report (note: humidity readings not available for 5 MEs in cluster 3). The humidity averaged in the 40% range. Temperatures averaged in the low 70º F range. The heating ventilation air conditioning (HVAC) system descriptions for clusters 1 and 3 are reported on page 108 of study report (not available for cluster 2). Cluster 1 reports the only air changes per hour (ACH), which is 8.1 ACH. It is unclear how the ACH was measured and if it represented ACH of outside make-up air or re-circulating air. However, based on the low vapor pressure of DDAC and expected minimal aerosol generation, the ACH is not a significant factor for this scenario (all air samples measured residues above the limit of quantification (LOQ)). Lighting levels were not measured.

2.0 Results

2.1 QA/QC Recovery Results

Controls: The non-fortified field and laboratory control samples were all less than the limit of quantification (LOQ). The LOQs for the various matrices are air sampling tubes 10 ng/sample, neck/face wipe 50 ng/sample, WBD sections 3 µg/sample, socks 1 µg/sample, and hand wash 1 µg/sample.

Laboratory Recoveries: Most of the individual laboratory fortified recovery values range within 70 to 120 percent. Exceptions include a few outside of the 120 percent upper bound, none below 70 percent. A summary of the overall concurrent laboratory recovery samples for each monitoring matrix by cluster is reported on page 94 of the study report. The mean recoveries in cluster 1 for all matrices range from 101 ± 4 to 113 ± 3; cluster 2 ranged from 100 ± 5 to 110 ± 9; and cluster 3 ranged from 95 ± 4 to 107 ± 7.

Field Recoveries: Most of the individual field fortified recovery values range within 70 to 120 percent. Exceptions include a few outside of the 120 percent upper bound, none below 70 percent. A summary of the overall field fortified recovery samples for each monitoring matrix by cluster is reported on page 95 of the study report. The mean recoveries in cluster 1 for all matrices range from 91 ± 8 to 108 ± 22; cluster 2 ranged from 91 ± 7 to 109 ± 8; and cluster 3 ranged from 92 ± 11 to 102 ± 8. All exposure/field matrices were corrected for the field fortified recovery results.

2.2 Calculating Unit Exposures

Dermal Unit Exposure: Dermal exposure is measured using 100% cotton inner and outer "whole body dosimeters" (WBD). The inner WBDs were worn underneath normal work clothing (i.e., long-sleeved shirt, long pants, socks and shoes). The normal work clothing worn over the inner WBDs were also analyzed and reported as "outer" dosimeters. In addition, dermal exposures also included hand washes (collected at the end of the day and during breaks), face/neck wipes (also collected during the ME to wipe off sweat; see study report page 40), and inner and outer socks worn underneath shoes. The inner and outer WBDs are sectioned and analyzed by body part (i.e. upper and lower arms, front and rear torso, and upper and lower legs). The inner WBD sections were only analyzed if the corresponding outer dosimeter section tested above the LOQ. One-half the LOQ was substituted for all non detected samples. If the outer dosimeter was ND then the inner dosimeter for the same body section was also considered to be ND and ½ LOQ was substituted for those WBD sections as well. The study report for total dermal exposure substituted a single ½ LOQ value for multiple ND samples. EPA has recalculated the total dermal exposure substituting ½ LOQ for each of the ND WBD sections (resulting in a minimal impact on the results). All samples are adjusted as appropriate according to recovery results from field fortification samples.

Dermal exposures to the hands and face/neck are also corrected for sampling efficiency (see study report pages 59 and 60). A removal efficiency study for hand washes and wipes was performed using the test substance, DDAC, in a previous study (Boatwright 2007, MRID

47214801). The hand wash removal efficiency for DDAC is 90.3%. The same study also performed wipes. The wipe removal efficiency is calculated as 58.8% and is used to correct the face/neck samples.

Total dermal exposure is calculated by summing exposure across all body parts for each individual monitored. The following WBD sections are summed to calculate the clothing configuration of long pants, long-sleeved shirts (plus inner socks, face/neck wash, and hand wash):

- inner lower and inner upper arms,
- inner front and inner rear torso, and
- inner lower and inner upper legs.

The following WBD sections are summed to calculate the clothing configuration of long pants, short-sleeved shirts (plus inner socks, face/neck wash, and hand wash):

- outer and inner lower arm,
- inner upper arm,
- inner front and inner rear torso, and
- inner lower and inner upper leg.

The following WBD sections are summed to calculate the clothing configuration of short pants, short-sleeved shirts (plus inner socks, face/neck wash, and hand wash):

- outer and inner lower arm,
- inner upper arm,
- inner front and inner rear torso,
- inner upper leg, and
- inner and outer lower leg.

Dermal unit exposures (i.e., mg/lb ai handled) are calculated by dividing the summed total exposure by the amount of active ingredient handled. The AEATF II's study report normalized the dermal exposures by milligrams (mg) of active ingredient applied. EPA recalculated the exposures and expressed the results as mg/lb ai applied. EPA prefers the normalization by pounds to coincide with the English units reported on pesticide labels (e.g., pounds, ounces).

Inhalation Exposure: Inhalation exposure is measured using a personal air sampling pump and an OSHA Versatile Sampler (OVS) tubes. The tube is attached to the worker's collar to continuously sample air from the breathing zone. The sampling pumps were run continuously, even during break. Collected residue, per standard practice, is adjusted for recovery from field fortification samples.

Inhalation unit exposures (i.e., $\mu g/m^3$/lb ai handled) are calculated by dividing the air concentrations by the amount of ai handled.

2.3 Dermal and Inhalation Exposure Results

Results -- A summary of the 18 MEs and their dermal and inhalation UEs for the mop scenario are presented in Table 2 (long pants, long sleeved-shirts), Table 3 (long pants, short-sleeved shirts), and Table 4 (short pants, short-sleeved shirts). These tables report the results for each individual worker along with empirical statistical summaries of each cluster and overall exposures. The inhalation UEs are the same for each of the clothing configurations (i.e., the three clothing scenarios are from the same worker). Therefore, the inhalation exposures are only reported once (in Table 2).

Appendix A provides alternative statistical models to estimate the exposure summary statistics, including:

- Empirical simple random sampling model (see Appendix A Table 1);
- Lognormal simple random sampling model (see Appendix A Tables 3 through 6); and
- Lognormal mixed model (see Appendix A Table 2).

The results of the lognormal mixed model have been selected to best represent the summary statistics for the unit exposures (as reported in Table 1 above). For a detailed discussion of the lognormal mixed model calculations and results the reader is referred to Appendix A.

Observations -- This mop study includes the recording of individual participant activities by observers. Observations recorded during each ME are reported starting on page 266 of the study report and record the "real world" events during mopping as a worker would normally do. There is one aberrant dermal exposure recorded for subject number ID M6 in cluster 1. For M6, the outer dosimeter on the lower leg has a residue value of 3607 µg. The observer noted that for this worker the mop brushed the lower leg when exiting through a door and mop solution also splashed on knee when pushing the bucket over door threshold. This one value on M6's outer lower leg impacts the summary statistics for the short pants clothing scenario. The empirical results with and without (outer lower leg set to 0) the lower legs are as follows for the short pants scenario:

- Mean dermal exposure with the high lower leg residue value is 89.0 ± 120 versus 59.0 ± 33.7 mg/lb ai without the high lower leg residue value for subject number ID M6.
- 95^{th}%tile dermal exposure with the high lower leg residue value is 189 versus 108 mg/lb ai without the high lower leg residue value for subject number ID M6.

The JRC views incidental contact of the mop brushing against the leg within the norm of what may occur during mopping of floors. Therefore, the lower leg value is not treated as a statistical outlier and the JRC recommends using the dermal UE based on a data set which includes the lower leg value for subject number ID M6.

Impact of Non-detects -- Minimal exposure inside of the clothing was expected for many of the body parts sampled for the mop pesticide application pesticide technique. Even with sensitive analytical methods for the surrogate compound, DDAC, many samples were non-detect (ND). Samples with results less than the limit of quantification (LOQ) are included in the calculation of

total exposure as ½ LOQ. All of the hand and air samples were greater than the LOQ. For the face/neck wipe samples 2 of 18 samples were less than the LOQ. For the inner WBD 66 of 72 sectioned body parts are less than the LOQ and 15 of the 18 inner socks were less than the LOQ.

The impact of the ND samples for the short pants, short-sleeved shirt, shoes, socks, and no glove clothing configuration for the dermal UE is minimal. The following data presentation (empirical estimates) illustrate the change in the dermal UE values when NDs were substituted with 0, ½ LOQ, and the full LOQ.

Comparison of Dermal UE (mg/lb ai) for Non-detects Equal to 0, ½ LOQ, Full LOQ			
Statistic	NDs = 0	NDs = ½ LOQ	NDs = Full LOQ
Mean	87	89	91
95^{th}%tile	188	189	191

A similar analysis was not performed for the long pants, long-sleeved shirt or the long pants, short-sleeved shirt (plus shoes, socks, and no gloves) clothing configurations but the impact of the non-detects on these clothing configurations is expected to be minimal too. This expectation is based on the higher contribution of the hand exposure to total dermal exposure for the long pants, long-sleeved shirt clothing configuration. For the long pants, long-sleeved shirt configuration, 93 percent of the total dermal exposure is attributed to the hand exposure. In comparison, 38 percent of the total dermal exposure for the short pants, short-sleeved shirt scenario is attributed to the hands.

Table 2. Summary (Empirical) of Dermal and Inhalation Results for Mop -- Long Pants, Long-sleeved Shirt, Shoes/socks, and No Glove Scenario.

Cluster	Subject Order	Subject Number ID	Task Duration (minutes)	Surface Area (sq ft)	Number Buckets	Pounds ai Handled	Dermal Exposure (µg)	Inhalation Exposure (µg/m3)	Unit Exposures	
									Dermal (mg/lb ai)	Inhalation (µg/m3/lbai)
1	MW-01	M13	31	3324	3	0.00308	40.7	0.413	13.2	133.9
	MW-02	M6	45	4996	6	0.00669	42.8	0.334	6.4	49.9
	MW-03	M12	59	5050	3	0.00584	136.3	0.333	23.3	57.0
	MW-04	M28	67	4189	4	0.00538	289.4	0.209	53.7	38.8
	MW-05	M15	53	1884	5	0.00556	191.8	0.437	34.5	78.5
	MW-06	M27	85	5155	2	0.00419	75.7	0.292	18.1	69.7
		Mean	**57**	**4100**	**4**	**0.00513**	**129**	**0.336**	**24.9**	**71.3**
		Std	**19**	**1291**	**1**	**0.00129**	**98**	**0.083**	**17.0**	**33.7**
2	MW-07	M8	38	5884	6	0.00556226	66.9	0.123	12.0	22.1
	MW-08	M24	51	4390	5	0.01833364	154.3	0.107	8.4	5.8
	MW-09	M2	63	8295	5	0.00406091	66.9	0.108	16.5	26.6
	MW-10	M4	69	4952	4	0.0061509	162.7	0.242	26.5	39.3
	MW-11	M10	79	14191	4	0.00546085	112.3	0.216	20.6	39.6
	MW-12	M21	90	6688	3	0.00482371	134.3	0.128	27.8	26.5
		Mean	**65**	**7400**	**5**	**0.00740**	**116**	**0.154**	**18.6**	**26.7**
		Std	**19**	**3599**	**1**	**0.00540**	**42**	**0.0592**	**7.8**	**12.5**
3	MW-13	M7	38	4008	6	0.00838418	288.3	0.273	34.4	32.6
	MW-14	M18	49	4989	6	0.00703495	116.5	0.391	16.6	55.6
	MW-15	M26	59	5425	5	0.00740312	365.2	0.431	49.3	58.2
	MW-16	M14	69	4339	4	0.00699086	70.3	0.257	10.1	36.8
	MW-17	M20	79	5362	4	0.00528448	79.2	0.249	15.0	47.1
	MW-18	M1	89	6161	3	0.00392864	95.9	0.195	24.4	49.6
		Mean	**64**	**5047**	**5**	**0.00650**	**169**	**0.299**	**25.0**	**46.6**
		Std	**19**	**783**	**1**	**0.00161**	**125**	**0.091**	**14.7**	**10.2**
Overall		Mean	62	5516	4	0.00634	138	0.263	22.8	48.2
		Std	18	2553	1	0.00328	92	0.110	13.3	27.6
		Median	61	5023	4	0.00556	114	0.253	19.3	43.3
		Geo Mean	59	5094	4	0.00585	114	0.239	19.5	40.9
		95th%tile	89	9179	6	0.00988	301	0.432	50.0	86.8

Table 3. Summary (Empirical) of Dermal Results for Mop -- Long Pants, Short-sleeved shirt, Shoes/socks, and No Glove Scenario.								
Cluster	Subject Order	Subject Number ID	Task Duration (minutes)	Surface Area (sq ft)	Number Buckets	Pounds ai Handled		Unit Exposures Dermal (mg/lb ai)
1	MW-01	M13	31	3324	3	0.00308		20.3
	MW-02	M6	45	4996	6	0.00669		12.3
	MW-03	M12	59	5050	3	0.00584		25.2
	MW-04	M28	67	4189	4	0.00538		62.4
	MW-05	M15	53	1884	5	0.00556		40.3
	MW-06	M27	85	5155	2	0.00419		18.4
		Mean	**57**	**4100**	**4**	**0.00513**		**29.8**
		Std	**19**	**1291**	**1**	**0.00129**		**18.5**
2	MW-07	M8	38	5884	6	0.00556		12.6
	MW-08	M24	51	4390	5	0.01833		8.50
	MW-09	M2	63	8295	5	0.00406		17.5
	MW-10	M4	69	4952	4	0.00615		27.5
	MW-11	M10	79	14191	4	0.00546		24.9
	MW-12	M21	90	6688	3	0.00482		34.9
		Mean	**65**	**7400**	**5**	**0.00740**		**21.0**
		Std	**19**	**3599**	**1**	**0.00540**		**9.87**
3	MW-13	M7	38	4008	6	0.00838		35.3
	MW-14	M18	49	4989	6	0.00703		18.6
	MW-15	M26	59	5425	5	0.00740		55.2
	MW-16	M14	69	4339	4	0.00699		14.1
	MW-17	M20	79	5362	4	0.00528		15.8
	MW-18	M1	89	6161	3	0.00393		26.9
		Mean	**64**	**5047**	**5**	**0.00650**		**27.6**
		Std	**19**	**783**	**1**	**0.00161**		**15.6**
Overall		Mean	62	5516	4	0.00634		26.1
		Std	18	2553	1	0.00328		14.7
		Median	61	5023	4	0.00556		22.6
		Geo Mean	59	5094	4	0.00585		22.8
		95th%tile	89	9179	6	0.00988		56.3

Table 4. Summary (Empirical) of Dermal Results for Mop -- Short Pants, Short-sleeved shirt, Shoes/socks, and No Glove Scenario.								
Cluster	Subject Order	Subject Number ID	Task Duration (minutes)	Surface Area (sq ft)	Number Buckets	Pounds ai Handled	Dermal Exposure (µg)	Unit Exposures Dermal (mg/lb ai)
1	MW-01	M13	31	3324	3	0.00308	82	26.4
	MW-02	M6	45	4996	6	0.00669	3690	551.2
	MW-03	M12	59	5050	3	0.00584	569	97.5
	MW-04	M28	67	4189	4	0.00538	565	104.9
	MW-05	M15	53	1884	5	0.00556	253	45.4
	MW-06	M27	85	5155	2	0.00419	103	24.7
		Mean	**57**	**4100**	**4**	**0.00513**	**877**	**141.7**
		Std	**19**	**1291**	**1**	**0.00129**	**1395**	**203.6**
2	MW-07	M8	38	5884	6	0.00556	698	125.5
	MW-08	M24	51	4390	5	0.01833	493	26.9
	MW-09	M2	63	8295	5	0.00406	227	56.0
	MW-10	M4	69	4952	4	0.00615	232	37.8
	MW-11	M10	79	14191	4	0.00546	400	73.2
	MW-12	M21	90	6688	3	0.00482	198	41.1
		Mean	**65**	**7400**	**5**	**0.00740**	**375**	**60.1**
		Std	**19**	**3599**	**1**	**0.00540**	**196**	**35.9**
3	MW-13	M7	38	4008	6	0.00838	789	94.1
	MW-14	M18	49	4989	6	0.00703	440	62.5
	MW-15	M26	59	5425	5	0.00740	505	68.2
	MW-16	M14	69	4339	4	0.00699	245	35.0
	MW-17	M20	79	5362	4	0.00528	152	28.8
	MW-18	M1	89	6161	3	0.00393	403	102.5
		Mean	**64**	**5047**	**5**	**0.00650**	**422**	**65.2**
		Std	**19**	**783**	**1**	**0.00161**	**222**	**29.9**
Overall		Mean	62	5516	4	0.00634	558	89.0
		Std	18	2553	1	0.00328	807	120
		Median	61	5023	4	0.00556	401	59.2
		Geo Mean	59	5094	4	0.00585	358	61.3
		95th%tile	89	9179	6	0.00988	1224	189

2.4 Evaluation of Scenario Benchmark Objectives

Primary Benchmark Objective -- The data from the mop study have been analyzed to see if this mop scenario meets the primary AEATF II objective of a relative 3-fold accuracy (i.e., K=3). Using the SAS code developed by the Agricultural Handler Exposure Task Force (AHETF) and independently confirmed by the Health Effects Division (HED) (and now modified by AD), EPA has determined and presents the analysis that the mop study results meet the 3-fold relative accuracy objective (Sarkar 2010). Appendix A provides the detail benchmark analysis which is summarized as follows:

Primary Benchmark Objective: fold Relative Accuracy (fRA)

The primary benchmark objective for AEATF II scenarios is for select statistics – the geometric mean (GM), the arithmetic mean (AM), and the 95th percentile (P95) – to be accurate within 3-fold with 95% confidence (i.e., "fold relative accuracy"). EPA has analyzed the data using various statistical techniques to evaluate this benchmark. First, to characterize the unit exposures (also referred to as "normalized exposure"), lognormal probability plots of dermal and inhalation UEs (adjusted for residue method collection efficiencies) are provided in Figures 2 to 5 for the 3 clothing configurations as well as inhalation exposure.

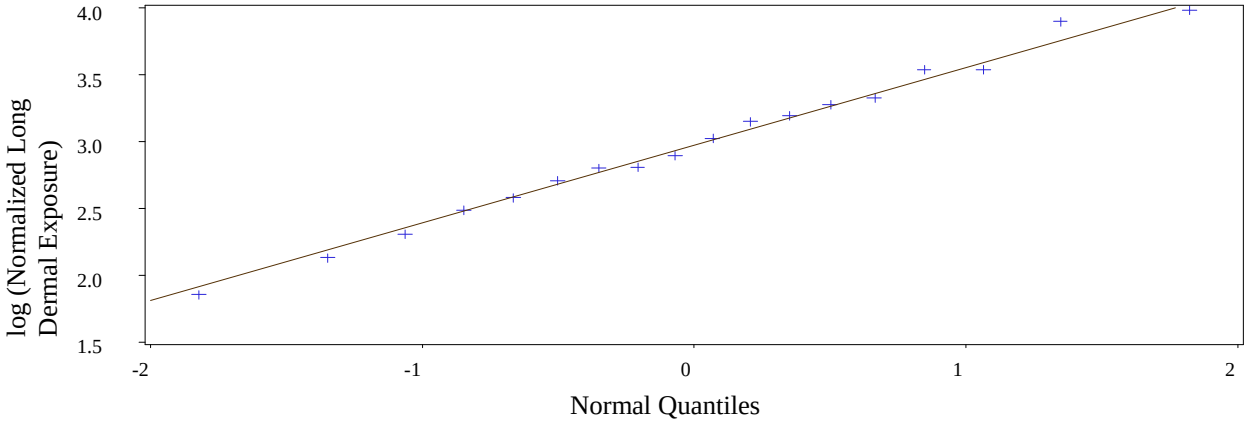

Figure 2: Quantile plot normalized long dermal exposure data with a lognormal distribution normalized by pounds of Active Ingredient handled.

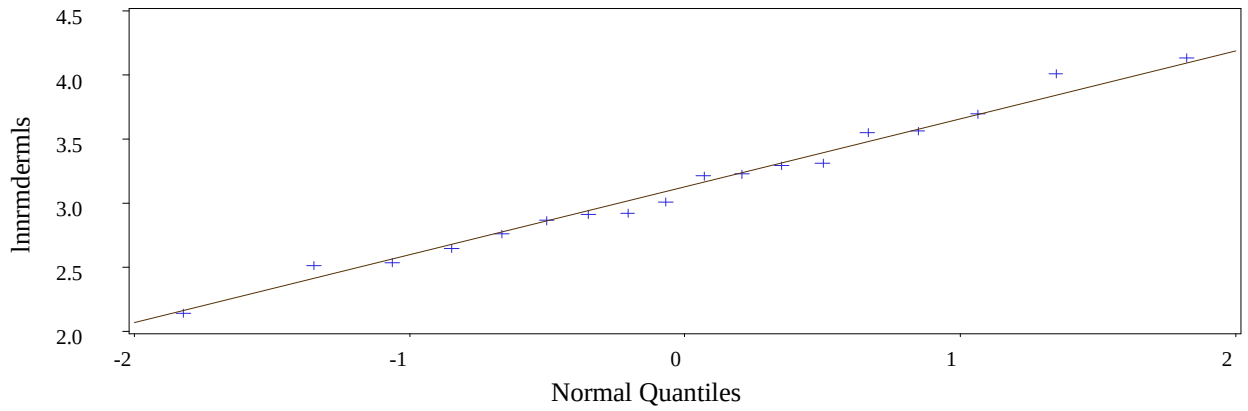

Figure 3: Quantile plot normalized long short dermal exposure data with a lognormal distribution normalized by pounds of Active Ingredient handled.

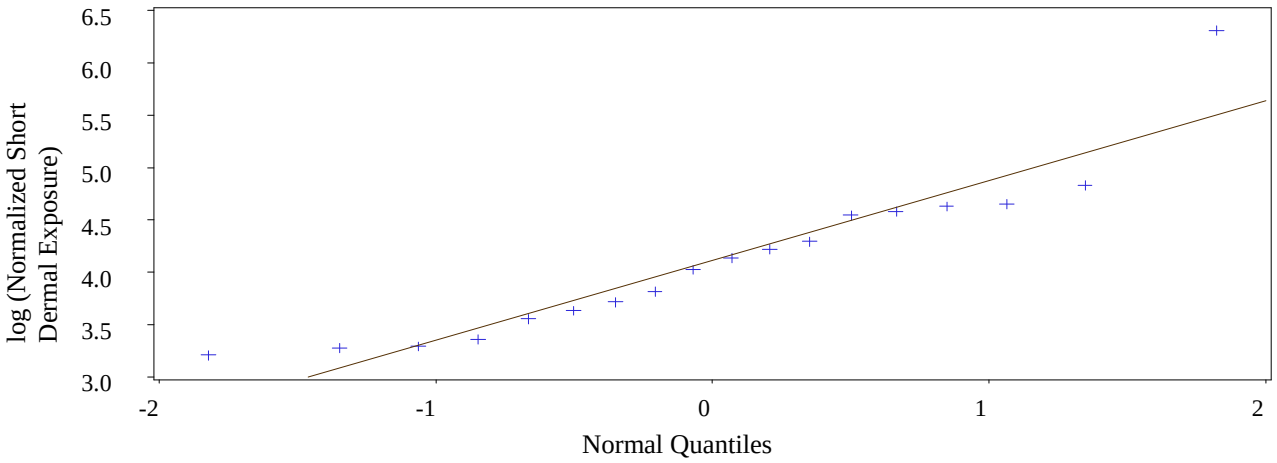

Figure 4: Quantile plot normalized short dermal exposure data with a lognormal distribution normalized by pounds of Active Ingredient handled.

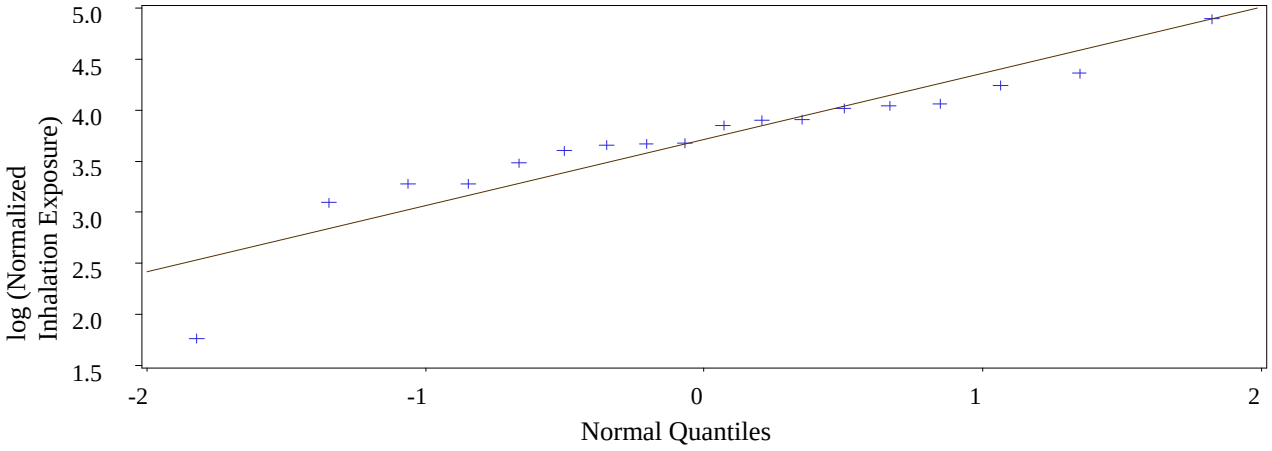

Figure 5: Quantile plot normalized inhalation exposure data with a lognormal distribution normalized by pounds of Active Ingredient handled.

Next, EPA calculated estimates of the GM, AM and P95 based on three different calculation methods:

- Empirical estimates;
- Assuming a lognormal distribution and a simple random sample (SRS); and,
- Hierarchical variance component modeling to account for potential ME correlations.

The 95% confidence limits for each of these estimates were obtained by generating 10,000 parametric bootstrap samples. Then, the fRA for each was determined as the maximum of the two ratios of the statistical point estimates with their respective upper and lower 95% confidence limits. Table 5 below presents the results for the long pants, short-sleeved shirt and the inhalation exposures. The results of the benchmark analysis for the other clothing configurations are reported in Appendix A, Table 3 (long pants, long-sleeved shirt) and Appendix A, Table 4 (short pants, short-sleeved shirt).

Table 5. Results of Primary Benchmark Analysis for Long Pants, Short-sleeved Shirt and Inhalation.

	Dermal Exposure			Inhalation Exposure		
Statistic	**Unit Exposure Estimate (mg/lb ai)**	**95% CI**	**fRA**	**Unit Exposure Estimate (ug/m^3/lb ai)**	**95% CI**	**fRA**
GM_S	22.8	17.9 - 29.3	1.3	40.9	22.2 – 75.3	1.8
GSD_S	1.7	1.4 – 2.0	1.2	1.9	1.5 – 2.7	1.4
GM_M	22.8	17.9 – 29.3	1.3	40.9	22.2 – 75.3	1.8
GSD_M	1.7	1.4 – 2.0	1.2	2.0	1.5 – 3.1	1.5
ICC	0	0 – 0.4	--	0.5	0 – 0.8	--
GM_S = geometric mean assuming SRS = "exp(average of 18 ln(UE)) values" GSD_S = geometric standard deviation assuming SRS = "exp(standard deviation of 18 ln(UE)) values" GM_M = variance component model-based geometric mean GSD_M = variance component model-based geometric standard deviation ICC = intra-cluster correlation						
AM_S	26.1	20.1 – 34.0	1.3	48.2	26.0 – 95.9	2.0
AM_U	26.3	20.2 – 34.5	1.3	50.5	26.4 – 97.7	1.9
AM_M	26.3	20.3 – 34.6	1.3	52.4	27.0 – 105.7	2.0
AM_S = average of 18 unit exposures AM_U = arithmetic mean based on $GM_S = GM_S * \exp\{0.5*(\ln(GSD_S)^2\}$ AM_M = variance component model-based arithmetic mean = $GM_M * \exp\{0.5*(\ln(GSD_M)^2\}$						
$P95_S$	62.4	37.1 – 110.5	1.8	133.9	53.9 – 327.0	2.5
$P95_U$	54.7	37.0 – 79.3	1.5	119.0	53.4 – 263.5	2.2
$P95_M$	54.7	37.2 – 80.3	1.5	130.0	54.8 – 317.5	2.4
$P95_S = 95^{th}$ percentile (i.e., estimated as the maximum unit exposure from the 18 unit exposures) $P95_U = 95^{th}$ percentile based on $GM_S = GM_S * GSD_S^{1.645}$ $P95_M$ = variance component model-based 95^{th} percentile = $GM_M * GSD_M^{1.645}$						

The benchmark of 3-fold accuracy for dermal and inhalation unit exposures has been met for the mop scenario for all 3 clothing scenarios and inhalation exposures for all 3 statistical models, except for the empirical 95^{th} percentile for the short pants, short-sleeved shirt configuration where the fold relative accuracy is 4.5 (see Appendix A, Table 4).

Secondary Benchmark Objective -- A secondary objective of the study was to evaluate the presumption of proportionality between exposure and amount of active ingredient handled (AaiH). EPA's secondary statistical benchmark is to be able to distinguish, with 80% statistical power, complete proportionality from complete independence between exposure and amount of active ingredient handled.

To evaluate the relationship for this scenario EPA performed regression analysis of ln(exposure) and ln(AaiH) to determine if the slope is not significantly different than 1 – providing support for a proportional relationship – or if the slope is not significantly different than 0 – providing support for an independent relationship.

A simple linear regression, a mixed-effect regression, and a more complex "repeated measure" model (see Appendix A pages 32 and 33 for more details) were used to analyze the data to take into account the clustered nature of the data and were used to evaluate the relationship between exposure and AaiH. Appendix A also provides an analysis of the proportionality for each of the 3 clothing configurations. The results of the proportionality analysis for the 3 clothing configurations are inconsistent; either all or none of the clothing configurations should show proportionality to AaiH. To investigate the proportionality issues further, an alternative model ("repeated measure") was developed to fit the data from all of the clothing configurations. The reader is referred to the SAS code for specific details on this repeated measure model.

The resulting regression slope and confidence intervals are summarized in Table 6 and in Figure 6 (inhalation only) below. Note that a confidence interval width of 1.4 (or less) indicates at least 80% statistical power, which was achieved for dermal and inhalation exposures. The results of the dermal model indicate that exposure is proportional to AaiH (i.e., confidence interval includes 1 but not 0 and the estimated slope is 0.78). However, for inhalation exposure the simple linear and mixed-effects models are different and neither model shows proportionality of inhalation exposure and AaiH. For more details the reader is referred to Appendix A, Table 7.

Table 6. Summary Results of log-log Regression Slopes for Dermal and Inhalation Exposure

Regression Model	Dermal Exposure			Inhalation Exposure			
	Estimate	95% CI	CI Width	Regression Model	Estimate	95% CI	Width
"Repeated Measures"	0.78	0.09 to 1.46	1.37	Simple Linear	-0.20	-0.84 to 0.44	1.29
				Mixed-Effects	-0.03	-0.49 to 0.44	0.93

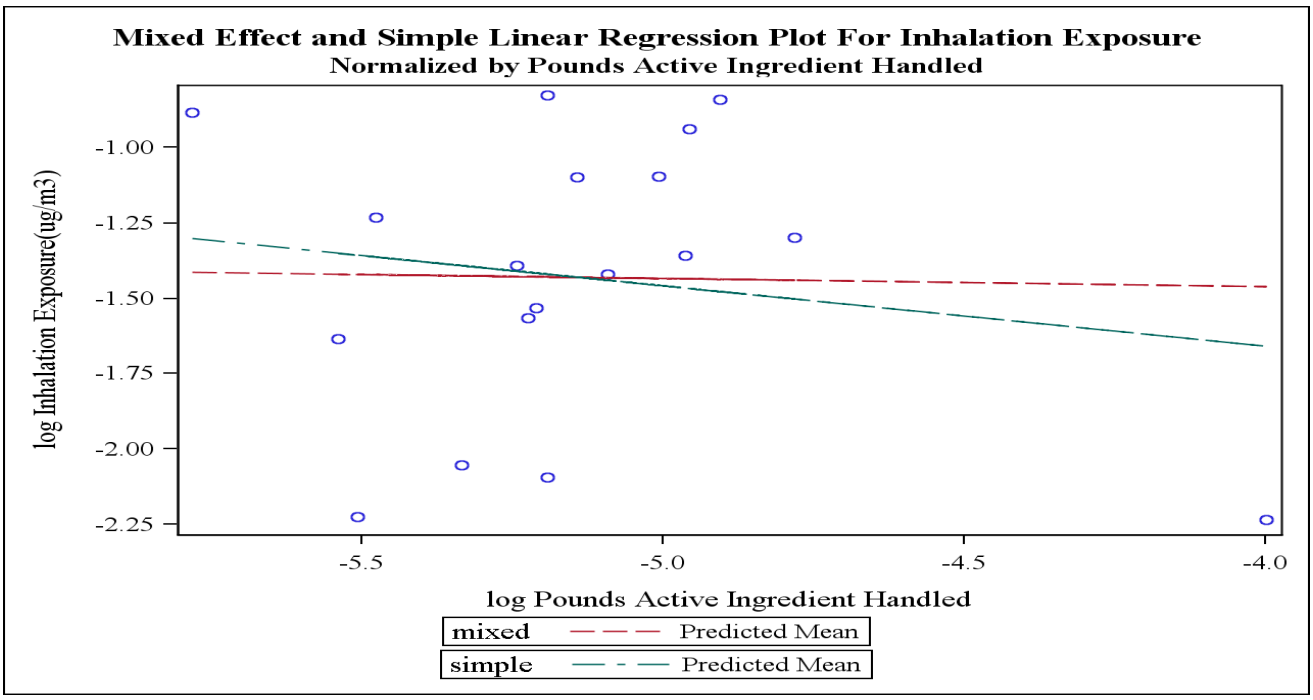

Figure 6: Inhalation Exposure Regression

3.0 Discussion of Data Generalizations and Limitations

The regulatory need for a generic data base of pesticide handlers for antimicrobial pesticide products has been discussed previously (Myrta 2007). This mop study represents one study in the overall design of an AEATF II generic handler data base. This mop study was designed to represent the high end of potential exposure for mopping activities (e.g., selection of string mop & bucket, duration of sampling). The study design also incorporated random diversity selection where feasible. Such a study design requires a discussion of how the data can be generalized and the limitations of the results. The following items are provided to characterize the results of this sampling effort:

(1) The study purposively selected Fresno, CA, as the study location. This selection criterion, rather than a random selection of sites across the country, limits to some degree the statistical generalizations of the data. Thus we cannot determine whether these results provide unbiased estimates of exposure distributions from mopping activities in locations other than Fresno, CA, and it is not possible to use these data to estimate the potential bias or the geographic variability. To generalize these results to the whole country requires an assumption that the exposure distribution for these scenarios is independent of the geographic location. The statistical limitations of the purposive site selection are deemed acceptable by the JRC. It is reasonable to assume that the mechanics of mopping floors inside buildings in Fresno are not substantially different than mopping of floors inside other buildings throughout the country. Given a limited set of resources for the overall AEATF II monitoring program, the assumption that indoor mopping of floors does not vary geographically was sufficiently reasonable to forgo the random site selection in favor of

spending the limited resources to monitor additional distinctly different scenarios (e.g., wiping, aerosol cans, painting, metal working fluids, pressure treatment of wood, etc).

(2) The data generated in this study are acceptable to use as surrogate for assessing other chemicals considered to have low volatility (i.e., vapor pressures less than ~1E-4 mmHg @ 20C). This "rule-of–thumb" for the vapor pressure threshold is reviewed by EPA on a case-by-case basis, particularly for those antimicrobial pesticides with vapor pressures that are near to this threshold. For example, for those chemicals with vapor pressures of ~1E-4 mmHg, EPA reviews the pesticide application method for the potential for aerosol generation and the available inhalation toxicity data to see if the toxicity studies were performed as a gas or with an aerosol.

(3) The data generated in this study are acceptable to use as surrogate to assess pesticide labeled uses of mopping floors. A pesticide product that indicates a product can be applied by mop generally does not require or limit the specific type of mop to be used (e.g., string mop or sponge mop). The JRC reviewed the use of the string mop application equipment during the protocol development stage and decided that the exposures resulting from the use of a string mop would be a reasonable surrogate for other type of mops (e.g., sponge mop) that would not underestimate the exposure.

(4) The dermal mop exposure data generated in this study are acceptable to use for clothing configurations of long pants, long-sleeved shirts (plus shoes/socks and no gloves), long pants, short-sleeved shirts (plus shoes/socks and no gloves), as well as short pants, short sleeved-shirts (plus shoes/socks and no gloves).

(5) The small sample size by itself does not cause statistical limitations other than the high level of uncertainty shown by wide confidence intervals for some of the summary statistics. More important is the fact that the original sets of subject participants, locations, and dates from which the subjects, clusters, and sampling dates were chosen were limited and hence might not be representative of all Fresno moppers (e.g., moppers that did not volunteer), buildings (e.g. only empty buildings were eligible for this study), and time periods (e.g., winter vs summer, night vs day, etc.). In other words, the most significant limitation is that these data were not derived from a stratified random sample of MEs even though the statistical analyses made that assumption. At a minimum this increases the uncertainty of the estimates (so the calculated confidence intervals are too narrow) and there may also be some bias (e.g., study participants not in the volunteer pool might be more or less prone to exposure than the selected group).

(6) EPA will continue using exposures normalized by AaiH as a default condition. The results of the dermal exposure for this mop study support use of this assumption. Data will continue to be collected by the AEATF II to add to the knowledge base of normalized exposures.

4.0 Conclusion

EPA has reviewed the AEATF II mop study and concludes that the AEATF II made the appropriate changes to the protocol proposed by the EPA and HSRB and has executed the study successfully. The protocol deviations that occurred and were reported on have not adversely impacted the reliability of these data. The EPA recommends that the inhalation and dermal UE generated in this mop study be used provided the data are used within the boundaries set forth in this review.

The following is a summary of our conclusions.

- The AEATF II data for inhalation and dermal exposures represent reliable data for assessing mopping of floors with antimicrobial products. Alternative data sources or special circumstances will be considered on a case by case basis.

- Estimates of the GM, AM, and P95 were shown to be accurate within 3-fold with 95% confidence for all of the analyses, except for the empirical (empirical results reported in Appendix A) 95^{th} percentile for the short pants, short-sleeved shirt configuration where the fold relative accuracy is 4.5. Although the estimated UEs were not based on the empirical results, the fold relative accuracy of 4.5 may have been the result of the incidental contact for subject M6 in cluster 1.

- The data provided 80% statistical power to distinguish complete proportionality or independence between exposure and AaiH for both dermal and inhalation routes of exposure. Proportionality between dermal exposure and AaiH was established but not for inhalation exposure.

5.0 References

Boatwright, M. (2007) Determination of Removal Efficiency of Didecyl Dimethyl Ammonium Chloride (DDAC) from Hand Surfaces Using Isopropyl Alcohol/Water Wash. Unpublished study prepared by Golden Pacific Laboratories under Study No. 050211. 341 p. MRID 47214801.

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Selim, S., and Taylor, M. (2010) A Study for Measurement of Potential Dermal and Inhalation Exposure During Application of a Liquid Antimicrobial Pesticide Product Using Bucket and Mop Equipment for Cleaning Indoor Surfaces: Supplement 1 to MRID 48210201. Unpublished study prepared by Golden Pacific Laboratories, LLC, under Project No. AEA03, Report No. 070265. 1146 p. (MRID 48231201)

Selim, S., and Taylor, M. (2010) A Study for Measurement of Potential Dermal and Inhalation Exposure During Application of a Liquid Antimicrobial Pesticide Product Using Bucket and Mop Equipment for Cleaning Indoor Surfaces: Supplement 2 to MRID 48210201. Unpublished study prepared by Golden Pacific Laboratories, LLC, under Project No. AEA03, Report No. 070265. 35 p. (MRID 48231901)

Selim, S. (2008) A Study For Measurement of Potential Dermal and Inhalation Exposure During Application of a Liquid Antimicrobial Pesticide Product Using Bucket and Mop Equipment for Cleaning Indoor Surfaces. Unpublished protocol dated January 16, 2008, prepared by Golden Pacific Laboratories for the Antimicrobial Exposure Assessment Task Force II under Sponsor ID AEA03 and GPL Study No. 070265. 134 p., plus 335 p. supplement containing IRB correspondence.

Appendix A

Statistical Review of the AEATF II Mop Study

(See separate electronic .pdf file)

Cohen, J. (2010) AEATF Mop Study Statistical Review for HSRB. Unpublished memorandum dated 28 Sept 2010 from J. Cohen to T. Leighton of EPA, prepared by ICF International under Contract No.: EP-W-06-091; Work Assignment 3-02. 73 p.