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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM

Date: [placeholder for final date]

SUBJECT: **DRAFT** Review of "Determination of Dermal and Inhalation Exposure to Workers During Mixing / Loading Wettable Powders in the United States" (AHE80)

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This memorandum presents EPA's review of the analytical and field phase reports for AHE80 (Rosenheck and Baugher, 2016), an Agricultural Handler Exposure Task Force (AHETF) study that monitored dermal and inhalation exposure for workers while mixing and loading pesticide products formulated as wettable powders. It reflects comments and advice provided by the Human Studies Review Board following its review in July 2016[1]. AHE80 meets EPA standards for occupational pesticide exposure monitoring and is considered acceptable and appropriate for use in occupational exposure/risk assessments of workers handling wettable powder pesticide products.

The data from AHE80 supplements existing data from another AHETF study (AHE39; Klonne, 2007) that monitored five (5) workers mixing/loading wettable powder products in 2006; results

[1] [placeholder for final HSRB report]

and review of that data are presented in a separate document (Williams and Crowley, 2016). The scenario monograph (AHE1015: Klonne and Holden, 2016), which incorporate the monitoring data from AHE80 and AHE39 into a single composite dataset and includes statistical analysis of study objectives, is also reviewed under separate cover (Crowley, 2016).

1.0 Executive Summary

The Agricultural Handler Exposure Task Force (AHETF) study AHE80 monitored dermal and inhalation exposure for 19 workers that mixed and loaded pesticide products formulated as wettable powders (WP). The study protocol (AHETF, 2011) specified monitoring of 20 workers, however monitoring for one worker (worker M15) was terminated due to a malfunctioning water source. Additionally, by design, to match the intended use of the data as a discrete mixing/loading scenario, the monitoring does not represent exposure during application of the finished pesticide spray solution.

Monitoring was conducted across four U.S states and three years. The workers' activity involved opening the package containing the product, emptying the wettable powder into mixing/holding tanks or directly into pesticide application equipment partially filled with water, and diluting to the desired solution concentration. When the process involved dilution in an intermediate mixing or holding tank, monitoring included transfer of the dilute solution to pesticide application equipment. All practices were consistent with the intended use of these types of formulations and industry norms as well as the instructions on product labels. Table 1 presents a high-level summary of qualitative characteristics of the exposure monitoring.

Table 1. AHE80 Summary

Worker ID	Type of Mixing/Loading Activity	State	Monitoring Year	Age (years)
M2	Mixed directly in application equipment tank	NY	2012	54
M3	Mixed directly in application equipment tank			55
M4	Mixed directly in application equipment tank			31
M5	Mixed directly in application equipment tank			53
M17	Mixed directly in application equipment tank		2014	71
M1	Mixed in intermediate tank (on-board inductor)	FL	2011	53
M6	Mixed directly in application equipment tank		2012	55
M7	Mixed directly in application equipment tank			41
M18	Mixed directly in application equipment tank		2014	31
M20	Mixed in intermediate tank (on-board inductor)			42
M12	Mixed directly in application equipment tank	MI	2013	37
M13	Mixed in intermediate pre-mix tanks			54
M14	Mixed directly in application equipment tank			62
M16	Mixed directly in application equipment tank (in tank hatch)			30
M8	Mixed directly in application equipment tank	CA	2013	50
M9	Mixed directly in application equipment tank			69
M10	Mixed directly in application equipment tank			53
M11	Mixed directly in application equipment tank			68
M19	Mixed directly in application equipment tank		2014	18

Note: all study subjects were male.

Monitored on actual days of work, workers mixed and loaded between 710 and 12,500 gallons of solution over 3 to 25 separate mixing/loading events in 1 to 9 hours, totaling a range of 55 to 925 lbs of active ingredient handled. All workers wore long-sleeved shirts, pants, shoes/socks and chemical-resistant gloves and eye protection; some workers wore respirators.

Dermal exposure was measured using hand washes, face/neck wipes, and whole body dosimeters (100% cotton union suits) for the remainder of the body (torso, arms, and legs). Inhalation exposure was measured using personal air sampling pumps and glass fiber filters in cassette cartridges mounted on the shirt collar.

The study followed the applicable and most up-to-date AHETF standard operating procedures (SOPs) and the corresponding protocol. Protocol amendments and deviations were appropriately documented. Applicable analytical field and laboratory recovery results were acceptable, mostly averaging between 70 and 120% recovery, and all coefficients of variation except one were less than 25%. All field samples were appropriately adjusted for the corresponding field fortification recovery adjustment factors.

Total dermal exposure, calculated by summing the results for inner dosimeters, hand washes and face/neck wipes, as well as dermal exposure normalized to body weight and also normalized to the amount of active ingredient handled are summarized in Table 2 below.

Table 2. AHE80 Dermal Exposure Summary[1]

Statistic[2]	Total Exposure (µg)	Normalized by Body Weight (µg/kg BW)	Normalized by Amount ai Handled (µg/lb ai)[3]
Minimum	589	6.80	0.637
Maximum	61,497	812	237
Mean	9,600	105	46.8

[1] Results are shown for AHE80 only. The review for AHE39 as well as the review for the "Mixing/Loading Wettable Powder" scenario monograph (AHE1015) should be referenced for complete dermal exposure results.
[2] Means are simple averages (i.e., sum of values ÷ n)
[3] Though other exposure metrics are shown in this table, exposure normalized to the amount of active ingredient handled is typically the format used by EPA as an input in standard handler exposure calculations.

Total inhalation exposure, calculated[2] assuming a breathing rate of 16.7 L/min[3], as well as inhalation exposure normalized to body weight and also normalized to amount of active ingredient handled are summarized in Table 3 below.

Table 3. AHE80 Inhalation Exposure Summary[1]

Statistic[2]	Total Exposure (µg)	Normalized by Body Weight (µg/kg BW)	Normalized by Amount ai Handled (µg/lb ai)[3]
Minimum	2.51	0.028	0.031
Maximum	2,325	30.7	13.5
Mean	293	3.33	1.70

[1] Results are shown for AHE80 only. The review for AHE39 as well as the review for the "Mixing/Loading Wettable Powder" scenario monograph should be referenced for complete inhalation exposure results.
[2] Means are simple averages (i.e., sum of values ÷ n)

[2] Inhalation exposure (µg) = Residue collected * [Breathing rate (L/min) ÷ Pump rate (L/min)]. Pump rates generally were 2 L/min. Note: AHE80 presents only the total active ingredient collected (µg), not results adjusted for breathing rates as shown here.
[3] NAFTA, 1998: 16.7 L/min represents light activity.

[3] Though other exposure metrics are shown in this table, exposure normalized to the amount of active ingredient handled is typically the format used by EPA as an input in standard handler exposure calculations.

2.0 Summary of Field Study Characteristics

This section provides summary characteristics for AHE80. While a summary is provided, the submitted AHE80 report should be consulted for more specific details (applicable sections, tables, and/or page numbers are provided).

2.1 Administrative Summary

AHE80 was sponsored by the AHETF and adequately followed both the protocol and scenario construction plan (AHETF, 2011), the AHETF Governing Document (AHETF, 2008 and 2010), and applicable AHETF SOPs.

The study was conducted in compliance with Good Laboratory Practice Standards (GLPS) (40 CFR §160) and met the standards in EPA Test Guidelines Series 875 – Occupational and Residential Exposure (875.1100 – dermal exposure; 875.1300 – inhalation exposure). The protocol was amended six (6) times and the AHETF documented four (4) instances of deviations from the protocol. Signed copies of acceptable Quality Assurance and Data Confidentiality statements were provided.

Most protocol amendments were intended to expand the potential pool of eligible workers via modifying how recruitment lists were developed as well as relaxing some of the inclusion/exclusion criteria. Deviations included field fortification issues, a worker not wearing required eye protection for part of monitoring, and potential lack of handwash samples prior to smoking.

EPA considers the amendments reasonable and helpful additions for obtaining results consistent with the intent of the study's purpose and original protocol. No protocol deviation is considered to have negatively impacted the study conduct or results. For a more detailed summary of protocol amendments, see Section 4.0 below and refer to AHE80 pages 10-12 as well as AHE80 Appendix A (pages 256-278).

2.2 Test Materials

The protocol specified four potential surrogate active ingredients that could be used by the monitored workers: sulfur, thiophanate-methyl, DCPA, and permethrin. Ultimately – because thiophanate-methyl was no longer available at the time of monitoring, use of permethrin required more PPE than specified per the protocol, and DCPA was only available for use on turf and nurseries – all monitored workers mixed and loaded products containing sulfur as the active ingredient.

Four (4) different EPA-registered products were used, each a 30 lb heavy paper or plastic bag containing the wettable powder formulation; they are outlined in Table 4 below. In the AHE80 study report, Table 2 on page 63 provides more specific details on the products used.

Table 4. AHE80 Summary of Pesticide Products Used			
Product Name	**EPA Reg. No.**	**Active Ingredient (% ai on product label)**	**Worker ID**
Yellow Jacket Wettable Sulfur II	6325-13	Sulfur (90%)	M2
			M3
			M4
			M14
Microfine Sulfur	6325-13-34704	Sulfur (90%)	M5
			M17
			M1
			M6
			M12
Microthiol Disperss	70506-187	Sulfur (80%)	M7
			M20
			M13
			M16
			M9
			M10
			M11
Micro Sulf	55146-75	Sulfur (80%)	M18
			M8
			M19

Per GLP, AHETF analyzed the test substances for purity. Certificates of Analysis, which formally document analysis of the test substances, are provided in AHE80 Appendix C pages 774-796. In terms of exposure monitoring in this study, purity analysis is important for the purposes of determining the amount of active ingredient handled by each worker. The amount of product and active ingredient handled by each worker is outlined in the AHE80 study report in Table 6 on pages 72-75. This is also described more in Section 2.7 below.

2.3 Sample Size, Monitored Workers, and Locations

According to the AHE80 study protocol (AHETF, 2011) and the AHETF Governing Document (AHETF, 2008 and 2010), a "5 x 4" configuration was deemed a reasonable approach for these scenarios. That is, a total of 20 "monitoring units" (MU), obtained by monitoring exposure from 4 spatially distinct study locations across the U.S., each with 5 workers per location would likely satisfy pre-defined accuracy benchmarks. In one instance, monitoring of a worker (M15) was terminated prior to handling any test substance due to a malfunctioning water source, resulting in a total of 19 monitored workers.

Due to logistical recruitment difficulties related to limited availability of wettable powder pesticide products, the goal of efficiently monitoring in spatial and temporal proximity was not possible. Monitoring extended through 3 years from 2012-2014, across four U.S. states (Florida, New York, California, and Michigan) resulting in large temporal separation of monitoring even within the same geographic area. Thus, instead of the intended (more efficient set up of) 4

"clusters", the 19 monitored workers in AHE80 ultimately comprised 8 distinct "clusters", when considering spatial proximity as well as a temporal proximity threshold of no more than 90 days apart. Per protocol, no worker was monitored twice (no "repeat measures") and, to reduce any potential similarities related to training, all workers were employed by different farms/employers.

Table 5 below provides a summary of the characteristics of the 19 monitored workers, while the AHE80 study report provides additional details in Table 3 on pages 64-67.

Table 5. AHE80 Worker and Location Summary

Worker ID	Gender	Weight (lb)	Work Experience (years)	Monitoring Location (U.S. State)	Monitoring Year	Age (years)
M2	Male	242	39	NY	2012	54
M3	Male	158	15			55
M4	Male	167	15			31
M5	Male	234	40			53
M17	Male	196	20		2014	71
M1	Male	262	8	FL	2011	53
M6	Male	258	2		2012	55
M7	Male	315	Not recorded			41
M18	Male	190	17		2014	31
M20	Male	279	20			42
M12	Male	189	9	MI	2013	37
M13	Male	165	33			54
M14	Male	198	35			62
M16	Male	260	10			30
M8	Male	225	35	CA	2013	50
M9	Male	184	44			69
M10	Male	241	35			53
M11	Male	250	30			68
M19	Male	165	1		2014	18

2.4 Environmental Conditions

Temperature (including heat index), humidity, wind speed and direction, cloud cover, and rainfall were all reported. The maximum reported temperature was 84° F (FL, October 2012) and the lowest reported temperature was 38° F (MI, April 2013). Though monitoring was halted for worker M6 (FL, October 2012) as a result of the ambient temperature exceeding the pre-defined threshold of concern for potential heat-related injury (105° F accounting for the heat index), the monitoring was of sufficient duration (approximately 3 hours) that results were not discarded. Rain did not impact any of the monitoring. Maximum reported wind speed was approximately 14 miles per hour.

For more details on environmental conditions see the AHE80 report Table 7 (pages 76-79).

2.5 Clothing and Personal Protective Equipment (PPE)

Per the stated goals of the AHETF, monitoring of mixing and loading wettable powder pesticide products was conducted to represent exposure while wearing long-sleeve shirts, pants, shoes/socks, chemical-resistant gloves and no respiratory protection. Monitoring was conducted while the workers wore their normal clothing on the scheduled monitoring day, so long as the clothing met the standards of the EPA Worker Protection Standard (WPS) for pesticides. In one instance (M15) a worker's short-sleeve shirt was replaced with a long-sleeve shirt by the AHETF; in another instance (M18) a small tear in a shirt sleeve was closed with waterproof tape.

Per protocol, new chemical-resistant gloves were supplied by the AHETF to all workers at the beginning of the day and were available throughout the day according to WPS requirements. All chemical-resistant gloves used were of made of natural or nitrile rubber, a material consistent with requirements on the labels of products used (for reference, see products outlined in Section 2.2 above). Prior to initiating mixing and loading, one worker (M8) was noted to have opened a bag of product to feel the powder with bare hands.

Additionally, 5 of 19 workers wore respiratory protection and all wore eye protection.[4] In these cases, to simulate workers who do not wear a respiratory or eye protection, the exposure measurements were adjusted (according to AHETF SOP 9.K) to extrapolate deposited residue to those portions of the face/head covered by the respirator or protective eyewear (see Section 3.2.2.2)[5].

More specific details on work clothing and PPE can be found in the AHE80 study report in Tables 4 and 5 on pages 68-71.

2.6 Mixing/Loading Equipment and Methods

Monitoring was conducted during mixing and loading the wettable powder products into application equipment. Mixing of the wettable powder was done either directly in the tank of the application equipment or in an intermediate/pre-mix tank. When the process involved dilution in a holding tank or intermediate solution tank, monitoring included loading/transfer of the solution to the pesticide application equipment. All practices were consistent with the intended use of these types of formulations and industry norms as well as the instructions on product labels. By design, to match the intended use of the data as a discrete mixing/loading scenario, monitoring was not conducted during application of the dilute solution.

All workers mixed and loaded product intended for application via airblast sprayers with tank capacities ranging from 300 to 1,000 gallons. Three workers mixed the powder in an on-board inductor tank or within the tank hatch before adding directly to the sprayer tank, while one other mixed in holding tanks then transferred the product to the airblast sprayer tank; the remaining 15 mixed the product directly in the spray tank.

The AHE80 study report provides more details in Table 6 on pages 72-75.

[4] For the pesticide products used in this study (see Section 2.2), eye protection is required, respirators are not. Thus, when respirators were worn in this study, it was due to worker preference.

[5] These calculations and results are presented by the AHETF in their scenario monograph (AHE1015), but not in the submission for AHE80.

2.7 Application Rates and Amount of Active Ingredient Handled (AaiH)

According to the AHE80 study protocol (AHETF, 2011) and the AHETF Governing Document (AHETF, 2008 and 2010), the total amount of active ingredient applied should be diversified across the scenario and within each study location.

Workers handled between 60 and 1140 lbs of product, mixing between 700 and 12,500 gallons of solution over the course of 1 to 9 hours. Using the product concentration – determined by laboratory purity analysis – and the amount of product handled, the amount of active ingredient handled can be determined. Workers handled between 55 and 925 lbs of active ingredient (in this study, sulfur).

Table 6 below provides more detail on solution and application information. The submitted AHE80 study report Table 6 (on pages 72-75) should also be referenced.

Table 6. AHE80 Mixing/Loading Summary

Worker ID	Product handled (lbs)	% ai in product[a, b]	Total Solution Prepared (gallons)	# Loads Mixed	Exposure Time (hrs)	AaiH (lbs)[c]
M1	60	91	3000	3	3.4	54.6
M2	120	90	1800	6	3.2	108
M3	330	91	5500	11	7.3	300
M4	750	91	12500	25	9.1	685
M5	480	91	6500	13	5.4	438
M6	100	97	5000	5	2.8	97.0
M7	240	82	4000	4	3.5	196
M8	405	78	4500	9	9.1	316
M9	120	78	2400	4	3.8	93.6
M10	120	80	2400	4	1.5	96.0
M11	90	78	1500	3	4.9	69.9
M12	120	98	920	3	3.5	118
M13	1140	81	6100	13	3.4	925
M14	360	96	1600	4	2.5	346
M16	150	81	2000	5	8.1	122
M17	90	82	1500	3	0.6	79.8
M18	180	79	3000	3	2.5	143
M19	90	80	710	3	1.8	71.7
M20	90	80	3000	3	2.5	71.7

[a] Active ingredient (ai) = sulfur.
[b] The % ai is based on the Certificates of Analysis (see AHE80 Appendix C), not the % ai on the product label.
[c] AaiH is approximated by the calculation: Product handled (lbs) * % ai in product

2.8 Representativeness of Exposure Monitoring

As part of the study protocol, the AHETF conducted opinion polling within each monitoring area of local farm experts at the conclusion of the field phase of AHE80 to evaluate whether various characteristics of the monitoring was reasonably representative of the conditions during mixing/loading wettable powders in that area. The characteristics surveyed were: the specific county in which monitoring occurred, grower vs. commercial applicator, monitored individual

was grower, owner or employee, type of crop, crop acreage/acreage treated, worker experience, and the type of mixing/loading activity and application equipment used.

Though the survey was informal, only one individual (in NY) stated that they thought some of the monitoring characteristics were not typical for their monitoring area. Thus, it appears based on this informal survey/poll of local experts that the participants in AHE80 were not atypical of the population of individuals who mix/load wettable powder pesticides. A summary of the findings is provided in Table 7 below.

Table 7. AHE80 Synopsis of Informal Survey of Local Farm Experts

Monitoring Area	Recruited	Responded	Response
NY	• 7 Agricultural Extension Agents • 1 Dept Horticulture Science (NYSAES) • 1 Spray Tech Expert (NYSAES)	4 of 9	• 3 agreed the monitoring was typical • 1 did not think the monitoring was typical.
FL	• 7 Agricultural Extension Agents	5 of 7	• 4 agreed the monitoring was typical. • 1 declined comment, lacking requisite expertise.
MI	• 3 Agricultural Extension Agents • 1 Integrated Pest Management Agent • 1 Farm Manager, MI Hort. Research Station • 1 from MI AG Experiment Station • 1 MSUE Small Fruit Educator	4 of 7	• 2 agreed the monitoring was typical. • 2 declined comment.
CA	• 6 Agricultural Extension Agents • 1 former Agricultural Extension Agent (now private Ag Research Economist) • 1 Commercial Applicator Service Manager	3 of 7	• 1 agreed the monitoring was typical. • 2 did not comment but recommended others to survey.

2.9 Exposure Monitoring and Analytical Methods

Per applicable AHETF SOPs, standard passive dosimetry methods recognized by EPA as appropriate for worker exposure monitoring were utilized for all monitoring. No biomonitoring samples were collected. Dermal exposure was measured as described below, and are combined (i.e., the measurement results summed together) to reflect dermal exposure underneath a single layer of work clothing (long-sleeve shirt, pants, shoes/socks) and chemical-resistant gloves.

- Hand exposure was measured using a hand rinse method administered at the end of the workday as well as at lunch, restroom breaks, or other instances where workers would otherwise wash their hands as outlined in AHETF SOP 8.B.
- Exposure to the face/neck was measured using a wipe technique as outlined in AHETF SOP 8.C and extrapolated to non-wiped portions of the head according to AHETF SOP 9.K. Thus, for those workers who wore eye protection and/or respirators, the extrapolation to the whole head renders the resulting measurement representative of

face/neck/head exposure without that additional gear. Generally, 1-2 face/neck wipe samples were collected for each worker and then analyzed as a composite sample.
- Dermal exposure to the remainder of the body (torso, arms, and legs) was measured using whole body dosimeters (100% cotton union suits), sectioned into six pieces and analyzed separately according to AHETF SOP 8.A.

Inhalation exposure was measured using glass fiber filters mounted on the worker's collar and personal sampling pumps (set at 2 liters per minute) according to AHETF SOP 8.D and 10.G. The concentrations measured represent the chemical available in each worker's breathing zone.

Validated analytical methods specific to sulfur and each type of monitoring matrix (i.e., inner dosimeters, hand rinses, etc.) were used to extract residues. The analytical methods listed below are described in more detail in the analytical report in Appendix B:

- AHE212, "Validation of Worker Exposure Methods for the Analysis of Sulfur in Worker Exposure Matrices"
- AHETF-AM-051, "Determination of Sulfur on Six-Piece Cotton Inner Dosimeters"
- AHETF-AM-053, "Determination of Sulfur on Face/Neck Wipe Samples"
- AHETF-AM-052, "Determination of Sulfur in Hand Wash Solutions"
- AHETF-AM-054, "Determination of Sulfur on Cassette Filters"

Limits of quantification and detection (as defined in AHETF SOP 9.A) for sulfur are presented in Table 8 below.

Table 8. AHE80 Analytical Limits for Sulfur (µg/sample)

Monitoring Matrix	Limit of Quantification (LOQ)	Limit of Detection (LOD)
Inner Dosimeter[1]	1.0	0.23
Hand Rinse	1.0	0.24
Glass Fiber Filter (per section)	0.1	0.03
Face/Neck Wipe	1.0	0.18

[1]The AHE80 report submission incorrectly identified the LOD for inner dosimeters as 0.10 ug/sample in the Field Report section.

3.0 Results

This section provides a discussion of quality assurance and quality control sampling and the actual field monitoring measurements of workers.

3.1 Quality Assurance

All phases of each study were subject to appropriate quality assurance processes according to EPA's GLPs which included an audit by the AHETF Quality Assurance Unit (QAU) per AHETF SOPs (AHETF SOP Chapter 5: A-K). The inspected phases were: Application/Sampling, Study Data, Draft Report, Final Report, and Post-Audit. The study contains a signed quality

assurance compliance statement as required by GLPs. Protocol amendments or deviations were addressed appropriately per GLP guidance and are described further in Section 4.0.

3.2 Quality Control

AHETF instituted various quality control measures to ensure proper field conduct including calibration of sprayers, preparation and handling of exposure measurement matrices, evaluation of test material, and field observations (AHETF SOP Chapter 10: A-G). Analytical methods were validated appropriately ensuring that all exposure matrices could be measured for all of the proposed surrogate active ingredients (in this study, only those for sulfur applied). Analytical quality control measures for ensuring the integrity of measurements captured in the research were also instituted according to AHETF SOP 9.J.

Exposure monitoring matrices (inner whole body dosimeters, hand washes, face/neck wipes) were fortified with known amounts of active ingredient to assess their stability during field, transit, and storage conditions according to AHETF SOP 8.E. Laboratory control samples were also fortified at the level of quantification and at levels capturing the range of expected field exposures for each matrix. Generally, field fortification samples were collected in triplicate at each of 3 levels (high, middle, and low) on each sampling day. Travel fortifications were generally conducted on each day of sampling in duplicate only at the high fortification level. Untreated control samples – included to determine if there are significant background sources or contamination during sample processing – were generally conducted in duplicate on each day of sampling.

The following sections provide results for all quality control sampling across all exposure measurement matrices for all chemicals used.

3.2.1 Field and Laboratory Control Samples

No laboratory and field control (blank) samples contained detectable residues. More detailed results can be found in AHE80 Appendix B Tables 11-23 on pages 418-484.

3.2.2 Field Fortification Recoveries

Field fortification sampling matrices are spiked with known amounts of chemical, then placed under similar conditions and duration as the actual sampling matrices used on the workers (including drawing air through glass fiber filters). The intent of these samples is to quantify potential residue losses due to the sampling methods used under actual field conditions. Additional samples are also fortified to assess degradation of the sample during transit from the field to the lab and during sample storage. However, per AHETF protocol, these are only analyzed if anomalous field fortification recoveries indicate potential degradation during transport and sample storage. No storage or transport fortification samples were analyzed since field fortification results did not indicate any problems related to excessive degradation of residues.

Field fortifications were conducted at 3 levels to capture the expected range of results, with triplicate samples taken on each day at each fortification level. Once analyzed, the average recovery results (expressed as a percentage of known amount applied) are used as multipliers to adjust, or correct, all measured field samples to 100%. As the fortification samples are conducted at levels to capture the range of expected field sample results, adjustments are done using the average percent recovery for the fortification level closest to the measured field sample[6]. The mid-point between each fortification level is used as the threshold in determining the average recovery percentage for use in adjusting the field sample.

With some exceptions, field fortification averages for each fortification level and each monitoring matrix were in the range of 70-120% with almost all coefficients of variation less than 25%. For more details on field fortification results see AHE80 Table 11 on pages 176-191 and Table 12 on pages 192-207. A summary for each matrix is provided in the sections below.

3.2.2.1 Inner Dosimeters

Results for inner whole body dosimeter (WBD) field fortification samples were acceptable, with average recoveries ranging from 70% to 120% and coefficients of variation less than 15%. Only two results – mid-level recovery for worker M6 of 9.6% and high-level recovery for worker M19 of 44.7% – were considered anomalous and excluded from average recovery calculations.

The study protocol specified fortifying inner dosimeters at 5, 100, and 5000 µg. This regimen was followed for monitoring of workers M2-M5, but not for worker M1 where fortifications were done at 100, 500, and 2500 µg. This was noted in protocol deviation #1, but did not negatively impact the study results as even the incorrect fortification levels were adequate to bracket the field results. Additionally, after observing some of the initial exposure monitoring, protocol amendment #5 altered the WBD fortification levels for workers M6-M20 to 350, 3500, and 15,000 µg to better bracket the anticipated field exposures.

Adjustments based on results at each fortification level were applied to field samples falling into the following ranges.

- Worker M1: $\leq$ 300 µg, > 300 to $\leq$ 1,500 µg, and > 1,500 µg
- Workers M2-M5: $\leq$ 52.5 µg, > 52.5 to $\leq$ 2,550 µg, and > 2,550 µg
- Workers M6-M20: $\leq$ 1,925 µg, > 1,925 to $\leq$ 9,250 µg, and > 9,250 µg

3.2.2.2 Face/Neck Wipes

Results for face/neck wipe field fortification samples were acceptable, with average recoveries ranging from approximately 70% to 120% and coefficients of variation less than 10%. No results were excluded as anomalous, although one mid-level fortification sample (worker ID M1) was broken in transit and not analyzed.

[6] Per AHETF standard procedure, if average recovery is > 120% the maximum ("downward") adjustment value applied is 1.2.

The study protocol specified fortifying face/neck wipe at 5, 100, and 2500 µg. This regimen was followed for monitoring of workers M2-M5, but not for worker M1 where fortifications were done at 100, 2000, and 5000 µg. This was noted in protocol deviation #1, but did not negatively impact the study results as even the incorrect fortification levels were adequate to bracket the field results. Additionally, after observing some of the initial exposure monitoring, protocol amendment #5 altered the face/neck wipe fortification levels for workers M6-M20 to 50, 500, and 2,500 µg to better bracket the anticipated field exposures.

Adjustments based on results at each fortification level were applied to field samples falling into the following ranges.

- Worker M1: $\leq$ 550 µg, > 550 to $\leq$ 1,750 µg, and > 1,750 µg
- Workers M2-M5: $\leq$ 52.5 µg, > 52.5 to $\leq$ 1,300 µg, and > 1,300 µg
- Workers M6-M20: $\leq$ 275 µg, > 275 to $\leq$ 1,500 µg, and > 1,500 µg

3.2.2.3 Hand Washes

Results for hand wash field fortification samples were acceptable, with average recoveries ranging from approximately 70% to 120% and coefficients of variation generally less than 25%. Very few atypical recoveries (M17 high-level handwash recovery of 347%; M2 and M3 mid- and high-level recovery of 18.7% and 8.6% respectively) were excluded.

The study protocol specified fortifying hand washes at 5, 100, and 2500 µg. This regimen was followed for monitoring of workers M2-M5, but not for worker M1 where fortifications were done at 100, 1000, and 2500 µg. This was noted in protocol deviation #1, but did not negatively impact the study results as even the incorrect fortification levels were adequate to bracket the field results. Additionally, after observing some of the initial exposure monitoring, protocol amendment #5 altered the face/neck wipe fortification levels for workers M6-M20 to 75, 300, and 1,000 µg to better bracket the anticipated field exposures.

Adjustments based on results at each fortification level were applied to field samples falling into the following ranges.

- Worker M1: $\leq$ 1,050 µg, > 1,050 to $\leq$ 3,500 µg, and > 3,500 µg
- Workers M2-M5: $\leq$ 52.5 µg, > 52.5 to $\leq$ 1,300 µg, and > 1,300 µg
- Workers M6-M20: $\leq$ 188 µg, > 188 to $\leq$ 650 µg, and > 650 µg

3.2.2.4 Glass Fiber Filter Air Samplers

Results for glass fiber filter field fortification samples were acceptable, with average recoveries ranging from approximately 70% to 120% and coefficients of variation less than 25%. Only one atypical result was reported (worker M1) – a mid-level recovery result of 34.5% characterized as an outlier. Additionally the samples at the low-level for worker M1 did not appear to be fortified so lower exposure results would use the mid-level fortification recovery percentage.

The study protocol specified fortifying glass fiber filters at 0.05, 5, and 500 µg. However, 0.05 µg was below the LOQ for this matrix; therefore, low-level fortification samples for workers M2-M5 were set at 0.5 µg (as noted above, there were not low-level fortification samples for M1). Additionally, after observing some of the initial exposure monitoring, protocol amendment #5 altered the glass fiber filter fortification levels for workers M6-M20 to 25, 150, and 300 µg.

Adjustments based on results at each fortification level were applied to field samples falling into the following ranges.

- Worker M1: ≤ 252.5 µg, > 252.5 µg
- Workers M2-M5: ≤ 2.75 µg, > 2.75 to ≤ 253 µg, and > 253 µg
- Workers M6-M20: ≤ 87.5 µg, > 87.5 to ≤ 225 µg, and > 225 µg

3.3 Field Measurements

The following sections summarize the exposure monitoring results, conducted as described in Section 2.8. Exposure values reflect total exposure for workers across their monitoring periods, not normalized by any exposure metric. All measurements were appropriately adjusted for field fortification recoveries (see Section 3.2.2). Where applicable due to use of eye protection or respirators, face/neck wipe measurements were extrapolated to un-wiped portions of the face and head according to AHETF SOP 9.K[7,8]. For samples below the LOQ or LOD, ½ LOQ or ½ LOD was used.

3.3.1 Inner Dosimeters

Without field fortification adjustments, individual WBD sections ranged from 12.2 – 21,221 µg. Out of a total of 114 inner dosimeter samples, none were below the LOQ or LOD. AHE80 Table 14 on page 209 provides more details on these samples.

After adjusting for field fortification recoveries and summing the six separate body sections, the total dermal exposure underneath the long-sleeve shirt and pants ranged from 483 – 54,172 µg with an average of 7,645 µg.

3.3.2 Face/Neck Wipes

Without field fortification adjustments, face/neck wipe samples ranged from 4.01 – 2,240 µg. Out of a total of 19 face/neck wipe samples, none were below the LOQ or LOD. AHE80 Table 15 on page 210 provides more details on these samples.

[7] PPE adjustment factors: 1 = no adjustment; 1.1 = goggles/safety glasses; 1.1 half-face respirator w/thin straps; 1.2 = half-face respirator w/thick straps; 1.3 = eye protection + half-face respiratory w/thin straps; 1.4 = eye protection + half-face respiratory w/thick straps.

[8] PPE-adjusted value (µg) = collected residue (µg) X PPE adjustment factor.
Extrapolated Total Head (µg) = Total Face/Neck Residue (µg) + {Total Face/Neck Residue (µg) X [(Ratio Face/Neck SA (cm^2):Total Body SA (cm^2)) ÷ (Ratio "Rest of Head" SA (cm^2):Total Body SA (cm^2))]}

Because some workers wore eye protection and respirators, and because measurements cannot be easily conducted on hair, extrapolations from those portions of the face/neck that are wiped need to be made to portions of the head that are not measured. Specifics on these adjustment factors can be found in AHETF SOP 9.K. After adjusting for field fortification recoveries and extrapolating to non-wiped portions of the head described above, total head exposure ranged from 7.0 – 6004 µg with an average of 708 µg.

3.3.3 Hand Washes[9]

Per protocol, hand washes were collected at the end of each work day and at points where workers would normally wash their hands such as during restroom or lunch breaks. Most workers had 1 or 2 hand wash samples taken; one worker had 4 hand washes and four workers had 3 hand washes. The following table outlines the number of hand wash samples broken down by the work duration.

Table 9. AHE80 Hand Wash Summary

		Work Duration (hours)			
		< 3	**3-5**	**5-7**	**≥ 7**
Mix/Load WP	Percentage of Workers	37%	37%	5%	21%
	# of Hand Washes	1-3	1-3	2	2-4

Without field fortification adjustments, individual hand wash samples ranged from < LOD to 821 µg. Out of a total of 34 hand wash samples, 9 were below the LOQ or LOD. AHE80 Table 15 on page 210 provides more details on these samples.

After adjusting for field fortification recoveries and summing each worker's hand wash samples, hand exposure (representing use of chemical-resistant gloves) ranged from 0.36 – 1,365 µg with an average of 273 µg.

3.3.4 Glass Fiber Filter Air Samplers/Inhalation Exposure

Front and back sections of the glass fiber filter samplers were analyzed separately. All front section samples had detected residues, while only 2 of 19 back sections had detectable residues. Without field fortification adjustments, front sections ranged from 0.185 – 291 µg and back sections ranged were all < LOD, except for one sample < LOQ and two detected residues of 1.49 and 0.337 µg. AHE80 Table 16 on page 211 has more details on these results. After adjusting for field fortification recoveries, the total (front section + back section) collected active ingredient amounts ranged from 0.31 – 280 µg with an average of 35 µg.

[9] Upon review of the handwash samples in the AHE80 submission, EPA identified handwash samples in the analytical report for workers M1 and M3 that were omitted from the exposure calculations. Calculations in the AHE80 submission for both hand exposure and total dermal exposure include one handwash sample for workers M1 and M3 – each of those workers, however, had two handwash samples conducted. Despite this error, this results in only a very small effect – approximately a 1-2% increase in total dermal exposure – therefore, dermal exposure results/calculations throughout this review do not currently correct this error.

The values above describe results for the mass of active ingredient collected by the air sampling units. The AHE80 report – as it is mainly a presentation of field and analytical results – presents only total mass of active ingredient collected by the air sampling units. Separate AHETF monograph submissions (under separate EPA reviews) present worker inhalation exposures applying an assumed breathing rate. To calculate worker inhalation exposures, the measured (mass) amounts are adjusted based on the sampling pump's air flow rate (in liters per minute) and a typical worker's breathing rate for this type of activity.

For workers mixing and loading wettable powder formulations, a breathing rate of 16.7 liters per minute was used, representing light activities (NAFTA, 1998). The calculation is as follows:

*Inhalation exposure = Adjusted residue (µg) * [Breathing rate (LPM) ÷ Pump flow rate (LPM)]*

Based on these calculations, worker inhalation exposures ranged from 2.51 – 2325 µg with an average of 293 µg.

3.4 Exposure Calculations

This section provides total exposures (expressed as mass active ingredient), as well as exposures normalized to (i.e., dividing by) body weight and amount of active ingredient handled (AaiH).

3.4.1 Dermal Exposures

Total dermal exposure, calculated by summing the results for inner dosimeters, hand washes and face/neck wipes, are summarized below as well as exposure normalized to body weight and amount of active ingredient handled.

Table 10. AHE80 Dermal Exposure Summary

Scenario	Statistic	Total Exposure (µg)	Normalized by Body Weight (µg/kg BW)	Normalized by Amount ai Handled (µg/lb ai)
Mix/Load WP	Minimum	589	6.80	0.637
	Maximum	61497	812	237
	Mean	9600	105	46.8

Note: Means are simple averages (i.e., sum of values ÷ n)

3.4.2 Inhalation Exposures

As shown in Section 3.3.4, inhalation exposure is calculated based on the chemical in air over the monitoring period, the pump flow rate, and the worker's breathing rate. Results are summarized below as well as exposure normalized to body weight and amount of active ingredient handled.

Table 11. AHE80 Inhalation Exposure Summary

Scenario	Statistic	Total Exposure (µg)	Normalized by Body Weight (µg/kg BW)	Normalized by Amount ai Handled (µg/lb ai)

Mix/Load WP	Minimum	2.51	0.028	0.031
	Maximum	2325	30.7	13.5
	Mean	293	3.33	1.70
Note: Means are simple averages (i.e., sum of values ÷ n)				

3.5 Field Observations

Field researchers observed each worker and recorded their behavior throughout the work day. The observations indicate that the monitored workers' behaviors are not atypical of these types of formulations and industry norms. These can be found in the AHE80 report in Table 9 on pages 81-136.

Many of the observations detailed routine mixing/loading procedures (e.g., MU M17 @ 0737: "Sets sulfur bag #2, climbs up, slits bag open with knife pours powder in, dusting noted as pouring."). Other observations may potentially provide clues as to determinants of exposure – examples of these types of observations include:

- Dust plumes during pouring bags – MU M2 @ 0838: "Worker cut sulfur bag #5 open with a knife and dumped it in spray rig #2. Note: a visible cloud of sulfur dust occurred when the sulfur was added to spray rig #2."
- Potential contact with surface residues – e.g., MU M3 @ 0532: "Mixed spray rig #3 without sulfur, exposure is still possible due to visible sulfur dust on outside of sprayer."
- Pouring technique – e.g., MU M7 @ 1016: "Stepped up onto spray rig, opened both bags of sulfur and added them slowly to avoid creating a plume."

Data users are recommended to review the field observations to get a sense of the variation in worker practices within this exposure scenario.

4.0 Protocol Amendments and Deviations

Amendments to and deviations from the study protocol are detailed below. For additional details, see the AHE80 study report on pages 10-12 as well as Appendix A on pages 254-278. The study amendments were reasonable accommodations to accomplish the research and deviations did not adversely impact the study conduct or the exposure monitoring results.

Protocol Amendments:

- Amendment 1
  - Change to Study Director and Principal Field Investigator.
- Amendment 2
  - Removed the requirement for experience with mixing/loading wettable powders within the past year of monitoring.
  - Enabled the Study Director to recruit and schedule on an individual basis without first having to set up an "efficient configuration" within the same area and timeframe.

    - Allowed use of manufacturer's certification to determine active ingredient concentration in the absence of GLP-sourced references.
- Amendment 3
    - Removing the requirement for worker's to have experience with a particular piece of equipment.
- Amendment 4
    - Expanded list of qualified principal investigators.
    - Added permethrin as a potential surrogate active ingredient.
    - Removed county-level monitoring area restrictions, so monitoring could be expanded to entire states.
    - Replaced protocol Section 4 regarding recruitment, allowing for more efficient construction of recruitment.
    - Replaced "grower/growers" with "employer/employers".
    - Replaced text in protocol Section 6.2 which described similarity restrictions within configuration of monitoring in the same location and timeframe. The revised text allowed the Study Director to not delay monitoring while waiting for an efficient configuration to materialize.
    - Replaced protocol Section 6.3 with text that was consistent with other protocol amendment changes.
- Amendment 5
    - After observing initial results, field fortification levels were adjusted to better bracket anticipated exposures.
- Amendment 6
    - Expanded heat-related illness monitoring to include use of a wet-bulb globe temperature (WBGT) system.

Protocol Deviations:

- Deviation 1 (all related to worker M1): fortification samples conducted at levels different than specified in the protocol.
- Deviation 2 (all related to workers M2, 4, 5): air sampling fortifications conducted at 0.5 µg rather than protocol specified 0.05 µg.
- Deviation 3 (worker M17): did not wear label-required eye protection during the first tank load.
- Deviation 4: potential failure to collect handwash samples before the subject smoked a cigarette (number of instances unknown).

5.0 Conclusion

As the studies followed their corresponding protocols as well as EPA guidelines for occupational pesticide exposure monitoring, the results are reliable for assessment of exposure and risk for mixing and loading wettable powder formulation pesticides.

Since these exposure data were collected with the intent of populating a generic pesticide exposure database, reviewers are directed to the additional information and statistical analyses in the AHETF Mix/Load Wettable Powder Scenario Monograph (AHE1015: Klonne and Holden,

2016). Review of the monographs as well as recommendations for use of the data by EPA exposure assessors are in a separate review memorandum (Crowley, 2016).

6.0 References

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