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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM

Date: [placeholder for final date]

SUBJECT: Review of "Determination of Dermal and Inhalation Exposure to Workers During Mixing / Loading of Pesticide Products in Water Soluble Packets in the United States" (AHE120)

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This memorandum presents EPA's review of the analytical and field phase reports for AHE120 (Cañez and Baugher, 2015), an Agricultural Handler Exposure Task Force (AHETF) study that monitored dermal and inhalation exposure for workers while mixing and loading pesticide products packaged in water-soluble packets. It reflects comments and advice provided by the Human Studies Review Board following its review in July 2016[1].

This study meets EPA standards for occupational pesticide exposure monitoring and is considered acceptable and appropriate for use in occupational exposure/risk assessments of workers handling water-soluble packet pesticide products. The scenario monograph (Klonne and Holden, 2015), which incorporate the monitoring data from AHE120 into a single/composite

[1] [placeholder for final HSRB report]

dataset and includes statistical analysis of study objectives, is reviewed under separate cover (Crowley, 2016).

1.0 Executive Summary

The Agricultural Handler Exposure Task Force (AHETF) monitored dermal and inhalation exposure for 16 workers that mixed and loaded pesticide products in water-soluble packaging (WSP). The study protocol (AHETF, 2010a) specified monitoring of 25 workers; however 9 were either not monitored or had monitoring results excluded from the final dataset due to practices or situations considered outside of the scope of the "mixing/loading water-soluble packaging" exposure scenario. Additional recruitment was not conducted due to the achievement of study objectives with the 16 monitored workers and consideration of the recruitment difficulties experienced over the approximately 3 year duration of the study. 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 six U.S states and three years. The workers' activity involved adding water-soluble packets or bags containing pesticide formulations into mixing, holding, or application equipment containers, and diluting the packets and formulations in water via mechanical agitation. When the process involved dilution in a mixing or holding container, monitoring included transfer of the dilute solution to pesticide application equipment.

Table 1 presents a high-level summary of all of the exposure monitoring.

Table 1. AHE120 Summary

Worker ID	Type of Mixing/Loading Activity	State	Monitoring Year	Age (years)
M3	Mixed directly in application equipment tank	FL	2011	38
M6	Mixed directly in application equipment tank	ND	2012	52
M7	Mixed directly in application equipment tank	ND	2012	71
M10	Mixed directly in application equipment tank	FL	2013	26
M11	Mixed in holding tank, then loaded/transferred	CA	2013	52
M12	Mixed in holding tank, then loaded/transferred	LA	2013	62
M13	Mixed directly in application equipment tank	CA	2014	68
M14	Mixed directly in application equipment tank	ND	2014	23
M15	Mixed directly in application equipment tank	MS	2014	62
M18	Mixed in intermediate solution tank, then loaded/transfered	LA	2014	22
M20	Mixed in holding tank, then loaded/transferred	MN	2014	19
M21	Mixed directly in application equipment tank	FL	2014	58
M22	Mixed directly in application equipment tank	FL	2014	31
M23	Mixed directly in application equipment tank	CA	2014	26
M24	Mixed directly in application equipment tank	CA	2014	48
M25	Mixed directly in application equipment tank	CA	2014	18

Note: all study subjects were male.

Monitored on actual days of work, workers mixed and loaded between 200 and 9000 gallons over 2 to 9 separate mixing/loading events in 1 to 10 hours, totaling a range of 0.92 to 272 lbs of

active ingredient handled. All workers wore long-sleeved shirts, pants, shoes/socks and chemical-resistant gloves, with some wearing eye protection. No worker wore a respirator.

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 OSHA Versatile Samplers (OVS) 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 were appropriately documented; no deviations occurred. Analytical field and laboratory recovery results were acceptable, generally averaging between 70 and 120% recovery, with almost all coefficients of variation less than 25%. All field samples were appropriately adjusted for the corresponding 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. Dermal Exposure Summary

Statistic[1]	Total Exposure (µg)	Normalized by Body Weight (µg/kg BW)	Normalized by Amount ai Handled (µg/lb ai)[2]
Minimum	2.70	0.027	0.334
Maximum	2014	19.9	36.3
Mean	356	3.47	7.66

[1] Means are simple averages (i.e., sum of values ÷ n)
[2] 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. Inhalation Exposure Summary

Statistic[1]	Total Exposure (µg)	Normalized by Body Weight (µg/kg BW)	Normalized by Amount ai Handled (µg/lb ai)[2]
Minimum	0.046	0.00043	0.00056
Maximum	229	2.26	3.89
Mean	39.7	0.373	0.583

[1] Means are simple averages (i.e., sum of values ÷ n)
[2] Though other exposure metrics are shown in this table, exposure normalized to the amount of active

[2] Inhalation exposure (µg) = Residue collected * [Breathing rate (L/min) ÷ Pump rate (L/min)]. Pump rates generally were 2 L/min. Note: AHE120 presented the total active ingredient collected (µg), not results adjusted for breathing rates as shown here. AHETF monograph submissions, reviewed separately, perform the calculation shown here.
[3] NAFTA, 1998: 16.7 L/min represents light activity.

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 AHE120. While a summary is provided, the submitted AHE120 report should be consulted for more specific details (applicable sections, tables, and/or page numbers are provided).

2.1 Administrative Summary

AHE120 was sponsored by the AHETF and adequately followed both the protocol and scenario construction plan (AHETF, 2010a), the AHETF Governing Document (AHETF, 2008 and 2010b), 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). No protocol deviations were reported. Signed copies of acceptable Quality Assurance and Data Confidentiality statements were provided.

A summary of major protocol amendments is provided below. To mitigate recruitment difficulties experienced in the study, most protocol amendments were intended to expand the potential pool of eligible workers to monitor. Others were designed to exclude monitoring of work practices outside the scope of the intended monitoring that were observed in the early stages of the study.

- Changed requirements for workers to have experience loading WSPs specifically to experience with mixing/loading in general.
- Changed requirement for workers to have experience loading the exact equipment in the study.
- Allowed for less cost-efficient "cluster" design.
- Expanded monitoring areas to include entire U.S. state rather than smaller geographic areas within designated states.
- Allowed for additional sources to identify potential operators/growers/employers.
- Disallowed certain practices related to breaching the WSP that are considered outside of the scope of the intended use of the monitoring data (see Section 2.6).
- Provided specific guidance on proper WSP mixing practices, consistent with their intended use and product labels.

EPA considers the amendments reasonable and helpful additions for obtaining results consistent with the intent of the study's purpose and original protocol. For a more detailed summary of protocol amendments, see Section 4.0 below and refer to AHE120 pages 10-12 as well as AHE120 Appendix A (pages 213-247).

2.2 Test Materials

The protocol specified four surrogate active ingredients that could be used by the monitored workers: acephate, dithiopyr, imidacloprid, and thiophanate-methyl. Ultimately, monitored workers used 3 of the 4 surrogates (acephate, imidacloprid and thiophanate-methyl). The five (5) different EPA-registered products that were used are outlined in Table 4 below; all were solid/powder material inside water-soluble packaging, with small packets/bags of about 1.6 ounces or larger ones of about 1-2 pounds. In the AHE120 study report, Table 2 on page 66 provides more specific details on the products used.

Table 4. AHE120 Summary of Pesticide Products Used

Product Name	EPA Reg. No.	Active Ingredient	WSP size	Worker ID
Topsin M WSB	73545-16-70506	Thiophanate-methyl	1 lb	M3
				M6
				M7
				M11
				M15
Malice 75 WSP	34704-1009	Imidacloprid	1.6 oz	M10
				M13
				M22
				M23
				M24
				M25
Merit 75 WSP	432-1318	Imidacloprid	1.6 oz	M21
T-Methyl 70 WSB	228-655	Thiophanate-methyl	1 lb	M14
				M18
				M20
Acephate 90 WSP	34704-862	Acephate	2.5 lb	M12

Per GLP, AHETF analyzed the test substances for purity. Certificates of Analysis, which formally document analysis of the test substances, are provided in AHE120 Appendix F pages 634-652. 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 AHE120 study report in Table 7 on pages 76-79. This is also described more in Section 2.7 below.

2.3 Sample Size, Monitored Workers, and Locations

According to the Mix/Load WSP Scenario Construction Plan (AHETF, 2010a) and the AHETF Governing Document (AHETF, 2008 and 2010b), a "5 x 5" configuration was deemed a reasonable approach for these scenarios. That is, a total of 25 "monitoring units" (MU), obtained by monitoring exposure from 5 spatially distinct study locations across the U.S., each with 5 workers per location would likely satisfy pre-defined accuracy benchmarks.

Due to logistical recruitment difficulties, the goal of efficiently monitoring in spatial and temporal proximity was not possible. Additionally, monitoring for 9 workers was not included in the final dataset following issues that were not anticipated at the onset of the study: 6 workers conducted practices considered outside the scope of the AHETF mixing/loading WSP scenario, and monitoring for 3 workers was not conducted or terminated due to improper dissolution or

broken packaging (see Section 2.6). Additional recruitment was not conducted due to the achievement of study objectives with the 16 monitored workers and considering the recruitment difficulties experienced over the approximately 3 year duration of the study.

Thus, the final dataset consisted of 16 separate workers monitored while mixing/loading water-soluble packet pesticide products in six U.S. states (Florida, North Dakota, California, Mississippi, Louisiana, and Minnesota) from 2011-2014. Instead of the intended 5 "clusters", the 16 monitored workers ultimately comprised 10 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 16 monitored workers, while the AHE120 study report provides additional details in Table 3 on pages 67-70.

Table 5. AHE120 Worker and Location Summary

Worker ID	Gender	Age (years)	Weight (lb)	Work Experience (years)	Monitoring Location (U.S. State)	Monitoring Year
M3	Male	38	298	15	FL	2011
M6	Male	52	223	2	ND	2012
M7	Male	71	240	7	ND	2012
M10	Male	26	165	5	FL	2013
M11	Male	52	246	4	CA	2013
M12	Male	62	184	39	LA	2013
M13	Male	68	220	40	CA	2014
M14	Male	23	210	7	ND	2014
M15	Male	62	235	50	MS	2014
M18	Male	22	198	7	LA	2014
M20	Male	19	213	3	MN	2014
M21	Male	58	232	24	FL	2014
M22	Male	31	190	10	FL	2014
M23	Male	26	170	8	CA	2014
M24	Male	48	223	30	CA	2014
M25	Male	18	165	1	CA	2014

2.4 Environmental Conditions

Temperature[4] (including heat index), humidity, wind speed and direction, cloud cover, and rainfall were all reported. The maximum reported temperature was 89.7° F (ND, July 2012) and the lowest reported temperature was 41.8° F (CA, March 2014). No monitoring was affected or halted as a result of the ambient temperature exceeding the pre-defined threshold of concern for potential heat-related injury. 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 AHE120 report Table 8 (pages 80-83).

[4] EPA identified a minor error in the AHE120 submission regarding the temperature measurements for March 28, 2013 when worker M11 was monitored. The submission shows units of degrees Fahrenheit but the values are shown for that date are in degrees Celsius. The correct temperatures in degrees Fahrenheit should be 51.4 (minimum) and 74.3 (maximum).

2.5 Clothing and Personal Protective Equipment (PPE)

Per the stated goals of the AHETF, monitoring of mixing and loading WSP pesticide products was conducted to represent exposure while wearing long-sleeve shirts, pants, shoes/socks, chemical-resistant gloves and no respiratory protection. No deviations, such as workers wearing additional chemical-resistant aprons or headgear, were noted. 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 no instance did a worker's clothing need to be replaced.

Anticipating potential sampling problems due to deviations from protocol-specified work practices, the Study Director attempted to "re-sample" worker M10 after the first three loading events with a fresh inner dosimeter and air sampling equipment. However at that point, the worker's (outer) work clothing was not clean and potentially could cause some cross-contamination problems, so this worker's exposure sample is constituted of only the exposure experienced through the first three loading events. The monitoring during the first three loading events was determined to be consistent with the work practices outlined in the protocol and protocol amendments.

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).

Additionally, many workers, due to worker preference or required by the pesticide label, wore protective eyewear. In these cases, to simulate workers who do not wear any 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 protective eyewear (see Section 3.3.2)[5].

More specific details on work clothing and PPE can be found in the AHE120 study report in Tables 4 and 5 on pages 71-74.

2.6 Mixing/Loading Equipment and Methods

For these studies, as indicated above, monitoring was conducted only for exposure during mixing and loading the WSP products into application equipment – 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 solutions. Mixing of WSP products was done in one of three types of containers: directly in the application equipment; in a holding/nurse/pre-mix tank at the same concentration as the final spray dilution; or an intermediate mixing tank or bucket (e.g., slurry tank) containing a concentrated solution. When the process involved dilution in a holding tank

[5] These calculations and results are presented by the AHETF in their scenario monograph (AHE1014), but not in the submission for AHE120.

or intermediate solution tank, monitoring included loading/transfer of the solution to the pesticide application equipment.

Table 6 below outlines the different methods of mixing/loading and different types of pesticide application equipment the material was loaded into. The AHE120 study report provides more details in Table 7 on pages 76-79.

Table 6. AHE120 Mixing/Loading Summary

Worker ID	Mixing/Loading Type	Pesticide Application Equipment	Capacity of mix tanks (gallons)	Height of tank hatch from ground (feet)
M3	Directly in application equipment tank	Groundboom tractor	1000	Not reported
M6	Directly in application equipment tank	Groundboom tractor	1000	12
M7	Directly in application equipment tank	Groundboom tractor	1200	12
M10	Directly in application equipment tank	Groundboom tractor	500	8
M11	Holding tank, then loaded/transferred	Airblast sprayer	1050 (mix tank) 600 (sprayer)	8
M12	Holding tank, then loaded/transferred	Airplane	800 (holding tank) 320 (airplane)	5
M13	Directly in application equipment tank	Airblast sprayer	500	5
M14	Directly in application equipment tank	Groundboom tractor	1500	10
M15	Directly in application equipment tank	Groundboom tractor	750	4
M18	Intermediate solution tank, then loaded/transfered	Airplane	150 (slurry tank) 500 (airplane)	4
M20	Holding tank, then loaded/transferred	Airplane	500 (mix tank) 500 (airplane)	4
M21	Directly in application equipment tank	Groundboom tractor	1000	Not reported
M22	Directly in application equipment tank	Airblast sprayer	1000	6
M23	Directly in application equipment tank	Airblast sprayer	500	6
M24	Directly in application equipment tank	Airblast sprayer	500	5
M25	Directly in application equipment tank	Airblast sprayer	400	6

Generally, workers would first partially fill the tank or bucket with water then add the water soluble packets. Mechanical agitation and recirculation was then employed to dissolve the packets and the formulation inside the packets. Once dissolved, additional water would be added to achieve the desired spray solution concentration. During the initial stages of field monitoring work, the AHETF identified work practices that both the AHETF and EPA agreed ran counter to the use of WSP as an engineering control intended to reduce exposure potential[6]. These included

[6] AHETF-EPA conference call on June 21, 2012.

placing the WSPs into baskets hanging over the mix tank and spraying them with water to dissolve the outer packaging or, when WSPs were placed in water in the tank, using overhead solution recirculation to dissolve the outer packaging. These issues resulted in exclusion of monitoring for 6 of the recruited workers[7]. Appendix G of AHE120 provides full details of excluded monitoring for AHE120, including worker observations, photographs, and, in some cases, available monitoring results.

As a result of these issues, specific instructions were provided to workers by the AHETF (outlined in protocol amendments 6, 8 and 13), beyond mixing/loading instructions on the product labels. The instructions were mainly intended to prevent overhead spray of the WSPs in order to dissolve them, including having mechanical agitation/recirculation come from the bottom of the mix tank without overhead recirculation, unless the hatch was closed. If overhead circulation is required, the hatch lid should be closed during dissolution. Provided as Appendix B in the AHE120 study report, the mixing instructions in the protocol were as follows:

- Remove any strainer basket from the tank hatch.
- Fill tank to approximately one-third to one-half of the desired final volume of spray.
- Stop adding water and any agitation.
- Add WSPs to the surface of the water in the tank.
- Start mechanical and recirculation agitation from the bottom of tank without using any overhead recirculation.
- If you must work near the tank hatch, close the lid.
- If overhead recirculation cannot be turned off, close the hatch before starting agitation.
- Do not direct water from a hose or fill pipe to break the bags.
- Dissolving the WSPs may take up to 5 minutes or longer, depending on water temperature, hardness and intensity of agitation. Check periodically, avoiding any dusts or re-circulating spray mix.
- When the bags have fully dissolved and the powder has gone into suspension in the water, other products may be added.
- Resume filling the tank with water to the desired level.
- Maintain agitation while filling and driving/flying to the spray site and during application.
- Follow all other label instructions regarding the handling of WSPs.

Field observations, described below in Section 3.5 and provided in detail in AHE120 should also be referenced for descriptions of the mixing and loading activities. Upon review of the field observations, EPA agrees that the practices of the 16 monitored workers were consistent with those outlined above and the intended scope of this AHETF scenario.

2.7 Application Rates and Amount of Active Ingredient Handled

[7] Monitoring for a total of 9 workers are not represented in the dataset. The 6 as indicated, plus an additional 3: monitoring for 2 workers was not conducted because the outer packaging was broken/breached (and no longer a WSP) and monitoring for 1 worker was terminated due to the addition of WSPs after loading fertilizer which resulted in poor dissolution (product labels instruct users to dissolve WSPs prior to other spray tank additives such as fertilizer).

According to the AHE120 study protocol (AHETF, 2010a) and the AHETF Governing Document (AHETF, 2008 and 2010b), the total amount of active ingredient applied should be diversified across the scenario and within each study location.

Workers handled between 1.8 and 396 lbs of product, mixing between 200 and 9,000 gallons of solution over the course of 1 to 10 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 0.92 and 272 lbs of active ingredient (in this study: thiophanate-methyl, imidacloprid, or acephate).

Table 7 below provides more detail on solution and application information. The submitted AHE120 study report Table 7 (on pages 76-79) should also be referenced.

Table 7. AHE120 Application Rate Information

Worker ID	Mixing/Loading Type	WSP Size	# WSPs handled	% ai in product[a, b]	Total Solution Prepared (gallons)	# Loads Mixed	Exposure Time (hrs)	AaiH (lbs)[c]
M3	Directly in application equipment tank	1 lb	90	68	9000	9	6.9	61
M6	Directly in application equipment tank	1 lb	306	69	4650	5	10.5	212
M7	Directly in application equipment tank	1 lb	208	68	2520	4	3.0	142
M10	Directly in application equipment tank	1.6 oz	12	76	1500	3	1.5	0.92
M11	Holding tank, then loaded/transferred	1 lb	80	72	4200	4	8.3	58
M12	Holding tank, then loaded/transferred	2.5 lb	14	68	700	4	1.1	24
M13	Directly in application equipment tank	1.6 oz	18	73	1500	3	6.1	1.3
M14	Directly in application equipment tank	1 lb	85	69	1900	3	3.0	58
M15	Directly in application equipment tank	1 lb	120	69	2250	3	2.7	82
M18	Intermediate solution tank, then loaded/transfered	1 lb	106	69	700	2	0.7	73
M20	Holding tank, then loaded/transferred	1 lb	396	69	1700	4	4.0	272
M21	Directly in application equipment tank	1.6 oz	300	72	3000	3	3.8	21

M22	Directly in application equipment tank	1.6 oz	94	65	3000	3	3.8	6.1
M23	Directly in application equipment tank	1.6 oz	24	76	200	4	3.7	1.8
M24	Directly in application equipment tank	1.6 oz	24	73	200	4	3.7	1.7
M25	Directly in application equipment tank	1.6 oz	30	76	600	3	2.1	2.3

[a] Active ingredient (ai) = thiophanate-methyl, acephate, or imidacloprid.
[b] The % ai is based on the Certificates of Analysis (see AHE120 Appendix F), not the % ai on the product label.
[c] AaiH is approximated by the calculation: WSP Size * # WSPs * % 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 AHE120 to evaluate whether various characteristics of the monitoring was reasonably representative of the conditions during mixing/loading water soluble packets in that area. The characteristics surveyed were: the specific county and location 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 AHE120 were not atypical of the population of individuals who mix/load water soluble packets. A summary of the findings is provided in Table 8 below.

Table 8. AHE120 Synopsis of Informal Survey of Local Farm Experts

Monitoring Area	Recruited	Responded	Response
NY	• 2 Agricultural Extension Agents • 1 Dept Horticulture Science (NYSAES) • 1 Spray Tech Expert (NYSAES)	3 of 4	• 1 agreed the monitoring was typical • 1 agreed, except for newer technology and farm size • 1 responded that they lacked expertise.
FL	• 7 Agricultural Extension Agents	5 of 7	• 4 agreed the monitoring was typical. • 1 declined comment, lacking requisite expertise.
LA/MS	• 7 Agricultural Extension Agents • 3 current/former LA AAA officers	8 of 10	• 6 replied that they were not cleared to provide information. • 2 agreed the monitoring was typical.
ND/MN/MI	• 4 Agricultural Extension Agents	1 of 4	• 1 agreed the monitoring was typical.

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 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 are 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 two pieces and analyzed separately according to AHETF SOP 8.A.

Inhalation exposure was measured using OVS tubes 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 each active ingredient 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 AHE120 analytical reports (Appendices C, D, and E):

- Acephate
    - AHE06, "Validation of Methods for the Analysis of Exposure Matrices for Acephate"
    - AHE218, "Validation of a Worker Exposure Analytical Method for the Analysis of Acephate on Two-Piece Inner Dosimeters
- Thiophanate-methyl
    - AHE233, "Validation of Worker Exposure Methods for the Determination of Thiophanate-Methyl as its Carbendazim Hydrolysis Product in Worker Exposure Matrices"
- Imidacloprid

- AHETF-AM-059, "An Analytical Method for the Determination of Residues of Imidacloprid, Clothianidin, Carboxin, and Metylaxyl in Face Wipes, Hand Washes, and Dosimeter Garments
- AHETF-AM-066, "An Analytical Method for the Determination of Residues of Imidacloprid, Clothianidin, Carboxin, and Metylaxyl in OVS-2 Air Monitoring Tubes"

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

Table 9. Analytical Limits (µg/sample) for AHE120

Monitoring Matrix	Limit of Detection			Limit of Quantification		
	Acephate	TPM	Imidacloprid	Acephate	TPM	Imidacloprid
Inner Dosimeter	0.12	0.17	0.30	1.0	1.0	1.0
Hand Rinse	0.04	0.20	0.30	0.2	1.0	1.0
OVS air sampler (per section)	0.003	0.01	0.0015	0.01	0.01	0.005
Face/Neck Wipe	0.25	0.28	0.30	0.5	1.0	1.0

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 the surrogate active ingredients proposed. 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

Only two instances of detectable residues were found in control samples (two inner dosimeter field control samples)[8]. More detailed results can be found in AHE120 Appendix C Tables 6-10 on pages 281-285, Appendix D Tables 6-14 on pages 361-378, and Appendix E Tables 3-11 on pages 492-512.

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 OVS samplers). 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 are 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[9]. 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.

[8] One sample (0.348 µg) was slightly above the LOD (0.3 µg), while the other (0.954 µg) was approximately 3X the LOD. In neither case were the field samples adjusted for these results.

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

With some exceptions, field fortification averages for each fortification level and each monitoring matrix were in the range of 70-120% with coefficients of variation generally less than 25%. For one worker (M20), field fortification samples were not conducted; thus field samples are adjusted using recovery results for other monitoring for the same active ingredient (thiophanate-methyl). For more details on field fortification results see AHE120 Table 11 on pages 144-155. 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%. No results were excluded from recovery calculations as outliers.

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

- Thiophanate-methyl
    - Applicable to workers M3, M6, M7, M11, M15, M18, and M20
        - ≤ 27.5 µg, > 27.5 to ≤ 275 µg, and > 275 µg
    - Applicable to worker M14
        - ≤ 52.5 µg, > 52.5 to ≤ 2050 µg, and > 2050 µg
- Imidacloprid:
    - Applicable to workers M10, M13, M21, M22, M23, M24, and M25
        - ≤ 27.5 µg, > 27.5 to ≤ 275 µg, and > 275 µg
- Acephate
    - Applicable to worker M12
        - ≤ 27.5 µg, > 27.5 to ≤ 275 µg, and > 275 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 20%. No results were excluded from recovery calculations as outliers.

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

- Thiophanate-methyl
    - Applicable to workers M3, M6, M7, M11, M15, M18, and M20
        - ≤ 27.5 µg, > 27.5 to ≤ 275 µg, and > 275 µg
    - Applicable to worker M14
        - ≤ 52.5 µg, > 52.5 to ≤ 1050 µg, and > 1050 µg
- Imidacloprid:
    - Applicable to workers M10, M13, M21, M22, M23, M24, and M25
        - ≤ 27.5 µg, > 27.5 to ≤ 275 µg, and > 275 µg
- Acephate

- Applicable to worker M12
  - ≤ 27.5 µg, > 27.5 to ≤ 275 µg, and > 275 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 less than 15%. Only two hand wash fortification samples were excluded from calculation of the average recovery: a 32.8% value (M12) and a value of 142% (M13).

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

- Thiophanate-methyl
  - Applicable to workers M3, M6, M7, M11, M15, M18, and M20
    - ≤ 27.5 µg, > 27.5 to ≤ 275 µg, and > 275 µg
  - Applicable to worker M14
    - ≤ 52.5 µg, > 52.5 to ≤ 1050 µg, and > 1050 µg
- Imidacloprid:
  - Applicable to workers M10, M13, M21, M22, M23, M24, and M25
    - ≤ 27.5 µg, > 27.5 to ≤ 275 µg, and > 275 µg
- Acephate
  - Applicable to worker M12
    - ≤ 27.5 µg, > 27.5 to ≤ 275 µg, and > 275 µg

3.2.2.4 OVS Air Samplers

Results for OVS field fortification samples were acceptable, with average recoveries ranging from approximately 70% to 120% and all but one coefficient of variation (27%, mid-level, thiophanate-methyl) less than 25%. Only one sample, a recovery value of 139% (M18) was excluded from calculation of an average recovery.

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

- Thiophanate-methyl
  - Applicable to workers M3, M6, M7, M11, M15, M18, and M20
    - ≤ 2.53 µg, > 2.525 to ≤ 27.5 µg, and > 27.5 µg
  - Applicable to worker M14
    - ≤ 2.53 µg, > 2.525 to ≤ 252.5 µg, and > 252.5 µg
- Imidacloprid:
  - Applicable to workers M10, M13, M21, M22, M23, M24, M25
    - ≤ 2.53 µg, > 2.525 to ≤ 27.5 µg, and > 27.5 µg
- Acephate
  - Applicable to worker M12
    - ≤ 2.53 µg, > 2.525 to ≤ 27.5 µg, and > 27.5 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). Face/neck wipe measurements were extrapolated to un-wiped portions of the face and head according to AHETF SOP 9.K. For samples below the LOQ or LOD, ½ LOQ or ½ LOD was used.

3.3.1 Inner Dosimeters

Without field fortification adjustments, WBD sections ranged from non-detectable to 1107 µg. Out of a total of 32 inner dosimeter samples, 4 were below the LOQ or LOD. AHE120 Table 14 on page 164 provides more details on these samples.

After adjusting for field fortification recoveries and summing the two separate body sections, the total dermal exposure underneath the long-sleeve shirt and pants ranged from 1.3 – 985 µg with an average of 254 µg.

3.3.2 Face/Neck Wipes

Without field fortification adjustments, face/neck wipe samples ranged from non-detectable to 20.1 µg. Out of a total of 16 face/neck wipe samples, 8 were below the LOQ or LOD. AHE120 Table 15 on page 165 provides more details on these samples.

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[10,11].

After adjusting for field fortification recoveries and extrapolating to non-wiped portions of the head described above, total head exposure ranged from 0.210 – 27.7 µg with an average of 8.62 µg.

3.3.3 Hand Washes

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 only 1 hand wash sample taken; six workers had 2 hand wash samples and one had

[10] 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.

[11] 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))]}

3 hand wash samples. The following table outlines the number of hand wash samples broken down by the work duration.

		Table 10. AHE120 Hand Wash Summary		
		Work Duration (hours)		
		< 3	3-6	≥ 6
Mix/Load WP	Percentage of Workers	25%	50%	25%
	# of Hand Washes	1	1-2	2-3

Without field fortification adjustments, individual hand wash samples ranged from < LOQ to 747 µg. Out of a total of 23 hand wash samples, 3 were below the LOQ (none < LOD). AHE120 Table 15 on page 165 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 0.5 – 1,041 µg with an average of 93.4 µg.

3.3.4 OVS Air Samplers/Inhalation Exposure

Front and back sections of the OVS tube were analyzed separately. All but one back section sample were less than the LOQ or LOD. All but two front section samples had quantifiable residues. Without field fortification adjustments, front sections ranged from < LOQ to 24.6 µg and back sections were all < LOQ or LOD, except for one sample measuring 0.00844 µg. AHE120 Table 16 on page 166 has more details on these results. After adjusting for field fortification recoveries, the total (front section + back section) collected active ingredient amounts ranged from 0.006 – 27.2 µg with an average of 4.78 µg.

The AHE120 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. A separate AHETF submission describing the mixing/loading WSP scenario (under separate EPA review) presents 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 water soluble packet 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 0.045 – 229 µg with an average of 39.7 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 presented below as well as normalized to body weight and amount of active ingredient handled.

Table 11. AHE120 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	2.70	0.027	0.334
	Maximum	2014	19.9	36.3
	Mean	356	3.47	7.66
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 presented below.

Table 12. AHE120 Inhalation Exposure Summary				
Equipment	**Statistic**	**Total Exposure (µg)**	**Normalized by Body Weight (µg/kg BW)**	**Normalized by Amount ai Handled (µg/lb ai)**
M/L WSP	Minimum	0.046	0.00043	0.00056
	Maximum	229	2.26	3.89
	Mean	39.7	0.373	0.583
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. These can be found in the AHE120 report in Table 9 on pages 84-128.

Many of the observations detailed routine mixing/loading procedures (e.g., MU M18 @ 0810: "M18 finishes adding 53 lbs of WSB to mix tank. M18 turns on agitation."). Other observations may potentially provide clues as to determinants of exposure – examples of these types of observations include:

- Visible dust plumes
  - e.g., MU M18 @ 0821: "With water approx. half ful (above pipe inlet) M18 begins adding WSB by following same procedures, minimal plumes visible."
  - e.g., MU M7 @ 1103: "Finished adding WSPs. During last 10 WSPs or so, dust was visible around the hatch opening, This is product coming from party dissolved bags floating on water and some is blown out of hatch. Wind blows dust away from worker."

- Contact with spray solution – e.g., MU M3 @ 1030: "A small amount of tank mix splashed on left shoulder of worker. Two one inch diameter spots visible."

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 the study protocol are detailed below; no protocol deviations were reported. For additional details, see the AHE120 study report on pages 10-12 as well as Appendix A on pages 213-247. The fifteen (15) protocol amendments were reasonable accommodations to accomplish the research and did not adversely impact the study conduct or the exposure monitoring results. Most protocol amendments were intended to expand the potential pool of eligible workers to monitor, while a few were designed to exclude monitoring of work practices outside the scope of the intended monitoring.

Protocol Amendments:

- Amendment 1
  - Change to Study Director and Principal Field Investigator.
- Amendment 2
  - Removed requirement to have experience with mixing/loading water soluble packets; required only any mixing/loading experience within year.
  - Allowed for a less cost-efficient configuration of monitoring areas
  - Change to Principal Analytical Investigator and analytical facility
  - Allowed use of manufacturer's certification to determine active ingredient concentration in the absence of GLP-sourced references
- Amendment 3
  - Removed requirement to have experience with a particular piece of pesticide application equipment.
- Amendment 4[12]
  - Expanded list of qualified Principal Field Investigators
  - 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.

[12] In the AHE120 submission EPA identified a missing page (page 11 of 14) related to protocol amendment 4. AHETF subsequently supplied the entire protocol amendment documenting the missing page.

- Amendment 5
    - Change to Principal Analytical Investigator.
- Amendment 6
    - Disallowed use of baskets in tank hatches.
- Amendment 7
    - Increased the amount of thiophanate-methyl that could be handled.
- Amendment 8
    - Expanded and replaced Amendment 6 to disallow additional practices and provide better WSP mixing instructions.
- Amendment 9
    - Change contact information for field and analytical staff.
    - Discontinued review of MSDS (per AHETF SOP 11.E).
    - Expanded Louisiana monitoring areas to include some counties in Mississippi.
- Amendment 10
    - Change to Principal Analytical Investigator.
- Amendment 11
    - Change to Principal Analytical Investigator contact information.
- Amendment 12
    - Expanded heat-related illness monitoring to include use of a wet-bulb globe temperature (WBGT) system.
- Amendment 13
    - Final compilation of WSP handling practices covered by monitoring.
- Amendment 14
    - Change to quality assurance personnel and Principal Analytical Investigator
- Amendment 15
    - Change to Principal Analytical Investigator.

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 workers mixing and loading pesticide products in water soluble packaging.

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 Water Soluble Packet Scenario Monograph (AHE1014: Klonne and Holden, 2015). 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). Review of those monographs as well as recommendations for use of the data by EPA exposure assessors are in a separate review memorandum (Crowley, 2015a and 2015b).

6.0 References

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