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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM

Date: [placeholder], 2020

SUBJECT: **DRAFT** Review of "Determination of Dermal and Inhalation Exposure to Workers during Closed System Loading of Liquids in Returnable and Non-Returnable Containers" (AHE500)

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This memorandum presents EPA's review of the analytical and field phase reports for AHE500 (Bruce, 2019), an Agricultural Handler Exposure Task Force (AHETF) study that monitored dermal and inhalation exposure for workers while using closed systems to mechanically transfer liquid pesticides. It reflects comments and advice provided by the Human Studies Review Board following its January 2020 review[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 using closed systems. The scenario monograph (Bruce and Holden, 2019a), which incorporates the monitoring data from AHE500 and two additional studies (AHE13 and AH501) into a single/composite dataset and includes statistical analysis of study objectives, is reviewed separately (Crowley, 2020; D454706).

[1] [placeholder]

1.0 Executive Summary

The Agricultural Handler Exposure Task Force (AHETF) monitored dermal and inhalation exposure for 36 workers while mechanically transferring liquid pesticides into application equipment or pre-mix tanks without manually pouring pesticide containers. Work activity consisted of transferring liquid pesticides from returnable or non-returnable containers[2] to mix tanks or application equipment tanks using pumps, hoses and piping with suction/extraction, gravity flow, or container breach systems which are considered "closed systems" under EPA's Worker Protection Standard (WPS)[3]. Monitored on actual days of work, workers loaded between 20 gallons to almost 500 gallons of concentrated liquid product, ranging from 76 to more than 2000 lbs of active ingredient (ai) handled. On each monitoring day workers loaded product in 3 to 11 separate loads, preparing between 330 and 14,000 gallons of solution over approximately 1 to 9 hours.

As planned by the AHETF, 21 workers mechanically transferred pesticides from non-returnable containers[4] and 15 workers transferred pesticides from returnable/refillable containers. Monitoring was conducted across 12 U.S states over the course of 5 years (2012-2016). Table 1 presents a high-level summary of the exposure monitoring.

Table 1. AHE500 Summary

Worker ID		Monitoring Date	U.S. State	Age (years)	Type of Container	Type of System
C	M01	11/29/2012	FL	34	Returnable	Suction/Extraction
H	M03	3/9/2013	MS	26	Non-Returnable	Suction/Extraction
E	M04	3/12/2013	TX	29	Non-Returnable	Suction/Extraction
I	M05	3/14/2013	MS	44	Non-Returnable	Suction/Extraction
J	M06	4/26/2013	FL	48	Returnable	Suction/Extraction
K	M07	5/30/2013	MI	56	Returnable	Gravity Flow
A	M08	6/13/2013	FL	47	Returnable	Gravity Flow
O	M09	9/25/2013	WA	35	Non-Returnable	Suction/Extraction
P	M10	10/11/2013	WA	30	Returnable	Gravity Flow
Q	M11	11/13/2013	WA	27	Non-Returnable	Container Breach
S	M12	5/7/2014	MI	29	Returnable	Gravity Flow
R	M13	6/18/2014	AZ	31	Non-Returnable	Suction/Extraction
R	M14	6/19/2014	AZ	31	Returnable	Suction/Extraction
N	M15	7/4/2014	MI	29	Returnable	Gravity Flow
U	M16	10/2/2014	WA	26	Non-Returnable	Suction/Extraction
U	M17	10/3/2014	WA	26	Returnable	Gravity Flow
AA	M18	6/9/2015	NE	27	Returnable	Suction/Extraction
AB	M19	6/19/2015	CO	34	Returnable	Gravity Flow
Y	M20	6/22/2015	MI	37	Non-Returnable	Suction/Extraction
W	M21	6/27/2015	CO	43	Non-Returnable	Suction/Extraction
AA	M22	7/11/2015	NE	27	Non-Returnable	Suction/Extraction
AK	M24	4/4/2016	LA	30	Non-Returnable	Suction/Extraction
AF	M25	4/5/2016	LA	45	Non-Returnable	Suction/Extraction
AH	M26	4/12/2016	NE	25	Non-Returnable	Container Breach

[2] Returnable containers are those that are brought back to or refilled by distributor. Non-returnable containers are those that are disposed of or recycled.

[3] At the time of the study, the applicable regulation was 40 CFR §170.240(d). Currently "closed systems" are covered under a revised Worker Protection Standard at 40 CFR §170.305 and §170.607.

[4] Monitoring data for 2 of the 21 workers using non-returnable containers were determined to be invalid.

Table 1. AHE500 Summary						
Worker ID		**Monitoring Date**	**U.S. State**	**Age (years)**	**Type of Container**	**Type of System**
AG	M27	4/13/2016	NE	24	Returnable	Gravity Flow
AI	M28	4/15/2016	NE	56	Returnable	Gravity Flow
AM	M29	6/4/2016	MI	65	Non-Returnable	Gravity Flow
AJ	M30	6/8/2016	OR	23	Returnable	Suction/Extraction
AL	M31	6/14/2016	MI	27	Non-Returnable	Suction/Extraction
AN	M32	6/23/2016	NE	26	Non-Returnable	Gravity Flow
Z	M33	7/21/2016	GA	27	Non-Returnable	Suction/Extraction
AO	M34	9/21/2016	CO	41	Returnable	Gravity Flow
AP	M35	10/11/2016	MS	27	Non-Returnable	Suction/Extraction
AQ	M36	10/14/2016	SC	28	Non-Returnable	Suction/Extraction

Notes:
- Worker AI/M28 was the only female.
- 36 workers were monitored, though Table 1 presents 34. Samples for two monitored workers were considered invalid, see Section 2.3.

Dermal exposure was measured using hand washes, face/neck wipes, socks, and whole-body dosimeters (100% cotton union suits) for the remainder of the body (torso, arms, and legs). Per the study protocol (AHETF, 2011a and 2011b), in cases where workers wore eye protection and/or respirators (e.g., due to product label requirements) dermal exposures were extrapolated to areas covered by that equipment. Inhalation exposure was measured using personal air sampling pumps and OSHA Versatile Samplers (OVS) mounted on the shirt collar. Thus, exposure monitoring results represent workers wearing long-sleeved shirts, pants, shoes/socks and chemical-resistant gloves with no respiratory protection.

The study followed the applicable and most up-to-date AHETF standard operating procedures (SOPs) (AHETF, 2015) and the corresponding protocol (AHETF, 2011a and 2011b). Protocol amendments and deviations were appropriately documented (see Section 4.0). Analytical field and laboratory recovery results were acceptable, generally averaging between 70 and 120% recovery, with coefficients of variation largely less than 25%. Field samples, control samples, and exposure calculations were independently validated (Attachment 1). It is therefore considered acceptable and appropriate for use in assessing exposure and risk for workers using closed systems to mechanically transfer liquid pesticides.

A high-level summary of dermal and inhalation exposures is provided in Table 2 below. For more formal use and application of the data in exposure assessment beyond simply the data results presented in this review, users are directed to a separate EPA review (Crowley, 2020; D454706).

Table 2. AHE500 Exposure Summary[1]					
Statistic[2]	**Dermal Exposure (µg)**				**Inhalation Exposure (µg)[7]**
	Hands[3]	**Head[4]**	**Body[5]**	**Total[6]**	
Minimum	0.15	0.12	0.57	3.94	0.14
Maximum	16,209	755	13,537	29,825	54.4
Mean	1,926	62.1	947	2,935	6.02

[1] Results shown include adjustments for field fortification sampling. See Section 3.2.2.
[2] Means are simple averages (i.e., sum of values ÷ n).
[3] Exposure underneath chemical-resistant gloves.
[4] Results include extrapolation of face/neck wipe samples to non-wiped portions of the face/neck/head.

[5] Reflects the sum of two inner dosimeter samples for each worker (upper body and lower body), representing exposure underneath a single layer of work clothing.
[6] "Total" does not (necessarily) correspond to the sum of the results for the individual body parts shown in this table (i.e., the worker with maximum total dermal exposure may not have also had the maximum hand exposure).
[7] Inhalation exposure (µg) = Residue collected * [Breathing rate (L/min) ÷ Pump rate (L/min)]. Pump rates generally were 2 L/min; breathing rate of 16.7 L/min assumed (NAFTA, 1998).

2.0 Summary of Field Study Characteristics

This section provides summary characteristics for AHE500. While this review provides summaries in addition to EPA considerations and conclusions, the submitted AHE500 report (Bruce, 2019) should be consulted for more specific details; applicable sections, tables, and/or page numbers are provided.

2.1 Administrative Summary

AHE500 was sponsored by the AHETF and adequately followed the study protocol (AHETF, 2011a and 2011b), 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). Signed copies of acceptable Quality Assurance and Data Confidentiality statements were provided.

The protocol was amended 3 times and 6 protocol deviations were reported; appropriate documentation was provided. Amendments were largely aimed at increasing the potential for employer and worker participation by expanding monitoring areas or adding possible test substances. Protocol deviations included: analytical laboratory methodology changes; lack of protocol-specified worker training; lack of closed systems inspections; lack of dermal sampling at protocol-specified times.

EPA considers the amendments reasonable and useful additions for obtaining results consistent with the intent of the study's purpose and original protocol. Furthermore, EPA agrees that no deviation adversely affected the conduct or outcomes of the study. For a more detailed summary of protocol amendments and deviations, see Section 4.0 below and refer to AHE500 pages 12-13 as well as AHE500 Appendix A (pages 490-511).

2.2 Test Materials

The protocol specified 13 surrogate active ingredients that could be used by the monitored workers[5]. Additionally, in May 2015 protocol amendment 2 added chlorpyrifos as an additional potential surrogate chemical. Ultimately, monitored workers used 4 of the possible 14 surrogates (chlorothalonil, 2,4-D, glyphosate, imazapyr). The various EPA-registered products containing those active ingredients are outlined in Table 4 below; AHE500 pages 117-118 and 311 provide

[5] Carbaryl, chlorothalonil, DCPA, fosamine, glyphosate, imazapyr, imidacloprid, malathion, simazine, sulfur, thiophanate-methyl, 2,4-D, 2,4-DB.

more specific details. EPA agrees that the active ingredients used as surrogates have valid analytical methods for dermal and inhalation exposure monitoring and the products were handled and in the study in accordance with product labels and applicable EPA regulations with deviations properly documented.

Table 3. AHE500 Summary of Pesticide Products Used			
Active Ingredient	**Product Name**	**EPA Reg. No.**	**# Workers Used**
2,4-D	Weedone LV6 EC	71368-11	3
	Amine 4 2,4-D Herbicide	42750-19-55467	2
	Shredder 2,4-D LV6	1381-250	1
	Agri Star 2,4-D LV6	42750-20	1
Glyphosate	Touchdown HiTech	100-1182	1
	Credit 41 Extra	71368-20	1
	Credit Xtreme	71368-81	1
	RoundUp PowerMax	524-549	13
	Durango DMA	62719-556	3
	Accord XRT II		
	Buccaneer Plus	55467-9	1
	Mad Dog Plus	34704-890	1
	RoundUp WeatherMax	524-537	2
	Imitator Plus	19713-526	1
	Makaze Yield Pro	347804-1033	
Chlorothalonil	Echo 720	60063-7	1
Imazapyr	Arsenal Applicators Concentrate	241-299	2

Per GLP, AHETF analyzed the test substances for purity, with all tests demonstrating that the actual product active ingredient content percentages adequately match nominal label statements. Certificates of Analysis, which formally document analysis of the test substances, are provided in AHE500 Appendix F pages 1340-1386. In terms of exposure monitoring in this study, purity analysis is important for the purposes of determining the amount of active ingredient handled (AaiH) by each worker. The amount of product and active ingredient handled by each worker is outlined in Section 2.7 below.

2.3 Sample Size, Monitored Workers, and Locations

According to the AHE500 study protocol (AHETF, 2011a and 2011b) and the AHETF Governing Document (AHETF, 2008 and 2010), given the anticipated variability and correlation structures, a '3 x 5' design – monitoring of a total of 15 different workers, 3 workers in each of 5 separate 'clusters' or monitoring areas monitored around approximately the same time – was used for the returnable container "sub-scenario"[6] and a '3 x 7' design was proposed for the non-returnable container "sub-scenario"[7]. Though all 15 intended monitoring samples of returnable containers and 21 intended monitoring samples for non-returnable containers were collected, the cost-effective 'cluster' approach was not completely achieved due to recruitment difficulties. While monitoring was conducted in the 7 originally planned geographic regions, additional spatial (i.e., expanding to 4 additional states) and temporal differences resulted in a (less cost-

[6] Monitoring of 15 workers was considered adequate to augment 16 non-returnable container data points from existing data (9 datapoints from AHE13 conducted in 2004 and 7 data points from AH501 conducted in 1991).
[7] No existing data were available so new monitoring of 21 workers was considered sufficient to create this scenario.

effective) configuration. However, per protocol, no worker was monitored twice (no "repeat measures") within each "sub-scenario"[8] and, to reduce any potential similarities related to training, all workers were employed by different farms/employers. Though the final construct of the data did not exactly match the protocol, EPA believes that the (less cost-effective) outcome resulted in a more diverse dataset than originally planned.

The AHETF invalidated monitoring for 2 workers due to analytical issues or deviation from normal worker activity:

- M23 was invalidated because there were no valid analytical results for an inner dosimeter piece and for an OVS tube section.
- M2 was invalidated because a) the subject did not use fresh water to rinse the jugs (pesticide spray solution was used), b) incorrect plumbing resulted in a spill by leaving the rinse valve open while the jug was removed, and c) the subject did not clean up the spill with extra clothing/personal protective equipment (PPE) to match the AHETF closed system scenario. Samples were collected but not analyzed for this worker.

EPA agrees with these determinations, resulting in a final dataset of 34 monitored worker exposure days while mechanically transferring liquid pesticides using closed systems. Table 4 below provides a summary of the characteristics of the 34 monitored workers.

Table 4. AHE500 Summary of Workers

Worker ID		Employment[1]	U.S. State	Age (years)	Work Experience (years)	Weight (lbs)
C	M01	CAE	FL	34	14	256
H	M03	CAE	MS	26	4	233
E	M04	CA	TX	29	14	318
I	M05	CAE	MS	44	Not recorded	195
J	M06	CA	FL	48	30	218
K	M07	FE	MI	56	5	205
A	M08	CAE	FL	47	26	243
O	M09	CAE	WA	35	3.5	235
P	M10	CAE	WA	30	7	214
Q	M11	FO	WA	27	8	221
S	M12	FE	MI	29	4	175
R	M13	CAE	AZ	31	6	250
R	M14	CAE	AZ	31	6	249
N	M15	FE	MI	29	4	276
U	M16	CAE	WA	26	5	225
U	M17	CAE	WA	26	5	228
AA	M18	CAE	NE	27	2	206
AB	M19	FO	CO	34	10	162
Y	M20	FE	MI	37	13	241
W	M21	CAE	CO	43	2	140
AA	M22	CAE	NE	27	2	202
AK	M24	FE	LA	30	9	224
AF	M25	FE	LA	45	20	316
AH	M26	CAE	NE	25	1	155

[8] Worker ID AA was monitored twice – once using a returnable container (M18) and another time using a non-returnable container (M22).

Table 4. AHE500 Summary of Workers						
Worker ID		**Employment[1]**	**U.S. State**	**Age (years)**	**Work Experience (years)**	**Weight (lbs)**
AG	M27	CAE	NE	24	5	172
AI	M28	CAE	NE	56	19	198
AM	M29	FO	MI	65	1	176
AJ	M30	CAE	OR	23	3	227
AL	M31	FE	MI	27	2	204
AN	M32	FE	NE	26	6	156
Z	M33	CAE	GA	27	7	170
AO	M34	FO	CO	41	14	193
AP	M35	CAE	MS	27	4	209
AQ	M36	CAE	SC	28	1	189
[1] CAE = Commercial Applicator Employee; FE = Farm Employee; FO = Farm Owner; CA = Commercial Applicator (owner)						

2.4 Environmental Conditions

Temperature (including heat index), humidity, wind speed and direction, and rainfall were all reported. The maximum reported temperature was 94° F (NE in June 2015) and the lowest reported temperature was 30° F (NE in April 2016). 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 samples. Maximum reported wind speed was approximately 20 miles per hour. As a result of the spatial and temporal variability in the study, the diversity of environmental conditions for this scenario are adequately represented. For more details on environmental conditions see the AHE500 report tables on pages 135-138 and 325-327.

2.5 Clothing and Personal Protective Equipment (PPE)

Per the stated goals of the AHETF, monitoring of transferring liquid pesticides using closed systems 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. In two instances, workers were not wearing long-sleeved shirts, so the AHETF provided them. Per protocol, new chemical-resistant gloves were supplied by the AHETF. All chemical-resistant gloves were nitrile rubber, a material consistent with requirements on product labels (for reference see products outlined in Section 2.2 above). Importantly, for some of the products used, EPA's WPS allows for relaxation of PPE requirements when using closed systems. Despite this, the study followed the AHETF protocol which required workers to wear chemical-resistant gloves. Use of the data with "back-calculations" representing bare hand exposure is covered separately (Crowley, 2020).

Additionally, where workers wore face or head PPE such as protective eyewear, respirators (e.g., approximately 40% of the workers wore protective eyewear and/or respirators), dermal exposure without the PPE is simulated according to AHETF SOP 9.K which extrapolates from the face/neck wipe exposure measurements to those portions of the face/head covered by the

face/head PPE (see Section 3.3.2). The study noted where this additional PPE was only worn for part of the day so time-weighted adjustments (prorating) could be applied.

More specific details on work clothing and PPE can be found in the AHE500 study report tables on pages 123-126 and 315-318.

2.6 Types of Mechanical Transfer Systems

At the time of the study, closed systems were defined in EPA's Worker Protection Standard (40 CFR §170.240(d)) as those that "enclose the pesticide to prevent it from contacting handlers or other persons".[9] Based on this regulation, the protocol for AHE500 outlined the variety of possible closed system configurations commonly used (e.g., system types, transfer set-up, container size, and degree of openness) that the AHETF would target in their monitoring. Though protocol deviations 4 and 6 (see Section 4.0) state that the Study Director was not able to inspect the closed systems to ensure proper functioning in all cases, the AHETF evaluated the systems prior to monitoring, documented the system types (example shown in Attachment 2) and observed their functioning during the monitoring; no significant functional issues with the systems warranted halting any monitoring.

System Type

The AHE500 listed and targeted the diversity of possible system types:

- Non-returnable containers:
    - Suction/extraction systems – extraction via pump and hose from a probe inserted into container; probes are often integrated into returnable/refillable containers but are also often user-fabricated and inserted loosely into the containers; mechanism necessary to rinse probe prior to removal
    - Direct drop / gravity feed systems (involve inverting the container) – container is placed inverted onto system which opens the container and product flows into tank with container rinsing mechanism incorporated
    - Container Breach – system punctures container and contents flow into tank via gravity with integration of puncturing device and rinsing mechanism; typically used with smaller containers
    - Other systems (e.g., glove boxes)
- Returnable containers:
    - Suction/extraction systems
    - Other systems (e.g., gravity flow from large containers)

As reflected in the monitoring and by recruitment efforts, most users of non-returnable containers utilize suction/extraction or container breach systems and most users of returnable containers utilize suction/extraction or gravity flow systems.

[9] Since completion of the study, revisions to the WPS at 40 CFR §170.305 and §170.607 describe closed systems as removing "…the pesticide from its original container and transfers the pesticide product through connecting hoses, pipes and couplings that are sufficiently tight to prevent exposure of handlers to the pesticide product, except for the negligible escape associated with normal operation of the system."

Transfer Process

The protocol also listed and targeted the diversity of transfer set-ups:

- Transfer to a mixing tank only
- Transfer to a mixing tank plus transfer to an application tank
- Transfer directly to an application tank

Most users of both returnable and non-returnable containers transferred pesticides into the application tank usually with a two-step transfer process.

Container Size

As expected, non-returnable containers used by workers in the study were smaller than returnable containers: all non-returnable containers were less than 55 gallons (most were 30 gallons or less) while returnable containers were mostly in the 100- to 300-gallon range.

Degree of Openness

The AHE500 protocol indicated that mechanical transfer systems may not be completely closed, stating "…for example suction/extraction systems that are not securely attached to the container, the system might not be completely closed and these systems are not preferred for inclusion in these scenarios. However, AHETF believes such systems still minimize contact during transfer of the liquid and so will be acceptable for inclusion if sufficient numbers of completely closed systems are not readily located during employer recruitment."

Based on the monitoring, some "degree of openness" appears common when transferring liquids mechanically (i.e., only 9 of the 34 monitored workers used "completely closed" systems). Many systems had some degree of openness, whether it be a gap between the container's opening and the pipe/hose or whether a pipe/hose emptied liquid over an open tank hatch. It appears most suction/extraction style systems for non-returnable containers were not completely closed due to a loose connection/gap between the extraction probe and its entry point in the product container.

Rinsing

As returnable containers are not intended to be rinsed by workers (the containers are typically disconnected and picked up or refilled on-site by the distributor)[10], only non-returnable containers were rinsed in the study, details of which were as follows:

- Rinse jet inside container breach system ("open rinsing")

[10] 40 CFR §156 outlines requirements for rinsing refillable and non-refillable containers.

- Triple-rinsing drums by spraying some water into the drum, tipping/shaking/rolling, and pouring out the rinsate ("open rinsing")
- Pressure rinsing drums by inverting the drum over a mix tank and spraying water up into the drum and allowing rinsate to flow into the tank ("open rinsing")
- Pressure rinsing drums via a stinger or probe that is attached to the drum and suctions out the rinsate ("closed rinsing")

EPA agrees that the diversity of mechanical transfer systems is well-represented in the monitoring. Table 5 below summarizes characteristics of the mechanical transfer systems used in AHE500.

Table 5. AHE500 Mechanical Transfer System Characteristics

Worker ID		Type of Container[1]	Type of System[2]	Container Size (gallons)	Degree of Openness[3]	Rinsing
C	M01	R	S/E	250	Completely Closed	None
H	M03	NR	S/E	30	G	Closed
E	M04	NR	S/E	30	G	Open
I	M05	NR	S/E	30	G	Open
J	M06	R	S/E	30	OT	None
K	M07	R	G	120	Completely Closed	None
A	M08	R	G	275	OT	None
O	M09	NR	S/E	30	G, OT	Open
P	M10	R	G	250	OT	None
Q	M11	NR	CB	2.5	OT	Open
S	M12	R	G	265	Completely Closed	None
R	M13	NR	S/E	30	G, OT	Open
R	M14	R	S/E	150	G, OT	None
N	M15	R	G	250	Completely Closed	None
U	M16	NR	S/E	30	G, OT	Open
U	M17	R	G	15	OT	None
AA	M18	R	S/E	265	G	None
AB	M19	R	G	250	Completely Closed	None
Y	M20	NR	S/E	30	G	Open
W	M21	NR	S/E	30	Completely Closed	Closed
AA	M22	NR	S/E	55	G, OT	Open
AK	M24	NR	S/E	30	G	Open
AF	M25	NR	S/E	30	G	Open
AH	M26	NR	CB	2.5	OT	Open
AG	M27	R	G	265	Completely Closed	None
AI	M28	R	G	2400	OT	None
AM	M29	NR	G	30	OT	Open
AJ	M30	R	S/E	15, 30	G, OT	None
AL	M31	NR	S/E	30	OT	Closed
AN	M32	NR	G	55	Completely Closed	None
Z	M33	NR	S/E	30	G, OT	None
AO	M34	R	G	265	Completely Closed	None
AP	M35	NR	S/E	30	G	Open
AQ	M36	NR	S/E	15	G, OT	Open

[1] NR = non-returnable; R = returnable
[2] S/E = suction/extraction; G = gravity flow; CB = container breach
[3] G = gap in connection between container and hose/pipe; OT = open tank hatches (e.g., liquid solution empties from pump/hose/pipe into tank opening)

2.7 Application Rates and Amount of Active Ingredient Handled

According to the AHE500 study protocol (AHETF, 2011a and 2011b) and the AHETF Governing Document (AHETF, 2008 and 2010), to facilitate a data analysis objective (evaluating the relationship between exposure and the amount of active ingredient handled) the total amount of active ingredient handled (AaiH) applied should be sufficiently diversified across the dataset as well as within each study location. Specifically, each worker in a monitoring area was intended to handle within a certain range (or 'strata') of amount of active ingredient:

For the CSLL-R scenario:
(1) From 60 to 119 pounds ai handled
(2) From 120 to 1,200 pounds ai handled
(3) From 1,201 to 2,400 pounds ai handled

For the CSLL-NR scenario:
(1) From 12 to 30 pounds ai handled
(2) From 31 to 310 pounds ai handled
(3) From 311 to 800 pounds ai handled

As previously described workers used products containing one of four active ingredients: glyphosate, imazapyr, chlorothalonil, and 2,4-D. In cases where glyphosate, imazapyr, and 2,4-D were used, because the AHETF's analytical methods express the exposure sampler content in terms of the free acid, the amount of active ingredient handled is also based on the free acid form. Samples based on chlorothalonil are based on the parent chemical. EPA agrees with the AHETF's use of the free acid form (conversions were independently validated, Attachment 1).

Using the product concentration – ranging from approximately 3 to 6 lbs active chemical per gallon of product (confirmed by laboratory purity analysis, see Section 2.2 above), conversion to free acid where necessary – and the amount of product handled, the AHETF calculated the amount of active ingredient handled for each worker. While the intended configuration of "workers within AaiH strata" was not achieved, the range of active ingredient handled was more than an order of magnitude, from 76 to 2203 lbs.

Table 6. AHE500 Amount of Active Ingredient Handled

Worker ID		Loads Prepared	Total product loaded (gallons)	Amount Solution Prepared (gallons)	Exposure Time (hrs)	AaiH (lbs)[c]
C	M01	5	459	5880	6.1	2203
H	M03	7	175	3525	3.3	527
E	M04	11	150	4730	3.9	660
I	M05	3	30	1725	4.1	139
J	M06	6	120	5040	4.2	548
K	M07	3	20.1	1500	2.7	87.6
A	M08	3	210	1350	2.5	861
O	M09	6	45	600	2.3	176
P	M10	3	34.5	1200	1.5	137
Q	M11	11	82.5	13420	5.9	443

Table 6. AHE500 Amount of Active Ingredient Handled						
Worker ID		Loads Prepared	Total product loaded (gallons)	Amount Solution Prepared (gallons)	Exposure Time (hrs)	AaiH (lbs)[c]
S	M12	3	54	3200	3.6	207
R	M13	3	30	432	1.5	135
R	M14	5	325	4700	3.9	1428
N	M15	7	181	8075	8.9	815
U	M16	3	150	1350	2.3	445
U	M17	3	120	1250	2.2	514
AA	M18	3	112.5	Not recorded	3.9	434
AB	M19	6	196.5	5634	5.6	863
Y	M20	5	75	3000	5.4	337
W	M21	3	90	540	2.3	495
AA	M22	3	201	1041	4.7	768
AK	M24	3	40	2250	2.1	178
AF	M25	4	120	1200	2.2	535
AH	M26	3	27.5	330	2.2	158
AG	M27	4	53	2974	8.6	234
AI	M28	4	194	716	2.0	1065
AM	M29	3	54.8	3000	4.3	243
AJ	M30	3	20.6	1730	6.2	91.9
AL	M31	3	25.5	1450	6.0	76.4
AN	M32	3	21	1500	2.5	85.9
Z	M33	3	25.5	800	1.2	150
AO	M34	4	20	2000	2.4	109
AP	M35	11	72.3	5350	8.9	286
AQ	M36	3	22.2	1995	7.3	89.8

2.8 Representativeness of Exposure Monitoring

As part of the study protocol following input from the HSRB, the AHETF conducted opinion polling within each monitoring area of local experts at the end of the field phase of AHE500 to evaluate whether various characteristics of the monitoring were reasonably representative of closed systems in their area. Across the 7 monitoring areas (12 U.S. states), a total of 115 surveys were distributed to mostly university extension agents; 38 surveys were returned/completed. They were asked to provide their opinion as to whether the following characteristics about the monitoring were representative of their area: 1) location of the monitoring event, 2) whether the study participant was an employee or owner of the facility, 3) number of experienced pesticide mixer/loaders at the facility, and 4) description of the closed or semi-closed mixing/loading equipment and loading methods at the facility.

Though the survey was informal, only three responses indicated the characteristics of the monitoring were not representative – all three based their judgment on the size of the company from which the worker was recruited. Thus, it appears based on this informal survey/poll of local experts that the participants in AHE500 were not atypical of the population of closed system users.

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 required, planned, or collected.

Dermal exposure was measured as described below, and are combined (i.e., the measurement results summed together) for each worker 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 additional face or head protection (i.e., eye protection, 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 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 (with front and back sections) 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. Protocol deviations 5 and 6 outlined updated analytical methods for imazapyr and glyphosate. The analytical methods listed below are described in more detail in the AHE500 analytical reports (AHE500 Appendices B, C, D, and E).

- Chlorothalonil
    - ARF004 (1999): "Validation of Method for the Analysis of Worker Exposure and Reentry Matrices for Chlorothalonil"
        - ARTF-001 (1997): "Determination of Chlorothalonil in Dermal Dosimeters"
        - ARTF-004 (1997): "Determination of Chlorothalonil in Facial/Neck Wipes"
        - ARTF-002 (1997): "Determination of Chlorothalonil in Hand Wash Solutions"
        - ARTF-003 (1997): "Determination of Chlorothalonil in OVS Air Sampling Tubes"

- Glyphosate[11]
    - AHE400 (2015): "Validation of Analytical Methods for the Determination of Glyphosate in/on Worker Exposure Matrices using High Performance Liquid Chromatography/Mass Spectrometry with Derivatization"
        - AHETF-AM-081 (2013): "Determination of Glyphosate in Two-Piece and Six-Piece Cotton Inner Dosimeters by High Performance Liquid Chromatography/Mass Spectrometry with Derivatization"
        - AHETF-AM-082 (2013): "Determination of Glyphosate in Face/Neck Wipes by High Performance Liquid Chromatography/Mass Spectrometry with Derivatization"
        - AHETF-AM-083 (2013): "Determination of Glyphosate in Hand Wash Solutions by High Performance Liquid Chromatography/Mass Spectrometry with Derivatization"
        - AHETF-AM-084 (2013): "Determination of Glyphosate in OVS XAD-2 Tubes by High Performance Liquid Chromatography/Mass Spectrometry with Derivatization"
- Imazapyr
    - AHE211 (2014): "Validation of Worker Exposure Analytical Methods for the Analysis of Imazapyr in Worker Exposure Matrices"
        - AHETF-AM-046 (2011): "Determination of Imazapyr on Six-Piece Cotton Inner Dosimeters"[12]
        - AHETF-AM-048 (2011): "Determination of Imazapyr on Face/Neck Wipe Samples"
        - AHETF-AM-047 (2011): "Determination of Imazapyr in Hand Wash Solutions"
        - AHETF-AM-049 (2011): "Determination of Residues of Imazapyr in OVS Air Sampling Tubes"
- 2,4-D
    - AHE67 (2010): "Validation of Inner Dosimeter, Face/Neck Wipe, Hand Wash, and OVS Tube Methods for the Analysis of 2,4-D and 2,4-DB in Exposure Matrices"
        - AHETF-AM-036 Version 1 (2014): "Determination of 2,4-D and 2,4-DB on Two-Piece Cotton Inner Dermal Dosimeters"
        - AHETF-AM-033, Version 1 (2012): "Determination of 2,4-D and 2,4-DB in Face/Neck Wipe Samples"
        - AHETF-AM-034, Revision 1 (2012): "Determination of 2,4-D and 2,4-DB in Hand Wash Exposure Samples"
        - AHETF-AM-035, Version 1 (2012): "Determination of 2,4-D and 2,4-DB in OVS Air Sampling Tubes"

[11] As noted in protocol deviation 6, the signed study protocol (March 7, 2012) referenced existing glyphosate analytical methods (AHETF-AM-023 to -026). However, analysis of AHE500 samples used updated methods (that include a derivatization step) AHETF-AM081 to -084 referenced here. As the validation of the newer methods preceded extraction of AHE500 samples in January 2013, EPA agrees that this was a legitimate deviation.

[12] As noted in protocol deviation 5, a validated method for analysis of imazapyr on two-piece dosimeters (as was conducted in AHE500) is not available, so the method for six-piece dosimeters referenced here was applied. EPA agrees with AHETF that it is equally legitimate as the material/matrix, analytical limits, etc. are all the same.

Limits of quantification and detection (as defined in AHETF SOP 9.A) are presented in Table 7 below (copied from AHE500 Section 2.3).

Table 7. Analytical Limits (µg/sample) for AHE500								
Monitoring Matrix	**Limit of Detection (LOD)**				**Limit of Quantification (LOQ)**			
	CTH	**2,4-D**	**GLY**	**IMZ**	**CTH**	**2,4-D**	**GLY**	**IMZ**
Inner Dosimeter	0.30		0.139	0.041	1.0			
Face/Neck Wipe			0.143	0.317	1.0			
Hand Rinse			0.179	0.167	1.0			
OVS air sampler (per section)	0.0015		0.0016	0.0005	0.005			
Chemical legend: CTH = chlorothalonil; GLY = glyphosate; IMZ = imazapyr								

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: Exposure Monitoring, Study Data, and Final Report. 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 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 (see Section 2.9 above). 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, socks, head patches, OVS tubes) were fortified with known amounts of active ingredient to assess their stability during field, transit, and storage conditions (and analyzed when necessary) 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

There were several instances where field control samples contained detectable residues, mostly in whole body dosimeter and OVS tube samples and only at levels slightly above the LOD; very few laboratory controls had residues above the matrix LOD. EPA does not believe that either outcome indicates there were systematic analytical issues. Per AHETF practice, monitoring matrix samples were not adjusted/reduced for presence of the chemical in control samples.

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 but are only analyzed when necessary.

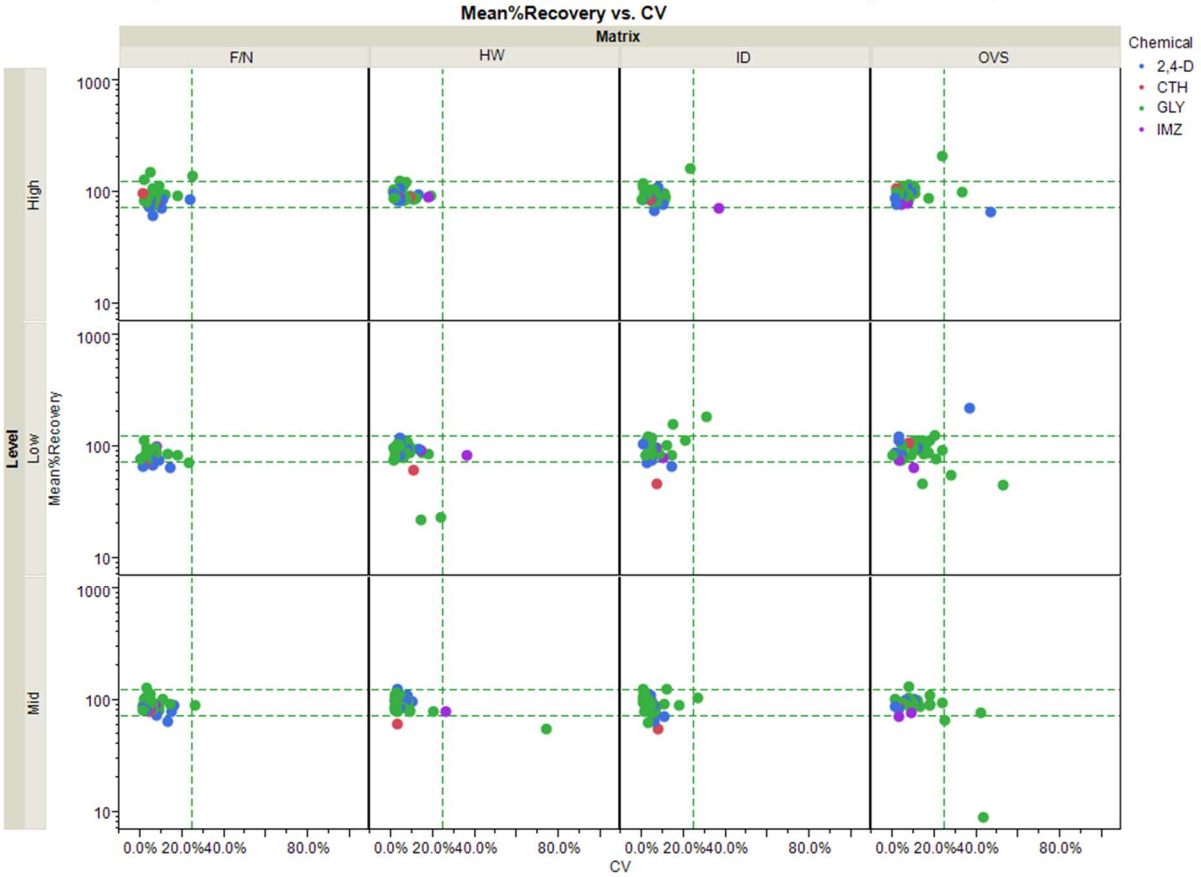
Field fortifications are conducted at 3 levels to capture the expected range of results, with triplicate samples taken on each day at each fortification level. Once analyzed, the average recovery results (expressed as a percentage of known amount applied) are used as multipliers to adjust, or correct, all measured field samples to 100%.

As the fortification samples are conducted at levels to capture the range of expected field sample results, adjustments to field samples are done using the average percent recovery for the fortification level closest to the measured field sample[13]. 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 coefficients of variation (CV) generally less than 25%. Figure 1 below shows the field fortification results (CV by Mean % Recovery) across all fortification levels, dosimetry matrices and chemical, overlaid with the 70-120% and 25% benchmarks (green dashed lines). A summary for each matrix is then provided in the sections below.

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

Figure 1 - Field Fortifications (CV vs Mean; Fortification Level by Matrix by Chemical)



Matrix legend: F/N = Face/neck wipe; HW = hand wash; ID = inner dosimeter; OVS = inhalation sampler
Chemical legend: CTH = chlorothalonil; GLY = glyphosate; IMZ = imazapyr

3.2.2.1 Inner Dosimeters

Results for inner whole-body dosimeter (WBD) field fortification samples were acceptable, with recoveries averaging from 70% to 120% with few exceptions and coefficients of variation less than 25%. About 13% (12 of 93 WBD fortification samples) were outside the 70-120% recovery range and 3% (3 of 93) were above a CV of 25%.

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 25% with a few exceptions. About 10% (10 of 93 face/neck fortification samples) were outside the 70-120% recovery range and 1% (1 of 93) were above a CV of 25%.

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 25% with a few

exceptions. About 10% (9 of 93 hand wash fortification samples) were outside the 70-120% recovery range and 3% (3 of 93) were above a CV of 25%.

3.2.2.4 OVS Air Samplers

Results for OVS fortification samples were acceptable, with average recoveries ranging from approximately 70% to 120% and coefficients of variation less than 25% with a few exceptions. About 13% (12 of 93 OVS fortification samples) were outside the 70-120% recovery range and 8% (7 of 93) were above a CV of 25%.

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 applicable 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 and head patches were extrapolated to head surface area as described in Section 2.8 above. 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 < LOQ to 11,920 µg. Out of a total of 69 inner dosimeter samples, 2 were < LOQ. After adjusting for field fortification recoveries and summing the two body sections, the total dermal exposure underneath the long-sleeve shirt and pants ranged from 0.57 – 13,537 µg with an average of 947 µg.

3.3.2 Face/Neck Wipes

Without field fortification adjustments, face/neck wipe samples ranged from < LOQ to 385.1 µg. Out of a total of 35 face/neck wipe samples, 6 were < LOQ. Because some workers wore eye protection and/or 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[14]. After adjusting for field fortification recoveries and extrapolating to non-wiped portions of the head described above, total head exposure ranged from 0.12 – 755 µg with an average of 62.1 µg.

3.3.3 Hand Washes

[14] 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; 1.4 = eye protection + half-face respiratory w/thick straps.
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))]}.

Per protocol, hand wash samples 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. The number of hand wash samples ranged from 1 to 6: 17 workers had only one sample (at the end of the day), 7 workers had 2 samples, 8 workers had 3 samples, 1 worker had 4 samples, 1 worker had 5 samples and 1 worker had 6 samples.

Without field fortification adjustments, individual hand wash samples ranged from < LOQ to 14,950 µg. Out of a total of 70 hand wash samples, 6 were < LOQ. After adjusting for field fortification recoveries and summing each worker's hand wash samples, hand exposure (representing use of chemical-resistant gloves) ranged from 0.15 – 16,209 µg with an average of 1,925 µg.

3.3.4 OVS Air Samplers/Inhalation Exposure

Front and back sections of the OVS tube were analyzed separately. All front-section samples had quantifiable residues while most back-section samples were < LOQ. Without field fortification adjustments, front sections ranged from 0.0191 to 3.228 µg. After adjusting for field fortification recoveries, the total (front section + back section) collected active ingredient amounts ranged from 0.0171 – 6.45 µg with an average of 0.720 µg.

To calculate worker inhalation exposures from the OVS samples, 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. The AHE500 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 (under separate EPA review; Crowley, 2020; D454706) presents worker inhalation exposures based on an assumed breathing rate. For workers transferring/loading pesticides using closed systems, 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 0.143 – 54.4 µg with an average of 6.02 µg.

3.4 Field Observations

Field researchers observed each worker and recorded their behavior throughout the work day. These can be found in the AHE500 report in Table 9 on pages 141-207 and 330-371.

Many of the observations detailed routine loading procedures. For example: work M32 at 7:02 am – "He then opens water lever on ½ inch hose which goes into connection at top of cone & rinses premix tank out. There is a separate pump motor for water & to pump into spray tank". Though not otherwise covered in this review, demonstrating the benefit of observing and documenting worker activity, in a separate submission (Bruce and Holden, 2019b) the AHETF used the worker observation notes to tabulate characteristics such as leaks of test substance or spray mixture transfer systems, disconnecting contaminated product transfer hoses and removing

unrinsed extraction probes to determine potential factors for observed differences in dermal exposure potential. In that submission the AHETF documented that removing unrinsed extraction probes can lead to higher dermal exposures.

4.0 Protocol Amendments and Deviations

Amendments to the study protocol and protocol deviations are copied below from AHE500. For additional details, see AHE500 Appendix A (pages 490-511). The protocol amendments outlined were reasonable accommodations to accomplish the research and did not adversely impact the study conduct or the exposure monitoring results.

- Amendment 1 (April 16, 2014):
    - Allow management of heat exposure using a wet bulb/globe/dry bulb temperature (WBGT) system in accordance with SOP AHETF-11.N.
- Amendment 2 (May 4, 2015):
    - List chlorpyrifos as a potential surrogate for the study.
- Amendment 3 (August 16, 2016):
    - Clarify that subject pesticide safety training must be in compliance with the Worker Protection Standard (WPS).
    - Add the requirement that researchers discuss pertinent sections of the Directions for Use (e.g., mixing instructions) from test substance labels with subjects before monitoring begins.
    - Allow the final 3 MUs to be collected in any monitoring area.

The six protocol deviations are copied below – EPA agrees they do not adversely impact the study's results:

- Deviation 1
    - September 25, 2013: Worker O was enrolled in the pesticide exposure study and provided MU M9; however, this worker was an employee of a pesticide registrant. This is contrary to the inclusion criteria listed in SOP 11.B.7 which is cited by the protocol.
- Deviation 2
    - November 29, 2012: MU M1 handled three containers of product, but samples of only two of the three containers were obtained for purity analysis and archives. Because there was no lot number identified for these returnable containers, it is possible that the third container was a different lot from the others and so perhaps one lot was not sampled as required by the protocol.
    - May 7, 2014: MU M12 did not have a face/neck wipe performed before eating food during his monitoring period.
- Deviation 3
    - June 14, 2016: The subject that conducted MU M31 was not trained according to the Worker Protection Standard for handlers.
- Deviation 4
    - September 20, 2016: For the field fortification event on 9/20/16, there were insufficient intact ampoules delivered to the field, so seven field fortification

samples were not prepared, including: one low level sample for HW and FW; one mid-level sample for WBD, HW, and FW; and both Travel spikes for WBD.
    - Various dates: Prior to most MUs in the study, it was not possible for researchers to confirm the closed systems and delivery setups selected by cooperators were operating properly and were free from significant leaks.
    - October 11, 2016: MU M35 involved closed system loading of liquids with non-returnable containers (CSLL-NR) and was conducted in the state of Mississippi (Area 506) although the cooperator was on the Potentially Eligible Employer List for Area 502 (Florida, which was expanded to include Georgia and South Carolina). The protocol implies MUs should be collected (physically) within the geographic area specified for each monitoring area.
    - October 14, 2016: The subject that conducted MU M36 did not wear chemical-resistant gloves when transferring the diluted spray mixture to the helicopter. This involved opening and closing valves and connecting and disconnecting the completely closed delivery hose to the helicopter.
- Deviation 5
    - March 7, 2017: For MUs M35 and M36, a (modified) analytical method for imazapyr content designed for 6-piece WBDs was used for the 2-piece WBDs collected in the study.
- Deviation 6
    - November 29, 2012: Closed systems could not always be evaluated prior to use in the study to ensure they were operating properly.[15]
    - January 25, 2013: The protocol specified the wrong glyphosate analytical methods to analyze all four of the exposure matrices in the study (note that the proper methods were used).

5.0 Conclusion

As the study followed the corresponding protocol as well as EPA guidelines for occupational pesticide exposure monitoring, the results are reliable for assessment of exposure and risk for workers mechanically transferring liquid pesticides into mix tanks or application equipment tanks.

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 Monograph: Mechanical Transfer of Liquid Pesticides (AHE1022: Bruce and Holden, 2019a). Review of the monograph as well as recommendations for use of the data by EPA exposure assessors is in a separate EPA review memorandum (Crowley, 2020; D454706).

6.0 References

AHETF, (2008). Volume IV AHETF Revised Governing Document for a Multi-Year Pesticide Handler Worker Exposure Monitoring Program. Version Number: 1. April 7, 2008. Agricultural Handlers Exposure Task Force (AHETF). EPA MRID 47172401.

[15] EPA confirmed with the AHETF that this deviation is a duplicate of a similar issue described in Deviation 4.

AHETF, (2010). Governing Document for a Multi-Year Pesticide Handler Exposure Monitoring Program, Version 2, August 12, 2010.

AHETF (2011a). Monitoring Unit Selection and Construction Plan for Scenarios: Closed Loading of Liquids in Non-Returnable Containers and Closed Loading of Liquids in Returnable Containers. July 13, 2011.

AHETF (2011b). Closed System Loading Liquids Scenario (CSLL), Study AHE500, Protocol for EPA Review, August 3, 2011.

AHETF, (2015). Agricultural Handler Exposure Task Force Standard Operating Procedures. Revision date January 12, 2015.

Bruce, E. (2019). Determination of Dermal and Inhalation Exposure to Workers during Closed System Loading of Liquids in Returnable and Non-Returnable Containers. Study Number AHE500. Unpublished study sponsored by the Agricultural Handler Exposure Task Force. 1386 p. April 24, 2019. EPA MRID 50846201.

Bruce, E. and Holden, L. (2019a). Agricultural Handler Exposure Scenario Monograph: Mechanical Transfer of Liquids. Report Number AHE1022. Unpublished study sponsored by the Agricultural Handlers Exposure Task Force. 311 p. July 16, 2019. EPA MRID 50940301.

Bruce, E. and Holden, L. (2019b). Closed System Loading of Liquids (CSLL) Rationale for a Single Monograph: Mechanical Transfer of Liquids (MTL). Unpublished study sponsored by the Agricultural Handlers Exposure Task Force. 46 p. October 7, 2019.

Crowley, M. (2020). Memorandum: Review of Agricultural Handler Exposure Task Force (AHETF) Monograph: "Mechanical Transfer of Liquids" (AHE1022). D454706. [date placeholder], 2020.

NAFTA - Dept. of Pesticide Regulation (DPR), California EPA, HSM-98014, April 24, 1998. http://www.cdpr.ca.gov/docs/whs/memo/hsm98014.pdf

Attachment 1
Versar, Inc. Review of AHE500 Field and Analytical Data
(filename=TAF 2-164 Versar QC103019.xlsx)

Study Number: AHE500

Description of QC Checks:	Checked	MU's Checked	Passes QC Check?	Numbers Same in the Report?	Comment
Was the lb/gallon calculated correctly?	Yes	1, 11, 27, 33, 34, 35	Yes	Yes	The MU's selected to QC include five different test products with four different active ingredients. Label reported lb ai/gallon was not provided for RoundUp PowerMax, Echo 720, and Arsenal Applicators Concentrate. Obtained Labels to verify. One lb ai/gallon value off by 0.1 and three values off by 0.01. Lb free acid per gallon of product was addressed for some of the active ingredients.
Was the total amount of product handled calculated correctly?	Yes	1, 11, 27, 33, 34, 35	Yes	Yes	Straight forward calculation. Lbs ai/handled = product loaded x lbs of active ingredient. Ounces taken for purity analysis were accounted for in the equation.
Was the amount of active ingredient handled used in exposure calculations correctly?	Yes	1, 11, 27, 33, 34, 35	Yes	Calculated values not provided in the Study Report.	Straight forward calculation. Total dermal exposure and inhalation exposure were calculated but the results were not provided in the report. TDE and inhalation exposure was calculated as ug/MU and as ug/ lb ai handled.
Were field fortification recoveries calculated correctly?	Yes	1, 11, 27, 33, 34, 35	Yes	Yes	Yes, straight forward calculation.
Were field fortification adjustments calculated and used correctly?	Yes	1, 11, 27, 33, 34, 35	Yes	Field fortification adjustment factors were same as spreadsheets. Adjusted residues were not provided in	When field fortification recoveries were >120%, the maximum adjustment factor used was 1.20. Residues below the LOQ were not adjusted. Mid-points between field fortification concentrations were calculated and sample residues were adjusted according to the most representative field fortification level. Field Recovery Adjustment Factors were reported as percentages instead of decimal factors for MU M35 & M36 (Table CSLL-NR-12).

				the Study Report.	
Were the back portions of OVS tubes accounted for?	Yes	1, 11, 27, 33, 34, 35	Yes	Yes	Total OVS residues consisted of the sum of both the front and back portions.
Were Control Residues Accounted for?	Yes	1, 11, 27, 33, 34, 35	Yes	Yes	Residues were detected on field control samples; however, only Laborary Fortification samples were adjusted for control residues. Author says this is consistent with AHETF practice. All matrices, the residues found in control samples are well below the lowest field fortification level.
Were Face/Neck PPE adjustments done correctly?	Yes	1, 11, 27, 33, 34, 35	Yes	Adjustments were not provided in the Study Report.	Adjustments were made for MU's wearing protective eyewear. The following PPE adjustment factors were used: 1 = no adjustment; 1.1 = goggles/safety glasses; 1.1 = dust mask; 1.3 = eye protection + mask; and 1.4 = eyewear + respirator. PPE-adjusted value (µg) = collected residue (µg) X PPE adjustment factor.
Were Face/Neck wipe residues extrapolated for whole head exposure?	Yes		Yes	Calculated values not provided in the Study Report.	Face/Neck wipe residues were first adjusted for PPE worn on the face. Next the non-F/N portion of the head was extrapolated (residue x 2.95/4.84 - for men). Then the total head residue was calculated by adding the PPE-Adjusted F/N residue and the non-F/N resiue.
Were Total Dermal Exposure calculations done correctly?	Yes	1, 11, 27, 33, 34, 35	Yes	Calculated values not provided in the Study Report.	Total Dermal Exposure = WBD + handwashes + Head (adjusted F/N wipes)

Were inhalation exposure calculations done correctly?	Yes	1, 11, 27, 33, 34, 35	Yes	Calculated values not provided in the Study Report.	Yes. Inhalation exposure was calculated by: 1) adjusting residues for field fortification recovery; 2) combining adjusted residues from both the front and back portions of the OVS tube; 3) inhalation exposure calculated by residue x breathing rate/avg sample flow rate; and 4) inhalation exposure / lb ai handled. TWA flow rate was used in inhalation exposure calculation when MU sampling pump changes were required ([duration (min) x avg flow rate (LPM)] + [duration (min) x avg flow rate (LPM)])/total min. The NAFTA breathing rate used in the inhalation exposure calculations is 16.7 L/min for light activities. It is not certain if this was the correct choice without knowing the weight of the product containers. According to NAFTA-recommended inhalation rates, 16.7 L/m for light activities would be used for mixer/loaders handling containers less than 50 lbs and 26.7 L/min for mixer/loaders handling containers greater than 50 lbs.

lb ai / gallon check																									
			product label	meas ured		prod uct label	meas ured	calculat ed (conver ted)							Labe l repo rted		calcul ated	REP ORT		Spread sheet					
MU	Produc t	pg	% ai	% ai	lot numbe r	% salt - nomi nal	% acid	salt %	pg	Surr salt or ester	salt/ ester : acid ratio	pg	acid equiv/ gallon	pg	lbs ai/ga llon	EPA REG	lb ai/ gallo n	Repo rted lb ai / gallo n	pg	Report ed lb ai / gallon		total lb ai/handle d QC'd			
1	Touch down HiTech	311	---	---	36767 8	52.3	41.3	50.7	1342	glyphos ate, K	1.22 53	28 2	5	28 1			4.84	4.85	31 1	4.85	off by 0. 01	220 3 (der mal)	1312 (inhalat ion)		
	Touch down HiTech	311	---	---	30037 7	52.3	42.3	51.8	1341	glyphos ate, K	1.22 53	28 2	5	28 1			4.96	4.95	31 1	4.95	off by 0. 01				
11	Weed one LV6 EC	118	---	---		87.3	56.6	85.3	1352	2,4-D, 3-EHE	1.50 77	28 2	5.5	78			5.38	5.37	11 8	5.37	off by 0. 01	443			
27	Round Up Power Max	311	---	---		48.7	38.94	47.72	1374	glyphos ate, K	1.22 53	28 2	4.5	-- -		REG 524- 537	4.41	4.41	31 1	4.41	sa m e	234			
33	Echo 720	117	54	53.1		---	---	---	1382	Chlorot halonil	---	-- -	---	-- -	6	REG 6006 3-7	6	5.9	11 7	5.9	off by 0. 1	150			
34	Weed one LV6 EC	311	---	---		87.3	57.5	86.7	1383	2,4-D, 3-EHE	1.50 77	28 2	5.5	78			5.46	5.46	31 1	5.46	sa m e	109			
35	Arsena l Applic ators Conce ntrate	117	---	---	HA181 55044	53.1	43.45	53.28	1385	Imazapr y, IPA	1.22 62	28 2	4	-- -		REG 241- 299	4.01	4.01	11 7	4.01	sa m e	286			
	Arsena l Applic ators Conce ntrate	117	---	---	HA161 80216	53.1	42.04	51.55	1385	Imazapr y, IPA	1.22 62	28 2	4	-- -		REG 241- 299	3.88	3.88	11 7	3.88	sa m e				

													Label verified		Label verified	obtained label									
lb ai / handled check																									
					removed for testing																					
MU ID	**Tank Mix No.**	**Container No. (Container = a drum)**	**Lot No.**	**Product Loaded (Gallons)**	**Product Loaded (Fluid Ounces)**	**Pounds of Active per Gallon**	**Total Volume of Spray Mixture Prepared (gallons)**	**Volume of Spray Mixture Transferred to Spray Tank (gallons)**	**Pounds of Active Ingredient Handled**																	
M35	1	C1	HA16180216	9.5	-3.0	3.88	500	500	36.8																
M35	2	C1	HA16180216	9.5	0.0	3.88	500	500	36.9																
M35	3	C1	HA16180216	9.0	0.0	3.88			34.9																
M35	3	C2	HA18155044	0.5	-3.0	4.01	500	500	1.9																
M35	4	C2	HA18155044	9.5	0.0	4.01	500	500	38.1																
M35	5	C2	HA18155044	4.3	0.0	4.01	350	350	17.2																
M35	6	C7	HA18155044	5.0	0.0	4.01	500	500	20.1																
M35	7	C7	HA18155044	5.0	0.0	4.01	500	500	20.1																
M35	8	C7	HA18155044	5.0	0.0	4.01	500	500	20.1																
M35	9	C7	HA18155044	5.0	0.0	4.01	500	500	20.1																
M35	10	C7	HA18155044	5.0	0.0	4.01	500	500	20.1																
M35	11	C7	HA18155044	5.0	0.0	4.01	500	500	20.1																

Loads Prepared:		**11**	**loads prepared**																											
Containers Handled:			**3**	**containers, in part or entirely (here containers = 30-gallon drums)**																										
Total Product Mixed:		**72.3**	**gallons**	**Versar calculated value. Registrant also reports 72.3 gallons but their equation did not take into account the 6 FL ozs taken out for analysis.**																										
Total Mixture Prepared:		**5350**	**gallons**																											
Total Mixture Transferred:		**5350**	**gallons**																											
Aa iH:	**286**	**pounds ai**		**The lbs ai handled equation does adjust for the ounces analyzed.**																										

Attachment 2
Example Closed System Notes/Diagram for Worker M11 during AHETF monitoring

CSLL Equipment Operation Verification

Transfer from Product Container:

Describe connection: Container breach into The Handler tank

Any leaks detected: Essentially no splashing out of tank

Any corrective actions taken: None necessary

Transfer into Pre-Mix or Bulk Tank:

Describe connection: The Handler is pre-mix tank

Any leaks detected: None

Any corrective actions taken: None necessary

Transfer into Application Tank:

Describe connection: 2" plumbed hose from Handler to 3" flex w/ quick disconnect to 4" flex w/ QD to Load Command (LC) connector at sprayer

Any leaks detected: Very little dripping at LC, some drips from QD, but mostly water since mixture transfers quickly.

Any corrective actions taken: None

Methods of Measuring Volumes:

Measure Test Substance: Entire jugs only since container breach

Calibration: N/A

Measure Carrier: Auto sensor on spray rigs

Calibration: None

Completed by [signature] Date 11/13/13

AHETF Study No. AHE500 // Monitoring Area 505 // MU ID: M11

MIXING/LOADING — Equipment and Procedures

Container Type: ☐ Returnable (R) ☒ Non-Returnable (NR)

Closed System ID No.: THE HANDLER III - No ID

Closed System Type (identify and describe, include make/model if available):

☐ Suction / Extraction: _____

☒ Container Breach: The Handler

☐ Gravity Feed: _____

☐ Other: _____

☐ Completely Closed, or ☒ Not Completely Closed System

Set-Up for Transfer of Product and/or Mixture (identify and describe):

☐ Transfer to mix tank only: _____

☒ Transfer to mix tank, then application tank: HANDLER to Spray Rig

☐ Transfer directly to application tank: _____

Pre-Mix or Bulk Tank Capacity: 175 ☒ gal ☐ L ☐ None used

Application Tank Capacity: 1,200 ☒ gal ☐ L

_____ ☐ gal ☐ L (if more than one)

_____ ☐ gal ☐ L (if more than one)

Height of Mix Tank Opening: 5 feet when on mixing platform

Height of Application Tank Opening: 4 feet = Load Command

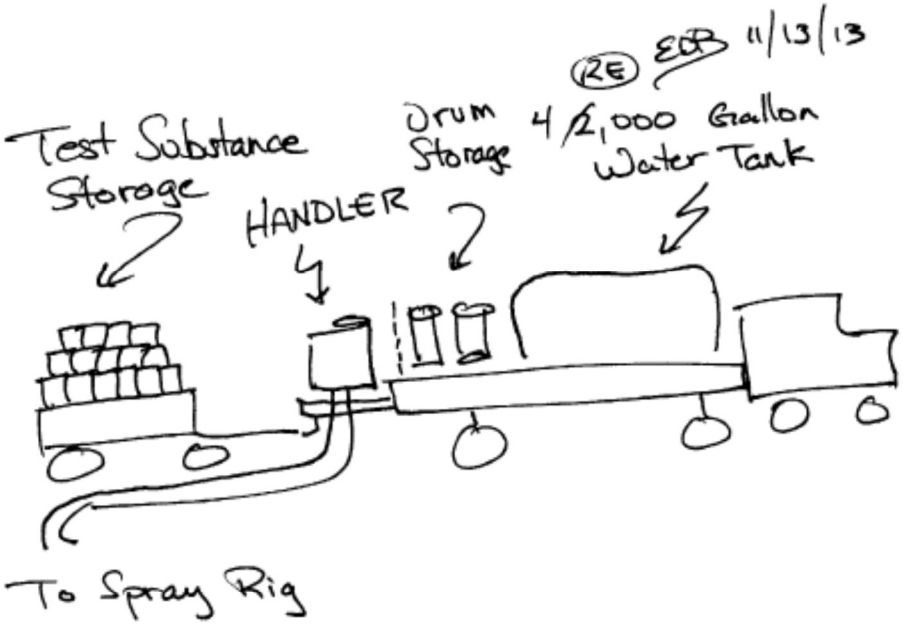
Diluent / Carrier: Water

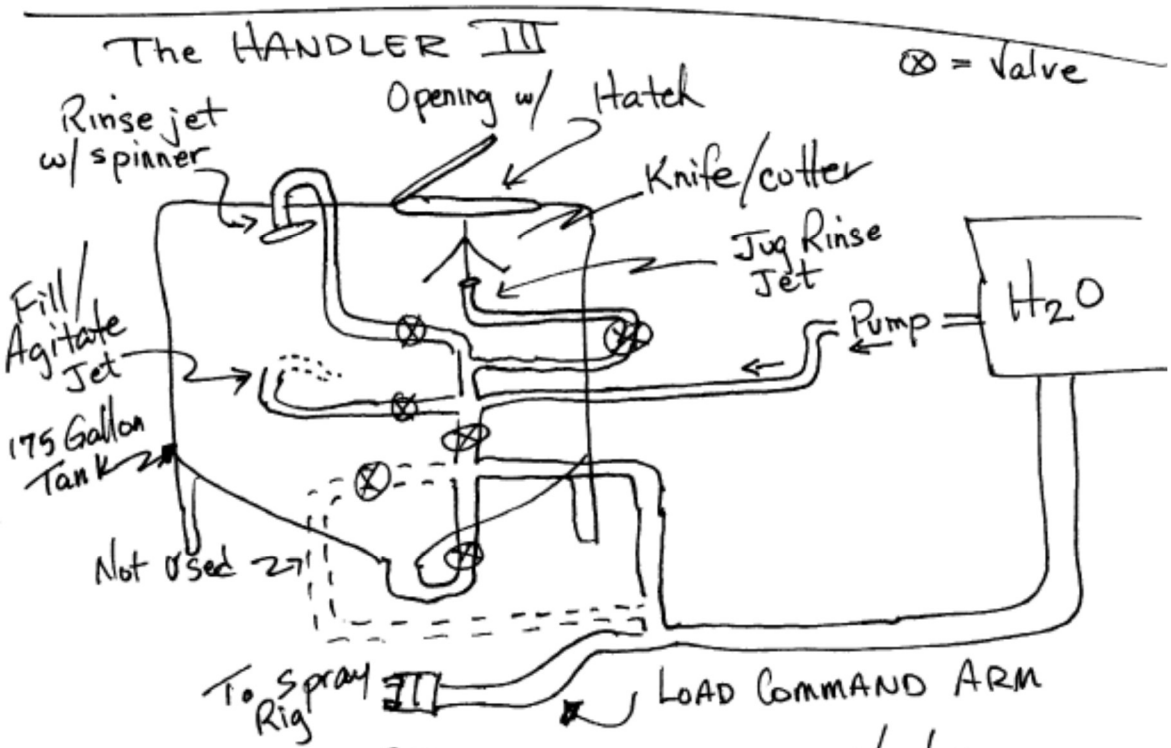
Describe procedure for transfer, mixing, and/or loading: Load Command is a John Deere connection/filling system with a hydraulic plunger activated automatically that opens a cam-lock type stopper and an air-inflated bladder that connects pieces.

Completed by SDB Date 11/13/13

AHETF Study No. AHE500 // Monitoring Area 505 // MU ID: M11

Schematic of Closed Mixing / Loading System





Completed by EDP Date 11/13/13
AHETF Study No. AHE500 // Monitoring Area 505 // MU ID: M11