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

**OFFICE OF CHEMICAL SAFETY**
**AND POLLUTION PREVENTION**

**MEMORANDUM**

**Date:** [placeholder]

**SUBJECT:** **DRAFT** Review of "Determination of Dermal and Inhalation Exposure to Workers During Open Pour Loading of Granules" (AHE170)

**PC Code:** --
**Decision No.:** --
**Petition No.:** --
**Risk Assessment Type:** --
**TXR No.:** --
**MRID No.:** 50419301

**DP Barcode:** [placeholder]
**Registration No.:** --
**Regulatory Action:** --
**Case No.:** --
**CAS No.:** --
**40 CFR:** --

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This memorandum presents EPA's review of the analytical and field phase reports for AHE170 (Bruce, 2017), an Agricultural Handler Exposure Task Force (AHETF) study that monitored dermal and inhalation exposure for workers while open pouring granule pesticides into application equipment. It reflects comments and advice provided by the Human Studies Review Board following its January 2018 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 handling granule pesticide products. The scenario monograph (Bruce and Holden, 2017), which incorporate the monitoring data from AHE170 into a single/composite dataset and includes statistical analysis of study objectives, is reviewed under separate cover (Crowley, [placeholder for date]).

[1] [placeholder for final HSRB report].

## 1.0 Executive Summary

The Agricultural Handler Exposure Task Force (AHETF) monitored dermal and inhalation exposure for 21 workers while manually loading granule pesticide products into application equipment via open pouring of the product packages. Notably, two workers had incomplete dermal exposure monitoring as some of their hand exposure samples were broken and lost following collection. Imputation of those lost samples to make use of complete dermal exposure results is addressed in a separate EPA review (Crowley, [date]).

Monitoring was conducted across nine U.S states over 15 months. The workers' activity consisted of opening granule pesticide product bags/packages, typically by hand or using a knife, and manually pouring the contents into application equipment such as tractor planters or spreaders. As the monitoring was intended to represent manual lifting, opening and pouring of standard bags/packages, loading using "mini-bulk" packaging or "super sacks" was not included. Also by design, to match the intended use of the data as a discrete pesticide product loading scenario, the monitoring does not represent exposure during application of the granule pesticides.

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

**Table 1. AHE170 Summary**

| Worker ID | Type of Application Equipment | Relative Height of Loading | State | Monitoring Date | Age (years) |
|---|---|---|---|---|---|
| M1 | 12-Row Planter | Abdomen | FL | 3/19/2015 | 49 |
| M2 | Twin-Row Planter | Chin | FL | 3/21/2015 | 28 |
| M3 | Drop Spreader | Chest | FL | 4/2/2015 | 59 |
| M4 | Rotary Spreader | Thigh | NC | 4/4/2015 | 56 |
| M5 | 12-Row Planter | Waist | IA | 4/28/2015 | 56 |
| M6 | 12-Row Planter | Waist | IN | 5/1/2015 | 45 |
| M7 | 6-Row Planter | Waist | IA | 5/3/2015 | 30 |
| M8 | 6-Row Planter | Chest | PA | 5/14/2015 | 63 |
| M9 | 6-Row Planter | Waist | IA | 5/19/2015 | 28 |
| M10 | Rotary Spreader | Upper Chest | GA | 6/2/2015 | 20 |
| M11 | Drop Spreader | Face | GA | 8/18/2015 | 25 |
| M12 | 24-Row Planter | Waist | MN | 4/14/2016 | 46 |
| M13 | 12-Row Planter | Waist | IN | 4/20/2016 | 62 |
| M14 | 12-Row Planter | Waist | MN | 4/22/2016 | 70 |
| M15 | 6-Row Planter | Waist | MN | 4/23/2016 | 59 |
| M16 | 16-Row Planter | Waist | IN | 4/25/2016 | 33 |
| M17 | 16-Row Planter | Waist | NE | 5/6/2016 | 54 |
| M18 | 12-Row Planter | Waist | NE | 5/7/2016 | 26 |
| M19 | 8-Row Planter | Waist | NE | 5/7/2016 | 78 |
| M20 | 24-Row Planter | Chest | NE | 5/16/2016 | 22 |
| M21 | 12-Row Planter | Waist | SD | 5/18/2016 | 35 |

*Note: all study subjects were male.*

Monitored on actual days of work, workers loaded between 50 and 2,720 pounds of product over 3 to 6 separate loading events in 2 to 8 hours, totaling a range of 6 to 175 lbs of active ingredient handled. Results represent workers wearing long-sleeved shirts, pants, shoes/socks and chemical-resistant gloves. In some cases, due to product safety requirements, some workers

wore eye protection and/or respirators, which required extrapolation of dermal exposure to areas covered by that equipment.

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). Per the study protocol (AHETF, 2014), in cases where product safety requirements instructed workers to wear two layers of clothing, the whole-body dosimeter served as the required second layer of clothing. 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 and deviations were appropriately documented. Analytical field and laboratory recovery results were acceptable, generally averaging between 70 and 120% recovery, with coefficients of variation largely less than 25%.

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, users are directed to a separate EPA review (Crowley, [date]).

**Table 2. AHE170 Exposure Summary[1]**

| | Dermal Exposure (µg) | | | Inhalation Exposure (µg)[6] |
|---|---|---|---|---|
| Statistic[2] | Hands[3] | Head[4] | Body[5] | |
| Minimum | 0.04 | 0.80 | 1.7 | 1.86 |
| Maximum | 132 | 105 | 403 | 162 |
| Mean | 15 | 28 | 113 | 30.6 |

[1] Results shown include adjustments for field fortification sampling.
[2] Means are simple averages (i.e., sum of values ÷ n)
[3] Results do not include imputation for lost hand wash samples for workers M1 and M2.
[4] Results include extrapolation of face/neck wipe samples to non-wiped portions of the face/neck/head.
[5] Represents the sum of two (upper and lower body) inner dosimeter samples.
[6] Inhalation exposure (µg) = Residue collected * [Breathing rate (L/min) ÷ Pump rate (L/min)]. Pump rates generally were 2 L/min; breathing rate of 26.7 L/min assumed (NAFTA, 1998).

## 2.0 Summary of Field Study Characteristics

This section provides summary characteristics for AHE170. While a summary is provided, the submitted AHE170 report should be consulted for more specific details (applicable sections, tables, and/or page numbers are provided).

### 2.1 Administrative Summary

AHE170 was sponsored by the AHETF and adequately followed both the protocol and scenario construction plan (AHETF, 2014), 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.

Amendments to the protocol were appropriately documented and followed and protocol deviations were reported. To mitigate recruitment difficulties experienced in the study, most protocol amendments were intended to expand the potential pool of eligible workers to monitor by adding a potential surrogate active ingredient and to allow some workers to be monitored outside of pre-designated monitoring areas. Protocol deviations included use of (valid) analytical methods not specified in the protocol, lack of fully sampling some test substance, and lack of a hand wash at a protocol-specified instance.

EPA considers the amendments reasonable and useful additions for obtaining results consistent with the intent of the study's purpose and original protocol. For a more detailed summary of protocol amendments and deviations, see Section 4.0 below and refer to AHE170 pages 12-13 as well as AHE170 Appendix A (pages 277-295).

### 2.2 Test Materials

The protocol specified 10 surrogate active ingredients that could be used by the monitored workers[2]. Additionally, in March 2015 protocol amendment 1 added 2,4-D as an additional potential surrogate chemical. Ultimately, monitored workers used 5 of the 11 surrogates (tefluthrin, chlorpyrifos, pendimethalin, permethrin, and 2,4-D). The various EPA-registered granule products containing those active ingredients are outlined in Table 4 below.

All products were standard/typical granule formulations[3]; none were considered engineered to be reduced dust or include carriers such as polymer coatings. All were packaged in paper or plastic bags weighing approximately 50 pounds. In the AHE170 study report, Table 2 on page 88-89 provides more specific details on the products used.

**Table 4. AHE170 Summary of Pesticide Products Used**

| Product Name | EPA Reg. No. | Active Ingredient (% product content) | Worker ID |
|---|---|---|---|
| Force G | 100-1075 | Tefluthrin (3%) | M8 |
| | | | M6 |
| | | | M13 |
| | | | M16 |
| | | | M12 |
| | | | M15 |
| | | | M17 |
| | | | M18 |
| | | | M19 |
| | | | M20 |
| 2,4-D Granules | 228-61 | 2,4-D | M4 |

[2] Carbaryl, dithiopyr, tefluthrin, ethalfluralin, chlorpyrifos, imidacloprid, mefenoxam, pendimethalin, permethrin, thiophanate-methyl

[3] From AHE170: EPA "considers granular pesticide products to include those products composed of a high percentage (generally greater than 90%) of granular inert carrier(s) (corn cobs, clay, limestone, sand, food) and a minimal amount of sticker/binder (generally 5% or less of the formulation)".

| Table 4. AHE170 Summary of Pesticide Products Used | | | |
|---|---|---|---|
| **Product Name** | **EPA Reg. No.** | **Active Ingredient (% product content)** | **Worker ID** |
| | | (19%**) | |
| Pendulum 2G | 241-375 | Pendimethalin (2%) | M10 |
| Lorsban 15G | 62719-34 | Chlorpyrifos (14.75%) | M1 |
| | | | M5 |
| | | | M9 |
| Chlorpyrifos 15G | 19713-505 | Chlorpyrifos (14.7%) | M11 |
| | | | M2 |
| | | | M7 |
| | | | M14 |
| Precept Insecticide | 100-1075-524 | Tefluthrin (2.9%) | M21 |
| Pounce 1.5G | 279-3059 | Permethrin (1.5%) | M3 |

**The nominal concentration on the product label is 28.9% 2,4-D ethylhexyl ester ($C_{16}H_{22}CL_2O_3$). However, because the analytical method for the exposure dosimetries are based on the 2,4-D free acid ($C_8H_6CL_2O_3$), the contents in the product are also expressed as the free acid. AHE170 Appendix G shows the free acid content of the test substance at 19% which converts to 29% of the ester, matching the stated concentration on the product label.

Per GLP, AHETF analyzed the test substances for purity, with all tests demonstrating the actual product active ingredient content percentages matching nominal label statements. Certificates of Analysis, which formally document analysis of the test substances, are provided in AHE170 Appendix G pages 814-841. 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 Section 2.7 below.

### 2.3 Sample Size, Monitored Workers, and Locations

According to the AHE170 study protocol (AHETF, 2014) and the AHETF Governing Document (AHETF, 2008 and 2010), a "7 x 3" configuration was deemed a reasonable approach for these scenarios. That is, a total of 21 "monitoring units" (MU), obtained by monitoring exposure from 7 distinct study locations across the U.S., each with 3 workers per location would likely satisfy pre-defined data accuracy benchmarks.

In actuality, this cost-effective approach was not completely achieved. Though 7 distinct geographical locations were monitored, the temporal differences resulted in a (less cost-effective) configuration of 8 clusters. Additionally, 4 workers (instead of 3) were monitored in each of two monitoring areas. This slight change to the data configuration (outlined in protocol amendment 4) was largely due to recruitment difficulties related to significant rainfall in the northeast U.S in the 2016 spring planting season.

Thus, the final dataset consisted of 21 separate workers[4] monitored loading granule pesticide products in nine U.S. states (Iowa, Florida, Georgia, Nebraska, South Dakota, Pennsylvania, North Carolina, Indiana, and Minnesota) from 2015-2016. Instead of the intended 7 "clusters", the 21 monitored workers ultimately comprised 8 distinct "clusters", when considering spatial proximity as well as a temporal proximity. 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 21 monitored workers, while the AHE170 study report provides additional details in Table 3 on pages 90-93.

**Table 5. AHE170 Worker and Location Summary**

| Worker ID | Gender | Age (years) | Weight (lb) | Work Experience (years) | Monitoring Location (U.S. State) | Monitoring Year |
|---|---|---|---|---|---|---|
| M1 | Male | 49 | 224 | 8 | FL | 3/19/2015 |
| M2 | Male | 28 | 229 | 9 | FL | 3/21/2015 |
| M3 | Male | 59 | 202 | 9 | FL | 4/2/2015 |
| M4 | Male | 56 | 204 | 30 | NC | 4/4/2015 |
| M5 | Male | 56 | 350 | 35 | IA | 4/28/2015 |
| M6 | Male | 45 | 161 | 20 | IN | 5/1/2015 |
| M7 | Male | 30 | 278 | 3 | IA | 5/3/2015 |
| M8 | Male | 63 | 170 | > 30 | PA | 5/14/2015 |
| M9 | Male | 28 | 175 | 3 | IA | 5/19/2015 |
| M10 | Male | 20 | 133 | < 1 | GA | 6/2/2015 |
| M11 | Male | 25 | 145 | 10 | GA | 8/18/2015 |
| M12 | Male | 46 | 210 | 10 | MN | 4/14/2016 |
| M13 | Male | 62 | 196 | 30 | IN | 4/20/2016 |
| M14 | Male | 70 | 162 | 40 | MN | 4/22/2016 |
| M15 | Male | 59 | 168 | 30 | MN | 4/23/2016 |
| M16 | Male | 33 | 306 | 5 | IN | 4/25/2016 |
| M17 | Male | 54 | 254 | 28 | NE | 5/6/2016 |
| M18 | Male | 26 | 152 | 7 | NE | 5/7/2016 |
| M19 | Male | 78 | 173 | 50 | NE | 5/7/2016 |
| M20 | Male | 22 | 146 | 5 | NE | 5/16/2016 |
| M21 | Male | 35 | 278 | 15 | SD | 5/18/2016 |

## 2.4 Environmental Conditions

Temperature (including heat index), humidity, wind speed and direction, and rainfall were all reported. The maximum reported temperature was 89° F (NE in May 2016 and GA in August 2015) and the lowest reported temperature was 37° F (IA in May 2015). 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, though as previously stated in Section 2.3, rainfall in the northeast U.S. in 2016 resulted in recruitment difficulties, ultimately altering the overall spatial and temporal configuration of the dataset. Maximum reported wind speed was approximately 19 miles per hour.

[4] As previously mentioned, only 19 workers had complete dermal exposure monitoring results. Worker IDs M1 and M2 had incomplete dermal exposure results due to lost hand wash samples. Imputation of those results is not covered by this review. See Section 3.3.3 for more information.

For more details on environmental conditions see the AHE170 report Table 7 (pages 102-105).

### 2.5 Clothing and Personal Protective Equipment (PPE)

Per the stated goals of the AHETF, monitoring open pour loading of granule 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. In one instance (worker M1), because the participant did not have label-required chemical-resistant footwear, the AHETF provided rubber boots.

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 nitrile rubber, barrier laminate, or Viton®, materials consistent with requirements on the labels of all the products used (for reference see products outlined in Section 2.2 above). Also in accordance with the protocol, where products required wearing two layers of clothing, the whole-body dosimeter served as the second layer; this was the case for the 7 workers handling chlorpyrifos-containing products.

Additionally, 8 workers wore protective eyewear and/or respirators due to product safety requirements. In these cases, to simulate workers who do not wear any eye protection or respirators, 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 or respirator (see Section 3.3.2)[5].

More specific details on work clothing and PPE can be found in the AHE170 study report in Tables 4 and 5 on pages 94-97.

### 2.6 Loading Equipment and Methods

For these studies monitoring was conducted only for exposure during loading granule products into application equipment – by design, to match the intended use of the data as a discrete loading scenario, monitoring was not conducted during application. All products were approximately 50 lb paper or plastic bags, however some were opened slightly different than others. For example, some of the bags were designed to easily open up half-way across the top, while workers used knives to cut open others. Additionally, the heights from which the workers poured the bag's contents into the equipment varied, with most workers pouring from waist height while others were at head height. Loading was done by manually lifting and pouring the contents into the "hoppers" of granule application equipment such as planters and spreaders.

[5] These calculations and results are presented by the AHETF in their scenario monograph (AHE1017), but not in the submission for AHE170.

Workers who load granule pesticides using more automated systems such as mini-bulk containers or super sacks were not monitored in this study.

Table 6 below summarizes the loading characteristics. The AHE170 study report provides more details in Table 6 on pages 98-101.

| Table 6. AHE170 Loading Summary | | | | |
|---|---|---|---|---|
| **Worker ID** | **Relative Loading Height** | **Equipment** | **No. of hoppers** | **Type of Bag** |
| M1 | Abdomen | 12-Row Planter | 12 | Paper |
| M2 | Chin | Twin-Row Planter | 6 | Plastic |
| M3 | Chest | Drop Spreader | 3 | Paper |
| M4 | Thigh | Rotary Spreader | 1 | Plastic |
| M5 | Waist | 12-Row Planter | 12 | Paper |
| M6 | Waist | 12-Row Planter | 12 | Plastic |
| M7 | Waist | 6-Row Planter | 6 | Plastic |
| M8 | Chest | 6-Row Planter | 6 | Plastic |
| M9 | Waist | 6-Row Planter | 6 | Paper |
| M10 | Upper Chest | Rotary Spreader | 1 | Paper |
| M11 | Face | Drop Spreader | 6 | Plastic |
| M12 | Waist | 24-Row Planter | 24 | Plastic |
| M13 | Waist | 12-Row Planter | 12 | Plastic |
| M14 | Waist | 12-Row Planter | 12 | Plastic |
| M15 | Waist | 6-Row Planter | 6 | Plastic |
| M16 | Waist | 16-Row Planter | 16 | Plastic |
| M17 | Waist | 16-Row Planter | 16 | Plastic |
| M18 | Waist | 12-Row Planter | 12 | Plastic |
| M19 | Waist | 8-Row Planter | 8 | Plastic |
| M20 | Chest | 24-Row Planter | 24 | Plastic |
| M21 | Waist | 12-Row Planter | 12 | Plastic |

## 2.7 Application Rates and Amount of Active Ingredient Handled

According to the AHE170 study protocol (AHETF, 2014) and the AHETF Governing Document (AHETF, 2008 and 2010), the total amount of active ingredient applied should be diversified across the scenario and within each study location.

Workers handled between 50 and 2720 lbs of product over the course of 2 to 8 hours. Using the product concentration – determined by laboratory purity analysis – and the amount of product handled, the AHETF calculated the amount of active ingredient handled. Workers handled between 6 and 175 lbs of active ingredient (tefluthrin, chlorpyrifos, permethrin, 2,4-D, or pendimethalin). Table 7 below provides more detail on the amount of active ingredient handled. The submitted AHE170 study report Table 6 (on pages 98-101) should also be referenced.

| Table 7. AHE170 Amount of Active Ingredient Handled | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Worker ID** | **Bag Size (lb)** | **# Bags handled** | **Amount Product Handled (lb)** | **% ai in product[a, b]** | **# Loads** | **Exposure Time (hrs)** | **AaiH (lbs)[c]** |
| M1 | 50 | 12 | 600 | 14.75 | 4 | 7.0 | 88.5 |
| M2 | 50 | 6 | 300 | 14.7 | 3 | 5.3 | 44.0 |
| M3 | 50 | 8 | 388 | 1.5 | 3 | 6.1 | 5.8 |
| M4 | 50 | 4 | 200 | 19 | 3 | 2.8 | 38.2 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| M5 | 50 | 21 | 1025 | 14.75 | 3 | 7.0 | 157.6 |
| M6 | 50 | 6 | 300 | 3 | 3 | 4.6 | 8.7 |
| M7 | 50 | 3 | 150 | 14.7 | 4 | 3.5 | 22.3 |
| M8 | 50 | 5 | 250 | 3 | 3 | 4.0 | 7.3 |
| M9 | 50 | 1 | 50 | 14.75 | 3 | 1.9 | 7.4 |
| M10 | 40 | 68 | 2720 | 2 | 6 | 3.8 | 53.3 |
| M11 | 50 | 13 | 650 | 14.7 | 4 | 4.8 | 93.8 |
| M12 | 50 | 24 | 1200 | 3 | 3 | 6.8 | 36.4 |
| M13 | 50 | 14 | 700 | 3 | 3 | 6.3 | 20.9 |
| M14 | 50 | 23 | 1150 | 14.7 | 3 | 6.2 | 174.5 |
| M15 | 50 | 6 | 300 | 3 | 3 | 3.9 | 8.6 |
| M16 | 50 | 26 | 1270 | 3 | 3 | 6.8 | 39.0 |
| M17 | 50 | 20 | 1000 | 3 | 4 | 7.8 | 28.5 |
| M18 | 50 | 18 | 900 | 3 | 4 | 7.2 | 26.8 |
| M19 | 50 | 6 | 300 | 3 | 3 | 6.5 | 8.8 |
| M20 | 50 | 18 | 900 | 3 | 3 | 4.7 | 28.4 |
| M21 | 50 | 12 | 600 | 2.9 | 4 | 7.4 | 17.6 |

[a] See Table 4 for active ingredients.
[b] The % ai is based on the Certificates of Analysis (see AHE170 Appendix G), not the % ai on the product label.
[c] AaiH is approximated by the calculation: lbs product handled * % ai in product

### 2.8 Exposure Monitoring and Analytical Methods

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

- Hand exposure was measured using a hand rinse method administered at the end of the workday as well as at lunch, restroom breaks, or other instances where workers would otherwise wash their hands as outlined in AHETF SOP 8.B.
- Exposure to the face/neck was measured using a wipe technique as outlined in AHETF SOP 8.C and extrapolated to non-wiped portions of the head according to AHETF SOP 9.K. Thus, for those workers who wore eye protection and/or respirators the extrapolation to the whole head renders the resulting measurement representative of face/neck/head exposure without that additional gear. Generally, 1-2 face/neck wipe samples were collected for each worker 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. Protocol amendment 1 added analytical methods for 2,4-D and amendment 3 clarified the chlorpyrifos

and tefluthrin analytical methods. The analytical methods listed below are described in more detail in the AHE170 analytical reports (AHE170 Appendices B, C, D, E, and F):

- Chlorpyrifos
    - AHE240, "Validation of Analytical Methods for the Determination of Residues of Chlorpyrifos, Ethalfluralin, and Tefluthrin in/on Worker Exposure Matrices"
        - AHETF-AM-111: Determination of Residues of Chlorpyrifos, Ethalfluralin, and Tefluthrin on Two- and Six-Piece Cotton Inner Dosimeters
        - AHETF-AM-112: Determination of Residues of Chlorpyrifos on Cotton Face/Neck Wipe Samples
        - AHETF-AM-113: Determination of Residues of Chlorpyrifos in Hand Wash Solutions
        - AHETF-AM-114: Determination of Residues of Chlorpyrifos, Ethalfluralin, and Tefluthrin in OVS Air Sampling Tubes
- Tefluthrin
    - AHE240, "Validation of Analytical Methods for the Determination of Residues of Chlorpyrifos, Ethalfluralin, and Tefluthrin in/on Worker Exposure Matrices"
        - AHETF-AM-111: Determination of Residues of Chlorpyrifos, Ethalfluralin, and Tefluthrin on Two- and Six-Piece Cotton Inner Dosimeters
        - AHETF-AM-114: Determination of Residues of Chlorpyrifos, Ethalfluralin, and Tefluthrin in OVS Air Sampling Tubes
        - AHETF-AM-116: Determination of Residues of Ethalfluralin and Tefluthrin in Hand Wash Solutions
        - AHETF-AM-117: Determination of Residues of Ethalfluralin and Tefluthrin on Cotton Face/Neck Wipe Samples
- Pendimethalin
    - AHE236, "Validation of Analytical Methods for the Determination of Residues of Pendimethalin in/on Worker Exposure Matrices"
        - AHETF-AM-091: Determination of Residues of Pendimethalin on Six-Piece Cotton Inner Dosimeters (adapted by laboratory for 2-piece dosimeters)
        - AHETF-AM-092: Determination of Residues of Pendimethalin on Cotton Face/Neck Wipe Samples
        - AHETF-AM-093: Determination of Residues of Pendimethalin in Hand Wash Solutions
        - AHETF-AM-094: Determination of Residues of Pendimethalin in OVS Air Sampling Tubes
- Permethrin
    - AHE227, "Validation of Analytical Methods for the Determination of Residues of Permethrin in/on Worker Exposure Matrices"
        - AHETF-AM-115: Determination of Residues of Permethrin on Two-Piece Cotton Inner Dosimeters (see Protocol Deviation 4)
        - AHETF-AM-077: Determination of Residues of Permethrin in Hand Wash Solutions

        - AHETF-AM-078: Determination of Residues of Permethrin on Cotton Face/Neck Wipe Samples
        - AHETF-AM-080: Determination of Residues of Permethrin in OVS Air Sampling Tubes
- 2,4-D
    - AHE67, "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: Determination of 2,4-D and 2,4-DB on Two-Piece Cotton Inner Dosimeters (see Protocol Deviation 2)
        - AHETF-AM-033: Determination of 2,4-D and 2,4-DB in Face/Neck Wipe Samples
        - AHETF-AM-034: Determination of 2,4-D and 2,4-DB in Hand Wash Solutions
        - AHETF-AM-035: Determination of 2,4-D and 2,4-DB in OVS Air Sampling 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 AHE170**

| Monitoring Matrix | Limit of Detection | | | | | Limit of Quantification | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | 2,4-D | CPY | PERM | PEND | TEF | 2,4-D | CPY | PERM | PEND | TEF |
| Inner Dosimeter | 0.30 | 0.13 | 0.38 | 0.17 | 0.06 | 1.0 | 1.0 | 1.0 | 1.0 | 1.0 |
| Face/Neck Wipe | 0.3 | 0.07 | 0.15 | 0.24 | 0.19 | 1.0 | 1.0 | 1.0 | 1.0 | 1.0 |
| Hand Rinse | 0.30 | 0.07 | 0.38 | 0.22 | 0.11 | 1.0 | 1.0 | 1.0 | 1.0 | 1.0 |
| OVS air sampler (per section) | 0.0015 | 0.0011 | 0.0006 | 0.0006 | 0.0013 | 0.005 | 0.005 | 0.005 | 0.005 | 0.005 |

## 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: Protocol, Exposure Monitoring, Preliminary Study Data, Draft Final Report, Final Report, and Post-Audit 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. 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

There were several instances where field control samples contained detectable residues, mostly for OVS samplers which have relatively low analytical limits. In three instances concurrent laboratory controls had residues slightly above the matrix LOD. Per AHETF practice, field samples were not adjusted/reduced for presence of the chemical in control samples. More detailed results can be found in AHE170 Appendix B Tables 6-13 on pages 351-364, Appendix C Tables 6-10 on pages 462-467, Appendix D Tables 6-10 on pages 530-534, Appendix E Tables 6-10 on pages 599-604 and Appendix F Tables 6-13 on pages 710-731.

### 3.2.2 Field Fortification Recoveries

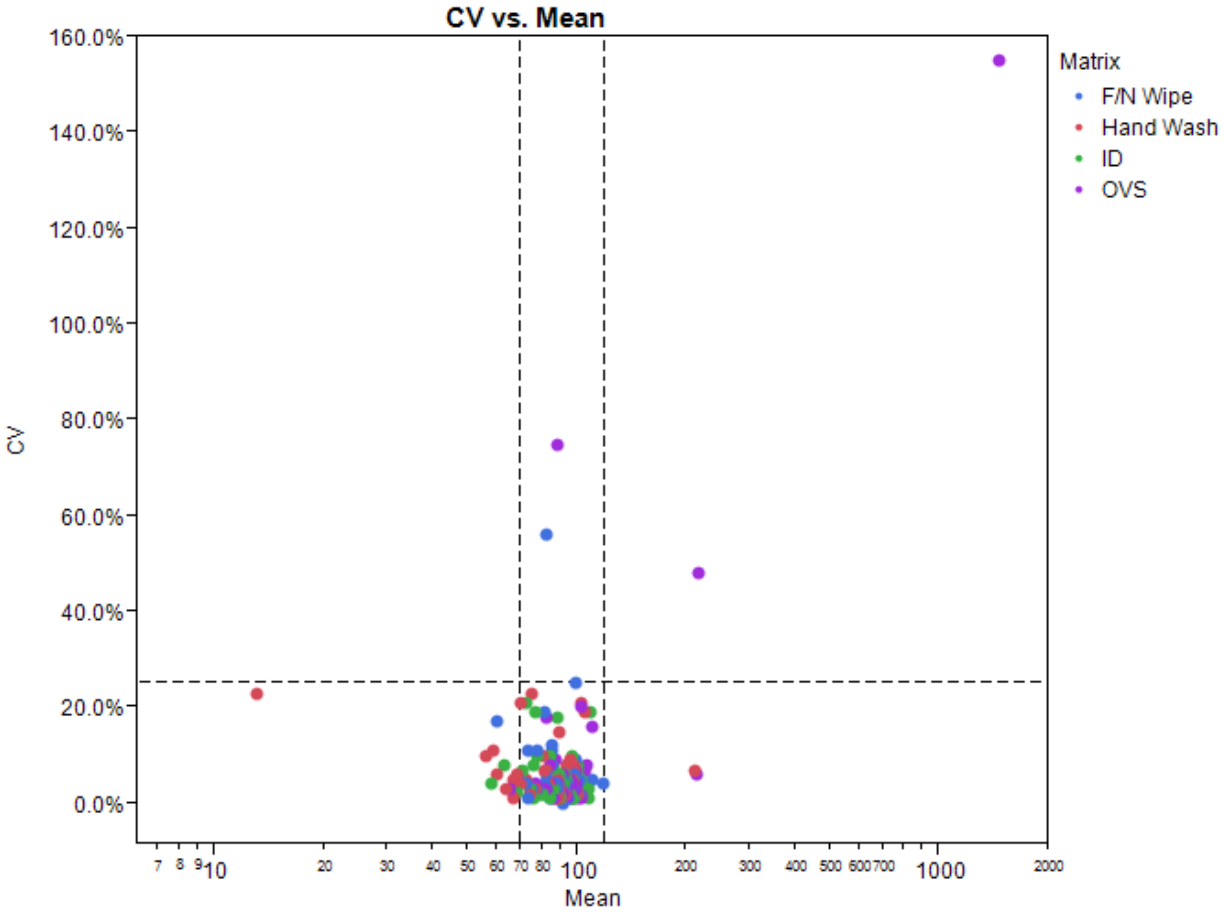
Field fortification sampling matrices are spiked with known amounts of chemical, then placed under similar conditions and duration as the actual sampling matrices used on the workers (including drawing air through OVS samplers). The intent of these samples is to quantify potential residue losses due 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 significant 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[6]. The mid-point between each fortification level is used as the threshold in determining the average recovery percentage for use in adjusting the field sample.

With some exceptions, field fortification averages for each fortification level and each monitoring matrix were in the range of 70-120% with coefficients of variation (CV) generally less than 25%. Figure 1 below shows the field fortification results (CV by Average) across all fortification levels and dosimetry matrices, overlaid with the 70-120% and 25% benchmarks. For more details on field fortification results see AHE170 Table 11 on pages 199-213. A summary for each matrix is provided in the sections below.

**Figure 1 - Field Fortifications (CV by Mean)**




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

#### 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%.

#### 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.

Four face/neck wipe fortification samples from monitoring date 5/1/15 (corresponding to M6) were broken or leaked and could not be used. However, the results were moot as all face/neck wipe samples for M6 were < LOQ and did not require any adjustments based on field fortifications.

#### 3.2.2.3 Hand Washes

Results for hand wash field fortification samples were acceptable with coefficients of variation less than 25%, though a number of average recoveries were outside the benchmark range of 70% to 120%. Some notable instances include:

- In the case of M3 the low level fortification had an average recovery of 212%, however no hand wash sample for M3 corresponded with that low level.
- One hand wash fortification sample on monitoring date 4/22/16 (corresponding to worker M14) was broken or leaked and could not be used. This did not affect the results as this fortification level did not correspond to hand wash field samples for M14.
- Hand wash fortification samples were also broken/compromised for those corresponding to M1 and M2 (monitoring date 3/21/15). However, the fortification level corresponding to the field samples still had useful/reliable results.
- High level fortifications for monitoring date 6/2/15 (M10) had very low recoveries, with the AHETF suspecting the magnitude exceeded the limit of solubility for that particular active ingredient (pendimethalin). No worker samples corresponded to that level however, so there was no issue as to whether to make use of the result.
- For monitoring date 8/18/15 (M11) a single anomalous result in the triplicate set was not included in the calculation of the mid-level average.

#### 3.2.2.4 OVS Air Samplers

Results for OVS field fortification samples were acceptable, with average recoveries largely ranging from 70% to 120% and coefficients of variation less than 25%. Notable instances include:

- The low level OVS fortification for monitoring date 4/2/15 (corresponding to M3) had the largest outlier across all fortification sampling in terms of both the average recovery

(> 1000%) and the coefficient of variation (155%); any samples corresponding to the low level were adjusted by the result for the mid-level recovery[7].

- The low level fortification for monitoring date 4/4/15 was similarly high at 217% with a CV of 48%; contamination was suspected.
- In the case of monitoring date 6/2/15 (M10), low level fortifications were consistently high; for samples corresponding to this level, the AHETF chose to use the results from the mid-level fortification.

### 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 < LOQ to 344 µg. Out of a total of 42 inner dosimeter samples, 2 were < LOQ while none were < LOD. AHE170 Table 14 on page 230 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 1.7 – 403 µg with an average of 113 µg.

#### 3.3.2 Face/Neck Wipes

Without field fortification adjustments, face/neck wipe samples ranged from < LOQ to 48.99 µg. Out of a total of 21 face/neck wipe samples, 4 were < LOQ while none were < LOD. AHE170 Table 14 on page 230 provides more details on these samples.

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[8].

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[7] The AHE170 report incorrectly notes on page 200 (footnote "a") that no field sample corresponded to this level. The back-section from the OVS sample for M3 would have corresponded to this fortification level however was instead adjusted by the mid-level recovery.

[8] 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 (cm2))]}.

After adjusting for field fortification recoveries and extrapolating to non-wiped portions of the head described above, total head exposure ranged from 0.80 – 105 µg with an average of 28 µg.

### 3.3.3 Hand Washes

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 4: 5 workers had only one sample (at the end of the day), 6 workers had 2 samples, 7 workers had 3 samples, and 3 workers had 4 samples.

Notably, hand wash samples for workers M1 and M2 were lost and could not be analyzed. In the case of worker M1, 3 out of 4 samples were lost; for M2, 2 out of 3 samples were lost. In order to make use of their results, imputation of the lost samples would be necessary with different assumptions and methods employed regarding the magnitude of the missing results. How best to impute the lost samples is not addressed here; the EPA review of the submitted AHETF scenario monograph should be consulted (Crowley, [date]). Thus this section summarizes hand wash sample results including only the (singular) samples available for workers M1 and M2.

Without field fortification adjustments, individual hand wash samples ranged from < LOD to 60 µg. Out of a total of 50 hand wash samples, 4 were < LOD while 14 were < LOQ. As previously stated, 5 of those 50 samples were lost. AHE170 Table 14 on page 230 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 0.04 – 132 µg with an average of 15 µg. Again, these results do not include imputation of the lost samples for workers M1 and M2.

### 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 4 of 21 back section samples were < LOD. Without field fortification adjustments, front sections ranged from 0.132 to 11 µg and back sections ranged from < LOD to 0.072 µg. AHE170 Table 15 on page 231 has more details on these results. After adjusting for field fortification recoveries, the total (front section + back section) collected active ingredient amounts ranged from 0.14 – 12.1 µg with an average of 2.31 µg.

The AHE170 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 open pour loading granules scenario (under separate EPA review; Crowley, [date]) presents worker inhalation exposures based on 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 handling granule products, a breathing rate of 26.7 liters per minute was used, representing moderate activities such as lifting heavy bags (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 1.86 – 162 µg with an average of 30.6 µg.

### 3.4 Field Observations

Field researchers observed each worker and recorded their behavior throughout the work day. These can be found in the AHE170 report in Table 9 on pages 108-163.

Many of the observations detailed routine loading procedures. For example: M15 at 8:25 am – "Opened bag C1, lifted to waist high, poured ~ 1/3 into each of right three hoppers (6 pours total), shook all granules out, and closed hoper lids". Other observations can potentially provide clues as to determinants of exposure – examples of these types of observations include:

- M16 at 7:06 am: "Slight dusting noted as pouring. The boxes are at waist height. Dusting noted as shaking bag empty. He lays empty bags on ground. He does carry & hold bags against front of body."
- M17 at 12:50 pm: "Donned gloves and commenced load. This load used 2 hoppers per bag. TS almost filled each hopper and some TS dust blew out, but strong winds blew away from worker. TS bag had small holes and small amount of TS poured to ground near feet. Dust is visible on stacked bags and blows upward when weight is dropped on bags near arms."
- M9 at 7:03 am: "Lifted bag, held against chest and poured a small amount in each hopper (~2-3 lbs). Wind is strong, carrying visible plume away from worker. Working left to right on planter."

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

## 4.0 Protocol Amendments and Deviations

Amendments to the study protocol and protocol deviations are detailed below. For additional details, see the AHE170 study report on pages 12-13 as well as Appendix A on pages 277-295.

The four protocol amendments outlined were reasonable accommodations to accomplish the research and did not adversely impact the study conduct or the exposure monitoring results.

Protocol Amendments:

- Amendment 1

    - Added 2,4-D as a surrogate active ingredient. This chemical was not included in the list of potential surrogates in the original protocol; it was added in this amendment in March 2015 as it had the potential to increase participation in the research. One worker out of 21 loaded a granule pesticide containing 2,4-D.
- Amendment 2
    - To allow for quicker recruitment potential, allowed for AHETF to make initial contact with an employer referred to by another employer. This amended the process where the AHETF would rely on the employer to make initial contact with their referral. AHETF found this process hampered by a lack of time for one employer to contact another.
- Amendment 3
    - Changed analytical methods for tefluthrin and ethalfluralin from AHETF-AM-112 (face/neck wipe analyses) and -113 (hand wash analyses) to AHETF-AM-116 (hand wash analyses) and -117 (face/neck wipe analyses). AHETF found that analytical methods -112 and -113 were not adequate for extraction/removal of tefluthrin.
- Amendment 4
    - Relaxed some protocol recruitment requirements due to difficulties in obtaining remaining 2 of 21 participants (significant rainfall during 2016 spring planting season in northeast U.S.)
    - Allowed for up to 5 workers within a monitoring area
    - Allowed for the remaining two monitored workers to handle an amount of active ingredient within the same AaiH strata as another worker monitored in the same area.

The four protocol deviations are outlined below including EPA conclusions with respect to their lack of adverse impact on study results:

- Deviation 1
    - Researcher did not conduct hand wash sample when worker M1 smoked a cigarette. M1 did not wash hands during this break, so significant residues are not expected to have been lost by this deviation.
    - M1 did not wear product-required gloves for handling pesticide-containing seed. The treated seed did not contain the surrogate active ingredient handled by M1, so exposure results were not affected.
- Deviation 2
    - Inner dosimeter analytical method AHETF-AM-032 for 2,4-D incorrectly referenced. The proper method – AHETF-AM-036 – applicable for two-piece dosimeter analysis was used by the laboratory.
    - Researchers provided M7 and M9 with nitrile gloves for a product listing barrier laminate and Viton® as recommendations. Nitrile gloves however, are also suitable for granular products.
    - Only 1 lot of 3 test substances handled by M10 were sampled/analyzed. The label-specified nominal concentration was used to calculate the amount of active ingredient handled. No issues as across AHE170 test results consistently

demonstrated that product label statements of active ingredient content matched analytical purity.
    - Grower names did not accurately specify the type of corn for three monitoring areas. Identification of corn type was intended to maximize recruitment; lists were already sufficiently large enough to mitigate any issues associated with this deviation.
- Deviation 3
    - Various fortification samples not taken due to lack of intact ampoules. No impact on study as no field sample corresponded to these unavailable fortification levels.
    - Flow rate not measured for a malfunctioning air sampling pump. Period of malfunction was only a total of 4 minutes, and initial flow rate for functioning pump is reasonable; sample still considered valid.
- Deviation 4
    - Protocol not amended to incorporate proper permethrin analytical method for two-piece inner dosimeters. AHETF-AM-076 (six-piece dosimeter method) specified, however AHETF-AM-115 (two-piece method) was used. Though the protocol was not amended, AHETF-AM-115 is the proper/validated analytical method for two-piece dosimeter analysis.

## 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 manually open pour loading of granule pesticides.

Since these exposure data were collected with the intent of populating a generic pesticide exposure database, reviewers are directed to the additional information and statistical analyses in the AHETF Open Pour Loading Granules Monograph (AHE1017: Bruce and Holden, 2017). 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, [date]).

## 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.

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

AHETF, (2014). Protocol Authorization – Determination of Dermal and Inhalation Exposure to Workers During Open Pour Loading of Granules. May 31, 2014. Final signed date December 5, 2014.

Bruce, E. (2017). Determination of Dermal Exposure and Inhalation Exposure to Workers During Open Pour Loading of Granules. Study Number AHE170. Unpublished study sponsored

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Bruce, E. and Holden, L. (2017). Agricultural Handler Exposure Scenario Monograph: Open Pour Loading of Granules. Report Number AHE1017. Unpublished study sponsored by the Agricultural Handlers Exposure Task Force. 258 p. October 25, 2017. EPA MRID 50426101.

Crowley, M. (date). Memorandum: Review of Agricultural Handler Exposure Task Force (AHETF) Monograph: "Open Pour Loading of Granules" (AHE1017). D[placeholder]. [date placeholder].

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