



Closed Loading Systems: Updated Pesticide Risk Assessment Data

SFIREG Joint Working Committee
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Background

- OPP/HED relies on worker exposure monitoring data to conduct occupational pesticide risk assessments
- Data from the Agricultural Handler Exposure Task Force (AHETF), an industry consortium, is the primary source for handler risk assessments and has been developing data for approximately 20 years
- As new AHETF data becomes available and is appropriately reviewed, OPP/HED incorporates the data in its risk assessments (replacing previously-used data)
- In 2019, AHETF submitted exposure data for workers using closed systems to load liquid pesticide formulations
- EPA's Human Studies Review Board (HSRB) reviewed both the protocol (2011) and completed study (2020)
- OPP/HED finalized its review in early 2021 and is now preparing to routinely use the new data for assessing exposure and risk for handlers using closed systems to load liquid pesticides



Closed Loading Systems: Issues for Stakeholder Outreach

1. Requiring handlers to rinse suction/extraction (S/E) probes within pesticide containers prior to removal
2. To reflect EPA's Worker Protection Standard (WPS) Closed System PPE exception provisions (40 CFR 170.607), risk assessments for closed loading systems will include exposures with and without personal protective equipment (PPE) (specifically chemical-resistant gloves and respirators)



Closed System Loading Liquids

Transfer of liquid pesticides to mix tanks or application equipment tanks using a system of pumps, hoses, piping, etc.



"Open Pour"



Closed System Loading Liquids

EPA's Worker Protection Standard (40 CFR 170)

§ 170.305 – Definitions

Closed system means an engineering control used to protect handlers from pesticide exposure hazards when mixing and loading pesticides.

§ 170.607 – Exceptions to personal protective equipment requirements specified on pesticide product labeling

(d)(2)(i) ...removes 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

[Note: as of 1/2/17, § 170.607 replaced § 170.240 Personal Protective Equipment. See § 170.2]



AHETF Exposure Monitoring Methods

Dermal Exposure			Inhalation Exposure
Hands	Head	Body	
<p>Wash</p>  <p><i>Multiple samples analyzed separately</i></p>	<p>Face/neck wipe</p>  <p><i>Multiple samples analyzed as one</i></p>	<p>Whole-Body Dosimeter</p>  <p><i>WBD analyzed in sections</i></p>	<p>Air pump (~2 L/min)</p>  <p>OVS tube</p>  <p><i>Front and back sections analyzed separately</i></p>



AHETF Closed Loading Liquids Data: System Types

Suction/Extraction



Container Breach



Gravity Flow



Many varieties, brands, and manufacturers...that meet EPA's Closed System definition



AHETF Closed Loading Liquids Data: Activity

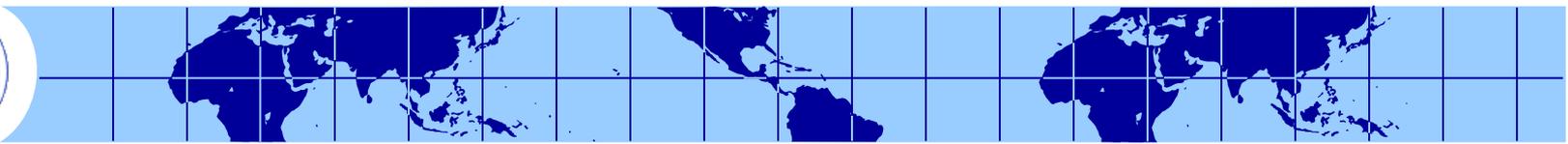
- Connect product container to system
- Transfer liquid product to mix tank or application equipment tank
- Rinse container (applicable to non-returnable containers)
- Transfer rinsate to solution/mixture
- Disconnect
- Dispose of or return/refill container



AHETF Closed Loading Liquids Data: Workers

N	Gender	Age	Work Experience	Weight	Employment
56	54 men 2 women	23 – 65 years	1 – 40 years	139 – 318 lbs	Commercial applicators/Farm Owners/Farm Employees

	Returnable	Non-Returnable
AHE500	15	19
AHE13	7	--
AH501	15	--

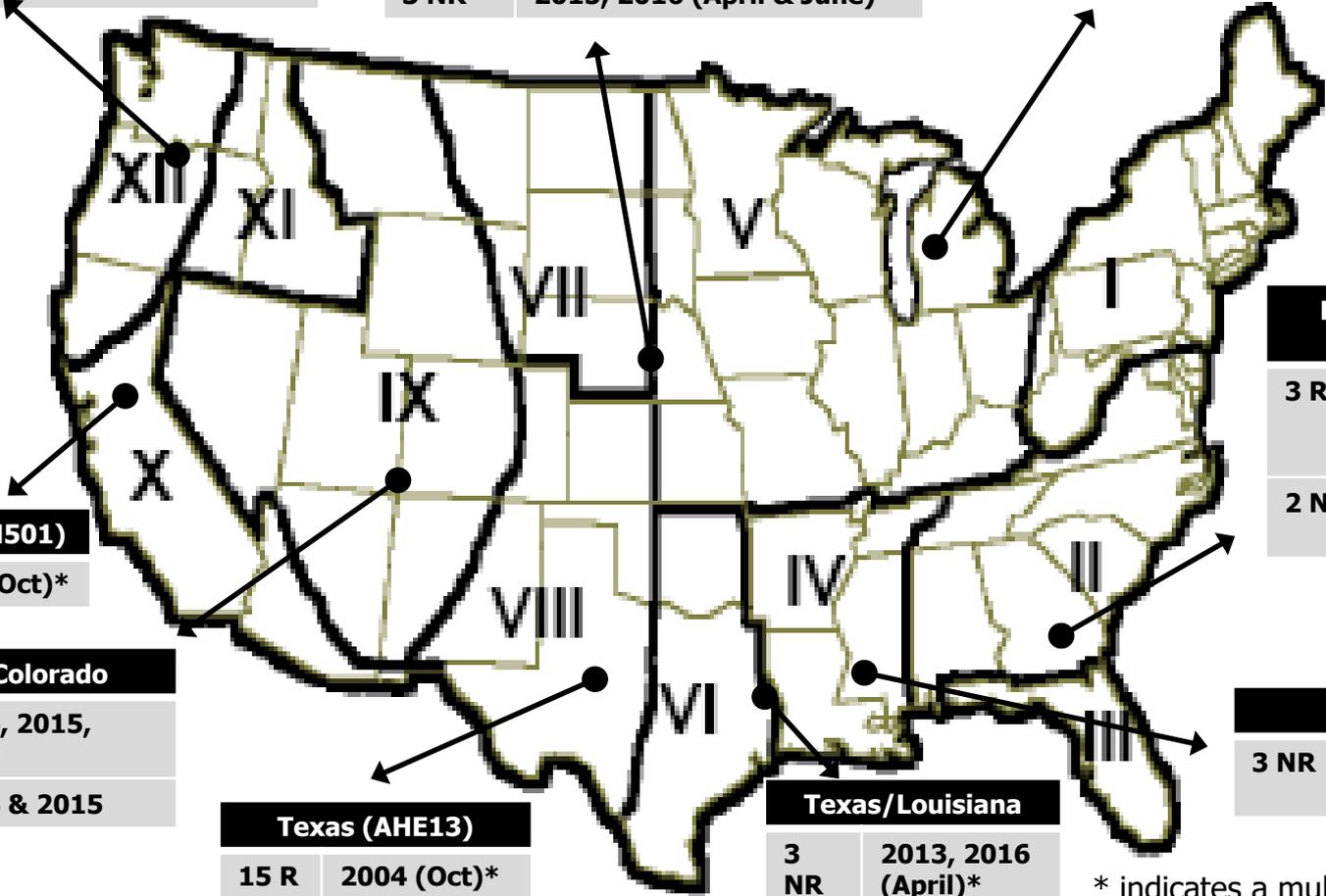


AHETF Closed Loading Liquids Data: Where/When

Washington/Oregon	
3 R	2013, 2014, 2016
3 NR	2013 (Sep & Nov), 2014

Nebraska	
3 R	2015, 2016 (April)*
3 NR	2015, 2016 (April & June)

Michigan	
3 R	2013, 2014 (May & July)
3 NR	2015, 2016 (June)*



Florida/Georgia/S. Carolina	
3 R	2012, 2013 (April & June)
2 NR	2016 (July & Oct)

Mississippi	
3 NR	2013 (Mar)*, 2016

California (AH501)	
7 R	1991 (Oct)*

Arizona/Colorado	
2 R	2014, 2015, 2016
3 NR	2014 & 2015

Texas (AHE13)	
15 R	2004 (Oct)*

Texas/Louisiana	
3 NR	2013, 2016 (April)*

* indicates a multi-worker cluster



AHETF Closed Loading Liquids Data: Loading Info.

	Tank Loads	Time (hrs)	Liquid concentrate handled (gallons)	Solution prepared (gallons)	AaiH (lb)
Min	2	0.5	20	173	76
Max	14	11	970	13,420	9603
Avg.	6	5	244	2,397	1,963



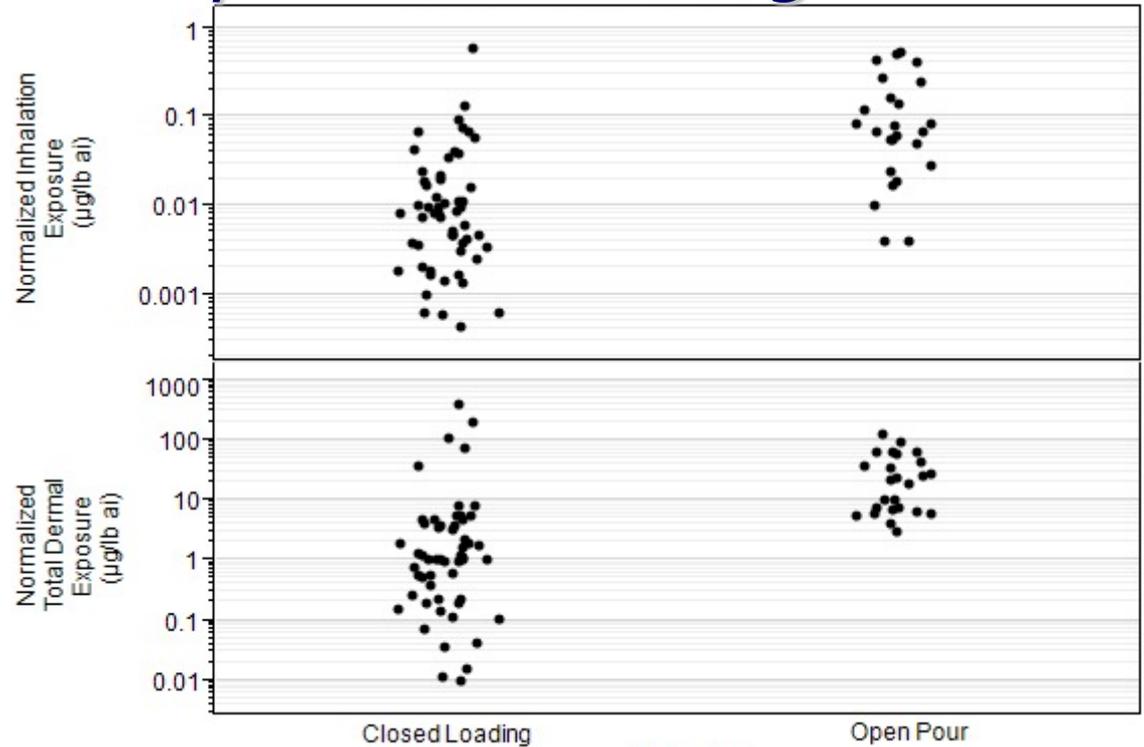
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Closed Loading Liquids Exposure Monitoring Results

After analyzing the data, AHETF observed unexpectedly high dermal exposures – comparable with open pouring liquid concentrates



Scenario





Closed Loading Liquids Exposure Monitoring Results

- AHETF subsequently tabulated worker observation data in order to quantitatively evaluate any particular “standout” variable
 - Removing unrinsed extraction probes (i.e., “contaminated stingers”)
 - Disconnecting contaminated product transfer hoses
 - Rinsing empty test substance containers with an open system
 - Rinsing empty test substance containers with a closed system
 - Leaks in test substance or spray mixture transfer systems
 - Repairs involving test substance or spray mixture transfer systems
 - Rinsing gloves during the monitoring interval



Closed Loading Liquids Exposure Monitoring Results

- AHETF found that workers using suction/extraction systems without rinsing extraction probes (“stingers”) prior to removing them had the potential for higher dermal exposures

result in distinctly different exposure potential. Detailed examination of conditions associated with all 56 Monitoring Units (MUs) in the CSLL dataset identified a task that was statistically associated with higher nTDE: removing contaminated product transfer probes (stingers). That is, removing a contaminated stinger at least once during the monitoring interval was associated with a statistically higher nTDE. AHETF therefore combined MUs that handled

The only parameter that was statistically significantly associated with nTDE was removing contaminated stingers from product containers ($p = 0.0005$). The results of these statistical

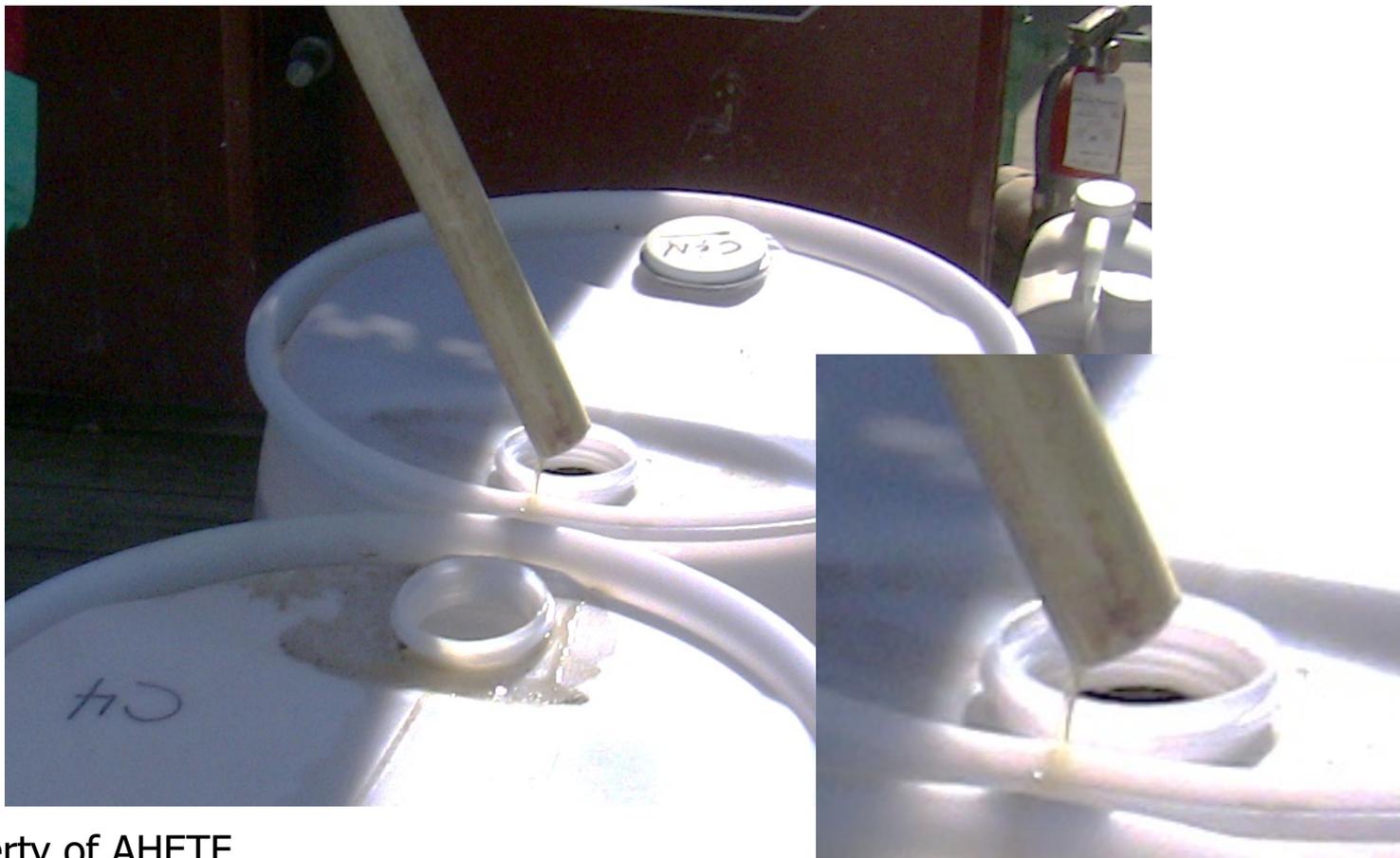
Bruce and Holden, 2019. “Single Scenario Rationale”



Closed Loading Liquids – Rinsing S/E Probes

Suction/Extraction Systems

Probe not rinsed within container before removal

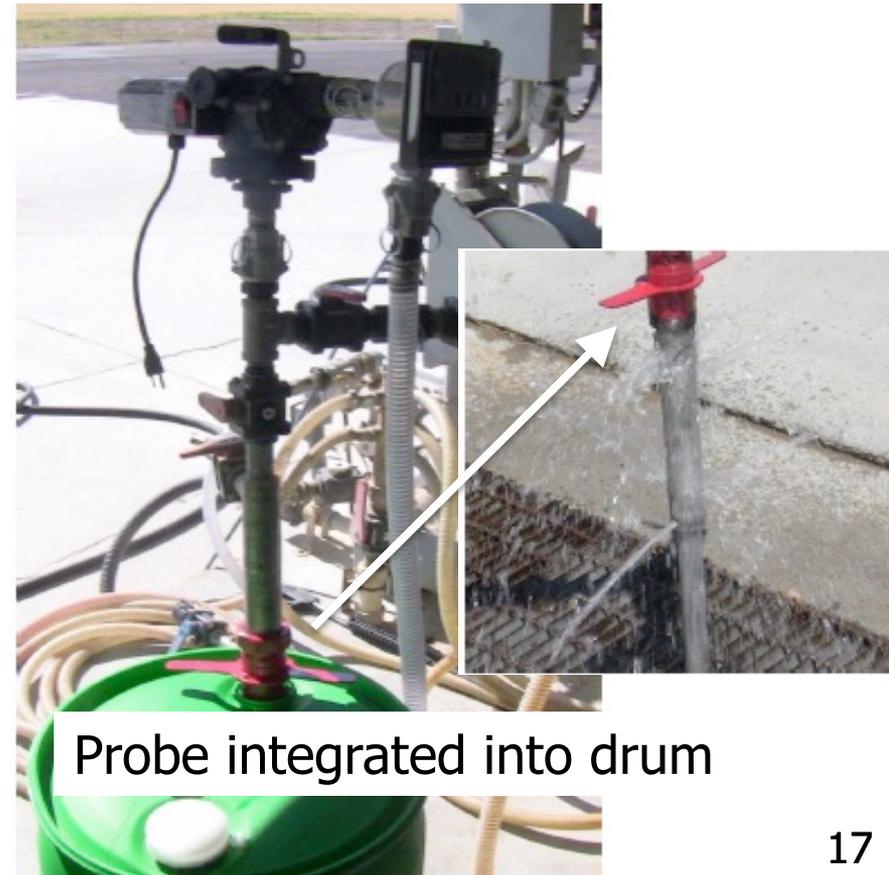




Closed Loading Liquids – Rinsing S/E Probes

Suction/Extraction Systems

Probe is rinsed within container before removal





Closed Loading Liquids – Rinsing S/E Probes

- AHETF final submission excludes workers who removed unrinsed probes
 - 18 workers removed unrinsed probes in AHETF studies (from n = 56 to n = 38)
- EPA agreed with using the new data in this fashion
 - New data represents diversity of exposure conditions when using closed systems
 - Lack of rinsing probes is inconsistent with closed system principles
- HSRB Review (January 2020)
 - “Develop a plan for using the data from the scenarios when workers remove the suction probe prior to rinsing. These data represented a large proportion of the study population and may represent a common work practice. If in fact removing the suction probe prior to rinsing is a common work practice, excluding the data from the scenario would underestimate exposure and risk.”
 - “If EPA continues to exclude workers who remove the suction probe prior to rinsing, EPA may consider developing guidance for proper suction probe use either through risk assessment- or training-based approaches, as EPA determines.”



Closed Loading Liquids – Rinsing S/E Probes

- EPA and AHETF agree use of new data requires commensurate regulatory action for ensuring extraction probes are rinsed
- Analogous to water-soluble packet issue discussed with SFIREG in 2016
 - Workers dissolving/opening packets outside of spray tank was inconsistent with WSP/closed system
 - Activity excluded from monitoring data (amendment to study protocol) and HED's WSP risk assessments
 - OPP worked with stakeholders to amend WSP labels to include instructions that match underlying HED risk assessments
- S/E Probe Rinsing Implementation strategy
 - OPP/HED risk assessments for closed loading liquids will clearly indicate new data represents extraction probe rinsing
 - Product labeling instructions will require probe rinsing or use of containers/drums with integrated (unremovable) probes
 - Pesticide handler education/outreach also under discussion



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Closed System PPE Exceptions

- EPA's Worker Protection Standard allows for reduction in PPE when closed systems are used [170.607(d)(i)-(ii)]
 - Depending on a pesticide's "signal word" a closed system user may not have to, for example, wear chemical-resistant gloves that are otherwise required on product labels
- AHETF closed system data represents handlers wearing chemical-resistant gloves
 - AHETF argues that use of chemical-resistant gloves when using closed systems is both widespread and a good practice and that the WPS provision should not apply for chemical-resistant gloves
- OPP/HED recognizes overlap with WPS PPE exception provision and will include "no gloves" and "with gloves" risk estimates
 - OPP/HED will similarly present inhalation risk estimates with and without respirators
- Applicable for all closed systems (liquids, solids, and water-soluble packets)
- For some pesticides, this may subsequently require label language stating that PPE cannot be reduced or modified as indicated by the WPS closed system provisions



Conclusions

- New AHETF closed loading systems data:
 - Represents handlers rinsing extraction probes when using suction/extraction systems
 - Represents handlers wearing chemical-resistant gloves when using closed systems
- EPA recognizes:
 - Need for commensurate regulatory action for suction/extraction probe rinsing
 - Need for risk assessment clarity regarding closed system WPS PPE exception provisions
- Implementation strategy
 - Clear risk assessment characterization regarding suction/extraction probe rinsing and PPE-based risk estimates
 - Risk management to require product label instructions
 - Outreach and education