

US EPA ARCHIVE DOCUMENT



AHETF Scenario Design and Revised Field Study Protocol for Mixing and Loading Soluble or Wettable Powder Pesticides in Water-Soluble Packaging:

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Why has this protocol been revised?

- **June 2009**: EPA and the HSRB favorably reviewed the protocol (carbaryl and acephate as the surrogates)
- **Late 2009/Early 2010**: Became apparent that different surrogates may be needed
 - Carbaryl was no longer being sold in WSP packaging; not much acephate use
 - AHETF membership confirmed the need for the data and identified other suitable surrogates



What has changed?

- Three new surrogates + acephate
 - Three additional surrogates – dithiopyr, imidacloprid, and thiophanate-methyl
 - Acephate still included as a surrogate
 - Carbaryl no longer included
- Revised amount of active ingredient handled (AaiH) strata due to change in surrogates
- Revised monitoring areas for the new surrogates



What else has changed?

- Revisions to address comments from HSRB and EPA in 2009
 - Improved accuracy of Spanish translations
 - Specified a method for providing individual exposure information to subjects who request it
 - Detailed the procedure for analyzing representativeness of the monitored subjects
- Several updated SOPs; minor revisions to Governing Document
- Individual Product Risk Statements not being used



What hasn't changed

- The proposed procedures governing the ethical conduct of this research



***AHETF Scenario Design and
Revised Field Study Protocol for
Mixing and Loading Soluble or
Wettable Powder Pesticides in
Water-Soluble Packaging:***

Science Assessment

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Scenario Definition - Unchanged

- Mixing/Loading soluble or wettable powder pesticides enclosed in water soluble packets (WSP) for many crops under 3 sub-scenarios
 - Mixing of WSPs directly into the tank used for the pesticide application
 - Mixing of WSPs into a "pre-mix" tank at the same concentration to be applied to the crop
 - Mixing of WSPs into a tank as a concentrated solution/suspension that must be further diluted & transferred to the final application tank
- All 3 must be performed at each monitoring area/site
- 5 x 5 study design



Water Soluble Packets

*Packets containing
dry flowable
product*





Packets may be placed directly into the sprayer tank





Packets may also be placed into a variety of holding tanks either fully diluted for use or as concentrated solutions for further dilution and transfer to spray tanks at a later time



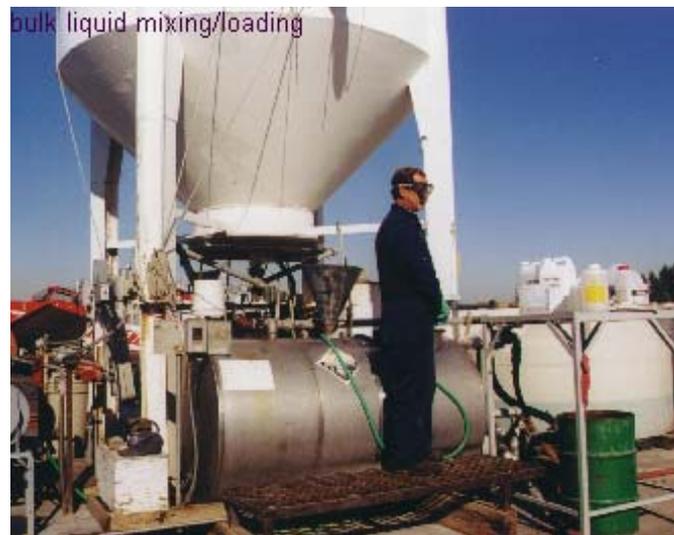


Many kinds of tanks are used





Tanks may be indoors or outdoors





Portable mixing stations may also be set up





Proposed Surrogate Pesticides

- Three of the proposed surrogate pesticides are new to the AHETF
 - Dithiopyr, imidachloprid, and thiophanate-methyl
 - Dithiopyr successfully used in post application monitoring study by the Outdoor Residential Exposure Task Force
 - Imidachloprid, successfully used by Bayer CropScience in post application monitoring study
 - Thiophanate-methyl successfully used in residue studies relying on similar surfactants and cotton collection media
 - These are pre-rule studies



Proposed Surrogate Pesticides

- Dithiopyr and imidacloprid have low application rates and are critical for collecting exposure measurements of participants using the lower AaiH strata
 - Florida and California
- Thiophanate-methyl has a high application rate and is useful for collecting exposure measurements of participants using the higher AaiH strata
 - widely used in North Dakota on high acreage crops



Proposed Surrogate Pesticides

- The AHETF acknowledges that collection of exposure measurements for all AaiH strata may not be possible in all monitoring areas.
 - In particular the lowest stratum.
 - Bearing in mind that for each monitoring unit, the participant must perform at least 3 mix/load activities during the monitoring period
 - Thus the selection of dithiopyr and imidacloprid and the inclusion of Florida and California which have a high numbers of acres of turfgrass grown for sod.



Proposed Surrogate Pesticides

- EPA accepts the AHETF's selection of three additional surrogate pesticides provided that:
 - Confirmation of analytical methods required prior to initiation of field studies
- EPA recognizes that in some monitoring areas measurements of participant exposure using all AaiH strata can not be achieved. AHETF will need to ensure:
 - Primary and secondary benchmark objectives are achieved (relative fold accuracy of 3 for the AM, GM, 95th and proportionality respectively)



Proposed AaiH Strata

- All exposure durations will be at least 4 hours
- Each subject will mix/load at least 3 tanks of spray mixture
- Five strata of AaiH in each cluster:
 - 3 to 7 pounds ai handled
 - 8 to 21 pounds ai handled
 - 22 to 56 pounds ai handled
 - 57 to 150 pounds ai handled
 - 151 to 400 pounds ai handled



Proposed Monitoring Areas

<i>Location</i>	<i>Climate</i>	<i>Crop Types</i>
New York	Cool	Orchard/Trellis/Row Crops (snap beans)
Louisiana	Hot/Humid	Field Crops (cotton, soybeans)
Florida	Hot/Humid	Turf (sod farms), Vegetables
California (central/southern)	Hot/Dry	Orchard/Trellis/Row Crops (lettuce), Turf
North Dakota (western portion)	Warm	Canola and Dry Beans



Not all stratum may be applied in each cluster

- Concern about achieving the lowest stratum (3 – 7 pounds ai handled)
 - Chemicals dithiopyr and imidacloprid selected specifically to achieve this range
 - Monitoring areas of CA and FL selected for having large areas of turfgrass for which dithiopyr and imidacloprid are registered



Margins of Exposure for Maximum AaiH (400 lbs)

Surrogate	Dermal MOE	Inhalation MOE	Combined MOE
Acephate	1,544	204	180
Dithiopyr	30,878	510	Acceptable when both routes combined
Imidacloprid	4,289	7,292	2,700
Thiophanate-Methyl	3,088	7,292	2,169



Conclusions of Science Assessment

- We agree with the AHETF plan to diversify these general equipment types
- That each of the three sub-scenarios must be monitored at least once within each monitoring area (i.e., cluster)
- Stress that all attempts be made to measure participants applying AaiH from each of the three stratum per monitoring area
 - Mindful of the AHETFs ability to achieve all AaiH strata in all regions with respect to achieving primary and secondary objectives
- Diversity will be achieved—randomly or purposively—in the course of assigning mixer/loaders to Amount active ingredient Handled (AaiH) strata within each cluster
- The proposal is for 25 subjects collected in 5 different monitoring areas having 5 subjects each is appropriate for this scenario



Conclusions of Science Assessment

- The analytical methods for acephate are robust
 - Confirmation of analytical methods are required dithiopyr, imidacloprid, and thiophanate-methyl
- The Scenario is well defined and the study is likely to produce reliable mixer/loader data to assess the potential exposure of handlers using water soluble packets



Charge Questions

If the revised AHETF scenario and field study proposal AHE120 is revised as suggested in EPA's reviews and if the research is performed as described:

1. Is the research likely to generate scientifically reliable data, useful for assessing the exposure of handlers who mix and load soluble or wettable powder pesticides in water-soluble packaging?
2. Is the research likely to meet the applicable requirements of 40 CFR part 26, subparts K and L?