US ERA ARCHIVE DOCUMENT

Agricultural Handlers Exposure Task Force (AHETF)

Study Design, Logistics and Conduct

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AHETF - Scope of Occupational Monitoring

33 application scenarios and the associated mixing/loading activities:

Aerial

Ground

Airblast

Greenhouse

Hand-held sprayers

Seed treatment

AHETF - Exposure Monitoring

Occupational Groups

Mixer/Loader (ML) Examples:

- Formulation type liquid, powder, granule
- Equipment open vs. closed system
- Packaging jugs, bags, WSP

Applicator (A) Examples:

- Aerial
- Ground boom open vs. closed cabs
- > Airblast
- Hand carry system

AHETF – Study Design

- Scenario selection defines the set of conditions requiring evaluation (i.e. open pour, open cab ground boom)
 - formulation type
 - packaging
 - delivery system
 - application technique
 - active ingredient
 - label restrictions/requirements
 - crop
 - timing (PPI herbicide is only use in the spring, etc.)
 - geographic location
 - PPE

AHETF – Study Design

- Guidelines for Regulatory Studies
 - Regulatory compliance
 - design review with Joint Regulatory Committee
 - FIFRA and Good Laboratory Practices
 - Ethical review (IRB and DPR, HSRB)
 - Monitoring Methodologies
 - Acceptably sensitive analytical methods for a.i.
 - Dosimetry (dermal and inhalation)

AHETF – Study Design

- Understanding of Agronomics of Scenario
 - variations of mix/load and application equipment
 - variations of practices in the field
 - variations of crops
 - typical area treated per day
 - typical volume handled per day

AHETF – Study Logistics

- Relationship between scenario conditions
 - Occupational setting farm, orchard, forestry area, etc...
 - Workers experienced in activity (tied to location)
 - Appropriate application equipment
 - Monitoring unit capacity (total number of workers and acre available to be treated)
 - Need for the actual treatment
- Relationship between occupational setting manager/operator and local coordinator

AHETF – Study Logistics

- Identify occupational setting farm, orchard, forestry area, etc...
 - Occupational setting Controlled by third party, such as Farmer or PCO, etc...
 - Gain approval to utilize facilities and equipment
 - Gain approval to invite employees of the third party to volunteer for the study
 - Each site has a limited pool of authorized ML/A

AHETF – Study Conduct

- Site meets Scenario requirements
 - All equipment present and operational
 - Appropriate quantity of test material is available
 - Study personal ready (1 per MU and 5 supporting)
 - Grower approval secured and worker informed consent acquired
 - Workers prepared with dosimetry and monitored by an observer while performing the normal ML/A activities.
 - Dosimetry collected when monitoring concluded

Summary

- Relationship between Scenario condition requirements are very important
 - Relationship between conditions are very complex and in many cases fixed
 - Testing sites/facility are not owned or controlled by the AHETF.
 - Test sites have a set finite pool of ML/A personal available
- Cost effective random sampling is extremely difficult due to the inherent and unbreakable relationships between so many required conditions
- A cost effective diversify sampling of the population guided by critical factors in determining exposure (varying individuals, AaiH, location, equipment, etc.) based on sound judgment of Ag experts utilize PDS.