

Test and Reference Substance Analyses
Chapter 7: TEST, REFERENCE, AND CONTROL SUBSTANCES
AHETF-7.E.1.

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1.0 PURPOSE AND SCOPE

- 1.1 This Standard Operating Procedure (SOP) describes how test substances will be characterized and documented for all Agricultural Handlers Exposure Task Force (AHETF) studies.
- 1.2 This SOP was revised to explain the concept of test substance use in AHETF exposure studies and describe the specific analyses to be determined on AHETF test and references substances.

2.0 TEST SUBSTANCE DEFINITION AND USAGE

- 2.1 The USEPA defines "test substance" {§ 160.3 (7)} as "...a substance or mixture ... added to a test system in a study, which...is the subject of an application for a research or marketing permit, ...or, ... a substance used in a study to assist in characterizing the toxicity, metabolism, or other characteristics..."
- 2.2 In respect to this definition, the AHETF use of a "test substance" does not fall within this scope. The AHETF is utilizing commercially available, registered products to provide an analytical marker in the determination of exposure routes to agricultural workers mixing, loading, ^{and/or} applying agricultural pesticides under typical working conditions.

- 2.3 The term “test substance” is used by the AHETF to describe all registered pesticides that may be used on an AHETF study for the sole purpose of providing detectable residues in the determination of a pesticide exposure profile.

3.0 ANALYTICAL INFORMATION AND DOCUMENTATION

- 3.1 The AHETF will obtain a GLP determination of the percent active ingredient for each lot of formulated test substance. The preferred means of obtaining this information is through a GLP certificate of analysis (COA) from the manufacturer. In the absence of a manufacturer’s GLP COA, the AHETF will determine the percent active ingredient under separate protocol using the manufacturer’s analytical methods, if readily available, or the designated analytical laboratory’s SOP if methods are not available. These analyses can be obtained prior to or concurrently with the field testing.
- 3.2 The AHETF prefers that GLP certified reference standards be used for all analyses. The percent purity will be documented in the analytical study file (A GLP certificate of analysis will be maintained by the manufacturer). If a non-GLP certified reference standard is available, the Study Director must be notified in advance and appropriate actions taken to ensure the integrity of the reference material(s).