

## IR-4 Advisory #2003-05 (Dec. 9, 2003)

**Title:** Weighing Field Trial and Processing Trial Residue Samples

**Issue/**

**Question:** Do the scales/balances used to establish estimated weights of field and processing trial residue samples need to be maintained in strict adherence to GLP?

**Background:** In two EPA inspections of IR-4 field test sites in year 2003, auditors noted that the “facility failed to maintain under GLP the scale used to determine field residue sample weights,” and in both cases this was recorded as a finding by the agency inspectors. This issue was not noted in a number of other recent EPA inspections at facilities where the weighing of residue samples was not completed under strict adherence to GLP.

IR-4 protocols generally require a “minimum” sample weight (and usually “preferably not more than...” a certain weight) of the crop. In Part 7B in the FDB, the “approximate weight” of each sample is recorded. These protocol and FDB prompts regarding sample weights are based on EPA “recommended” sample weights in Attachment 8 of the EPA Residue Chemistry Test Guidelines (OPPTS 860.1500, Crop Field Trials [Updated]). Additionally, IR-4 sometimes adjusts these EPA recommendations based on the needs of the laboratory that will analyze the samples.

**Resolution:** It is IR-4’s assessment that field trial and processing trial residue sample weights are not essential data points that require scales/balances to be operated and maintained in strict adherence to GLP. The following revisions to protocols, field data book prompts, and compliance statements will serve as the IR-4 policy that will allow the use of non-GLP maintained scales/balances to establish estimated residue sample weights in IR-4 GLP studies.

- 1) IR-4 protocols will include a footnote statement, such as the following: Weight measurements are considered estimates for the samples collected from field or processing trials, and the scales/balances used for this purpose do not need to be maintained in strict adherence to GLP.
- 2) Part 1C of field data books will include a statement to be checked if scales/balances used to establish estimated weights of field and processing trial residue samples were maintained in strict adherence to GLP.
- 3) In Part 7B of field data books, FRD will be prompted to answer “Yes” or “No” to the question “Was a GLP-maintained scales/balance used to determine residue sample weights?”
- 4) Compliance statements in IR-4 final study reports will consistently reflect this IR-4 policy.

**NOTE:** This IR-4 policy does not preclude the use of scales/balances (to establish estimated residue sample weights) that are maintained in strict adherence to GLP.

*(This advisory expands on this sample weight topic in Items 56 and 94 in the San Antonio Results Document, dated 9/27/02.)*

If you have any questions, please contact your Regional/ARS Field Coordinator or the appropriate Study Director for further guidance.