

IR-4 Advisory #2003-02

Title: Test Substance Container Disposal

Issue/

Question: Can IR-4 establish a system to inform all Field Research Directors (FRD) that test substance containers for a particular trial can now be discarded?

Background: IR-4 has not had a system by which FRD are informed, in a consistent and timely manner, when test substance containers can be discarded. As a result, over time old test substance containers have accumulated in FRD storage facilities. As indicated in IR-4 study protocols, "EPA regulations require that test substance container(s) must be retained until the final study report (Pesticide Tolerance Petition) is completed." Some FRD periodically send a list of test substances they still hold in their storage, to IR-4 headquarters (HQ), with a request that Study Directors (SD) confirm which ones they must retain and which ones can be discarded. One problem with this approach is that sometimes test substance from a single container is used in more than one GLP residue study, and if this is not properly identified by the FRD, the SD may approve disposal of a test substance container which was used in both a completed (submitted to EPA) and an active (not yet submitted to EPA) study.

Resolution: When a final study report (petition) is submitted to EPA from IR-4 HQ, a cover letter accompanies the volume(s) of the petition. This cover letter, copied to the Regional and ARS Field Coordinators (RFC), will serve as notification that the study has been completed. The following procedure should be adopted as a notification system for test substance container disposal throughout IR-4.

When RFC receive the submission cover letter (by U.S. mail/e-mail), they will:

- 1) forward a copy of the cover letter to FRD who conducted a trial(s) in the study or studies covered in the petition, or
- 2) notify the FRD in writing that the petition has been submitted.

Upon receipt of this official notification of study submission, FRD should dispose of the test substance container(s) from this study, **if** this test substance was not used in any other study for which the final report has not yet been submitted to EPA. If an FRD desires to return a container to the registrant, they should first contact the registrant to confirm this is acceptable, receive any specific shipping instructions, and confirm that the container is for disposal, not retention.

(This advisory addresses, in more detail, Item 40 in the San Antonio Results Document, and supercedes the response provided to this question in Item 66 in that 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.