IR-4 Advisory #2015-01 (3/12/15) – Amended Sept. 10, 2015

(Resolution 2 rewritten to eliminate temperature monitoring)

Title: **Storing and Maintaining Adjuvants (Spray Additives) for Use in IR-4 Field Residue Studies**

Issue/ Question: The IR-4 Regional Field Coordinators, after discussion at the 2014 National Research Planning meeting, agreed to take the lead in developing an IR-4 Advisory to provide guidance to Field Research Directors (FRDs) with regard to the data, handling, storage and documentation required for Spray Additives. The intent of this Advisory is to establish a policy that defines the expectations for maintaining spray additives, along with appropriate supporting data and documentation as part of IR-4 GLP residue studies.

Background: Per the 2015 IR-4 Field Data Book, the use of adjuvants (spray additives) with the test substance must be approved in the protocol or in a protocol amendment. Adjuvants (spray additives) are considered to be **reagents, not test substances.** EPA requires spray additives/adjuvants/surfactants/etc., to be treated as GLP "reagents." The GLP requirements for reagents are (per 40 CFR Part 160.83): "*All reagents and solutions in the laboratory areas [i.e., field sites] shall be labeled to indicate identity, titer or concentration, storage requirements, and expiration date. Deteriorated or outdated reagents and solutions shall not be used.*"

No GLP characterization is expected, but the GLP compliance statement must indicate if information pertaining to the following is missing or incomplete:

- the receipt of the adjuvant at the field facility (usually the purchase date)
- recommended storage conditions (from the adjuvant label or Safety Data Sheet [SDS])
- identity and concentration of the adjuvant (from the label or SDS)
- the expiration date (either from the label or assigned by field personnel)

This advisory intends to provide guidance as we move to address these requirements. IR-4 wishes to satisfy EPA requests but not unduly waste adjuvants currently available to FRDs.

Resolution: IR-4 FRDs will add a Standard Operating Procedure (SOP) to their current SOPs to address the labeling, handling, and storage of spray additives.

Expectations of SOPs addressing spray additives:

1) GLP labeling requirements for reagents (i.e. adjuvants, spray additives) are: name, concentration, storage conditions and expiration date. These will be required on all spray additives used for IR-4 GLP Residue Studies beginning with 2015 field trials and beyond.
    a. Secondary containers are permitted for storage (e.g. a 1 gallon container subdivided into 100 ml containers for ease of use and transport to remote sites), but must be properly labeled per the

original container and now take on all the requirements and properties of an “original container”.

b. If temporary containers are used (i.e. a subsample dispensed from the purchased container or a properly labeled secondary container [see b. below]) they should be used only for the purpose of measuring or preventing contamination. They should be adequately labeled to insure the product is uniquely identified, but need not be labeled per GLP as required for the original or secondary containers. Excess material poured into a temporary container should not be used for subsequent GLP trials and should be discarded, i.e., not returned to the original or secondary container.

2) Spray additives will be stored in a location that has limited access and according to storage requirements on the adjuvant label. If storage requirements and expiration date are not specified, attach a sticker to the container with the adjuvant’s expiration date (up to 60 months from date of receipt) and storage conditions. Obtain storage requirements from adjuvant’s MSDS or other supplemental information. If none are provided, assign “Store Ambient.”
3) Spray additives will be in good condition prior to use - the physical characteristics of the additive should not have changed from purchase or be compromised (i.e. different color, consistency [cloudy, darkened] or smell or appear rancid).
4) Spray additives must be handled in a manner to prevent cross contamination with test substances and other spray additives. Two suggested options are provided below. There are likely other methodologies that may be used if appropriately explained in your SOP.
    a. Spray additives will be dispensed into a temporary container (such as a beaker) prior to being used in a GLP residue trial. The spray additive once dispensed will not be used for a different trial or returned to the original or secondary container; it will be discarded.
    b. Spray additives will be dispensed from the original or secondary spray additive container using a newly opened pipette, pipette tip, syringe, or other appropriate measuring device, and after use this device is discarded. The measuring device never returns to the spray additive container, and no leftover adjuvant in the measuring device is returned to the adjuvant container. The test substance is also dispensed by a different newly opened pipette, pipette tip, syringe or other device, discarded after use.

    The critical element in both these examples is: no “double-dipping” into an original or secondary container. No measuring device will be placed directly into a spray adjuvant original or secondary container, and then directly into a spray tank or container intended to hold GLP test substance, and then back into the spray adjuvant container. Other methods that prevent double dipping into original or secondary containers are also acceptable.

Expectations of moving “old” spray additives (those which have not been monitored, and labeled per above) into current use:

1) Spray additives that have been directly dispensed with a measuring device that has been placed directly into a container with GLP Test substance, or any pesticide tank mix and placed again into a spray additive container will no longer be used for GLP residue studies.
2) All spray additives must be labeled per GLP reagent requirements (name, concentration, storage conditions and expiration date). If an expiration date is not available (i.e. on the label or SDS) then the FRD should assign one that does not exceed 5 years from the purchase date. It is also recommended that the FRD include the date the container was opened as a helpful reference date.
3) Spray additives will be in good condition prior to use - the physical characteristics of the additive should not have changed or be compromised (i.e. different color, consistency [cloudy, darkened] or smell or appear rancid). If the spray additive demonstrates any of these characteristics it should be removed from use in GLP residue trials.
4) Monitoring of spray additives, to document and thus assure that storage conditions have been met, should be in place for 2015 GLP field trials and beyond.
5) If there are any questions or concerns about the integrity or condition of the spray additive, it should be removed from use for GLP residue trials.

Expectations of QA units:

1) QA will check spray additives for appropriate labeling and use during critical phase inspections when spray additives are being used.
2) During all IR-4 facility inspections by QA where spray additives exist, QA will check the SOP for inclusion of requirements of this advisory. Any observations regarding issues with spray additives will be captured as findings in audits, thus requiring IR-4 personnel to immediately address the situation. Testing Facility Management review of such audit findings will result in sign-off when issues have been communicated as resolved.

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