

Review of Field Data Book Guidance Document

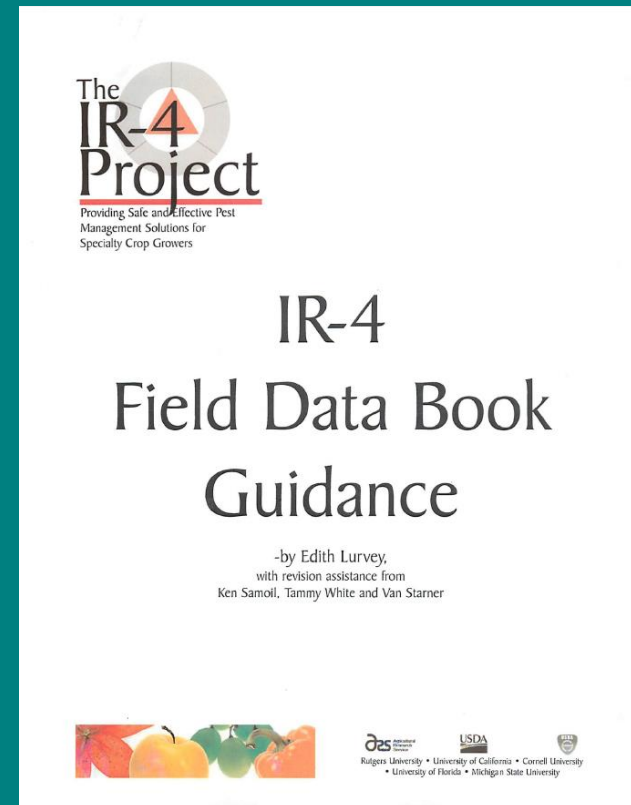
Roger B. Batts and Ken Samoil

IR-4 National Education Conference

February 28, 2017

Background

- Developed to help field personnel complete the FDB in accordance with GLPs and reduce the number of findings during the QC and QA processes.
- First version was 2002 (Lurvey, et al.)
- The last published version was 2006
- Lots of changes in FDB have occurred since 2006, so...



New for 2017...

(Access this document at <http://ir4.rutgers.edu/trainingadvisories.html>)

IR-4 Field Data Book (FDB) Guidance Document



Updated by Roger B. Batts

(Original by Edith Lurvey)

This document was reviewed/updated on behalf of the IR-4 Education & Training Committee

Van R. Starnes 20 Dec 2016
Van Starnes, Chair, IR-4 Education & Training Committee Date

Jerry Baron 20 Dec 2016
Jerry Baron, Exec. Director, IR-4 Project Date

Dec. 2016 revision, incorporating all FDB changes for 2017

New for 2017...

(Access this document at <http://ir4.rutgers.edu/trainingadvisories.html>)

IR-4 Field Data Book (FDB) Guidance Document



Updated by Roger B. Batts
(Original by Edith Lurvey)

This document was reviewed/updated on behalf of the IR-4 Education & Training Committee

Van R. Starnes 20 Dec 2016
Van Starnes, Chair, IR-4 Education & Training Committee Date

Jerry Baron 20 Dec 2016
Jerry Baron, Exec. Director, IR-4 Project Date

Dec. 2016 revision, incorporating all FDB changes for 2017

1

“Act quickly to get an autographed copy. Only three easy payments. Act within 10 minutes and we’ll send you a second one. Just pay extra shipping.”

2017 version

- <http://ir4.rutgers.edu/trainingadvisories.html>
- Sixteen pages
- More in-depth instructions than could be managed properly in the FDB itself.
 - Process instructions
 - Global (document-wide) instructions and reminders
 - Form-specific instructions
- Guidance document will now be edited annually to match the current FDB

The IR-4 Project

Home Food Crops Ornamental Horticulture Biopesticides & Organic Support Public Health International Activities Directory Outreach Materials Quality Assurance (QA)

Facilitating Registration of Sustainable Pest Management
Technology for Specialty Crops and Minor Uses

IR-4 Advisories

- #2015-01 Storing and Maintaining Adjuvants (Spray Additives) for Use in IR-4 Field Residue Studies (Amended September 10, 2015)
- #2014-01 Maintaining Freezer Storage Systems at IR-4 Field and Laboratory Research Sites
- #2007-01: Shipping with Dry Ice and Training/Certification Guidance
- #2006-01: Inventory and Transfer of GLP Raw Data and Other Records to IR-4 Headquarters (HQ)
- #2005-02: Field Research Director Disposal of Field Data Book Copies
- #2005-01: Test Substance Container Disposal Website Approval Procedure (Amended Nov. 21, 2008)
- #2004-02: IR-4 Application Type Definitions
- #2004-01: Foliar Broadcast Spray Swath vs. Plot Width
- #2003-05: Weighing Field Trial and Processing Trial Residue Samples
- #2003-04: Test/Reference Substance Container Labels - Required Information
- #2003-03: Conflicting Chemistries in IR-4 Studies
- #2003-02: Test Substance Container Disposal
- #2003-01: Responding to FDB QA Findings

Training

- IR-4 Education and Training Committee (TC)- objective, composition, membership responsibilities
- Phoenix Proceedings February 2006
- GLP Training Opportunities
- San Antonio Workshop Results
- Operational Handbook
- 2004 Southern/North Central Region GLP Training Session
- **IR-4 Field Data Book (FDB) Guidance Document**
- Laboratory Guidance Document

Contact Us **IR-4 Advisories/Training** Events Links Upload Files

Some (not all) Notable Items

2017 FDB Guidance Document

Notable Items

Process Instructions

- It is highly recommended that all trial participants read and understand all of the **IR-4 Advisories**.
- The instructions in this document do not represent the only way to complete a FDB. They are meant as guides to **make sure the data can be efficiently reviewed** by RFC, QC, QA and SD.
- It is recommended that the completed FDB be submitted to RFC within two months after samples are shipped to laboratory.

Notable Items

Document-wide Instructions and Reminders

- Double-sided pages are prohibited due to increased chances of data loss during subsequent copying activities.
- Entries should be clear and legible. “Do as I say, not as I do” --RBB
- Unused cells, forms and tables should be lined out with initials and date. If partially used forms and tables have more than 2 unused lines, these lines should be lined out with initials and date. Blank areas after written descriptions, calculations, etc. of similar size should be lined out with initials and date.
- Inserted printouts do not need blank areas lined out.
- Records (or True Copies) of calibration and/or verification of accuracy of any GLP-maintained device that is referenced in the trial should be included in the FDB. Min/max thermometers, balances, standard weights, etc.

Notable Items

Form-Specific Instructions

- 2A: Needs to be completed with names of 'data-generating personnel'. Those who entered data and/or worked on the trial, **with the exception of general field workers, harvest assistants, QC, QA, SD and RFC.**
- 2C: **Optional form** that may be used to list personnel that were involved but were not required to be listed on 2A.
- 4: Safety Data Sheets are not required in the FDB, but if they are included, Part 4 is the best location.
- 4: Test substance and adjuvant labels, Certificate(s) of Analysis and other supporting documents are to be placed **after the green page located behind 4F.**
- 5C1: This checklist is to help researcher meet plot plan requirements. All prompts must be addressed.
- 5E – 5H: If data is obtained verbally from cooperator, this communication should be documented in Part 3. **Should we add prompts on each of these pages to record this communication?**
- 5I: Treated crop must be kept out of the food chain, so crop destruction must be documented.

Notable Items

Form-Specific Instructions

- 6: There are different forms available on the IR-4 website for airblast and greenhouse trials. **Forms for seed treatment trial are currently being developed.**
- 6A, 6B, 6E and 6F may not need to be provided for each application if there are no changes from the originals, but 6C, 6D, and 6G – 6K must be provided for each application. 6G – 6K must be original raw data; no copies.
- 6C2: An alternate 6C2 has been developed for application devices with six or fewer nozzles/hoppers.
- 6L1 & 6L2: If a researcher has multiple trials assigned from the same protocol, each trial must be differentiated from the other(s) by filling out prompts on these two forms. Researchers should [refer to protocol section 11.4 for approved methods for trial differentiation in a particular protocol.](#)
- 6L and 6M do not need to be provided for each application.

Notable Items

Form-Specific Instructions

- 7: 'Harvest' is defined as the day the plant is cut, dug, or picked. Preharvest intervals (PHI) listed in the protocol refer to this event. 'Sampling' is defined as the collection and storage of the crop fraction(s) defined in the protocol.
- 7: Harvest and sampling events need to be thoroughly explained so subsequent reviewers understand the sequence of activities.
- 7A1, 7A2 and 7B: Each of these forms will be completed for each sampling event.
- 10: Pages in this section do not have to be paginated, but they do need to be identified with the trial number.
- Deviation form: The original of a deviation should be sent to the SD, even though the notification was made by phone, e-mail or FAX. A true copy is to be retained in Part 10 of the FDB.

Thank You.

Are there any questions for Ken?