Global Minor Use Summit: GLP Field Trials and Field Data Books

Dr. Robin Bellinder
Cornell University
Department of Horticulture
Field Research Director
USA
Outline

• Chain of Events
• Field Research Director
• The Basic’s
  – The Protocol
  – Standard Operating Procedures
  – Field Data Book
• Residue Trial Walk Through
Field Research Director (FRD)

Role

1. Conduct GLP field residue trials
2. IR-4 Partner – outreach to local growers
3. Budget and funding of IR-4 Field Research Center
Field Research Director (FRD)

Responsibilities
1. Conduct/oversee field trials according to the protocol and GLP standards.
2. Act as work partner in GLP compliance (understand & implement)
3. Collect and submit data in a timely manner
4. Develop, update and implement SOPs
5. Provide oversight of science/agronomics of field research
6. Communicate and provide feedback to SD, QA, and Staff
7. Respond promptly to QA questions
8. Provide leadership and training to personnel
9. Maintain Research Facility
10. Working partnership within IR-4 (RFC, SD, QA, etc.)
11. Review protocols and provide comments to the SD
12. Serve as knowledgeable resource on crop production in region
13. Provide solutions to trial problems in conjunction with SD on day-to-day problems
14. Educate public and administration on role of IR-4. Communicate IR-4 mission to growers and other stakeholders
15. Develop budget for the IR-4 Field Research Center. Provide funds and “physical” resources
16. Find additional sources of funding for equipment/employees
The Basic’s

- Good Laboratory Practices (GLP’s)
- The Protocol
- Standard Operating Procedures (SOP’s)
- Field Data Books (FDB)
Good Laboratory Practices (GLP)

Definition: Are a set of principles that provides a framework within which laboratory/field studies are planned, performed, monitored, recorded, reported and archived.

- They consist of a system of management controls to ensure the consistency and reliability of results
- Assure the regulatory agency (EPA) that data submitted are a true reflection of the results obtained during the study

“(GLP’s) compliance monitoring program ensures the quality and integrity of test data submitted to the Agency in support of a pesticide product registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)…” EPA
The Basic's

The Protocol

• Definition: Contains both the field and laboratory phases of the study and detail the proposed sites for the research.
• Every IR-4 study has one protocol
• Approved by the SD with a signature and date
• FRD and the LRD receive entire protocol to provide information on rates of test substance application, crop sampling, and lab analysis info.
• No trial should be initiated until the FRD has a signed protocol in their possession.
The Basic’s
Standard Operating Procedures (SOP’s)

**Definition:** To provide guidance when conducting field research studies under GLP’s

- Required for all trials that are conducted in the support of the registration of pesticides.
- Part of *all* phases of research (Headquarters, Field and Laboratory)

**Consists of:**
- SOP # AND Revision #
- Who submitted and When
- Title
- Purpose
- Scope
The Basic’s SOP’s

- Specifically outline the procedures involved in all activities required to perform a residue trial
- Also outline research facility and equipment
- Are revised as-needed, but at least every five years
- Are signed by the FRD and Regional Field Coordinator prior to the beginning of each season
- IR-4 HQ archives
The Basic's

SOP's

STANDARD OPERATING PROCEDURES

TABLE OF CONTENTS

GENERAL
SOP #: 1.1.7 General requirements......................................................1
SOP #: 1.2.8 Numbering system..........................................................3
SOP #: 1.3.9 Format..............................................................................4
SOP #: 1.4.10 Designation of Field Research Director...............................5
SOP #: 1.5.11 SOP's for sponsored research..........................................6

PERSONNEL
SOP #: 2.1.12 Personnel.................................................................7

FACILITIES
SOP #: 3.1.13 Site selection for field studies.........................................8
SOP #: 3.2.14 Field season data storage............................................10
SOP #: 3.3.15 Chemical storage facility............................................11

EQUIPMENT/CALIBRATION
SOP #: 4.1.16 Calibration and use of a laboratory balance..................12
SOP #: 4.2.17 Measuring a liquid formulation.....................................13
SOP #: 4.3.18 Calibration/maintenance of CO2 backpack sprayer...........14
SOP #: 4.4.19 Calibration of CO2 "G" sprayer....................................16
SOP #: 4.5.20 Calibration of sprayer for directed applications................18
SOP #: 4.6.21 Calibration of sprayer for banded applications...............20
SOP #: 4.7.22 Calibration of instruments and gauges..........................23
SOP #: 4.8.23 Maintenance of freezers............................................24
SOP #: 4.9.24 Remedial action for equipment malfunction....................25
SOP #: 4.10.25 Calibration/maintenance of mist blower.......................26

AGRONOMIC PRACTICES
SOP #: 5.1.16 Field preparation for seeding or transplanting..............27
SOP #: 5.2.17 Method for seeding and transplanting..........................29
SOP #: 5.3.18 Commodity maintenance............................................30

PESTICIDE APPLICATION
SOP #: 6.1.19 General procedures in the application of pesticides.........31
SOP #: 6.2.20 Procedures for application of study pesticide(s).............32
SOP #: 6.3.21 Cleanup of application equipment................................34

DATA HANDLING
SOP #: 7.1.22 Recording of raw data...............................................35
SOP #: 7.2.23 Completion of data and sample collection forms..............36
SOP #: 7.3.24 Collection and recording of data from monitoring devices...38
SOP #: 7.5.25 Data storage during the active life from monitoring.........40

RESIDUE SAMPLE HANDLING
SOP #: 8.1.26 When to obtain residue samples................................42
SOP #: 8.2.27 Method of sample collection.......................................43
SOP #: 8.3.28 Sample identification and records...............................44
SOP #: 8.4.29 Packing and storage procedures.................................45
SOP #: 8.5.29 Sample shipping procedures......................................47

REPORTING
SOP #: 9.3.30 Disposition of forms and reports...............................49

DATA RETENTION
SOP #: 10.1.31 General procedures regarding data retention.............50
SOP #: 10.2.32 Retention times for documents...............................51
SOP #: 10.3.33 Information to be retained.....................................52

EPA AUDIT PROCEDURES
SOP #: 11.2.34 Procedures to follow prior to an EPA inspection.........53
SOP #: 12.2.35 Procedures to follow during to an EPA inspection.......56
SOP #: 12.3.36 Procedures to follow after an EPA inspection............56

APPENDIX
Summary of SOP revisions, including dates of inactivated SOP's...........57
The Basic’s Field Data Book (FDB)

- Contains all information for a particular trial
- Is *the* legal document
- Where everything is documented:
  - PART 1. Good Laboratory Practice Compliance Information
  - PART 2. Personnel Log
  - PART 3. Notes & Communication Log
  - PART 4. Test Substance Records
  - PART 5. Trial Site Information
  - PART 6. Application Records
  - PART 6a. Application Records-Airblast Sprayer
  - PART 7. Sample Collection and Storage
  - PART 8. Residue Sample Shipping
  - PART 9. Meteorological and Irrigation Records
- Also Contains Protocol Changes
The Basic's Field Data Book (FDB)

FIELD ID NO: __________

CHAIN OF CUSTODY FOR IR-4 FIELD DATA BOOK

FIELD RESEARCH DIRECTOR

Upon receipt of this IR-4 Field Data Book, the Field Research Director shall sign the chain of custody by completing the first part. Once the data entry has begun in the Field Data Book, the data book is to be in the custody of the Field Research Director or personnel under the Field Research Director’s supervision. When the Field Data Book is transferred to another individual, e.g., sending completed Field Data Book to IR-4 Regional Field Coordinator, the sender must note whom and when the data book is sent. The recipient must sign the next block and date the form upon receipt.

Signature of Field Research Director: __________________________ Date: __________

Printed name: __________________________ Initials: __________

Field Data Book is given to: __________________________ Date: __________

Signature of recipient: __________________________ Date Received: __________

Printed name of recipient: __________________________ Initials: __________

Field Data Book is given to: __________________________ Date: __________

Signature of recipient: __________________________ Date Received: __________

Printed name of recipient: __________________________ Initials: __________

Field Data Book is given to: __________________________ Date: __________

Signature of recipient: __________________________ Date Received: __________

Printed name of recipient: __________________________ Initials: __________

PART 6: APPLICATION RECORDS

IR-4 FIELD DATA BOOK

A. EQUIPMENT

INSTRUCTIONS: Complete a separate form for each piece of test equipment application equipment used in the trial.

EQUIPMENT USED FOR APPLICATION NUMBER____________

EQUIPMENT IDENTIFIER:

Each piece of equipment used for the application must have a unique identifying number or code.

APPLICATION EQUIPMENT TYPE (check one):

TRACTOR ______ RANCH RIDE ______ OR GRANULAR ______

OTHER ______ (Describe)

PROPELLANT (check one):

CO________ COMpressed AIR______ PUMP______

OTHER ______ (Describe)

NUMBER OF NOZZLES OR NOZZLE OUTLETS USED:

SPACING BETWEEN NOZZLE OR NOZZLE OUTLETS:

MEAS SIZE USED IN THE STRAINER:

NOZZLE BRAND/DY SIZE: 3/8" or 5/8", even shorter

TYPE OF APPLICATION (Check all that apply):

1) FOLLAR TO THE GROUND

2) BROADCAST

3) BANDED

4) DIRECTED

5) INFURRO

6) OTHER ______ (Describe)

TREATED AREA:

Calculate width of spray exchange pattern (CP/EP) at proper boom height. Length of plot sprayed or treated. For broadcast application, CP/EP = 6 ft of nozzle(s) x nozzle spacing. For a broad application, CP/EP = r ft of nozzle(s) x nozzle spacing. Total application rate sprayed was 2.0 gallons of water. All applications were performed on rows with 30" 0ff-set. Length of plot sprayed or treated, measured runs with 0ff-set, from actual row height when the actual row height is greater than local row height. In this circumstance, the application rate should be calculated using the maximum crop height, and an explanation should be included on this page. Contact the Study Director for assistance when necessary.

DOES TREATED AREA = PLOT AREA (From Form 1G and 1F)? YES ______ NO ______

IF NOT, PLEASE EXPLAIN: __________

__________________________ Date: __________

Page 1 of 2

Trial Year 2007
Process Involved in Residue Trial (Field Residue)

- Receipt of Test Substance
- Sprayer Calibration
  - Weigh out T.S. Balance calibration (Dry)
- Sample Collection
- Sample Freezing
- Application
- Sample Shipping to Laboratory
- Freezer Temperature Log
- Field Data Book Submission
- Protocol Received
- Sprayer Cleaning
  - Initial Sprayer Calibration
Field Season Data Storage

- All data books in locked cabinets
- Cabinet in building with fire protection devices
- Limited access
Test Substance Receiving and Storage

- Beginning point of record keeping
- T.S. is evaluated for proper container information
- Each T.S. container is given a unique ID
- S.D. contacted with any irregularities
- T.S. storage temperature is monitored and logged weekly
- T.S. under lock and key
- Chemical log is initiated
Weighing a Dry Substance & Balance Calibration

- Serviced/Calibrated Annually
- Re-calibrated immediately prior to weighing using standardized weights
  - 1 weight above and 1 weight below T.S.
- Calibration records
- All excess product returned to container
- Documentation of amount removed
Measuring a Liquid Formulation

- Accuracy +/- 1% Vol.
- Pipettes or syringes
- Funnel/Glass Container
- Directly into spray tank/trt. bottles
- Record volume removed
Sprayer Cleaning & Calibration

- Initial pre-season cleaning/calibration
  1. Nozzles & Screens cleaned with 50% solution acetone
  2. Triple rinse
  3. Boom flushed 50% acetone or ammonia solution
  4. Triple rinse
- Record maintenance

Calibration*:
  1. Timed discharge/nozzle
  2. Capture discharge
  3. Record volume collected
  4. < 5% variation allowed
  5. Repeat 3X = Ave. total boom output

*Performed prior to each appl.
Speed Calibration

- Assures accurate application
- Especially useful with tractor appl.
- Repeat 3X
- Assists with variable field conditions
Application Equipment

CO₂ Delivery System
Application Equipment

- Broadcast Boom
- Adjustable Directed Boom
- Adjustable Boom
- Unique Boom ID
Application Equipment

Offset-Mounted Spray Boom

Mist-Blower Backpack
Application

- All personnel involved will be trained
- Lower rates applied first
- Field/Envir. conditions recorded
- Mixing/Appl. time recorded
- Appl. pass time
- Back calculation-determine how much was actually applied
  - % deviation
- Post-Appl. conditions (rain or irrigation)
### Application Cont’

#### For dry formulations:

\[
\text{Actual Rate} = \text{Boom Discharge \ X \ Pass Time \ X \ 43560 \ ft}^2/\text{A} \ \text{X} \ \text{Product (g) \ \div \ 453.59 \ g/lb \ \times \ No. \ lb \ ai} \\
(\text{lb ai/A}) \ \text{Rate (ml/sec)} \ \text{(sec)} \ \text{Treated area (ft}^2) \ \text{Volume mix (ml)} \ \text{100 lb product}
\]

#### For liquid formulations:

\[
\text{Actual Rate} = \text{Boom Discharge \ X \ Pass Time \ X \ 43560 \ ft}^2/\text{A} \ \text{X} \ \text{Product (ml) \ \div \ 3785 \ ml/gal \ \times \ No. \ lb \ ai} \\
(\text{lb ai/A}) \ \text{Rate (ml/sec)} \ \text{(sec)} \ \text{Treated area (ft}^2) \ \text{Volume mix (ml)} \ \text{gal product}
\]

7. Calculate the percent deviation from the desired (protocol) rate, using the following formula:

\[
\text{Actual Rate} – \text{Desired Rate} \ \times \ 100 = \% \text{ deviation from protocol} \\
\text{Desired Rate}
\]
FIELD ID NO: __________

IR-4 FIELD DATA BOOK

PART 5. APPLICATION RECORDS

A. EQUIPMENT

INSTRUCTIONS: Complete a separate form for each piece of equipment used in the trial.

EQUIPMENT IDENTIFIER: Each piece of equipment must have a unique identifying name or code.

APPLICATION EQUIPMENT TYPE (check one) [ ] TRACTOR [ ] BACKPACK [ ] GRANULAR

OTHER [ ] (Describe)

PROPELLANT (check one) [ ] CO2 [ ] COMPRESSED AIR [ ] PUMP

OTHER [ ] (Describe)

NUMBER OF NOZZLES OR HOPPER OUTLETS USED

SPACING BETWEEN NOZZLES OR HOPPER OUTLETs

NOZZLE BRAND/TYPE/SIZE (e.g., T-JET 999, 16 in.

TREATMENT # (check all that apply): 1) POLAR TO THE GROUND 2) BROADCAST 3) RANDED 4) DIRECTED 5) IN-FURROW

TREATMENT # (Describe)

TREATED AREA

_Calculated width of nozzles discharge pattern (CNWDP) at proper boom height. X length of plot sprayed or treated.

For a broadcast application, CNWDP = # of nozzles X X nozzle spacing. For a banded application, CNWDP = # of nozzles X X nozzle spacing. If application is directed, enter treated row width X # of rows X X length of plot sprayed or treated. Treated row width may differ from actual row width when the actual row width is wider than local commercial practices. In this circumstance, the application row should be calculated using the maximum commercial row width, and an explanation should be included on this page. Contact the Study Director if guidance is needed.

DOES TREATED AREA = PLOT AREA (from Part 1C and 5P)? [ ] YES [ ] NO

IF NOT, PLEASE EXPLAIN:

ABOVE DATA ENTERED BY: __________________________ DATE: __________

PART 4 PAGE __ Trial Year 2007

WAS APPLICATION RATE WITHIN 5% TO 10% OF PROTOCOL RATE? [ ] YES [ ] NO

IF NO, CONTACT THE STUDY DIRECTOR IMMEDIATELY.

ABOVE DATA ENTERED BY: __________________________ DATE: __________

PART 6 PAGE __ Trial Year 2007
Sample Collection

- Sample methodology/size determined by protocol/crop
- Untreated -> lower rates -> higher rates
- Representative sample from each plot
- Avoid plot edges
- Duplicate samples harvested individually
- Samples weighed, bagged, labeled, and placed into a freezer
- Treated and untreated in separate coolers
Sample Collection cont’

- Avoid diseased or under/oversized crop parts
- Do not remove surface residue during handling
- Clean harvest tools
- Do not remove plant parts or trim crop unless outlined in protocol
- Additional ID Card sample with:
  - FRD
  - Project #
  - T.S./Crop
  - Dates of TRT
  - Dosage Rate
  - Plant parts collected
  - Sample date

-> Place ID card in moisture proof bag

- Samples should be placed in freezer immediately
Storage of Samples

- Time from harvest to freezer must be recorded.
- All samples will be frozen (-12.2 C) until they reach the lab.
  - *Delay in return to -12.2 C for more than 24h will be a deviation.*
- Samples must be physically separated in freezer.
- Freezer temperature is logged.
- If sample thawing occurs, notify SD and lab to see if samples are salvageable.
- Log of items in freezer, their study affiliation, and number of sample bags to be kept.
Sample Shipping

- Goal is to maintain sample frozen until they reach the laboratory
- IR-4 utilizes a freezer truck service or in some cases coolers with dry ice via shipping service
- Laboratory is notified of shipping dates
- All shipping documentation is placed in FDB
- All shipping carton containers should have name of sender and laboratory personnel and phone numbers
Conclusions

- SOP’s are the backbone to residue trials
- Documentation is critical
- Good planning to avoid overlap is essential