Bayer CropScience

2009 BCS Field Residue Program Information Session

Agenda

- Introductions/Organization/Responsibilities
- Administrative Items (Bidding, Contracts, PO's, Invoices)
- Data Handling (electronic/hard copy)
- Study Logistics/Conduct (test substance, sampling, notifications/deviations, etc…)
- FieldNotes® and FARM
- Data Summary Reports
- Contractor Feedback/Evaluation
- QAU Items
- General Q&A

Roles/Responsibilities/Contact Info - 2009

Lab/Trial Support (Program Coordination, Support, etc.) – Ross DeHaan

Pat Freeseman (pat.freeseman@bayercropscience.com) – responsible for bidding/contract administration and coordination for trials performed in USA. Responsible for test substance (formulation) ordering. Coordination of FN e-notebook preparation and sending (e-mailing).

Robert Hoag (robert.hoag@bayercropscience.com) – responsible for bidding/contract administration and coordination for trials performed in LatAm.

Valerie Lemke (valerie.lemke@bayercropscience.com) – responsible for preparing purchase orders (PO's) and for invoice approval (once logged into system via Pittsburgh, etc.).; prepared 2008 data summary templates (FDSR).

Tim Grace (tim.grace@bayercropscience.com) - responsible for 1st-level FieldNotes support; subcontract with Crest Ag (Erik Kundrats).

Carol Keffer (temporary, part time) – currently assisting with data review & compilation

Cheryl Lenz (cheryl.lenz@bayercropscience.com) - responsible for commercial processing contracts/communications. Assists with test substance (formulation) ordering.

Debra Payne (debra_m.payne@bayercropscience.com) – responsible for sample receipt and homogenization.

Residue/Env. Chemistry (Study Directors, Analytical) – Martin Cole

"Study Directors" – see protocol for contact information; Study Directors responsible (first contact) for any study-related questions (e.g. application rate/timing, sampling, interpretation of protocol, clarifications, questions on raw data, etc.)

Bidding

- No change from 2008; continuing a streamlined competitive bid process (fewer rounds of bidding than pre-2008)
- Process will normally be communicated via e-mail of protocol worksheet (spreadsheet) containing critical study information. Read the e-mail and worksheet carefully so that all aspects of study costs/performance are considered. EXAMPLES to note:
  - Purchase of supplies, including shipping boxes, adjuvant(s), etc.
  - Special timing; special sampling (residue reduction/FQPA samples);
  - Completion of FN notebook, and data summary spreadsheet (or other forms)
  - Intended 60 day turn-around of data – i.e. finalized, QA'd and sent to Bayer
  - Other items from today's presentation
- Provide the best price that enables you to deliver a timely and quality data package (all inclusive).
- Monitor your own "capacity" – don't bid on/accept more trials than can be performed to the standards described/expected by Bayer.

How We (Env. Research) Choose Contractors – 2008/2009

1. Per regional requirements of a study, identify contractors which have capabilities.
2. Obtain bids/cost estimates from contractors.
3. Trial coordinator (P. Freeseman – USA; R. Hoag - LatAm) works directly with Study Directors to choose which cooperators to work with based first on historical quality of work and personal experience, and then also price.

Single most important criteria in choosing contractors year to year is:

Quality of work/performance (as defined by a number of criteria); consistency of quality (”track record”) over time.

Once per year (Jan) all Study Directors meet as a team to discuss contractor performance……(more on that later….)

Contract Logistics (2009) – Letter of Agreements (LOAs)

- Contract language for 2009 largely unchanged; however, sections will be consolidated/reorganized to allow easier review – so LOA will look different. Bayer (R. DeHaan) will be signing all contracts (LOA's) following signature of contactor.
- Important information requested from contractor (last page of 2009 LOA):
  - Date of first application (or planting): this date is logged internally and used as the single guide for test substance shipment (we will ship a minimum of 30 days before this date; likely earlier in 2009). Discuss with the PFI…..; provide an actual month/day (e.g. not Q2). Date is also useful for Study Directors for planning.
  - Date of last harvest: this date is logged internally and used as guide for expected date for data receipt, and for receipt of special samples (residue reduction, FedEx, etc.); also for notifying commercial processors. Provide an actual month/day (e.g. not Q2, Q3, or June, etc.)
  - Calculation of test substance (formulation) needs: This is an important calculation; determines amount of TS that will be sent. Do not guess! Ask the PFI to confirm estimate, based on actual equipment being used, plot sizes, etc. Asking for too much is better than not enough!

  ** If any dates/TS amounts change post-signing of LOA, please notify P. Freeseman and the Study Director ASAP.
- Other important items from the LOA:
  - Committing to intent of delivering a complete, QA'd data package (including FN notebook, field data summary, etc.), to Bayer within 60 days of last sampling. Please communicate with your QA regarding this timeline. If this is an anticipated challenge, please communicate before signing.
  - Committing to using Bayer QA audit review checklist on final FieldNotes e-notebook. Make sure your QA knows this.
- Payment Terms: same as 2008 – paying 100% upon study start (as soon as LOA is signed by contractor, and PO number for the year received).

PO's and Invoicing – 2009

- As for 2008, you will receive one "blanket" PO number for 2009 to be used for invoicing of all 2009 work. You should get your new 2009 PO number in approx. 2 weeks following Bayer's receipt of the 1st LOA for 2009.
- Don't reference the 2008 PO number on any 2009 invoices! (closed, no funds/$$). For any work contracted late 2008 (transition), be careful which PO number is used (2008 vs. 2009).
- Invoice total (100% of study cost) upon signing your LOA and upon receiving the PO number for 2009.
- We recommend one invoice per study (SAP order number). If you do enter multiple studies on a single invoice, it is critical that the total $$ for each study (SAP order number) is clearly indicated. Keep invoice to one page.
- Invoice must contain, at a minimum, the following (clearly indicated):
  - A unique invoice number and invoice date.
  - Correct 2009 PO number. Note: if you do work for other divisions (e.g. BCS BioScience, or BCS Env. Science, BCS Canada) take special care that you reference the BCS CropScience PO number ("they all look the same"…)
  - SAP order number (e.g. J1CQstudynumber or E2CQstudynumber - located on front page of protocol; if not sure - call V. Lemke).
  - A brief description of the work/study being invoiced (e.g. study title, or similar)
  - The Total Amount prominently displayed for each study (SAP order number) listed.
- This is important because…highly automated and computerized processing of invoices + manual data entry (contracted, Spain)…; it needs to be "close to perfect"!

PO's and Invoicing – 2009 (cont'd)

- As stated on the PO; send all invoices to Bayer CropScience, P.O. Box 98, Pittsburgh, PA 15230-0098
- If interested in electronic invoicing (submitting as e-mail attachment in *.pdf format), please call **Lisa Retz at 919-549-2095**. She will assist with set up, etc.
- If you have a question regarding a submitted invoice (status of invoice, questions regarding payment, etc.), then first call the **Bayer Partner Service Team @ 1-866-283-6752 (or e-mail at vendors.bcs.usa@bayer.es).**
- DO NOT re-submit an invoice without first contacting the Partner Service Team!
- If resolution for payment still not obtained via the Partner Service Team, then contact Valerie Lemke for assistance (special cases only).

Sending of Data (Electronic and Paper)

Send electronic raw data to **bcs_residues@bayercropscience.com**

Send paper raw data to **Field Program Administration**, Bayer Research Park – Bldg2, 17745 S. Metcalf, Stilwell, KS 66085. DO NOT SEND to Study Director.

Electronic Raw Data:

- Continue to e-mail FN transfers/updates (*.zip files) to the bcs_residues mailbox with copy to the Study Director. Same is true for the electronic copy of the Field Data Summary Report (FDSR).
- New for 2009: the bcs_residues e-mail mailbox is monitored only by an automated e-mail "agent" that moves and files all attachments automatically for database upload, etc. The mailbox is not routinely monitored by a person (so questions, etc. embedded in e-mail will not normally be answered by bcs_residues). Study related questions, comments are best e-mailed directly to Study Director.
- DO NOT manually re-name the FN export (transfer-out) file (example: adding an "a" or to file name). If re-named, the file will not correctly upload into the database! Can be a big problem.
  - Example: AM0148001**a**.ZIP

It is important that the last/final FN update is marked in FN as **"FINAL"** (after QA audit using the Bayer check-list). Please do this! (we run database queries based on this entry alone).

Sending of Data (Electronic and Paper)

Paper Raw Data: what to include….

- Test Substance Chain of Custody and Cert. of Analysis
- Field Data Summary Report, with all requested signatures (after QA review, etc.)
- Correspondence (study related)
- Any trial-specific raw data collected on paper
- Any other "forms" provided by Bayer

- Quality assurance summary statement – PFI is responsible for ensuring/checking that a QA statement has been prepared and sent. It is recommended that this is sent under separate cover (not bundled with the other "raw data"). Be sure to send to the correct address (Field Program Administration) – DO NOT send to Study Director.

- If the QA statement is bundled with the paper raw data package - please mark clearly!!

- NOTE: Do NOT send multiple "updates" of QA summaries; send one FINAL summary only.

Sending of Data (Electronic and Paper)

Paper Raw Data: what NOT to include….

DO NOT include copies of site logs:

e.g. Chemical storage temperature logs, Sample storage temperature logs, Weather data.

DO NOT include copies of CV's

DO NOT include a complete printout of FieldNotes.

DO NOT include a copy of protocol or amendments (we already have these).

DO NOT include QA AUDITS, Bayer FN Audit Checklist, copies thereof - they are not raw data.

Would a Table of Contents Form from BAYER, indicating via "check box" what is (and by reference what isn't) to be included in the Paper Raw Data be useful??

OTHER:

DO NOT send a Chain of Custody form with the Raw Data – these will not be filled out or returned. If verification is desired, use tracking options available with FedEx, UPS, USPS, etc.

DO always keep a copy of all raw data sent.

FieldNotes 4.1 – 2009

- Support will be through BCS Stilwell (Tim Grace) and also through Crest Ag (Erik Kundrats).
- BCS will not provide support for running FN 4.1 on VISTA; will only support Windows XP. Other solution available if you must (or wish) to run VISTA. New XP machines can still be purchased *(on-line, etc.).
- FN replacement (FARM) is still planned for the 2010 season.
- Most common problem (30%+ of calls): Incompatibility with other programs - examples: Windows Office 2003 for XP (and versions above 2003), Apple Quicktime, Adobe Photoshop, etc..
- These generally interfere with FN ability (via MS Access) to save (import) plot diagrams, other images (e.g. airblast configuration).
- **New 2009:** To address these "incompatibility" problems, BAYER is in final stages of evaluating and alternate installation of FN (using VMWare) that will shield FN from all other software/OS on your computer.

  Intend to roll out one at a time – beginning March/April (hopefully before most trials start)

  Same technology will be used for FARM (get some preliminary experience in 2009)

  Will allow handling of plot diagrams, images, etc. (better for SD, and QA); will eliminate verification requirement upon re-install, new install.

  Some "minor" differences (extra step for transfer-out and e-mail, set up a new file structure, additional printer configuration)

  If you want to be one of the first - please contact Tim Grace.

FARM – FieldNotes® Replacement in 2010

FARM ("Field Application Residue Module")

A new field data collection tool is under development by Bayer CropScience for worldwide replacement of FieldNotes® in 2010.

The FARM software is Microsoft Windows based, to run on a PC with a "live" connection to a central server/database.

FARM will operate either off-line (e.g., during data entry in the field) or on-line (e.g., for upload and download of data in the office via internet connection).

- No more e-mail updates!

FARM will run on a virtual machine (VMware) to keep the application independent of the operating system and programs running on the user's PC

- Insures that the application will run within a uniform and controlled environment (for stability and GLP compliance)

Although attempt has been made to maintain a similar organization of modules and work-flow to that of FieldNotes®, the "look" of FARM will be different from FieldNotes®

FARM – FieldNotes® Replacement in 2010

FARM timeline:

Initiation of the FARM Project – 2006

Start of software development (3rd party software developer) – November, 2008

Testing and GLP Validation – November, 2008 to October, 2009. We are looking for cooperators who would have interest in evaluating and testing early releases (beta versions) of the FARM software. Please contact (e-mail) Dave Fischer (david_r fishcer@bayercropscience.com) or Ross DeHaan (ross.dehaan@bayercropscience) if interested.

Training (internal and external) – November 2009 to February 2010

* A number of training options being considered (2010 NAICC meeting, DVD/online media, regional "hands-on" training, etc.)

* Please provide thoughts/suggestions as to what you would find most effective.

Implementation – 2010 field residue program (a challenge!)

Study Logistics / Conduct – List of Items to Review

- Test Substance – Shipment, Receipt, Storage, Disposal
- Samples: Bagging, Boxing, Labeling, and Shipping
- Notification of Study Start / Reporting of Updates, etc.
- Calibration (Re-verification) and Plot History
- Reporting of Weather and Sample Storage Data
- Field Data Summary Report
- Frequency of Data Updates
- Deviations

Test Substance – Shipment, Receipt, Storage, Disposal

- For 2009, the intent is to ship a majority of all Test Substance by May/June – i.e. ship all at once and then be done. Therefore you may(?) have to store Test Substance longer than in previous years.
- Upon receipt, it is recommended to always check the Test Substance label and expiration date – is this the substance referenced in the protocol? And will it be GLP compliant (i.e. not expired) based on planned date of use? Please check!
- NEW for 2009: To maintain GLP compliance and further harmonization with global facilities, the default storage temperature for all test substance will be 2˚C to 30˚C (36˚F to 86˚F). Depending on facility setup/design, may(?) need to store in refrigerator. Protocol may outline cases which allow broader temperature range (e.g. available MSDS, etc.).
- Reminder: When multiple containers of test substance (for use in more than 1 trial/study) are received in a single shipment,……
  - 1) place the original test substance COC and COA in the study file of the first trial listed on the COC.
  - 2) Then place a verified exact copy of the test substance COC and COA in the study file for each of the other trials.

Test Substance – Shipment, Receipt, Storage, Disposal

- As started in 2008, Bayer will no longer be administrating/handling Test Substance returns – i.e. don't ship containers/contents back to Bayer.
- After the last application, contents may be disposed of according to local regulations and TS containers triple rinsed and stored.
- Alternatively, you can store the container and contents as is.
- Container (and contents) do not need to be environmentally controlled.
- NEW beginning 2009:
  - Test Substance containers must be stored/kept at your facility for 3 years following last application.
  - After 3 years (from last use/application), the Test Substance (container and contents) can be disposed – unless otherwise specifically stated in the protocol.
  - Default protocol language will state 3 years - >95% of studies are completed in that time frame (exception may be 12 month plant-back rot crop, as example).
- It is important to document disposal of Test Substance containers (contents) on your facility records (QA, GLP).

Samples: Bagging, Boxing, Labeling, and Shipping

- As initiated in 2008, please purchase your own bags/boxes from Trammel Farms, Inc. (ACDS). If alternative source is identified (same size boxes, etc.) please contact Debra Payne for approval.
- Required sizes remain the same: Only 14” x 14” x 24” boxes (Bayer freezer storage, etc. depends on this uniform size).

REMINDER on SAMPLE LABELLING PROCEDURES:

- The required bags all contain a paper tag sewn onto sample bag
- Put FieldNotes-generated bar code label on this tag.
- Wrap clear plastic tape around label and tag.
- Write the Study Number, Trial Number, and Sample Number on the outside of the bag with a permanent marker.
- Place a second set of labels (white, one for each bag in the box) on the outside of the box for easy scanning upon receipt at Bayer.
- If “control” sample is shipped in same box as “treated” sample, put control sample inside and additional plastic bag.
- Put all necessary Chain of Custody documents inside the box. REMINDER: Bayer will not return signed copies of sample COC’s.

Samples: Bagging, Boxing, Labeling, and Shipping

- Bayer will pay ACDS shipping as in past; and will also provide Bayer FedEx account number upon request (call Debra Payne).
- Accurate completion of the Bayer-specific ACDS weigh bill (invoice) is important. Identity of correct SAP order number/code is needed (J1CQ+study number or E2CQ+study number – see page 1 of protocol).
- For "special samples" (FQPA/ residue reduction) that are shipped via FedEX, non-frozen, etc, **please call Deb Payne <u>prior</u> to sending** – per protocol.
  - WHY? These require immediate handling upon receipt (planning needed), including special forms, QA audit, etc. <u>Surprises are not appreciated</u>!

Notification of Study Start / Reporting Frequency

STUDY START NOTIFICATION

- The first FN “update” is our notification that your trial has started; this notification was formerly accomplished (pre 2008) with Form F-00066.
- This notification is an important in order for Study Directors to demonstrate “study control” per GLP.
- Therefore, PROMPTLY (within 1 week of first application) send us a FieldNotes update so SD’s are able to monitor actual study start (defined by GLP as 1st application of test substance).

REPORTING FREQUENCY / UPDATES/ FINAL NOTEBOOKS, etc.

- Reporting frequency timelines/intervals are no longer specifically stated in the protocol (deviation trap).
- However, Bayer expects that updates are sent promptly (within 1 week) following every critical event (application, sampling, sample shipping).
- Bayer also expects the FINAL FieldNotes update (after QA audit) to be sent within 60 days of last sampling (as also noted on the contract/LOA).

Study Conduct - Calibration

- As noted in Protocol, if you calibrate the day before . . .
  - Don't forget to re-verify prior to application (see conditions in Protocol)
  - Re-verification includes running one additional calibration catch from your applicator equipment and verifying that the nozzle outputs have not significantly changed
  - Document the re-verification in an additional note in FieldNotes and include the catch volumes used.

Study Conduct – Plot History

- Bayer accepts a 1 year pesticide history for a RAC or processing study (unless otherwise noted in the protocol)
- Bayer still requires a 3 year pesticide history for a rotational study.
  - Reminder: know before you bid if you can obtain that field history

Study Conduct – Deviations

- Deviation procedure is not being consistently followed. Study Directors are having to write deviations on deviations.
  - Document deviation in FieldNotes. DO NOT enter “Effect on the Study”.
  - Fax, express mail, or e-mail (*.pdf) copy of deviation to your study director.
  - SD enters “Effect on the Study” onto the deviation copy.

  - NEW for 2009:

    Depending on criticality of the deviation, SD will not always return the completed deviation to the contractor.

    Contractor will no longer be responsible for transcribing the “Effect on the Study” into FieldNotes. (Language will be removed from protocol.)

    Post-presentation follow-up: To provide confirmation to the PFI that the e-mailed deviation has been received (acknowledged), Bayer SD’s will send a brief “reply” e-mail acknowledging receipt.

Field Data Summary Reports

Reports for 2007:

Unexpected large number of transcription errors (even after field QA), and several formatting variations.

Therefore, for 2008:

Revised template with more "locked" formatting and entry, including color-coding of cells (yellow, blue, red) to indicate direct entry, calculated entry, etc.

Prepared a comprehensive instruction document, to used by both PFI and QA, detailing step-by-step how to fill out the template and where to specifically find the information in FieldNotes. Useful??

Just beginning review of 2008 reports……; anticipate much better data quality than in 2007.

For 2009:

Will use template similar to 2008 version. We would like feedback on the 2008 template (pro's/cons), instruction document, etc.

Intend to add a "reviewed by QA" signature line in addition to PFI signature. Please sign.

Plans for 2010: All reporting should be handled directly using the FARM application.

Field Data Summary Reports

Weather & Meteorlogical Data – Calculation of AVERAGE Min/Max temperatures: See detailed example in the instruction document…….

Instructions and Examples: Weather/Meteorological Data – Average Minimum and Maximum Temperatures.

Enter month (with year) for every month in which the study is performed (from first application to last harvest. **Example**: If the study began on June 18 (first application) and ended on Sept 5 (last sample harvested); entries would be made for the months of June, July, August, and September.

Enter the actual AVERAGE minimum temperature for each month listed. **Example:** see below data for a theoretical month of June, 2008. From this example the AVERAGE Minimum temperature for June 2008 entered into the FDSR would be 57 °F (rounded to nearest whole number); the AVERAGE Maximum temperature for June 2008 entered into the FDSR would be 71 °F (rounded to nearest whole number). Historical averages would also be entered as whole numbers.

Dates – June 2008	Daily Low Temp (Minimum)	Daily High Temp (Maximum)
1	42	58
2	45	55
3	52	57
4	51	65
5	46	63

Items Considered - Cooperator Performance

"Quality" – *examples of what we mean*

Timeliness of data – *timeliness of updates, timeliness of final data package, including QA, etc..; response to "urgent" requests*

Completeness of data package - *loss of time/efficiency if we need to follow up with you for late date, incomplete data, etc.*

Study performance – *correct implementation of protocol (application rate/intervals, sampling intervals, etc.); critical phase audits,*

Observations from Site Audits/SD visits – *general organization, neatness, records, plot "quality", etc.*

Quality of QA – *thoroughness (do they catch what they are supposed to), timeliness of audit reports to Bayer, etc.*

Communication – *appropriate, timely, e.g notification of study start, sample shipment, notification of significant deviation; problems with study, change in critical date estimates – surprises are not good! When asked a question (voice mail, e-mail) – how long to respond….*

Cost – *are costs comparable to competition; note: if quality is good, then cost is rarely a deal breaker (??) – emphasis is on value, etc.*

2009 Note: reorganizing Env. Res. team to allow more active monitoring of key study activities, timely/front-end screening of data, etc. Expect more interaction/communication in 2009 relating to these items.

Summary of Study Director/QA feedback re: Cooperator Performance can be provided……

Feedback from cooperators regarding experience with Study Directors is also welcomed (provide to R. DeHaan or M. Cole).

2009 Field Program – In Planning

- **Snapshot of program** –

US trials only; some of which (approx 30) have already started.

CROP	Approx No. of Trials
Almonds	3
Apple	3
Avocado	2
Barley	9
Bulb Onion	3
Cherry	3
Corn	5
Cotton	12
Cucumber	6
Grapes	3
Grapefruit	3
Lemon	2
Lettuce	3
muskmellon	3
Oats	12
Orange	9
Peach	3
Pear	2
Pepper	4
Potato	3
Rice	20
Rye	5
Soybean	40 * (GMO)
Squash	2
Strawberry	3
Tomato	6
Wheat	16

SOIL	
Dissipation	9
Run-off	1

2009 Field Program – TEMIK on Cotton

- Standard Cotton RAC study – 12 trials (3 stripper harvest, 3 picker harvest)
- The test substance is aldicarb, or TEMIK 15G
- Two applications of a granular material, soil incorporated
  - 10 lb at planting - apply granules in a 4 to 6-inch band (T-Band) over open seed furrow and immediately cover with soil
  - 14 lb at early bloom (90 days preharvest) - side dress in a furrow that is 6 to 10 inches to one or both sides of plant row to a depth of 2 to 3 inches
- GLP calibration of a granular application, preferably from “commercial” equipment (Gandy box or Lock n Load), but other rigs are acceptable if you can make the application accurately

Bayer CropScience

QA Topics

BCS Quality Assurance

Deb Wallace

debra_m.wallace@bayercropscience.com

Auditing a Field Study & FieldNotes Notebooks

- QA – What to look for
- FieldNotes Notebook Checklist
- Quality Assurance Statement

Auditing a Field Study & FieldNotes Notebooks

1. Verify there is documentation as per protocol for both
    - number of plants/quantity sampled
    - weight of sample

Auditing a Field Study & FieldNotes Notebooks

2. Verify that it is documented in 'sampling description' that samples were placed in the freezer immediately or in coolers with ice as per protocol

Auditing a Field Study & FieldNotes Notebooks

3. When the sprayer is calibrated the day before application,

   - re-verify that sprayer nozzle outputs have not significantly changed &

   - record re-verification (as an additional note with ‘catch’ volume)

Auditing a Field Study & FieldNotes Notebooks

4. Disposal of test substance container – document disposal in test site records (after the required time period – 3 years)

FieldNotes Checklist - NEW Coversheet

Checklist has some changes

Please use new version

Bayer CropScience Residue Study
Field Notebook Review Checklist

Study Title:	
Study Number:	
Trial Number:	
Principal Investigator:	

Circulation	Signature	Date
QAU Inspector:		
Principal Investigator:		
Principal Investigator Management:		
Study Director:		
Study Director Management:		

Auditing a Field Study & FieldNotes Notebooks

5. FieldNotes notebook (QA) checklist

- If there is a 'no' on the checklist determine if a deviation needs to be written and follow-up that it is written by PI and sent to SD

- attach the checklist to the audit

Auditing a Field Study & FieldNotes Notebooks

6. Field Data Summary Report (FDSR)

   - verify each value for accuracy/correctness

   - QA signs “Reviewed By”

Quality Assurance Statement

GLP Requirement:

Prepare a

- signed statement

-dates inspections were made

-dates inspections were reported to the study director & management

Quality Assurance Statement

Principal Field Investigator's Quality Assurance

- One summary statement
  - signed by the facility QA Officer

- Which includes

  - dates of & critical events audited
  - dates the audits were sent to:
    - Study Director / Study Director's Management
    - Principal Field Investigator (PFI)/PFI Management

Quality Assurance Statement

Wording to use:

- Notebook Review
- Field Data Summary Report Audit (FDSR Audit)

QUALITY ASSURANCE STATEMENT

Study Title:

Study Number:

Trial Number:

Principal Investigator:

Inspections of this trial were conducted as required by Good Laboratory Practice regulations of USEPA 40 CFR Part 160. The inspections are listed below:

Inspection Dates	Phase Inspected	Date Reported to Study Director/ S.D. Management	Date Reported to Principal Investigator/PI Management
	Notebook Review		
	FDSR Audit		

Quality Assurance: _____ Date: _____

Quality Assurance Statement

- Send QA Statements to
  - Residue mailbox (not to the study director)

    Field Program Administration

    Bayer research Park, Building 2

    17745 South Metcalf

    Stilwell, KS 66085-9104

  - If QA Statement is sent with RD, please flag it

- Send QA audits to the study director

  (please don't send with data)

Questions