IR4-Field Data Notebook Review Checklist

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| --- | --- | --- | --- |
| Field Research Director: | **David Ennes** | **Reviewer:**  | **Mika Tolson** |
| Study Title: | **Isofetamid Magnitude of the Residue on Hemp** |
| Study Director: | **Philip Moore** |
| Test Site Location: | **Parlier, CA** |

Please fill out the following checklist and explain any deficiencies in an email or other electronic document.

**Please note:** Any problems which are likely to affect the study’s integrity found during the course of this

review must be brought to the attention of the Study Director immediately.

**Field Trial Critical Events Log**

|  |  |  |
| --- | --- | --- |
| **Event** | **Date** | **Temperature Log Dates** |
| Test substance receipt |  |  |
| Test substance applications |  |  |
|  |  |  |
| Sampling |  |  |
| Sample Shipping and Receipt |  |  |

Parts 1,2,3. GLP YES NO N/A

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1. | Chain of Custody for Field Data Book completed |  |  |  |
|  2. | SOPs referenced or present (Part 1) |  |  |  |
| 3. | GLP Compliance Statement signed by Field Research Director (Part 1) |  |  |  |
|  | a. Signed by FRD just prior to sending in FDB to RFC |  |  |  |
|  4. | Study personnel signatures complete (Part 2A) |  |  |  |
| 5. | Qualifications summary (cvs, training records) (Part 2B) |  |  |  |
| 6. | Notes with sufficient detail to reconstruct what was done |  |  |  |
| 7. | All transcriptions acknowledged and traceable |  |  |  |
| 8. | All in use pages signed and dated |  |  |  |
|  9. | All entries properly dated and initialed |  |  |  |
|  10. | Pages properly identified (Test Substance/Crop/Field ID No.) |  |  |  |
|  11. | All unused pages removed or lined out, initialed and dated |  |  |  |

Part 4. Test Substance YES NO N/A

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  1. | Chemical Receipt, Storage, and Disposition (Part 4A) |  |  |  |
|  | a. Date received and/or placed in storage |  |  |  |
|   | b. Name on label |  |  |  |
|  | c. Batch/Lot number |  |  |  |
|   | d. Expiration date of test substance and source (label, CoA) |  |  |  |
|   | e. Amount received, type & condition of container |  |  |  |
|  2. | Chemical use log (completed/documented (Part 4B) |  |  |  |
|  3. | Disposition of remaining compound / containers documented (Part 4C) |  |  |  |
|  4. | Identification and receipt of spray additives (Part 4D) |  |  |  |
|  | 1. Expiration Date?
 |  |  |  |
|  | 1. Storage conditions?
 |  |  |  |
|  5 | Chemical storage building temperature log (temperatures/temperature range -receipt to last application) (Part 4E) **(RDFN: Section 4C)** |  |  |  |
|  | 1. Temperatures compliant with range on label/CoA
 |  |  |  |
|  6. | Balance calibration check (bracketing weights for test substance) (Part 4F) **(RDFN: Section 4D)** |  |  |  |
| 7. | Chemical receipt (exact copy in raw data) or Certificate of Analysis |  |  |  |

Part 5. Trial Site YES NO N/A

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  1. | Directions to trial site (map included) (Part 5A) |  |  |  |
|  2. | Directions to test plot (map included) (Part 5B) |  |  |  |
|  3. | UTC and TRT plot layout (detailed, accurate and neatly drawn, with actual plot size and permanent reference noted, distance of UTC to TRT, approx. slope of the plots, north direction, # rows and direction) (Part 5, C1 & C2) |  |  |  |
|  | 1. If plot stacking, permission from all Study Directors included
 |  |  |  |
|  4. | Test crop records (variety, species, source, lot #, age) (Part 5D) |  |  |  |
|  | 1. Plot dimensions, row width and plant spacing
 |  |  |  |
|  | 1. # Rows/beds match plot plan
 |  |  |  |
|  5. | Soil characterization (GLP soil analysis or SCS survey data) (Part 5E) |  |  |  |
|  | 1. % sand / silt / clay, org material, org carbon or CEC, pH
 |  |  |  |
|  6. | Pesticide/fertilizer history documented. (Part 5F) Number of years? \_\_\_ |  |  |  |
|  7. | Cultural practices (incl depth) adequately documented (Part 5G) |  |  |  |
|  8. | Maintenance chemicals (fertilizers/pesticides) use documented (Part 5H) |  |  |  |
|  | 1. Transplant and/or treated seed use documented
 |  |  |  |
|  9. | Crop destruct: description provided to adequately explain crop destruction or handling so that the crop is not consumed by human or animal? Date of destruction and source of info? (Part 5I) |  |  |  |

Part 6. Application YES NO N/A

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  1. | Application equipment description (Part A); Diagram/photograph (Part B) |  |  |  |
|  2. | Application calibration accurate, verified, and according to protocol and SOP (Parts 6: C, D, E, F, each application) **(RDFN: Section 4E/F)** |  |  |  |
|  | a. Calibration records (If “NO,” contact Study Director immediately) |  |  |  |
|  | b. Rate calculations (If “NO,” contact Study Director immediately) |  |  |  |
|  3. | Application Records (Part 6G) |  |  |  |
|  | 1. Application interval matches protocol
 |  |  |  |
|  | 1. Time mixed, applied, agitated within ½ hour
 |  |  |  |
|  | 1. Tank mix accurately calculated
 |  |  |  |
|  | e. Measuring equipment used including increments |  |  |  |
|  | f. Mixing order |  |  |  |
| 4. | Part 6H: Plant growth (height, stage, vigor, moisture, % soil coverage) |  |  |  |
|  | a.Wind speed/direction |  |  |  |
|  | b. % Clouds, humidity, dew, soil tilth, moisture, temp |  |  |  |
|  | c. Equipment cleaning and who cleaned |  |  |  |
| 5. | Pass times and application narrative (Part 6I) **(RDFN: Section 6J)** |  |  |  |
| 6. | Post application rate confirmation (Part 6J) |  |  |  |
| 7. | Date/amount of first rain and first irrigation after each application (Part 6J). Also any phytotoxicity noted (Part 6K) |  |  |  |
| 8. | Phytotoxicity and ratings if required by protocol (Part 6K) |  |  |  |
| 9. | Trial differentiation L1: Relevant (y/n) L2: Sufficiently differentiated? Study Director approval if necessary? |  |  |  |
| 10. | Equipment maintenance log (sprayers, balances, etc.)(Part 6M) |  |  |  |

Parts 7, 8 Sample Collection and Shipment YES NO N/A

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  1. | General sampling information (harvest/sample dates, PHI) (Part 7A) |  |  |  |
|  2. | Method of sampling (Part 7A) Description (Part 7A2) |  |  |  |
|  3. | Sample modifications, time to cooler |  |  |  |
|  4. | Sample inventory (Part 7B: sample #s/weights per protocol |  |  |  |
|  5. | Interval from sampling to freezing (Notify Study Director immediately in the case of freezer failure and/or loss of sample integrity) (Part 7B) |  |  |  |
|  6. | Freezer temperature log (temperatures/temperature range - harvest to shipment) (Part 7C) **(RDFN: Section 7D)** |  |  |  |
|  7. | Freezer contents log (do dates match sampling log? - check-in and check-out of samples) (Part 7D) **(RDFN: Section 7C)** |  |  |  |
|  8. | Freezer maintenance log (Part 7E) **(RDFN: No specific prompt)** |  |  |  |
|  9. | Sample shipping information and date to carrier (Part 8A), notification of lab according to protocol |  |  |  |
|  10. | Sample chain of custody form in raw data (Part 8B) |  |  |  |
|  | a. Fed Ex receipt/ACDS bill of lading included/other |  |  |  |
|  11. | Confirmation of receipt by lab included |  |  |  |

Part 9. Meteorological/Irrigation YES NO N/A

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1. | Daily weather records (temp and rainfall from first application to harvest), location of weather record collection and meteorological data (Part 9A) |  |  |  |
|  2. | Irrigation amounts and/or schedule of irrigation events |  |  |  |
|  3. | Additional meteorological data / on-site observations / comments (Part 9B) |  |  |  |

Part 10. Additional Information YES NO N/A

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  1. | Original protocol signed (Part 10A) |  |  |  |
|  2. | Protocol amendments included (Part 10A) |  |  |  |
| 3. | Deviations noted and Study Director informed |  |  |  |