

**AAFC PESTICIDE RESIDUE STUDY PLAN
BYI 02960: MAGNITUDE OF THE RESIDUE ON CANEBERRY
STUDY #: AAFC12-054R**

**AGRICULTURE AND AGRI-FOOD CANADA (AAFC)
PESTICIDE RESIDUE STUDY PLAN**

BYI 02960: MAGNITUDE OF THE RESIDUE ON CANEBERRY

**STUDY #: AAFC12-054R
(IR-4 Project: 10860 – for reference only)**

**STUDY DIRECTOR:
Mitchell Pogoda
AAFC Minor Use Pesticide Program
4902 Victoria Avenue North
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Vineland Station, Ontario L0R 2E0
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FIELD TRIAL LOCATION:

Refer to Section 10, page 3.

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1. STUDY TITLE:

BYI 02960: Magnitude of the Residue on Caneberry.

2. JUSTIFICATION AND OBJECTIVES:

Agriculture and Agri-Food Canada (AAFC) and IR-4 have received a request for the minor use label expansion of BYI 02960 on caneberry. To establish a Maximum Residue Limit (MRL)/tolerance, it is required that the magnitude of the residue on the commodity be determined as per Regulatory Directive 98-02 (June 1, 1998), Residue Chemistry Guidelines and Directive 2010-05 Revisions to the Residue Chemistry Crop Field Trial Requirements (December 21, 2010). The purpose of this study is to collect and analyse treated and untreated residue samples from appropriate field sites according to the application parameters requested to provide the sponsor with residue chemistry data to support a pesticide registration submission. To determine the magnitude of the residue on caneberry, this study plan will be implemented using applicable Standard Operating Procedures (SOPs) and conducted under provisions outlined in Organization for Economic Cooperation and Development (OECD) Principles of Good Laboratory Practices (GLP) (1997 Revision). Any work conducted in the USA will be conducted according to Environmental Protection Agency (EPA) Good Laboratory Practice standards, 40 CFR part 160, which are acceptable to OECD standards.

3. SPONSOR/TESTING FACILITY NAME, ADDRESS AND PHONE:

AAFC Minor Use Pesticide Program, Building 57, Central Experimental Farm,
960 Carling Avenue, Ottawa, ON, K1A 0C6, Phone: (613) 715-5390, Fax: (613) 694-2323

4. STUDY DIRECTOR:

Mitchell Pogoda, 4902 Victoria Avenue North, P.O. Box 6000, Vineland Station, ON L0R 2E0,
Phone: (905) 562-4113 ext. 265, Fax: (905) 562-4335, Email: mitchell.pogoda@agr.gc.ca

5. COMPLIANCE:

The test facility and appropriate test sites (field and laboratory) will be responsible for certifying that its portion of the study will be conducted in accordance with the OECD Principles of GLP (1997 Revision). Any work conducted in the USA will be conducted according to EPA Good Laboratory Practice standards, 40 CFR part 160, which are acceptable to OECD standards. A statement of compliance, together with any deviations will be signed and submitted by the responsible Study Director in the Final Report and by the Principal Investigator in their Raw Data Field Notebook (RDFN) or analytical report.

6. QUALITY ASSURANCE:

Quality Assurance (QA) duties and responsibilities will be in conformance with the OECD Principles of GLP (1997 Revision). Any work conducted in the USA will be conducted according to EPA Good Laboratory Practice standards, 40 CFR part 160, which are acceptable to OECD standards. A Quality Assurance Statement will be provided by the QA for each site, for each Raw Data Field Notebook, Final Analytical Report and Final Report. It shall include the type of inspections, the date inspections were made and date(s) any findings were reported to the Study Director, Principal Investigator (if applicable), and Management(s).

7. TEST FACILITY RECORD KEEPING:

A study file will be initiated and maintained by the Test Facility. Original study plan, amendment(s) and deviation(s) (if any), as well as the original raw data (e.g. RDFNs, laboratory data [each of which may contain copies of facility records]), final analytical report and final report will be archived by the Test Facility.

8. PROPOSED DATES:

Experimental Start: April 2012 Experimental Termination: June 2014

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9. STUDY SIGNATURES:

MK Pogoda Feb 16 2012

Study Director/ Date
Mitchell Pogoda
AAFC Minor Use Pesticide Program
4902 Victoria Avenue North
P.O. Box 6000
Vineland Station, ON L0R 2E0
Phone: (905) 562-4113 ext. 265
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Stéphane Laprise Feb 13 2012

Quality Assurance/ Date
Stéphane Laprise
AAFC Minor Use Pesticide Program
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Ottawa, ON K1A 0C6
Phone: (613) 759-1965
Fax: (613) 694-2323
Email: stéphane.laprise@agr.gc.ca

J. Ballantine Feb 13, 2012

Test Facility Management/ Sponsor Representative/ Date
Jennifer Ballantine (A/Submission Manager)
AAFC Minor Use Pesticide Program
Building 57, Central Experimental Farm
960 Carling Avenue
Ottawa, ON K1A 0C6
Phone: (613) 759-7953
Fax: (613) 694-2323
Email: jennifer.ballantine@agr.gc.ca

10. FIELD PERSONNEL/TRIAL ID NO:

(Responsible for Sections 11-23)

The Principal Investigator and Site Management must sign and return the attached GLP acceptance form (see Appendix A) for each Trial ID #.

PRINCIPAL INVESTIGATOR:

Tom Freiburger
Rutgers Fruit Research Centre
283 Rt. 539
Cream Ridge, NJ 08514
Phone: 609-758-7311 ext. 19, Fax: 609-758-7085
Email: freiberger@aesop.rutgers.edu

TRIAL ID No. (Zone 1)

AAFC12-054R-316
(raspberry)

TEST SITE MANAGEMENT:

Edith Lurvey
Cornell University – NYSAES
Entomology Department
630 W. North Street
Geneva, NY 14456-1371
Phone: 315-787-2308, Fax: 315-787-2326
Email: ell10@cornell.edu

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PRINCIPAL INVESTIGATOR:

Bernard H. Zandstra
Michigan State University; Department of Horticulture
A440 Plant and Soil Science Building
East Lansing, MI 48824-1325
Phone: 517-353-6637, Fax: 517-432-2242
Email: zandstra@msu.edu

TRIAL ID No. (Zone 5)

AAFC12-054R-317 (decline)
(blackberry)

TEST SITE MANAGEMENT:

Satoru Miyazaki
Michigan State University; IR-4 North Central Reg. Res. Ctr.
3815 Technology Boulevard, Suite 1031B
Lansing, MI 48910-8396
Phone: 517-336-4611, Fax: 517-432-2098
Email: ncrir4@msu.edu

PRINCIPAL INVESTIGATOR:

Jean-François Dubuc
Agriculture and Agri-Food Canada
430 boul. Gouin
St. Jean-sur-Richelieu, QC J3B 3E6
Phone: 450-515-2039, Fax: 450-346-7740
Email: jean-francois.dubuc@agr.gc.ca

TRIAL ID No. (Zone 5B)

AAFC12-054R-335
(raspberry)

TEST SITE MANAGEMENT:

Noubar Bostanian
Agriculture and Agri-Food Canada
430 boul. Gouin
St. Jean-sur-Richelieu, QC J3B 3E6
Phone: 450-515-2014, Fax: 450-346-7740
Email: noubar.bostanian@agr.gc.ca

PRINCIPAL INVESTIGATOR:

Sharon D. Benzen
USDA-ARS
Crop Improvement & Protection Res.
1636 East Alisal St.
Salinas, CA 93905
Phone: 831-755-2828, Fax: 831-755-2814
Email: sharon.benzen@ars.usda.gov

TRIAL ID No. (Zone 10)

AAFC12-054R-318
AAFC12-054R-319
(both trials on raspberry)

TEST SITE MANAGEMENT:

Paul Schwartz
USDA/ARS/Office of Minor Use Pesticides
Rm. 212, BARC-W
10300 Baltimore Avenue, BLDG 007
Beltsville, MD 20705
Phone: 301-504-8256, Fax: 301-504-5048
Email: paul.schwartz@ars.usda.gov

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PRINCIPAL INVESTIGATOR:

Joe DeFrancesco
Oregon State University
Integrated Plant Protection Centre
2040 Cordley Hall, Corvallis, OR 97331-2915
Phone: 541-737-0718, Fax: 541-737-3080
Email: defranci@science.oregonstate.edu

TRIAL ID No. (Zone 12)
AAFC12-054R-320 (decline)
(raspberry)
AAFC12-054R-321
(raspberry)
AAFC12-054R-322
(blackberry)

TEST SITE MANAGEMENT:

Rebecca Sisco
University of California; Department of Environmental Toxicology
Meyer Hall, Rm. 4218
One Shields Avenue, Davis, CA 95616
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Email: rsisco@ucdavis.edu

PRINCIPAL INVESTIGATOR:

Markus Clodius
Agriculture and Agri-Food Canada
6947 Highway #7, P.O. Box 1000
Agassiz, BC V0M 1A0
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Email: markus.clodius@agr.gc.ca

TRIAL ID No. (Zone 12)
AAFC12-054R-323
(raspberry)

TEST SITE MANAGEMENT:

Robert Vernon
Agriculture and Agri-Food Canada
6947 Highway #7, P.O. Box 1000
Agassiz, BC V0M 1A0
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Email: bob.vernon@agr.gc.ca

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11. TEST SYSTEM/CROP:

Caneberry - use a commercially-cultivated variety. At a minimum, record the variety and age of planting, if available. Field trials will be conducted at the designated sites.

NOTE: If a Principal Investigator is assigned more than one trial in this study, the trials must be conducted at different locations or, if at the same location, different varieties must be used. To further differentiate these trials, choose one option from any three of the five sets below (for a minimum of three criteria met).

| Set | Option | Description |
|-----|--------|--|
| 1 | A | Spray volume must vary by at least 25% of the lower volume (minimum 10 GPA (93.5 L/ha) difference) Example 1, Trial A has a volume of 20 GPA (187 L/ha) and Trial B has a volume \geq 30 GPA (281 L/ha) Example 2, Trial A has a volume of 60 GPA (561 L/ha) and Trial B has a volume \geq 75 GPA (701 L/ha) The trial with the lowest spray volume for the first application must remain the lowest for each application; the trial with the highest must remain the highest for each, and so on |
| | | |
| 2 | A | Different adjuvant class: Crop oil concentrate, Nonionic surfactant (non-silicone) or methylated seed oil surfactant (Do not contradict instructions on the label of either the adjuvant or the test substance). To avoid conflicts, confirm the choice of surfactant with the Study Director before use. |
| | | |
| 3 | A | Different foliar application type: foliar directed or foliar broadcast |
| | B | Different types of application equipment be used in each trial (for example, boom sprayer, airblast sprayer, axial fan orchard sprayer, proptec sprayer, tower sprayer, over-row sprayer, tunnel sprayer, backpack sprayer) |
| | C | Different people make the applications, using hand-held equipment such as backpack sprayers, waist pack sprayers |
| | D | Different spray droplet size (fine, medium, coarse, very coarse, or extra coarse) This may be accomplished by changing nozzles and/or by changing spray pressure Document (in the RDFN) the droplet size that results from the pressure and nozzles used in the trial (nozzle catalog may be used as a reference) |
| | E | Not applicable |
| | F | Not applicable |
| | G | Not applicable |
| 4 | A | Different crop variety (different size at maturity, rough vs. smooth surface, different amount of foliage shielding the commodity, etc.)—confirm with the Study Director if this option will be chosen |
| | B | Different irrigation type (drip or furrow or sprinkler/over-the-top) (Irrigation must be applied at least once after each application, but over-the-top irrigation must not be applied within one hour of an application, and irrigation is not needed following the last application if samples are to be collected on the same day) |
| | C | Not applicable |
| | D | Not applicable |
| | E | One trial shall have trellised plants and the other shall not |
| | F | Not applicable |
| | G | Different maturity of trees or bushes in fruit and nut studies—young trees or bushes in one trial and mature trees or bushes in the other; minimum 5 year age difference |
| 5 | A | Trial sites must be separated by at least 20 miles (32 km) |
| | B | First application in each trial is separated by at least 30 days |
| | C | Not applicable |

Please document the methods used to differentiate multiple trials in the RDFN. Contact the Study Director for appropriate forms, if necessary. If these criteria cannot be met to separate multiple trials, contact the Study Director to discuss possible alternatives that can be amended to the study plan. Trials conducted in different calendar years are exempt from these requirements.

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12. TRIAL SYSTEM DESIGN and STATISTICAL METHOD:

Each trial will consist of an untreated control plot and a treated plot. Each individual plot will be established with a minimum of one row, and must consist of a minimum length of 12 m (39.4 feet).

For a decline trial, the individual plots will be established with a minimum length of 20 m (65.6 feet) for the treated plots and 12 m (39.4 feet) for the untreated plots.

At a minimum, a 5 m (16.4 ft) buffer zone will be employed around the treated and untreated plots to prevent contamination¹. Since this pesticide use is not registered on this crop, federal law requires that the treated crop must be destroyed or handled in such a way that it is not consumed as a human food or animal feed. Document crop destruction in the RDFN. If any questions arise regarding crop disposition, contact the Study Director. Mark plots with identifiable markers containing at a minimum the Trial ID # (AAFC12-054R-XXX), and treatment number or treatment name that will persist for the duration of the field research trial or that can be readily replaced. A plot map enabling trial site relocation by a third party must be created. This study is not designed for the statistical evaluation of field data.

13. TRIAL SITE PREPARATION AND MAINTENANCE:

Prepare or select a trial site that has been and will continue to be maintained following local, good agricultural practices for the production of caneberry, including fertilization, irrigation and other practices that ensure good crop production. The trial site must be maintained throughout the season to ensure that weeds do not interfere with treatment applications or crop maturity. The trial site cannot have been treated with a chemical similar in nature to the test item (as outlined in Section 17) for a minimum of 1 year prior to use. The trial site will have a known pesticide history of a minimum of 1 year and preferably 3 years.

Note: A soil analysis (≤ 5 years old) must be provided for each trial (see Section 21 for details). If an artificial medium is used, provide a detailed description of its composition in place of a soil analysis.

14. TEST ITEM:

Use the 200 SL formulation (formulation code SP102000021884) of BYI 02960 (200 g a.i./L, 1.67 lb a.i./gallon) **that has been characterized to meet GLP standards**. BYI 02960 is also known as flupyradifurone and Sivanto. AAFC will arrange procurement of GLP test item from the Registrant. Upon receipt, document the lot/batch number, condition, quantity received and confirmation of GLP characterization. Contact the Study Director if there are any concerns regarding the GLP characterization, label identification of the test item (e.g. the name on the bottle or certificate of analysis (CoA) is different from the study plan), etc. or if the test item does not come with a CoA. Store the test item in a secure, clean, dry area at temperature ranges noted in the product label or other references.

Prior to test item disposal, contact the Study Director for specific instructions.

Unless otherwise specified, the registrant will archive a retention sample of the test item.

15. TEST ITEM APPLICATION:

Each trial requires a unique spray mixture (i.e. do not use the same spray mixture from one field trial on another field trial). Ensure that the test item is well-mixed. If practical, agitate during the application and observe the test item in the spray mixture; provide documentation in the RDFN that the test item was completely dissolved/mixed in the carrier before application. Use application equipment that will provide uniform application of the test item in the required spray volume (see Section 16). Apply the test item as specified (see Section 16), in a manner that

¹ Note that the buffer zone is considered the area outside of the plot and the spray zone that is a conflicting chemistry and test item free zone. The spray zone is an area before and after the treated plot that allows the operator to activate the boom and get up to the appropriate speed before entering the plot; and it is an area after the plot that allows the application to continue outside of the treated plot; which helps to ensure a uniform coverage to the treated plot. It is also an area where the boom can be primed and discharged, as long as contamination of the plot is avoided.

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represents or simulates the major application technique that is used by area commercial growers. The test item, if applied in a mixture, must be applied to the test system within two hours of mixing. The test item must be applied when wind speeds are less than 10 km/hour (6.2 miles/hour) (unless approved by the Study Director), and in a manner to ensure accurate delivery and to prevent contamination of adjacent plots.

To ensure accurate delivery, calibration for output and speed must be performed. Just prior² to the application of test item, calibrate for nozzle or hopper output and speed (equipment or walking speed) by performing a minimum of three consecutive acceptable checks (within $\pm 5\%$ of the average output or -5 to $+10\%$ of the target pass time for speed calibration), or by performing a minimum number of runs for which at least 75% of the total number of checks are acceptable (i.e. 3 acceptable runs out of a total of 4 checks performed. Note in this situation only, the values from the 3 acceptable runs will be used for calibration calculation). This is considered a **complete calibration**. Conduct the speed calibration at the edge of the test plot, or on similar terrain. The uncharged spray boom may be held over or directed at the plot.

At a minimum, for multiple applications performed on the same day within a trial or between trials, a single recheck of the output and speed is necessary. A single output check must be conducted to confirm consistent delivery ($\pm 5\%$ of the last complete calibration) just prior to subsequent applications. This is considered a **calibration recheck**. Note: a calibration recheck is only acceptable if application parameters or equipment components have not changed. If the **calibration recheck** results in an output that differs from the mean output of the **complete calibration** by more than $\pm 5\%$, then the equipment must be completely re-calibrated.

If application parameters (e.g. application type, water volume) or equipment components (e.g. nozzle tips) have changed from the initial calibration, another **complete calibration** (of nozzle output and/or speed, depending on what was modified) must be performed and documented, even if the equipment has been changed back to the parameters of the initial calibration. Equipment logs should be used to document changes in the equipment parameters.

If the complete calibrations were conducted as part of another trial, a true copy of all complete calibrations references, along with the required rechecks performed for this trial, are to be included in the raw data field notebook. **Calculations for the amount of test item to be applied will always be based upon mean output calculated from the most recent complete nozzle output or speed calibration data, not on the recheck results.**

Record actual application pass time(s) in the field notebook and verify the accuracy of the application. The application is considered acceptable if the accuracy is within -5% and $+10\%$ of the application rate specified in the study plan. If the application does not meet this range, the Study Director must be notified of this deviation before proceeding with this trial.

Use application methods that result in maximum coverage. Ensure the targeted spray area receives a consistent spray by starting and ending the application before and after the defined plot area, respectively (this includes the plot ends and guard rows that will not be sampled from). For directed applications, in which the treated area is less than the plot area (row/bed spacing), do not proportionally reduce the application rate (the amount of active ingredient applied per hectare). Direct the entire per-hectare rate into the treated area. If row widths in the research plots are greater than local commercial practices, the application rate should be calculated using the maximum commercial row width. Contact the Study Director for guidance, if necessary.

²"Just prior" includes the day prior to the application, but calibration on the day of use is preferred.

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16. APPLICATION TREATMENTS AND TIMING:

| Trt # | Treatment | Target Rate of active ingredient | Target Rate of formulated product* | Application Type** | Spray Volume*** |
|-------|-----------|---------------------------------------|------------------------------------|--------------------|------------------------------------|
| 01 | Untreated | Not Applicable | Not Applicable | Not Applicable | Not Applicable |
| 02 | BYI 02960 | 205 g a.i./ha (0.183 lb a.i./acre) | 1025 mL/ha**** (414.8 mL/acre) | Foliar | 280 to 935 L/ha (30 to 100 GPA) |

*The nominal formulation concentration of the test item will be used in calculating the final application rate (see Section 14 for the nominal concentration).

**Make 2 foliar applications at a 7 (\pm 1) day intervals with the last application on the day of harvest (0-day PHI).

***L/ha = litres per hectare, GPA = gallons per acre

****Rounding differences may exist when converting a.i. to product rate, as well as between metric and U.S. units. Therefore, use the values as listed in the table. Specifically, use the product rate to verify accuracy of application(s).

Adjuvant: All applications must include either a non-ionic (at 0.2% v/v), methylated seed oil (at 0.25% v/v) or crop oil concentrate (at 1% v/v) adjuvant. Include a copy of the label in the RDFN.

Note: for any other additive to the spray solution (such as but not limited to antifoaming agents or pH adjusters) contact the Study Director for approval.

17. SUPPLEMENTAL CROP TREATMENTS:

The integrity of the field trial should be protected by minimizing damage to the test crop caused by pests. Only registered maintenance pesticides applied according to labelled directions may be used, unless approved by the Study Director. Approval from the Study Director to use non-registered pesticides is to be documented in the RDFN. Make identical applications to the untreated and treated plots; document all supplemental crop treatments. **DO NOT USE** pesticides that contain a chemical from the chloronicotinyl class of compounds (e.g. imidacloprid, thiamethoxam, thiacloprid, acetamiprid, etc.) or other chemicals that might interfere with analysis of the test item. If unsure, contact the Study Director.

18A. RESIDUE SAMPLE COLLECTION (SEE SAMPLE INVENTORY IN STUDY PLAN PART 19A):

On the day of last application (0-day PHI), collect two samples from the untreated plot and two samples from the treated plot.

Each sample is to be collected in a manner to ensure a representative, impartial sample. Collect samples when berries are mature, starting with the untreated plot first, if both plots are being harvested by the same person. Otherwise, order in which the samples are collected will not be an issue, if contamination between plots is minimized. A minimum of 1 m (3.3 feet) from the plot ends must be avoided when sampling. Collect a minimum sample weight of 0.5 kg (1.1 lb) of berries from at least 12 separate areas of each plot.

Follow proper handling practices with clean or gloved hands and clean tools to prevent transfer of pesticide residue from one sample to another. **If practical**, complete harvest and sample preparation for one plot before proceeding to the next. Store all samples in plastic-lined cloth bags or bags approved by the Study Director. **To reduce the loss of juice from the fruit, berries may be collected into smaller, sealable plastic bags, which are then placed in the**

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larger sample bags. See Section 20 for residue sample handling directions. Document how sampling was conducted in the RDFN. Identify each bag of samples as follows:

Trial ID No. - enter Trial ID Number (AAFC12-054R-XXX); **Commodity (Crop)** - enter crop fraction; **Chemical** - enter common chemical name and formulation; **Sample ID No.** - enter sample ID; **Date Sampled** - enter harvest/sampling dates; **Applic. Rate (g a.i./ha)** - enter application rate or not applicable (for untreated samples only) and **Investigator:** enter name of Principal Investigator.

NOTE: An extra set of samples may be collected if deemed necessary (i.e. for shipping assurance) by the PI or Study Director. Document the collection, labelling and disposal procedures for these samples in the RDFN. If extra samples are taken, then identify each sample according to instructions outlined in the paragraph above, with the addition of the word 'DUPLICATE' or "EXTRA" along side of the sample ID No. Contact the Study Director for approval regarding disposal of duplicate samples.

18B. SAMPLE COLLECTION (FOR DECLINE TRIAL ID outlined in Section 10 ONLY):
(SEE SAMPLE INVENTORY IN STUDY PLAN PART 19B)

In addition to the samples required in Section 18A, collect two samples from the treated plot at 3 (± 1), 7 (± 1), 10 (± 1) and 14 (± 1) days from the last application. Follow the sampling method described above.

19A. RESIDUE SAMPLE INVENTORY:

| SAMPLE ID | TRT # | TREATMENT | DAYS AFTER LAST APPLIC. | MINIMUM SAMPLE | CROP FRACTION |
|-----------|-------|-----------|-------------------------|-----------------|---------------|
| A | 01 | Untreated | N/A ¹ | 0.5 kg (1.1 lb) | berry |
| B | 01 | Untreated | N/A ¹ | 0.5 kg (1.1 lb) | berry |
| C | 02 | BYI 02960 | 0 | 0.5 kg (1.1 lb) | berry |
| D | 02 | BYI 02960 | 0 | 0.5 kg (1.1 lb) | berry |

¹Note the days after last application is not applicable (N/A) since they were not treated. However, these samples should be targeted for collection at the same timing as the treated samples (PHI=0).

19B. DECLINE SAMPLE INVENTORY (FOR DECLINE TRIAL ID outlined in Section 10 ONLY):

| SAMPLE ID | TRT # | TREATMENT | DAYS AFTER LAST APPLIC. | MINIMUM SAMPLE | CROP FRACTION |
|-----------|-------|-----------|-------------------------|-----------------|---------------|
| A | 01 | Untreated | N/A ¹ | 0.5 kg (1.1 lb) | berry |
| B | 01 | Untreated | N/A ¹ | 0.5 kg (1.1 lb) | berry |
| C | 02 | BYI 02960 | 0 | 0.5 kg (1.1 lb) | berry |
| D | 02 | BYI 02960 | 0 | 0.5 kg (1.1 lb) | berry |
| E | 02 | BYI 02960 | 3 (± 1) | 0.5 kg (1.1 lb) | berry |
| F | 02 | BYI 02960 | 3 (± 1) | 0.5 kg (1.1 lb) | berry |
| G | 02 | BYI 02960 | 7 (± 1) | 0.5 kg (1.1 lb) | berry |
| H | 02 | BYI 02960 | 7 (± 1) | 0.5 kg (1.1 lb) | berry |
| I | 02 | BYI 02960 | 10 (± 1) | 0.5 kg (1.1 lb) | berry |
| J | 02 | BYI 02960 | 10 (± 1) | 0.5 kg (1.1 lb) | berry |
| K | 02 | BYI 02960 | 14 (± 1) | 0.5 kg (1.1 lb) | berry |
| L | 02 | BYI 02960 | 14 (± 1) | 0.5 kg (1.1 lb) | berry |

¹Note the days after last application is not applicable (N/A) since they were not treated. However, these samples should be targeted for collection at the same timing as the treated samples (PHI=0).

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20. RESIDUE SAMPLE HANDLING AND SHIPMENT:

Place the samples into a freezer. If the samples cannot be placed into a freezer within approximately one hour after collection, an appropriate method of cooling samples must be used to maintain sample integrity and container temperatures must be monitored. The methods used in harvest, sample handling and storage will be outlined generally in SOPs, and must be in the raw data. For pre-shipment storage, the samples will be held frozen at temperatures generally less than -18°C (0°F), allowing for normal variations due to freezer cycling, sample movement, etc. Freezer logs must be used to document all sample additions to and removals from freezer storage. All storage temperatures must be monitored and documented. Shipment of frozen samples must be by freezer truck or "express" shipment, unless approved by the Study Director. Samples must be frozen prior to shipment. Shipments sent via express shipment (overnight carriers such as Federal Express or Purolator) will require the addition of quantities of dry ice sufficient to maintain sample integrity while in transit to the laboratory. Document the notification made to the sample destination by use of e-mail, fax, telephone log, raw data field notebook, communication note, etc. **Send samples to the laboratory identified in the table below as soon as practical. For samples packed with dry ice, avoid shipments from Thursday through Sunday.**

| Trial ID No. | Ship to: (Trial ID No., Contact and Shipping Address) |
|---|--|
| AAFC12-054R-316, AAFC12-054R-317, AAFC12-054R-318, AAFC12-054R-319, AAFC12-054R-320, AAFC12-054R-321, AAFC12-054R-322, AAFC12-054R-323, AAFC12-054R-335 | AAFC12-054R-324 Debra Payne Bayer Research Park Building 1, Processing Room 17745 South Metcalf Stillwell, KS 66085-9104 Telephone: 913-433-5378 Fax: 913-433-5503 Email: debra_m.payne@bayer.com |

21. FIELD DOCUMENTATION AND RECORD KEEPING:

All operations, data and observations appropriate to this study should be recorded directly and **promptly** into the RDFN. The content of the RDFN should be sufficiently detailed to completely reconstruct the field trial. At a minimum, collect and maintain the following raw data:

- Names of all personnel conducting specific research functions
- Study plan amendments relevant to the field trial
- Deviations from study plan and standard operating procedures
- Trial site information, including historic pesticide use
- Plot maps
- Test item receipt, use and disposition records
- Test item storage conditions (including minimum and maximum temperatures)
- Data regarding calibration and use of application equipment
- Treatment application
- Crop maintenance pesticides, crop production and cultural practices
- Residue sample identification, collection, storage conditions and handling
- Residue sample shipping information
- Description of crop destruction, or explanation for lack of destruction
- Meteorological/Irrigation records³

³ Weather/irrigation records for the entire month are required from planting of annual crops or for a minimum of one month prior to the first application onto perennial crops, until last residue sample collection. These records do not need to be determined under GLP standards. Daily climatic records for the trial year (growing period) and at a minimum the 10 year mean data, rainfall and temperature (if possible with standard deviations) must be provided.

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- Pass times (if applicable) and other data to confirm amount of material applied to plots
- Other applicable data requested in the RDFN⁴ that are needed to prove that the conduct of the study was in accordance with the study plan.

22. STUDY PLAN/SOP MODIFICATIONS - FIELD RESEARCH:

Consult with the Study Director regarding desired changes to the Study Plan prior to occurrence. If appropriate an amendment will be issued. Any deviations to the Study Plan or to a Standard Operating Procedure will require the Principal Investigator or Study Director to complete a deviation form. Any deviation should be communicated to the Study Director either verbally, by fax or email within **48 hours** (document in communication log) and in writing on the form provided within **7 days** of occurrence or recognition. The Study Director will assess the impact of the deviation on the study and act accordingly.

23. FIELD RESEARCH REPORT/ARCHIVING:

The Principal Investigator will ensure that the completed **original** RDFN is forwarded to GLP Admin after sample shipment and appropriate review. The Principal Investigator will maintain a scan or printed copy of these field documents.

24. LABORATORY PERSONNEL/TRIAL ID NO.:

(Responsible for Sections 28-38)

The Principal Investigator and Test Site Management must sign the GLP Acceptance form (Appendix A) and return as directed.

PRINCIPAL INVESTIGATOR:

The PI will be indicated at a later date and added via an amendment.

TRIAL ID No.

AAFC12-054R-324

TEST SITE MANAGEMENT:

The Test Site Management will be indicated at a later date and added via an amendment.

The laboratory will be identified at a later date, at which time the appropriate information will be added by amendment.

25. LABORATORY SAMPLE INVENTORY:

Treated and untreated crop samples will be received from the field sites outlined in Section 20 (for responsible persons see Section 10). Notify the appropriate Principal Investigator and Study Director of sample receipt by faxing back copy of the completed Chain of Custody form.

26. LABORATORY SAMPLE IDENTIFICATION:

Each sample (raw commodity, crop fractions, storage stability, method validation, etc.) is to be assigned a unique laboratory sample number by the laboratory personnel (note: use of the field sample identification number is acceptable). A cross-reference must be maintained between the assigned laboratory sample number and the identification utilized in the Sample Chain of Custody Form received from the field sites. Both identification numbers must be reported in the analytical report.

⁴ Report soil information from a soil analysis that is ≤ 5 years old (organic matter, pH, Cationic Exchange Capacity, textural fractions, and preferably soil texture) as well as from any official documents necessary, such as a Soil Survey, to accurately document the requested information for this trial. The nature of this study is such that soil characteristics do not need to be determined under GLP standards. If an artificial medium is used, provide a detailed description of its composition, in place of a soil analysis.

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27. LABORATORY SAMPLE STORAGE/PREPARATION:

Store samples in a limited access area at temperatures that will maintain frozen sample integrity (generally less than -18°C (0°F)), allowing for normal variations due to freezer cycling, sample movement, etc] until extraction. The samples may be stored whole or macerated, depending on the standard procedure of the analytical laboratory. Note: the entire sample is to be macerated prior to taking a sample for analysis **and samples are not to be composite**. Contact the Study Director if guidance is needed. All storage temperatures, conditions and location of sample storage must be monitored and documented.

Information for Sections 28 – 35 will be identified at a later date, at which time the appropriate information will be added by amendment.

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APPENDIX A

GLP Acceptance Form

Trial ID #: AAFC12-054R-_____

I acknowledge that I have read, and understood, the material contained in the assigned Sections of this Study Plan. The research will be conducted in accordance with this Study Plan and the OECD GLP Principle of Good Laboratory Practices (revision 1997). Any work conducted in the USA will be conducted according to EPA Good Laboratory Practice standards, 40 CFR part 160, amended as effective Oct 16, 1989, which are acceptable to OECD standards. In addition, I will cooperate with the Quality Assurance Personnel in scheduling needed inspections and documenting responses to QA audit reports.

Principal Investigator

| | | |
|--------------|-----------|------|
| Printed Name | Signature | Date |
|--------------|-----------|------|

Acknowledged by Test Site Manager:

| | | |
|--------------|-----------|------|
| Printed Name | Signature | Date |
|--------------|-----------|------|

The following Individual or Company will be responsible for the Quality Assurance for this trial

 Name of Quality Assurance (Print)

*Form Completion and Return Instructions: At a minimum, the PI is to sign this form prior to performing any experimental work. Once the form has been completed, a **copy of the form** needs to be inserted in the RDFN and the original must be returned to the individual identified below.*

GLP Admin
 AAFC Minor Use Pesticide Program
 Building 57, Central Experimental Farm
 960 Carling Avenue
 Ottawa, ON, Canada
 K1A 0C6