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

DPX-QGU42: MAGNITUDE OF THE RESIDUE ON BASIL (GREENHOUSE)

STUDY #: AAFC12-068R
IR-4 PR# 10772 (for reference only)

STUDY DIRECTOR:
Karen Bedford
AAFC Minor Use Pesticide Program
AAFC Pacific Agri-Food Research Centre
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Email: Karen.Bedford@agr.gc.ca

FIELD TRIAL LOCATION:

Refer to Section 10, page 3.

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1. STUDY TITLE:
DPX-QGU42: Magnitude of the Residue on Basil

2. JUSTIFICATION AND OBJECTIVES:
Agriculture and Agri-Food Canada (AAFC) has received a request for the minor use of DPX-QGU42 on basil. 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. The purpose of this study is to collect and analyze 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 definition on basil, 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:
Karen Bedford, AAFC Pacific Agri-Food Research Centre, 4200 Hwy. 97, Box 5000, Summerland, BC V0H 1Z0, Phone: (250) 494-6370, Fax: (250) 494-2114;
Email: Karen.Bedford@agr.gc.ca

5. COMPLIANCE STATEMENT:
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 GLP 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 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 inspection made, 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: March 2012 Experimental Termination: June 2014

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9. STUDY SIGNATURES:

Karen E. Bedford Feb. 7, 2012
Study Director/ Date
Karen Bedford
AAFC Minor Use Pesticide Program
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Stéphane Laprise Jan 27, 2012
Quality Assurance/ Date
Stéphane Laprise
AAFC Minor Use Pesticide Program
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J. Ballantine Jan 27, 2012
Test Facility Management/ Sponsor Representative/ Date
Jennifer Ballantine A/Submission Manager
AAFC Minor Use Pesticide Program
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Phone: (613) 759-7953
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Cell: (613) 858-5726
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:
David Nield
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4200 Highway 97, P.O. Box 5000, Summerland, BC V0H 1Z0
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Email: David.Nield@agr.gc.ca

TRIAL ID No.
AAFC12-068R-296

TEST SITE MANAGEMENT:
Michael Smirle
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AAFC PESTICIDE RESIDUE STUDY PLAN
DPX-QGU42: MAGNITUDE OF THE RESIDUE ON BASIL (GREENHOUSE)
STUDY #: AAFC12-068R

PRINCIPAL INVESTIGATOR:
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Univ. of MD/LESREC
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Email: mross@umd.edu

TRIAL ID No.
AAFC12-068R-297

TEST SITE MANAGEMENT:
Ms. Edith L. Lurvey
Dept. of Food Science & Tech.
630 W. North Street
Geneva, NY 14456 USA
Phone: (315) 787-2308; Fax: (315) 787-2397
Email: ell10@cornell.edu

11. TEST SYSTEM/CROP:
Basil - use a commercial variety. At a minimum record the variety and the seeding or transplant date. Trials will be conducted at the designated sites to support the establishment/maintenance of a MRL/tolerance.

NOTE: If a Principal Investigator is assigned more than one trial in this study, an independently prepared spray solution is required in each trial. **Also**, multiple trials at the same location must be conducted using at a minimum of different varieties. If this cannot be used to separate multiple trials at a test site, contact the Study Director to discuss possible alternatives.

12. TEST SYSTEM DESIGN and STATISTICAL METHOD:

Each test site will consist of one untreated control plot and one treated plot. Use separate greenhouses or compartments or use barriers or a 5m (15 ft) buffer zone within a greenhouse to separate the untreated and treated plots. Provide the Study Director with a diagram of the proposed plot design/plot map. Plots must be of sufficient size to ensure collection of the required sample size as outlined in Sections 18 and 19.

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 destruct 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 # (AAFC12-068R-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 greenhouse trial site that has been and will continue to be maintained following local, good agricultural practices for the production of basil, including fertilization, irrigation and other practices that ensure good greenhouse crop production. The trial site must be thoroughly cleaned prior to planting or transplanting the test crop, to ensure no conflict from previous trials with the test item, or a chemical similar in nature to the test item (as outlined in section 17) for a minimum of 1 year prior to use. Note: A soil analysis ($\leq$ 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 DPX-QGU42 OD (100 g a.i./L) formulation of DPX-QGU42 (CAS #1003318-67-9; PCP No./EPA Reg. No.: not registered) **that has been characterized to meet GLP** standards. 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 CoA does not come with the test item. 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 spray mixture from one field trial on another field trial). To ensure that the test item is well mixed, agitate during the application, if practical. Observe the test item in solution and 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 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 2 hours of mixing. The test item must be applied in a manner to ensure accurate delivery and to prevent contamination to adjacent plots.

To ensure accurate delivery, calibration for output and speed must be performed. Just prior[1] 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; 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 speed calibration in an area adjacent to the test plot, or on similar terrain.

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 for each trial. A single output check must be conducted to confirm consistent delivery (± 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 ± 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 times in the field notebook and verify the accuracy of the

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

application. The application is considered acceptable if the accuracy is within -5% and +10% of the study plan specified application rate. If the application did 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 crop canopy penetration and coverage. Ensure the entire plot receives consistent spray coverage by starting and ending the application before and after the defined plot area, respectively.

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	DPX-QGU42	**35 g a.i./ha** (0.5 oz a.i./acre = 0.03125 lb a.i./acre or 14.175 g a.i./acre)	350 ml /ha + **surfactant*** ** (142 ml/acre)	Foliar directed	Min. 100 L/ha (min. 30 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).
L/ha = liters per hectare; GPA = gallons per acre. Minimum values are provided. **Use higher volumes as needed to provide maximum crop canopy penetration and coverage (Section 15)

***Surfactant:**
For US trials: Use a non-ionic surfactant (NIS), modified seed oil, spreader sticker or crop oil concentrate at a recommended label rate for all foliar applications.
Include a copy of the label in the RDFN.

For Canadian trials: Use the lowest registered label rate of a non-ionic surfactant (NIS), modified seed oil, spreader sticker or crop oil concentrate for all foliar applications.
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.

Make 4, foliar directed applications at a 5 (±1) day interval with the last application on the day of harvest (0 day PHI).

17. SUPPLEMENTAL CROP TREATMENTS:

The integrity of the greenhouse trial should be protected by minimizing damage to the test crop caused by pests. Only registered maintenance pesticides applied according to labeled directions can 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 which are similar to the test item, or other chemicals that might interfere with analysis of the test item. If unsure, contact the Study Director.

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

Fresh basil: 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 on the day of the last application (4th), after the spray has dried, when basil plants 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 2 plants from the plot ends must be avoided when sampling. Harvest a minimum sample weight of 0.5 kg (1.1 lb) consisting of whole plants (above ground portion, stems and leaves) from at least 12 separate areas within the plot. Remove dead and senesced leaflets only, except for the following circumstance: To reduce sample weight, woody portions of the stems may be cut off and discarded, retaining the leaves for the samples. If the basil plants are very large (greater than 225 g (8 oz) each, on average, after removal of woody portions) then further reduce the sample weight by sub-sampling whole branches with foliage from high and low, all quarters of the plants.

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. 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 (AAFC12-068R-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, labeling 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.

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)	Fresh stems and leaves
B	01	Untreated	N/A[1]	0.5 kg (1.1 lb)	Fresh stems and leaves
C	02	DPX-QGU42	0	0.5 kg (1.1 lb)	Fresh stems and leaves
D	02	DPX-QGU42	0	0.5 kg (1.1 lb)	Fresh stems and leaves

[1]Note 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 within ± 1 day.

20. RESIDUE SAMPLE HANDLING AND SHIPMENT:

After residue sample collection, place the samples into a freezer. If the fresh 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 described in 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 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)**
AAFC12-068R-296, AAFC12-068R-297	AAFC12-068R-330 *The shipping address will be identified at a later date, at which time the shipping information will be added by amendment* See section 24 for responsible person for this trial ID No.

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 records[3]
- Pass times (if applicable) and other data to confirm amount of material applied to plots
- Other applicable data requested in the RDFN[4] that are needed to prove that the conduct of the study was in accordance with the study plan.

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[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.

[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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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 the Study Director after sample shipment and appropriate review. The Principal Investigator will maintain a complete certified true copy of these field documents.

24. LABORATORY PERSONNEL/TRIAL ID NO.:
(Responsible for Sections 25-35)
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.
AAFC12-068R-330

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.

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 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 #: AAFC12-068R-_____

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