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

CARFENTRAZONE-ETHYL: MAGNITUDE OF THE RESIDUE ON LAVENDER

STUDY #: AAFC18-012R

STUDY DIRECTOR:

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FIELD TRIAL LOCATION:

Refer to Section 10, page 3

AAFC PESTICIDE RESIDUE STUDY PLAN
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1. STUDY TITLE:
Carfentrazone-ethyl: Magnitude of the Residue on Lavender

2. JUSTIFICATION AND OBJECTIVES:
Agriculture and Agri-Food Canada (AAFC) has received a request for the minor use label expansion of carfentrazone-ethyl on lavender. 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 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 on lavender, this Study Plan will be implemented using applicable Standard Operating Procedures (SOPs) and conducted under provisions outlined in Organisation 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 Pesticides Program, Building 57, Central Experimental Farm, 960 Carling Avenue, Ottawa, ON, K1A 0C6, Phone: 613-715-5390, Fax: 613-759-1400

4. STUDY DIRECTOR:
Greg O'Neill, Building 57, Central Experimental Farm, 960 Carling Avenue, Ottawa, ON, K1A 0C6, Phone: 613-694-2454, Fax: 613-759-1400, Email: greg.o'neill@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 Final 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.

AAFC PESTICIDE RESIDUE STUDY PLAN
CARFENTRAZONE-ETHYL: MAGNITUDE OF THE RESIDUE ON LAVENDER
STUDY #: AAFC18-012R

8. PROPOSED DATES:
Experimental Start: June 2018 Experimental Termination: June 2021

9. STUDY SIGNATURES:

May 28/2018

Study Director/ Date
Greg O'Neill
AAFC Minor Use Pesticides Program
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Phone: 613-694-2454
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May 25, 2018

Quality Assurance/ Date
Stéphane Laprise
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Phone: 613-759-1965
Fax: 613-759-1400
Email: stephane.laprise@agr.gc.ca

28 May 2018

Test Facility Management/ Sponsor Representative/Date
for Ian Gardiner, Submission Manager
AAFC Minor Use Pesticides Program
Building 57, Central Experimental Farm
960 Carling Avenue
Ottawa, ON K1A 0C6
Phone: 613-759-1581
Fax: 613-759-1400
Email: ian.gardiner@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 No.

PRINCIPAL INVESTIGATOR:
Rob Wismer
Agriculture and Agri-Food Canada
P.O. Box 6000, 4902 Victoria Avenue N.
Vineland Station, ON L0R 2E0
Phone: 905-562-2022
Email: robert.wismer@agr.gc.ca

TRIAL ID No. (Zone 5)
AAFC18-012R-184
(decline)

TEST SITE MANAGEMENT:
Jennifer Ballantine
Agriculture and Agri-Food Canada
Building 57, Central Experimental Farm
960 Carling Avenue
Ottawa, ON K1A 0C6
Phone: 613-759-7953
Email: jennifer.ballantine@agr.gc.ca

AAFC PESTICIDE RESIDUE STUDY PLAN
CARFENTRAZONE-ETHYL: MAGNITUDE OF THE RESIDUE ON LAVENDER
STUDY #: AAFC18-012R

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

TRIAL ID No. (Zone 5)
AAFC18-012R-185
(processing & exaggerated rate)

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

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

TRIAL ID No. (Zone 11)
AAFC18-012R-186

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

11. TEST SYSTEM/CROP:
Lavender- use a commercially established cultivar. At a minimum, record the cultivar name 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 following requirements must be met. Contact the Study Director prior to trial initiation to confirm trial distinction requirements.

An independently prepared tank mix must be used in each trial.
Also, select at a minimum: one option from Set 1 OR two options from Set 2, or a combination using Set 1 and Set 2 options

Set	Option*	Description
1	A	Trial sites must be separated by at least 32 km (20 miles)
	B	First application in each trial is separated by at least 30 days
	C	Different crop cultivar (different size or shape at maturity, rough vs. smooth surface, different amount of foliage shielding the commodity, different rate of growth, or representative of the major cultivars grown within the region) — **confirm with Study Director if this option will be chosen**
2	A	Spray volume must vary by at least 25% of the lower volume (minimum 100 L/ha (10.7 GPA) difference) Example : Trial A has a volume of 200 L/ha (21 GPA) and Trial B has a volume ≥ 300 L/ha (32 GPA) 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
	F	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 Raw Data Field Notebook the droplet size that results from the pressure and nozzles used in the trial (nozzle catalog may be used as a reference) Coarse, very coarse, and extra coarse are appropriate for herbicides only

***For clarity, the options that are not applicable, or not sufficient for trial distinction have been removed.**

If these criteria cannot be met to separate multiple trials, the Principal Investigator should 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.

12. TEST SYSTEM DESIGN and STATISTICAL METHOD:
Each trial site will consist of an untreated plot and a treated plot, except trial ID# AAFC18-012R-185 will have one additional treated plot to generate samples for the 5X exaggerated application rate purpose. Each individual plot will be established with a minimum area of 40 m^2. The untreated and treated plots for the decline trial will be a minimum of 40 m^2 and 60 m^2, respectively.

At a minimum, a 5 m buffer zone will be employed around the treated and untreated plots to prevent contamination[1]. Since this pesticide use is not registered on this crop, federal law requires that the treated (and untreated if specified in Section 17) crop must be destroyed, or handled in such a way that it is not consumed as a human food, or animal feed. Document the 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 # (AAFC18-012R-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 the crop, 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: Soil information 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 AIM EC Herbicide (240 g a.i./L), an emulsifiable concentrate formulation of carfentrazone-ethyl (CAS No. 128639-02-1; PCP Reg No. 28573; U.S. EPA Reg. No. 279-3194) **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, expiration date, 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. and 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 same spray mixture from one field trial for another field trial). To ensure that the test item is well mixed, agitate during the application, if practical. If practical, observe the test item in the spray mixture and provide documentation in the RDFN that the test item was completely dissolved/ mixed in the carrier

[1] Note that the buffer zone is considered to be 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 reach the appropriate speed before entering the plot; 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.

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 when wind speeds are less than 10 km/hour **on average** (unless approved by the Study Director), and 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[2] 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 ±5% of the average output, or -5% to +10% of the target pass time for speed calibration); or 3 acceptable runs out of the last 4 sequential checks. Note in this situation only the values from the 3 acceptable runs will be used for the 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 using the same equipment and application parameters, a single recheck of the output and speed is necessary. 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 application. The application is considered acceptable if the accuracy is within -5% and +10% of the study plan specified application rate, surfactant rate and the spray volume range limits. 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, then the application rate should be calculated using the maximum commercial row width. Contact the Study Director if guidance is needed.

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

16A. APPLICATION TREATMENTS AND TIMING (for TRIAL IDs# AAFC18-012R-184 and AAFC18-012R-186 outlined in SECTION 10):

Trt #	Treatment	Target Rate of active ingredient (g a.i./ha)	Target Rate of formulated product* (mL/ha)	Application Type**	Minimum Spray Volume (L/ha)
01	Untreated	Not Applicable	Not Applicable	Not Applicable	Not Applicable
02	Carfentrazone-ethyl	28	117	Ground application using a hooded sprayer applied between lavender rows (row middles)	100

*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 one ground application using a hooded sprayer applied between the rows (row middles) on both sides of emerged lavender crop, timed to obtain a 0-day pre-harvest interval (0-day PHI) for dry flower buds. DO NOT concentrate the application rate. The rate specified is for the treated area.**

Surfactant: Uses either Agral 90, or Ag-Surf at 0.25% v/v (0.25 litres surfactant per 100 litres of spray solution) with the test item.

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.
If it appears that phytotoxicity has resulted from applications made in this trial, contact the Study Director. If possible, take one or more photographs and send them to the Study Director via email to facilitate the evaluation of crop/test item effects.

16B. APPLICATION TREATMENTS AND TIMING (for PROCESSING TRIAL ID# AAFC18-012R-185 outlined in SECTION 10):

Trt#	Treatment	Target Rate of active ingredient (g a.i./ha)	Target Rate of formulated product* (mL/ha)	Application Type**	Minimum Spray Volume (L/ha)	Crop Fraction
01	Untreated	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Fresh flowers and dry flower buds
02	Carfentrazone -ethyl	28	117	Ground application using a hooded sprayer applied between lavender rows (row middles)	100	Dry flower buds
03	Carfentrazone -ethyl	140	585	Ground application using a hooded sprayer applied between lavender rows (row middles)	100	Fresh flowers

*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 one ground application using a hooded sprayer applied between the rows (row middles) on both sides of emerged lavender crop, timed to obtain a 0-day pre-harvest interval (0-day PHI) for fresh flowers and dry flower buds. DO NOT concentrate the**

application rate. The rate specified is for the treated area.

Surfactant: Uses either Agral 90, or Ag-Surf at 0.25% v/v (0.25 litres surfactant per 100 litres of spray solution) with the test item.

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.
If it appears that phytotoxicity has resulted from applications made in this trial, contact the Study Director. If possible, take one or more photographs and send them to the Study Director via email to facilitate the evaluation of crop/test item effects.

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 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. If an unregistered maintenance pesticide is used, crop from both the treated and untreated plots must be destroyed (Section 12). 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.

18A. RESIDUE SAMPLE COLLECTION (REVIEW SAMPLE INVENTORY IN SECTION 19A)
For each crop matrix, harvest **samples after the application (0-day PHI)** and after the spray droplets have dried. Harvest lavender starting with the untreated plot first, if both plots are being harvested by the same person. Otherwise, the order in which the samples are collected will not be an issue, if contamination between plots is minimized. A minimum of 30 cm, from the plot ends must be avoided when sampling. Collect two samples from the untreated plot and two samples from each treated plot at the appropriate harvest timing. Each sample is to be collected in a manner to ensure a representative, impartial sample.

After spray droplets have dried, harvest a minimum of **0.5 kg** (preferably not more than 1 kg) of dry flower buds, or fresh flowers per sample from at least 12 separate areas within each plot avoiding plot ends.

Dry Flower Buds Samples:
Harvest closed flower buds just prior to crop bloom and up to 10% crop bloom within the plot, making sure to avoid harvesting opened flower buds. Use a clean cutting device to cut stems from the lavender plants to obtain the closed flower buds. These cut stems containing closed flower buds can be bundled together and hung to dry in an area protected from moisture and contamination. Once the harvested material has dried to 8-12% moisture content, the dry flower buds must be stripped off of the stems and collected to be placed into labelled sample bag(s). Since this protocol has a 0-day PHI, harvest after the spray droplets have dried and take care not to contaminate the sample with spray residue.

Fresh Flowers Samples:
Harvest the fresh flowers when the majority of the crop has attained up to 90% bloom within the plot. Use a clean cutting device to cut fresh flowers from the lavender plants. Collect these cut fresh flowers directly into a labelled sample bag (preferred), or into a clean labelled container for transfer into a labelled sample bag. Since this protocol has a 0-day PHI, harvest after the spray droplets have dried and take care not to contaminate the sample with spray residue. The harvested fresh flowers will be used to process samples to oil.

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 (AAFC18-012R-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' beside the sample ID No. Contact the Study Director for approval regarding disposal of duplicate samples.

18B. SAMPLE COLLECTION (For DECLINE TRIAL ID# AAFC18-012R-184 outlined in SECTION 10, REVIEW SAMPLE INVENTORY IN SECTION 19B)
In addition to the samples required in Section 18A, collect two samples from the treated plot at **2(±1), 5 (±1) and 8 (±1)** days from the application. Follow the sampling method described in Section 18A.

18C. SAMPLE COLLECTION (For PROCESSING TRIAL ID# AAFC18-012R-185 outlined in SECTION 10, REVIEW SAMPLE INVENTORY IN SECTION 19C)
In addition to the samples required in Section 18A, collect one, 16 kg sample of fresh flowers from the untreated plot and one, 8 kg sample of fresh flowers from the treated plot #03 at 0-day from the application. Follow the sampling method described in Section 18A.

19A. RESIDUE SAMPLE INVENTORY (TRIAL ID# AAFC18-012R-186 ONLY):

SAMPLE ID	TRT #	TREATMENT	DAYS AFTER APPLIC.	MINIMUM SAMPLE WEIGHT (kg)	CROP FRACTION
A	01	Untreated	N/A[1]	0.5	Dry flower buds
B	01	Untreated	N/A[1]	0.5	Dry flower buds
C	02	Carfentrazone-ethyl	0	0.5	Dry flower buds
D	02	Carfentrazone-ethyl	0	0.5	Dry flower buds

[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, or 1-day before the 0-day PHI.

19B. DECLINE SAMPLE INVENTORY (DECLINE TRIAL ID# AAFC18-012R-184 ONLY):

SAMPLE ID	TRT #	TREATMENT	DAYS AFTER APPLIC.	MINIMUM SAMPLE WEIGHT (kg)	CROP FRACTION
A	01	Untreated	N/A[1]	0.5	Dry flower buds
B	01	Untreated	N/A[1]	0.5	Dry flower buds
C	02	Carfentrazone-ethyl	0	0.5	Dry flower buds
D	02	Carfentrazone-ethyl	0	0.5	Dry flower buds
E	02	Carfentrazone-ethyl	2 (±1)	0.5	Dry flower buds
F	02	Carfentrazone-ethyl	2 (±1)	0.5	Dry flower buds
G	02	Carfentrazone-ethyl	5 (±1)	0.5	Dry flower buds
H	02	Carfentrazone-ethyl	5 (±1)	0.5	Dry flower buds
I	02	Carfentrazone-ethyl	8 (±1)	0.5	Dry flower buds
J	02	Carfentrazone-ethyl	8 (±1)	0.5	Dry flower buds

[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, or 1-day before the 0-day PHI.

19C. PROCESSING SAMPLE INVENTORY (PROCESSING TRIAL ID# AAFC18-012R-185 ONLY):

SAMPLE ID	TRT #	TREATMENT	DAYS AFTER APPLIC.	MINIMUM SAMPLE WEIGHT (kg)	CROP FRACTION
A	01	Untreated	N/A[1]	0.5	Dry flower buds
B	01	Untreated	N/A[1]	0.5	Dry flower buds
C	02	Carfentrazone-ethyl	0	0.5	Dry flower buds
D	02	Carfentrazone-ethyl	0	0.5	Dry flower buds
K	01	Untreated	0	16	Fresh flowers
L	03	Carfentrazone-ethyl	0	8	Fresh flowers

[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, or 1-day before the 0-day PHI.

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 described in raw data. For pre-shipment storage, the samples will be held frozen at temperatures generally less than -18°C (0°F). To allow for temperature variations due to door opening, 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 the samples are delivered to analytical lab by field trial personnel. 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. Note: A PI must be identified in Section 24 prior to sample shipment. If this information is not included in Section 24, please contact the Study Director.**

Trial ID No.	Ship to: (Trial ID No., Contact and Shipping Address)
All trials listed in Section 10 (Except samples K and L from trial ID# AAFC18-012R-185)	AAFC18-012R-187 (laboratory facility) Attention: Heather Black AAFC-Vineland 4902 Victoria Avenue N. Vineland, Ontario L0R 2E0 Phone: 905-562-2011 Fax: 905-562-4335 Email: heather.black@agr.gc.ca See Section 24 for responsible person for this Trial ID No.
Trial ID# AAFC18-012R-185 samples K and L	AAFC18-012R-221 (processing facility) *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
- Pass times (if applicable) and other data to confirm amount of material applied to plots
- 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]
- Report soil information (organic matter, pH, Cationic Exchange Capacity) from a soil analysis that is ≤ 5 years old, unless otherwise approved by the Study Director. Soil textural percentages may be reported from any official documentation (e.g. Soil Survey or soil analysis) 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.
- Other applicable data requested in the RDFN 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

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[3] Weather/irrigation records 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) must be provided.

deviation form. Any deviation should be communicated to the Study Director either verbally, by fax or email within **48 hours** (document in communication log) of occurrence or recognition. The Study Director will assess the impact of the deviation on the study and act accordingly.

23. RAW DATA FIELD NOTEBOOK /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. PROCESSING PERSONNEL/TRIAL ID NO.:
(Responsible for Sections 25-27, the processing of designated samples)

The Principal Investigator and Test Site Management must sign and return the attached GLP acceptance form (see Appendix A).

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

TRIAL ID No.
AAFC18-012R-221

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

The processing facility will be identified at a later date, at which time the appropriate information will be added via an amendment.

25. PROCESSING SAMPLE INVENTORY:
As soon as samples arrive, place them in a freezer. The samples will be held frozen at temperatures generally less than -18°C, 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. **Samples should be processed within 7 days of arrival at the processing trial site.**

Immediately prior to processing[4], remove a representative sub-sample of fresh flowers from the untreated and treated samples (minimum 0.25 kg for each sub-sample) and place material into suitable clean containers. Label each container with Trial ID No. AAFC18-012R-221, Crop, Treatment No., Treatment Name and Processed Sample ID. See the table below for detailed information.

Using simulated commercial processing (provide detailed description of equipment and procedures), produce oil from the designated untreated and treated fresh flower samples. Process untreated fresh flower samples first, followed by the treated fresh flower samples. Follow proper handling practices with clean, or gloved hands and clean tools to prevent transfer of pesticide residue from one sample to another. The processing activities must reflect commercial processes. During the processing activity, clean, labelled containers must be used to collect processed material. Record initial and final sample weights, as well as the weight of any removed fraction. See the table below for Sample ID and quantity information. Place each oil sample into a separate clean container and label each container with Trial ID No. AAFC18-012R-221, Crop, Treatment No., Treatment Name, Processed Sample ID and Processing Date.

If the processed samples cannot be placed into a freezer within one hour of collection, an appropriate method of cooling samples must be used to maintain sample integrity. Temperatures of the samples must be monitored.

4 "Immediately prior" includes the day of processing.

AAFC PESTICIDE RESIDUE STUDY PLAN
CARFENTRAZONE-ETHYL: MAGNITUDE OF THE RESIDUE ON LAVENDER
STUDY #: AAFC18-012R

PROCESSED SAMPLE INVENTORY:

FRESH FLOWERS SAMPLE USED	PROCESSED SAMPLE ID	TRT #	TREATMENT	SAMPLE TYPE	MINIMUM SAMPLE SIZE
K	AA	01	Untreated	Fresh flowers subsample	0.25 kg
L	BB	03	Carfentrazone-ethyl	Fresh flowers subsample	0.25 kg
K	CC	01	Untreated	Oil	80 mL
L	DD	03	Carfentrazone-ethyl	Oil	40 mL

26. PROCESSING SAMPLE INVENTORY:

For Processed Sample IDs AA, BB, CC and DD: Place the sample into a freezer. For pre-shipment storage, the sample will be held frozen at temperatures generally less than -18°C, 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, processing raw data field notebook, communication note, etc.

Send samples to the laboratory identified in Section 28. For samples packed with dry ice, avoid shipments from Thursday through Sunday. Note: A PI must be identified in Section 28 prior to sample shipment. If this information is not included in Section 28, please contact the Study Director.

Trial ID No.	Ship to: (Trial ID No., Contact and Shipping Address)
AAFC18-012R-221 Processed Sample IDs AA, BB, CC and DD	AAFC18-012R-187 (laboratory facility) Attention: Heather Black AAFC-Vineland 4902 Victoria Avenue N. Vineland, Ontario L0R 2E0 Phone: 905-562-2011 Fax: 905-562-4335 Email: heather.black@agr.gc.ca See Section 24 for responsible person for this Trial ID No.

27. PROCESSING DOCUMENTATION AND RECORD KEEPING:

The following information should also be recorded directly and promptly into the Processing Raw Data Field Notebook (PRDFN) provided by AAFC:
The events and procedures involved in processing of lavender fresh flowers into oil will be fully detailed and will at a minimum include:
-Names of all personnel conducting specific processing functions
-Test site information, including processing field trial location and processing facility (or facilities) location
-Date and condition of samples upon receipt at all facilities handling the samples
-Temperature records for sample storage

-Processing methodology used to process the samples into oil
-Identification of equipment used (make/model, ID No.)
-Method used to clean the equipment prior to use and between samples
-Disposal method of any unused portion of the samples
-Details of shipment of processed samples to the analytical laboratory
-Amendments and deviations from this Study Plan

28. LABORATORY PERSONNEL/TRIAL ID NO.:
(Responsible for Sections 29-45)
The Principal Investigator and Test Site Management must sign the GLP Acceptance form (Appendix A) and return as directed.

PRINCIPAL INVESTIGATOR:
Heather Black
AAFC-Vineland
4902 Victoria Avenue N.
Vineland, ON L0R 2E0
Phone: 905-562-2011
Fax: 905-562-4335
Email: heather.black@agr.gc.ca

TRIAL ID No.
AAFC18-012R-187

TEST SITE MANAGEMENT:
Marcos Alvarez
Building 57, Central Experimental Farm
960 Carling Avenue
Ottawa, ON K1A 0C6
Phone: 613-759-7135
Fax: 613-759-1400
Email: marcos.alvarez@agr.gc.ca

29. LABORATORY SAMPLE INVENTORY:
Treated and untreated crop samples will be received from the field sites and processing facility outlined in Section 20 (for responsible persons see Section 10 and Section 24). Notify the appropriate Principal Investigator and Study Director of sample receipt by returning (by fax, email, or mail) a copy of the completed Chain of Custody form, or a similar laboratory form used for sample arrival confirmation.

30. 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 Final Analytical Report.

31. LABORATORY SAMPLE STORAGE/PREPARATION:
Store samples in a limited access area at temperatures that will maintain frozen sample integrity at generally less than –18°C (0°F), allowing for temperature variations [due to door opening, freezer cycling, sample movement, etc.] until extraction. The samples may be stored whole or macerated, depending on the standard procedure of the analytical laboratory. However, if maceration will cause residue deterioration, then samples must be stored whole until extraction. 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.

Upon receipt of the samples and reference item(s), using a macerated control sample, prepare

and freeze four provisional sets of samples (three fortified samples plus four unfortified samples per set) fortified at the targeted highest concentration of method validation. These provisional sample sets will be analyzed **only** if there is a delay for frozen storage stability analysis as outlined in Section 38. Should analysis of the provisional sample sets be necessary, the samples will be analyzed at two time points: 1) as soon as possible after method validation is completed and approved by Study Director, and 2) at a time to cover the period from the earliest harvest date of any sample from any trial in this study to the last date of sample analysis.

Information for Sections 32-45 will be identified at a later date, at which time the appropriate information will be added by amendment.

AAFC PESTICIDE RESIDUE STUDY PLAN
CARFENTRAZONE-ETHYL: MAGNITUDE OF THE RESIDUE ON LAVENDER
STUDY #: AAFC18-012R

APPENDIX A

GLP Acceptance Form

Trial ID #: AAFC18-012R-_____ (add unique three digit trial ID. No)

I acknowledge that the research for this trial will be conducted in accordance with the Study Plan and any amendments under the OECD GLP Principle of Good Laboratory Practices (revision 1997). 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 sent to the individual identified below and copied to the Study Director.* ***The original form should be retained in the RDFN, PRDFN or lab raw data.***

GLP Admin
AAFC Minor Use Pesticides Program
Building 57, Central Experimental Farm
960 Carling Avenue
Ottawa, ON, Canada
K1A 0C6
Fax: 613-759-1400
Email: GLPArchivist@AGR.GC.CA

STUDY PLAN AMENDMENT

Study Number: AAFC18-012R Carfentrazone-ethyl: Magnitude of the Residue on Lavender

Study Plan Sections: 1) 18A. Residue Sample Collection (Review Sample Inventory in Section 19A)
2) 18C. Sample Collection (For Processing trial ID# AAFC18-012R-185 outlined in Section 10, Review Sample Inventory in Section 19C)
3) 14. Test Item:

Description of Changes:

1) 18A. Residue Sample Collection (Review Sample Inventory in Section 19A)
EFFECTIVE DATE: June 25, 2018

Change from:

After spray droplets have dried, harvest a minimum of **0.5 kg** (preferably not more than 1 kg) of dry flower buds, or fresh flowers per sample from at least 12 separate areas within each plot avoiding plot ends.

Dry Flower Buds Samples:
Harvest closed flower buds just prior to crop bloom and up to 10% crop bloom within the plot, making sure to avoid harvesting opened flower buds. Use a clean cutting device to cut stems from the lavender plants to obtain the closed flower buds. These cut stems containing closed flower buds can be bundled together and hung to dry in an area protected from moisture and contamination. Once the harvested material has dried to 8-12% moisture content, the dry flower buds must be stripped off of the stems and collected to be placed into labelled sample bag(s). Since this protocol has a 0-day PHI, harvest after the spray droplets have dried and take care not to contaminate the sample with spray residue.

Fresh Flowers Samples:
Harvest the fresh flowers when the majority of the crop has attained up to 90% bloom within the plot. Use a clean cutting device to cut fresh flowers from the lavender plants. Collect these cut fresh flowers directly into a labelled sample bag (preferred), or into a clean labelled container for transfer into a labelled sample bag. Since this protocol has a 0-day PHI, harvest after the spray droplets have dried and take care not to contaminate the sample with spray residue. The harvested fresh flowers will be used to process samples to oil.

Change to:

After spray droplets have dried, harvest sufficient fresh flower buds, from at least 12 separate areas within each plot, to yield a minimum of **0.5 kg** (preferably not more than 1 kg) of dry flower buds avoiding plot ends.

Dry Flower Buds Samples:
Harvest fresh flower buds just prior to crop bloom and up to 10% crop bloom within the plot. Use a clean cutting device to cut stems with fresh flower buds from the lavender plants. After harvest, dry the sample material to 8-12% moisture content. These cut stems with flower buds should be dried in an area protected from moisture and contamination. Bundling together of stems for hang drying is an acceptable drying method. After drying, dried flower buds must be stripped from the stems and placed into labelled sample bag(s) (Samples may be placed into smaller, plastic bags, for ease of weighing, which are then placed into the larger labelled sample bags). Since this study plan has a 0-day PHI, harvest after the spray droplets have dried and take care not to contaminate the sample with spray residue.

Reason for Change:

To delete instructions in Section 18A related to harvesting fresh flowers and to move those instructions to Section 18C. To provide clarity related to harvesting fresh flower buds to generate the dried flower buds samples.

2) 18C. Sample Collection (For Processing trial ID# AAFC18-012R-185 outlined in Section 10, Review Sample Inventory in Section 19C)

Change from:

In addition to the samples required in Section 18A, collect one, 16 kg sample of fresh flowers from the untreated plot and one, 8 kg sample of fresh flowers from the treated plot #03 at 0-day from the application. Follow the sampling method described in Section 18A.

Change to:

In addition to the samples required in Section 18A, collect one, 16 kg sample of fresh flowers from the untreated plot and one, 8 kg sample of fresh flowers from the treated plot #03 at 0-day from the application. Follow the sampling method described in Section 18A.

Fresh Flowers Samples:
Harvest the fresh flowers when the majority of the crop has attained up to 90% bloom within the plot. Use a clean cutting device to cut fresh flowers **with no stem** from the lavender plants. Collect these cut fresh flowers directly into a labelled sample bag (preferred), or into a clean labelled container for transfer into a labelled sample bag. Since this protocol has a 0-day PHI, harvest after the spray droplets have dried and take care not to contaminate the sample with spray residue. The harvested fresh flowers will be used to process samples to oil.

Reason for Change:

To delete instructions in Section 18A related to harvesting fresh flowers and to move those instructions to Section 18C. Also, to emphasize the areas to harvest fresh flowers and to exclude stems in the harvest of fresh flowers.

3) 14. Test Item:

Change from:

Use the AIM EC Herbicide (240 g a.i./L), an emulsifiable concentrate formulation of carfentrazone-ethyl (CAS No. 128639-02-1; PCP Reg No. 28573; U.S. EPA Reg. No. 279-3194) **that has been characterized to meet GLP** standards.

Change to:

Use the AIM EC Herbicide (240 g a.i./L), **or AIM 2 EC Herbicicde (22.3%, 2 lbs a.i./US gallon) which are** an emulsifiable concentrate formulation of carfentrazone-ethyl (CAS No. 128639-02-1; PCP Reg No. 28573; U.S. EPA Reg. No. 279-**3241**) **that has been characterized to meet GLP standards.**

Reason for Change:

To provide information related to an alternative name of the test item and to correct a typo in the U.S. EPA Reg. No.

Signatures:

Study Director: Greg O'Neill — Date: July 3/2018

Test Facility Management/: Sponsor Representative: Shuhua Liu (Acting Submission Manager) — Date: 3 July 2018

Reviewed by: Quality Assurance: Ting Xie — Date: July 3. 2018

Temporary/Short-Term Change of Study Director
Changement temporaire ou à court terme de directeur d'étude

Description of Change / Description de la modification:

Study Number/ Numéro d'étude:	AAFC18-012R
Study Director/ Directeur d'étude:	Greg O'Neill
Temporary Study Director/ Directeur d'étude temporaire:	Kalidas Subedi AAFC Minor Use Pesticide Program Building 57, Central Experimental Farm 960 Carling Avenue Ottawa, ON K1A 0C6 Phone /Téléphone: 613-715-5536 Fax/ Téléc: 613-759-1400 Email /courriel: kalidas.subedi@agr.gc.ca
Dates:	July 14 to July 29, 2018 14 juillet au 29 juillet, 2018

Reason for change / Motif de la modification:

The Study Director for AAFC18-012R will be unavailable for the dates listed above. During this period please contact the temporary Study Director listed above. After the end date listed above, all communications must be transferred to the Study Director.

Le directeur d'étude pour AAFC18-012R ne sera pas disponible pour les dates indiquées ci-dessus. Pendant cette période, s' il vous plaît contacter le directeur d'étude temporaire indiqué ci-dessus. Après la date de fin indiquée ci-dessus, toutes les communications doivent être adressées au directeur d'étude.

Signatures

Study Director/
Directeur d'étude: Greg O'Neill — July 10/2018 — Date

Temporary Study Director/
Directeur d''étude temporaire: Kalidas Subedi — 10 July, 2018 — Date

Test Facility Management- Sponsor Representative/
Direction de l'installation d'essai - Donneur d'ordre : Shuhua Liu — 10 July 2018 — Date

Reviewed by/Révisé par
Quality Assurance /Assurance qualité: Ting Xie — July 10. 2018 — Date

STUDY PLAN AMENDMENT

Study Number: AAFC18-012R Carfentrazone-ethyl on Lavender

Study Plan Section(s): 32 to 45

Description of Changes:

Change: Addition of Sections 32 through 45 to the Study Plan.

32. ANALYTICAL SPECIFICATIONS:

- **Residue Definition** – carfentrazone-ethyl, 3-hydroxymethyl carfentrazone chloropropionic acid and carfentrazone chloropropionic acid
- **Analyte Definition** – carfentrazone-ethyl, 3-hydroxymethyl carfentrazone chloropropionic acid and carfentrazone chloropropionic acid
- **Crop fractions/Matrices** – dried flower buds, flowers and oil
- **Lowest Level of Method Validation (LLMV)** = 0.05 ppm

33. LABORATORY REFERENCE ITEM(S):

Laboratory Reference Items, carfentrazone-ethyl, 3-hydroxymethyl carfentrazone chloropropionic acid and carfentrazone chloropropionic acid obtained from the Registrant are to be used, unless otherwise approved by the Study Director. If required, to procure the Reference Items, contact: Theresa Geil, FMC Corporation at phone: (226) 979-2247, email: theresa.geil@fmc.com, and document the request in the raw data. Document the date the Reference Items are received, the source, lot number, stated purity, storage conditions, and expiration date. Use only Reference Items that have been characterized to meet GLP standards. Contact the Study Director if there are any concerns regarding the GLP characterization, label identification of the Reference Items (e.g., the name on the bottle, or certificate of analysis (CoA) is different from the Study Plan), etc. and if the Reference Items do not come with the CoA. Characterization of the Reference Items (purity, identity, stability, and solubility) and maintenance of an archival sample is the responsibility of the Registrant unless otherwise specified by the Study Director.

34. REFERENCE METHOD:

Residue Methodology for the Determination of F8426 and Its Acid Metabolites in/on the Small Grain Crops, P-3263 (revised 7/98), Study# 842MVL97R1. FMC Corporation. Natalie Shevchuk, July 30, 1998.

Acceptable modifications to the reference method can be found in the following documents:

Magnitude of the Residues of Carfentrazone-Ethyl (F8426) and its Major Metabolites in/on Soybeans Treated with F8426 2EC, F8426 2EW or F8426 40DF Herbicide. P-3768R (Revised 8/2005), Study# 842SOY04R1. FMC Corporation. Audrey Chen. August 24, 2005

and

Magnitude of the Residues of Sulfentrazone and Carfentrazone-ethyl and Their Respective Major Metabolites in/on Clover and Alfalfa Treated with Spartan Charge and AIM Herbicides. PC0515. Study# 000NGR08R1. FMC Corporation. Audrey Chen. March 22, 2010.

If modifications to the reference method are necessary to analyze the specific crop fractions, a working method is to be prepared. The working method is to provide all necessary steps in the analysis, including instrument conditions, and is to have a section outlining the need for major

modifications from the reference method.

Note: any MS method must have a minimum of two MRM transitions for each analyte, one for quantification and one for confirmation.

Provide the Study Director with the information specified in Section 43, prior to method validation.

35. CALIBRATION STANDARDS PREPARATION:
Unless approved by the Study Director, calibration curves are to be comprised of a minimum of five calibration standards prepared from a) at least two different stock solutions (i.e., individually prepared from different weighings of the Reference Items) and injected in alternation[1] or b) a single stock solution that has been verified against the concentration of a second stock solution. Calibration standards response **must bracket:** the lowest and highest levels of method validation samples; the analyte response of the fortification samples; treated samples with residues above the LLMV; and (if applicable) method validation extension samples. The use of a zero standard[2] or blank as part of the calibration series is not acceptable. A calibration curve is to be generated for each analyte listed in the analyte definition using solvent-based calibration standards. Use of matrix-matched calibration standards instead of solvent-based calibration standards must be experimentally justified during method validation and approved by Study Director for further use.

36. ANALYTICAL SETS:
The analytical system must be equilibrated/conditioned before the start of an analytical run to ensure that the entire system is suitable for analysis. If conditioning injections are included as part of a sequence, they must be clearly designated as conditioning runs. In each analytical run, the solvent blank(s), reagent blank(s) and matrix blank (if matrix-matched standards are used) must be run before the first set of calibration standards. In addition, a solvent blank must be run immediately after the highest calibration standard, or the highest level fortification sample, to ensure the analysis is free of carryover and/or interferences. The complete calibration set (all calibration standards used to prepare the curve) must be injected before the first and after the last sample. Additionally, calibration standards must be interspersed during the analytical run to ensure goodness of fit to the calibration curve. The acceptable back-calculated[3] concentrations for injected calibration standards are to be within ±20% of the respective theoretical concentrations. Values outside of this range must be justified and sent to the Study Director.

Each injection set (including those with re-injected or diluted sample extracts) should include calibration standards, control (untreated) sample(s), fortified sample(s), a reagent and solvent blank, and if applicable, treated samples.

All field and fortified sample injections must be made in duplicate. The difference in response between duplicate injections is to be ≤10%, otherwise the sample is to be re-injected in duplicate. The mean residue value from the two acceptable injections is to be reported and used in all subsequent calculations. If the re-injection fails, the issue must be investigated. If responses of the duplicate injection are both below the lowest calibration standard, re-injection is not required.

37. METHOD VALIDATION:

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[1] For example, (X, O, X, O, X) but not (X, X, X, O, O), where X is the calibration standard prepared from one stock solution and O is the calibration standard prepared from a second stock solution.
[2] A zero standard is a calibration solution containing no analyte of interest (may contain the internal standard).
[3] Back-calculated means determining the concentrations of the calibration standards using the regression equation. The calculated concentration of each calibration standard is then compared to the actual concentration using the formula: *observed concentration/theoretical concentration x 100.*

The method must be validated for each compound in the Residue Definition, for each crop fraction, by using either store-purchased (preferably organic) crop fraction or using one of the untreated field samples. To validate the method(s) analyze a minimum of one control (untreated) sample and three replicate fortifications, at each of the following levels: **LLMV, 2X LLMV and 10X LLMV**. The minimum number of validation samples required is 10. The acceptable recovery range is 70-120% and %RSD ≤20%. Documented approval from the Study Director is needed for all recoveries outside of this range.

Document the working method, with "stopping points", that will be used for sample analysis. This validated step-by-step working method must outline all changes from the reference method.

Method LOD and LOQ:
As part of the method validation, it must be possible to calculate the method LOD and LOQ for each analyte in each matrix. Either the LOD and LOQ must be determined using a method approved by the SD, or a minimum of six fortified control samples at LLMV must be analyzed and used to calculate LOD and LOQ.

Method Validation Extension:
During sample analysis, if residue levels are greater than the highest concentration validated, the method validation needs to be extended. As soon as practical, analyze three replicates of a control (untreated) sample fortified at a concentration above the highest level of residues found in the treated samples (for further guidance see Section 39). A solvent blank is to be analyzed after the highest fortified sample. The acceptable recovery range is 70-120% and %RSD ≤20%. Documented approval from the Study Director is required for all recoveries outside of this range.

Statistical Method(s):
Unweighted linear regression (y=mx +b), which is not forced through the origin, is to be used to generate calibration curves, unless otherwise approved by the Study Director. Calibration curves will have the coefficient of determination (r^2) ≥ 0.99 and back-calculated calibration standard concentrations are to be within ±20% of the theoretical concentration. In general, data points for calibration curves will not be dropped unless justification is sent to, and approved by, the Study Director.

Provide the Study Director with the information specified in Section 43, for Study Director's approval, prior to sample analysis.

38. STABILITY ANALYSIS:

Stability of Standard Solutions (stock, intermediate/working, and calibration solutions):
Standard solution stability is the stability of a compound, in a unique solvent and storage condition combination, for a defined period of time. If standard solutions for compounds identified in the residue and analyte definitions are not prepared and stored as stated above, or are not prepared fresh daily, or unless documentation of standard stability is provided and approved by the Study Director, standard stability must be conducted. This is to be done by analyzing a solvent/reagent blank to ensure there is no interference, and then comparing the average response factor (a minimum of five replicate injections) of the aged standard solution (aged for the longest time period the standard was used in the study) to the average response factor (a minimum of five replicate injections) of a freshly prepared[4] standard solution. The compound will be considered stable in solution if the response factor of the aged standard is within ±10% of the freshly prepared standards. Values outside of this range may require re-analysis, as determined by the Study Director, or Principal Investigator.

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[4] Freshly prepared standard – a standard prepared from a new weighing of the Reference Items on the DATE of comparison.

Stability of Analytes in Stored Extracts:
All extracts should be stored in a refrigerator[5]. Stability of analytes in stored extracts must be demonstrated if extracts are not analyzed within 24 hours of preparation, unless previously determined for longer time frame. Stability is to be conducted in the following way:

- Analyze a set of samples and then age the samples. After a specific period of time, re-analyze the sample set. If average results in the first analysis (original set) are within ±10% of those in the second analysis (aged set), the extracts will be considered stable.

Other stability testing methods must be approved by the Study Director.

Frozen Storage Stability Analysis:
If extraction of treated and control (untreated) samples is completed within **30 days** of harvest analysis of frozen storage stability samples will not be required.

If frozen[6] storage stability analysis is required, it should be set up as soon as possible after method validation. Utilizing a control sample from each crop fraction, samples are to be prepared by fortifying them with each compound in the residue definition at the highest level of method validation. For day 0 (the same day the frozen storage samples are prepared), three freshly fortified samples and one control sample are to be analyzed. For all other timeframes (for each timeframe required plus two contingency sets), place a minimum of three fortification samples and four unfortified control samples in frozen storage. After the appropriate storage period, beginning at 30 ± 5 days, and then every 90 ± 10 days thereafter, for each compound per crop fraction, three freshly fortified frozen control samples are to be prepared and analyzed along with an unfortified control sample and three aged fortified samples. The last storage sample is to be analyzed at a time period greater than the longest interval between harvest and extraction[7],[8]. Recoveries of the aged fortified samples are to be compared to the recoveries of the freshly fortified samples. If at any time point the recoveries differ by 20% or more, the results will be reported within a week to the Study Director and another sample set will be analyzed as soon as possible (usually within a week of occurrence). The Study Director must also be notified within a week if freshly fortified recoveries deviate from the acceptable recovery range of 70-120% and %RSD of ≤20%.

39. SAMPLE ANALYSIS:
Samples are to be analyzed and reported for all compounds in the Residue Definition, following the successful validation of the working method. The analysis is to be conducted in the same manner as that used for the method validation. **Any modifications to the working method may require method re-validation, and must be approved by the Study Director**. Whenever possible, notify the Study Director prior to occurrence. Any modification to the working method must be documented in the raw data and the Final Analytical Report.

For each field trial associated with this study, analyze at least one control (untreated) and all treated residue samples for each crop fraction. Contact the Study Director immediately if

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[5] Refrigerator refers to storage temperatures of generally 2 to 9°C, with normal variations due to door opening, etc. To allow for normal temperature variations due to refrigerator cycling, sample movement, etc., temperature fluctuations between 2°C and 15°C for a duration of no longer than six hours are acceptable; however, samples must remain frozen at all times. Contact the Study Director as soon as possible if refrigerator temperatures rise above 15°C.
[6] Frozen storage refers to storage of samples at temperatures generally less than -18°C (0°F). To allow for normal temperature variations due to freezer cycling, sample movement, etc., temperature fluctuations between -18°C and 0°C for a duration of no longer than six hours are acceptable; contact the Study Director as soon as possible if freezer temperatures rise above 0°C.
[7] The final time period may be longer or shorter than the scheduled 90-day interval, as approved by the Study Director.
[8] Provisional samples collected in Section 31, if needed, should be analysed as described in Section 38.

residues above 20% of the LLMV are detected in the control samples, for any crop fraction. The Study Director must also be notified within a week if residues in any of the treated samples are higher than the highest level of method validation or if they fall outside of the calibration range.

In addition to the treated samples, at least one control (untreated) sample and a minimum of two concurrent fortification samples, each one at a different level (that bracket the expected residue levels), for each compound in the residue definition for each crop fraction, are to be analyzed per analytical set. The Study Director must be notified within a week if concurrent recoveries deviate from the acceptable recovery range of 70-120% and %RSD ≤20%.

Sample extracts with analyte response that exceeds the calibration curve range will be diluted accordingly, and re-injected in a timely manner. The method validation may also need to be extended (see Section 37). Any treated samples with residue levels higher than the level validated during the original method validation must be re-extracted and re-analyzed with a concurrent fortification above the expected residue level (in addition to the method validation extension fortifications Section 37). In such a case, the treated samples may be injected with bracketing concurrent fortifications either during the method validation extension set or in a separate set.

Provide the Study Director with the information specified in Section 43, for Study Director's review and approval.

40. DISPOSITION OF SAMPLES:
A minimum of 100 g of the remaining frozen treated and control crop samples must be retained for at least 12 months after the Final Analytical Report is completed. The Study Director's approval is required prior to discarding remaining samples from the field or frozen storage stability study. Sample extracts may be disposed of after data analysis.

41. LABORATORY STUDY PLAN/SOP MODIFICATIONS - LABORATORY RESEARCH:
Consult with the Study Director regarding desired changes to the Study Plan **prior to occurrence**. If appropriate, an amendment will be issued. Any unauthorized changes to the Study Plan will require the Principal Investigator or Study Director to complete a deviation outlining the changes. This deviation should be provided to the Study Director promptly (e.g., usually within 24 hours of noticing the occurrence) for review and signature. All deviations from the approved SOPs also require documentation and approval by the Study Director.

42. LABORATORY DOCUMENTATION AND RECORD KEEPING:
A study file shall be developed and maintained by the Principal Investigator throughout the analysis. It will contain a true copy of the Study Plan, all pertinent raw data, documentation, records, correspondence, and the Final Analytical Report. In addition, records of equipment maintenance and calibrations will be maintained and archived by the Laboratory Facility.
All operations, data, and observations shall be recorded in the analyst's notebook, log books, or forms, which must be signed and dated upon entry. All pages of the raw data should include the Trial ID# and page number. At a minimum, collect and maintain the following raw data:

- Names of personnel conducting specific laboratory functions
- Chain of custody records
- Reference items, Certificate of Analysis, receipt, use, storage location conditions and disposition records
- Sample storage conditions and locations
- Standard solution(s) and prepared reagents: storage conditions, dilution calculations and preparation records
- Solvent(s) name, lot number, expiration date and source (manufacturer)
- Sample analysis worksheets, including details of dilution of extracts
- Concurrent recovery fortification records

- Storage stability fortification records
- All chromatograms, including those that are not reported
- Calculation work sheets, statistical assessment, (means, standard deviations)
- Deviations from the Study Plan, working method and SOPs

43. LABORATORY REPORTING TO THE STUDY DIRECTOR:

At each reporting phase, at a minimum, a copy of the following documents is to be sent to the Study Director:

Method Validation Preparation:

- Certificate(s) of Analysis for all laboratory Reference Items
- Explanation of key modifications to the Reference Method
- The proposed working method

Method Validation:

- Working method (including stopping points and any changes if different from method validation preparation)
- Results, including:
    - summary of data
    - acquisition information
    - calibration curves with equation for the applied regression and coefficient of determination (r^2)
    - chromatograms of the solvent, reagent blank, standards, fortified samples and control (untreated) sample
    - calculation worksheets (formula and calculations) including:
        - details of dilution of extracts
        - back-calculation for calibration standard concentrations
        - % difference in duplicate injections, mean and standard deviation, % recovery, and % RSD
- Standard solution(s): worksheets for preparation, storage conditions, dilution calculations and preparation records
- Worksheets for preparation of frozen storage stability samples (if applicable)

Sample Analysis:

- Results, including:
    - summary of data
    - acquisition information
    - calibration curves with equation for the applied regression and coefficient of determination (r^2)
    - chromatograms of the solvent, reagent blank, standards, fortified samples, treated and untreated sample
    - calculation worksheets (formula and calculations) including:
        - residue analysis
        - details of dilution of extracts
        - back-calculation for calibration standard concentrations
        - % difference in duplicate injections, mean and standard deviation, % recovery, and % RSD

44. FINAL ANALYTICAL REPORT:

The Final Analytical Report sent to the Study Director shall contain, but not be limited to:

- Reference items COAs and identity including name, structure, purity, lot number, expiration date, source (manufacturer) and storage
- Cross-reference of sample identification numbers
- Detailed description of sub-sampling, maceration procedures and sample storage
- Modifications to the Reference Method and purpose/justifications of those modifications

- Calibration standards weights and preparation procedures
- Complete copy of the step-by-step analytical working method
- Detailed description of stock solutions and standard solutions storage (container type, storage description including place and number, temperature range, and any temperature fluctuations)
- Clearly presented example calculations and statistical evaluations
- Discussion of results (method validation, concurrent fortification results, field sample results, stability analysis results) including how Study Plan requirements were met, and any modifications or deviations from the Study Plan and/or working method
- Method validation data
- Summary data associated with calibration standards and calibration curves (concentration range, regression type, correlation of x and y)
- Summary of quantitative data associated with fortified samples should be provided (e.g., sample weights, final volumes, injection volumes, peak areas/heights, recoveries, % RSDs.)
- Summary of important experimental dates (harvest dates, sample receipt dates, maceration dates, extraction dates, analysis dates, and number of days between harvest date and extraction date)
- Residue levels for untreated and treated samples
- Stability data of standard solutions and analytes in extracts (if required as per Section 38)
- Frozen sample storage stability data (if required in Section 38)
- Representative chromatograms including the following (note: a "set" represents an analytical injection run done on a particular day):
    - Calibration standards (for each analyte), include one chromatogram for each concentration level and the corresponding calibration curve for one set. In addition, include one chromatogram from each set at the LLMV
    - If matrix-matched standards are used, a solvent-based calibration curve as well as one chromatogram at the LLMV must be included for comparison
    - Method validation (for each compound and crop fraction): one chromatogram for each fortification level used (including method validation extensions)
    - Concurrent recoveries (for each compound and crop fraction): chromatograms showing recoveries at the LLMV, as well as the high level fortification
    - Controls (for each compound and crop fraction): at least one untreated control (UTC) chromatogram per trial, ensuring these include one UTC chromatogram per set
    - Treated samples (for each compound and crop fraction): minimum of ten chromatograms (all if less than 10 in the study), depicting representative samples per Trial ID covering each day of harvest and covering each day of analysis (ensuring a mixture of C or D samples, a mixture of E or F, etc.)
    - Blanks: one solvent, one reagent and one matrix blank chromatogram. Additionally, include solvent blank chromatogram that was run after a highest level analytical standard or the highest level fortification sample
    - Any chromatograms with unusual or inconsistent results
- Supporting information (acquisition method and run sequences)

45. LABORATORY ARCHIVES:

When the Final Analytical Report is completed, the report and all original raw data (hard copy and a scanned [electronic] copy) will be sent to the Study Director, unless another location is designated by the Study Director. The Principal Investigator/Testing Laboratory will maintain a scan, or printed copy of these documents. The original raw data will be secured in the archives of the Sponsor once the study is completed.

Reason for Change: Sections 32 through 45 include information related to the laboratory and analytical method to be used for this study. This information was not available for inclusion in the Study Plan when it was issued.

Signatures:

Study Director:	Greg O'Neill	Sept 20/2018 Date
Test Facility Management/: Sponsor Representative	Sheryl Lonsbary Acting Submissions Manager	19-Sept-18 Date
Reviewed by: Quality Assurance	Ting Xie	Sept 17, 2018 Date

STUDY PLAN AMENDMENT

Study Number: AAFC18-012R Carfentrazone-ethyl on Lavender

Study Plan Section(s): 1) 10
2) 24

Description of Changes:

1) Section 10:

Change from:

PRINCIPAL INVESTIGATOR:
Rob Wismer
Agriculture and Agri-Food Canada
P.O. Box 6000, 4902 Victoria Avenue N.
Vineland Station, ON L0R 2E0
Phone: 905-562-2022
Email: robert.wismer@agr.gc.ca

TRIAL ID No. (Zone 5)
AAFC18-012R-184
(decline)

TEST SITE MANAGEMENT:
Jennifer Ballantine
Agriculture and Agri-Food Canada
Building 57, Central Experimental Farm
960 Carling Avenue
Ottawa, ON K1A 0C6
Phone: 613-759-7953
Email: jennifer.ballantine@agr.gc.ca

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

TRIAL ID No. (Zone 5)
AAFC18-012R-185
(processing & exaggerated rate)

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

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

TRIAL ID No. (Zone 11)
AAFC18-012R-186

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

Change to:

PRINCIPAL INVESTIGATOR:
Rob Wismer
Agriculture and Agri-Food Canada
P.O. Box 6000, 4902 Victoria Avenue N.
Vineland Station, ON L0R 2E0
Phone: 905-562-2022
Email: **robert.wismer@canada.ca**

TRIAL ID No. (Zone 5)
AAFC18-012R-184
(decline)

TEST SITE MANAGEMENT:
Jennifer Ballantine
Agriculture and Agri-Food Canada
Building 57, Central Experimental Farm
960 Carling Avenue
Ottawa, ON K1A 0C6
Phone: 613-759-7953
Email: **jennifer.ballantine@canada.ca**

PRINCIPAL INVESTIGATOR:
Rob Wismer
Agriculture and Agri-Food Canada
P.O. Box 6000, 4902 Victoria Avenue N.
Vineland Station, ON L0R 2E0
Phone: 905-562-2022
Email: robert.wismer@canada.ca

TRIAL ID No. (Zone 5)
AAFC18-012R-185
(processing & exaggerated rate)

TEST SITE MANAGEMENT:
Jennifer Ballantine
Agriculture and Agri-Food Canada
Building 57, Central Experimental Farm
960 Carling Avenue
Ottawa, ON K1A 0C6
Phone: 613-759-7953
Email: jennifer.ballantine@canada.ca

PRINCIPAL INVESTIGATOR:
David Nield
Agriculture and Agri-Food Canada
Highway 97
Summerland, BC V0H 1Z0
Phone: 250-494-6374, Fax: 250-494-2114
Email: david.nield@canada.ca

TRIAL ID No. (Zone 11)
AAFC18-012R-186

TEST SITE MANAGEMENT:
Tom Forge
Agriculture and Agri-Food Canada
Highway 97
Summerland, BC V0H 1Z0
Phone: 250-494-2119, Fax: 250-494-7714
Email: tom.forge@canada.ca

2) Section 24:

Change from

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

TRIAL ID No.
AAFC18-012R-221

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

Change to:

PRINCIPAL INVESTIGATOR:
Rob Wismer
Agriculture and Agri-Food Canada
P.O. Box 6000, 4902 Victoria Avenue N.
Vineland Station, ON L0R 2E0
Phone: 905-562-2022
Email: robert.wismer@canada.ca

TRIAL ID No.
AAFC18-012R-221

TEST SITE MANAGEMENT:
Jennifer Ballantine
Agriculture and Agri-Food Canada
Building 57, Central Experimental Farm
960 Carling Avenue
Ottawa, ON K1A 0C6
Phone: 613-759-7953
Email: jennifer.ballantine@canada.ca

Reason for Changes: This information was not available for inclusion in the study plan when it was issued. Also, email addresses for Agriculture and Agri-Food Canada staff has been updated.

Signatures:

Study Director: Greg O'Neill — Oct 25/2018 — Date

Test Facility Management/: Sponsor Representative — Ian Gardiner, Submissions Manager — Oct 24/18 — Date

Reviewed by: Quality Assurance — Ting Xie — Oct 22, 2018 — Date

STUDY PLAN AMENDMENT

Study Number: AAFC18-012R Carfentrazone-ethyl on Lavender

Study Plan Sections: 1) All relevant Sections of the Study Plan and all Amendments
2) Section 10 (amendment #4)
3) Section 12
4) Section 16A
5) Section 16B
6) Section 18A (amendment #1)
7) Section 18C (amendment #1)
8) Section 19A
9) Section 19C
10) Section 20
11) Sections 24 to 27 inclusive (amendment #4)
12) Section 28

Description of Changes:

1) Change email addresses of all AAFC employees throughout the study plan and all amendments, as applicable, according to the email list noted on page 8.

2) Section 10:

Change from:

PRINCIPAL INVESTIGATOR:
Rob Wismer
Agriculture and Agri-Food Canada
P.O. Box 6000, 4902 Victoria Avenue N.
Vineland Station, ON L0R 2E0
Phone: 905-562-2022
Email: robert.wismer@canada.ca

TRIAL ID No. (Zone 5)
AAFC18-012R-184
(decline)

TEST SITE MANAGEMENT:
Jennifer Ballantine
Agriculture and Agri-Food Canada
Building 57, Central Experimental Farm
960 Carling Avenue
Ottawa, ON K1A 0C6
Phone: 613-759-7953
Email: jennifer.ballantine@canada.ca

PRINCIPAL INVESTIGATOR:
Rob Wismer
Agriculture and Agri-Food Canada
P.O. Box 6000, 4902 Victoria Avenue N.
Vineland Station, ON L0R 2E0
Phone: 905-562-2022
Email: robert.wismer@canada.ca

TRIAL ID No. (Zone 5)
AAFC18-012R-185
(processing & exaggerated rate)

TEST SITE MANAGEMENT:
Jennifer Ballantine
Agriculture and Agri-Food Canada
Building 57, Central Experimental Farm
960 Carling Avenue
Ottawa, ON K1A 0C6
Phone: 613-759-7953
Email: jennifer.ballantine@canada.ca

Change to:

PRINCIPAL INVESTIGATOR:
Rob Wismer
Agriculture and Agri-Food Canada
P.O. Box 6000, 4902 Victoria Avenue N.
Vineland Station, ON L0R 2E0
Phone: 905-562-2022
Email: robert.wismer@canada.ca

TRIAL ID No. (Zone 5)
AAFC18-012R-184
(decline)

TEST SITE MANAGEMENT:
Oualid Ellouz
Agriculture and Agri-Food Canada
P.O. Box 6000, 4902 Victoria Avenue N.
Vineland Station, ON L0R 2E0
Phone: 905-562-2024
Email: oualid.ellouz@canada.ca

PRINCIPAL INVESTIGATOR:
Rob Wismer
Agriculture and Agri-Food Canada
P.O. Box 6000, 4902 Victoria Avenue N.
Vineland Station, ON L0R 2E0
Phone: 905-562-2022
Email: robert.wismer@canada.ca

TRIAL ID No. (Zone 5)
AAFC18-012R-185

TEST SITE MANAGEMENT:
Oualid Ellouz
Agriculture and Agri-Food Canada
P.O. Box 6000, 4902 Victoria Avenue N.
Vineland Station, ON L0R 2E0
Phone: 905-562-2024
Email: oualid.ellouz@canada.ca

3) Section 12:

Change from:

12. TEST SYSTEM DESIGN and STATISTICAL METHOD:
Each trial site will consist of an untreated plot and a treated plot, except trial ID# AAFC18-012R-185 will have one additional treated plot to generate samples for the 5X exaggerated application rate purpose. Each individual plot will be established with a minimum area of 40 m^2. The untreated and treated plots for the decline trial will be a minimum of 40 m^2 and 60 m^2, respectively.

Change to:

12. TEST SYSTEM DESIGN and STATISTICAL METHOD:
Each trial site will consist of an untreated plot and a treated plot. Each individual plot will be established with a minimum area of 40 m^2. The untreated and treated plots for the decline trial will be a minimum of 40 m^2 and 60 m^2, respectively.

4) Section 16A:

Change from:

16A. APPLICATION TREATMENTS AND TIMING (for TRIAL IDs# AAFC18-012R-184 and AAFC18-012R-186 outlined in SECTION 10):

Change to:

16A. APPLICATION TREATMENTS AND TIMING (for TRIAL IDs# outlined in SECTION 10):

5) Section 16B: Delete entire Section from Study Plan.

6) Section 18A:

Change from:

After spray droplets have dried, harvest sufficient fresh flower buds, from at least 12 separate areas within each plot, to yield a minimum of **0.5 kg** (preferably not more than 1 kg) of dry flower buds avoiding plot ends.

Fresh Flowers Samples:
Harvest the fresh flowers when the majority of the crop has attained up to 90% bloom within the plot. Use a clean cutting device to cut fresh flowers from the lavender plants. Collect these cut fresh flowers directly into a labelled sample bag (preferred), or into a clean labelled container for transfer into a labelled sample bag. Since this protocol has a 0-day PHI, harvest after the spray droplets have dried and take care not to contaminate the sample with spray residue. The harvested fresh flowers will be used to process samples to oil.

Change to:

After spray droplets have dried, harvest sufficient fresh flower buds, from at least 12 separate areas within each plot, to yield a minimum of **0.5 kg** (preferably not more than 1 kg) of dry flower buds avoiding plot ends, **for trial ID# AAFC18-012R-184. For trial IDs# AAFC18-012R-185 and AAFC18-012R-186, after spray droplets have dried, harvest sufficient fresh flower buds, from at least 12 separate areas within each plot, to yield a minimum of 0.2 kg of dry flower buds avoiding plot ends.**

7) Section 18C: Deleted entire Section from Study Plan.

8) Section 19A:
Change from:

19A. RESIDUE SAMPLE INVENTORY (TRIAL ID# AAFC18-012R-186 ONLY):

SAMPLE ID	TRT #	TREATMENT	DAYS AFTER APPLIC.	MINIMUM SAMPLE WEIGHT (kg)	CROP FRACTION
A	01	Untreated	N/A[1]	0.5	Dry flower buds
B	01	Untreated	N/A[1]	0.5	Dry flower buds
C	02	Carfentrazone-ethyl	0	0.5	Dry flower buds
D	02	Carfentrazone-ethyl	0	0.5	Dry flower buds

[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, or 1-day before the 0-day PHI.
Change to:

19A. RESIDUE SAMPLE INVENTORY (TRIAL IDs# AAFC18-012R-185 and AAFC18-012R-186 in SECTION 10):

SAMPLE ID	TRT #	TREATMENT	DAYS AFTER APPLIC.	MINIMUM SAMPLE WEIGHT (kg)	CROP FRACTION
A	01	Untreated	N/A[1]	**0.2**	Dry flower buds
B	01	Untreated	N/A[1]	**0.2**	Dry flower buds
C	02	Carfentrazone-ethyl	0	**0.2**	Dry flower buds
D	02	Carfentrazone-ethyl	0	**0.2**	Dry flower buds

[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, or 1-day before the 0-day PHI.

9) Section 19C: Delete entire Section from Study Plan

10) Section 20:
Change from:

Trial ID No.	Ship to: (Trial ID No., Contact and Shipping Address)
All trials listed in Section 10 (Except samples K and L from trial ID# AAFC18-012R-185)	AAFC18-012R-187 (laboratory facility) Attention: Heather Black AAFC-Vineland 4902 Victoria Avenue N. Vineland, Ontario L0R 2E0 Phone: 905-562-2011 Fax: 905-562-4335 Email: heather.black@agr.gc.ca See Section 24 for responsible person for this Trial ID No.
Trial ID# AAFC18-012R-185 samples K and L	AAFC18-012R-221 (processing facility) *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.

Change to:

Trial ID No.	Ship to: (Trial ID No., Contact and Shipping Address)
All trials listed in Section 10	AAFC18-012R-187 (laboratory facility) Attention: Heather Black AAFC-Vineland 4902 Victoria Avenue N. Vineland, Ontario L0R 2E0 Phone: 905-562-2011 Fax: 905-562-4335 Email: heather.black@**canada.ca** See Section 24 for responsible person for this Trial ID No.

11) Sections 24 to 27:

Description of Change:
Processing trial AAFC18-012R-221 and associated activities are cancelled.

Reason for cancellation:
The Pest Management Regulatory Agency (PMRA) has concluded that a processing trial is not required to meet the data requirements for this study.

Status of Data:
No work has been initiated for the processing trial, therefore, there is no raw data. The cancellation of this trial requires Sections 24 to 27 (inclusive) to be deleted from the study plan.

12) Section 28:

Change from:

28. LABORATORY PERSONNEL/TRIAL ID NO.:
(Responsible for Sections 29-45)
The Principal Investigator and Test Site Management must sign the GLP Acceptance form (Appendix A) and return as directed.

PRINCIPAL INVESTIGATOR:
Heather Black
AAFC-Vineland
4902 Victoria Avenue N.
Vineland, ON L0R 2E0
Phone: 905-562-2011
Fax: 905-562-4335
Email: heather.black@agr.gc.ca

TRIAL ID No.
AAFC18-012R-187

TEST SITE MANAGEMENT:
Marcos Alvarez
Building 57, Central Experimental Farm
960 Carling Avenue
Ottawa, ON K1A 0C6
Phone: 613-759-7135
Fax: 613-759-1400
Email: marcos.alvarez@agr.gc.ca

Change to:

28. LABORATORY PERSONNEL/TRIAL ID NO.:
(Responsible for Sections 29-45)
The Principal Investigator and Test Site Management must sign the GLP Acceptance form (Appendix A) and return as directed.

PRINCIPAL INVESTIGATOR:
Heather Black
AAFC-Vineland
4902 Victoria Avenue N.
Vineland, ON L0R 2E0
Phone: 905-562-2011
Fax: 905-562-4335
Email: heather.black@**canada.ca**

TRIAL ID No.
AAFC18-012R-187

TEST SITE MANAGEMENT:
Helen Penny
Building 57, Central Experimental Farm
960 Carling Avenue
Ottawa, ON K1A 0C6
Phone: **613-759-7828**
Fax: 613-759-1400
Email: **helen.penny@canada.ca**

Reason for Changes:

1) To update email address for all AAFC employees throughout the study plan and all amendments.
2) To change the test site management for the principal investigator for trial IDs# AAFC18-012R-184 & 185. Also, to remove the processing and exaggerated rate descriptor for trial ID# AAFC18-012R-185.
3) To remove the need to have one additional treated plot to generate samples for the 5X exaggerated application rate purpose at trial ID# AAFC18-012R-185.
4) To update the title of Section 16A to ensure all trials noted in Section 10 follow Section 16A.
5, 7, 9) The noted Sections associated with processing elements are deleted from the study plan. No activities associated with processing lavender samples are required for this study.
6) To update the minimum sample weight for trial IDs# AAFC18-012R-185 & 186 to 0.2 kg. Also to remove the "fresh flower" sample collection text as this crop fraction is not required for this study.
8) To update the title of Section 19A to ensure trial IDs# AAFC18-012R-185 & 186 follow Section 19A. Also, to change the minimum sample weight requirements for trial IDs# AAFC18-012R-185 & 186 to 0.2 kg.
10) To remove the shipping information for the processing facility because a processed crop fraction is not required for this study and to update the email address for the laboratory principal investigator.
11) To cancel the processing trial and associated activities because a processed crop fraction is not required for this study.
12) To update the test site management for the laboratory principal investigator and to update the email address for the laboratory principal investigator.

List of PMC Study Personnel and their New Email Address

Name	New Email address	Name	New Email address
Marcos Alvarez	marcos.alvarez@canada.ca	Julia Reekie	julia.reekie@canada.ca
Jennifer Ballantine	jennifer.ballantine@canada.ca	Martin Laforest	martin.laforest@canada.ca
Ian Gardiner	ian.gardiner@canada.ca	Robert Nurse	robert.nurse@canada.ca
Sheryl Lonsbary	sheryl.lonsbary@canada.ca	Alick Mulenga	Alick.Mulenga@Canada.ca
Shuhua Liu	shuhua.liu@canada.ca	Tom Forge	tom.forge@canada.ca
Heather Black	heather.black@canada.ca	Wim van Herk	wim.vanherk@canada.ca
Ting Xie	ting.xie@canada.ca	Darrell Hanscomb	darrell.hanscomb@canada.ca
Stéphane Laprise	stephane.laprise2@canada.ca	Dominic Cloutier	dominic.cloutier@canada.ca
Martin Trudeau	martin.trudeau2@canada.ca	Julie Smaers	julie.smaers@canada.ca
Mitchell Pogoda	mitchell.pogoda@canada.ca	Robert Wismer	robert.wismer@canada.ca
Marcia Hooper	marcia.hooper@canada.ca	Geoffrey Riddle	geoffrey.riddle@canada.ca
Shai Ben-Shalom	shai.ben-shalom@canada.ca	Mary Weber-Henricks	mary.henricks@canada.ca
Jennifer Allen	jennifer.allen2@canada.ca	Daniel Ulrich	dan.ulrich@canada.ca
Shiyou Li	shiyou.li2@canada.ca	David Nield	david.nield@canada.ca
David Courcelles	david.courcelles@canada.ca	Markus Clodius	markus.clodius@canada.ca
Mohammed Akalach	mohammed.akalach@canada.ca	GLP Admin	aafc.glpadmin-adminbpl.aac@canada.ca
Chunquan Chen	chunquan.chen@canada.ca	Helen Penny	helen.penny@canada.ca
Jean-Francois Dubuc	jean-francois.dubuc@canada.ca		
Thilaka Krishnaraj	rangathilakam.krishnaraj@canada.ca		
Ross Malegus	ross.malegus@canada.ca		
Byeongseok Ahn	byeongseok.ahn@canada.ca		
Pawel Czechura	pawel.czechura@canada.ca		
Greg O'Neill	greg.oneill@canada.ca		
Heather Peill	heather.peill@canada.ca		
Kalidas Subedi	kalidas.subedi@canada.ca		

Signatures:

Study Director: Greg O'Neill — May 21/2019
Greg O'Neill — Date

Test Facility Management/:
Sponsor Representative: Ian Gardiner — May 21/19
Ian Gardiner
Submissions Manager — Date

Reviewed by:
Quality Assurance: Ting Xie — May 15 2019
Ting Xie — Date

Temporary/Short-Term Change of Study Director
Changement temporaire ou à court terme de directeur d'étude

Description of Change / Description de la modification:

Study Number/ Numéro d'étude:	AAFC18-012R
Study Director/ Directeur d'étude:	Greg O'Neill
Temporary Study Director/ Directeur d'étude temporaire:	Kalidas Subedi AAFC Minor Use Pesticide Program Building 57, Central Experimental Farm 960 Carling Avenue Ottawa, ON K1A 0C6 Phone /Téléphone: 613-715-5536 Fax/ Téléc: 613-759-1400 Email /courriel: kalidas.subedi@canada.ca
Dates:	July 8 to July 19, 2019 8 juillet au 19 juillet, 2019

Reason for change / Motif de la modification:

The Study Director for AAFC18-012R will be unavailable for the dates listed above. During this period please contact the temporary Study Director listed above. After the end date listed above, all communications must be transferred to the Study Director.

Le directeur d'étude pour AAFC18-012R ne sera pas disponible pour les dates indiquées ci-dessus. Pendant cette période, s' il vous plaît contacter le directeur d'étude temporaire indiqué ci-dessus. Après la date de fin indiquée ci-dessus, toutes les communications doivent être adressées au directeur d'étude.

Signatures

Study Director/ Directeur d'étude:	Greg O'Neill	July 4/2019 Date
Temporary Study Director/ Directeur d''étude temporaire:	Kalidas Subedi	04 Jul. 2019 Date
Test Facility Management- Sponsor Representative/ Direction de l'installation d'essai - Donneur d'ordre :	Ian Gardiner	July 4/19 Date
Reviewed by/Révisé par Quality Assurance /Assurance qualité:	Ting Xie	July 3, 2019 Date

STUDY PLAN AMENDMENT

Study Number: AAFC18-012R Carfentrazone-ethyl on Lavender

Study Plan Sections: 1) Section 32
2) Section 33

Description of Changes:

1) Section 32
Change from:

32. ANALYTICAL SPECIFICATIONS:

- **Residue Definition** – carfentrazone-ethyl 3-hydroxymethyl carfentrazone chloropropionic acid and carfentrazone chloropropionic acid
- **Analyte Definition** – carfentrazone-ethyl 3-hydroxymethyl carfentrazone chloropropionic acid and carfentrazone chloropropionic acid
- **Crop fractions/Matrices** – dried flower buds flowers and oil
- **Lowest Level of Method Validation** (LLMV) = 0 05 ppm

Change to:

32. ANALYTICAL SPECIFICATIONS:

- **Residue Definition** – carfentrazone-ethyl **(F8426)**, 3-hydroxymethyl carfentrazone chloropropionic acid **(3-OH-F8426-Cl-PAc)**, carfentrazone chloropropionic acid **(F8426-Cl-PAc), 3-hydroxymethyl carfentrazone benzoic acid (3-OH-F8426-BAc) and carfentrazone benzoic acid (F8426-BAc)**
- **Analyte Definition** – carfentrazone-ethyl **(F8426)**, 3-hydroxymethyl carfentrazone chloropropionic acid **(3-OH-F8426-Cl-PAc)**, carfentrazone chloropropionic acid **(F8426-Cl-PAc), 3-hydroxymethyl carfentrazone benzoic acid (3-OH-F8426-BAc) and carfentrazone benzoic acid (F8426-BAc)**
- **Crop fractions/Matrices** – dried flower buds
- **Lowest Level of Method Validation** (LLMV) = 0 05 ppm

2) Section 33
Change from:

33. LABORATORY REFERENCE ITEM(S):
Laboratory Reference Items, carfentrazone-ethyl, 3-hydroxymethyl carfentrazone chloropropionic acid and carfentrazone chloropropionic acid obtained from the Registrant are to be used, unless otherwise approved by the Study Director If required to procure the Reference Items, contact Theresa Geil, FMC Corporation at phone (226) 979-2247 email theresa geil@fmc com, and document the request in the raw data Document the date the Reference Items are received, the source, lot number, stated purity, storage conditions and expiration date Use only Reference Items that have been characterized to meet GLP standards Contact the Study Director if there are any concerns regarding the GLP characterization, label identification of the Reference Items (e.g., the name on the bottle, or certificate of analysis (CoA) is different from the Study Plan), etc, and if the Reference Items do not come with the CoA Characterization of the Reference Items (purity, identity, stability, and solubility) and maintenance of an archival sample is the responsibility of the Registrant unless otherwise specified by the Study Director

Change to:

33. LABORATORY REFERENCE ITEM(S):
Laboratory Reference Items, carfentrazone-ethyl **(F8426)**, 3-hydroxymethyl carfentrazone chloropropionic acid **(3-OH-F8426-Cl-PAc)**, carfentrazone chloropropionic acid **(F8426-Cl-PAc) and 3-hydroxymethyl carfentrazone benzoic acid (3-OH-F8426-BAc) and carfentrazone benzoic acid (F8426-BAc)** obtained from the Registrant are to be used, unless otherwise approved by the Study Director. If required, to procure the Reference Items, contact: Theresa Geil, FMC Corporation at phone: (226) 979-2247, email: theresa.geil@fmc.com, and document the request in the raw data. Document the date the Reference Items are received, the source, lot number, stated purity, storage conditions, and expiration date. Use only Reference Items that have been characterized to meet GLP standards. Contact the Study Director if there are any concerns regarding the GLP characterization, label identification of the Reference Items (e.g., the name on the bottle, or certificate of analysis (CoA) is different from the Study Plan), etc. and if the Reference Items do not come with the CoA. Characterization of the Reference Items (purity, identity, stability, and solubility) and maintenance of an archival sample is the responsibility of the Registrant unless otherwise specified by the Study Director.

Reason for Changes: Correspondence with PMRA has revealed the need to quantified additional metabolites of the active ingredient used in this study and to analyze dried flower buds as the crop matrix. This information was not available for inclusion in the Study Plan when it was issued.

Signatures:

Study Director: Greg O'Neill — July 31/2019
Greg O'Neill — Date

Test Facility Management/ Sponsor Representative: for Ian Gardiner, Submissions Manager — 30 July 2019
Date

Reviewed by: Quality Assurance: Ting Xie — July 30, 2019
Ting Xie — Date

STUDY PLAN AMENDMENT

Study Number: AAFC18-012R Carfentrazone-ethyl on Lavender

Study Plan Sections: 1) 31
2) 38 (amendment #3)

1) Section 31

Change from:

31. LABORATORY SAMPLE STORAGE/PREPARATION:

Upon receipt of the samples and reference item(s) using a macerated control sample prepare and freeze four provisional sets of samples (three fortified samples plus four unfortified samples per set) fortified at the targeted highest concentration of method validation These provisional sample sets will be analyzed **only** if there is a delay for frozen storage stability analysis as outlined in Section 38 Should analysis of the provisional sample sets be necessary the samples will be analyzed at two time points 1) as soon as possible after method validation is completed and approved by Study Director, and 2) at a time to cover the period from the earliest harvest date of any sample from any trial in this study to the last date of sample analysis.

Information for Sections 32-45 will be identified at a later date at which time the appropriate information will be added by amendment

Change to:

31. LABORATORY SAMPLE STORAGE/PREPARATION:

Upon receipt of the samples and reference item(s) using a macerated control sample, six sets (consisting of 3 replications per set of fortified samples at the targeted highest concentration of method validation and 4 replications per set of unfortified samples) will be prepared and frozen These samples will be analyzed according to Section 38

Information for Sections 32-45 will be identified at a later date at which time the appropriate information will be added by amendment

2) Section 38

Change from:

Frozen Storage Stability Analysis:
If extraction of treated and control (untreated) samples is completed within **30 days** of harvest analysis of frozen storage stability samples will not be required

If frozen[6] storage stability analysis is required, it should be set up as soon as possible after method validation. Utilizing a control sample from each crop fraction samples are to be prepared by fortifying them with each compound in the residue definition at the highest level of method validation For day 0 (the same day the frozen storage samples are prepared) three freshly fortified samples and one control sample are to be analyzed For all other timeframes (for each timeframe required plus two contingency

[6] Frozen storage refers to storage of samples at temperatures generally less than -18°C (0°F) To allow for normal temperature variations due to freezer cycling sample movement etc temperature fluctuations between -18°C and 0°C for a duration of no longer than six hours are acceptable contact the Study Director as soon as possible if freezer temperatures rise above 0°C

sets), place a minimum of three fortification samples and four unfortified control samples in frozen storage. After the appropriate storage period, beginning at 30 ± 5 days, and then every 90 ± 10 days thereafter, for each compound per crop fraction, three freshly fortified frozen control samples are to be prepared and analyzed along with an unfortified control sample and three aged fortified samples. The last storage sample is to be analyzed at a time period greater than the longest interval between harvest and extraction[7]
Recoveries of the aged fortified samples are to be compared to the recoveries of the freshly fortified samples. If at any time point the recoveries differ by 20% or more, the results will be reported within a week to the Study Director and another sample set will be analyzed as soon as possible (usually within a week of occurrence) The Study Director must also be notified within a week if freshly fortified recoveries deviate from the acceptable recovery range of 70-120% and %RSD of ≤20%

Change to:

Frozen Storage Stability Analysis:
Samples used to generate frozen sample storage stability data for this study will be prepared and frozen according to Section 31

Three fortified samples of each analyte will be analyzed after the appropriate storage period beginning as soon as possible after method validation is completed and approved by the Study Director, and then every 90 ± 10 days thereafter; the last storage sample is to be analyzed at a time period greater than the longest interval between harvest and extraction[7]. One frozen control and three freshly fortified control samples will also be included at each analysis date
Recoveries of the aged fortified samples are to be compared to the recoveries of the freshly fortified samples. If at any time point the recoveries differ by 20% or more, the results will be reported within a week to the Study Director and another sample set will be analyzed as soon as possible (usually within a week of occurrence) The Study Director must also be notified within a week if freshly fortified recoveries deviate from the acceptable recovery range of 70-120% and %RSD of ≤20%

Reasons for Change:

1. A revision of frozen storage stability plan is required as method validation has taken longer than expected which has extended the frozen storage period of samples In addition, footnote #8 has been removed from the study as it no longer applies

Signatures:

Study Director:	Greg O'Neill	Aug 21/2019 Date
Test Facility Management/: Sponsor Representative	Ian Gardiner Submissions Manager	Aug 16, 2019 Date
Reviewed by: Quality Assurance	Ting Xie	Aug 15, 2019 Date

[7] The final time period may be longer or shorter than the scheduled 90-day interval, as approved by the Study Director

STUDY PLAN AMENDMENT

Study Number: AAFC18-012R Carfentrazone-ethyl on Lavender

Study Plan Sections: 1) Section 32 (amendment #7)
2) Section 33 (amendment #7)

Description of Changes:

1) Section 32
Change from:

32. ANALYTICAL SPECIFICATIONS:

- **Residue Definition** – carfentrazone-ethyl **(F8426)**, 3-hydroxymethyl carfentrazone chloropropionic acid **(3-OH-F8426-Cl-PAc)**, carfentrazone chloropropionic acid **(F8426-Cl-PAc), 3-hydroxymethyl carfentrazone benzoic acid (3-OH-F8426-BAc) and carfentrazone benzoic acid (F8426-BAc)**
- **Analyte Definition** – carfentrazone-ethyl **(F8426)**, 3-hydroxymethyl carfentrazone chloropropionic acid **(3-OH-F8426-Cl-PAc),** carfentrazone chloropropionic acid **(F8426-Cl-PAc), 3-hydroxymethyl carfentrazone benzoic acid (3-OH-F8426-BAc) and carfentrazone benzoic acid (F8426-BAc)**
- **Crop fractions/Matrices** – dried flower buds
- **Lowest Level of Method Validation (LLMV)** = 0.05 ppm

Change to:

32. ANALYTICAL SPECIFICATIONS:

- **Residue Definition** – carfentrazone-ethyl **(F8426)**, carfentrazone chloropropionic acid **(F8426-Cl-PAc)**
- **Analyte Definition** – carfentrazone-ethyl **(F8426)**, carfentrazone chloropropionic acid **(F8426-Cl-PAc)**
- **Crop fractions/Matrices** – dried flower buds
- **Lowest Level of Method Validation (LLMV)** = 0.05 ppm for carfentrazone-ethyl **(F8426)** and 0.5 ppm for carfentrazone chloropropionic acid **(F8426-Cl-PAc)**

2) Section 33
Change from:

33. LABORATORY REFERENCE ITEM(S):

Laboratory Reference Items, carfentrazone-ethyl **(F8426)**, 3-hydroxymethyl carfentrazone chloropropionic acid **(3-OH-F8426-Cl-PAc),** carfentrazone chloropropionic acid **(F8426-Cl-PAc) and 3-hydroxymethyl carfentrazone benzoic acid (3-OH-F8426-BAc) and carfentrazone benzoic acid (F8426-BAc)** obtained from the Registrant are to be used, unless otherwise approved by the Study Director. If required, to procure the Reference Items, contact: Theresa Geil, FMC Corporation at phone: (226) 979-2247, email: theresa.geil@fmc.com, and document the request in the raw data. Document the date the Reference Items are received, the source, lot number, stated purity, storage conditions, and expiration date. Use only Reference Items that have been characterized to meet GLP standards. Contact the Study Director if there are any concerns regarding the GLP characterization, label identification of the Reference Items (e.g., the name on the bottle, or certificate of analysis (CoA) is different from the Study Plan), etc. and if the Reference Items do not come with the CoA. Characterization of the Reference Items (purity, identity, stability, and solubility) and maintenance of an archival sample is the responsibility of the Registrant unless otherwise specified by the Study Director.

Change to:

33. LABORATORY REFERENCE ITEM(S):
Laboratory Reference Items, carfentrazone-ethyl **(F8426)**, carfentrazone chloropropionic acid **(F8426-Cl-PAc)** obtained from the Registrant are to be used, unless otherwise approved by the Study Director. If required, to procure the Reference Items, contact: Theresa Geil, FMC Corporation at phone: (226) 979-2247, email: theresa.geil@fmc.com, and document the request in the raw data. Document the date the Reference Items are received, the source, lot number, stated purity, storage conditions, and expiration date. Use only Reference Items that have been characterized to meet GLP standards. Contact the Study Director if there are any concerns regarding the GLP characterization, label identification of the Reference Items (e.g., the name on the bottle, or certificate of analysis (CoA) is different from the Study Plan), etc. and if the Reference Items do not come with the CoA. Characterization of the Reference Items (purity, identity, stability, and solubility) and maintenance of an archival sample is the responsibility of the Registrant unless otherwise specified by the Study Director.

Reason for Changes:

1) Due to difficulties to analyze for 3-hydroxymethyl carfentrazone chloropropionic acid (3-OH-F8426-Cl-PAc), 3-hydroxymethyl carfentrazone benzoic acid (3-OH-F8426-BAc) and carfentrazone benzoic acid (F8426-BAc) in lavender, approval has been obtained to remove these compounds from analysis.
2) The LLMV for carfentrazone chloropropionic acid (F8426-Cl-PAc) has been raised to 0.5 ppm to accommodate detection capabilities for this compound in lavender matrix.

Signatures:

Study Director:	Greg O'Neill	Jan 17/2020 Date
Test Facility Management/: Sponsor Representative	Ian Gardiner Submissions Manager	Jun 16, 2020 Date
Reviewed by: Quality Assurance	Ting Xie	Jan 15, 2020 Date