

**REPORT OF A
GOOD LABORATORY PRACTICE INSPECTION
COMPLIANCE REVIEW AND STUDY AUDITS
CONDUCTED PURSUANT TO THE
FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT (FIFRA)**

LABORATORY: ScitoVation
100 Capitola Dr. Suite 106
Durham, NC 27713

INSPECTION NUMBER: 2020295019

RESPONSIBLE OFFICIAL: Dr. Marjory Moreau
Phone: 919-354-5220
Mmoreau@scitovation.com

DATE OF INSPECTION: February 6, 2020

SIGNATURES:

Inspector/Auditor: _____
William Wimbish, Compliance Officer
Office of Compliance/GLP

Administrative/
Technical Reviewer: _____

Approver: _____

SUMMARY

A U.S. Environmental Protection Agency (EPA) Federal Insecticide, Fungicide, Rodenticide, Act (FIFRA) Good Laboratory Practice (GLP) inspection was conducted to determine compliance with 40 CFR 160 and 40 CFR 169.2(k). One study audit was conducted by the inspector. In addition, a GLP compliance inspection was conducted to determine the laboratories current adherence to the GLP regulations. Findings from the FIFRA GLP inspection and study audits are summarized below.

- There was no documentation that the program was validated 40 CFR 169. (2)(k)

I. INTRODUCTION

A Neutral Scheme FIFRA GLP inspection was conducted at ScitoVation, on February 6, 2020 to determine compliance with 40 CFR 160 and 40 CFR 169.2(k). The inspector assigned was Mr. William Wimbish and was accompanied by Ms. Frances Liem, Director of U.S. EPA's GLP Program. ScitoVation has two main scientific branches in their company focusing on Computational Toxicology and Cell-Based Assays. ScitoVation does not currently perform GLP work. For more information visit: <https://www.scitovation.com/>

II. OPENING CONFERENCE

An opening conference was held beginning at approximately 9:00am on February 6, 2020. The inspection was led by Mr. William Wimbish, Physical Scientist, from the EPA's GLP Program. Official credentials were presented to Dr. Moreau, Manager. A FIFRA Notice of Inspection [Exhibit 1] was also presented to and signed by Dr. Moreau. A list of attendees at the opening and closing conference is provided as [Exhibit 4].

III. NARRATIVE

The following GLP compliance inspection and study audits were accomplished during the inspection.

GLP Compliance Inspection:

The GLP standards compliance inspection was conducted through interviews with facility personnel and tours of laboratory. Personnel *curricula vitae* and training records were reviewed. No ongoing study was audited.

Study Audit:

One study audit was accomplished through review of available raw data, records, reports, interviews with study personnel and a review of laboratory operations. The audit was based on: completeness of raw data, conformance of raw data to study report findings and conclusions, and record keeping.

The following describe observations made and activities undertaken during the facility inspection and audit of the study with respect to the U.S. EPA FIFRA GLP regulations under 40 CFR §160:

Study Title: 50879601 / Development and Application of Physiologically-Based Pharmacokinetic Models to the Evaluation of Age-Dependent Sensitivity to Pyrethroid Insecticides

Sponsor: Council for the Advancement of Pyrethroid Human Risk Assessment, LLC (CAHRA)
c/o Household and Commercial Products Association
1667 K Street NW, Suite 300
Washington, DC 20006

- Finding: There was no documentation that the program was validated

Citation: 40 CFR 169. (2)(k)

Facility Response: Facility Response [**Exhibit 5**]

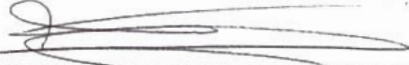
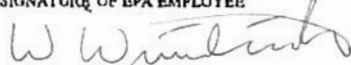
IV. **EXIT DISCUSSION**

The exit conference was held Thursday February 6, 2020 by William Wimbish to review findings and recommendations of the FIFRA GLP standards inspection and data audit. Inspection Observations form [**Exhibit 2**] was completed and copied for the facility providing written indication of the inspector's observations discussed during the inspection and closing conference.

A FIFRA Receipt for Samples [**Exhibit 3**] was provided to the facility for documents obtained during the inspection.

V. EXHIBITS

Exhibit 1	FIFRA <u>Notice of Inspection</u>	(1 page)
Exhibit 2	<u>Inspection Observations form</u>	(1 page)
Exhibit 3	FIFRA <u>Receipt for Samples</u>	(1 page)
Exhibit 4	Sign-in Sheet	(2 pages)
Exhibit 5	Facility Response	(4 pages)

 U.S. ENVIRONMENTAL PROTECTION AGENCY GOOD LABORATORY PRACTICE NOTICE OF INSPECTION		ADDRESS (EPA Office) EPA HQ 1200 Pennsylvania Ave NW Washington, DC 20004	
		DATE 2/6/2020	HOUR 9:00 AM PM
FIRM NAME Scitovation		FIRM ADDRESS (NUMBER, STREET, CITY, STATE AND ZIP CODE) 100 Capitol Drive Suite 100 Durham, NC 27713	
NAME OF OWNER OR AGENT IN CHARGE Marjory Morcan			
SIGNATURE OF OWNER OR AGENT IN CHARGE (SIGNATURE GRANTS CONSENT TO INSPECTION) 		SIGNATURE OF EPA EMPLOYEE 	
TITLE Manager PMPK Division		TITLE Physical Scientist	
REASON FOR INSPECTION: ☒ FOR THE PURPOSE OF PERFORMING AN INSPECTION PURSUANT TO THE GOOD LABORATORY PRACTICE STANDARDS SPECIFIED IN SECTION 40 CFR PART 160 ☒ FOR THE PURPOSE OF INSPECTING AND OBTAINING COPIES OF THOSE RECORDS SPECIFIED IN THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT, SECTIONS 9 and 12(a)(2)(B), AND IN SECTION 40 CFR PART 169. ☐ ☐			
VIOLATION SUSPECTED: None			



INSPECTION OBSERVATIONS

ADDRESS/PHONE (EPA OFFICE)

EPA HQ
1200 Pennsylvania Ave NW
Washington DC 20004

DATE 2/6/2020

PRINTED NAME OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: MARJORY MOREAU

INVESTIGATION ID NUMBER

2020295019

FIRM NAME AND ADDRESS: Scito Vation
100 Capitola Drive Suite 106
Durham, NC 27713

FACILITY INSPECTED ADDRESS

100 Capitola Drive Suite 106
Durham, NC 27713

DURING AN INSPECTION / AUDIT OF YOUR FACILITY, THE FOLLOWING POTENTIAL VIOLATIONS WERE OBSERVED BY AGENCY INSPECTORS:

Books and Records Inspection
1. There was no documentation that the ~~study~~ ^{program} was ~~validated~~ ^{validated} 40 CFR 169.22(k) RL

NOTE: This form provides only preliminary determinations by Agency inspectors. Final determinations concerning the number, nature and extent of violations will be made following enforcement review of the inspection report.

ACKNOWLEDGMENT
THE UNDERSIGNED ACKNOWLEDGES RECEIPT OF A COPY OF THIS INFORMATION

SIGNATURE

TITLE

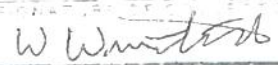
Manager.

PREPARED BY:

William Wimbley

TITLE

Physical Scientist

 U.S. ENVIRONMENTAL PROTECTION AGENCY RECEIPT FOR SAMPLES		ADDRESS (EPA Regional Office) EPA HQ 1200 Pennsylvania Ave NW Washington, DC 20004 DATE 2/6/2020
NAME OF INDIVIDUAL MARJORY MOREAU FIRM NAME Scito Vation	TITLE MANAGER ADDRESS (Street, City, State and Zip Code) 100 Capitola Drive suite 106 Durham, NC 27713	
SAMPLE NUMBERS		
SAMPLES COLLECTED (Describe fully, List Registration, Lot, Batch, Model, Serial Numbers and other positive identifications.) The following samples were collected by the U.S. Environmental Protection Agency and receipt is hereby acknowledged pursuant to Section 9.(a) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (7 U.S.C. 136 g). This section is quoted on the reverse of this form. 1. Scito Vation Company Information (7 Pages)		
ACKNOWLEDGMENT OF PRODUCER REGISTRANT The undersigned acknowledges that the samples shown above were obtained from pesticides or devices that were packaged, labeled, and released for shipment		
SIGNATURE (Owner, Operator, or Agent) 	TITLE (Owner, Operator or Agent) Manager	
☒ DUPLICATE SAMPLES REQUESTED AND PROVIDED ☐ DUPLICATE SAMPLES NOT REQUESTED	SAMPLES WERE ☐ PURCHASED N/A ☐ BORROWED	
AMOUNT PAID FOR SAMPLES \$ None	CASH ☐ VOUCHER ☒ TO BE BILLED ☐	
NAME OF COLLECTOR (Full Name) William Wimbish	TITLE OF COLLECTOR Physical Scientist SIGNATURE OF COLLECTOR 	

Sign-In Sheet

Company Name and Address: *ScitoVation 100 Capitola Drive Suite 106 Durham, NC 27713*

Date(s): *2/6/2020*

Attendance for OPENING / CLOSING conference

Printed Name:	Title:	Email:	Phone:	Company/ Department
William Wimbish	Physical Scientist	Wimbish.william@epa.gov	202-564-1355	U.S. EPA/OC/GLP
<i>Francisca Lieu</i>	<i>Director, GLP</i>	<i>lieu.francisca@epa.gov</i>	<i>202-564-2365</i>	<i>US EPA</i>
<i>Thomas Brimble</i>	<i>CAP/RA Science Lead</i>	<i>tom@sciencestrategies.com</i>	<i>434-962-3436</i>	<i>Science Strategies</i>
<i>Marjory Moreau</i>	<i>Manager</i>	<i>moreau@scitovation.com</i>	<i>919-579-3474</i>	<i>Scitovation</i>

Sign-In Sheet

Company Name and Address: Scitovation 100 Capitola Drive Suite 106 Durham NC 27713

Date(s): 2/6/2020

Attendance for OPENING / CLOSING conference

Printed Name:	Title:	Email:	Phone:	Company/ Department
William Wimbish	Physical Scientist	Wimbish.william@epa.gov	202-564-1355	U.S. EPA/OC/GLP
Francis Lie	Director, GUP	lie.francoise@epa.gov	202-564-2365	EPA
Tom Osuna	Manager	tom.osuna@epa.gov	934-962-3436	CAPRA Science Strategies, LLC
Margery Moreau	Manager PRE division	moreau.margery@epa.gov	919-579-3476	Scitovation