syngenta

Event SYHT0H2 Soybean

Flanking Sequence Determination

Final Report

DATA REQUIREMENT(S): Not Applicable

AUTHOR: [redacted]

STUDY COMPLETION DATE: May 14, 2012

PERFORMING LABORATORY:
Syngenta Crop Protection, LLC
Product Safety
3054 East Cornwallis Road
Research Triangle Park, NC 27709-2257 USA

LABORATORY PROJECT ID:
Report Number: TK0059646
Task Number: TK0059646

SUBMITTER:
Syngenta Seeds, Inc.
3054 East Cornwallis Road
Post Office Box 12257
Research Triangle Park, NC 27709-2257 USA

SPONSOR:
Syngenta Crop Protection, LLC
410 Swing Road
Post Office Box 18300
Greensboro, NC 27419-8300 USA

VOLUME 1 OF 2 OF STUDY

STATEMENTS OF DATA CONFIDENTIALITY CLAIMS

The following statement applies to submissions to the United States Environmental Protection Agency (US EPA).

Statement of Data Confidentiality Claim

A claim of confidentiality is being made for information contained in this report on the basis of its falling within the scope of Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Section 10 (d) (1) (A), (B), or (C). The information claimed confidential has been removed to a confidential volume and is cited by cross reference number in the body of this volume.

Company: *Syngenta Seeds, Inc.*

Company Representative:

[redacted] May 11, 2012

Date

Manager, Regulatory Affairs

These data are the property of Syngenta Seeds, Inc. and, as such, are considered to be confidential for all purposes other than compliance with the regulations implementing FIFRA Section 10. Submission of these data in compliance with FIFRA does not constitute a waiver of any right to confidentiality that may exist under any other provision of common law or statute or in any other country.

The following statement applies to submissions to regulatory agencies and other competent authorities other than the US EPA and all other viewers.

This Document Contains Confidential Business Information

This document contains information that is proprietary to Syngenta and, as such, is considered to be confidential for all purposes other than compliance with the relevant registration procedures.

Without the prior written consent of Syngenta, this information may (i) not be used by any third party including, but not limited to, any other regulatory authority for the support of regulatory approval of this product or any other product, and (ii) not be published or disclosed to any third party including, but not limited to, any authority for the support of regulatory approval of any products.

Its submission does not constitute a waiver of any right to confidentiality that may exist in any other country.

GOOD LABORATORY PRACTICE COMPLIANCE STATEMENT

This study was conducted in compliance with the relevant provisions of Good Laboratory Practice Standards (40 CFR Part 160, US EPA 1989) pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act except that the confirmatory sequencing analysis prior to shipping the DNA samples to GENEWIZ was not conducted under Good Laboratory Practice.

Study Director:

[redacted] _____ May 14, 2012
Date

Technical Expert, Product Safety
Syngenta Crop Protection, LLC

Submitted by:

[redacted] _____ May 11, 2012
Date

Manager, Regulatory Affairs
Syngenta Seeds, Inc.
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Sponsor:

[redacted] _____ 10 May 2012
Date

Technical Leader, Product Safety
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QUALITY ASSURANCE STATEMENT

Study Title: Event SYHT0H2 Soybean: Flanking Sequence Determination

Study Director: [redacted]

Study Number: TK0059646

Pursuant to Good Laboratory Practice Regulations (40 CFR Part 160), this statement verifies that the aforementioned study was inspected and/or audited and the findings reported to Management and to the Study Director by the Quality Assurance Unit on the dates listed below.

Inspection/Audit Type	Inspection/Audit Dates	Reporting Date
Audit Protocol	September 13, 2011	September 13, 2011
Inspect Analytical	October 6, 2011	October 6, 2011
Audit Final Report (1st Audit)	March 27, 2012	March 30, 2012
Audit Final Report (2nd Audit)	May 10, 2012	May 10, 2012

Please reference the analytical phase report for additional audit/inspection dates.

Prepared by: [redacted] Date: May 10, 2012

Staff Quality Assurance Auditor
Quality Assurance Unit
Syngenta

GENERAL INFORMATION

Contributors

The following contributed to this report in the capacities indicated:

Name	Title
[redacted]	Study Director, Syngenta Crop Protection, LLC
	Principal Investigator, GENEWIZ, Inc.
	Technical Scientist, GENEWIZ, Inc.

Study dates

Study initiation date:	September 19, 2011
Experimental start date:	October 4, 2011
Experimental termination date:	November 9, 2011

Records Retention

Raw data, the original copy of this report, and other relevant records are archived at Syngenta, 3054 East Cornwallis Road, Research Triangle Park, NC 27709-2257, USA. Facility records generated at GENEWIZ are archived at GENEWIZ's archives.

Additional Test Site

GENEWIZ, Inc.
115 Corporate Boulevard
South Plainfield, NJ 07080, USA

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LIST OF ACRONYMS AND ABBREVIATIONS

avhppd-03	*p*-hydroxyphenylpyruvate dioxygenase gene derived from oat
AvHPPD-03	*p*-hydroxyphenylpyruvate dioxygenase enzyme encoded by *avhppd-03*
bp	base pair
CBI	Confidential Business Information
DNA	deoxyribonucleic acid
dsDNA	double-stranded DNA
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
HPPD	*p*-hydroxyphenylpyruvate dioxygenase enzyme
pat	phosphinothricin acetyltransferase gene
PAT	phosphinothricin acetyltransferase enzyme
PCR	polymerase chain reaction
US EPA	United States Environmental Protection Agency
v.	version

1.0 EXECUTIVE SUMMARY

Soybean (*Glycine max* [L.] Merrill) has been genetically modified to express the novel genes *avhppd-03* derived from oat (*Avena sativa* L.) and *pat* from *Streptomyces viridochromogenes*. The gene *avhppd-03* encodes a *p*-hydroxyphenylpyruvate dioxygenase (HPPD) enzyme, designated AvHPPD-03, that catalyzes the formation of homogentisic acid, the aromatic precursor in plastoquinone and vitamin E biosynthesis. In comparison with the native soybean HPPD, the AvHPPD-03 isozyme from oat has lower binding affinity for mesotrione, an herbicide that inhibits HPPD. Expression of *avhppd-03* in transgenic Event SYHT0H2 soybean plants confers a mesotrione-tolerance phenotype. The gene *pat* encodes the enzyme phosphinothricin acetyltransferase (PAT), which inactivates the herbicide glufosinate, an inhibitor of glutamine synthetase, an enzyme in the nitrogen assimilation pathway. Expression of *pat* confers a glufosinate-tolerance phenotype, which was used as a selectable marker in the development of SYHT0H2 soybean.

The purpose of this study was to determine the soybean genomic deoxyribonucleic acid (DNA) sequence flanking each side of the SYHT0H2 insert. The flanking sequences were amplified from genomic DNA extracted from SYHT0H2 soybean, using polymerase chain reaction. The amplification products were cloned, and several clones were sequenced in order to generate a consensus sequence for each flanking region.

2.0 INTRODUCTION

Soybean (*Glycine max* [L.] Merrill) has been genetically modified to express the novel genes *avhppd-03* derived from oat (*Avena sativa* L.) and *pat* from *Streptomyces viridochromogenes*. The gene *avhppd-03* encodes a *p*-hydroxyphenylpyruvate dioxygenase (HPPD) enzyme, designated AvHPPD-03, that catalyzes the formation of homogentisic acid, the aromatic precursor in plastoquinone and vitamin E biosynthesis. In comparison with the native soybean HPPD, the AvHPPD-03 isozyme from oat has lower binding affinity for mesotrione, an herbicide that inhibits HPPD. Expression of *avhppd-03* in transgenic Event SYHT0H2 soybean plants confers a mesotrione-tolerance phenotype. The gene *pat* encodes the enzyme phosphinothricin acetyltransferase (PAT), which inactivates the herbicide glufosinate, an inhibitor of glutamine synthetase, an enzyme in the nitrogen assimilation pathway. Expression of *pat* confers a glufosinate-tolerance phenotype, which was used as a selectable marker in the development of SYHT0H2 soybean.

The purpose of this study was to determine the soybean genomic deoxyribonucleic acid (DNA) sequence flanking both sides of the SYHT0H2 insert.

3.0 MATERIALS AND METHODS

3.1 Test Substance

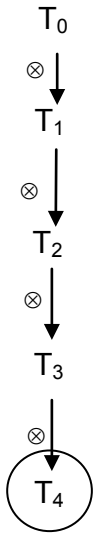
The test substance for this study was SYHT0H2 soybean seed in the genetic background 'Jack' (Nickell *et al.* 1990). Table 1 shows the material identification for the test substance. Figure 1 is a pedigree chart illustrating the production of the test substance.

TABLE 1 Test Substance

Seed identification	Material identification
SYHT0H2 T_4 soybean	09SG052316

The test substance was characterized by real-time polymerase chain reaction (PCR) analysis (Ingham *et al.* 2001) to confirm identity and purity (Burgin 2011).

FIGURE 1 Pedigree Chart for SYHT0H2 Soybean Illustrating the Production of the Test Substance Used in this Study



The transformation recipient line is 'Jack'

T_0 = original transformant
⊗ = self-pollination
The generation used in this study is denoted with a circle.

3.2 Plant Tissue for Genomic DNA Extraction

The test substance seed was grown in a greenhouse located at Syngenta, in Research Triangle Park, NC, USA. Following verification of the plants' identity by real-time PCR analysis, leaf tissue from plants grown from the test substance was pooled into a sampling bag and stored at –80°C ± 10°C (Burgin 2011).

3.3 Genomic DNA Extraction

Genomic DNA was isolated from the pooled leaf tissue using a modification of the method described by Saghai-Maroof *et al*. (1984) (Nesbitt 2011).

3.4 DNA Quantitation

DNA concentrations were measured using an Invitrogen Quant-iT™ PicoGreen® dsDNA kit. A two-point standard curve was generated using a lambda DNA standard. The linear attribute of the standard curve was verified with samples generated from a serial dilution of lambda DNA standard. Genomic DNA was quantified by interpolation from the two-point standard curve, and each genomic DNA was assayed in triplicate using the Turner Biosystems TBS-380 Mini-Fluorometer.

3.5 PCR Amplification

Genomic DNA of the SYHT0H2 T_4 generation was used as a template for the JumpStart™ REDAccuTaq® LA DNA Polymerase PCR system to amplify the soybean genomic sequences flanking the 5′ and 3′ regions of the SYHT0H2 insert. The sequence of the PCR primers is shown in Table 2. Table 3 lists the thermal cycling parameters for PCR amplification. Three separate PCR reactions were performed to amplify each flanking sequence.

TABLE 2 Primers Used to Amplify the Genomic Sequences Flanking the SYHT0H2 Insert

{Volume 2: Confidential Business Information (CBI) Cross-reference Number 1}

TABLE 3 Thermal Cycling Parameters for PCR Amplification

Cycle	Step	Temperature (°C)	Time	Number of cycles
A	1	96	30 s	1
B	1	94	15 s	35
	2	59	30 s	
	3	68	3 min 15 s with 5 s extension / cycle	
C	1	68	10 min	1
D	1	4	hold	1

min = minute
s = second

The PCR products were cloned into the Invitrogen pCR®4-TOPO® TA vector. From each cloning reaction, three colonies were randomly selected and grown. The plasmid DNA from each colony was extracted and digested with the restriction enzyme *Eco*RI to confirm the presence of the expected size insert. Following this confirmation, one clone was randomly selected for each cloning reaction. The presence of the expected insert in each clone was confirmed by single sequencing runs on the ends of the clone using primers located in the pCR®4-TOPO® cloning vector.

3.6 Sequencing

For each flanking sequence, the three clones, obtained from separate PCR reactions and confirmed to contain the expected insert, were sequenced individually by GENEWIZ Inc. (South Plainfield, NJ, USA), as reported in Appendix A. The sequences of the clones were analyzed and aligned using DNA Sequence Analysis software v. 5.3 from Applied BioSystems and Lasergene® v. 8 from DNASTAR, in order to generate a consensus sequence for each flanking sequence.

3.7 Control of Bias

PCR fragments were cloned, and one colony from each cloning reaction was randomly chosen. Any rejected data and the documented reasons for the rejection of those data were retained in the study file.

3.8 Statistical Analysis

No statistical analysis was conducted in this study.

4.0 RESULTS AND DISCUSSION

4.1 Flanking Sequences

The 1000 base pairs (bp) of soybean genomic sequence flanking each side of the SYHT0H2 insert are reported. Figure 2 shows the 5′ flanking sequence, and Figure 3 shows the 3′ flanking sequence.

FIGURE 2 Soybean Genomic Sequence Flanking the 5′ Region of the SYHT0H2 Insert (1000 bp)

{Volume 2: CBI Cross-reference Number 2}

FIGURE 3 Soybean Genomic Sequence Flanking the 3′ Region of the SYHT0H2 Insert (1000 bp)

{Volume 2: CBI Cross-reference Number 3}

4.2 SYHT0H2 Insert Sequence

The SYHT0H2 insert sequence was determined in a separate analysis (de Framond 2012). Figure 4 shows a map of the SYHT0H2 insert and the genomic sequences flanking the insert. Figure 5 and Appendix B show the insert and the 5′ and 3′ flanking sequences.

FIGURE 4 Map of the SYHT0H2 Soybean Insert, Including the Flanking Genomic Sequences

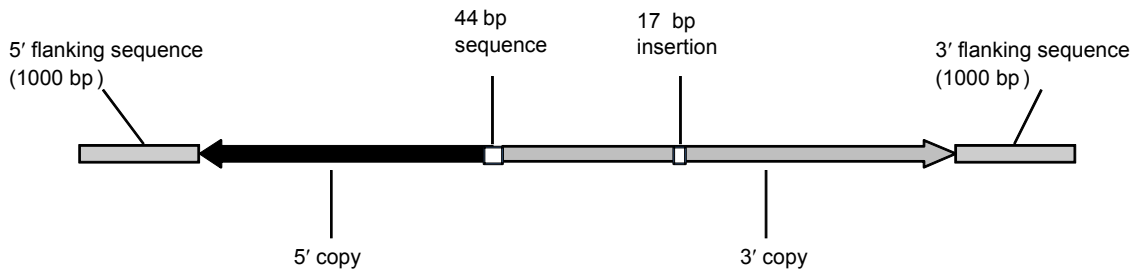


FIGURE 5 Sequence of the SYHT0H2 Soybean Insert and the Soybean Genomic Flanking Sequences

{Volume 2: CBI Cross-reference Number 4}

4.3 Data Quality and Integrity

No circumstances occurred during the conduct of this study that would have adversely affected the quality or integrity of the data generated.

5.0 CONCLUSION

The soybean genomic sequences flanking the SYHT0H2 insert were determined.

6.0 REFERENCES

Burgin K. 2011. *Event SYHT0H2 Soybean: Test and Control Substance Characterization of T_4, T_5, and T_6 Generations and 'Jack' Soybean*. Report No. TK0055856. Research Triangle Park, NC: Syngenta Crop Protection, LLC.

de Framond A. 2012. *Event SYHT0H2 Soybean: Insert Sequence Analysis.* Study No. TK0059645 (ongoing). Research Triangle Park, NC: Syngenta Crop Protection, LLC.

Ingham DJ, Beer S, Money S, Hansen G. 2001. Quantitative real-time PCR assay for determining transgene copy number in transformed plants. *BioTechniques* 31:132–140.

Nesbitt M. 2011. *Event SYHT0H2 Soybean: Genetic Stability Analysis*. Report No. TK0055857. Research Triangle Park, NC: Syngenta Crop Protection, LLC.

Nickell CD, Noel GR, Thomas DJ, Waller R. 1990. Registration of 'Jack' soybean. *Crop Sci* 30:1365.

Saghai-Maroof MA, Soliman KM, Jorgensen RA, Allard RW. 1984. Ribosomal DNA spacer-length polymorphisms in barley: Mendelian inheritance, chromosomal location, and population dynamics. *P Natl Acad Sci USA* 81:8014–8018.

US EPA. 1989. Good Laboratory Practice Standards. 40 CFR Part 160.

APPENDICES SECTION

APPENDIX A Sequencing Phase Report

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Amended GLP Phase Report
GW-Syn-002

Event SYHT0H2 Soybean: Flanking Sequence Determination

Sponsor

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Sponsor Study No. TK0059646

Study Director

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I. Phase Summary

GENEWIZ INC. provided regulatory submission-quality sequencing services for the sample submitted by Annick de Framond, Syngenta. Double-strand and four-fold sequencing coverage is provided for the regions of interest. All ambiguities were resolved on each strand. The consensus sequences match the Sponsor-provided reference sequences.

II. Amendments

This Report is amended as follows:

Amendment	Page	Reason
"DNA Star" is changed to "DNASTAR"	4	DNASTAR is the "correct" spelling of the software name
The GLP compliance statement is changed from: ''AS PRINCIPAL INVESTIGATOR, I MAINTAIN THAT THIS PHASE WAS PERFORMED IN COMPLIANCE WITH APPLICABLE GOOD LABORATORY PRACTICE (GLP) REGULATION AND ANY NONCOMPLIANCE OR DEVIATIONS ARE ADDRESSED IN THIS REPORT.'' To: "AS PRINCIPAL INVESTIGATOR, I MAINTAIN THAT THIS PHASE WAS CONDUCTED IN COMPLIANCE WITH THE RELEVANT PROVISIONS OF GOOD LABORATORY PRACTICE STANDARDS (40 CFR PART 160) PURSUANT TO THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT (FIFRA). THIS PHASE PLAN WAS ALSO PERFORMED TO APPLICABLE GLP REGULATION AS PROMULGATED BY FDA 21CFR PART 58. ADDITIONAL APPLICABLE CGMP MEASURES HAVE ALSO BEEN APPLIED TO THIS PHASE. ANY NONCOMPLIANCE OR DEVIATIONS ARE ADDRESSED IN THIS REPORT."	7	The GLP Compliance Statement must indicate the specific GLP guidelines followed during the analytical phase (e.g. 40 CFR Part 160).
The QA statement is changed from "THIS PHASE REPORT IS COMPLETE AND ACCURATELY REFLECTS THE CONDUCT AND DATA OF THE PHASE PLAN. THIS PHASE PLAN WAS PERFORMED TO APPLICABLE GLP REGULATION AS PROMULGATED BY FDA 21CFR PART 58 AND US EPA GLPS, 40 CFR PART 160. ADDITIONAL APPLICABLE CGMP MEASURES HAVE ALSO BEEN APPLIED TO THIS PHASE. ALL QA AUDIT OBSERVATIONS HAVE BEEN SATISFACTORILY RESOLVED." To: "THIS STATEMENT VERIFIES THAT THE AFOREMENTIONED STUDY COMPLETE AND ACCURATELY REFLECTS THE CONDUCT AND DATA OF THE PHASE PLAN AND, PURSUANT TO GOOD LABORATORY PRACTICE REGULATIONS (40 CFR PART 160 and 21 CFR PART 58), WAS INSPECTED AND/OR AUDITED AND THE FINDINGS REPORTED TO MANAGEMENT AND TO THE STUDY DIRECTOR BY THE QUALITY ASSURANCE UNIT ON THE DATES LISTED BELOW. ALL QA AUDIT OBSERVATIONS HAVE BEEN SATISFACTORILY RESOLVED."	7	To increase accuracy of QA statement.
"Study Audit Report was sent to the Study Director" Section added to the QA Statement	7	Date must be included in Report

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III. Phase Dates

Initiation Date: Oct. 21, 2011

Draft Report Date: Nov. 21, 2011

Completion Date: Dec. 07, 2011

Amendment Date: May 3, 2012

IV. Phase Results

The sequences of the regions of interest from the samples submitted by the Sponsor on 10/20/2011 and 11/04/2011 were determined by the sequencing reactions described in this report. The consensus sequences match the Sponsor-provided reference sequences. The consensus sequences are shown in Attachment A.

V. Key GENEWIZ Project Personnel

Principal Investigato[redacted] Date 3 May 2012

Associate Manager
Regulatory Services

Technical Scientist: [redacted] Date 4 May 2012

Associate Scientist II
Regulatory Services

Quality Assurance: [redacted] Date 4 May 2012

Director of Quality Assurance

VI. Test Article

The following test articles were provided by the Sponsor:

Test Article	Lot# (or Description)
DNA Fragments	A1-1, A2-1, A3-1; B1-1, B2-1, B3-2 Vials of stock received on 10/20/2011
DNA Fragments	B1-2 Vials of stock received on 11/04/2011

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VII. Experimental Design and Methods Used

1. Test Article

Upon the initiation of this project, the project identifier "GW-Syn-002" was assigned. The samples were stored at -20 °C in freezer GW-0041.

The submitted frozen sample stock was thawed at room temperature. An aliquot was used for sequence reactions. The rest of the sample stock was kept at -20 °C in freezer GW-0041.

2. Sequencing Primers

The sequencing primers, which are listed in Attachment B, were designed by the Sponsor and GENEWIZ and synthesized by IDT. Primers are based on the reference sequence provided by the Sponsor.

3. Sequencing Reactions

Primer extension sequencing reactions were assembled using the Big Dye Terminator Cycle Sequencing Ready Reaction Kit with AmpliTaq DNA Polymerase, FS (Version 3.1, Applied BioSystems). GENEWIZ alternative protocols for the difficult regions were also used.

4. Sequencing Data Analysis

Sequencing reactions were analyzed on the ABI 3730xl automated DNA sequencer (Applied Biosystems) validated at GENEWIZ for GLP studies. Raw data was collected using data collection software version 3.0 (Applied BioSystems). The data was analyzed using Sequence Analysis software, Version 5.3 (Applied BioSystems). Sequence data was further analyzed and assembled using LaserGene Version 8 (DNASTAR).

5. Consensus Sequence Analysis

Each consensus sequence is derived from combining the sequence of three independent clones per fragments.

VIII. Acceptance Criteria

1. Raw data with quality scores (QS) of 40 and above.
2. Four-fold coverage for the region indicated.
3. Plasmid (pGEM) that is used as the reaction and instrument controls for each sequence reaction plate with QS ≥ 40 and a CRL (continuous read length) ≥ 800.
4. Control plasmid (pGEM) with two correct sequencing motifs, nt 24-27 (GGGG) and nt 479-487 (CCGTAAAAA), to control for plate orientation and to serve as identity QC markers.

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IX. Record Retention

The phase records are retained as per SOP GW.018. Original signed reports are remitted to the Sponsor at the completion of the phase as per SOP GW.042.

GENEWIZ will transfer the original phase plan, original phase report, and all raw data and records, except for the facility-specific records, to Syngenta Crop Protection, LLC. for archiving within 90 days of study completion. Facility-specific records supporting this study will be retained by GENEWIZ for an indefinite period.

X. Sample Handling and Retention

The samples were tracked and retained as per SOP GW.007 and the Phase Plan. Samples will be stored at GENEWIZ for three months after the data is uploaded. After three months, samples will be discarded or returned to the Sponsor upon request.

XI. Delivery of Results

The project deliverables include the following items:

1. The final Phase Report reviewed and approved by GENEWIZ QA Unit.
2. GLP Statement provided by the Principal Investigator.
3. A signed QA Statement confirming that all work is completed in accordance with Good Laboratory Practice Standards (GLPS) as specified by FDA 21 CFR, Part 58 and US EPA GLPS, 40 CFR Part 160.
4. A CD containing this Phase Report and the raw data in .ab1, .phd, and .seq formats.

XII. Investigations

The OOS document “GW11-OOS-011” (Date: Oct. 25, 2011; Notebook GW-125) was filed at GENEWIZ to document that clone B1-1 appear to be a mixed population. Sample B1-2 was received from the Sponsor and replaces B1-1. The document and the original laboratory notebook are available for onsite inspection/audit by authorized personnel. No negative impact to this study was found.

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XIII. SOP Used in the Phase

SOP No.	Title
GW.006	Laboratory Notebook Issuance and Use
GW.007	Sample Handling and Tracking Procedure for Regulated Services
GW.231	Primer Design and Synthesis
GW.232	Single- and Double-Stranded Primer Walking
GW.129	Measuring OD of dsDNA using the NanoDrop Spectrophotometer
GW.125	Analysis, Quality Control Check, and Scoring of Sequencing Data
GW.115	DNA Sequencing Using Big Dye v3.1 Chemistry
GW.116	Alternative Protocols for Difficult Templates
GW.143	Post-Cycling Processing of Sequencing Plates Using MicroFlo Liquid Dispensers
GW.127	Plate Processing using Precipitation Protocol
GW.008	Installation, Calibration and Maintenance of the ABI 3730 DNA Analyzer
GW.009	Sequencing Data Back Up for ABI 3730
GW.011	Procedure for the Operation, Calibration, and Maintenance of Pipettes
GW.010	Installation, Calibration and Maintenance of the Thermocyclers
GW.015	Investigation of Out of Specification (OOS) and Unexpected results
GW.016	Change Control Procedure
GW.018	Document Control
GW.020	Procedure for Handling Deviations in GLP Studies
GW.026	Conducting and Monitoring of GLP Studies
GW.042	GLP Study Protocol & Report
GW.012	Preparing, Performing and Archiving a Study Audit by the QAU
GW.013	Preparing, Performing and Archiving a Facility Audit by the QAU

XIV. QA Oversight

Independent QA oversight of this phase was performed as promulgated by applicable FDA 21CFR Part 58 and US EPA GLPS, 40 CFR Part 160 regulations. QA oversight of this phase included but was not limited to handling of the Master Schedule, Phase Protocol Approval, In-Process Auditing, Review and Approval of the Final Report and Archiving of phase documentation. A signed QA statement is included in this project report. Additional applicable cGMP measures have also been applied to this phase.

XV. Table of Attachments

ATTACHMENT	PROCESS/TOPIC	# PAGES	ENTERED BY (DATE)
Attachment A	Consensus Sequences	2	[redacted] (11/21/2011)
Attachment B	Sequencing Primers	1	[redacted] (11/21/2011)
Attachment C1	Full Length Contig (A Clones)	1	[redacted] (11/21/2011)
Attachment C2	Full Length Contig (B Clones)	1	[redacted] (11/21/2011)
Attachment D1	Full Length Alignments (Reference vs Consensus; A Clones)	2	[redacted] (11/21/2011)
Attachment D2	Full Length Alignments (Reference vs Consensus; B Clones)	2	[redacted] (11/21/2011)

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GLP COMPLIANCE STATEMENT

AS PRINCIPAL INVESTIGATOR, I MAINTAIN THAT THIS PHASE WAS CONDUCTED IN COMPLIANCE WITH THE RELEVANT PROVISIONS OF GOOD LABORATORY PRACTICE STANDARDS (40 CFR PART 160) PURSUANT TO THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT (FIFRA). THIS PHASE PLAN WAS ALSO PERFORMED TO APPLICABLE GLP REGULATION AS PROMULGATED BY FDA 21CFR PART 58. ADDITIONAL APPLICABLE CGMP MEASURES HAVE ALSO BEEN APPLIED TO THIS PHASE. ANY NONCOMPLIANCE OR DEVIATIONS ARE ADDRESSED IN THIS REPORT.

GLP Principal Investigator Signature/Date [redacted] 3 MAY 2012

QA STATEMENT

THIS STATEMENT VERIFIES THAT THE AFOREMENTIONED STUDY COMPLETE AND ACCURATELY REFLECTS THE CONDUCT AND DATA OF THE PHASE PLAN AND, PURSUANT TO GOOD LABORATORY PRACTICE REGULATIONS (40 CFR PART 160 and 21 CFR PART 58), WAS INSPECTED AND/OR AUDITED AND THE FINDINGS REPORTED TO MANAGEMENT AND TO THE STUDY DIRECTOR BY THE QUALITY ASSURANCE UNIT ON THE DATES LISTED BELOW. ALL QA AUDIT OBSERVATIONS HAVE BEEN SATISFACTORILY RESOLVED.

QA Audits Performed

Phase/Stage	Date Conducted
In Process Audit	11/21/2011
Draft Report & Raw Data No significant findings were found.	12/07/2011
Audit reports were sent to the Study Director	02/01/2012

QA Director Signature/Date: [redacted] / 4 May 2012

PHASE REPORT FINAL APPROVAL

Company Representative	Signature	Date
Principal Investigator	[redacted]	3 MAY 2012
QA		4 May 2012

APPENDIX A Sequencing Phase Report (Continued)

{Volume 2: CBI Cross-reference Number 5}

APPENDIX B Sequence of the SYHT0H2 Insert and Soybean Genomic Flanking Sequences in GenBank Format

{Volume 2: CBI Cross-reference Number 6}