

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
INVESTIGATIVE AND ENFORCEMENT SERVICES

REPORT OF INVESTIGATION

Case Number: MT140008-BR

Subject(s): Monsanto Company
(*Contact Information*) 800 North Lindbergh Boulevard
Saint Louis, Missouri 63167
Phone: (314) 694-1000
Fax: (314) 694-2306
Web: www.monsanto.com

Registered Agent:
Corporation Service Company
2711 Centerville Road, Suite 400
Wilmington, DE 19808
Phone: (302) 636-5400
Fax: (302) 636-5454
E-mail: csrcontact@cscinfo.com

Montana State University,
Southern Agricultural Research
Center
748 Railroad Highway
Huntley, Montana 59037
Phone: (406) 348-3400
Fax: (406) 348-3410
Web: www.sarc.montana.edu

Investigator:
(*Contact Information*) USDA, APHIS, IES
2150 Centre Avenue, Bldg. B-3W10
Fort Collins, Colorado 80526

Date of Report: October 7, 2015

- Substantiated allegation(s)**
- No violation(s)**
- Insufficient evidence**
- Fact finding**
- Contains Confidential Business Information**

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Reviewer: _____, Area Director

SYNOPSIS

On 07/07/14, _____ Montana State University (MSU), Southern Agricultural Research Center (SARC) notified for the Monsanto Company (Monsanto) that wheat volunteers¹ growing in a field at SARC appeared to be resistant to Roundup². In addition, _____ informed Monsanto representatives that Enzyme-Linked Immunosorbent Assay³ (ELISA) tests indicated the volunteers were positive for the CP4 EPSPS⁴ protein. In response, _____ and two other Monsanto representatives visited MSU, SARC on 07/09/14 to observe the wheat volunteers and collect samples. They collected leaf material from 60 wheat volunteers for testing. Monsanto tested the samples from 07/09/14 through 07/13/14 to determine whether the plants contained the *cp4 epsps* gene (a gene found in Roundup Ready (RR) crops), and Event 33391/MON71800⁵ (a RR wheat event developed by Monsanto). All the samples tested positive for the *cp4 epsps* gene and for Event 33391/MON71800.

On 07/14/14, _____ spoke with Dr. Edward Jhee, the Director of the Regulatory Operations Program for the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Biotechnology Regulatory Services (BRS) and notified him of the presence of glyphosate resistant wheat volunteers in a field at MSU, SARC. On 07/15/14, _____ provided written notification of the discovery to Dr. Jhee and the parties agreed to have a meeting on 07/16/14 to discuss the issue. APHIS, Monsanto, and MSU, SARC officials participated in the meeting. During the meeting, the parties discussed the discovery, appearance, location, and herbicide application history of glyphosate resistant wheat. _____ provided information about MSU, SARC's research and farming practices and the university's participation with Monsanto's glyphosate resistant wheat trials carried out through APHIS's notification procedures applicable to genetically engineered (GE) material (7 C.F.R. § 340.3).

Monsanto conducted over 100 field trials with wheat containing this specific glyphosate resistant trait in 17 states (including Montana) from 1998 through 2005, under APHIS's notification procedures. APHIS has not deregulated GE wheat; therefore, it is not commercially available in the United States and cannot lawfully grow in unregulated areas. From 2000 through 2003, MSU, SARC was a research cooperator for Monsanto and the university participated in four GE wheat field trials. The trials took place in two fields, _____ at SARC.

¹ Wheat plants not intentionally planted.

² Roundup is a glyphosate-based agricultural herbicide developed by Monsanto in the 1970s to kill weeds, such as annual broadleaf weeds and grasses. Monsanto has formulated many glyphosate-based herbicide products using the Roundup® brand.

³ The intended use of the ELISA test was to determine the presence of the CP4 EPSPS endotoxins in genetically modified organisms, and in turn to determine whether the product is of genetically modified organism (GMO) origin and whether it is herbicide resistant plant.

⁴ CP4 EPSPS is an acronym for the protein 5-enolpyruvylshikimate-3-phosphate synthase isolated from *Agrobacterium* sp. Strain CP4; *epsps* (lowercase) refers to the gene, and EPSPS (upper case) refers to the protein.

⁵ Event 33391/MON71800 is a genetically engineered wheat variety that Monsanto developed to allow the use of glyphosate, the active ingredient in the herbicide Roundup®, as a weed control option in spring wheat. Monsanto developed the event by introducing the CP4 EPSPS coding sequences into the spring wheat variety, Bobwhite, using *Agrobacterium*-mediated transformation.

After learning of the GE volunteers, APHIS initiated an investigation and assembled a field response team. The team's primary objectives included the following:

- Identify suspect volunteers and determine whether the plants contained the CP4 EPSPS protein and Event MON71800.
- Identify whether the GE wheat volunteers were known wheat cultivars or determine which known wheat cultivars most closely resembled the volunteers.
- Determine if the wheat volunteers originated from trials.
- Determine if the volunteers are the same as or similar to the GE wheat that was discovered during the 2013 Oregon wheat incident⁶.
- Determine who introduced the GE wheat volunteers into the environment at SARC and how it occurred.
- Determine how long GE wheat volunteers have persisted in the environment at SARC.
- Ensure the GE volunteers were contained to the facility and not allowed to enter commerce.
- Obtain information about SARC's participation in Monsanto's GE wheat field trials and their general research and farming practices.
- Determine if Monsanto was required to obtain a permit from BRS prior to removing GE wheat plant material from MSU, SARC when the company conducted preliminary genetic testing for Roundup resistance in July 2014.
- Determine why SARC and Monsanto officials did not immediately report the discovery of GE wheat to APHIS.

The team traveled to MSU, SARC and obtained additional information about the facility, SARC's research and educational programs, current and past cropping histories, crop management practices, and equipment usage. The APHIS team issued USDA, APHIS, BRS Emergency Action Notifications, while they assessed the situation and controlled access to the affected fields. The team observed volunteers, collected samples for testing, and scouted the area for other glyphosate resistant volunteers. From 07/18/14 through 08/08/14, the team collected over 200 wheat plant and grain samples. They sent the samples to the USDA, Grain Inspection, Packers and Stockyards Administration (GIPSA), Technology and Science Division (TSD) and/or the USDA, Agricultural Research Services (ARS), Western Regional Small Grains Genotyping Center (WRSGGC). The team sent samples to GIPSA to confirm the presence of CP4 EPSPS protein and Event MON71800. GIPSA's results concluded samples from
 were positive for CP4 EPSPS and Event MON71800. The team
 also collected samples

the team sent the samples to GIPSA for testing.
 MSU, SARC,

The samples from this field tested negative for the presence of a GE event, and APHIS officials took no further action involving this field. Once GIPSA completed testing, GIPSA forwarded many of the samples to the USDA, ARS, WRSGGC for molecular marker analysis. The purpose of the analysis was to determine the volunteers' genetic makeup and identify which wheat samples most closely resembled the volunteers. ARS's genetic testing indicated the samples did not represent multiple

⁶ In 2013, APHIS conducted a fact-finding investigation in response to the detection of GE wheat volunteers, containing transgenic event MON71800, in a single Oregon field. During this investigation, APHIS collected and tested samples of the volunteers.

populations and the heterogeneity⁷ frequency within the population of samples indicates they were in an early generation selection from a possible backcross. Consequently, ARS officials could not determine an exact match to a known cultivar.

To mitigate, control, and/or destroy the presence of GE wheat volunteers, BRS reviewed and approved various field actions and plans submitted by SARC. The primary objectives of the field actions and plans were to ensure SARC and APHIS officials properly monitored, maintained, harvested, stored, and disposed of SARC's wheat crops. Ultimately, APHIS officials monitored the harvesting and disposal of wheat at SARC in 2014. BRS also established and approved a plan to address any recurring volunteers during SARC's 2015 and subsequent growing seasons.

The APHIS team reached the following conclusions based on the investigation and the information provided by BRS, Monsanto, MSU, SARC, and other officials:

1. APHIS confirmed the presence of GE wheat volunteers, containing the *cp4 epsps* gene and Event MON71800, at MSU, SARC.
2. APHIS was not able to match the GE wheat volunteers to a known cultivar because their genetic characteristics were representative of an early generational population and not of a known wheat cultivar. GIPSA determined the volunteers most likely represented Hard Red Winter Wheat based on their visual inspection of the kernels extracted from some of the mature samples.
3. The GE wheat volunteers discovered at MSU, SARC are not the same as or similar to the GE wheat volunteers detected in Oregon in 2013.
4. The evidence obtained during the investigation suggests the 2014 GE wheat volunteers most likely originated from the GE wheat fields trials that took place at MSU, SARC from 2000 to 2003.
5. The GE wheat volunteers were contained to the facility and did not enter commerce in 2014; however, there was not sufficient evidence available to prove the GE wheat volunteers did not exist at the facility prior to 2014.
6. There is not sufficient evidence to show that Monsanto representatives removed viable⁸ GE wheat plant material from MSU, SARC. The evidence obtained suggests Monsanto only removed non-viable plant tissue; therefore, they were not required to notify or obtain authorization from APHIS to remove the non-viable material.
7. Based on APHIS's interpretation of 7 C.F.R. § 340.3, MSU, SARC and Monsanto should have immediately reported the presence of glyphosate resistant wheat to USDA when they first suspected it at the facility. Instead, both parties waited to notify BRS of the discovery until 07/14/14, which is seven days after MSU, SARC notified Monsanto of the wheat volunteers and after Monsanto confirmed the presence of GE wheat through additional testing.

⁷ Heterogeneity (*i.e.*, genetic diversity) means having dissimilar pairs of genes for any given pair of hereditary characteristics.

⁸ Viable pertains to plant material, such as seeds, which are capable of normal growth and development without human intervention.

BACKGROUND

Subject(s) Information

Monsanto Company is an American multinational agrochemical and agricultural biotechnology corporation headquartered in Saint Louis, Missouri. The company engages in the research, development, production, and sale of various agricultural products. Among other things, Monsanto produces GE crop seed and the herbicide glyphosate⁹. Monsanto markets this herbicide under the Roundup brand. For fiscal year 2014, Monsanto reported net sales of \$15.855 billion, and the company employs approximately 22,000 people worldwide. Monsanto is a Delaware Domestic Corporation and its Corporate File number is 3174788. Hugh Grant is the Chairman and Chief Executive Officer and Brett D. Begemann is the President and Chief Operating Officer.

Montana State University (MSU), Southern Agricultural Research Center (SARC) is one of seven agricultural research centers that make up Montana Agricultural Experiment Station (MAES) Research Center System. MSU's College of Agriculture and MAES, Montana

SARC is a 462 acre facility and part of the of the research component of MSU-Bozeman. The United States Bureau of Reclamation originally created this facility as a demonstration farm in 1907. MSU became involved with the facility in 1910, when it became a USDA Bureau of Plant Industries Field Station. The U.S. Bureau of Reclamation formally transferred ownership of the facility to the State of Montana in 1953. The State of Montana closed the facility in 1995 due to budgetary constraints; however, they reopened it in February 1998. Currently, ten members of MSU, SARC's personnel work at the facility and At the facility, SARC officials conduct agronomic research and related educational programs relevant to agriculture in the dryland and irrigated areas of south central Montana. From 2000 to 2003, MSU, SARC was a research cooperator with Monsanto and participated in four of Monsanto's wheat field trials carried out under APHIS's notification provisions for GE material.

Subject(s) Previous History

Prior Enforcement Actions

On 09/21/15, APHIS issued Monsanto a settlement agreement of \$81,200 to resolve alleged violations involving Monsanto's failure to maintain and dispose of GE dicamba-resistant soybean volunteers (APHIS regulated article) prior to flowering and as to prevent the dissemination and establishment of a plant pest, which could result in persistence in the environment (MN140042-BR). Monsanto accepted and paid the settlement on 09/24/15.

Prior Adjudications

N/A

⁹ Glyphosate (*N*-(phosphonomethyl) glycine) is a broad-spectrum systemic herbicide used to kill weeds, such as annual broadleaf weeds and grasses. Monsanto discovered the chemical could be used as a herbicide 1970 and the company later marketed the herbicide under the trade name Roundup in 1974.

NARRATIVE**Basis for Investigation**

On 07/16/14, Dr. Jhee requested that USDA, APHIS, Investigative and Enforcement Services (IES) initiate an investigation to the discovery of GE wheat volunteers that tested positive for the CP4 EPSPS protein and Event MON71800, at MSU, SARC. APHIS has not deregulated GE wheat and it is not commercially available in the United States. The introduction of GE wheat requires notification and approval from APHIS and is regulated by 7 C.F.R. Part 340.

Investigative Findings**Investigative Findings Content:**

- A. Discovery of GE Wheat at MSU, SARC
 - 1. Background Information from MSU, SARC
 - 2. ELISA Tests Conducted by MSU, SARC
 - 3. Monsanto's Initial Response to Discovery
 - 4. Monsanto's Testing of Wheat Volunteers and Reporting of Results to APHIS
- B. Overview of Monsanto's GE Wheat Field Trials and Event MON71800
- C. APHIS Response to the Discovery and Report
 - 1. APHIS Field Team Response and Sample Collection
- D. GIPSA and ARS Sample Testing and Results
- E. MSU, SARC Facility Information
 - 1. General Information
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 - 3. Field Management and Cropping History
 - 4. Pesticide Applications for Field Management
- F. Field Actions and Equipment Usage, Cleaning, and Inspections
 - 1. Field Actions
 - 2. Equipment Usage and Cleaning
 - 3. Equipment Inspections
- G. SARC's Participation in Monsanto's GE Wheat Field Trials
 - 1. 2000 GE Wheat Trial and USDA Notification No. 00-038-19n
 - 2. 2001-2003 GE Wheat Trials and USDA Notifications Nos. 01-016-24n, 02-032-07n, and 03-022-01n
- H. Additional Information from Monsanto
- I. Investigative Conclusions

A. Discovery of GE Wheat at MSU, SARC

- 1. Background Information from MSU, SARC

On 07/07/14, _____ notified _____, via _____ of Monsanto, that wheat volunteers were growing in a field at MSU, SARC, which appeared to be resistant to Roundup

(Exhibit 1, pg. 10 ¶ 28). identified the field as
 According to , these areas are dryland and ,
 MSU, SARC, was responsible for them since 2008
 (Exhibit 1, pg. 10 ¶ 26). stated he became suspicious the volunteers were glyphosate
 resistant on 06/20/14 when informed him his staff treated the areas with Roundup
 and the herbicide killed all plant material except for wheat. shared a photograph
 (Exhibit 2) with , which shows a healthy wheat plant surrounded by dead plant
 material and wheat volunteers growing in the background

(Exhibit 3, pg. 5 ¶ 16).

He claimed his staff haphazardly controls the weeds in these areas. According to ,
 around the beginning of May 2014, his assistant, , sprayed the
 with RT 3,¹² at a 22 or 24 ounce per acre application rate (Exhibit 3, pg. 5 ¶ 20).
 confirmed this fact and provided the application date and rate as 05/12/14 and 24 ounce per acre
 (Exhibit 4, pgs. 4 and 5 ¶ 14). By the time brought the issue to
 attention, the volunteers were approximately twelve to eighteen inches tall and in the late boot
 stage¹³ of growth (Exhibits 1, pg. 10 ¶ 28 and 3, pg. 8 ¶ 29). SARC officials made the decision
 to reapply RT 3 at 32 ounce per acre application rate. SARC officials applied the application on
 06/24/14 and they allowed the herbicide to set approximately for two weeks to ensure it had time
 to work. According to , he mowed the western two days prior to this
 application (Exhibit 4, pg. 5 ¶ 15). documented the herbicide applications in his field
 management records (Exhibit 5). The specimen label for RT 3 indicates performance is better
 for controlling wheat when the grower applies it before the plant reaches the boot stage of
 growth (Exhibit 6, pg. 11). According to the label, the maximum application rate of RT 3 is 22
 ounce per acre for plants eighteen inches tall.

When the second application had no effect on the volunteers, contacted Monsanto.
 According to , he did not contact USDA because it was not on his “radar” (Exhibit 1,
 pg. 11 ¶ 28). In contrast, claimed he and initially thought to contact
 USDA, but they were not sure the volunteers were actually glyphosate resistant and were
 concerned USDA would shut down SARC’s research (Exhibit 3, pg. 8 ¶ 30).

2. ELISA Tests Conducted by MSU, SARC

Prior to notifying Monsanto, MSU,
 SARC, tested some of the suspect volunteers using an ELISA test kit designed to detect the
 presence of the CP4 EPSPS protein in corn, cotton, and soybeans (Exhibits 7, pg. 2 ¶ 4 and 343).
 claimed he conducted the test during the first week of July. According to , the
 volunteers were in the heading stage¹⁴ at the time of the test. explained he completed
 two separate test runs following the kit’s protocol. He stated the majority of the samples tested
 positive for the CP4 EPSPS protein. He indicated, however, he suspected the results might be

¹⁰ Fallow means the grower does not plant on the land for one or more growing seasons.

¹¹ Dryland is a farming method used by growers in semiarid areas without the aid of irrigation, using drought-resistant crops and conserving moisture.

¹² RT 3 is a glyphosate-based agriculture herbicide product that Monsanto formulated from its Roundup® herbicide technology.

¹³ Boot stage begins when the head of the wheat develops and becomes visible beneath the sheath on the stalk. The booting stage ends when the tips of the head, called awns, begin to emerge.

¹⁴ Heading Stage begins when the awns emerge from the sheath, flowering begins, and pollination and fertilization occurs.

inconclusive due to the age of the plants and the possibility of false positives. took photographs of the ELISA tests (Exhibit 8) and shared them with . The photos show tested eight samples, which he suspected as RR wheat. emailed the photos of the ELISA tests and a photo of the area where the test samples originated to on 07/07/14 (Exhibits 8 – 10). confirmed Monsanto was aware of the ELISA tests conducted by , but maintained this type of testing is unreliable (Exhibit 11, pgs. 13 and 14 ¶ 37). He explained no one has validated CP4 protein based detection methods for wheat and use of such testing methods can produce false positives.

3. Monsanto's Initial Response to Discovery

After learning of the RT 3 resistant wheat, Monsanto officials, which included , and , visited MSU, SARC on 07/09/14 to observe the wheat volunteers and collect samples (Exhibit 11, pg. 14 ¶ 37).

Monsanto. According to , he observed approximately 1500 wheat volunteers, which were close to heading in the

(Exhibit 40, pg. 3).

explained the team believed the volunteers were not likely glyphosate-resistant based on the information provided by and their observations. He believed SARC officials had not applied the herbicide properly and explained why Monsanto did not notify USDA at the time. stated since Monsanto could not conclusively eliminate Roundup resistance as a possibility, Monsanto determined further testing was necessary to make an appropriate scientific determination as to glyphosate resistance. Monsanto did not perform any onsite field tests using lateral flow test strips for example, because according to these methods produce unreliable results and are not valid for wheat. confirmed Monsanto collected green leaf material to use for genetic testing in Missouri. claimed the material did not contain any viable plant parts, and thus did not require approval from USDA to remove it from SARC. Before leaving SARC, advised to that he should prevent the volunteers from developing viable seed without actually destroying the plants until Monsanto completed testing (Exhibit 11, pgs. 14 - 16 ¶¶ 38 – 44). opted to mow the areas on 07/09/14 to stop the volunteers from flowering (Exhibit 1, pg. 11 ¶ 29).

4. Monsanto's Testing of Wheat Volunteers and Notification of Results to APHIS

According to Monsanto's testing documentation, delivered 60 wheat samples to Monsanto's laboratory on 07/09/14. Monsanto's laboratory personnel manually processed the samples and then tested them multiple times from 07/09/14 through 07/13/14 using Event Specific Taqman¹⁵ PCR (polymerase chain reaction) assays¹⁶ (Exhibit 12). The documentation shows Monsanto conducted multiple tests on the samples due to performance issues with the assays. claimed Monsanto has validated this PCR-based testing method, which

¹⁵ TaqMan are hydrolysis probes designed to increase the specificity of quantitative PCR. The Taqman probe principle relies on the 5' – 3' exonuclease activity of *Taq* polymerase to cleave a dual-labeled probe during hybridization to the complementary target sequence and fluorophore-based detection.

¹⁶ Assay is an analytical procedure for qualitatively assessing or quantitatively measuring the presence or amount of a component of a mixture, in this case a transgene in a wheat tissue sample.

produces reliable results (Exhibit 11, pg. 15 ¶ 44).¹⁷ The purpose of the testing was to determine if the samples contained the *cp4 epsps* gene and Event 33391/MON71800 or Event 33512/MON71400¹⁸. According to _____, all the samples tested positive for the *cp4 epsps* gene and Event 33391/MON71800 (Exhibit 11, pg. 16 ¶ 44).

On 07/14/14, _____ orally notified Dr. Jhee about the discovery of glyphosate resistant wheat volunteers at MSU, SARC (Exhibits 11, pg. 16 ¶ 45, and 14, pg. 1 ¶ 3). _____ claimed the notification occurred immediately after Monsanto's laboratory determined the samples were positive. On 07/15/14, _____ provided written notification to Dr. Jhee about the discovery (Exhibit 15). According to the notification, Monsanto identified glyphosate resistant wheat volunteers, which were positive for the *cp4 epsps* gene, _____ MSU, SARC. The letter indicated four regulated RR wheat field trials previously occurred at the facility, under APHIS notification numbers 00-038-19n, 01-016-24n, 02-032-07n, and 03-022-01n. On the same day, _____ orally informed Dr. Jhee that Monsanto conducted event specific PCR testing and the results indicated the volunteers contained Event 33391/MON71800 (Exhibit 14, pg. 2 ¶ 9).

B. Overview of Monsanto's GE Wheat Field Trials and Event MON71800

From 1998 through 2005, Monsanto conducted over 100 field trials with wheat containing this specific glyphosate resistant trait under APHIS's notification procedures for the introduction of GE articles (Exhibit 16, pg. 2). The trials occurred in 17 states, including Montana. APHIS Notifications, Letters to the State Departments of Agriculture, letters to Monsanto, and Wheat Field Trial Reports for 00-038-19n (Exhibits 17 – 21), 01-016-24n (Exhibits 22 – 25), 02-032-07n (Exhibits 26 – 29), and 03-022-01n (Exhibits 30 – 33) shows the State Departments of Agriculture and APHIS authorized the trials that occurred at MSU, SARC from 2000-2003. The APHIS Notifications also show Monsanto derived the glyphosate tolerant wheat used in the trials from the cultivar, Bobwhite, and contained Event 33391/MON71800. The Center for Environment Risk Assessment (CERA), GM Crop Database, shows Monsanto developed Event MON71800 by introducing the CP4 EPSPS coding sequences into the Bobwhite spring wheat variety using *Agrobacterium*¹⁹- mediated transformation (Exhibit 34, pg. 1 ¶ 4).

On 05/10/04, Monsanto announced its termination of its RR wheat breeding and research program due to the lack of commercial opportunities and its desire to refocus on other crops (Exhibit 35). In 2009, Monsanto reentered the wheat business (Exhibit 35 and 36). At which point it started a second wheat research project involving a different wheat event and small-scale entry-level trials in North Dakota and Canada (Exhibit 36).

¹⁷ In 2013, GIPSA performed a validation of this method and determined it was appropriate for detecting 33391/MON71800 in wheat (Exhibit 13).

¹⁸ Event 33512/MON71400 is a genetically engineered wheat variety that Monsanto developed to allow the use of glyphosate, the active ingredient in the herbicide Roundup®, as a weed control option in spring wheat. Monsanto developed it by introducing the CP4 EPSPS coding sequences into the spring wheat variety, Bobwhite, using *Agrobacterium*-mediated transformation.

¹⁹ *Agrobacterium* is a genus of Gram-negative bacteria that uses horizontal gene transfer to cause tumors in plants. This bacteria is well known for its ability to transfer DNA between itself and plants, and for this reason, it has become an important tool for genetic engineering.

During three trials that occurred at MSU, SARC from 2001-2003, _____, was Monsanto’s lead wheat seed breeding research partner. _____ provided the GE wheat seed for the trials SARC’s responsible researchers (Exhibit 11, pg. 8 ¶¶ 26 and 27).

C. APHIS Response to the Discovery and Report

On 07/16/14, APHIS, Monsanto, and MSU, SARC officials participated in the meeting via phone or in person to discuss the discovery of GE wheat volunteers at MSU, SARC (Exhibits 11, pg. 16 ¶ 45; and 14, pg. 3 ¶ 10 – 11). Two of the APHIS officials who participated in the meeting were Dr. Jhee and _____ (Exhibits 14 and 40).

According to Dr. Jhee and _____, _____, and _____ represented Monsanto, while _____ and _____ represented MSU, SARC. _____ Monsanto’s _____ Monsanto, _____ MSU’s College of Agriculture and Montana Agriculture Experiment Station.

During the meeting, Monsanto and SARC officials provided information pertaining to the discovery, appearance, location, and the herbicide application history of the GE wheat volunteers. Monsanto shared photos of the volunteers and affected _____ (Exhibits 37 and 38) and maps of the facility (Exhibit 39) amongst the participants.

MSU, SARC _____ Monsanto and SARC officials also provided information pertaining to MSU, SARC’s research and farming practices and involvement with Monsanto’s GE wheat trials (Exhibits 14, pgs. 3 – 6 ¶¶ 10 and 11, and 40, pgs. 3 – 6 ¶¶ 8 - 13).

In regards to the discovery, Dr. Jhee and _____ stated MSU, SARC and Monsanto officials did not mention _____ conducted ELISA tests. Dr. Jhee and _____ agreed Monsanto and SARC should have immediately reported the discovery to USDA on 07/07/14, when they first suspected the volunteers could be glyphosate resistant (Exhibits 14, pg. 3 ¶ 11 and 40, pg. 5 ¶ 10). Both stated Monsanto reported it collected at least 60 samples for testing, and Dr. Jhee explained Monsanto should have obtained approval from BRS if they removed viable GE plant material from SARC (Exhibit 14, pg. 4 ¶ 11). According to Dr. Jhee and _____, Monsanto and SARC officials reported the presence of 800 – 1000 volunteers in the _____ which were mowed early in the season and described as being dwarfed spring wheat with a distinct head. Monsanto and/or SARC officials also reported that SARC mowed the volunteers again after Monsanto’s initial site visit to delay further growth. In regards to the location of the volunteers, the

(Exhibit 40, pg. 3 ¶ 9). SARC _____ (Exhibits 5, pg. 3; and 40, pg. 4 ¶ 9). In regards to the herbicide application history, Dr. Jhee and _____ verified Monsanto and/or SARC reported the RT3 applications and rates (Exhibits 14, pg. 3 ¶ 11 and 40, pg. 5 ¶ 10). Both stated _____ indicated he waited almost two weeks to contact Monsanto after the second application of RT3 because the chemical needed time to work due to the maturity of the volunteers and to ensure there was no application error. When discussing the presence of volunteers in 2014 and previous years, Dr. Jhee and _____ explained _____ mentioned more than once that _____ and _____ have

reputations for poor field management and it was not unusual to see weeds and volunteers in fields they managed (Exhibits 14, pg. 5 ¶ 11 and 40, pg. 6 ¶13).

In regards to the trials, Dr. Jhee and _____ verified SARC and Monsanto officials told them the trials took place in _____ MSU, SARC (Exhibits 14, pg. 4 ¶ 11 and 40, pg. 3 ¶ 9).

SARC _____ According to Dr. Jhee, Monsanto and/or SARC informed them the wheat used in the trials was hard red spring wheat. _____ explained Monsanto representatives claimed they scouted areas outside the _____, specifically, _____ during their visit and claimed they did not observe any wheat volunteers (Exhibit 40, pg. 5 ¶ 11). According to _____, during the time frames of the trials Monsanto did not report any infractions, unusual occurrences, and/or unauthorized releases, which could explain the presence of GE wheat volunteers in 2014 (Exhibit 40, pg. 6 ¶ 12).

1. APHIS Field Team Response and Sample Collection

After the meeting, Dr. Jhee asked IES to initiate an investigation and APHIS officials assembled a field response team to respond to the incident (Exhibits 14, pg. 6 ¶ 12).

Investigator for USDA, APHIS, IES was assigned the investigation (Exhibit 41). The initial field response team consisted of Investigator _____, BRS Biological Scientist _____, IES Investigator _____, and PPQ Plant Health Safeguarding Specialist _____. APHIS personnel rotated in and out throughout the response. According to Investigator _____ the team's primary focus and objectives was (Exhibit 41, pg. 1 ¶ 4):

- To identify suspect volunteers and determine whether the plants contained the CP4 EPSPS protein and Event MON71800.
- Ensure the GE volunteers are contained at MSU, SARC and not allowed to enter commerce.
- Obtain information about SARC's participation in Monsanto's GE wheat field trials and its research and farming practices.
- Determine the cultivars of the GE wheat volunteers and if they were derived from trials and/or related to the 2013 Oregon wheat incident.
- Determine who introduced the GE wheat volunteers into the environment at SARC and how it occurred.
- Determine how long GE wheat volunteers have been persisting in the environment at SARC.
- Determine if Monsanto was required to obtain a permit from BRS prior to removing GE plant material from MSU, SARC.
- Determine if MSU, SARC and Monsanto reported the discovery to APHIS accordingly.

From 07/18/14 through 08/08/14, the APHIS response team field-tested and collected over 200 wheat plant and grain samples following several sampling plans. The team arrived at MSU, SARC on 07/18/14 and met with _____ and _____, as explained in the declarations of Investigator _____ and _____ (Exhibits 40, pg. 6 ¶ 14; 41, pg. 2 ¶ 5; and 42, pg. 5 ¶ 18). _____ and _____ escorted the team to the _____ and shortly thereafter APHIS officials issued USDA, APHIS, PPQ Emergency Action Notification (EAN) No. 408836-DM to _____ (Exhibit 43). The EAN restricted access to _____ APHIS personnel, necessary MSU personnel, and Monsanto personnel. The notice

also prohibited SARC from moving, harvesting, or destroying plant material from the field without prior approval from APHIS.

The team then focused on the objectives outlined in the first sampling plan titled, “*Tactical Plan for Collection of Field Samples*” (Exhibit 44). The objectives were:

- To identify wheat volunteers in the _____ and test them for the presence of the CP4 EPSPS protein using the EnviroLogix QuickStix™ Kit for Roundup Ready® CornBulk Grain²⁰ (Exhibit 45).
- Collect the positive volunteers and ship them to GIPSA for additional testing and analysis.
- Scout additional areas at SARC for volunteers and obtain information about the facility and its research.

The team used test kits designed for RR corn because the kits were readily available and test kits designed for wheat do not exist (Exhibits 14, pg. 7 ¶ 14; 40, pg. 6 ¶ 15; and 42, pg. 6 ¶ 19).

_____ for USDA, GIPSA, confirmed GIPSA provided the kits to the team, and explained GIPSA completed an assessment of this test kit in 2013 in order to determine if it could detect the presence of the CP4 EPSPS protein in wheat containing Event MON71800 (Exhibit 46, pg. 2 ¶ 6). GIPSA concluded this particular kit detected the presence of the event in wheat at the 1/200 limit of detection, and achieved results at a high degree of confidence.

Following the plan, the team field-tested and collected leaf tissue samples from 93 volunteers

(Exhibits 40 – 42). Specifically, on 07/18/14 the team tested and collected 57 samples from the _____ and identified them as 1-57 (Exhibit 41, pg. 5 ¶ 8). The samples included 53 positive and 4 negative control samples (identified as 41C, 44C, 45C, and 51C). On 07/19/14 the team tested and collected three samples from volunteers found on the _____ (Exhibit 41, pg. 8 ¶ 13). The samples on the _____ tested negative and the team identified them as controls samples, 58C and 59C. The sample from _____, number 60, tested positive for containing the CP4 EPSPS protein. On 07/24/14, IES Investigator _____ joined the APHIS response team (Exhibit 47). On 07/24/14, the team tested and collected 37 positive samples _____ and _____ described these samples as fully-grown and mature plants (Exhibits 40, pg. 7 ¶ 20 and 42, pg. 7 ¶ 22). _____ indicated the plants were highly polymorphic and may contain properties of both winter and spring wheat. The team identified the samples as 93-127 and split samples 101 and 118 because they were very large (Exhibits 41 and 47).

The team photographed the samples, lateral flow test strips, and the collection process (Exhibits 48 – 53). The photos of the first samples collected show newer green leaf material emerging from the crowns of the plants. Some of the plants had awns emerging from the sheaths. The crowns of the plants contained old cut leaf material that indicated they had been mowed recently (Exhibit 48). The photos of the second group of samples show the two volunteers on

²⁰ The design of the EnviroLogix QuickStix™ Kit for Roundup Ready® CornBulk Grain (lateral flow and/or rapid flow test kit) is to extract and detect the presence of CP4 EPSPS protein at levels typically expressed in RR corn.

(Exhibit 49).

SARC

The

photos from the third set of samples show the fully-grown mature wheat plants

Many of the photos show plants that varied in height and maturity (Exhibit 50). The photos of the test strips show the volunteers tested positive for the CP4 EPSPS protein, as indicated by the development of a pink control and test line (Exhibits 51-53). The team saved these images onto compact discs (Exhibit 54-56).

The team shipped the samples to GIPSA for PCR testing on 07/18/14, 07/22/14, 07/24/14 and 07/25/15, as shown by the Chain of Custodies and United Parcel Service (UPS) tracking information (Exhibits 57-63). A copy of USDA, APHIS, BRS Permit No. 14-198-103m accompanied the samples (Exhibit 64). UPS delivered the samples on 07/19/14, 07/23/14 and 07/28/14. Shortly after the first group of samples arrived, GIPSA discovered samples 15 and 46 were missing. After a thorough search, the APHIS response team was unable to locate these samples (Exhibit 41, pg. 6 ¶ 8).

In response to the positive volunteer that the team collected at the

APHIS officials revised USDA, APHIS, PPQ EAN 408836-DM (Exhibit 41, pg. 10 ¶ 19). The revised EAN limited access to to APHIS, necessary MSU, and Monsanto personnel, and prohibited SARC from moving, harvesting, or destroying plant material from these fields without prior approval from APHIS. All the fields identified in the EAN contained wheat in 2014. The team issued the EAN on 07/23/14 MSU,

APHIS officials established a second plan titled, “Tactical Plan for Delivery of Plants to ARS” for the collection of the entire wheat plants (Exhibit 66). The objectives were:

- To identify wheat volunteers in the and test them for the presence of the CP4 EPSPS protein using the lateral flow test strips.
- Transplant the positive volunteers and deliver them to the USDA, ARS, Western Regional Small Grains Genotyping Center for molecular marker analysis.
- Take remedial action to prevent the remaining volunteers in the from developing further.

Following this plan, the team field-tested and transplanted 32 positive wheat volunteers and identified them as samples 61- 92 (Exhibits 14, 41 and 42). During the process, tested a few control plants to ensure the test strips were working properly. The team identified the controls as samples 1- 4; however, they were not collected. The team took digital photographs of all the samples, the lateral flow test strips, and the collection process (Exhibits 67-70). The photos of the plants show newer green leaf material growing from the crowns of the plants. Some plants had awns emerging from the sheaths. The crowns of the plants contained old cut leaf material, which indicated they had been mowed (Exhibit 67 and 69). The photos of the test strips show positive results for the volunteers, as indicated by the development of a pink control and test line (Exhibit 70). The team saved the images onto compact discs (Exhibits 71-73).

, Investigator for USDA, APHIS, IES delivered the samples to ,

for the USDA, ARS laboratory on 07/24/14 as shown by the Chain of Custodies (Exhibit 74). A copy of USDA, APHIS, BRS Permit No. 14-198-103m (Exhibit 64) accompanied the samples.

On 07/23/14, the team collected wheat grain samples from three plastic bins (Exhibit 41, pg. 12 ¶ 24). According to _____, the bins contained residual grain from the 2012 and 2013 growing season that SARC officials collected from the moisture machine.

_____ for USDA, GIPSA, Federal Grain Inspection Service (FGIS) collected the grain samples. He collected approximately five pounds from each bin and placed them into separate bags. A team member took digital photographs of the bins, grain, and collection process (Exhibit 75) and saved the images onto a compact disc (Exhibit 72). A team member shipped the samples to GIPSA on 07/24/14, as shown by the Chain of Custodies (Exhibit 76) and UPS shipping label and tracking information (Exhibit 77).

On 07/25/14 and 07/26/14, _____ took remedial actions to control the remaining volunteers in the _____ and prevent them from developing further (Exhibit 41, pg. 13 ¶¶ 32 – 33). Specifically, BRS and SARC officials decided _____ would treat the _____ with glyphosate and mow them, as indicated in their email correspondences (Exhibit 78). Once _____ completed the remedial actions, he took digital photographs of the _____ (Exhibit 79). The photos show the conditions of the _____ SARC officials applied Roundup Powermax at a 32 ounces/per acre application rate and mowed them. Investigator saved the images taken by _____ onto a compact disc (Exhibit 80). The specimen label for Roundup Powermax (Exhibit 81, pg. 22 and 23) indicates performance is better for controlling wheat if the applicator uses the product before the plant reaches the boot stage of growth. The specimen label further recommends a maximum application rate of 22 ounce per acre for plants eighteen inches in height.

The APHIS response team established and implemented a third sampling plan, titled “*GE Wheat Scouting, Testing and Collection Plan*” (Exhibit 82). The plan included instructions for the use of lateral flow test strips on leaf tissue and seed. The objectives of this plan were to identify wheat volunteers in designated areas at MSU, SARC, test them for the presence of the CP4 EPSPS protein using the lateral flow test strips, collect the positive volunteers, and ship them to GIPSA for additional testing and analysis (Exhibit 41, pg. 15 ¶ 41). IES provided guidance to the response team on how to process, label, and ship samples to GIPSA (Exhibit 83). Following these plans, the team members collected 44 samples from _____, _____ from 07/30/14 through 08/07/14. IES Investigators _____ processed the samples and identified them as 200, 300-315, 400-424, and 500-501 (Exhibits 47, 84-87). The team discovered sample 315 in _____ (Exhibit 84, pg. 2).

_____ Team members took digital photographs of the samples, the lateral flow test strips used, and collection process (Exhibits 88-92) and saved the images onto compact discs (Exhibits 93-96). The team shipped the samples to GIPSA on 07/30/14, 08/04/14, and 08/06/14, as shown by the Chain of Custodies (Exhibits 97-100) and UPS shipping label and tracking information (Exhibits 101-104).

In response to the positive volunteers that the team identified in _____ APHIS officials issued USDA, APHIS, PPQ, EAN No. 411376-DM to _____ on 08/07/14 (Exhibit 105). This EAN limited access to _____ to APHIS personnel and necessary MSU, SARC and Monsanto personnel. It also requested that SARC submit a protocol to APHIS on how the university planned to harvest, move, store, and destroy all plant material from this field.

While part of the response team continued to scout, test, and collect plant material from wheat volunteers, the other part of the team collected and processed grain samples from wheat fields/sections that were mature and ready for harvest (Exhibit 41, pg. 16 ¶ 43). APHIS officials established the following plans for each field/section: “ _____ *Winter Wheat Sampling Section,* _____ *Spring Wheat Bulk Sampling Section,* _____ *Winter Wheat Sampling Section, and* _____ *: Spring Wheat Bulk Sampling Section*” (Exhibits 106-109). The objectives of these plans were to collect a sufficient amount of wheat grain from each field/section using the SeedCalc8²¹ method to obtain a uniform and true representative sample from each area. IES Investigators _____ observed the grain collection and processed the samples (Exhibits 110 and 111). Following the plans, the team collected multiple samples from each field/section and, ultimately, combined the samples for each field/section to make one sample for each designated area. They identified the samples as G30-G33. The G30 samples were from _____ (section 3); the G31 samples were from _____; the G32 samples were from _____ and the G33 samples were from _____. The team took digital photographs of the fields/sections, collection process, and of the samples and saved them onto compact discs (Exhibits 112-115). The team shipped the samples to GIPSA on 08/04/14 and the laboratory received the samples on 08/05/14, as shown by the Chain of Custodies (Exhibit 116) and the UPS shipping label and tracking information (Exhibit 117).

Specialist _____ and IES Investigators _____ collected three more wheat samples when they inspected approximately 30 pieces of MSU, SARC’s machinery on 08/04/14 (Exhibits 47, pg. 4; 86, pg. 1, and 118). _____ listed this machinery on SARC’s _____ (Exhibit 119) and identified it as possibly being used in _____. During the inspections, the team members discovered wheat plant material on an all-terrain vehicle (ATV) and two trucks. They collected, processed, and labeled the plant samples as 128-130, and took digital photos of the equipment and the plant material (Exhibit 120), which Investigator _____ saved the images on a compact disc (Exhibit 94). They relinquished the samples to Investigator _____ as shown by the Chain of Custodies (Exhibit 121). Investigator _____ photographed (Exhibit 122) and shipped the samples to GIPSA on 08/06/14 for testing, as shown by the Chain of Custodies (Exhibit 121) and the UPS tracking information and proof of delivery (Exhibit 123). The response team finished all scouting and field-testing activities at MSU, SARC on 08/08/14 (Exhibit 41, pg. 17 ¶ 46).

D. GIPSA and ARS Sample Testing and Results

Once received, GIPSA processed and tested the wheat plant tissue and grain samples submitted by the response team to confirm they contained the CP4 EPSPS protein and Event MON71800 (Exhibit 46, pg.

²¹ SeedCalc8 – is a Microsoft Excel® application that can be used to design seed testing plans for purity/impurity characteristics, including testing for adventitious presence levels of biotech traits in conventional seed lots.

3 ¶ 7). Laboratory personnel tested the samples using a Qualitative MON71800 PCR assay test²² or a Real Time Quantitative PCR assay test.²³ As explained by _____, PCR testing is a very sensitive technique, which can detect deoxyribonucleic acid (DNA)²⁴ sequences at very low levels. _____ further explained when transgenic plants have a specific DNA sequence inserted into their native genome; it creates a unique transformation, i.e., event. The gene in the DNA sequence reprograms the plants to produce a protein that causes the plant to express a unique trait, such as herbicide tolerance. Each attempt at modification is considered a unique event as the insertion techniques place the DNA in a particular region location (Exhibit 46, pg. 2 ¶ 4). GIPSA specifically used the *Roundup Ready® Wheat MON71800 5'-Junction Event Specific Endpoint TaqMan® PCR with acc Control for Seed Pools of 200 and Roundup Ready® Wheat MON71800 3'-Junction Event Specific Endpoint TaqMan® PCR with acc Control for Seed Pools of 200* as the qualitative and quantitative testing methods (Exhibit 46, pg. 3 ¶ 7). Monsanto provided these methods, which GIPSA validated during the 2013 Oregon GE wheat investigation (Exhibit 13). _____ for GIPSA, created and provided a spreadsheet that shows the method that laboratory personnel used to test each sample (Exhibit 124).

On 07/28/14, _____ provided the results for samples 1-60 (Exhibit 125), which she described as wheat plant tissue with no mature seed heads (Exhibit 46, pg. 4 ¶ 11). All the samples tested positive for the CP4 EPSPS protein and Event MON71800, except for 15, 16, 19, 45, 46, 58, and 59. Samples 15 and 46 were missing as previously noted, 58 and 59 were negative, and 16, 19, and 45 were undetermined because laboratory personnel could not extract enough viable DNA for testing. Samples 41 and 44, which the response team identified as controls because they yielded negative results in the field, actually tested positive per GIPSA. Once GIPSA completed testing, they forwarded these initial samples to _____ of ARS for molecular analysis, as shown by the Chain of Custodies (Exhibits 126).

_____ received samples 1-60 on 07/23/14 and 07/24/14 (Exhibit 127). Neil Hoffman, Science Advisor for BRS, requested services from ARS to determine the genetic makeup of the samples, identify the wheat cultivar that they represent, and conduct a comparison of the Montana samples to the Oregon samples to determine if they are similar or the same (Exhibit 127, pg. 2 ¶ 5).

_____ described the samples 1 – 60 as containing leaf, stem, and spike plant material and confirmed he did not receive samples for the numbers 15 and 46 (Exhibit 127, pg. 2 ¶ 7). _____ explained he stored the samples by transferring them to a minus 80° Celsius freezer until his laboratory personnel could extract DNA and conduct the molecular analysis work. On 01/21/15, _____ completed his analysis and provided his raw molecular marker work data in Excel spreadsheets and his interpretation of the results in a summary report (Exhibits 128 – 130). Investigator _____ saved the data and the report on a compact disc (Exhibit 131).

According to _____ and his report (Exhibit 127, pg. 3 ¶¶ 7 and 130), his laboratory personnel extracted good quality DNA from the samples for their PCR molecular marker analysis. To complete his analysis,

²² Qualitative MON71800 PCR test is an endpoint assay for live tissue and single seeds that is an event-specific testing method that can confirm the presence of the MON71800 event in wheat tissue and how much of the DNA is present.

²³ Real Time Quantitative PCR testing is used for single seed and bulk seed analysis and is an assay used to measure the amount of a specific DNA sequence in a sample.

²⁴ DNA is a self-replicating material present in nearly all living organisms as the main constituent of chromosomes. It is the carrier of genetic information. In plants, DNA is a blueprint that determines the traits of a plant, such as height, color, and type.

selected 37 simple sequence repeat (SSR) markers, i.e., microsatellites²⁵, for the PCR testing. described the SSR marker technology that his personnel used as being very informative and he further described the SSR markers as highly polymorphic²⁶ (Exhibit 127, pg. 3 ¶ 8). believed 31 of the 37 SSR markers were of sufficient quality for analysis (Exhibit 130). After analyzing these markers, concluded based on allele²⁷ frequencies the Montana samples came from a consistent set of samples and did not represent multiple populations. He also concluded the frequency of homozygosity²⁸ within most of the individual samples indicated the population did not undergo any outcrossing²⁹ in the field. explained wheat typically self-pollinates due to the growth development and the structure of the plant and further explained wheat pollen is only viable in the environment for a very short time and is limited in how far it can travel. stated these factors make it very difficult for wheat plants to outcross (Exhibit 127, pg. 5 ¶ 14). In regards to the developmental stage of the samples, was not able to determine the exact filial³⁰ generation of the samples. However, based on the marker information and the amount of heterozygosity³¹ and heterogeneity within the population he claimed the samples appear to be in an early filial (F₁) generation selection from a possible backcross³² (BC₁) that has had multiple generations of selfing.³³ Based on the molecular marker work, was not able to determine how many generations of selfing occurred within the sample population or how long the population may have been persisting in the environment (Exhibit 127, pg. 5 and 6 ¶ 17).

During his analysis, compared the molecular marker data from the Montana samples to remnant DNA from the Oregon samples (numbered as 205-207, 184-186, and 221-223 in column “C” of the Excel spreadsheet) and he determined they were not similar (Exhibit 127, pg. 4 ¶ 11). He explained the data from the Montana samples indicated they likely came from the same starting source and do not represent multiple populations. This differs from the Oregon samples, which appeared to originate from multiple populations. also compared the Montana samples to a large panel of known Pacific Northwest wheat cultivars to identify the unknown samples (Exhibits 129 and 130). was not able to match the samples to a known wheat cultivar due to the early generation of the sample material; however, he provided a list of ten cultivars that he determined were most closely related to the Montana samples. This list included wheat varieties

SU, SARC (Exhibit 11, pg. 8 ¶ 25-27). The similarity of the Montana samples to was approximately 45-46 percent (Exhibit 127, pg. 6 ¶ 18).

²⁵ Microsatellites are repeating sequences of 2-5 base pairs of DNA used for molecular marker analysis, for kinship, population, and other studies. They can also be used for studies of gene duplication or deletion, marker assisted selection, and fingerprinting.

²⁶ Polymorphism is variation among SSR markers. It involves the existence of different forms (alleles) of the same gene in plants or a population of plants.

²⁷ Allele is an alternative form of a gene (one member of a pair) that is located at a specific position on a specific chromosome. These DNA coding determines distinct traits that can be passed on from parents to offspring. Organisms have two alleles for each trait.

²⁸ Homozygosity is having identical pairs of genes for any given pair of hereditary characteristics.

²⁹ Outcrossing is to pollinate a plant with pollen from a different plant of the same species, often one that is unrelated or is of a different species.

³⁰ Filial pertains to the sequence of generations following the parental generation; an “F” followed by a subscript number indicating its place in the sequence designates each generation.

³¹ Heterozygosity is having dissimilar pairs of genes for any given pair of hereditary characteristics.

³² Backcrossing is the crossing of a hybrid with one of its parents or an individual genetically similar to its parents to achieve offspring with a genetic identity, which is closer to that of the parent.

³³ Selfing is self-pollinating, self-fertilizing.

On 07/30/14, [redacted] provided the results for samples 93-127 (Exhibits 46, pg. 5 ¶ 13 and 132). She described these samples as mature wheat plants seed heads, which laboratory personnel tested using the *Roundup Ready® Wheat MON71800 3'-Junction Event Specific Endpoint TaqMan® PCR with acc Control for Seed Pools of 200* method. All the samples tested positive for the CP4 EPSPS protein and Event MON71800 (Exhibit 133). Once GIPSA completed their testing, they selected some of the best seed heads from each sample, dried them, and shipped them to [redacted] for molecular analysis, as shown by the Chain of Custodies (Exhibits 134).

On 08/08/14, [redacted] received samples 93-127 (Exhibit 127, pg. 6 ¶ 20). [redacted] explained his laboratory personnel collected the seeds from the spikes (heads) and stored them appropriately until BRS requested molecular marker testing. Once BRS requested testing, [redacted] explained his personnel grew the seeds in a controlled greenhouse environment, and they collected and processed plant tissue for testing. On 04/30/15, [redacted] completed his analysis of the samples and provided his raw molecular marker work data in Excel spreadsheets and his interpretation of the results in a summary report (Exhibits 135-137). Investigator [redacted] saved his data and report to a compact disc (Exhibit 138). Samples 315 A and B, which were found in [redacted] at SARC and hand-delivered to [redacted] on 02/04/15, were included in this group of test samples (Exhibits 127, pg. 7 ¶ 21 and 139).

According to [redacted] summary report (Exhibit 136), his personnel conducted the tests using same SSR markers they used to test the original samples (Samples 1-60). The purpose of the testing was to identify the similarities between the two groups of samples and to determine the probable progenitors,³⁴ if possible. To obtain the necessary green leaf material for DNA extraction, laboratory personnel germinated and grew the seeds in controlled access greenhouse. As stated in his report, [redacted] personnel were able to extract quality DNA from all the samples. To complete his analysis, [redacted] selected 31 SSR markers for the PCR testing, however, only 24 of the markers were of sufficient quality for analysis. After analyzing these markers, [redacted] concluded based on the allele frequencies this group of samples came from a consistent set of samples originally and did not represent multiple populations. He also concluded the frequency of homozygosity within the samples indicated the population did not undergo any outcrossing in the field. In regards to the developmental stage of the samples, [redacted] was not able to determine the exact filial generation of the samples. Based on the marker information and the amount of heterozygosity and heterogeneity within the population, he indicated the samples appear to be in early generation selection from a possible backcross (BC₂F₁) that has undergone multiple generations of selfing.

[redacted] analysis compared the molecular marker data from samples 93-127 and 315 A and B to samples 1-60, and indicated the second group of samples did not represent a distinctly different population than the first (Exhibit 136). [redacted] concluded the two groups of samples came from the crossing of the same material originally. [redacted] explained he observed some differences between the two groups and stated these differences could be attributable to the grower backcrossing the seeds from the original crossing with a recurrent parent. [redacted] also compared the second group of Montana samples to a large panel of known Pacific Northwest wheat cultivars in order to try to identify the variety of the samples. Again, [redacted] was not able to match the samples to a known wheat cultivar due to the early generation of the sample material; however, he provided a list of ten cultivars that he determined were most closely related to this group of samples. This list did not include any of the known wheat varieties (Bobwhite, [redacted]), which Monsanto used to develop the

³⁴ Progenitors is a person or thing from which a person, animal, or plant is descended or originates; an ancestor or parent.

GE wheat seed that researchers planted during the 2000 – 2003 trials at MSU, SARC (Exhibits 11, pg. 4 and 8 ¶¶ 10 and 25-27). did not test the 32 potted plants identified as samples 61- 92.

According to , he did not conduct any molecular marker work on these samples because his personnel extracted enough DNA from the initial samples for testing (Exhibits 127, pg. 6 ¶ 19 and 159). He stated his laboratory personnel collected the spikes from these plant samples once they reached maturity and they are being stored at the ARS laboratory.

On 08/05/14, provided the results for the three bags of mixed wheat grain samples identified as samples G1 – G3 (Exhibits 46, pg. 4 ¶¶ 12 and 140). According to , laboratory personnel tested the grain by grinding it, extracting DNA from the grinds, and testing the DNA using the *Roundup Ready® Wheat MON71800 3' Junction Event Specific Endpoint TaqMan® PCR with acc Control for seed Pools of 200* method. She explained 60-70 grinds were tested and they concluded the bags were negative for Event MON71800.

On 08/08/14 and 08/13/14, provided the results for the wheat grain samples identified as G30 – G33 and the plant tissue samples identified as 200, 300-315, 400-424, and 500-501 (Exhibits 46, pg. 5 ¶ 14, 141 and 142). reported the samples (G30 and G33) collected from were negative and the samples (G31 and G33) collected from were positive for containing Event MON71800. According to , multiple grinds from the samples were tested using the Real Time Quantitative PCR testing method at the 1/300 seed limit of detection and one-third of the grinds for were positive and two-thirds of the grinds were positive for SARC officials had planted the positive fields in Choteau and Yellowstone wheat varieties.

Dr. Jhee

In regards to plant samples 200, 300-315, 400-424, and 500-501, indicated they tested them using the Qualitative PCR testing method. She stated all of them were positive, except for 422-424 and 500-501 (Exhibits 46, pg. 5 ¶ 14 and 142). The team had collected the negative samples from SARC's Fields E and J. Since the samples from were negative, BRS officials withdrew USDA, APHIS, PPQ, EAN No. 411376-DM and lifted all the restrictions placed on the field on 08/14/14 (Exhibit 157).

On 08/21/14, provided the results for the three samples the team collected from SARC's equipment. The team identified the samples as 128 – 130 and GIPSA determined they yielded negative results (Exhibit 158).

On 05/07/2015, IES Investigator contacted to obtain information pertaining to the class/type of wheat the Montana GE samples represented (Exhibit 160). was not able to make an assessment based on his area of expertise, as indicated in his email (Exhibit 161). indicated the samples visually appeared to be Hard Red Winter Wheat (HRWW) (Exhibit 162). assessment was based on information she obtained from , who are employed by USDA, GIPSA, FGIS (Exhibit 163). According to , they visually inspected at least 50 samples isubmitted to GIPSA for testing and concluded the samples represented HRWW based on their knowledge of wheat grain morphological characteristics (Exhibits 164 and 165).

E. MSU, SARC Facility Information

Throughout the investigation, the field team obtained information from MSU, SARC officials. The information pertained to the facility's personnel, daily operations, on-going educational and research programs/studies, cropping history, farm management practices, equipment usage practices, and participation in the Monsanto GE wheat field trails. The purpose for obtaining the information was to assist the APHIS team with the field response and addressing the following objectives:

- Determine the source of the GE wheat volunteers and determine who was responsible for introducing the material into the environment.
- Determine how the GE wheat volunteers came to exist and determine how long they have been persisting in the environment.
- Identify the GE wheat volunteers and determine if they are the same as or similar to the known commercial wheat varieties planted at the facility.
- Determine if the GE wheat volunteers are the same as or similar to GE wheat varieties planted during the field trials.
- To ensure the GE wheat volunteers were contained to MSU, SARC and not allowed to enter commerce.

Initially, the response team focused on obtaining information about the areas affected by the GE wheat volunteers and the areas adjacent to them. The team also focused on the obtaining information about the

locations of the GE wheat field trials. IES Investigator and obtained the initial information from MSU, SARC regarding the crops and on-going research projects in and locations of the 2000-2003 GE wheat field trials, which occurred in (Exhibits 41, pg. 6 ¶¶ 10 and 166).

The investigators saved these images on compact discs (Exhibits 54 and 71).

1. General Information

The team obtained general information related to SARC’s SARC) MSU, SARC, “SARC Field Managed by SARC

Personnel SARC’s This indicated the areas affected by the GE wheat volunteers contained

SARC

MSU, SARC

Southern Ag Research Center, Huntley,

MT,

MSU, SARC

2. Cropping History

provided field charts for each calendar year from 1999 through 2014 that specify annual crop information for each irrigated and dryland field at MSU, SARC (Exhibit 186).

MSU, SARC

SARC

MSU, SARC at Huntley, MT

For the wheat planted in SARC shipped the grain to MSU, Montana for processing. confirmed SARC's participation in the seed development and production program (Exhibit 1, pg. 13 ¶ 36). He claimed SARC obtained all the seeds from

SARC

SARC

(Exhibit 189). He explained SARC officials usually plant and harvest the sites first, before any other facility crops. and he claimed they sell all the harvested wheat for milling, not seed production. He stated SARC uses the same planter and combine each year and he claimed they clean the machinery before it leaves the facility. He stated SARC officials bring all the harvested wheat from the sites to the facility for agronomic processing. confirmed the information provided by (Exhibit 3). He claimed the wheat seed used for the sites comes from MSU. He provided a list of all the sites since 2010 (Exhibit 190) and documentation for the various he has been responsible for at SARC since 2008 (Exhibits 191 – 193). SARC, (Exhibit 192), (sections 7 and 8) (Exhibit 193).

IES also collected information regarding SARC's wheat seed purchases and wheat grain sales. According to MSU, SARC obtained most of its commercial wheat seed from SARC's (Exhibit 1, pg. 13 ¶ 36). Investigator obtained sales receipts from the on 10/16/14 (Exhibit 194). acquired in 2005 (Exhibit 195). The sales receipts show SARC purchased the following varieties of commercial wheat seed from this company from 2006 to 2013: Hank, Promontory, Yellowstone, Genou, AP604CL, Volt, Choteau, Willow Creek, Vida, and Norris (Exhibit 196). All these varieties of seeds are certified or registered hard red spring or hard red winter wheat.

compared many of these commercial varieties to the positive samples that the field team collected, as shown by his Excel molecular data spreadsheets (Exhibits 128, 129, 136 and 137).

SARC MSU, SARC

SARC

MSU, SARC's wheat from 1999 to 2013 (Exhibit 198). These records indicated from 2003-2013 SARC

SARC

SARC

Exhibit 200).

3. Field Management and Cropping History

The investigative team also obtained SARC's management records for the years 2000 – 2014 from . These records provided additional information pertaining to SARC's wheat cropping history and field management activities. Investigator reviewed these records and sorted them by relevance to wheat to determine if any of the documents show there was a presence GE wheat volunteers at the facility prior to 2014. Within the management records there were hand-drawn and computer generated field maps for (Exhibit 202). SARC

Monsanto RR wheat field trials

There were also some wheat research worksheets for the years 2000-2004 (Exhibit 203). Most of these appeared to be for the Foundation seed production program that SARC participated in from 1999-2004. The worksheets indicated SARC

204)

(Exhibit 205).

(Exhibit
MSU, SARC

MSU, SARC (Exhibit 206). Many of these notes provided

wheat varietal and planting location information. The notes also included a few additional varieties of wheat, such as

4. Pesticide Applications for Field Management

provided the pesticide application records for all of SARC's fields. The investigative team reviewed all the records and focused their attention mainly on the documents that pertained to the fields, which were affected with the GE wheat volunteers in 2014, including , and the locations of the Monsanto GE wheat field trials

The team reviewed these records to determine if SARC officials applied chemicals to unregulated areas at SARC to control RR wheat during and prior to 2014. As stated in an email from SARC personnel generated the pesticide records using the facility's centralized database (Exhibit 207). explained he does not require SARC to enter the pesticide applications associated with particular field experiments into the database. In regards to missing application records, explained sometimes they have computer issues and personnel might forget to enter the information into the database. The team reviewed the pesticide applications records for (Exhibits 208 and 209), (Exhibit 210), (Exhibit 211), and (Exhibit 212). Many of the records indicated SARC officials identified there was a "target pest" of volunteer wheat/grain and applied Roundup to the fields (Exhibits 208, pgs. 9, 13, and 25; 209, pgs. 5 and 9; and 210, pgs. 4 and 7). The target pest of wheat/grain and Roundup applications did not appear on consecutive dates within the records. The 2004 pesticide records for show SARC officials applied Select, Assure II, and Gramoxone Extra to this field to control volunteer wheat and/or RR volunteer spring wheat (Exhibit 211, pgs. 6 – 8). According to the product labels, growers use these herbicides to control and/or suppress of grasses (Exhibits 213 – 215). Throughout the pesticide records for , SARC described the "target pests" as grassy weeds; therefore, it was difficult for the reviewer to determine if SARC was trying to control wheat volunteers (Exhibit 212). One of the records for indicates the herbicides applied on 04/30/01 were for the control of volunteer RR spring wheat in (Exhibit 212, pg. 28). was not the location of the 2000 Monsanto GE wheat trial and RR wheat volunteers should have not been growing in this area (Exhibit 202, pg. 2). When asked, claimed there was no RR wheat volunteers found in this section (Exhibit 1, pg. 5 ¶ 14). He explained a transcription error occurred, and the comment should have indicated he found RR wheat volunteers in

(Exhibit 216). These records show SARC commonly used RT3 in the plots of the crop rotation study at a 22 or 24 ounce per acre application rate. They also show in 2013 that SARC personnel increased the application rate of RT3 to a 32 ounce per acre.

During the investigation, APHIS officials did not review any management or pesticide records, which indicated GE wheat volunteers were persisting in unregulated areas of SARC prior to 2014. During the interviews of , all claimed they never observed wheat plants at MSU, SARC, which appeared to be resistant to glyphosate, prior to 2014 (Exhibits 1, pg. 12 ¶ 33; 3, pg. 5 ¶ 20; 4, pg. 4 ¶ 13; and 7, pg. 3 ¶ 5).

F. Field Actions and Equipment Usage, Cleaning, and Inspections

To ensure all GE wheat material from MSU, SARC was contained to the facility and properly disposed, SARC, Monsanto and APHIS officials established and followed various plans and field actions. These plans pertained to the following actions:

- The access, monitoring, and management of fields at SARC, which APHIS officials designated as restricted in the issued EANs.
- The harvest, storage, and disposal of all of SARC's 2014 wheat crops and other crops possibly contaminated with GE wheat material.
- The mitigation and eradication procedures for any GE wheat volunteer issues that might arise during SARC's 2015 and subsequent growing seasons.
- The usage and cleaning of equipment by SARC personnel and machinery inspections by APHIS personnel.

SARC, Monsanto, and APHIS officials documented these field actions in email correspondences, written proposals, memorandums, compliance agreements, statements, and photographs (Exhibits 217-234). Many of the field actions show _____ was complying with the EANs.

Some of the significant plans and field actions pertained to the mitigation and eradication of GE wheat volunteers in the _____ (Exhibits 217, 222, 224, 229, 230 and 232); the harvest, retention, and disposal of MSU, SARC's on and off station 2014 wheat crops (Exhibits 218, 226, 227 and 234); the planting of the _____ wheat locations for 2015 (Exhibit 231); and the mitigation and eradication procedures for all fields covered by EAN 408836-DM for 2015 and subsequent years (Exhibit 233).

1. Field Actions

Throughout the field response, APHIS and SARC officials worked together to monitor, manage, and prevent the further development of the GE wheat volunteers in _____
 Once APHIS officials determined they would not need to collect any more samples from this area, _____ established a plan to destroy all existing volunteers and permanently prevent re-establishment of them (Exhibit 229). BRS officials approved this plan. In regards to the harvest and retention of SARC's _____ 2014 wheat crops, Investigator _____ observed the holding facilities and containers that _____ was planning on using to store their harvested wheat (Exhibit 41, pg. 9 ¶ 16). Investigator _____ took digital photographs of her observations to share with BRS officials to assist them with determining whether SARC's retention and storage capabilities were adequate (Exhibit 218). These photos show the buildings and containers, which _____ planned to use for the storage of wheat grain, and the equipment that SARC officials would use for the cleaning and processing of wheat. Once APHIS officials completed a risk assessment in regards to SARC's _____ wheat, _____ established and submitted a plan for the harvest, retention, and disposal of these crops (Exhibit 226). APHIS officials approved this plan. _____ also established a harvest, retention, and disposal plan for _____ (fields covered by the EANs), which APHIS approved as shown by the compliance agreement between the SARC and BRS (Exhibit 227). Ultimately, these plans allowed SARC to harvest and haul its wheat to the local landfill for destruction. SARC officials completed the process by mid-October 2014, as shown by the landfill invoices (Exhibit 234, pgs. 3-19). The invoices show Monsanto paid for the

disposal of the wheat. Specialist inspected the equipment and machinery that SARC officials used during the harvest and disposal process, as documented by his statement (Exhibit 234, pg. 1). According to Specialist he was able to clear most of the equipment on the same day of the inspection, except for one field combine. For future cropping seasons an abatement proposal was established and approved for the destruction of GE volunteers, which may remain on site or may grow from seeds that exist in the soil of subject fields (Exhibit 233). This proposal superseded the previous mitigation proposal for the 2014 growing season.

2. Equipment Usage and Cleaning

During the course of the investigation, provided information pertaining to SARC's equipment/machinery usage and cleaning procedures. also provided inventories for all of SARC's machinery and equipment and identified which pieces SARC officials used in (Exhibits 119 and 235). According to , they use and store all of SARC's equipment and machinery at the facility, except for items use at the locations (Exhibit 1, pg. 13 ¶ 37). He stated SARC personnel share the equipment/machinery and he claimed SARC does not loan its equipment to non-SARC personnel, such as local farmers. In regards to cleaning, explained SARC personnel do not typically clean equipment and machinery in between usage, unless the personnel use it for the planting or harvesting of confirmed the sharing of equipment and described SARC's cleaning procedures as being minimal (Exhibit 3, pg. 7 ¶ 25). He explained in the past he has used equipment in and then used it in without cleaning it in between. explained there are no predefined procedures for cleaning equipment at SARC (Exhibits 4, pg. 4 ¶ 11 and 7, pg. 1 ¶ 2). Both confirmed equipment the sharing of equipment at SARC.

3. Equipment Inspections

For 2014, APHIS personnel inspected the equipment and machinery that SARC personnel used in the fields covered by EAN 408836 to prevent the further spread of GE wheat material. APHIS personnel documented the inspections in their statements and by taking photographs. and Investigator conducted one of the first inspections on 07/23/14 (Exhibits 41, pg. 11 ¶ 21 and 42, pg. 10 ¶ 29). The inspection was of a combine that SARC personnel used in Investigator took digital photographs of the combine and inspection process (Exhibit 236). Prior to this inspection, removed parts from the combine and placed them in the back of an ATV, which he parked at the When inspected the parts, she found an entire wheat head inside one of the parts. When she spoke to about it, indicated he did not seem concerned even though the movement of contaminated equipment could be a mechanism for spreading volunteers. Specialist led the rest of the inspections as shown by his statements (Exhibit 237). IES Investigators accompanied Specialist during the inspections. He inspected, quickly cleared, and released most of the equipment, except for a combine that used to swath down camelina plants located in Specialist had to inspect this combine three times before clearing it because cleaning was inadequate (Exhibit 237, pgs. 2 and 3). Investigator took photographs during one of the re-inspections. The photos show plant material still attached to specific areas of the equipment (Exhibit 238).

G. MSU, SARC's participation in Monsanto's GE wheat field trials

IES obtained and reviewed information regarding SARC's participation in Monsanto's GE wheat field trials to determine the varieties of the GE wheat seed Monsanto and SARC officials used during the trials, and identify any possible issues that might have occurred during the trials, which could explain the existence of GE wheat volunteers at MSU, SARC in 2014.

1. 2000 Trial and USDA Notification No. 00-038-19n

USDA Notification No. 00-038-19n (Exhibit 17) shows _____ was the responsible researcher for the 2000 GE wheat field trial, which involved a _____ (Exhibit 1, pg. 2 ¶ 5).

(Exhibit 239).

_____ identified his Monsanto Point of Contact (POC) for the trial as _____, and stated the GE wheat seed that he used during the trial were _____ (Exhibit 1, pgs. 2 and 3 ¶¶ 5 – 7).

IES obtained and reviewed the following records pertaining to the 2000 trial: Unsigned Service Agreement between Monsanto and MSU (Exhibit 240), Confined Coop Trials of Transgenic RR Wheat Lines protocol (Exhibit 241), Request Form for the Release, Movement or Importation of RR wheat (Exhibit 242), Wheat Field Release Performance Standards (Exhibit 243), Acknowledgement and Certification of Field Trial Compliance (Exhibit 244), Monsanto Sample Transfer Form (Exhibit 245), Bio-Tech Field Compliance Check List (Exhibit 246), In-Season Field Monitoring Forms (Exhibit 247), Monitoring for Volunteers Forms (Exhibit 248), RR Spring Wheat Trial Analysis (Exhibit 249), 2000 Wheat Field Trial Reports (Exhibit 250), and Email Communications between _____ and Monsanto representatives (Exhibit 251).

In regards to the Service Agreement, Monsanto could not locate a signed copy of the document, as explained in a letter from _____ (Exhibit 252, pg. 2). _____ claimed this unsigned agreement, which _____ received on 04/12/00 (Exhibit 251, pg. 2), represents the terms and conditions that were agreed upon by both parties.

While reviewing the other documents pertaining to trial (Exhibits 241 – 251) and comparing them to the information provided by _____ (Exhibit 1), IES noted multiple inconsistencies and possible discrepancies. These issues pertained to training the responsible research was supposed to receive prior to the start of the trial and the responsible researcher's failure to follow the Monsanto's trial design and performance standards. Specifically, the issues pertained to Monsanto not providing adequate training to _____, the improper storage of GE wheat material, inadequate isolation distances for the trial site, the removal of identification stakes from the trial site prior to the completion of the trial, inconsistencies with the data recorded on the monitoring forms and final reports, and _____ planting of a non-transgenic crop in the trial site during the volunteer monitoring period. Investigator _____ addressed some of these issues with _____ Dr. Jhee.

An email communications shows Monsanto had arranged APHIS compliance training for the trial participants (Exhibit 251, pg. 1); however, SARC and Monsanto officials did not provide a

confirmation showing the training took place as scheduled. In addition, the Acknowledgement and Certification of Field Trial Compliance completed by _____ indicated he did not receive compliance training (Exhibit 244, pg. 1). During his interview, _____ did not recall Monsanto providing any formal training related to the trial; however, he claimed provided instructions and guidance over the phone regularly during the trial (Exhibit 1, pg. 2 ¶ 5). _____ addressed this issue as shown by his letter (Exhibit 252, pg. 3). According to _____ and other SARC personnel received training on 04/04/00, prior to the start of the trial. He provided a sign-in sheet and copies of the training transparencies, which Monsanto officials probably used during the training (Exhibit 253). The protocol for the trial indicates Monsanto

(Exhibit 240). Protocol guidelines states GE wheat seed must be stored in a secured facility, with signage indicating regulated seed is being stored and unauthorized personnel access to the area is denied (Exhibit 240, pg.4). The Monsanto Sample Transfer Form shows _____ received the GE seed for this trial on 05/15/00 (Exhibit 244). _____ stated he probably stored the GE material he received for the trial on his desk until planting (Exhibit 1, pg. 3 ¶ 8). _____ stated his office did not have the required signage, but he claimed he usually locks his office when he is not present. Both _____ and Dr. Jhee stated _____ should have followed the instructions provided in regards to storage of GE material (Exhibits 11, pg. 5 ¶ 13; and 14, pg. 11).

The protocol for the trial indicates a 20-foot isolation distance is required around the entire trial site (Exhibit 241, pg. 2 and 4). When _____ completed the Acknowledgement and Certification of Field Trial Compliance, he indicated the required isolation distance was 10 feet (Exhibit 244). _____ explained he planted conventional wheat on all four sides of the trial site. He described the northern and western sides of the site as containing a 10-foot buffer of conventional wheat (Exhibit 1, pg. 3 ¶ 6). Dr. Jhee stated an isolation distance of 10 feet would have been acceptable to BRS as long as _____ treated the area as it contained regulated material (Exhibit 14, pg. 11). _____ remedied the issue by referring to trial documentation, which shows there was actually an excess of 20 feet surrounding the trial. The 2000 field layouts for _____ (Exhibits 239 and 254), SARC's facility map (Exhibit 167), and field charts (Exhibit 186) indicate the isolation distance surrounding the trial site was more than 20 feet and they show SARC officials did not plant small grains near the trial site.

The performance standards indicate the responsible researcher should clearly mark the trial site and the site should remain marked for at least one year after harvest (Exhibit 243, pg. 3).

_____ stated he removed the identification stakes at the completion of the experiment (after harvest) to avoid public disclosure, but he claimed the site was still discernable by landmarks (Exhibit 1, pg. 3 ¶ 6). Dr. Jhee addressed this issue by explaining the responsible researcher should use markers to delineate the boundaries of the trial site so volunteers can be identified within the marked area (Exhibit 14, pg. 11). He stated _____ should have followed the instructions he received from Monsanto.

The Bio-Tech Field Compliance Check List indicates _____ planted the GE seed on 05/16/00 and harvested the site on 09/15/00 (Exhibit 246). The dates recorded on the In-Season Field Monitoring Forms (Exhibit 247) and the Wheat Field Trial Reports for Yellowstone County, MT (Exhibit 250) indicate _____ harvested the trial site on 08/15/00. According to _____, he harvested the site on 08/15/00 (Exhibit 1, pg. 5 ¶ 13). _____ claimed he

did not remove any plant material or grain from the trial site and he stated he destroyed all GE plant material by disking it into the ground the next day. However, an email communication from _____, dated 09/15/00, indicates he placed the harvested grain into storage under lock and key after harvest while waiting for destruction instructions (Exhibit 251, pg. 21).

The Wheat Field Release Performance Standards indicates the volunteer monitoring period for this trial was 12 months or until the responsible researchers does not observe volunteers for one year (Exhibit 243). The Monitoring for Volunteers forms _____ completed show the last time he observed volunteers was on 06/01/01 and his last observation was on 09/11/01 (Exhibit 248). According to the performance standards, _____ should have extended the volunteer monitoring period to 06/01/02. _____ stated he monitored the trial site for volunteers for at least two years (Exhibit 1, pg. 5 ¶ 14). He explained a monitoring form for the second year does not exist because he probably just sent a communication to Monsanto indicating he did not observe any volunteers. Neither, _____ nor Monsanto provided any communications pertaining to the second year of volunteer monitoring.

The Monitoring for Volunteers form indicates the responsible researcher should monitor for volunteers on a monthly basis, and that the researcher may not plant the trial site to any non-transgenic crop during the following season, but he/she can plant the site to other appropriate rotational transgenic crops (Exhibit 248, No. 3). It states the researcher may plant the site to a non-transgenic crop after the trial area has laid fallow for one year. The form shows _____ did not record any observations for the month of August and that he planted conventional soybeans at the site during the volunteer monitoring stage. According to _____, he interpreted Monsanto's instructions as stating the researcher could plant a conventional crop as long as it was not wheat (Exhibit 1, pg. 5 ¶ 14). Dr. Jhee addressed this issue and he explained the planting of conventional soybeans would have been acceptable to BRS as long as the researcher could still properly monitor and control volunteers (Exhibit 14, pg. 13).

2. 2001-2003 GE Wheat Trials and USDA Notification Nos. 01-016-24n, 02-032-07n, and 03-022-01n

In regards to the 2001-2003 trials, USDA Notifications 01-016-24n, 02-032-07n, and 03-022-01n (Exhibits 22, 26, and 30), _____ was the responsible researcher for the trials until _____ took over for him when he left in 2004 (Exhibit 255, pg. 3 ¶ 7). Both, _____ and _____ verified _____ was their Monsanto POC for the trials, which took place in _____ (Exhibits 1, pgs. 6 and 7 ¶¶ 16, 17 and 20; and 255, pgs. 2 and 3 ¶¶ 7 and 10). _____ (Exhibit 255, pg. 3 ¶ 9). Neither, _____ nor _____ could provide any information pertaining to the GE wheat seed that was used during these trials (Exhibits 1, pgs. 6 and 8 ¶¶ 18 and 21; and Exhibit 255, pg. 4 ¶ 11).

IES obtained and reviewed the following records pertaining to the 2001-2003 trials: 2001-2003 Service Agreements between Monsanto and _____ (Exhibit 256-258), Monsanto Agricultural Group Protocols 2001-01-66-04, 2001-01-66-05, 2002-01-66-01, 2002-01-66-02, 2003-01-66-01 and 2002-01-66-02, (Exhibits 259-265), Wheat Field Release Performance Standards for 2001 – 2003 (Exhibits 266-268), Letter from Monsanto and Acknowledgement signed by _____ showing the post-harvest volunteer monitoring phase was extended to

two years in May 2001 (Exhibit 269), Monsanto Material Transfer Form for 2001 (Exhibit 270) and Roundup Ready Wheat Sample Transfer Forms from _____ for 2002 and 2003 (Exhibits 271 and 272), Acknowledgement and Certification of Field Trials Compliance for 2001 (Exhibits 273), Planting Information and Certification of Field Trial Compliance for 2002 and 2003 (Exhibits 274 and 275), Trial Map for _____ for the 2001 – 2003 trials (Exhibit 276), Bio-Tech Field Compliance Check List for 2001 (Exhibit 277), In-Season Field Monitoring Forms for the 2001 – 2003 trials (Exhibits 278-280), Monitoring for Volunteers Forms for the 2001 – 2003 trials (Exhibit 281-283), 2001 – 2003 Wheat Field Trial Reports (Exhibit 284-286), Letter from Monsanto to APHIS indicating the responsible researcher for the trials had changed from _____ to the _____ in November 2003 (Exhibit 287), and Email Communications between _____, and Monsanto representatives pertaining to the 2002 and 2003 trials (Exhibit 288).

As shown by the protocols, the objectives of the trials were to

_____ Exhibits 259-265). The Material and Sample Transfer Forms indicated

_____ (Exhibits 270-272). While reviewing the documents for the 2001-2003 trials and comparing them to the information provided by _____ and _____, investigators identified some possible discrepancies. These issues pertained to the harvest and destruction of the GE wheat material from the trials, and to the volunteer monitoring activities that occurred in _____ when _____ took over for _____.

In regards to the harvest and destruction of the GE material, the 2003 In-Season Field Monitoring Form (Exhibit 280) and the 2003 Wheat Field Test Report (Exhibit 286) show _____ harvested the trial site on 08/07/03 and he destroyed it on 08/20/03. _____ addressed these dates to explain why it took almost two weeks for the destruction to occur after harvest. _____ stated there would have been no reason for harvested grain to sit for almost two weeks before it was destroyed (Exhibit 255, pg. 6 ¶ 15). He stated he buried the harvested grain on the trial site and he explained the destruction date recorded on the forms might actually be the date he tilled the site. This corresponds with an email from _____ to Monsanto, which indicates he tilled the plot area on 08/20/03 (Exhibit 288, pg. 2).

The next issue pertained to the burial of the harvested grain from the 2003 trial site and _____ volunteer monitoring activities. According to _____, he harvested approximately 50 bushels from each trial and buried it on the trial sites in a pits or trenches (Exhibit 255, pg. 6 ¶ 15). _____ could not recall how deep the pit/trenches were and/or how much soil he used to cover the material. He explained he would have placed a sufficient amount of soil over the grain to keep it from resurfacing. _____ recalled asking if a ditcher was available to bury the harvested grain from the 2003 trial, and explained the ditcher digs a “V” shaped trench, up to approximately three feet deep (Exhibit 1, pg. 8 ¶ 22). _____ confirmed he was responsible for the volunteer monitoring from the spring of 2004 until the end of 2005 (Exhibit 1, pg. 9 ¶ 23). He explained during this period he had to monitor the entire field because he was not able to distinguish the locations of the trails sites within _____ also told Investigator

_____ (Exhibit 47, pg. 4). According to Investigator

used a sub-soiler in the field that brought the buried GE grain to the surface, and he claimed birds and vermin could have spread the grain throughout the facility. The Monitoring for Volunteer forms for the 2002 trial show observed an abundance of volunteers in in 2004 (Exhibit 282, pg. 6). In the comment section of the form, indicated the volunteers were likely from the 2003 burial ditch.

(Exhibit 276).

Monsanto

confirmed he was the local POC for the field trials. He stated of Monsanto was the POC for compliance issues (Exhibit 289, pg. 2). claimed he was not able to provide any information related to the GE wheat seed that used in the trials (Exhibit 289, pg. 4). stated the responsible researchers should have buried the harvested GE wheat grain at a minimum depth of 12 inches in the absence of tillage. He explained when tillage is used the should bury the grain deeper than the deepest tillage (Exhibit 289, pg. 6). confirmed he observed an abundance of wheat volunteer at SARC in 2004. According to , he recommended that spray the trial site with a high dose of paraquat and disk it to destroy the volunteers. He claimed he did not observe any volunteers outside the trial sites during his visits.

SARC (Exhibit 290, pg. 4). explained he used a disk ripper that cuts 12 to 18 inches deep to prepare the field for planting, and claimed he did not notice any wheat grain near or on the ground surface during this process. Monsanto or SARC

stated he uses his own equipment and he admitted he does not thoroughly clean it between uses (Exhibit 290, pg. 3 and 4). SARC a SARC.

Monsanto

(Exhibit 288, pg. 16). Additional emails from Monsanto representatives to show Monsanto continuously reminded about his volunteer monitoring responsibilities (Exhibit 288, pgs. 15, 17, 19, and 24). An email from states there was a gap in monthly monitoring activities and a few monitoring dates were missing from his volunteer monitoring forms in November 2005 (Exhibit 288, pg. 26). Email communications show treated with Gramoxone Extra on 09/17/04 and left it fallow for the spring and summer of 2005 (Exhibit 288, pgs. 29 and 31).

3. Information Related to All GE Wheat Field Trials at SARC

and asserted no spills, unintentional releases, unusual occurrences or other infractions occurred during the trials (Exhibits 1 and 255). They claimed they used or destroyed all GE seed they received for the trials following Monsanto's instructions. They also claimed they destroyed all wheat volunteers prior to seed set. According to ,

Monsanto could not locate any records pertaining to spills, accidental or unintentional releases, unusual occurrences or other infractions for the trials (Exhibit 11, pg. 13 ¶ 36).

IES requested that Monsanto and/or provide samples of the GE wheat seed that SARC used in the trials, so APHIS could conduct comparison testing (Exhibits 11, pgs. 4 and 9 ¶¶ 11 and 28; and 291). The purpose of the comparison was to determine if the Montana samples were the same or similar to the GE wheat seed that planted during the trials. According to , Monsanto provided samples of all the GE wheat seeds that they had in their possession during the Oregon investigation (Exhibits 11, pgs. 4 and 9 ¶¶ 11 and 28).

Monsanto Material Transfer and Chain of Custodies forms show provided GE wheat seeds containing Monsanto Events 33391, 33512, 25372, and 25397 to Investigator on 05/24/13 (Exhibits 292-293). In an email, explained the seeds were all (Exhibit 294). In another email, explained they could not provide samples of the GE wheat seed that SARC planted during the trials because Monsanto destroyed it when they shut down its RR wheat program (Exhibit 295).

provided a letter pertaining to the termination of the program and destruction of the seed (Exhibit 296) and declarations of and MSU employees verifying the destruction, devitalization, and/or storage by USDA of RR wheat seed by (Exhibits 297).

IES also requested that Monsanto provide data pertaining to any molecular marker/genetic testing it conducted on the 60 samples collected from MSU, SARC in 2014 (Exhibits 11, pg. 16 ¶ 46 and 298, pg. 1 #'s 9 and 10). IES also requested that Monsanto provide information pertaining to any genetic comparisons it conducted to determine if the Montana GE wheat samples were the same as or similar to the Oregon samples and/or the GE wheat planted during the trials. Monsanto

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H. Additional information from Monsanto

Throughout the field response and investigation, Monsanto representatives provided information related to its collection and testing of additional wheat samples, the use of CP4 test strips in wheat, reports sent to Monsanto pertaining to glyphosate failures in wheat, the removal of GE wheat plant material from SARC by Monsanto, the timeliness of Monsanto reporting the discovery of GE wheat at SARC to USDA, third party audits of the 2000-2003 trials, and information pertaining to

³⁵ Gold Standard Source – is a product pedigree, which indicates the GE seed are the transformation sources for the original introgression of the given transgene.

occurred since the last trial (Exhibit 314).

SARC

I. Investigative Conclusions

Throughout the investigation, the investigative team obtained information and documentation from BRS, Monsanto, and MSU, SARC officials. The team reviewed everything and reached the following conclusions in regards to the objectives:

1. APHIS confirmed the presence of GE wheat volunteers MSU, SARC. The volunteers were positive for CP4 and Event MON71800.
2. With extensive testing, APHIS was not able to determine the cultivars of the Montana GE wheat volunteers. The genetic testing APHIS conducted indicated the collected volunteer samples were in an early generational breeding stage; therefore, APHIS could not match them to a known wheat cultivar. During genetic testing, APHIS compared DNA from the Montana samples to the Oregon samples and it determined the samples were not similar and did not originate from the same source. APHIS was not able to determine if the Montana wheat volunteers were similar or the same as the GE wheat that planted during the 2000-2003 Monsanto trials at MSU, SARC. APHIS was not able to obtain samples of the GE wheat seed that Monsanto used during the trials, and could not make a direct comparison.
3. APHIS was not able to conclusively prove how the GE wheat volunteers were introduced in the environment at MSU, SARC in 2014, or how long the volunteers have been persisting in environment. Dr. Neil E. Hoffman, a Senior Science Advisor for the USDA, APHIS, BRS, Office of the Deputy Administrator analyzed the investigation and the supporting evidence and concluded the 2014 GE wheat volunteers most likely originated from the GE wheat fields trials that took place at MSU, SARC from 2000 to 2003 (Exhibits 346 and 347). During the investigation, APHIS obtained and reviewed hundreds of records pertaining to SARC's farm management practices, and participation in Monsanto GE wheat field trials. These records dated from 2000-2014. APHIS also interviewed several key employees of MSU, SARC. According to the records and information obtained during the investigation, the 2014 GE wheat volunteers were discovered in which were near the fields that the 2000-2003 trials took place in. Both, the 2014 GE wheat volunteers and the GE wheat used during the trials contained the same transgenic event (MON71800). According to the SARC cooperators, they used or destroyed all of the GE wheat seed and harvested grain from the trials. They destroyed the unused GE wheat seed and harvested grain by burial on the trial sites. During the investigation, APHIS officials identified a significant GE wheat volunteer issue that occurred in during the volunteer monitoring phases of the 2002 and 2003 trials, which SARC and Monsanto officials remediated the with graminicides. SARC and Monsanto officials did not diligently scout or apply graminicides to . From 2000-2014, SARC routinely shared equipment and machinery and moved it from field to field without cleaning. Throughout the investigation, SARC failed to satisfactorily clean equipment placed under inspection by APHIS officials. Based on Dr. Hoffman's official capacity and his knowledge and analysis of the investigation, APHIS determined the most plausible explanation for the origin of the 2014 wheat volunteers is that SARC researchers dispersed harvested GE

wheat seed from the _____ via _____ contaminated equipment (Exhibit 346). Based on the number of volunteers observed, the distribution and density of the volunteers, and the genetic testing APHIS conducted, APHIS determined it is possible that GE wheat existed at SARC prior to 2014.

4. APHIS is confident it contained the GE wheat volunteers to SARC's facility in 2014, and that no GE wheat from SARC entered commerce in 2014. The APHIS field response team scouted SARC's entire facility _____ for wheat volunteers and worked together with SARC and Monsanto officials to establish and follow various plans that ensured no contaminated wheat or other crops entered commerce. APHIS continues to work closely with SARC officials to ensure they follow established plans to prevent any GE wheat from entering commerce in subsequent years. APHIS collected and tested wheat samples _____ SARC.

SARC

In regards to _____ wheat _____ studies, SARC officials claimed they clean the equipment used for planting and harvesting prior to it leaving the facility. Based on the information APHIS obtained during the course of the investigation, it determined it is unlikely that GE wheat spread outside of SARC. Prior to 2014, SARC _____ SARC typically commingles its wheat _____ with its bulk wheat once the appropriate data is collected.

5. Monsanto representatives collected and removed at least 60 plant tissue samples, which originated from wheat volunteers that tested positive for the CP4 EPSPS protein and Event MON71800. APHIS officials did not obtain any evidence indicating the plant tissue contained viable plant parts; therefore, they determined Monsanto was not required to obtain a permit from APHIS prior to removing the samples from SARC.
6. On or around 07/07/14, SARC and Monsanto officials became aware there might be a problem with glyphosate resistant wheat at MSU, SARC; however, they did not report the possible issue to APHIS until 07/14/14. According to 7 C.F.R. § 340.3(d)(5) Notification for the introduction of certain regulated articles (5) the Administrator shall be notified of any unusual occurrence within the time periods and in the manner specified in 7 C.F.R § 340.4(f)(10). This section specifies the Administrator must be orally notified immediately upon discovery and notified in writing within 24 hours in the event of any accidental or unauthorized release of the regulated article. _____ claimed he did not report the discovery to USDA when he first suspected it because it was not on his "radar." _____, on the other hand, claimed their initial thought was to contact USDA, but they were not sure the volunteers were glyphosate resistant and they were concerned APHIS would shut down SARC's research. Monsanto claimed they did not initially believe the volunteers were resistant to glyphosate, but were the result of missed areas of glyphosate during the application process. Monsanto dismissed the results of the ELISA tests _____ conducted because it believed the test was not validated for wheat and could produce false positives. Monsanto claimed it notified APHIS appropriately once it confirmed the volunteers were indeed glyphosate resistant and positive for the CP4 protein.

ADDITIONAL INFORMATION

Email correspondences related to the SeedCalc8, dated 07/23/14 through 07/25/14, and a printout of Monsanto’s PowerPoint presentation (Exhibit 315) provides information about grain collection methods and how APHIS used it to establish plans to collect wheat grain from fields at MSU, SARC.

In 2013, BRS conducted a fact-finding investigation in response to the detection of GE wheat volunteers, containing transgenic event MON71800, in an Oregon field (OR130018-BR). Since Monsanto developed and field-tested this event, they were involved with this investigation. During the investigation no allegations of violations of 7 C.F.R. § 340.3 were substantiated.

Print-out of USDA, APHIS, News Release, dated 09/26/14, shows the organization announced the closure of the Oregon GE wheat investigation, the discovery of the GE wheat at MSU, SARC, and the opening of a new investigation (Exhibit 316).

Printouts obtained from www.monsanto.com provide information about the company, its locations, history, and staff leadership (Exhibits 317-320).

Copies of Domestic Corporation documents from the Delaware and Rhode Island Secretary of State Websites, LexisNexis report, and Certificate of Incorporation provides business information about Monsanto (Exhibits 321 – 324).

Copies of United States Patents US6689880 B2, dated 02/10/04, and US7268274 B2, dated 09/11/07, owned by Monsanto for an invention related to a DNA construct for conferring improved glyphosate tolerance to a wheat plant. The invention relates to glyphosate-tolerant wheat plant 33391 (MON71800) and progeny thereof, and to assays for detecting the presence of wheat plant 33391 (MON71800) DNA in a sample and compositions thereof (Exhibits 325 and 326).

Copies of Biotechnology Consultation Note to the File BNF No. 000080 and Agency Response Letter pertaining to Monsanto Roundup Ready® Wheat Event MON71800 indicates foods and feeds derived from this event are as safe and nutritious as current commercial varieties of wheat and the comparable foods and feed derived from them (Exhibits 327 and 328).

Copy of Wheat Field Release Design Protocol to Meet or Exceed the USDA Performance Standards obtained from Monsanto provides information about the company’s current performance standards (Exhibit 329).

www.sarc.montana.edu

MSU, SARC

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Copies of SmartLinx® Business and Dun and Bradstreet reports, obtained from an IES Investigative Analyst on 04/09/2015, provides business information for MSU, SARC (Exhibits 344 and 345).

<u>LIST OF PERSONS INVOLVED WITH OR INTERVIEWED</u> <u>AS PART OF THE FACT FINDING INVESTIGATION</u> <i>Provide First, MI and Last Name with Complete Address</i>		
Name	Title	Address / Phone Number
	Investigator	USDA, APHIS, IES 2150 Centre Avenue Building Fort Collins, CO 80526 (970) 494-7485
	Investigator	USDA, APHIS, IES 2150 Centre Avenue Building Fort Collins, CO 80526 (970) 494-7485
	Great Plains Area Manager	USDA, APHIS, IES 2150 Centre Avenue Building Fort Collins, CO 80526 (970) 494-7485
	Investigator	USDA, APHIS, IES 2150 Centre Avenue Building Fort Collins, CO 80526 (970) 494-7485
	Investigator	USDA, APHIS, IES 2150 Centre Avenue Building Fort Collins, CO 80526 (970) 494-7485
	Investigator	USDA, APHIS, IES 2150 Centre Avenue Building Fort Collins, CO 80526 (970) 494-7485
	Investigator	USDA, APHIS, IES 920 Main Campus Drive Raleigh, NC 27606 (919) 855-7080
	Investigator	USDA, APHIS, IES 2150 Centre Avenue Building Fort Collins, CO 80526 (970) 494-7485
	Investigator	USDA, APHIS, IES 2150 Centre Avenue

		Building Fort Collins, CO 80526 (970) 494-7485
	Investigator	USDA, APHIS, IES 920 Main Campus Drive Raleigh, NC 27606 (919) 855-7080
	Investigator	USDA, APHIS, IES 2150 Centre Avenue Building Fort Collins, CO 80526 (970) 494-7485
Edward Jhee, Ph.D.	Director	USDA, APHIS, BRS 4700 River Road Unit 91 Riverdale, MD 20737
Neil E. Hoffman, Ph.D.	Senior Science Advisor	USDA, APHIS, BRS 4700 River Road Unit 98 Riverdale, MD 20737
	Senior Regulatory Specialist	USDA, APHIS, BRS 4700 River Road Unit 91 Riverdale, MD 20737
	Biological Scientist	USDA, APHIS, BRS Western Compliance Assurance Branch 2150 Centre Avenue Fort Collins, CO 80526
Gary D. Adams	State Plant Health Director	USDA, APHIS, PPQ 1220 Cole Avenue Helena, MT 59601
	Plant Health Safeguarding Specialist	USDA, APHIS, PPQ 1629 Avenue D Billings, MT 59102
	Chief, Biotechnology and Analytical Services Branch	USDA, GIPSA, Technology and Science Division 10383 North Ambassador Drive

		Kansas City, MO 64153 (816) 891-0459
	Supervisory Chemist	USDA, GIPSA, Technology and Science Division 10383 North Ambassador Drive Kansas City, MO 64153 (816) 891-0459
	Grain Inspector, Member for the Board of Appeals and Review	USDA, APHIS, FGIS 10383 N. Ambassador Dr. Kansas City, MO 64153
	Agricultural Commodity Grain Grader, Senior Member for the Board of Appeals and Review	USDA, APHIS, FGIS 10383 N. Ambassador Dr. Kansas City, MO 64153
	Grain Inspector	USDA, GIPSA, FGIS P.O. Box 13427 Grand Forks, ND 58208
	Research Geneticist	USDA, ARS Western Regional Small Grains Genotyping Center 209 Johnson Hall Washington State University Pullman, WA 99164
		MSU, MT
		MSU, MT

		MSU, SARC 748 Railroad Highway Huntley, MT 59037
	MSU, SARC	WI
		MSU, SARC 748 Railroad Highway Huntley, MT 59037
		MSU, SARC 748 Railroad Highway Huntley, MT 59037
		MSU, SARC 748 Railroad Highway Huntley, MT 59037
		Monsanto Company 800 North Lindbergh Boulevard St. Louis, MO 63167
	Former Monsanto Employee, Retired Technical Development Associate	May - October , MT November – April AZ
	Monsanto legal counsel	D.C.

		Monsanto Company 800 North Lindbergh Boulevard St. Louis, MO 63167
		Montana
	achinery	
	Association Owner	MT
	Location Manager	MT
	Manager	MT

CASE REPORT DISTRIBUTION (cc)

Program Official(s)

Edward Jhee, Ph.D.
Director, Regulatory Operations Program
USDA, APHIS, Biotechnology Regulatory Services
4700 River Road, Unit 91
Riverdale, MD 20737

IES Manager(s)

, Great Plains Area Director
USDA, APHIS, IES
2150 Centre Ave., Bldg.
Fort Collins, CO 80526
(970) 494-7485

CASE UPDATES

Program Official(s)

Edward Jhee, Ph.D.
Director, Regulatory Operations Program

Primary Investigator

IES Area Director

IES Deputy Regional Director

IES Regional Director

Timothy R. Fordahl

<u>EXHIBIT LIST</u>			
Exhibit #	Description	Date	Total Pages
1	Declaration of	10/06/2014	7
2	Photograph provided by	06/20/2014	1
3	Declaration of	10/03/2014	9
4	Declaration of	10/03/2014	6
5	Copy of Field Management Record provided by	2008 – 2014	3
6	Print-out of RT3 Specimen Label obtained from Agrian website	N/A	13
7	Declaration of	10/28/14	3
8	Photographs of ELISA tests performed by and provided by Monsanto	N/A	2
9	Copy of Email from to of Monsanto	07/07/14	2
10	Photograph taken by and provided by Monsanto	N/A	1
11	Declaration of	04/23/15	18
12	Copy of Manual Processing of Wheat Samples for Taqman Testing document	07/09/14	4
13	Copy of Validation of the Monsanto Roundup ready Wheat MON71800 Event Specific End-Point Taqman® PCR with <i>acc</i> Internal Control for Seed Pools of 1:15 document	06/14/13	6
14	Declaration of Dr. Edward Jhee	12/12/14	14
15	Copy of Letter from to Dr. Ed Jhee	07/15/14	1
16	Print-out of Questions and Answers obtained from www.monsanto.com/gmwheat	03/10/15	3
17	Confidential and CBI Deleted Copies of Monsanto's Notification with Reference ID 2000-78XRAB and USDA No. 00-038-19n	02/04/00	17
18	Copies of Letters to State Agriculture Departments in MO, MT, and ND	02/08/00	3
19	Copy of Acknowledgement Letter to Monsanto for Notification 00-038-19n	02/28/00	1

20	Copies of Confidential and CBI Deleted 2000 Wheat Field Trial Report for Notification No. 00-038-19n	05/13/01	6
21	Copies of Confidential and CBI Deleted 2000 Wheat Field Trial Report for Notification No. 00-038-19n	12/07/01	6
22	Confidential and CBI Deleted Copies of Monsanto's Notification with Reference ID 2001-73XRAB and USDA No. 01-016-24n	01/10/01	16
23	Copies of Letters to State Agriculture Departments in MT, MO, and HI	01/17/01	3
24	Copy of Acknowledgement Letter to Monsanto for Notification 01-16-24n	02/16/01	1
25	Copies of Confidential and CBI Deleted 2001 Wheat Field Trial Report for Notification No. 01-016-24n	08/30/02	5
26	Confidential and CBI Deleted Copies of Monsanto's Notification with Reference ID 2001-811XRAB and USDA No. 02-032-07n	N/A	21
27	Copies of Letters to State Agriculture Departments in MT and MOI	02/04/02	2
28	Copy of Acknowledgement Letter to Monsanto for Notification 02-032-07n	03/01/02	1
29	Copies of Confidential and CBI Deleted 2002 Wheat Field Trial Report for Notification No. 02-032-07n	09/04/03	10
30	Confidential and CBI Deleted Copies of Monsanto's Notification with Reference ID 2003-23XRAB and USDA No. 03-022-01n	01/17/03	16
31	Copy of Letter to MT State Agriculture Department	01/22/03	1
32	Copy of Acknowledgement Letter to Monsanto for Notification 03-022-01n	01/28/03	1
33	Copies of Confidential and CBI Deleted 2003 Wheat Field Trial Report for Notification No. 03-022-01n	04/23/04	11
34	Print-out from the GM Crop Database for MON71800	2004	5
35	Print-out of Monsanto's History of GM Wheat obtained from www.monsanto.com/gmwheat	03/10/15	3
36	Print-out of Monsanto's Current Research of GM Wheat obtained from www.monsanto.com/gmwheat	03/10/15	2
37	Print-out of Photograph provided by Monsanto, titled Wheat Plant at Time of Observation	N/A	1
38	Print-out of Photograph provided by Monsanto, titled	N/A	1

39	Copies Maps in birds-eye view of MSU, SARC	N/A	3
40	Declaration of	12/01/14	6
41	Declaration of Investigator		
42	Declaration of	12/23/14	7
43	Copy of USDA, APHIS, PPQ, EAN No. 408836-DM	07/18/14	2
44	Copy of Tactical Plan for Collection of Field Samples	N/A	3
45	Copy of Insert for QuickStix Kit for Roundup Ready Corn Bulk Grain	07/20/11	2
46	Declaration of	02/02/15	6
47	Declaration of Investigator	08/07/14	6
48	Print-outs of photographs taken by Investigator of Samples 1-57	07/18/14	138
49	Print-outs of photographs taken by Investigator of samples 58C, 59C, and 60	07/19/14	26
50	Print-out of photographs taken by Investigator of samples 93-127	07/24/14	55
51	Print-out of photographs taken by Investigator of lateral flow test strips for samples 1-57	01/20/15	5
52	Print-out of photographs taken by Investigator of lateral flow test strips for samples 58C, 59C, and 60	02/25/15	1
53	Print-out of photographs taken by Investigator of lateral flow test strips for samples 93-125	03/05/15	1
54	Compact Disc containing photographs taken by Investigator of wheat plant samples	07/18/14 and 07/19/14	2
55	Compact Disc containing photographs taken by Investigator of wheat plant samples	07/24/14	2
56	Compact Disc containing photographs taken by Investigator of lateral flow test strips for samples 1-57	01/20/15 – 03/05/15	2
57	Copies of Chain of Custodies for Samples 1-57	07/18/14	55
58	Copies of Chain of Custodies for Samples 58C, 59C, and 60	07/19/14	3
59	Copies of Chain of Custodies for Samples 93-127	07/24/14	36
60	UPS Proof of Delivery for	07/20/14	1

61	UPS Proof of Delivery for	07/25/14	1
62	UPS Shipping Receipt and Proof of Delivery for	07/25/14 and 03/04/15	2
63	UPS Shipping Receipt and Proof of Delivery for	07/25/14 and 03/04/15	2
64	Copy of USDA, APHIS, BRS Permit No. 14-198-103m	07/17/14	11
65	Copy of USDA, APHIS, PPQ EAN No. 408836-DM	07/23/14	2
66	Copy of Tactical Plan for Delivery of Plants to ARS	N/A	3
67	Print-outs of photographs of Samples 61-92	07/23/14	38
68	Print-outs of photographs of Control Samples 1-4	07/23/14	4
69	Print-outs of photographs of whole plant samples collected from	07/23/14	2
70	Print-out of photographs of lateral flow test strips for samples 61-92 and control samples 1-4	03/02/15	3
71	Compact Disc containing photographs taken by Investigator of wheat volunteers, SARC's premise, equipment inspection, and wheat grain	07/23/14	2
72	Compact Disc containing photographs taken by Investigator of wheat volunteers	07/23/14	2
73	Compact Disc containing photographs taken by Investigator of lateral flow test strips for samples 61-92 and control samples 1-4	03/02/15	2
74	Original Chain of Custodies for Samples 61- 92	07/23/14	32
75	Print-outs of photographs taken by Investigator of residual lab test grain	07/23/14	5
76	Copies of Chain of Custodies for Samples G1-G3	07/25/14	3
77	Copy of UPS Shipping Label, Tracking Information, and Proof of Delivery for	07/24/14 – 07/31/14	4
78	Email Correspondences pertaining to mitigation/control of GE wheat volunteers in	07/24/14 – 07/27/14	13
79	Print-out of photographs taken by of	07/26/14 – 07/27/14	4
80	Compact Disc containing photographs taken by of	07/26/14 – 07/27/14	2
81	Print-out of Specimen Label for Roundup PowerMax	N/A	26

82	Copy of GE Wheat Scouting, Testing and Collection Plan and Insert for QuickStix Kit for Roundup Ready Plant Tissue	N/A	8
83	Copy of MT140008-BR, IES Sample Collection Overview and Plan	N/A	3
84	Declaration of _____	08/12/14	2
85	Declaration of _____	08/02/14	3
86	Declaration of _____	08/15/14	3
87	Declaration of _____	08/13/14	2
88	Print-outs of photographs taken by Investigator of sample 200	08/02/14	3
89	Print-outs of photographs taken by Investigator of samples 300-315	08/02/14	50
90	Print-outs of photographs taken by Investigator of samples 400-421	08/02/14	44
91	Print-outs of photographs taken by Investigator of sample 500 and 501 and _____	08/13/14	12
92	Print-outs of photographs of lateral flow test strips for samples 200, 300-315, 400-424, 500, and 501	06/02/15	4
93	Compact Disc containing photographs taken by Investigator of wheat samples 300-315 and of _____	07/30/14 – 08/06/14	2
94	Compact Disc containing photographs taken by Investigator of wheat samples 400-424 and of equipment inspection	07/30/14 – 08/06/14	2
95	Compact Disc containing photographs taken by Investigator of samples 500 and 501 and of the _____ wheat field	08/05/14 – 08/11/14	2
96	Compact Disc containing photographs taken by Investigator of lateral flow test strips for samples 200, 300-315, 400-424, and 500-501.	06/02/15	2
97	Copies of Chain of Custodies for Samples 200, 300, and 400	07/30/14	3
98	Copies of Chain of Custodies for Samples 301-315 and 401-421	07/31/14 – 08/01/14	36
99	Copies of Chain of Custodies for Samples for 422-424	08/05/14	3
100	Copies of Chain of Custodies for Samples 500-501	08/06/14	2
101	Copy of Proof of Delivery for _____	07/30/14 – 07/31/14	1

102	Copy of UPS Shipping Receipt and Proof of Delivery for	08/04/14 – 08/05/14	2
103	Copy of UPS Shipping Receipt and Proof of Delivery for	08/06/14 – 08/07/14	2
104	Copy of UPS Shipping Receipt and Tracking information for	08/06/14 – 08/07/14	3
105	Copy of USDA, APHIS, PPQ, EAN No. 411376-DM	08/07/14	2
106	Copy of Winter Wheat Sampling Section plan	N/A	3
107	Copy of Spring Wheat Bulk Sampling Section plan	N/A	2
108	Copy of Winter Wheat Sampling Section plan	N/A	3
109	Copy of : Spring Wheat Bulk Sampling Section plan	N/A	2
110	Declaration of Investigator	08/06/14	5
111	Declaration of Investigator	08/01/14	5
112	Print-outs of labeled digital photographs taken by Investigator of wheat grain collection process/samples	07/30/14 – 08/01/14	47
113	Print-outs of labeled digital photographs taken by Investigator of wheat grain collection process/samples	07/30/14 – 08/01/14	62
114	Compact Disc containing digital photos taken by Investigator of wheat grain collection process/samples	07/30/14 – 08/01/14	2
115	Compact Disc containing digital photos taken by Investigator of wheat grain collection process/samples	07/30/14 – 08/01/14	2
116	Copies of Chain of Custodies for Samples G30-G33	07/30/14 – 08/01/14	11
117	Copy of UPS Shipping Receipt and Proof of Delivery for	08/04/14 and 08/05/14	2
118	Statement obtained from Specialist	08/07/14	1
119	Copy of MSU, SARC's	2014	2
120	Print-outs of labeled digital photographs taken by Investigator of machinery inspections	08/04/14	9
121	Copies of Chain of Custodies for Samples 128-130	08/04/14	3
122	Print-out of labeled digital photograph taken by Investigator of Samples 128 - 130	08/06/14	1

123	Copy of UPS tracking and Proof of Delivery information for	08/07/14	3
124	Email Correspondence and Excel spreadsheet from GIPSA pertaining to testing methods used	01/28/15	17
125	Email Correspondence and copy of GIPSA's test results for tissue samples received 07/19/14-07/23/14	07/18/14	4
126	Copies of Chain of Custodies for Samples 1-60	07/18/14	58
127	Declaration of Investigator	02/12/15	7
128	Email Correspondences pertaining to molecular work for samples 160	01/21/15	3
129	Print-outs of Excel spreadsheets containing his data for molecular work conducted on samples 1-60	N/A	6
130	Copy of APHIS Report Summary for samples 1-60	N/A	2
131	Compact Disc containing Excel spreadsheet and summary report for samples 1-60	01/21/15	2
132	Email Correspondences pertaining to GIPSA's test results for samples 93-127	07/30/14	2
133	Copy of GIPSA test results for tissue samples received 07/19/14-07/23/14	N/A	3
134	Copies of Chain of Custodies for Samples 93-127	07/24/14	35
135	Email Correspondence pertaining to molecular work for samples 93-127 and 315	04/30/14	1
136	Copy of APHIS Report Summary for samples 93-127 and 315	N/A	2
137	Print-outs of Excel spreadsheets containing his data for molecular work conducted on samples 93-127 and 315	N/A	16
138	Compact Disc containing Excel spreadsheet and summary report for samples 93-127 and 315	04/30/15	2
139	Copy of Chain of Custody for sample 315 A and B	08/01/14	1
140	Email Correspondences pertaining to GIPSA test results three bulk samples for grain	08/05/14	2
141	Email Correspondences pertaining to GIPSA test results for samples G30-G33	08/08/14	2
142	Copy of GIPSA test results for tissue and seed samples received 07/31/14-08/07/14	08/13/14	3
143	Declaration of Investigator	08/14/15	3

144	Print-outs of photographs taken by Investigator	08/13/14	2
145		08/16/14	1
146	Copy of	08/12/14	1
147	Declaration of Investigator	08/12/14	1
148	Declaration of Investigator	08/21/14	1
149	Copies of Chain of Custodies for samples 1-3 collected from	08/12/14	3
150	UPS Delivery Notifications for Tracking Numbers	08/13/14	6
151	and Print-outs of photographs taken by Investigators	08/13/14	25
152	Print-outs of photographs taken by Investigators	08/13/14	10
153	Print-outs of photographs taken by Investigators	08/13/14	3
154	Compact Disc containing photographs taken by Investigator	08/12/14	2
155	Email Correspondence pertaining to negative results for samples collected from	08/14/14	1
156	Print-outs of photographs taken by Investigators	08/13/14	6
157	Email Correspondences pertaining to EAN revocation	08/14/14	2
158	Email Correspondence pertaining to results of samples 128-130	08/21/14	1
159	Email Correspondence from pertaining to the testing of potted plant samples	01/21/15	4
160	Email Correspondences pertaining to	05/07/15	1
161	Email Correspondences pertaining to wheat class/type	05/07/15 – 05/08/15	2
162	Email Correspondences pertaining to wheat class/type	05/07/15 – 06/09/15	3
163	Email Correspondences pertaining to wheat class/type	05/07/15 – 06/17/15	6
164	Declaration of Investigator	06/18/15	2
165	Declaration of Investigator	06/18/15	2

166	Copy of typed notes for	N/A	2
167	Print-out of MSU, SARC facility map that includes location of 2000 GE wheat field trial in	N/A	1
168	Print-outs of digital photographs of taken by Investigator	07/18/14	29
169	Print-outs of digital photographs of and adjacent areas taken by Investigator	07/23/14	8
170	Print-outs of digital photographs of taken by Investigator	07/18/14	2
171	Print-outs of digital photographs of taken by Investigator	07/23/14	19
172	Print-outs of digital photographs of taken by Investigator	07/19/14	10
173	Print-outs of digital photographs of taken by Investigator	07/23/14	2
174	Print-outs of digital photographs of taken by Investigator	07/18/14	11
175	Print-outs of digital photographs of taken by Investigator	07/18/14	2
176	Print-outs of digital photographs of taken by Investigator	07/19/14	20
177	Print-outs of digital photographs of by Investigator taken	07/19/14	47
178	Print-outs of digital photographs of by Investigator taken	07/19/14	14
179	Print-outs of digital photographs of taken by Investigator	07/19/14	5
180	List of Permanent Employees of the MSU, SARC	07/30/14	1
181	List of SARC Fields Managed by SARC personnel and/or in 2014	2014	3
182	Emails and Google map pertaining to wheat fields MSU, SARC	07/21/14	3
183	Emails pertaining to wheat fields MSU, SARC	07/21/14	5
184	Copy of Distribution of Wheat Acreage at SARC spreadsheet	2014	1
185	Print-outs of Google map created by of MSU, SARC's fields	N/A	9
186	Copy of MSU, SARC's Field Charts	1999 – 2014	16

187	Emails and Summary of Seed Production at the MSU, SARC	1999 – 2004	3
188	Emails pertaining to MSU, SARC's wheat research sites	08/02/14	3
189	Declaration of	08/04/14	3
190	Copy of Locations	2010 – 2014	3
191	Copy of MSU, SARC	2008 – 2014	2
192	Copy of	2014	5
193	Copy of	2008 – 2014	5
194	Declaration of	11/25/14	2
195	Print-out from website	10/07/14	2
196	Copies of Sales Receipt	03/16/06 – 09/23/13	41
197	Declaration of	11/25/14	2
198	List of MSU, SARC's Commercial Sale of Wheat	1999 – 2013	3
199	Print-out from website	10/07/14	1
200	Declaration of	11/25/14	2
201	Copies of MSU, SARC's Scale Tickets for Wheat sold to	2003 – 2013	38
202	Copies of MSU, SARC's Field Management Maps	2000 – 2014	25
203	Copies of MSU, SARC management worksheets for Foundation Seed Program	1999 – 2004	11
204	Copies of wheat seed labels obtained from MSU, SARC's management records	N/A	5
205	Copies of wheat invoices and sale receipts	2000 – 2013	15
206	Copies of hand-written notes obtained from MSU, SARC's management records	2004 – 2013	14
207	Copy of emails pertaining to MSU, SARC's pesticide application records	08/04/14	2
208	Copies of MSU, SARC's Pesticide Application Records for	2000 – 2014	53
209	Copies of MSU, SARC's Pesticide Application Records for	2000 – 2014	20

210	Copies of MSU, SARC's Pesticide Application Records for _____	2000 – 2014	45
211	Copies of MSU, SARC's Pesticide Application Records for _____	2000 – 2004	8
212	Copies of MSU, SARC's Pesticide Application Records for _____	2000 – 2014	71
213	Copy of Label for Select 2 EC Herbicide	03/17/00	2
214	Copy of Label for DuPont Assure II Herbicide	N/A	15
215	Copy of Label for Zeneca Gramoxone Extra Herbicide	N/A	17
216	Copy of Summary Herbicide Application records for _____	07/29/14	30
217	Copies of emails pertaining to field action requests from _____	07/21/14	4
218	Copies of an email and photographs pertaining to MSU, SARC's wheat storage capabilities	07/21/14	14
219	Copy of email pertaining to field action request from _____	07/22/14	1
220	Copy of email pertaining to field action request from _____	07/24/14	1
221	Copies of emails pertaining to field action requests from _____ related to _____	07/25/14	3
222	Copy of email requesting specific actions from _____ to EAN 408836-DM	07/31/14	1
223	Copies of emails pertaining to field action requests from _____ related to _____	07/25/14 and 07/31/14	2
224	Copies of emails pertaining to field action requests from _____ related to control of RR wheat Volunteers	07/24/14 and 07/31/14	2
225	Copies of emails pertaining to field action requests related to _____	07/25/14 – 08/01/14	15
226	Copies of emails and proposals pertaining to the harvest, retention, and disposal of MSU, SARC's wheat _____	08/04/14 – 08/06/14	15
227	Copies of emails, proposals, and compliance agreement pertaining to the harvest, retention, and disposal of MSU, SARC's 2014 wheat	08/07/14	6
228	Copy of email pertaining to field action request from _____ related to herbicide applications	08/14/14	3
229	Copies of emails, proposal, and declaration of _____ pertaining to the mitigation of GE wheat volunteers	08/14/14 – 09/03/14	10

230	Copy of email pertaining to field action request from _____ related to wheat harvest in _____	09/04/14	1
231	Copies of email and proposal pertaining to the planting of MSU, SARC's _____ winter wheat crops	08/25/14 – 09/08/14	3
232	Copies of emails pertaining to field action requests from _____ related to the mowing of _____	10/09/14 – 10/14/14	2
233	Copies of emails and proposal pertaining to the abatement of feral glyphosate tolerant wheat at MSU, SARC	03/31/15	4
234	Statement of Specialist _____ spreadsheet and invoices related to the disposal of MSU, SARC's wheat in local landfill in 2014	08/28/14 – 11/03/14	19
235	Copy of MSU, SARC's _____	2014	235
236	Print-outs of digital photographs taken by Investigator _____	07/23/14	9
237	Statements of Specialist _____ related to equipment and machinery inspections	07/26/14 – 08/13/14	7
238	Print-outs of digital photographs taken by Investigator _____	07/30/14	5
239	Copy of 2000 Field Map for _____ SARC	2000	1
240	Copy of Unsigned Service Agreement between MSU and Monsanto	05/01/00	9
241	Copy of Protocol, titled "Confined Coop Trials of Transgenic RR Wheat Lines	05/11/00	10
242	Copy of Genetically-Modified Crop Information for the USDA/APHIS Release or Importation Notifications	2000	4
243	Copy of Wheat Field Release Performance Standards for the 2000 trial	N/A	4
244	Copy of Acknowledgment and Certification of Field Trial Compliance for USDA Notification 00-034-19n	03/14/00	3
245	Copy of Monsanto Sample Transfer Form for USDA Notification 00-038-19n	05/15/00	1
246	Copy of Bio-Tech Field Compliance Check List for USDA Notification 00-038-19n	N/A	2
247	Copy of In-Season Field Monitoring forms for USDA Notification 00-038-19n	N/A	7
248	Copy of Monitoring for Volunteers form for USDA Notification 00-038-19n	03/01/01 – 09/11/01	1
249	Copy of _____ result Summary and Weather Report for USDA Notification 00-038-19n	07/16/14	3

250	Copy of 2000 Wheat Field Trial Reports for USDA Notification 00-038-19n	05/13/01, 12/07/01, and 06/28/01	10
251	Copies of Email Correspondences between _____ and Monsanto representatives related to the 2000 trial	03/27/00 – 09/13/02	29
252	Copy of Letter from _____	04/24/15	6
253	Copies of Compliance Training Check-In Sheet and Monsanto Training Documents	04/04/00	55
254	Copy of Monsanto RR Spring Wheat Trial Entry Plot Map	2000	1
255	Declaration of _____	11/26/14	7
256	Copy of Service Agreement between Monsanto and _____ for the 2001 trial	03/05/01	3
257	Copy of Service Agreement Renewal between Monsanto and _____ for the 2002 trial	04/02/02	1
258	Copy of Service Agreement Renewal between Monsanto and _____ for the 2003 trial	04/15/03	1
259	Copy of Monsanto Agricultural Group Protocol 2001-01-66-04	03/12/01	5
260	Copy of Monsanto Agricultural Group Protocol 2001-01-66-05	03/12/01	5
261	Copy of Monsanto Agricultural Group Protocol 2002-01-66-01	03/28/02	5
262	Copy of Monsanto Agricultural Group Protocol 2002-01-66-02	03/28/02	4
263	Copy of Monsanto Agricultural Group Protocol 2002-01-13-02	03/28/14	4
264	Copy of Monsanto Agricultural Group Protocol 2003-01-66-01	03/21/03	3
265	Copy of Monsanto Agricultural Group Protocol 2003-01-66-04	03/21/03	4
266	Copy of Wheat Field Release Performance Standards for the 2001 trial	09/2000	8
267	Copy of Wheat Field Release Performance Standards for the 2002 trial	01/2002	4
268	Copy of Wheat Field Release Performance Standards for the 2003 trial	01/2003	4
269	Copy of Notification Letter from Monsanto to Cooperator	05/21/01	2
270	Copy of Monsanto Material Transfer Form for USDA Notification 00-016-24n	03/22/01	1
271	Copy of Roundup Ready Wheat Sample Transfer Form	03/18/02	1

272	Copy of Roundup Ready Wheat Sample Transfer Form	03/24/03	1
273	Copy of Acknowledgment and Certification of Field Trial Compliance for USDA Notification 01-016-24n	03/17/01	3
274	Copy of Planting Information and Certification of Field Trial Compliance for USDA Notification 02-032-07n	04/17/02	2
275	Copy of Planting Information and Certification of Field Trial Compliance for USDA Notification 02-032-07n	05/01/03	4
276	Copy of 2001-2003 Trial Map for	09/10/04	1
277	Copy of Bio-Tech Field Compliance Check List for USDA Notification 01-016-24n	02/16/01	2
278	Copy of In-Season Field Monitoring forms for USDA Notification 01-016-24n	09/04/01	4
279	Copy of In-Season Field Monitoring forms for USDA Notification 02-032-07n	08/16/02	4
280	Copy of In-Season Field Monitoring forms for USDA Notification 03-022-01n	08/21/03	3
281	Copy of Monitoring for Volunteers form for USDA Notification 01-016-24n	08/20/03	2
282	Copy of Monitoring for Volunteers form for USDA Notification 02-032-07n	08/21/03	6
283	Copy of Monitoring for Volunteers form for USDA Notification 03-022-01n	11/11/05	3
284	Copy of 2001 Wheat Field Trial Reports for USDA Notification 01-016-24n	08/30/02	5
285	Copy of 2001 Wheat Field Trial Reports for USDA Notification 02-03207n	09/04/03	10
286	Copy of 2001 Wheat Field Trial Reports for USDA Notification 03-022-01n	04/23/04	1
287	Copy of Monsanto Letter to APHIS	11/06/03	1
288	Copy of Email Communications between SARC and Monsanto pertaining to 2001-2003 trials	07/09/03 – 11/17/05	34
289	Statement of	N/A	7
290	Declaration of	11/20/14	6
291	Email Correspondences from Investigator to Monsanto representatives	04/16/15 and 05/06/15	2
292	Copy of Monsanto Material Transfer Form for GE wheat seed	05/24/13	1

293	Copies of Chain of Custodies for GE wheat seed obtained from Monsanto		05/24/13	6
294	Email Correspondence from Investigator	to	05/06/15	2
295	Email Correspondence from Investigator	to	05/08/15	3
296	Copy of Monsanto Letter to		09/27/04	2
297	Copies of Declarations of Verification of Destruction/Devitalization/Storage by USDA of Roundup Ready Wheat Seed by signed by and MSU employees		04/29/05	6
298	Email Correspondence from Investigator	to	04/02/15	2
299	Copy of Letter from		05/28/15	2
300	Copy of Letter from		08/06/14	2
301	Copy of Letter from		08/14/14	2
302	Copy of 2014 Wheat Sample results Summary		07/28/14	1
303	Copy of Monsanto's Manual Processing of Wheat Samples for Taqman Testing for thirty samples collected from		08/11/14	4
304	Copy of Letter from		08/18/14	2
305	Copy of Monsanto Letter to pertaining to lateral flow test strips		06/26/01	1
306	Copy of Letter from		08/26/14	3
307	Email Correspondence from Investigator	to	06/11/13	2
308	Copy of Letter from		09/24/14	6
309	Copy of Letter from		05/14/15	3
310	Copy of Containment Survey Report for 2001 Monsanto Company Herbicide Tolerant Wheat Trials		2001	10
311	Copy of Containment Survey Report for 2002 Monsanto Company Herbicide Tolerant Wheat Trials		01/10/03	9
312	Copy of Containment Survey Report for 2003 Monsanto Company Herbicide Tolerant Wheat Trials		07/02/04	9

313	Copy of Criterion 204 Roundup Ready Wheat Regulated Trials Project Summary	04/2005	8
314	Copy of Letter from	05/18/15	2
315	Email correspondences from Monsanto related to the SeedCalc8 and print-out of Monsanto's PowerPoint presentation for grain sampling	07/23/14 – 07/25/14	29
316	Print-out of USDA, APHIS, News Release	09/26/14	3
317	Print-out obtained from www.monsanto.com	04/10/15	2
318	Print-out obtained from www.monsanto.com	07/20/14	2
319	Print-out obtained from www.monsanto.com	04/10/15	9
320	Print-out obtained from www.monsanto.com	04/10/15	3
321	Copy of Domestic Corporation documents from the Delaware Secretary of State for Monsanto	04/14/15	1
322	Copy of Domestic Corporation documents from the Rhode Island Secretary of State for Monsanto	04/09/15	3
323	Copy of LexisNexis Report for Monsanto	N/A	10
324	Copy of Certificate of Incorporation for Monsanto	02/09/00	7
325	Copy of United States Patents US6689880 B2	02/10/04	13
326	Copy of United States Patents US7268274 B2	07/08/04	17
327	Copy of Biotechnology Consultation Note to the File BNF No. 000080	07/22/04	8
328	Copy of Agency Response Letter pertaining to Monsanto Roundup Ready® Wheat Event MON71800	07/22/04	2
329	Copy of Wheat Field Release Design Protocol to Meet or Exceed the USDA Performance Standards obtained from Monsanto	01/2014	7
330	Print-out obtained from www.sarc.montana.edu	09/08/14	2
331	Print-out obtained from www.sarc.montana.edu	09/08/14	2
332	Print-out obtained from www.sarc.montana.edu	07/19/14	15
333	Copy of MSU, SARC's Employee List for 2014	07/30/14	1
334	Print-out obtained from www.animalrange.montana.edu	09/10/14	2

335	Copies Montana Department of Agriculture Pesticide Application licenses for MSU, SARC personnel	N/A	5
336	Copy of MONB00655 Project	03/01/09	20
337	Copy of Montana Wheat Production Guide from MSU	N/A	32
338	Copy of news article obtained from	09/26/14	2
339	Email sent by _____ and attachments containing Google maps for	07/28/14	4
340	Email sent from _____ to Investigator	08/06/14	1
341	Copy of U.S. Congressional Patent 1308889	05/14/53	5
342	Copy of Memorandum of Agreement between MSU	04/18/03	5
343	Copy of CP4 EPSPS protein ELISA test kit insert	N/A	6
344	Copy of SmartLinx® Business for MSU	04/09/15	9
345	Copy of Dun and Bradstreet report MSU, Inc.	N/A	9
346	Declaration of Dr. Neil E. Hoffman	11/24/15	2
347	Copy of Dr. Niel E. Hoffman's Curriculum Vitae	N/A	11