



United States
Department of
Agriculture

Animal and
Plant Health
Inspection
Service

Biotechnology
Regulatory
Services

4700 River Road
Unit 91
Riverdale, MD
20737-1236

February 8, 2016

Warning Letter

PII [REDACTED]

PII [REDACTED]

Monsanto Company
800 North Lindbergh Blvd
Creve Coeur, MO 63167

Dear PII [REDACTED]

We believe that Monsanto Co. violated the Plant Protection Act (7 U.S.C. § 7712 et seq.) (PPA), as described below.

Date of Violation: July 14, 2014

7 C.F.R. § 340.3(c) Notification for the introduction of certain regulated articles.

This section describes required performance standards for the introduction of genetically engineered (GE) material under the notification procedure.

From approximately 2000 through 2003, Montana State University (MSU), Southern Agriculture Center (SARC) was a research cooperator with Monsanto Company (Monsanto) in four field trials (USDA Reference Nos. 00-038-19n, 01-016-24n, 02-032-07n, and 03-022-01n) involving a specific glyphosate resistant wheat variety known as Event 33391/MON71800. Monsanto developed and owns this GE wheat event (United States Patent 7268274).

On July 14, 2014, Monsanto notified the United States Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS), Biotechnology Regulatory Services (BRS) of the presence of glyphosate resistant wheat volunteers at MSU SARC. APHIS' investigation verified that multiple wheat volunteers near the original trial sites tested positive for the cp4epsps gene, which indicates genetically modified material, and for the specific Event 33391/MON71800.

The fact finding investigation is complete and APHIS determined that Monsanto is responsible for MSU SARC's failure to adhere to performance standards for the introduction of regulated material under the notification procedure. MSU SARC is currently under Emergency Action Notification (EAN) DM-408836. APHIS BRS expects Monsanto and MSU SARC to continue to fulfill obligations under the EAN until otherwise instructed by the Agency.



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We acknowledge that Monsanto and SARC took immediate action and aided BRS with the investigation. In addition, SARC's 2014 wheat harvest was disposed of in a landfill in order to ensure no material entered the commodity stream and no wheat was grown at SARC in 2015. SARC is currently under an Emergency Action Notification which requires it to follow specific protocols to ensure the premise is free of GE wheat.

We acknowledge Monsanto's cooperation in voluntarily disclosing and correcting incidents at its facilities. Please feel free to contact me at PII [REDACTED] or PII [REDACTED]@aphis.usda.gov if you have questions or need additional information.

Sincerely,

PII [REDACTED]

PII [REDACTED]

Compliance Evaluation and Enforcement Branch
Regulatory Operations Programs
Biotechnology Regulatory Services
Animal and Plant Health Inspection Service
4700 River Road, Unit 91
Riverdale, MD 20737
(301) 851-3117

cc:

PII [REDACTED] USDA/APHIS/BRS
PII [REDACTED] USDA/APHIS/BRS
PII [REDACTED] USDA/APHIS/BRS
CI20140397P