



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

Montana State University  
Southern Agricultural Research Center  
748 Railroad Highway  
Huntley, Montana 59037

Dear PII

We believe that MSU SARC 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 MSU SARC failed to adhere to performance standards for the introduction of regulated material under the notification procedure.

We acknowledge that 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



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SARC in 2015. SARC is currently under Emergency Action Notification (EAN) DM-408836 which requires it to follow specific protocols to ensure the premise is free of GE wheat. APHIS BRS expects MSU SARC to continue to fulfill all obligations under the EAN until otherwise instructed by the Agency.

We acknowledge MSU'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] [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

PII [redacted]

cc: PII [redacted] USDA/APHIS/BRS  
PII [redacted] USDA/APHIS/BRS  
PII [redacted] USDA/APHIS/BRS  
CI20140397P

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