



Animal and Plant Health Inspection Service
U.S. DEPARTMENT OF AGRICULTURE

USDA APHIS Case Study 2

MON 87411-*SmartStax Pro*[™]

SCRA Workshop

September 20, 2023

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Petitions for Determination of Nonregulated Status

Until March 31, 2021, any person could submit to APHIS BRS a petition seeking a determination of nonregulated status

- Nonregulated status means the organism developed using genetic engineering would not be subject to regulation.
- Petition information should support the conclusion that the modified organism is unlikely to pose a greater plant pest risk than the comparator.
- **On April 1, 2021, the petition process was replaced by the Regulatory Status Review process.**

[USDA APHIS | Legacy Petition Process](#)

[USDA APHIS | Regulatory Status Review \(RSR\)](#)



Background of MON 87411-SmartStax Pro™ Corn

- Developed by Monsanto Company
- *Agrobacterium tumefaciens* transformation
- Two traits of interest to corn producers and processors:
 - Resistance to corn rootworm
 - Tolerance to the herbicide glyphosate



[k1289-17 : USDA ARS](#)



[k10173-2 : USDA ARS](#)

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By APHIS BRS Document Control Officer at 2:55 pm, Dec 18, 2013

Petition for Determination of Nonregulated Status for Corn Rootworm Protected and Glyphosate Tolerant MON 87411 Maize

The undersigned submits this petition under 7 CFR § 340.6 to request that the Administrator make a determination that the article should not be regulated under 7 CFR part 340

October 4, 2013
(Revised December 18, 2013)

OECD Unique Identifier: MON-87411-9

Monsanto Petition Number: CR240-13U1

USDA-APHIS Petition Number 13-290-01p



Background of MON 87411 Corn (Cont.)

- MON 87411 was considered regulated by USDA:
 - A plant pest (*A. tumefaciens*) was used to create the event.
 - Border sequences were derived from *A. tumefaciens*.
 - Some of the introduced genetic sequences came from plant pest organisms listed in 7 CFR 340.2 (legacy regulations).
- In October 2013, Monsanto Company submitted a petition for determination of nonregulated status to USDA to declare the MON 87411 corn event as not regulated (deregulate).





APHIS Risk Assessment for MON 87411 Corn



Plant Pest Risk Assessment (PPRA)

- Assess if a plant modified using genetic engineering (modified plant) is unlikely to pose a plant pest risk.
- Under authority of the Plant Protection Act of 2000.



National Environmental Policy Act Assessment (NEPA)

- Broadly evaluate environmental impacts of APHIS determination.
- Includes consideration of the Endangered Species Act (ESA).



Components of the Plant Pest Risk Assessment

- Molecular Characterization
- Potential Plant Pest and Disease Impacts
- Potential Impacts on Non-Target Organisms Beneficial to Agriculture
- Potential for Enhanced Weediness of MON 87411 Corn
- Potential Impacts on the Weediness of Any Other Plants with which MON 87411 Corn Can Interbreed (Sexually Compatible Relatives)
- Potential Changes to Agriculture or Cultivation Practices
- Impacts from Gene Transfer into Organisms with which MON 87411 Corn Cannot Interbreed



Molecular Characterization of MON 87411 Corn

- A single copy of PV-ZMIR10871 insert
 - DvSnf7 suppression cassette, and cry3Bb1 and cp4 epsps expression cassettes
- Free of backbone plasmid sequences
- Stably integrated at a single locus and inherited over multiple generations
- No allergenicity or toxicity of Cry3Bb1 and CP4 EPSPS proteins
- Compositionally equivalent to parental line and conventional corn

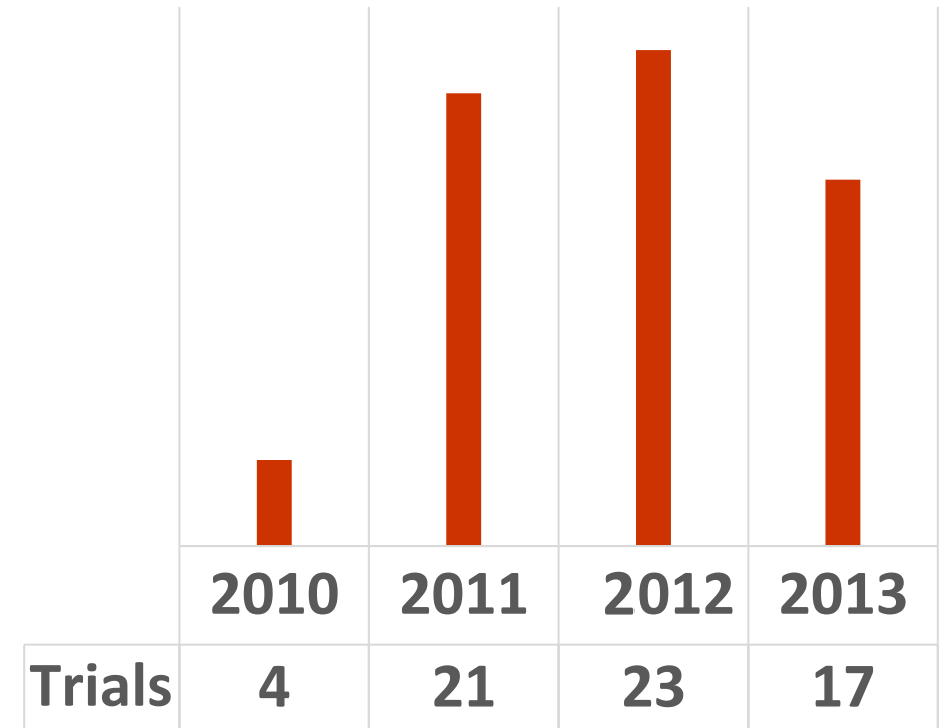


Conclusion:

MON 87411 corn poses no more of a plant pest risk from the introduction of the three genes and changes to plant metabolism or composition than its original parental line or other conventional corn hybrids.

Field Release Authorizations for Agronomic and Disease Susceptibility Studies

- Monsanto released MON 87411 into the environment as a regulated article under APHIS-authorized notifications and permits.
- Releases occurred in 22 U.S. States (AR, CA, CO, GA, HI, IA, IL, IN, KS, LA, MI, MN, MO, MS, NC, NE, OH, PA, SD, TN, TX, and WI) and one U.S. Territory (Puerto Rico).



Potential Plant Pest and Disease Impacts

- Data from 9 field trials compared susceptibility or resistance of MON 87411 corn and control plants to pests and diseases.
- No biologically meaningful differences were observed that indicate that MON 87411 is or could be more susceptible to pests and diseases.
- The genes inserted into MON 87411 corn are not expected to cause disease.



Conclusion:

MON 87411 corn does not exhibit increased plant pest or disease characteristics. Its use will not lead to new plant pests or to the dissemination of plant pests.

Potential Impacts on Non-Target Organisms Beneficial to Agriculture

Based on:

- Evaluation of the gene products and their specificity
- Results of bioassays involving the insecticidal double-stranded RNA and its effects on a range of insects varying in ecological function and on insects closely related taxonomically to corn rootworm
- Extensive literature and experience with genetically engineered plants expressing Cry proteins and EPSPS CP4 proteins



Conclusion:

Exposure to and/or consumption of MON 87411 corn are unlikely to adversely impact nontarget organisms beneficial to agriculture.

Potential for Enhanced Weediness of MON 87411 Corn

- Corn is not a weed in the U.S. and does not have weedy characteristics
- Current management practices to control corn as a weed are available
- Field trial data showed no evidence for altered growth characteristics:
 - Nine replicated field trials across the U.S. corn belt
 - Assessed 13 plant growth and development characteristics



Conclusion:

MON 87411 corn is no more likely to become weedier or more difficult to control as a weed than conventional corn.

Impacts on the Weediness of Sexually Compatible Plants

- In the U.S., *Zea mays* is potentially sexually compatible with:
 - Teosintes, wild *Zea* spp. typically confined to tropical and subtropical regions.
 - *Tripsacum*, a genus of grass in the U.S.
- Gene flow, hybridization, and/or introgression of inserted genes from MON 87411 corn to teosinte and *Tripsacum* is not likely to occur.
- Teosinte and *Tripsacum* are not considered weedy or invasive; any accidental gene flow from MON 87411 is unlikely to transform corn wild relatives into more weedy species.



Conclusion:

Use of MON 87411 corn will not cause sexually compatible relatives to become weeds.

Potential Changes to Agriculture or Cultivation Practices

- No significant changes to agricultural or cultivation practices.
- No increased use of insecticides or herbicides.



Conclusion:

Significant changes to agricultural or cultivation practices (e.g., pesticide applications, tillage, irrigation, harvesting, etc.) from adoption of MON 87411 corn are not expected.

Potential Impacts from Gene Transfer into Organisms with which MON 87411 Corn Cannot Interbreed

HORIZONTAL GENE TRANSFER (HGT)

- HGT has been intensively studied since the 1940s.
- HGT between MON 87411 corn and bacteria or fungi is highly unlikely.
- HGT between MON 87411 corn and viruses is highly unlikely.
- HGT between MON 87411 corn and parasitic plants is highly unlikely.



Conclusion:

Horizontal gene transfer of the new genetic material inserted into MON 87411 corn to other organisms is highly unlikely and is an extremely low risk.

NEPA Environmental Assessment



Agricultural Production



Environmental Resources



Impact on Biological Resources



Impact on Human and Animal Health



Impact on Threatened and Endangered Species



Summary

- USDA protection goals are aimed at protecting plant health and the environment.
- Corn rootworm is a devastating pest of corn in the United States.
- APHIS regulates plants developed using genetic engineering if they post a plant pest risk.
- BRS reviewed the Monsanto corn petition and conducted risk assessments based on the scientific data provided by Monsanto.
- It was determined that MON 87411 corn is unlikely to pose a plant pest risk and should not be subject to the regulations at 7 CFR part 340 (legacy).
- Petition process was replaced by RSR on April 1, 2021.





Exemptions: Previously Reviewed Plants

- Plants modified to contain a plant-trait-MOA combination that is the same as one that was previously evaluated and determined by APHIS not to be regulated are also exempt from the regulations. Previous evaluations may have occurred under the:
 - Petition process in the prior 340 regulations; or
 - Regulatory Status Review process in the revised 340 regulations.

[7 CFR part 340 | Movement of Organisms Modified or Produced Through Genetic Engineering](#)



USDA Revised Regulations

- **CONFIRMATION OF EXEMPTIONS (CR)**

Developers may elect to seek confirmation from USDA that the product meets an exemption and is not subject to the biotechnology regulations.

- **REGULATORY STATUS REVIEW (RSR)**

If a plant does not meet a regulatory exemption, the developer may seek a RSR for a plant developed using genetic engineering to determine whether it is regulated.

Regulatory Status Review (RSR)

RSR evaluates plant pest risk based on:



The biological
properties of the
plant



The trait (or new
characteristic)



The mechanism of
action (or how the
developer caused
the new trait to
occur)

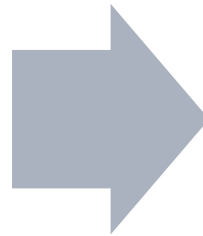
Regulatory Status Review (RSR)

The RSR is a two-step process:

1

Initial review problem formulation
to identify whether there are
plausible pathways to increased
plant pest risk

Complete in 180 Days



2

Plant Pest Risk Assessment (PPRA)
Determines likelihood and
consequence of any plausible
pathways in the initial review

**Full Evaluation Complete
within 15 Months**

Thank You!

