

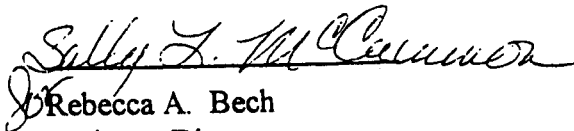


Approval of AgrEvo Request (98-349-01p) Seeking Extension of Determination of  
Non-regulated Status For Male Sterile Corn Event MS6

**Environmental Assessment and  
Finding of No Significant Impact**

March 1999

The Animal and Plant Health Inspection Service (APHIS), United States Department of Agriculture (USDA), has prepared an environmental assessment (EA) prior to approving an extension (APHIS Number 98-349-01p) to the determination of nonregulated status granted for petition 95-228-01p received from AgrEvo USA Company under APHIS regulations at 7 CFR Part 340. The subject of the extension request 98-349-01p, male sterile corn transformation event MS6 has been genetically engineered with a gene whose expression results in the plant being male sterile with a glufosinate herbicide tolerance as a marker gene. Based on the analysis carried out in the EA, APHIS has reached a finding of no significant impact (FONSI) to the environment from its determination that male sterile corn transformation event MS6 shall no longer be considered a regulated article.



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### APPENDICES

**Appendix A:** Environmental Assessment and Finding of No Significant Impact  
95-228-01p

**Appendix B:** Determination of Nonregulated Status 95-228-01p

### III. SIMILARITIES AND DIFFERENCES BETWEEN ANTECEDENT ORGANISM AND MS6

Male sterile corn transformation event MS6 is similar to the antecedent organism described in the AgrEvo petition 95-228-01p except that it was developed by a new transformation event using the same biolistic particle bombardment technique. MS6 expresses the barnase (ribonuclease) from *B. amyloliquefaciens* whose transcription is directed by the corn PCA55 pollen-specific promoter and whose termination signal is from nopaline synthase gene from *Agrobacterium tumefaciens* and a selectable marker gene phosphinothricin acetyltransferase (*bar*) from *Streptomyces hygroscopicus* whose transcription is directed 35S cauliflower mosaic caulimovirus (CaMV) promoter and whose termination signal is from nopaline synthase. The nopaline synthase terminator gene for barnase was truncated. Event MS3 had different pollen specific promoter than MS6. MS6 does not contain the complete beta-lactamase gene (*bla*) or the bacterial origin of replication (*ori*).

MS6 is male sterile and based on the data submitted by the applicant exhibits the agronomic characteristics essentially identical to the antecedent organism MS 3.

### IV. POTENTIAL ENVIRONMENTAL IMPACTS

APHIS has considered all the information provided by AgrEvo in its petition and other scientific data relating to the potential plant pest risk of male sterile corn transformation event MS6 and its progeny. A thorough evaluation of the potential for significant impact to the human environment through the unconfined agricultural use of male sterile corn transformation event MS6 leads APHIS to a Finding of No Significant Impact (FONSI). This conclusion is based upon: (1) MS6 corn is essentially identical to the antecedent organism MS3; (2) exhibits no plant pathogenic properties; (3) is no more likely to become a weed than corn lines developed by traditional breeding techniques; (4) is unlikely to increase the weediness potential of any other cultivated plant or native wild species with which MS6 corn can interbreed; (5) will not harm threatened and endangered species and other organisms, such as bees, which are beneficial to agriculture; and 6) will not cause damage to processed agricultural commodities.

In conjunction with the FONSI, APHIS has made the determination that the male sterile corn transformation event MS6 and its progeny have no potential to pose a plant pest risk, and therefore are no longer considered regulated articles (see Appendix A attached to the EA of 95-228-01p).

Because the regulated article MS6 is agronomically similar the antecedent organism MS3, it does not present any new potential environmental impact issues other than addressed in the EA associated with determination 95-228-01p. Therefore, this EA is

tiered to the original EA of 95-228-01p (see Appendix A) in which potential for impacts to the human environment through unrestricted use in agriculture of male sterile corn transformation event MS6 and its progeny have been addressed in detail.

## V. CONCLUSIONS

In accordance with the requirements of the National Environmental Policy Act (NEPA), as amended (42 U.S.C. 4321 *et. seq.*) APHIS has considered the potential for significant impact on the environment of a proposed action, i.e., reaching the determination that MS6 and its progeny have no potential to present a plant pest risk, and therefore should no longer be considered a regulated article under the regulations at 7 CFR Part 340. After careful analysis of the available information, APHIS concludes that its proposed action should not have a significant impact on the environment and that the proper alternative is to determine that MS6 and its progeny would have a nonregulated status when grown in the United States and its territories. APHIS has identified no factors that would suggest any impact to the environment of the United States and its territories. While isolated environments, such as are found in Hawaii, Puerto Rico, or in territories or possessions of the United States, have fragile ecologies that have frequently been damaged through human intervention, APHIS has determined that in these environments MS6 and its progeny will have impacts no different from male sterile corn varieties that are developed via traditional plant breeding that are not regulated articles in the regulations at 7 CFR Part 340 before they enter agriculture. All the factors that were considered for the determination of nonregulated status of MS6 and its progeny are found in APPENDIX B. The following key points were considered for a FONSI:

1. The regulated article in question MS6 corn and its progeny are similar to the antecedent organism as both have been genetically engineered with a gene that make the plant male sterile and with the same marker gene, and that both exhibit similar agronomic characteristics.
2. MS6 corn exhibits no plant pathogenic properties. Although components of pathogenic organisms were used in their development, these corn plants are not infected by these organisms nor can these plants incite disease in other plants.
3. MS6 corn is no more likely to become a weed than male sterile corn that has been developed by traditional breeding techniques. Corn is not a serious, principal, or common weed pest in the U.S. and there is no reason to believe that male sterility would enable corn to become a weed pest.
4. Multiple barriers, including sterility of this line, insure that gene introgression from MS6 corn into wild or cultivated sexually-compatible plants is extremely unlikely, and such rare events should not increase the weediness potential of any resulting progeny or adversely impact biodiversity.

5. Seeds of MS6 corn are substantially equivalent in composition, quality and other characteristics to nontransgenic corn and should have no adverse impacts on raw or processed agricultural commodities.

6. MS6 corn exhibits no significant potential to either harm threatened or endangered species or organisms beneficial to the agricultural ecosystem.

## **VI. REVIEWERS**

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