

Determination of Nonregulated Status for the Scotts Company and Monsanto Company ASR368 Creeping Bentgrass

In response to petition 15-300-01p from the Scotts Company and Monsanto Company (hereinafter referred to as Scotts/Monsanto), the Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA) has determined that Scotts/Monsanto glyphosate resistant ASR368 Creeping Bentgrass (hereinafter referred to as ASR368 CBG) and progeny derived from it are not likely to pose a plant pest risk and are no longer to be considered regulated articles under APHIS' Biotechnology Regulations at Title 7 of the Code of Federal Regulations, part 340 (7 CFR part 340). Since APHIS has determined that ASR368 CBG is unlikely to pose a plant pest risk, APHIS will approve the petition for nonregulated status of ASR368 CBG. Therefore, APHIS authorizations previously required for environmental release, interstate movement, or importation under these regulations will no longer be required for ASR368 CBG and its progeny. The commitments of Scotts under the Memorandum of Agreement signed with APHIS on September 2, 2015 will continue to apply to glyphosate resistant CBG present in the environment after this approval of nonregulated status for ASR368 CBG.

This Determination of nonregulated status for ASR368 CBG is based on APHIS' analyses of field and laboratory data submitted by Scotts/Monsanto, references provided in the petition, peer-reviewed publications, and other relevant information as described in the Plant Pest Risk Assessment (PPRA) for ASR368 CBG. In addition, in their petition for non-regulated status Scotts/Monsanto states they "have no intention to and will not commercialize or further propagate such plants in the future and will not grant a license to or otherwise allow other entities to obtain, use, or propagate such plants." Although weed risk does not affect APHIS' plant pest risk determination, this statement informs APHIS' conclusions in the PPRA.

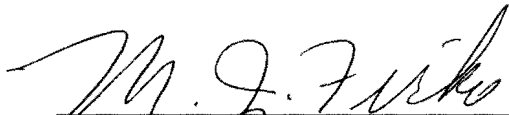
The PPRA conducted on ASR368 CBG concluded that it is unlikely to pose a plant pest risk and should no longer be subject to the regulations at 7 CFR part 340 for the following reasons:

- (1) No plant pest risk was identified from the transformation process, the insertion and/or expression of new genetic material, or from changes in metabolism in ASR368 CBG.
- (2) Disease and pest incidence and/or damage were not observed to be significantly increased or atypical in ASR368 CBG compared to the non-genetically engineered counterpart or other comparators in field trials. Observed agronomic traits also did not reveal any significant differences that would indirectly indicate that ASR368 CBG is more susceptible to pests or diseases. Therefore, no plant pest effects are expected on these or other agricultural products.
- (3) Based on an evaluation of the gene products and observations from multi- year U.S. field trials, exposure to and/or consumption of ASR368 CBG is unlikely to adversely impact non-target organisms beneficial to agriculture.

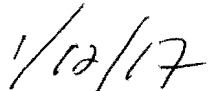
- (4) ASR368 CBG (and feral CBG that acquires the glyphosate resistance trait) is no more likely to become weedier than conventional varieties of CBG based on the observed agronomic characteristics of ASR368 CBG, the weediness potential of CBG, and current management practices available to control CBG as a weed. Glyphosate resistant CBG plants may be somewhat more difficult to control than glyphosate sensitive CBG in riparian habitats, grass seed production fields, and some hayfields and pastures, but can still be managed using a variety of currently available methods. ASR368 CBG is unlikely to pose a significant weed problem and there are unlikely to be any adverse consequences as a result of the escape of ASR368 CBG from field trials and its subsequent persistence in the environment..
- (5) ASR368 CBG is not likely to increase the weed risk potential of other species with which it can interbreed in the U.S. or its territories. Gene flow, hybridization and/or introgression of inserted genes from ASR368 CBG to other sexually compatible relatives with which it can interbreed is not likely to occur since glyphosate resistant CBG is rare in the environment and ASR368 CBG will not be cultivated in the future. If gene introgression does occur, the new phenotype conferred by genetic engineering is not likely to increase the weediness of hybrid plants or any of these compatible relatives. The new phenotype may make these relatives somewhat more difficult to control, but they can still be managed using a variety of currently available methods and alternative herbicides. Glyphosate resistant sexually compatible relatives are unlikely to pose a significant weed problem and any adverse consequences from gene flow from ASR368 CBG or other glyphosate resistant CBG to wild or weedy species in the United States and its territories are highly unlikely.
- (6) Significant changes to agricultural or cultivation practices (e.g. pesticide applications, tillage, irrigation, harvesting, etc.) are not expected since glyphosate resistant CBG is rare in the environment and ASR368 CBG will not be cultivated in the future.
- (7) Horizontal gene transfer of the new genetic material inserted into the GE plant to other organisms is highly unlikely, and is not expected to lead directly or indirectly to disease, damage, injury or harm to plants, including the creation of new or more virulent pests, pathogens, or parasitic plants.

Prior to this Determination of nonregulated status, APHIS completed a Final Environmental Impact Statement (FEIS) which explored the potential environmental impacts that a determination of nonregulated status for ASR368 CBG and its progeny would have on the quality of the human environment. The FEIS concluded, among other things, that a determination of nonregulated status for ASR368 CBG and its progeny will have no effect on federally-listed threatened and endangered species, species proposed for listing, or their designated or proposed critical habitats.

Based on my full and complete review and consideration of all the scientific and environmental data, analyses and information, the input from the public involvement process, the conclusions of the PPRA, the FEIS and its Record of Decision, and my knowledge and experience as the APHIS Deputy Administrator for Biotechnology Regulatory Services, I have determined and decided that this Determination of nonregulated status for ASR368 CBG is the most scientifically sound and appropriate regulatory decision.



Michael J. Finko, Ph.D.



Date

APHIS Deputy Administrator
Biotechnology Regulatory Services
Animal and Plant Health Inspection Service
U.S. Department of Agriculture