Record of Decision

The Scotts Company and Monsanto Company Petition (15-300-01p) for Determination of Nonregulated Status for ASR368 Creeping Bentgrass

OVERVIEW

The United States Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) completed and published a Final Environmental Impact Statement (EIS) after receiving a petition submitted by The Scotts Company LLC of Marysville, OH and Monsanto Company of St. Louis, MO (Scotts and Monsanto), seeking a determination of nonregulated status for ASR368 creeping bentgrass that has been engineered to be resistant to the herbicide glyphosate (Scotts and Monsanto, 2015a).

The petition states that ASR368 is unlikely to pose a plant pest risk and, therefore, should not be regulated under APHIS' regulations in 7 Code of Federal Regulations (CFR) part 340. These Part 340 regulations are authorized by the Plant Protection Act to prevent the introduction or dissemination of plant pests and the decision on whether or not to approve the petitions is based on this authority.

APHIS prepared the EIS in order to evaluate the impacts on the quality of the human environment[1] that may result from a determination of nonregulated status of this genetically engineered (GE) creeping bentgrass event. APHIS examined two alternatives in the EIS:

- Alternative 1: continue to regulate ASR368 creeping bentgrass (No Action Alternative);
- Alternative 2: approve the petition for nonregulated status of ASR368 creeping bentgrass (Preferred Alternative).

This Record of Decision documents APHIS' decision on the alternatives examined in the EIS. In accordance with its statutory authority and following the publication of its EIS, APHIS is choosing Alternative 2.

Additionally, APHIS' regulatory determinations of nonregulated status of ASR368 creeping bentgrass pursuant to the Part 340 regulations will become effective upon publication in the *Federal Register*. APHIS' regulatory determination is entitled:

- Determination of Nonregulated Status for The Scotts Company LLC and Monsanto Company ASR368 creeping bentgrass.

BACKGROUND

Coordinated Framework

APHIS is one of the Federal agencies with regulatory responsibilities as described in the 1986 Federal Coordinated Framework for the Regulation of Biotechnology (hereafter Coordinated

[1] Under NEPA regulations, the "human environment" includes "the natural and physical environment and the relationship of people with that environment" (40 CFR §1508.14).

Framework) published by the Office of Science and Technology Policy, Executive Office of the President. The Coordinated Framework is a Federal policy statement that "describes the comprehensive Federal regulatory policy for ensuring the safety of biotechnology research and products." The Coordinated Framework explains the proper allocation and coordination of oversight responsibilities under the relevant Federal statutes and among the relevant Federal agencies.

The Coordinated Framework thus addresses who shall have oversight authority in each instance, but does not address how that authority should be exercised in situations in which a statute leaves the implementing agency latitude for discretion. To that end, the Office of Science and Technology Policy published a notice of Federal policy in the *Federal Register* in 1992 in which it set forth "the proper basis for agencies' exercise of oversight authority within the scope of discretion afforded by statute."

The notice describes:

"a risk-based, scientifically sound approach to the oversight of planned introductions of biotechnology products into the environment that focuses on the characteristics of the biotechnology product and the environment into which it is being introduced, not the process by which the product is created. Exercise of oversight in the scope of discretion afforded by statute should be based on the risk posed by the introduction and should not turn on the fact that an organism has been modified by a particular process or technique."

The policy statement of 1992 states further:

> In order to ensure that limited federal oversight resources are applied where they will accomplish the greatest net beneficial protection of public health and the environment, oversight will be exercised only where the risk posed by the introduction is unreasonable, that is, when the value of the reduction in risk obtained by additional oversight is greater than the cost thereby imposed. The extent and type of oversight measure(s) will thus be commensurate with the gravity and type of risk being addressed, the costs of alternative oversight options, and the effect of additional oversight on existing safety incentives.

The Coordinated Framework explains the regulatory roles and authorities for the three major agencies involved in regulating GE organisms: USDA APHIS, the Environmental Protection Agency (EPA), and the Food and Drug Administration (FDA).

EPA Regulation of Biotechnology

The EPA is responsible for regulating the sale, distribution, and use of pesticides, including those that are expressed by an organism modified using techniques of modern biotechnology, identified as plant-incorporated protectants (PIPs).[2] The EPA regulates these PIPs under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S. Code (U.S.C.) 136, *et seq.*) and certain biological control organisms under the Toxic Substances Control Act (15 U.S.C. 53, *et seq.*). Before planting a crop containing a PIP, a company must seek an experimental use

[2] A list of EPA Current and Previously Registered Section 3 PIP Registrations can be found here: http://www.epa.gov/pesticides/biopesticides/pips/pip_list.htm.

permit from the EPA. Commercial production of crops containing PIPs for purposes of seed increases and sale requires a FIFRA Section 3 Registration with the EPA. Before the EPA can register a pesticide there must be sufficient data demonstrating that it will not pose unreasonable risks to human health or the environment when used according to label directions. When assessing the potential risks of genetically engineered PIPs, the EPA requires extensive studies examining numerous factors, such as risks to human health, nontarget organisms and the environment, potential for gene flow, and the need for insect resistance management plans.

FDA Regulation of Biotechnology

The FDA regulates GE organisms under the authority of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*). The FDA published its policy statement concerning regulation of products derived from new plant varieties, including those derived from genetic engineering, on May 29, 1992 (57 FR 22984). Under this policy, the FDA implements a voluntary consultation process to ensure that human food and animal feed safety issues or other regulatory issues, such as labeling, are resolved before commercial distribution of food derived from GE products.[3]

APHIS Regulation of Biotechnology

In 1987, APHIS promulgated its biotechnology regulations (7 CFR part 340) under the authority of the Federal Plant Pest Act and the Plant Quarantine Act[4] to address potential risks that certain GE organisms might pose as plant pests. The regulations refer to such GE organisms as "regulated articles."[5]

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[3] A list of all completed Biotechnology consultations on Genetically Engineered foods evaluated under FDA's 1992 Statement of Policy: Foods Derived from New Plant Varieties can be found here: http://www.accessdata.fda.gov/scripts/fdcc/?set=Biocon.

[4] The Federal Plant Pest Act and Plant Quarantine Act were consolidated along with other statutory authorities into the Plant Protection Act of 2000, in which Congress found that: "it is the responsibility of the Secretary to facilitate exports, imports, and interstate commerce in agricultural products and other commodities that pose a risk of harboring plant pests…in ways that will reduce, to the extent practicable, as determined by the Secretary, the risk of dissemination of plant pests…; decisions affecting imports, exports, and interstate movement of products regulated under this title shall be based on sound science…"
The Plant Protection Act of 2000 defines a plant pest as:

> PLANT PEST—The term ''plant pest'' means any living stage of any of the following that can directly or indirectly injure, cause damage to, or cause disease in any plant or plant product:
>
> (A) A protozoan.
> (B) A nonhuman animal.
> (C) A parasitic plant.
> (D) A bacterium.
> (E) A fungus.
> (F) A virus or viroid.
> (G) An infectious agent or other pathogen.
> (H) Any article similar to or allied with any of the articles specified in the preceding subparagraphs.
> (7 U.S.C. §7702(14)

[5] A "regulated article" is defined as: "Any organism which has been altered or produced through genetic engineering, if the donor organism, recipient organism, or vector or vector agent belongs to any genera or taxa designated in § 340.2 and meets the definition of plant pest, or is an unclassified organism and/or an organism whose classification is unknown, or any product which contains such an organism, or any other organism or product

The APHIS regulations codified at 7 CFR part 340 were amended in 1993 to provide a procedure for the deregulation (i.e., a petition for nonregulated status) of such GE plants that are unlikely to present a plant pest risk and, therefore, should no longer be regulated. 7 CFR 340.6 describes the process for submitting petitions for nonregulated status, the data requirements, and actions that the APHIS Administrator may take on the petition. It is under this procedure that APHIS received a petition request from Scotts and Monsanto seeking a determination of nonregulated status of ASR368 creeping bentgrass. On January 8, 2016, APHIS published the new petition for a 60-day public comment period, closing March 8, 2016 (81 FR 902-903). The docket received a total of 169 public submissions. Some of the submissions to the docket contained multiple attached comments gathered by organizations from their members. Contained within the 169 submissions were a total of 5,852 public comments.

In response to the Scotts and Monsanto petition, APHIS prepared a plant pest risk assessment (PPRA) to assess the plant pest risk for ASR368 creeping bentgrass pursuant to the Plant Protection Act (USDA-APHIS, 2016). APHIS also examined the environmental impacts of its potential regulatory decision for nonregulated status of ASR368 creeping bentgrass pursuant to the National Environmental Policy Act (NEPA) with the publication of the EIS.

For most petitions for a determination of nonregulated status of GE organisms that APHIS has evaluated previously, it has prepared an environmental assessment to provide the APHIS decisionmaker with an environmental review and analysis that identifies whether there may be any significant environmental impacts. If the Agency makes a finding of no significant impact (FONSI), the NEPA process stops and a FONSI decision is issued. If significant environmental impacts are identified, the process continues with the preparation of an EIS before a determination is made. For ASR368 creeping bentgrass, the decision to prepare the EIS was discretionary on the part of APHIS based on a perceived need for the level of thoroughness afforded by the EIS process due to the complexity of issues that needed to be addressed. Accordingly, as part of the scoping process, APHIS published a Notice of Intent in the *Federal Register* to prepare the EIS and sought public input during a 30 day comment period (August 3, 2016 to September 2, 2016). The docket received a total of 18 public comments.

On September 30, 2016, APHIS published a notice in the Federal Register (81 FR 51174-51176) announcing the availability of the draft Environmental Impact Statement (EIS) and preliminary plant pest risk assessment (PPRA) for a 45-day public review and comment period. The EIS, PPRA, and supporting documents were made available to the public on the regulations.gov docket (APHIS-2015-0096) and on APHIS' webpage.[6] The public was given 45 days, from September 30, 2016 through November 14, 2016, to submit their comments to the docket.

APHIS received a total of 16 public submissions. One of the submissions to the docket contained multiple attached comments gathered by the Center for Biological Diversity from its members. Contained within the 16 submissions were a total of 928 public comments. APHIS reviewed and

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altered or produced through genetic engineering which the Administrator, determines is a plant pest or has reason to believe is a plant pest. Excluded are recipient microorganisms which are not plant pests and which have resulted from the addition of genetic material from a donor organism where the material is well characterized and contains only non-coding regulatory regions." (7 Code of Federal Regulations (CFR) 340.0)

[6] http://www.aphis.usda.gov/biotechnology/petitions_table_pending.shtml.

evaluated all of the public comments received on the draft EIS for ASR368 creeping bentgrass. The comments were compiled by related issue and are summarized in Appendix A of the final EIS along with the APHIS responses. On December 9, 2016, a Notice in the *Federal Register* (81 FR 89095) announced the availability of the final EIS to the public. Additionally, APHIS distributed the final EIS to all interested individuals who had specifically requested a copy of the EIS and also posted it on its website.[7]

PURPOSE AND NEED FOR AGENCY ACTION

In both the draft and final EIS, APHIS identified a purpose and need to respond to the Scotts and Monsanto petition for ASR368 creeping bentgrass for a determination of nonregulated status in accordance with its current regulatory authority. As required by 7 CFR 340.6, APHIS must respond to petitioners that request a determination of the regulated status of a GE organism, including GE plants such as ASR368 creeping bentgrass, and must make a regulatory determination on whether the GE organism is likely to pose a plant pest risk. If APHIS determines, based on its PPRA, that the GE organism is unlikely to pose a plant pest (as defined in the Plant Protection Act) risk, APHIS has no legal basis to continue to regulate that GE organism and must deregulate the GE organism. In summary, the purpose and need of this project is to make a decision on this petition that is consistent with APHIS's statutory authority under the Plant Protection Act and 7 CFR part 340.

PLANT PEST RISK ASSESSMENT

The PPRA characterizes the potential plant pest risks associated with the GE product (crop) that is the subject of the petition for nonregulated status relative to its conventional varieties. It is based on information supplied in the petition for a determination of nonregulated status together with other relevant publically available scientific data.

APHIS concluded from its PPRA that ASR368 creeping bentgrass is unlikely to pose a plant pest risk based on the following reasons (USDA-APHIS, 2016):

(1) No plant pest risk was identified from the transformation process or the insertion of new genetic material in ASR368 creeping bentgrass because it was developed with biolistic transformation protocols, it contains a single stable DNA insertion with no unintended sequence rearrangement, and none of the inserted sequences from plant pests encode a plant pest or infectious agent.

(2) No increase in plant pest risk was identified in ASR368 creeping bentgrass due to expression from the inserted genetic material of new proteins or changes in metabolism or composition because the CP4 EPSPS protein is structurally similar and functionally identical to endogenous plant EPSPS enzymes, except for its insensitivity to glyphosate, and there are no substantive compositional differences between ASR368 creeping bentgrass and conventional creeping bentgrass.

(3) Disease and pest incidence and/or damage were not observed to be significantly increased or atypical in ASR368 creeping bentgrass compared to the nontransgenic counterpart or other

[7] The final EIS can be viewed at https://www.aphis.usda.gov/brs/aphisdocs/15_30001p_feis.pdf

comparators in field trials. Observed agronomic traits also did not reveal any significant differences that would indirectly indicate that ASR368 creeping bentgrass is more susceptible to pests or diseases. Therefore, no plant pest effects are expected on ASR368 creeping bentgrass and ASR368 creeping bentgrass is unlikely to differ from conventional creeping bentgrass in its ability to harbor or transmit plant pathogens or pests and cause indirect plant pest effects on other agricultural products.

(4) Exposure to and/or consumption of ASR368 creeping bentgrass is unlikely to have any adverse impacts on organisms beneficial to agriculture based on the analysis of the safety of the protein CP4 EPSPS, observations from multi-year U.S. field trials looking for adverse non-target interactions with the use of ASR368 creeping bentgrass and the past evaluations of the impact of the EPSPS protein within approved petitions.

(5) ASR368 creeping bentgrass (or feral creeping bentgrass that acquires the glyphosate resistance trait) is unlikely to be weedier than conventional varieties of creeping bentgrass based on its observed agronomic characteristics, the weediness potential of the crop, and current management practices available to control glyphosate-resistant creeping bentgrass as a weed. Glyphosate-resistant creeping bentgrass plants may be more difficult to control than glyphosate sensitive creeping bentgrass in riparian habitats, grass seed production fields, and some hayfields and pastures, but can still be managed using a variety of currently available methods, including mechanical and cultural methods and alternative herbicides. Glyphosate-resistant creeping bentgrass is unlikely to pose a significant weed problem and any adverse consequences from the escape and persistence of glyphosate-resistant creeping bentgrass are expected to be minimal or unlikely under typical weed management programs.

(6) ASR368 creeping bentgrass is not expected to increase the weed risk potential of other species with which it can interbreed in the Unites States or its territories. Gene flow, hybridization and/or introgression of inserted genes from escaped or feral glyphosate-resistant creeping bentgrass to other sexually compatible relatives with which they can interbreed is not likely to occur since glyphosate-resistant creeping bentgrass is rare in the environment and 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 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 glyphosate-resistant creeping bentgrass to wild or weedy species in the United States and its territories are unlikely.

(7) Significant changes to agricultural or cultivation practices of creeping bentgrass (e.g. pesticide applications, tillage, irrigation, harvesting, etc.) from adoption of ASR368 creeping bentgrass is not expected to be any different than that of conventional creeping bentgrass with the exception of the use of glyphosate to control weeds in ASR368 cultivated fields. However, this will not occur since Scotts/Monsanto do not intend to commercialize or further propagate such plants in the future.

(8) Horizontal gene transfer of the new genetic material inserted into ASR368 creeping bentgrass to other organisms is 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.

FINAL ENVIRONMENTAL IMPACT STATEMENT

APHIS prepared a final EIS to examine the potential impacts on the human environment from a determination of nonregulated status of ASR368 creeping bentgrass. [8] APHIS evaluated potential environmental impacts in the final EIS associated with the regulatory decision to approve the petition requesting a determination of nonregulated status for ASR368 creeping bentgrass. A summary of the environmental analyses contained in the final EIS is set forth below, in the section entitled "Environmental Consequences Associated with the Determination of Nonregulated Status under Alternative 2."

Alternatives Considered in the Final EIS

Alternative 1: No Action Alternative – Continuation as a Regulated Article

Under the No Action Alternative, APHIS would deny the petition seeking a determination of nonregulated status of ASR368 creeping bentgrass. All interstate movements and environmental releases for ASR368 creeping bentgrass would remain subject to the regulations in 7 CFR part 340. Although no permits for outdoor planting have been requested since 2005 and we have no reason to anticipate any future requests since all commercial ASR368 creeping bentgrass seed stock has been destroyed (Scotts, 2016), any introduction of ASR368 creeping bentgrass would still require authorization by APHIS. In addition, measures to ensure physical and reproductive confinement of ASR368 creeping bentgrass would continue to be implemented for any existing or new authorization.

Alternative 2: Preferred Alternative – Determination that ASR368 Creeping Bentgrass is No Longer a Regulated Article

Under Alternative 2, if ASR368 creeping bentgrass was determined unlikely to pose a plant pest risk and the event received nonregulated status, ASR368 creeping bentgrass and progeny derived from it would no longer be regulated articles under the regulations at 7 CFR part 340. APHIS would no longer require authorizations for introductions of ASR368 creeping bentgrass and progeny derived from this event.

Although this petition seeks nonregulated status for ASR368 creeping bentgrass, Scotts and Monsanto have stated in the petition that they have no intention to and will not commercialize or further propagate such plants in the future. Further, Scotts and Monsanto have stated that they will not grant a license to or otherwise allow other entities to obtain, use, or propagate such plants (Scotts and Monsanto, 2015a). Additionally, Scotts has destroyed all commercial ASR368 creeping bentgrass seed stock and withdrew their EPA label amendment application for any glyphosate-based product for use on ASR368 creeping bentgrass (Scotts and Monsanto, 2015b; Scotts, 2016). Scotts has documented in a signed MOA their commitment not to commercialize ASR368 creeping bentgrass and reiterated their company's commitment to the management of

[8] The final EIS can be viewed at https://www.aphis.usda.gov/brs/aphisdocs/15_30001p_feis.pdf or under docket number APHIS-2015-0096 at regulations.gov.

ASR368 creeping bentgrass in the three affected counties where it currently exists (USDA-APHIS, 2015a).

The above information informs the proposed action and the analyses of the environmental impacts in the areas affected by the alternatives in the EIS. Should at any time in the future the proposed action change in a manner that raises significant new circumstances or new information relevant to the environmental concerns that may impact the affected environment, APHIS will prepare a supplemental EIS addressing the new circumstances' or new information's impact on the human environment. APHIS will then follow the procedures outlined in CEQ regulations (40 CFR §1502.9).

Major Issues Addressed in the EIS

The EIS described the two alternatives considered and assessed the potential impacts of the deregulation of ASR368 creeping bentgrass on the human environment. APHIS sought input from members of the public on issues and alternatives the Agency should consider in preparation of the EIS related to a determination of nonregulated status of ASR368 creeping bentgrass. The resource areas considered in the EIS were developed based upon the relevant concerns and issues identified in the Notice of Intent to prepare an EIS that APHIS published in the *Federal Register* on August 3, 2016 (81 FR 51174). The following resource areas were assessed and evaluated by APHIS in the EIS:

Agricultural Production Considerations:

- Acreage and Range of Creeping Bentgrass
- Agronomic Practices
- Creeping Bentgrass Seed Production

Environmental Considerations:

- Soil Quality
- Water Resources
- Air Quality
- Climate Change
- Animal Communities
- Plant Communities
- Gene Flow and Weediness
- Microorganisms
- Biodiversity

Human Health Considerations:

- Consumer Health
- Worker Safety

Livestock Health Considerations:

- Animal Feed/Livestock Health

Socioeconomic Considerations:

- Domestic Economic Environment
- Trade Economic Environment

Although Scotts and Monsanto have stated that they have no intention to and will not commercialize or further propagate ASR368 creeping bentgrass now or in the future and that they will not grant a license to or otherwise allow other entities to obtain, use, or propagate such plants (Scotts and Monsanto, 2015a; USDA-APHIS, 2015b; 2015a; Scotts, 2016) the Preferred Alternative would not prohibit new plantings of ASR368 creeping bentgrass to occur anywhere in the United States. For this reason, the scope of the EIS included the direct and indirect impacts to the affected environment from a determination of nonregulated status of ASR368 creeping bentgrass in areas where creeping bentgrass is currently known to exist. This includes naturalized populations of creeping bentgrass throughout the United States, commercially produced cultivars of conventional creeping bentgrass in Oregon and Idaho, and cultivated varieties of conventional creeping bentgrass on many, if not most, of the golf courses in the United States.

APHIS considered the FDA regulatory assessments in making its evaluation of the potential impacts of a determination of nonregulated status of ASR368 creeping bentgrass. Scotts and Monsanto submitted a safety and nutritional assessment of food and feed derived from ASR368 creeping bentgrass to the FDA in September 2002. The FDA completed consultation on September 23, 2003 stating in their response that based on the safety and nutritional assessment Monsanto and Scotts have conducted, glyphosate-tolerant creeping bentgrass forage derived from the new variety is not materially different in composition, safety, and other relevant parameters from creeping bentgrass forage currently on the market and that the genetically engineered creeping bentgrass does not raise issues that would require premarket review or approval by FDA with no further questions (US-FDA, 2003a; 2003b).[9]

PUBLIC COMMENTS RECEIVED ON THE FINAL EIS

On December 9, 2016, APHIS published the final EIS for its determination on the petition for nonregulated status of ASR368 creeping bentgrass. The 30-day "review period" required under NEPA[10] closed on January 9, 2017. APHIS received 114 total submissions from the public on the final EIS. One of the submissions supported the deregulation of ASR368 creeping bentgrass and 113 were opposed to the deregulation. These comments did not raise any new substantive issues with regard to the final EIS. As with previous public comments, these submissions expressed general concerns relating to pesticide use, GE plants, or ASR368 creeping bentgrass. Other commenters opposed to the deregulation were concerned about the weediness of ASR368 creeping bentgrass and it being more difficult to control in some areas. Other commenters voiced concerns about possible gene flow between ASR368 creeping bentgrass and wild relatives. A number of commenters were concerned about potential economic impacts, especially impacts to growers and landowners controlling ASR368 creeping bentgrass on their property. Finally, some commenters were concerned that ASR368 creeping bentgrass may have impacts on native plants and threatened and endangered species. However, such concerns and issues were previously assessed and addressed in the text and appendices of the EIS.

APHIS' RECORD OF DECISION ON THE FINAL EIS

[9] The completed FDA consultations for ASR368 creeping bentgrass (BNF No. 79) can be accessed at FDA's website: http://www.accessdata.fda.gov/scripts/fdcc/index.cfm?set=Biocon&id=SMG-36800-2

[10] 40 CFR §1506.10(b)(2)

APHIS is selecting Alternative 2, approving the petition request for a determination of nonregulated status of ASR368 creeping bentgrass. This Record of Decision on the final EIS is based on APHIS' full and complete review and consideration of all of the scientific and environmental data, analyses, information, and conclusions of the PPRA; the final EIS; the public comments on the draft EIS; the agency's response to comments on the draft EIS; and comments on the final EIS.

APHIS is selecting Alternative 2 of the final EIS because:

- Alternative 2 best meets the purpose and need for agency action, which is to make a decision on the petition consistent with our statutory authority and 7 CFR part 340. APHIS must respond to petitioners that request a determination of the regulated status of GE organisms, including GE plants such as ASR368 creeping bentgrass. When a petition for nonregulated status is submitted, APHIS must make a determination if the GE organism is unlikely to pose a plant pest risk. If APHIS concludes, based on its PPRA, that the GE organism is unlikely to pose a plant pest risk, APHIS must then issue a determination of nonregulated status, since the agency does not have statutory authority to regulate GE organisms that are not plant pests in the meaning of the Plant Protection Act.

  According to the PPRA published on September 30, 2016, APHIS concluded that ASR368 creeping bentgrass is unlikely to pose a plant pest risk. APHIS has therefore concluded that the selection of Alternative 2 in this Record of Decision is consistent with the plant pest provisions of the Plant Protection Act of 2000, the regulations codified at 7 CFR part 340, and the biotechnology regulatory policies in the Coordinated Framework.

- APHIS reviewed the conclusions it reached in the final EIS on the environmental consequences of Alternative 2 and, in light of those conclusions, as well as those of the final PPRA, APHIS finds that Alternative 2 best serves the purpose and need for agency action as identified in the final EIS, as well as being in accord with APHIS' regulatory authority under 7 CFR 340. The potential environmental consequences of Alternative 2 are discussed in the next section.

ENVIRONMENTAL CONSEQUENCES ASSOCIATED WITH THE DETERMINATIONS OF NONREGULATED STATUS UNDER ALTERNATIVE 2

The following is a summary of the conclusions APHIS reached on the potential environmental consequences of Alternative 2. Although ASR368 creeping bentgrass could be planted anywhere in the United States under Alternative 2, Scotts and Monsanto have stated in the petition that they have no intention to and will not commercialize or further propagate such plants in the future. Further, Scotts and Monsanto have stated that they will not grant a license to or otherwise allow other entities to obtain, use, or propagate such plants (Scotts and Monsanto, 2015a). Additionally, Scotts has destroyed all commercial ASR368 creeping bentgrass seed stock and withdrew their EPA label amendment application for any glyphosate-based product for use on ASR368 creeping bentgrass (Scotts and Monsanto, 2015b; Scotts, 2016). Scotts has documented in a signed MOA their commitment not to commercialize ASR368 creeping bentgrass and reiterated their companies commitment to the management of ASR368 creeping bentgrass in the three affected counties where it currently exists (USDA-APHIS, 2015a).

The above information informs the proposed action and the analyses of the environmental impacts in the areas affected by the alternatives in the EIS. Should at any time in the future the proposed action change in a manner that raises significant new circumstances or new information relevant to the environmental concerns that may impact the affected environment, APHIS will prepare a supplemental EIS addressing the new circumstances' or new information's impact on the human environment. APHIS will then follow the procedures outlined in CEQ regulations (40 CFR §1502.9).

Agricultural Production Considerations

Acreage and Range

The decision to grant nonregulated status to ASR368 creeping bentgrass is not expected to directly or indirectly cause a measurable change in agricultural acreage or area devoted to creeping bentgrass cultivation in the United States. Since Scotts and Monsanto have stated that they will not commercialize or further propagate ASR368 creeping bentgrass, deregulation of ASR368 creeping bentgrass would not be expected to affect the total acres and range of U.S. conventional creeping bentgrass nor the acreage and range of ASR368 creeping bentgrass currently in the environment.

Agronomic Practices

ASR368 creeping bentgrass is phenotypically and agronomically comparable to conventional commercially cultivated creeping bentgrass with the exception of the glyphosate resistance trait (Scotts and Monsanto, 2015a). As a result, under Alternative 2, agronomic practices such as seed bed preparation, post-harvest residue management, the application of agricultural chemicals, core aeration, and sand topdressing would not change from those currently used for production and management of conventional creeping bentgrass. ASR368 creeping bentgrass would not alter agronomic requirements for cultivation.

Under Alternative 2, herbicide use would be unchanged from the No Action Alternative. Growers and landowners would continue to manage existing ASR368 creeping bentgrass, as necessary, as part of their routine weed management program using the same registered herbicides used under the No Action Alternative.

Physical Environment

ASR368 creeping bentgrass is similar to conventional creeping bentgrass in its agronomic and compositional characteristics (Scotts and Monsanto, 2015a). Growers would be able to continue using established creeping bentgrass production practices. Approving the petition for nonregulated status of ASR368 creeping bentgrass under Alternative 2, would have the same potential impacts to water, soil, air quality, and climate change as that of conventional creeping bentgrass varieties currently available. Agronomic practices that have the potential to impact soil, water and air quality, and climate change such as tillage, agricultural inputs (fertilizers and pesticides), and irrigation would not change because ASR368 creeping bentgrass is similar to conventional creeping bentgrass except for the use of glyphosate and ASR368 will not be commercialized.

Biological Resources

Under Alternative 2, the direct and indirect impacts of approving the petition to animal and plants communities, microorganisms, and biodiversity would be similar to the impacts under the No Action Alternative. With the exception of the glyphosate-resistance trait, ASR368 creeping bentgrass has been shown to be agronomically and compositionally similar to conventional creeping bentgrass varieties currently in cultivation.

Animal communities would not be affected by direct contact or consumption of ASR368 creeping bentgrass. This assessment is based on the lack of toxicity or allergenicity from the CP4 EPSPS protein and due to its nutritional and compositional equivalence to conventional creeping bentgrass varieties. Therefore, ASR368 creeping bentgrass would pose no greater risk to animal communities than conventional bentgrass species. Animals can also be impacted indirectly by agricultural practices. Adopting Alternative 2 will not result in any changes in agricultural practices in comparison to the No Action Alternative. The environmental risks of herbicide use on wildlife and wildlife habitat are assessed by EPA in the pesticide registration process and are regularly reevaluated by EPA for each pesticide to maintain its registered status under FIFRA.

Under Alternative 2, growers and landowners will continue to manage existing ASR368 creeping bentgrass, as necessary, in the same way as under the No Action Alternative. Should growers choose to manage ASR368 creeping bentgrass as a weed, herbicides may be used in accordance with their approved labels, with growers being encouraged to integrate ASR368 creeping bentgrass management into their routine weed management programs, most likely using a combination of registered herbicides and physical and mechanical techniques. Potential impacts to the environment from herbicides are evaluated by the EPA under its FIFRA registration and registration review process.

Choosing Alternative 2 would not change the acreage and range as well as the agronomic practices used in the cultivation of creeping bentgrass, and therefore, would not change the potential impacts to the plant communities, microorganisms, and biodiversity compared to the No Action Alternative.

Gene Flow and Weediness

ASR368 creeping bentgrass is both agronomically and compositionally similar to conventional creeping bentgrass varieties with the exception of the glyphosate-resistance trait. ASR368 creeping bentgrass did not exhibit any changes in reproductive characteristics that would increase likelihood of gene flow, such as fecundity, seed dispersal, increased persistence, pollen viability, or differences in general pollen or flower morphology when compared to its conventional control variety (Scotts and Monsanto, 2015a). Under Alternative 2, there is no evidence of and no reason to believe that the likelihood of gene flow from ASR368 creeping bentgrass would be different than the levels of ASR368 creeping bentgrass gene flow that currently exists. ASR368 creeping bentgrass is no more likely to be a weed compared to conventional creeping bentgrass (USDA-APHIS-PPQ, 2014). There are no differences in the potential for gene flow and weediness between Alternative 2 and the No Action Alternative.

Human Health and Animal Feed

Creeping bentgrass is not consumed directly by humans, but could be used as a forage/feed crop. ASR368 creeping bentgrass has been shown to be compositionally equivalent to conventional creeping bentgrass with the exception of the glyphosate-resistance trait and is not expected to create any adverse human health effects from direct or indirect human contact.

Scotts and Monsanto submitted safety and nutritional assessment of food and feed derived from ASR368 creeping bentgrass to the FDA in September 2002. The FDA evaluated the submission and on September 23, 2003 the consultation was complete with no further questions. No change in food and feed safety is expected to occur under Alternative 2.

Scotts and Monsanto have stated that they have no intention to and will not commercialize ASR368 creeping bentgrass. Therefore, a determination of nonregulated status for ASR368 creeping bentgrass would not be expected to affect human health differently than the No Action Alternative since it would be unlikely for people to be exposed to ASR368 creeping bentgrass other than where it currently exists. Additionally, choosing Alternative 2 would not be expected to affect animal feed differently than the No Action Alternative since it would be unlikely for new plantings of ASR368 creeping bentgrass to occur for use as animal forage.

APHIS has not identified any direct or indirect effects on worker safety that would result from choosing Alternative 2. Under Alternative 2, there would be no change to the agronomic practices used in the production of creeping bentgrass. Potential hazards to workers associated with the various agronomic production practices used to grow creeping bentgrass would be the same as those under the No Action Alternative. The potential human health impacts associated with herbicide use to control ASR368 creeping bentgrass would be unchanged from the No Action Alternative, with growers integrating ASR368 creeping bentgrass management, as necessary, into their routine weed management programs using registered herbicides. The management of existing ASR368 creeping bentgrass would not increase worker exposure to herbicides or any other weed management practice that would create a worker health risk.

Socioeconomics

Under Alternative 2, APHIS concludes that a determination of nonregulated status of ASR368 creeping bentgrass will have no foreseeable adverse impacts on domestic commerce or trade. Scotts and Monsanto have stated that they have no intention to and will not commercialize or further propagate ASR368 creeping bentgrass and they have stated that they will not grant a license to or otherwise allow other entities to obtain, use, or propagate such plants. Scotts and Monsanto have also stated in their petition that they do not intend to make any submissions for approval of ASR368 creeping bentgrass to foreign governments. Therefore, a determination of nonregulated status for ASR368 creeping bentgrass would be expected to have the same impacts on the domestic economic environment as the No Action Alternative since ASR368 creeping bentgrass will not be introduced into commerce.

Under Alternative 2, growers with ASR368 plants needing control will be encouraged to incorporate ASR368 creeping bentgrass management into their current weed management practices, most likely in the form of a tank mix with herbicides currently used or physical or mechanical techniques. To the extent growers choose to manage existing ASR368 creeping

bentgrass, they may experience a marginal incremental cost associated with herbicide use, but that cost would be the same under the No Action Alternative.

Threatened and Endangered Species

Section 7 (a)(2) of the Endangered Species Act (ESA) requires that Federal agencies, in consultation with U.S. Fish & Wildlife Service (USFWS) and/or the National Marine Fisheries Service (NMFS), ensure that any action they authorize, fund, or carry out is "not likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of designated critical habitat." It is the responsibility of the Federal agency taking the action to assess the effects of their action and to consult with the USFWS and NMFS if it is determined that the action "may affect" listed species or designated critical habitat. To facilitate their ESA consultation requirements, APHIS met with the USFWS from 1999 to 2003 to discuss factors relevant to APHIS' regulatory authority and effects analysis for petitions for nonregulated status and developed a process for conducting an effects determination consistent with the Plant Protection Act of 2000 (Title IV of Public Law 106-224). APHIS uses this process to help fulfill its obligations and responsibilities under Section 7 of the ESA for biotechnology regulatory actions.

APHIS met with USFWS officials on June 15, 2011, to discuss and clarify whether APHIS has any obligations under the ESA regarding analyzing the effects on threatened and endangered (T&E) species that may occur from use of pesticide associated with GE crops. As a result of these joint discussions, USFWS and APHIS have agreed that it is not necessary for APHIS to perform an ESA effects analysis on pesticide use associated with GE crops currently planted because the EPA has both regulatory authority over the labeling of pesticides under FIFRA, and the necessary technical expertise to assess pesticide effects on the environment. APHIS has no statutory authority to authorize or regulate the use of pesticides by growers. Under APHIS' Part 340 regulations, APHIS only has the authority to regulate ASR368 creeping bentgrass or any GE organism as long as APHIS believes they may pose a plant pest risk (7 CFR § 340.1). APHIS has no regulatory jurisdiction over any other risks associated with GE organisms including risks resulting from the use of pesticides on those organisms.

APHIS, as described below, evaluated the potential effects that a determination of nonregulated status of ASR368 creeping bentgrass may have, if any, on federally-listed T&E species and species proposed for listing, as well as designated critical habitat and habitat proposed for designation.

For its analysis of potential effects on T&E plants and critical habitat, APHIS focused on the agronomic differences between ASR368 creeping bentgrass and conventional creeping bentgrass varieties currently grown; the potential for increased weediness; and the potential for gene movement to native plants, listed species, and species proposed for listing. For its analysis of potential effects on T&E animal species, APHIS focused on the implications of exposure to the modified 5-enol pyruvylshikimate-3-phosphate synthase (EPSPS) protein expressed in ASR368 creeping bentgrass as a result of the transformation, and the ability of the plants to serve as a host for a T&E species. APHIS' analysis is summarized as follows:

- APHIS has determined that no T&E species will be exposed to ASR368 creeping bentgrass as a result of a determination of nonregulated status. Scotts and Monsanto have stated that they have no intention to and will not commercialize or further propagate ASR368 creeping bentgrass. Further, Scotts and Monsanto have stated that they will not grant a license to or otherwise allow other entities to obtain, use, or propagate such plants (Scotts and Monsanto, 2015a; USDA-APHIS, 2015b; 2015a; Scotts, 2016). Scotts has documented in a signed MOA their commitment not to commercialize ASR368 creeping bentgrass and reiterated their company's commitment to the management of ASR368 creeping bentgrass in the three affected counties where it currently exists (USDA-APHIS, 2015a). In addition, all commercial seed stocks developed for marketing ASR368 creeping bentgrass have been destroyed (Scotts, 2016). Furthermore, the herbicide glyphosate is not labeled for use on ASR368 creeping bentgrass, and the EPA has informed APHIS that all pesticide registration applications for use of glyphosate on ASR368 creeping bentgrass have been withdrawn. Based on these facts, as outlined in the petition and obtained from EPA, APHIS concluded that no exposures will occur to T&E species as a result of a determination of nonregulated status for ASR368 creeping bentgrass.

- APHIS considered the weediness potential of ASR368 creeping bentgrass, and further evaluated for the potential to impact T&E species and critical habitat. No differences were detected between ASR368 creeping bentgrass and conventional creeping bentgrass in growth, reproduction, or interactions with pests and diseases, other than the intended effect of resistance to glyphosate. Based on agronomic field data and a survey of scientific literature on weediness potential, the inserted genes do not alter weediness potential of ASR368 creeping bentgrass, and thus this variety will have no effect on federally-listed T&E species or critical habitat as a troublesome or invasive weed.

- APHIS evaluated the potential of ASR368 creeping bentgrass to cross with a listed species. While there are at least 11 well characterized species of *Agrostis* and 2 species of *Polypogon* in the United States with which it is known that *A. stolonifera* can directly hybridize, after reviewing the list of T&E plant species or plants proposed for listing, APHIS concluded that none of the relatives of creeping bentgrass are federally-listed T&E species or species proposed for listing.

- Compositional analysis of ASR368 creeping bentgrass demonstrated that ASR368 creeping bentgrass is compositionally equivalent to conventional creeping bentgrass with respect to key nutrients and components. Additionally, Scotts and Monsanto submitted a safety and nutritional assessment of food and feed derived from ASR368 creeping bentgrass to the FDA in September 2002. On September 23, 2003 the FDA completed their consultation with no further questions. Consequently, ASR368 creeping bentgrass is not expected to have adverse nutritional effects on any animal that feeds upon it including any federally-listed T&E species and species proposed for listing.

- An assessment of the allergenic potential of the protein supports the conclusion that the CP4 EPSPS protein does not pose an allergenic risk to humans or animals (Scotts and Monsanto, 2015a). The donor organisms for the CP4 EPSPS coding sequence, *Agrobacterium* sp. strain CP4, is ubiquitous in the environment and not commonly

known for human or animal pathogenicity or allergenicity. The CP4 EPSPS protein lacks structural similarity to allergens, toxins or other proteins known to have adverse effects on mammals. The CP4 EPSPS protein is rapidly digested in simulated digestive fluid and demonstrates no oral toxicity in mice at the level tested (Scotts and Monsanto, 2015a). Based on the above information, the consumption of the CP4 EPSPS protein from ASR368 creeping bentgrass or its progeny is considered safe for humans and animals.

- APHIS evaluated whether ASR368 creeping bentgrass could serve as host plants for federally-listed T&E species or species proposed for listing (i.e., a listed insect or other organism that may use the creeping bentgrass plants to complete its lifecycle). A review of the species list indicated there are no federally-listed T&E species or species proposed for listing that use creeping bentgrass or any of its relatives as a host plant to complete its lifecycle.

Based on the analysis, summarized above, APHIS concluded that a determination of nonregulated status of ASR368 creeping bentgrass will have no effect on federally-listed T&E species or species proposed for listing, and would not affect designated habitat or habitat proposed for designation because there is no direct or indirect exposure to listed or proposed species or critical habitat as a result of this determination.

The above analysis is based on the proposed action outlined in the petition for nonregulated status. Should at any time in the future the proposed action change in a manner that raises significant new circumstances or new information relevant to direct or indirect exposure to listed or proposed species or critical habitat (i.e., listed resources), APHIS will prepare a revised effects analysis and supplemental EIS addressing the new circumstances' or new information's impact on listed resources. APHIS will then follow the procedures outlined in the Engendered Species Act for consultation, if appropriate, and CEQ regulations (40 CFR §1502.9).

ENVIRONMENTALLY PREFERRED ALTERNATIVE

The environmentally preferred alternative is not only the alternative that causes the least harm to the biological and physical environment, but also the alternative which best protects, preserves, and enhances historic, cultural, and natural resources. APHIS analyzed the impacts of the two alternatives on the human environment in detail in the final EIS. Because there is no difference in the potential impacts between the Preferred Alternative and the No Action Alternative, APHIS has not identified an Environmentally Preferred Alternative.

ASR368 creeping bentgrass is not agronomically or compositionally different from conventionally cultivated creeping bentgrass. APHIS determined that the deregulation of ASR368 creeping bentgrass would not result in an increase in creeping bentgrass acreage in areas already in creeping bentgrass production or result in changes in where creeping bentgrass is currently grown. In addition, ASR368 creeping bentgrass would not affect natural (e.g., soil, water, air, and climate) or biological (e.g., animal, insect, plant) resources any differently than conventionally cultivated creeping bentgrass currently grown under the No Action Alternative. APHIS determined that no change in food and feed safety is expected to occur under Alternative 2. The direct and indirect impacts on each resource area for Alternative 2 are the same as for the No Action Alternative. Under Alternative 2, ASR368 creeping bentgrass would not have effects

on the human environment different than the No Action Alternative. Because there is no difference in the potential impacts between the alternatives, there is no environmentally preferable alternative.

MITIGATIONS OF IMPACTS ASSOCIATED WITH ALTERNATIVE 2

In an analysis of cumulative impacts, APHIS found that the potential for impacts of ASR368 creeping bentgrass would not result in any changes to the resource areas when compared to the No Action Alternative. No cumulative impacts are expected from approving the petition for nonregulated status for ASR368 creeping bentgrass, when taken in consideration with related activities, including past, present, and reasonably foreseeable future actions.

The Alternatives were analyzed for potential effects to acreage and area of creeping bentgrass production; agronomic practices; the physical environment; biological resources; public health and animal feed; and domestic and trade economic environments. Under Alternative 2, ASR368 creeping bentgrass would not have impacts on the human environment different than the No Action Alternative. Because there is no difference in the potential impacts between the alternatives, no mitigation is required.

REQUEST TO ADD HERBICIDE RESISTANT CREEPING BENTGRASS TO THE APHIS FEDERAL NOXIOUS WEED LISTING

As mentioned above, on September 30, 2016, APHIS published the draft EIS for the petition for determination of nonregulated status for ASR368 creeping bentgrass for public review and comment (81 FR 51174) for a 45-day comment period which closed on November 14, 2016. APHIS received 928 public comments on its draft EIS. One commenter on the draft EIS included a specific request for APHIS to consider their comments simultaneously as a noxious weed petition to APHIS and for APHIS to apply its noxious weed authority to the proposed deregulation of ASR368 creeping bentgrass.

APHIS, in its Response to Comments in Appendix A of the final EIS, addressed the noxious weed petition that was included with the comments on the draft EIS. APHIS explained to the commenter that APHIS regulates plant pests and noxious weeds under separate and distinct regulatory frameworks. A petition for a determination of nonregulated status under 7 CFR part 340 of a GE organism is evaluated pursuant to those regulations; APHIS makes such a determination on the basis of whether the GE organism is likely to pose a plant pest risk. On the other hand, a petition to list a plant as a noxious weed is evaluated under APHIS' 7 CFR part 360 regulations, and pursuant to those regulations, APHIS makes a determination on the basis of whether the plant should be listed on APHIS' noxious weed list. APHIS noted in its response to that comment and in the EIS that APHIS previously assessed the weed risk potentials of glyphosate resistant and non-glyphosate resistant types of creeping bentgrass, using APHIS' weed risk assessment guidelines following a petition from the International Center for Technology Assessment and the Center for Food Safety requesting that the Agency list glyphosate-resistant creeping bentgrass as a Federal noxious weed. The results of the assessment found the two types of creeping bentgrass to be the same in terms of weed risk potential (USDA-APHIS-PPQ, 2014). As a result, APHIS did not add glyphosate-resistant creeping bentgrass nor conventional creeping bentgrass to the Federal list of noxious weeds.

If a new petition to re-evaluate APHIS' assessment to list the plant as a noxious weed under 7 CFR part 360 is received along with new supporting scientific data and in accordance with 7 CFR part 360, APHIS will accept and re-evaluate that plant using the noxious weed regulatory framework set forth in the Federal regulations at 7 CFR 360.500, "Petitions to Add a Taxon to the Noxious Weed List." APHIS will re-evaluate the noxious weed petition based on an analysis of available scientific data, a weed risk assessment, and other available information; and when such evaluation is complete will inform the petitioner and the public of their decision on the noxious weed petition.

COMPLIANCE WITH APPLICABLE LAWS, EXECUTIVE ORDERS, AND REGULATIONS

This Record of Decision has been prepared in accordance with: (1) the National Environmental Policy Act (NEPA), (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500-1508), (3) USDA regulations implementing NEPA (7 CFR part 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

The Record of Decision considered Executive Order (EO) 12898, "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations;" EO 13045, "Protection of Children from Environmental Health Risks and Safety Risks;" EO 13175, "Consultation and Coordination with Indian Tribal Governments;" EO 13112, "Invasive Species;" EO 13186, "Responsibilities of Federal Agencies to Protect Migratory Birds;" and EO 12114, "Environmental Effects Abroad of Major Federal Actions." No disproportionate adverse effects are expected on minorities, low-income populations, or children.

The Record of Decision was determined to be compliant with other Federal Statutes including, the Clean Water Act; the Clean Air Act; the National Historic Preservation Act of 1966 as amended; and the Endangered Species Act.

M. J. Firko

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U.S. Department of Agriculture

6/12/17

Date

References:

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USDA-APHIS-PPQ (2014) "Weed Risk Assessments for nonherbicide resistant and herbicide resistant types of Agrostis stolonifera L." Plant Epidemiology and Risk Analysis Laboratory Center for Plant Health Science and Technology.

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