

Record of Decision

Glyphosate –Tolerant Alfalfa Events J101 and J163: Request for Nonregulated Status

Overview

The United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS) has completed and published a Final Environmental Impact Statement (FEIS) in response to a petition for nonregulated status of glyphosate tolerant alfalfa events J101 and J163 (GT alfalfa) and is announcing the agency's decision for this request in this record of decision (ROD). APHIS is announcing its decision to grant nonregulated status to alfalfa events J101 and J163 and progeny derived from these events. APHIS is choosing Alternative 2 as described in the FEIS. Nonregulated status will be granted to GT alfalfa upon publication in the Federal Register a document entitled "Determination of Nonregulated Status for Monsanto and Forage Genetics International RoundupReady® Alfalfa Events J101 and J163."

APHIS prepared an FEIS to examine the potential environmental impacts of GT alfalfa and interrelated socioeconomic impacts associated with granting the petition for nonregulated status. In the FEIS, APHIS examined three alternatives: deny the petition (No Action Alternative), grant the petition in full (Deregulation Alternative), and grant the petition in part (Isolation/Geographic Restrictions Alternative). The two action alternatives were identified as co-preferred alternatives.

Background

Coordinated framework

APHIS is one of the Federal agencies with regulatory responsibilities under the 1986 Federal Coordinated Framework for the Regulation of Biotechnology (hereafter Coordinated Framework) published by the Office of Science and Technology Policy (OSTP), Executive Office of the President. The Coordinated Framework is a policy statement which "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 several relevant statutes and among the several relevant federal agencies.

The Coordinated Framework thus addressed who shall have oversight authority in each instance, but did not address how that authority should be exercised in the frequent situations in which a statute leaves the implementing agency latitude for discretion. To that end, OSTP 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.”

APHIS regulation of biotechnology

In 1987, APHIS promulgated its biotechnology regulations (7 CFR Part 340) under the authority of the Federal Plant Pest Act (FPPA) and the Plant Quarantine Act (PQA)¹ to address potential risks that certain genetically engineered (GE) organisms might pose as plant pests. The regulations refer to such GE organisms as “regulated articles.”²

The APHIS regulations codified at 7 CFR part 340 were amended in 1993 to provide a procedure for the release from regulation of such plants which do not present a plant pest risk and therefore should no longer be regulated. 7 CFR 340.6 describes the petition process, the data requirements, and actions that the Administrator may take on the petition. It is under this procedure that APHIS received the petition to grant nonregulated status to alfalfa events J101 and J163.

¹ The FPPA and PQA 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 PPA 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).

² 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 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 CFR 340.0).

On April 16, 2004, APHIS received a petition from Monsanto Company and Forage Genetics International (Monsanto and FGI), requesting a determination of nonregulated status under 7 CFR part 340 for two alfalfa events designated as J101 and J163, which have been genetically engineered for resistance to the herbicide glyphosate.

APHIS assessed the plant pest risks posed by the use of GT alfalfa events J101 and J163 and prepared an Environmental Assessment (EA). The EA was prepared to identify and evaluate any environmental impacts that could result from the approval of the petition. In a notice published in the *Federal Register (FR)* on June 27, 2005 (70 FR 36917–36919, Docket No. 04-085-3), APHIS advised the public of its determination, effective June 14, 2005, that the Monsanto and FGI GT alfalfa events J101 and J163 did not pose a plant pest risk and were therefore no longer considered regulated articles under 7 CFR part 340.

Approximately 9 months later, a group of organic alfalfa growers and several other associations filed a lawsuit in the United States District Court for the Northern District of California that challenged APHIS' decision to grant nonregulated status to GT alfalfa events J101 and J163. On February 13, 2007, the Court issued an opinion finding that the APHIS EA failed to consider certain environmental and interrelated economic impacts adequately, as required by the National Environmental Policy Act (NEPA). The Court, however, did not question the validity of APHIS' Plant Pest Risk Assessment, which concluded that the alfalfa events J101 and J163 did not pose a plant pest risk. The Court also accepted APHIS' determination that the GT alfalfa did not have any harmful health effects on humans or livestock. The Court vacated APHIS' decision to grant nonregulated status to GT alfalfa events J101 and J163 based on its finding that the EA was inadequate and ordered APHIS to prepare an Environmental Impact Statement (EIS) before deciding whether to grant nonregulated status to GT alfalfa events J101 and J163.

With respect to the NEPA violations, the Court found that the EA failed to adequately analyze the possibility of gene transmission from GT alfalfa and conventional and organic alfalfa, which could occur through cross pollination or by seed admixture. The Court found that if this occurred, it would have significant negative economic and socioeconomic effects on organic farmers. The Court also found that the deregulation of GT alfalfa could contribute to the development of glyphosate resistant weeds and that APHIS failed to consider the cumulative impacts of deregulating numerous glyphosate resistant crops on weed resistance. Finally, the Court found that APHIS did not adequately analyze whether the deregulation of GT alfalfa would result in increased use of glyphosate.

The Court's order provided that as of March 12, 2007, all GT alfalfa sales were halted, and as of March 30, 2007, any further planting of GT alfalfa was prohibited. On March 23, 2007, APHIS published a notice in the *Federal Register* (72 FR 13735-13736 APHIS Docket No. 04-085-1) announcing the Court's decision that Monsanto and FGI GT alfalfa events J101 and J163 were once again regulated articles under 7 CFR part 340.

The Court decided that growers who had already planted GT alfalfa during the two years that the product had been deregulated would not have to remove the plants. Those plants were permitted to be harvested, used and sold. In the two growing seasons that GT alfalfa was on the market (2005 and 2006), approximately 200,000 total acres were planted in 1,552 counties in 48 states (no plantings occurred in Alaska and Hawaii). These GT alfalfa fields were permitted to be

harvested, but the fields were subject to court-ordered stewardship practices to minimize the potential that GT alfalfa will be present in harvests of non-GT alfalfa.

APHIS prepared an EIS in compliance with the order by the Court that vacated the determination of nonregulated status of J101 and J163 alfalfa. In December 2009, APHIS released the draft EIS (DEIS) for public comment. The DEIS was available for an extended 75-day comment period, which closed on March 3, 2010. APHIS also held four public meetings across the United States during the comment period. Approximately 133 people attended these public meetings. Approximately 244,000 comments were received. All comments and recommended study reports were considered by APHIS and revisions of the final EIS (FEIS) were made by the agency as appropriate.

On December 23, 2010, the EPA published a notice announcing the availability of the FEIS to the public. Prior to publication of this notice in the FR, APHIS had distributed the FEIS and also posted it on its website.³

USDA hosted a meeting on December 20, 2010, with representatives from a wide array of stakeholders, including representatives from the plaintiffs in the alfalfa litigation. The meeting brought together this diverse group of stakeholders for a dialogue, to explore practical, reasonable approaches that would support coexistence among the various forms of alfalfa production. More than fifty persons participated in the meeting, including representatives of industry and grower groups, technology developers, and various non-governmental organizations. A full transcript of the meeting is available on APHIS' website.⁴

Purpose and Need for Agency Action

In the FEIS, APHIS identified a purpose and need to review the petition for nonregulated status in accordance with its authority under the current regulatory scheme. "APHIS is required by 7 CFR § 340.6 to make a determination on petitions submitted to the agency under this part. The agency may grant the petition in whole or in part, or it may deny the petition. The determination is based on the data required in 7 CFR 340.6(c), which are provided by the applicant and supported by the best available science. The purpose of this action is to determine if the use of GT alfalfa in the U.S. agricultural environment presents a greater plant pest risk than varieties on non-GE, commercially available alfalfa." (FEIS p.9). In summary, the agency's need is to make a decision on the petition that is consistent with the regulatory requirements in 7 CFR part 340.

APHIS also indicated that, "the USDA values and promotes coexistence of many different agricultural production practices. These practices include the use of GE organisms and non-GE organisms in conventional agricultural management systems and the use of non-GE organisms in organic production systems. The Department's purpose and need is to promote programs that support coexistence of all types of agricultural practices. The analysis in this EIS will help to inform USDA on the interaction of GT alfalfa and coexistence programs." (FEIS p.9).

³ The FEIS can be viewed at http://www.aphis.usda.gov/biotechnology/downloads/alfalfa/gt_alfalfa%20_feis.pdf

⁴ A transcript of the meeting can be found at http://www.aphis.usda.gov/newsroom/content/2010/12/printable/alfalfa_meeting_12_20_10_transcript.pdf

Public comment on the FEIS

APHIS received over 16,000 comments on the FEIS between December 16 and January 24, 2011. None of these comments presented information that would require preparation of a supplement to the FEIS. None of the comments provide new information beyond what was already received during the comment period on the draft EIS and analyzed in the FEIS. The majority of the comments were form letters that expressed support for alternative 1, the no action alternative. Many of these comments were generally against GE products. Others expressed their opinion that GT alfalfa was not necessary because the commenter did not need it to manage his own alfalfa. There were also comments from beekeepers that supported alternative 1 because they were concerned that the types of management practices used for GT alfalfa could affect their bees.

APHIS also received comments from trade organizations and growers that supported Alternative 2. Many of these commenters believe that APHIS lacks the authority to implement Alternative 3. Many also believe that Alternative 3 restricts grower choice. Many of these commenters also believe that adopting Alternative 2 is consistent with past deregulation decisions.

Another group of growers and trade organizations supported Alternative 3, or requested a delay in the decision until measures to address the economic issues related to low-level presence of the GE trait in non GE alfalfa were in place. These growers believe that the adoption of Alternative 2 will preclude them from producing alfalfa for their markets under their current production practices. Many of these growers market their alfalfa to GE sensitive markets.

The Environmental Protection Agency (EPA) submitted comments on the FEIS in accordance with their responsibilities under Section 309 of the Clean Air Act and Section 102(2) (e) of the National Environmental Policy Act (NEPA), APHIS has reviewed these comments and has taken them into consideration before making a decision on the FEIS.

Decision

Based on APHIS' Plant Pest Risk Assessment, the analysis in the EIS, and public comments on the DEIS and FEIS, APHIS is selecting Alternative 2 and granting nonregulated status to alfalfa events J101 and J163. These events have been genetically engineered to resist the over the top application of glyphosate, a broad spectrum herbicide.

APHIS is selecting Alternative 2 because:

- Alternative 2 best meets the purpose and need for agency action. As stated in the FEIS, "The purpose of this action is to determine if the use of GT alfalfa in the U.S. agricultural environment presents a greater plant pest risk than varieties of non-GE, commercially available alfalfa. The agency's need is to make a decision on the petition that is consistent with the regulatory requirements in 7 CFR part 340." We have determined that alfalfa events J101 and J163 do not pose a greater plant pest risk than other conventional alfalfa varieties. In fact, there is no evidence of plant pest risk associated with these two alfalfa

events. The selection of Alternative 2 is consistent with the plant pest provisions of the PPA, the regulations codified at 7 CFR part 340, and the biotechnology regulatory policies in the Coordinated Framework.

- The FEIS informed USDA on the interaction of GT alfalfa and coexistence programs. As noted above, USDA hosted a meeting on December 20, 2010, with representatives from a wide array of stakeholders, including representatives from the plaintiffs in the alfalfa litigation. The meeting brought together this diverse group of stakeholders for a dialogue, to explore practical, reasonable approaches that would support coexistence among the various forms of alfalfa production. The preparation of the FEIS, the stakeholder discussion that followed, and the comments received on the FEIS have clarified for USDA the broad range of coexistence issues and stakeholder needs, and highlighted the complexities and difficulties of finding solutions that meet the needs of all stakeholders involved.
- In view of the regulatory requirements in the PPA, the complexity and broad scope of issues involved in fostering coexistence, and considering the positive steps already taken by industry groups to promote best management practices and stewardship measures⁵, APHIS believes Alternative 2 best meets the overall purpose and need for agency action identified in the FEIS.

Plant Pest Risk Assessment

The Plant Pest Risk Assessment characterizes the potential plant pest risks associated with the subject of the petition relative to conventional varieties. It is based on information supplied in the petition for determination of nonregulated status together with other relevant scientific data. The regulations codified at 7CFR 340.6 (c) list the information to be submitted for APHIS' consideration of a petition for nonregulated status.

APHIS is selecting Alternative 2 because alfalfa events J101 and J163 do not present a greater plant pest risk than other conventional alfalfa varieties. In fact, APHIS has not found any direct or indirect plant pest risks associated with J101 and J163. APHIS concluded in its Plant Pest Risk Assessment (PPRA) that alfalfa Events J101 and J163 are not likely to pose a plant pest risk and should be granted nonregulated status for the following reasons:

- (1) They exhibit no plant pathogenic properties – although a plant pathogen was used in their development, these plants are not infected by this organism nor do they contain genetic material from pathogens used as a donor organism that can cause plant disease.
- (2) They exhibit no characteristics that would cause them to be weedier than the non-transgenic parent alfalfa or other cultivated alfalfa and several control options besides glyphosate are available for control of feral or volunteer plants or for stand take-out.
- (3) Gene introgression from J101 and J163 to native, introduced, or naturalized species of *Medicago* in the United States is extremely unlikely and even if it were to occur, is not likely to increase the weediness potential of any resulting progeny any more than would introgression from other cultivated alfalfa.

⁵ <http://www.alfalfa.org/CSCoexistenceDocs.html>

(4) Disease and insect susceptibility and compositional profiles (other than the intended CP4 EPSPS protein conferring glyphosate tolerance) of J101 and J163 are similar to those of the parent variety and other alfalfa cultivars grown in the United States, therefore pest and disease control methods are expected to be similar and no direct or indirect plant pest effect on raw or processed plant commodity is expected.

(5) Field observations, compositional data including components related to nitrogen fixation and nodulation, and data on the safety of the engineered EPSPS protein all indicate that J101 and J163 should not have a greater potential than other cultivated alfalfa to damage or harm organisms beneficial to agriculture.

(6) Horizontal gene transfer from these alfalfa events to organisms with which they cannot interbreed is highly unlikely to occur, and is not expected to pose a plant pest risk. In addition to considering the potential plant pest risks posed by J101 and J163, APHIS prepared an EIS to examine the impacts on the human environment of granting nonregulated status to these alfalfa events. APHIS has identified and evaluated impacts in the FEIS associated with the decision to grant nonregulated status. A summary of the analysis contained in the FEIS is set forth below in the section entitled "Environmental Consequences Associated with Granting Nonregulated Status."

Alternatives considered in the FEIS

Alternative 1: No Action Alternative

Under the No Action Alternative, APHIS would deny the petition to grant nonregulated status to glyphosate-tolerant (GT) alfalfa events J101 and J163. The events would continue to be subject to the regulation pursuant to 7 CFR part 340. Permits or notifications would continue to be required to introduce viable GT alfalfa plant material⁶. Permit conditions would be specified by APHIS. These conditions would be designed to confine GT alfalfa. The size of planting would be limited to help maintain confinement. In addition, the number of permits granted would be limited by agency resources, both in terms of the number of permits which could be reviewed by APHIS, and in APHIS' ability to inspect the fields and enforce compliance with regulations. Therefore, the number of acres planted and the amount of seed and hay transported between states would likely be far less than the current commercial production of conventionally-bred alfalfa for seed and hay in the U.S. In time it is expected that the number of acres of GT alfalfa would decrease because the alfalfa that was planted while GT alfalfa had nonregulated status would be replaced by conventional varieties.

Alternative 2: Grant the petition for nonregulated status

Under Alternative 2, GT alfalfa would be granted nonregulated status and would no longer be subject to regulation pursuant to 7 CFR part 340. Permits or notifications issued by APHIS would no longer be required for introductions of GT alfalfa derived from these events. Under this alternative, growers could freely move and plant GT alfalfa seed without further oversight from APHIS. Although APHIS would no longer have any regulatory control over the planting, distribution, or other actions related to GT alfalfa, Monsanto's technology use agreement

⁶ The term "Introduce" is defined in 7CFR 340.1 as: To move into or through the United States, to release into the environment, to move interstate, or any attempt thereat.

imposes contract restrictions on growers.⁷ These nonregulatory restrictions include managing hay to prevent seed production, harvesting at or before ten percent bloom in areas where seed is produced, and prohibitions on use in wildlife feed plots. Similarly, Forage Genetics International (FGI) requires contracted growers who raise alfalfa seed to follow FGI Best Practices. These management practices include pollinator management, specific isolation distances, stand termination documentation, and product segregation⁸. The developer, Forage Genetics International, predicts that approximately 50 percent of the alfalfa acres may eventually be planted with GT alfalfa. The majority of these acres are predicted to be located in the western U.S. Glyphosate is not labeled for use on seed in all states. Therefore, GT alfalfa seed production will likely only occur in the states where glyphosate can be used in its production.

Alternative 3: Grant the petition for nonregulated status in part

Alternative 3 describes a combination of isolation distances and geographic restrictions on hay and seed production to address and resolve concerns about risks of cross pollination and other potential impacts to organic and other non GE alfalfa producers while allowing the commercialization of GT alfalfa. This third alternative would impose management practices on the planting, harvesting, use or sale of GT alfalfa seed and in some locations hay. This alternative could be implemented by an APHIS decision to approve the petition in part, or through a Federal/industry partnership arrangement. Under this alternative, the developer (marketer) of GT alfalfa would ensure that end users are using the required management practices. They might choose to do this through contracts or licenses, or by other means. A training component would also be part of the program to educate producers about the required stewardship practices. Reporting requirements for the developer (marketer) subject to verification would be used to ensure compliance with the terms of the program. Under this alternative, failure to comply with the requirements could result in penalties to the developer (marketer). The required management practices would undergo periodic reviews to determine if modifications were warranted. Changes to the management practices would be approved based on available data on their effectiveness in addressing concerns about risks of cross pollination and other potential impacts to organic and other non GE alfalfa producers.

A description of the specific management practices can be found in the FEIS (section 2.b.3).

Environmental Consequences Associated with Granting Nonregulated Status

The following is a summary of the conclusions APHIS has reached on the environmental consequences of Alternative 2 granting the petition for nonregulated status for GT alfalfa events J101 and J163.

Gene flow in Alfalfa

- Movement of genes between alfalfa plants depends on weather, timing of flowering, availability of pollinators, successful pollination, distance between plants, and time needed for seed maturity.
- Alfalfa does not naturally hybridize with any wild relatives in North America.

⁷ <http://www.monsanto.com/SiteCollectionDocuments/Technology-Use-Guide.pdf>

⁸ <http://www.foragegenetics.com/pdf/ValidationFGIBestPractices.pdf>

- Gene flow could occur via transfer of pollen, most commonly by insect pollinators, or by dispersal or accidental mixing of seeds. GT alfalfa genes therefore may occur in non GT alfalfa.
- We note that the National Alfalfa and Forage Alliance (NAFA) has developed best management practices that are designed to limit the presence of the GE trait to below 0.5% in conventional alfalfa seed lots.
- The Association of Seed Certifying Agencies has developed a management practice standard, ASSP-2010, intended to limit the presence of the GE trait to levels that are not detectable by standard industry tests.

Herbicide Use

- Glyphosate use in the United States would increase under deregulation due primarily to the greater use of glyphosate for establishing and maintaining GT alfalfa stands compared to conventional alfalfa stands. The magnitude of this increase depends on a number of factors, including the fraction of conventional alfalfa acreage that would be replaced by GT alfalfa, the co-use (tank mixing) of glyphosate with other herbicides for GT alfalfa establishment and maintenance, and the stand life.
- Other (non-glyphosate) herbicides used for establishing and maintaining GT alfalfa stands could either increase or decrease, depending on the same factors as above. Glyphosate is currently used on conventional alfalfa to “take out” (remove) an alfalfa field. Thus, although glyphosate use overall for alfalfa would increase, its use to take out conventional alfalfa stands would decrease as GT alfalfa replaces conventional alfalfa (glyphosate cannot be used for removal of GT alfalfa stands).
- Glyphosate is less environmentally adverse than other herbicides because it has a lower environmental impact quotient compared to other herbicides currently used in alfalfa production. The net effect on alfalfa production with the increased adoption and planting of GT alfalfa will likely be some increased use of glyphosate with a decreased, an unchanged, or an increased use of other herbicides.
- Threatened and Endangered (T&E) animal species are not at risk. Terrestrial and semi-aquatic T&E plants might be at some risk of direct effects from exposure to glyphosate used in agriculture, if they are found near alfalfa fields. All plants are at some risk of direct effects from exposure to herbicides currently used in alfalfa production.

Weeds in Alfalfa

- Deregulation of GT alfalfa would encourage the use of glyphosate, as that would be the most effective way of achieving weed-free alfalfa stands. The Deregulation Alternative when combined with other past, present, and reasonably foreseeable actions, could result in cumulative impacts because it could contribute to an increase in the total number of glyphosate-resistant weeds.
- Evolution of glyphosate-resistant weeds may occur in GT alfalfa stands. However, because alfalfa is a perennial crop that is regularly mowed, glyphosate use in GT alfalfa is relatively low when compared to annual GT crops, and that once alfalfa is established

it acts as a suppressor of weeds, it may contribute less to the development of glyphosate resistant weeds than other GT row crops. If GT alfalfa is widely adopted in areas where alfalfa is a major crop, the potential that alfalfa acreage would overlap with glyphosate-resistant weed locations increases, and such weeds could arise in GT alfalfa fields. Thus, it is more likely that weeds that are already tolerant or resistant to glyphosate will occur in GT alfalfa fields than that novel glyphosate resistant biotypes will emerge.

- Management regimes that incorporate only glyphosate are more likely to result in selection of glyphosate resistant weeds than management practices that incorporate additional herbicides or other cultural methods.
- BMPs can help control the development of glyphosate-resistant weeds. BMPs include:
 - a) identifying weeds and monitoring for escapes to determine if current practices need to be modified to achieve acceptable levels of weed control
 - b) using proper herbicide rates and timing
 - c) using crop rotation to facilitate use of different modes of action over time
 - d) using agronomic management practices to supplement herbicide weed control;
 - e) alternating herbicides with different modes of action
 - f) tank mixing herbicides of different modes of action

Additional potential Impacts of GT Alfalfa

The GT alfalfa gene product is not expected to adversely affect plants and animals, including threatened and endangered (T&E) species.

- Several agronomic traits were evaluated and no biological differences between GT and non-GT alfalfa were noted for traits that could influence weediness, including seed dormancy, seed germination, seedling emergence, seedling vigor, winter survival, spring vigor, seed yield, vegetative growth, plant dormancy, survival, and relationship with symbiotic organisms. Therefore GT alfalfa is not expected to become more invasive in natural environments or have any different effect on critical habitat than their parental non-GT event. In addition, the nutritional profiles of GT alfalfa and non-GT alfalfa are not different (within normal cultivar variations); therefore animal nutrition is not expected to be different. There are also no palatability differences.
- Analysis of forage samples from several locations demonstrated that GT alfalfa is compositionally and nutritionally equivalent to other alfalfa varieties currently on the market except for the expression of the transgene protein, and therefore is not expected to have nutritional effects on any animals that feed upon it.
- GT alfalfa is not expected to be toxic or allergenic to plants or animals. The 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) protein from plants and from the CP4 *Agrobacterium* strain is not known to have pathogenic or toxic effects on humans, animals, or plants based on numerous laboratory and field studies with these purified proteins or plants expressing these proteins.
- Hybrids between alfalfa and other *Medicago* species in the United States are limited to hybridization between *M. sativa* subspecies. Evidence of any sexually compatible, free-living, or native relatives of *Medicago* species in the United States or North America is nonexistent. Hence, the genetic resources of these plant species will not be affected by

the release of GT alfalfa in the United States. Possible movement of the transgene via pollen from GT alfalfa to other species of *Medicago* would not occur in the United States, or it would only occur following the introduction and establishment of a reproductively compatible, non-native species growing near GT alfalfa.

- APHIS reached a no effect determination and therefore concluded that the GT alfalfa gene product would have no effect on federally listed T&E species or species proposed for listing, and has concluded it will have no effect on designated critical habitat or habitat proposed for designation, compared to current agricultural practices. As we discussed in the EIS: APHIS has determined that GT alfalfa would not be sexually compatible with any listed TES plant or plant proposed for listing. Based on the composition and nutritional quality of GT alfalfa, APHIS concluded it would not be toxic to TES animals that consume GT alfalfa. Based on toxicity studies of the EPSPS protein and laboratory exposure studies with representative pollinators, soil organisms, beneficial arthropods, and pest species exposed to tissues from GE crops that contain the CP4 EPSPS protein, a lack of toxicity was observed. Other studies concluded that its potential to be a food allergen is minimal. As these studies revealed that GT alfalfa is unlikely to pose a hazard, the risk of GT alfalfa harming TES animal species is unlikely. APHIS considered whether the new phenotype would expand the range of alfalfa and concluded it would not because alfalfa is not weedy, GT alfalfa is not weedier than conventional alfalfa, and the agronomic properties of GT alfalfa are not statistically different from currently available alfalfa varieties. Thus it would not be planted in new lands not already used for agricultural production. APHIS has not identified any stressor that could affect the reproduction, numbers, or distribution of a listed TES or species proposed for listing. APHIS has considered the effect of GT alfalfa production on designated critical habitat or habitat proposed for designation and could identify no difference from effects that would occur from the production of other alfalfa varieties.

Increased glyphosate use, due to the adoption of GT alfalfa, could affect non-target plants, but is not expected to adversely affect animals.

- Because of the high toxicity of glyphosate to plants, adoption of GT alfalfa could adversely affect individual plants near GT alfalfa fields if they are exposed to glyphosate. Glyphosate exposure could occur through aerial drift, runoff of surface waters containing glyphosate, or leaching of glyphosate into drainage systems. Plants exposed to glyphosate via aerial drift might experience impaired germination or growth characteristics. To mitigate potential adverse effects due to glyphosate drift, the U.S. Environmental Protection Agency (EPA) has imposed specific label use restrictions for glyphosate use when applied with aerial equipment, including “the product should only be applied when the potential for drift to adjacent sensitive areas (e.g., residential areas, bodies of water, known habitat for threatened or endangered species, non-target crops) is minimal (e.g., when wind is blowing away from the sensitive areas).” The potential for glyphosate transport from terrestrial to aquatic environments is limited and glyphosate is not expected to reach groundwater due to sorption and degradation in the soil.
- Glyphosate has low toxicity to mammals, birds, and fish, but is slightly toxic to amphibians. However, amphibians exhibited greater sensitivity to Roundup[®] formulations than to glyphosate tested as an acid or isopropylamine (IPA) salt, likely due

to the surfactant, polyethoxylated tallowamine (POEA), which has been used for a long time in agricultural formulations. POEA has been found to be more toxic to amphibians and other aquatic animals than the herbicide itself. Adoption of GT alfalfa, however, is unlikely to adversely affect amphibians, if glyphosate formulations without POEA are used near water. EPA labeled a glyphosate product (EPA Reg No. 71368-25) for aquatic use after publication of the FEIS. This product is not currently labeled for use on GT alfalfa.

- APHIS does not regulate herbicide use associated with GT plants that are granted nonregulated status. The use of glyphosate is regulated under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Under FIFRA, EPA registers pesticides and prescribes the conditions for use of the pesticide. Applying pesticides in a way that is inconsistent with the label is illegal. On the label, EPA includes instructions on how glyphosate herbicides should be applied. Directions include application restrictions that minimize impacts on nearby environments. EPA has determined that there is no unreasonable environmental risk if the user adheres to the labeled directions. EPA's pesticide registration process considers the potential for risk to non-target organisms, and label use restrictions are required when necessary to avoid unreasonable adverse effects to the environment. Through registration review, EPA is reviewing each registered pesticide every 15 years to determine whether it still meets the FIFRA standard for registration. In this way, EPA is ensuring that all registered pesticides do not cause unreasonable risks to human health, workers, or the environment when used as directed on product labeling. EPA intends to meet its responsibility under the Endangered Species Act in the registration review program. Glyphosate is scheduled to complete registration review in 2015, at which time EPA will complete its national endangered species assessment of all registered uses of the herbicide.

Socioeconomic Impacts

- There is evidence that GT alfalfa can offer alfalfa hay farmers high quality alfalfa hay at relatively lower costs.
- To the extent that GT alfalfa is adopted by alfalfa hay farmers, the overall supply curve for high quality alfalfa could shift, increasing the quantity of high quality alfalfa hay and decreasing its price.
- There is evidence that some U.S. consumers prefer nonGE foods in the United States over products containing GE components. This preference is likely more prevalent among consumers of organic products. However, the extent to which this preference translates to decreased demand (sales) for conventional and organic products if there were low-level GE presence in feed used for dairy and meat cattle in the production chain of organic foods is unclear. The impact of GT alfalfa deregulation on domestic demand might best be analyzed by analogizing it to a small GT-sensitive market within the domestic conventional and organic alfalfa markets.
- Producers of organic and non GE alfalfa may incur costs to create additional buffer zones or to implement testing protocols. Some of these producers are concerned that it will not be possible to produce alfalfa seed with non-detectable levels of the GE trait in areas where GT alfalfa is also grown.

- Among U.S. main export markets for alfalfa hay and seed, there is evidence of some sensitivity to GE alfalfa products. The GT alfalfa sensitive segment is likely to be only a portion of the existing export market.
- The extent to which GE sensitive domestic and foreign alfalfa markets are affected by GT alfalfa deregulation depends on the extent to which gene flow can be controlled through stewardship programs. These programs may increase the costs of seed production for sensitive markets. To the extent that they do, the impact on overall demand is likely to be low, given the low sensitivity of the demand for alfalfa seeds to changes in its price.

Human Health and Safety

- GT alfalfa has no adverse effects on human health and worker safety.
- Overall risk of glyphosate and other herbicide use on human health and worker safety does not change with the adoption of GT alfalfa. EPA has determined that use of herbicides in accordance with the labeling of currently registered pesticide products containing glyphosate has a reasonable certainty of no harm to humans and no unreasonable adverse effects to the environment.

Land Use and Physical Environment

- Overall, land devoted to alfalfa cultivation would be affected largely by the price of alfalfa hay and not by the availability of GT technology.
- GT alfalfa is not expected to have an adverse impact on soils, climate or air quality, or water and water use.

Decision not to choose Alternative 3

APHIS identified Alternative 3, the Isolation/Geographic restrictions alternative, as a co-preferred alternative in the FEIS. This alternative was developed in the FEIS based on public comments received in response to the DEIS. Alternative 3 is described briefly in the section of the FEIS entitled "Alternatives considered in the EIS."

APHIS considered the impacts to the human environment associated with Alternative 3. We concluded that the comparative impacts of Alternative 2 and Alternative 3 on biological resources, the physical environment, and human health are similar. If Alternative 3 were to result in fewer acres planted with GT alfalfa, the associated impacts of increased glyphosate use would not be realized in the areas where GT alfalfa was not adopted. However, it is not at all certain that fewer acres of GT alfalfa would in fact be planted under Alternative 3. If Alternative 3 were selected, there could be a shift in acres planted with GT alfalfa forage to counties where it would be allowed to be planted. Ultimately, under both Alternatives 2 and 3, the amount of GT alfalfa planted would be determined by the market for the hay.

Under Alternative 3 the socioeconomic impacts of the use of GT alfalfa are different than under Alternative 2. Under Alternative 2, alfalfa growers who cater to GE sensitive markets might incur additional costs to produce their product. These additional costs may come in the form of

additional testing for the GE trait or changes in management practices to avoid low level presence of GT alfalfa in their product. Some alfalfa seed producers may lose market share to alfalfa seed produced outside the US, where GT alfalfa is not grown. Under Alternative 3 these costs either would not be incurred or would be reduced compared to Alternative 2 because the seed supplies would be geographically isolated. Under Alternative 3, growers in restricted areas (certain counties in Tier III) who might have otherwise chosen to use GT alfalfa to produce their forage crop would not be allowed to plant GT alfalfa. APHIS estimates that approximately 3 percent of the nation's hay production falls into this category. That is, APHIS estimates that the land which produces approximately 23% of the hay in the US could not be used under Alternative 3 to grow GT alfalfa.

The FEIS includes a market projection that about 75% of the likely adopters of GT alfalfa will be in Tier III states. This is presumably because herbicide use for growing alfalfa is used more frequently in Tier III states than other regions. Alternative III would remove the choice for growing GT alfalfa for the substantial number of farmers who are most likely to choose to use this technology. To the extent that GT alfalfa hay allows for the production of high quality hay at a lower price, these growers may lose profits.

APHIS has decided not to select Alternative 3 because:

- GT alfalfa does not exhibit a greater plant pest risk in the geographically restricted areas described in Alternative 3. As described above, APHIS has not identified any plant pest risks associated with J101 and J163. In light of these findings and after further consideration of Alternative 3, we have determined that the restrictions in Alternative 3 are not consistent with APHIS' regulatory authorities or the biotechnology regulatory policies embodied in the Coordinated Framework. Therefore Alternative 3 does not meet the agency's purpose and need to act on the petition in accordance with its regulatory authorities.
- The impacts on biological resources, the physical environment, and human health are similar to Alternative 2.
- It is uncertain whether the economic benefits associated with Alternative 3 offset the losses associated with Alternative 3. There was limited data available to quantify the economic effects of adventitious presence of GT alfalfa in conventional or organic alfalfa. APHIS analyzed some scenarios comparing the costs of GT alfalfa production with the costs of conventional alfalfa production. APHIS has described these analyses in the FEIS. However, the scenarios described in the FEIS were based on limited data and predicted changes in specific production practices.
- Other non-regulatory options are available to manage low level presence of GE traits. These mechanisms can be effective and can help promote coexistence. These methods include industry led best management practices, USDA process verification certification, or private testing and verification programs.

Environmentally Preferred Alternative

The environmentally preferred alternative is that alternative that causes the least harm to the biological and physical environment. APHIS has analyzed the impacts of three alternatives on the biological and physical environment. APHIS has concluded that the GT alfalfa plants will

not have a different impact of the physical and biological environment than conventional alfalfa plants. However, using GT alfalfa under recommended management strategies will likely result in an increase in glyphosate use on alfalfa. This could be accompanied by either an increase or a decrease in other herbicide use. Increased use of glyphosate could increase the likelihood of exposure of nearby plants to glyphosate. As described in the FEIS, this exposure could lead to increased mortality of nontarget plants in the vicinity of GT alfalfa fields. Under FIFRA, EPA registers pesticides and prescribes the conditions for use of the pesticide. Applying pesticides in a way that is inconsistent with the label is illegal. On the label, EPA includes instructions on how glyphosate herbicides should be applied. Directions include application restrictions that minimize impacts on nearby environments. EPA has determined that there is no unreasonable environmental risk if the user adheres to the labeled directions.

APHIS has identified the no action alternative as the environmentally preferred alternative. Under the no action alternative, the increase in glyphosate use associated with the use of GT alfalfa would not occur. As analyzed in the FEIS, the majority of alfalfa hay acres (83%) are not treated with herbicides so the adoption of GT alfalfa beyond 17% of the acres where herbicide is used would result in an increased use of glyphosate that would not result in a decrease in other herbicide use on the untreated acres. On alfalfa acres that are intensively managed with herbicides, a decrease in other herbicide use may occur, but that decrease could be negated if weed shifts to glyphosate resistant or tolerant weeds occur. Therefore, because both of the action alternatives are likely to result in an increase in herbicide use on alfalfa, the no action alternative is the environmentally preferred alternative. The no action alternative may not be the environmentally preferred alternative in the case of other GT crops that have different herbicide use patterns and other agricultural practices.

APHIS also considered the contribution of GT alfalfa to the development of glyphosate resistant weeds. Based on the analysis in the FEIS, glyphosate resistant weeds are less likely to develop in GT alfalfa than in annual row crops because management practices associated with alfalfa can break the life cycle of many weeds. Selection cannot act in the absence of complete life cycles. Weeds that are controlled by regular mowing or other cultural practices are less likely to develop resistance in GT alfalfa fields. However, GT alfalfa may still contribute to the development of glyphosate resistant weeds because its use will likely increase the number of acres of glyphosate resistant crops on the landscape and the number of acres in a continual GT crop rotation. Therefore, with respect to the development of glyphosate resistant weeds, GT alfalfa could contribute to the development of these weeds in agricultural systems. The FEIS recommends management strategies that can reduce the likelihood of glyphosate resistant weed developing. USDA funds research both to understand the mechanism of herbicide resistance in weed populations and to develop management strategies for herbicide resistance weeds.

APHIS is not choosing the environmentally preferred alternative because it does not meet the agency's purpose and need. As stated in the FEIS, it is the agency's need to make a decision that is consistent with its existing statutory authority and regulatory program. As described above, APHIS has not identified any plant pest risks associated with J101 and J163. Therefore, it would be inconsistent with the PPA, the regulations codified at 7 CFR part 340, and the biotechnology regulatory policies embodied in the Coordinated Framework, to prevent the commercial release of alfalfa events J101 and J163.

Mitigations of Impacts Associated with Alternative 2

APHIS has identified the potential for impacts for the increased use of glyphosate associated with the adoption of GT alfalfa. Impacts to plants can be mitigated by following the EPA label. EPA regulates the use of pesticides under FIFRA. EPA labels products containing glyphosate for use on GT alfalfa; they have concluded that using glyphosate products according to the label will not result in unreasonable adverse effects to the environment and a reasonable certainty of no harm to people. APHIS also concluded that the use of GT alfalfa could contribute to the development of glyphosate resistant weeds or weed shifts to glyphosate tolerant and resistant weeds in alfalfa. Because GT alfalfa adds an additional glyphosate resistant crop which could be used in rotation with other glyphosate resistant crops, the use of GT alfalfa may contribute to the overall emerging problem of glyphosate resistant weeds. The USDA has recognized that the development of herbicide resistant weeds is an issue for US agriculture and has committed resources to the understanding of the development of these weeds and control of them in agricultural systems. USDA currently has committed resources in a variety of programs related to herbicide resistance and weedy invasive species, including \$4.4 million dollars for Agricultural Research Service (in house) research, \$4.6 million in competitive grants through the National Institute of Food and Agriculture (NIFA) and additional support through Land-Grant University funding. ARS programs include research for weed biology and integrated management practices for herbicide resistant weeds. NIFA funds research in biology of invasive species in agroecosystems, supports extension outreach to growers, and a new web-based training system, IPM3, with a module in herbicide resistance and management strategies.

As part of the effort to mitigate and prevent development of herbicide resistant weeds, several ARS research projects have been initiated or redirected to address herbicide resistance. The following are some specific examples:

1. Scientists at the Global Change and Photosynthesis Research Unit in Urbana, IL are identifying seed survival traits that might be manipulated to control weed species, such as Palmer amaranth and waterhemp, that are known to develop herbicide resistance.
2. Scientists at the Crop Production Systems Research Unit in Stoneville, MS are conducting studies to determine the development and management of herbicide resistant weeds based on the biology, physiology, and ecology of weeds. Through an understanding of the mode-of-action of herbicides and mechanisms of resistance, the reproduction and spread of weeds, and the development of integrated weed management techniques, strategies will be developed for the sustainable management of existing populations and to prevent future incursions of herbicide-resistant weeds.
3. Other research at the Crop Production Systems Research Unit will develop herbicide programs that utilize different modes of action coupled with residual herbicides to reduce late season weeds in glyphosate-resistant soybean and develop best management practices for difficult to control weeds in herbicide resistant crops.
4. Scientists at the Crop Protection and Management Research Unit in Tifton, GA are conducting studies to determine the ecological and edaphic factors affecting the reproduction, spread, and survival of invasive, herbicide-resistant, and herbicide-tolerant weeds of agronomic and vegetable crops. The results of these studies will be used to develop integrated systems for the management of herbicide-resistant and invasive weeds.

5. Scientists at the Natural Products Utilization Research Unit in University, MS are conducting studies to discover natural product-based chemistries with new modes of action for the control of weeds. The results of these studies will provide new tools to control weeds resistant to current herbicides.

Compliance with Applicable Laws, Executive Orders, and Regulations.

The 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).

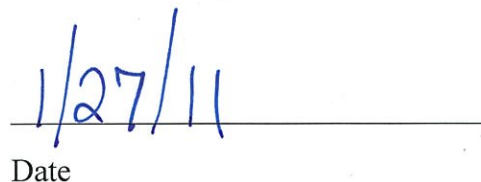
The decision considered the directives of Executive Order (EO) 12898 (US-NARA, 2008), "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations;" EO 13045 (US-NARA, 2008), "Protection of Children from Environmental Health Risks and Safety Risks;" EO 13112 (US-NARA, 2008), "Invasive Species;" EO 13186 (US-NARA, 2008); "Responsibilities of Federal Agencies to Protect Migratory Birds;" and EO 12114 (US-NARA, 2008), "Environmental Effects Abroad of Major Federal Actions."

The decision was determined to be in compliant with other Federal Statutes including, the Clean Water Act; the Clean Air Act; the Federal Insecticide, Fungicide, and Rodenticide Act; the Pollution Prevention Act; and the Endangered Species Act.

The decision was made under the authority of the Plant Protection Act as amended (7 United States Code (U.S.C.) 7701-7772), as codified in the Code of Federal Regulations at 7 CFR part 340, and in consideration of Executive Policy (Executive Office of the President, Office of Science and Technology Policy "Exercise of Federal Oversight within Scope of Statutory Authority; Planned introductions of biotechnology products into the environment." FR Feb 27 1992.vol 57 (39):6753).



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Date