

Executive Summary

The U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) is proposing to grant the petition in whole or in part to genetically engineered (GE) glyphosate-tolerant (GT) alfalfa lines J101 and J163 based on the agency's analysis and conclusions that these GE alfalfa lines are unlikely to pose plant pest risks.

Purpose and Need

“Protecting American agriculture” is the basic charge of the U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS). APHIS provides leadership in ensuring the health and care of plants and animals. In doing so, the agency improves agricultural productivity and competitiveness and contributes to the national economy and public health. The APHIS Biotechnology Regulatory Service's (BRS) mission is to protect America's agriculture and environment using a dynamic and science-based regulatory framework that provides for the safe development and use of GE organisms.

The regulations in 7 Code of Federal Regulations (CFR) part 340, “Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There Is Reason to Believe Are Plant Pests,” regulate, among other things, the introduction (importation, interstate movement, or release into the environment) of organisms and products altered or produced through genetic engineering that are plant pests or that there is reason to believe are plant pests. Such GE organisms and products are considered “regulated articles.” The regulations in § 340.6(a) provide that any person may submit a petition to APHIS seeking a determination that an article does not pose a plant pest risk and should therefore not be regulated under 7 CFR part 340. Paragraphs (b) and (c) of § 340.6 describe the form that a petition for a determination of nonregulated status must take and the information that must be included in the petition.

Background

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 lines designated as J101 and J163, which have been genetically engineered for tolerance to the herbicide glyphosate.

APHIS assessed the plant pest risks posed by the use of GT alfalfa lines J101 and J163 and prepared an Environmental Assessment (EA). The EA was prepared to identify and evaluate any environmental impacts on the human environment 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 lines 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 (U.S.) District Court for the Northern District of California that challenged the APHIS decision to grant nonregulated status to J101 and J163. On February 13, 2007, the Court ruled that the APHIS EA failed to consider certain environmental and economic impacts adequately, as required by the National Environmental Policy Act (NEPA). The Court vacated the APHIS decision to grant nonregulated status to J101 and J163. The Court also ordered APHIS to prepare a NEPA-compliant Environmental Impact Statement (EIS) before deciding whether to grant nonregulated status to J101 and J163. In addition, as of March 12, 2007 all sales of 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 lines 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 may still be harvested, but the fields are subject to court-ordered stewardship practices to minimize the potential that GT alfalfa will be present in harvests of non-GT alfalfa. APHIS prepared this EIS in connection with the order by the United States District Court for the Northern District of California that vacated the determination of deregulated status of J101 and J163 alfalfa.

In December 2009, APHIS made the draft EIS (DEIS) available 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 open comment period. Approximately 133 people attended these public meetings. Approximately 244,000 comments were received. Substantive comments and recommended study reports were considered for incorporation into and revisions of the final EIS (FEIS) were made as appropriate.

Purpose and Need for Agency Action

Any party can petition APHIS to no longer regulate an organism that is regulated under 7 CFR part 340. The petition documents the evidence that the GE organism is unlikely to pose a greater plant pest risk than the unmodified organism from which it was derived.

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 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.

The USDA values and promotes the 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.

Alternatives

In a Notice of Intent (NOI) published on January 7, 2008, APHIS suggested three alternatives for evaluation in the DEIS. In the DEIS, APHIS had removed from consideration the concept of approving only one of the GT alfalfa lines (either J101 or J163) and not both lines because the APHIS plant pest risk assessment concluded that neither of the GT alfalfa lines J101 and J163 are unlikely to pose a plant pest risk. The DEIS considered two of the alternatives described in the NOI: to grant nonregulated status to GT alfalfa lines J101 and J163 (Preferred Alternative), or to maintain the status of GT alfalfa lines J101 and J163 as regulated articles (No Action Alternative). Alternatives were analyzed with regard to their potential impacts on gene flow between GT alfalfa and non-GT alfalfa, weed development, wildlife species, special status species, herbicide use, plant species, socioeconomics (including conventional and organic alfalfa markets, dairy and beef markets, and trade), human health and safety, land use and production practices, and the physical environment (including soil, climate and air quality, and water).

In addition to the No Action Alternative and the Deregulation Alternative, based on comments received on the DEIS, the FEIS includes the analysis of a third alternative that takes into account mandatory measures to provide for isolation distances and geographical restrictions. This Isolation/Geographic Restriction Alternative could use partial deregulation or Federal/Industry partnerships that would require the segregation of seed production of GT alfalfa and non-GT varieties through the use of geographically restricted areas where GT alfalfa cannot be grown and isolation distance where both GT alfalfa hay or seed and non-GT alfalfa seed can be grown. The inclusion of this third alternative in the detailed analysis is based on public comments on the DEIS. Several commenters believed that an alternative that incorporated isolation and geographic restrictions was reasonable and should not have been dismissed from detailed consideration as it was in the DEIS.

In this EIS APHIS has identified two preferred action alternatives. One preferred alternative is to grant non-regulated status. APHIS has identified this alternative as a

preferred alternative based on the purpose and need for the agency action. The purpose of this action is to determine if the use of GT alfalfa in the U.S. agricultural environment presents a plant pest risk. The agency's need is to make a decision on the petition that is consistent with the requirements of the PPA and in the regulations codified at 7 CFR part 340. The deregulation alternative meets this purpose and need. The second preferred alternative would approve the petition in part and includes isolation distances and geographic restrictions. This alternative is identified as a preferred alternative because it meets the USDA's purpose and need to promote programs that support coexistence of all types of agricultural practices and addresses concerns expressed by some members of the public about the potential for cross pollination and other related impacts to non-GE alfalfa. This alternative incorporates measures to facilitate coexistence and reduces the potential of impacts from GT alfalfa to other forms of alfalfa grown for GE sensitive markets.

Affected Environment

Alfalfa (*Medicago sativa* L.), a deep-rooted and short-lived perennial, is among the most important forage crops in the United States with more than 20 million acres in cultivation. It is recognized as the oldest plant grown solely for forage. Conventional alfalfa (alfalfa that is not a GE variety and is not grown using organic practices) has been used by farmers as livestock feed for decades because of its high protein and low fiber content. Alfalfa ranks fourth on the list of most widely grown crops by acreage, behind corn, soybeans, and wheat, and is ranked third among agricultural crops in terms of value. Because it is widespread and is typically grown as a perennial crop, alfalfa also provides important habitat for wildlife (Hubbard 2008).

Dairy farmers would be the most likely users of GT alfalfa because they often depend on pure alfalfa stands that are free of weeds and grasses, whereas beef cattle producers and horse owners typically feed their animals a mix of alfalfa-grass hay (Putnam 2005). About 40 percent of U.S. alfalfa acreage is planted as pure stands, and about 25 percent is planted with grasses or another companion crop (Rogan and Fitzpatrick 2004).

Little evidence exists to suggest that alfalfa is considered a weed (see appendices G and H of this EIS), other than as a volunteer in agricultural settings. Alfalfa is predominantly cross-pollinated and the flowers depend entirely on bees for cross-pollination. Wind cross-pollination in alfalfa does not occur (Viands et al. 1988).

Environmental Consequences

Based on the impact analyses in this FEIS, the following represents a summary of conclusions APHIS has made on the environmental consequences of the Deregulation Alternative to granting nonregulated status to GT alfalfa lines J101 and J163.

Biology of 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. Although the probability is low, GT

alfalfa genes could be found in non-GT alfalfa at low levels. The American Organization of Seed Certifying Agencies ASSP-2010 standard is designed to provide seed lots where the GT transgene would be very likely to not be detected in standard industry tests.

Weeds in Alfalfa

- Biology/ecology of alfalfa (perennial status) and production practices (mowing, less glyphosate used compared to other crops) in alfalfa farming suggest that glyphosate-resistant weeds would be slow to develop in GT alfalfa stands. Weeds which have already developed resistant to glyphosate or are tolerant to glyphosate are more likely to occur in alfalfa (weed shifts to glyphosate-resistant or glyphosate tolerant weeds) than is the development of novel glyphosate resistant biotypes.

Impacts of GT Alfalfa on Plants and Animals

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 line. 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 for 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 concludes that the GT alfalfa gene product would have no effect on federally listed T&E species or species proposed for listing, nor is it expected to adversely modify designated critical habitat or habitat proposed for designation, compared to current agricultural practices.

Increased glyphosate use, due to the adoption of GT alfalfa, could affect nontarget 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, because none of the glyphosate formulations that contain surfactants are approved for use over or near surface waters.
- APHIS has no authority under the Plant Protection Act to 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. Therefore, APHIS has determined that the use of EPA-registered glyphosate for GT alfalfa production will not adversely impact federally listed

T&E species or species proposed for listing, and would not adversely impact designated critical habitat or habitat proposed for designation.

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 environmentally less adverse than other herbicides (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 the glyphosate with a decreased, an unchanged, or an increased use of herbicides.
- Animal T&E species are not at risk, and 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.

Socioeconomic Impacts

- There is some 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 of consumer preference for nongenetically modified foods in the United States. 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 under the potential low-level presence of GE content 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 imagining a small GT-sensitive market within the domestic conventional and organic alfalfa markets.

- Among U.S. main export markets for alfalfa hay and seed, there is evidence of some sensitivity to GE products. As in the case of the domestic organic markets, 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 markets are affected by GT alfalfa deregulation depends on the extent to which gene flow can be controlled through stewardship programs. These programs might or might not 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.
- There is no evidence that the domestic or export market for organic dairy and meat derived from alfalfa-fed cattle would be lost to domestic alfalfa producers with GT alfalfa deregulation, nor that the credibility of the National Organic Program would be compromised, although testing for GE content in alfalfa seed might be increasingly required for access to GT-sensitive markets.

Human Health and Safety

- GT alfalfa has no adverse effects on human health and worker safety.
- Overall risk of glyphosate and other herbicide use to human health and worker safety does not change with the adoption of GT alfalfa. EPA has determined that the use in accordance with the labeling of currently registered pesticide products containing glyphosate and other herbicides will not pose unreasonable risks or adverse effects to humans or the environment, including its use on alfalfa.

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.